厚生労働科学研究費補助金

地域医療基盤開発推進研究事業

医療安全に寄与する患者参加の推進に資する研究

令和３年度　総括研究報告書

研究代表者　永井庸次

令和４（2022）年　５月

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厚生労働科学研究費補助金（地域医療基盤開発推進研究事業）
総括研究報告書

医療安全に寄与する患者参加の推進に資する研究

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研究要旨

医療安全において、「患者参加」の概念（定義）を議論・確認せず、夫々、種々の概念（定義）で疑問を持つことなく、頻用している。本研究は、医療安全における「患者参加」の概念（定義）整理を行うとともに、国内外の医療安全の向上を意図した患者参加活動の実態を把握し、「患者参加」を効果的に推進する方法を明らかにすることを目的とする。令和 2 年度調査より明らかになった患者相談の現状と課題を整理した上で、令和 3 年度は、医療従事者および外来・入院患者を対象にしたアンケート調査を行い、「患者参加」の概念（定義）とその活動の実態を明らかにするほか、全国のセンターを対象にしたアンケート調査を行い、センターにおける患者相談および病院との連携の現状と課題、患者相談を医療安全の向上に活かす方法等を明らかにすることを目的とした。また、患者団体を対象にしたインタビュー調査およびアンケート調査を行い、患者団体による「患者参加」の概念（定義）とその活動の実態を明らかにするほか、文献調査等より医療安全の向上に寄与する「患者参加」の方法をそのエビデンスと共に明らかにすることを目的とした。

令和 3 年度は、令和 2 年度に引き続き COVID-19 の感染拡大と政府の緊急事態宣言の発出により、調査研究を一部修正する必要はあったが、昨年度の繰り越し分調査を年度前半に実施し、年度後半に令和 3 年度に予定していた調査研究も概ね完了した。

医療安全支援センターを対象にしたアンケート調査については、有効回答率は、58.2%（231/397）を得た。医療安全支援センターの医療に関わる苦情・相談の受付体制、取り組み、医療機関等との連携状況について確認することができた。

医療従事者および入院患者を対象にしたアンケート調査については、5 病院（練馬総合病院、ひたちなか総合病院、済衆館病院、栗橋病院、白岡中央総合病院）の、医療従事者 500 人、入院患者 500 人を対象として実施、有効回答率は医療従事者向けが 93.4%（467/500）、入院患者向けが 60.6%（303/500）であった。病院における医療従事者と入院患者の患者参加に対する認識の違い等が明らかになった。

患者団体を対象にしたインタビュー調査およびアンケート調査については、事前に 5 団体（一般社団法人グループ・ネクサス・ジャパン、公益社団法人日本リウマチ友の会、一般社団法人全国腎臓病協議会、認定 NPO 法人難病こども支援全国ネットワーク、認定 NPO 法人ささえあい医療人権センターCOML）に対してアンケート調査を実施した上で、インタビュー調査を行った。主な団体の「患者参加」の概念（定義）および関連する取り組み状況と医療安全支援センター等との連携状況、課題や展望が明らかになった。

文献調査等について、英国の National Institute for Health and Care Excellence（NICE）や Guidelines International Network（GIN）における診療ガイドライン作成時の患者参加の取り組みについて資料の提供を受け、内容をまとめた。

今後は、得られた研究結果を活用し、医療機関における「患者参加」の推進に資する取り組み、施策について検討するとともに、国民への「患者参加」についての普及啓発について考察する必要がある。

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A．研究目的

第 3 回閣僚級世界患者安全サミットでは、医療安全管理への患者及び患者家族の参加の推進が必要であるとされた。しかし、本来は医療提供側が保証すべき医療安全において、患者参加という一定の役割を患者側に課すことの是非、および理論的根拠などの概念は必ずしも明確にされていない。患者参加の概念（定義）を明確にせず、したがって、患者参加活動とは何かを、あいまいにして活動している。医療安全全国共同行動では、患者にフルネームを名乗ってもらうなどの方法を例示しているが、それらの有効性や、各医療機関の取り組みの実態、患者側の主体的な参加の実態等は十分に明らかにされていない。我々の先行研究（H17-医療-一般-033）は、患者による医療事故やヒヤリハットの発見と報告が有効な患者参加の手段の一つであることを示した。医療機関の患者相談窓口と、都道府県の医療安全支援センター（以下、センター）には、患者や患者家族が気づいた医療安全上の問題や不安について相談を受け、その情報を臨床現場へ効果的にフィードバックすることが期待されている。しかし、両者の取り組みとその連携の効果は明らかにされていない。医療機関の医療対話推進者は、患者と医療従事者との対話推進により、患者参加の推進に寄与している可能性があるが、その活動の実態や効果は明らかにされていない。

本研究は、医療安全における患者参加の概念整理を行うとともに、国内外の医療安全の向上を意図した患者参加活動の実態を把握し、患者参加を効果的に推進する方法を明らかにすることを目的とした。

B．研究方法

令和 3 年度は、令和 2 年度に引き続き COVID-19 の感染拡大と政府の緊急事態宣言の発出により、調査研究を一部修正する必要はあったが、昨年度の繰り越し分調査を年度前半に実施し、年度後半に令和 3 年度に予定していた調査研究も概ね完了した。

本年度における調査研究は、以下の小研究から構成される。

（1）全国のセンターを対象にしたアンケート調査

センターの担当者を対象にしたアンケー

ト調査により、センターにおける患者相談の現状と課題、病院または病院の患者相談窓口との連携の実態、患者相談を医療安全の向上に活かす方法等を明らかにする。

（２）医療従事者および入院患者を対象にしたアンケート調査

令和２年度の患者窓口へのインタビュー調査等で協力を得られるとの回答を得た病院の医療従事者および入院患者を対象にしたアンケート調査により患者参加の実態を明らかにする。5 病院の、医療従事者 500 人（100 人×5 病院）、入院患者 500 人（100 人×5 病院）を対象とし、医療従事者と患者、両者の患者参加に対する認識の差異、患者が病院の提供する医療内容に医療安全上疑問を感じた経験と対応、患者満足度を明らかにする。

（３）患者団体を対象にしたアンケート調査およびインタビュー調査

患者団体を対象にしたアンケート調査、インタビュー調査により、組織構成、会員への情報提供、医療安全上の注意喚起など活動内容について明らかにする。

（４）文献調査

①患者参加を JDream Ⅲで文献検索した。

検索式＝((患者参加 OR 患者参画）AND（意義 OR 定義 OR 成果 OR 意味））AND（2001-2019）で 25 件ヒットした。

②患者参加を定義している病院を Google で検索した。

③文献調査及び国内外の専門家へのインタビュー調査

医療安全における患者参加の概念、役割についての概念整理を行うとともに、患者参加の方法、成功事例について、医中誌 Web、PubMed 等の文献データベースを用いた文献調査や国内外の専門団体への調査等を行う。特に、医療における患者参加として先進的な取り組みの一つとして、診療ガイドライン作成における患者参加がある。医療安全における患者参加の推進に資する参考情報を得るために、NICE の担当者に対するヒアリングと文献調査にもとづき、NICE の診療ガイドライン作成過程への患者参加の取り組みを紹介する。

（倫理面への配慮）

本研究の研究計画は、公益社団法人全日本病院協会倫理審査委員会の審査を受け、承認された（承認番号：R2-001）。

Ｃ．研究結果

（１）医療安全支援センターを対象にしたアンケート調査（資料 1, 2）

全国のセンター395 箇所を対象に、郵送法によるアンケート調査を令和 4 年 1 月 7 日に発送、1 月 31 日に回収という日程で実施した。有効回答率は 58.2%（231/397）であった。

センターの体制について、センターの職員としては、行政職の兼任、看護師・保健師の方が多く、管轄医療機関数に応じてばらつきが見られた。センター職員の平均勤続年数は 3.9 年であり、相談業務に関わる研修の受講については約 5 割のセンターでは定めていた。

苦情・相談への対応について、９割以上のセンターは外部委託をせず、業務を実施しており、電話対応を基本として予約なしの面談希望にも約８割のセンターが対応をしていた。その中で、面談のための個室を確保できているのは約６割であり、個室を確保できていないセンターではプライバシー確保のため、パーテーションを設ける等の工

夫が確認された。

医療機関との連携については、約７割のセンターが日頃からは連携を取っていないこと、連携をしている場合の内容としては「専門性の高い苦情・相談について」が多いことが明らかになった。医療機関以外の関係団体との連携については約３割のセンターが行っており、医師会や歯科医師会が多かった。行政機関との連携は約６割のセンターで行われており、他のセンターや保健所との連携が確認された。

苦情・相談への対応業務で負担に感じることとして、長時間の対応や相談者の納得が得られないことが挙げられており、負担感がやや負担・負担と答えたセンターは８割以上であった。苦情・相談への対応の中で、医療事故に該当するかどうかの判断基準は約５割で定められていなかった。医療機関へのフィードバックについては、約５割が相談者の意向から判断しており、相談者へのフィードバックも相談者の希望を重視していた。フィードバックの決まった書式は８割以上のセンターが定めていなかった。医療機関へのフィードバックに際しては、相談者と医療機関の言い分が異なることに対して負担に感じているセンターが約７割と多かった。そのためか、伝達する際に伝達内容は相談者の主観によるものだと前置きしていると答えたセンターが約６割あった。蓄積された苦情・相談内容については、約９割のセンターがなんらかの形で業務に活用していた。

医療機関向け「医療安全の確保に必要な情報」の提供方法はホームページ、紙媒体、電子媒体、研修会と様々な方法が確認された。一方、住民向けの情報提供手段としてはホームページが約５割であり、他の手段はほとんどなかった。また、住民向けの情報提供については活用状況の確認や効果測定まではほとんどなされていなかった。

今後センターの運営を円滑に進めるために必要なツールとして、「センター職員のための教育ツール」と回答したセンターが約７割あった。

（２）医療従事者および入院患者を対象にしたアンケート調査（資料 3-6）

5 病院（練馬総合病院、ひたちなか総合病院、済衆館病院、栗橋病院、白岡中央総合病院）の、医療従事者 500 人（100 人×5 病院）、入院患者 500 人（100 人×5 病院）を対象とした患者参加の実態調査（アンケート調査）は、令和 4 年 1 月 7 日に発送、1 月 31 日に回収という日程で実施した。有効回答率は、医療従事者向けが 93.4%（467/500）、入院患者向けが 60.6%（303/500）であった。

① 回答者

調査対象となった 5 病院は、最小で 224 床、最大で 331 床であり、4 病院が急性期病院、1 病院がケアミックス病院であった。所在地は埼玉県に 2 病院、茨城県、東京都、愛知県に 1 病院ずつであった。アンケートの回収数は、医療従事者用が 467/500（回収率 93.4%）3、入院患者用が 303/500（回収率 60.6%）であった。医療従事者用の職種別の回収数は、医師 74、看護師 234、その他職種 158 であった。

② 患者参加を定義している病院は 14%である。定義の内容は多様である。

各用語と患者参加の関係は、順に（患者参加と同じ・患者参加に含まれる・患者参加を含む・一部同じ・異なる）回答の割合（%）患者参画（23・19・14・9・2）、患者中心 6・24．15・14・9）、患者主体（8・22・13・

18・7)、患者思考（6・13・7・19・23）であった。

③患者参加推進活動の実施状況

患者参加推進活動の実施状況に関する質問の回答結果を表 1 に示す。患者参加を促す説明に関する項目である「1（表 1)，患者自身も医療チームの一員であるという説明」は、医療従事者側の実施の認識が 61.6%（医療従事者向け調査項目 4）であったのに対し患者側の経験の認識は 38.4%（入院患者向け調査項目 1）であった。協働意思決定に関する活動 5 項目のうちの 4 項目（医療従事者向け調査項目 5-9、入院患者向け調査項目 2-6）は、医療従事者側・患者側とも比較的高値であった。ただし「5,（表 1）意思決定支援ツールの提供」は、医療従事者側が 38.9%（医療従事者向け調査項目 8)、患者側 50.2%（入院患者向け調査項目 5）であった。医療事故防止に直接かかわる活動のうち、「7,（表 1）確認行為の実施」に関しては医療従事者・患者ともに高い水準であるといえたが、「8,（表 1）危険や懸念を伝えてほしいという説明」は、双方とも 6 割程度であった。患者の意見や苦情収集に関する活動 2 項目については、どちらも患者側の認識が低い傾向にあった。

（3）患者団体を対象にしたインタビュー調査、およびアンケート調査（資料 7-17）

患者団体を対象とした調査は、5 団体（一般社団法人グループ・ネクサス・ジャパン、公益社団法人日本リウマチ友の会、一般社団法人全国腎臓病協議会、認定 NPO 法人難病こども支援全国ネットワーク、認定 NPO 法人ささえあい医療人権センター COML）を対象として、インタビュー調査のためのアンケート調査を令和 4 年 1 月 7 日に発送、1 月 31 日に回収をした。アンケート調査の結果に基づいて、令和 4 年 1 月から 2 月までインタビュー調査を実施、以下のことが明らかになった。

①患者の高齢化、治療法の改善により、患者団体の会員数が減少している。

②患者団体と患者支援団体は目的・活動が異なり、患者参加へのアプローチも異なる可能性がある。

③多くの団体は判断決定共有（SDM)、ACP 等における患者の自己決定権、合意に基づく治療への参加、多職種チーム医療への参加、医療・医療制度の知識エンパワーメント（医療・医療制度を理解）を通して、医療・治療等を医療者と考えることが患者参加の定義と考えている。

④自分事として積極的に医療者と協働し、自身の選択権を行使することも患者参加の定義に入る。

⑤これらの支援は患者団体、患者支援団体の務めであるが、あくまで選択権は患者にある。

⑥高齢化、治療法の改善に伴い、治療目標だけではなく、日常・社会生活レベルの目標選択も患者参加の要素である。

⑦いわゆる患者力が患者参加には必須である。

⑧患者参加に関して、学会、医療機関等と話し合っている団体は少ない。

⑨患者参加の状況は、未だに医療者、患者双方による治療法の話し合い、双方向のインフォームドコンセントができておらず、判断決定共有への道のりは遠い。

⑩患者参加の前提として、子どものころからの医療・医療制度教育が重要である。

⑪患者参加の前提として、患者ニーズに合致した医療側からの標準的で信頼できる治療サイトのネット提示が必要である。

⑫病院相談窓口、医療安全支援センターの認知度は患者団体、患者支援団体、患者いずれにおいても低い。

本研究の趣旨である患者参加については、明確に定義付けている団体は認められず、患者支援団体は患者参加について、患者参加を支援する事業等を実施していることが明らかになった。さらに、患者参加支援そのものというよりも、あくまでのその前提条件（知識、行動方法等）の構築を支援していることが多いことも確認された。一方、患者団体は患者参加について、患者個人が患者参加に直接参加する行動そのものを支援する対応をしていることが多く、患者団体特有の疾患の患者参加行動とその前提知識を具体的に支援・提供していることが明らかになった。

（4）文献調査

①患者参加を明確に定義する

JDream Ⅲおよび Google 検索とともに、（2）（3）の調査でも明らかになったが、以下の関連用語を、患者参加とほぼ同義に考えている人・組織が多かった。

患者第一、患者中心、患者主体、患者参画、患者関与、患者主権、権限移譲、エンパワーメント、患者指向、患者志向、患者思考である。

文献の定義では、「自らの医療に対する治療方針を決定する」、「治療に主体的に参加する」、「病院運営に関わる」、「他の患者の診療を支援する」等がある。

多くが Carman の定義「患者参加型医療とは、患者、家族、代理人、医療者が医療のさまざまなレベル、すなわち直接の診療、病院の体制の構築とガバナンス、医療政策レベルで、医療の質と安全向上のために積極的に協働することである。（Carman KL、et al. Health Affairs 32:223、 2013）」を引用している。

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②Google で検索した病院では、患者参加として実施する活動の記述はあるが、患者参加を明確に定義する病院・団体は稀である。

群馬大学は、患者参加型医療推進委員会規程第 2 条に「患者参加型医療とは、患者自身が自らの疾病や医療を十分理解し、主体性をもって医療に参加するもの」と定義している。

③文献調査および専門家へのインタビュー調査（資料 18-21）

患者参加の概念整理のために、診療ガイドライン作成における患者参加をすすめる英国の事例を取り上げ、作成組織に対するインタビュー、資料提供の依頼、文献調査を実施した。

医療における患者参加として先進的な取り組みの一つとして、診療ガイドライン作成における患者参加がある。診療ガイドラインは、エビデンスのシステマティックレビュー、益と害の評価に基づく推奨を含み、患者と医療者の意思決定の参考資料となる文書である。1990 年代より診療ガイドライン作成過程に、利用者としての患者の参加が推奨されおり、その中でも英国の National Institute for Health and Care Excellence（NICE）は診療ガイドライン作

成における患者参加について積極的に取り組んできた組織である。

NICE の診療ガイドライン作成に関するマニュアルでは、診療ガイドライン作成過程において、「最低 2 名」の非専門家が参加することとなっている（NICE. Developing NICE guidelines: the manual. 2014.）。非専門家には、患者を含むサービスの利用者、その家族や支援者、一般市民が含まれる。NICE の非専門家の参加に関する活動を行う Public Involvement Programme (PIP) は、患者参加の活動に関するレポート（NICE. Public Involvement at NICE Annual report 2019/20. 2020.）の中で、2019/20 年度に 39 名の非専門家が診療ガイドライン作成委員会に参加したと報告している。会議の前後には、会議前の相談、情報提供、参加可能性を高めるための日程・場所の調整、会場へのアクセス可能性の確認、積極的に貢献できるようにするための会議中の座席場所の検討、会議後の相談等を行うとしている。

同レポートでは、委員会に参加する非専門家に対して、トレーニングを提供しているとされる。トレーニングは、「委員会の時間を最大限に活用するための知識と技術」の習得を目的とし、診療ガイドラインの作成方法、会議の準備方法、以前に参加したことのある非専門家の知識・経験・アイディアを提供するとされる。2019/20 年度には、32 名の非専門家が本セミナーに参加していた。また、トレーニング内容をオンラインで提供することの検討が進められている。

トレーニング内容について詳細な情報を得るために、NICE の担当者に対してメールでヒアリングを行った。ヒアリングの内容は、診療ガイドライン作成過程への患者参加の方法の指針の有無、及び、参加する患者へのトレーニングの概要とした。患者参加の方法の指針については、独自に準備していないこと、そして、Guidelines International Network (GIN)の患者参加マニュアル（後述）を参考にしているとのことであった。また、診療ガイドライン作成過程へ参加する患者に対するトレーニングについては、各回 8～18 人が参加していることにあわせて、トレーニング（1 日コース）のプログラムの提供を受けた。

GIN は、診療ガイドラインに関する組織・個人のネットワークであり、診療ガイドラインに関する国際学会と言える。GIN が有する様々な委員会の 1 つの GIN Public Working Group が、先に触れた診療ガイドライン作成における患者参加に関する方法をまとめている（GIN PUBLIC. GIN Public Toolkit: patient and public involvement in guidelines. 2021.、以下、ツールキット）。ツールキットの作成委員長は、先の NICE のメンバーである。ツールキットは、2012 年に初版が作成された後、2015 年に改訂が行われ、2021 年に最新版が発行されている。最新版の目次は次の通りである。「GIN PUBLIC toolkit のイントロダクション」、「市民・対象者からの情報収集方法」、「患者・市民の見解に関する研究を診療ガイドラインに組み入れる方法」、「診療ガイドライン作成における患者・市民のリクルート、支援、彼らの参加の障壁を乗り越える方法」、「患者・市民参加を支援するためのガイドライン委員会委員長の役割：リクルート、トレーニング、支援」、「システマティックレビューにおける患者・市民参加」、「ガイドラインに関する患者・市民向けの情報の作成方法」、「ガイドラインを用いた

共有意思決定の促進方法」、「ガイドラインの普及・活用促進における患者・市民参加」、「ガイドラインを超えて：医療記述評価への患者参加を支援するツール」。このように診療ガイドラインの作成に関する患者参加だけでなく、意思決定場面や診療ガイドラインの普及に関しても患者の役割が提案されていた。

D．考察

（1）医療安全支援センターを対象にしたアンケート調査

患者参加において医療安全支援センターは大きな役割を担っていると考えられる。本年度の調査により、センターの体制、取り組み、現状の課題等が明らかになった。センター職員の平均勤続年数が 3.9 年であることから職員の苦情・相談業務に必要なスキルの引継ぎ、確保が重要であると考えられる。しかし、研修の受講を定めているセンターは約 5 割であり、センター職員のための教育ツールを必要だと考えているセンターも約 7 割であることから、スキル獲得のためのツールの提供や研修受講制度等の整備の重要性が示唆された。

苦情・相談受付体制については、電話対応を基本としつつ、個別の面談も受け付けているセンターがほとんどであった。専用個室のないセンターにおける相談者のプライバシーの確保が課題と考えられたが、各センターでプライバシーを考慮する対策を取っていることが確認された。また、平日夜間や休日も留守電や電子メール等を活用して受け付けているセンターもあり、受付窓口としてきちんと機能していると考えられる。

一方、日頃から医療機関と連携していると回答したセンターは約 3 割だったことから、タイムリーな医療安全上の課題の共有という点で課題があると考えられる。センターに寄せられる苦情・相談の傾向や医療機関におけるヒヤリハットの実例等を共有することで、相談対応の質向上が期待される。また、センターから住民への医療安全に関わる注意喚起や患者参加の普及啓発活動にもつながると考えられる。

受け付けた苦情・相談内容を医療機関にフィードバックするかどうか、どのような形式でフィードバックするか、医療事故に該当するかどうか、立ち入り検査部門に引き継ぐかどうかといったことに対して、基準を設けていない、またはばらつきがあることに対して、円滑なセンター運営のため基準や書式等の標準化が一つの課題であると考えられる。今後、センター運営の効率化の観点から、マニュアルの整備等さらなる検討が必要である。

現状、センター職員の負担感は強く、相談受付業務が主体であり、情報発信や研修会の開催まで資源が回らないことが伺えた。相談受付業務の効率化やセンター運営の定期的な見直しを行うことで改善につなげていく必要が示唆された。

（2）医療従事者および入院患者を対象にしたアンケート調査

医療安全に寄与する可能性がある患者参加推進活動 10 項目の中で、医療従事者側の実施の認識と患者側の経験の認識に差異があることが明らかになった。

患者参加を促進するためには、まず患者と医療従事者は医療チームの一員であり対等に協力し合う存在であること、患者にも求められる役割があること、について説明し理解を得ることが必要と考えられる。し

かし「1, 患者自身も医療チームの一員であるという説明」に関して、患者側の実施の認識は 3 割にとどまった。今後、こうした説明をより確実に、明示的に行う方策を検討すべきと考える。

協働意思決定に関する活動 5 項目のうち 4 項目において医療従事者側・患者側双方の認識が高かったのは、その必要性と具体的手順が医療従事者に認識され、かつ患者とのコミュニケーションの中で広く実践されているためと考えられた。一方で、「5, 意思決定支援ツールの提供」は、10 項目中唯一患者側の認識のほうが優位に高かった項目であり、患者は医療従事者が想像するよりも、リーフレットや動画、ウェブサイト等から多くの意思決定に関する情報を得ていることが示唆された。

「7, 確認行為の実施」に関する認識は医療従事者、患者ともに高水準であり、医療安全のための基礎的な患者参加活動である確認行為は広く普及していることが確認された。一方、「8, 危険や懸念を伝えてほしいという説明」は医療従事者、患者の認識とも 6 割程度であった。医療事故等の発見と防止は患者に期待される役割の一つであることを、医療従事者と患者双方に周知すべきと考えられる。

患者の意見や苦情収集に関する活動に関して、「9, 意見や苦情の積極的収集」では患者側の認識は約半分にとどまり、患者相談窓口の存在の周知が必ずしも十分でないことが示唆された。「10, 医療安全支援センターとの連携」の認識はさらに低かった。既存の窓口などの資源について患者に周知することで、医療安全に関する患者からの意見や情報の効率的な収集に資する可能性が示唆された。

（3）患者団体を対象にしたインタビュー調査、およびアンケート調査

インタビュー調査を通じて、患者団体が会員に対して患者参加を推進していくためには、前提となる明確な定義付けが必要であることが示唆された。

患者団体として取り組むことが可能な患者参加には、直接的な患者参加の具体的な内容（判断決定共有（SDM）、ACP 等における患者の自己決定権、合意に基づく治療への参加、多職種チーム医療への参加、医療制度の知識エンパワーメント（医療・医療制度を理解））の構築・支援と患者参加に不可欠な体制・知識らの構築と強化が必要であると考えられる。

今後とも、患者団体・患者支援団体の支援作業と、学会・行政等との連携が必要であり、患者参加の基盤ツールとして重要な電子医療記録（EMR）、電子健康記録（EHR）、個人健康記録（PHR）の基盤構築、標準化、共有化と患者のアクセス権、個人認証、セキュリティ基盤の充実・推進が患者参加活動には必要であると考えられる。

（4）文献調査

(2)（3）の結果と符合する結果であった。

①患者参加の定義

各人（組織）各様で患者参加を考えており、その多くが、定義を明確に意識していないことが分った。

②患者参加としての活動

患者参加活動に関しても同様である。

③文献調査及び国内外の専門家へのインタビュー調査

NICE の診療ガイドライン作成における患者参加の取り組みに関する検討から、患

者参加を効果的に実施するためには、情報提供、トレーニングを含めた参加のための準備が重要となることが明らかになった。医療安全における患者参加についても、それを効果的なものとするためには、患者に求める役割の整理とともに、環境整備、情報提供、トレーニング等が必要であることが示唆された。

Ｅ．結論

病院の患者相談窓口の体制や医療安全活動と、病院の患者参加推進活動、および病院、患者団体、センターの連携の実態等が明らかになった。本研究で得られた情報、資料は我が国における患者参加の現状、海外の取り組みを知るための基礎資料となると考える。今後、患者参加の定義の統一や患者参加の普及啓発・推進活動の在り方について検討するためには、さらなる調査研究が必要である。

Ｆ．健康危険情報

なし。

Ｇ．研究発表

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Ｈ．知的財産権の出願・登録状況

なし。

以上

表１　患者参加推進活動の実施状況に対する患者側・医療従事者側の認識

			あり (%)		なし (%)		計
患者参加を促す説明に関する活動							
1	患者も医療チームの一員であるという説明	患者	59	(30.6)	134	(69.4)	193
		医療者	285	(61.6)	178	(38.4)	463
協働意思決定に関する活動							
2	治療のゴールに関する話し合い	患者	182	(76.2)	57	(23.8)	239
		医療者	358	(77.2)	106	(22.8)	464
3	治療方針の選択肢の説明	患者	217	(86.8)	33	(13.2)	250
		医療者	384	(82.9)	79	(17.1)	463
4	説明への理解度の確認	患者	213	(83.5)	42	(16.5)	255
		医療者	383	(82.5)	81	(17.5)	464
5	意思決定支援ツールの提供	患者	121	(50.2)	120	(49.8)	241
		医療者	180	(38.9)	283	(61.1)	463
6	価値観や希望の聞き出し	患者	152	(68.2)	71	(31.8)	223
		医療者	337	(72.8)	126	(27.2)	463
医療事故防止に直接かかわる活動							
7	確認行為の実施	患者	279	(95.9)	12	(4.1)	291
		医療者	407	(87.5)	58	(12.5)	465
8	危険や懸念を伝えてほしいという説明	患者	135	(60.3)	89	(39.7)	224
		医療者	281	(60.8)	181	(39.2)	462
患者の意見や苦情収集に関する活動							
9	意見や苦情の積極的収集	患者	128	(50.4)	126	(49.6)	254
		医療者	390	(83.7)	76	(16.3)	466
10	医療安全支援センターとの連携	患者	45	(17.7)	209	(82.3)	254
		医療者	240	(52.7)	215	(47.3)	455

資料1

医療安全支援センターの活動状況に関する調査

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全日本病院協会　医療の質向上委員会

永井　庸次

医療安全の向上には患者及び患者家族の参加の推進が必要とされています。医療安全支援センターは患者参加を促進するうえで重要な役割を果たしていると考えられます。しかし、各医療安全支援センターの活動の実態等は十分に明らかにされていません。本研究は、医療安全支援センターの活動の実態を把握し、その役割を効果的に推進する方法を明らかにすることを目的としております。

お忙しいところ恐縮ですが、ご回答賜りますようお願い申し上げます。

ご回答の注意

・**1月31日（月）まで**にご回答ください。
・本調査票は、**センター代表者の方**がご回答ください。
・原則として当てはまるもの1つにチェック（✓）をつけてください。
・（　　）には適当な数字、文章でお答えください。

＜医療安全支援センターの基礎的な情報＞

1. 貴センターの設置区分について教えてください。
   - □01 都道府県センター
   - □02 二次医療圏センター
   - □03 保健所設置市区センター

2. 貴センター所管区域内の医療施設数について教えてください。
   - 01 病院　（　　）施設
   - 02 診療所　（　　）施設
   - 03 その他　（　　）施設

3. 現在の職種別常勤換算職員数について教えてください。（該当しない職種には0とお答えください）
   - 01 技術職（医師）　（　　）人
   - 02 技術職（看護師・保健師）　（　　）人
   - 03 技術職（薬剤師）　（　　）人
   - 04 行政職　（　　）人
   - 05 その他　（　　）人
   - 06 常勤換算総職員数　（　　）人

注：次を目安に常勤換算数を書いてください。

週40時間以上勤務されている方→1.0人
週32時間程度勤務されている方→0.8人
週24時間程度勤務されている方→0.6人
週16時間程度勤務されている方→0.4人
週　8時間程度勤務されている方→0.2人
週　8時間未満勤務されている方→0.1人

4. センターの職員としての平均勤続年数は、およそ何年ですか。
   （　　）年

5. 職員に対して相談業務に関わる研修の受講を定めていますか。（当てはまるもの全て選択）
   - □01 医療安全支援センター総合支援事業開催の研修
   - □02 センター・自治体の研修
   - □03 上記以外の外部の研修　（具体的な研修内容）
   - □04 定めていない

資料1

＜苦情・相談への対応について＞

6. 苦情・相談の受付方法について教えてください。（当てはまるもの全て選択）

□01 電話　□02 面談（予約有）　□03 面談（予約無）　□04 電子メール

□05 手紙・FAX　□06 その他 （　　）

7. 貴センター内に面談のための個室を確保していますか。

□01 確保している　→**問9へ**

□02 確保していない

8. 問7で「確保していない」と回答された場合、具体的な面談希望者への対応方法とプライバシーへの配慮方法を教えてください。

01 面談希望者への対応方法

02 プライバシーへの配慮方法

9. 1週間のうち、苦情・相談に対応可能な総時間を教えてください。

（　　）時間

10. 平日夜間（18時以降）に苦情・相談の対応をしていますか。

□01 している （具体的な方法：　　）

□02 していない

11. 土日、祝祭日に苦情・相談の対応をしていますか。

□01 している （具体的な方法：　　）

□02 していない

12. 苦情・相談受付業務の外部委託状況について教えてください。

□01 全て委託している

□02 一部委託している

□03 委託はしていない　→**問14へ**

13. 問12で「全て委託している」「一部委託している」と回答された場合、相談受付業務の委託先と委託している業務内容について教えてください。

01 委託先 （　　）

02 委託している業務内容（具体的な内容）

14. 年間の苦情受付件数および相談受付件数はそれぞれ何件ですか。（医療安全支援センター総合支援事業でご回答いただいた内容を参考に、昨年度の数値をご回答ください。）

01	受付総数	（　　）件
02	01のうち相談受付件数	（　　）件
03	01のうち苦情受付件数	（　　）件
04	01のうち医療機関へのフィードバック件数	（　　）件
05	01のうち立入検査部門への引継ぎ件数	（　　）件
06	01のうち医療事故が疑われる事例	（　　）件

15. 受付内容について、内訳をそれぞれ回答してください。（医療安全支援センター総合支援事業でご回答いただいた内容を参考に、該当する項目に昨年度の数値をご回答ください。）

01	医療行為・医療内容	（　　）件
02	コミュニケーションに関すること	（　　）件
03	医療機関等の施設	（　　）件
04	医療情報の取扱	（　　）件
05	04のうちカルテ情報	（　　）件
06	04のうちセカンドオピニオン	（　　）件
07	04のうち、05, 06以外のもの	（　　）件
08	医療機関などの紹介・案内	（　　）件
09	医療費（診療報酬など）	（　　）件
10	医療知識などを問うもの	（　　）件
11	10のうち健康や病気に関すること	（　　）件
12	10のうち薬品に関すること	（　　）件
13	10のうち、11, 12以外のもの	（　　）件
14	その他	（　　）件

16. 苦情・相談受付業務において、貴センター内で相談者の属性や相談内容を整理するための統一した分類方法を使用していますか。

□01 はい
□02 いいえ

17. 苦情・相談受付業務について、日頃から医療機関と連携していますか。

□01 している
□02 していない　　**→問19へ**

18. 問17で「している」と回答された場合、連携内容について教えてください。
（当てはまるもの全て選択）

□01 専門性の高い苦情・相談内容に対して相談している
□02 意見交換会や連絡会を開催している
□03 その他 （　　）

19. 苦情・相談受付業務について、日頃から関係団体と連携していますか。

□01 している
□02 していない　　**→問21へ**

20. 問19で「している」と回答された場合、連携団体について教えてください。
（当てはまるもの全て選択）

□01 医師会
□02 歯科医師会
□03 薬剤師会
□04 患者会
□05 法テラス（日本司法支援センター）・医療ADR・弁護士会
□06 女性センター・男女共同参画センター
□07 消費者センター
□08 NPO等民間機関
□09 その他 （　　）

21. 苦情・相談受付業務について、日頃から他の行政機関と連携していますか。

□01 している
□02 していない　　**→問23へ**

22. 問21で「している」と回答された場合、連携機関について教えてください。
（当てはまるもの全て選択）

□01 他の医療安全支援センター
□02 保健所
□03 立入検査部門
□04 厚生労働省
□05 警察
□06 社会福祉協議会
□07 その他 （　　）

23. 苦情・相談への対応で負担に感じた事例を教えてください。（当てはまるもの全て選択）
- □01 1日の受付件数が多かったこと
- □02 対応が長時間になったこと
- □03 相談者の納得が得られなかったこと
- □04 相談者から暴言を受けたこと
- □05 相談者から暴力を受けた／受けそうになったこと
- □06 その他 （ ）
- □07 ない

24. 苦情・相談受付業務について、業務の負担感を教えてください。
- □01 非常に負担に感じる
- □02 やや負担に感じる
- □03 あまり負担に感じない
- □04 全く負担に感じない

25. 医療事故が疑われる事例を受け付けた場合に、医療事故に該当するかどうかを誰が判断していますか。

- □01 相談受付者が判断する
- □02 センターの代表者が判断する
- □03 会議体で判断する
  （具体的な会議体: ）
- □04 その他 （ ）
- □05 定めていない

26. 苦情・相談内容を医療施設へフィードバックするかどうかを誰が判断していますか。
- □01 相談者の意向による
- □02 相談受付者が判断する
- □03 センターの代表者が判断する
- □04 会議体で判断する
  （具体的な会議体: ）
- □05 その他 （ ）
- □06 定めていない

27. 苦情・相談内容を医療機関へフィードバックする際に、貴センター内で統一した書式を使用していますか。

- □01 はい
- □02 いいえ

28. 苦情・相談内容を医療施設へフィードバックする際に、負担に感じていることを教えてください。
（当てはまるもの全て選択）
- □01 医療機関の連絡先窓口が不明な場合があること
- □02 診療時間の妨げにならないよう苦慮すること
- □03 フィードバック方法に苦慮すること
- □04 フィードバックに対する医療機関の受付対応に拒否感があること
- □05 相談者と医療機関の言い分が異なること
- □06 その他 （具体的に: ）
- □07 ない

29. 医療施設へフィードバックする際の伝達方法の工夫を教えてください。（当てはまるもの全て選択）

□01 診療時間外に連絡するようにしている
□02 相談者を匿名化している
□03 苦情・相談の対象となった医療施設職員を匿名化している
□04 伝達内容・方法をセンター内で検討してから連絡している
□05 齟齬がないよう文章で伝えるようにしている
□06 伝達内容は相談者の主観によるものだと前置きをしている
□07 その他 （具体的な工夫の方法）

□08 工夫はしていない(そのまま伝えている)

30. 相談者の連絡先が明らかな場合、医療機関にフィードバックしたことを相談者に報告していますか。
（当てはまるもの全て選択）

□01 全件報告している
□02 相談者から希望があった場合は報告している
□03 報告していない
→**問32へ**
□04 都度判断している

31. 問30で「都度判断している」と回答された場合、誰が判断をしていますか。
（当てはまるもの全て選択）

□01 相談受付者が判断する
□02 センターの代表者が判断する
□03 その他 （ ）
□04 定めていない

32. フィードバックした苦情・相談内容について、医療機関からその後の対応報告を求めていますか。
（当てはまるもの全て選択）

□01 全件求めている
□02 一部求めている （基準: ）
□03 求めていない

33. 立入検査部門に苦情・相談内容を引き継いでいますか。
(2020年度実績より当てはまるもの全て選択)

□01 全件引き継いでいる
□02 相談者から希望があった場合は引き継いでいる
□03 引き継いでいない
→**問35へ**
□04 案件による

34. 問33で「案件による」と回答された場合、具体的な基準を教えてください。

35. 苦情・相談事例の分析方法を教えてください。（当てはまるもの全て選択）

□01 年次報告よりも詳細な受付内容の分類
□02 受付内容の傾向の把握
□03 専門性が高かった内容の対応方法の検討
□04 相談者の納得が得られなかった事例の検討
□05 その他 （ ）
→**問36へ**
□06 分析はしていない →**問38へ**

36. 分析した苦情・相談事例をどのように活用されていますか。（当てはまるもの全て選択）

□01 医療安全の確保に関する情報提供の一部としている
□02 研修会で紹介、情報提供をしている
□03 医療安全推進協議会で報告
□04 その他 （ ）
□05 活用はしていない
□06 苦情・相談受付業務の改善のために利用

→問38へ

37. 問36で「苦情・相談受付業務の改善のために利用」と回答された場合、具体的な改善事例を教えてください。

＜医療安全の確保に必要な情報の提供について＞

38. 医療安全の確保に関する情報をどのように収集していますか。（当てはまるもの全て選択）

□01 苦情・相談受付事例から収集
□02 医療機関から収集
□03 医療安全推進協議会を通して収集
□04 外部機関・団体から収集
　□041 日本医療機能評価機構
　□042 医薬品医療機器総合機構
　□043 日本医療安全調査機構
　□044 その他 （ ）
□05 学会・学術誌から収集
　□051 医療の質・安全学会
　□052 日本医療マネジメント学会
　□053 日本医療・病院管理学会
　□054 その他 （ ）
□06 行政通知
□07 その他 （ ）
□08 情報収集はしていない

39. 医療機関向け「医療安全の確保に必要な情報」の提供方法を教えてください。
（当てはまるもの全て選択）

□01 ホームページ上で公開
□02 紙媒体（冊子等）で配布
□03 電子媒体（メールマガジン等）で配布
□04 研修会を開催
□05 会議体で報告
□06 学会で発表
□07 その他 （ ）

40. 問39の選択肢の中で、特に重要だと考えている方法はどちらですか。
（01～07の番号でお答えください）
（ ）

41. 住民向け「医療安全の確保に必要な情報」の提供方法を教えてください。
（当てはまるもの全て選択）

□01 ホームページ上で公開
□02 紙媒体（冊子等）で配布
□03 電子媒体（メールマガジン等）で配布
□04 市民講座を開催
□05 学会で発表
□06 その他 （ ）

42. 問41の選択肢の中で、特に重要だと考えている方法はどちらですか。
（01～06の番号でお答えください）
（ ）

43. 医療機関へ提供した情報について、各医療機関での活用状況を確認していますか。
□01 確認していない　→**問45へ**
□02 確認している

44. 問43で「確認している」と回答された場合、活用状況をどのように確認していますか。
（当てはまるもの全て選択）
□01 アンケート調査をしている
□02 ヒアリング調査をしている
□03 意見交換会・連絡会を開催している
□04 その他 （　　）

45. 住民への情報提供について、効果測定をしていますか。
□01 している（具体的な方法：　　）
□02 していない

＜医療機関の管理者、従業者に対する医療安全に関する研修の実施について＞

46. 医療機関向け研修会について、開催形態別実施回数を教えてください。
（2020年度実績についてお答えください）
01 講演会（オンラインを含む）　（　　）回
02 グループワーク・演習を中心とした研修会　（　　）回
03 その他の形式　（　　）回

47. 医療機関向け研修会で取り扱ったテーマについて教えてください。（過去3年間の実績）

48. 研修会の開催について、効果測定をしていますか。
□01 している （具体的な方法：　　）
□02 していない

＜その他＞

49. センターの運営について、定期的な見直しをしていますか。
□01 見直していない　→**問51へ**
□02 見直している

50. 問49で「見直している」と回答された場合、見直している内容を教えてください。
（当てはまるもの全て選択）
□01 苦情・相談受付業務について見直している
□02 情報提供業務について見直している
□03 研修会の開催業務について見直している
□04 全体の予算、人員配置について見直している
□05 その他（　　）

51. 現在と今後の各業務のおおよその資源配分について、あなたの考えを教えてください。
（合計が100（%）になるようにお答えください）
＜現状＞
01 苦情・相談受付業務　（　　）%
02 情報提供業務　（　　）%
03 研修会の開催業務　（　　）%
04 その他の業務　（　　）%

＜今後＞
01 苦情・相談受付業務　（　　）%
02 情報提供業務　（　　）%
03 研修会の開催業務　（　　）%
04 その他の業務　（　　）%

52. 各業務について、目標に対する達成度を教えてください。
（100点満点でお答えください）

01 苦情・相談受付業務　　（　　）点／100点
02 情報提供業務　　（　　）点／100点
03 研修会の開催業務　　（　　）点／100点
04 その他の業務　　（　　）点／100点

53. 貴センターの活動を円滑に実施するために、今後、必要だと考えられるものを教えてください。
（当てはまるもの全て選択）

□01 業務全般について、センター職員のための教育ツール
□02 苦情・相談受付業務について、医療機関へのフィードバックの書式（フォーマット）
□03 苦情・相談受付業務について、受付内容を整理するための分類方法（フォーマット）
□04 情報提供業務について、医療安全の確保に関する最新の情報源
□05 研修会の開催業務について、研修会の標準的プログラム
□06 研修会の開催業務について、研修会にて講演する講師の紹介
□07 その他 （　　）

54. その他に貴センターで独自の医療安全に関する取り組みを行っている場合、具体的な内容を教えてください。

55.回答者ご連絡先
後日、ご回答いただいた内容について詳細をお伺いする可能性があります。
（差し支えなければ）本調査の趣旨をご理解の上、ご協力賜りますよう、お願い申し上げます。

センター名 （必須）		
お名前 *（任意）*		
電話番号 *（任意）*		*電子メールアドレス（任意）* *@*

調査項目は以上です。
調査へのご協力ありがとうございました。

問い合わせ先：
東邦大学医学部 社会医学講座
大西遼
〒143-8510　東京都大田区大森西5-21-16
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health@med.toho-u.ac.jp

基礎集計

「医療安全支援センターの活動状況に関する調査」

配布・回収数

配布数：397 件

回収数：231 件（回収率　58.2%）

＜医療安全支援センターの基礎的な情報＞

１．貴センターの設置区分について教えてください。

	n	%
都道府県センター	67	29.6
二次医療圏センター	93	41.2
保健所設置市区センター	66	29.2
合計	226	100

２．貴センター所管区域内の医療施設数について教えてください。

	病院	診療所	その他
平均値	40.9	580.0	240.8
標準偏差	69.6	919.3	763.1

３．現在の職種別常勤換算職員数について教えてください。

	医師	看護師・保健師	薬剤師	行政職	その他	総数
平均	0.3	2.6	1.6	3.0	2.1	7.3
標準偏差	0.5	4.0	2.2	4.6	4.9	10.8
最小	0	0	0	0	0	0
最大	3	20	12	35	37	72

４．センターの職員としての平均勤続年数は、およそ何年ですか。

	勤続年数
平均	3.9
標準偏差	3.4

5．職員に対して相談業務に関わる研修の受講を定めていますか。（複数選択）

	n	%
医療安全支援センター総合支援事業	91	40.1
センター・自治体	33	14.5
その他	6	2.6
定めていない	119	52.4

（その他）

- 具体的には定めてないが、必要な研修を受講することと定めている
- 医務主幹会議
- 北海道厚生局の研修
- 内容証明について
- 民事調定
- 医療訴訟について調べスタッフ内で発表し知識を深めた
- 厚生支局主催
- 近畿厚生局主催医療安全シンポジウム
- 京都府看護協会医療安全の研修会

＜苦情・相談への対応について＞

6．苦情・相談の受付方法について教えてください。（複数選択）

	n	%
電話	229	99.1
面談（予約有）	187	81.0
面談（予約無）	185	80.1
電子メール	173	74.9
手紙・FAX	172	74.5
その他	5	2.2

（その他）

- 市のホームページで対応
- 神戸市ホームページ
- 庁内、他部署からの紹介、相談案件
- 他所属からの転移

7．貴センター内に面談のための個室を確保していますか。

	n	%
確保している	146	63.2
確保していない	81	35.1
無回答	4	1.7

８．問７で「確保していない」と回答された場合、具体的な面談希望者への対応方法とプライバシーへの配慮方法を教えてください。

（個室がない場合、面談希望者への対応方法）

- 受付窓口で対面で実施
- 個室ではない共有の打ち合わせスペースで面談を行っている。（予約無の場合）
- 原則として電話相談のみ
- 他業務との併用の個室あり（予約なしの面接では利用しないこともある）。
- 共有の面接室に空きがなければ、執務室の隅にある相談コーナーで対応している。
- 個室に準じたスペースを利用している。
- 原則電話による受付であること及び面談ではプライバシーへの配慮ができないことを伝えた上で、面談を希望される方に対して面談対応を実施。
- 医療安全相談センターの部屋のドアを閉めることにより、外部に聞こえないようにしている。
- 面談については原則予約対応としている。

（個室がない場合の、プライバシーへの配慮方法）

- 声の大きさに留意する（個室で対応する場合もある）
- 個室を希望する場合は、庁内会議室を確保した上で、実施していることから、必ず事前予約及び日程調整を行い、面談している。
- 窓口に設置されたパーテーション
- 専用室としては確保していないが、必要に応じて使用できる個室を確保する。
- 必要に応じて個室で対応する。
- 共有の会議室を使用。
- デスク間の間隔を開け、他が使用していない時に使用。
- 個室に準じたスペースを利用している。
- 隣の席は空ける
- パーテーションを用いて、可能な限り会話が周りに漏れないよう配慮している。
- 相談ごとに相談者に対して氏名等や相談内容を医療機関等に知らせてよいか確認している。
- 予め窓口での対応について了承していただいている。状況に応じ会議室等の別室を使用する。

９．１週間のうち、苦情・相談に対応可能な総時間を教えてください。

	総時間
平均	25.8
標準偏差	26.2

１０．平日夜間（18 時以降）に苦情・相談の対応をしていますか。

	n	%
している	8	3.5
していない	223	96.5

（具体的対応）

- 緊急的な案件の場合、相談者及び医療機関等に架電等にて対応。
- 夜間休日用の携帯電話に電話してもらう。
- 留守番電話の活用
- 所用携帯電話へ架電がある可能性あり。
- 相談を中断しない。
- 電話があれば（職員が残業中なら対応）
- 緊急で対応が必要なケースについては対応。

１１．土日、祝祭日に苦情・相談の対応をしていますか。

	n	%
している	6	2.6
していない	224	97.0
無回答	1	0.4

（具体的対応）

- 緊急的な案件の場合、相談者及び医療機関等に架電等にて対応。
- 夜間休日用の携帯電話に電話してもらう。
- 留守番電話の活用
- 所用携帯電話へ架電がある可能性あり。
- 緊急で対応が必要なケースは対応。

１２．苦情・相談受付業務の外部委託状況について教えてください。

	n	%
全て委託	4	1.7
一部委託	2	0.9
委託していない	225	97.4

１３．問１２で「全て委託している」「一部委託している」と回答された場合、相談受付業務の委託先と委託している業務内容について教えてください。

（委託先）

- ダイヤルサービス（株）
- 県医師会、県歯科医師会
- ALSOK あんしんケアサポート株式会社

（業務内容）

- 苦情・相談・医療機関案内・報告書作成
- 県医師会：医療安全支援センター（苦情相談センター）必要時医師が対応。県歯科医師会：県民歯科相談。歯科医師対応あり。
- 患者相談窓口に寄せられた相談・苦情への対応
- 電話での医療相談業務
- 電話による苦情・相談（内容については相談受付票に入力して翌日送付）
- 電話相談窓口にかかってきた電話に対する対応

１４．年間の苦情受付件数および相談受付件数はそれぞれ何件ですか。

	受付総数	相談	苦情	医療機関へのフィードバック	立入検査部門への引継ぎ	医療事故が疑われる事例
平均	316.0	208.3	101.9	24.6	3.6	2.1
標準偏差	811.1	498.4	277.6	54.3	23.5	12.7
最小	0	0	0	0	0	0
最大	9689	5216	3371	609	327	147

１５．受付内容について、内訳をそれぞれ回答してください。

	医療行為・医療内容	コミュニケーション	施設
平均	67.9	52.4	8.8
標準偏差	153.0	143.4	23.4

	医療情報	医療情報_カルテ情報	医療情報_セカンドオピニオン	医療情報_その他	医療機関の紹介・案内
平均	13.2	3.5	1.1	8.6	45.6
標準偏差	29.8	8.1	2.7	20.5	85.6

	医療費	医療知識	医療知識_健康や病気	医療知識_薬品	医療知識_その他	その他
平均	24.9	96.9	72.1	8.3	16.7	61.0
標準偏差	67.8	250.5	173.6	23.0	77.8	222.6

１６．苦情・相談受付業務において、貴センター内で相談者の属性や相談内容を整理するための統一した分類方法を使用していますか。

	n	%
している	171	74.0
していない	59	25.6
無回答	1	0.4

１７．苦情・相談受付業務について、日頃から医療機関と連携していますか。

	n	%
している	68	29.4
していない	163	70.6

１８．問１７で「している」と回答された場合、連携内容について教えてください。（複数選択）

	n	%
専門性の高い苦情・相談	29	42.6
意見交換会・連絡会	13	19.1
その他	32	47.1

（その他）

- 医療機関への情報提供時に、必要に応じてお互いの持つ情報を交換している。
- 相談のあった医療機関に可能な範囲で情報提供する。
- 医療安全推進協議会の委員を関係団体から推薦してもらっている。また、3 ケ月に一度、主な相談内容を関係団体へ送付している。
- 対応困難事例について対象の医療機関に事実確認等を行っている。
- 事後対応（改善含む）を促すうえから、情報提供することがある。
- 個々の相談事例に対する情報提供、助言等を行っている。
- 相談者の了承を得たうえで、対象医療機関へ相談内容を報告している。
- 医師会、市内 12 病院に電話連絡。
- 随時共有している。精神保健分野や難病医療機関への立入などで日頃から関係あり。

１９．苦情・相談受付業務について、日頃から関係団体と連携していますか。

	n	%
している	79	34.2
していない	149	64.5
無回答	3	1.3

２０．問１９で「している」と回答された場合、連携団体について教えてください。（複数選択）

	n	%
医師会	68	86.1
歯科医師会	60	75.9
薬剤師会	43	54.4
患者会	2	2.5
弁護士会等	29	36.7
女性センター・男女共同参画センター	5	6.3
消費者センター	33	41.8
NPO	0	0.0
その他	26	32.9

（その他）

- 看護協会
- 社会保険事務所
- 2 次救急病院、看護協会
- 社会保険事務所、厚生局
- 看護協会、国民健康保険団体連合会、PTA 連絡協議会、老人クラブ連合会
- 看護協会、人権擁護委員協議会
- 他部署
- 県医療政策課（立入検査部門）
- 社会保険事務所（年金事務所ほか）
- 看護協会、病院協会、医療ソーシャルワーカー協会など
- 自立相談支援センター
- 看護協会、病院協会、精神科病院協会
- 看護協会、栄養士会
- 保健所内＋保健福祉センター（南・北）
- 地域包括支援センター

２１．苦情・相談受付業務について、日頃から他の行政機関と連携していますか。

	n	%
している	140	60.6
していない	89	38.5
無回答	2	0.9

２２．問２１で「している」と回答された場合、連携機関について教えてください。（複数選択）

	n	%
他の医療安全支援センター	98	69.0
保健所	88	62.0
立入検査部門	65	45.8
厚生労働省	20	14.1
警察	6	4.2
社会福祉協議会	5	3.5
その他	15	10.6

（その他）

- 県の他部署、市町村国保主管課、市町村障がい者福祉主管課
- 県庁主管課（医療安全相談窓口は保健所内に設置）保健所職員が兼務
- 保健センター
- 不妊専門相談センター
- 消費生活センター
- 精神保健福祉センター
- 労働基準監督署
- 厚生局
- 相談内容に応じて関係機関と連携している

２３．苦情・相談への対応で負担に感じた事例を教えてください。（複数選択）

	n	%
１日の受付件数が多かったこと	50	21.9
対応が長時間になったこと	194	85.1
相談者の納得が得られなかったこと	163	71.5
相談者から暴言を受けたこと	125	54.8
相談者から暴力を受けた／受けそうになったこと	22	9.6
その他	30	13.2
ない	7	3.1

（その他）

- 精神疾患の方に対し、どのような対応をすればよいか分からないとき。ex、相談者が興奮されている時、言葉が聞きとりにくい時、繰り返し同じ相談ばかりされる時。
- 特定の相談者から頻回の長時間に及ぶ苦情相談のため他の相談者の専用窓口での対応が出来なかった。
- 理不尽な要求
- 特定の苦情申立者から連日苦情を受ける場合があること。
- クレーマーへの対応。精神疾患のある方に対する対応。

- 心の病と思われる相談者が複数回、被害妄想と思われる苦情をしてくること。
- 看護や社会福祉の専門知識を持つ職員がいないため対応できなかったこと。
- 上司から、クレーマーの対応を指示されたこと。
- 相談者の医療機関に対する怒りを抑えるのに難渋する。
- 対応になれていない。
- 相談者が自殺をほのめかし切電したとき。
- 対象医療機関への改善、指導、仲裁してほしいと言われること。
- 感情的な言葉を一方的に聞くこと
- 相談者がリピーターとなったり、医療機関側が対応等について協力的でなく板挟みになったこと。
- 相談者からの情報のまちがい
- メール相談を受けているが、電話と違い意図が伝わりにくく、返信の作成に労力がかかる。
- 特定の人から頻繁に電話があり同じ話しのくりかえしになっている。
- 対応できないことを要求されたこと。
- 相談窓口に介入を求められるが当事者間の解決しか方法がない事例。

２４．苦情・相談受付業務について、業務の負担感を教えてください。

	n	%
非常に負担	60	26.0
やや負担	135	58.4
あまり負担に感じない	29	12.6
全く負担に感じない	4	1.7
無回答	3	1.3

２５．医療事故が疑われる事例を受け付けた場合に、医療事故に該当するかどうかを誰が判断していますか。

	n	%
相談受付者	13	5.6
センター代表	35	15.2
会議体	11	4.8
その他	62	26.8
定めていない	104	45.0
無回答	6	2.6

（具体的な会議体）

- 保健所内での会議
- 所長、次長、課長、担当者で合議
- 医療安全支援センター事例検討会
- 所属長を含めた所内会議

（その他）

- 判断していない
- 判断はしない。医療 ADL や法テラスを案内。
- 医療事故に該当するかどうかの判断はしていない。遺族が医療事故と疑われている場合は、遺族への説明を医療機関に依頼している。
- 行政は医療事故の判断はしない。
- 苦情・相談の内容によっては、当センターでは医療事故に該当するかどうかの判断を
- 助言機関のため、判断はしない。
- 判断できません。
- 北海道で定めた「事故等発生時の報告事務取扱要領」に基づく。
- 保健所内で協議する。
- 該当例ないが、疑い事案はその都度判断することになる。
- ケースバイケースで対応する。
- 医療事故制度に基づき医療機関が判断するため、当センターでの判断は行わない。
- 本庁主管課と協議。
- 立入検査部門と協議して決める。
- 当該医療機関の医療安全委員会。
- 所長、部長、課長と協議。本庁と相談。
- 県庁医療政策課、塩釜保健所（本所）
- 相談受付者が発案し、次にセンター関係職員で協議し決定。
- 医療仲裁センター岡山等を紹介している。
- 相談内容に応じて、相談員全体で共有をし、意見をまとめて判断する。判断に迷う場合は、所属長に相談し、組織として判断する。
- 立入検査担当部門に情報提供している。
- センター代表者である医療安全課長と医療安全医務監で協議し、判断する。
- 判断していない。
- 相談をうけ、所内で協議。
- センターを所管する県庁地域医療課に報告し課として判断。
- 事例はないが、上司、保健所医師に相談する。
- 保健所長
- 関係課と相談の上対応
- 近年は疑わしい事例なし。
- 相談受付内容をセンター内で合議して判断する。

２６．苦情・相談内容を医療施設へフィードバックするかどうかを誰が判断していますか。

	n	%
相談者の意向	120	51.9
相談受付者	21	9.1
センター代表	8	3.5
会議体	7	3.0
その他	13	5.6
定めていない	28	12.1
無回答	34	14.7

（具体的な会議体）

- 所内システムによる。
- 所長、次長、課長、担当者で合議
- 所属長を含めた所内会議
- 保健所内会議
- 所内会議で協議

（その他）

- 相談者の意向があり、受付者も必要と感じた場合、責任者が判断する。
- 相談内容に応じ、個別に判断。
- センターの担当者間で検討し判断する。
- 所内会議
- 所長、次長に相談して判断する。
- 担当者、課長、部長、所長、場合によっては、本庁担当課
- 県庁医療政策課、塩釜保健所（本所）
- 相談受付者が発案し、次にセンター関係職員で協議し決定。
- 立入検査担当部門に情報提供している。
- 保健所長

２７．苦情・相談内容を医療機関へフィードバックする際に、貴センター内で統一した書式を使用していますか。

	n	%
はい	28	12.1
いいえ	200	86.6
無回答	3	1.3

２８．苦情・相談内容を医療施設へフィードバックする際に、負担に感じていることを教えてください。（複数選択）

	n	%
医療機関の連絡先窓口が不明な場合があること	51	22.5
診療時間の妨げにならないよう苦慮すること	84	37.0
フィードバック方法に苦慮すること	51	22.5
フィードバックに対する医療機関の受付対応に拒否感があること	67	29.5
相談者と医療機関の言い分が異なること	154	67.8
その他	18	7.9
ない	32	14.1

（その他）

- 相談者からの要望内容が一方的な内容であり、匿名希望され、伝える必要を感じない時、診療所の場合、医師に伝える事が多く、医師の受け取り方が予想できず、無理難題を言われるとき。
- 直接のフィードバックは行っていない。
- 相談者の苦情が一方的であったり、信憑性に欠ける時。・正しい情報であるのか迷う時。
- 医療機関の言い分がわからないこと。
- 医療機関から、苦情を受けること。（フィードバック内容に対して）
- フィードバックに対して医療機関からクレームが入り、新たなクレーム対応をしなくてはならない場合があること。
- 医療機関の立入検査を行う保健所からのフィードバックであることで、医療機関が保健所からの「指導」と受けとる可能性があること。
- 相談者よりトラブルの仲介を求められること。
- 医療施設内で事例が共有されていない場合がある。
- 相談者が匿名を希望されることでフィードバックがうまくいかないケースがある。（不利益が生じることを心配し匿名とされる）
- たまに医師に逆ギレされることがある。
- 相談者の氏名を聞きたがる。
- 医療機関（特に診療所）によっては対応が一方的である。

２９．医療施設へフィードバックする際の伝達方法の工夫を教えてください。（複数選択）

	n	%
診療時間外に連絡するようにしている	42	18.4
相談者を匿名化している	77	33.8
苦情・相談の対象となった医療施設職員を匿名化している	25	11.0
伝達内容・方法をセンター内で検討してから連絡している	77	33.8
齟齬がないよう文章で伝えるようにしている	6	2.6
伝達内容は相談者の主観によるものだと前置きをしている	136	59.6
その他	33	14.5
していない/そのまま伝える	19	8.3

（その他）

- 匿名の希望があれば匿名としている
- 相談者の希望があった場合のみ、個人情報を伝える。
- 相談者の希望を聞き取り、文書化して整理した上で、口頭で伝える。
- 直接のフィードバックは行わないこと。
- 常に中立的立場を崩さない。
- 文書で送付しているが、文案は相談者に了解を得るまで、何回も擦り合わせを行っている。
- 相談者から強い希望があったことを前置きして伝える。
- 病院の場合：RM 又は SW へ、RM が看護職だと話の理解が早い。クリニック等の場合事務職、リーダ看護師へ。
- 伝達内容の多くが個人の特定がされるものなので、あらかじめ了承を得ておく。
- 施設管理者の都合の良い時間を確認し、その時間に伝達している。
- 文章での回答をお願いしている。
- 中立の立場なので指導はしないことを前置きして説明している。
- 行政職員から連絡する。
- 行政指導ではないことを伝える。

３０．相談者の連絡先が明らかな場合、医療機関にフィードバックしたことを相談者に報告していますか。（複数選択）

	n	%
全件	3	1.3
相談者の希望に基づき	155	68.0
していない	44	19.3
都度判断	34	14.9

３１．問３０で「都度判断している」と回答された場合、誰が判断をしていますか。（複数選択）

	n	%
相談受付者	19	55.9
センター代表	5	14.7
その他	8	23.5
定めていない	7	20.6

（その他）

- 相談者が聞きたいと言われた場合は連絡をしてもらう。
- 上司へ相談
- 協議をもって判断
- 常勤職員
- 基本は報告しないが相談者の状況によって報告することがある。
- センターの代表者を含めて協議または文書で報告。
- 相談受付者が発案し、次にセンター関係職員で協議し決定。

３２．フィードバックした苦情・相談内容について、医療機関からその後の対応報告を求めていますか。

	n	%
全件求めている	12	5.2
一部求めている	52	22.5
求めていない	159	68.8
無回答	8	3.5

（一部求めているとした際の基準）

- 必要に応じて
- 医療機関へのフィードバック後も、相談者からセンターに何度も相談がある場合。
- 相談者からの希望があった場合及び立入検査にまでは至らないが、改善状況の確認が必要な場合。
- 相談者へ回答を要する場合、保健所として対応を把握したい場合
- 改善確認が必要と認めたもの
- 継続した対応が必要な場合
- 案件ごとに判断
- 法令違反がある場合
- 医療法 25 条に関連した場合のみ
- その後対応しなかった場合に相談者の健康に重大な影響を及ぼしかねないケースで求めることがある。
- 対応後に問題が生じた場合
- 法違反や感染対策等
- 医療法等保健所所管法令に関する改善等が必要な場合

- 明確な基準はなく、都度センター内で相談し、必要があると判断した場合
- 相談内容に医療機関に非がある場合

３３．立入検査部門に苦情・相談内容を引き継いでいますか。（2020 年度実績より当てはまるもの全て選択）

	n	%
全件	72	32.0
相談者の希望による	29	12.9
引継いでいない	43	19.1
案件による	87	38.7

３４．問３３で「案件による」と回答された場合、具体的な基準を教えてください。

相談者に保健所や近畿厚生局等に直接連絡してもらうよう伝えている。

- 対応が必要と判断された場合のみ。
- 医療法上の施設基準等に抵触しているかどうか。
- センター担当職員と立入検査部門の担当職員が同一のため、立入検査部門に全件引き継いでいる。
- 立入検査で確認できるもの、した方が良いもの。
- 医療法の立入検査項目であるかどうか。
- 明らかな医療法違反が疑われる場合は引き継ぐ。
- 患者に不利益を与えると判断した医療機関に対して。
- 法令、違反が疑われる場合。
- 調剤過誤、誤処方、無資格者による医療行為、医療事故、施設基準不適合、個人情報漏えい、院内感染が相談内容に含まれる場合。
- 定期的に実施している立入検査にて指導すると判断した緊急性の無いもの。②医療法 25 条の対応が必要な（無資格者等）もの。
- 具体的な基準はない。
- 対応状況が確認できてない場合。
- 医療法上定められている清潔保持に違反する恐れがある場合。
- 誤処方。
- 無資格者による医療行為。
- 施設基準が満たされていない。
- 同一案件を複数受けた場合。
- センターの判断による。

３５．苦情・相談事例の分析方法を教えてください。（複数選択）

	n	%
年次報告よりも詳細な受付内容の分類	33	14.5
受付内容の傾向の把握	79	34.8
専門性が高かった内容の対応方法の検討	26	11.5
相談者の納得が得られなかった事例の検討	30	13.2
その他	7	3.1
分析はしていない	128	56.4

（その他）

- 年次推移
- 分析する件数がない。
- 立入検査部署につながった事例の検討。
- 協議会に議題として相談事例を提出し、委員から助言してもらっている。
- 数や内容について、年ごとに傾向を見ている。

３６．分析した苦情・相談事例をどのように活用されていますか。（複数選択）

	n	%
医療安全の確保に関する情報提供の一部としている	34	34.7
研修会で紹介、情報提供をしている	29	29.6
医療安全推進協議会で報告	50	51
その他	7	7.1
活用はしていない	10	10.2
苦情・相談受付業務の改善のために利用	13	13.3

（その他）

- 所内で共有
- 医師会報への掲載
- 事例検討会で医務指導係に報告。医師会・歯科医師会・薬剤師会へ報告。
- 立入検査部門と情報共有
- 市の福祉部門の審議会での報告
- 医師会、県センターとの情報共有
- 医師会、歯科医師会に事例提供している

３７．問３６で「苦情・相談受付業務の改善のために利用」と回答された場合、具体的な改善事例を教えてください。

- 同様の苦情・相談が寄せられた場合や同一人物からの苦情・相談に円滑に対応するために利用している。
- 年２回、弁護士に対応事例相談（今年度は中止）
- 相談対応によって解決できるものと関係機関へいち早く報告すべきものなのか選別ができる。

- 相談業務にあたる者で共有
- 同様の苦情や相談があった時は適切なアドバイスができるようにしている。

＜医療安全の確保に必要な情報の提供について＞

３８．医療安全の確保に関する情報をどのように収集していますか。（複数選択）

	n	%
苦情・相談受付事例	132	57.4
医療機関	19	8.3
医療安全推進協議会	37	16.1
外部機関・団体	97	42.2
日本医療機能評価機構	73	31.7
医薬品医療機器総合機構	44	19.1
日本医療安全調査機構	58	25.2
その他の外部機関・団体	4	1.7
学会・学術誌	28	12.2
医療の質・安全学会	22	9.6
日本医療マネジメント学会	6	2.6
日本医療・病院管理学会	3	1.3
その他の学会・学術誌	3	1.3
行政通知	175	76.1
その他	8	3.5
していない	12	5.2

（その他の外部機関・団体）

- 医療事故調査・支援センター
- 医療関連サービス振興会・愛知県医師会医療安全支援センター、東京大学医療安全管理学講座
- ささえあい医療人権センターコムル（COML）

（その他の学会・学術誌）

- 愛知県医師会医療安全支援センター報告集
- 医療事故調査・支援センターなどから送られて来るリーフレット等など
- 薬事日報、ドラッグインホメーション、日本医事新報

（その他）

- 医療安全支援センター総合支援事業相談対応ガイドブック
- メディアファクス、新聞記事
- 県本庁から
- 他の行政機関のホームページ等
- 県センターからの情報提供による

- 研修：医療安全支援センター研修会、東京都福祉保健局講習会等
- 東京都との連絡会

３９．医療機関向け「医療安全の確保に必要な情報」の提供方法を教えてください。（複数選択）

	n	%
ホームページ	78	33.8
紙媒体（冊子等）	32	13.9
電子媒体（メールマガジン等）	36	15.6
研修会	59	25.5
会議体で報告	18	7.8
学会で発表	0	0.0
その他	34	14.7

（その他）

- 厚生労働省からの受託業者からの「医療安全情報」をメール配信
- 医療監視時に情報提供
- 県センターがホームページ上で公開
- 県医師会、歯科医師会等の求めに応じ資料提供
- 高知県医療安全支援センターとして研修会を開催している
- メール
- 厚生労働省等通知の送付
- 医療安全研修会の中で報告
- 県本庁で対応
- 必要に応じて電話で提供している
- 必要時紙媒体で配布（立入検査、相談時）
- 立入り検査部門から通知
- 関係団体を通して提供
- 保健所を通じて通知等を発出することなどにより提供している
- 必要に応じて検討する
- ポスター掲示
- 市の広報に掲載

４０．問３９の選択肢の中で、特に重要だと考えている方法はどちらですか。（複数選択）

	n	%
ホームページ	65	38.5
紙媒体（冊子等）	16	9.5
電子媒体（メールマガジン等）	19	11.2
研修会	52	30.8
会議体で報告	6	3.6
その他	11	6.5

４１．住民向け「医療安全の確保に必要な情報」の提供方法を教えてください。（複数選択）

	n	%
ホームページ	114	49.4
紙媒体（冊子等）	15	6.5
電子媒体（メールマガジン等）	0	0.0
市民講座	16	6.9
学会で発表	0	0.0
その他	18	7.8

（その他）

- 医療相談窓口をポスター、ホームページで公開
- 県センターがホームページ上で公開
- 高知県医療安全支援センターとして市民講座を開催している
- 保健所年報公開
- 紙媒体を書架に掲示
- 必要に応じて検討する
- ポスター掲示
- 医療安全研修会への参加をよびかける
- レディオ MoMo
- 実施していないが、10 ケ条等を窓口で配布することを検討している
- 相談窓口において適宜情報提供を行っている
- 市の広報誌に掲載

４２．問４１の選択肢の中で、特に重要だと考えている方法はどちらですか。

	n	%
ホームページ	125	82.2
電子媒体（メールマガジン等）	1	0.7
市民講座	20	13.2
その他	6	3.9

４３．医療機関へ提供した情報について、各医療機関での活用状況を確認していますか。

	n	%
確認していない	207	89.6
確認している	8	3.7
無回答	16	100

４４．問４３で「確認している」と回答された場合、活用状況をどのように確認していますか。

	n	%
アンケート	0	0.0
ヒアリング	1	14.3
意見交換会・連絡会	0	0.0
その他	6	85.7

（その他）

- 協議会で確認している
- 立入り検査部門が立入り時に確認している
- 病院立入検査や診療所医療調査を時に確認している
- 保健所での立入検査等の機会を通じて必要に応じ確認している
- 医療監視時に聴き取り

４５．住民への情報提供について、効果測定をしていますか。

	n	%
している	2	0.9
していない	210	90.9
無回答	19	8.2

（具体的に）

- 満足度調査
- 講演会後のアンケート実施

＜医療機関の管理者、従業者に対する医療安全に関する研修の実施について＞

４６．医療機関向け研修会について、開催形態別実施回数を教えてください。（2020 年度

実績についてお答えください）

	講演会	研修会	その他
平均	0.36	0.05	0.06
標準偏差	0.86	0.27	0.24
最小	0	0	0
最大	6	2	1

４７．医療機関向け研修会で取り扱ったテーマについて教えてください。（過去 3 年間の実績）

文末参照

４８．研修会の開催について、効果測定をしていますか。

	n	%
している	35	15.2
していない	152	65.8
無回答	44	19.0

（具体的に）

- アンケート

＜その他＞

４９．センターの運営について、定期的な見直しをしていますか。

	n	%
していない	173	74.9
している	49	21.2
無回答	9	3.9

５０．問４９で「見直している」と回答された場合、見直している内容を教えてください。（複数選択）

	n	%
苦情・相談受付業務	37	75.5
情報提供業務	20	40.8
研修会の開催業務	15	30.6
全体の予算、人員配置	14	28.6
その他	3	6.1

（その他）

- 他の業務と兼務のため、他の業務の遂行状況等も勘案して見直しを検討している。

- 県民に対する相談窓口案内の内容
- 医療安全推進検討会の実施方法

５１．現在と今後の各業務のおおよその資源配分について、あなたの考えを教えてください。（合計が１００（%）になるようにお答えください）

＜現状＞

	苦情・相談受付業務	情報提供業務	研修会の開催業務	その他の業務
平均	70.6	7.8	5.1	16.6
標準偏差	31.1	9.7	10.1	30.1

＜今後＞

	苦情・相談受付業務	情報提供業務	研修会の開催業務	その他の業務
平均	66.9	9.4	7.1	16.2
標準偏差	31.0	10.2	11.3	29.7

５２．各業務について、目標に対する達成度を教えてください。（１００点満点でお答えください）

	苦情・相談受付業務	情報提供業務	研修会の開催業務	その他の業務
平均	82.0	58.6	38.4	54.2
標準偏差	17.2	35.1	38.6	38.4

５３．貴センターの活動を円滑に実施するために、今後、必要だと考えられるものを教えてください。（複数選択）

	n	%
業務全般：センター職員のための教育ツール	162	70.1
苦情・相談受付業務：医療機関へのフィードバックの書式（フォーマット）	32	13.9
苦情・相談受付業務：受付内容を整理するための分類方法（フォーマット）	23	10.0
情報提供業務：医療安全の確保に関する最新の情報源	79	34.2
研修会の開催業務：研修会の標準的プログラム	42	18.2
研修会の開催業務：研修会にて講演する講師の紹介	53	22.9
その他	23	10.0

（その他）

- 他センターでの業務事例等を参考にさせて頂いているため、共有していただけると

ありがたい。（あまり古い時代（診療）に合わない）
- 医療安全支援センター総合支援事業における、各種研修について、現在も Zoom を使用したオンライン研修を開催されているが、県のセキュリティー上、Zoom 会議に参加できない。Zoom 会議以外の方法も検討して欲しい。
- 適任者の配置
- 外部に委託
- 他機関との連携、相談員へのフォロー
- センター職員のケアに関するツール
- 相談員の育成
- 入力だけで集計が同時にできるシステム
- 財源の確保、全国の事例を踏まえた相談対応マニュアルの作成（各自治体で活用できるもの）
- センター職員の増員
- 医療安全支援センターの役割や業務について、住民や医療機関への普及啓発
- 専門職の設置
- 研修会の統一実施（保健所設置市単位での実施は予算面、人材面等に限界があります。）
- 医療安全支援センターの存在を医療機関にもっと知ってもらう。看護協会の研修に行政の職員が参加し、医療安全支援センターのことを発信する。
- 研修等への参加による情報収集
- センター職員の専従
- 医療安全相談の専任職員
- 他自治体との定期的な連絡会等の実施
- 専任職員の配置 or 委託
- 相談窓口の委託化
- 過去の医療相談事例集を作成し、対応方法の参考にしている。
- 専任の職員
- 医療機関、医療団体との情報共有等を目的とする会議、検討会

５４．その他に貴センターで独自の医療安全に関する取り組みを行っている場合、具体的な内容を教えてください。
- 月に１回、医療相談員と事務担当者とのミーティングを行い、相談内容の傾向の把握、苦慮した相談事例等について情報共有を行っている。
- コミュニケーションエラーを防止することが重要と考えており、センターが所属する部署（医務課）内での相談・報告・連絡を徹底し、相談内容の評価が日常的に行える環境を整えている。
- センター独自のマニュアルと事例集を作成し、年度ごとに内容を更新している。
- 県民向けの講習会の実施。
- 年度をまたぎ頻回に相談苦情のある方について個別にチャートを作成。（担当が変わっても一貫した対応ができるようにするため）

- 立入検査部署への情報提供時に対応フロー図、情報提供シートを活用している。

５５．回答者ご連絡先
（省略）

文末資料

問４７　テーマ一覧

- 新型コロナウイルス感染症の概論と地域医療の連携・対応について
- 「拡散防止が必要な感染症と薬剤耐性菌」、「抗菌薬適正使用に向けての取り組み」、「標準予防策の実際」
- 医療安全相談室の運営等について（概要、実績）
- 医療機関における苦情、クレーム対応。～新型コロナの影響やカスハラ事例をふまえて～。※R2、R 元年はコロナ等の影響により中止。
- 「納得して決めるために～医療者が行う意思決定支援～」（H30 度）「医療事故当事者に対するメンタルケア、ピアサポートについて」（H31 度）「新型コロナと感染対策」（R2 度）
- R1 年度コンフリクトマネジメント　R2 年度パーソナリティ障害　R3 年度中止
- 訪問看護（在宅）におけるリスクマネジメント
- 新型コロナウイルス感染症対策
- R2「災害テロ対応からコロナ対策まで」－世界の経験から－　R1「世界の経験、地域に生かす」－外務省 26 年間の勤務経験から学んだこと－
- 新型コロナ対策
- 新型コロナウイルス感染症等の感染対策、医療安全、感染症に関する危機管理チーム医療、災害医療、アンガーマネジメント
- コミュニケーション研修
- H30：H30 医療安全セミナー及び H30 院内感染対策講習会に係る伝達講習、医療訴訟の動向と対応について。R1：開催中止。R2：医療監視の結果について、最近のトピックス、医療広告の留意点。
- 医療安全（2019 年度）院内感染（2018 年度）
- 相談・苦情受付の実務研修。医療安全管理者養成研修。
- 新型コロナウイルス感染症感染拡大防止対策研修会。
- 近年の報告事例から考える医療安全。
- 医療現場における効果的なコーチングについて。
- 「医療の安全に関する研修」―広島市医療安全支援センターへの相談事例から―
- チームで取り組む医療安全。R2・R3 年度は新型コロナウイルス感染症のため中止。
- 新型コロナウイルス感染状況と当市の取り組みについて。②医療機関における新型コロナウイルス感染症対策について。③新型コロナウイルスワクチン接種計画と新型コロナワクチンの取り扱いについて。④自宅療養者に対する健康観察に係る研

修。

- 2019「なぜ医療安全に診療記録が重要か」。2018「対応困難患者への法的及び臨床的対応」。
- 医療機関における医療安全の取組みについて。
- 感染管理の役割と実践。
- 平成 30 年度「検査・処置と医療安全」、令和元年度「医療安全と医療メディエーション」、令和 2 年度「医療機関における新型コロナウイルスなどの感染対策について」。
- 立入検査からみる医療安全について。・新型コロナウイルス感染症について。
- 「医療従事者が知っておきたい日常診療に関わる法律～患者トラブルを起こさないために～」
- 院内感染対策（コロナ）、立入検査結果フィードバック（医療安全関係項目）、抗菌薬の適正使用。
- 医療関連感染防止に係る基本的実務。新型コロナウイルス感染症対応。医療関連感染防止対策に係る課題と実務等。
- 院内感染対策、医療安全情報
- R 元（2019）年度　医療事故調査制度の最近の動向。H30（2018）年度　医事紛争（裁判）から何を学ぶか～記録の大切さを中心に～。
- 外国人が医療機関を受診した場合の対応について（平成 31 年度）
- 2020 年度　中止。2019 年度　医療相談の聞き方と相談員のセルフケア。2018 年度①患者・家族とどう向き合うか。相談が基本技術－医療対話推進者研修から。②「安全対策部「医療相談の実際と対応」～対応による関係の再構築」。
- 「長崎県内の新型コロナウイルス感染症の発生状況について」
- 医療安全施策の動向について。・医療事故は低減できる～科学的因果関係を解明し、理に適った対策をする～
- R1 医療安全について。H30 働き方改革の法改正概要と労働災害防止対策。H29 結核の動向
- 医療安全に関する最近の動向
- 令和元年度「医療過誤を起こさないために」・令和 2 年度「新型コロナウイルス感染症の現状と対策」・令和 3 年度「診療用放射線の安全利用のための研修
- 「COVID-19 で見えてきた超高齢社会のリスクと課題」（令和 3 年度）
- 「施設・環境整備から考える医療安全」（令和元年度）
- 「医事紛争の法的責任と患者とのトラブル対策」（令和元年度）
- 病院 BCP（業務継続計画）策定研修会 2019.11.19
- 医療安全推進の動向について
- 新型コロナウイルス感染症の概論と地域医療機関の連携、対応について。
- 肺結核の早期発見と感染症対策について。
- 診療所における感染症対策（麻疹、風疹、インフルエンザ）。
- 新型コロナウイルス感染症の基本的安全管理について。
- 医療安全も ONE TEAM で！・医療安全のすすめ。

- 新型コロナウイルス感染症対策。医療関連法規と個人情報保護。
- 画像診断報告書未確認、医療事故調査制度、コロナ時代の情報共有。
- BCP、COVID-19 対応医療従事者に対するメンタルケア。
- 患者相談窓口の関わり、患者との会話術。
- 院内感染対策
- R1：日常診療における対話への医療メディエーション技法の応用、ヒューマンエラー対策における効果的なダブルチェック。R2：医療安全と医療メディエーション、新型コロナウイルス感染対策と医療安全。R3：新型コロナと医療安全、新型コロナの制御の難しさ（新潟県内の事例に基づく課題の共有）。
- 2020 中止。2019「困難事例やクレームへの対応」。2018「患者・医療機関双方の視点からみた医療相談対応」
- 令和元年度：看者側弁護士からみた医療安全。令和 2 年度：開催中止。令和 3 年度：命をまもる確認業務
- 講習会を開催予定であったが、新型コロナのため中止し、相談事例集の郵送配布を実施。
- 2019　みんなで取り組む医療安全～患者と医療者の協働～。2018　みんなで取り組む医療安全～身体抑制が本当に医療安全につながっているか～。
- 結核の現状と対策
- 医療現場における法的知識～事例に学ぶクレーム対応。
- 職員の安全確保（院内暴力への対応）。・医療関連感染対策。
- クラスター発生防止
- H30　講演「インシデント対応」R 元　中止（新型コロナウイルス感染症対策のため）予定は「医療安全セミナー伝達講習」「医療訴訟の動向と対応」R2　資料配布「院内感染対策（新型コロナウイルス感染症」
- 医療者と患者のギャップを埋める。医療安全のための快適な職場づくり。患者トラブルの対応について、児童虐待～横浜市の現状と対策～・小児画像診断における医療安全、患者安全の全体像、予期せぬ事態に柔軟に対応するチームマネジメント、くすりの安全・多職種連携について。
- 新型コロナウイルス感染症の概論と地域医療機関の連携・対応について。
- 肺結核の早期発見と感染症対策について。
- 診療所における感染症対策（麻疹・風疹・インフルエンザ）。
- R1：患者トラブル対応。R2、3 は新型コロナの影響で未実施。
- コミュニケーションスキル（Team STEPPS）、院内暴力への対応について。
- COVID-19 関連の苦情対応、対応困難事例。
- 「医療事故を防ぐには」「医事紛争の法律的な側面」各テーマに関する講演会を県内 4 地区で実施した。
- 事例から学ぶ医療安全。
- 医療安全対策について。
- 最近の事故事例から学ぶ医療安全。・弁護士と読み解く応召義務違反―正しい理解に基づく適切な対応―

- 医療機関における苦情・クレーム対応（R3 年度)。R1.2 はコロナで中止。
- R1.ラクビーワールドカップ 2019 日本大会に向けた感染症研修会。R2.新型コロナウイルス感染症対策における感染管理について。R3.医療福祉施設等における新型コロナ感染症対策。
- 新型コロナウイルス感染症予防対策について。
- 弁護士による講演会「患者さんとのトラブル回避に必要なこと」（令和元年度）
- 事例から学ぶ患者トラブル対応。医療関係法と個人情報保護法。医療安全のためのコミュニケーションスキル。
- 令和 3 年度：医療保健施設における感染症予防の知識。令和 2 年度：世界の経験災害テロ対応からコロナ対策まで。令和元年度：感染症の発生動向と危機管理。
- R2「新型コロナウイルス感染症の現状と対策」R 元「医療安全に関するトピックス」H30「医療機関における感染症対策について」
- 院内感染対策について、医療現場のコミュニケーションについて、医療機関と患者のコミュニケーションについて。
- 安全に欠かせない対話関係の質・医療の質を高める～心理からのアプローチ～（H31）世界標準の医療安全－WHO 患者安全カリキュラムに学ぶ（H30）
- 相談内容の傾向について
- ホームレスが救急搬送された場合の取扱いについて。
- 県が毎年病院向けの研修会を開催している為、単独での実施はしていない。
- 新型コロナ感染クラスター発生時の初動対応とクラスター対策。・歯科診療における院内感染対策。
- 院内感染対策
- BCP の策定。
- 新型コロナウイルス感染症に関すること。
- 苦情相談対応の基礎及び相談担当者のメンタルヘルスケア（H30）R1、R2 については新型コロナウイルス感染症の影響もあり、開催を見送った。
- 感染予防対策。・予防接種における事故防止。
- 2018 患者家族と医療者の良好な関係づくり。2019 医療相談・トラブル対応からみえること。患者参加・患者啓発を考える。
- 患者と医療者のコミュニケーション
- 患者参加、患者啓発を考える。
- 医療相談・トラブル対応からみえること。患者家族と医療者の良好な関係づくり。
- 薬剤耐性対策、院内感染の進め方（H30 年)、医療機関として災害にどう備えるか（パネルディスカッション）（令和元年)、医療期間における COVID-19 対策（オンライン研修）（令和 2 年）

患者参加推進活動と職員満足度に関する調査

令和3年度厚生労働科学研究
医療安全に寄与する患者参加の推進に資する研究
研究代表者
全日本病院協会　医療の質向上委員会　永井　庸次

本調査の目的は、医療安全の向上をのための患者参加推進活動の実態を把握し、患者参加を効果的に推進する方法を明らかにすること、および、患者参加推進活動と患者満足度、職員満足度との関係を明らかにすることです。

本調査は、調査への協力を承諾してくださった病院の、一定数の医療従事者の方を対象に実施されています。本調査の結果は、病院名や個人が特定できない形で集計され、研究のみに使用されます。また、皆さまのプライバシーには十分配慮し、回収した調査票の管理には十分注意いたします。なお、本調査の結果は、後日、研究報告書、論文、学会での報告等で発表される予定です。

お忙しいところ恐縮ですが、何卒ご回答たまわりますようお願い申し上げます。
調査票は、**専用封筒で密封のうえ、貴院で定められた方法でご提出**ください。
選択肢は、設問ごとに**当てはまるものを1つ選択**してください。

Ⅰ．患者参加を推進する活動へのあなたの関わり方について

患者参加に関する活動へのあなたの関わりや、患者参加という概念・用語に関するあなたの考えについてお聞きします。

1	あなたは、患者の治療方針や治療法の選択に関わる説明と同意に、説明者または同席者として関与することがありますか	あ[1]る・な[2]い
2	あなたは「患者参加」という用語を知っていますか	よく知っ[1]ている ・ 言葉は聞い[2]たことがある ・ 知ら[3]ない
3	あなたが「患者参加」ときいて思い浮かべることを書いてください。キーワードでもかまいません。	

Ⅱ．貴院における患者参加を推進する活動について

貴院における患者参加を推進する活動の実施状況について、あなたの考えを回答してください。

		思う	まあまあ思う	あまり思わない	思わない
4	私たちの病院では、「患者も『医療チーム』の一員であり、治療の方針などを決める議論には積極的に参加してほしい」ということを患者に説明している	□01	□02	□03	□04
5	私たちの病院では、治療のゴール（どの程度まで回復することを目標にするか）について患者と話し合っている	□01	□02	□03	□04
6	私たちの病院では、治療方針の選択肢を十分に説明している	□01	□02	□03	□04
7	私たちの病院では、説明に対する患者または患者家族の理解度を確認している	□01	□02	□03	□04
8	私たちの病院では、患者の意思決定を支援するツール（疾病や治療法に関するリーフレットや動画、Webサイト等）を患者に提供している	□01	□02	□03	□04

（次頁につづく）

Ⅰ.「患者参加」の経験について(つづき)

		思う	まあまあ思う	あまり思わない	思わない
9	私たちの病院では、治療方針や治療法の選択に関わる患者の価値観や希望を十分に聞き出している	□01	□02	□03	□04
10	私たちの病院では、患者の価値観や希望を反映した治療方針が選択されている	□01	□02	□03	□04
11	私たちの病院では、「処置・投薬などの行為や、病院の施設・設備などに関して、『事故に至るかもしれない、危ない』と感じることがあれば、遠慮なく職員に伝えてほしい」と説明している	□01	□02	□03	□04
12	私たちの病院では、人生の最終段階の医療・ケアの方針について、患者本人が家族や医療・ケアチームと事前に繰り返し話し合う取り組み(人生会議・ACP)を積極的に行っている	□01	□02	□03	□04
13	私たちの病院では、患者等の意思決定に基づき、心停止時には心肺蘇生法を行わないこと(DNAR)を事前に確認する取り組みを積極的に行っている	□01	□02	□03	□04
14	私たちの病院では、地域住民を対象に疾病や健康管理に関する勉強会(市民公開講座等)を積極的に開催している	□01	□02	□03	□04
15	私たちの病院では、外来・入院患者を対象に疾病や健康管理に関する勉強会(糖尿病教室等)を積極的に開催している	□01	□02	□03	□04
16	私たちの病院では、患者や患者家族の意見や苦情を積極的に収集している(患者相談窓口、投書箱等の活動)	□01	□02	□03	□04
17	私たちの病院では、都道府県等が設置する『医療安全支援センター』と積極的に連携し、情報のやりとりをしている	□01	□02	□03	□04
18	私たちの病院では、患者や患者家族の意見や苦情を活用し、業務改善に取り組んでいる	□01	□02	□03	□04
19	私たちの病院では、医療安全に関する確認行為への患者参加(フルネームでの名乗り、タイムアウトへの参加、患者とのダブルチェック等)を積極的に行っている	□01	□02	□03	□04

Ⅲ. 患者参加と医療安全に関するあなたの体験について

患者参加によって医療安全に寄与したと思われる事例に関する、あなた自身の体験について教えてください。

20	あなたは今までに、患者から医療安全に関する指摘を受けたことがありますか(投書箱、患者安全窓口等を通じた指摘も含む)	1 はい・2 いいえ

→問20が「はい」の方は問21へ、**「いいえ」の方はⅣ. 職員やりがい度(問24)へ進んでください**

21	指摘の内容について教えてください (具体的に:)	
22	あなたは、患者の指摘を反映して、自分の業務の改善を行ったことがありますか	1 はい・2 いいえ
23	あなたは、患者の指摘を、インシデントレポートなどによって上司・病院上層部へ報告したことがありますか	1 はい・2 いいえ

(次頁につづく)

Ⅳ. 職員やりがい度

		思う	まあまあ思う	どちらともいえない	あまり思わない	思わない
24	職場の雰囲気や人間関係は良好だと思いますか？	□01	□02	□03	□04	□05
25	現在の仕事にやりがいがあると思いますか？	□01	□02	□03	□04	□05
26	現在の処遇条件(報酬や福利厚生)を満足だと思いますか？	□01	□02	□03	□04	□05
27	現在の勤務条件(休日や勤務時間)を満足だと思いますか？	□01	□02	□03	□04	□05
28	学習や成長の機会があると思いますか？	□01	□02	□03	□04	□05
29	精神的な不安を感じずに仕事ができると思いますか？	□01	□02	□03	□04	□05
30	仕事の成果や能力が適正に評価されていると思いますか？	□01	□02	□03	□04	□05
31	あなたの上司を信頼できると思いますか？	□01	□02	□03	□04	□05
32	これからも、この病院で働き続けたいと思いますか？	□01	□02	□03	□04	□05
33	病院として、知人に勧めようと思いますか？	□01	□02	□03	□04	□05
34	あなたの病院を職場として勧めようと思いますか？	□1 勧める・□2 まあまあ勧める・□3 どちらともいえない・□4 あまり勧めない・□5 勧めない				

Ⅴ. 背景情報

35 所 属

□01 診療部門(医局)(診療科:)
□02 外来
□03 内科系病棟
□04 外科系病棟
□05 内科・外科混合病棟
□06 その他の病棟(診療科:)
□07 検査部門(検体・生理機能・放射線等)
□08 手術部門
□09 救命救急部門・集中治療室
□10 薬剤部門
□11 リハビリテーション部門
□12 栄養部門・食堂
□13 その他( )

36 職 種

□01 看護師・助産師・保健師
□02 看護助手・介護職員
□03 医師 (研修医以外)
□04 研修医
□05 薬剤師
□06 栄養士・調理従事者
□07 理学療法士・作業療法士・言語聴覚士・視能訓練士
□08 技師(臨床検査、診療放射線、臨床工学 等)
□09 その他( )

37 性 別

□01 男性 □02 女性

38 年 齢

□01 29歳以下 □02 30～39歳 □03 40～49歳
□04 50歳以上

39 直近1週間の労働時間(貴院における勤務のみ)

□01 1年未満 □02 1～5年 □03 6～10年
□04 11～15年 □05 16～20年 □06 21年以上

40 1ヶ月の当直・夜勤回数

□01 0回 □02 1～4回 □03 5～8回
□04 9～12回 □05 13回以上

41 1ヶ月の休日日数

□01 4日未満 □02 4～6日 □03 7～9日
□04 10日以上

42 この病院での勤務年数

□01 1年未満　□02 1～5年　□03 6～10年
□04 11～15年　□05 16～20年　□06 21年以上

43 今の職種に就いてからの経験年数

□01 1年未満　□02 1～5年　□03 6～10年
□04 11～15年　□05 16～20年　□06 21年以上

44 過去1年以内に院内で開催された医療安全の研修会に参加しましたか

□01 参加しなかった　□02 1回参加した　□03 2回以上参加した

45 過去1年以内に医療安全に関する院内報告(医療事故やヒヤリハット)を何件報告しましたか

□01 0件　□02 1件　□03 2件
□04 3件　□05 4件　□06 5件以上

46 医療安全情報(日本医療機能評価機構が毎月発行)は、どの程度目を通していますか

□01 全部　(年に12件)
□02 ほとんど全部　(年に10件程度)
□03 半分程度　(年に6件程度)
□04 少し　(年に2件程度)
□05 全くない　(年に0件)
□06 わからない

Ⅵ. ご意見

47 患者参加の推進または医療安全の向上について、何かご意見があればお書きください。

調査へのご協力ありがとうございました。

「患者参加推進活動と職員満足度に関する調査（医療従事者向け）」

配布・回収数

配布数：500 件（1 病院 100 件ずつ、5 病院に配布）

回収数：467 件（回収率　93.4%）

Ⅰ．患者参加を推進する活動へのあなたの関わり方について

１．あなたは、患者の治療方針や治療法の選択に関わる説明と同意に、説明者または同席者として関与することがありますか

	n	%
ある	330	70.7
ない	136	29.1
無回答	1	0.2
合計	467	100.0

２．あなたは「患者参加」という用語を知っていますか

	n	%
よく知っている	65	13.9
言葉は聞いたことがある	259	55.5
知らない	133	28.5
無回答	10	2.1
合計	467	100.0

３．あなたが「患者参加」ときいて思い浮かべることを書いてください。キーワードでもかまいません。

- インフォームドコンセント
- 終末期の在り方、ACP
- 患者の積極的な意見、意志が尊重される
- 患者中心にチーム医療の図が構築
- 合同カンファレンス、意志決定支援、看護倫理
- 患者に正しい情報を提供し、患者・家族とともに治療法や方針を決定していくこと。
- 治療法の選択、今後の方針の自己決定、セカンドオピニオン、担当者会議。
- 治療に対しての意思選択、自己決定。
- 患者主導
- チーム、平等、信頼
- 治療の選択、病院運営、医療の質の向上、患者と家族のケア、在宅指導、入院中の面会、患者主体となる。
- 看護ケア
- 誤認防止
- 患者さんがわかるような治療説明、患者中心
- 患者様が社会へ参加

- 治療方針、方向性など患者本人も意見を言うことができる
- 治療の決定について患者様の意見もうかがう
- 病院の会議的なことに参加する。治療方針の決定や治療法の選択についての話し合いに参加する。
- 患者会、治療法の選択、セカンドオピニオン
- 病気の治療のアプローチについて理解し、自分で選択すること。
- 治療方針を患者が決める。
- 患者も一緒に知識を共有して取り組む。医療安全の認識共有。
- 患者が自ら治療などに参加するように援助する。
- 患者が主。治療に対して、患者が選択。
- 治療選択をいくつかの中から患者自身が熟慮して決定できる。患者を中心としたチーム医療。
- 治療方針への意見を患者自身から出してもらう。
- 患者の意志・意見をききとりながら治療を選択する。
- 患者本人への説明と同意。治療や今後の方針、希望する退院先や介ご状態について確認する。
- 意見箱の設置
- 医療安全
- 医療者と協働で医療の質と安全を向上させること。
- 医療安全構築のため必要
- 患者の自己決定権。リスボン宣言。インフォームドコンセント。成年後見制度。
- 治療方針や延命処置など、患者自身も医師や家族と一緒に決定していく。
- 医師が治療方針をいくつか提示され、患者が治療法を選択する。
- 患者本人も治療方針に関与し、自分の病気にむきあえるようにするイメージ。
- 治療方針・病院研修会・〇〇教室・医療チーム
- 市民公開講座等
- 患者誤認のための氏名確認
- 終末医療。選択する権利。チーム医療。
- 告知、手術、化学療法
- 患者が参加して治療方針や退院後の生活などの方針を医療従事者と共に決定していくこと。
- 患者参加型医療。患者参加型看護。患者参加型看護計画。
- ダブルチェック
- 今までは患者中心だった医療チームは患者も輪の一員として医療に参加することを目指すようになった。インフォームドコンセント。
- 自分の病気について充分に説明を受ける。医師・看護師と相談し治療や看護の内容を決定する。
- 患者様の意志、尊重、傾聴、思い、サポート、支援
- 患者・家族を含めたカンファレンス。(退院支援も含めた)
- 外来などで診察券を見せ生年月日と氏名を見せる。フルネーム、生年月日を伝える。フルネームを名乗る。
- 名前を名乗ってもらう。リストバンドを確認。照合に協力。
- 治療方針や治療法の説明の際、患者に同席してもらうだけでなく、患者さん自身が意味を理解した上での判断ができるように説明を行うこと。
- 自律尊重
- すべて医者に任せるのではなく、自ら情報収集するなど主体性を持って治療に参加する。病気や治療への知識を高めて、医師や看護師などと関わりを持つ。
- 病気について充分に説明を受ける。Ns に相談できる。入院時から退院後について、支援する。

資料4

- 患者参加型看護。目標計画実践評価を看護師と患者が考える。
- 説明と同意・ケアプラン・看護計画・治療方針
- IC、セカンドオピニオン、カンファレンス、リビングウィル
- 自助、shared decision making
- 拡大カンファ、多転種、緩和ケア、manalive
- 患者が主体的に方針決定にかかわる。話しあう（説明と同意ではない）

（以上、一部抜粋）

Ⅱ．貴院における患者参加を推進する活動について

４．私たちの病院では、「患者も『医療チーム』の一員であり、治療の方針などを決める議論には積極的に参加してほしい」ということを患者に説明している

	n	%
思う	74	15.8
まあまあ思う	211	45.2
あまり思わない	144	30.8
思わない	34	7.3
無回答	4	0.9
合計	467	100.0

５．私たちの病院では、治療のゴール（どの程度まで回復することを目標にするか）について患者と話し合っている

	n	%
思う	105	22.5
まあまあ思う	253	54.2
あまり思わない	98	21.0
思わない	8	1.7
無回答	3	0.6
合計	467	100.0

６．私たちの病院では、治療方針の選択肢を十分に説明している

	n	%
思う	104	22.3
まあまあ思う	280	60.0
あまり思わない	71	15.2
思わない	8	1.7
無回答	4	0.9
合計	467	100.0

７．私たちの病院では、説明に対する患者または患者家族の理解度を確認している

	n	%
思う	112	24.0
まあまあ思う	271	58.0
あまり思わない	76	16.3
思わない	5	1.1
無回答	3	0.6
合計	467	100.0

８．私たちの病院では、患者の意思決定を支援するツール（疾病や治療法に関するリーフレットや動画、Web サイト等）を患者に提供している

	n	%
思う	34	7.3
まあまあ思う	146	31.3
あまり思わない	209	44.8
思わない	74	15.8
無回答	4	0.9
合計	467	100.0

９．私たちの病院では、治療方針や治療法の選択に関わる患者の価値観や希望を十分に聞き出している

	n	%
思う	69	14.8
まあまあ思う	268	57.4
あまり思わない	118	25.3
思わない	8	1.7
無回答	4	0.9
合計	467	100.0

１０．私たちの病院では、患者の価値観や希望を反映した治療方針が選択されている

	n	%
思う	80	17.1
まあまあ思う	286	61.2
あまり思わない	92	19.7
思わない	5	1.1
無回答	4	0.9
合計	467	100.0

１１．私たちの病院では、「処置・投薬などの行為や、病院の施設・設備などに関して、『事故に至るかもしれない、危ない』と感じることがあれば、遠慮なく職員に伝えてほしい」と説明している

	n	%
思う	81	17.3
まあまあ思う	200	42.8
あまり思わない	156	33.4
思わない	25	5.4
無回答	5	1.1
合計	467	100.0

１２．私たちの病院では、人生の最終段階の医療・ケアの方針について、患者本人が家族や医療・ケアチームと事前に繰り返し話し合う取り組み（人生会議・ACP）を積極的に行っている

	n	%
思う	38	8.1
まあまあ思う	190	40.7
あまり思わない	183	39.2
思わない	51	10.9
無回答	5	1.1
合計	467	100.0

１３．私たちの病院では、患者等の意思決定に基づき、心停止時には心肺蘇生法を行わないこと（DNAR）を事前に確認する取り組みを積極的に行っている

	n	%
思う	242	51.8
まあまあ思う	176	37.7
あまり思わない	41	8.8
思わない	5	1.1
無回答	3	0.6
合計	467	100.0

１４．私たちの病院では、地域住民を対象に疾病や健康管理に関する勉強会（市民公開講座等）を積極的に開催している

	n	%
思う	63	13.5
まあまあ思う	173	37.0
あまり思わない	184	39.4
思わない	44	9.4
無回答	3	0.6
合計	467	100.0

１５．私たちの病院では、外来・入院患者を対象に疾病や健康管理に関する勉強会（糖尿病教室等）を積極的に開催している

	n	%
思う	65	13.9
まあまあ思う	190	40.7
あまり思わない	167	35.8
思わない	40	8.6
無回答	5	1.1
合計	467	100.0

１６．私たちの病院では、患者や患者家族の意見や苦情を積極的に収集している（患者相談窓口、投書箱等の活動）

	n	%
思う	125	26.8
まあまあ思う	265	56.7
あまり思わない	68	14.6
思わない	8	1.7
無回答	1	0.2
合計	467	100.0

１７．私たちの病院では、都道府県等が設置する『医療安全支援センター』と積極的に連携し、情報のやりとりをしている

	n	%
思う	36	7.7
まあまあ思う	204	43.7
あまり思わない	185	39.6
思わない	30	6.4
無回答	12	2.6
合計	467	100.0

１８．私たちの病院では、患者や患者家族の意見や苦情を活用し、業務改善に取り組んでいる

	n	%
思う	103	22.1
まあまあ思う	260	55.7
あまり思わない	89	19.1
思わない	13	2.8
無回答	2	0.4
合計	467	100.0

１９．私たちの病院では、医療安全に関する確認行為への患者参加（フルネームでの名乗り、タイムアウトへの参加、患者とのダブルチェック、等）を積極的に行っている

	n	%
思う	181	38.8
まあまあ思う	226	48.4
あまり思わない	54	11.6
思わない	4	0.9
無回答	2	0.4
合計	467	100.0

Ⅲ．患者参加と医療安全に関するあなたの体験について

２０．あなたは今までに、患者から医療安全に関する指摘を受けたことがありますか（投書箱、患者安全窓口等を通じた指摘も含む）

	n	%
はい	62	13.3
いいえ	403	86.3
無回答	2	0.4
合計	467	100.0

２１．指摘の内容について教えてください

- 床がぬれている。
- 医師が患者の話をしっかり聞かない。非常勤医師が術後見にこない。
- 外来時手渡すファイルを別の人のものとまちがえて患者から指摘されたことがあります。
- 廊下のテープがはがれていて、つまづきそうだと指摘されたことがある。
- 抗てんかん薬の投与量まちがいについて、本来の投与される量よりも過剰に投与された。同診療、科内での出来事として、患者に説明、身体的治療を行った。
- 名乗ってもらい、ネームバンドで認証する事はまちがい防止には必要なこと。
- トイレの手すりがないので危ない。
- 点滴に空気が入っている。
- DIV の投与速度について、確認された。
- 患者の移乗方法について、指摘を受けた。
- 窓口対応、待ち時間の長さ等。
- 給食での異物混入。
- 「あなたにやってほしくない」と言われた（検査）
- 採血後に痛みがあったと指摘を受けた。
- 診療に関する待ち時間の改善。事務的なシステム改善はできるが、患者の病状によることも、関わることもあるので、後者に関しては納得して頂くしかない。
- 転倒、点滴抜針
- 私の○○ですね！と確認された。検体、結果など。
- 入院患者より、書字が困難のため意見箱があっても書いて入れることができない。看護師に言っても、改善されず入院生活に大きなストレスをかかえていると言われたことがあります。
- 点滴の薬剤内容について質問されることがある。
- 医師の診断ミスを指摘。合併症についての説明不足により医療事故だと家族から指摘。
- 外来受付時、名前を確認せず、対応していた患者と新規の患者を間違えた。
- 差額ベット代の説明が十分でなかった。
- 説明不足・言葉の“あや”トラブルなど。
- 受け持ち患者の抑制を患者が外していて、それが原因で転倒（ベッドからの転落）をした。
- 高齢の患者が多いため、意志決定者が Fa となることが多い。たとえ、本人が決定できる人であっても、Fa の意志を優先することも有り、本人への説明と矛盾が発生し、Pt が怒ってしまうなどトラブルが発生する。（本人：早く帰りたい。症状ないし、もう治療はしたくない。Fa：完全に治るまで入院してほしい。）

資料4

- 医師の診察について
- 救急外来窓口に駐車した患者同伴者に（日中、時間外）正面玄関での場所移動を説明したところ、言動が不ゆ快だと苦情の訴えがあった。
- 名前の確認をしないで書類の取り違えがあった。
- 大腸がん手術の ope、ope 後合併症にて状態悪化あり ope 手技に問題があるのではないかとご家族より医師への苦情、不信感に対応した。
- アレルギーで中止となっていた物が患者に提供されてしまった。
- 複数の内服薬の袋をホチキスでとめるのはあぶない。
- 医療安全ラウンドでの指導
- 子供への採血を実施したところ、子供がはげしく泣いてあばれたため採血の中止を求められた。
- 同意取得に際し、key person に連絡がつながらず第 2 番の連絡先の他に家人から同意を得たことに際し、key person から指摘あり。
- 外来、更衣室のいす、手すり、ロッカーの配置について。
- 転倒に関わる危険性があった事を言われ、勘善策を講じた。
- 食事介助の内容、方法の変更。看護助手における介助する患者の状態を明文化したこと又、食事介助におけるカテーテルチップ等の使用を禁止した。
- 廊下が濡れていたと指摘あり対応した。
- 採血時、手袋交換、採決時の神経損傷に対する指摘。
- 設備に対する不備
- 手すりの固定が悪い。
- 別の職員が退室時にナースコールを患者さんの手の届かないところに置いてしまい私が訪室した際に指摘を受けた。
- 薬剤誤投与（モルヒネ過量投与）
- 実際にミスが行ってしまった際（院内での転倒等）に、改善すべき点について指摘をうけた。（患者の状況についての家族への報告、つきそいの要否についての判断）
- 主に研修医の検査立ち合い、指導について、患者さんより検査がつらかったと言われた事があります。
- 患者さんの退院の話を家族にした際に、入院の費用がいくらか？ときかれたが、定時を過ぎており、翌日が土曜であったため明示することができなかった。それに関して退院の際に指摘を受けた。
- 業務中の私語について不適切と指摘された。
- 医師からの説明が不十分。自分の思いがうまくくみとってもらえない。
- 点滴管理について

２２．あなたは、患者の指摘を反映して、自分の業務の改善を行ったことがありますか

	n	%
はい	59	12.6
いいえ	2	0.4
無回答	406	86.9
合計	467	100.0

資料4

２３．あなたは、患者の指摘を、インシデントレポートなどによって上司・病院上層部へ報告したことがありますか

	n	%
はい	46	9.9
いいえ	15	3.2
無回答	406	86.9
合計	467	100.0

Ⅳ．職員やりがい度

２４．職場の雰囲気や人間関係は良好だと思いますか？

	n	%
思う	98	21.0
まあまあ思う	241	51.6
どちらともいえない	83	17.8
あまり思わない	31	6.6
思わない	12	2.6
無回答	2	0.4
合計	467	100.0

２５．現在の仕事にやりがいがあると思いますか？

	n	%
思う	92	19.7
まあまあ思う	223	47.8
どちらともいえない	95	20.3
あまり思わない	41	8.8
思わない	13	2.8
無回答	3	0.6
合計	467	100.0

２６．現在の処遇条件(報酬や福利厚生)を満足だと思いますか？

	n	%
思う	34	7.3
まあまあ思う	147	31.5
どちらともいえない	105	22.5
あまり思わない	98	21.0
思わない	80	17.1
無回答	3	0.6
合計	467	100.0

２７．現在の勤務条件(休日や勤務時間)を満足だと思いますか？

	n	%
思う	68	14.6
まあまあ思う	172	36.8
どちらともいえない	92	19.7
あまり思わない	76	16.3
思わない	55	11.8
無回答	4	0.9
合計	467	100.0

資料4

２８．学習や成長の機会があると思いますか？

	n	%
思う	60	12.8
まあまあ思う	198	42.4
どちらともいえない	114	24.4
あまり思わない	61	13.1
思わない	31	6.6
無回答	3	0.6
合計	467	100.0

２９．精神的な不安を感じずに仕事ができると思いますか？

	n	%
思う	38	8.1
まあまあ思う	133	28.5
どちらともいえない	137	29.3
あまり思わない	96	20.6
思わない	59	12.6
無回答	4	0.9
合計	467	100.0

３０．仕事の成果や能力が適正に評価されていると思いますか？

	n	%
思う	41	8.8
まあまあ思う	175	37.5
どちらともいえない	142	30.4
あまり思わない	65	13.9
思わない	41	8.8
無回答	3	0.6
合計	467	100.0

３１．あなたの上司を信頼できると思いますか？

	n	%
思う	98	21.0
まあまあ思う	205	43.9
どちらともいえない	90	19.3
あまり思わない	43	9.2
思わない	28	6.0
無回答	3	0.6
合計	467	100.0

３２．これからも、この病院で働き続けたいと思いますか？

	n	%
思う	72	15.4
まあまあ思う	149	31.9
どちらともいえない	155	33.2
あまり思わない	50	10.7
思わない	38	8.1
無回答	3	0.6
合計	467	100.0

３３．病院として、知人に勧めようと思いますか？

	n	%
思う	46	9.9
まあまあ思う	103	22.1
どちらともいえない	167	35.8
あまり思わない	81	17.3
思わない	65	13.9
無回答	5	1.1
合計	467	100.0

３４．あなたの病院を職場として勧めようと思いますか？

	n	%
勧める	41	8.8
まあまあ勧める	112	24.0
どちらともいえない	167	35.8
あまり勧めない	78	16.7
勧めない	60	12.8
無回答	9	1.9
合計	467	100.0

Ⅴ．背景情報

３５．所属

	n	%
内科系病棟	87	18.6
看護師･助産師･保健師	69	14.8
外科系病棟	57	12.2
内科・外科混合病棟	46	9.9
検査部門（検体・生理機能・放射線等）	42	9.0
リハビリテーション部門	36	7.7
その他の病棟	34	7.3
薬剤部門	21	4.5
外来	16	3.4
栄養部門・食堂	8	1.7
救命救急部門・集中治療室	5	1.1
手術部門	2	0.4
その他	41	8.8
無回答	3	0.6
合計	467	100.0

３６．職種

	n	%
看護師･助産師･保健師	234	50.1
医師（研修医以外）	61	13.1
技師（臨床検査、診療放射線、臨床工学 等）	51	10.9
理学療法士・作業療法士・言語聴覚士・視能訓練士	35	7.5
薬剤師	20	4.3
研修医	13	2.8
看護助手・介護職員	8	1.7
栄養士・調理従事者	8	1.7
その他	36	7.7
無回答	1	0.2
合計	467	100

資料4

３７．性別

	n	%
男性	150	32.1
女性	317	67.9

３８．年齢

	n	%
29 歳以下	115	24.6
30～39 歳	156	33.4
40～49 歳	118	25.3
50 歳以上	77	16.5
無回答	1	0.2
合計	467	100.0

３９．（削除）

４０．１ヶ月の当直・夜勤回数

	n	%
0 回	196	42.0
1～4 回	206	44.1
5～8 回	55	11.8
9～12 回	5	1.1
13 回以上	1	0.2
無回答	4	0.9
合計	467	100.0

４１．１ヶ月の休日日数

	n	%
4 日未満	7	1.5
4～6 日	57	12.2
7～9 日	241	51.6
10 日以上	160	34.3
無回答	2	0.4
合計	467	100.0

資料4

４２．この病院での勤務年数

	n	%
1 年未満	41	8.8
1～5 年	172	36.8
6～10 年	100	21.4
11～15 年	74	15.8
16～20 年	33	7.1
21 年以上	36	7.7
無回答	11	2.4
合計	467	100.0

４３．今の職種に就いてからの経験年数

	n	%
1 年未満	22	4.7
1～5 年	88	18.8
6～10 年	98	21.0
11～15 年	84	18.0
16～20 年	62	13.3
21 年以上	99	21.2
無回答	14	3.0
合計	467	100.0

４４．過去１年以内に院内で開催された医療安全の研修会に参加しましたか

	n	%
参加しなかった	52	11.1
1 回参加した	145	31.0
2 回以上参加した	252	54.0
無回答	18	3.9
合計	467	100.0

４５．過去１年以内に医療安全に関する院内報告（医療事故やヒヤリハット）を何件報告しましたか

	n	%
0 件	128	27.4
1 件	108	23.1
2 件	74	15.8
3 件	58	12.4
4 件	25	5.4
5 件以上	62	13.3
無回答	12	2.6
合計	467	100.0

４６．医療安全情報（日本医療機能評価機構が毎月発行）は、どの程度目を通していますか

	n	%
全部	70	15.0
ほとんど全部	92	19.7
半分程度	54	11.6
少し	101	21.6
全くない	76	16.3
わからない	57	12.2
無回答	17	3.6
合計	467	100.0

４７．患者参加の推進または医療安全の向上について、何かご意見があればお書きください

- スタッフぎりぎり一人休めば苦しい状況。患者のサービス安全がゆき届かない。余裕ある看護ケアが行えれば、心にゆとりあり PC にもっと声かけよりそうことが出来る。現状はムリ、病院の方針？事故が起きないようミスがないよう毎日気をつける意識は高い！！
- 医療安全へのとり組みは大事だと思うが、形式やハウトゥーになってしまってはいけないと思う。
- スタッフの人数が少ないのに病棟内の備品が十分ではなくスタッフの労力がかかり、体にも負担がかかりやすい。又、医療事故にもつながりやすい。
- 現状、患者さん自身も病識・治療方針が明確に分かっていない様子であると思います。ゆえに、食事制限があるにも関わらず買い食いがなおらない方、それに対する教育に関しても Ns が数名関わるだけで、すごしていることに疑問を感じます。コロナで、あまりできないことは承知ですが、カンファレンスをふやして頂きたいです。
- 患者参加型医療は医療安全向上のため重要と思うが実際に行う上で各々の患者家族さんの性格、行動に問題がある場合もあり難しい時もあると考える。
- 限られた医業資源でできる範囲でサービスを提供すれば、人手コストが必要です。
- 患者が意見を述べられる機会をもう少しふやした方がいい。
- 転倒に対する良い器具（防止策）などがあればよい。また、自己抜針が多いので対策など。
- 医療安全の向上にインシデント報告が貢献しているが、未だ、失敗やミス→責められる。絶対起きてはならないものと認識している方が多いと感じる。ヒヤリ・ハットで済んだものでもレポートとして報告し情報共有と他者、他職種協力してダブルチェックで行なう環境を整え、認識を統一すべき。・患者参加の推進はやはり診療時の「傾聴」を大切にすべきと考える。より多くの患者を診る、外来をまわす為に傾聴（傾聴の姿勢）

目をみる、うなずき等、おろそかにしている医師、医療スタッフが多いと感じる。

- 医師が主となっている感は変わらない。看護師の意見を聞いてもらえるようになれば（医師＝特にベテラン）患者の意見もひろくはんえいできるようになるのではないか。
- 超高齢化社会となり、患者参加と言っても高齢な患者を支援する人達へのサポートも必要となってくる。決して施設の職員であったり、ケアマネだけでは無理です。キーパーソンとなる方への推進活動をすすめていければと思います。
- 患者参加については医師の協力が不可欠のため医者の意識を向上させる必要がある。
- 各部署がどのような取り組みをしているのか知らない。内視鏡検査や眼科 ope の流れへの患者説明文書などみてみたい。（麻酔説明文書など）
- 患者誤認防止対策として「照合」を浸透させるとよいと思う。
- 「医療安全」という言葉より「患者安全」の方が色々な意味で良いと思います。
- 高れいの患者が多いことから医師が本人への参加を促すことがないため、医療者と家族のみで治療方針、今後の方向性が決定してしまう現状がある。年配の医師はパターナリズムが未だ根強く残っているため、患者の思いにより添えていない。看護師の様に、新しい情報を取り入れ、柔軟に対応できる医療を行っていきたい。
- 患者参加、医療安全の向上には医療チームの連携が必要だが、まだまだ当院は医師の医療安全への意識が低いと感じる。患者への説明と同意は“説明と説得”であり医師と患者がパートナーではない。若い年代の医師はある程度医療安全を理解しているが古い年代の医師への医療安全への意識が高まる研修や組織での取りくみが必要であると思う。
- 個々人の個別事項についての留意もさることながら病院等、組織全体での取り組み（啓発やルール作りなど）が重要と考えます。
- 「長」と付く方々の意識が低い場合、改善するのが困難である。外部からの力が必要と思います。
- 医療で 100%安全という事はあり得ない。従って常に医療安全 100%を目指して取り組むべきである。
- 医療者個々人の意識が大事と思います。
- 患者参加型医療において、一番の問題は医師の保守的な部分だと感じることも少なくありません。又コメディカルがいくら仕組みをととのえても、医師の協力又は、率先がないのが事実だと感じます。
- 市民公開講座等等行い。スタッフにまずは周知することが大切かと思います。
- コロナ禍で直接面会が難しい分、TV 電話などで家族と現状や今後について顔が見える形での相談や話し合いができる環境を整えたいと思っています。
- 安全教育を病院全体としてもっと強化すべき。
- 恥ずかしながら「患者参加」について、多くを理解しておりませんでした。医療安全の向上に対し、自身の医療安全に対する理解度をアップデートし、今後、対応していきたいと思います。
- 病棟看護師の数が少なく常にマンパワー不足です。大きな事故やミスが頻発せず日々を過ごしていることが不思議な位スタッフは身体的にも精神的にもおいつめられて仕事をしています。この現状が少しでも改善されることを切に願います。
- 患者参加の推進について、患者さん本人・その家族が「死」について語ってないことが多く、いざ体調が悪くなってから「とりあえず胃ろうを…」「とりあえず人工呼吸器を」など、安易に延命を考えている方が多いと感じています。「死」をタブーとするのではなく、積極的に日頃から話し、「自分はどういう最期を迎えたいか」ということを考える社会であったら、と思います。
- 薬剤部門で勤務しております。調剤過誤の件数をいかに減らすか常に対策など考えておりますが、なかなか正しい正解と方法に達することができないでおります。各施設での取り組みなど情報交換ができる。幸いです。失礼いたしました。

資料5

医療への患者参加と患者満足度に関する調査（入院患者さん向け）

令和3年度厚生労働科学研究
医療安全に寄与する患者参加の推進に資する研究
研究代表者
全日本病院協会　医療の質向上委員会　永井　庸次

「患者参加」とは、患者さん自身が、さまざまな形で主体的に医療に参加することをいいます。
この調査の目的は、「患者参加」の現状を調べ、より効果的に進める方法について明らかにすることです。
この調査は、入院している患者さんを対象にしています。患者さんご本人が記入できない場合は、ご家族の方が代わりに記入していただいてもかまいません。
このアンケートは、退院までに、専用封筒で密封し、各病院で指定された方法でご提出ください。
選択肢は、設問ごとに当てはまるものを1つ選択してください。

Ⅰ.「患者参加」の経験について

今回の入院、入院準備のための外来受診の際の、あなたの経験や考えについて回答してください。

		はい	いいえ	わからない	該当しない
1	「患者さん自身も『医療チーム』の一員であり、治療の方針などを決める議論には積極的に参加してほしい」と説明されましたか	□01	□02	□03	□04
2	医師や看護師などと、治療のゴール（どの程度まで回復することを目標にするか）について話し合いましたか	□01	□02	□03	□04
3	治療方針の選択肢について十分に説明されましたか	□01	□02	□03	□04
4	あなたが病気のことや治療方針についての説明を理解できたかどうかについて、医師や看護師などから確認されましたか	□01	□02	□03	□04
5	治療方針を決めるうえで参考になる資料（病気や治療法に関する説明書類やリーフレット、動画、Webサイト等）を提供されましたか	□01	□02	□03	□04
6	治療方針の選択に関わるあなたの価値観や希望について、十分に聞かれましたか	□01	□02	□03	□04
7	診察・検査・処置・手術などを受ける際、毎回名前をフルネームできかれましたか	□01	□02	□03	□04
8	「処置・投薬などの行為や、病院の施設・設備などに関して、『事故に至るかもしれない、危ない』と感じることがあれば、遠慮なく職員に伝えてほしい」と説明されましたか	□01	□02	□03	□04
9	病院に対する意見や苦情を伝えたり、困りごとについて相談することのできる病院の窓口（『患者相談窓口』など）があることを知っていますか	□01	□02	□03	□04
10	病院で受けた医療に関する苦情や心配について、都道府県等が設置する『医療安全支援センター』に相談できることを知っていますか	□01	□02	□03	□04
11	治療を受ける病院や治療法を選ぶ際に、患者団体（同じ健康問題を抱える患者の集まり）に相談しましたか	□01	□02	□03	□04

		思う	やや思う	あまり思わない	思わない
12	あなたは、価値観や希望を反映した治療方針を選択することができたと思いますか	□01	□02	□03	□04
13	あなたは、医療職員と目標や方針を共有する『医療チーム』の一員として、あなた自身の治療や、医療に関する安全のための活動に積極的に参加・協力したいと思いますか	□01	□02	□03	□04
14	あなたは、自分の病気やその治療法について自発的に学び、治療の方針などを決める際に活かせていると思いますか	□01	□02	□03	□04
15	あなたは、処置・投薬などの行為や、病院の施設・設備などに関して、『事故に至るかもしれない、危ない』と感じる場面があったとしたら、そのことを職員へと伝えられると思いますか	□01	□02	□03	□04

Ⅰ.「患者参加」の経験について(つづき)

16	処置・投薬などの行為や、病院の施設・設備などに関して、『事故に至るかもしれない、危ない』と実際に感じたことはありますか	[1]はい・[2]いいえ

→「はい」の方は問17へ、**「いいえ」の方はⅡ.満足度について(問21)へ進んでください**

17	あなたが、『事故に至るかもしれない、危ない』と感じたことについて教えてください 具体的に:	
18	あなたは、そのことについて病院職員へ申し出ましたか	[1]はい・[2]いいえ

→「はい」の方は問19へ、**「いいえ」の方はⅡ.満足度について(問21)へ進んでください**

19	あなたの申し出に対する病院側の対応について教えてください その場での対応・事後の説明など具体的に:	
20	あなたの申し出に対する病院側の対応に納得しましたか	[1]はい・[2]いいえ

Ⅱ. 満足度について

この病院に対するあなたの満足度についてお伺いします。

		とても満足	やや満足	どちらともいえない	やや不満	とても不満	利用なし
21	医師による診療・治療内容に満足していますか	□01	□02	□03	□04	□05	□06
22	医師との対話に満足していますか	□01	□02	□03	□04	□05	□06
23	看護師の対応に満足していますか	□01	□02	□03	□04	□05	□06
24	事務職員の対応に満足していますか	□01	□02	□03	□04	□05	□06
25	その他の病院スタッフの対応に満足していますか	□01	□02	□03	□04	□05	□06
26	痛みや症状を和らげる対応に満足していますか	□01	□02	□03	□04	□05	□06
27	精神的なケアに満足していますか	□01	□02	□03	□04	□05	□06
28	病室でのプライバシー保護の対応に満足していますか	□01	□02	□03	□04	□05	□06
29	病室・浴室・トイレなどに満足していますか	□01	□02	□03	□04	□05	□06
30	食事の内容に満足していますか	□01	□02	□03	□04	□05	□06

31	この病院を親しい方にも勧めようと思いますか	[1]勧める・[2]まあまあ勧める・[3]どちらともいえない [4]あまり勧めない・[5]勧めない

Ⅲ. 患者さんのことについて

32 患者さんの性別を教えてください

□01 男性　　□02 女性

33 患者さんの年齢を教えてください

□01 0～9歳　□02 10歳代　□03 20歳代　□04 30歳代　□05 40歳代
□06 50歳代　□07 60歳代　□08 70歳代　□09 80歳代　□10 90歳以上

34 今回の入院中に手術はありましたか

□01 はい　　□02 いいえ

35 「患者参加」の推進や、医療の安全の向上について、何かご意見があればお書きください

調査へのご協力ありがとうございました。この調査の結果は、個人が特定できない形で集計され、研究の目的のみに使用されます。また、皆様のプライバシーには十分配慮し、回収した調査票の管理には十分注意いたします。この調査の結果は、後日、研究報告書、論文、学会での報告等で発表される予定です。

資料6

「医療への患者参加と患者満足度に関する調査（入院患者向け）」

配布・回収数

配布数：500 件（1 病院 100 件ずつ、5 病院に配布）

回収数：303 件（回収率　60.6%）

Ⅰ.「患者参加」の経験について

1.「患者さん自身も『医療チーム』の一員であり、治療の方針などを決める議論には積極的に参加してほしい」と説明されましたか

	n	%
はい	59	19.5
いいえ	134	44.2
わからない	89	29.4
該当しない	13	4.3
無回答	8	2.6
合計	303	100.0

2．医師や看護師などと、治療のゴール（どの程度まで回復することを目標にするか）について話し合いましたか

	n	%
はい	182	60.1
いいえ	57	18.8
わからない	47	15.5
該当しない	11	3.6
無回答	6	2.0
合計	303	100.0

3．治療方針の選択肢について十分に説明されましたか

	n	%
はい	217	71.6
いいえ	33	10.9
わからない	37	12.2
該当しない	8	2.6
無回答	8	2.6
合計	303	100.0

4．あなたが病気のことや治療方針についての説明を理解できたかどうかについて、医師や看護師などから確認されましたか

	n	%
はい	213	70.3
いいえ	42	13.9
わからない	35	11.6
該当しない	5	1.7
無回答	8	2.6
合計	303	100.0

5．治療方針を決めるうえで参考になる資料（病気や治療法に関する説明書類やリーフレット、動画、Web サイト等）を提供されましたか

	n	%
はい	121	39.9
いいえ	120	39.6
わからない	46	15.2
該当しない	7	2.3
無回答	9	3.0
合計	303	100.0

6．治療方針の選択に関わるあなたの価値観や希望について、十分に聞かれましたか

	n	%
はい	152	50.2
いいえ	71	23.4
わからない	59	19.5
該当しない	8	2.6
無回答	13	4.3
合計	303	100.0

7．診察・検査・処置・手術などを受ける際、毎回名前をフルネームできかれましたか

	n	%
はい	279	92.1
いいえ	12	4.0
わからない	5	1.7
該当しない	0	0.0
無回答	7	2.3
合計	303	100.0

8.「処置・投薬などの行為や、病院の施設・設備などに関して、『事故に至るかもしれない、危ない』と感じることがあれば、遠慮なく職員に伝えてほしい」と説明されましたか

	n	%
はい	135	44.6
いいえ	89	29.4
わからない	64	21.1
該当しない	8	2.6
無回答	7	2.3
合計	303	100.0

9. 病院に対する意見や苦情を伝えたり、困りごとについて相談することのできる病院の窓口（『患者相談窓口』など）があることを知っていますか

	n	%
はい	128	42.2
いいえ	126	41.6
わからない	44	14.5
該当しない	0	0.0
無回答	5	1.7
合計	303	100.0

１０. 病院で受けた医療に関する苦情や心配について、都道府県等が設置する『医療安全支援センター』に相談できることを知っていますか

	n	%
はい	45	14.9
いいえ	209	69.0
わからない	43	14.2
該当しない	2	0.7
無回答	4	1.3
合計	303	100.0

１１. 治療を受ける病院や治療法を選ぶ際に、患者団体（同じ健康問題を抱える患者の集まり）に相談しましたか

	n	%
はい	9	3.0
いいえ	260	85.8
わからない	15	5.0
該当しない	12	4.0
無回答	7	2.3
合計	303	100.0

１２．あなたは、価値観や希望を反映した治療方針を選択することができたと思いますか

	n	%
思う	150	49.5
やや思う	92	30.4
あまり思わない	36	11.9
思わない	14	4.6
無回答	11	3.6
合計	303	100.0

１３．あなたは、医療職員と目標や方針を共有する『医療チーム』の一員として、あなた自身の治療や、医療に関する安全のための活動に積極的に参加・協力したいと思いますか

	n	%
思う	137	45.2
やや思う	101	33.3
あまり思わない	50	16.5
思わない	10	3.3
無回答	5	1.7
合計	303	100.0

１４．あなたは、自分の病気やその治療法について自発的に学び、治療の方針などを決める際に活かせていると思いますか

	n	%
思う	97	32.0
やや思う	117	38.6
あまり思わない	67	22.1
思わない	15	5.0
無回答	7	2.3
合計	303	100.0

１５．あなたは、処置・投薬などの行為や、病院の施設・設備などに関して、『事故に至るかもしれない、危ない』と感じる場面があったとしたら、そのことを職員へと伝えられると思いますか

	n	%
思う	142	46.9
やや思う	96	31.7
あまり思わない	44	14.5
思わない	12	4.0
無回答	9	3.0
総計	303	100.0

資料6

１６．処置・投薬などの行為や、病院の施設・設備などに関して、『事故に至るかもしれない、危ない』と実際に感じたことはありますか。

	n	%
はい	15	5.0
いいえ	279	92.0
無回答	9	3.0
合計	303	100.0

１７．１６で「はい」と回答した方。

あなたが、『事故に至るかもしれない、危ない』と感じたことについて教えてください。

（省略）

- 点滴で血液が逆流し、固まった状態となったが、生理食塩水でむりくり血液へ追し流した。
- 同じ病室の人が夜中に拘束を解いて歩き出していた。足首の骨折ときいていたので、歩いて大丈夫かと心配した。
- レントゲン室に向かう途中、外来のトイレを借りました。床が水で濡れていて滑りそうにみえました。
- 夜に部屋の入口の電気がついていなかったこと。
- 内視鏡時、麻酔で意識が朦朧とするなか、長いす処置でおちそうになった。
- 実際に処置してから、それを次にどうするかなどの連携、準備が不十分だと思った。
- 通常は元気でも自分の身に注意しなくて急に血圧が上がった。
- 駐車場において、院内玄関口を通過すると入場ゲートがあり、そこを通過直後左折したところに院内玄関口に通じるスロープがあるが、混んでいる時にスロープ前で一時停車（荷物積おろし）をする車両があり、入場ゲートがつまっていたにもかかわらず、対応する職員がいなかった。入場ゲート通過直後のところに停止している車あり、は後続に迷わく。
- 通路（廊下）を走っている人が多く衝突の可能性がある（病室出入との出会がしら）
- ドライヤー使用するにあたり、コンセントがなく、差し込まれているコンセントを抜いて使っていたが本当に抜いていいコンセントなのか分からなかった。
- 右足首骨折しているが車いすにのっている時２回おとしよりにけとばされた。わざとではない。

１８．あなたは、そのことについて、病院職員へ申し出ましたか。

	n	%
はい	5	33.3
いいえ	10	66.7
合計	15	100.0

１９．１８で「はい」と回答した方。

あなたの申し出に対する病院側の対応について教えてください（その場での対応。事後の説明など具体的に）。

- 2 回程度看護師から呼びかけられる名前が別の人だったので、1 回目は聞き間違えかと思ったが 2 回目はネームバンドを見て指摘した。「すみません」と即謝られた。2 回とも薬を持ってきてもらった時だったので（内容チェック済）「薬さえ間違ってなければいいです」と伝えた。「薬は看護師複数名で確認してます」と言われました。
- 申し出る前に宿直の看護師さんが早急に対応していた。
- そばにいらした看護師さんがすぐに清掃の人に伝え、拭き取っていただき大事に至りませんでした。
- こまかい事にすぐ対応して下さいます。
- 伝えた職員は一時的に対応にあたったかもしれないが、その後に変化は感じられない。何とも言えない。起きた事象が異例？

２０．あなたの申し出に対する病院側の対応に納得しましたか。

	n	%
はい	3	5.0
いいえ	0	92.1
無回答	2	3.0
合計	5	100.0

資料6

Ⅱ．満足度について

２１．医師による診療・治療内容に満足していますか

	n	%
とても満足	171	56.4
やや満足	86	28.4
どちらとも言えない	29	9.6
やや不満	7	2.3
とても不満	1	0.3
利用無し	2	0.7
無回答	7	2.3
合計	303	100.0

２２．医師との対話に満足していますか

	n	%
とても満足	159	52.5
やや満足	94	31.0
どちらとも言えない	34	11.2
やや不満	6	2.0
とても不満	3	1.0
利用無し	2	0.7
無回答	5	1.7
合計	303	100.0

２３．看護師の対応に満足していますか

	n	%
とても満足	188	62.0
やや満足	72	23.8
どちらとも言えない	30	9.9
やや不満	6	2.0
とても不満	1	0.3
利用無し	2	0.7
無回答	4	1.3
合計	303	100.0

２４．事務職員の対応に満足していますか

	n	%
とても満足	144	47.5
やや満足	83	27.4
どちらとも言えない	45	14.9
やや不満	4	1.3
とても不満	0	0.0
利用無し	18	5.9
無回答	9	3.0
合計	303	100.0

２５．その他の病院スタッフの対応に満足していますか

	n	%
とても満足	157	51.8
やや満足	90	29.7
どちらとも言えない	37	12.2
やや不満	0	0.0
とても不満	1	0.3
利用無し	6	2.0
無回答	12	4.0
合計	303	100.0

２６．痛みや症状を和らげる対応に満足していますか

	n	%
とても満足	148	48.8
やや満足	87	28.7
どちらとも言えない	39	12.9
やや不満	2	0.7
とても不満	3	1.0
利用無し	13	4.3
無回答	11	3.6
合計	303	100.0

２７．精神的なケアに満足していますか

	n	%
とても満足	131	43.2
やや満足	76	25.1
どちらとも言えない	61	20.1
やや不満	4	1.3
とても不満	2	0.7
利用無し	14	4.6
無回答	15	5.0
合計	303	100.0

２８．病室でのプライバシー保護の対応に満足していますか

	n	%
とても満足	124	40.9
やや満足	101	33.3
どちらとも言えない	51	16.8
やや不満	13	4.3
とても不満	3	1.0
利用無し	3	1.0
無回答	8	2.6
合計	303	100.0

２９．病室・浴室・トイレなどに満足していますか

	n	%
とても満足	118	38.9
やや満足	102	33.7
どちらとも言えない	28	9.2
やや不満	26	8.6
とても不満	13	4.3
利用無し	5	1.7
無回答	11	3.6
合計	303	100.0

資料6

３０．食事の内容に満足していますか

	n	%
とても満足	89	29.4
やや満足	99	32.7
どちらとも言えない	53	17.5
やや不満	33	10.9
とても不満	3	1.0
利用無し	13	4.3
無回答	13	4.3
合計	303	100.0

３１．この病院を親しい方にも勧めようと思いますか

	n	%
勧める	133	43.9
まあまあ勧める	90	29.7
どちらともいえない	58	19.1
あまり勧めない	3	1.0
勧めない	1	0.3
無回答	18	5.9
合計	303	100.0

資料6

Ⅲ．患者さんのことについて

３２．患者さんの性別を教えてください

	n	%
男	158	52.1
女	134	44.2
無回答	11	3.6
合計	303	100.0

３３．患者さんの年齢を教えてください

	n	%
0-9	2	0.7
10代	2	0.7
20代	18	5.9
30代	22	7.3
40代	40	13.2
50代	42	13.9
60代	59	19.5
70代	65	21.5
80代	44	14.5
90代以上	4	1.3
無回答	5	1.7
合計	303	100.0

３４．今回の入院中に手術はありましたか

	n	%
はい	135	0.4
いいえ	149	49.2
無回答	19	6.3
合計	303	100.0

３５.「患者参加」の推進や、医療安全の向上について、何かご意見があればお書きください

- 患者参加はあくまで意欲の問題だと思うので（もともと不調だから入院しているわけなので、そこを求められることが負担）医師、看護師や関わる皆さんが心と頭の余裕を持てる環境作りを強化されることの方が有意義だと思います。医師はずっと休みなしで休憩もなかった様子がありました。職業柄チェックしてしまうので見ていると…。
- 歳をとったら（50 代後半とか）オペしない。（おじいちゃん先生が帝王切開して帝王切開癒痕症候群になったので。）
- 患者参加はとても良い事だと思います。
- 今回は緊急入院して忙しく自分が参加まではなかなかむずかしいと思う（気持ち的に）ただ事前に最悪パターンを Net で調べていた為「まさか」とおどろきつつ対応できたので事前の患者側情報取得が大切かなと。
- どこにこの事について書いてある web 等があれば知りたい。
- 患者参加はとても必要な事ですが、時間とのバランスも考慮せねばならない場合もあり、今回の私の治療では早く薬剤を投与する事を優先されたのだと感じています。今後の患者参加の推進に期待します。
- 「患者参加」という言葉を初めて聞き、とまどったのが正直な気持です。医療スタッフと患者が対当な関係で情報を交換・共有することがと理解しましたが、理解しずらいネーミングであるとの印象です。
- 治療のため、精神科同様に人間性を無視する拘束する治療行為が実施され、本人は自死を＝覚悟しなければならない恐怖に落し入れて安全な治療とは云えない。患者の本意と話し合うべきではないか。
- 退院日数が以前より短かくなり良い事だと思う。
- 医療関係者の方々は神経をすり減らすような、お仕事と思いますが、私たち一般人の最も尊敬しお頼りするところですので、取り違えなどの事故の無いように心よりおねがい申しあげます。又看護師さんは忙殺されているようにお見受けします。
- 見かけではなく本当に内容の伴なったものにしてほしい。
- 患者は医学について素人なので、分かりやすい言葉で病気やケガの状態を医師に説明頂き、治療等の選択肢を提示頂いた上で、患者の意志を確認頂ければ、より良い対応がお互いに出来るのではと思います。
- 先生、看護師さんとても良くしてもらいました。始めてだったので不安でしたが、いい人達だったので不安はなくなりました。
- 患者参加とはかけはなれてると思います。また説明では内視鏡で無理なら外科に移行と説明があったのに後日にまた前処置のたいへんな思いをしないといけない。
- 患者さんの主体的な意思は医療を向上させると思います。
- 医士への負担にならないよう、バランスをとりながら進めてほしい。
- 医薬品に頼りすぎている様な気がする。そのために患者自身の体力が落ちてしまうのが心配。
- 気軽に相談が出来て不安もなく、また先の見えるアドバイスを頂きました。
- 患者が治療の方針など決める議論に参加するのは難しい。それよりも、医師が患者に真剣に向き合ってくれる、治療内容もよく説明してくれることが患者にとっての望み。このようなアンケート調査は進めて行くべき。
- 「患者参加」というならば、こちらも知識を入れておかなければ向上には繋がらないと思う。
- 複数の治療法がある場合説明頂き、選択希望できるとよい。
- 医療の安全と言っても可能性の問題であり選択肢のある治療があるなら知りたいもの。
- 氏名、年齢の確認および手術部位の確認がされており間違い防止が図られている。
- 医療チームと受容したのは・医師、看護師補助者を、カントク、コーチ、トレーナー・受診者、患者治療者を連習者、受講者競技選手、の見解で判断しました。医療、患者の参加構築として、医療、患者の参加構築向上へ、現状把握や解析を研究論文、学会作業のデータ発表で終らず所定の医療機関、療養組織への標準レ

ベルに欠けていることを機関や施設に指摘、改善方針、当所機関へレベル向上の支援をと思います。

- 家族との話会いができているのでそれで十分ではないか！！
- 医療スタッフのしつが病院によってものすごくちがいます。ほんとうに患者の事を考えよりそって治療に全力をつくしてくれる病院に行けるとほんとうにラッキーですが、心、ハート、技術、患者の声をききまっすぐに患者とともに治療をしてほしい。いい病院に行くとラッキ、だめな所はアンラッキ、そういう所がないようにすべての病院がラッキであってほしい、患者の心のケアができるすばらしい医療病院をのぞみます。
- ○○さん、丁寧な説明と子供の変化に気づいて対応頂きありがとうございました。他、各情報がバラバラできて皆さんの情報共有されてないようです。
- 設備的な面では共用トイレの個室はとても狭いので利用しにくい。下が2室しか利用できないのは患者数に対して少なく感じる（病院移転にて解消？）衛生面ではコロナウイルス感染拡大の中、気を使っている部分も多いだろうと思うがまだまだ改善すべき事はありそうです。・点滴の管長めの設定は扱い易いが床に付いてしまい、ゴミ付着が気になる。（着替の際などは途中部分を切離す等直接ふれる）・清掃員がベットまわりを拭きに来るが、どこを拭いてきたか分からない布で窓の下→テーブルと拭き出したので断った。（拭けば良いのではない）
- 良い事だと思います。まず病院でその様な組織編成をすることが必要です。
- 地域の医療貢献には日々感謝しております。引続き住民が安心して生活できる環境提供をお願いします。
- 夜間のナースの方が大変なご様子なので、今よりもナースの皆さまが増えてくださると良いと思います。ナースボタンを押すのが申し訳けなくなる時があります。
- チーム医療での先生方のちょっとした言葉が違う事があるので混乱します。
- 初耳ですが有難い事に思います。
- 何事においてもすぐに対応していただいていますのでレスポンスには満足しています。
- この「患者参加」について、患者の様態等によっては、つらい病状中にそのような余裕があるかどうかわからないが、患者を含めた医療の考え方は良いと思う。
- 病気の内容やどんな治療、薬等説明がほしい。

資料7

令和 3 年度厚生労働科学研究
医療安全に寄与する患者参加の推進に資する研究（研究代表者：永井庸次）
インタビュー調査について

1. 調査の趣旨

医療安全の向上には患者及び患者家族の参加の推進が必要であるとされています。患者参加を推進する方法には、患者による医療事故やヒヤリハットの発見と報告や、患者にフルネームを名乗ってもらうなどが知られています。一方で、患者団体における患者参加の取り組みや患者側の主体的な参加の実態は十分に明らかにされていません。本調査では、患者団体における患者参加の取り組みの実態を明らかにすることを目的としております。

2. 調査データの取り扱い

調査結果は、厚生労働科学研究の報告書（Web にて公開予定）又は全日本病院協会を通じて関係者・関係団体へフィードバックを行います。本調査で収集したデータは、研究目的でのみ使用いたします。回答者は、回答者または組織にとって不利な情報についての回答を拒否すること、回答内容について後日訂正・撤回することができます。調査記録は、報告書に掲載する前に内容について回答者の同意を得ます。

3. 事前アンケート・インタビューについて

（1） 目的

・患者団体の患者参加の取り組み内容を明らかにする
・患者団体が医療安全の向上に寄与する患者参加の取り組み内容を明らかにする

（2） 対象団体（対象疾患）

・一般社団法人グループネクサス（悪性リンパ腫）
・公益社団法人日本リウマチ友の会（リウマチ）
・一般社団法人全国腎臓病協議会（腎臓病）
・認定 NPO 法人難病こども支援全国ネットワーク（小児難病）
・認定 NPO 法人ささえあい医療人権センターCOML（なし）

（3） 対象者

・理事長・会長、事務局長等の団体の活動内容を把握されている方

（4） 事前アンケート・インタビュー項目

・貴団体の現況等について次頁からのアンケート調査にご協力ください
・ご回答頂いた内容を元に、後日インタビュー調査（対面・Zoom 等）を依頼させて頂く予定としています

＜アンケート・インタビュー項目＞

各質問項目について、2020 年度の実績をもとに、当てはまるもの全てに○をつけてください。□には文章をお書きください。

1. 団体の組織構成・事業内容について
以下の項目が記載されている資料（年報・パンフレット等）の提供で代替頂くことも可能です。

1-1. 組織の規模（会員数・支部の数）についてお答えください。

会員数	人
支部の数	か所

1-2. 貴団体の主な事業内容についてお答えください。

1-3. 医療機関・医療従事者との連携についてお答えください（理事や幹事に医療従事者が入っている。団体会員として医療機関が加入している等）。

2. 患者参加の定義

2-1.「患者参加」について、患者団体としての定義やお考えをお答えください。

＜例＞

「患者参加」とは患者が自分の病気に向き合い、主体的に治療に参加することと患者団体として定義しています。

2-2. 患者団体が、患者参加を推進していく上でどのような役割を担っているとお考えをお答えください。

＜例＞

患者が主体的に治療に参加する患者参加を推進していくために、患者団体は会員や会員家族に対して情報提供を行ったり、患者の相談を受けたりなどする役割を担っていると考えています。

3. 相談事業の体制について

実施の有無	有　・　無
実施形態	電話　・　メール　・　対面　・　その他（　　）
相談体制	●相談の対象 会員のみ　・　制限なし ●相談可能な日時 ●相談の担当者
相談件数	件／年間
相談内容と件数 （貴団体で使用している分類とその件数をお答えください。）	
受け付けた 相談事例の対応 （例：専門病院・専門医の紹介、別の機関を紹介等）	

医療事故を疑う相談事例 件数/年	件
事例への対応方法	
事例への対応での工夫	

4. **「患者参加」に寄与する患者教育の実施について**
（以下の問について、「有」の場合、具体的な内容についてお答えください。）

病気や治療等に関するリーフレットの作成配布	有　・　無
web サイトでの情報提供	有　・　無
e-learning を用いた患者教育の提供	有　・　無
医療安全上の注意喚起についての情報提供	有　・　無
医療安全上の注意喚起についての情報提供	有　・　無

5. 会員、他患者団体、同疾患患者とのつながり・連携の実施状況について

（以下の問について「有」の場合、具体的な内容についてお答えください。）

患者同士のネットワーク作り（交流会の開催、勉強会の開催等）	有 ・ 無
他の患者団体との連携	有 ・ 無
ピアサポートの活動	有 ・ 無
その他	有 ・ 無

6. 貴団体が「患者参加」に寄与する活動として考えられる活動の実施状況について

（以下の問について、「有」の場合、具体的な内容についてお答えください。）

行政・医療政策への参加（国・地方自治体等の審議会・委員会等の患者委員等、国への要望書の提出、署名活動、提言活動）	有　・　無
学会への参加（所属している学会、学会総会での講演・シンポジウムの講師、診療ガイドラインの作成委員・評価委員）	有　・　無
医療機関への活動の参加（倫理審査委員会の委員、医療機関の運営委員）	有　・　無
医育機関への活動の参加（医療系の学生に対する講義、演習での模擬患者）	有　・　無
その他に考えられる活動	

＜アンケート・インタビュー項目＞【一般社団法人全国腎臓病協議会】

各質問項目について、2020 年度の実績をもとに、当てはまるもの全てに○をつけてください。□には文章をお書きください。

1. 団体の組織構成・事業内容について
以下の項目が記載されている資料（年報・パンフレット等）の提供で代替頂くことも可能です。

1-1. 組織の規模（会員数・支部の数）についてお答えください。

会員数	約 70,000 人
支部の数	47 か所（正会員＝各都道府県組織）

1-2. 貴団体の主な事業内容についてお答えください。

腎臓病に関する正しい知識の普及及び社会啓発並びに腎臓病患 者の自立と社会参加の促進を図り、社会の発展に寄与することを目的とする。
（１）腎臓病の予防及び治療に関する知識の普及と啓発事業
（２）腎臓病患者の自立を支援する事業
（３）腎臓病に関する調査研究と政策提言
（４）広報誌の発行及びホームページの運営等の広報事業
（５）腎臓病患者を支援する基金事業
（６）その他、この法人の目的を達成するために必要な事業

1-3. 医療機関・医療従事者との連携についてお答えください（理事や幹事に医療従事者が入っている。団体会員として医療機関が加入している等)。

日本透析医会、日本透析医学会と連携し、透析に関する十分な医療保険の確保を図るとともに、医療者側から患者に対するリクエスト、アドバイスを周知し、透析医療の向上に寄与する。

2. 患者参加の定義

2-1.「患者参加」について、患者団体としての定義やお考えをお答えください。

＜例＞

「患者参加」とは患者が自分の病気に向き合い、主体的に治療に参加することと患者団体として定義しています。

慢性腎臓病患者がステージⅣを経てステージⅤに至る、すなわち保存的腎臓療法（conservative kidney management: CKM）から腎代替療法（renal replacement therapy: RRT）が必要になったとき、十分な医療側の説明のもとに患者として意思決定する共同意思決定（shared decision making: SDM）と、本人が家族等や医療・ケアチームと事前に繰り返し話し合うプロセスであるアドバンス・ケア・プランニング（advance care planning: ACP）の概念の重要さに基づき、医学的知識の無い、患者としては初めて直面する場面において、最終的かつ全面的決定権を有していること。

2-2. 患者団体が、患者参加を推進していく上でどのような役割を担っているとお考えをお答えください。

＜例＞

患者が主体的に治療に参加する患者参加を推進していくために、患者団体は会員や会員家族に対して情報提供を行ったり、患者の相談を受けたりなどする役割を担っていると考えています。

現在の当会の活動は、腎代替療法に移行した患者、主として透析療法を施行中の会員（透析中に移植を受けた患者を含む）に対し、医療、保険、福祉について周知を行っているが、今後は積極的にち保存的腎臓療法を受けている者、すなわち慢性腎臓病患者にアプローチしたい。具体的には、国の CKD 対策事業、2028 年までに年間新規透析導入患者数を 35,000 人以下にするとの目標達成に協力する y。

3. 相談事業の体制について

実施の有無	(有)・ 無
実施形態	(電話)・(メール)・(対面)・(その他)（FAX、各県組織も対応）
相談体制	●相談の対象 会員のみ ・ (制限なし) （患者・家族、医療機関・介護施設スタッフ、行政、企業等） ●相談可能な日時 ①事務局員による相談：月～金（土日祝日除く）10 時～18 時

	②専門家による相談：特定の日時に予約制（各種月 1～2 回/午後） ●相談の担当者 上記①：事務局の相談担当者 上記②：委嘱した管理栄養士、社会福祉士、認定心理士（かつ当事者）
相談件数	1072 件／年間（2020 年度事業報告より以下同様）
相談内容と件数 （貴団体で使用している分類とその件数をお答えください。）	上記①事務局による相談：864 件 上記②専門家による相談：208 件 栄養・食事相談：67 件 生活・福祉相談：107 件（医療 60 件・医療費 2 件・年金 3 件・福祉制度 12 件・生活 12 件・心理 12 件・就労 3 件・その他 3 件） こころの相談：34 件
受け付けた 相談事例の対応 （例：専門病院・専門医の紹介、別の機関を紹介等）	事務局による相談：傾聴、かかりつけ医・専門家への相談の勧め、別機関の紹介等

医療事故を疑う相談事例件数/年	2～3　件
事例への対応方法	傾聴、「訴えたい」等の場合は ADR 等専門機関の紹介
事例への対応での工夫	初回相談時は、強い感情を伴う訴えが圧倒的に多いため、相談者が客観的に状況を整理できるよう傾聴に努める。

4. 「患者参加」に寄与する患者教育の実施について
(以下の問について、「有」の場合、具体的な内容についてお答えください。)

病気や治療等に関するリーフレットの作成配布	有 ・ 無
	透析ハンドブック
web サイトでの情報提供	有 ・ 無
	ホームページ
e-learning を用いた患者教育の提供	有 ・ 無
医療安全上の注意喚起についての情報提供	有 ・ 無
	新型コロナウィルスに関して複数回

5. 会員、他患者団体、同疾患患者とのつながり・連携の実施状況について

（以下の問について「有」の場合、具体的な内容についてお答えください。）

患者同士のネットワーク作り（交流会の開催、勉強会の開催等）	有 ・ 無
	全国大会開催時の交流会 社員代表シンポジウム 役員に対する勉強会
他の患者団体との連携	有 ・ 無
	日本難病・疾病団体協議会 日本障害者協議会
ピアサポートの活動	有 ・ 無
	各県組織の役職員のピアサポート向上のため研修会を実施
その他	有 ・ 無

6. 貴団体が「患者参加」に寄与する活動として考えられる活動の実施状況について

（以下の問について、「有」の場合、具体的な内容についてお答えください。）

行政・医療政策への参加（国・地方自治体等の審議会・委員会等の患者委員等、国への要望書の提出、署名活動、提言活動）	有 ・ 無
	全国署名を添えての国会請願の実施 関係省庁への要望書提出 全国大会時に大会宣言
学会への参加（所属している学会、学会総会での講演・シンポジウムの講師、診療ガイドラインの作成委員・評価委員）	有 ・ 無
	日本透析医学会提言作成外部委員及び査読委員
医療機関の活動への参加（倫理審査委員会の委員、医療機関の運営委員）	有 ・ 無
	ただし、各県組織には実例有り
医育機関の活動への参加（医療系の学生に対する講義、演習での模擬患者）	有 ・ 無
	看護学校生へ透析について講義
その他に考えられる活動	有 ・ 無

＜アンケート・インタビュー項目＞

各質問項目について、2020 年度の実績をもとに、当てはまるもの全てに〇をつけてください。□には文章をお書きください。

1. 団体の組織構成・事業内容について

以下の項目が記載されている資料（年報・パンフレット等）の提供で代替頂くことも可能です。

1-1. 組織の規模（会員数・支部の数）についてお答えください。

会員数	764 人
支部の数	0 か所

1-2. 貴団体の主な事業内容についてお答えください。

1. 相談活動

◎電話相談室

ネットワーク電話相談室、遺伝相談、遺伝（先天異常）特別相談

◎ピアサポート

国立成育医療研究センター、東京都立小児総合医療センター、慶應義塾大学病院、神奈川県立こども医療センター、埼玉県立小児医療センター

ピアサポーター養成講座

◎小児慢性特定疾病児童等自立支援員による支援

2. 交流活動

◎サマーキャンプ“がんばれ共和国”の建国

みちのく七夕キャンプ（岩手県一関市）、あしがらキャンプ（神奈川県大井町）、しぞーかキャンプ（静岡県島田市）、おいでんほうらい（愛知県新城市）、阿蘇ぼう!キャンプ（熊本県阿蘇市）、つながろうキャンプ in 関西（兵庫県淡路市）、おーきな輪 with みゃーくがに（沖縄県恩納村）

◎親の会連絡会

定例会議（関東・関西・ZOOM）、親の会ブース出展、研修旅行、研修・会議室の貸与

◎いのちの輝き毎日奨励賞・いのちの輝き親の会奨励賞

◎サンタクロースの病院訪問

◎プレイリーダー

プレイリーダー養成講座、プレイリーダー活動支援、病児の遊びとおもちゃケア、あそボラ（遊びのボランティア派遣）

◎ハロウィンパーティ

◎難病・慢性疾患全国フォーラム

◎交流会の開催

3. 啓発活動
◎こどもの難病シンポジウム
◎病弱教育セミナー
◎自立支援員研修会
◎広報活動
　機関誌「がんばれ！」の発行、ホームページの開設および運営、チャリティイベントなどへのブース出展と講演活動

4. 地域活動（みんなのふるさと“夢”プロジェクト）
◎“あおぞら共和国”の建国（開発・建築・運用・広報）

1-3.　医療機関・医療従事者との連携についてお答えください（理事や幹事に医療従事者が入っている。団体会員として医療機関が加入している等）。

・役員（理事・監事）に医療従事者がいる。
・電話相談員に医師、看護師、認定遺伝カウンセラーがいる。
・国立成育医療研究センター、神奈川県立こども医療センター、東京都立小児総合医療センター、埼玉県立小児医療センターの院内に相談（ピアサポート）窓口を設置している。
・サマーキャンプの開催時に地域の医療機関から医療班（医師・看護師）の派遣を受けている。
・国立成育医療研究センター、慶應義塾大学病院などの顧問や倫理審査委員の委嘱を受けている。

2. 患者参加の定義

2-1.「患者参加」について、患者団体としての定義やお考えをお答えください。

＜例＞

「患者参加」とは患者が自分の病気に向き合い、主体的に治療に参加することと患者団体として定義しています。

・団体としての定義はありません。 福島個人としては、 ・Patient and family-centered care を実現するために、患者およびその家族が支援者と協働すること。

2-2. 患者団体が、患者参加を推進していく上でどのような役割を担っているとお考えをお答えください。

＜例＞

患者が主体的に治療に参加する患者参加を推進していくために、患者団体は会員や会員家族に対して情報提供を行ったり、患者の相談を受けたりなどする役割を担っていると考えています。

・団体としての考えは表明していません。 福島個人としては、 ・患者個人の治療法の選択・決定、セルフケアへの支援のほか、病院運営、医学系研究、医療政策などのすべてにおいて密接に関わる役割を担っていると考えます。

3. 相談事業の体制について

実施の有無	有
実施形態	電話　・　メール　・　対面　・　その他（LINE）
相談体制	●相談の対象 制限なし ●相談可能な日時 電話相談　平日 11 時～15 時 遺伝（先天異常）特別相談　毎月第 4 金 14 時～17 時 ピアサポート　毎週 3～4 日　10 時～15 ないし 16 時 LINE 相談　火・金 11 時～14 時 ●相談の担当者 電話相談　看護師、社会福祉士、精神保健福祉士 遺伝（先天異常）特別相談　医師、認定遺伝カウンセラー ピアサポート　ボランティア LINE 相談　ボランティア

相談件数	電話相談　395 件／年間 遺伝（先天異常）特別相談　6 件／年間 ピアサポート　68 件／年間 ※コロナ禍の影響により例年より大幅に減少。 LINE 相談　火・金 11 時～14 時　新規事業
相談内容と件数 （貴団体で使用している分類とその件数をお答えください。）	・別紙参照
受け付けた 相談事例の対応 （例：専門病院・専門医の紹介、別の機関を紹介等）	・電話相談は、難病や慢性疾病、障害のある子どもを育てる家族からの医療・教育・福祉などに関する相談全般。 ・ピアサポートは、難病や慢性疾病、障害のある子どもを育てた経験のある人たちをピアサポーターとして養成し、その体験的な知識を活かした相談。 ・いずれも、医師や病院の紹介はしていません。

医療事故を疑う相談事例 件数/年	数件のみ
事例への対応方法	・傾聴と情報提供
事例への対応での工夫	

4. 「患者参加」に寄与する患者教育の実施について

（以下の問について、「有」の場合、具体的な内容についてお答えください。）

病気や治療等に関するリーフレットの作成配布	無
web サイトでの情報提供	無
e-learning を用いた患者教育の提供	無
医療安全上の注意喚起についての情報提供	無

5. 会員、他患者団体、同疾患患者とのつながり・連携の実施状況について

（以下の問について「有」の場合、具体的な内容についてお答えください。）

患者同士のネットワーク作り（交流会の開催、勉強会の開催等）	有
	・親の会連絡会の活動支援：定例会議（関東・関西・ZOOM）、親の会ブース出展、研修旅行、研修・会議室の貸与。
他の患者団体との連携	有
	・親の会連絡会　68 団体 ・難病・慢性疾患全国フォーラムの開催
ピアサポートの活動	有
	・国立成育医療研究センター、神奈川県立こども医療センター、東京都立小児総合医療センター、埼玉県立小児医療センターの院内に窓口を設置しているほか、慶應義塾大学病院でも不定期にピアサポート活動を実施。　※コロナ禍の影響により活動を大幅に縮小。 ・電話や LINE によるピアサポートも開始。
その他	有　・　無

6. 貴団体が「患者参加」に寄与する活動として考えられる活動の実施状況について

（以下の問について、「有」の場合、具体的な内容についてお答えください。）

行政・医療政策への参加 （国・地方自治体等の審議会・委員会等の患者委員等、国への要望書の提出、署名活動、提言活動）	有
	社会保障審議会専門委員、神奈川県慢性疾病児童支援協議会委員、千葉県慢性疾病児童支援協議会委員、千葉県移行期医療支援連絡協議会委員、東京都小児慢性特定疾病児童等移行期医療支援推進会議委員など
学会への参加 （所属している学会、学会総会での講演・シンポジウムの講師、診療ガイドラインの作成委員・評価委員）	有
	日本育療学会理事、日本小児科学会移行支援に関する提言作成ワーキンググループ委員、日本小児保健協会倫理委員会委員など
医療機関の活動への参加 （倫理審査委員会の委員、医療機関の運営委員）	有
	国立成育医療研究センター顧問、国立成育医療研究センター倫理審査委員会委員、国立成育医療研究センター臨床研究審査委員会委員、国立成育医療研究センターヒト ES 細胞研究倫理審査委員会委員、慶應義塾臨床研究審査委員会委員、慶應義塾大学病院治験審査委員会委員など
医育機関の活動への参加 （医療系の学生に対する講義、演習での模擬患者）	有
	学生に対する講義：淑徳大学、愛知医科大学、東京慈恵会医科大学など
その他に考えられる活動	有
	日本製薬工業協会患者団体推進委員会アドバイザリーボード委員、米国研究製薬工業協会患者アドバイザーなど

＜アンケート・インタビュー項目＞【認定NPO法人ささえあい医療人権センターCOML】

各質問項目について、2020年度の実績をもとに、当てはまるもの全てに○をつけてください。□には文章をお書きください。

1. 団体の組織構成・事業内容について

以下の項目が記載されている資料（年報・パンフレット等）の提供で代替頂くことも可能です。

1-1. 組織の規模（会員数・支部の数）についてお答えください。

会員数	約800人
支部の数	支部はありません

1-2. 貴団体の主な事業内容についてお答えください。

（１）会報誌発行・講師派遣等の普及啓発活動
（２）電話・手紙・ＦＡＸ・メール等による医療に関する相談
（３）研修会・フォーラム・シンポジウム等の開催
（４）ＳＰ（模擬患者）の活動
（５）病院探検隊の実施
（６）委員派遣等の政策提言活動
（７）その他、目的達成のための事業

1-3. 医療機関・医療従事者との連携についてお答えください（理事や幹事に医療従事者が入っている。団体会員として医療機関が加入している等）。

＊理事10名中、医療従事者が6名（医師3名、薬剤師1名、看護師1名、事務長1名）
＊団体賛助会員に医療機関多数
＊個人の正会員、賛助会員にも医療従事者多数

2. 患者参加の定義

2-1.「患者参加」について、患者団体としての定義やお考えをお答えください。

＜例＞

「患者参加」とは患者が自分の病気に向き合い、主体的に治療に参加することと患者団体として定義しています。

個人としての「患者」であれば、医療者任せにするのではなく、病気を自分の持ち物と自覚し、自分にできる努力や工夫をしながら積極的に治療に参加していく協働する姿勢が必要と考えています。 講義の患者参加では、医療の制度、しくみなどについて理解し、利用者の視点で地域の医療の現状やその原因を知り、どうすればいいのかを一緒に考える姿勢だと思っています。つまり、医療を個人の問題としてとらえるにとどまらず、社会を視野に入れながら考えることと位置づけています。

2-2. 患者団体が、患者参加を推進していく上でどのような役割を担っているとお考えをお答えください。

＜例＞

患者が主体的に治療に参加する患者参加を推進していくために、患者団体は会員や会員家族に対して情報提供を行ったり、患者の相談を受けたりなどする役割を担っていると考えています。

ミニセミナー「患者塾」や「医療をささえる市民養成講座」(1回3時間×5回）などを開催し、医療におけるさまざまな課題や制度、しくみを知る機会を提供しています。また、「医療をささえる市民養成講座」を基礎コースと位置づけ、全回修了した人を対象にアドバンスコース「医療関係会議の一般委員養成講座」(1回3時間×7回）を開催し、第6回目と第7回目で模擬検討会をおこない、発言の姿勢や内容を採点。合否判定をしています。合格者は「COML委員バンク」に登録できるシステムで、COMLに委員養成などがあった場合に推薦、派遣をしています。

3. 相談事業の体制について

実施の有無	(有) ・ 無
実施形態	(電話) ・ (メール) ・ 対面 ・ その他（ ）
相談体制	●相談の対象 会員のみ ・ (制限なし) ●相談可能な日時 月・水・金：10:00～13:00　14:00～17:00 土：10:00～13:00 ●相談の担当者 常勤スタッフとボランティアスタッフ
相談件数	1990～2021 年で約 64,000 件　　年によって変動あり
相談内容と件数 （貴団体で使用している分類とその件数をお答えください。）	別紙添付します。
受け付けた 相談事例の対応 （例：専門病院・専門医の紹介、別の機関を紹介等）	相談者の話に耳を傾け、問題整理のお手伝いをしたうえで、可能な情報提供やアドバイスをする。

医療事故を疑う相談事例 件数/年	その内容で統計はとっていません。別紙添付の法的解決や示談交渉という項目をご参考までにご参照ください。
事例への対応方法	
事例への対応での工夫	

4. 「患者参加」に寄与する患者教育の実施について
（以下の問について、「有」の場合、具体的な内容についてお答えください。）

病気や治療等に関するリーフレットの作成配布	有　・　(無)
web サイトでの情報提供	有　・　(無)
e-learning を用いた患者教育の提供	有　・　(無)
医療安全上の注意喚起についての情報提供	有　・　無

5. 会員、他患者団体、同疾患患者とのつながり・連携の実施状況について

（以下の問について「有」の場合、具体的な内容についてお答えください。）

患者同士のネットワーク作り（交流会の開催、勉強会の開催等）	（有）・ 無
他の患者団体との連携	（有）・ 無
	緩やかな連携です。
ピアサポートの活動	有 ・ （無）
	当方は「患者会」ではなく「患者支援団体」なので。
その他	有 ・ 無

6. 貴団体が「患者参加」に寄与する活動として考えられる活動の実施状況について

（以下の問について、「有」の場合、具体的な内容についてお答えください。）

行政・医療政策への参加（国・地方自治体等の審議会・委員会等の患者委員等、国への要望書の提出、署名活動、提言活動）	（有）・ 無
	厚生労働省の各種審議会、医療機能評価機構の医療事故収集事業運営委員会、医療事故調査・支援センターの運営委員会、再発防止委員会など
学会への参加（所属している学会、学会総会での講演・シンポジウムの講師、診療ガイドラインの作成委員・評価委員）	（有）・ 無
	所属している学会は医療の質・安全学会（会員かつ理事）、医学教育学会会員・評議員 学会での講演、シンポジウムは多数 診療ガイドラインの外部委員も複数
医療機関の活動への参加（倫理審査委員会の委員、医療機関の運営委員）	（有）・ 無
	特定機能病院の医療安全監査委員会（8 病院）
医育機関の活動への参加（医療系の学生に対する講義、演習での模擬患者）	（有）・ 無
	広島大学歯学部の客員教授、大学医学部等の非常勤講師は多数、模擬患者は 1992 年から活動していて、これまでの派遣回数は約 1700 回（内 OSCE 約 500 回）
その他に考えられる活動	有 ・ 無

1-1. 医療機関・医療従事者との連携についてお答えください（理事や幹事に医療従事者が入っている。団体会員として医療機関が加入している等）。

2-1.「患者参加」について、患者団体としての定義やお考えをお答えください。

＜例＞

「患者参加」とは患者が自分の病気に向き合い、主体的に治療に参加することと患者団体として定義しています。

2-2. 患者団体が、患者参加を推進していく上でどのような役割を担っているとお考えをお答えください。

＜例＞

患者が主体的に治療に参加する患者参加を推進していくために、患者団体は会員や会員家族に対して情報提供を行ったり、患者の相談を受けたりなどする役割を担っていると考えています。

2-3. 相談事業の体制について

実施の有無
実施形態
相談体制
相談件数
相談内容と件数（貴団体で使用している分類とその件数をお答えください。）
受け付けた相談事例の対応（例：専門病院・専門医の紹介、別の機関を紹介等）
医療事故を疑う相談事例（件数/年）

事例への対応方法
事例への対応での工夫

2.4.「患者参加」に寄与する患者教育の実施について

病気や治療等に関するリーフレットの作成配布
web サイトでの情報提供
e-learning を用いた患者教育の提供
医療安全上の注意喚起についての情報提供

．会員、他患者団体、同疾患患者とのつながり・連携の実施状況について

患者同士のネットワーク作り（交流会の開催、勉強会の開催等）
他の患者団体との連携
ピアサポートの活動
その他

一般社団法人グループ・ネクサス・ジャパンインタビュー要約
日時：2022 年 1 月 28 日
インタビュイー：理事長 1 名
インタビュアー：研究代表者、研究分担者 2 名、研究協力者 2 名

・2017 年患者の医療機関の選択について、ヒアリング実施して以来 2 回目である。
・昨年度は患者参加、相談窓口についての病院側の考え方と行政の全国医療安全支援センター（事務局質安全学会）にヒアリングした。
・今年度は患者団体、病院職員、入院患者、医療安全支援センターに改めてアンケート調査する。それによって、患者参加の在り方、センターの在り方の見直しを行いたい。
・患者団体はたくさんあるが、有効に活動し理念がある団体にヒアリングしたいと思い、5 団体に限定してヒアリングする。

悪性リンパ腫患者団体としての患者参加について
患者参加の定義
・団体としての明確な明文化ない。
・しかし、患者参加は患者が治療選択について適切な情報を得られる状態で患者自身の意向に沿って（主体的に）、治療選択ができることと考えている。
・患者は、悪性リンパ腫という命に係わる疾患で告知を受け、身体的・精神的の相当にプレッシャーを感じながら意思決定している前提条件がある。一般の患者は合理的に意思決定できる状況だが、がん患者はそうでなく情報をあたえれば合理的に意思決定できるかというのではない。精神的なプレッシャーを感じながら意思決定を迫られている患者をどのように支えていくかが基本的な考えである。
・主体的という言葉はどう意味なのか。例えば患者の意向が重要である。家族の意向もある。医療職の最適治療に関する意向もある。血液がんの治療は多様で、悪性リンパ腫も多様、治癒が期待できる治療、治癒は期待できないが症状の進行を抑制できる治療、仕事しながらでも可能な治療などの選択肢がある。そのような選択肢の中で、患者の意向、価値観、生活に基づいて患者自身が考えて決めていくことが主体的であると考える。家族医療者の意向ではない。
・もっともな意見であるが、当たり前のことを主体的ということは何か意味があるのか。
・要は、情報把握ができ患者自身が判断でき、動ける状態・状況に持っていくことが患者参加に必要である。
・SDM の場合、個々の患者に主体的に患者参加について教育することは難しい（講演会などを含めても）。
・個々の患者の対応に関しては、オンラインでは患者の言い分、主治医の言っていることが分からない。現在でも治療選択肢の選択もできていない状況である。その場合、オンライン

で説明し、選択肢を整理しながら実施するのが良い。
・個々の医療機関への SDM など患者参加に関する働きかけは難しい。全国がん連合会ではできるが、ネクサス単独では難しくてできていない。

適切な情報提供、患者と医療者との関係整理
・患者が自分で決定する
・医学的に合理的でなくても良い
・手持ちの情報カードを整理することを患者に勧めている
・治療受けた後に別治療法がある、治験があることがわかり、後で後悔することもある。手持ちのカードに何があるかを知らずに選択することはやめた方が良いと言っている。
・サバイバー増えてきて、がんもタイムスパンが変わってきている。がんも慢性疾患的な考え方に変わってきている。生活スタイルとの共存など。リウマチなどの慢性疾患では治療はあくまで自己実現、自身の社会参加の一環であるということが前提であるが。
・若年患者での治療選択では、進学、就職、結婚などの大イベントと重なり、精神的ショックが大きく、心身的にも未熟で、意思決定には慎重に支援する。経済的困窮患者も多く、相談窓口等をより過剰に説明する必要がある（親族の支援があればよいのだが)。深刻な孤独感が強い→オンラインで少し改善された。
・患者の状態で求める情報もかなり変わる。
＊治癒期待
＊病状緩和
＊初回治療、治癒期待できる場合の目的は生活犠牲しても治癒
＊再発、治癒期待できない場合、日常生活の中で病気といかに付き合うかが問題となる。
＊置かれている状況で患者がどう考えるに関わってくる

患者団体として患者参加への支援及び新型コロナの影響
・患者力を患者参加の目安と考えるという意見もあるが、SDM、教育エンパワーメントをあげるという意味での会としての支援方法はある。
・情報提供の面からは、専門の医療者血液内科などの専門の医師やメヂカルスタッフを招いた医療講演会の開催はオンラインで実施している。HP や会報誌で情報提供している。さらに患者の電話相談を設けている。オンラインで ZOOM やラインでの交流会も実施している。
・電話相談件数は年間 300 件程度。電話相談は火木土 3 時間ずつ相談を受けている。常勤はいないので、非常勤の役職員が対応（天野さんを含めて患者経験 10 年以上）
・会の電話相談も素人があつかうものであり、こういう情報があります、ただあなたに当てはまるかどうかわかりませんと付け加えている。
・経験をしている患者同士の体験や思いをシェア共有して自分自身の参考にしてもらう機会を設けている（ピアサポート)。

・ピアサポートに関しても、時にメンタルである不眠、自殺企図に関しては対応しない。がん診療拠点病院の相談支援センターに相談することを伝える。抑うつが強い患者にはメンタルクリニックや精神腫瘍科受診を勧める。第一選択はがん診療拠点病院の相談支援センターである。
・血液がんはコロナにはハイリスクであるので、コロナで変わった。交流会も各支部で実施していた。東京ではがんセンター中央病院で 1 回 100 名参加。オンラインでの交流会はコロナ禍前では不評であった（対面で実施したい、ツールへの抵抗感強かった）が、現在、交流会もすべてオンラインで実施している。従来だと参加者の動線が遠いなどのクレームや治療中だと参加できないなどがあったが、オンラインだと場所や時間を選ばなくて良くなり、治療を受けながらの参加も可能になった。
・地方や支部により差があったが、現在は交流の機会が増えた。支部がなくても参加できる、住んでいる場所に関わらず参加できるようになった。
・セカンドオピニオンを受けたいが、遠い、お金がかかるなどあったが、それがなくなった。国立がん研究センター中央病院がオンラインでセカンドオピニオンを提供している。患者がコロナの影響なく受診できる。センターの医師と患者と主治医ともオンラインに参加することがある。直接医師同士で話ができる。話が早くなる。オンラインのセコンドオピニオンは大きな影響がある。
・オンライン診療が変わってきた。オンライン診療には限界はある。血液内科の医師は抵抗がある医師が多いが、その理由はオンラインだと患者の体調などが分かりにくいから。しかし、セカンドオピニオンはオンラインにできると思う。使い分けが必要で、オンラインでできることはオンラインでやってほしい。
・患者に提供する情報を他団体と共有することは実施している。昨年度からキャンサーネットジャパンと連携し、血液がんフォーラムをオンラインで開催し、療養上のこと、経済的なこと、就労支援などの情報提供している。

<u>ピアサポートについて</u>

・通常は対面だと思うが、オンラインでのピアサポート状況は？
・ZOOM の抵抗感や知識習得のためにお試し会を毎月実施して機器の使用方法など教えていた。IT 知識に乏しい自分たちでの説明は難しい面がある。
・私たちはオンラインには限界があると認識して使用する必要がある。患者の動作や表情で感じ取れないものがある。交流会では気づいて個別支援を実施できるが、オンラインでは難しい。オンラインでは手振り、身振りを大げさにするように指導している。

<u>医療安全支援センターとの関係</u>

・センターの存在は知っている。
・医療安全や訴訟についての相談はあまり多くない。年間数件程度。相談があれば COML を

紹介して話を聞いていただく。
・医療安全や訴訟の可能性のあるものは数件以上で少し多いので、それは会で受けている。患者の誤解のことが多い。患者の考えを聞いて、医療過誤には当たらないだろう的な話をしている。医療機関の言い分もあるので。

専門病院にたどり着く方法
・造血幹細胞専門施設に集中、アクセスよりもお返しするときにはどうなっているのかが現在問題となっている。
・これは血液がんでは解消されていない。悪性リンパ腫は長寿になり、フォローアップが大変で、血液内科も大変。
・地域でフォローアップしていくというのではなく、終末期看取りの問題が出てきている。終末期は輸血が大変で、在宅も難しいが、在宅医のネットワークができつつある。大阪市立大で血液内科出身で開業された医師のネットワークを作る動きがある。
・しかし、カゼでも行き場所がない。コロナでより深刻になっている。総合内科で見る必要があるのではないか。学会では限界であるが、プライマリー学会の若手が問題意識を有している。
・診れる病院・施設の可視化が必要。医師同士は知っていることが、それを患者と共有出来ていない。病院間、病院内での共有する必要がある。チーム医療が患者に可視化されていないのが問題である。

療養支援、病院相談窓口について
・患者が知っていない。
・相談窓口などもそうである、両立支援コーディネータ、ソーシャルワーカ、産業医を知っている患者は少ない。
・医師、看護師もその必要を理解していない。
・相談窓口案内は外来に貼ってあるが、入院患者は見ない。
・これらのことは会として周知していく必要がある。
・入院オリエンテーション時にそのような説明がない
・病院によってはハローワークとも共同している。がんなのになぜ働くのなど不適切な説明するハローワークもある。疾病を抱えた方を支援する職員を置いている施設もある。
・会としては、就労支援している CSR プロジェクトなどに紹介しているが、その他、COML に紹介している。
・静岡がんセンターでは、最初主治医に会わせない。最初オリエンテーションし、看護師が相談窓口、経済的なこともヒアリングしている。漏れがなくなって良いが、この仕組みが他病院では実施されていない（がんだけをみていないという理由で）。

公益社団法人日本リウマチ友の会インタビュー要約
日時：2022 年 1 月 26 日
インタビュイー：会長 1 名
インタビュアー：研究代表者、研究分担者 5 名、研究協力者 1 名

・友の会の迅速な対応に感謝しています。5 年前飯田、長谷川、瀬戸、永井で病院選択に関してヒアリング対応していただいたことにも感謝しています。
・リウマチ白書も 5 年目の新版ができたということで、活用したいと思います。

・今回は患者参加に関する実態、方向性について、ヒアリングしたいと思います。本来昨年度の予定でしたが、コロナの関係でできなくて、今年になりました。
・アンケートにお答えしていただいているが、その他補充したいのでよろしくお願いしたい。

会の内容
・会員数 9438 人で 47 支部あるが、会員数だいぶ減少した。
・その背景は、高齢化と治療の有効性向上である。専門医での治療が奏効すると、患者は患者団体に入会しない。さらに、高齢化で会員の死亡増とともに、高齢化で認知症を合併し、施設入所により会員として参加できない。
・団体として公益事業は不変である。
(1) リウマチ性疾患を有する者の治療及び機能回復に関する必要な施策の充実・強化を図るための啓発、広報に関する事業。
(2) リウマチ性疾患を有する者の治療及び機能回復のための療養相談に関する事業。
(3) リウマチ性疾患を有する者の治療及び機能回復のための用具の研究、紹介及び斡旋並びにこれに付帯する事業。
(4) 会員相互の親睦、福祉厚生に関する事業。
(5) その他前条の目的を達成するために必要な事業。

会としての患者参加の定義
・治療に関しては、現在のリウマチ治療は患者とリウマチ医の合意に基づいて行われ、治療を推進（学会と共に）することで、Treat To Target が定義である。
・治療目標がターゲットである。そこに患者参加の概念が入ってくる。
・要は、患者が自分の治療に主体的に向きあうことである。
・その場合の主体性とは、患者、病院、患者団体、病院団体で異なるのではないか（病院でも患者参加をうたっている病院があるが）。
・自分の治療目標を決めることが患者参加である。

・治療目標としては、日常生活、社会参加に関する目標を設定する
・社会での役割を見据えた治療目標を設定しなおすことが重要である。
・患者参加には患者力が必須：自分の意思を決定できるようなものをいう。
・ただし、主治医に聞いた方がよい内容をリスト化していない。聞きたいことを要約してから聞きなさいとは言っている。
・医療者も責任があるが、患者本人にも責任がある
・患者、医療者の合意に基づいて患者参加を推進する
・治療にきちんと参加する。
・患者だけではなく医療者にも参加してもらう。
・同意に基づいて参加する。
・医療者と患者との関係、友の会との関係も同意に基づいて参加する。
・患者本人も団体も話し合っていく必要がある。
・日常正確、社会生活などの目標を医療者との関係の上で築いていくことが重要である。
・患者が希望すること、主治医に希望すること、医療連携してほしい、他課と連携してほしい、もっと説明してほしい、患者の気持ちを理解してほしいという気持ちを理解して支援していく。
・リウマチ白書では、医師と治療な内容を話し合っている患者は少ないことが分かる。
・リウマチ白書実態アンケート調査では、患者（会員）は60%回答し、医療者は606人（30%回答）回答している。医療者の声は大事である。

・医療政策に関しては、医療政策に患者・国民の声が反映されていない現状に対して、2008年「患者の声協議会」を他団体と立ち上げた。その後、医療の憲法というべき「医療基本法」制定の働きかけを患者の権利法をつくる会等と共に働きかけ、2019年議員連盟が発足した。現在コロナ禍で足踏み状態である。

<u>会としての患者参加への支援</u>
・患者の「はい」は「はい」ではない。患者は医療者に「はい」といってから患者団体に説明を求めてくる。
・団体としては、それは医療者に聞きなさいと言っている。もちろん、患者の理解力の問題もあるが。
・具体的には、機関紙の発行、講演会を開催しているが、なかなかむずかしい。
・早期診断、早期治療が重要である
・8000件の相談件数で、半数以上が健診で見つかり、近くの専門医を紹介しろというものが多く、専門医を紹介することが多い。基本は本人が選択して決定すること
・きちんと指導するのは専門医の役割で、その後の部分では医師以外を含めたチーム医療がリウマチ治療では重要である。会としては、チーム医療を希望している。リウマチ医療では

チーム医療が動きつつある。リハの分野の登録制度も推進している。病院団体にも働きかけているが、基本的には医療基本法の制定が重要と考える。
・リウマチ医療も地域差があるが、会としては地域全体を取りしきれていない。
・近くの専門医、医療費など医療制度等の相談内容などは、現状では不具合はないが、愚痴は友の会に回ってくる。
・制度的なことは事務職員でもこなせるようにしているが、基本は主治医に聞いてくれと言っている。主治医に聞けないこともあるが、聞くことと言っている。
・主治医は忙しいそうだからとか、その場合は、医療福祉など他の職種にも聞けることはその職種に聞くことと、患者相談室に聞くことを言っている。
・検査結果が良いと症状について主治医が聞いてくれないことが多い。
・病院職員も患者も患者相談室を知らないケースも多い。
・会が「患者参加」に寄与する活動として考えられる活動実施状況としては、地域の保健福祉計画の委員などとして参加している。
・リウマチ学会との関係は 62 年前に会を開設して以来連携している。ずいぶん支援してもらった。機関紙でも協力してもらい、会に入会してくれる医師もいる。
・学会＋友の会共同で、相談、啓蒙しているが、実際の患者すべてに情報がいきわたっていないのではと危惧している。

<u>リウマチ相談員養成講座の開設支援</u>
・患者はリウマチ相談員がいることを知らない。
・リウマチ学会が厚労省委託事業で実施している（最初は予防協会が、その後学会が)。
・講座受講者は行政の方も多いが、その後活用としてるかどうか不明である（相談員が養成後、地方に帰った時にどのように活用されているか不明)。
・半日の研修で認証をもらう。
・今年は 100 名単位（全国で)。
・活用がうまくいっていないようなのはもったいない。
・患者団体としてはリウマチ相談員のことを周知しているので、会員はわかっているが、入会していない患者には周知されていない。
・リウマチ相談員養成講座の講義内容は、白書の内容を講義し、個人の私見は入れない。
＊リウマチの知識
＊一緒に決める場合の力関係
＊治療の結果への納得性は
＊どれが患者さんでは重要か

<u>医療安全支援センター</u>
・個人としても、会としても知らない。

・そのようなものがあるなら利用したい。
・患者も知らないことが多い。
・行政、病院、患者、患者団体が共同でいろいろなことができるとよい

リウマチ友の会事前アンケート内容

＜アンケート・インタビュー項目＞

各質問項目について、2020 年度の実績をもとに、当てはまるもの全てに〇をつけてください。□には文章をお書きください。

1. 団体の組織構成・事業内容について

以下の項目が記載されている資料（年報・パンフレット等）の提供で代替頂くことも可能です。

1-1. 組織の規模（会員数・支部の数）についてお答えください。

会員数	9,438 人
支部の数	47 支部

1-2. 貴団体の主な事業内容についてお答えください。

定款第 4 条

(6) リウマチ性疾患を有する者の治療及び機能回復に関する必要な施策の充実・強化を図るための啓発、広報に関する事業。

(7) リウマチ性疾患を有する者の治療及び機能回復のための療養相談に関する事業。

(8) リウマチ性疾患を有する者の治療及び機能回復のための用具の研究、紹介及び斡旋並びにこれに付帯する事業。

(9) 会員相互の親睦、福祉厚生に関する事業。

(10) その他前条の目的を達成するために必要な事業。

1-3. 医療機関・医療従事者との連携についてお答えください（理事や幹事に医療従事者が入っている。団体会員として医療機関が加入している等)。

・会員構成：医療関係者多く加入している

普通会員：患者・家族

特別会員：目的に賛同する医療関係者（医師・看護師・薬剤師・PT・OT MSW 他）

理事会構成

理事 20 名（患者１３，医師５，MSW１，PT１）

監事 2 名（医師１、看護師１）

2. 患者参加の定義

2-1.「患者参加」について、患者団体としての定義やお考えをお答えください。

＜例＞

「患者参加」とは患者が自分の病気に向き合い、主体的に治療に参加することと患者団体として定義しています。

治療に関して ・現在のリウマチ治療は、患者とリウマチ医の合意に基づいて行われ、治療を推進（学会と 共に）Treat To Target ・医療政策に関して 医療政策に患者・国民の声が反映されていない現状に対して、2008 年「患者の声協議会」を他団体と立ち上げた。その後医療の憲法というべき「医療基本法」制定の働きかけを患者の権利法をつくる会等と共に働きかけ、2019 年議員連盟が発足。現在コロナ禍で足踏み状態。

2-2. 患者団体が、患者参加を推進していく上でどのような役割を担っているとお考えをお答えください。

＜例＞

患者が主体的に治療に参加する患者参加を推進していくために、患者団体は会員や会員家族に対して情報提供を行ったり、患者の相談を受けたりなどする役割を担っていると考えています。

機関誌や公開講演会のテーマとし、専門医に依頼して情報提供。 実態調査の中で、患者の意識調査と共に希望することをまとめている。

3. 相談事業の体制について

実施の有無	(有) ・ 無
実施形態	電話 ・ メール ・ 対面 ・ その他（ ）
相談体制	●相談の対象 注：○会員のみ ・ ○制限なし 注）月 1 回専門医による電話相談 会員のみ（予約制） セカンドオピニオンとして ●相談可能な日時 通常 月～金 10：00~16：00 ●相談の担当者 事務局員・理事
相談件数	件／年間
相談内容と件数	年間 約 8,000 件（一般 約 7 割）

（貴団体で使用している分類とその件数をお答えください。）	
受け付けた 相談事例の対応 （例：専門病院・専門医の紹介、別の機関を紹介等）	・近くの専門医を知りたい ・制度（医療・福祉について） ・医療に関する不備・思い等） 注）治療に関しては主治医に聞くようにしている。

医療事故を疑う相談事例 件数/年	ほとんどなし
事例への対応方法	
事例への対応での工夫	

４.「患者参加」に寄与する患者教育の実施について

（以下の問について、「有」の場合、具体的な内容についてお答えください。）

病気や治療等に関するリーフレットの作成配布	㊒　・　無
	機関誌に掲載
web サイトでの情報提供	㊒　・　無
e-learning を用いた患者教育の提供	有　・　�無
医療安全上の注意喚起についての情報提供	有　・　�無

５．　会員、他患者団体、同疾患患者とのつながり・連携の実施状況について

（以下の問について「有」の場合、具体的な内容についてお答えください。）

患者同士のネットワーク作り（交流会の開催、勉強会の開催等）	㊧有　・　無
	・全国大会時：前夜祭での全国会員の交流 ・支部での制度等の勉強会
他の患者団体との連携	㊧有　・　無
	・患者の声協議会 ・日本障害者協議会 ・難病・慢性疾患全国フォーラム
ピアサポートの活動	㊧有　・　無
その他	有　・　無

６．　貴団体が「患者参加」に寄与する活動として考えられる活動の実施状況について

（以下の問について、「有」の場合、具体的な内容についてお答えください。）

行政・医療政策への参加（国・地方自治体等の審議会・委員会等の患者委員等、国への要望書の提出、署名活動、提言活動）	㊀有　・　無
	・地域保健福祉計画等委員（各地）
学会への参加（所属している学会、学会総会での講演・シンポジウムの講師、診療ガイドラインの作成委員・評価委員）	㊀有　・　無
	日本リウマチ学会 ・学会のシンポジウムでの講師（薬価等） ・診療ガイドライン作成委員（2014 年　2020 年） ・ライフステージに応じた患者支援ガイドライン作製委員（2020 年）
医療機関の活動への参加（倫理審査委員会の委員、医療機関の運営委員）	㊀有　・　無
	・治験安全委員会委員
医育機関の活動への参加（医療系の学生に対する講義、演習での模擬患者）	㊀有　・　無
	・大学の薬学・看護部門での講師（例年　単独） ・模擬患者
その他に考えられる活動	有　・　無

一般社団法人全国腎臓病協議会インタビュー要約
日時：2022 年 2 月 1 日
インタビュイー：専務理事 1 名
インタビュアー：研究代表者、研究分担者 5 名、研究協力者 2 名

・患者参加に関する定義:各病院での定義付けは曖昧であり、病院も明らかにできていない。
・医療安全支援センターの業務の在り方の検討も必要であり、センターの相談機能も世間への周知ができていない。
・医療安全、患者参加に関する病院職員、患者へのアンケート調査とセンターへのアンケート調査、さらに患者団体へのヒアリングを予定している。

事業内容
・7 万の会員数、47 か所の支部であり、支部は正会員で理事となっている。
・患者支援団体ではなく、患者団体である。
・透析に移行すると福祉が入り、ステージⅤになり身体障碍者になるが、当会はこのステージⅤの患者の患者団体である。ステージⅣまでは医療の世界である。
・事業内容:腎臓病に関する正しい知識の普及及び社会啓発並びに腎臓病患者の自立と社会参加の促進を図り、社会の発展に寄与することを目的とする。
（1）腎臓病の予防及び治療に関する知識の普及と啓発事業
（2）腎臓病患者の自立を支援する事業
（3）腎臓病に関する調査研究と政策提言
（4）広報誌の発行及びホームページの運営等の広報事業
（5）腎臓病患者を支援する基金事業
（6）その他、この法人の目的を達成するために必要な事業
・医療機関・医療従事者との連携では、日本透析医会、日本透析医学会と連携し、透析に関する十分な医療保険の確保を図るとともに、医療者側から患者に対するリクエスト、アドバイスを周知し、透析医療の向上に寄与する。
・現在 7 万人（最盛期 20 万人）
・70 代で透析導入では、高齢で会に参加する意思もない。
・慢性腎炎からではなく糖尿病由来が多い。慢性腎疾患では教育の効果大であるが、糖尿病はなかなか生活習慣を変えられない。
・難病特例疾病も 300 あり、腎疾患も難病としての対象となっている。

患者団体としての機能
・圧力団体としての機能（診療報酬、政治、行政など）もある。
・患者から依頼があれば発信するが、依頼なければ発信できない。

・会としては教育、リテラシーなどへの体系的な関与はできていない。

患者参加の定義

・患者団体と患者支援団体との違いもあるが、当協会としては、慢性腎臓病患者がステージⅣを経てステージⅤに至る、すなわち保存的腎臓療法（conservative kidney management: CKM）から腎代替療法（renal replacement therapy: RRT）が必要になったとき、十分な医療側の説明のもとに患者として意思決定する共同意思決定（shared decision making: SDM）と、本人が家族等や医療・ケアチームと事前に繰り返し話し合うプロセスであるアドバンス・ケア・プランニング（advance care planning: ACP）の概念の重要さに基づき、医学的知識の無い、患者としては初めて直面する場面において、最終的かつ全面的決定権を有していることと個人的には定義している。一言でいれば、治療方針決定に患者が関与することと考えている。
・その理由は、透析を想像できず、導入後に後悔する患者も多いので、透析導入時の十分な意思決定材料の提供、十分な判断材料が患者には必要である。
・会としての明確な定義はない。
・慢性のCKDから透析、腎移植、ACP各ステージにおいて、患者のSDMに関して支援することが重要である。
・ただし、相談が来れば支援するが、当会は透析に移行した段階での患者団体であるので、当該ステージで相談が来た場合に限定される。介入できない。
・それ以前の慢性腎疾患（CKD）の時期には介入方法はない。CKDの患者団体はないので、個々の医師の頑張りで医療提供等を実施しており、マンツーマンで医師に依存している。支援団体、患者団体がなく、患者は不安な状態である。
・会としては、CKD患者を取り込む必要があるが、CKD患者へのルートはないので大学病院の腎臓内科医、医会の医師と共同でアプローチ展開したい。CKD患者からの会への参加はない。
・患者のＳＤＭ（判断決定共有）に関して、団体として審議会などで話し合う場所はない。医師会の腎臓部会やせいぜい透析医会などでの話し合いの場しかない。さらに、透析以前の段階では透析医会の範疇に入らず、腎臓内科の世界である。医師の手にあるCKD患者にどう介入できるか。

患者参加への支援活動

・患者は透析導入時に十分ＩＣを得て納得しているが、医療では素人なので、患者は食事などについても知識不足である。
・講演会、会報発行、HPで情報提供し、教育啓もうしている。
・講演会には医師や他職種も入っているし、患者以外にも家族も入ってくる。透析中の運動療法、食事療法も大事でリハビリ、管理栄養士も参加してもらっている。

・日常生活の体調対応などの情報提供を日々行っているが、ステージごとの支援に関してはあまりできていない。
・医師の説明について理解できなかったので、その説明依頼が会にくるが、具体的には全国の支部が日常的に相談に乗っている。
・現在の当会の活動は、腎代替療法に移行した患者、主として透析療法を施行中の会員（透析中に移植を受けた患者を含む）に対し、医療、保険、福祉について周知を行っている。
・支部と本部とは別で、各支部の統計もとれていない。
・腎友会（支部）が都道府県に存在している。支部は社団法人の社員である。方針決定は全腎協がやるが、個別のことは支部がやっている。支部の影響の方が大きい。役員の勉強会もしている。
・医療者側の話し合い、意思判断決定共有はどうなっているか。本部と東京支部とは連携してしているか。都道府県レベルでそのアプロ―チ方法が種々である。
・医療・保健福祉での支援
・患者の知識増加に対する教育支援
・ＳＤＭを支援する研修会
・以上の支援、研修会は全国的にはできない。東京にある本部としての行政との圧力団体としての仕事はできるが。
・透析導入時代の初期の時には個人負担が大きかった。当初は医療費の３０～５０％支払い義務。透析機器も不足していた。しかし、会の活動で、補助金などで透析施設も拡大し、医療費負担もなくなってきた。現在は会としては、透析の現状の維持が意義であり、後退しないようにすることが活動の中心である。国会にも現在の制度後退に反対と請願している。

<u>ＡＣＰにおける患者参加支援</u>
・透析を継続すれば腎臓で死亡することはない。
・透析を中止したい患者は相当数いるが、その場合の対応を透析医会は困っている。透析医学会、透析医会で学会に提言出した（21 年 7 月に公表)。SDM、チーム医療をうたっているだけで、決定権は患者にあるので、なかなか難しい。医学会の提言は厚労省の「終末期における医療と介護」を受けたサブ提言のようなもので、フォーマットもないし、これを参考にしたマニュアル通りでも法的免責はない。
・医学会の統計では医師の 40%がそのような経験がある。
・会としては、このような患者が出ることを想定していない。いつでもどこでも安定して透析できるという提言を会はしているので、会の方向性と異なる。
・最終的な決定権は患者にあるので、法定な問題、倫理委員会など、医療者側も困っている。
・ＡＣＰ、ＤＮＡＲに関しては会としてはリーダシップを取っていない。

今後の課題

・今後は積極的に保存的腎臓療法を受けている者、すなわち慢性腎臓病患者にアプローチしたい。
・具体的には、国の CKD 対策事業、2028 年までに年間新規透析導入患者数を 35,000 人以下にするとの目標達成に協力する。
・ＣＫＤのステージからの教育が必要である（ＣＫＤへの教育も拡大したい)。
・医療、社会的の教育が必要ではないか。
・学童期の検尿段階からの教育。移植について小中高校の教育課程で授業を設けるように文科省に依頼している。
・透析医療が予算を食っているという財務省の存在が課題である（年間１名透析導入に 500 万要している)。従って、厚労省を含めて新規透析導入患者数を 35000 人以下にという目標を大事に考えている。
・具体的にどうするのか。透析患者の会ではない、慢性腎臓病患者にして、具体的にはあまり入会しないようにしていきたい（キャンペーン)。
・相談があればＣＫＤにも対応できるが、その相談ルートができていない。
・ＣＫＤに対しては支援団体としての働きしかできない。
・CKD の会を当会の中に作る必要があるが、指導できるのは医師側であり、腎臓内科などの関与が重要である。支部は各大学の腎臓内科支援会はできているが、医師しか患者情報を保持していないので、支援の会には患者情報をもらえないし、医師に患者に関する講演会のパンフレットなどを渡せない。医師会などを通じた腎臓関係の部署に介入するしかない。
・高齢化社会の中で会としての存在意義は？
・認知症患者の透析はどう考えるか？患者の自己決定権は尊重するが、認知症になった場合、家族の意思を尊重する。それを会としては種々支援している。
・透析を断る患者もいる。厚労省による透析患者発生の抑制には参加したい。
・経済的には問題ない（自己負担はない)。しかし、就労しているかというと、安定した収入は得られていない。実質的な収入確保は難しい。週 3 日の通院ができない。通院支援が会として具体的な問題となっている。ＣＫＤ対策が功を奏して、透析導入の平均年齢は 70 歳であるので、高齢者で通院は難しい。家族も介護しているようなものである。

病院の広報で不足しているもの

・ニーズに合っていない。基準的なサイトが必要。医師が適切な情報源を提供する仕組みができればよいのだが。

＜アンケート・インタビュー項目＞

各質問項目について、2020 年度の実績をもとに、当てはまるもの全てに〇をつけてください。□には文章をお書きください。

1. 団体の組織構成・事業内容について

以下の項目が記載されている資料（年報・パンフレット等）の提供で代替頂くことも可能です。

1-1. 組織の規模（会員数・支部の数）についてお答えください。

会員数	約 70,000 人
支部の数	47 か所（正会員＝各都道府県組織）

1-2. 貴団体の主な事業内容についてお答えください。

腎臓病に関する正しい知識の普及及び社会啓発並びに腎臓病患 者の自立と社会参加の促進を図り、社会の発展に寄与することを目的とする。
（１）腎臓病の予防及び治療に関する知識の普及と啓発事業
（２）腎臓病患者の自立を支援する事業
（３）腎臓病に関する調査研究と政策提言
（４）広報誌の発行及びホームページの運営等の広報事業
（５）腎臓病患者を支援する基金事業
（６）その他、この法人の目的を達成するために必要な事業

1-3. 医療機関・医療従事者との連携についてお答えください（理事や幹事に医療従事者が入っている。団体会員として医療機関が加入している等)。

日本透析医会、日本透析医学会と連携し、透析に関する十分な医療保険の確保を図るとともに、医療者側から患者に対するリクエスト、アドバイスを周知し、透析医療の向上に寄与する。

2. 患者参加の定義

2-1.「患者参加」について、患者団体としての定義やお考えをお答えください。

＜例＞

「患者参加」とは患者が自分の病気に向き合い、主体的に治療に参加することと患者団体として定義しています。

> 慢性腎臓病患者がステージⅣを経てステージⅤに至る、すなわち保存的腎臓療法（conservative kidney management：CKM）から腎代替療法（renal replacement therapy：RRT）が必要になったとき、十分な医療側の説明のもとに患者として意思決定する共同意思決定（shared decision making：SDM）と、本人が家族等や医療・ケアチームと事前に繰り返し話し合うプロセスであるアドバンス・ケア・プランニング（advance care planning：ACP）の概念の重要さに基づき、医学的知識の無い、患者としては初めて直面する場面において、最終的かつ全面的決定権を有していること。

2-2. 患者団体が、患者参加を推進していく上でどのような役割を担っているとお考えをお答えください。

＜例＞

患者が主体的に治療に参加する患者参加を推進していくために、患者団体は会員や会員家族に対して情報提供を行ったり、患者の相談を受けたりなどする役割を担っていると考えています。

> 現在の当会の活動は、腎代替療法に移行した患者、主として透析療法を施行中の会員（透析中に移植を受けた患者を含む）に対し、医療、保険、福祉について周知を行っているが、今後は積極的に保存的腎臓療法を受けている者、すなわち慢性腎臓病患者にアプローチしたい。具体的には、国の CKD 対策事業、2028 年までに年間新規透析導入患者数を 35,000 人以下にするとの目標達成に協力する。

3. 相談事業の体制について

実施の有無	(有)・ 無
実施形態	(電話)・(メール)・(対面)・(その他)（FAX、各県組織も対応）
相談体制	●相談の対象 会員のみ ・ (制限なし)（患者・家族、医療機関・介護施設スタッフ、行政、企業等） ●相談可能な日時 ①事務局員による相談：月～金（土日祝日除く）10 時～18 時 ②専門家による相談：特定の日時に予約制（各種月 1～2 回/午後）

	●相談の担当者 上記①：事務局の相談担当者 上記②：委嘱した管理栄養士、社会福祉士、認定心理士（かつ当事者）
相談件数	1072 件／年間（2020 年度事業報告より以下同様）
相談内容と件数 （貴団体で使用している分類とその件数をお答えください。）	上記①事務局による相談：864 件 上記②専門家による相談：208 件 栄養・食事相談：67 件 生活・福祉相談：107 件（医療 60 件・医療費 2 件・年金 3 件・福祉制度 12 件・生活 12 件・心理 12 件・就労 3 件・その他 3 件） こころの相談：34 件
受け付けた 相談事例の対応 （例：専門病院・専門医の紹介、別の機関を紹介等）	事務局による相談：傾聴、かかりつけ医・専門家への相談の勧め、別機関の紹介等

医療事故を疑う相談事例 件数/年	2～3 件
事例への対応方法	傾聴、「訴えたい」等の場合は ADR 等専門機関の紹介
事例への対応での工夫	初回相談時は、強い感情を伴う訴えが圧倒的に多いため、相談者が客観的に状況を整理できるよう傾聴に努める。

4. **「患者参加」に寄与する患者教育の実施について**

（以下の問について、「有」の場合、具体的な内容についてお答えください。）

病気や治療等に関するリーフレットの作成配布	有　・　無
	透析ハンドブック
web サイトでの情報提供	有　・　無
	ホームページ
e-learning を用いた患者教育の提供	有　・　無
医療安全上の注意喚起についての情報提供	有　・　無
	新型コロナウィルスに関して複数回

5. 会員、他患者団体、同疾患患者とのつながり・連携の実施状況について

（以下の問について「有」の場合、具体的な内容についてお答えください。）

患者同士のネットワーク作り（交流会の開催、勉強会の開催等）	有　・　無
	全国大会開催時の交流会 社員代表シンポジウム 役員に対する勉強会
他の患者団体との連携	有　・　無
	日本難病・疾病団体協議会 日本障害者協議会
ピアサポートの活動	有　・　無
	各県組織の役職員のピアサポート向上のため研修会を実施
その他	有　・　無

6. 貴団体が「患者参加」に寄与する活動として考えられる活動の実施状況について

（以下の問について、「有」の場合、具体的な内容についてお答えください。）

行政・医療政策への参加（国・地方自治体等の審議会・委員会等の患者委員等、国への要望書の提出、署名活動、提言活動）	有　・　無
	全国署名を添えての国会請願の実施 関係省庁への要望書提出 全国大会時に大会宣言
学会への参加（所属している学会、学会総会での講演・シンポジウムの講師、診療ガイドラインの作成委員・評価委員）	有　・　無
	日本透析医学会提言作成外部委員及び査読委員
医療機関の活動への参加（倫理審査委員会の委員、医療機関の運営委員）	有　・　無
	ただし、各県組織には実例有り
医育機関の活動への参加（医療系の学生に対する講義、演習での模擬患者）	有　・　無
	看護学校生へ透析について講義
その他に考えられる活動	有　・　無

認定NPO法人難病こども支援全国ネットワークインタビュー要約
日時：2022年1月28日
インタビュイー：事務局長 1名
インタビュアー：研究代表者、研究分担者2名、研究協力者2名

・アンケート感謝。2016年に1回別件でヒアリングしたときには小林専務理事、今回は小林さまから福島様にヒアリング先が変更

事業内容
患者相談窓口、ピアサポート、電話窓口、小児慢性特定疾患自立支援、サマーキャンプなどである。以下アンケート内容を参照。

COVID１９まん延における患者支援方法の変化
・活動内容の変更はあった。
・ピアサポートは従来から病院内に限定されていた。主な場所は、成育医療センター、神奈川小児病院、埼玉小児、慶應大学であった。コロナ禍で支援団体にご遠慮願う依頼が来て、数か所うまくいかなくなった。
・サマーキャンプもイベント系なので、規模縮小、中止、リモート採用などに変化した。
・懇親会、親の会の交流会もZOOMを活用。コロナ前はZOOM活用なかったが、次第に慣れてきた。利点として、地域差、時間差の障害がなくなった。
・ＺＯＯＭ活用で患者団体にも利点があった。年３～４回関東と関西で定期的に話し合いしていたが、コロナ禍以後はZOOMで実施し、垣根がなくなった。家で子どものケアを常時している人でも参加しやすくなった。交流しやすくなったが、一方では親の会の連絡会では、会終了後の飲み会ができなくなり、飲み会の方が活動には有効であったので、少し有効性が減少している。良い話し合いができなくなった。
・研修会はオンデマンドで見逃し配信している。

患者参加に関する会の考え方
・団体としての定義はない。
・小児難病の幅広い支援、小児科と内科医との関係、移行期の問題の中での患者参加とは、福島個人としては、 Patient and family-centered care を実現するために患者およびその家族が支援者と協働すること。患者団体、行政、福祉も含めて支援者間で協働することである。
・この際の患者の定義には患者及び家族が入る。患者と家族が主体である。
・患者・家族の意向に沿って支援する。
・その際の主体的参加とは、

＊患者が積極的に参加する
＊判断決定は共同で決定する
＊患者の意向にそって支援する治療などの部分は患者に決定権がある（ＩＣもそうである)。
・知識習得、患者エンパパワーメントやＳＤＭなどの文脈では、何が患者参加に重要か？こどもの場合は親に主体がある。これがまた移行期の問題になる。
・会の支援は患者選択権、ＳＤＭ、知識エンパワーメント、チーム医療などの支援活動までで、患者参加自体は自分で決めなさいよという立場である
・病院は何のためにある？病院は患者のためにある（もちろん医療者のためでもあるが)。その意味で患者は当然その中心にあるべきである。
・特殊なので小児難病の場合の患者参加は難しい。
・患者参加のやり方を支援していない。
・患者教育はほとんどしていない。
・チーム医療に関しては、会として相談に乗っている。
・病院や医師の紹介はしないが、これは会の決まりである。
・患者参加、自己決定、選択権などに関して年齢制限はしていない。親から見た子どもということ。
・年齢、病態別での理解力、判断力の差異はどうするのか？知的障害、発達障害の子もいるので一概に言えないが、英国では９歳でも責任を負わせる。自己決定権に関しては、発達障害などもあるので一概に言えない。
・ただし、通常の場合、自己決定権・判断の責任の取り方に関して、会としては、患者家族に任せる、責任も患者家族にある。子どもの患者参加に関して、親にまかせるのであればそれで良いと思う。
・会の支援のもとに患者がＳＤＭなどに参加してもらうことが重要。講習会などの教育資材を素材にして、患者が積極的にＳＤＭを可能にするように支援していくことに取り組んでいる。ただし、ＳＤＭできない子どもの場合はどうするかも問題である。
・患者・家族中心医療の重要な要素は選択、決定なのか？そこまで考えての決定ではなく、あらゆる問題で中心にあるべきものと考えている。人により視点が違うが、個人の治療の選択権などでも異なる。中心にいるのというときは、治療選択時などであると思う、しかし、人によっては医師にもう少し説明してくれとの要望もある。
・治療成績も改善し長生きできている。従来は患者中心とは治療選択であったが、社会復帰も含めて社会生活的生活スタイルの選択、人生観の選択などにも拡大してきている
・移行期などもこの数年で変化してきている。国も移行期支援センターの設置し、小児科学会も移行期の提言を出している

<u>小児難病における親子の問題</u>
・小児科医は、親には話して、子どもには話しかけない。小児科医は親と話すが、内科医は

子どもとじかに話す。このことが子どもにとってのギャップになり、その解消が大変である。
・当然、子どもの支援の中では、子どもの自立支援も重要である。子どもの親離れも重要であるが、親の子離れも重要である。これのフォローも会では重要な課題である。この辺りを交流会、講習会などで教育している。

会の患者参加支援活動
・患者団体ではなく、患者支援団体である。
・親なので、親の考え方はあるがそれが会の考え方と同じかというとそうでもない。親だけではなく医療者も参加している。
・治療などに関して情報提供するが、患者参加に関しては患者が決めることである。
・親の会であれば、ある程度情報提供できるので、間接的には親の会を紹介できるが、直接的には支援していない。
・相談件数は多い
・中核病院ではピアサポートあるが、地域格差などを含めて病院の相談窓口につなぐことはある
・会で受ける通常の相談内容と異なる場合は病院の窓口につなぐようなことはある。
・遺伝関係の支援はしており、月に1回臨床遺伝専門医が電話で相談している。その他、親の会で講演を依頼している。

難病の子どもで重要な移行期（トランジション）の支援活動
・会は本活動を重点的に実施している。
・移行期間での会への相談：突然これからは診れないからと言われてどうしたらよいかという問い合わせがある。大まかな情報提供はできるが、即断可能な情報提供はしない。
・お友達の紹介はできる。同じ病気のヒトと会いたいという希望は強い。しかし、希少疾患では親の会もないので、紹介は難しい。会に登録してもらって、あくまで承諾を得たうえで、電話相談室で個人的におつなぎの仲立ちしている。その場合、会員でなくてもよい。会の方でマッチングする（病名で）。相手の承諾を得て、連絡先を交換する。初めての疾患の場合は機関紙に紹介する。現在の登録数は400－500名。

ピアサポート
・会で訓練したボランティアが病院内で活動しているが、会の独立活動なのか、病院との共同作業かというと、明確ではない。
・会としての考え方は、あくまで会独自の活動であり、その際の入手情報は基本的には病院には伝達していない（虐待などは例外）。ただし、情報共有はしないが、話し合いはし、個別ケースの話し合いはしない。
・ピアサポートも病院内活動であるので、現在の病院の治療方針には口を出さない。最終的

な選択は患者・家族にまかせる。情報は提供するが決定は患者家族である。
・実態は、病院の場所を買い取り、曜日と時間を決めて、ボランティアが在席し、予約性ではないのでは、いつでもどうぞというスタンスである（病院職員は立ち会わない)。
・患者が直接くる場合もあるし、病棟看護師が直接つれて来ることもあるが、それは少数である。
・ボランティア（ピアサポート）は子供を育てた親であることが条件である。キャンプに参加した人なども含める。その他の遊びのボランティアはそのような制限はないので、子育てが終わった女性のことが多い。

医療安全支援センターとの関係
全国に 400 か所センターはあるが、そことの連携はない。
・クレームがあった場合、センターにつなぐことはない。
・医療安全関連の相談は当会にはほとんどない。時折医療事故があり解決してほしいという要望もあるが、あくまで愚痴に留まっている。

＜アンケート・インタビュー項目＞
各質問項目について、2020 年度の実績をもとに、当てはまるもの全てに〇をつけてください。□には文章をお書
きください。
1. 団体の組織構成・事業内容について
以下の項目が記載されている資料（年報・パンフレット等）の提供で代替頂くことも可能です。
1-1.　組織の規模（会員数・支部の数）についてお答えください。
会員数 764 人
支部の数 0 か所
1-2.　貴団体の主な事業内容についてお答えください。
1. 相談活動
◎電話相談室
　ネットワーク電話相談室、遺伝相談、遺伝（先天異常）特別相談
◎ピアサポート
　国立成育医療研究センター、東京都立小児総合医療センター、慶應義塾大学病院、神奈川県立こ
ども医療センター、埼玉県立小児医療センター
ピアサポーター養成講座
◎小児慢性特定疾病児童等自立支援員による支援
２．交流活動
◎サマーキャンプ“がんばれ共和国”の建国
　みちのく七夕キャンプ（岩手県一関市)、あしがらキャンプ（神奈川県大井町)、しぞーかキャンプ（静
岡県島田市)、おいでんほうらい（愛知県新城市)、阿蘇ぼう！キャンプ（熊本県阿蘇市)、つながろう
キャンプ in 関西（兵庫県淡路市)、おーきな輪 with みゃーくがに（沖縄県恩納村）
◎親の会連絡会
　定例会議（関東・関西・ZOOM)、親の会ブース出展、研修旅行、研修・会議室の貸与
◎いのちの輝き毎日奨励賞・いのちの輝き親の会奨励賞
◎サンタクロースの病院訪問
◎プレイリーダー
　プレイリーダー養成講座、プレイリーダー活動支援、病児の遊びとおもちゃケア、あそボラ（遊びのボ
ランティア派遣）

◎ハロウィンパーティ
◎難病・慢性疾患全国フォーラム
◎交流会の開催
３．啓発活動
◎こどもの難病シンポジウム
◎病弱教育セミナー
◎自立支援員研修会
◎広報活動
機関誌「がんばれ！」の発行、ホームページの開設および運営、チャリティイベントなどへのブース出
展と講演活動
４．地域活動（みんなのふるさと“夢”プロジェクト）
◎“あおぞら共和国”の建国（開発・建築・運用・広報）
1-3. 医療機関・医療従事者との連携についてお答えください（理事や幹事に医療従事者が入っている。団体
会員として医療機関が加入している等)。
・役員（理事・監事）に医療従事者がいる。
・電話相談員に医師、看護師、認定遺伝カウンセラーがいる。
・国立成育医療研究センター、神奈川県立こども医療センター、東京都立小児総合医療センター、埼
玉県立小児医療センターの院内に相談（ピアサポート）窓口を設置している。
・サマーキャンプの開催時に地域の医療機関から医療班（医師・看護師）の派遣を受けている。
・国立成育医療研究センター、慶應義塾大学病院などの顧問や倫理審査委員の委嘱を受けている。
2. 患者参加の定義
2-1.「患者参加」について、患者団体としての定義やお考えをお答えください。
＜例＞
「患者参加」とは患者が自分の病気に向き合い、主体的に治療に参加することと患者団体として定義していま
す。
・団体としての定義はありません。
福島個人としては、
・Patient and family-centered care を実現するために、患者およびその家族が支援者と協働するこ
と。

2-2. 患者団体が、患者参加を推進していく上でどのような役割を担っているとお考えをお答えください。

＜例＞

患者が主体的に治療に参加する患者参加を推進していくために、患者団体は会員や会員家族に対して情報
提供を行ったり、患者の相談を受けたりなどする役割を担っていると考えています。

・団体としての考えは表明していません。

福島個人としては、

・患者個人の治療法の選択・決定、セルフケアへの支援のほか、病院運営、医学系研究、医療政策な
どのすべてにおいて密接に関わる役割を担っていると考えます。

3. 相談事業の体制について

実施の有無 有

実施形態 電話 ・ メール ・ 対面 ・ その他（LINE）

相談体制 ●相談の対象

制限なし

●相談可能な日時

電話相談 平日 11 時～15 時

遺伝（先天異常）特別相談 毎月第 4 金 14 時～17 時

ピアサポート 毎週 3～4 日 10 時～15 ないし 16 時

LINE 相談 火・金 11 時～14 時

●相談の担当者

電話相談 看護師、社会福祉士、精神保健福祉士

遺伝（先天異常）特別相談 医師、認定遺伝カウンセラー

ピアサポート ボランティア

LINE 相談 ボランティア

相談件数 電話相談 395 件／年間

遺伝（先天異常）特別相談 6 件／年間

ピアサポート 68 件／年間

※コロナ禍の影響により例年より大幅に減少。

LINE 相談 火・金 11 時～14 時 新規事業

相談内容と件数

（貴団体で使用している分
類とその件数をお答えくだ
さい。）

・別紙参照

受け付けた
相談事例の対応
（例：専門病院・専門医の紹
介、別の機関を紹介等）
・電話相談は、難病や慢性疾病、障害のある子どもを育てる家族からの
医療・教育・福祉などに関する相談全般。
・ピアサポートは、難病や慢性疾病、障害のある子どもを育てた経験の
ある人たちをピアサポーターとして養成し、その体験的な知識を活かし
た相談。
・いずれも、医師や病院の紹介はしていません。
医療事故を疑う相談事例
件数/年
数件のみ
事例への対応方法 ・傾聴と情報提供
事例への対応での工夫
4. 「患者参加」に寄与する患者教育の実施について
（以下の問について、「有」の場合、具体的な内容についてお答えください。）
病気や治療等に関するリー
フレットの作成配布
無
web サイトでの情報提供 無
e-learning を用いた患者教
育の提供
無
医療安全上の注意喚起に
ついての情報提供
無
5. 会員、他患者団体、同疾患患者とのつながり・連携の実施状況について
（以下の問について「有」の場合、具体的な内容についてお答えください。）
患者同士のネットワーク作り
（交流会の開催、勉強会の
開催等）
有
・親の会連絡会の活動支援：定例会議（関東・関西・ZOOM)、親の会
ブース出展、研修旅行、研修・会議室の貸与。
他の患者団体との連携 有

・親の会連絡会　68 団体
・難病・慢性疾患全国フォーラムの開催
ピアサポートの活動 有
・国立成育医療研究センター、神奈川県立こども医療センター、東京都立小児総合医療センター、埼玉県立小児医療センターの院内に窓口を設置しているほか、慶應義塾大学病院でも不定期にピアサポート活動を実施。　※コロナ禍の影響により活動を大幅に縮小。
・電話や LINE によるピアサポートも開始。
その他 有　・　無
6. 貴団体が「患者参加」に寄与する活動として考えられる活動の実施状況について
（以下の問について、「有」の場合、具体的な内容についてお答えください。）
行政・医療政策への参加
（国・地方自治体等の審議会・委員会等の患者委員等、国への要望書の提出、署名活動、提言活動）
有
社会保障審議会専門委員、神奈川県慢性疾病児童支援協議会委員、千葉県慢性疾病児童支援協議会委員、千葉県移行期医療支援連絡協議会委員、東京都小児慢性特定疾病児童等移行期医療支援推進会議委員など
学会への参加
（所属している学会、学会総会での講演・シンポジウムの講師、診療ガイドラインの作成委員・評価委員）
有
日本育療学会理事、日本小児科学会移行支援に関する提言作成ワーキンググループ委員、日本小児保健協会倫理委員会委員など
医療機関の活動への参加
（倫理審査委員会の委員、医療機関の運営委員）
有
国立成育医療研究センター顧問、国立成育医療研究センター倫理審査委員会委員、国立成育医療研究センター臨床研究審査委員会委員、国立成育医療研究センターヒト ES 細胞研究倫理審査委員会委

員、慶應義塾臨床研究審査委員会委員、慶應義塾大学病院治験審査委員会委員など
医育機関の活動への参加
（医療系の学生に対する講義、演習での模擬患者）
有
学生に対する講義：淑徳大学、愛知医科大学、東京慈恵会医科大学など
その他に考えられる活動 有
日本製薬工業協会患者団体推進委員会アドバイザリーボード委員、米国研究製薬工業協会患者アドバイザーなど。

認定NPO法人ささえあい医療人権センターCOMLインタビュー要約
日時：2022年1月31日
インタビュイー：理事長 1名
インタビュアー：研究代表者、研究分担者3名、研究協力者2名

COMLの東京支社：5名（4名同僚：電話相談も含めて）で運営。

各病院の患者参加の考えた方、各病院の職員と入院患者へのアンケート調査、患者団体へのヒアリングとアンケート調査を本年度実施。

医療安全支援センターの全国アンケート調査を実施したが、COMLとしてはe-learning講習会の材料作成以外にも各種関与している。

患者支援団体からみた患者参加の定義
・人任せにせず自分毎にして考えるのが主体であり、医療制度を理解し、社会を視野に入れて地域の医療状況も考えることが重要で、そのために、COML はミニセミナー患者塾を主催している。
・個人として「患者」であれば、医療者任せにするのではなく、病気を自分の持ち物と自覚し、自分にできる努力や工夫をしながら積極的に治療に参加していく、医療者との協働姿勢が必要。
・広義の患者参加は、医療の制度、しくみなどを理解し、利用者の視点で地域の医療の現状やその原因を知り、どうすればいいのかを一緒に考える姿勢。つまり、医療を個人の問題としてとらえるにとどまらず、社会を視野に入れながら考えることと位置づけ。
・患者さん毎に背景・文脈が異なるので、広義での患者参加は一言で言えるが、個々の事例での患者参加は別であり、個々の患者参加は個々の課題を個別に検討する必要がある。
・某患者団体は何かあればCOMLに情報を流すといっているようであるが、COMLとしてはそんな認識はない。

患者支援団体の役割
・ミニセミナー「患者塾」開催
＊医療におけるさまざまな課題や制度、しくみを知る機会を提供。
＊91年から実施しているミニセミナーでオンラインでも数回実施。
＊毎月第一土曜にCOMLから話題提供し、GW実施していたが、コロナ禍で集まれなくなった。
＊会場費高く、インターネット普及で赤字になり、COML の事務所で隔月実施に変更した。
＊塾参加者には医療不信の方もいるが、参加医療者の本音を聞いて、冷静になり、不信感を払しょくする方もいる。

＊SDM に参加するプロセスを共有するというような仕組みに関しては、SDM を含めて多職種参加、主体的参加のあり方、知識取得、納得、日々の受診への生かし方などに活用できる方法を講座で提示
＊テーマで内容、雰囲気が変わるが、さまざまな医療の問題を理解したい、納得したい、日々の受診にいかしたい、受診行動を改めたいなどの要求が参加者にはある。
＊過去実施回数 245 回
＊他の講座は実施しているが患者塾はまだ東京では未開催（患者塾も東京で再開したい)。
＊患者塾は COML の玄関口

・「医療をささえる市民養成講座」(1 回 3 時間×5 回) 開催
＊医療におけるさまざまな課題や制度、しくみを知る機会を提供。
＊2005 年前後からいろいろのところで患者参加を求められる場面が認められた（種々の厚労省の会議で辻本さん)。前任者の辻本さんの考え方では、参加に値する人を要請する仕組みを考えるということであった。
＊医療現場で病院ボランティア、患者情報室、模擬患者、電話相談などでボランティア活用を図る。従って、広く浅く、医療を理解し、知識を持って、医療に参加できる人材を養成したい。
＊2009 年に本講座を開設
＊初年度から 120 人参加
＊参加者の位置付けは、以前から興味があった、学びたかった、患者支援ができるのであれば、知的好奇心が高まるなどであった。医療を知るともっと知りたいという知的好奇心が出てくる。医療の背景理解できると自分事として意識が変わってくる。急性期病院から追い出されるという考え方が次はどこに行けばよいかと考えるようになる
＊ただし、この講座だけでは委員として派遣できない。推進する人にはならない。

・アドバンスコース「医療関係会議の一般委員養成講座」(1 回 3 時間×7 回) 開催
＊2017 年度にアドバンスコース開設「医療をささえる市民養成講座」を基礎コースと位置づけ、講座を修了した人を対象に開設
＊講座終了者を対象に物事を俯瞰し、こだわりの意見を言うのではなく、他人でもわかるような意見を言える人を育成。
＊本講座は専門委員、事務局：教授、医師会、厚労省などに支援されている
＊リベートセミナー2 回で、会議で意見を言えるようなリベートセミナーであり、例えば、救急車の有料化に対する賛否をリベートさせる。聞いている聴衆に納得させることができるかどうかがである。賛成、反対にアサインして、相手をリスペクトしながら討議させる。
＊5 回目は傍聴報告会 (2 つ以上傍聴して、議論内容、一般委員の発言内容をどう思ったか、会議では何が重要と思ったかを言わせる)。

＊第 6 回目と第 7 回目で模擬検討会をおこなっている。厚労省の資料使い、事務局の説明あり、模擬検討あり、専門委員らのフィードバックあり。発言の姿勢や内容を専門委員、事務局、COML で採点し、合否判定出す。一般委員の定義とは何か？何を目指すか。最後に、会議を 2 つ指定（厚労省、文科省）し、検討会の議事録をもって、どのような発言できるか検討させる。
＊合格者を COML 委員バンクに登録。30% 20 名が合格（5 年間で 70 名程度の受講者）
＊合格者は「COML 委員バンク」に登録できるシステムで、COML への委員要請時に推薦、派遣
＊患者経験、純粋に医療に関心のあった人、医療系の会社に勤めている人。認可者は若い、20 歳台、30，40 台が多く、メディア、製薬会社の社員もいる。
＊プロトタイプはないが、東大の医科研武藤教授は倫理審査委員会でも一般委員養成が必要と考えており、倫理審査委員養成講座を 2016 年 5 回コースとして、武藤・山口 2 名で実施した。倫理審査委員会の一般委員養成講座で実際の傍聴では、大学によって異なる体制なので対応に困った。
＊講座だけでは判断できないので選別が必要、公的には選別ができないむずかしさがあり、Minds の場合もそうである、合否の説明責任を山口がだせばＯＫと考えた。1 回だめでもチャンスはある。リベンジはできる。

<u>患者団体と患者支援団体</u>
患者団体と患者支援団体は全く異なると考えている。患者支援団体として、COML は、
・賢い患者
・医療情報判断の共有（SDM）を目指している。
・特定の疾患を対象にしていない。
・ピアサポートもしていない。
・患者の自立支援が主体であり、電話相談でも本人が主体的に解決するための支援をしている。
・患者会はその病気を学び、効果的な治療を検討し、社会復帰活動などを検討することが多く、利害関係があり、何かを要求することもあり、それに対する一般的な反感もあり、そこが難しい。
・COML は利害関係になく、要求事項ないので発言しやすい。
・患者会が COML の講座に学びに来ることも多い。医療制度の仕組みらを含めて、自分の病気以外の理解が乏しかったという感想も多い。また、いつも会議では要求することを念頭にしているが、そうでない場合もあったという感想も得ている。
・患者団体とのコラボ：患者会のリーダー研修会にＣＯＭＬに講演依頼されることが多い
・患者会からの相談もある（ケースバイケース）、司会を依頼される。
・最近患者会も内向きの活動だけではだめだと感じているのでコラボしやすくなっている。

・製薬協もファイザー、グラクソ、CSK でも患者会の研修会にＣＯＭＬの講演を依頼されることも多い。COML の講座参加費用を製薬会社が患者会に支援している。

ＣＯＭＬの活動変化（支援団体に要求される内容・活動の変化）

・2014～2015 年ごろから変化あった。

・会発足後 10 年たった 2000 年ごろには医療者から敵でないと認知されてきた。病院探検隊で患者の視点で病院を変えたい、模擬患者に関して医学生以外に他の医療職にも活用したい。コラボで向上したいという医療者のアプローチが増加。さらに、被害者から直接聞くのはきついが、ＣＯＭＬを介して、患者のどのような時に不安、不信感を持つのかというような講演依頼がある。患者からも被害者団体からの話ではなく、ＣＯＭＬから話を聞きたいという意見（自身が被害者ではないけれども）もでるようになった。

・2010 年に辻本さんから山口さんにバトンタッチ。以前は大阪が拠点であったが、活動拠点が厚労省、文科省、その他団体の役員、委員、理事に移行

・厚労省も以前は患者の立場を入れておかないといけないという雰囲気だったが、事故調査報告制度の議論のころから変化してきた。2012 年から事故調の議論が始まった。2014 年西澤班。

・臨床研究の在り方検討会にも参加し、臨床研究法成立にも関与した。

・2015 年群大、東京女子医大特定機能病院承認取り消し事例が発生し、大学病院等の医療安全に関するタスクフォース発足：審議官と課長が委員、外部から 3 名顧問出席、その 1 名が山口さんに委嘱された。84 の特定機能病院集中立ち入り検査実施時に当たって、従来とおりの厚生局の立ち入り検査を実施するのではあれば無意味であり、個々の病院では個々の課題・問題点があり、ヒアリングを中心に自院の医療安全の課題を見いだせるようなヒアリングが必要と発言し、顧問にはアドバイス可能な権限が与えられた。その結果、24 病院の立ち入り検査に参加し、レポートを報告した。それ以降委員の数が増えた（自身の）。
発言する委員を増加させる必要も実感し、養成講座の開催につながった。

・2018 年賢い患者新書出版時での記念会で、協働の実現素地ができてきた。医療者、患者、行政の垣根を取っ払って実現していこうという雰囲気。

・臨床現場がまだまだそうなっていないことを実感した。特定機能病院も松竹梅ある。1 県 1 医大ではどこでも群馬大になりうる。医薬品の選定もあいまいである。

・透明性の確保・担保、外部委員を入れることで特定機能病院も変化してきている。毎年向上している。2017 年から特定機能病院には医療安全の監査委員会は絶対必要となった。京大、北里大の監査委員会の委員長に委嘱された。委員会での資料提出が大幅に改善してきている。

医療安全支援センター

・初任者研修にも参加している。欠けているものは何か？相談者研修には 3 年かかる。専門職はいるが事務職員などもおり、当事者に配属の被害者意識があり、先輩もいない中で、できない理由探しをする。一定の相談機能レベルまでには到達できていない。要は研修がうまくできていない。
・質安全学会では以前は理事で、今回再度理事になった。体制も変わった。センターを改善する必要がある。
・最初に初任者研修でたやすく学べる e-learning（15 分）を質安全学会で立ち上げる予定である。総合支援事業の中で実施予定であったが、今年度からできるようになった。
・医療安全支援セッターはＣＯＭＬの相談員にも役に立っていない。事故調のことも知らないので、事故調にという投げかけもできない。
・相談機関としての機能にはスタッフの継続性が必要である。もともと、研修は医療機能評価機構がやっていたが、途中から東大の寄付講座で児玉さんが実施、その後、児玉さんが講座を降りたので、質安全学会に移行された。今回、さらに児玉さんが学会の理事を降りられたので、京大の松村先生（質安全学会の現理事長）のところで、再度仕切り直しとなった。総合支援事業の委託業者が若干力不足であったので、質安全学会でも担当を決めて実際的に展開する予定である。

<u>今後の展望</u>
・医師の眼に入った段階で患者になるのではなく、患者になる前に医療知識などは知っておく必要がある。自己決定、情報理解は受け身だけでは済まない。患者になる前に知識習得、生き方などを考えていく必要がある。これをあらかじめやっておかないと突然ＡＣＰといわれても対応できない。子どものころから医療の基本的なことや自身が命の主人公であり、体の責任者であるという自覚が必要。
・そのために、医者にかかる 10 か条（患者用）以外に、親子で学ぼう 10 か条（子ども用）の 10 か条も作成。受診の際の心構え、医療制度などを日常的に正確に知っておく必要がある。それも、こどものころから必要である。子どもの教育の実践事例としては、命と体の 10 か条を 3 万冊用意し、親子で学ぼう 10 か条のワークショップを子どもと保護者同伴で開催。
・働いている人が福利厚生制度を活用し、職場で学ぶ機会を作れないかと考えている。そうすると、介護離職も防止できる、働く世代の就労問題も解決できる。もう少し知っていればということが多いが、要はリテラシーの問題である。
・ほとんど知識もない患者が病院受診したときに、病院としてどうしたらよいか？IC は未だ一方交通であり、やはりＳＤＭが必要である。さらに、ネット上の適正な検索サイトを医療者から提供できればよい。なかなかそのような事例は少ないが。ネットサーフィンよりは良い。

＜アンケート・インタビュー項目＞

各質問項目について、2020 年度の実績をもとに、当てはまるもの全てに〇をつけてください。□には文章をお書きください。

1. 団体の組織構成・事業内容について

以下の項目が記載されている資料（年報・パンフレット等）の提供で代替頂くことも可能です。

1-1. 組織の規模（会員数・支部の数）についてお答えください。

会員数	約 800 人
支部の数	支部はありません

1-2. 貴団体の主な事業内容についてお答えください。

（１）会報誌発行・講師派遣等の普及啓発活動
（２）電話・手紙・ＦＡＸ・メール等による医療に関する相談
（３）研修会・フォーラム・シンポジウム等の開催
（４）ＳＰ（模擬患者）の活動
（５）病院探検隊の実施
（６）委員派遣等の政策提言活動
（７）その他、目的達成のための事業

1-3. 医療機関・医療従事者との連携についてお答えください（理事や幹事に医療従事者が入っている。団体会員として医療機関が加入している等）。

＊理事 10 名中、医療従事者が 6 名（医師 3 名、薬剤師 1 名、看護師 1 名、事務長 1 名）
＊団体賛助会員に医療機関多数
＊個人の正会員、賛助会員にも医療従事者多数

2. 患者参加の定義

2-1.「患者参加」について、患者団体としての定義やお考えをお答えください。

＜例＞

「患者参加」とは患者が自分の病気に向き合い、主体的に治療に参加することと患者団体として定義しています。

> 個人としての「患者」であれば、医療者任せにするのではなく、病気を自分の持ち物と自覚し、自分にできる努力や工夫をしながら積極的に治療に参加していく協働する姿勢が必要と考えています。
> 広義の患者参加では、医療の制度、しくみなどについて理解し、利用者の視点で地域の医療の現状やその原因を知り、どうすればいいのかを一緒に考える姿勢だと思っています。つまり、医療を個人の問題としてとらえるにとどまらず、社会を視野に入れながら考えることと位置づけています。

2-2. 患者団体が、患者参加を推進していく上でどのような役割を担っているとお考えをお答えください。

＜例＞

患者が主体的に治療に参加する患者参加を推進していくために、患者団体は会員や会員家族に対して情報提供を行ったり、患者の相談を受けたりなどする役割を担っていると考えています。

> ミニセミナー「患者塾」や「医療をささえる市民養成講座」(1回3時間×5回)などを開催し、医療におけるさまざまな課題や制度、しくみを知る機会を提供しています。また、「医療をささえる市民養成講座」を基礎コースと位置づけ、全回修了した人を対象にアドバンスコース「医療関係会議の一般委員養成講座」(1回3時間×7回)を開催し、第6回目と第7回目で模擬検討会をおこない、発言の姿勢や内容を採点。合否判定をしています。合格者は「COML委員バンク」に登録できるシステムで、COMLに委員養成などがあった場合に推薦、派遣をしています。

3. 相談事業の体制について

実施の有無	有 ・ 無 （○）
実施形態	（電話） ・ （メール） ・ 対面 ・ その他（ ）
相談体制	●相談の対象 会員のみ ・ （制限なし） ●相談可能な日時

	月・水・金：10:00～13:00　14:00～17:00 土：10:00～13:00 ●相談の担当者 常勤スタッフとボランティアスタッフ
相談件数	1990～2021 年で約 64,000 件　　年によって変動あり
相談内容と件数 （貴団体で使用している分類とその件数をお答えください。）	別紙添付します。
受け付けた 相談事例の対応 （例：専門病院・専門医の紹介、別の機関を紹介等）	相談者の話に耳を傾け、問題整理のお手伝いをしたうえで、可能な情報提供やアドバイスをする。

医療事故を疑う相談事例件数/年	その内容で統計はとっていません。別紙添付の法的解決や示談交渉という項目をご参考までにご参照ください。
事例への対応方法	
事例への対応での工夫	

4. **「患者参加」に寄与する患者教育の実施について**

（以下の問について、「有」の場合、具体的な内容についてお答えください。）

病気や治療等に関するリーフレットの作成配布	有　・　無
web サイトでの情報提供	有　・　無
e-learning を用いた患者教育の提供	有　・　無
医療安全上の注意喚起についての情報提供	有　・　無

5. 会員、他患者団体、同疾患患者とのつながり・連携の実施状況について

（以下の問について「有」の場合、具体的な内容についてお答えください。）

患者同士のネットワーク作り（交流会の開催、勉強会の開催等）	有 ・ 無
他の患者団体との連携	有 ・ 無
	緩やかな連携です。
ピアサポートの活動	有 ・ 無
	当方は「患者会」ではなく「患者支援団体」なので。
その他	有 ・ 無

6. 貴団体が「患者参加」に寄与する活動として考えられる活動の実施状況について

（以下の問について、「有」の場合、具体的な内容についてお答えください。）

行政・医療政策への参加（国・地方自治体等の審議会・委員会等の患者委員等、国への要望書の提出、署名活動、提言活動）	有 ・ 無 ○
	厚生労働省の各種審議会、医療機能評価機構の医療事故収集事業運営委員会、医療事故調査・支援センターの運営委員会、再発防止委員会など
学会への参加（所属している学会、学会総会での講演・シンポジウムの講師、診療ガイドラインの作成委員・評価委員）	有 ・ 無 ○
	所属している学会は医療の質・安全学会（会員かつ理事）、医学教育学会会員・評議員 学会での講演、シンポジウムは多数 診療ガイドラインの外部委員も複数
医療機関の活動への参加（倫理審査委員会の委員、医療機関の運営委員）	有 ・ 無 ○
	特定機能病院の医療安全監査委員会（8 病院）
医育機関の活動への参加（医療系の学生に対する講義、演習での模擬患者）	有 ・ 無 ○
	広島大学歯学部の客員教授、大学医学部等の非常勤講師は多数、模擬患者は 1992 年から活動していて、これまでの派遣回数は約 1700 回（内 OSCE 約 500 回）
その他に考えられる活動	有 ・ 無

患者団体へのインタビュー調査結果まとめ

５団体（リウマチ友の会、グループ・ネクサス・ジャパン、全国腎臓病協議会、難病こども支援全国ネットワーク、ささえあい医療人権センターCOML）を対象としてインタビュー調査を実施した。以下に全体要約を示す。

① 患者の高齢化、治療法の改善により、患者団体の会員数が減少している。
② 患者団体と患者支援団体は目的・活動が異なり、患者参加へのアプローチも異なる可能性がある。
③ 多くの団体は判断決定共有（SDM）、ACP等における患者の自己決定権、合意に基づく治療への参加、多職種チーム医療への参加、医療・医療制度の知識エンパワーメント（医療・医療制度を理解）を通して、医療・治療等を医療者と考えることが患者参加の定義と考えている。
④ 自分事として積極的に医療者と協働し、自身の選択権を行使することも患者参加の定義に入る。
⑤ これらの支援は患者団体、患者支援団体の務めであるが、あくまで選択権は患者にある。
⑥ 高齢化、治療法の改善に伴い、治療目標だけではなく、日常・社会生活レベルの目標選択も患者参加の要素である。
⑦ いわゆる患者力が患者参加には必須である。
⑧ 患者参加に関して、学会、医療機関等と話し合っている団体は少ない。
⑨ 患者参加の状況は、未だに医療者、患者双方による治療法の話し合い、双方向のインフォームドコンセントができておらず、判断決定共有への道のりは遠い。
⑩ 患者参加の前提として、子どものころからの医療・医療制度教育が重要である。
⑪ 患者参加の前提として、患者ニーズに合致した医療側からの標準的で信頼できる治療サイトのネット提示が必要である。
⑫ 病院相談窓口、医療安全支援センターの認知度は患者団体、患者支援団体、患者いずれにおいても低い。

以下、個別に検討する。

１．患者参加の定義について

・明確に定義付けている団体は認められなかった。

・患者支援団体は患者参加について、患者参加を支援する事業等を実施している。患者参加支援そのものというよりも、あくまでのその前提条件（知識、行動方法等）の構築を支援していることが多い。

・一方、患者団体は患者参加について、患者個人が患者参加に直接参加する行動そのものを支援する対応をしていることが多い。当該患者団体特有の疾患の患者参加行動とその前提

知識を具体的に支援・提供している。もちろん、患者参加及びその中の選択肢の選択等は、あくまで患者に決定権があることが前提である。
・患者参加の定義を、社会・地域・医療・医療制度を視野に入れた、医療の制度、仕組みなどを理解し、利用者の視点で地域医療の現状や課題を知り、どうすれば良いかを医療提供者と一緒に考える姿勢と考えている患者支援団体もある。
・患者参加を自分事して考え、SDM、多職種チーム医療への参加、医療制度の知識取得、納得感、受診への生かし方等に関して、積極的に関与・参加することが患者参加である。
・IC も未だに一方交通であり、その意味では SDM は必須アイテムである。
・自己決定・情報理解は受動態では取得できない。
・医療制度などの理解を含めて、それらを背景とした医療者との SDM を患者参加とすると、その行動を支援することが患者団体・患者支援としては必要である。
・個々の患者事情により患者参加の在り方は異なる。
・患者参加には、患者になる前から、可能なら子どものことからの医療知識習得や教育・啓もう、いわゆる医療に関するリテラシー教育が必須である。

・患者支援団体の１つは、ミニセミナー患者塾、医療をささえる市民養成講座開催、医者にかかる 10 か条（患者用）、親子で学ぼう 10 か条（こども用）、命と体の 10 か条等の作成を患者支援団体の患者参加支援・啓もう事業としている。
・支援団体と患者団体との共同は可能である。
・ある特定の疾患の患者を対象としている患者団体と異なり、患者支援団体では、個々の患者には個々の疾患と患者固有の事情があり、患者参加も個別にその課題を検討する必要がある。

・患者支援団体の１つは、対象が小児のことも影響している可能性がある。
・統一されたものではないが、患者参加の定義を患者・家族中心（の視点に立った）のケア実現のための患者・家族・医療者の協働と考えている。
・患者参加には、患者の他、患者支援団体、患者団体、行政・福祉も入っている。
・患者中心とは医療に積極的に参加し、患者の意向に沿って医療が提供されるということである。
・最近は生活スタイル、社会生活、人生観なども患者の治療における選択内容に入っているが、あくまで決定権は患者・家族にある。
・患者支援団体として、患者の選択権、SDM、知識エンパワーメント、チーム医療などの患者参加に関して患者・家族を支援するという建付けである。
・患者参加のやり方を決定・支援していない。
・治療などの情報提供はするが、患者参加自体は本人が決めることである。

・患者団体の１つは、より具体的に疾患特有の事情に合わせて患者参加活動を支援している。すなわち、透析患者であれば、すでに透析導入すみの患者の団体であり、導入時の判断決定はいかんともしがたいが、透析導入後の腎移植、ACP の自己決定権、透析中止などのステージでの判断決定に関しては十分に患者と医療提供者の SDM が可能になるような支援活動している。
・そのためには判断決定の判断材料の提供、教育啓もう（研修会を含む）、医療側のチーム医療の推進と患者参加活動などを進めている。
・しかし、患者団体の立場上、決定権はあくまで患者にあり、ACP、DNAR などで患者団体はリーダシップをとっているわけではない。

・患者団体の１つは、治療目標を決めること自体を患者参加と考えている。具体的には患者の高齢化、治療内容の改善等により、直接的治療目標の他、日常・社会生活目標に関しても医療側（学会を含む）と判断共有していくことが患者参加である。
・患者は主体的に自分事として病気・目標を捉えることが患者参加の大前提であり、これを「患者力」という言葉で総括しているが、その主体性は患者、医療機関、患者団体、病院団体等で異なる。
・具体的には患者参加には主治医に聞いた方が良い内容リストの事前作成が必要である。
・患者参加には医療者側、患者側双方に責任が生じる。
・相談者養成講座の支援も実施している。

・患者団体の１つは、患者参加について、治療選択等について適切な情報入手を前提に、患者が自身の意向に沿って（主体的に）治療選択できることと定義している。また、合理的判断が不可能な状況にも患者自身が判断できる状況に持っていくことを支援することが患者団体の責務である。
・主体には、患者、家族、医療者があるが、患者参加にはあくまで患者の意向、価値観、生活スタイル等が重要である。
・実際に治療選択もできていない状況で、教育等で SDM などを支援することは難しい。
・患者参加の具体的対策として、手持ちの情報カードの整理を推奨している。

２．患者参加の現状について
・患者の「はい」は「はい」ではない。ある白書によると、未だに医療者、患者双方で治療内容を話しあっている事例は少ない。
・インフォームドコンセントも一方向であり、SDM になっていない。
・治療選択もできていないので、SDM は不可能である。
・患者参加に関して、その定義、内容、方法等について、学会、医療機関、病院団体等と話

っている団体は少ない。ただし、学会、個々の医療機関と SDM、ピア支援等で協働している団体は一部にはある。
・個々の医療機関へ SDM を依頼することも困難である。
・臨床現場はまだまだ医療者、患者、行政らの垣根が取り払われていない。
・これは患者側、医療者側双方の努力不足も一因であるが、幼少期からの医療全般（医療制度を含む）に関する教育・啓もう不足、医療者側の標準的で信頼できる治療サイトのネット等への提示の欠如等もその要因である。
・対策としては、幼少期や職域での医療制度教育と前述のネット上での医療サイドからの標準的で信頼できる治療法等への検索サイトの提示等である。

３．医療安全支援センターへの対応について
・医療安全支援センターに協力している団体は１団体だけであった。
・その協力内容はセンターの e-Learning 講習会材料の提供等であった。
・他団体で協力している団体はなかった。
・各団体のセンターへの見方は、認知度がない、職員教育に一貫性がない、有効に活動できていない、医療事故制度等の基本的知識がなく活用できないなどであった。
・病院の相談窓口についても医療安全支援センターに対する見解と同様の見解を有する患者・患者支援団体は多い。

４．WHO の患者参加に対する考え方と我が国の PHR と患者参加に関する考え方
2020 年 WHO が考える患者参加の 6 要素とは、
① 患者中心プロセス・システムを設計・開発する
② 患者が自身の EHR にアクセスできる
③ 政策策定への患者参加
④ 患者経験とアウトカム情報の収集
⑤ 医療教育・訓練
⑥ 国民を教育・エンパワーすることで健康ニードの認識とタイムリーな医療検索であり、PHR、スマートフォンアプリは患者参加の 6 要素と、医療専門職の教育・訓練をエンハースする。

個人健康記録（PHR）が患者参加に資する取り組みに関しては、ISO/TR 14292： Health informatics − Personal health records − Definition, scope and context（ 2012-03-15 ）は以下の項目を考えている。
・健康状態を監視し、その測定を長期的な疾病管理に役立てる
・治療に関する意思決定プロセスを共有できる
・健康維持、予防的健康対策に参加できる

・治療の有効性、副作用を文書化できる
・ケアパス内の治療、セルフケア活動を調整できる
・専門家にいつ、どこで紹介するかを決定・予約できる
・読書、ウェブ、ローカル、オンラインコミュニティでの検索を通じたケアへのさまざまなアプローチが可能になる
・将来の健康のための目標・願望を設定できる
・パーソナルフィットネスやウェルネスプログラムに参加できる
・支払い/福利厚生/保険サービスを管理できる

さらに、近年の内閣府のマイナポータルの医療への活用に関しては、マイナポータル API を定義することにより、患者と医療機関の医療情報共有の可能性が示唆されている。今後は、マイナポータル API を活用して、
・予約システムへのアクセス・変更・予約（合意された臨床サービスのため）
・繰り返し処方箋(補充)の活用
・双方で合意した治療の要求
・臨床医へ返信を含むメッセージを送信し、臨床医とのオンライン会話を実施
・薬局へ返信を含むメッセージを送信し、薬剤師とのオンライン会話を実施
・モニタリングデータやポータブル/ウェアラブル機器によるデータ送信・アップロード
・長期的な状態管理(BP 測定、血糖測定、ホルターモニターなど)
・検査、X 線診断、処置結果などの臨床情報の表示
・医師と治療要約を共有
・個人の健康リスク評価ツールの活用とスコア化の実施
・患者指向の健康教育リソースへのアクセス
・承認された医療情報・教育サイトにリンク
などが可能になり、患者参加活動が進むことが期待される。

５．今後の展望
・患者参加のより明確な定義付けが必要である。
・患者参加には、直接的な患者参加の具体的な内容（判断決定共有（SDM)、ACP 等における患者の自己決定権、合意に基づく治療への参加、多職種チーム医療への参加、医療制度の知識エンパワーメント（医療・医療制度を理解））の構築・支援と患者参加に不可欠な体制・知識らの構築と強化が必要である。
・今後とも、患者団体・患者支援団体の支援作業と、学会・行政等との連携が必要である。
・患者参加の基盤ツールとして重要な電子医療記録（EMR)、電子健康記録（EHR)、個人健康記録（PHR）の基盤構築、標準化、共有化と患者のアクセス権、個人認証、セキュリティ基盤の充実・推進が患者参加活動には必要である。

Making an impact

専門職ではない NICE ガイドライン作成委員会メンバーのための トレーニングデイ

2021 年 7 月 14 日（水）

National Institute for Health and Care Excellence

議題

オンライン参加登録/参加受付　9:45～

10.00 am	**歓迎の挨拶とイントロダクション**
10.40 am	**ガイドライン作成： how to make an impact** Part 1 - 委員会はどんなエビデンスを検討するのか？
11:45 am	**休憩**
11.55 am	**ガイドライン作成：how to make an impact** Part 2 - 委員会はどのようにエビデンスを集めるのか？
1.15 pm	**昼食**
2:00 pm	**ガイドライン作成： how to make an impact** Part 3 - 委員会はどのように会議を準備するのか？ Part 4 - 委員会はどのようにエビデンスを用いるのか？
3.10 pm	**休憩**
3:20 pm	**ガイドライン作成：how to make an impact** Part 4 – 委員会はどのようにエビデンスを用いるのか？（続き）
4:20 pm	**Making an impact：知識、経験、アイディアの共有**
4.40 pm	**閉会の挨拶**

NICE

National Institute for Health and Care Excellence

Public Involvement at NICE
Annual report 2019/2020

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Introduction

1. From our inception working with patients and the public, and the organisations who support them, has been core to NICE's work. It is embedded in our principles and our patient and public involvement policy. This report describes the work of the Public Involvement Programme (PIP), and broader public involvement activities across NICE, in the financial year 2019 to 2020.

2. We have supported the involvement of patients, people who use services, their families, carers and the public in the development of guidance and standards. We have recruited, trained and supported people to enable them to take part meaningfully in our work. We have also worked with our voluntary and community sector stakeholders to build relationships and improve how we involve those stakeholders in our work.

3. We have continued to support and promote public involvement at a national and international level through our work with the Health Technology Assessment International (HTAi) Patient and Citizen's Involvement Group (PCIG), the International Network of Agencies for Health Technology Assessment (INAHTA) Patient Engagement Learning Group and through the Guidelines International Network (G-I-N) Public Working Group.

4. We have supported the growing shared decision-making agenda, holding the 6th meeting of our Shared Decision-Making Collaborative and contributing to ongoing developments in the field.

5. Finally, although extending beyond this reporting period, we have included information on public involvement work in response to the COVID-19 pandemic and our plans for the future in the extraordinary times in which we find ourselves.

Acknowledgements

6. We would like to acknowledge the huge contribution that patients, people who use services, their families, carers and the public have made to our work across the breadth of our activities, and to thank them for their dedication and commitment. We would also like to acknowledge our patient, voluntary and community sector stakeholders who have continued to participate in our work, help us to improve our processes for public involvement, and to act as a critical friend to NICE.

Facts and figures

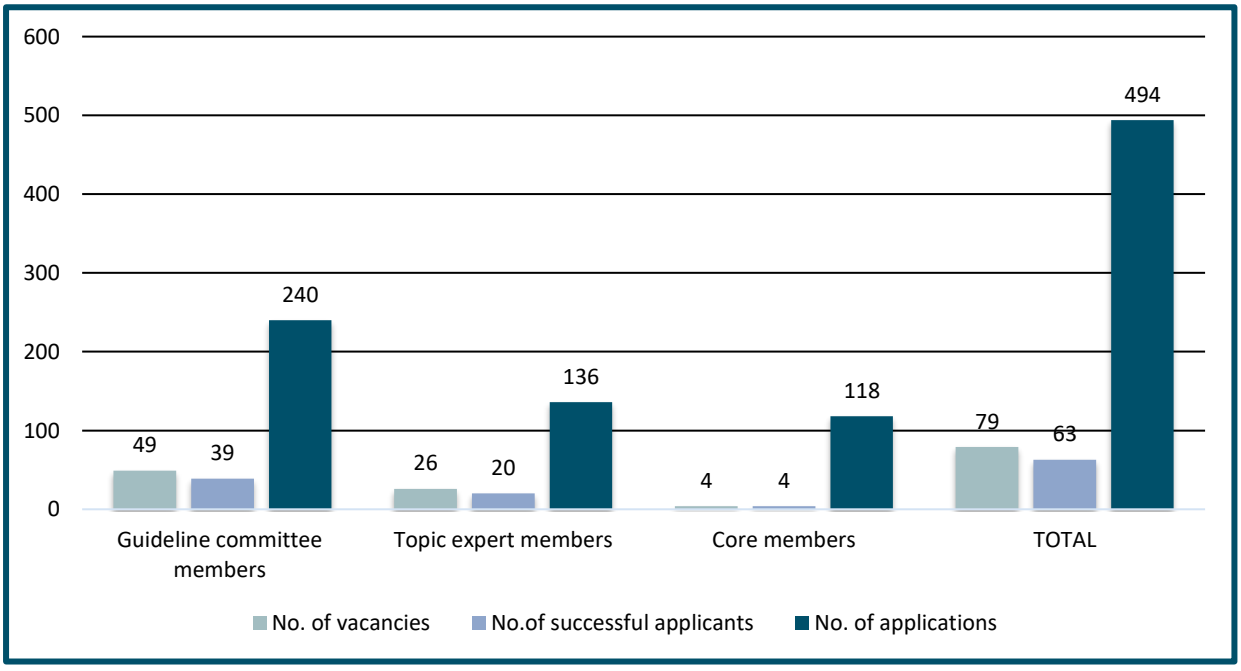
Recruiting and identifying people to take part in our work

7. PIP supports the recruitment of patients, people who use services, their families, carers and members of the public across all NICE work programmes; in most cases we describe the people we recruit as ‘lay members’ (although some variation in that terminology occurs across the organisation). Our policy states that committees should have a least two lay members as part of their membership. In 2019/20 we received 494 applications for 79 committee vacancies and in the end recruited 63 people to join a variety of committees.

8. The disparity between the number of vacancies and the number of people recruited was a result of several factors, including:

    - challenges in recruiting in topic areas where there is low voluntary and community sector activity – for example infectious skin conditions and ‘flu
    - recruiting for topics affecting very young children and babies
    - the diabetes suite of topics, where a range of different experiences was required, resulting in 9 potential vacancies. Ultimately either not all elements of experience could be recruited to or one applicant was able to speak to more than one type of experience.

Figure 1 – recruited lay members and applicants



Download the data set for this chart

9. As well as recruiting lay members we have supported 13 lay people to join our quality standards advisory committees as invited specialist committee members, 16 lay people to contribute to NICE Scientific Advice meetings, and 57 lay people to share their knowledge and experience with committees as a patient expert.

Involving individual people

10. Once recruited to a committee, lay members receive induction and training as well as ongoing support from a named member of the Public Involvement Programme. They also receive support from the team who are running their committee.

11. We are keen that our support meets the needs of the people who we are working with. In some instances we need to adapt the way we work to ensure that people's needs can be met.

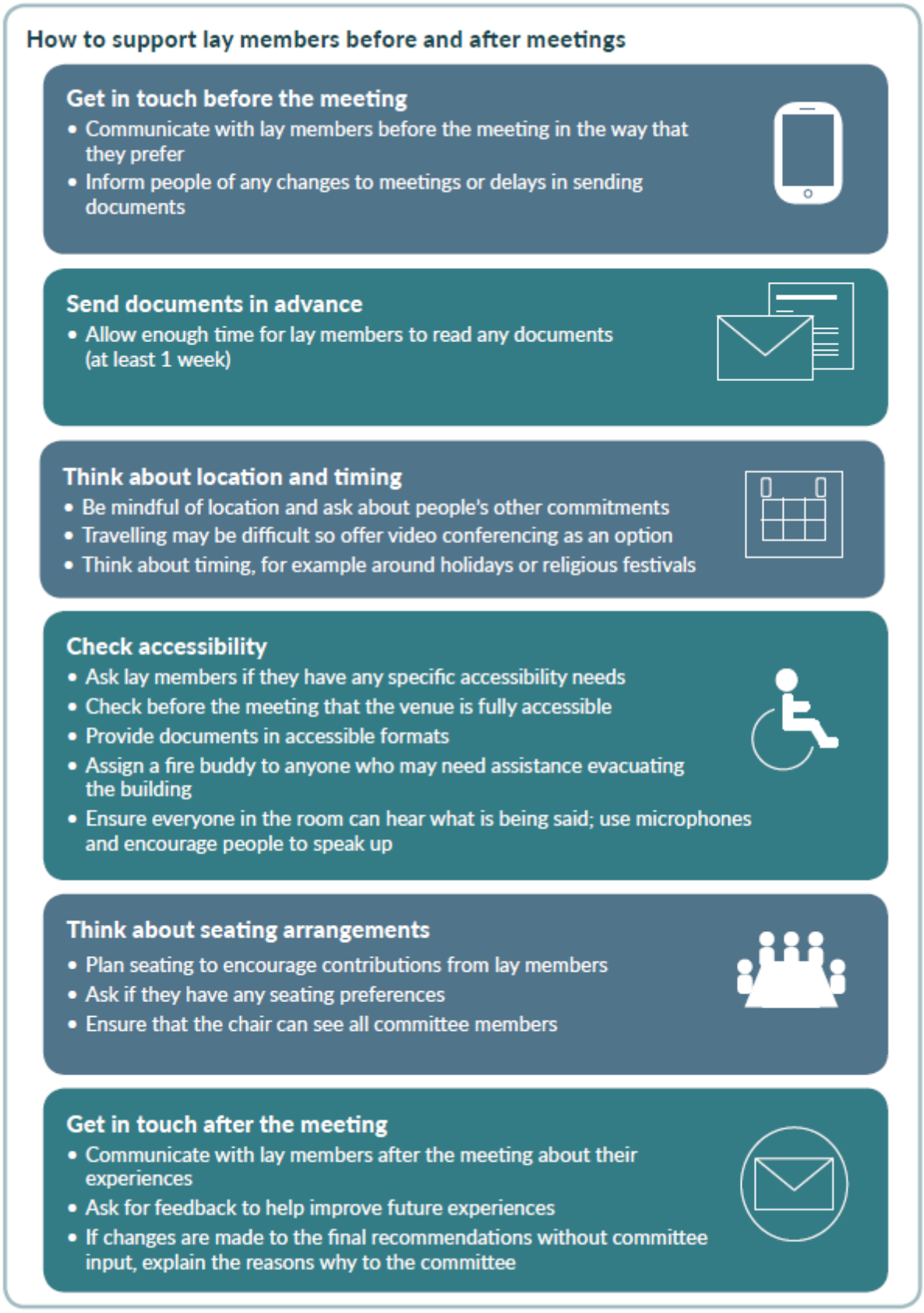
Case study: supporting lay members with ME/CFS

The Guideline Committee (GC) for ME/CFS (Myalgic Encephalomyelitis (or encephalopathy)/chronic fatigue syndrome) includes 5 lay members, 4 of whom are living with diagnosed ME/CFS. Due to the impact of the condition and the demands of GC meetings, the PIP team and the guideline developer have made significant adjustments to our regular process to safeguard the health and wellbeing of our lay members. This includes special seating arrangements (recliners) during training and GC meetings; additional overnight accommodation before and after meetings as needed, to allow for additional rest; longer lunch breaks than other GC meetings to allow for rest; lap desks to use for papers while using recliners and overnight accommodation at the same venue as GC meetings to minimise travel.

Lay members were consulted on what might help them and these adjustments were led by suggestions from them. This has also had a significant resource impact which was accounted for. Feedback from lay members has been extremely positive and they feel that the expected payback on their health has been much mitigated due to these adjustments.

12. In 2019/20 we created a guide for NICE staff which outlines the role and value of lay members and gives tips and suggestions from lay members themselves about how to support them during their work with us (shown in Figure 2). Please note that the guide was developed before the introduction of virtual committee working as a consequence of COVID-19. This will be amended to reflect new ways of working once these have bedded in.

Figure 2: How we support lay members – a guide for NICE staff

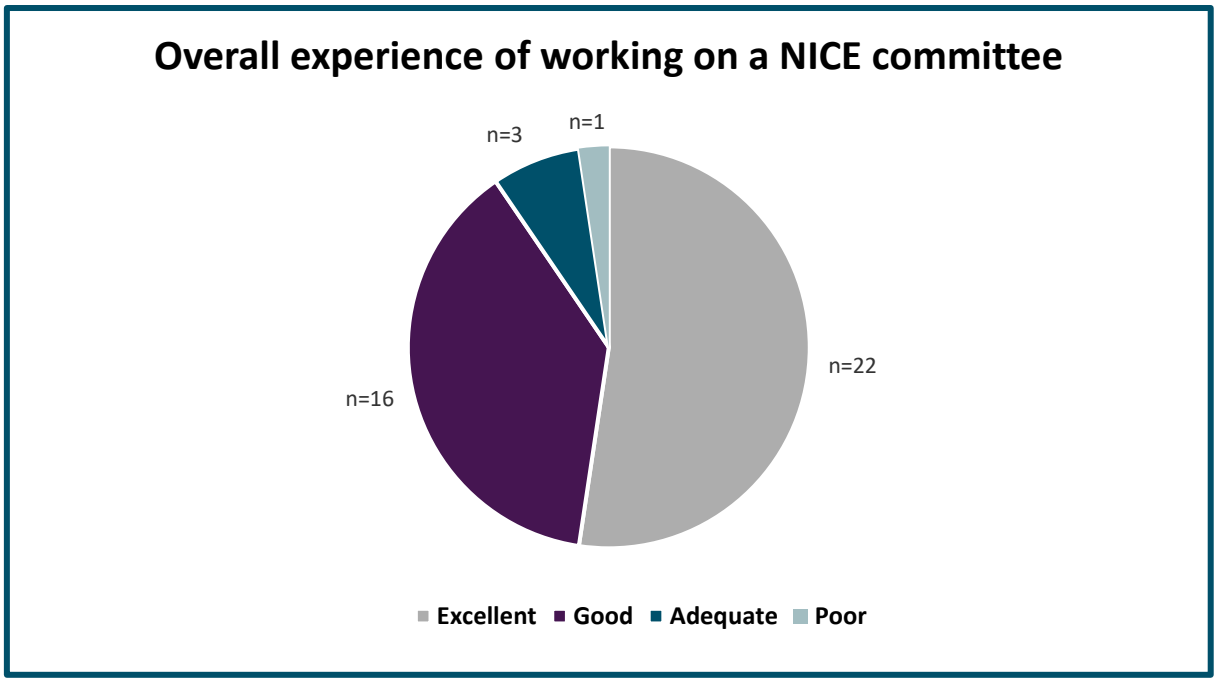


Exit surveys

13. When a lay member finishes their work with us we ask them to complete an exit survey to hear about their experiences, and to hear any suggestions they might have for improvements. The data we receive is shared with internal teams and our external guideline developers, and an annual exit survey report is produced.

14. In 2019/20 we sent out 76 exit surveys and received 42 responses - an overall response rate of 55%. This is an increase from the response rate of 47% for the previous year. Ninety percent of respondents rated their experience of working with us as 'good' or 'excellent' this is down from ninety-five percent in the previous year, however the result still represents a positive picture of people's experiences.

Figure 3 – overall experience of working on a NICE committee



Download the data set for this chart

15. Participants reflected on both the positive and negative aspects of their work with NICE and our guideline developer centres. Committee working and the role of the chair were highlighted as particularly positive elements of lay members' experiences. The following factors were also identified as being influential in their experience of working on a committee:

- being listened to and having their views considered, respected and valued (n=12)
- being an equal committee member (n=6)

- a ‘friendly committee – made to feel welcome’ (n=5).

> *‘The chair of the committee made it really accessible, and so as a lay person I didn't feel lost or left out. The environment…was open and calm.’* – NICE lay member

16. In response to the question 'What went well during your time on the committee?', 18 respondents (43%) across a range of programmes specifically complimented their committee chair, mentioning a key aspect of creating a constructive, open, calm and friendly environment.

17. Where chairing was felt to have been poor [n=3], respondents indicated that this prevented lay members from contributing effectively, demonstrating how crucial the role of the chair is to effective involvement. Other challenges that lay members faced related to meeting arrangements and administration – just over half (16 out of 29) of lay members who mentioned meeting arrangements and administration noted that they had had a problem. This included papers being sent late or tight deadlines being given [n=4], IT issues in meetings [n=3] and poor communication with developer teams [n=2].

18. Ninety percent of respondents were able to give at least one example of the impact they thought they had made on their committee. Eighteen respondents (43%) commented that their greatest achievement was ‘simply being there and representing the patient/carer view’. Nineteen other people (43%) were able to elaborate on how their involvement impacted on the guidance. The following themes demonstrate where lay members thought they had had an impact on the guidance:

    - influencing rationales and recommendations (n=9)
    - creating decision aids (n=2)
    - identifying gaps in committee expertise and recruiting new members (n=1)
    - challenging professionals’ views of the patient (n=4)
    - highlighting patient views from consultation comments (n=1)
    - influencing health economic factors (n=1)
    - publishing the guideline (n=1).

Support and learning

Training days

19. As part of our support for new people joining guideline committees, we ran 3 face-to-face training days to equip them with the knowledge and skills to get the

most out of their time on the committee. The training was focused around making an impact and covers:

- developing guidelines – what evidence NICE uses and how we look for and assess that evidence
- preparing for meetings - what to expect and how committees use evidence
- making an impact – sharing knowledge, experience and ideas with former lay members.

20. Speakers from both within NICE and our developer centres contributed to each training session. Former lay members took part to share their experiences and knowledge of working with us. In total 32 people received training this year.

21. We asked attendees to provide feedback following each training day. Participants were asked to score (1-10) for each aspect of the workshop, where 10 = very good; 1 = very poor. Twenty-one participants completed a feedback form and an overview of this feedback is provided in table 1.

Table 1 – Summary of training day feedback scores

Session	Range	Mean score
I know what support and training is available to me	6 to 10	9.0
I understand my role as a lay member	7 to 10	9.2
I understand the guideline development process	5 to 10	8.9
I understand the different types of evidence that my committee will be looking at	6 to 10	9.1
I understand how evidence is prepared for my committee	6 to 10	9.1
I understand how committees develop recommendations	6 to 10	9.0
I know how to prepare for meetings	7 to 10	9.4
I feel confident that I can have a positive impact in meetings	6 to 10	9.2

Online training modules

22. We have continued developing a suite of online training modules for lay members, which will enable them to access training resources at a time which is convenient for them. We developed training content in the Electronic Staff Record (ESR) platform, using the functions available for staff training. Lay members then tested the training modules using ESR as the platform to access them. We received valuable feedback from our users. Challenges with different

web browsers and incompatibility with Apple products meant that ESR did not ultimately meet our requirements.

23. Following the user testing we have continued to explore how and where we can make training modules available to lay members. We have continued to develop modules using PowerPoint and voice-overs. In 2020/21 we will trial NICE Share as a potential platform to enable access to training modules. This will give us less sophisticated content as it will be in PowerPoint format but should enable the modules to be made available and easily accessible to our users.

Building relationships with voluntary and community sector organisations

24. Voluntary and community sector (VCS) organisations are a key stakeholder group for NICE. They make an invaluable contribution to our work throughout guidance development, and in supporting and promoting the uptake of our guidance. Developing and strengthening our relationships with VCS organisations is a key component of PIP's work and one of the means by which we can achieve meaningful patient and public involvement.

Speaking engagements and meetings with voluntary and community sector organisations

25. In 2019/20 PIP took part in 9 national and international events as a speaker or panel member to share our learning and experiences of involving patients and the public in guidance development. We also held 12 meetings with voluntary and community sector organisations or umbrella groups. These meetings discussed NICE work in a specific topic area, gave an induction to the organisation for those who are new to working with us, and provided opportunities to address any issues raised.

Training and support for voluntary and community sector organisations

26. During the year we held two masterclasses for voluntary and community sector organisations. These were free to attend and were held in our London office.

> *'Overall really helpful and I would definitely recommend to anyone thinking of engaging with NICE process.'* – masterclass participant

27. Eighteen participants attended our 'Intro to NICE' masterclass and took part in interactive sessions exploring the range of guidance NICE produces as well as the opportunities to get involved in our work. The masterclass also included insight from two organisations who have worked extensively with NICE and who

shared their experiences around involvement and the implementation of NICE guidance.

28. Our second masterclass specifically explored the highly specialised technologies (HST) programme. Fifteen participants from a range of rare disease organisations attended and took part in a range of activities to both build their knowledge about HST evaluations and discuss effective participation in the programme.

29. For both masterclasses we received detailed, thoughtful, and generally positive feedback from participants which is invaluable for planning future sessions. We are grateful to NICE staff, lay members, and the staff from voluntary and community sector organisations who contributed to the agenda for our masterclasses, and to all participants for their engagement and interest.

30. A further masterclass was planned for March 2020 with an agenda specifically covering implementation and the role of voluntary and community sector organisation in supporting and promoting the uptake of our guidance. Due to the COVID-19 pandemic this masterclass was postponed and will be rescheduled to take place virtually.

Patient involvement in health technology assessments: taking a coproduction approach

31. Starting in late 2018 and concluding in late 2019 we engaged voluntary and community sector organisations in a piece of work to look at ways of improving patient involvement in health technology assessments across NICE. This was part of a broader programme of transformation work undertaken by the Centre for Health Technology Evaluation.

32. The work took a co-production approach, overseen by a working group which included 6 people from voluntary and community sector organisations, working alongside NICE staff. Wider engagement and consultation took place with voluntary and community sector organisations including an independently-facilitated stakeholder workshop attended by 22 organisations. We conducted a targeted consultation, via a survey, which yielded responses from 52 organisations. Throughout the project external engagement, such as speaking engagements and meetings with organisations, took place to encourage participation in the work.

33. Areas for development within our processes, as identified by our voluntary and community sector stakeholders, included:

- providing information about uncertainties that patient evidence might help address
- exploring the role of real-world evidence in patient involvement
- providing training and support to patient organisations
- creating inclusive committee cultures
- including additional steps during HTAs to incorporate patient evidence.

34. A final report, containing 18 detailed recommendations has been submitted to the Centre for Health Technology Evaluation and these will be considered for inclusion in updated process and methods guides which will be subject to public consultation during 2020. We will also consider how these recommendations might apply in relation to the Centre for Guidelines and across other NICE programmes.

Beyond guidance development

35. Voluntary and community sector organisations have engaged with NICE beyond our usual guidance development processes. They have contributed perspectives and insight to NICE Impact reports and helped to develop a number of NICE patient decision aids.

Working internationally

36. In 2019/20 PIP has maintained and built on its profile as a world leader in patient and public involvement.

Guidelines International Network (G-I-N)

37. The G-I-N Public working group (currently chaired by a PIP staff member) promotes good practice on involving patients and the public in developing and implementing guidelines across international guideline developers. Led by NICE and including chapters written by members of the PIP team, the G-I-N public working group is updating the G-I-N Public Toolkit and aims to publish an updated toolkit in 2020/21.

Health Technology Assessment International (HTAi)

38. PIP have continued our involvement in the Health Technology Assessment International's Patient and Citizens' Involvement Group (HTAi PCIG), including as a member of the steering group for the PCIG. This year we have worked on a number of projects with our colleagues, including:

- Co-leading work to develop a summary of information for patients (SIP) for patients and organisations taking part in an HTA. The SIP provides information about the medicine or device, written in plain language, to enable patients to provide targeted input into HTAs. The key deliverables from the work will be a template SIP for use by industry, plus guides for patients, industry and HTA agencies and an introductory slide deck.
- Presenting two vignettes, an oral presentation and taking part in a panel session and workshop at the HTAi 2019 conference in Cologne.

PARADIGM

39. We took part in the HTAi PARADIGM workshop on Early Dialogues (similar to NICE Scientific Advice) in October 2019. The workshop explored tools to support the rationale for patient involvement, to review methods and frameworks and to develop tools for recruiting, interviewing and supporting patient experts in Early Dialogues. Several agencies took part from France, Germany, UK, Italy, Hungary, Spain, Norway and Sweden. NICE was invited to provide expertise and insight to support the development of standardised tools and resources.

    There were several outcomes, including agreement on:

    - documents to support the rationale for patient involvement in Early Dialogues for all stakeholder groups (e.g., values statements, fact-sheets, including the goals of patient involvement, and case studies to highlight the value of involvement)
    - a process framework for in Early Dialogues: interviews and the meetings (despite variation between agencies)
    - the types of resources needed to support the process, including guidance for stakeholders (e.g., what companies and patients can expect) and templates (e.g., invitation emails, conflict of interest forms and contracts)
    - tools to support the interview and meeting processes, including logistical preparation checklists for meetings and guidance on interview techniques or support for the interviewer.

International Network of Agencies for Health Technology Assessment

40. PIP joined the International Network of Agencies for Health Technology Assessment (INAHTA) Patient Engagement Learning Group in 2019. The group’s purpose is to share knowledge and experience about patient engagement amongst member HTA agencies. We presented NICE’s approach to patient engagement and involvement in HTA via a webinar, focussing on our work evaluating the impact of patient input into the highly specialised technologies and interventional procedures programmes.

EVOLVE

41. PIP has taken part in the EVOLVE (giving patients a mEaningful VOice in the design and deLiVery of care) study as a steering group member, contributing to the research protocol and advising the project team. The aim of the EVOLVE study is to evaluate patient and public involvement (PPI) in clinical practice guidelines and to design and test an involvement model for PPI in urological cancer guidelines. The University of Aberdeen is the sponsor for the study with endorsement from European Association of Urology (EAU) Guidelines Office. The study is funded by Scottish urological cancer charity UCAN.

Supporting shared decision-making

NICE Shared Decision-Making Collaborative

42. In June 2019 PIP convened the 6th meeting of the NICE Shared Decision-Making Collaborative. Forty-eight people attended the event representing academia, voluntary and community sector organisations, professional organisations, regulators, Arm's Length Bodies and commercial organisations, all of whom have a commitment to and interest in shared decision-making. The agenda facilitated updates on shared decision-making from a range of speakers, capturing national and international developments and addressing issues around health literacy and risk communication.

43. A 'World Café' approach was taken for the afternoon session where participants moved through a number of different groups, discussing key areas for action around shared decision making. New actions for the Collaborative were identified and refined at a follow-up meeting of core Collaborative members in November 2019. Launch and promotion of the new areas for action was planned for March 2020 but has been postponed to a more appropriate time given the COVID-19 pandemic and consultation on the upcoming shared decision-making guideline.

Communications

Social media

44. We have increased our presence on social media using the PIP team's @NICEGetinvolved account. This has helped us to reach more members of the public and different communities, work and communicate more effectively with our stakeholders, and to take part in campaigns with our voluntary and community sector stakeholders.

45. In 2019/20 we achieved:

- 715 tweets
- 951,200 impressions
- 8 thousand profile views
- 18% more followers.

46. In October 2019 @NICEGetinvolved ran a twitter campaign for World Mental Health day. The campaign was delivered in partnership with our lay members and key stakeholders, promoting relevant NICE guidance, user experience, and examples of how services are being improved. 516 users directly engaged with the campaign, with messages generating 57,151 impressions.

Public involvement in a pandemic – meeting the challenge of COVID-19

47. The emergence of the COVID-19 pandemic in the spring of 2020 has had a profound effect on the way we work, and on the challenges faced by those we seek to involve. Although largely beyond the parameters for this annual report (2019/20 financial year) it would be remiss not to provide an update on the impact of COVID-19 on our work, and the contributions of voluntary and community sector organisations to NICE's response to the pandemic.

COVID-19 rapid guidelines

48. Early on in the pandemic NICE was commissioned to develop and publish rapid guidance on a range of issues related to COVID-19. This necessitated a highly accelerated development process, in some cases reduced to one week. A targeted consultation exercise with stakeholders formed part of the process with a consultation period in some cases of only 5 hours, with 2 or 3 days' notice.

49. PIP worked to identify voluntary and community sector organisations to take part in the targeted consultations and engaged with those organisations to explain the constraints we were working under and to encourage their participation where possible. As a consequence of our work building relationships with those stakeholders, as detailed earlier in this report, the response from voluntary and community sector organisations was overwhelmingly positive and they stepped up to the challenge magnificently, providing insightful comments across the COVID-19 rapid guideline topics.

50. We are aware however that the COVID-19 pandemic has had a profound effect on the voluntary and community sector with significant numbers of staff being furloughed and with huge uncertainty over funding for those organisations. PIP

has maintained a dialogue with key voluntary and community sector umbrella groups to understand the impact on organisations and work with them to support their continued involvement where we can.

Involvement in a virtual world

51. The lockdown implemented in response to the threat from COVID-19 has moved patient and public involvement into the virtual world. NICE committee meetings are now held via videoconference which presents new challenges and opportunities for the meaningful involvement of lay members and patient experts in committee meetings.

52. Led by a cross-NICE team, training and support has been provided to committee members to enable them to take part in meetings successfully in the new virtual environment, and to train other members of staff to run virtual meetings. PIP has supported lay members in this change and regularly gathers informal feedback about people's experiences of working in this way to ensure their contributions continue to be meaningful.

53. Use of virtual meeting software has allowed PIP to engage with patient experts attending committee meetings in a different way. An adviser from PIP has attended each technology appraisals committee meeting to provide support to patient experts joining those meetings. We have implemented a group waiting room for patient experts where PIP can provide information and answer any questions people might have before they move to the main committee group. The chat function in virtual meeting software means that participants have been able to ask PIP questions privately, or ask for clarification during a meeting – something that wouldn't be possible face-to-face in a large meeting room.

Conclusion and future plans

54. As ever the Public Involvement Programme's future plans will be guided by NICE's overall strategic development. However there are several strands of work for which we have ambitions over the coming months. These include:

Policy and service review

55. We will initiate a formal policy review to ensure that we are adhering to best practice in relation to public involvement. As part of this we are planning to develop a conceptual framework for involvement so that our intentions and practice are transparent and explicit. This will lead into a review of our services and what we can offer to the internal and external landscape.

Strategic relationships with patient, voluntary and community stakeholders

56. We will develop and plan our future strategic relationship with patient, community and voluntary sector organisations, particularly building on the experience and learning during the pandemic which has significantly adversely affected our stakeholder community. Working with external stakeholders and internal colleagues from the Audience Insight team we will consider how stakeholder engagement might be reconceptualised in a way that works well for our stakeholders, enables them to contribute to our work efficiently and effectively, and is useful for us. Our relationship with patient, community and voluntary sector organisations is fundamental to our work and we need to make sure that it is fit for the future and takes into account the challenges that our stakeholders face, especially in the ongoing context of COVID-19.

Deliberative public engagement

57. We will work with our colleagues in the Science Policy and Research team to revive NICE's activities in relation to deliberative engagement with members of the public, enabling us to gain the UK citizen's perspective on issues of ethical concern and debate.

Equality and Diversity

58. We will work to support NICE's ongoing commitment to supporting equality and increasing the diversity of our lay members and of the organisations with whom we work. We will also work with our colleagues in the guidance producing centres on any future developments of the equality impact assessments associated with all guidance.

International work

59. We will work with our colleagues in the Communications directorate to help plan and deliver NICE's hosting of the 2021 HTAi conference, to be held in Manchester. One of the key plenary sessions is 'patients at the heart of innovation' which is an opportunity to showcase the different methods and processes by which patient organisations and individual patients are involved in supporting access to new medicines and other technologies.

60. We will continue to support international initiatives such as the European Patients Academy for Therapeutic Innovation (EUPATI) of which we are part of the founding and ongoing faculty. This gives patient advocates across Europe the opportunity for intensive and practical study in the field of medicines development from the laboratory, to licensing and health technology assessment.

61. Our role as Chair of the G-I-N public working group continues, and we will play a key role in developing and publishing the revised G-I-N public toolkit for developing guidelines in a patient-centred way. We will also work with INAHTA to publish a Patient Engagement Position Statement.

62. We will collaborate with our colleagues within NICE International to ensure that patient and public involvement is high on the agenda for international engagement

‘People like us’

63. The collaboration with our colleagues in the other Arm’s Length Bodies (through the People and Communities Forum) will be maintained, to ensure we are sharing good practice and working jointly and collaboratively wherever possible on matters of engagement with patients and the public.

64. We will also offer advice to other organisations within the health and social care field who wish to develop their patient and public involvement strategies, in order to build capacity and promote good practice.

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September 2020

NICE National Institute for Health and Care Excellence

Developing NICE guidelines: the manual

Process and methods

Published: 31 October 2014
www.nice.org.uk/process/pmg20

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1 Introduction

In January 2022, we made changes to prepare for a larger update later in 2022. This larger update will set out quicker and more flexible methods and processes that are needed so that we can produce dynamic living guideline recommendations, as outlined in the NICE strategy for 2021 to 2026. The updated methods and processes will:

- take into account up-to-date evidence and data (digital, data and real-world evidence), which can be rapidly incorporated into guidelines
- focus on topic areas that represent key priorities (areas that have the greatest impact on health and reducing health inequalities)
- allow for agile guideline development that is quicker, more flexible and more responsive to our audience.

To find out what has changed in the January 2022 update and since the manual first published in 2014, see the section on update information.

In January 2021, NICE amended the text on assessing new medicines and significant new indications to clarify that this will be carried out in line with the 2019 voluntary scheme for branded medicines pricing and access published on the GOV.UK website.

In October 2020, NICE amended the text on topic-specific committees to indicate that they may work on multiple guidelines within a topic area, with membership subject to renewal for a total period of up to 10 years.

In July 2020, we published our NICE interim process and methods for guidelines developed in response to health and social care emergencies.

In January 2020, we published our new list of NICE's principles. The principles set out our approach to developing guidance, and the ethics and values that should guide the decisions of our advisory committees. They supersede our social value judgements document which was first published in 2005. However, they do not signal a departure from our current methods and approaches: the new principles are consistent with the social value judgements which are in turn reflected in the current version of this manual. The formal process for updating this manual will begin in 2021. Meanwhile, we expect our independent advisory committees to use and refer to the new principles to inform their decisions and provide a clear operating framework.

The National Institute for Health and Care Excellence (NICE) is a non-departmental public body that provides national guidance and advice to improve health and social care in England. Decisions on how NICE guidelines apply in other UK countries are made by ministers in the Welsh Government, Scottish Government and Northern Ireland Executive.

This manual explains the processes and methods used to develop and update NICE guidelines, the guidance that NICE develops covering topics across clinical care (in primary, secondary and community care settings), social care and public health. For more information on the other types of NICE guidance and advice (including technology appraisal guidance), see about NICE on the NICE website.

1.1 NICE guidelines

NICE guidelines make evidence-based recommendations on a wide range of topics, from preventing and managing specific conditions, improving health, and managing medicines in different settings, to providing social care and support to adults and children, and planning broader services and interventions to improve the health of communities. Guidelines promote individualised care and integrated care (for example, by covering transitions between children's and adult services and between health and social care).

Guideline recommendations set out:

- the care and services that are suitable for:
  - most people with a specific condition or need
  - particular populations, groups or people in particular circumstances or settings (for example, when being discharged from hospital)
- ways to promote and protect good health or prevent ill health
- the configuration and provision of health and social care services **and/or**
- how national and local public sector organisations and partnerships can improve the quality of care and services (for example, how the NHS and social care services work together).

Many guideline recommendations are for individual health and social care practitioners, who should use them in their work in conjunction with their own judgement and discussion with people using services. Some recommendations are for local authorities, commissioners and managers, and cover planning, commissioning and improving services; others are for providers (organisations

providing services), schools, and local and national organisations and partnerships in the public, private and voluntary sectors. Guideline recommendations are also useful for people who use health and social care services (including people who purchase their own social care), their families and carers, and organisations representing their interests.

In addition to the recommendations, guidelines also summarise the evidence behind the recommendations and explain how the recommendations were derived from the evidence.

1.2 Information about this manual

This manual explains the processes and methods NICE uses for developing, maintaining and updating NICE guidelines. It is primarily for:

- NICE staff involved in developing guidelines
- NICE contractors (such as those doing evidence reviews, economic analysis and other engagement work)
- members of the committees that develop the guidelines (see the section on who is involved).

It is also likely to be of interest to a broader audience, including developers of other guidance, stakeholders and users of NICE guidelines.

The processes and methods described in this manual are based on internationally recognised standards, and the experience and expertise of the teams at NICE, the contractors that work with NICE, NICE committee members and stakeholders. They are based on internationally accepted criteria of quality, as detailed in the AGREE Enterprise's Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument, and primary methodological research and evaluation undertaken by the NICE teams. They draw on the Guideline Implementability Appraisal tool to ensure that recommendations are clear and unambiguous, making them easier to implement.

This manual describes the development of NICE guidelines from referral and development through to publication, implementation, checking the need for an update, and the updating process. The process is summarised in the section on the main stages of guideline development. There is also information in the chapter on resources to support putting the guideline into practice on the support NICE provides to help organisations use each guideline.

This manual covers methods and processes for clinical, public health and social care topics, and service guidance (see the appendix on service delivery – developing review questions, evidence

reviews and synthesis). The best approach to take may depend on the topic; this manual gives alternatives and examples to help select the best methods and processes to use. Options should be considered from the outset, and the approach discussed and agreed with NICE staff with responsibility for quality assurance. The chosen approach should be documented in the methods for the guideline or the individual evidence review, together with the reasons for the choice. Decisions will be reviewed for consistency. In exceptional circumstances, significant deviations from the methods and process described in this manual may be needed; in these cases, NICE's senior management team must approve the approach before guideline development begins.

All guidelines produced using this manual are known as NICE guidelines, whether they are developed by internal NICE teams or by external organisations that NICE has contracted to carry out the work.

NICE uses a different process for producing guidelines related to the COVID-19 pandemic. This process is covered in the appendix on interim process and methods for guidelines developed in response to health and social care emergencies.

1.3 Choice of guideline topics

NICE guidelines are a key source for the development of NICE quality standards and therefore any new guidelines developed by NICE are usually agreed with the relevant commissioning body (NHS England or the Department of Health and Social Care).

Decisions on which new topics to develop guidelines on, and in what order, are based on factors such as:

- the priority given to the topic by commissioners and professional organisations, and organisations for people using services, their families and carers
- the health and care burden, and the potential to improve outcomes and quality of life.

A topic selection oversight group at NICE considers topics for guideline development, taking these factors into account. NICE then discusses topics identified in this way with NHS England, the Department of Health and Social Care, and Public Health England, and a prioritised list is agreed by these 3 bodies.

Topics are then formally referred to NICE and scheduled into NICE's guideline development plans.

1.4 Key principles for developing guidelines

NICE develops guidelines according to the following core principles:

- The guideline is based on the best available evidence of what works, and what it costs.
- The guideline is developed by independent and unbiased committees of experts, from across a range of health and social care professions.
- All our committees include at least 2 lay members (people with personal experience of using health or care services, including carers, or from a community affected by the guideline).
- Regular consultation allows organisations and individuals to comment on our recommendations.
- Once published, all NICE guidelines are regularly checked, and updated in the light of new evidence or intelligence if necessary.
- We are committed to advancing equality and diversity, reducing inequalities and ensuring that the NICE's principles reflect the values of society.
- We ensure that our processes, methods and policies remain up-to-date.

Using the best available evidence to develop recommendations

NICE guideline recommendations are based on the best available evidence. We use a wide range of different types of evidence and other information – from scientific research using a variety of methods, to testimony from practitioners and people using services.

Review questions guide the search for evidence, and the type of evidence used depends on the type of question (see the chapter on developing review questions and planning the evidence review). For example, a randomised controlled trial is often the most appropriate type of study to assess the efficacy or effectiveness (including cost effectiveness) of an intervention. However, a range of other non-randomised evidence, such as observational evidence (including that derived from the analysis of primary data sources such as patient registries), experimental and qualitative evidence, may also be used to inform assessments of effectiveness, or aspects of effectiveness. This evidence may include ways of delivering services, or the experience of people using services and how this contributes to outcomes. For some topics, there is little evidence from scientific studies, or the evidence is weak or contradictory. In these cases, we look for evidence from other sources to see if it agrees or differs ('triangulation'). When there is little or no evidence, the committee may also use expert testimony, make consensus recommendations using their knowledge and experience, or

make recommendations for further research.

Whatever evidence is used, it is selected and quality assessed using clear, consistent and appropriate methods (see the chapters on identifying the evidence: literature searching and evidence submission, reviewing research evidence and incorporating economic evaluation).

Involving people affected by the guideline

When developing guidelines, NICE involves people who might be affected by the guideline recommendations in a collaborative and transparent way. This includes commissioners, practitioners and others involved in providing services. People using health and care services, carers and the public also contribute to ensure that guidelines address issues relevant to them, reflect their views, and meet their health and social care needs.

There are 2 main ways to get involved:

- organisations can register as a stakeholder
- individuals can join a committee that works on guidelines, or advise a committee as co-opted experts on a particular issue.

There is more information about stakeholders and committee members in the section on who is involved and in our guide for stakeholders and the public (Developing NICE guidelines: how to get involved).

The public involvement programme at NICE provides advice and support to committees, developers and NICE staff, about involving the public in developing NICE guidelines. A public involvement adviser is allocated to each topic.

The Guidelines International Network Public toolkit includes best practice examples from NICE on how to involve patients and the public in guideline development.

Practitioners and people who use health and care services, family members, carers and the public may also be involved as:

- expert witnesses invited to give testimony to the committee (see the section on other attendees at committee meetings in the chapter on decision-making committees)

- members of a reference group, focus group or other advisory group set up when standard involvement and consultation processes are likely to be insufficient (for example, when the topic covers a population group that is not part of the committee, such as children, or adults with a learning disability (see the section on what happens during consultation in the chapter on the validation process for draft guidelines, and dealing with stakeholder comments).

Advancing equality and diversity, and upholding NICE principles

NICE is committed to ensuring that its guideline development process:

- fully meets duties under the Equality Act (2010) to have due regard to the need to eliminate discrimination, foster good relations and advance equality of opportunity in relation to people who share the protected characteristics of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation, including the public sector equality duty to tackle discrimination and provide equality of opportunity for all
- enables it to meet requirements under the Human Rights Act (1998).

NICE's 5-year strategy (2021 to 2026) reaffirms our commitment to identifying and reducing health inequalities through our work. This is linked to NICE's equality objectives and equality programme (2021 to 2024), which summarises NICE's legal and other equality obligations and describes NICE's approach to meeting them, particularly the process of equality impact assessment. NICE uses this approach to consider:

- equality in relation to groups sharing the characteristics protected by the Equality Act 2010 (for example sex, age or race)
- health inequalities that could be related to:
  - socioeconomic differences (such as low income or unemployment)
  - geographical variation (urban or rural)
  - the experiences of particular groups (for example homeless people, sex workers, vulnerable migrants, or gypsy, Roma and traveller communities).

Considering these groups is an aspect of NICE's compliance with both general public law requirements to act fairly and reasonably, and human rights obligations. It is aligned to duties placed on integrated care systems as outlined in the Health and Social Care Bill (2021).

1.5 Who is involved

NICE guidelines, and the procedures NICE uses to develop them, also take account of NICE's principles that are universal to all NICE's guidance and standards and explains the morals, ethics and values that underpin NICE's recommendations.

The committee

The committee is the independent advisory group that considers the evidence and develops the recommendations, taking into account the views of stakeholders. It may be a standing committee working on many guideline topics, or a topic-specific committee put together to work on a specific guideline or multiple guidelines within a topic area (see the chapter on decision-making committees). Committee members include practitioners (both specialists in the topic and generalists), service or care providers or commissioners, and others working in the area covered by the guideline (see the chapter on decision-making committees). In addition, at least 2 members of every committee are people using services, their family members or carers, or members of the public and community or voluntary sector with relevant experience (lay members).

If needed for a topic, the committee can co-opt members with specific expertise to contribute to developing some of the recommendations (see the sections on standing committees and topic-specific committees in the chapter on decision-making committees).

Registered stakeholders

Registered stakeholders are organisations that have registered with NICE because they have an interest in the guideline topic, or they represent people whose practice or care may be directly affected by the guideline. They play an important role in developing and advocating for, or implementing, NICE guidelines. During guideline development, NICE keeps registered stakeholders informed of progress by email. NICE also adds information on progress to the guideline page on the NICE website. The schedule for the guideline, the scope and details of the committee are also available on the NICE website.

Stakeholder organisations are encouraged to get involved in guideline development in a range of ways. The NICE website explains how to register as a stakeholder and how to contribute to the development of a guideline. Registered stakeholders comment on the draft scope and draft guideline, and they may be invited to provide evidence during guideline development. NICE formally responds to comments from registered stakeholders, and these responses are published on the NICE website. Stakeholders support implementation of the guideline once it is published.

Stakeholders include:

- national organisations for people who use health and social care services, their families and carers, and the public
- local Healthwatch organisations and local organisations that have no national group to participate on their behalf
- national organisations that represent health and social care practitioners and other relevant professionals whose practice may be affected by the guideline, or who can influence uptake of the guideline recommendations
- public sector providers and commissioners of care or services (for example, GP practices)
- private, voluntary sector and other independent providers of care or services
- companies that manufacture medicines, devices, equipment or adaptations, and commercial industries relevant to public health (excluding the tobacco industry)
- organisations that fund or carry out research
- government departments and national statutory agencies
- overseas agencies with a remit covering England.

Individuals cannot register as stakeholders but NICE encourages anyone with an interest in the topic to express their views to a registered stakeholder listed on the guideline page on the NICE website. Although NICE will consider comments on the draft scope and guideline from individuals, we do not have the resources to write responses to these comments.

Local or regional professional or practitioner groups, and local or regional groups for people who use health and social care services cannot register as stakeholders unless there is no national organisation that represents the group's specific interests.

Although NICE is established as an England-only body, our guidelines are used in other countries in the UK. We want our guidelines to be useful in these countries, so encourage stakeholders from anywhere in the UK to take part in developing them.

Tobacco companies and those who speak for them or are funded by them (collectively referred to as 'tobacco organisations') cannot register as stakeholders. This is in line with NICE's obligation under Article 5.3 of the World Health Organization (WHO) Framework Convention on Tobacco

Control (FCTC) to protect public health policies from the commercial and other vested interests of the tobacco industry. Tobacco organisations are simply referred to as 'respondents'. Any comments received during consultation from respondents are reviewed for factual inaccuracy claims and are made public along with any responses.

NICE staff and contractors who work with the committee

The committees are assisted by teams whose work covers guideline development, evidence review and support, and quality assurance.

These teams are represented at committee meetings and contribute to discussions. They are not committee members, do not contribute to the quorum of the committee or the development of recommendations during meetings, and do not hold voting rights.

Quality assurance by NICE

NICE staff carry out quality assurance of the guideline to ensure that processes have been followed appropriately, and that the methods are clear and transparent. This includes ensuring that the reviews of the evidence and any economic analysis are up-to-date, credible, robust and relevant. They also check that there is a valid link between the evidence and the recommendations. These staff may also be responsible for commissioning the developer. Staff with responsibility for quality assurance must declare any interests, which are managed in line with NICE's policy on declaring and managing interests for board members and employees. Quality assurance takes place throughout development and during checks of the guideline after publication (surveillance). The responsibilities of NICE staff involved in guideline quality assurance are summarised below:

- The NICE **centre director** is responsible for ensuring that the guideline is produced in accordance with this manual. The centre director is also responsible for appointing the committee chair and committee members.
- The NICE **guideline lead** is responsible for the development and quality assurance of the guideline (including the scope), and has delegated responsibility for approving the consultation draft and the final guideline, before approval by NICE's Guidance Executive. The guideline lead also advises the committee chair and the developer on matters of method and process. Guideline commissioning managers help them with this.
- The NICE clinical, public health or social care **adviser** is responsible for providing advice on the guideline topic during all stages of guideline development.

- The NICE **guideline commissioning manager** is responsible for ensuring that NICE's processes and methods are followed. They also coordinate with other quality assurance staff and advise the guideline lead as needed.
- The NICE **technical lead** is responsible for ensuring the technical quality of the non-economic evidence reviews.
- The NICE **economic lead** is responsible for ensuring the technical quality of the economic evidence and any economic analysis.
- The NICE **medicines adviser** is responsible for providing advice on any medicines and prescribing aspects of the guideline.
- The NICE **editor** is responsible for ensuring that the guideline is clear and accessible to readers, and in line with NICE's style guide.

Quality assurance of guideline surveillance reflects quality assurance of guideline development. The NICE associate director for surveillance is responsible for ensuring that processes are followed and that decisions to update or not update guidelines are robust and fit for approval by NICE's Guidance Executive. The NICE technical adviser for surveillance ensures the technical quality of the surveillance review, and the NICE clinical, public health or social care adviser provides advice at all stages.

Development

The **developer** may be a team within NICE, or in an organisation contracted by NICE to develop guidelines. The developer is responsible for scoping the guideline, supporting the committee and documenting the recommendations, committee discussions and decisions, evidence reviews and methods.

Administrators, **coordinators** and **project managers** provide administrative and management support to the committee, planning and scheduling the work, arranging meetings, liaising with stakeholders and all individuals and organisations contributing to the development of guidelines.

The **evidence review team** (comprising an information specialist, systematic reviewer and, for most guidelines, an economist) work together to identify, review and summarise the evidence, and undertake economic analyses. Sometimes developers may commission other organisations to review the evidence.

The **information specialist** identifies relevant literature to answer the review questions (see the

chapter on identifying the evidence: literature searching and evidence submission), creates databases to manage the search results and keeps a log of search results and strategies.

The **systematic reviewer** critically appraises the evidence, distils it into evidence tables and writes brief summaries (including GRADE tables, GRADE-CERQual or evidence statements, if used) for presentation to the committee (see the chapter on reviewing research evidence). The reviewer also summarises the main issues with the evidence for the committee and contributes to their discussions.

For most guidelines, an **economist** identifies potential economic issues in discussion with the committee, summarises the published economic evidence and performs additional economic analyses as needed (see the chapter on incorporating economic evaluation).

Support

Staff from other NICE teams work on the guidelines at different stages. They may attend committee meetings and comment on the guideline during consultation and at other times.

NICE media relations team

The media relations team supports committee members, the developer, and NICE staff with responsibility for quality assurance, on all aspects of communications, including contacts with the media and managing any issues, throughout guideline development and after publication.

NICE resource impact assessment team

The resource impact assessment team works with the committee, and NICE staff carrying out quality assurance, to provide information on the resource impact (costs and savings) of recommendations. Final cost estimates are available to support the implementation of the guideline.

NICE adoption and impact team

The adoption and impact team produces tools and signposts to other support that can help organisations put guideline recommendations into practice. The implementation support team works with external organisations on selected priority areas, which depend on the interests of our partner organisations and resources.

NICE system engagement team

The system engagement team includes the field team who work with regional and local organisations to promote the guideline and help to put it into practice. The NICE endorsement and shared learning programmes also support implementation with external resources and implementation case study examples.

NICE system support for implementation team

The system support for implementation team works with national partners in health and social care, encouraging and helping them to promote the use of NICE products.

NICE public involvement programme

The public involvement programme (PIP) advises on ways to effectively involve people who use health and care services, family members, carers and the public, and supports their participation in guideline development. PIP encourages organisations representing service user, carer and community interests to register as stakeholders. It also advertises for people using services, carers and the public to apply to join committees and supports them in their roles as committee members.

NICE medicines and advice team

The medicines and advice team provides advice on medicines and prescribing issues in evidence reviews.

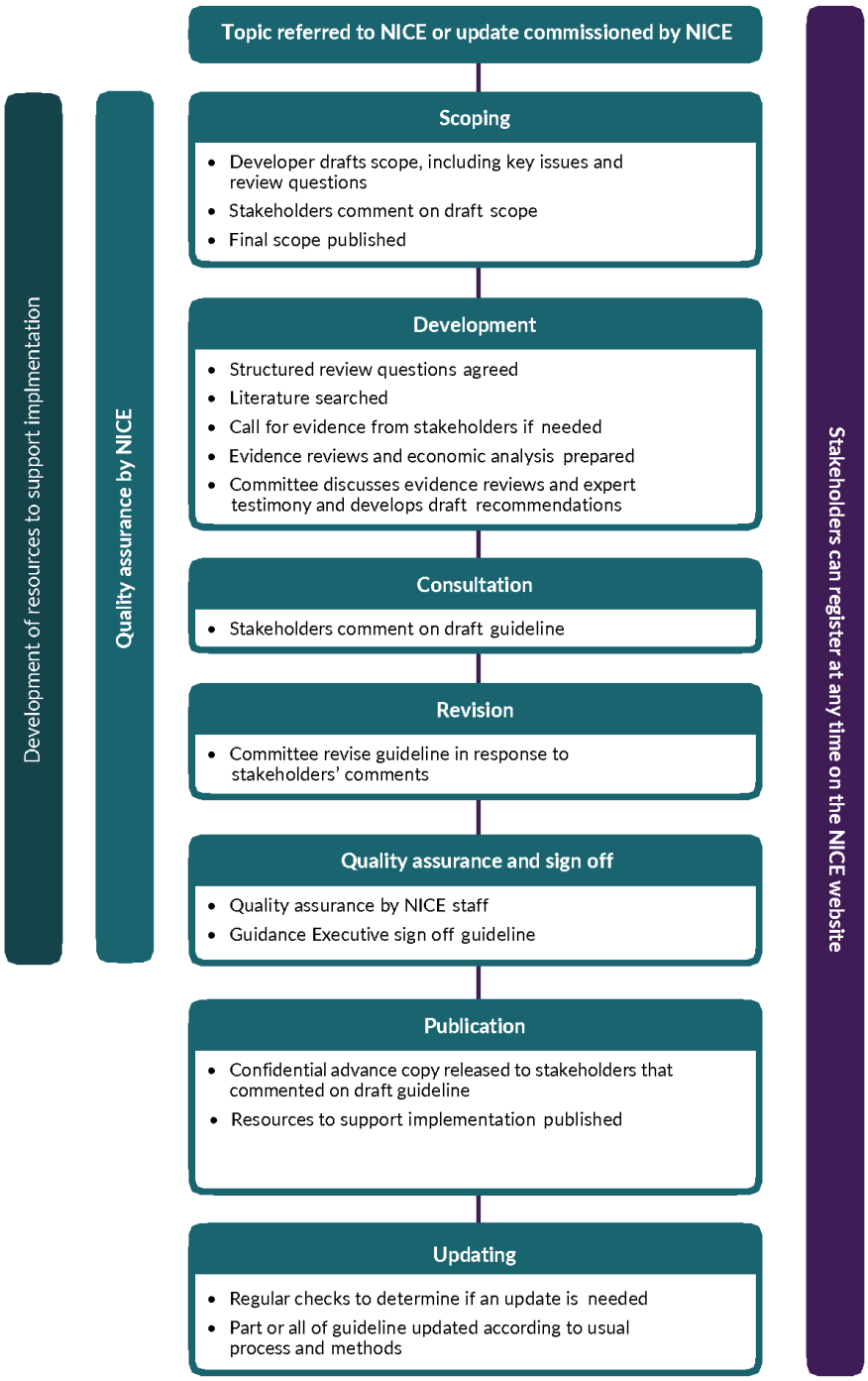
NICE publishing team

Editors from the publishing team work with the committee, the developer and NICE staff with responsibility for guideline quality assurance. They ensure that the guideline and related products are written and presented in a way that is clear and accessible to a range of different audiences. For some topics, they may produce a visual summary of the recommendations.

1.6 Main stages of guideline development

The development time for guidelines depends on the size of the topic areas. Figure 1.1 summarises the main stages.

Figure 1.1 Stages of guideline development



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1.7 Publication and implementation of the guideline

Guideline recommendations are published on the NICE website alongside the rationales for the recommendations, evidence reviews, including summaries of the committee discussions, and methods. Any resources to help users implement the guideline are also published.

Resources to help people put the guideline into practice include tools that help users assess what needs to change. These resources inform action planning or audit, estimate costs and savings to help build a business case, or meet the education and learning needs of practitioners (see the chapter on resources to support putting the guideline into practice for information about the support available to help implement guideline recommendations).

Updating this manual

A substantial update to this manual will start in 2022. This will set out quicker and more flexible methods and processes that are needed so that we can produce dynamic living guideline recommendations, as outlined in the NICE strategy 2021 to 2026. Future updates will be more regular, and will look at specific sections of the manual rather than the whole document.

When significant changes are made, there will be a stakeholder consultation. The updated manual will then be published, along with a list of changes from the previous version of the manual. All registered stakeholders will be invited to comment on proposed changes.

We welcome comments on the content of this manual and suggested subjects for inclusion in the next update. These should be addressed to GuidelinesManualUpdate2022@nice.org.uk.

New methods may be piloted before formal consultation, to fully assess the implications before recommending changes. For small changes to be put in place without stakeholder consultation, they must fulfil all of the following criteria:

- no fundamental stage in the process is added or removed
- no fundamental method, technique or step is either added or removed
- no stakeholders will obviously be disadvantaged
- the efficiency, clarity or fairness of the process or methodology will be improved.

Changes that meet all of these criteria will be published on the NICE website. The manual will be updated, and changes from the previous version of the manual will be listed.

1.8 References and further reading

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2 The scope

The scope sets out what a NICE guideline will and will not cover. Preparing the scope is the first step in developing a guideline. The scope is used to create a framework for the development work (see the chapters on developing review questions and planning the evidence review, identifying the evidence: literature searching and evidence submission, reviewing research evidence, and incorporating economic evaluation).

2.1 Purpose of the scope

The scope sets boundaries that ensure the work stays within the referral and the resulting guideline can support any relevant quality standard (see the section on choice of guideline topics in the introduction chapter). The scope:

- defines the population(s) and setting(s) that will and will not be covered
- describes what the guideline will and will not consider
- identifies the key issues that will be considered and lists the draft questions
- describes the economic perspective(s) to be used.

The scope also includes:

- a brief description of the guideline topic (for example, a description of the condition or disease, health or social care services, organisation of services, or areas of public health practice)
- a brief overview of the context (current policy and practice) in which the guideline will be developed
- a summary of why the guideline is needed and where it will add value, including how the relationship between commissioners and providers may affect outcomes and costs
- how the guideline will build on, rather than simply reproduce, the actions required by legislation and statutory guidance
- how the guideline will link to other NICE recommendations and quality standards that are published or in development (see the chapter on linking to other guidance)

- potential equality issues among groups sharing protected characteristics and how these will be considered
- health inequalities, as categorised in the Public Health England report on place-based approaches for reducing health inequalities.

The title of the guideline (as given in the scope) should accurately reflect the content of the scope. Occasionally, it may be necessary when preparing the scope to seek clarification from the commissioning body (see the section on choice of guideline topics in the introduction chapter) on the referral (for example, to clarify how the NICE guideline will add value in relation to existing non-NICE guidance or to specify the boundaries and the extent of the work).

When a guideline is being partially updated or replaced, the scope of the existing guideline may be used unchanged, the scope of the existing guideline may be modified or a new scope developed. The scope lists which sections will be updated, and any that will be removed, for example, because:

- they are now covered by other NICE guidance, or by legislation or other sources of advice
- they are no longer current practice
- they are outside of NICE's remit.

2.2 Who is involved in developing the scope

The draft scope is prepared by the developer or by a team at NICE. Topic-specific expertise may be provided by members of the committee (if early appointment is appropriate) and the topic adviser if there is one (see the section on topic-specific committees in the chapter on decision-making committees). Lay expertise may be provided by 1 or more lay people recruited specifically to support scope development, or 1 or more lay members of the committee if early recruitment is appropriate.

When several related guidelines are being developed simultaneously, cross-representation of expertise on each scoping group may also be considered.

The following are usually involved:

- the chair and/or topic adviser
- a lead from NICE's Publishing team

- a lead from NICE's public involvement programme
- a lead from NICE's resource impact assessment team
- the developer's information specialist, systematic reviewer and economist
- NICE staff with responsibility for quality assurance.

The draft scope is signed off by a senior NICE staff member with responsibility for quality assurance.

2.3 Standard scope development process

The scope is developed in 7 stages:

- stage 1: the scoping search
- stage 2: understanding the context
- stage 3: identifying the population and key issues
- stage 4: identifying and making decisions on overlaps with other NICE guidance
- stage 5: checking the population and selected key issues with stakeholders
- stage 6: consulting on the draft scope
- stage 7: finalising the scope after consultation.

Stage 1: the scoping search

To support scope development a scoping search is undertaken. The sources searched will depend on the topic, the type of questions the guideline will seek to address and the type(s) of evidence sought. Unpublished sources of data that might provide relevant high-quality evidence, such as audits and registries, should also be identified at this stage. Topic advisers or committee members may also identify relevant sources and evidence.

The search for evidence to support scope development should identify any appropriate:

- NICE guidance and guidance from other developers
- policy and legislation

- key systematic reviews and epidemiological reviews
- economic evaluations
- information on current practice, including costs and resource use and any safety concerns
- routine health and social care data (for example audits, surveys and registries), if appropriate
- types of interventions that may be appropriate and their safety
- statistics (for example, on epidemiology or service configuration), national prevalence data and data on the natural history of the condition
- information on the views and experiences of people using services, their family members or carers, or the public.

The search should not aim to be exhaustive. It should be based on the need to inform the development of the draft scope and the issues to be discussed at a scoping workshop (if this is held). The search can also reveal the evidence base, start to identify gaps in the evidence and indicate whether there is sufficient evidence to answer the draft questions. The search should focus on identifying secondary sources, such as reviews of the evidence. If there is insufficient review-level information, the scoping search should be extended to identify relevant primary studies and data sources (including those sources that might not be identified using traditional search strategies). When searching for systematic reviews, it may be efficient to use specific systematic review databases (such as Epistemonikos). This can reduce the volume of results when compared with a general database (such as MEDLINE) with a systematic review filter.

The information specialist should discuss the time available for both searching and reference sifting (screening) with the topic team as soon as possible. This can help with decisions around the breadth of review questions, to ensure they are answerable in the time available.

In some cases, a scoping search for economic evidence may be conducted (see the section on reviewing economic evaluations in the chapter on incorporating economic evaluation).

The search should be fully documented (see the section on documenting the search in the chapter on identifying the evidence: literature searching and evidence submission) and if new issues are identified at a scoping workshop, the search may be updated. The appendix on suggested sources for scoping provides a list of suggested sources for the scoping search.

For a guideline that is an update of existing NICE guidance, and for which the scope of the existing guideline is being modified, the developer can use any background information (including briefing

papers and searches undertaken as part of the process for reaching an update decision) to inform the searches at the scoping stage. (See the chapters on ensuring that published guidelines are current and accurate and updating guideline recommendations for information on updating guidelines.)

More information on identifying evidence to support guideline development is provided in the chapter on identifying the evidence: literature searching and evidence submission.

When gaps in the evidence are identified, NICE staff with responsibility for quality assurance, the developer or committee members (if recruited early) may believe that there is relevant evidence not identified by the searches. In these cases, the developer should start to compile a list of the gaps identified during scoping, along with details of stakeholders who might be able to provide information, as part of a call for evidence (see the section on calls for evidence from stakeholders in the chapter on identifying the evidence: literature searching and evidence submission) or as expert witnesses (see the section on other attendees at committee meetings in the chapter on decision-making committees).

Stage 2: understanding the context

To develop guidelines that identify and promote effective practice, it is important to understand current health and social care context. Context can include:

- the reason for referral of the topic
- the burden of disease
- the differential impact of health inequalities and inequities on the disease, and on services and outcomes
- how care and support is currently delivered and who is responsible for commissioning and providing it
- the cost of care and support
- workforce issues and variance in service organisation
- use of interventions
- legislative or regulatory frameworks
- user experience and safety concerns.

Understanding the current context and how the guideline topic fits within this context will help to ensure that:

- the guideline focuses on achieving improvement in areas where it is most needed
- potential implementation issues and resource impact are identified early and used to inform the guideline and relevant resources.

The developer continues to collect contextual information during development so that the guideline can adapt to changes in context.

Using a conceptual framework to construct a logic model

For some guidelines, it may be helpful to construct a topic- or question-specific conceptual framework. Two different, but interlinked, models can be used: problem-oriented and design-oriented.

A problem-oriented conceptual model can aid understanding of existing or planned interventions or services and identify areas for improvement. It provides information on how factors interact and ensures that key areas are approached in the most logical and efficient way. It helps to focus questions, as well as identifying how the discrete questions are linked and how much of the intervention or service will be covered. A problem-oriented conceptual model can be developed as part of the scoping process (for example, at the stakeholder scoping workshop) and should not be limited by what is feasible.

The problem-oriented model links to a design-oriented conceptual model (or logic model), which is used to inform the structure, assumptions and data needed for simulation models (implementation models) to assess effectiveness (including cost effectiveness). The design-oriented model can also be used to help structure the review questions and to specify the data and evidence needed to develop an economic model to inform recommendations.

Stage 3: identifying the population and key issues

Stage 3 includes identifying the population and considering the key issues for inclusion in the scope. These may have emerged during preliminary work, or may be identified by the scoping search, by considering any health inequalities and impacts on equality, and consulting experts.

Identifying the population is critical because it helps determine the breadth and depth of the work. It also means that feasible measures can be included in any related NICE quality standard.

Identifying the key issues ensures that the guideline focuses on areas in which providers and commissioners of care and support, or services most need advice. For example, areas in which there is unacceptable variation in practice or uncertainty about best practice, areas of unsafe practice, uncertainty around the optimal service configuration, or where new evidence suggests current practice may not be optimal. It may also be important to identify populations in which there is evidence to suggest different effects from an intervention due to the intervention's mechanism of action; for example, subgroups with different responses to pharmacological interventions resulting from underlying genetic variation.

Consideration should be given as to whether there are specific aspects of the views or experiences of people using services that need addressing. When these are identified, they should be included in the scope if they are not covered by existing guidelines and are supported as a priority area (see the chapter on developing review questions and planning the evidence review).

Guidelines do not usually include key issues that are covered by other arms-length or government bodies such as the Department of Health and Social Care, NHS England or Public Health England. They do not usually cover training requirements, because these are the responsibility of the Royal Colleges and professional associations, but they may make recommendations on the need for specific knowledge and skills for a particular aspect of care.

The process should ensure that a range of care and support, or services is considered, including key areas for quality improvement, and that the resulting guideline can be used to inform the development or update of a NICE quality standard.

Equality and equity issues at the scoping stage

During development of the scope, it is important to consider and assess any health equality and equity issues, to establish:

- whether there is any risk of unlawful discrimination arising from the guideline
- whether the guideline offers any opportunities for advancing equality or reducing inequalities
- whether there might need to be reasonable adjustments to a recommendation to avoid putting any group of people covered by the scope at a substantial disadvantage
- whether, and to what extent, particular equality issues should be included in the scope.

Considerations should be reflected in the equality impact assessment. The draft scope should set out the groups or issues that have been identified for specific consideration – including, when

relevant, a statement to indicate that no groups or issues have been identified.

Health inequalities are categorised in the Public Health England report on place-based approaches for reducing health inequalities.

Identifying and prioritising key issues

Box 2.1 lists the factors (including relevant equality issues) that should be considered when identifying and prioritising key issues, health inequalities and impacts on equality. At this stage, the developer (in discussion with NICE staff with responsibility for quality assurance) should also consider the composition of the committee, and the approach to be taken when key population groups are excluded from committee membership (for example, for topics covering children – see the section on forming the committee in the chapter on decision-making committees and the appendix on approaches to additional consultation and commissioned primary research).

Box 2.1 Factors to consider when identifying and prioritising key issues for inclusion in the draft scope

Uncertainty or disagreement on best practice

Is there variation in current care provision and practice?

Is there variation in the level of integration of care and support for people using services or accessing care?

Is there evidence suggesting that common practice may not be best practice?

Is there debate in the literature?

Potential to improve outcomes or make better use of resources

How many people are affected and in which age groups or sectors of the population?

What is the potential for improved outcomes at acceptable cost?

What is the potential for reducing ineffective care?

What is the potential to provide care and support in a more efficient way (for example, through organisation of services to integrate care and support, or telecare)?

Are there safety concerns that need addressing?

What is the potential for achieving cost savings with acceptable outcomes?

What is the potential for improving employment outcomes among people out of work because of ill health?

Potential for avoiding unlawful discrimination, advancing equality and reducing health inequalities

Are there any health inequalities or impacts on equality?

Are there any specific access issues? For example:

- socio-economic status (for example low income or poor housing)
- vulnerable groups (for example vulnerable migrants)
- protected characteristics under the Equality Act 2010
- geography (for example for urban or rural areas).

Are exclusions (for example, populations, interventions or settings, or groups sharing a protected characteristic) justified?

Have all relevant mental health issues been considered, including where topics focus on physical health problems?

Are there any specific issues for people with a learning disability?

Do inequalities in prevalence, access, outcomes or quality of care and support for any groups (particularly those sharing protected characteristics) need to be addressed by the scope?

Might there be a need to consider reasonable adjustments for a particular group when making recommendations?

Likelihood that the guideline could contribute to change

Is a new review of the evidence or an economic evaluation likely to reduce existing uncertainties?

How does the guideline fit with existing legal frameworks, statutory and professional guidance or government policies, and what is its anticipated impact?

What is the potential for achieving consensus within the committee and in the wider stakeholder community?

Other important factors

Will the guideline update or incorporate any recommendations in other published NICE

guidance?

Will the guideline take into account other NICE guidance (for example, technology appraisal guidance)?

Key issues and draft questions addressing these issues should be included in the scope. Depending on the type of guideline, whether it is an update (see the chapter on updating guideline recommendations) and the type of question, these could be very high level or could more precisely describe the populations, interventions, or particular approaches and aspects of service delivery to be compared and the outcomes of interest (see the chapter on developing review questions and planning the evidence review). These draft questions will be used as the basis for the final review questions (see the chapter on developing review questions and planning the evidence review) in the guideline.

Examples of key issues and draft questions are shown in box 2.2.

Box 2.2 Examples of key issues and draft questions that could be included in draft scopes for consultation

Issues relating to services

Rehabilitation programmes to support people back to work

Integration of services to support people after a stroke

Draft questions relating to services

What types of rehabilitation programmes should be provided to support people back to work?

How can services be organised to provide integrated and coordinated support to people after a stroke?

Issues relating to interventions

Training to assist foster carers in managing behaviour that challenges

Pharmacological interventions to treat pneumonia

Digital interventions to support behaviour change

Identifying pregnant women who smoke

Draft questions relating to interventions

What training should be provided to assist foster carers in managing behaviour that challenges?

What antibiotics should be used and for how long when treating pneumonia?

What interventions (or types of interventions) are effective at identifying pregnant women who smoke?

What interventions (including art therapy) are effective in treating mild to moderate depression?

Issues relating to experience of people using services

Information and support for people with epilepsy

Coordination and integration of support for people with a learning disability

Making structural changes to homes to support independent living

Draft questions relating to experience of people using services

What are the information and support needs of people with epilepsy, and how should these be met?

How does coordinated or integrated support (or the lack of it) affect the experience of people with a learning disability?

Issues relating to health inequalities and equality

Differential access to services or treatment for different population groups (categorised by socio-economic status, protected characteristics, vulnerable groups, and geography).

Draft key questions relating to health inequalities and equality

How can structural interventions and aids to support independent living be delivered for people who live in rented accommodation?

What factors improve access to primary care services among asylum seekers and refugees, and Gypsy, Roma and Traveller communities?

What approaches are effective in increasing access to affordable healthy food for people on low income?

Identifying the main outcomes

The scope should include a section listing the main outcomes of interest to be used when considering the evidence. This need not be an exhaustive list, but should always include quality of life and some important condition- or service-specific outcomes that are important to people

receiving care and support or using services, or those providing care and support or services. Core outcome sets should be used if these are suitable based on quality and validity; 1 source is the COMET database. The Core Outcome Set Standards for Development (COS-STAD) and Core Outcome Set Standards for Reporting (COS-STAR) should be used to assess suitability. The outcome list is likely to include capability, functioning, effectiveness, cost effectiveness, resource use and safety. It is also desirable to specify any negative effects of different approaches, such as adverse effects of treatment, or aspects of service delivery considered in the guideline (see also the appendix on service delivery – developing review questions, evidence reviews and synthesis).

Stage 4: identifying and making decisions on overlaps with other guidance

Identifying related NICE guidance (both published and in development) is a key element of scoping. This helps to see where and how the guideline recommendations are likely to relate to existing recommendations in other guidance.

This process should aim to identify any gaps where new recommendations would be of value, and areas where recommendations already exist (see the chapter on linking to other guidance).

Stage 5: checking the population and selected key issues with stakeholders

It is important to seek the views of stakeholders to confirm that the population group(s) and key issues identified by the developer are relevant and appropriate. This includes organisations led by people using services, and organisations that represent the interests of people with the condition or people using services and their family members or carers, or the public.

For some guidelines, registered stakeholders (see the section on who is involved in the introduction chapter) may be invited to a scoping workshop to talk about the key issues in the scope, and discuss any other aspects as needed. A workshop may be held if the referral is in a new area, there is a new audience for NICE guidelines, or a guideline topic or an area of practice has unique complexities. Following discussions with the developer, NICE staff with responsibility for quality assurance decide whether, and when, to hold a scoping workshop, and document the reasons for the decision. They also arrange the workshop.

The workshop is usually held before the consultation on the draft scope, but may be held during or after the consultation period. Attendance is usually limited to 1 person from each registered stakeholder organisation. In some circumstances, an organisation can nominate more than

1 person (for example, if it represents the views of both practitioners and people using services) if space permits.

If there are large numbers of stakeholders, it may not be practical for all registered stakeholders to attend. NICE may specify groups or roles of stakeholders who are needed. The aim of the workshop is to include as wide a range of views as possible. Attendees, including representatives of relevant service user, carer and community organisations, should have specific knowledge of, or experience in, the topic area.

The scoping workshop, if held, is in addition to the formal consultation on the draft scope. Stakeholder organisations with representatives attending the scoping workshop are also encouraged to submit comments in writing as part of the scope consultation. Depending on the needs of stakeholder groups, virtual workshops, such as webinars, may be held in place of face-to-face workshops.

The scoping workshop is chaired by a senior member of NICE staff with responsibility for guideline quality assurance.

The objectives of the scoping workshop may include:

- obtaining feedback on the selected key issues, including any important considerations for implementation
- identifying whether there are specific aspects of the views or experiences of people using services that need addressing and are not covered by existing guidelines
- identifying contextual issues, such as national policy or areas of care in which there is known variation in service provision
- obtaining views on what should be included and what should be excluded (for example, populations, settings, interventions, main outcomes)
- identifying which people using services or population subgroups should be specified for particular consideration (if any)
- considering existing NICE recommendations and how the planned guideline relates to them
- seeking views on the composition of the committee (see the introduction to the chapter on decision-making committees)
- encouraging applications for committee membership.

People attending the scoping workshop are sent a draft of the scope, which is intended as a starting point for discussion.

At the workshop, NICE staff with responsibility for quality assurance, the developer and other teams provide details about:

- the scope
- the timetable and process for guideline development
- the nature of stakeholder input into the guideline (including the involvement of people using services, family members and carers).

For some guidelines, they also explain the processes for recruiting committee members (see the chapter on decision-making committees).

This introduction is followed by a structured discussion of the key issues.

After the scoping workshop, the developer writes a summary of the discussions and key themes that emerged. The summary includes a list of organisations represented at the workshop. When the workshop is held before consultation on the scope, this summary is posted on the NICE website during consultation, along with the draft of the scope that was refined after the scoping workshop. When the scoping workshop is held during consultation, the summary is posted on the NICE website with the final scope.

For some topics, additional meetings or specific discussions with key stakeholders may be needed. However, this is exceptional and the reasons will be documented in the guideline.

If a scoping workshop has been held, the developer (with input from other teams) considers the issues raised and refines the scope after the workshop.

Equality impact assessment

Before the draft scope is signed off for consultation, an equality impact assessment is completed by the developer and the committee chair to show which equality issues have been identified and considered during scoping, and to provide assurance that risks of adverse impacts on equality of any exclusions from the scope have been assessed and can be justified. The equality impact assessment is signed off by a member of NICE staff with responsibly for quality assurance, and published on the NICE website with the draft scope. The assessment is updated by the developer and the committee chair after the scope consultation.

Stage 6: consulting on the draft scope

The draft scope is signed off for consultation by a senior member of NICE staff with responsibility for quality assurance. It is posted on the NICE website for a 4-week consultation, and registered stakeholders are notified. Information and prompts to support stakeholder input are posted with the draft scope. The purpose of these prompts is to seek their views on key issues (such as whether the identified outcome measures are in line with what matters to people with the condition or people using services) and to ask what should be included or excluded. NICE asks stakeholders to suggest areas where cost savings could be achieved.

Comments are invited from registered stakeholders. In particular circumstances, comments will also be solicited from the relevant regulatory organisation; for example, the Medicines and Healthcare products Regulatory Agency (MHRA), when the off-label use of medicines is likely to be considered within the guideline, or when advice is required on regulations related to medicines.

Registered stakeholders comment on the draft scope (and later on the draft guideline and evidence; see the section on what happens during consultation in the chapter on the validation process for draft guidelines, and dealing with stakeholder comments). Comments should be constructed as reasoned arguments and be submitted for the purpose of improving the draft scope. NICE reserves the right not to respond to comments that are hostile or inappropriate.

Tobacco companies and those who speak for them or are funded by them (collectively referred to as 'tobacco organisations') cannot register as stakeholders. Tobacco organisations are simply referred to as 'respondents'. Any comments received during consultation from respondents are reviewed for factual inaccuracy claims and are made public along with any responses.

The developer, NICE staff responsible for quality assurance and NICE's public involvement programme (see the section on who is involved in the introduction chapter) routinely review the list of registered stakeholders to check whether any key organisations are missing. Registered stakeholders are also encouraged to identify potential stakeholders who are not registered. When the guideline covers social care, the NICE team with responsibility for social care should be asked about appropriate stakeholders.

Stage 7: finalising the scope after consultation

Dealing with stakeholder comments

After consultation, the developer finalises the scope in line with the comments received ensuring that the scope stays in line with the referral for the guideline.

Sometimes registered stakeholders ask for the scope of a guideline to be broadened (for example, to include additional aspects of care and support, an additional population, a wider age range or an additional setting).

If the developer considers that a request to expand the scope would mean the guideline could not be completed on schedule, this should be discussed with NICE staff with responsibility for quality assurance. Sometimes lower-priority areas are removed from the scope to keep the development work manageable. This is done in collaboration with the lead for any related quality standards. Suggestions that are clearly outside the original referral should not be included.

All comments from registered stakeholders, and the actions taken by the developer and NICE in response to each comment, are clearly documented by the developer in a 'scope consultation table'. This is published on the NICE website with the final scope. The process for responding to comments from registered stakeholders should follow the principles described in the section on principles of responding to stakeholder comments in the chapter on the validation process for draft guidelines, and dealing with stakeholder comments. Comments received from non-registered stakeholders and individuals are reviewed by the developer and NICE. A formal response is not given and these comments are not made available on the NICE website.

NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.

Signing off the final scope

The final scope is signed off by a senior member of NICE staff with responsibility for quality assurance. Once the final scope has been published no changes should be made to it except in exceptional circumstances.

The final scope, the scope consultation table with comments from registered stakeholders and responses to these comments, and the equality impact assessment are posted on the NICE website.

2.4 Quicker scope development process for small updates

A quicker process can be used for small updates of 1 or 2 review questions.

This process may be used if:

- the review questions and review protocols from the original guideline do not need substantial changes for the update **and**
- these original questions and protocols can be used as the basis for the update scope and the draft questions.

This process is not suitable for updating topic areas that have complex pathways or overlaps with other guidelines, or topic areas that need new complex analysis or health economic modelling.

This quicker process follows the standard scoping process, but some of the stages may be reduced or are not needed at all.

Differences in the quicker process

Stage 1: the scoping search

A scoping search may not be needed, if a surveillance search has been done and the update will be looking at the same questions as the surveillance review.

Stage 2: understanding the context and Stage 3: identifying the population and key issues

If the review questions and review protocols from the original guideline do not need substantial changes for the update, these stages may only involve minor changes. Similarly, the main outcomes can be taken from the original guideline. The core outcomes set databases should be checked, if they have been updated since the original guideline published.

The approach to developing review protocols and the timing for agreeing them should be discussed and agreed with NICE staff with responsibility for quality assurance. If review protocols are developed and agreed during the scoping phase, then it is possible that only the committee chair and early recruited members will be able to provide input. If review protocols are agreed during development, the usual process can be followed (see the chapter on developing review questions and planning the evidence review).

Equality and equity issues should still be considered in full, and a new equality impact assessment should be prepared.

Stage 4: identifying and making decisions on overlaps with other guidance

No changes.

Stage 5: checking the population and selected key issues with stakeholders

There is no scoping workshop. Topic-specific committee members may be recruited early, or the experts used during the surveillance review may be asked to provide expertise for the scope.

Stage 6: consulting on the draft scope and Stage 7: finalising the scope after consultation

The consultation and validation period is shorter.

2.5 Amending the final scope after publication on the NICE website

In exceptional circumstances, the final scope may need amending after it has been signed off and posted on the NICE website. For example, amendments may be needed in the light of policy changes, the withdrawal of a medicine, or inclusion of a NICE technology appraisal in development (see the section on related NICE technology appraisal guidance in the chapter on linking to other guidance). The decision on whether to amend the scope is made by a senior member of NICE staff with responsibility for quality assurance, based on advice from the committee or developer as appropriate.

If a final scope is amended after publication, registered stakeholders are informed and the revised scope is published on the NICE website. No further consultation on the scope would usually be expected.

2.6 References and further reading

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3 Decision-making committees

3.1 Introduction

This chapter describes the different types of decision-making committees, the training of committee members, the general principles of committee meetings and how committees make group decisions.

A decision-making committee (either a standing committee or a topic-specific committee) draws on its expertise to develop recommendations in the areas defined by the scope of the guideline. Convening an effective committee is therefore one of the most important stages in producing a NICE guideline. The committee:

- may refine and agree the review questions to be addressed by the evidence reviews (for example, when topic-specific input is needed to further define outcomes or specify appropriate comparators) as defined in the scope
- advises on developing the review protocol and alternative analyses
- considers the evidence
- develops the recommendations for practice and research
- considers the likely costs and savings associated with implementing the recommendations
- considers factors that may help or hinder implementation ('levers and barriers')
- advises on implementation support that may be needed.

Therefore the committee needs to be multidisciplinary and include:

- practitioners, professionals, providers, commissioners and researchers (specialists and generalists from the public, private or voluntary sectors, from other independent providers of care and support, or from services)
- lay members (people using services, family members and carers, and members of the public and community or voluntary sector with relevant experience).

Committee members are selected for their knowledge and experience, and do not represent their

organisation(s). Lay members champion the perspectives of people who use services, carers or the public. They do not have a healthcare, public health or social care professional or practitioner background in the topic. Lay members should be willing to reflect the experiences of a wide range of people affected by the guideline rather than basing their views solely on personal experience. All committee members are independent of NICE.

In most cases, organisations with a direct commercial interest in interventions or services are not represented on the committee because of potential conflicts of interest, but they contribute to guideline development as registered stakeholders. However, there may be situations in which members of such organisations are included to ensure that this perspective is represented. For example, when guidelines are likely to cover systems and processes relevant to the pharmaceutical or medical devices industries, the committee may include members of the Association of the British Pharmaceutical Industry (ABPI). Any conflicts of interests should be managed in accordance with NICE's policy on declaring and managing interests for NICE advisory committees.

The exact composition of the committee is tailored to the guideline topic and is agreed by the developer and NICE staff with a role in guideline quality assurance. Developers should ensure that all committees can comprehensively consider mental health aspects of guideline topics (Royal College of Psychiatrists 2013). Members with expertise in service transformation, change management or implementation science are recruited if needed to support the committee in considering implementation issues throughout guideline development.

For some guideline topics, it may be important for the committee to include other types of expert (for example, an epidemiologist, researcher, statistician or economist with specialist knowledge, or a health inequalities champion). Members with experience of integrating delivery of services across service areas may also be recruited, particularly where the development of a guideline requires more flexibility than conventional organisational boundaries permit. If the guideline contains recommendations about services, committee members with a commissioning or provider background are needed, in addition to members from relevant professional or practitioner networks or local authorities.

When several related guidelines are being developed at the same time by different committees, some committee members may sit on more than one committee, depending on expertise.

As far as possible, the committee should aim for diversity in membership, an objective of NICE's equality scheme. Equality and anti-discrimination considerations are reflected at every stage of recruitment and anonymised data from recruitment is submitted to NICE's corporate office who use this to report to the NICE Board.

Ideally, committee members have experience of the UK healthcare setting and are drawn from different parts of England. But this depends on the expertise available and does not exclude people from other countries in the UK.

All committee members, including practitioner, provider, commissioner and lay members, have equal status, acknowledging the importance of the expertise and experience that each member brings to the committee.

The committee may also be supported by co-opted members who are invited to contribute to formulating recommendations in a specific part of the guideline only. They take part fully in discussions, but do not have voting rights or count towards quorum.

Expert witnesses may also be invited to some committee meetings to provide additional evidence (see the appendix on call for evidence and expert witnesses).

3.2 Forming the committee

The committee can be formed in 2 ways:

- from members of a NICE standing committee, with additional recruitment of topic expert members
- from multidisciplinary recruitment of all committee members (topic-specific committee).

The resulting committee should, as far as practically possible, reflect the range of stakeholders and groups whose activities, services or care will be covered by the guideline. The type of committee chosen is likely to reflect the nature of the work.

For all guidelines covering children and young people and those focusing on people with a learning disability or cognitive impairment, the developer should consider how to involve people affected by the guideline when they begin work on the topic, and should reflect this in its plans. NICE's public involvement programme can advise on options and methods for involving people affected by the guideline. They can target adverts for committee members to specific groups and signpost to sources of specialist advice (see the appendix on approaches to additional consultation and commissioned primary research and the page on the NICE website on involving children and young people in NICE's patient and public involvement policy). They will work with the developer on tailored support where this is needed.

For some topics it may be possible to recruit young people aged 16 to 18 years or people with a

learning disability as members of the committee, or as co-opted members or topic experts. With specialist support and reasonable adjustments, a developer has successfully included people with a learning disability as committee members for NICE guidelines on improving care for this population. This was achieved through specialist support and adjustments to the process to enable their full and equal involvement.

When there are particular reasons why people affected by the guideline cannot be recruited as lay committee members (for example, when the guideline covers children), other approaches are needed to ensure that their views and experiences are incorporated in the recommendations. These might include working with an external agency to obtain user views or consulting with a reference group of people using services, at key stages of guideline development. For example, for the NICE guideline on child abuse and neglect, the developer commissioned the independent charity Against Violence and Abuse (AVA) to recruit and facilitate an expert reference group of young people as a subgroup of the committee (see the appendix on Children and Young People's Expert Reference Group summary report). Another approach could involve a targeted consultation with people affected by the guideline to fine-tune selected draft recommendations (see the section on what happens during consultation in the chapter on the validation process for draft guidelines, and dealing with stakeholder comments and the appendix on approaches to additional consultation and commissioned primary research).

If other approaches to engaging people affected by the guideline are needed, the developer should document the reasons, together with a proposal for the work, including possible methods to be used, and the anticipated costs and time. The proposal should be discussed and agreed with members of NICE staff with a quality assurance role and the public involvement programme, and approved by the centre director. When the work is approved, the reasons for the approach and methods should be documented in the guideline.

All committee members are recruited in accordance with NICE's appointment to advisory bodies policy and procedure. Positions are advertised on the NICE website and other appropriate places (for example, NICE Twitter, social media and websites of stakeholders, Royal Colleges and professional organisations), and relevant stakeholders are notified. Candidates are required to submit a declaration of interest, curriculum vitae (CV) and covering letter, or application form in the case of lay members. They are encouraged to complete an equality monitoring form.

The committee chair

The chair guides the committee in terms of task (developing the guideline, focusing on any referral, the scope and timescale) and process (how the group works). The chair helps the committee to

work collaboratively, ensures a balanced contribution from all committee members, and is mindful that some members may need support to ensure full participation.

The chair is appointed for their expertise and skill in chairing groups, and although they may have some knowledge of the topic, this is not their primary role in the group. Specialist knowledge is provided by other committee members, including in many cases a topic adviser (see the section on topic-specific committees).

The chair ensures adherence to NICE's equality scheme and that the committee takes account of NICE's principles. The chair and a senior member of the developer's team consider any potential conflicts of interest of committee members. The chair also ensures that the guideline recommendations reflect the evidence and the committee's considerations. The chair should ideally be appointed before guideline scoping and may contribute to early development of the scope. NICE has some chairs who may be appointed to chair more than 1 topic-specific committee (see the section on topic-specific committees). More details on the role of the chair can be found in the appendix on guideline committee Terms of Reference and Standing Orders.

3.3 Standing committees

NICE has multiple standing committees in operation at any one time. Some guideline topics are allocated to a standing committee before scoping.

Standing committees usually include between 12 and 18 members (both practitioner and lay members). The size of the committee depends on the complexity and breadth of the guideline. Some members are generalists (core members) and some have specialist expertise (topic expert members). Each standing committee consists of:

- a chair
- core members
- topic expert members.

Additional members with specialist knowledge may also be co-opted to the committee for 1 or more meetings to contribute to formulating recommendations in a specific part of the guideline.

More details on the role of committee members can be found in the appendix on guideline committee Terms of Reference and Standing Orders.

Core members of standing committees

The number of core members of a standing committee depends on the complexity and breadth of the guideline programme, but is usually between 6 and 12. This number allows members to contribute effectively to discussions while including a broad range of experience and knowledge. Core members should include at least 1 practitioner member.

Some core members will have experience of commissioning or implementing interventions, services or care at regional and local levels. Others will have specific expertise in assessing the quality of the evidence presented to the committee, and in its interpretation.

Core members should include at least 1 lay member. Lay members help ensure that the committee's recommendations are relevant to specific groups or to the general public. They also help to identify where the recommendations should acknowledge general or specific preferences and choice by people using services, family members and carers, or members of the wider public.

Core members of a standing committee are appointed to a single committee for a 3-year term in the first instance. All members are eligible for re-appointment after 3 years.

Topic expert members of standing committees

When a new guideline is allocated to a standing committee, the core members of the committee are complemented by topic expert members. They have specialist knowledge of the topic and may include providers, commissioners and practitioners, and should include at least 1 lay member. The lay member either has direct experience of the topic or is a member of a relevant organisation or support group. The number of topic expert members varies but should be no more than half of the total number of committee members.

Topic expert members are usually recruited for a specific guideline, but may be appointed for up to 3 years, at the discretion of NICE, so that they can work on subsequent related guidelines. This might mean they move between standing committees during their term, depending on the guidelines being produced. All members are eligible for reappointment after 3 years.

The process of appointing topic expert members is completed at least 6 weeks before the first committee meeting for the guideline and takes into account the final scope of the guideline. Topic expert members are full members of the committee, with voting rights. They join in discussions, contribute to formulating recommendations and count towards the quorum.

3.4 Topic-specific committees

The chair and members of a topic-specific committee are appointed for the development of a particular guideline or for up to 3 years to work on multiple guidelines within a broad topic area, with membership subject to renewal for a total period of up to 10 years. Chairs may also be appointed to chair more than 1 topic-specific committee. The chair, the topic adviser (if there is one) and possibly 1 or 2 other committee members are likely to be appointed before guideline scoping and contribute to the development of the scope (see the chapter on the scope).

The final composition of a topic-specific committee is agreed by the developer and NICE staff with a role in guideline quality assurance and takes into account the final scope for the guideline. The committee usually comprises between 13 and 15 members. This number allows members to contribute effectively to discussions while including a broad range of experience and knowledge. Occasionally when the topic is very broad, a larger committee may be convened. A topic-specific committee is made up of:

- a chair
- a topic adviser (not all topic-specific committees have topic advisers)
- practitioner and professional members, providers and commissioners
- at least 2 lay members (people using services, family members and carers, and members of the public, community or voluntary sector with relevant experience); examples of topics where there may be more than 2 lay members include topics where personalisation and choice are particularly important, where a scope is large and covers different areas, and topics covering all age groups.

Additional members with specialist knowledge may also be co-opted to the committee for 1 or more meetings to contribute to formulating recommendations in a specific part of the guideline.

The topic adviser of a topic-specific committee

A topic adviser with specialist knowledge may be appointed to a topic-specific committee (for example, when the committee chair does not have topic expertise). The topic adviser is a member of the committee but also supports the developer. The topic adviser contributes to the development of the scope (see the chapter on the scope) and is therefore appointed before scoping work starts.

The topic adviser's exact responsibilities depend on the guideline and the expert input needed. Responsibilities may include working with the systematic reviewer on the evidence reviews (if

topic-specific knowledge is needed), or checking the guideline to ensure that the terminology and language are correct.

Practitioner and professional members of topic-specific committees

Practitioner and professional members of a topic-specific committee may be recruited before the scope is finalised (see the section on stages of scope development in the chapter on the scope). They should reflect the views and experiences of practitioners, professionals, providers and commissioners working in the area covered by the guideline.

Practitioner and professional committee members have appropriate knowledge and skills; detailed research expertise is not necessary, although an understanding of evidence-based practice is essential and some experience of service transformation or delivering integrated services across boundaries is desirable. Practitioner and professional members contribute their own views to the committee and do not represent the views of their professional organisations.

A topic-specific committee usually includes between 9 and 11 practitioner or professional members (occasionally when the topic is very broad, more members may be recruited). The spread of interest and experience of practitioner and professional members is agreed between the developer and members of NICE staff with responsibility for guideline quality assurance.

Lay members of topic-specific committees

All committees have at least 2 lay members with experience or knowledge of issues that are important to people using services, family members and carers, and the community affected by the guideline. This helps to ensure that the guideline is relevant to people affected by the recommendations and acknowledges general or specific preferences and choice.

Lay members usually have direct experience of the condition, services or topic being covered by the guideline – as a patient, person using services, carer or family member, or as a member or an officer of a lay stakeholder organisation or support group. However, they do not represent the views of any particular organisation.

When appropriate, lay members may be recruited before the scope is finalised (see the section on stages of scope development in the chapter on the scope).

3.5 Other attendees at committee meetings

Expert witnesses

If the committee does not have sufficient evidence to make recommendations in a particular area (for example, if there are gaps in the evidence base or subgroups are under-represented), it may call on external experts (expert witnesses) who can provide additional evidence from their experience and specific expertise, to help the committee to consider and interpret the evidence.

Once the committee has established that it needs evidence in a particular area from an expert witness, committee members and NICE's public involvement programme are asked by the developer to nominate experts who might fulfil this role. Expert witnesses may also be identified by the developer or NICE staff with a quality assurance role, or if required, by active recruitment through stakeholder organisations and the NICE website. Experts may be drawn from a wide range of areas as appropriate, including government and policy, research, practice, people using services and carers or the community and voluntary sector.

Before seeking expert testimony from children or other vulnerable groups, expert advice should be sought about the ethics and implications of the involvement. Adjustments and additional support may be needed, such as giving testimony via video recording, or in private session. There is no minimum age for young people providing expert testimony. If a child or young person attends a committee meeting, they must be accompanied by their parent, carer or other appropriate adult with responsibility for their welfare (see appendix 1 on children, young people and safeguarding in NICE's patient and public involvement policy).

Expert witnesses attending a committee meeting are invited to answer questions from members of the committee. They may be invited to present their evidence at a committee meeting in the form of expert testimony based on a written paper. The written expert testimony paper may be shared with the committee before the meeting or the paper may be submitted by the expert after the meeting. Sometimes the developer writes up the expert testimony and agrees this with the witness after the meeting. Expert testimony papers are posted on the NICE website with other sources of evidence when the guideline is published.

Expert witnesses are not members of the committee; they do not have voting rights, and they should not be involved in the final decisions or influence the wording of recommendations.

Committee support roles

The committee is assisted by a range of people, who have a role in:

- quality assurance
- development
- support.

These are technical and project management staff from the developer or NICE staff with a quality assurance role. Other NICE staff (such as editors and members of the NICE resource impact assessment team) also attend some meetings. They are not committee members and do not have voting rights at committee meetings.

Public access to meetings

Enabling public access to NICE advisory body meetings is part of NICE's commitment to openness and transparency. It enables stakeholders and the public to better understand how evidence is assessed and interpreted, how consultation comments are taken into account and how recommendations are formulated. Public access to all guideline committee meetings is not possible because of financial pressures. In addition, all or part of a meeting may need to be held in closed session because expert evidence involves the disclosure of a person's health problems, or the consideration of national policy that has not been agreed by ministers, or the drafting of recommendations might affect commercial interests.

Standing committee meetings are usually held in public; topic-specific committee meetings are held in private. Public access to standing committee meetings is arranged according to the NICE policy (see the appendix on guideline committee Terms of Reference and Standing Orders).

To promote public access to standing committee meetings, NICE publishes a notice with a draft agenda, alongside details of how the meeting can be accessed, on its website in advance of the meeting.

Standing committee meetings may be held entirely in public or split into 2 parts: part 1 with the public having access, and part 2 a closed session with no public access. On rare occasions a standing committee meeting may be entirely closed. The decision to hold a closed session is made by the committee chair and the NICE centre director responsible for the guideline.

3.6 Code of conduct and declaration of interests

Declaring interests

All committee members, including the chair, and anyone who has direct input into the guideline

(including the developer and expert witnesses) must declare any potential conflicts of interest in line with NICE's policy on declaring and managing interests for NICE advisory committees. For committee members, including the chair, this happens on application for committee membership. Any relevant interests, or changes to interests, should also be declared publicly at the start of each committee meeting. Before each meeting, any potential conflicts of interest are considered by the committee chair and a senior member of the developer's team. Any decisions to exclude a person from all or part of a meeting should be documented. Any changes to a member's declaration of interests should be recorded in the minutes of the meeting. Declarations of interests are recorded in a register for each guideline and are published on NICE's website.

Code of conduct and confidentiality

NICE has developed a code of conduct for committee members (see the appendix on code of conduct for committee members), which sets out the responsibilities of NICE and the committee, and the principles of transparency and confidentiality.

Everyone who sees documents containing confidential information or who is party to part 2 (closed session) discussions about a guideline before public consultation must sign a confidentiality agreement before becoming involved.

If committee members are asked by external parties – including stakeholders, their professional organisation or the media – to provide information about the work of the committee, they should contact the developer for advice.

Terms of Reference for committees

Details of the role of committee members, and the procedural rules for managing the work of committees, can be found in the appendix on guideline committee Terms of Reference and Standing Orders.

All committee members should be committed to developing NICE guidelines according to NICE's methods and processes, and to working within NICE's equality scheme.

New members, with the exception of co-opted members, should not usually be added to the committee after the first meeting, because this may disturb the group dynamic. However, when a resignation leaves a gap in experience and expertise, recruitment of new members is considered.

3.7 Identifying and meeting training needs of

committee members

Induction

All committee members, including topic expert members and co-opted members, receive an induction from NICE or the developer covering:

- key principles for developing NICE guidelines
- the process of developing NICE guidelines, including the importance of being familiar with relevant chapters of this manual
- how the elements of the guideline development process fit together, and the relationship to quality standards and products supporting implementation
- the role of the committee, including Terms of Reference and Standing Orders, and how lay members contribute
- the role of the developer and NICE teams
- formulating review questions
- reviewing evidence
- the basics of how economics methods are used in decision-making
- developing and wording recommendations
- how guidelines are presented on the NICE website
- information about resource impact and how this is considered alongside the economic evidence
- information about implementation
- NICE's principles and equality scheme
- declaration of interests.

The induction may be scheduled on appointment of the member, or during an early committee meeting. To work effectively, committee members may need training and support in some technical areas of guideline development, such as systematic reviewing and economics. Such sessions are arranged by NICE or the developer, as required. Before beginning their work in a committee,

members may also be invited to observe a meeting of another committee.

All committee members are encouraged to provide information to NICE staff about any needs they have for additional support to enable them to participate fully in the work of the committee.

Training for the committee chair

The person selected to perform the role of committee chair may need support and training so that they can carry out their role effectively. The chair needs in-depth knowledge of the NICE guideline development process and an understanding of group processes. Anyone appointed as a committee chair is required to attend the chairs' induction session provided by NICE, which in addition to the above covers the key tasks that the chair is expected to perform, including:

- facilitating meetings so that all committee members are involved
- ensuring that lay members of the committee can contribute to discussions
- ensuring that people requiring adjustments who are members (including topic expert, co-opted or lay members) can contribute to discussions
- declaring interests and dealing with conflicts of interest
- planning and organising the work of the committee, including how the evidence is considered, consensus approaches and developing recommendations.

In addition to the specific induction session, the developer should identify and meet any additional training needs of a committee chair. The developer may consider a 'buddying' approach in which a new committee chair learns from someone with previous experience.

Training for lay members

Lay members of the committee are offered support and training by NICE's public involvement programme. This is in addition to the induction and any training they receive alongside other members of the committee, and allows specific questions and needs to be addressed. The training advises lay members about effective participation in guideline development and gives them the opportunity to learn from people who have had a lay role on previous committees. Public involvement advisers also offer ongoing support tailored to a lay member's needs.

3.8 Committee meetings

General principles

The committee is multidisciplinary and its members bring with them different beliefs, values and experience. All these perspectives are valued by NICE and should be considered. Each member should have an equal opportunity to contribute to the development of the guideline, and should receive any additional support they need to do this. For this reason, it is important for the chair to check that the terminology used is understood by all committee members and is clarified if needed. The chair should ensure that there is sufficient discussion to allow a range of possible approaches to be considered, while keeping the group focused on the guideline scope, the evidence being reviewed, and the timescale of the project.

Meeting documentation

Meeting documentation is usually sent to committee members to arrive at least 5 working days before a committee meeting.

The developer takes formal minutes during committee meetings and these are reviewed and approved at the next meeting. The approved minutes of each meeting are posted on the NICE website during guideline development. The information includes:

- where the meeting took place
- who attended
- apologies for absence
- declarations of interests of those attending, including actions and decisions made about any conflicts of interest
- a list of the subjects discussed
- date, time and venue of the next meeting.

Meeting schedule

The number of committee meetings depends on the size and scope of the topic. There are usually between 2 and 15 meetings for each topic; most are 1-day meetings, but some may take place over 2 days.

Initial meetings

During the initial meeting(s), it may be helpful to establish a framework that clarifies the objectives of the committee, the specific tasks that need to be carried out and the timetable. This allows the group to focus on the task and to develop a working relationship that is structured and well defined.

Initial meetings may be used to consider the background to the guideline, the scope, and review protocols for the evidence reviews and any economic analysis that is needed. Drafts or completed evidence reviews may be included in initial meetings if they are available. At initial meetings of standing committees, topic expert members may be invited to give presentations on their area of work, practice or experience, to familiarise core committee members with key topic issues.

If review questions and protocols are still in development, the developer evidence review team will draft the review protocols and present them to the committee for comment (the chapter on developing review questions and planning the evidence review describes the process of developing review questions). The committee is asked whether the draft review protocols and economic analysis are likely to answer the review questions. Committee members are asked to suggest any amendments or improvements (for example, to further define outcomes or specify appropriate comparators).

During initial meetings, the committee may also be asked to discuss the development plans and to suggest areas that might benefit from expert testimony. The committee may be asked to suggest people who can provide that testimony and discuss and consider evidence. They will also be asked if they are aware of any health inequalities or equity issues.

For some topics, the committee may also be asked to discuss options or plans for involving groups who may not be part of the decision-making process (for example, children and young people or people with a cognitive impairment; see the section on forming the committee).

Development meetings

Evidence reviews and economic analyses are presented to the committee over the course of a defined number of meetings. The committee considers the evidence review for each review question, any economic analyses and any additional evidence (for example, expert testimony, views of people using services from a reference group, information from focus groups or other exceptional consultation activity). It discusses how these answer the review questions and summarises each area of evidence. To facilitate guideline development, the committee may work in smaller subgroups whose proposals are then considered by the whole committee.

The committee also discusses the wording of any draft recommendations (see the chapter on writing the guideline). The discussions and rationales for the recommendations are recorded.

NICE staff (for example, the lead editor, public involvement lead and media relations lead for the guideline and members of the resource impact assessment team) may give presentations and/or provide information to explain their roles to the committee. Committee members may be asked to volunteer to work with NICE on the following:

- activities and tools that support implementation of the guideline (see the chapter on resources to support putting the guideline into practice)
- promoting the guideline (see the chapter on finalising and publishing the guideline).
- developing content for the information for the public section on the topic webpage, including the guideline's key messages.

Final meetings

Towards the end of guideline development, the committee discusses and agrees the final wording of the draft guideline for consultation, including the draft recommendations (see the chapter on writing the guideline).

After consultation the committee discusses the comments received during consultation, any changes needed to the guideline, and agrees the final wording of the recommendations (see the chapter on finalising and publishing the guideline).

Record-keeping

The developer should maintain records throughout guideline development and ensure that record-keeping standards are appropriate for audit. The following information should be readily available if requested by NICE staff with a quality assurance role:

- details of the committee members, including declarations of interest
- details of the search strategies, including when the most recent searches were conducted
- details of the draft recommendations and the rationales for the recommendations
- details of the included and excluded studies and associated review protocols
- data-extraction forms

- draft evidence reviews with evidence tables
- details of the economic analysis, including any working models
- minutes of committee meetings
- any additional information presented to the committee (for example, expert testimony papers, presentations, examples of practice).

3.9 Making group decisions and reaching consensus

Reaching agreement

Committee members need to make collective decisions throughout guideline development. This can include agreeing the review questions (see the chapter on developing review questions and planning the evidence review) and protocols (see the section on planning the evidence review in the chapter on developing review questions and planning the evidence review), interpreting the evidence to answer these questions (see the chapters on reviewing research evidence and incorporating economic evaluation) and developing recommendations (see the chapter on writing the guideline).

There are many different approaches to making group decisions, and there are no rules that set out which approach should be used in which circumstances. Also, because committees work in different ways to reflect their individual membership, it is difficult to be prescriptive about the approach that should be used. In most cases, the committee reaches decisions through a process of informal consensus. In all cases the approach used should be documented.

The role of the committee chair in reaching consensus is to ensure that:

- everyone on the committee, including lay members, can present their views
- assumptions can be debated
- discussions are open and constructive.

The chair needs to allow sufficient time for all committee members to express their views without feeling intimidated or threatened, and should check that all of them agree to endorse any recommendations. If the committee cannot come to consensus in a particular area, the reasons for this should be documented, and the wording of the recommendation reflect any underlying uncertainty (see the chapter on writing the guideline).

Formal consensus within the group

In exceptional circumstances, some committees may choose to use formal voting procedures or formal consensus methods for certain decisions (for example, when members disagree or when there is no evidence; see the appendix on guideline committee Terms of Reference and Standing Orders). NICE does not offer advice on which of the many methods might be used. However, the methods for achieving consensus should be recorded in the minutes of the meeting and a clear statement made about the factors that have been considered. This should also be documented in the guideline methods, ensuring the process is as transparent as possible.

The views of all committee members should be considered, irrespective of the method used to reach consensus.

Formal consensus outside the group

In certain cases, for example, if the literature search has found no evidence that addresses the review question, the committee may wish to identify wider views on best practice by using formal consensus methods (such as the Delphi technique or the nominal-group technique) outside of the group. The use of these methods and the constituency of the wider group should be discussed on a case-by-case basis with members of NICE staff with responsibility for guideline quality assurance, and the NICE public involvement programme lead. The final decision on whether these methods are warranted is made by NICE staff with responsibility for quality assurance. If it is decided that such methods may be used, the planning and methods will be clearly documented and the methods described in the guideline. In all cases the approach used should be documented.

3.10 Further contributions of committee members

Some committee members may be invited to apply to join the Quality Standards Advisory Committee that is developing a quality standard related to the guideline. Some members may also be invited to contribute to a future review of the guideline and a check of the need for an update.

3.11 References and further reading

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4 Developing review questions and planning the evidence review

At the start of guideline development, the key issues and draft questions listed in the scope should be translated into review questions and review protocols.

Review questions and review protocols define the scope of the review and therefore must be clear and focused. They provide the framework for the design of the literature searches, inform the planning, methods and process of the evidence review, and act as a guide for the development of recommendations by the committee.

This chapter describes how review questions are developed and agreed. It describes the different types of review question and provides examples. It also provides information on the different types of evidence and how to plan the evidence review. The best approach may vary depending on the topic. Options should be considered by the developer, and the chosen approach discussed and agreed with NICE staff with responsibility for quality assurance. The approach should be documented in the review protocol (see the appendix on review protocol template) and the guideline, together with the reasons for the choice.

4.1 Number of review questions

The number of review questions for each guideline depends on the topic and the breadth of the scope. However, it is important that the total number of review questions:

- provides sufficient focus for the guideline, and covers all key areas outlined in the scope
- can be completed in the time and with the resources available.

Review questions can vary considerably in terms of both the number of included studies and the complexity of the question and analyses. For example, a single review question might involve a complex comparison of several interventions, in a number of population subgroups, across multiple outcomes, and including many studies that are using different study designs (including systematic reviews). At the other extreme, a review question might investigate the effects of a single intervention compared with a single comparator and there may be few primary studies or no study meeting the inclusion criteria. The number of review questions for each guideline, and how much time and resources are needed for them, will therefore vary depending on the topic and its complexity.

4.2 Developing review questions from the scope

The review questions should cover all key areas specified in the scope but should not introduce new areas. They should build on the draft questions in the scope and usually contain more detail.

Review questions are usually drafted by the developer. They are then refined and agreed with the committee members. This enables the literature search to be planned efficiently. Sometimes the questions need refining before the development of review protocols, or very occasionally after the evidence has been searched. Any such changes to review questions (with reasons) should be agreed with a member of NICE staff with a quality assurance role. All changes should be clearly documented in the review protocol and evidence review, so it is auditable.

4.3 Formulating and structuring different review questions

Review questions should be clear and focused. The exact structure of each question depends on what is being asked. The aims of questions will differ, but are likely to cover at least one of the following:

- extent and nature of the issue as described in the scope
- associations between factors or variables and the outcome of interest, the epidemiology or aetiology of a disease or condition
- interventions that work best in ideal circumstances and might work in specific circumstances or settings (the extent to which something works, how and why)
- technologies or tests that work best to diagnose certain diseases or conditions
- a relevant programme theory, theory of change, or mechanisms of action likely to explain behaviour or effects
- views and experiences of people using services or affected by the recommendation (for example, the acceptability and accessibility of interventions, or people's values and preferences).
- practitioners', providers' or commissioners' views, experiences and working practices (including any factors hindering the implementation of the intervention and factors supporting implementation)

- potential for an intervention to do harm or have unintended consequences.

Conceptual frameworks or logic models can be useful when developing review questions.

When developing review questions, it is important to consider what information is needed for any planned economic modelling. This might include information about quality of life, rates of, and inequalities in, adverse effects and use of health and social care services. The nature and type of review questions determines the type of evidence that is most suitable (Petticrew and Roberts 2003). There are examples of different types of review questions and the type of evidence that might best address them throughout this chapter. Developers should consider whether particular review questions might be addressed through analysis of primary data, based on an understanding of the evidence base (and possible limitations) and different sources available (see the section on stages of scope development in the chapter on the scope).

Review questions about the effectiveness of an intervention

A helpful structured approach for developing questions about interventions is the PICO (population, intervention, comparator and outcome) framework (see box 4.1). The setting for the question should also be specified if relevant.

However, other frameworks exist (such as SPICE; setting, perspective, intervention, comparison, evaluation) and can be used as appropriate.

Box 4.1 Formulating a review question on the effectiveness of an intervention using the PICO framework

Population: Which population are we interested in? How best can it be described? Are there subgroups that need to be considered?

Intervention: Which intervention, treatment or approach should be examined?

Comparators: Are there alternatives to the intervention being examined? If so, what are these (for example, other interventions, standard active comparators, usual care or placebo)?

Outcome: Which outcomes should be considered to assess how well the intervention is working (including outcomes on both benefits and harms)? What is really important for people using services? Core outcome sets should be used if suitable based on quality and validity; one source is the COMET database. The Core Outcome Set Standards for Development (COS STAD) and Core Outcome Set Standards for Reporting (COS STAR) should be used to assess the suitability of identified core outcome sets.

For each review question, factors that may affect the outcomes and effectiveness of an intervention, including any wider social factors that may affect health and any health inequalities, should be considered. Outcomes (on both benefits and harms) and other factors that are important should be specified in the review protocol. In general, a range of 5 to 9 outcomes should be defined. Guidance on prioritising outcomes is provided by the GRADE working group.

Box 4.2 Examples of review questions on the effectiveness of interventions

- What types of mass-media intervention help prevent children and young people from taking up smoking? Are the interventions delaying rather than preventing the onset of smoking?
- Which of the harm-reduction services offered by needle and syringe programmes (including advice and information on safer injecting, onsite vaccination services, and testing for hepatitis B and C and HIV) are effective in reducing blood-borne viruses and other infections among people who inject drugs?
- What types of intervention and programme are effective in increasing physical activity levels among children under 8 - particularly those who are not active enough to meet the national recommendations for their age - or help to improve their core physical skills?
- Does brief advice from GPs increase adult patients' physical activity levels?
- What are the most effective school-based interventions for changing young people's attitudes to alcohol use?
- For people with IBS (irritable bowel syndrome), are antimuscarinics or smooth muscle relaxants effective compared with placebo or no treatment for the long-term control of IBS symptoms? Which is the most effective antispasmodic?
- Which first-line opioid maintenance treatments are effective and cost effective in relieving pain in patients with advanced and progressive disease who require strong opioids?
- What are the most effective methods of care planning, focusing on improving outcomes for people with dementia and their carers?
- What is the effectiveness and cost effectiveness of intermediate care and reablement for people living with dementia?

Review questions about pharmacological management will usually only include medicines with a UK marketing authorisation for some indication, based on regulatory assessment of safety and efficacy. Use of a medicine outside its licensed indication (off-label use) may be considered in some circumstances; for example, if this use is common practice in the UK, if there is good evidence for this use, and there is no other medicine licensed for the indication (see also the section on recommendations on medicines, including off-label use of licensed medicines). Medicines with no UK marketing authorisation for any indication will not usually be considered in a guideline because there is no UK assessment of safety and efficacy to support their use.

A review question about the effectiveness of an intervention is usually best answered by a randomised controlled trial (RCT), because a well-conducted RCT is most likely to give an unbiased estimate of effects. However, RCT evidence on the effectiveness of an intervention may not always be available. In addition, for many health and social care interventions it can be difficult or unethical to assign populations to control and intervention groups (for example, for interventions which aim to change policy). In such cases, other study designs (such as non-randomised studies) might be appropriate for assessing association, possible cause and effect, or longer-term outcome data. There are also some reviews that may include analysis of large, high-quality primary data sources (such as patient registries). The Medical Research Council (MRC) has produced guidance on evaluating complex interventions and using natural experiments to evaluate health interventions delivered at population level. Advice on finding data on the adverse effects of an intervention is also available in the Cochrane handbook for systematic reviews of interventions and the SuRe Info (Summarized Research in Information Retrieval for HTA) resource.

There are also circumstances in which non-RCT evidence could be used to establish the benefits and harms of an intervention. For example, the impact or effectiveness of a nationally implemented policy (such as the ban on smoking in enclosed public places and workplaces) may be more appropriately addressed by a natural experiment or interrupted time series study. Non-RCT evidence may also be useful to establish the benefits and harms of interventions if:

- there are long-term adverse outcomes (cohort or longitudinal studies could be used)
- the intervention gives a large benefit or shows a clear dose–response gradient that is unlikely to be a result of bias (a very large cohort study could demonstrate this)
- there is a convincing mechanism of action (such as a pathophysiological basis) for the intervention.

When review questions are about the effectiveness of interventions, additional types of evidence may be needed to answer different aspects of the question. For example, additional evidence might

address the views of people using services or the communities where services are based, or barriers to use as reported by practitioners or providers. In this case 2 related review questions (a quantitative intervention review question and a qualitative review question) may be used to address the issues. Sometimes a single review may be suitable, if it uses different sources of evidence or types of data (for example, a review may combine current practice or map or integrate quantitative information with qualitative data [that is, a mixed methods review]). A review on effectiveness may also include evidence of the intervention's mechanism of action, that is, evidence of how the intervention works. All these examples of questions about the effectiveness of interventions may be addressed by 2 related review questions or by a mixed methods review.

Box 4.3 Examples of mixed methods reviews

For further guidance and examples of mixed methods reviews, see chapter 8 of the JBI Manual for Evidence Synthesis.

What is the clinical effectiveness of larvae therapy for wound healing, and what do patients perceive the acceptability of larvae therapy to be?

What is the clinical effectiveness of self-management in adolescents with asthma, and what factors are perceived by them as important to maintain adherence to their self-management plan?

What is the effectiveness of integrated working among registered social workers and other practitioners to support adults with complex needs, and based on their views and experiences what are the barriers to integrated working?

Review questions that consider implementation

Review questions on effectiveness may also consider implementation, for example, 'What systems and processes should be in place to increase shared decision-making?'

Review questions that consider cost effectiveness

For more information on review questions that consider cost effectiveness, see the chapter on incorporating economic evaluation.

Review questions about the accuracy of diagnostic tests

Review questions about diagnosis are concerned with the performance of a diagnostic test or test

strategy. Diagnostic tests can include identification tools, physical examination, signs and symptoms, history-taking, laboratory or pathological examination and imaging tests.

Broadly, review questions that can be asked about a diagnostic test are of 2 types:

- questions about the diagnostic accuracy (or diagnostic yield) of a test or a number of tests individually against a comparator (the reference standard)
- questions about the diagnostic accuracy (or diagnostic yield) of a test strategy (such as serial testing) against a comparator (the reference standard).

In studies of the accuracy of a diagnostic test, the results of the test under study (the index test) are compared with those of the best available test (the reference standard). It is important to be clear when deciding on the question what the exact proposed use of the test is (for example, as an identification tool, an initial 'triage' test or after other tests).

The PICTO (population, index test, comparator, target condition and outcome) framework can be useful when formulating review questions about diagnostic test accuracy (see box 4.4). However other frameworks (such as PPIRT; population, prior tests, index test, reference standard, target condition) can be used if helpful.

Box 4.4 Features of a well-formulated review question on diagnostic test accuracy using the PICTO framework

Population: To which populations would the test be applicable? How can they be best described? Are there subgroups that need to be considered?

Index test: The test or test strategy being evaluated for accuracy.

Comparator/reference standard: The test with which the index test is being compared, usually the reference standard (the test that is considered to be the best available method for identifying the presence or absence of the condition of interest – this may not be the one that is routinely used in practice).

Target condition: The disease, disease stage or subtype of disease that the index test(s) and the reference standard are being used to identify.

Outcome: The diagnostic accuracy of the test or test strategy for detecting the target condition. This is usually reported as test parameters, such as sensitivity, specificity, predictive values, likelihood ratios, or – when multiple thresholds are used – a receiver operating characteristic (ROC) curve. This should also include issues of importance to people having the test, such as acceptability.

A review question about diagnostic test accuracy is usually best answered by a cross-sectional study in which both the index test and the reference standard are performed on the same sample of people. Cohort and case–control studies are also used to assess the accuracy of diagnostic tests, but these types of study design are more prone to bias (and often result in inflated estimates of diagnostic test accuracy). Further advice on the types of study to include in reviews of diagnostic test accuracy can be found in the Cochrane handbook for diagnostic test accuracy reviews.

Box 4.5 Examples of review questions on diagnostic test accuracy

What is the accuracy of imaging (MRI, CT scan, PET scan, X ray, ultrasonography) for diagnosing osteomyelitis compared with invasive bone biopsy?

What is the accuracy of D dimer assay for diagnosing deep vein thrombosis compared with compression ultrasonography?

In people suspected of having coronary artery disease, can multi-slice spiral CT of coronary arteries be used as replacement for conventional invasive coronary angiography?

In patients suspected of cow's milk allergy, should skin prick tests rather than an oral food challenge with cow's milk be used for diagnosis and management?

In adults receiving care in non-specialist settings, should serum or plasma cystatin C rather than serum creatinine concentration be used for diagnosing and managing renal impairment?

Although assessing test accuracy is important for establishing the usefulness of a diagnostic test, the value of a test lies in how useful it is in guiding treatment decisions or the provision of services, and ultimately in improving outcomes. 'Test and treat' studies, for example, compare outcomes for people who have a new diagnostic test (in combination with a management strategy) with outcomes of people who have the usual diagnostic test and management strategy. These types of study are not very common. If there is a trade-off between costs, benefits and harms of the tests, a decision-analytic model may be useful (see Lord et al. 2006).

Review questions aimed at establishing the value of a diagnostic test in practice can be structured in a similar way as questions about interventions. The best study design is test-and-treat RCT. Review questions about the safety of a diagnostic test should be structured in the same way as questions about the safety of interventions.

Review questions about prognosis

Prognosis describes the likelihood of a particular outcome, such as disease progression, the development of higher levels of need, or length of survival after diagnosis or for a person with a particular set of risk markers. A prognosis is based on the characteristics of the person or user of services ('prognostic factors'). These prognostic factors may be disease specific (such as the presence or absence of a particular disease feature) or demographic (such as age or sex). They may also include the likely response to treatment or care and the presence of comorbidities. A prognostic factor does not need to be the cause of the outcome, but should be associated with (in

other words, predictive of) that outcome.

Information about prognosis can be used within guidelines to:

- classify people into risk categories (for example, cardiovascular risk or level of need) so that different interventions or preventative strategies can be applied
- define subgroups of populations that may respond differently to interventions
- identify factors that can be used to adjust for case mix (for example, in investigations of heterogeneity)
- help determine longer-term outcomes not captured within the timeframe of a trial (for example, for use in an economic model).

Review questions about prognosis address the likelihood of an outcome for a person or user of services from a population at risk for that outcome, based on the presence of a proposed prognostic factor.

Review questions about prognosis may be closely related to questions about aetiology (cause of a disease or need) if the outcome is viewed as the development of the disease or need based on a number of risk factors.

Box 4.6 Examples of review questions on prognosis

> Are there factors related to the individual (characteristics either of the individual or of the act of self-harm) that may predict outcomes (including suicide, non-fatal repetition, other psychosocial outcomes) from self-harm?
>
> Which people having neoadjuvant chemotherapy or chemoradiotherapy for rectal cancer do not need surgery?

A review question about prognosis is best answered using a prospective cohort study with multivariate analysis. Case-control studies and cross-sectional studies are not usually suitable for answering questions about prognosis because they do not estimate baseline risk, but give only an estimate of the likelihood of the outcome for people with and without the prognostic factor.

Review questions about predicting an individual prognosis or identifying an individual diagnosis

In some circumstances, advanced statistical analyses can be used to develop prediction models for a specific diagnosis or prognosis. These models are usually developed using multivariable modelling methods. Multivariable prediction models are developed to help healthcare professionals estimate the probability or risk that a specific disease or condition is present (diagnostic prediction models) or that a specific event will occur in the future (prognostic prediction models). These models are used to inform decision-making. They are usually developed using a multivariable model – a mathematical equation that relates multiple predictors for a particular person to the probability of or risk for the presence (diagnosis) or future occurrence (prognosis) of a particular outcome. Other names for a prediction model include risk prediction model, predictive model, prognostic (or prediction) index or rule, and risk score.

Diagnostic prediction models can be used to inform who should be referred for further testing, whether treatment should be started directly, or to reassure patients that a serious cause for their symptoms is unlikely. Prognostic prediction models can be used for planning lifestyle or treatment decisions based on the risk for developing a particular outcome or state of health in a given period.

Prediction model studies can be broadly categorised into those that develop models, those that validate models (with or without updating the model) and those that do both. Studies that report model development aim to derive a prediction model by selecting the relevant predictors and combining them statistically into a multivariable model. Logistic and Cox regression are most frequently used for short-term (for example, disease absent versus present, 30-day mortality) outcomes and long-term (for example, 10-year risk) categorical outcomes, respectively. Studies may also focus on quantifying how much value a specific predictor (for example, a new predictor) adds to the model.

Quantifying the predictive ability of a model using the same data from which the model was developed (often referred to as apparent performance) tends to overestimate performance. Studies reporting the development of new prediction models should always include some form of validation to quantify any optimism in the predictive performance (for example, calibration and discrimination). There are 2 types of validation: internal validation and external validation. Internal validation uses only the original study sample with methods such as bootstrapping or cross-validation. External validation evaluates the performance of the model with data not used for model development. The data may be collected by the same investigators or other independent investigators, typically using the same predictor and outcome definitions and measurements, but sampled from a later period (temporal or narrow validation). If validation indicates poor

performance, the model can be updated or adjusted on the basis of the validation data set. For more information on validating prediction models, see Steyerberg et al. 2001, 2003, 2009; Moons et al. 2012; Altman et al. 2009; and Justice et al. 1999.

Well-known prediction models include QCancer, GerdQ, Ottawa Ankle Rules, and the Alvarado Score for diagnosis; and for prognosis, QRISK2, QFracture, FRAX, EuroScore, Nottingham Prognostic Index, the Framingham Risk Score and the Simplified Acute Physiology Score.

For more information, see the TRIPOD statement in the Annals of Internal Medicine and the TRIPOD statement: explanation and elaboration in the Annals of Internal Medicine.

Although assessing predictive accuracy is important for establishing the usefulness of a prediction model, the value of a prediction model lies in how useful it is in guiding treatment or management decisions, or the provision of services, and ultimately in improving outcomes. Review questions aimed at establishing the value of a prediction model in practice, for example, to compare outcomes of people who were identified from a prediction model (in combination with a management strategy) with outcomes of people who were identified opportunistically (in combination with a management strategy) can be structured in the same way as questions about interventions.

Box 4.7 Examples of review questions on prediction models

Diagnostic prediction models

Which scoring tools for signs and symptoms (including Centor and FeverPAIN) are most accurate in predicting sore throat caused by group A beta-haemolytic streptococcus (GABHS) infection in primary care?

What are the accuracy, clinical utility and cost effectiveness of clinical prediction models/ tools (clinical history, cardiovascular risk factors, physical examination) in evaluating stable chest pain of suspected cardiac origin?

Prognostic prediction models

What risk assessment or prediction tool best identifies people with multiple conditions who are at risk of unplanned hospital admission?

What risk tool best identifies people with type 2 diabetes who are at risk of reduced life expectancy?

Which risk assessment tools are the most accurate in predicting the risk of fragility fracture in adults with osteoporosis or previous fragility fracture?

What factors and baseline characteristics are accurate in predicting positive treatment outcomes in people with pancreatic cancer?

Review questions about views and experiences of people using or providing services, family members or carers and the public

In some circumstances, specific questions should be formulated about the views and experience of people using services, family members or carers and the public. The views and experiences of those providing services may also be relevant. These can cover a range of dimensions, including:

- views and experiences of people using or providing services, family members or carers or the public on the effectiveness and acceptability of interventions
- preferences of people using services, family members or carers or the public for different treatment or service options, including the option of foregoing treatment or care

- views and experiences of people using or providing services, family members or carers or the public on what constitutes a desired, appropriate or acceptable outcome.

Such questions should address experiences of an intervention or approach that are considered important by people using or providing services, family members or carers or the public. Such questions can address a range of issues, including:

- elements of care or a service that are of particular importance to people using or providing services
- factors that encourage or discourage people from using interventions or services
- the specific needs of certain groups of people using services, including those sharing the characteristics protected by the Equality Act (2010)
- information and support needs specific to the topic
- which outcomes reported in studies of interventions are most important to people using services, family members or carers or the public
- health and care inequalities.

As for other types of review question, questions that are broad and lack focus (for example, 'What is the experience of living with condition X?') should be avoided.

NICE guidelines should not reiterate or re-phrase recommendations from the NICE guidelines on patient experience in adult NHS services, service user experience in adult mental health, people's experience in adult social care services, babies, children and young people's experience of healthcare, shared decision making, or other NICE guidelines on the experience of people using services. However, whether there are specific aspects of views or experiences that need addressing for a topic should be considered during the scoping of every guideline. Specific aspects identified during scoping should be included in the scope if they are not covered by existing guidelines and are supported as a priority area. These are likely to be topic-specific and should be well-defined and focused. The PICo (Population, Interest, Context) framework and the SPIDER framework in McMaster University's National Collaborating Centre for Methods and Tools registry of tools are examples of frameworks that can be used to structure review questions on the views or experiences of people using or providing services, family members or carers or the public.

Box 4.8 Examples of review questions on the views or experiences of people using or providing services, family members or carers or the public

What elements of care on the general ward are viewed as important by patients following their discharge from critical care areas?

How does culture affect the need for and content of information and support for bottle or breastfeeding?

What are the perceived risks and benefits of immunisation among parents, carers or young people? Is there a difference in perceived benefits and risks between groups whose children are partially immunised and those who have not been immunised?

What are the views and experiences of health, social care and other practitioners about the practicality and implementation of home-based intermediate care?

A review question about the views or experiences of people using or providing services, family members or carers or the public could be answered using qualitative studies or cross-sectional surveys (or both), although information on views and experiences is also becoming increasingly available as part of some intervention studies.

When there is a lack of evidence on issues important to people affected by the guideline (including families and carers, where appropriate), the developer should consider seeking information via a call for evidence (see the section on calls for evidence from stakeholders in the chapter on identifying the evidence: literature searching and evidence submission), or approaching experts who may have access to additional data sources, such as surveys of user views and experiences, to present as expert testimony. For more information, see:

- the section on other attendees at committee meetings in the chapter on decision-making committees)
- the appendix on approaches to additional consultation and commissioned primary research
- the appendix on call for evidence and expert witnesses.

Review questions about service delivery

Guidelines often cover areas of service delivery. These might include how delivery of services could improve or what are the different core components of services and how different components could be re-configured.

Box 4.9 Examples of review questions on service delivery

In people with hip fracture what is the clinical and cost effectiveness of hospital-based multidisciplinary rehabilitation on the following outcomes: functional status, length of stay in secondary care, mortality, place of residence or discharge, hospital readmission and quality of life?

What is the clinical and cost effectiveness of surgeon seniority (consultant or equivalent) in reducing the incidence of mortality, the number of people requiring reoperation, and poor outcome in terms of mobility, length of stay, wound infection and dislocation?

What are the best service models to support the identification of people who may be entering their last year of life?

What types of needle and syringe programmes (including their location and opening times) are effective and cost effective?

What regional or city level commissioning models, service models, systems and service structures are effective in:

- reducing diagnostic delay for TB
- improving TB contact tracing
- improving TB treatment completion?

A review question about the effectiveness of service delivery models is usually best answered by an RCT. However, a wide variety of methodological approaches and study designs have been used, including observational evidence (including routine healthcare and audit data), experimental and qualitative evidence. Other types of questions on service delivery are also likely to be answered using evidence from study types other than RCTs. For example, in order to determine whether an intervention will work for a particular subgroup or setting, we might want to know how the intervention works, which will require evidence of the relevant underlying mechanisms.

Depending on the type of review questions, the PICO framework may be appropriate but other frameworks can be used.

When a topic includes review questions on service delivery, approaches described in the chapter on incorporating economic evaluation and the appendix on service delivery – developing review

questions, evidence reviews and synthesis may be used. Such methods should be agreed with NICE staff with responsibility for quality assurance and should be clearly documented in the guideline.

Review questions about epidemiology

Epidemiological reviews describe the problem under investigation and can be used to inform other review questions. For example, an epidemiological review of incidence or prevalence of a condition would provide baseline data for further evidence synthesis, an epidemiological review of accidents would provide information on the most common accidents, as well as morbidity and mortality statistics, and data on inequalities in the impact of accidents.

Box 4.10 Examples of review questions that might benefit from an epidemiological review

What are the patterns of physical activity among children from different populations and of different ages in England?

Which populations of children are least physically active and at which developmental stage are all children least physically active?

What is the incidence of Lyme disease in the UK?

The structure of the question and the type of evidence will depend on the aim of the review.

Another use of epidemiological reviews is to describe relationships between epidemiological factors and outcomes – a review on associations. If an epidemiological review has been carried out, information will have been gathered from observational studies on the nature of the problem. However, further analysis of this information – in the form of a review on associations – may be needed to establish the epidemiological factors associated with any positive or negative behaviours or outcomes.

Box 4.11 Examples of review questions that might benefit from a review on associations

What factors are associated with children's or young people's physical activity and how strong are the associations?

What physiological and aetiological factors are associated with coeliac disease?

What physical, environmental and sociological factors are associated with the higher prevalence of multiple sclerosis in European countries?

4.4 Evidence used to inform recommendations

In order to formulate recommendations, the guideline committee needs to consider a range of evidence about what works, why it works, and what might work (and how) in specific circumstances. The committee needs evidence from multiple sources, extracted for different purposes and by different methods.

Scientific evidence

Scientific evidence should be explicit, transparent and replicable. It can be context-free or context-sensitive. Context-free scientific evidence assumes that evidence can be independent of the observer and context. It can be derived from evidence reviews or meta-analyses of quantitative studies, individual studies or theoretical models. Context-sensitive scientific evidence looks at what works and how well in real-life situations. It includes information on attitudes, implementation, organisational capacity, forecasting, economics and ethics. It is mainly derived using social science and behavioural research methods, including quantitative and qualitative research studies, surveys, theories, cost-effectiveness analyses and mapping reviews. Sometimes, it is derived using the same techniques as context-free scientific evidence. Context-sensitive evidence can be used to complement context-free evidence, and can so provide the basis for more specific and practical recommendations. It can be used to:

- supplement evidence on effectiveness (for example, to look at how factors such as occupation, educational attainment and income influence effectiveness)
- inform the development and refinement of conceptual frameworks or logic models (see the section on stages of scope development in the chapter on the scope) and causal pathways (for example, to explain what factors predict teenage parenthood)
- provide information about the characteristics of the population (including social circumstances and the physical environment) and about the process of implementation

- describe psychological processes and behaviour change.

Quantitative and qualitative information can also be used to supplement conceptual frameworks or logic models (see the section on stages of scope development in the chapter on the scope). They can also be combined in a single review (mixed methods) when appropriate (for example, to address review questions about factors that help or hinder implementation or to assess why an intervention does or does not work).

Existing systematic reviews

Often reviews of quantitative or qualitative studies (secondary evidence) already exist (for example, those developed by internationally recognised producers of systematic reviews such as Cochrane, the Campbell Collaboration and the Joanna Briggs Institute among others). Existing reviews may include systematic reviews (with or without a meta-analysis or individual patient data analysis) and non-systematic literature reviews and meta-analyses. Well-conducted systematic reviews may be of particular value as sources of evidence (see the appendix on appraisal checklists, evidence tables, GRADE and economic profiles for checklists to assess risk of bias or quality of studies when developing guidelines). Some reviews may be more useful as background information or as additional sources of potentially relevant primary studies. This is because they may:

- not cover inclusion and exclusion criteria relevant to the guideline topic's referral and parameters (for example, comparable research questions, relevant outcomes, settings, population groups or time periods)
- group together different outcome or study types
- include data that are difficult or impossible to separate appropriately
- not provide enough data to develop recommendations (for example, some reviews do not provide sufficient detail on specific interventions making it necessary to refer to the primary studies).

Conversely, some high-quality systematic reviews may provide enhanced data not available in the primary studies. For example, authors of the review may have contacted the authors of the primary studies or other related bodies in order to include additional relevant data in their review, or may have undertaken additional analyses (such as individual patient data analyses). In addition, if high-quality reviews are in progress (protocol published) at the time of development of the guideline, the developer may choose to contact the authors for permission to access pre-publication data for inclusion in the guideline (see the appendix on call for evidence and expert witnesses).

Systematic reviews can also be useful when developing the scope and when defining review questions, outcomes and outcome measures for the guideline evidence reviews. The discussion section of a systematic review can also help to identify some of the limitations or difficulties associated with a topic, for example, through a critical appraisal of the limitations of the evidence base. The information specialists may also wish to consider the search strategies of high-quality systematic reviews. These can provide useful search approaches for capturing different key concepts. They can also provide potentially useful search terms and combinations of terms, which have been carefully tailored for a range of databases.

High-quality systematic reviews that are directly applicable to the guideline review question can be used as a source of data, particularly for complex organisational, behavioural and population level questions.

When considering using results from an existing high-quality review, due account should be taken of the following:

- The parameters (for example, research question, PICO, inclusion and exclusion criteria) of the review are sufficiently similar to the review protocol of the guideline review question. In such cases, a search should be undertaken for primary studies published after the search date covered by the existing review.
- Whether the use of existing high-quality reviews will be sufficient to address the guideline review question if the evidence base for the guideline topic is very large.

Colloquial evidence

'Colloquial evidence' has been described as informal evidence that can complement scientific evidence or provide context to other forms of evidence in guidance development. It can come from expert testimony (see the section on other attendees at committee meetings in the chapter on decision-making committees, and the appendix on call for evidence and expert witnesses), from members of the committee, from a reference group of people using services (see the section on forming the committee in the chapter on decision-making committees) or from comments from registered stakeholders (see the section on what happens during consultation in the chapter on the validation process for draft guidelines, and dealing with stakeholder comments). Colloquial evidence includes evidence about values (including political judgement), practical considerations (such as resources, professional experience or expertise and habits or traditions, the experience of people using services) and the interests of specific groups (views of lobbyists and pressure groups).

An example of colloquial evidence is expert testimony. Sometimes oral or written evidence from

outside the committee is needed for developing recommendations, if limited primary research is available or more information on current practice is needed to inform the committee's decision-making. Inclusion criteria for oral or written evidence specify the population and interventions for each review question, to allow filtering and selection of oral and written evidence submitted to the committee.

Other evidence

Depending on the nature of the guideline topic and the review question, other sources of relevant evidence such as reports, audits, service evaluation or other real-world evidence may be included. This should be agreed with NICE staff with responsibility for quality assurance before proceeding. The quality, reliability and applicability of the evidence is assessed according to standard processes (see the appendix on appraisal checklists, evidence tables, GRADE and economic profiles).

See also the chapter on linking to other guidance (which also covers using evidence from non-NICE guidance).

4.5 Planning the evidence review

For each guideline evidence review, a review protocol is prepared that outlines the background, the objectives and the planned methods. In addition, the review protocol should make it possible for the review to be repeated by others at a later date. A protocol should also make it clear how equality issues have been considered in planning the review work, if appropriate.

Structure of the review protocol

The protocol should describe any differences from the methods described in this manual (chapters on identifying the evidence: literature searching and evidence submission, reviewing research evidence, and incorporating economic evaluation), rather than duplicating the methodology stated here. It should include the components outlined in the appendix on the review protocol template.

When a guideline is updating a published guideline, the protocol from the published guideline, if available, should be used to outline how the review question would be addressed. Information gathered during surveillance and scoping of the guideline should also be added. This might include new interventions and comparators, and extension of the population.

Process for developing the review protocol

The review protocol should be drafted by the developer, with input from the guideline committee,

after the review question has been agreed and before starting the evidence review. It should then be reviewed and approved by NICE staff with responsibility for quality assurance.

All review protocols should consider registering on the PROSPERO database before the data extraction commences, if possible and appropriate. The review protocol and a version of the economic plan (see the section on prioritising questions for further economic analysis in the chapter on incorporating economic evaluation) are published on the NICE website at least 6 weeks before the draft guideline goes out for consultation. Any changes made to a protocol in the course of guideline development should be agreed with NICE staff with responsibility for quality assurance and should be described and updated on the PROSPERO database (if registered).

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5 Identifying the evidence: literature searching and evidence submission

5.1 Introduction

The systematic identification of evidence is an essential step in developing NICE guidelines. Literature searches should be systematic, transparent and reproducible to minimise 'dissemination biases'. These may affect the results of reviews and include publication bias and database bias.

This chapter provides advice on the sources to search and on how to develop strategies for systematic literature searches to identify the best available evidence. It also provides advice on other areas of information management that form an important part of guideline development. These include quality assurance, re-running searches, documenting the search process, and the use of reference management or systematic review software. The methods for undertaking scoping searches are described in the chapter on the scope. For information on searching for economic evidence, see the chapter on incorporating economic evaluation. For information on searching for surveillance evidence, see the chapter on ensuring that published guidelines are current and accurate.

NICE encourages the use of search methods that balance recall and precision. The aim is to identify the best available evidence to address a particular question without producing an unmanageable volume of results. If review questions are so broad that the information specialist has to restrict the searches to complete the review in the time available, this should be acknowledged as a limitation in the final review document.

A flexible approach to the search for evidence should be adopted, guided by the subject of the question and type of evidence sought. When the guideline is an update, the approach can also be informed by searches for the existing guideline and subsequent surveillance review. Searching includes:

- tailoring the search approach to the eligibility or inclusion criteria of the review question, as specified in the review protocol
- selecting appropriate sources according to the eligibility or inclusion criteria of the review question, as specified in the review protocol

- using additional search techniques, such as citation searching, as appropriate
- continuous review of how best to find evidence and where.

A flexible approach will allow evidence to be identified both systematically and in the most efficient manner. For example, for a review question on the effectiveness of a pharmacological intervention it may be possible to search a relatively small number of sources (see the section on sources) and to develop a systematic search strategy using the PICO framework (see the section on developing search strategies). For questions about complex interventions, the evidence may be more widely scattered across sources and less consistently described. In these cases it may be necessary to search a wider range of sources and consider other question frameworks and search approaches, including the use of additional searching techniques.

The chapter on searching for and selecting studies in the Cochrane handbook for systematic reviews of interventions and the Campbell Collaboration's searching for studies methods guide offer good overviews of literature searching (Lefebvre et al. 2021; Kugley et al. 2017). The SuRe Info resource also provides research-based advice on information retrieval for systematic reviews and is updated twice a year.

5.2 Search protocols

Search protocols should be developed by the information specialist and agreed with the other members of the developer's team before undertaking a systematic search. Search protocols are part of the review protocol (see the appendix on the review protocol template), which is signed off by the committee. When developing search protocols, the information specialist may ask the committee for expert advice (for example, when a condition is described in many different ways in the literature).

Search protocols pre-define how the evidence is identified and provide a basis for developing the search strategies. Search protocols should include the following elements:

- search approach, tailored to the review question
- sources to be searched (see the section on sources)
- plans to use any additional or alternative search techniques, when known at the protocol development stage, and the reasons for their use
- limits to be applied to the search.

5.3 Sources

Searches should include a mix of bibliographic databases, websites and other sources depending on the subject of the review question and the type of evidence sought.

For most searches there will be key sources that should be prioritised, and other potentially relevant sources that could be considered. It is important to ensure adequate coverage of the relevant literature and to search a range of sources, but there should be clear reasons, with only those likely to yield relevant results included. (See also the section on reviewing economic evaluations in the chapter on incorporating economic evaluation for information on searching for economic literature.)

The selection of sources will vary according to the requirements of the review question. For reviews of the effectiveness of pharmacological interventions the following should be prioritised for searching:

- the Cochrane Central Register of Controlled Trials (CENTRAL)
- the Cochrane Database of Systematic Reviews (CDSR)
- Embase
- MEDLINE
- the Medicines and Healthcare products Regulatory Agency (MHRA) – for drug safety information.

For other questions, it might be as or more important to search other sources. Examples of other sources include, but are not limited to:

- PsycINFO (psychology and psychiatry)
- ASSIA (Applied Social Sciences Index and Abstracts)
- Social Policy and Practice, Social Care Online
- Sociological Abstracts
- HMIC (Health Management Information Consortium)
- HealthTalk.

For service delivery questions, some of the evidence may be in the form of modelling studies published in journals related to operational research, statistical and mathematical methods rather than in health journals. These are less likely to be indexed in healthcare databases such as MEDLINE, and consideration should be given to sources likely to retrieve this evidence.

The following sources may be useful for service delivery questions:

- Science Citation Index
- HMIC
- Social Care Online or Social Policy Online
- Kings Fund.

Evidence may also be primary data needed to inform parameters identified in the design-oriented conceptual model. For information on searching for model inputs, see the chapter on incorporating economic evaluation.

For some review questions, for example, where evidence is likely to be published in non-journal sources, it may be appropriate to search for grey literature. Useful sources of grey literature include:

- HMIC
- CORE.

Reports from organisations such as the European Medicines Agency and the US Food and Drug Administration may also be of value. The Canadian Agency for Drugs and Technology in Health (CADTH) Grey Matters may also be useful for identifying sources for grey literature, as may web search tools, such as NICE Evidence Search and TRIP. Topic experts on the committee may also be able to suggest appropriate sources for grey literature.

A list is provided in the appendix on sources for evidence reviews as a starting point for identifying potential relevant sources.

5.4 Developing search strategies

Devising a search strategy

The approach to devising and structuring search strategies should be informed by the review question. For example, the PICO (population, intervention, comparator and outcome) or the SPICE (setting, perspective, intervention, comparison, evaluation; Booth 2006) framework can be used to structure a search strategy for an intervention question. For other types of question, other frameworks may be more suitable. It may also be appropriate for the search framework to differ from that of the review question, and the choice should reflect the question type and search approach. Davies (2011) undertook a review of possible frameworks and SuRe Info has a useful summary of alternatives to PICO which have been evaluated. When using a framework, it is important to consider which concepts to include in the strategy because some concepts may not be mentioned in the titles, abstracts or subject headings of a database record. This is a particular challenge when the literature is less well defined and/or indexed. It is important to ensure that relevant studies are not missed as a result of an overly complex search structure.

Some topics are complex, for example, where search requirements evolve as evidence is identified and it is important to balance recall and precision. One approach, when the relevant literature for a question is less well defined or indexed, is to use a multi-stranded method. This involves developing several shorter search strategies (strands) with an emphasis on precision. Each strand should reflect 1 way in which the relevant literature may be described. The strands are then combined.

Another approach is to use an iterative and/or 'stepped' method. Searching is done in several stages, with each search taking into account the evidence that has already been retrieved. Searching in stages allows the reviewers to review the most relevant, high-quality information first. It also gives the opportunity to stop searching, omitting some steps if this is felt appropriate for the topic. Additional steps are added if the developer decides that the quantity or quality of the evidence already gathered is not sufficient. It may also be appropriate to add an additional search step to identify literature published between the final search date of a study and its inclusion in a systematic review. If the developer then finds there are topics of interest not covered by existing reviews, it would be appropriate to carry out additional searching on specific topics. A decision to use a stepped or iterative approach should be agreed by the developer and NICE staff with responsibility for quality assurance because it can affect timelines.

Some topics may have multiple information needs, for example, sometimes indirect evidence is needed for network meta-analyses. This may involve developing iterative searches for a set of relevant comparators as opposed to a search for pre-determined comparators (Hawkins et al.

2009). This type of searching can be time consuming and the developer should agree a decision to do this with NICE staff with responsibility for quality assurance. Searching for observational data for service delivery questions can also be very time consuming. For example, registry data can be a source of estimates of treatment effects, but if the committee cannot estimate the extent or direction of any biases, the value of the data is greatly reduced and the usefulness of searching is low.

For some types of review question, for example, questions for which qualitative research is more appropriate, it may not be necessary to identify all the literature on a topic. The objective may be to reach theoretical saturation, where any additional studies identified merely support the existing line of argument, rather than identify all relevant studies. In this context, it may be possible to undertake searches which are more precise. The search approaches for this type of evidence have been reviewed and summarised by Booth (2016) and can be used to guide practice.

Review questions that overlap and can be grouped together should be identified for searching purposes. For example, questions with the same population may involve comparing several interventions. This should make it possible to carry out a single search that covers all the interventions, although this approach may retrieve a large number of studies.

Identifying search terms

Search strategies should usually consist of a combination of subject headings and 'free-text' terms from the titles and abstracts of relevant studies. When identifying subject headings, variations in thesaurus and indexing terms for each database should be taken into account: for example, MeSH (Medical Subject Headings) in MEDLINE, Emtree in Embase. Not all databases will have indexing terms and some databases will contain records which have not yet been indexed. Also, not all search concepts will have a subject heading, so free-text terms should also be used.

Free-text terms may include synonyms, acronyms and abbreviations, spelling variants, old and new terminology, brand and generic medicine names, and lay and medical terminology. For a guideline that is being updated, previous search strategies, including surveillance searches, should be reviewed and used to inform search strategy design. New or changed terms should be identified, as well as any changes to indexing terms. This also applies when an existing review, for example, a Cochrane review, is being updated to answer a review question. Known key studies can be a useful source to identify search terms, but additional sources such as reports, guidelines, and topic-specific websites or topic experts can also be helpful.

Comprehensively identifying search terms may present challenges. For example, for public health,

social care or implementation reviews, many databases do not use a controlled vocabulary for indexing records. Sometimes controlled vocabularies are used but do not include terms that adequately cover the search concept(s), which often cross a number of disciplines. In addition, the use of natural language varies between studies, and concepts may not be described in a consistent way. In light of these challenges, the development of a search strategy should always be an iterative process between the information specialists), the developer and, when necessary, the committee and NICE staff with responsibility for quality assurance (Alpi 2005, Papaioannou et al. 2010).

A further challenge may arise from websites or certain databases having limited search functionality. It may be necessary to simplify the search strategy, using fewer search terms or undertaking multiple searches of the same resource with different search term combinations.

It may be helpful to use frequency analysis or text mining to develop the search strategy (Stansfield et al. 2017, Hausner et al. 2012). Tools such as PubReMiner and Medline Ranker can help, either by highlighting search terms that might not otherwise be apparent, or by flagging terms of high value when exhaustive synonym searching is unfeasible or inadvisable. This is a rapidly developing area, but in principle NICE supports the use of such technologies to inform search development.

Limits and filters

Searches should be limited to studies reported in English. When there are likely to be animal studies in the evidence base, these can be excluded from the search results in some databases.

Limiting searches by date will depend on the topic and the nature of the evidence base (for example, when most of the research was published). When the guideline is an update, searches may be limited by date, but only if appropriate (for example, the inclusion and exclusion criteria for the update are the same as for the existing guideline). If there are relevant good-quality published systematic reviews (see the chapter on developing review questions and planning the evidence review), it may be possible to limit additional searching to the time since the searches for the published reviews were conducted. For some databases, restricting the search by date is difficult. When this is the case, searches can be run without date limits, using reference management or systematic review software to separate new results. The date range for the search, and the use of existing reviews, should be agreed before searching and documented in the search protocol (see the section on search protocols).

Depending on the review question, it may be appropriate to limit searches to particular study designs. For example, for review questions on the effectiveness of interventions, it may be more efficient to search for systematic reviews, followed by controlled trials followed by observational

studies. This prevents unnecessary searching and review work. The best way to limit searches by study design is to use an appropriate search filter (strings of search terms), rather than using database publication type field limits, to ensure the search strategy is transparent and reproducible. Additional classifiers, such as the Cochrane RCT classifier, could be used to further attempt to limit the search to particular study types.

Other search filters relating to age, setting, geography, and health inequalities can also be applied as relevant. The most comprehensive list of available search filters is the search filter resource of the InterTASC Information Specialists' Sub-Group. This resource also includes critical appraisal tools, which can be used for filter selection. Additionally, McKibbon (2009) reviews the performance of 38 randomised controlled trial filters. Both sources may be useful when choosing a filter. Search filters should, however, be used with caution because concepts such as study design, age, setting and geography may not be adequately described in the title or abstract of a database record, and may not be captured by the indexing.

NICE is not prescriptive about which search filters should be used because there is often limited evidence on the performance of individual filters. Alternative methods for refining a search to achieve an adequate balance of recall and precision should be used when filters are not appropriate.

Additional or alternative search techniques

Additional or alternative search techniques should be used in addition to database searching when it is known, or reasonably likely, that relevant evidence is either not indexed in bibliographic databases and/or that it is difficult to retrieve from databases in a way that adequately balances recall and precision. These techniques might include forward and backward citation searching, journal hand-searches or contacting experts and stakeholders.

Reviews (for example, systematic reviews, literature reviews and meta-analyses) may provide an additional source of primary studies, with reference lists being used to identify these.

All search techniques should follow the same principles of transparency, rigour and reproducibility as other search methods.

Additional or alternative search techniques should be considered at the outset and documented in the search protocol (see the section on search protocols), if possible. They should also be documented in the evidence review.

5.5 Calls for evidence from stakeholders

Stakeholders' role in providing evidence

In some topic areas or for some review questions, NICE staff with responsibility for quality assurance, the developer or committee may believe that there is relevant evidence in addition to that identified by the searches. In these situations, the developer may invite stakeholders, and possibly also other relevant organisations or individuals with a significant role or interest (see the section on other attendees at committee meetings in the chapter on decision-making committees on expert witnesses), to submit evidence. A call for evidence is issued directly to registered stakeholders and via the NICE website. Examples and details of process are included in the appendix on call for evidence and expert witnesses. Confidential information should be kept to an absolute minimum.

5.6 Health inequalities and equality and diversity

All searches should be inclusive, capturing evidence related to health inequalities or impacts on equality relevant to the guideline topic. For example, if the population group is 'older people' a search for 'older people' should pick up subpopulations such as 'disabled older people' or 'black and minority ethnic older people'. Similarly, if the setting is 'communities and religious places', the search terms should cover all relevant faith settings (such as 'church', 'temple' and 'mosque').

5.7 Quality assurance

Quality assuring the literature search is an important step in guideline development. Studies have shown that errors do occur (Sampson 2006). Although developed specifically for Cochrane reviews, the Methodological Expectations of Cochrane Intervention Reviews (MECIR) manual may be useful to guide practice. They set out the components which can ensure that the identification of the evidence base is comprehensive, transparent and reproducible (Higgins et al. 2021).

For each search (including economic searches), the principal database search strategy should be quality assured by a second information specialist to maintain a consistently high standard for identifying the evidence. A checklist should be used to ensure clarity and consistency when quality assuring search strategies. An example is the PRESS 2015 Guideline Evidence-Based Checklist (McGowan et al. 2016).

Each time the principal database strategy is adapted for use in another database, it is good practice for it to be peer reviewed by a second information specialist to ensure quality and consistency is

maintained.

As part of quality assurance, there is also an opportunity to undertake an audit of search results to analyse how the evidence for the guideline was identified. Using the final list of included studies, it is possible to determine the contribution of individual sources and search techniques. This can provide valuable data for informing the search approach for future surveillance and guideline updates.

5.8 Reference management

Electronic records of the references retrieved by searches should be stored using EPPI-Reviewer.

5.9 Documenting the search

Details of the search are included in the individual evidence reviews, and are available with the consultation on the draft guideline, and the final guideline.

Thorough documentation facilitates future surveillance and updating, and there are several published guides that cover this. NICE uses the PRISMA-S standards to inform search reporting (Rethlefsen et al 2021). Documenting the search begins with creating the search protocol (see the section on search protocols). If using an emergent 'stepped' approach, initial search strategies, key decision points and the reasons for subsequent search steps should be clearly documented in the search protocol.

Records should be kept of the searches undertaken during guideline development for all review questions to ensure that the process for identifying the evidence base is transparent and reproducible.

For each question, or group of questions, the following information should be documented:

- details of search approach with reasons (this should include any notable differences between the searches for an existing guideline and those for an update of the guideline)
- dates on which the searches were carried out, including the dates of any re-run searches (see the section on re-running searches)
- names of the databases, database host systems and database coverage dates or specific segments

- names of any non-database sources searched and number of citations retrieved
- search strategies for all sources and number or citations retrieved (these should be annotated to explain any decisions on included and excluded terms which are not self-explanatory)
- details of any supplementary searching undertaken, including the reasons
- any limits or search filters applied to the search (for example, language, date, study design).

5.10 Re-running searches

Searches undertaken to identify evidence for each review question (including economics searches) may be re-run to identify any further evidence that has been published since the search was last run. For example, searches should be re-run if the evidence base changes quickly, or if there is reason to believe that substantial new evidence exists, or if the development time is longer than usual. Searching PubMed or OVID's MEDLINE Epub Ahead of Print at this stage, in addition to MEDLINE, is useful to identify 'ahead-of-print' citations.

A decision to re-run searches will be taken by the developer and members of NICE staff with a quality assurance role.

If undertaken, searches should be re-run at least 6 to 8 weeks before the final committee meeting before consultation.

If evidence is identified after the last cut-off date for searching but before publication, a judgement on its impact should be made by the developer and NICE staff with a quality assurance role. In exceptional circumstances, this evidence can be considered if its impact is judged as substantial.

5.11 References and further reading

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6 Reviewing research evidence

Reviewing evidence is an explicit, systematic and transparent process that can be applied to both quantitative (experimental and observational) and qualitative evidence (see the chapter on developing review questions and planning the evidence review). The key aim of any review is to provide a summary of the relevant evidence to ensure that the committee can make fully informed decisions about its recommendations. This chapter describes how evidence is reviewed in the development of guidelines.

Evidence reviews for NICE guidelines summarise the evidence and its limitations so that the committee can interpret the evidence and make appropriate recommendations, even where there is uncertainty.

Evidence identified during literature searches and from other sources (see the chapter on identifying the evidence: literature searching and evidence submission) should be reviewed against the review protocol to identify the most appropriate information to answer the review questions. The evidence review process used to inform guidelines must be explicit and transparent, and involves 7 main steps:

- writing the review protocol (see the section on planning the evidence review in the chapter on developing review questions and planning the evidence review)
- identifying and selecting relevant evidence (including a list of excluded studies with reasons for exclusion)
- critical appraisal
- extracting relevant data
- synthesising the results (including statistical analyses such as meta-analysis)
- assessing quality/certainty in the evidence
- interpreting the results.

Any substantial deviations from these steps need to be agreed, in advance, with NICE staff with responsibility for quality assurance.

6.1 Identifying and selecting relevant evidence

The process of selecting relevant evidence is common to all evidence reviews; the other steps are discussed in relation to the main types of review questions. The same rigour should be applied to reviewing all data, whether fully or partially published studies or unpublished data supplied by stakeholders. Care should be taken to ensure that multiple reports of the same study are identified and ordered in full text to ensure that data extraction is as complete as possible, but study participants are not double counted in the analysis.

Published studies

Titles and abstracts of the retrieved citations should be screened against the inclusion criteria defined in the review protocol, and those that do not meet these should be excluded. A percentage (at least 10%, but possibly more depending on the review question) should be screened independently by 2 reviewers (that is, titles and abstracts should be double-screened). The percentage of records to be double-screened for each review should be specified in the review protocol.

If reviewers disagree about a study's relevance, this should be resolved by discussion or by recourse to a third reviewer. If, after discussion, there is still doubt about whether or not the study meets the inclusion criteria, it should be retained. If double-screening is only done on a sample of the retrieved citations (for example, 10% of references), inter-rater reliability should be assessed against a pre-specified threshold (usually 90% agreement, unless another threshold has been agreed and documented). If agreement is lower than the pre-specified threshold, the reason should be explored and a course of action agreed to ensure a rigorous selection process. A further proportion of studies should then be double-screened to validate this new process until appropriate agreement is achieved.

Once the screening of titles and abstracts is complete, full versions of the selected studies should be obtained for assessment. As with title and abstract screening, a percentage of full studies should be checked independently by 2 reviewers, with any differences being resolved and additional studies being assessed by multiple reviewers if sufficient agreement is not achieved. Studies that fail to meet the inclusion criteria once the full version has been checked should be excluded at this stage.

The study selection process should be clearly documented and include full details of the inclusion and exclusion criteria. A flow chart should be used to summarise the number of papers included and excluded at each stage and this should be presented in the evidence review (see the PRISMA

statement). Each study excluded after checking the full version should be listed, along with the reason for its exclusion. Reasons for study exclusion need to be sufficiently detailed (for example, 'editorial/review' or 'study population did not meet that specified in the review protocol').

Priority screening

Priority screening refers to any technique that uses a machine learning algorithm to enhance the efficiency of screening. Usually, this involves taking information on previously included or excluded papers, and using this to order the unscreened papers from those most likely to be included to those least likely. This can be used to identify a higher proportion of relevant papers earlier in the screening process, or to set a cut-off for manual screening, beyond which it is unlikely that additional relevant studies will be identified.

There is currently no published guidance on setting thresholds for stopping screening where priority screening has been used. Any methods used should be documented in the review protocol and agreed in advance with NICE staff with responsibility for quality assurance. Any thresholds set should, at minimum, consider the following:

- the number of references identified so far through the search, and how this identification rate has changed over the review (for example, how many candidate papers were found in each 1,000 screened)
- the overall number of studies expected, which may be based on a previous version of the guideline (if it is an update), published systematic reviews, or the experience of the guideline committee
- the ratio of relevant/irrelevant records found at the random sampling stage (if undertaken) before priority screening.

The actual thresholds for used for each review question should be clearly documented, either in the guideline methods chapter or in the evidence reviews.

Ensuring relevant records are not missed

Regardless of the level of double-screening, and whether or not priority screening was used, additional checks should always be made to reduce the risk that relevant studies are not identified. These should include, at minimum:

- checking reference lists of included systematic reviews, even if these reviews are not used as a source of primary data

- checking with the guideline committee that they are not aware of any relevant studies that have been missed
- looking for published papers associated with key trial registry entries or published protocols.

It may be useful to test the sensitivity of the search by checking that it picks up known studies of relevance.

Conference abstracts

Conference abstracts seldom contain enough information to allow confident judgements about the quality and results of a study, although they may be useful in interpreting evidence reviews. It can be difficult to trace the original studies or additional data, and the information found may not always be useful. Also, good-quality studies will often publish full text papers after the conference abstract, and these will be identified via routine searches. Conference abstracts should therefore not routinely be included in the search strategy, unless there are good rationales for doing so. For example, if surveillance has identified a number of ongoing studies and conference abstracts would be a good source for tracking the full studies, or if a call for evidence is planned and conference abstracts can be used to trace unpublished research. If conference abstracts are searched for, the investigators may be contacted if additional information is needed to complete the assessment for inclusion.

Legislation and policy

Relevant legislation or policies may be identified in the literature search and used to inform guidelines (such as drug safety updates from the Medicines and Healthcare products Regulatory Agency [MHRA]). Legislation and policy does not need quality assessment in the same way as other evidence, given the nature of the source. National policy or legislation can be quoted verbatim in the guideline (for example, Health and Social Care Act [2012]), where needed.

Unpublished data and studies in progress

Any unpublished data should be quality assessed in the same way as published studies (see the section on assessing quality of evidence: critical appraisal, analysis, and certainty in the findings). Ideally, if additional information is needed to complete the quality assessment, the investigators should be contacted. Similarly, if data from studies in progress are included, they should be quality assessed in the same way as published studies. Confidential information should be kept to a minimum, and a structured abstract of the study must be made available for public disclosure during consultation on the guideline.

Grey literature

Grey literature may be quality assessed in the same way as published literature, although because of its nature, such an assessment may be more difficult. Consideration should therefore be given to the elements of quality that are most likely to be important.

6.2 Assessing quality of evidence: critical appraisal, analysis, and certainty in the findings

Introduction

Assessing the quality of the evidence for a review question is critical. It requires a systematic process of assessing potential biases through considering both the appropriateness of the study design and the methods of the study (critical appraisal) as well as the certainty of the findings (using an approach, such as GRADE).

Options for assessing the quality of the evidence should be considered by the developer. The chosen approach should be discussed and agreed with NICE staff with responsibility for quality assurance, where the approach deviates from the standard (described in critical appraisal of individual studies). The agreed approach should be documented in the review protocol (see the appendix on review protocol template) together with the reasons for the choice. If additional information is needed to complete the data extraction or quality assessment, study investigators may be contacted.

Critical appraisal of individual studies

Every study should be appraised using a checklist appropriate for the study design (see the appendix on appraisal checklists, evidence tables, GRADE and economic profiles for checklists). If a checklist other than those listed is needed, or the one recommended as the preferred option is not used, the planned approach should be discussed and agreed with NICE staff with responsibility for quality assurance and documented in the review protocol.

Before starting the review, the criteria from the checklist (if not all) that are likely to be the most important indicators of biases for the review question should be agreed. These criteria will be useful in guiding decisions about the overall risk of bias of each individual study.

Sometimes, a decision might be made to exclude certain studies or to explore any impact of bias through sensitivity analysis. If so, the approach should be specified in the review protocol and

agreed with NICE staff with responsibility for quality assurance.

Criteria relating to key areas of bias may also be useful when summarising and presenting the evidence (see the section on summarising evidence). Topic-specific input (for example, from committee members) may be needed to identify the most appropriate criteria to define subgroup analyses, or to define inclusion in a review, for example, the minimum biopsy protocol for identifying the relevant population in cancer studies.

For each criterion that might be explored in sensitivity analysis, the decision on whether it has been met or not, and the information used to arrive at the decision, should be recorded in a standard template for inclusion in an evidence table (see the appendix on appraisal checklists, evidence tables, GRADE and economic profiles for examples of evidence tables).

Each study included in an evidence review should preferably be critically appraised by 1 reviewer and checked by another. Any differences in critical appraisal should be resolved by discussion or recourse to a third reviewer. Different strategies for critical appraisal may be used depending on the topic and the review question.

Data extraction

Characteristics of data should be extracted to a standard template for inclusion in an evidence table (see the appendix on appraisal checklists, evidence tables, GRADE and economic profiles). Care should be taken to ensure that newly identified studies are cross-checked against existing studies to avoid double-counting. This is particularly important where there may be multiple reports of the same study.

If complex analysis is needed for a review question (for example complex network meta-analyses), data extraction should be checked by 2 reviewers to avoid data error, which is time-consuming to fix (see the DECiMAL guide to data extraction for complex meta-analyses).

Analysing and presenting results for studies of interventions

Meta-analysis may be appropriate if treatment estimates of the same outcome from more than 1 study are available. Recognised approaches to meta-analysis should be used, as described in the handbook from Cochrane, the Centre for Reviews and Dissemination (2009), in Higgins et al. (2021) and documents developed by the NICE Guidelines Technical Support Unit.

There are several ways of summarising and illustrating the strength and direction of quantitative evidence about the effectiveness of an intervention, even if a meta-analysis is not done. Forest

plots can be used to show effect estimates and confidence intervals for each study (when available, or when it is possible to calculate them). They can also be used to provide a graphical representation when it is not appropriate to do a meta-analysis and present a pooled estimate. However, the homogeneity of the outcomes and measures in the studies needs to be carefully considered: a forest plot needs data derived from the same (or justifiably similar) outcomes and measures.

Head-to-head data that compares the effectiveness of interventions is useful for a comparison between 2 active management options. Comparative studies are usually combined in a meta-analysis where appropriate. A network meta-analysis is an analysis that can include trials that compare the interventions of interest head-to-head and also trials that allow an indirect comparison via a common third intervention.

The same principles of good practice for evidence reviews and meta-analyses should be applied when conducting network meta-analyses. The reasons for identifying and selecting the randomised controlled trials (RCTs) should be explained, including the reasons for selecting the treatment comparisons. The methods of synthesis should be described clearly in the methods section of the evidence review.

When multiple competing options are being appraised, a network meta-analysis should be considered. The data from individual trials should also be documented (usually as an appendix). If there is doubt about the inclusion of particular trials (for example, because of concerns about limitations or applicability), a sensitivity analysis in which these trials are excluded should also be presented. The level of consistency between the direct and indirect evidence on the interventions should be reported, including consideration of model fit and comparison statistics such as the total residual deviance, and the deviance information criterion (DIC). Results of further inconsistency tests, such as those based on node-splitting, should also be reported, if available. Results from direct comparisons may also be presented for comparison with the results from a network meta-analysis; this may be the results from the direct evidence within the network meta-analysis, or from direct pairwise comparisons done outside the network meta-analysis, depending on which is considered more informative.

When evidence is combined using network meta-analyses, trial randomisation should typically be preserved. If this is not appropriate, the planned approach should be discussed and agreed with NICE staff with responsibility for quality assurance. A comparison of the results from single treatment arms from different RCTs is not acceptable unless the data are treated as observational and analysed as such.

Further information on complex methods for evidence synthesis is provided by the documents developed by the NICE Guidelines Technical Support Unit.

To promote transparency of health research reporting (as endorsed by the EQUATOR network), evidence from a network meta-analysis should usually be reported according to the criteria in the modified PRISMA-NMA checklist in the appendix on network meta-analysis reporting standards.

Evidence from a network meta-analysis can be presented in a variety of ways. The network should be presented diagrammatically with the direct and indirect treatment comparisons clearly identified, and show the number of trials in each comparison. Further information on how to present the results of network meta-analyses is provided by the documents developed by the NICE Guidelines Technical Support Unit.

There are a number of approaches for assessing the quality, or confidence in outputs derived from network meta-analysis that have recently been published (Phillippo et al. 2019, Phillippo et al. 2017, Caldwell et al. 2016, Purhan et al. 2014, Salanti et al. 2014). The strengths and limitations of these approaches and their application to guideline development are currently being assessed, but none of these approaches are currently required in NICE guideline development.

Analysing and presenting results of studies of diagnostic test accuracy

Information on methods of presenting and synthesising results from studies of diagnostic test accuracy is being developed by the Cochrane Screening and Diagnostic Tests Methods Group and the GRADE working group. The quality of the evidence should be based on the critical appraisal criteria from QUADAS-2 (see the appendix on appraisal checklists, evidence tables, GRADE and economic profiles). If meta-analysis is not possible or appropriate, there should be a narrative summary of the results that were considered most important for the review question.

Evidence on diagnostic test accuracy may be summarised in tables or presented as Receiver Operating Characteristic curves (**ROC curves**). Meta-analysis of results from a number of diagnostic accuracy studies can be complex. Relevant published technical advice (such as that from Cochrane) should be used to guide reviewers.

Analysing and presenting results of studies of prognosis, or prediction models for a diagnosis or prognosis

There is currently no general consensus on approaches for synthesising evidence from studies on prognosis, or prediction models for diagnosis or prognosis. A narrative summary of the quality of the evidence should be given, based on the quality appraisal criteria from the quality assessment

tool used (for example, PROBAST [for prediction models], or QUIPS [for simple correlation/ univariate regression analyses in prognostic studies], see the appendix on appraisal checklists, evidence tables, GRADE and economic profiles). Characteristics of data should be extracted to a standard template for inclusion in an evidence table (see the appendix on appraisal checklists, evidence tables, GRADE and economic profiles). Methods for presenting syntheses of evidence on prognosis and prediction models are being developed by the GRADE working group.

Results may be presented as tables. Reviewers should be wary of using meta-analysis to summarise results unless the same prognostic factors or predictors and confounding factors have been examined across all studies and the same outcome measured. It is important to explore whether all likely confounding factors have been accounted for, and whether the metrics used to measure exposure (or outcome) are universal. When studies cannot be pooled, results should be presented consistently across studies (for example, the median and ranges of predictive values). For more information on prognostic reviews, see Collins 2015 and Moons 2015.

Analysing and presenting results of qualitative evidence

Qualitative evidence occurs in many forms and formats and so different methods may be used for synthesis and presentation (such as those described by the Cochrane Qualitative & Implementation Methods Group). As with all data synthesis, it is important that the method used to evaluate the evidence is easy to follow. It should be written up in clear English and any analytical decisions should be clearly justified. Critical appraisal of qualitative evidence should be based on the criteria from the Critical Appraisal Skills Programme (CASP; see the appendix on appraisal checklists, evidence tables, GRADE and economic profiles).

Qualitative evidence should be synthesised and then summarised in GRADE-CERQual. If synthesis of the evidence is not appropriate, a narrative summary may be adequate; this should be agreed with NICE staff with responsibility for quality assurance. The approach used depends on the volume and consistency of the evidence. If the qualitative evidence is extensive, then a recognised method of synthesis is preferable. If the evidence is more disparate and sparse, a narrative summary may be appropriate.

The simplest approach to synthesise qualitative data in a meaningful way is to analyse the themes (or 'meta' themes) in the evidence tables and write second level themes based on them. This 'second level' thematic analysis can be carried out if enough data are found, and the papers and research reports cover the same (or similar) findings or use similar methods. (These should be relevant to the review questions and could, for example, include intervention, age, population or setting.)

Synthesis can be carried out in a number of ways, and each may be appropriate depending on the question type, and the evidence identified. Papers reporting on the same findings can be grouped together to compare and contrast themes, focusing not just on consistency but also on any differences. The narrative should be based on these themes.

A more complex but useful approach is 'conceptual mapping' (see Johnson et al. 2000). This involves identifying the key themes and concepts across all the evidence tables and grouping them into first level (major), second level (associated) and third level (subthemes) themes. Results are presented in schematic form as a conceptual diagram and the narrative is based on the structure of the diagram.

Alternatively, themes can be identified and extracted directly from the data, using a grounded approach (Glaser and Strauss 1967). Other potential techniques include meta-ethnography (Noblit and Hare 1988) and meta-synthesis (Barroso and Powell-Cope 2000), but expertise in their use is needed.

Analysing and presenting results of mixed methods reviews

All qualitative evidence from a mixed methods review should be synthesised and then summarised in GRADE-CERQual. If appropriate, all quantitative data (for example, for intervention studies) should be presented using GRADE. An overall summary of how the quantitative and qualitative evidence are linked should be presented in either simple matrices or simple thematic diagrams.

Certainty or confidence in the findings of analysis

The certainty or confidence in the findings should be presented at outcome level using GRADE or GRADE-CERQual (for individual or synthesised studies). If this is not appropriate, the planned approach should be discussed and agreed with NICE staff with responsibility for quality assurance. It should be documented in the review protocol (see the appendix on review protocol template) together with the reasons for the choice.

Certainty or confidence in the findings by outcome

Before starting an evidence review, the outcomes of interest which are important to people using services and the public for the purpose of decision-making should be identified. The reasons for prioritising outcomes should be documented in the evidence review. This should be done before starting the evidence review and clearly separated from discussion of the evidence, because there is potential to introduce bias if outcomes are selected when the results are known. An example of this would be choosing only outcomes for which there were statistically significant results.

The committee discussion section should also explain how the importance of outcomes was considered when discussing the evidence. For example, the committee may want to define prioritised outcomes into 'important' and 'critical'. Alternatively, they may think that all prioritised outcomes are crucial for decision making. In this case, there will be no distinction between 'critical' or 'important' for all prioritised outcomes. The impact of this on the final recommendations should be clear.

GRADE and GRADE-CERQual assess the certainty or confidence in the review findings by looking at features of the evidence found for each 'critical' and 'important' outcome or theme. GRADE is summarised in box 6.1, and GRADE-CERQual in box 6.2.

Box 6.1 GRADE approach to assessing the certainty of evidence for intervention studies

GRADE assesses the following features for the evidence found for each outcome:

- study limitations (risk of bias) – the internal validity of the evidence
- inconsistency – the heterogeneity or variability in the estimates of treatment effect across studies
- indirectness – the extent of differences between the population, intervention, comparator for the intervention and outcome of interest across studies
- imprecision – the extent to which confidence in the effect estimate is adequate to support a particular decision
- other considerations – publication bias, the degree of selective publication of studies.

Box 6.2 GRADE-CERQual approach to assessing the confidence of evidence for qualitative studies

GRADE-CERQual assesses the following features for the evidence found for each finding:

- methodological limitations – the internal validity of the evidence
- relevance – the extent to which the evidence is applicable to the context in the review question
- coherence – the extent of the similarities and differences within the evidence
- adequacy of data – the extent of richness and quantity of the evidence.

The certainty or confidence of evidence is classified as high, moderate, low or very low. In the context of NICE guidelines, it can be interpreted as follows:

- **High** – further research is very unlikely to change our recommendation.
- **Moderate** – further research is likely to have an important impact on our confidence in the estimate of effect and may change the strength of our recommendation.
- **Low** – further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the recommendation.
- **Very low** – any estimate of effect is very uncertain and further research will probably change the recommendation.

The approach taken by NICE differs from the standard GRADE and GRADE-CERQual system in 2 ways:

- it also integrates a review of the quality of cost-effectiveness studies (see the chapter on incorporating economic evaluation)
- it does not use 'overall summary' labels for the quality of the evidence across all outcomes or for the strength of a recommendation, but uses the wording of recommendations to reflect the strength of the evidence (see the chapter on writing the guideline).

In addition, although GRADE does not yet cover all types of review questions, GRADE principles can be applied and adapted to other types of questions. The GRADE working group continues to refine existing approaches and to develop new approaches. Developers should check the GRADE website for any new guidance or systems when developing the review protocol. Any substantial

changes, made by the developer, to GRADE should be agreed with NICE staff with responsibility for quality assurance before use.

GRADE or GRADE-CERQual tables summarise the certainty in the evidence and data for each critical and each important outcome or theme and include a limited description of the certainty in the evidence. GRADE or GRADE-CERQual tables should be available (in an appendix) for each review questions.

6.3 Equality and diversity considerations

NICE's equality and diversity duties are expressed in a single public sector equality duty ('the equality duty', see the section on key principles that guide the development of NICE guidance and standards in the introduction chapter). The equality duty supports good decision-making by encouraging public bodies to understand how different people will be affected by their activities. For NICE, much of whose work involves developing advice for others on what to do, this includes thinking about how people will be affected by its recommendations when these are implemented (for example, by health and social care practitioners).

6.4 Health inequalities

In addition to meeting its legal obligations, NICE is committed to going beyond compliance, particularly in terms of tackling health inequalities. Specifically, NICE considers that it should also take account of socioeconomic factors and the circumstances of certain groups of people (such as looked-after children and people who are homeless). If possible, NICE's guidance aims to reduce and not increase identified health inequalities.

Ensuring inclusivity of the evidence review criteria

Any equalities criteria specified in the review protocol should be included in the evidence tables. At the data extraction stage, reviewers should refer to the PROGRESS-Plus criteria (including age, sex, sexual orientation, disability, ethnicity, religion, place of residence, occupation, education, socioeconomic position and social capital; Gough et al. 2012) and any other relevant protected characteristics, and record these where reported, as specified in the review protocol. Review inclusion and exclusion criteria should also take the relevant groups into account, as specified in the review protocol.

Equalities should be considered during the drafting of the reviews. Equality considerations should be included in the data extraction process and should be recorded in the committee discussion

section if they were important for decision-making.

6.5 Summarising evidence

Presenting evidence

The following sections should be included in the evidence review:

- an introduction to the evidence review
- summary of the evidence identified, in either table or narrative format
- evidence tables (usually presented in an appendix)
- full GRADE or GRADE-CERQual profiles (in an appendix)
- evidence statements (if GRADE [or a modified GRADE approach], or GRADE-CERQual is not used)
- an overall summary of merged quantitative and qualitative evidence (either using matrices or thematic diagrams) for mixed methods reviews
- results from other analysis of evidence, such as forest plots, area under the curve graphs, network meta-analysis (usually presented in an appendix; see the appendix on network meta-analysis reporting standards).

The evidence should usually be presented separately for each review question; however, alternative methods of presentation may be needed for some evidence reviews (for example, where review questions are closely linked and need to be interpreted together). In these cases, the principles of quality assessment, and data extraction and presentation should still apply.

Any substantial deviations in presentation need to be agreed, in advance, with NICE staff with responsibility for quality assurance.

Summary of the evidence

A summary of the evidence identified should be produced. The content of this summary will depend on the type of question and the type of evidence. It should also identify and describe any gaps in the evidence.

Short summaries of the evidence should be included with the main findings. These should:

- summarise the volume of information gleaned for the review question(s), that is, the number of studies identified, included, and excluded (with a link to a PRISMA selection flowchart, in an appendix)
- summarise the study types, populations, interventions, settings or outcomes for each study related to a particular review question.

Evidence tables

Evidence tables help to identify the similarities and differences between studies, including the key characteristics of the study population and interventions or outcome measures. This provides a basis for comparison.

Data from identified studies are extracted to standard templates for inclusion in evidence tables. The type of data and study information that should be included depends on the type of study and review question, and should be concise and consistently reported. The appendix on appraisal checklists, evidence tables, GRADE and economic profiles contains examples of evidence tables for quantitative studies (both experimental and observational).

The types of information that could be included are:

- bibliography (authors, date)
- study aim, study design (for example, RCT, case–control study) and setting (for example, country)
- funding details (if known)
- population (for example, source and eligibility)
- intervention, if applicable (for example, content, who delivers the intervention, duration, method, dose, mode or timing of delivery)
- comparator, if applicable (for example, content, who delivers the intervention, duration, method, dose, mode or timing of delivery)
- method of allocation to study groups (if applicable)
- outcomes (for example, primary and secondary and whether measures were objective, subjective or otherwise validated)

- key findings (for example, effect sizes, confidence intervals, for all relevant outcomes, and where appropriate, other information such as numbers needed to treat and considerations of heterogeneity if summarising a systematic review or meta-analysis)
- inadequately reported data, missing data or if data have been imputed (include method of imputation or if transformation is used)
- overall comments on quality, based on the critical appraisal and what checklist was used to make this assessment.

If data are not being used in any further statistical analysis, or are not reported in GRADE tables, effect sizes (point estimate) with confidence intervals should be reported, or back calculated from the published evidence where possible. If confidence intervals are not reported, exact p values (whether or not significant), with the test from which they were obtained, should be described. When confidence intervals or p values are inadequately reported or not given, this should be stated. Any descriptive statistics (including any mean values and degree of spread such as ranges) indicating the direction of the difference between intervention and comparator should be presented. If no further statistical information is available, this should be clearly stated.

The assessment of potential biases should also be presented. When study details are inadequately reported, or absent, this should be clearly stated.

The type of data that should be included in evidence tables for qualitative studies is shown in the example in the appendix on appraisal checklists, evidence tables, GRADE and economic profiles. This could include:

- bibliography (authors, date)
- study aim, study design and setting (for example, country)
- funding details (if known)
- population or participants
- theoretical perspective adopted (such as grounded theory)
- key aims, objectives and research questions; methods (including analytical and data collection technique)
- key themes/findings (including quotes from participants that illustrate these themes or findings, if appropriate)

- gaps and limitations
- overall comments on quality, based on the critical appraisal and what checklist was used to make this assessment.

Evidence statements

Full GRADE or GRADE-CERQual tables that present both the results of the analysis and describe the confidence in the evidence should normally be provided (in an appendix).

If GRADE or GRADE-CERQual is not appropriate for the evidence review, evidence statements should be included. Examples of where evidence statements may be needed are review questions covering prognosis/clinical prediction models (where data cannot be pooled), review questions covering service delivery, or where formal consensus approaches have been taken to answer a review question.

Evidence statements should provide an aggregated summary of all of the relevant studies or analyses, regardless of their findings. They should reflect the balance of the evidence, and its strength (quality, quantity and consistency, and applicability). Evidence statements should summarise key aspects of the evidence but should also highlight where there is a lack of evidence (note that this is different to evidence for a lack of effect).

Evidence statements are structured and written to help committees formulate and prioritise recommendations. They can help committees decide:

- whether or not there is sufficient evidence (in terms of strength and applicability) to form a judgement
- whether (on balance) the evidence demonstrates that an intervention, approach or programme is effective or ineffective, or is inconclusive
- the size of effect and associated measure of uncertainty
- whether the evidence is applicable to people affected by the guideline and contexts covered by the guideline.

Structure and content of evidence statements

If evidence statements are presented, one or more evidence statements are prepared for each review question or subsidiary question. (Subsidiary questions may cover a type of intervention, specific population groups, a setting or an outcome.)

Each evidence statement should stand alone as an accessible, clear summary of key information used to support the recommendations (see the section on interpreting the evidence to make recommendations in the chapter on writing the guideline). The guideline should ensure that the relationship between the recommendations and the supporting evidence statements is clear.

Evidence statements should identify the sources of evidence and their quality in brief descriptive terms and not just by symbols. Each statement should also include summary information about the:

- content of the intervention, management strategy (for example, what, how, where?) and comparison, or factor of interest
- populations, number of people analysed, and settings (for example, country)
- outcomes, the direction of effect (or correlation) and the size of effect (or correlation) if applicable
- strength of evidence (reflecting the appropriateness of the study design to answer the question and the quality, quantity and consistency of evidence)
- applicability to the question, people affected by the guideline and setting (see the section on equality and diversity considerations in the chapter on reviewing research evidence).

Note that the strength of the evidence is reported separately to the direction and size of the effects or correlations observed.

Where important, the evidence statement should also summarise information about:

- whether the intervention has been delivered as it should be (fidelity of the intervention)
- what affects the intervention achieving the outcome (mechanism of action).

An evidence statement indicating where no evidence is identified for a specific outcome should be included.

'Vote counting' (merely reporting on the number of studies) is not an acceptable summary of the evidence.

If appropriate, the direction of effect or association should be summarised using 1 of the following terms:

- positive

- negative
- mixed
- none.

However, appropriate context/topic-specific terms (for example, 'an increase in HIV incidence', 'a reduction in injecting drug use' and 'smoking cessation') may be used.

These terms should be used consistently in each review and their definitions should be reported in the methods section.

Evidence statements for quantitative evidence

An example of an evidence statement from a prognostic review is given in box 6.3. The example has been adapted from the original and is for illustrative purposes only:

Box 6.3 Example of an evidence statement from a prognostic review

Association between communication and contraceptive use

There is moderate evidence from 3 UK cross-sectional studies (Kettle et al. 2007, Jarrett et al. 2007, Morgan et al. 2000; n=254), about the correlation between young people's communication skills around safer sex and a reduction in the number of teenage pregnancies. The evidence about the strength of this correlation is mixed. One study (Kettle et al. 2007) found that discussing condom use with new partners was associated with an increase in actual condom use at first sex (odds ratio [OR] 2.67 [95% confidence interval 1.55 to 4.57]). Another study (Morgan et al. 2000) found that not talking to a partner about protection before first sexual intercourse was associated with an increase in teenage pregnancy (OR 1.67 [1.03 to 2.72]). And, another study (Jarrett et al. 2007) found small positive correlations between condom use, discussions about safer sex ($r=0.072$, $p<0.01$) and communication skills ($r=0.204$, $p<0.01$).

6.6 References and further reading

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7 Incorporating economic evaluation

7.1 Introduction

This chapter describes the role of economics in developing NICE guidelines, and suggests possible approaches to use when considering economic evidence. It also sets out the principles for conducting new economic modelling if there is insufficient published evidence that can be used to assess the cost effectiveness of key interventions, services or programmes.

It should be noted that significant methodological developments in this area are anticipated, and this manual will be updated in response to these. Developments in methodology for considering the economic aspects of delivering services will also be taken into account.

7.2 The role of economics in guideline development

Economic evaluation compares the costs and consequences of alternative courses of action. Formally assessing the cost effectiveness of an intervention, service or programme can help decision-makers ensure that maximum gain is achieved from limited resources. If resources are used for interventions or services that are not cost effective, the population as a whole gains fewer benefits.

It is particularly important for committee members to understand that economic analysis is not only about estimating the resource consequences of a guideline recommendation, but is concerned with evaluating costs in relation to benefits (including benefits to quality of life) and harm of alternative courses of action. NICE's principles usually take precedence over economics.

Guideline recommendations should be based on the balance between the estimated costs of the interventions or services and their expected benefits compared with an alternative (that is, their 'cost effectiveness'). In general, the committee should be increasingly certain of the cost effectiveness of a recommendation as the cost of implementation increases.

Common types of health economic analysis are summarised in box 7.1.

Box 7.1 Types of economic analysis

- Cost-minimisation analysis: a determination of the least costly among alternative interventions that are assumed to produce equivalent outcomes
- Cost-effectiveness analysis (CEA): a comparison of costs in monetary units with outcomes in quantitative non-monetary units (for example, reduced mortality or morbidity)
- Cost–utility analysis (CUA): a form of cost-effectiveness analysis that compares costs in monetary units with outcomes in terms of their utility, usually to the patient, measured in QALYs
- Cost–consequence analysis: a form of cost-effectiveness analysis that presents costs and outcomes in discrete categories, without aggregating or weighting them
- Cost–benefit analysis (CBA): a comparison of costs and benefits, both of which are quantified in common monetary terms

The committee may require more robust evidence on the effectiveness and cost effectiveness of recommendations that are expected to have a substantial impact on resources. Economic analysis must be done when there is no robust evidence of cost effectiveness to support these recommendations. Any uncertainties must be offset by a compelling argument in favour of the recommendation. However, the cost impact or savings potential of a recommendation should not be the sole reason for the committee's decision.

Resource impact is considered in terms of the additional cost or saving above that of current practice for each of the first 5 years of implementing the guideline. Resource impact is defined as substantial if:

- implementing a single guideline recommendation in England costs more than £1 million per year **or**
- implementing the whole guideline in England costs more than £5 million per year.

The aim is to ensure that the guideline does not introduce a cost pressure into the health and social care system unless the committee is convinced of the benefits and cost effectiveness of the recommendations.

Defining the priorities for economic evaluation should start during scoping of the guideline, and

should continue when the review questions are being developed. Questions on economic issues mirror the review questions on effectiveness, but with a focus on cost effectiveness. Health economic input in guidelines typically involves 2 stages. The first is a literature review of published economic evidence to determine whether the review questions set out in the scope have already been assessed by economic evaluations. Reviews of economic evidence identify, present and appraise data from studies of cost effectiveness. They may be considered as part of each review question undertaken for a guideline. If existing economic evidence is inadequate or inconclusive for 1 or more review questions, then the second stage may involve a variety of economic modelling approaches such as adapting existing economic models or building new models from existing data.

Reviews of economic evidence and any economic modelling are quality assured by the developer and a member of NICE staff with responsibility for quality assurance. The nature of the quality assurance will depend on the type of economic evaluation, but will consider the evaluation in terms of the appropriate reference case and be based on a methodology checklist (for example, those in the appendix on appraisal checklists, evidence tables, GRADE and economic profiles).

7.3 The reference case

A guideline may consider a range of interventions, commissioned by various organisations and resulting in different types of benefits (outcomes). It is crucial that reviews of economic evidence and economic evaluations undertaken to inform guideline development adopt a consistent approach depending on the type of interventions assessed. The 'reference case' specifies the methods considered consistent with the objective of maximising benefits from limited resources. NICE is interested in benefits to patients (for interventions with health outcomes in NHS and personal social services [PSS] settings), to individuals and community groups (for interventions with health and non-health outcomes in public sector settings) and to people using services and their carers (for interventions with a social care focus).

Choosing the most appropriate reference case depends on whether or not the interventions undergoing evaluation:

- are commissioned by the NHS and PSS alone or by any other public sector body
- focus on social care outcomes.

The reference case chosen should be agreed for each decision problem (relevant to a review question), should be set out briefly in the scope and detailed in the economic plan. A guideline may use a different reference case for different decision problems if appropriate (for example, if a guideline reviews interventions with non-health- and/or social care-related outcomes). This should

be agreed with NICE before any economic evaluation is conducted.

Table 7.1 summarises the reference case according to the interventions being evaluated.

Table 7.1 Summary of the reference case

Element of assessment	Interventions funded by the NHS and personal social services (PSS) with health outcomes	Interventions funded by the public sector with health and non-health outcomes	Interventions funded by the public sector with a social care focus
Defining the decision problem	The scope developed by NICE	The scope developed by NICE	The scope developed by NICE
Comparator	Interventions routinely used in the NHS, including those regarded as current best practice	Interventions routinely used in the public sector, including those regarded as best practice	Interventions routinely delivered by the public and non-public social care sector (Social care costs are the costs of interventions which have been commissioned or paid for in full, or in part by non-NHS organisations)
Perspective on costs	NHS and PSS; for PSS include only care that is funded by NHS (such as 'continuing healthcare' or 'funded nursing care')	Public sector – often reducing to local government Societal perspective (where appropriate) Other (where appropriate); for example, employer	Public sector – often reducing to local government Societal perspective (where appropriate) Other (where appropriate); for example, employer

Element of assessment	Interventions funded by the NHS and personal social services (PSS) with health outcomes	Interventions funded by the public sector with health and non-health outcomes	Interventions funded by the public sector with a social care focus
Perspective on outcomes	All direct health effects, whether for people using services or, when relevant, other people (principally family members and/or informal carers)	All health effects on individuals. For local government and other settings, where appropriate, non-health effects may also be included	Effects on people for whom services are delivered (people using services and/or carers)
Type of economic evaluation	Cost–utility analysis	Cost–utility analysis (base case) Cost-effectiveness analysis Cost–consequences analysis Cost–benefit analysis Cost-minimisation analysis	Cost–utility analysis (base case) Cost-effectiveness analysis Cost–consequences analysis Cost–benefit analysis Cost-minimisation analysis
Synthesis of evidence on outcomes	Based on a systematic review, with a preference for treatment effects from randomised controlled trials (RCTs)	Based on a systematic review, with a preference for treatment effects from RCTs	Based on a systematic review, with a preference for treatment effects from RCTs
Time horizon	Long enough to reflect all important differences in costs or outcomes between the interventions being compared	Long enough to reflect all important differences in costs or outcomes between the interventions being compared	Long enough to reflect all important differences in costs or outcomes between the interventions being compared

Element of assessment	Interventions funded by the NHS and personal social services (PSS) with health outcomes	Interventions funded by the public sector with health and non-health outcomes	Interventions funded by the public sector with a social care focus
Measuring and valuing health effects	Quality-adjusted life years (QALYs): the EQ-5D-3L is the preferred measure of health-related quality of life in adults (See NICE position statement on the EQ-5D-5L)	QALYs: the EQ-5D-3L is the preferred measure of health-related quality of life in adults (See NICE position statement on the EQ-5D-5L)	QALYs: the EQ-5D-3L is the preferred measure of health-related quality of life in adults (See NICE position statement on the EQ-5D-5L)
Measure of non-health effects	Not applicable	Where appropriate, to be decided on a case-by-case basis	Capability or social care-related quality of life measures where an intervention results in both health and capability or social care outcomes
Source of data for measurement of quality of life	Reported directly by people using service and/or carers	Reported directly by people using service and/or carers	Reported directly by people using service and/or carers
Source of preference data for valuation of changes in health-related quality of life	Representative sample of the UK population	Representative sample of the UK population	Representative sample of the UK population

Element of assessment	Interventions funded by the NHS and personal social services (PSS) with health outcomes	Interventions funded by the public sector with health and non-health outcomes	Interventions funded by the public sector with a social care focus
Discounting	The same annual rate for both costs and health effects (currently 3.5%) Sensitivity analyses using rates of 1.5% for both costs and health effects may be presented alongside the reference-case analysis, particularly for public health interventions In certain cases, cost-effectiveness analyses are very sensitive to the discount rate used. In this circumstance, analyses that use a non-reference-case discount rate for costs and outcomes may be considered	The same annual rate for both costs and health effects (currently 3.5%) Sensitivity analyses using rates of 1.5% for both costs and health effects may be presented alongside the reference-case analysis, particularly for public health interventions In certain cases, cost-effectiveness analyses are very sensitive to the discount rate used. In this circumstance, analyses that use a non-reference-case discount rate for costs and outcomes may be considered	The same annual rate for both costs and health effects (currently 3.5%) Sensitivity analyses using rates of 1.5% for both costs and health effects may be presented alongside the reference-case analysis, particularly for public health interventions In certain cases, cost-effectiveness analyses are very sensitive to the discount rate used. In this circumstance, analyses that use a non-reference-case discount rate for costs and outcomes may be considered
Equity considerations: QALYs	A QALY has the same weight regardless of the other characteristics of the people receiving the health benefit	A QALY has the same weight regardless of the other characteristics of the people receiving the health benefit	A QALY has the same weight regardless of the other characteristics of the people receiving the health benefit
Equity considerations: other	Equity considerations relevant to specific topics, and how these were addressed in economic evaluation, must be reported	Equity considerations relevant to specific topics, and how these were addressed in economic evaluation, must be reported	Equity considerations relevant to specific topics, and how these were addressed in economic evaluation, must be reported

Element of assessment	Interventions funded by the NHS and personal social services (PSS) with health outcomes	Interventions funded by the public sector with health and non-health outcomes	Interventions funded by the public sector with a social care focus
Evidence on resource use and costs	Costs should relate to the perspective used and should be valued using the prices relevant to that perspective Costs borne by people using services and the value of unpaid care may also be included if they contribute to outcomes	Costs should relate to the perspective used and should be valued using the prices relevant to that perspective Costs borne by people using services and the value of unpaid care may also be included if they contribute to outcomes	Costs should relate to the perspective used and should be valued using the prices relevant to that perspective Costs borne by people using services and the value of unpaid care may also be included if they contribute to outcomes

Interventions funded by the NHS and PSS with health outcomes

For decision problems where the intervention evaluated is solely commissioned by the NHS and does not have a clear focus on non-health outcomes, the reference case for 'interventions funded by the NHS and PSS with health outcomes' should be chosen.

More details on methods of economic evaluation for interventions with health outcomes in NHS and PSS settings can be found in NICE's guide to the methods of technology appraisal 2013. This includes a reference case, which specifies the methods considered by NICE to be the most appropriate for analysis when developing technology appraisal guidance. The reference case is consistent with the NHS objective of maximising health gain from limited resources.

Biosimilar medicines are considered to differ from the original product in price only (in line with the NICE technology appraisal position statement on the use of biosimilars). It may be necessary to consider modelling scenarios for different levels of uptake for biosimilars, and whether there is any relevant MHRA or government guidance on switching to biosimilars.

All relevant NHS and PSS costs that change as a result of an intervention should be taken into account. Important non-NHS and PSS costs should also be identified and considered for inclusion in sensitivity analysis, or to aid decision-making. These may include costs to other central government departments and local government. Service recommendations are likely to have additional costs, which include implementation costs not usually included in the analysis and costs to other

government budgets, such as social care. Implementation costs should be included in a sensitivity analysis, where relevant, while costs to other government budgets can be presented in a separate analysis to the base case.

Productivity costs and costs borne by people using services and carers that are not reimbursed by the NHS or PSS should usually be excluded from any analyses (see NICE's guide to the methods of technology appraisal 2013). That is, a societal perspective will not normally be used.

Interventions funded by the public sector with health and non-health outcomes

For decision problems where the interventions evaluated are commissioned in full or in part by non-NHS public sector and other bodies, the reference case for 'interventions funded by the public sector with health and non-health outcomes' should be chosen. For the base-case analysis, a cost–utility analysis should be done using a cost per QALY (quality-adjusted life year) where possible.

This reference case may be most appropriate for public health interventions paid for by an arm of government, and would consider all the costs of implementing the intervention, and changes to downstream costs. In some cases, the downstream costs are negative, and refer to cost savings. For example, an intervention such as increasing physical activity, whose effects may include preventing type 2 diabetes, may be paid for by local government, but may result in cost savings to the NHS in the form of fewer or delayed cases of diabetes. A public sector cost perspective would aggregate all these costs and cost savings. A narrower local government cost perspective would consider only the cost of implementation, whereas an NHS cost perspective would consider only the cost savings. When examining interventions that are not paid for by an arm of government (such as workplace interventions), the perspective on costs should be discussed and agreed with NICE staff with responsibility for quality assurance.

Productivity costs should usually be excluded from both the reference-case and non-reference-case analyses; exceptions (for example, when evaluating interventions in the workplace) can only be made with the agreement of NICE staff with responsibility for quality assurance.

For public health interventions, all direct health effects for people using services or, when relevant, other people such as family members and/or informal carers will be included. Non-health effects may also be included. When required, the perspective will be widened to include sectors that do not bear the cost of an intervention, but receive some kind of benefit from it.

Interventions with a social care focus

For decision problems where the interventions evaluated have a clear focus on social care outcomes, the reference case on 'interventions with a social care focus' should be chosen. For the base-case analysis, a cost–utility analysis should be done using a cost per QALY approach where possible.

Public sector funding of social care for individual service users is subject to eligibility criteria based on a needs assessment and a financial assessment (means test). Therefore users of social care may have to fund, or partly fund, their own care. A public sector perspective on costs should still be adopted, but should consider different scenarios of funding.

A public sector perspective is likely to be a local authority perspective for many social care interventions, but downstream costs that affect other public sector bodies may be taken into account where relevant, especially if they are a direct consequence of the primary aim of the intervention. When individuals may pay a contribution towards their social care, 2 further perspectives may also be pertinent: a societal perspective (which takes account of changes to the amount that individuals and private firms pay towards the cost of care, on top of the public sector contributions) and an individual perspective (which accounts for changes in individual payments only). The value of unpaid care may also be included in sensitivity analysis, or to aid decision-making. The value of unpaid care should be set at the market value of paid care. Productivity costs should usually be excluded from both the reference-case and non-reference-case analyses; exceptions can only be made with the agreement of NICE staff with responsibility for quality assurance.

For social care interventions, the usual perspective on outcomes will be all effects on people for whom services are delivered including, when relevant, family members and/or informal carers. When required, the perspective may be widened to include sectors that do not bear the cost of an intervention, but receive some kind of benefit from it.

Other perspectives

Other perspectives (for example, employers) may also be used to capture significant costs and effects that are material to the interventions. If other perspectives are used, this should be agreed with NICE staff with responsibility for quality assurance before use.

7.4 Reviewing economic evaluations

Identifying and examining published economic evidence that is relevant to the review questions is

an important component of guideline development. The general approach to reviewing economic evaluations should be systematic, focused and pragmatic. The principal search strategy (see the section on developing search strategies in the chapter on identifying the evidence: literature searching and evidence submission), including search strategies for health economic evidence, should be posted on the NICE website 6 weeks before consultation on the draft guideline.

Searching for economic evidence

The approach to searching for economic evidence should be systematic. The strategies and criteria used should be stated explicitly in the guideline and applied consistently.

The advice in the chapter on identifying the evidence: literature searching and evidence submission about identifying the evidence may be relevant to the systematic search for economic evaluations. The types of searches that might be needed are described in the following 2 sections.

Initial scoping search to identify economic evaluations

A scoping search may be performed to look for economic evaluations relevant to current practice in the UK and therefore likely to be relevant to decision-making by the committee (see the chapter on decision-making committees). This should cover areas likely to be included in the scope (see the chapter on the scope).

Economic databases (see the appendix on sources for evidence reviews) should be searched using the population terms used in the evidence review. Other databases relevant to the topic and likely to include relevant economic evaluations should also be searched using the population terms with an economics search filter (see the section on developing search strategies in the chapter on identifying the evidence: literature searching and evidence submission). At the initial scoping stage, it may be efficient to limit any searches of databases that are sources for NHS economic evaluation database (EED) to studies indexed after December 2014 when the searches to identify studies for NHS EED ceased.

Economic evaluations of social care interventions may be published in journals that are not identified through standard searches. Pragmatic searches based on references of key articles and contacting authors should be considered for identifying relevant papers.

Further systematic search to identify economic evaluations

For some review questions a full systematic search, covering all appropriate sources (see the appendix on sources for evidence reviews), should be performed to identify all relevant economic

evaluations. There are several methods for identifying economic evaluations and the developer should choose the appropriate method and record the reasons for the choice in the search protocol. It may also be appropriate to focus on cost–utility analysis studies (see the InterTASC Information Specialists' subgroup Search Filters Resource), or to apply geographical search filters, for example to limit studies to OECD countries (as suggested in Ayiku et al., in press).

- All relevant review questions could be covered by a single search using the population search terms, combined with a search filter where appropriate, to identify economic evaluations and health-state utility data.
- Another approach may be to use the search strategies derived with/from the review questions combined with search filters to identify economic evaluations and health-state utility data. If using this approach, it may be necessary to adapt strategies in some databases to ensure adequate sensitivity (Wood et al. 2017).
- Another option is to identify economic evaluations and quality-of-life data alongside screening for evidence for effectiveness. Further guidance on searching for economic evaluations is available from SuRe Info.

Selecting relevant economic evaluations

The process for sifting and selecting economic evaluations for assessment is essentially the same as for effectiveness studies (see the section on identifying and selecting relevant evidence in the chapter on reviewing research evidence). It should be targeted to identify the papers that are most relevant to current UK practice and therefore likely to inform the committee's decision-making.

Inclusion criteria for sifting and selecting papers for each review should specify populations and interventions relevant to the review question. They should also specify:

- An appropriate date range, because older studies may reflect outdated practices.
- The country or setting, because studies conducted in other countries might not be relevant to the UK. In some cases it may be appropriate to limit consideration to the UK or countries with similar healthcare systems.

The review should also usually focus on economic evaluations that compare both the costs and consequences of the alternative interventions under consideration. Cost–utility, cost–benefit, cost-effectiveness, cost-minimisation or cost–consequences analyses (see box 7.1 in the section on the role of economics in guideline development) can be considered depending on what the committee deems to be the most relevant perspective and likely outcomes for the question. Non-comparative

costing studies, 'burden of disease' studies and 'cost of illness' studies should usually be excluded; but non-comparative costing studies (such as econometric, efficiency, simulation, micro-costing and resource use, and time-series) may be included for some service delivery questions. Sometimes, the published economic evidence is extremely sparse. In such cases, the inclusion criteria for studies may be broadened. The decision to do this is taken by the developer in consultation with NICE staff with responsibility for quality assurance and, when appropriate, with the committee or its chair.

Assessing the quality of economic evaluations

All economic evaluations relevant to the guideline should be appraised using the methodology checklists (see the appendix on appraisal checklists, evidence tables, GRADE and economic profiles). These should be used to appraise published economic evaluations, as well as unpublished papers, such as studies submitted by registered stakeholders and academic papers that are not yet published. The same criteria should be applied to any new economic evaluations conducted for the guideline (see the section on approaches to original economic evaluation).

Exclusion of economic evaluations will depend on the applicability of evidence to the NICE decision-making context (usually the reference case), the amount of higher-quality evidence and the degree of certainty about the cost effectiveness of an intervention (when all the evidence is considered as a whole). Lower-quality studies are more likely to be excluded when cost effectiveness (or lack of it) can be reliably established without them.

Sometimes reported sensitivity analyses indicate whether the results of an evaluation or study are robust despite methodological limitations. If there is no sensitivity analysis, judgement is needed to assess whether a limitation would be likely to change the results and conclusions. If necessary, the health technology assessment checklist for decision-analytic models (Philips et al. 2004) may also be used to give a more detailed assessment of the methodological quality of economic evaluations and modelling studies. Judgements made, and reasons for these judgements, should be recorded in the guideline.

Summarising and presenting results for economic evaluations

Cost-effectiveness or net benefit estimates from published or unpublished studies, or from original economic evaluations conducted for the guideline, should be presented in the guideline, for example, using an 'economic evidence profile' (see the appendix on appraisal checklists, evidence tables, GRADE and economic profiles). This should include relevant economic information (applicability, limitations, costs, effects, cost-effectiveness and/or net benefit estimates as appropriate). It should be explicitly stated if economic information is not available or if it is not thought to be relevant to the review question.

A short evidence statement that summarises the key features of the evidence on cost effectiveness should be included in the evidence review.

7.5 Prioritising questions for further economic analysis

If a high-quality economic analysis that addresses a key issue and is relevant to current practice has already been published, then further modelling may not be needed. However, often the economic literature is not sufficiently robust or applicable. Original economic analyses should only be performed if an existing analysis cannot easily be adapted to answer the question.

Economic plans

The full economic plan initially identifies key areas of the scope as priorities for further economic analysis and outlines proposed methods for addressing review questions about cost effectiveness. The full economic plan may be modified during development of the guideline; for example, as evidence is reviewed, it may become apparent that further economic evaluation is not needed for some areas that were initially prioritised. A version of the economic plan setting out the questions prioritised for further economic analysis, the population, the interventions and the type of economic analysis is published on the NICE website at least 6 weeks before the guideline goes out for consultation (see the section on planning the evidence review in the chapter on developing review questions and planning the evidence review). The reasons for the final choice of priorities for economic analysis should be explained in the guideline.

Discussion of the economic plan with the committee early in guideline development is essential to ensure that:

- the most important questions are selected for economic analysis
- the methodological approach is appropriate (including the reference case)
- all important effects and resource costs are included
- effects and outcomes relating to a broader societal perspective are included if relevant
- additional effects and outcomes not related to health or social care are included if they are relevant
- economic evidence is available to support recommendations that are likely to lead to substantial costs.

The number and complexity of new analyses depends on the priority areas and the information needed for decision-making by the committee. Selection of questions for further economic analysis, including modelling, should be based on systematic consideration of the potential value of economic analysis across all key issues.

Economic analysis is potentially useful for any question in which an intervention, service or programme is compared with another. It may also be appropriate in comparing different combinations or sequences of interventions, as well as individual components of the service or intervention. However, the broad scope of some guidelines means that it may not be practical to conduct original economic analysis for every component.

The decision about whether to carry out an economic analysis therefore depends on:

- the potential overall expected benefit and resource implications of an intervention both for individual people and the population as a whole
- the degree of uncertainty in the economic evidence review and the likelihood that economic analysis will clarify matters.

Economic modelling may not be warranted if:

- It is not possible to estimate cost effectiveness. However, in this case, a 'scenario' or 'threshold' analysis may be useful.
- The intervention has no likelihood of being cost saving and its harms outweigh its benefits.
- The published evidence of cost effectiveness is so reliable that further economic analysis is not needed.
- The benefits sufficiently outweigh the costs (that is, it is obvious that the intervention is cost effective) or the costs sufficiently outweigh the benefits (that is, it is obvious that the intervention is not cost effective).
- An intervention has very small costs, very small benefits and very small budget impact.

7.6 Approaches to original economic evaluation

General principles

Regardless of the methodological approach taken, the general principles described in this section should be observed. Any variation from these principles should be described and justified in the

guideline. The decision problem should be clearly stated. This should include a definition and justification of the interventions or programmes being assessed and the relevant groups using services (including carers).

Developing conceptual models linked to topic areas or review questions may help the health economist to decide what key information is needed for developing effectiveness and cost-effectiveness analyses (see the chapter on the scope for details). Models developed for public health and service delivery topics are likely to relate to several review questions, so most recommendations will be underpinned by some form of modelled analysis.

The choice of model structure is a key aspect of the design-oriented conceptual model. Brennan's taxonomy of model structures (Brennan et al. 2006) should be considered for guidance on which types of models may be appropriate to the decision problem.

Even if a fully modelled analysis is not possible, there may be value in the process of model development, because this will help to structure committee discussions. For example, a model might be able to demonstrate how a change in service will affect demand for a downstream service or intervention.

For service delivery questions, the key challenge is linking changes in service to a health benefit. This obviously poses a challenge when conducting health economic analyses, but it will also be difficult finding high-quality evidence of effectiveness. Modelling using scenario analysis is usually needed to generate the health effects used within the health economic analyses. Because of the considerable resource and health impact of any recommendations on service delivery, its cost effectiveness must be considered, either analytically or qualitatively (see the appendix on service delivery – developing review questions, evidence reviews and synthesis).

Economic analysis should include comparison of all relevant alternatives for specified groups of people affected by the intervention or using services. Any differences between the review questions and the economic analysis should be clearly acknowledged, justified, approved by the committee and explained in the guideline. The interventions or services included in the analysis should be described in enough detail to allow stakeholders to understand exactly what is being assessed. This is particularly important when calculating the cost effectiveness of services.

An economic analysis should be underpinned by the best-quality evidence. The evidence should be based on and be consistent with that identified for the relevant review question. If expert opinion is used to derive information used in the economic analysis, this should be clearly stated and justified in the guideline.

The structure of any economic model should be discussed and agreed with the committee early in guideline development. The reasons for the structure of the model should be clear. Potential alternatives should be identified and considered for use in sensitivity analysis. If existing economic models are being used, or are informing a new analysis, the way these models are adapted or used should be clear.

For service delivery questions, any analysis will need to consider resource constraints. These might be monetary, but might also be resources such as staff, beds, equipment and so on. However, affordability should not be the sole consideration for service recommendations; the impact of any proposed changes on quality of care needs to be considered.

Before presenting final results to a committee for decision-making, all economic evaluations should undergo rigorous quality assessment and validation to assess inputs, identify logical, mathematical and computational errors, and review the plausibility of outputs. The HM Treasury's review of quality assurance of government models (2013) provides guidance on developing the environment and processes required to promote effective quality assurance. This process should be documented.

Quality assurance of an economic evaluation may take various forms at different stages in development, as detailed in the HM Treasury Aqua Book (2015). It can range from basic steps that should always occur, such as disciplined version control, extensive developer testing of their own model, and independent testing by a colleague with the necessary technical knowledge, to external testing by an independent third party and independent analytical audit of all data and methods used. For developer health economists testing their own evaluation, or those of others ('model busting'), useful and practical validation methods include:

- 1-way and n-way sensitivity analyses, including null values and extreme values (Krahn et al. 1997)
- ensuring that the model results can be explained, for example, the logic and reason underlying the effect of a particular scenario analysis on results
- ensuring that predictions of intermediate endpoints (for example, event rate counts) and final endpoints (for example, undiscounted life expectancy) are plausible, including comparison with source materials.

Results should be reported of any analyses conducted to demonstrate external validity. However, relevant data should not be omitted just to facilitate external validation (for example, not including trials so that they can be used for subsequent validation).

Conventions on reporting economic evaluations should be followed (see Drummond et al. 1996 and Husereau et al. 2013) to ensure that reporting of methods and results is transparent. For time horizons that extend beyond 10 years, it may be useful to report discounted costs and effects for the short (1–3 years) and medium (5–10 years) term. The following results should be presented where available and relevant:

- endpoints from the analysis, such as life years gained, number of events and survival
- disaggregated costs
- total and incremental costs and effects for all options.

When comparing multiple mutually exclusive options, a fully incremental approach should be adopted that compares the interventions sequentially in rank order of cost or outcome, with each strategy compared with the next non-dominated alternative in ranking. Comparisons with a common baseline intervention should not be used for decision-making, although should be included in the incremental analysis, if it reflects a relevant option.

Any comparison of interventions in an economic model that are not based on head-to-head trial comparisons should be carefully evaluated for the between-study heterogeneity, and potential for modifiers of treatment effect should explored. Limitations should be noted and clearly discussed in the guideline.

Economic models developed for the guideline are available to registered stakeholders during consultation on the guideline. These models should be fully executable and clearly presented.

Different approaches to economic analysis

There are different approaches to economic analysis (see box 7.1 in the section on the role of economics in guideline development for examples). If economic analysis is needed, the most appropriate approach should be considered early during the development of a guideline, and reflect the content of the guideline scope.

Cost–utility analysis is a form of cost-effectiveness analysis that uses utility as a common outcome. It considers people's quality of life and the length of life they will gain as a result of an intervention or a programme. The health effects are expressed as QALYs, an outcome that can be compared between different populations and disease areas. Costs of resources, and their valuation, should be related to the prices relevant to the sector.

If a cost–utility analysis is not possible (for example, when outcomes cannot be expressed using a utility measure such as the QALY), a cost–consequences analysis may be considered. Cost–consequences analysis can consider all the relevant health and non-health effects of an intervention across different sectors and reports them without aggregation. A cost–consequences analysis that includes most or all of the potential outcomes of an intervention will be more useful than an analysis that only reports 1 or 2 outcomes.

A cost–consequences analysis is useful when different outcomes cannot be incorporated into an index measure. It is helpful to produce a table that summarises all the costs and outcomes and enables the options to be considered in a concise and consistent manner. Outcomes that can be monetised are quantified and presented in monetary terms. Some effects may be quantified but cannot readily be put into monetary form (for more details see the Department for Transport's Transport Analysis Guidance [TAG] unit 2.11). Some effects cannot readily be quantified (such as reductions in the degree of bullying or discrimination) and should be considered by decision-making committees as part of a cost–consequences analysis alongside effects that can be quantified.

All effects (even if they cannot be quantified) and costs of an intervention are considered when deciding which interventions represent the best value. Effectively, cost–consequences analysis provides a 'balance sheet' of outcomes that decision-makers can weigh up against the costs of an intervention (including related future costs).

If, for example, a commissioner wants to ensure the maximum health gain for the whole population, they might prioritise the incremental cost per QALY gained. But if reducing health inequalities is the priority, they might focus on interventions that work best for the most disadvantaged groups, even if they are more costly and could reduce the health gain achieved in the population as a whole.

Cost-effectiveness analysis uses a measure of outcome (a life year saved, a death averted, a patient-year free of symptoms) and assesses the cost per unit of achieving this outcome by different means. The outcome is not separately valued, only quantified; so the study takes no view on whether the cost is worth incurring, only focusing on the cost of different methods of achieving units of outcome.

Cost-minimisation analysis is the simplest form of economic analysis, which can be used when the health effects of an intervention are the same as those of the status quo, and when there are no other criteria for whether the intervention should be recommended. For example, cost-minimisation analysis could be used to decide whether a doctor or nurse should give routine injections when it is found that both are equally effective at giving injections (on average). In cost-

minimisation analysis, an intervention is cost effective only if its net cost is lower than that of the status quo. The disadvantage of cost-minimisation analysis is that the health effects of an intervention cannot often be considered equal to those of the status quo.

Cost–benefit analysis considers health and non-health effects but converts them into monetary values, which can then be aggregated. Once this has been done, 'decision rules' are used to decide which interventions to undertake. Several metrics are available for reporting the results of cost–benefit analysis. Two commonly used metrics are the 'benefit-cost-ratio' (BCR) and the 'net present value' (NPV) – see the Department for Transport's Transport Analysis Guide (TAG) Unit A1.1 for more information.

Cost–utility analysis is required routinely by NICE for the economic evaluation of health-related interventions, programmes and services, for several reasons:

- When used in conjunction with an NHS and PSS perspective, it provides a single yardstick or 'currency' for measuring the impact of interventions. It also allows interventions to be compared so that resources may be allocated more efficiently.
- Where possible, NICE programmes use a common method of cost-effectiveness analysis that allows comparisons between programmes.

However, because local government is largely responsible for implementing public health and wellbeing programmes and for commissioning social care, NICE has broadened its approach for the appraisal of interventions in these areas. Local government is responsible not only for the health of individuals and communities, but also for their overall welfare. The tools used for economic evaluation must reflect a wider remit than health and allow greater local variation. The nature of the evidence and that of the outcomes being measured may place more emphasis on cost–consequences analysis and cost–benefit analysis for interventions in these areas.

The type of economic analysis that should be considered is informed by the setting specified in the scope of the guideline, and the extent to which the effects resulting from the intervention extend beyond health.

There is often a trade-off between the range of new analyses that can be conducted and the complexity of each piece of analysis. Simple methods may be used if these can provide the committee with enough information on which to base a decision. For example, if an intervention is associated with better effectiveness and fewer adverse effects than its comparator, then an estimate of cost may be all that is needed. Or a simple decision tree may provide a sufficiently reliable estimate of cost effectiveness. In other situations a more complex approach, such as

Markov modelling or discrete event simulation, may be warranted.

Measuring and valuing effects for health interventions

The measurement of changes in health-related quality of life should be reported directly from people using services (or their carers). The value placed on health-related quality of life of people using services (or their carers) should be based on a valuation of public preferences elicited from a representative sample of the UK population, using a choice-based valuation method such as the time trade-off or standard gamble. The QALY is the measure of health effects preferred by NICE, and the EQ-5D is NICE's preferred instrument to measure health-related quality of life in adults.

For some economic analyses, a flexible approach may be needed, reflecting the nature of effects delivered by different interventions or programmes. If health effects are relevant, the EQ-5D-based QALY should be used. When EQ-5D data are not available from the relevant clinical studies included in the clinical evidence review, EQ-5D data can be sourced from the literature. The methods used for identifying the data should be systematic and transparent. The justification for choosing a particular data set should be clearly explained. When more than 1 plausible set of EQ-5D data is available, sensitivity analyses should be carried out to show the impact of the alternative utility values.

When EQ-5D data are not available, published mapped EQ-5D data should be used, or they may be estimated by mapping other health-related quality-of-life measures or health-related effects observed in the relevant studies to the EQ-5D if data are available. The mapping function chosen should be based on data sets containing both health-related quality-of-life measures. The statistical properties of the mapping function should be fully described, its choice justified, and it should be adequately demonstrated how well the function fits the data. Sensitivity analyses exploring variation in the use of the mapping algorithms on the outputs should be presented.

In some circumstances, EQ-5D data may not be the most appropriate or may not be available. Qualitative empirical evidence on the lack of content validity for the EQ-5D should be provided, demonstrating that key dimensions of health are missing. This should be supported by evidence that shows that EQ-5D performs poorly on tests of construct validity and responsiveness in a particular patient group. This evidence should be derived from a synthesis of peer-reviewed literature. In these circumstances, alternative health-related quality of life measures may be used and must be accompanied by a carefully detailed account of the methods used to generate the data, their validity, and how these methods affect the utility values.

When necessary, consideration should be given to alternative standardised and validated

preference-based measures of health-related quality of life that have been designed specifically for use in children. The standard version of the EQ-5D has not been designed for use in children. An alternative version for children aged 7 to 12 years is available, but a validated UK valuation set is not yet available.

As outlined in NICE's guide to the methods of technology appraisal 2013 and the accompanying NICE position statement on use of the EQ-5D-5L valuation set for England (updated October 2019), the EQ-5D 5-level (5L) valuation set is not currently recommended for use by NICE. Guideline developers should:

- Use the 3L valuation set for reference-case analyses, where available.
- If data are available to allow mapping of EQ-5D-5L data to 3L, use the mapping function developed by van Hout et al. (2012) when several mapping functions are available (Hernandez Alava et al. 2017), for consistency with the current guide to the methods of technology appraisal.

The QALY remains the most suitable measure for assessing the impact of services, because it can incorporate effects from extension to life and experience of care. It can also include the trade-offs of benefits and adverse events. However, if linking effects to a QALY gain is not possible, links to a clinically relevant or a related outcome should be considered. Outcomes should be optimised for the lowest resource use. The link (either direct or indirect) of any surrogate outcome, such as a process outcome (for example, bed days), to a clinical outcome needs to be justified. However, when QALYs are not used, issues such as trade-offs between different beneficial and harmful effects need to be considered.

Measuring and valuing effects for non-health interventions

For some decision problems (such as for interventions with a social care focus), the intended outcomes of interventions are broader than improvements in health status. Here broader, preference-weighted measures of outcomes, based on specific instruments, may be more appropriate. For example, social care quality-of-life measures are being developed and NICE will consider using 'social care QALYs' if validated, such as the ASCOT (Adult Social Care Outcome Toolkit) set of instruments used by the Department of Health and Social Care in the Adult Social Care Outcomes Framework indicator on social care-related quality of life.

Similarly, depending on the topic, and on the intended effects of the interventions and programmes, the economic analysis may also consider effects in terms of capability and wellbeing. For capability effects, use of the ICECAP-O (Investigating Choice Experiments for the Preferences of Older

People CAPability measure for Older people) or ICECAP-A (Investigating Choice Experiments for the Preferences of Older People CAPability measure for Adults) instruments may be considered by NICE when developing methodology in the future. If an intervention is associated with both health- and non-health-related effects, it may be helpful to present these elements separately.

Economic analysis for interventions funded by the NHS and PSS with health outcomes

Economic analyses conducted for decisions about interventions with health outcomes funded by the NHS and PSS should usually follow the reference case in table 7.1 in the section on the reference case described in NICE's guide to the methods of technology appraisal 2013. Advice on how to follow approaches described in NICE's guide to the methods of technology appraisal 2013 is provided in the NICE Decision Support Unit's technical support documents. Departures from the reference case may sometimes be appropriate; for example, when there are not enough data to estimate QALYs gained. Any such departures must be agreed with members of NICE staff with responsibility for quality assurance and highlighted in the guideline with reasons given.

Economic analysis for interventions funded by the public sector with health and non-health outcomes

The usual perspective for the economic analysis of public health interventions is that of the public sector. This may be simplified to a local government perspective if few costs and effects apply to other government agencies.

Whenever there are multiple outcomes, a cost–consequences analysis is usually needed, and the committee weighs up the changes to the various outcomes against the changes in costs in an open and transparent manner. However, for the base-case analysis, a cost–utility analysis should be undertaken using a cost per QALY approach where possible.

A societal perspective may be used, and will usually be carried out using cost–benefit analysis. When a societal perspective is used, it must be agreed with NICE staff with responsibility for quality assurance and highlighted in the guideline with reasons given.

Economic analysis for interventions with a social care focus

For social care interventions, the perspective on outcomes should be all effects on people for whom services are delivered (people using services and/or carers). Effects on people using services and carers (whether expressed in terms of health effects, social care quality of life, capability or

wellbeing) are the intended outcomes of social care interventions and programmes. Although holistic effects on people using services, their families and carers may represent the ideal perspective on outcomes, a pragmatic and flexible approach is needed to address different perspectives, recognising that improved outcomes for people using services and carers may not always coincide.

Whenever there are multiple outcomes, a cost–consequences analysis is usually needed, and the committee weighs up the changes to the various outcomes against the changes in costs in an open and transparent manner. However, for the base-case analysis, a cost–utility analysis should be undertaken using a cost per QALY approach where possible.

Any economic model should take account of the proportion of care that is publicly funded or self-funded. Scenario analysis may also be useful to take account of any known differences between local authorities in terms of how they apply eligibility criteria. Scenario analysis should also be considered if the cost of social care varies depending on whether it is paid for by local authorities or by individual service users; the value of unpaid care should also be taken into account where appropriate.

It is envisaged that the analytical difficulties involved in creating clear, transparent decision rules around the costs that should be considered, and for which interventions and outcomes, will be particularly problematic for social care. These should be discussed with the committee before any economic analysis is undertaken and an approach agreed.

Identification and selection of model inputs

An economic analysis uses decision-analytic techniques with outcome, cost and utility data from the best available published sources.

The reference case across all perspectives (table 7.1 in the section on the reference case) states that evidence on effects should be obtained from a systematic review of randomised controlled trials. Some inputs, such as costs, may have standard sources that are appropriate, such as national list prices or a national audit, but for others appropriate data will need to be sourced.

Additional searches may be needed; for example, if searches for evidence on effects do not provide the information needed for economic modelling. Additional information may be needed on:

- disease prognosis
- the relationship between short- and long-term outcomes

- quality of life
- adverse events
- resource use or costs.

Although it is desirable to conduct systematic literature reviews for all such inputs, this is time-consuming and other pragmatic options for identifying inputs may be used. Informal searches should aim to satisfy the principle of 'saturation' (that is, to 'identify the breadth of information needs relevant to a model and sufficient information such that further efforts to identify more information would add nothing to the analysis' (Kaltenthaler et al. 2011). Studies identified in the review of evidence on effects should be scrutinised for other relevant data, and attention should be paid to the sources of parameters in analyses included in the systematic review of published economic evaluations. Alternatives could include asking committee members and other experts for suitable evidence or eliciting their opinions, for example, using formal consensus methods such as the Delphi technique or the nominal-group technique. If a systematic review is not possible, transparent processes for identifying model inputs should be reported; the internal quality and external validity of each potential data source should be assessed and their selection justified. If more than 1 suitable source of evidence is found, consideration should be given to synthesis and/or exploration of alternative values in sensitivity analyses.

Data from electronic health records, registries, audits and other sources of 'real-world' data may be used to better define and inform parameter estimates for economic models. For some parameters, real-world data are considered the most appropriate evidence source (for example, jurisdiction-specific administrative databases can be used to estimate control or untreated event probabilities, resource use counts and unit costs), so they should be the main source of such data in economic models. Real-world data should not be considered a substitute for published evidence from randomised controlled trials, when assessing differences in outcomes between interventions. Further guidance on searching and selecting evidence for key model inputs is available from Kaltenthaler et al. (2011) and Paisley (2016).

To obtain real-world data, it may be necessary to negotiate access with the organisations and individuals that hold the data, or to ask them to provide a summary for inclusion in the guidance if published reports are insufficient. Any processes used for accessing data will need to be reported in the health economic plan and in the guideline. Given the difficulties that organisations may have in extracting audit data, such requests should be focused and targeted: for example, identifying a specific audit and requesting results from the previous 3 years.

For some questions, there may be good reason to believe that relevant and useful information

exists outside of literature databases or validated national data sources. Examples include ongoing research, a relatively new intervention and studies that have been published only as abstracts. Typically, the method for requesting information from stakeholders is through a call for evidence (see the appendix on call for evidence and expert witnesses).

For some guidelines, econometric studies provide a supplementary source of evidence and data for bespoke economic models. For these studies, the database 'Econlit' should be searched as a minimum.

Some information on unit costs may be found in the Personal Social Services -Research Unit (PSSRU) report on unit costs of health and social care or the Department of Health's reference costs (provider perspective). Information on resource impact costings can be found in NICE's process guide on resource impact assessment. Some information about public services may be better obtained from national statistics or databases, rather than from published studies. Philips et al. (2004) provide a useful guide to searching for data for use in economic models.

In cases where current costs are not available, costs from previous years should be adjusted to present value using inflation indices appropriate to the cost perspective, such as the hospital and community health services (HCHS) index and the PSS pay and prices index, available from the PSSRU report on unit costs of health and social care or the Office for National Statistics (ONS) consumer price index.

Wherever possible, costs relevant to the UK healthcare system should be used. However, in cases where only costs from other countries are available these should be converted to Pounds Sterling using an exchange rate from an appropriate and current source (such as HM Revenue and Customs or Organisation for Economic Co-operation and Development).

As outlined in NICE's guide to the methods of technology appraisal 2013, the public list prices for technologies (for example, medicines or medical devices) should be used in the reference-case analysis. When there are nationally available price reductions (for example, for medicines procured for use in secondary care through contracts negotiated by the NHS Commercial Medicines Unit), the reduced price should be used in the reference-case analysis to best reflect the price relevant to the NHS. The Commercial Medicines Unit publishes information on the prices paid for some generic medicines by NHS trusts through its Electronic Market Information Tool (eMIT), focusing on medicines in the 'National Generics Programme Framework' for England. Analyses based on price reductions for the NHS will be considered only when the reduced prices are transparent and can be consistently available across the NHS, and when the period for which the specified price is available is guaranteed. When a reduced price is available through a patient access scheme that has

been agreed with the Department of Health and Social Care, the analyses should include the costs associated with the scheme. If the price is not listed on eMIT, then the current price listed on the British National Formulary (BNF) should be used. For medicines that are predominantly dispensed in the community, prices should be based on the Drug Tariff. In the absence of a published list price and a price agreed by a national institution (as may be the case for some devices), an alternative price may be considered, provided that it is nationally and publicly available. If no other information is available on costs, local costs obtained from the committee may be used.

Preference-based quality-of-life data are often needed for economic models. Many of the search filters available are highly sensitive and so, although they identify relevant studies, they also detect a large amount of irrelevant data. An initial broad literature search for quality-of-life data may be a good option, but the amount of information identified may be unmanageable (depending on the key issue being addressed). It may be more appropriate and manageable to incorporate a quality of life search filter when performing additional searches for key issues of high economic priority. When searching bibliographic databases for health-state utility values, specific techniques outlined in Ara (2017) and Golder et al. (2005) and Papaioannou et al. (2010) may be useful, and specific search filters have been developed that may increase sensitivity (Arber et al. 2017). The provision of quality-of-life data should be guided by the health economist at an early stage during guideline development so that the information specialist can adopt an appropriate strategy. Resources for identifying useful utility data for economic modelling are the dedicated registries of health-state utility values such as ScHARRHUD and Tufts CEA Registry and the NICE Decision Support Unit's technical support documents.

Exploring uncertainty

The committee should discuss any potential bias and limitations of economic models. Sensitivity analysis should be used to explore the impact that potential sources of bias and uncertainty could have on model results.

Deterministic sensitivity analysis should be used to explore key assumptions used in the modelling. This should test whether and how the model results change under alternative, plausible scenarios. Common examples of when deterministic sensitivity analysis could be conducted are:

- when there is uncertainty about the most appropriate assumption to use for extrapolation of costs and effects beyond the trial follow-up period
- when there is uncertainty about how the pathway of care is most appropriately represented in the analysis

- when there may be economies of scale (for example, when appraising diagnostic technologies)
- for infectious disease transmission models.

Deterministic sensitivity analysis should also be used to test any bias resulting from the data sources selected for key model inputs.

Probabilistic sensitivity analysis can be used to account for uncertainty arising from imprecision in model inputs. The use of probabilistic sensitivity analysis will often be specified in the health economic plan. Any uncertainty associated with all inputs can be simultaneously reflected in the results. In non-linear decision models where outputs are a result of a multiplicative function (for example, in Markov models), probabilistic methods also provide the best estimates of mean costs and outcomes. The choice of distributions used should be justified; for example, in relation to the type of parameter and the method of its estimation. Presentation of the results of probabilistic sensitivity analysis could include scatter plots or confidence ellipses, with an option for including cost-effectiveness acceptability curves and frontiers.

When a probabilistic sensitivity analysis is carried out, a value of information analysis may be considered to indicate whether more research is necessary, either before recommending an intervention or in conjunction with a recommendation. The circumstances in which a value of information analysis should be considered will depend on whether more information is likely to be available soon and whether this information is likely to influence the decision to recommend the intervention.

When probabilistic methods are unsuitable, the impact of parameter uncertainty should be thoroughly explored using deterministic sensitivity analysis, and the decision not to use probabilistic methods should be justified in the guideline.

Consideration can be given to including structural assumptions and the inclusion or exclusion of data sources in probabilistic sensitivity analysis. In this case, the method used to select the distribution should be outlined in the guideline (Jackson et al. 2011).

Discounting

Cost-effectiveness results should reflect the present value of the stream of costs and benefits accruing over the time horizon of the analysis. For the reference case, the same annual discount rate should be used for both costs and benefits. NICE considers that it is usually appropriate to discount costs and health effects at the same annual rate of 3.5%.

Sensitivity analyses using 1.5% as an alternative rate for both costs and health effects may be presented alongside the reference-case analysis, particularly for public health guidance. When treatment restores people who would otherwise die or have a very severely impaired life to full or near full health, and when this is sustained over a very long period (normally at least 30 years), cost-effectiveness analyses are very sensitive to the discount rate used. In this circumstance, analyses that use a non-reference-case discount rate for costs and outcomes may be considered. A discount rate of 1.5% for costs and benefits may be considered by the committee if it is highly likely that, on the basis of the evidence presented, long-term health benefits are likely to be achieved. However, the committee will need to be satisfied that the recommendation does not commit the funder to significant irrecoverable costs.

Subgroup analysis

The relevance of subgroup analysis to decision-making should be discussed with the committee. When appropriate, economic analyses should estimate the cost effectiveness of an intervention in each subgroup.

Local considerations

For service delivery questions, cost-effectiveness analyses may need to account for local factors, such as the expected number of procedures and the availability of staff and equipment at different times of the day, week and year. Service delivery models may need to incorporate the fact that each local provider may be starting from a different baseline of identified factors (for example, the number of consultants available at weekends). It is therefore important that these factors are identified and considered by the committee. Where possible, results obtained from the analysis should include both the national average and identified local scenarios to ensure that service delivery recommendations are robust to local variation.

Service failures

Service designs under consideration might result in occasional service failure – that is, where the service does not operate as planned. For example, a service for treating myocardial infarction may have fewer places where people can be treated at weekends compared with weekdays as a result of reduced staffing. Therefore more people will need to travel by ambulance and the journey time will also be longer. Given the limited number of ambulances, a small proportion may be delayed, resulting in consequences in terms of costs and QALYs. Such possible service failures should be taken into account in effectiveness and economic modelling. This effectively means that analyses should incorporate the 'side effects' of service designs.

Service demand

Introducing a new service or increasing capacity will often result in an increase in demand. This could mean that a service does not achieve the predicted effectiveness because there is more demand than was planned for. This should be addressed either in the analysis or in considerations.

Equity considerations

NICE's economic evaluation of healthcare and public health interventions does not include equity weighting – a QALY has the same weight for all population groups.

It is important to recognise that care provision, specifically social care, may be means tested, and that this affects the economic perspective in terms of who bears costs – the public sector or the person using services or their family. Economic evaluation should reflect the intentions of the system. Equity considerations relevant to specific topics, and how these were addressed in economic evaluation, must be reported.

7.7 Using economic evidence to formulate guideline recommendations

For an economic analysis to be useful, it must inform the guideline recommendations. The committee should discuss cost effectiveness in parallel with general effectiveness when formulating recommendations (see the chapter on writing the guideline).

Within the context of NICE's principles on social value judgements, the committee should be encouraged to consider recommendations that:

- increase effectiveness at an acceptable level of increased cost **or**
- are less effective than current practice, but free up sufficient resources that can be re-invested in public sector care or services to increase the welfare of the population receiving care.

The committee's interpretations and discussions should be clearly presented in the guideline. This should include a discussion of potential sources of bias and uncertainty. It should also include the results of sensitivity analyses in the consideration of uncertainty, as well as any additional considerations that are thought to be relevant. It should be explicitly stated if economic evidence is not available, or if it is not thought to be relevant to the question.

Recommendations for interventions informed by cost–utility

analysis

If there is strong evidence that an intervention dominates the alternatives (that is, it is both more effective and less costly), it should normally be recommended. However, if 1 intervention is more effective but also more costly than another, then the incremental cost-effectiveness ratio (ICER) should be considered.

Health effects

The cost per QALY gained should be calculated as the difference in mean cost divided by the difference in mean QALYs for 1 intervention compared with the other.

If 1 intervention appears to be more effective than another, the committee has to decide whether it represents reasonable 'value for money' as indicated by the relevant ICER. In doing so, the committee should also refer to NICE's principles on social value judgements (also see box 7.2).

Box 7.2 Comparing the cost effectiveness of different interventions

'NICE has never identified an ICER above which interventions should not be recommended and below which they should. However, in general, interventions with an ICER of less than £20,000 per QALY gained are considered to be cost effective. Where advisory bodies consider that particular interventions with an ICER of less than £20,000 per QALY gained should not be provided by the NHS they should provide explicit reasons (for example, that there are significant limitations to the generalisability of the evidence for effectiveness). Above a most plausible ICER of £20,000 per QALY gained, judgements about the acceptability of the intervention as an effective use of NHS resources will specifically take account of the following factors.

The degree of certainty around the ICER. In particular, advisory bodies will be more cautious about recommending a technology when they are less certain about the ICERs presented in the cost-effectiveness analysis.

The presence of strong reasons indicating that the assessment of the change in the quality of life has been inadequately captured, and may therefore misrepresent, the health gain.

When the intervention is an innovation that adds demonstrable and distinct substantial benefits that may not have been adequately captured in the measurement of health gain.

As the ICER of an intervention increases in the £20,000 to £30,000 range, an advisory body's judgement about its acceptability as an effective use of NHS resources should make explicit reference to the relevant factors considered above. Above a most plausible ICER of £30,000 per QALY gained, advisory bodies will need to make an increasingly stronger case for supporting the intervention as an effective use of NHS resources with respect to the factors considered above.'

When assessing the cost effectiveness of competing courses of action, the committee should not give particular priority to any intervention or approach that is currently offered. In any situation where 'current practice', compared with an alternative approach, generates an ICER above a level that would normally be considered cost effective, the case for continuing to invest in it should be carefully considered, based on similar levels of evidence and considerations that would apply to an investment decision. The committee should be mindful of whether the intervention is consuming more resource than its value is contributing based on NICE's cost per QALY threshold.

Equity considerations

In the reference case, an additional QALY should receive the same weight regardless of any other characteristics of the people receiving the health benefit.

The estimation of QALYs, as defined in the reference case, implies a particular position regarding the comparison of health gained between individuals. Therefore, in the reference case, an additional QALY is of equal value regardless of other characteristics of the individuals, such as their socio-demographic characteristics, their age, or their level of health.

Non-health effects

Outside the health sector, it is more difficult to judge whether the benefits accruing to the non-health sectors are cost effective, but it may be possible to undertake cost–utility analysis based on measures of social care-related quality of life. The committee should take into account the factors it considers most appropriate when making decisions about recommendations. These could include non-health-related outcomes that are valued by the rest of the public sector, including social care. It is possible that over time, and as the methodology develops (including the establishment of recognised standard measures of utility for social care), there will be more formal methods for assessing cost effectiveness outside the health sector.

Recommendations for interventions informed by cost–benefit analysis

When considering cost–benefit analysis, the committee should be aware that an aggregate of individual 'willingness to pay' (WTP) is likely to be more than public-sector WTP, sometimes by quite a margin. If a conversion factor has been used to estimate public sector WTP from an aggregate of individual WTP, the committee should take this into account. In the absence of a conversion factor, the committee should consider the possible discrepancy in WTP when making recommendations that rely on a cost–benefit analysis.

The committee should also attempt to determine whether any adjustment should be made to convert 'ability-to-pay' estimates into those that prioritise on the basis of need and the ability of an intervention to meet that need.

The committee should not recommend interventions with an estimated negative net present value (NPV) unless other factors such as social value judgements are likely to outweigh the costs. Given a choice of interventions with positive NPVs, committees should prefer the intervention that maximises the NPV, unless other objectives override the economic loss incurred by choosing an

intervention that does not maximise NPV.

Care must be taken with published cost–benefit analyses to ensure that the value of all the health and relevant non-health effects have been included. Older cost–benefit analyses, in particular, often consist of initial costs (called 'costs') and subsequent cost savings (called 'benefits') and fail to include monetarised health effects and all relevant non-health effects.

Recommendations for interventions informed by cost–consequences analysis

The committee should ensure that, where possible, the different sets of consequences do not double count costs or effects. The way that the sets of consequences have been implicitly weighted should be recorded as openly, transparently and accurately as possible. Cost–consequences analysis then requires the decision-maker to decide which interventions represent the best value using a systematic and transparent process. Various tools, such as multi-criteria decision analysis (MCDA), are available to support this part of the process, although attention needs to be given to any weightings used, particularly with reference to the NICE reference case and NICE's principles on social value judgements.

Recommendations for interventions informed by cost-effectiveness analysis

If there is strong evidence that an intervention dominates the alternatives (that is, it is both more effective and less costly), it should normally be recommended. However, if one intervention is more effective but also more costly than another, then the ICER should be considered. If one intervention appears to be more effective than another, the committee has to decide whether it represents reasonable 'value for money' as indicated by the relevant ICER.

The committee should use an established ICER threshold (see the section on cost–utility analysis). In the absence of an established threshold, the committee should estimate a threshold it thinks would represent reasonable 'value for money' as indicated by the relevant ICER.

The committee should take account of NICE's principles on social value judgements when making its decisions.

Recommendations for interventions informed by cost-minimisation analysis

Cost minimisation can be used when the difference in effects between an intervention and its comparator is known to be small and the cost difference is large (for example, whether doctors or nurses should give routine injections). If it cannot be assumed from prior knowledge that the difference in effects is sufficiently small, ideally the difference should be determined by an equivalence trial, which usually requires a larger sample than a trial to determine superiority or non-inferiority. For this reason, cost-minimisation analysis is only applicable in a relatively small number of cases.

Recommendations when there is no economic evidence

When no relevant published studies are found, and a new economic analysis is not prioritised, the committee should make a qualitative judgement about cost effectiveness by considering potential differences in resource use and cost between the options alongside the results of the review of evidence of effectiveness. This may include considering information about unit costs, which should be presented in the guideline. The committee's considerations when assessing cost effectiveness in the absence of evidence should be explained in the guideline.

Further considerations

Decisions about whether to recommend interventions should not be based on cost effectiveness alone. The committee should also take into account other factors, such as the need to prevent discrimination and to promote equity. The committee should consider trade-offs between efficient and equitable allocations of resources. These factors should be explained in the guideline.

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8 Linking to other guidance

This chapter describes how guidelines link to other NICE guidance in the topic area and to guidance from other developers.

Related NICE guidelines and guidance on health technologies should be identified during scoping of a guideline (see the chapter on the scope), or when checking if a guideline needs updating (see the chapter on ensuring that published guidelines are current and accurate). This includes identifying any related guidance or guidelines in development, as well as those that are published.

When a guideline topic covers guidance on health technologies that is published or in development, NICE staff with a quality assurance role work closely with NICE staff from the health technologies team to agree the approach to take.

8.1 Related NICE technology appraisal guidance

A guideline committee cannot usually publish its own recommendations on health technologies covered by published or in development health technologies guidance. In rare cases, technology appraisal guidance will be updated in the guideline (see the section on updating technology appraisal guidance in a guideline).

Technology appraisal being developed or updated alongside the guideline

When a technology appraisal is developed at the same time as a related NICE guideline, development should ideally be coordinated so that the appraisal recommendations are published in time for a link to be included in the consultation draft of the guideline. This is not always possible (for example, if the technology has not yet received a marketing authorisation). In this case, the guideline consultation draft should link to the appraisal consultation document or final appraisal determination. If guideline committee members wish to comment on the appraisal, they do this through the developer (see the NICE technology appraisal process guide).

The guideline committee chair and the developer may attend relevant appraisal committee meetings as advisers, but do not take part in the formal decision-making.

Updating technology appraisal guidance in a guideline

If there is new evidence for an existing NICE technology appraisal, it can be updated within the context of a guideline, as part of guideline development.

See our methods and process guides for more information on how NICE technology appraisals are developed:

- guide to the methods of technology appraisal
- guide to the processes of technology appraisal

These guides are being reviewed, and an updated version will publish in early 2022.

Early planning is essential to identify how the guideline developer will update technology appraisal guidance within a guideline. The developer should consider whether there are any data not in the public domain that are likely to be useful. If so, they should call for evidence from registered stakeholders, using the procedures described in the appendix on call for evidence and expert witnesses.

If there is significant new evidence or a change in costs since the technology appraisal guidance was published, the developer assesses cost effectiveness (performs an economic analysis) to determine whether a change in the recommendations is appropriate. In exceptional circumstances, it may not be clear that an economic analysis is needed until the evidence is reviewed and discussed by the committee. Nevertheless, the developer should start planning for any economic analysis at an early stage. The intended approach to cost-effectiveness (economic) analysis for technology appraisal updates should be included in the economic plan and discussed with the committee and a member of NICE staff with responsibility for quality assurance.

The approach should follow the principles described in the chapter on incorporating economic evaluation and should be similar to that used in the technology appraisal. Any differences must be justified by changes in the evidence base or the decision context (for example, a broader range of comparators in the guideline).

The developer may sometimes consider that cost effectiveness can best be assessed by modifying or building on the architecture of an existing economic analysis from the technology appraisal. If so, this should be discussed with a member of NICE staff with responsibility for quality assurance during development of the economic plan.

New medicines

Assessment of new medicines and significant new indications will be carried out in line with section 3.17 of the 2019 voluntary scheme for branded medicines pricing and access published on the GOV.UK website.

New technology appraisal referral during development of the guideline

When a new related technology appraisal is referred after the guideline has started development, and will be developed alongside the guideline, NICE's technology appraisals team informs the developer and NICE staff with responsibility for guideline quality assurance.

Referring to technology appraisals in recommendations

When related technology appraisal guidance is identified, the usual approach is for the guideline to make a recommendation to follow the technology appraisal recommendations. This recommendation should link to the relevant guidance pages. If needed, a brief explanation can be included in the guideline recommendation, for example, if it covers the sequencing of treatments recommended in technology appraisals. Any explanation needs to be agreed with the technology appraisals team at NICE.

In rare cases, technology appraisal recommendations may be included in the guideline, for example, if this is essential for readability or there is a need to highlight specific recommendations.

Sometimes a guideline covers a medicine for which there is technology appraisal guidance, but for a different population or indication (condition). In these cases, the committee developing the guideline recommendation should assess evidence of effectiveness using methods described in this manual. The guideline recommendations may be different from the technology appraisal recommendations if there is evidence of differing safety or effectiveness for the population or indications covered by the guideline.

8.2 Related NICE guidelines

Related published or in-development NICE guidelines should be identified by the developer at the scoping stage, or by the NICE surveillance team when checking if a guideline needs updating (see the chapter on ensuring that published guidelines are current and accurate). The scope should document which NICE guidelines are considered relevant for the guideline that is being developed. Any other related NICE guidelines that are highlighted during guideline development should be

discussed, and a joint approach agreed with NICE staff with responsibility for quality assurance.

During scoping, identified related guidelines should be reviewed to determine whether the guideline in development will link to existing published recommendations (that is, the key issues will be excluded from the scope of the guideline in development) or whether the guideline in development will consider similar review questions (that is, the key issues are included in the scope of the guideline in development).

When a guideline in development will link to recommendations in a published guideline, this will be specified in the scope.

Similar review question covered in another guideline

When a similar review question is identified in a published NICE guideline, and the evidence review underpinning any recommendations is considered appropriate, the committee developing the guideline can choose to link to the recommendations in the published guideline or to draft new recommendations, based on the evidence review for the published guideline.

In these cases, the committee should discuss and document whether:

- the review question in the guideline in development is similar enough to the question addressed in the published guideline
- the evidence base underpinning any recommendations is unlikely to have changed significantly since the publication of the related guideline
- the evidence review for the review question in the published guideline is relevant and appropriate to the question in the guideline in development.

If the committee agree that the evidence review is relevant for the guideline in development, they consider the recommendations based on the evidence review.

There are 3 options in these circumstances and these are described in the following sections.

Link to the recommendations in the other guideline

If the committee are happy to accept the intent and exact wording of the recommendations, and understand that any future changes (for example, as part of an update) would also apply to their guideline, then the guideline will link to the recommendations in the published guideline. If needed, a recommendation can be added to the guideline explaining anything users will need to take into

account when applying the recommendations from the published guideline (for example, if some parts of a recommendation do not apply to the population or setting covered by the new guideline). The committee's discussion and decision should be documented clearly in the guideline. This should include areas of agreement and difference with the committee for the published guideline (for example, in terms of key considerations – balance of benefits and harms or costs, and interpretation of the evidence).

Linking to other guidelines is preferred to copying recommendations into the guideline in development. In rare cases, recommendations may be copied into the guideline, for example, if this is essential for readability or there is a need to highlight specific recommendations.

Use the evidence review to make new recommendations

If the committee considers that the intent and wording of the published recommendations are not appropriate for their guideline, or they are not prepared to agree that any updates to recommendations would also apply to their guideline, they may make new recommendations based on the existing evidence review. When evidence reviews from another guideline are used to develop new recommendations, the decision should be made clear in the methods section of the guideline, and their independent interpretation and discussion of the evidence should be documented in the discussion section. The evidence reviews from the published guideline (including review protocol, search strategy, evidence tables and full evidence profiles [if available]) should be included in the guideline. They then become part of the whole evidence base for the guideline, and are updated as needed in future updates of the guideline.

Request a new evidence review

If the review question is not considered similar enough or the evidence review is not considered appropriate, the committee may request that a new evidence review is conducted. This should follow NICE's standard processes and methods, as described in this manual. The decision to conduct a new review should be agreed by NICE staff with responsibility for quality assurance, and documented in the methods section and the discussion section for the review question.

8.3 Related interventional procedures guidance

Interventional procedures (IP) guidance differs from other NICE guidance in that it addresses the safety and efficacy of interventions, and not their effectiveness or cost effectiveness. (For more details see the NICE interventional procedures programme manual.)

Any related published IP guidance should be identified during the scoping of a guideline or by the

surveillance review. The approach depends on whether the recommendation in the IP guidance is for 'standard' (previously known as 'normal') or 'special' arrangements for clinical governance, consent and audit or research. Because guidelines focus on placing established treatments in the care pathway, they will generally only include IP guidance that recommends 'standard' arrangements.

If IP guidance on a procedure relevant to a guideline starts development during development of the guideline, the IP programme will send the finalised scopes for the procedures to NICE staff with responsibility for quality assurance of the guideline.

IP guidance with recommendations for 'standard' arrangements

Review question is not justified

If the scoping group for a guideline decides that IP guidance for which 'standard' arrangements (previously known as normal arrangements) are recommended is relevant to the guideline but does not justify a review question, the guideline simply links to the IP guidance pages. The developer does not search for new evidence on procedures that are not incorporated into a review question. However, if in the course of their search for evidence for the guideline the developer finds new relevant evidence on that procedure, they inform the IP team at NICE.

Review question is justified

If the scoping group for a new guideline considers that IP guidance with 'standard' arrangements is likely to justify a review question, this is highlighted in the scope for the guideline. For example, comparisons of clinical and cost effectiveness could be included if there is IP guidance covering several procedures for the same condition. The IP team is contacted by NICE staff with responsibility for guideline quality assurance during scoping to seek their input on the proposed approach.

If the procedure is included in the final scope of the guideline, the developer considers its effectiveness using standard methods for guideline development (see the chapters on reviewing research evidence and incorporating economic evaluation).

If a guideline is being updated and the surveillance review identifies that IP guidance with 'standard' arrangements is likely to justify a review question in the updated guideline, this is highlighted in the surveillance report.

When a review question in a guideline relates to IP guidance, the IP guidance remains active unless

the IP team and NICE staff with responsibility for guideline quality assurance have identified reasons why not. This is because the IP guidance relates to the efficacy and safety of the procedure, and so the guideline and the IP guidance address different questions. Therefore IP guidance remains current even if the recommendations are supplemented by a guideline recommendation on the effectiveness of a procedure for 1 or more indications. IP guidance may also contain more detailed information that may be of value to practitioners and people considering having the procedure. Importantly, the IP guidance may also specify conditions for use of the procedure; for example, that the surgeon should have training, or that the procedure should be carried out within the context of a multidisciplinary team. The guideline will link to the IP guidance pages.

Other approaches

If NICE staff with responsibility for guideline quality assurance and the IP team agree that a different approach is needed, they present a paper to NICE's Guidance Executive. Decisions to take other approaches are made on a case-by-case basis. Examples include:

- Appraisal of the evidence indicates that a procedure with IP guidance is not effective, and the guideline recommends that it should not be used.
- There is considerable uncertainty about the clinical or cost effectiveness of a procedure.
- The guideline committee makes a 'research only' recommendation for a procedure with published IP recommendations for 'standard' arrangements.

IP guidance with recommendations for 'special' arrangements

If the guideline committee considers that a procedure with recommendations for 'special' arrangements has become part of NHS practice and falls into the area of a review question, the IP team is notified for potential review of the IP guidance. If the guidance is reviewed and the procedure's status is changed to 'standard' arrangements, the developer considers the procedure's effectiveness and cost effectiveness. If the procedure retains its 'special' arrangements status, the guideline should link to the IP guidance pages.

IP guidance with recommendations for 'research only' or 'do not use'

Sometimes IP guidance recommends that a procedure should only be carried out in research, or that it should not be used. A recommendation not to use a procedure is made if there is no evidence of efficacy and/or safety, or evidence of a lack of efficacy and/or safety. A 'research only' recommendation is made if the evidence shows that there are important uncertainties. The

evidence base for procedures with recommendations for 'research only' or 'do not use' usually reflects the fact that they are not established procedures. As such, they would not normally form part of a review question in a guideline.

Developing a guideline and IP guidance concurrently

When a newly notified procedure has been scoped and it has been agreed that it will be assessed by the IP team, the IP team informs the developer and NICE staff with responsibility for guideline quality assurance that the notified procedure is relevant to the guideline. The guideline can link to the IP guidance when it is published.

8.4 Guidance from other developers

Sometimes relevant guidelines published by organisations other than NICE are identified in the search for evidence and considered appropriate for inclusion in the evidence base. Guidelines accredited by NICE are not subject to further appraisal of the guideline development process because this has already been assessed by NICE. However, the evidence reviews in the guideline will still need to be critically appraised (using checklists in the appendix on appraisal checklists, evidence tables, GRADE and economic profiles) to ensure that the quality of the evidence is appropriate for deriving NICE recommendations. Intellectual property issues need to be considered when using content from other organisations.

Published guidelines not accredited by NICE are assessed for quality using the AGREE II instrument or the AGREE global rating scale instrument. There is no cut-off point for accepting or rejecting a guideline, and each committee needs to set its own parameters. These should be documented in the methods of the guideline, and a summary of the assessment included in the evidence review. The full results of the assessment should be presented with the guideline.

Reviews of evidence from guidelines that cover review questions being addressed by the committee may be considered as evidence if they:

- are assessed as being of high quality using the appropriate methodology checklist (see the appendix on appraisal checklists, evidence tables, GRADE and economic profiles)
- are accompanied by a GRADE table, GRADE-CERQual table or evidence statement and evidence tables
- are assessed as being sufficiently up to date

- do not have any intellectual property restrictions that would make it impossible to follow NICE's normal guideline development process.

If using evidence from published guidelines, the committee should create its own evidence summaries or statements (see the section on summarising evidence in the chapter on reviewing research evidence). Evidence tables from guidelines published by other organisations should be referenced with a direct link to the source website or a full reference of the published document. The committee should formulate its own recommendations, taking into consideration the whole body of evidence.

Recommendations from guidelines published by another organisation should not be quoted or linked to, unless the guideline has been accredited by NICE and the evidence reviews have been critically appraised to verify quality.

8.5 References and further reading

Brouwers MC, Kho ME, Browman GP et al. (2010) AGREE II: advancing guideline development, reporting and evaluation in health care. Canadian Medical Association Journal 182: E839–42

9 Writing the guideline

During development of the guideline, the developer and committee will write:

- the recommendations
- recommendations for research
- the rationale for the recommendations, and their likely impact on practice
- the context for the guideline – such as the need for the guideline, or the reason for updating an existing guideline
- summaries of evidence supporting shared decision-making, if there are preference-sensitive decision points in the guideline
- information about changes to published recommendations (if the guideline is an update)
- structured summaries of the committee's discussions
- summaries of the evidence – with details of analysis and any modelling
- the methods used for guideline development – highlighting the reasons for options taken, and any deviations from the methods and processes described in this manual.

For publication, the recommendations, recommendations for research, rationale for the recommendations and likely impact, context, and any summaries of evidence supporting shared decision-making are presented in a 'web version'. The committee's discussion and evidence are presented as PDFs in separate evidence reviews, along with the methods used during guideline development. Exactly how we organise and present the information is likely to change in future.

9.1 Interpreting the evidence to make recommendations

Assessment and interpretation of the evidence to inform guideline recommendations is at the heart of the work of the committee. Recommendations are developed using a range of scientific evidence (see the section on evidence used to inform recommendations in the chapter on developing review questions and planning the evidence review) and other evidence – such as expert testimony (see the appendix on call for evidence and expert witnesses, views of

stakeholders, people using services and practitioners, and the committee's discussions and debate (see the chapter on decision-making committees). Sometimes recommendations are made because of a legal duty or the consequences of not following a course of action are extremely serious. If there is a legal duty, the recommendation should refer to supporting documents and should build on the law or statutory guidance rather than simply repeating it.

The committee must use its judgement to decide what the evidence means in the context of the guideline referral and decide what recommendations can be made to practitioners, commissioners of services and others. The strength and quality of the evidence is assessed for both internal and external validity, but also requires interpretation. Evidence also needs to be assessed in light of any conceptual framework.

As soon as the committee has discussed the evidence, they should start drafting recommendations. They should decide what action to recommend and keep in mind which sectors (including which practitioners or commissioners within those sectors) should act on the recommendations. The record of the committee's discussion should explain clearly how they moved from the evidence to each recommendation, and document how any issues influenced their decision-making. In line with the GRADE principles on 'evidence to decisions', summaries of the discussions should describe the relative value placed on outcomes, benefits and harms, resource use, and the overall quality of the evidence, as well as other considerations (see Alonso-Coello et al. 2016, Schünemann et al. 2016).

Findings from several evidence reviews may be integrated into a single summary of the committee's discussions if they relate to the same recommendation or group of recommendations.

For each group of recommendations, the committee should briefly explain their rationale for making the recommendations and record their views on any likely impact of the recommendations on practice or services.

Quality of the evidence

The committee is presented with GRADE tables, GRADE-CERQual tables or (if GRADE or GRADE-CERQual is not used) evidence statements. These describe the number, type and quality of the studies for each review question and provide an overall rating of confidence (high, moderate, low or very low) in estimates of effect for each outcome (or each review finding, for qualitative reviews). The committee should agree that the reviews are a fair summary of the evidence and should discuss any uncertainty, including the precision of estimates, clinical decision thresholds, and the presence, likely magnitude and direction of potential biases.

GRADE tables, GRADE-CERQual tables and the summary of the committee's discussion should include the committee's view of the directness (or applicability) of the evidence to people affected by the guideline and the setting.

Trade-off between benefits and harms of an intervention

A key stage in moving from evidence to recommendations is weighing up the magnitude and importance of the benefits and harms of an intervention, and the potential for unintended consequences. This may be done qualitatively (for example, 'the evidence of a reduction in medicines errors in care homes outweighed a small increase in staff workload and resources') or quantitatively using a decision model.

The committee should assess the extent to which the available evidence is about efficacy (the extent to which an intervention produces a beneficial result under controlled experimental conditions), effectiveness (the extent to which a specific intervention, when used under 'real world' circumstances, does what it is intended to do) or both. Often the distinction between the 2 is not clear; this may be of particular importance in reports of complex interventions, because these are often evaluated only in pragmatic studies.

If several possible interventions are being considered, it is useful to include details of the committee's discussion of the relative position of interventions within a pathway of care or service model.

The committee should also assess whether, when recommending an intervention, they are able to recommend stopping other interventions because they have been superseded by the new one.

The committee should also assess the extent to which the recommendations may impact on health inequalities. This needs to be made clear, regardless of whether the recommendation is aimed at the whole population, specific subgroups or a combination of both.

Trade-off between economic considerations and resource use

As noted in the section on using economic evidence to formulate guideline recommendations in the chapter on incorporating economic evaluation, the committee should discuss cost effectiveness at the same time as effectiveness when formulating recommendations.

The guideline should include an explanation of how the implications of costs, resource use and economic considerations were taken into account in determining the cost effectiveness of an intervention. This may be informal, or may be more formal and include economic modelling (see the

chapter on incorporating economic evaluation).

If several possible interventions are being considered, it is useful to include the committee's discussion of the relative position of an intervention in a care pathway or service model, based on cost effectiveness.

Use of indirect evidence

Sometimes when there is no evidence directly relevant to a specific population or setting, indirect evidence from other populations or settings may be considered. For example, a review of systems for managing medicines in care homes for people with dementia may identify good practice that is relevant in other care home settings. The use of indirect evidence must be considered carefully by the committee, with explicit consideration of the features of the condition or interventions that allow extrapolation to a different context or population. This also applies when extrapolating findings from evidence in different care settings (for example, between primary and secondary care). The committee should consider and document any similarities in case mix, staffing, facilities and processes, and any limitations.

Availability of evidence to support implementation (including evidence from practice)

The committee should also judge to what extent it will be feasible to put the recommendations into practice. They can use expert evidence or testimony (see the appendix on call for evidence and expert witnesses), the experience of committee members or results from other approaches (see the chapter on the validation process for draft guidelines, and dealing with stakeholder comments and the appendix on approaches to additional consultation and commissioned primary research) if these have been used. They may also be able to draw on qualitative studies or other forms of evidence relating to organisational and political processes where appropriate.

The committee should consider the extent of change in practice that will be needed to implement a recommendation, staff training needs, policy levers and funding streams, and the possible need for carefully controlled implementation with, for example, training programmes. This should be documented in the guideline and in any resources to support implementation.

Size of effect and potential impact on population health

The committee should consider whether it is possible to anticipate effect sizes at the population level, if this is appropriate for the topic. If this is the case, it is important to consider effect sizes along the whole causal chain, not just at the endpoints.

Wider basis for making recommendations

The committee should take into account a range of issues (including any ethical issues, the NICE principles, equity considerations and inequalities in outcomes) and policy imperatives, as well as equality legislation (see the introduction chapter) to ensure that the guideline recommendations are ethical, practical and specific. There are no hard-and-fast rules or mechanisms for doing this: the committee should make conscious and explicit use of its members' skills and expertise. All evidence needs interpretation: evidence alone cannot determine the content of a recommendation. The development of evidence-based recommendations involves inductive or deductive reasoning:

- inductive because it involves using what is known (the evidence) while accepting that there is uncertainty about what is reasonably expected to happen as a consequence of implementing a recommendation
- deductive when it is drawn from theory or methodological principles that are generally held to be true so that any logical conclusion will be true.

NICE's principles on social value judgements explicitly acknowledge that non-scientific values are brought to bear, and all of NICE's advisory committees are encouraged to take account of (and to make explicit) the value judgements they make. The committee may also draw on the principles outlined in the report on ethical issues in public health by the Nuffield Council on Bioethics when making its judgements.

Conceptual framework or logic model

When the committee is developing its recommendations, it should consider any conceptual frameworks or logic models that have been used to inform the guideline because these may help to identify any practical issues involved with a recommendation that will change practice.

Equality considerations

The guideline should also document how the committee's responsibilities under equality legislation and NICE's equality scheme have been discharged in reaching the recommendations (see the section on key principles for developing guidelines in the introduction chapter), and how the recommendations address areas highlighted in the equality impact assessment. The committee needs to consider whether:

- the evidence review has addressed areas identified in the scope as needing specific attention with regard to equality issues

- criteria for access to an intervention might be discriminatory (for example, through membership of a particular group, or by using an assessment tool that might discriminate unlawfully)
- any groups of people might find it impossible or unreasonably difficult to receive or access an intervention
- recommendations can be formulated to advance equality (for example, by making access more likely for certain groups, or by tailoring the intervention to specific groups).

Insufficient evidence

If evidence of efficacy or effectiveness for an intervention is either lacking or too low quality, or too uncertain for firm conclusions to be reached, the committee has several options. It may:

- make a 'consider' recommendation based on the limited evidence (see the section on wording the recommendations)
- decide not to make a recommendation, and make a recommendation for research (see the section on formulating research recommendations)
- decide not to make a recommendation or a recommendation for research (they should include a rationale for this decision in the guideline)
- recommend that the intervention is used only in the context of research
- make a 'do not offer' recommendation for the intervention.

The principles for wording recommendations described in the section on wording the recommendations should be used, reflecting the strength of the evidence.

'Do not offer' recommendations

Reasons for the committee to make a 'do not offer' recommendation include:

- The intervention has no reasonable prospect of providing cost-effective benefits to people using services.
- Stopping the intervention is not likely to cause harm for people currently receiving it.
- The potential harms outweigh the potential benefits.

- Good-quality clinical evidence shows a lack of efficacy or effectiveness.
- There is a lack of evidence of efficacy or effectiveness for an intervention, or the quality of the evidence is too low or too uncertain.
- The intervention has a safety issue or warning from the MHRA.

'Only in research' recommendations

Reasons for the committee to make an 'only in research' recommendation include:

- The necessary research can realistically be set up or is already planned, or people using services are already being recruited for a study.
- The intervention should have a reasonable prospect of providing cost-effective benefits to people using services.
- There is a real prospect that the research will inform future NICE guidelines.

Strength of recommendations

The concept of the 'strength' of a recommendation (Guyatt et al. 2003) is key to translating evidence into recommendations. This takes into account the quality of the evidence but is conceptually different.

Some recommendations are 'strong' in that the committee believes that the vast majority of practitioners or commissioners and people using services would choose a particular intervention if they considered the evidence in the same way as the committee. This is generally the case if the benefits clearly outweigh the harms for most people and the intervention is likely to be cost effective. Similarly, if the committee believes that the vast majority of practitioners or commissioners and people using services would not choose a particular intervention if they considered the evidence in the same way as the committee, a 'do not offer' recommendation can be made. This is generally the case if the harms clearly outweigh the benefits for most people, or the intervention is not likely to be cost effective.

However, there is often a closer balance between benefits and harms, and some people would not choose an intervention whereas others would. This may happen, for example, if some people are particularly likely to benefit and others are not, or people have different preferences and values. In these circumstances, the recommendation is generally weaker, although it may be possible to make stronger recommendations for specific groups of people. The committee should also discuss making negative recommendations in such situations if they believe most people are particularly

likely to experience no benefit or experience harm, but that there may be a benefit for some. Be as specific as possible about the circumstances (for example, 'Do not offer…, unless…') or population.

NICE reflects the strength of the recommendation in the wording (see the section on wording the recommendations). NICE uses 'offer' (or words such as 'measure', 'advise', or 'refer') to reflect a strong recommendation, usually where there is clear evidence of benefit. NICE uses 'consider' to reflect a recommendation for which the evidence of benefit is less certain.

There might be little evidence of differences in effectiveness or cost effectiveness between interventions. In this case, all effective or cost-effective interventions may be recommended as options. However, interventions that are not considered cost effective should not usually be offered. This is because that course of action has been judged to be an inefficient use of limited resources, with the population as a whole gaining fewer benefits than from alternative (cost-effective) courses of action. In some cases though, considerations about equity may also affect the decision whether to recommend the intervention (see the section on approaches to original economic evaluation in the chapter on incorporating economic evaluation).

The committee's justifications for the strength of the recommendation should be summarised in the rationale and fully explained in the committee discussion of the relevant evidence review.

In most cases the committee reaches decisions through a process of informal consensus, but sometimes formal voting procedures are used. The proceedings should be recorded and a clear statement made about the factors considered and the methods used to achieve consensus. This ensures that the process is as transparent as possible. A structured summary of the generic and specific issues considered and the key deliberations should be included in the guideline.

Principles of person-centred care

All NICE guidelines advocate the principles of person-centred care: people using services and the wider public should be informed of their options and be involved in decisions about their care.

There are 5 guidelines specifically on the experience of people using services: NICE guideline on patient experience in adult NHS services, service user experience in adult mental health, people's experience in adult social care services, shared decision making, and babies, children and young people's experience of healthcare. These include general recommendations on the principles of person-centred care, such as communication and providing information, which should not be restated in topic-specific guidelines. Recommendations from these guidelines can be cross-referred to when needed.

Recommendations on person-centred care can be included in topic-specific guidelines if there is evidence of specific need for the topic.

9.2 Wording the recommendations

This section gives the principles of writing recommendations. For more on NICE style, see the NICE style guide and writing for NICE.

Focus on the action and what readers need to know

Recommendations should be clear about what needs to be done, without the reader having to read the committee's discussion of the evidence. When writing recommendations, keep in mind a reader asking, 'What does this mean for me?'

Include only one action per recommendation or bullet point, and use direct instructions wherever possible because these are easier to follow. Recommendations often start with a verb such as 'offer' (or 'do not'), 'consider', 'measure', 'advise', 'discuss', 'ask about'.

Exceptions to this principle include:

- Recommendations that specify who should take action, or cover service organisation. For example, 'A multidisciplinary team should provide care'.
- Recommendations that use 'must' or 'must not' (because of a legal duty or a very serious consequence of not following the recommendation).
- Recommendations to take different actions in different circumstances or for different populations. For example, it is often clearer to start with details of the population covered by the recommendation.

Think carefully about how much detail to include. Recommendations should be specific about interventions. But this needs to be balanced against the need to be clear and concise. Including a lot of detail can reduce the impact and make it harder for users to identify the most important actions.

Generally, avoid making recommendations about basic good practice unless there is evidence of poor practice or variation in practice.

Be clear about who should be offered an intervention, but don't spell this out in every recommendation if it is obvious from the context. Similarly, readers need to know which sections of

the guideline they need to act on. Clear subheadings can help here, for example, by spelling out the setting where the recommendations apply (for example, 'first treatment', 'in primary care' or 'in care homes').

The content and measurability of any related NICE quality standard will be affected by the clarity and precision of recommendation wording. If possible, be clear when interventions should take place, and include the reasoning in the rationale sections of the guideline and discussion sections of the evidence reviews.

Reflect the strength of the recommendation

The 'strength' of a recommendation (see the section on interpreting the evidence to make recommendations) should be reflected in the consistent wording of recommendations within and across guidelines.

In recommendations on activities or interventions that should (or should not) be offered, use directive language such as 'offer' (or 'do not offer'), 'advise', or 'ask about'. In keeping with the principles of shared decision-making, people may choose whether or not to accept what they are offered or advised.

If there is a closer balance between benefits and harms (activities or interventions that could be used), use 'consider'.

If there is a legal duty to apply a recommendation, or the consequences of not following a recommendation are extremely serious, the recommendation should use 'must' or 'must not' and be worded in the passive voice.

Box 9.1 Examples of recommendations made with 3 different levels of certainty

Recommendations for activities or interventions that must or must not be used

- Ultra rapid detoxification under general anaesthesia or heavy sedation (where the airway needs to be supported) must not be used. This is because of the risk of serious adverse events, including death.
- Patient group directions must be authorised only by an appropriate authorising body in line with legislation.

Recommendations for activities or interventions that should or should not be offered

- Offer a trial of supervised pelvic floor muscle training of at least 3 months' duration as a first treatment to women with stress or mixed urinary incontinence.
- Record the person's blood pressure every 6 months.
- Do not offer lamotrigine to treat mania.
- Do not offer tigecycline to treat diabetic foot infections, unless other antibiotics are unsuitable.

Recommendations for activities or interventions that could be offered

- Consider pelvic MRI to assess the extent of deep endometriosis involving the bowel, bladder or ureter.
- Consider referring people to other behavioural support services within the local health and care network (for example, to voluntary or community services) for interventions that are not available in the pharmacy.

Use 'person-centred', precise, concise, clear English

Person-centred language

Use language that is person centred, and acknowledges the experience of people who are directly affected by the recommendations (and family members, carers or advocates), and their role in decision-making. Generally use verbs such as 'offer' and 'discuss' in recommendations, rather than 'prescribe' or 'give'. Use 'people' or 'people with [condition]' (or 'people using services') rather than 'individuals', 'service users', 'cases' or 'subjects'. For more information see the section of the NICE

style guide on talking about people.

Clarity and consistency

Using clear, consistent wording is an important part of NICE's approach to presenting guidelines and other products, and is in line with gov.uk style.

Follow the principles of effective writing as described in writing for NICE and NICE's approach to consistency in language and terms across guidelines and other products. More information is available in the NICE style guide.

Use bullet lists and tables if they help to make recommendations easier to follow. Make sure there is a clear link back to the evidence and the committee's discussion for all information in a table.

Recommendations on medicines, including off-label use of licensed medicines and unlicensed medicines

Do not give dosages routinely

Readers are expected to refer to a medicine's summary of product characteristics (SPC) for details of dosages for licensed indications. Include dosage information only if there is evidence that a particular medicine is often prescribed at the wrong dosage, or there is clear evidence about the effectiveness of different dose levels. Information about dosage can be found in the BNF or BNF for Children as well as the SPC. SPCs can be found in the Electronic Medicines Compendium. Information on therapeutic monitoring and contraindications should only be included in recommendations if this information is not in the BNF or BNF for Children, or if the information in these sources need updating.

Dosage information for off-label use of a licensed medicine will usually not be included in the SPC (see the section on off-label use of licensed medicines). If off-label use is being recommended, check whether there is any relevant dosage information in the BNF or BNF for Children for the particular population or indication it is being recommended for. If there is none, NICE staff with responsibility for quality assurance will liaise with the BNF.

Off-label use of licensed medicines

Using a UK licensed medicine outside the terms of its marketing authorisation is classed as off-label use.

Recommendations are usually about the uses of medicines for which the regulatory authority has granted a marketing authorisation, either in the UK or under the European Centralised Decision Reliance Procedure (until January 2023). These uses are often referred to as the licensed indications. However, there are clinical situations in which the off-label use of a medicine may be judged by the prescriber to be in the best clinical interests of the person. For example, off-label use may be recommended if the clinical need cannot be met by a licensed product and there is sufficient evidence and/or experience of using the medicine to demonstrate its safety and efficacy to support this.

Off-label prescribing is particularly common in pregnant women and in children and young people because these groups have often been excluded from clinical trials during medicine development. When prescribing a medicine off label, the prescriber should follow relevant professional guidance (for example, the General Medical Council's Good practice in prescribing medicines – guidance for doctors) and make a clinical judgement, taking full responsibility for the decision. For more information, see the MHRA's guidance on prescribers' responsibilities for off-label or unlicensed use of medicines.

The guideline developer and committee should check recommended uses of a medicine against the licensed indications listed in the SPC. If there is uncertainty the developer should liaise with the NICE medicines adviser responsible for quality assurance. If the medicine does not have a UK marketing authorisation for the use being recommended (off-label use), add relevant information to the recommendation to ensure this is clear, for example 'In June 2018, this was an off-label use of donepezil and rivastigmine. See NICE's information on prescribing medicines.

Unlicensed medicines

A medicine that does not have a UK marketing authorisation for any indication is classed as an unlicensed medicine.

If a UK licensed medicine can meet the person's clinical need (even if it is used off-label), it should be used instead of an unlicensed product. An unlicensed medicine should not be used if a product available and licensed within the UK could be used to meet the person's clinical need.

Unlicensed medicines will not usually be included in NICE guidelines. The guideline developer may include an unlicensed medicine in exceptional circumstances, for example in complex conditions when there are no other treatment options. This should be agreed with the NICE medicines adviser responsible for quality assurance, and documented in the rationale.

If use of an unlicensed medicine is recommended, add relevant information to the recommendation

to ensure this is clear, for example:

'In January 2012, felbamate was not licensed for use in the UK. See NICE's information on prescribing medicines.'

Recommendations on medical devices, including off-label use

Using a CE- or UKCA-marked device outside its instructions for use is classed as off-label use.

Recommendations are usually about the use of devices within the terms of the instructions for their use. However, there are clinical situations in which the off-label use of a device may be judged by the prescriber and patient to be in the best interests of the patient. For example, off-label use may be recommended when using a device outside the time period specified in the instructions for use.

There is MHRA guidance on the off-label use of medical devices. The guideline developer and committee should check the instructions for use of a device and if the device is being recommended for off-label use, include this information in the recommendation:

At the time of publication (Month year), not all devices with a CE or UKCA mark for [intended purpose] are intended by the manufacturer for use as recommended here. The healthcare professional should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. MHRA's advice remains to use CE- or UKCA marked devices for their intended purpose where possible. See the MHRA guidance on off-label use of a medical device for more information.

9.3 Supporting shared decision-making

Identify preference-sensitive decision points

Guidelines should include information to support shared decision-making between people and their health or social care practitioners (see the recommendations on supporting people to make decisions about their care in the NICE guideline on patient experience in adult NHS services, service user experience in adult mental health, people's experience in adult social care services, shared decision making, and babies, children and young people's experience of healthcare). The committee should identify any recommendations where someone's values and preferences are likely to be particularly important in their decision about the best course of action for them.

When identifying these recommendations committees should take account of people's autonomy

and right to make individual decisions. They should, however, ensure that their recommendations represent an effective use of health and social care resources and so would not disadvantage other people using the services (see section 4.3 of NICE's principles).

These 'preference-sensitive decision points' occur when the committee recommends 2 or more options for investigation, treatment or care that deliver similar outcomes but:

- they have different types of harms and benefits which people may value differently **or**
- the likelihood of the harms or benefits may differ **or**
- the practicalities of the options are different (for example, the choice is between medicine and surgery, or the requirements for monitoring differ) **or**
- some people may consider the overall risks of harms for any of the options outweigh the overall benefits compared with no treatment.

Alternatively, a preference-sensitive decision point may occur if the choice between an investigation, treatment or care option and 'no treatment' is finely balanced.

When to identify preference-sensitive decision points

In some cases, preference-sensitive decision points might be apparent at the scoping stage of a guideline. In other cases, the committee will identify them when reviewing the evidence. This is the same evidence used to make the recommendations, and no additional evidence searches or syntheses are needed.

For updates, the committee only needs to identify decision points in the areas of the guideline being updated.

Summarise information to support decisions

When a preference-sensitive decision point is identified, the committee should create a summary of the evidence that will appear in the guideline. This is to make it easy for professionals and practitioners to compare the options and discuss them with the person.

This summary should set out information about the options clearly and simply. It should usually include the option of no treatment or investigation. This could include brief information, for each option, about:

- **efficacy or effectiveness**: how well something is likely to work for particular outcomes or circumstances and for particular subgroups of people
- **safety**: the risk of short- or long-term harms, and any contraindications
- **practical factors relevant to people using services**: people's experience of treatment or care – for example, ease of use (route of administration for medicines), monitoring requirements, side effects, or impact on quality of life
- **quality and certainty of the evidence**: an overall judgement about the quality of the underlying evidence for each option.

In some cases, NICE will develop additional decision aids (see the chapter on resources to support putting the guideline into practice and the NICE decision aid process guide).

9.4 Formulating research recommendations

The committee is likely to identify areas in which there are uncertainties or in which robust evidence is lacking. The NICE research recommendations process and methods guide details the approach to be used to identify key uncertainties and associated recommendations for research.

For guidelines where there could be many hundreds of uncertainties, it will not be possible to document every uncertainty in detail. Similarly, although committees could write research recommendations for dealing with each uncertainty, this is not likely to be feasible. The committee should select up to 5 key recommendations for research that are likely to inform future decision-making (based on a systematic assessment of gaps in the current evidence base). Methods such as value of information analyses can be useful in this process. They can also make other recommendations for research. These will be listed in the guideline after the key recommendations for research but will be of lower priority. The committee should justify why they have made or not made a research recommendation when there was uncertainty or a lack of evidence and document this justification in the discussion section of the relevant evidence review. Further information about how research recommendations should be derived and written can be found in the NICE research recommendations process and methods guide.

9.5 References and further reading

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Claxton K, Sculpher MJ (2006) Using value of information analysis to prioritise health research: some lessons from recent UK experience. Pharmacoeconomics 24: 1055–68

Glasziou P, Del Mar C, Salisbury J (2003) Evidence-based medicine workbook. London: British Medical Journal Books

Guyatt GH, Oxman AD, Vist GE et al. for the GRADE working group (2008) GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 336: 924 (see also the GRADE website)

Joint Royal College of Paediatrics and Child Health/Neonatal and Paediatric Pharmacists Group Standing Committee on Medicines (2013) The use of unlicensed medicines or licensed medicines for unlicensed applications in paediatric practice

Kelly MP, Moore TA (2012) The judgement process in evidence-based medicine and health technology assessment. Social Theory and Health 10:1–19

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Tannahill A (2008) Beyond evidence – to ethics: a decision making framework for health promotion, public health and health improvement. Health Promotion International 23: 380–90

Weightman A, Ellis S, Cullum A et al. (2005) Grading evidence and recommendations for public health interventions: developing and piloting a framework. London: Health Development Agency

10 The validation process for draft guidelines, and dealing with stakeholder comments

Consultation with stakeholders is an integral part of the guideline development process. Comments received from registered stakeholders are a vital part of the quality-assurance and peer-review processes, and it is important that they are addressed appropriately. Registered stakeholders are notified of the consultation dates in advance via the guideline page on the NICE website, and are reminded by email. (See NICE's webpage on registering as a stakeholder for more information.)

This chapter describes the validation process for draft guidelines. It includes information on what happens during the consultation, the principles of responding to stakeholder comments after the consultation and when a second consultation may be needed.

Before the draft guideline is signed off for consultation, an equality impact assessment is completed by the developer and the committee chair to show which equality issues have been identified and considered during guideline development. The equality impact assessment is signed off by a member of NICE staff with responsibly for quality assurance, and published on the NICE website with the draft guideline. The assessment is updated by the developer and the committee chair after the consultation.

10.1 What happens during consultation

Commenting on the draft guideline

The draft version of the guideline (recommendations, rationales, committee discussions, evidence reviews and methods) is posted on the NICE website for consultation with registered stakeholders. Stakeholders can register at any point during guideline development. NICE informs registered stakeholders that the draft is available, via email and through its promotional channels, and invites them to comment by the deadline. Questions for stakeholders are posted with the draft guideline. The purpose of these questions is to seek stakeholder views on factors such as the potential equality impact. NICE also asks stakeholders to comment on recommendations identified as likely to substantially increase costs, and their justification, and to consider whether any other draft recommendations are expected to add substantial costs. Questions related to implementation may also be included to identify practitioners who are already implementing the draft recommendations, or resources that could be fed into the NICE endorsement scheme.

The length of time for consultation depends on the size of the guideline and the number of review questions. Consultation on a new guideline or full update consisting of 15 to 20 review questions usually lasts for 6 weeks. A 4-week consultation may be used for partial updates of guidelines with less than 15 review questions, while small updates with 1 or 2 review questions will normally have a 2-week consultation. NICE staff with responsibility for quality assurance will decide how long the consultation will last, and stakeholders will be told well in advance.

NICE is unable to accept:

- more than 1 set of comments from each registered stakeholder organisation
- comments that are not presented correctly on the form provided
- comments with attachments such as research articles, letters or leaflets.

In these cases, NICE will invite a registered stakeholder to resubmit a single set of comments with no attachments before the consultation deadline. NICE is unable to accept any comments received after the deadline.

Comments should be constructed as reasoned argument and be submitted for the purpose of improving the draft guideline. NICE reserves the right not to respond to comments that are hostile or inappropriate.

Stakeholders should make sure that any confidential information or information that the owner would not wish to be made public is clearly underlined and highlighted. Confidential information should be kept to a minimum. Stakeholders should explain why the information is confidential and if and when it will become publicly available.

Where views on the guideline are shared by more than 1 stakeholder organisation, NICE encourages these organisations to work together to produce a joint response. This should be submitted by 1 registered stakeholder; other stakeholders supporting the joint response should respond to the consultation noting their endorsement.

When registering, and when commenting on the draft scope and draft guideline, stakeholders are asked to disclose whether their organisation has any direct or indirect links to, or receives or has ever received funding from, the tobacco industry. Disclosures will be included with the published consultation responses. Tobacco companies and those who speak for them or are funded by them (collectively referred to as 'tobacco organisations') cannot register as stakeholders. This is in line with NICE's obligation under Article 5.3 of the WHO Framework Convention on Tobacco Control

(FCTC) to protect public health policies from the commercial and other vested interests of the tobacco industry. Tobacco organisations are simply referred to as 'respondents' and any comments received during consultation are reviewed for factual inaccuracy claims and are made public along with any responses.

Approaches to additional consultation and commissioned primary research

Additional consultation is a targeted engagement exercise to obtain a range of views, experiences and expertise, independent from the committee. An additional consultation for a guideline is considered only on an exceptional basis and is additional to the routine stakeholder consultations.

Commissioned primary research can occasionally be useful for addressing topic areas where there is limited or no evidence. Commissioned primary research should start during the development of the guideline, and the findings should be used by the committee as part of the evidence base for developing recommendations.

For more information, see the appendix on approaches to additional consultation and commissioned primary research.

External expert peer review

Although NICE does not routinely commission peer review from external experts, members of NICE staff with responsibility for quality assurance, or the developer, may occasionally consider arranging additional external expert peer review of part or all of a guideline, or an evidence review, executable model or economic analysis. For example, review by external experts may be valuable if novel methods have been used in developing an evidence review.

External expert peer reviewers may include practitioners, those commissioning care, academics (for example, with expertise in economic or meta-analysis), or people with a lay perspective. Experts are selected on the basis of their experience in the particular issue under review.

External expert peer review may take place during guideline development or during consultation on the draft guideline. If it occurs during development the comments are not published, but the reviewers should be named in the guideline. Comments from external expert peer reviewers during the development of the guideline should be discussed by the committee, and their decisions fully documented in the committee discussion section of the relevant evidence review. If the reviewers also comment during consultation, their comments are responded to in the same way as comments

from registered stakeholders and are published in the guideline consultation table on the NICE website under 'external expert peer reviewers'. All external expert peer reviewers are required to complete a declaration of interests form (see the section on code of conduct and declaration of interests in the chapter on decision-making committees).

10.2 Principles of responding to stakeholder comments

After consultation the committee discusses the comments received during consultation, proposes any changes needed to the guideline, and agrees the final wording of the recommendations.

This section describes how developers should respond to consultation comments. The same principles apply when responding to comments on the draft scope (see the chapter on the scope).

Developers must take the following key points into account when responding to comments from registered stakeholders:

- Each comment must be acknowledged and answered as directly, fully and with as much information as possible.
- For a draft guideline, the committee must consider whether changes to the guideline are needed as a result of consultation comments; any changes to the guideline must be agreed by the committee before publication.
- If changes are made to a guideline as a result of a consultation comment, this must be made clear in the response to the comment. If no changes have been made, it should be clear from the response why not.
- Developers should maintain an audit trail of any changes made to the guideline.

Registered stakeholders who have commented on the draft guideline may be sent the final guideline, and comments and responses, in confidence before publication (see the chapter on finalising and publishing the guideline). Comments and responses are made available on the NICE website when the final guideline is published.

NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.

Comments received from non-registered stakeholders and individuals are reviewed to decide whether they have raised any key issues that the committee need to consider. A formal response is

not given and these comments are not made available on the NICE website. Comments received from 'respondents' are reviewed for factual inaccuracy claims and are made public along with any responses.

Comments received after the deadline are not considered and are not responded to; in such cases the sender will be informed.

When evidence is highlighted by stakeholders during consultation, this should be considered for inclusion in the guideline. The developer will take the evidence into account:

- if it meets all of the inclusion criteria for the relevant review (as set out in the review protocol), and should have been identified in the guideline searches/screening
- if it falls within the timeframe for the guideline search parameters.

Any effects on the guideline of including new evidence will be considered, and any further action agreed between the developer and NICE staff with responsibility for quality assurance.

If the new evidence falls outside of the timeframe for the guideline searches, the impact on the guideline will still need to be considered, and any further action agreed between the developer and NICE staff with responsibility for quality assurance.

10.3 When a second consultation may be needed

In exceptional circumstances, NICE may consider the need for a further stakeholder consultation after the first consultation. This additional consultation may be needed if either:

- information or data that would significantly alter the guideline were omitted from the first draft **or**
- evidence was misinterpreted in the first draft and the amended interpretation significantly alters the draft recommendations.

NICE staff with responsibility for guideline quality assurance make the final decision on whether to hold a second consultation, how long it should be.

11 Finalising and publishing the guideline

This chapter describes quality assurance and sign-off of the guideline after consultation, publication of the guideline, and launching and promoting the guideline.

11.1 Quality assurance of the guideline

After changes agreed by the committee have been made to the guideline in response to consultation comments from registered stakeholders, the guideline is reviewed by NICE staff with responsibility for guideline quality assurance. They check that the changes made to the guideline are appropriate and that the developer has responded appropriately to the registered stakeholders' comments. Further changes to the guideline may be needed; the developer continues to maintain an audit trail of all the changes. Any supporting resources are amended in line with any changes to the guideline. These also undergo quality assurance and are signed off within NICE.

Equality impact assessment

Before the guideline is signed off for publication, the equality impact assessment is updated by the developer and the committee chair to show whether any additional equality issues have been identified during consultation, and how these have been addressed. The equality impact assessment also undergoes quality assurance and is signed off by NICE. It is published on the NICE website with the final guideline.

11.2 Signing off the guideline

NICE's Guidance Executive considers and approves guidelines for publication on behalf of the NICE Board. The Guidance Executive is made up of NICE executive directors, centre directors and the communications director.

When considering a guideline for publication, the Guidance Executive reviews a report from NICE staff with responsibility for guideline quality assurance. The report details whether the guideline:

- addresses all the issues identified in the scope
- is consistent with the evidence quoted
- was developed using the agreed process and methods

- was developed with due regard to the need to eliminate discrimination, advance equality and foster good relations
- will lead to a resource impact when implemented.

If any major issue is identified by the Guidance Executive it may be necessary for the committee to meet again to address the problem.

11.3 Embargoed release (releasing an advance copy to stakeholders)

Registered stakeholders who have commented on the draft guideline (see the chapter on the validation process for draft guidelines, and dealing with stakeholder comments), and agreed to conditions of confidentiality, may be sent the final guideline, the evidence reviews and a copy of the responses to stakeholder consultation comments 2 weeks before publication. This information is confidential until the guideline is published. This step allows registered stakeholders to highlight to NICE any substantive errors, and to prepare for publication and implementation. It is not an opportunity to comment further on the guideline. NICE should be notified of any substantive errors at least 1 week before publication of the guideline.

11.4 Publication

The guideline, including evidence reviews, methods, key messages for the public, equality impact assessment, responses to stakeholder comments, and most support tools (see the chapter on resources to support putting the guideline into practice) are published on the NICE website at the same time.

11.5 Launching and promoting the guideline

The developer and committee work with NICE's media relations team and, if implementation support projects are planned, the implementation lead to disseminate and promote awareness of the guideline at the time of publication and afterwards. It is useful to consider at an early stage of guideline development how the guideline and its support tools will be promoted.

Members from the NICE media relations team discuss with the developer and the committee opportunities for promoting the guideline. Committee members may be asked to take part in such activities.

With help from the committee and the developer, they identify how to reach relevant audiences for

the guideline, including people using services, carers, the public, practitioners and providers.

NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as:

- notifying registered stakeholders of publication
- publicising the guideline through NICE's newsletter and alerts
- issuing a press release as appropriate, posting news articles and blogs on the NICE website, using social media channels, and promoting the guideline within NICE.

NICE may also use other means of raising awareness of the guideline – for example, training programmes, conferences, implementation workshops, NICE field team support and other speaking engagements. Some of these may be suggested by committee members (particularly members affiliated to organisations for people using services and carer organisations). Each guideline is different and activities for raising awareness will vary depending on the type and content of the guideline.

Press launches

A press release is not normally issued when the final guideline publishes, unless there is significant public interest in the guideline. Similarly, full press launches or press conferences are not normally held at guideline publication, unless there is heightened media interest. A press launch or conference allows for a more structured and considered exchange of information between NICE and the media, during which any potentially controversial aspects of the guideline can be explained and set in context. It also gives journalists an opportunity to interview people involved in developing the guideline (such as members of the guideline committee), and potentially other contributors (including people with personal experience in the area the guideline covers, or representatives from charities and other stakeholders who support the guideline).

The media relations team may set up interviews or filming with committee members. This can be done ahead of the guideline launch, or on the day itself. NICE can make good use of case studies or experts to illustrate or explain the guideline recommendations. They help to give context to the guideline, explain why the work has been carried out and can illustrate where recommendations have already been put in place or where lessons have been learned. Information may be provided to the media under embargo until the launch date for the guideline. Committee members and guideline developers should ensure that NICE is made aware of any press enquiries they receive before the guideline is launched, and should not answer them without the involvement of the media

relations team.

Committee members and guideline developers should tell the media relations team if they find out that external organisations are planning their own media promotion for the guideline (for example by issuing their own press release).

A guideline launch is usually accompanied by activity on social media which may include graphics, animations, videos and quotes from key committee members or NICE directors. In most cases, this work will be prepared ahead of the launch.

Committee members may also wish to arrange separate events at which practitioners, providers, commissioners and people using services and the public can learn more about the guideline. Developers should inform committee members that in such cases, the NICE's media relations team should be notified at the earliest possible opportunity. Any materials developed from guideline content by committee members should be submitted to NICE staff with a quality assurance role. Committee members who wish to publish their materials for a UK audience only may do so under the NICE UK Open Content Licence. This is a self-assessment exercise and no fee is involved. The international use of NICE content is subject to a formal licensing agreement, but without a fee for those who have contributed to the development of NICE guidance. Please see NICE's webpage on reusing our content.

12 Resources to support putting the guideline into practice

12.1 Introduction

Guideline committees consider implementation issues as an integral part of developing a guideline, and take account of comments on the draft guideline. NICE teams work with committees to consider what can be done to address implementation challenges, for example, by producing tools to help people put the guideline into practice, in line with our implementation strategy.

12.2 Tools for planning and resource impact assessment

NICE provides a baseline assessment tool for each guideline at the time of publication. This is a modifiable Excel spreadsheet that organisations can use to identify whether they are in line with practice recommended by NICE, and to help them plan and record activity to implement the guideline recommendations.

NICE resource impact assessment tools are intended to help organisations assess the potential costs and savings associated with implementing the guideline. A resource impact report and an associated resource impact template are produced for guidelines that will have a substantial resource impact. The template enables a local estimate to be made of the potential costs and savings involved in implementation. If the resource impact is deemed not to be substantial, a 1-page resource impact statement is produced.

12.3 Tools to support decision-making by practitioners and people using services

Visual summaries and quick guides

For some guidelines, there is a need for a visual summary of part of the guideline for health or care practitioners. For example, where practice needs to change, a practitioner needs to make quick decisions, or a specific audience needs support in implementing the recommendations.

Discussions about any visual summary or quick guide should happen as soon as possible. If NICE and the developer agree that a tool of this type will be helpful, the NICE editor will work with the developer to develop it for publication alongside the guideline.

For some topics, a quick guide is produced to help practitioners with putting recommendations into practice (for example, in a care home), or to support people using services to understand what to expect, and make decisions about their care.

Decision aids

If the committee identifies a preference-sensitive decision point in the guideline (see the section on supporting shared decision-making in the chapter on writing the guideline), NICE may develop a decision aid.

Decision aids supplement or support the discussion between the person and their health or care practitioner about a preference-sensitive decision point, rather than replacing it. The person facing the decision can also refer to the aid after their appointment, and discuss it with their family and carers if they wish. NICE decision aids are written in non-technical language and include information about:

- the treatment or care options recommended in NICE guidance
- the aims of treatment or care and how likely the person is to benefit
- possible adverse effects from the treatment or care options and the likelihood of experiencing them
- other issues likely to be important to the person facing the decision (such as additional monitoring requirements and duration of treatment).

Decision aids usually include a visual representation of the likelihood of benefits or harms. They may also include a table to support the person to think about the relative importance to them of different factors in their decision.

If the committee identifies an area where there is a particular need for support with decision-making, the developer should alert NICE staff with responsibility for quality assurance during guideline development. NICE will decide whether to produce a decision aid. This is based on factors such as:

- the value of a visual representation of the chance of benefits or harms
- the complexity of the issues or the number of options the person is choosing between
- whether or not the decision is 'high stakes' with possible life-changing consequences

- whether or not the risks and benefits between options are similar, so that preferences will be the determining factor.

Each decision aid is developed by a project group with expertise in the topic area, including practitioners and people who use health and care services.

12.4 Working with other organisations and endorsing resources

Organisations and individuals, both lay and practitioner, can play a key role in supporting the implementation of the guideline and NICE may work with external partners to help with this.

Implementation resources which have been jointly developed by NICE in collaboration with key national partner organisations, can be co-badged and carry the NICE logo, providing they are approved by a director and the placement of the logo is approved by the communications team.

Organisations other than NICE may produce resources for guideline implementation. These could include implementation and adoption resources, learning modules/educational packages and patient decision aids. These resources can be endorsed by NICE. A guideline should usually only link to externally developed tools and resources when the tools and resources have been endorsed by the NICE endorsement programme. Endorsement confirms that the resources accurately reflect the content of the NICE guideline and can be updated as needed. Endorsed resources do not carry the NICE logo. If developers identify a relevant tool during development of a guideline, they should contact the endorsement team.

NICE's shared learning case studies show how organisations have put our recommendations into practice. If developers hear about any examples of good practice, they should contact NICE's shared learning team.

If a guideline is expected to have a significant resource impact or be challenging to implement, the Guideline Resource and Implementation Panel reviews it, and advises on affordability and workforce issues. The panel works with NICE to produce a statement to support implementation; the statement is published alongside the guideline. The panel includes representatives from NICE, NHS England, NHS Improvement and Health Education England, along with topic experts and other national organisations if needed.

12.5 Other NICE implementation support

The following services and resources help to put all NICE guidance and standards into practice:

- The implementation support team at NICE works with national partners to support implementation.
- Members of the NICE field team support local organisations to implement NICE guidance and use quality standards.
- NICE medicines and prescribing associates and the medicines education team use their local networks to deliver specialist support for high-quality, cost-effective prescribing and medicines optimisation.
- NICE publishes reports and a database on uptake of NICE recommendations.
- NICE into practice resources cover the principles of changing practice and practical steps to implement NICE recommendations.
- An implementation strategy group made up of external academics meets twice a year to inform the NICE implementation strategy with new and ongoing developments in implementation science.
- NICE's public involvement team works with national and local voluntary and community sector organisations and members of the public to promote the use of our guidance and standards, and support implementation.

We also seek feedback from people who use our guidelines to make them, and any resources to support implementation, as easy to use as possible.

12.6 References and further reading

Auerbach AD, Landefeld CS, Shojania KG (2007) The tension between needing to improve care and knowing how to do it. New England Journal of Medicine 357: 608–13

Baker R, Camosso-Stefinovic J, Gillies C et al. (2010) Tailored interventions to overcome identified barriers to change: effects on professional practice and health care outcomes. Cochrane Database of Systematic Reviews issue 3: CD005470

Cabana MD, Rand CS, Powe NR et al. (1999) Why don't physicians follow clinical practice guidelines? A framework for improvement. JAMA 282: 1458–65

Eccles M, Grimshaw J, Walker A et al. (2005) Changing the behavior of healthcare professionals: the use of theory in promoting the uptake of research findings. Journal of Clinical Epidemiology 58: 107–12

Kneale D, Goldman R, Thomas J (2016) A scoping review characterising the activities and landscape around implementing NICE guidance [online; accessed 11 October 2018]

Leng G, Moore V, Abraham S, editors (2014) Achieving high quality care – practical experience from NICE. Chichester: Wiley

Michie S, Johnston M, Hardeman W et al. (2008) From theory to intervention: mapping theoretically derived behavioural determinants to behaviour change. Techniques in Applied Psychology: An International Review 57: 660–80

13 Ensuring that published guidelines are current and accurate

This chapter describes the process and methods for checking that published guidelines are current and deciding whether updates are needed (surveillance).

13.1 Aims of surveillance

The aim of surveillance is to check that guidelines are up to date. This is done by exploring if there is any new evidence to contradict, reinforce or clarify guideline recommendations. Surveillance also identifies new interventions that may need to be considered within the guideline. Finally, it explores changes in context that may mean modifications are needed, for example, changes in policy, infrastructure, legislation or costs.

NICE has more than 350 published guidelines, so the number of checks needed is considerable. A proactive approach (with an assessment of priority) is used to respond to events that may impact guideline recommendations at any time after guideline publication (for example a safety alert, or publication of a key study)

13.2 Proactive surveillance

Some topic areas change frequently, and this increases the risk of guidelines having out-of-date recommendations. NICE takes a proactive approach to surveillance, and monitors key events (such as ongoing studies) that are judged to be relevant to the guideline.

Events are identified through constant intelligence gathering. This starts during initial guideline development, as the guideline committee and stakeholders can flag up future events that need to be monitored for impact. Ongoing studies are typically identified through discussions with the National Institute for Health Research. This approach means that NICE can quickly identify changes in the evidence base, and assess the impact on recommendations and the need for any changes.

An event that could affect the guideline could include:

- publication of a study that is directly relevant to NICE guidance and has the potential to affect recommendations

- substantial changes in policy or legislation (an example includes changes to the UK physical activity guidelines by the Chief Medical Office)
- development of a related piece of NICE guidance that contradicts recommendations in another NICE guideline
- withdrawal of a drug from the market, or a clinically significant drug safety update from the Medicines and Healthcare products Regulatory Authority (MHRA) or the Commission on Human Medicines.

This list is not exhaustive and individual events will be considered on a case-by-case basis. To make the most efficient use of resource, events are triaged, to determine whether surveillance assessment is needed

- If an assessment is needed these are prioritised based on:
  - safety (always prioritised first)
  - health and social care system priorities
  - burden on services
  - population impact
  - potential impact on addressing health inequalities
  - evidence base: is it changing frequently and what is the degree of uncertainty?
  - what value NICE could add by incorporating the new information into a guideline.

13.3 Surveillance assessment process

The NICE surveillance team considers how an event could affect a guideline. This involves checking how the event could affect the guideline recommendations, and taking feedback from topic experts in the area. The check may include intelligence gathering and literature searches, if needed.

Stakeholders are not normally consulted on the decision to update (or not update) a guideline in response to a surveillance check. This is because these checks usually focus only on one important event and potentially a small section of a guideline. The decisions are published on the NICE website.

If the guideline needs updating, registered stakeholders are informed of the planned approach.

Topic expert engagement

Topic experts (including members of NICE's Expert Advisers Panel) are invited to participate in surveillance. They provide their views about how an event affects the recommendations, and their knowledge of recent developments in the topic area. If the response from topic experts is limited, or further specialist input is needed, we may seek input from other experts. This could include other government organisations, or representatives from a Quality Standards Advisory Committee.

Intelligence gathering

If needed, additional intelligence may be sought. This might include:

- feedback from internal teams within NICE who have expertise in the topic area (for example the NICE medicines or social care teams, if these are major areas in the guideline)
- asking stakeholders for their views, including organisations representing the interests of patients, people using services, carers, and the public
- external queries and comments received since publication of the guideline (these are collated in an issues log for consideration during surveillance)
- related NICE guidance and quality standards (including placeholder statements in NICE quality standards) developed since the guideline was published
- information about guideline implementation, including evidence derived from analysis of primary data on the uptake of recommendations
- information about important ongoing studies in the area covered by the guideline (identified through searches of trial databases)
- changes in licensing status of medicines
- updated or new national policy.

Literature searching

If needed, published evidence is identified by searching a range of bibliographic databases relevant to the topic. Surveillance searches generally use the same databases that were used during the development of the original guideline. The sources searched may vary depending on the topic. In general, MEDLINE, MEDLINE in Process, Embase, Cochrane Database of Systematic Reviews and

Cochrane Central Register of Controlled Trials (CENTRAL) would be considered.

Search approaches

The search approach will vary between topics. The following search approaches can be used:

- population or population/intervention search as needed for the guideline scope with:
  - randomised controlled trials (RCTs) and systematic reviews as a default
  - if RCTs are not appropriate because of the topic or guideline (for example, purely diagnostic), then other study types will be considered
- focused searches for a specific question or a new question, meaning that the study type searched for (RCTs or observational studies) should reflect the type expected to address the question
- citation search forward or back (this option would be supplemented with either a restrictive full scope search or focused searches).

Other considerations

It may be appropriate to consider setting limits for the searches, which could include, but are not limited to:

- study design using appropriate search filters
- date
- location
- populations and subpopulations
- intervention
- service delivery aspect
- prognostic factors.

Search period

The search period will start at the:

- end of the search for the last update of the guideline
- end of the search for the last standard check.

The search date ends on the date the search is conducted.

Decision making

Proposals on the need to update a guideline are based on:

- an assessment of the event and any other relevant evidence published since guideline publication (abstracts of primary or secondary evidence)
- information from topic expert engagement
- if relevant, intelligence gathering and feedback from stakeholder consultation.

The decision also includes an element of judgement.

The possible decisions are:

- update (reviewing the evidence and producing either a full update that replaces the original guideline, or a partial update of defined sections of the guidelines)
- no update (this also includes a decision to defer the update until later)
- amend (making changes to the guideline without reviewing the evidence)
- withdraw (either some recommendations or the whole guideline).

Unless the guideline is fully updated or completely withdrawn, there may also be a refresh (for more information on refreshing, see the section on refreshing the guideline recommendations in the chapter on updating guideline recommendations).

When a guideline is being updated, the original scope may be used (unchanged), the original scope may be modified (for example, where new areas have been identified that require an extension to the scope) or a new scope may be developed. See the chapters on the scope and on updating guideline recommendations for further details.

Stakeholder consultation

Consultations on proposed decisions will be held if there is value in doing so (for example, when it is

not clear to NICE if an update is needed or not). The consultation period will usually be 2 weeks.

Signing off the final decision

All surveillance proposals go through a validation and approval process at NICE, which includes signoff by the associate director and centre director.

13.4 References and further reading

Alderson LJ, Alderson P, Tan T (2014) Median life span of a cohort of National Institute for Health and Care Excellence clinical guidelines was about 60 months. Journal of Clinical Epidemiology 67: 52–5

Shekelle P, Eccles MP, Grimshaw JM et al. (2001) When should clinical guidelines be updated? British Medical Journal 323: 155–7

Shekelle PG, Ortiz E, Rhodes S et al. (2001) Validity of the Agency for Healthcare Research and Quality clinical practice guidelines: how quickly do guidelines become outdated? JAMA 286: 1461–7

14 Updating guideline recommendations

14.1 Scheduling updates

When scheduling updates of guideline recommendations, NICE prioritises topic areas according to need for both new and updated guidelines.

14.2 Full updates of guidelines

If a full update of a guideline is needed either:

- a new scope is prepared, following the process described in the chapter on the scope **or**
- the scope of the published guideline is used and registered stakeholders are informed.

Sometimes an existing topic-specific committee is asked to update a guideline in their topic area. Sometimes a new topic-specific committee is set up for the update. Recruitment of committee members follows the usual process (see the chapter on decision-making committees). Where possible, the developer informs all members of the topic-specific committee, or topic-expert members of the standing committee, for the published guideline if a new committee is being recruited. The composition of the committee should be tailored to new requirements if a new scope has been developed. The guideline is developed using the same methods and process as for a new guideline and the draft is subject to the normal 4- to 6-week consultation period (see the chapter on the validation process for draft guidelines, and dealing with stakeholder comments). The developer should maintain records appropriate for audit (see the section on committee meetings in the chapter on decision-making committees). The usual process for finalising and publishing the guideline is followed (see the chapter on finalising and publishing the guideline).

14.3 Updates of topic areas in guidelines

If only some topic areas of a guideline need to be updated, either:

- a new scope is prepared, following the process described in the chapter on the scope **or**
- parts of the scope of the published guideline are used (as determined by the check of the need for an update; see the chapter on ensuring that published guidelines are current and accurate), and registered stakeholders are informed. No new scope is produced.

In both cases, the scope is clear about exactly which sections of the guideline are being updated and which are not, including any sections that may be withdrawn (for example, if they are now covered in another guideline). Recommendations that are outside the scope of an update may be refreshed (see the section on refreshing the guideline).

The update is developed using the same methods and process as for a new guideline. Updates of some topic areas using the scope of the published guideline use the review questions and review protocols already defined by the existing guideline. However, if the review questions and/or protocols are unavailable, need refinement, or if there is ambiguity in the published guideline, the developer may approach the committee members with topic expertise for advice before starting the evidence review.

Update of topic areas in a guideline are subject to the same level of scrutiny as full updates and new guidelines. The underlying principles of transparency of process and methodological rigour continue to hold. The draft is subject to a consultation period of up to 6 weeks, depending on length and complexity (see the chapter on the validation process for draft guidelines, and dealing with stakeholder comments). The developer should maintain records appropriate for audit (see the section on committee meetings in the chapter on decision-making committees). The usual process for finalising and publishing the guideline is followed (see the chapter on finalising and publishing the guideline).

14.4 Refreshing the guideline recommendations

Refreshing guideline recommendations allow us to improve the usability of recommendations without changing the intent and therefore without the need for an evidence review or committee input. All refreshing changes are signed off by NICE's Guidance Executive.

Refreshing changes can be made to guideline recommendations even when the surveillance decision is not to update the guideline. All changes to recommendations made as part of the surveillance process should be agreed by the NICE surveillance team (see the chapter on ensuring that published guidelines are current and accurate).

When it has been agreed which topic areas need updating, the publishing team also identifies recommendations that may need refreshing to feed into the scoping process. Occasionally during development of the update, additional recommendations that are not part of the update may be identified for refreshing by the committee or the publishing team.

Refreshing might involve:

- amending or adding cross references to other NICE guidance or hyperlinks to other NICE-endorsed tools or resources
- adding or amending a footnote to reflect changes to a medicine's marketing authorisation, to reflect changes in service configuration (for example, a change from primary care trusts to clinical commissioning groups) or a change to an organisation's name
- ensuring recommendations take into account the latest government policy or guidelines, for example, on alcohol consumption
- amending recommendations to reflect the current practice context, for example, removing references to tools or resources that no longer exist
- bringing recommendations in line with NICE's current policy on wording without affecting the intent, for example:
  - reflecting the involvement of people in decisions about their care
  - using person-centred language.

Refreshing changes that are made during scoping and guideline development should be agreed with NICE staff with responsibility for quality assurance.

14.5 Presenting updates

A full update replaces an existing guideline and has a new set of recommendations, a new set of rationale and impact sections, new evidence reviews and new sections detailing the committee's discussion of the evidence. When a full update is published the old guideline is withdrawn.

When presenting updates of topic areas within guidelines, the aim is to ensure that there is a single set of publications that bring together the updated information and relevant information from all previous versions of the guideline. In this way, readers of the updated guideline will be able to easily identify what has changed. The rest of this section covers general principles to be used when part of a guideline has been updated.

Preparing an update of topic areas for consultation

Before consultation on an update of topic areas within a guideline, the developer should check the following:

- All sections have been updated as agreed.

- It is clear which sections have been updated and are open for comment during consultation.
- Recommendations from sections which have not been updated have been checked to determine whether any changes are essential (for example, if a medicine is no longer available).
- Refreshing changes (see the section on refreshing the guideline) to recommendations in sections that have not been updated are kept to a minimum (for example, changing from the passive voice to direct instructions).
- A summary of changes to recommendations is included.
- The status of any guidance incorporated in the previous version of the guideline has been confirmed with NICE. For example, has the other guidance been updated by the guideline update?
- All recommendations (new, updated and unchanged) have been assessed with respect to NICE's equality duties.

Preparing the final version of an update of topic areas for publication

The developer should check the following:

- It is clear which sections have been updated, and whether the recommendations have been updated or amended.
- The summary of changes to recommendations has been revised in line with the final recommendations.

Resources to support implementation are also checked for current relevance.

14.6 Post-publication changes

Measures are in place throughout the development of a guideline to avoid errors in the collection, synthesis, interpretation or presentation of the evidence as far as possible. On rare occasions errors are found after publication of the guideline, or users may ask for clarification.

Corrections or changes to published guideline recommendations are made if an error or lack of clarity:

- puts users of health or care services at risk, or affects their care or provision of services **or**

- damages NICE's reputation or
- significantly affects the meaning of a recommendation.

Errors or clarifications that do not warrant immediate changes to the recommendations are logged for consideration when the guideline undergoes surveillance (see the chapter on ensuring that published guidelines are current and accurate).

If an error or clarification meets the criteria for changing a published guideline recommendation, NICE's process for dealing with post-publication changes is followed. An explanation of the decisions and actions taken is sent to the person or organisation that reported the error or requested clarification.

Sometimes recommendations need to be removed because a medicine has been removed from the market or a few recommendations have been updated or replaced by recommendations in another guideline.

The guideline is amended. Resources to support implementation are also amended if necessary. The changes are explained in the guideline. Depending on the nature and significance of the change and the time since publication of the guideline, registered stakeholders may also be notified.

Routine maintenance

Routine maintenance changes may also be made after publication or update of a guideline. These include minor changes such as updating or fixing broken links or updating standard text in line with agreed template changes.

14.7 References and further reading

Clark E, Donovan EF, Schoettker P (2006) From outdated to updated, keeping clinical guidelines valid. International Journal for Quality in Health Care 18: 165–6

Eccles M, Rousseau N, Freemantle N (2002) Updating evidence-based clinical guidelines. Journal of Health Services Research and Policy 7: 98–103

Shojania KG, Sampson M, Ansari MT et al. (2007) Updating systematic reviews. AHRQ Technical Reviews and Summaries, technical review 16. Rockville, MD: Agency for Healthcare Research and Quality

Turner T, Misso M, Harris C et al. (2008) Development of evidence-based clinical practice guidelines (CPGs): comparing approaches. Implementation Science 3: 45–52

15 Appendices

Appendices A to L can be found via tools and resources.

- Appendix A: Service delivery – developing review questions, evidence reviews and synthesis
- Appendix B: Approaches to additional consultation and commissioned primary research
- Appendix C: Key roles and responsibilities of committee members
- Appendix D: Guideline committee Terms of Reference and Standing Orders
- Appendix E: Code of conduct for committee members
- Appendix F: Suggested sources for scoping
- Appendix G: Sources for evidence reviews
- Appendix H: Appraisal checklists, evidence tables, GRADE and economic profiles
- Appendix I: Review protocol template
- Appendix J: Call for evidence and expert witnesses
- Appendix K: Network meta-analysis reporting standards
- Appendix L: Interim process and methods for guidelines developed in response to health and social care emergencies

Glossary

Abstract

Summary of a study, which may be published alone or as an introduction to a full scientific paper.

AGREE (Appraisal of Guidelines for Research and Evaluation)

An international collaboration of researchers and policy makers whose aim is to improve the quality and effectiveness of practice guidelines. The AGREE II instrument, developed by the group, is designed to assess the quality of guidelines.

Allocation

The process by which study participants are allocated to a treatment group.

Applicability

How well an observation or the results of a study or review are likely to hold true in a particular setting.

Association

Statistical relationship between 2 or more events, characteristics or other variables. The relationship may or may not be causal.

Audit trail

Clear record of actions so that the reasons for the actions are apparent to a third party. For example, the reasons for changes to a draft guideline should be clearly recorded.

Baseline

A set of measurements before any intervention starts (after any initial 'run-in' period with no intervention), with which subsequent results are compared.

Bias

Systematic (as opposed to random) deviation of the results of a study from the 'true' results, caused by the way the study is designed or conducted.

Case–control study

An observational study to find out the possible cause(s) of a disease or condition. This is done by comparing a group of patients who have the disease or condition (cases) with a group of people who do not have it (controls) but who are otherwise as similar as possible (in characteristics thought to be unrelated to the causes of the disease or condition). This means the researcher can look for aspects of their lives that differ to see if they may have caused the condition.

For example, a group of people with lung cancer might be compared with a group of people the same age who do not have lung cancer. The researcher could compare how long both groups had been exposed to tobacco smoke. Such studies are retrospective because they look back in time from the outcome to the possible causes of a disease or condition.

Citation searching

Citation searching (also known as 'snowballing') can help to identify additional research. It has 2 dimensions:

- Backward citation searching is reviewing references cited in studies identified for inclusion in the review.
- Forward citation searching involves searching for additional studies that cite articles known to be relevant (such as those identified for inclusion in the review).

Cohort study

An observational study with 2 or more groups (cohorts) of people with similar characteristics. One group has a treatment, is exposed to a risk factor or has a particular symptom and the other group does not. The study follows their progress over time and records what happens.

Committee

The advisory group that considers the evidence and develops the recommendations, taking into account the views of stakeholders. NICE has standing committees (which work on multiple

guidelines) and topic-specific committees (which are put together for a single guideline topic or to work on multiple guidelines within a topic area). Members include practitioners and professionals (both specialists and generalists, and/or academics), care providers and commissioners, people using health and care services and/or their family members or carers, or people from communities affected by the guideline.

Committee chair

A member of the committee who leads committee meetings, and ensures that the committee keeps to the scope of the guideline, works collaboratively and adheres to NICE's equality policy and principles on social value judgements. The chair completes the equality impact assessment with the developer at scoping and final guideline stages, approves the draft guideline for consultation, and advises the developer on responses to comments from registered stakeholders.

Comparator

The standard (for example, another intervention or usual care) against which an intervention is compared in a study. The comparator can be no intervention (for example, best supportive care).

Conceptual framework

A theoretical structure of assumptions, principles and rules, which holds together the ideas comprising a broad concept. A conceptual model has been defined as the abstraction and representation of complex phenomena of interest in some readily expressible form, such that the individual stakeholders' understanding of the parts of the system, and/or the mathematical representation of that system, can be shared, questioned, tested and ultimately agreed.

Confidence interval

The confidence interval is a way of expressing how certain we are about the findings from a study, using statistics. It gives a range of results that is likely to include the 'true' value for the population. A wide confidence interval indicates a lack of certainty about the true effect of the test or treatment – often because a small group of patients has been studied. A narrow confidence interval indicates a more precise estimate (for example, if a large number of patients have been studied).

Consultation table

A table of all the comments received by NICE during consultation on a scope or draft guideline. The

committee considers the comments received, and the developer then responds to the comments in the table.

Contractors

Organisations contracted to do some aspects of guideline development for NICE. This might include doing evidence reviews or fieldwork, or the developer role.

Co-opted members

An expert invited to 1 or more meetings to contribute to formulating recommendations in a specific part of the guideline. They take part fully in discussions, but do not have voting rights or count towards quorum. Co-opted members can include people with expertise in user, carer or community experience and views, as well as those with professional or practitioner expertise.

Core members (standing committee)

The core members of a standing committee include at least 1 practitioner and 1 lay member, and may include an economist. A standing committee usually has between 6 and 12 core members. They serve for an initial period of up to 3 years and work on all guidelines developed by the committee during that period.

Correlates review

Correlates reviews describe relationships between epidemiological factors and outcomes.

Cost–benefit analysis

This is a type of economic evaluation in which the costs and benefits are measured using the same monetary units (for example, pounds sterling) to see whether the benefits exceed the costs.

Cost–consequences analysis

This is a type of economic evaluation in which the costs (such as treatment and hospital care) and the consequences (such as health outcomes) of a test or treatment are compared with those for a suitable alternative. Unlike cost–benefit analysis or cost-effectiveness analysis, it does not attempt to summarise outcomes in a single measure (such as the quality-adjusted life year) or in financial terms. Instead, outcomes are shown in their natural units (some of which may be monetary) and it is

left to decision-makers to determine whether, overall, the treatment is worth carrying out.

Cost-effectiveness analysis

This is a type of economic evaluation in which the benefits are expressed in non-monetary terms related to health, such as symptom-free days, heart attacks avoided, deaths avoided or life years gained (that is, the number of years by which the intervention extends life). Cost-effectiveness analysis assesses the cost of achieving the same benefit by different means. Cost-effectiveness analysis is also used as an umbrella term to cover all types of economic evaluation.

Cost-minimisation analysis

In a cost-minimisation analysis, the costs of different interventions that provide the same benefits are compared. If they are equally effective, only the costs are compared because the cheapest intervention will provide the best value for money. In practice, there are relatively few cost-minimisation analyses because it is rare for 2 healthcare interventions to provide exactly the same benefits.

Cost–utility analysis

This is a type of economic evaluation in which the benefits are assessed in terms of both quality and duration of life, and expressed as quality-adjusted life years (QALYs).

Cross-sectional survey

An observational study in which a population is examined to see what proportion has a particular outcome or has been exposed to a specific risk factor, or both. Cross-sectional surveys are usually used to determine the prevalence of outcomes or exposures to risk factors in populations. This type of survey may also be called a cross-sectional study or a prevalence study. Although cross-sectional surveys often provide useful estimates of disease burden for a particular population, they are less reliable for determining the prevalence of very rare conditions or conditions of short duration. Because cross-sectional surveys are descriptive rather than analytical, they cannot be used to estimate the relationship between cause and effect.

Decision-analytic model (and/or technique)

A model of how decisions are or should be made. This could be one of several models or techniques used to help people to make better decisions (for example, when considering the trade-off between

costs, benefits and harms of diagnostic tests or interventions). See also Markov modelling.

Delphi technique

A technique used for reaching agreement on a particular issue, without the participants meeting or interacting directly. It involves sending participants a series of questionnaires asking their views. After completing each questionnaire, participants are asked to give further views in the light of the group feedback until the group reaches a predetermined level of agreement. The judgements of the participants may be analysed statistically.

Design-oriented conceptual model

This is an explicit simplification and abstraction of the problem-oriented conceptual model, mediated by what is feasible and by the availability of evidence and data.

Developer

The team responsible for scoping the guideline, identifying and reviewing the evidence, undertaking economic analyses, supporting the committee and writing the guideline in light of the committee's discussions and decisions. The team includes administrators, coordinators and project managers who provide administrative and management support to the committee, plan and schedule the work, arrange meetings, and liaise with stakeholders, and all other people and organisations contributing to guideline development.

Discounting

Costs and perhaps benefits incurred today have a higher value than costs and benefits occurring in the future. Discounting health benefits reflects individual preference for benefits to be experienced in the present rather than the future. Discounting costs reflects individual preference for costs to be experienced in the future rather than the present.

Dosage

The amount of a medicine to be taken, including the size and timing of the doses.

Economic evaluation

The comparative analysis of alternative courses of action in terms of both their costs and

consequences.

Economist

A person with skills in economic analysis whose role is to advise on economic aspects of the key issues or questions, review economic literature, prioritise topics for further analysis and carry out additional cost-effectiveness analyses.

Effect (as in treatment effect, effect size)

The observed association between interventions and outcomes, or a statistic to summarise the strength of the observed association.

Effectiveness

The extent to which an intervention produces an overall benefit under usual or everyday conditions. In this manual effectiveness includes cost effectiveness unless otherwise indicated.

Endorsement

The NICE endorsement programme formally endorses resources produced by external organisations that support the implementation of NICE guidance and the use of quality standards in part or in full.

Epidemiological review

Epidemiological reviews describe a problem in terms of its causes, distribution, control and prevention, and can be used to help focus the review questions. For example, an epidemiological review of accidents would provide information on the most common accidents, morbidity and mortality statistics, and data on inequalities in the impact of accidents.

Equity

Fair distribution of resources or benefits.

Evidence

Information on which a decision or recommendation is based. Evidence can be obtained from a

wide range of sources, including randomised controlled trials, observational studies and expert opinion (of practitioners, people using services, family members and carers).

Evidence from practice

Information on context and current practice, which could be in the form of published implementation trials, audit data, manuscripts of case studies or service evaluation reports, or accounts from experts.

Evidence review

Identifying and reviewing the evidence, and undertaking economic analyses:

- The information specialist identifies relevant literature to answer the review questions, creates databases to manage the search results and keeps a log of search results and strategies.
- The systematic reviewer critically appraises the evidence, distils it into tables and writes brief summaries (including GRADE tables, GRADE-CERQual or evidence statements, if used). The reviewer also summarises the main issues for the committee and contributes to its discussions.
- The economist identifies potential economic issues to be considered in the guideline and performs economic analyses.

Exceptional update

Update of a guideline carried out sooner than originally planned because new data have become available.

Exclusion criteria (literature review)

Explicit criteria used to decide which studies should be excluded from consideration as potential sources of evidence.

Exclusion criteria (study participants)

Criteria that define who is not eligible to participate in a study.

Expert Advisers Panel

The Expert Advisers Panel provides a single repository of experts and practitioners (who have been through a robust recruitment process) for the NICE Centre for Guidelines, and can be called upon to contribute to various guideline development activities, such surveillance reviews and guideline updates.

Expert witness

An expert invited to attend a committee meeting to provide evidence from their experience and specific expertise. Expert witnesses answer questions from committee members and may be invited to present evidence in the form of expert testimony, which is published on the NICE website when the guideline is published. Expert witnesses are not members of the committee. They have expert knowledge of 1 or more of the following areas: experience and views of practitioners; people using services; carers or the community and voluntary sector; government and policy; or research and practice.

External validity

The degree to which the results of a study hold true in non-study situations (for example, in routine NHS practice). It may also be referred to as the generalisability of study results to non-study populations. For example, the external validity of a study that took place in Spain may be questioned if the results are applied to people in Australia.

Extrapolation

In data analysis, predicting the value of a parameter outside the range of observed values.

Follow-up

Observation over a period of time of a person, group or defined population to observe changes in health status or health- and social care-related variables.

Forest plot

A type of graph used to display the results of a meta-analysis.

Formal consensus methods

Formal consensus methods are techniques that can be used to enable a committee to reach an agreement on a particular issue. Methods include Delphi and nominal-group techniques, and consensus development conferences. These methods may be used during guideline development when there is a lack of strong research evidence in a particular area.

Free-text terms

Terms used for searching that are not controlled vocabulary as used in the database or information source, but standard terms used in natural language.

Full update of a guideline

When a guideline is identified for a full update, the existing guideline with its recommendations, are stood down and a replacement guideline is developed with new recommendations.

Generalisability

The extent to which the results of a study based on measurements in a particular population or a specific context hold true for another population or in a different context.

GRADE (Grading of Recommendations Assessment, Development and Evaluation)

A systematic and explicit approach to grading the quality of evidence and the strength of recommendations. GRADE is an evolving system and is continuously being adapted and extended to cover different areas and types of evidence; for example, CERQUAL for qualitative evidence and GRADE for diagnostic studies. See the GRADE working group for the latest news and publications.

GRADE table/GRADE profile

A table summarising, for each important outcome, the quality of the evidence and the outcome data (used as part of the GRADE approach to assessing the quality of the evidence).

Grey literature

Literature that is not formally published or that has a limited distribution, such as institutional

reports. Grey literature may not be easily identified through standard bibliographic retrieval systems.

Health inequalities

The Public Health England report on place-based approaches for reducing health inequalities defines health inequalities as unfair and avoidable differences in health across the population, and between different groups within society. They categorise health inequalities across 4 dimensions:

- socio-economic status and deprivation (for example, unemployment, poor housing, poor education, low income or people living in deprived areas)
- protected characteristics (for example, age, sex, race, sexual orientation, and disability)
- vulnerable groups of society, or 'inclusion health' groups (for example, vulnerable migrants, homeless people, sex workers, and Gypsy, Roma and Travellers)
- geography (for example, urban or rural areas).

Health-related quality of life

A combination of a person's overall physical, mental and social wellbeing; not merely the absence of disease.

Health Technology Assessment

Independent research about the effectiveness, costs and broader impact of healthcare (treatments and tests) for those who plan, provide or receive care in the NHS. The Health Technology Assessment (HTA) programme is part of the National Institute for Health Research (NIHR).

Implementation

The process of putting guideline recommendations into practice.

In confidence material

Information (for example, the findings of a research project) defined as 'confidential' because its public disclosure could affect the commercial interests of a particular company ('commercial in confidence') or the academic interests of a research or professional organisation ('academic in

confidence').

Inclusion criteria (literature review)

Explicit criteria used to decide which studies should be considered as potential sources of evidence.

Incremental cost-effectiveness ratio (ICER)

The difference in the mean costs between 2 interventions, strategies or programmes in the population of interest divided by the differences in the mean outcomes between the 2 interventions, strategies or programmes in the population of interest.

Index test

The test in a study which is being compared with the best available test (the reference standard).

Indication (specific)

The defined use of a medicine as licensed by the Medicines and Healthcare products Regulatory Agency (MHRA).

Indirect treatment comparison

An analysis to compare interventions that have not been compared directly in a head-to-head trial.

Internal validity

A measure of how well a research study has been designed and how well it avoids bias. That is, the extent to which the cause-and-effect relationships in a study are true for the people and conditions of the study.

Key issues

Key issues are included in the scope of a guideline and broadly define aspects of care or service provision for which most advice is needed.

Key questions

Key questions are included in the scope of a guideline and are broad questions related to the areas defined by the key issues. Key questions relate to the effectiveness and cost effectiveness of interventions that are being considered for a given population. Key questions are then used to develop more detailed review questions.

Lay member

A member of the committee who has personal experience of using health or care services, or who is from a community affected by the guideline. A lay member can also be someone with experience as a carer, an advocate, or a member or officer of a voluntary or community organisation.

Literature review

A summary of the evidence from several studies, with conclusions about the findings. It may or may not be systematically researched and developed.

Logic model

A model that incorporates the assumed relationships between action and outcomes as described in the conceptual framework.

Marketing authorisation

This was previously known as a product licence. Marketing authorisation is granted to medicines that meet the standards of safety, quality and efficacy set by a medicines regulator (for example, the Medicines and Healthcare products Regulatory Agency [MHRA] or the European Medicines Agency). It is normally necessary before a medicine can be prescribed or sold.

Markov modelling

A decision-analytic technique that predicts future events occurring in a group over a period of time by assigning group members to a fixed number of health states and then modelling transitions among the health states.

Medical devices

All products, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or disability.

Medicines and Healthcare products Regulatory Agency (MHRA)

The Executive Agency of the Department of Health and Social Care that is responsible for protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely.

Meta-analysis

A method often used in systematic reviews to combine results from several studies of the same test, treatment or other intervention to estimate the overall effect of the treatment.

Meta-ethnography

A process for sorting and combining the findings from qualitative studies.

Model inputs

Information needed for economic modelling. This may include information about effectiveness, adverse events, diagnostic accuracy, prognosis, quality of life, resource use and costs.

Narrative summary

Summary of findings presented as a written description rather than, for example, as a graph or table.

Net benefit estimates

In cost-effectiveness and cost–utility analysis, the net benefit estimate can be expressed in outcomes (for example, using quality-adjusted life years [QALYs]) or monetary terms. The net health (or outcome) benefit is the difference between the total expected QALYs (or outcome) and the health (or outcomes) expected to be forgone elsewhere (the total expected costs divided by the

maximum acceptable incremental cost-effectiveness ratio [ICER] value). The net monetary benefit is the difference between the monetary value of total expected QALYs (our outcome) multiplied by the maximum acceptable ICER value [ICER] and total expected costs. In cost–benefit analysis, the net benefit estimate is the estimate of the amount of money remaining after all payments made are subtracted from all payments received. This is used in the economic evidence profile for guidelines.

Network meta-analysis

An analysis that compares 3 or more interventions using a combination of direct evidence (from studies that directly compare the interventions of interest) and indirect evidence (from studies that do not compare the interventions of interest directly).

NICE guidance

Recommendations produced by NICE. There are 5 types of guidance:

- guidelines covering clinical topics, medicines practice, public health and social care
- interventional procedures guidance
- technology appraisals guidance
- medical technologies guidance
- diagnostics guidance.

All guidance is developed by independent committees and is consulted on.

NICE guidelines

Recommendations (and the evidence they are based on) on broad topics covering health, public health and social care in England. NICE guidelines include clinical, medicines practice, public health and social care guidelines.

Non-randomised controlled trial

These are trials in which participants (or groups) are allocated to receive either the intervention or a control (or comparison intervention) but the allocation is not randomised. This type of study is often called a controlled before-and-after (CBA) study.

Observational study

Retrospective or prospective study in which the investigator observes the natural course of events with or without control groups (for example, cohort studies and case–control studies).

Odds ratio

An odds ratio compares the odds of something happening in one group with the odds of it happening in another. An odds ratio of 1 shows that the odds of the event happening (for example, a person developing a disease or a treatment working) is the same for both groups. An odds ratio of greater than 1 means that the event is more likely in the first group than the second. An odds ratio of less than 1 means that the event is less likely in the first group than in the second group.

Sometimes probability can be compared across more than 2 groups – in this case, one of the groups is chosen as the 'reference category', and the odds ratio is calculated for each group compared with the reference category.

P value

The p value is a statistical measure that is used to indicate whether or not an effect is statistically significant.

People using services and the public

Anyone who is using health or care services, or a member of the public affected by a guideline.

Personal social services

Care services for vulnerable people, including those with special needs because of old age or physical disability and children in need of care and protection. Examples are residential care homes for older people, home help and home care services, and social workers who provide help and support for a wide range of people (Department of Health and Social Care definition).

PICO (population, intervention, comparison and outcome) framework

A structured approach for developing review questions about interventions. The PICO framework divides each question into 4 components: the population (the population being studied), the

interventions (what is being done), the comparators (other main treatment options) and the outcomes (measures of how effective the interventions are).

Placeholder statements

In NICE quality standards, placeholder statements are used for areas of care in need of quality improvement but for which there is no evidence-based guidance available to formulate quality statements or measures.

Practitioner

A healthcare, social care or public health worker.

Pragmatic clinical trial

A study comparing health interventions among a randomised, diverse population representing clinical practice, and measuring a broad range of health outcomes. To ensure generalisability, pragmatic trials should represent the intended patients to whom the treatment will be applied as best as possible. (Definition from GetReal glossary)

Problem-oriented conceptual model

This is a simplified, diagrammatic representation of the framework that describes the resources, processes and interactions in the delivery of interventions.

Prognosis

A probable course or outcome of a disease. Prognostic factors are characteristics of a patient or disease that influence the disease course. A good prognosis is associated with a low rate of undesirable outcomes; a poor prognosis is associated with a high rate of undesirable outcomes.

Project manager

The staff member who oversees and facilitates the guideline development process.

Proprietary name

The brand name a manufacturer gives to a medicine or device it produces.

QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies-2)

A tool for assessing the quality of studies of the accuracy of diagnostic tests.

Qualitative research

Qualitative research explores people's beliefs, experiences, attitudes, behaviour and interactions. It asks questions about how and why, rather than how much. It generates non-numerical data, such as a person's description of their pain rather than a measure of pain. Qualitative research techniques include focus groups and in-depth interviews.

Quality-adjusted life year (QALY)

A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health.

Quality assurance

NICE staff carry out quality assurance of the guideline, including reviews of the evidence and any economic analysis, to ensure that it is up-to-date, credible, robust and relevant. These staff may also be responsible for commissioning the developer.

- The centre director is responsible for ensuring that the guideline is produced in accordance with this manual. The centre director is also responsible for appointing the committee chair and committee members.
- The guideline lead is responsible for the development and quality assurance of the guideline (including the scope), and has delegated responsibility for approving the consultation draft, the final guideline, and other documents, before final approval by NICE's Guidance Executive. The guideline lead also advises the chair of the committee and the developer on matters of method and process. Guideline commissioning managers help them with this.
- The NICE clinical, public health or social care adviser is responsible for providing advice during all stages of guideline development.
- The technical lead is responsible for the technical quality assurance of the evidence reviews and other work undertaken by the developer. The technical lead commissions, coordinates and quality assures any fieldwork.

- The economic lead is responsible for ensuring the technical quality of the economic evidence and any economic analysis.

Quality assurance of guideline surveillance reflects quality assurance of guideline development. The NICE associate director – surveillance is responsible for ensuring that processes are followed and that decisions to update or not update guidelines are robust and fit for approval by NICE's Guidance Executive.

Quality of life

See Health-related quality of life.

Quality standards

Quality standards set out the priority areas for quality improvement in health and social care. They cover areas where there is variation in care. Each standard includes a set of statements to help improve quality, and information on how to measure progress.

Quorum

The smallest number of group members that must be present for a valid meeting. The quorum of a committee is 50% of the total potential membership. No recommendations should be confirmed unless the quorum is reached.

Randomised controlled trial

Trials in which participants (or clusters) are randomly allocated to receive either intervention or control. If well implemented, randomisation should ensure that intervention and control groups differ only in their exposure to treatment.

Real world evidence

See the GetReal glossary.

Recommendations

Specific advice in NICE guidelines on the care and services that are suitable for most people with a specific condition or need, or for particular groups or people in particular circumstances (for example, when being discharged from hospital). Recommendations may also cover ways to

promote good health or prevent ill health, or how organisations and partnerships can improve the quality of care and services.

Reference case

The reference case specifies the methods considered by NICE to be the most appropriate for estimating clinical and cost effectiveness when developing guidance. These are also consistent with an NHS objective of maximising health gain from limited resources.

Reference standard (or gold standard)

A method, procedure or measurement that is widely accepted as being the best available to test for or treat a disease.

Research recommendations

Recommendations for future research that cover areas of uncertainty or gaps in the evidence identified during guideline development.

Respondent

Tobacco organisations (for example, tobacco companies, those who speak for them or are funded by them) with an interest in a particular topic. The term 'respondent' acknowledges NICE's commitment to Article 5.3 of the WHO Framework Convention on Tobacco Control. This sets out an obligation to protect the development of public health policy from any vested interests of the tobacco industry.

Review protocol

A document that outlines the background, objectives and planned methods for an evidence review.

Review questions

Review questions guide a systematic review of the literature. They address only the key issues and questions covered in the scope of the guideline, and will usually be structured with a framework (for example, using PICO or SPICE).

Scoping search

A search of key sources at the scoping stage to identify previous guidelines, health technology assessment reports, key systematic reviews, randomised controlled trials and economic evaluations relevant to the guideline topic. The search also includes the NICE website, government, charity, and other community and voluntary sector websites to identify relevant policies and documents.

Scoping workshop

The scoping workshop is attended by registered stakeholders and is held when key issues that need discussion have been identified by the developer. The workshop may be held before during or after consultation.

Search filter

A collection of search terms designed to retrieve certain types of study (for example, those using a specific study design or on a specific topic).

Sensitivity (of a test)

This refers to how well a test detects what it is testing for. It is the proportion of people with the disease or condition that are correctly identified by the study test.

Sensitivity analysis

A means of exploring uncertainty in the results of economic evaluations. There may be uncertainty because data are missing, estimates are imprecise or there is controversy about methodology. Sensitivity analysis can also be used to see how applicable results are to other settings. The analysis is repeated using different assumptions to examine the effect of these assumptions on the results.

- Deterministic sensitivity analysis investigates how bias in selecting data sources for key model parameters might affect the results.
- One-way sensitivity analysis (univariate analysis) varies each parameter individually to investigate how this affects the results.

- Probabilistic sensitivity analysis assigns probability distributions to uncertain parameters and incorporates these into models using decision-analytic techniques (for example, Monte Carlo simulation).

Shared learning examples

These show how NICE guidance and standards have been put into practice by a range of health, local government and social care organisations.

Social care

Social care generally refers to all forms of personal care and other practical assistance for children, young people and adults who need extra support. This includes:

- children and young people who are at risk of, or who are already experiencing, social and emotional problems
- children, young people and adults with learning or physical disabilities or mental health problems
- people who misuse drugs or alcohol
- older people.

Social value judgements

The decisions in NICE guidance are based on the best available evidence. Sometimes the available evidence is not of good quality or can be incomplete, so the committees involved have to make scientific value judgements and social value judgements. Social value judgements take account of society's expectations, preferences, culture and ethical principles when making recommendations.

Specificity (of a test)

This refers to how well a test detects what it is testing for. The proportion of people classified as negative by the reference standard who are correctly identified by the study test.

SPICE framework

A structured approach for developing review questions that divides each question into 5 components: setting, perspective, intervention, comparison and evaluation (SPICE).

Stakeholders

Stakeholders are organisations with an interest in a particular guideline topic; they may represent people whose practice or care is directly affected by the guideline.

They include: national organisations for people who use health and social care services, their families and carers, and the public; local Healthwatch organisations; national organisations that represent health and social care practitioners and other people whose practice may be affected by the guideline, or who can influence uptake of the guideline recommendations; public sector providers and commissioners of care or services; private, voluntary sector and other independent providers of care or services; companies that manufacture drugs, devices, equipment or adaptations, and commercial industries relevant to public health; organisations that fund or carry out research; government departments and national statutory agencies.

Stakeholders are encouraged get involved at all stages. Registered stakeholders comment on the draft scope and draft guideline, may provide evidence, and support implementation of the guideline.

See also respondent.

Standing committee

A committee consisting of core members who work on multiple guidelines. Topic expert members are brought in to work on specific guidelines.

Survey

See cross-sectional study.

Surveillance report

A report that summarises the evidence and intelligence identified through the surveillance process and explains the reasons for updating or not.

Surveillance review

The process of checking whether a guideline needs to be updated. This generally includes consideration of new evidence and intelligence such as topic expert feedback, changes to

legislation or policy, and information on implementation.

Systematic review

A review that summarises the evidence on a clearly formulated review question according to a predefined protocol, using systematic and explicit methods to identify, select and appraise relevant studies, and to extract, analyse, collate and report their findings. It may or may not use statistical meta-analysis.

Time horizon

The time period over which the main differences between interventions in effects and the use of resources in health and social care are expected to be experienced, taking into account the limitations of the supporting evidence.

Topic adviser (topic-specific committee)

A member of the committee who also works closely with the developer to provide topic-specific support.

Topic expert members (of a standing committee)

Experts on the topic of a guideline who join a standing committee to work on that guideline. They may include lay members, practitioners, providers and commissioners.

Topic-specific committee

A committee consisting of members appointed for the development of a specific guideline or to work on multiple guidelines within a topic area.

Treatment options

The choices of intervention available.

Update information

Major changes since publication

January 2022: Major changes from the 2018 guidelines manual are shown below.

Chapter 1: introduction

We have put more emphasis on addressing health inequalities.

Chapter 2: the scope

We have added a new shorter process for scoping, with more emphasis on addressing health inequalities.

Chapter 4: Developing review questions and planning the evidence review

We have added more information on mixed methods reviews and prediction models.

Chapter 5: Identifying the evidence: literature searching and evidence submission

We have added an option for the use of RCT classifiers, and removed OpenGrey as a potential source.

Chapter 6: Reviewing research evidence

We have made searching for conference abstracts 'optional' and made it an option for there to be no distinction between 'critical' or 'important' outcomes. We have specified that data extraction for complex analyses (such as network meta-analyses) should be checked by 2 reviewers. We have added instructions for mixed methods reviews. Example evidence statements have been removed (apart from prognostic examples).

Chapter 7: Incorporating economic evaluation

We have removed the end-of-life modifier section as this was a technology appraisal policy applied to NICE guidelines, which the Centre for Health Technology Evaluations (CHTE) have now

withdrawn. NICE guidelines will also discontinue its application.

Chapter 8: Linking to other guidance

We have added information on updating NICE technology appraisals in guidelines.

Chapter 9: Writing the guideline

We have added clarification for 'offer', 'consider' and 'do not offer' recommendations. We have given more details on medicines, including dosing information and therapeutic monitoring. We have added options for not making a recommendation when there is insufficient evidence.

Chapter 10: The validation process for draft guidelines, and dealing with stakeholder comments

We have added an option for a 2-week consultation for a small update of 1 or 2 review questions, and added information to differentiate between additional consultation and commissioned primary research.

Chapter 11: Resources to support putting the guideline into practice

We have added information about press launches of guidelines.

Chapter 13: Ensuring that published guidelines are current and accurate

We have emphasised proactive surveillance, and removed 5-year routine surveillance.

Appendix B: Approaches to additional consultation and commissioned primary research

We have added information and guidance on additional consultation and commissioned primary research, and given more information on the differences between these 2 processes.

Appendix G: Sources for evidence reviews

We have added sources of primary or real-world data.

Appendix H: Appraisal checklists, evidence tables, GRADE and economic profiles

We have added a checklist for mixed methods reviews.

Appendix J: Call for evidence and expert witnesses

We have added more guidance on conducting a call for evidence and involving expert witnesses.

Appendix L: Interim process and methods for guidelines developed in response to health and social care emergencies

We have provided a new process and methods for guidelines developed in response to health and social care emergencies.

January 2021: We amended the text on assessing new medicines and significant new indications to clarify that this will be carried out in line with the 2019 voluntary scheme for branded medicines pricing and access published on the GOV.UK website.

October 2020: We amended the text on topic-specific committees to indicate that they may work on multiple guidelines within a topic area, with membership subject to renewal for a total period of up to 10 years.

July 2020: We added interim process and methods for guidelines developed in response to health and social care emergencies (appendix L).

October 2018: Major changes from the 2014 guidelines manual are shown below.

Service delivery

Methods for developing recommendations on service delivery have been incorporated into the manual, with information added to the chapters on scoping, searching, evidence submission and economics. We have added a new appendix (appendix A) with detailed advice on developing review questions in this area.

Primary data analytics

NICE is currently exploring the place of primary data analytics in our work and further advice will be shared as this develops.

Chapter 2 – the scope

We encourage developers to list areas where evidence is lacking and details of stakeholders who

might provide information in a call for evidence or who might identify expert witnesses.

We are clear that guidelines don't usually include key issues covered by bodies such as the Department of Health and Social Care, NHS England or Public Health England.

We remind developers that guidelines don't usually cover training requirements. However, recommendations may cover the need for specific knowledge and skills for a particular aspect of care.

Chapter 3 – decision-making committees

We encourage developers to think about other related NICE guidance in development and promote cross-representation across committees when topics are closely related.

We include advice for developers about seeking expert testimony from children and vulnerable groups, including use of video recording and giving testimony in private session.

We have made changes to ensure consistency with the updated code of practice for declaring and dealing with conflicts of interest. We have also clarified the involvement of tobacco companies as respondents rather than stakeholders.

Chapter 4 – developing review questions and planning the evidence review

We indicate that core outcome sets (one source is the COMET database) should be used if suitable based on quality and validity. We give standards for assessing the suitability of core outcome sets.

We include review questions that assess diagnostic prediction models and prognostic prediction models and link to external sources of further advice.

We have included a standard template for review protocols as an appendix (appendix I). Registration of the review protocol on the PROSPERO database is now mandatory.

Chapter 5 – identifying the evidence

We have included new sources, tools and approaches to searching, as well as a new prompt for identifying MHRA safety information.

Chapter 6 – reviewing the evidence

We now recommend GRADE as the first approach to quality assessment for all guidelines, including those covering public health and social care topics. We recommend GRADE-CERQual for qualitative evidence.

Results of the analysis and confidence in the evidence should now be presented as GRADE profiles. Evidence statements should be presented when the GRADE approach is not used.

We now have preferred 'checklists' for assessing the quality of the evidence (see appendix H). Use of any other checklist should be agreed in advance with NICE staff with a quality assurance role.

We now indicate that an agreed proportion of papers should be sifted by 2 analysts (not less than 10%) because duplicate sifting of all papers is time consuming and there are other ways of ensuring that relevant papers aren't missed. We have included details of using a machine learning algorithm for priority screening.

We include advice on the minimum outputs and reporting standards for network meta-analyses (see appendix K) and how these apply to developing NICE guidelines.

Chapter 7 – economic evaluation

For base-case analysis, we recommend a cost–utility analysis using a cost per QALY. This will allow more consistent decisions related to costs.

We have clarified that the same levels of evidence and considerations should be used for disinvestment and investment decisions.

We have added information on end of life criteria in line with technology appraisal methods.

Chapter 8 – linking to other guidance

We advise linking to technology appraisal recommendation in the NICE Pathway rather than incorporating TA recommendations verbatim in a guideline.

We have removed the details on updating technology appraisals within a guideline and have added a link to the policy from the Department of Health and Social Care.

We include advice for developers on what to do when similar review questions are covered in other guidelines. Options include linking to the recommendations in the other guideline, using the

evidence review to make new recommendations or doing a new systematic review.

Chapter 9 – writing the guideline

We have simplified advice on writing guidelines, and a separate writing guide with more details and examples will be coming soon.

The section on supporting shared decision-making has been clarified, and includes information on when a separate decision aid could be produced. The writing guide includes more detail on summarising evidence in the guideline to support a professional's discussion with the person making the decision.

We have added new advice on what to do when recommendations are made for the use of CE-marked devices outside their instructions for use. This includes standard footnote wording.

We have clarified advice on recommendations on the off-label use of medicines.

Chapter 10 – validation

We have defined the types of 'additional consultation' that can inform development. There is more information about the changes in appendix B.

Chapter 12 – implementation

Information on how we work and the tools we produce has been updated. A new section on how we work with other organisations, including endorsing resources, has also been added.

We highlight the role of the new Guideline Recommendations Implementation Panel.

Chapter 13 – surveillance

We have focused the process on event-driven checks of guidelines as well as a standard check every 5 years.

We plan themed surveillance of guidelines covering similar populations or settings to ensure that the process is efficient.

We have revised the process for considering whether to remove a guideline from the static list.

We have indicated that we may refresh some recommendations following an event-driven or standard check.

We have added information about the quality assurance of the surveillance process.

Chapter 14 – updating guidelines

We have added a new section on refreshing recommendations, to make minor changes to improve the usability of recommendations without the need for an evidence review or committee input.

Minor changes since publication

November 2020: We aligned the publication of declarations of interest for members of independent advisory panels (appendix L) with process and methods for standard guideline development (section 3.6).

January 2020: A statement was added to the introduction and overview section to reflect the publication of our list of NICE principles. They succeed our social value judgements document which was first published in 2005.

ISBN: 1-4731-0809-7

A digital version of this toolkit can be found at https://g-i-n.net/toolkit/

GIN Guidelines International Network

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GIN PUBLIC toolkit introduction

How to choose an effective involvement strategy

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One question we often get asked at GIN PUBLIC is 'how can we incorporate the patient's perspective and what is the best method to involve patients and the public in our guidelines?' to which we invariably respond, 'what do you really hope to achieve?' There are in fact many legitimate reasons why guideline developers want to involve patients and the public, and these reasons can be different from those that would motivate patients and the public to engage in this process. The *best* method is the one that can be used most effectively to achieve those goals, so there is definitely not a one-size-fits-all approach. Furthermore, each method requires time and resources to be implemented successfully, and it is therefore critical to have a clear focus right from the start. Last but not least, although patient and public involvement is widely perceived as a positive component of guideline development, different stakeholders often hold competing and potentially incompatible views over what they consider successful involvement, which may create tensions if these differences are not negotiated early on.[1]

The goal of this chapter is to get you started in developing your involvement plan by:

- Introducing the main involvement strategies discussed in the toolkit
- Helping you identify the strategy that best fits your needs

Three involvement strategies: consultation, participation and communication

Guideline organisations use a number of different methods to involve patients and the public.[2,3] It is helpful to distinguish three general involvement strategies, based on the flow of information between your organisation and the public:[4]

- **Consultation** strategies involve the collection of information *from* patients and the public. This can include methods such as surveys, focus groups, individual interviews, online consultation, the use of primary research on patients' needs and expectations, or the use of a systematic review of studies on patients' and the public's perspective.
- **Participation** involves the *exchange* of information between guideline developers and the public. This can be done through participation of patient and public representatives on guideline development groups and other methods.[5]
- **Communication** strategies involve the communication of information *to* patients and the public to support their individual health care decisions and choices. This can include the production of plain language versions of guidelines or the development of patient decision aids or education material.

Choosing the right strategy

Each involvement strategy has its specific strengths and weaknesses and may be more appropriate to achieve certain goals:

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- **Consultation** strategies are especially useful to gather the views of a large number of individuals regarding their needs, experience, and expectations. Consultation methods are often used in research and add to the evidence base being considered to inform the process of guideline development. Consultation can help assess the public acceptability of draft guideline recommendations and identify topics that appear most important for the public, and are therefore useful in early stages of the guideline development process. A drawback of using consultation strategies only is that it tends to seek out individual viewpoints, presenting an average of 'the need' of patients.

- **Participation** methods are useful to foster deliberation and mutual learning between participants with different expertise.[6] Participation as a member of the guideline development group has the advantage of enabling patients or public members to be present and actively participate in deliberation, which can foster mutual influence between patients and professionals, fostering the development of a collective perspective on guideline development. As such, participation methods are usually put in place to agree on *common group decisions* over guideline content and can be useful to support compromise or consensus between people with different perspectives. When used alone, a drawback of the participation method is that it often allows the involvement of a small number of people and may miss the perspective of vulnerable groups who may feel threatened to participate in meetings with health professionals. As discussed in the 'recruitment and support' chapter of the toolkit a critical issue for successful participation is to support participants' legitimacy as patient and public members, and their ability to contribute credible knowledge and experience relevant to guideline development.

- **Communication** strategies are most useful in the dissemination and implementation stage of guideline production. For strong 'black and white' guideline recommendations—where a single best course of action is clear—communication methods can increase the public's knowledge and awareness of recommended interventions in order to influence patients' health behaviours and increase uptake. In cases of 'grey zone' decisions—when more than one alternative is acceptable—patient decision aids can help expand the range of options available to patients and assist them in weighing the pros and cons of different choices.[7, 8]

Finally, it is common to combine different involvement strategies to build more comprehensive patient and public involvement interventions. For example, combining direct patient participation can be complemented with wider patient consultation through focus groups or surveys, which can allow patients to broaden their perspective and experience base, and increase their credibility and legitimacy as guideline development group members.[9] Furthermore, combining communication methods (e.g. development of patient information material) with participation methods (e.g. participation of patient representatives in the development of this information material) can help ensure the relevance and accuracy of the information produced.[10] Box 1 provides an example of a structured patient involvement intervention combining consultation, participation and communication strategies used for health care improvement.

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Box 1: Example of a mixed patient involvement intervention in guideline implementation

The effect of a mixed patient involvement intervention combining consultation, participation, and communication components has been tested in a cluster randomised trial and was found to be effective in increasing agreement between patients' and professionals' priorities for clinical care improvement, based on a list of measurable quality indicators derived from clinical practice guidelines.

Recruitment: Chronic disease patients were recruited through local patient organisations and professionals, using structured 'job descriptions'. A list of potential candidates was reviewed by the team, and a group of 15 patients were selected based on pre-defined criteria to ensure a balanced representation in terms of age, gender, disease status, and socioeconomic status.

Preparation: These patients were invited to a one-day preparation meeting to discuss their personal experiences in relation with chronic disease services, which helped broaden their perspective and understanding of patients from their community.

Consultation: At the end of this preparation meeting, all patients voted on their priorities for clinical care improvement for their community.

Participation: Four patients who participated in the preparation meeting agreed to participate in a 2-day deliberation meeting together with health professionals from their community. This meeting allowed patients and professionals to deliberate among themselves and agree on common priorities for improvement. All participants also received feedback about the consultation done with the broader group of 15 patients.

Communication: The quality indicators selected as priorities for health care improvement were implemented locally and its results were communicated to all patients who participated in the prioritisation, as well as to lay board members of the local health authority.

Although this patient involvement strategy was used locally for guideline implementation, its format could easily be applied to guideline development at a larger scale. Details of the intervention have been published elsewhere.[11]

In summary

Guideline organisations have experimented with a vast number of different methods to involve patients and the public. As summarised in Table 1, these involvement methods can usefully be grouped in three basic strategies: *consultation* from the public to inform the guideline development process, *participation* of patients and the public in deliberation with other guidelines developers, and *communication* of guideline content and other health information to patients and the public. Each strategy has its strengths and limitations and their use must be tailored to specific contexts and goals. Effective involvement starts with finding the *right method*, but is also about *doing it right*. The following chapters of the toolkit therefore provide best practice advice on how to implement these methods successfully within your organisation.

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Table 1: Methods available to involve patients and the public in guidelines

Involvement strategy	**Goals and strengths**	**Example of methods used by guideline organisations**	**Toolkit chapters**
Consultation (information is collected *from* patients and the public)	• Collect information from a large group of people • Possible to collect data from a variety of perspectives and from groups that are harder to involve in participation methods	• Open (online) consultation on guideline scope and topic • Comments on draft guideline • Focus groups, individual interviews, or surveys of patients' experience of care • Literature review of existing qualitative and quantitative research on patients' needs and expectations	Consultation Research
Participation (information is exchanged *between* the public and other guideline developers)	• Foster *mutual learning* and agreement between the public and other experts • Facilitate compromise and consensus on collective decisions about guideline recommendations, content, and process	• Patient or public participation in guideline development group to foster deliberation with other guideline developers	Recruitment and support Role of the chair Systematic reviews
Communication (information is communicated *to* patients and the public)	• Inform patients and the public about professional standards • Support individual health care decisions and choices among different health options	• Publish patient version of guideline and patient education material • Production of patient decision aids	Patient information Shared decision-making Using guidelines (dissemination and implementation)

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How to conduct public and targeted consultation

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Key messages of this chapter

- Consultation processes should involve patients and the public, as well as stakeholders who are health and social care professionals.
- Effective consultation with patients and the public adds value to the process of guideline development and can help support guideline use in practice, leading to more effective care.
- Consultation strategies are particularly useful to gather the views of a lot of individuals regarding their needs, values, preferences and experiences
- Best practice requires transparent and inclusive consultation.
- Consultation can be conducted at all key stages of the guideline development process, including the scoping, development, draft review, implementation, and updating stages.
- A diversity of methods, individuals and organisations are likely to be needed to capture the full range of relevant patient and public issues and perspectives.
- Consultation requires additional time and resources, which need to be factored in from the start. In standard consultation processes (such as feedback on topic prioritisation and draft guidelines), patient and public consultation can occur simultaneously with professional consultation.

Top tips

- When planning the guideline process, identify the stages and situations that require patient consultation methods.
- Identify and involve patients and the public at multiple consultation stages if resources allow, including the early stage when determining topic scope and key questions.

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- Have a clear aim for consultation and ensure that the method(s) chosen are appropriate for the purpose. When possible, choose a method of consultation that allows input from a range of patient subgroups, including ‘seldom heard’ or unrepresented groups.
- Consider involving patient or public advocates in co-designing a consultation model or novel methods of engagement.
- Show sensitivity and make adjustments for ways that patients and carers may be affected by the specific condition being addressed, for example, different visual, cognitive, or mobility abilities.
- Allocate time and resources for consultation in the guideline development process, while maintaining control of the timetable to ensure the guideline is produced in a timely fashion.
- Consider the optimum time period for consultations, balancing the need to produce an up-to-date guideline while taking into account stakeholders’ expectations (for example, some patient organisations consult their constituencies before responding).
- Set up efficient administrative systems for alerting people to consultations and managing responses in a timely manner, and provide advance notice of consultation dates.
- Create plain language consultation materials to ensure meaningful engagement.
- When consulting on draft documents, provide guidance on what respondents could consider commenting on, for example, a list of questions which incorporate patient or public perspectives and equality considerations. The questions could be translated into a survey for ease of response and analysis.
- Ensure that the final decisions in responding to consultation findings or feedback are in accordance with the guideline development group’s ongoing decision-making processes.
- Document the results of any research with patients and the public, including how the guideline group used the results. Give feedback to participants on how their views, ratings or responses have been taken into account.
- Make comments and responses, and findings from other types of consultation activity, publicly available, or at least offer a summary available on request.

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- Document the methods and process used for consultation activities and make this publicly available.
- Consider evaluating whether and how the consultation activity adds value to the guideline, including the particular contribution of patient or public participants or respondents.

Aims of this chapter

This chapter describes ways to conduct public and targeted consultation during the development of guidelines. It aims to raise awareness of key issues to take into account when developing a consultation strategy and related processes, including best practice principles and different methods to consider.

The chapter draws on examples from guideline bodies in several countries, which serve as models. These models are provided for illustrative purposes only and are not meant to be prescriptive because local circumstances, and the level of support and resources available will influence the type of approach adopted.

Terminology

Consultation and participation

Based on the typology of involvement described in Boivin et al. (2010), we use the term ‘consultation’ to refer to the process of collecting information from patient and public stakeholders to inform guideline development and implementation. Whereas ‘participation’ refers to patient and public stakeholders exchanging information with other stakeholders, for example, as members of a guideline development group. However, this distinction is not absolute; we include a few examples of patient engagement that combine or straddle consultation and participation.

Patients and the public

Patients and the public can refer to people with personal experience of a disease, condition or service (patients, consumers, users), their carers or family members, and people representing a collective group of patients or carers (representatives or advocates). It may also refer to members of society interested in health and social

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care services, or whose life is affected directly or indirectly by a guideline (citizens, taxpayers, the public).

Reasons for consultation

Consultation strategies are particularly useful to gather the views of a lot of individuals regarding their needs, values, preferences and experiences. Consultation can also be targeted to seldom heard or unrepresented groups who may be less likely to join a guideline group with health and social care professionals. Consultation can identify topics that appear most important for patients and the public and is therefore useful in determining the need for new or updated guidelines. It can also inform the scope of a guideline, its research questions and health or care outcomes of importance to patients. Consultation using research techniques can add to the evidence base being considered to inform the process of guideline development. It can also help assess the public acceptability of draft guideline recommendations. However, a drawback of using consultation strategies only is that they do not recognise the unique expertise of patients and the public and their value as development partners.

Several major bodies recommend using public and targeted consultation to inform the development of guidelines. The National Health and Medical Research Council in Australia (2016) and the US's Institute of Medicine (2011; now the National Academy of Medicine) include public consultation in their standards for developing guidelines. The consumer and stakeholder topic in the GIN-McMaster Checklist for Guideline Development (2014) recommends consulting consumers and stakeholders who are not directly participating on the guideline panel at specific milestones during the guideline development process. This could start at the stage of priority setting and topics for the guideline.

Some guideline developers include consultation as part of a wider strategy or programme of patient and public involvement in guideline development. Documented examples of this approach include:

- the UK's National Institute for Health and Care Excellence (NICE) guidelines manual (PMG20; 2014), and the NICE flowchart and accessible text-only version on how to get involved (2018)

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- the Scottish Intercollegiate Guidelines Network (SIGN) handbook for patient and carer representatives (2019) and the SIGN guideline developer's handbook (2019)
- the Nationalen Programms für VersorgungsLeitlinien (German National Disease Management Guidelines Programme) patient involvement handbook (2008) and methods report (2017), and
- the GuíaSalud (Spanish national guideline development programme) methods manual (2016).

Consultation and participation strategies have complementary roles in guidelines work. Using multiple strategies allows guideline developers to benefit from their different strengths and mitigate the limitations of a single strategy. Consultation can help mitigate the limitation associated with participation strategies when a small group of participants may not represent the broader population. For example, Armstrong et al. (2020) conducted a case study of question development for a single clinical guideline. They found that responses from a consultation survey were particularly helpful for reinforcing that a large group of patient stakeholders agreed with the 4 members of the question development group, who were patients, carers or advocates. This consultation benefit was seen to be particularly important given that these 4 members' views were contrary to professional opinions provided in the public commenting phase.

Table 1 outlines various stages of guidelines work when consultation with a broader group of patients or the public beyond the guideline development group may be helpful. Depending on available resources, guideline developers may need to prioritise key stages (such as early input and draft recommendations) to make consultation meaningful and achievable. Developers may also find it useful to consult Armstrong et al.'s 10 steps framework for continuous patient engagement in guideline development, which covers both consultation and participation approaches (2017).

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Table 1 Options for patient or public consultation at different stages of guidelines work

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Stage	Purpose of patient or public consultation	Examples of consultation methods
Nominating and prioritising the topic	Identify topics of importance to patients, carers and the community	• Solicit topic nominations from patient advocacy groups and the public • Survey patient groups
Scoping the topic and key research questions (this could extend to consultation on framing research questions, including selection of comparators and prioritisation of outcomes, and the research plan or protocol)	Help identify issues that are important to a broad range of patients and ensure these are taken into account from the beginning of the guideline project. This includes patients' experiences of care (including gaps in delivery), considerations for specific subpopulations, patient preferences and patient-important outcomes	• Solicit feedback on draft scope and questions through public comment or targeted consultation with patient advocacy groups and other stakeholders (workshop and online) • Survey patient groups, for example, using criteria-based rating processes • Conduct focus groups on identified topics to help frame the questions
Identifying evidence on patients' views and experiences	Identify sources of information on patients' views and experiences with a view to supplementing important gaps in the published evidence	• Ask stakeholders to suggest sources of information about patients' views and experiences that are not formally published, such as surveys by patient groups
Developing systematic review and forming conclusions	Suggest alternative interpretations of evidence from a patient, carer or community perspective	• Post draft evidence review for public comment and targeted consultation with stakeholders. To support meaningful public responses, provide draft review in plain language, with questions to guide responses
Developing recommendations	Help translate evidence-based conclusions into meaningful, clear and respectful recommendations that foster patient or family and professional partnerships Provide input on evidence gaps Describe variability in patient preferences	• Conduct focus groups and interviews • Survey patient groups • Post draft recommendations in plain language for public or targeted comment from patient groups and other stakeholders
Developing guideline-based performance measures or quality indicators	Rate recommendations from a patient perspective to ensure the professional expert view doesn't dominate the rating	Survey patient groups using systematic, criteria-based rating

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Stage	Purpose of patient or public consultation	Examples of consultation methods
Developing guideline-based patient information or patient versions and patient decision aids	Provide input from a broader range of patients beyond those involved in developing the product	• Invite feedback on the draft product from patients, carers and advocacy groups • Use research techniques to 'user test' the draft product
Disseminating and implementing the guideline	Gain support and endorsement for the guideline Facilitate engagement of other patients in dissemination Improve legitimacy and trustworthiness of the guideline process such that recommendations are more likely to be implemented	• Consult patients, carers and advocacy groups on dissemination and implementation barriers and facilitators (Also engage them in dissemination strategies using a more collaborative approach)
Reviewing the need to update a guideline	Identify when changes in public or stakeholder views might require an update to the guideline (in addition to identifying changes in the formal evidence base)	• Solicit patients' views on when or whether guidelines need updating. Or use a systematic, criteria-based rating or survey
Evaluating methods and impact of patient public involvement	Identify if engagement was meaningful and suggest options for improvement	• Conduct a survey with engaged patients and patient groups. (Evaluation could also take a more collaborative approach, for example, working with patient groups to design a survey and discuss results)

In summary, there are many good reasons for public and targeted consultation during the development of guidelines. These include:

- Helping to ensure that issues important to patients and the public are appropriately taken into account from the beginning of the guideline project and reflected in the final product. This complements the contribution of patient and public members on a guideline development group.

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- Supplementing evidence when there are gaps or obtaining a wider source of patient or public experiences and views than can be provided by patient and public members on a guideline development group.
- Improving the wording and presentation of the guideline and related products (for example, ensuring that the wording is respectful, and the recommendations foster partnership and shared decision making between patient and professional).
- Helping to ensure the guideline is relevant and acceptable to patients and the public, and to specific groups within the patient population, including those who are unrepresented or seldom heard.
- Paving the way for patient or public support for the final guideline and receptivity to its uptake and dissemination.
- In general, enhancing the legitimacy of the development process and the end product from a public perspective.

Ways of conducting consultation

Open or targeted consultation

Consultations may be open to the public, targeted to relevant patient or public groups and other stakeholders, or both. Open and targeted consultation methods each have potential advantages and disadvantages, as outlined in table 2. Awareness of these can help developers to select the most suitable method for a specific guideline.

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Table 2 Open or targeted consultation – selecting a suitable approach

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Type of consultation	Description	Potential advantages	Potential disadvantages
Open	Public posting of draft documents and questions, which would need to be well publicised. Guideline developers could have an interactive online feature to notify interested parties of the topics, anticipated comment periods, and actual postings	This option has the merit of transparency and, in theory, opens up the process to all interested parties and viewpoints	Guideline developers may be overwhelmed with the volume of feedback Guideline developers may receive inadequate feedback if publicity is limited and no one feels responsible
Targeted	By invitation to all relevant stakeholder organisations, or to groups and individuals with relevant interest	Targeting invitations may be more effective in generating responses When patient or public stakeholders are not known to guideline developers (or key organisations have not registered their interest), a focus on targeted consultation can help developers plan ahead to find individuals or groups and invite them to contribute to the guideline development process Invited organisations can be more willing to partner in other stages of the guideline, such as dissemination (sometimes organisations who have not had any involvement are reluctant to help with dissemination strategies) The volume of feedback should be manageable	Important viewpoints may be overlooked or avoided if targeted consultation is not combined with an open invitation to contribute Invited individuals or organisations may not be interested or able to respond in a timely manner
Open and targeted	Public posting of draft documents and questions combined with targeted invitations to all relevant stakeholder organisations or groups and individuals with relevant interest	Combines openness and transparency with reaching all relevant stakeholder organisations or targeted groups or individuals	Guideline developers may be overwhelmed with the volume of feedback

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Different approaches to consultation

Consultations may be conducted remotely (online for example), in face-to-face meetings or workshops, or a combination of these. Consultation may take the form of peer review with patient and public expert reviewers. It can also include research with patients and carers (using methods such as surveys, focus groups and interviews). Research participants are typically not expected to represent the views of other people, but to characterise their own views and experiences. Whichever approach is taken, consultation adds significantly to the time and resource requirements of guideline development and should be factored in at the outset. In most consultation processes, such as feedback on draft scoping documents and draft guidelines, patient or public consultation can occur simultaneously with professional consultation. As Cluzeau et al. (2012) concluded, for stakeholder engagement to be successful, it needs to be inclusive, equitable and adequately resourced. The box contains a summary of the main consultation approaches.

Main consultation approaches:

- inviting public comment including patient organisations and other stakeholders
- consulting patient and public experts as part of a peer review process
- using online engagement methods, such as modified-Delphi approaches, with patients, carers and others
- using research techniques with patients, carers and others, such as surveys, focus groups, interviews.

These different approaches can be combined, for example, inviting public comment or feedback from patient organisations and others through a survey.

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Public comment

Background

In public comment, guideline developers post guideline materials in a public forum for feedback. This typically involves posting materials online but can include an open forum for discussion. Materials shared for public comment include guideline scopes and research protocols (to obtain feedback before starting the systematic review) or draft guideline documents (to obtain feedback before final publication). Public comment can include feedback from individual professional and patient experts, but is generally considered distinct from external peer review, which is solicited.

In the US, the Institute of Medicine (now, the National Academy of Medicine) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines (CPGs) includes public comment in its external review standard 7.4:

'A draft of the CPG at the external review stage or immediately following it (i.e., prior to the final draft) should be made available to the general public for comment. Reasonable notice of impending publication should be provided to interested public stakeholders'. (Chapter 5; 2011).

Despite the fact that public comment is recommended by the Institute of Medicine, a review of guideline developer methodology manuals by Armstrong et al. (2017) found that only 6 of 101 US-based guideline developers posted protocols for guideline development at least some of the time. Only 1 organisation, the United States Preventive Services Task Force, posted a draft research plan using a public-friendly template (for example, using plain language, avoiding excessive background or technical information). Only a quarter of US guideline developers posted draft guidelines for public comment. One developer used a public hearing for public comment, while the remainder used online mechanisms. Most developers using online feedback posted materials for comment for 1 month (range 14 days to 60 days). There was no evidence that any guideline developer posted a patient-friendly version of the draft guideline for comment.

By way of comparison, Ollenschläger et al.'s (2018) assessment of all guidelines in the German national guideline registry in 2018/19 found that 58% had involved

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patients on the guideline group. However, only 14% (39/270) had provided plain language versions of the draft guideline for consultation.

Practical approaches for using public comment

As with other consultation approaches, guideline developers need to be intentional about using public comment approaches. Desired feedback will vary at different stages, such as between draft scope, protocols and draft guidelines, and may differ between developer types. For example, guideline developers representing national health systems or governing bodies may desire different feedback than professional organisations. Guideline developers must also consider available resources when considering public comment. Potential costs associated with public comment include developing public-friendly materials for posting, hosting a public forum or website, publicising the comment period, and allowing time to respond to public comments (including decision making, documenting comments and responses).

After choosing to use public comment as a consultation strategy, developers decide the stage(s) at which to use public comment (for example, scoping the topic, research protocol, draft guideline). To make optimal use of public comment, developers need to create materials that are likely to result in meaningful engagement and avoid tokenistic public comment. Many guidelines are aimed at professional audiences and can be hundreds of pages long. Difficulty in understanding medical terminology is one of the most common barriers to patient and public involvement in guidelines. (Jarrett et al. 2004; Légaré et al. 2011; Qaseem et al. 2012; van de Bovenkamp et al. 2009; van Wersch et al. 2001.) Thus, developers desiring meaningful feedback need to prepare patient- and public-friendly guideline documents for draft review. For developers working with patients to create patient guideline versions, this could also include preparing and posting a draft for public comment (see the chapter on how to develop information from guidelines for patients and the public for further information).

In conjunction with creating the materials for posting, developers must determine the feedback desired from respondents. For example, the U.S. Preventive Services Task Force (2017) posts 3 types of documents for public comment, as shown in table 3.

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Table 3 Public comment feedback requested by U.S. Preventive Services Task Force

Type of document	Response requested
Draft research plans	Respondents to indicate level of agreement and provide free-form comments on the: • analytic framework • proposed questions • proposed research approach (presented in tabular form)
Draft evidence review	Asks if the respondent: • thinks the report includes all of the relevant studies • agrees with the interpretation of the evidence • has suggestions for making the findings clearer
Recommendation statements	Asks the respondent: • how to make the statements clearer • if expected information is missing • whether the conclusions reflect the evidence • what associated tools would be useful • other experiences and comments

Many online public comment approaches are similar to those of the U.S. Preventive Services Task Force in that they use a web-based survey to ask the respondent to indicate his or her level of agreement (with questions, evidence synthesis, recommendations) and then allow open comments.

For meaningful feedback, developers must create a plan for notifying key public members regarding upcoming public comment periods. Potential strategies include notifying relevant professional and patient organisations regarding the public comment period and asking them to invite their members to participate. Government organisations desiring feedback may also provide advance notice to broader populations. For example, the external review standard 7.4 of the US Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice Guidelines recommends that developers provide reasonable notice of impending publication prior to posting (Chapter 5 2011). There are no best practices for posting length, but 1 month is a typical time frame (Armstrong et al. 2017). As with other consultation strategies, guideline developers should be prepared to respond to

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feedback provided through public comment (see responding to consultation comments).

Consulting patient and public stakeholder organisations

The UK's NICE uses an open consultation process, with draft consultation documents posted on its website at key stages in the guideline development process. This is similar to the public comment approach; however, to manage the volume of comments in a transparent way, NICE encourages individuals to respond through a relevant stakeholder organisation. These organisations receive a response to each of their comments, and both the comments and the developers' responses are published on the NICE website. Responses from individuals are acknowledged and considered, but do not receive a response unless they are designated peer reviewers.

In the NICE model, all registered stakeholder organisations are invited to contribute at key stages of the guideline development process. This includes:

- Setting the scope of the guideline and the key questions.
- Circulating NICE website advertisements to their members and networks for recruitment to the guideline development group (health and social care professional and patient or public members).
- Responding to calls for evidence if the guideline developers believe that their literature search has not found all the relevant information. Such evidence could include patient surveys and other real-world evidence on the impact of the condition on people's lives, the views of patients and carers about their treatment or care, or the difference a particular type of care or treatment might make.
- Commenting on the draft guideline.

To support stakeholder engagement, NICE maintains an extensive database of contacts for organisations representing patient and public interests and invites them to register their interest for new guideline topics. Staff in NICE's Public Involvement Programme help identify relevant organisations and offer information and advice to support their involvement.

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Identifying and reaching patient and public groups

Not all guideline developers have the structure and resources needed for the NICE model. The following suggestions may be helpful in identifying relevant patient and public groups (organisations and individuals) and inviting them to take part in consultations.

Networks of patient advocacy groups and charities may provide a useful avenue for reaching relevant patient or public stakeholders. For example, SIGN's Patient and Public Involvement Network members are notified of involvement opportunities when a new guideline is being developed.

Other sources for identifying relevant patient or public stakeholders include health professionals and their organisations, patient organisations that are already known to guideline developers, the internet and social media. In addition, if the guideline development group has been convened, it may be fruitful to work with patient and public members to identify key organisations and individuals with the desired perspectives and experiences.

Consider contacting national and international patient or public groups, because they can be a useful source of contacts and advice, as well as an avenue for collaboration. Examples include:

- National groups, such as Consumers United for Evidence-based Practice (CUE) in the US and Foro Español de Pacientes in Spain
- International groups, such as G-I-N Public (Guideline International Network's Public Working Group), CCNet (the Cochrane Consumer Network), and the Health Technology Assessment international's (HTAi) subgroup on Patient and Citizen Involvement in Health Technology Assessment.

Social media can be an excellent way to promote a consultation, by posting details about it and tagging in patient and public advocacy groups from the guideline's topic area. If the consultation is open to the public, this can also be an effective way of reaching a wider audience of people beyond the usual patients the guideline developers may work with. Increase the reach by using hashtags that are commonly used by patients or public in the topic field and post details of the consultation with

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relevant advocacy groups on social media or online patient forums. NICE has found social media helpful in building relationships with key patient and public stakeholders and supporting their involvement with NICE guidelines. NICE also uses social media to promote published guidelines, working with key stakeholders and communities to ensure the main messages reach the public.

Examples of consultation at key stages

Setting the scope of the guideline

It is important to include patient and public perspectives from the beginning of the guideline development process. With this end in mind, SIGN and NICE consult patient and public groups on the scope of a new guideline before the first meeting of the guideline development group. GuíaSalud in Spain also include consultation with patients at this preparatory stage of guideline development. For example, they used focus groups and interviews with patients to inform the scope and key questions for 2 guidelines on anxiety and insomnia (Díaz del Campo et al. 2011).

Four months before the first meeting of a new guideline development group, SIGN invites patient and carer organisations to highlight the issues they think the guideline should address. A form is supplied to enable them to structure their feedback in a useful way and to indicate the source of their suggestions (such as telephone helpline data, surveys). SIGN then summarises the information received and presents it to the guideline group at its first meeting. When published evidence is scarce and there is inadequate feedback from patient organisations, SIGN may seek patient and public views through direct contact with users of the service. This has been achieved using focus groups with patients in different regions of Scotland, attendance of SIGN staff at patient support group meetings, and SIGN-organised meetings for patients and members of the public. The information obtained from these approaches is reported to guideline groups to influence the development of key questions underpinning the guideline. (SIGN 100 2019; SIGN 50 2019.)

NICE involves patient organisations and other stakeholders in the scoping process in 2 ways: participation in a meeting and online consultation. All organisations that have registered an interest in a new guideline project are invited to attend the scoping meeting. This gives patient organisations and other stakeholders an opportunity to

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become familiar with the guideline development process and to take part in detailed discussions about the scope. It sets out what the guideline will and will not cover, defines the aspects of care that will be addressed, and outlines the key research questions. A draft scope is then produced, and stakeholders are invited to comment on it during a 4-week online consultation. This online process is designed to ensure openness and transparency, because all written comments receive a formal response from guideline developers, and both comments and responses are published on the NICE website. NICE encourages patient organisations to comment on the draft scope and provides prompting questions in its guide for stakeholders (NICE 2018). The purpose of the prompts is to seek their views on key issues (such as whether the identified outcome measures are in line with what matters to people with the condition or people using services), and to ask what should be included or excluded.

Some developers have used surveys to inform the research plan or protocol, as part of a strategy to incorporate evidence on patients' values and preferences in guideline development. For example, the German National Disease Management Guidelines Programme found a benefit in surveying patients with anal cancer to obtain their feedback on the relative importance of a range of health outcomes (Werner et al. 2020. In the survey, they asked patients (n=37) and members of the guideline group (n=25) to rate the relative importance of outcomes in different clinical situations using the GRADE scale. For example, they found that agreement between the expert and patient ratings was fair for stage I-II anal cancer, but low for stage III anal cancer. In another example, whereas patients rated some adverse effects (such as early morbidity, proctitis or urge, radiodermatitis) as critical, experts rated these as important but not critical. The survey results informed the development of the guideline and helped with the trade-off between desired and undesired effects of interventions when making recommendations.

The draft guideline

Consulting patients and the public on draft recommendations helps ensure the range of their values and preferences has been integrated into the recommendations. As noted by Kelson et al. (2012), such feedback can include desired outcomes, the ways in which people weigh up risks and benefits, preferred treatment and

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management options, and whether the draft recommendations have real-world applicability.

Patient or public stakeholders can make an important contribution at this stage. For example, Chambers and Cowl (2018) analysed documentary evidence of comments from consumer organisations on the draft recommendations from 7 NICE maternity guidelines. Their aim was to assess the levels of engagement, along with the impact of that engagement. For each of the 7 guidelines, comments from consumer organisations resulted in 5 or more changes to the wording or meaning of the recommendations. For a more detailed look at the impact of consumer organisation comments see the Slideshare presentation on NICE maternity services evaluation.

SIGN combines open consultation on the draft guideline with a later period of peer review. During the open consultation, SIGN may hold a national open meeting with professionals, patients and the public to discuss the draft recommendations. Draft guidelines are presented on the SIGN website and through social media. Anyone can respond to the online consultation and particular efforts are made to ensure all equality groups with a potential interest in the topic are made aware of the opportunity to comment.

NICE follows a similar online consultation process, inviting stakeholder organisations to comment on the draft guideline during a set period, using email, social media and other promotional channels to encourage responses. Consultation usually lasts for 6 weeks, during which stakeholders can review the draft recommendations and supporting information.

In NICE's experience, some patient or public stakeholders find it helpful to have questions or a checklist to guide their response. NICE encourages patient organisations and other stakeholders to consider issues such as:

- How well do the recommendations:
  - cover the issues in the guideline scope that patients, their families, and carers consider important?
  - reflect what the evidence says about treatment and care
  - take account of the choices and preferences of people affected by the guideline, and the information and support they need

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  - consider the needs of different groups (for example, children and young people, and people from black, Asian and minority ethnic groups)
  - use wording that is clear, easy to follow and respectful.
- Do the recommendations include anything that people affected by the guideline might find unacceptable?
- Is there any other evidence that should be included?
- Do the research recommendations cover key gaps in the evidence about important areas of patient and public experience? (NICE 2018)

Patient and public expert reviewers

When peer review by external individuals is a routine part of the process of guideline development, patients, members of the public or advocates should be included as expert reviewers. This inclusive approach to external review is recommended by major standard-setting agencies, such as the Institute of Medicine (2011; now the National Academy of Medicine). So, for example, all SIGN guidelines are reviewed in draft form by independent experts including at least 2 patient or public reviewers (SIGN 50 2019). At NICE, external review is mainly conducted through consultation with stakeholder organisations (2014). However, guideline developers may also consider arranging additional expert review of part or all of a guideline. Expert reviewers may include patients, members of the public and advocates, as well as health professionals. This review may take place during guideline development or at the final consultation stage. Expert reviewers are required to complete a declaration of interests form (NICE 2014; SIGN 50 2019).

Consulting patients and the public using online engagement methods

As discussed earlier in this chapter, public commenting is typically conducted online. Some guideline developers have used other online methods such as Delphi processes, voting tools, Wikis and discussion forums. Discussions could also be facilitated through social media channels, like Twitter, Facebook or an online patient forum. This kind of approach may be particularly useful for topics in which consultation with patient organisations might be limited and so a range of patient or public views is needed. It also allows the important flashpoints for patients, that

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appear in the guideline, to be framed in language that is easily understandable and relatable for members of the public.

Online methods can be particularly useful for engaging a lot of people who are geographically dispersed. This includes those who have difficulty attending face-to-face meetings because of illness or disability, and people who prefer a more anonymous method of contributing. Grant et al. (2018) examined the potential advantages and disadvantages of online engagement as part of a project to create a protocol that patients with Duchenne muscular dystrophy (DMD) and their carers could use to rate the perceived patient-centredness of guideline recommendations. From a rapid review of the literature on patient involvement in guideline development, the authors found that online methods can facilitate greater openness and honesty by patients, as well as having the potential to reflect the diversity of patient views. This can increase the utility of guideline products. The challenges of using online methods may include the extra time, skill and resources needed for patient engagement, and also the potential difficulty of involving specific patient populations. The authors concluded that online methods are most likely to be useful when guideline developers wish to engage a large, diverse and geographically dispersed group of patients, and have the required resources. The authors also suggest that online methods are particularly suitable when patients seek anonymity in order to share their views, and they are able to use online technology.

Khodyakov et al. (2020) suggest that an online modified-Delphi approach combining rounds of rating, anonymous feedback on group results, and a moderated online discussion forum is a promising way to involve large and diverse groups of patients and carers. They offer guidance on using such online approaches to facilitate engagement with patients, carers and other stakeholders in the guideline development process. The authors outline 11 practical considerations covering the preparation, implementation, evaluation and dissemination stages. Their first step is to co-develop an engagement approach with relevant patient representatives, such as a key patient advocacy organisation. The complete set of considerations proposed by Khodyakov et al. are reproduced below:

- co-develop an engagement approach with relevant patient representatives
- mirror methods used for expert and stakeholder engagement

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- pilot-test the engagement approach
- recruit patients with diverse perspectives
- assemble a panel of adequate size and composition
- build participant research and engagement capacity
- build 2-way interaction
- ensure continuous engagement and retention of patients
- conduct scientifically rigorous data analysis
- evaluate engagement activities
- disseminate results.

Consulting individual patients and the public using research techniques

Guideline developers may undertake consultation using research techniques with individual patients and others, either to inform the scoping, review questions or development stages, or to test the relevance and acceptability of draft recommendations. This work typically uses methods such as focus group discussions, interviews and surveys. Some guideline developers use surveys as part of, or alongside, a routine public comment consultation process. Other developers use research techniques with patients and carers to supplement gaps in one or more of the following areas:

- important gaps in the evidence base on patient views, values, preferences and experiences
- insufficient involvement or feedback from patient organisations (for example, for some guidelines or topics there may be no patient organisation with a focus on the topic)
- gaps in membership of the guideline development group in terms of patients' perspectives (for example, a broader range of experience is required or the guideline covers a population not directly represented on the group, such as children and young people)
- gaps in information on the perspectives of seldom heard patients who are not part of an organised group or who don't have an organisation to advocate for them, or

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potentially excluded groups, such as people from certain minority cultures or ethnic groups.

Before considering such work, it is important to check whether the information that the guideline developers are looking for might already be available. There may be relevant information on the views and experiences of patients and the public in the grey literature or from real-world evidence, including surveys conducted by advocacy organisations. For example, in the US the Listening to Mothers surveys are good examples of population-level resources about women's experiences of care, their knowledge and preferences, with coverage of topics from before pregnancy to well into the postpartum period. These Childbirth Connection surveys have been developed in concert with multi-stakeholder advisory groups, including consumer representatives.

Consulting patients and the public using research techniques is an exceptional option requiring additional human and financial resources. Guideline developers need to consider the recruitment strategy and choice of methods carefully, including the methods for analysing data to ensure the data generated produces robust evidence to feed into work on the guideline. Group-based methods and interviews are best for exploring how people feel and exploring topics in detail. Surveys or questionnaires are useful for quantifying the extent to which people hold beliefs, values and attitudes, and how much they vary between groups of people, for example.

Guideline developers need to ensure that those conducting this type of consultation have the relevant knowledge and skills, including expertise in research methodology and ideally expertise in conducting research with the relevant population. NICE commissions such work using a tender process. This involves interviewing prospective contractors to ensure they have appropriate expertise, policies and procedures for ensuring the safety and welfare of participants, as well as following best practice and the country's legal requirements for working with the affected population. Consent, incentives, and other ethical issues should be considered, including whether formal ethical approval is required from the relevant research governance body. Ethical approval can take time, in some cases many months, and this should be considered in the timelines. Researchers and guideline developers

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should also consider how participants will receive feedback about their impact during and on completion of the work, including how they will be acknowledged.

Techniques for eliciting people's views need to be tailored to the age, cognitive ability, and culture of participants. Materials and activities should be adjusted to suit participants and take into account any adaptations needed for people with physical or sensory impairments. In the UK, the National Children's Bureau has produced guidance on how to conduct research with children and young people, as well as advice on involving them more actively in the research process (Shaw et al. 2011). Also in the UK, the Alzheimer's Society's toolkit provides information on how to recruit adults with dementia and gain their consent for research.

Case studies of consultation

Netherlands

Pittens et al. (2013) reported on a consultation model for a guideline on the resumption of (work) activities after gynaecological surgery, for which there was no patient organisation. They consulted gynaecological patients and professionals separately, in 2 parallel trajectories. They found that to ensure the motivated involvement of an unorganised patient population, like gynaecological patients, a skilled facilitator was essential. The researchers convened 3 focus groups with patients at the beginning of the project to identify their problems, needs and preferences for peri-operative care and counselling in the resumption of (work) activities. They also sought participants' ideas for the development of a web-based patient version of the guideline. Participants received regular feedback during the project and were involved in the testing of the patient version. The researchers used an evaluation framework to assess the impact of this involvement and concluded that patients' input helped ensure the guideline was applicable in daily practice. The authors suggested that increased patient involvement could be achieved by integration of the 2 parallel trajectories with additional participatory activities, such as a dialogue meeting. They also suggested that more patient involvement in the development of the recommendations

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of the clinical guideline may result in increased relevance and quality of the recommendations.

NICE in the UK

Focus groups for the NICE guideline on end of life care for infants, children and young people with life-limiting conditions: planning and management (NG61; 2016): Because of limited evidence and in the absence of representative views from the guideline committee, young people with life-limiting and life-threatening conditions were asked for their views and opinions on selected review questions. This included their preferences for place of care, information and communication provision, personalised care planning, and psychological care (Report, appendix L, NG61).

Focus groups for the NICE guideline on self-harm in over 8s: short-term management and prevention of recurrence (CG16; 2004): The development of this guideline was informed by focus group discussions with people who experience mental distress and self-harm, in addition to a review of published and grey literature on their views and experiences. Both sources reported health services to be of variable quality. One finding from the group discussions was that people who self-harmed were not routinely offered anaesthesia for stitching their wounds in the emergency department. There was nothing in the literature to indicate this was an issue. As a result, the guideline included a recommendation that adequate anaesthesia and analgesia should be offered throughout the process of suturing or other painful treatments in people who have self-harmed. Other recommendations included staff training. See chapter 5 of the full guideline for further information.

Survey for the NICE guideline on sedation in under 19s (CG112; 2010): Guideline developers worked with a children's hospital to survey children and young people about their views and experiences of sedation for diagnostic and therapeutic procedures. Hospital staff obtained feedback

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through hand-held touch screen computers, which young children can use. The survey results were found to be very useful for the guideline development group's work. (See chapter 7 of the full guideline for further information.)

Spain

In-depth interviews and group discussions were conducted with patients for 2 GuíaSalud guidelines on anxiety and insomnia (Díaz del Campo et al. 2011). The findings, combined with information from a systematic review of the evidence, were used to inform the scope and key questions for each guideline. The information provided an important orientation on patient-focused outcomes.

Serrano-Aguilar et al. (2015) report on a consultation with Spanish patients for a guideline on systematic lupus erythematosus. The project's aim was to incorporate patients' perspectives in the design of this guideline. To this end, they conducted a systematic review of literature and consulted patients using a Delphi-based approach. Relevant topics from both sources were merged and discussed by the guideline development group (which included a patient representative) to set the key questions for the guideline to address. The authors recommended such a multi-component strategy to address the gap between the available evidence and current patient needs and preferences.

Responding to consultation comments

The guideline development group's chair or moderator has a key role in ensuring the group takes into account patient and carer perspectives from consultation feedback and other sources. The patient and public members can also help the group consider the inclusion of any material or amendment arising from patient or carer feedback that will strengthen and improve the guideline. Some recommendations will not be

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feasible for various reasons. Some patient and public members may be well placed to present the proposed modifications and rationale to the broader guideline development group. (This is a model that has been effective with systematic review development and has worked well in guideline groups with patient or public members, who choose to take on this role.) For all types of comments received, final uptake decisions should be in accord with the guideline development group's ongoing decision-making processes.

Key guideline bodies promote openness and transparency in the consultation process. The US's Institute of Medicine (2011; now the National Academy of Medicine) advises guideline developers to keep a written record of the rationale for modifying or not modifying a guideline, in response to reviewers' comments. Similarly, as part of Australia's National Health and Medical Research Council's (NHMRC 2016) approval process, guideline developers must provide details of consultation responses and explain why and how the guideline was altered. The NHMRC also advocates making a summary of submissions and developers' responses publicly available (2018). NICE enters all comments into a table, which includes a 'responses' column for acknowledging and answering each comment, including setting out what changes have been made to the guideline or explaining why no change has been made. The NICE guidelines manual sets out its process for dealing with stakeholder comments (2014). Other major guideline developers, such as GuíaSalud in Spain and the German Agency for Quality in Medicine (AEZQ), follow a similar open and transparent process for responding to feedback, including making the consultation comments and responses publicly available.

On publication of a guideline, thank all those who responded to the consultation. Consider using social media to publicly thank patient and public advocacy groups who took part in the consultation because this helps them to showcase their involvement in important guidelines work, as well as building relationships with key stakeholders. Doing this can also increase awareness of the guideline among patients and the public who follow the group on social media.

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Acknowledgements

The authors would like to thank the following for their contributions to this chapter:

Peer reviewers: Karen Graham, Kenneth McLean

Contributors to the 2012 version of this chapter: Jane Cowl, Helen Tyrrell, Carol Sakala, Javier Gracia, Nancy Huang

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Resources

Planning and managing consultations

The VOICE tool (Visioning outcomes in community engagement) provides planning and recording software that assists individuals, organisations and partnerships to design and deliver effective community engagement.

Online research-based patient and public views and experiences

DIPEx International is an association of expert researchers conducting qualitative research into people's personal experiences of health and illness. Member countries disseminate the results to the public and professionals in the form of multimedia resources on their websites. For example, healthtalk.org in the UK

Involving patients and public in research

Involve, part of the UK's National Institute for Health Research, provides advice and guidance on public involvement in research (research carried out with or by members of the public). Involve resources contains briefing notes for researchers on how to involve the public in research.

Research with specific patient populations

Children and young people – Guidance from the National Children's Bureau, a UK charity

People with Alzheimer's disease – Toolkit from the Alzheimer's Society, a UK charity.

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How to include research on patient and public views in guidelines

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Key messages

- Evidence about patient or public views can come from many sources, including research that is already published (such as from studies, reviews, and grey literature).
- Research can be used at all steps of the guideline development process - from scope and priority setting to dissemination and use.
- Both quantitative and qualitative research on patient or public views can provide relevant evidence.
- Several factors will influence how to plan for effective and efficient use of research evidence, such as: the sources, amount and relevance of the evidence; the resources available; and the potential impact of the evidence on the guideline and recommendations.
- Methods to identify, synthesise, assess, present and, most importantly, incorporate research on patient or public views are relatively new, but tools are currently available.

Top tips

- Consider using research, whether in traditional published sources or in reports, as part of a strategy to include patient or public views in a guideline.
- Balance the potential impact of and resources for using research about patient or public views in the various stages of the guideline process.
- Use current methods to find, synthesise, assess and present research about patient or public views. When not possible, be transparent about the methods

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used.

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- When using previously published research, additional time may be needed to assess the relevance of the research to the guideline and specific recommendations.
- For a more efficient process, search for and use previously synthesised research rather than conducting a new evidence synthesis.
- Remember to clearly document in the guideline and recommendations how evidence for patient views was used.

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Aims of this chapter

This chapter provides practical advice on how to incorporate research evidence on patient or public views in all stages of the guideline process. It is not a review of the literature about how patient or public views are not widely included in guidelines, nor a summary of where further exploration of methods are needed. This chapter is meant to assist guideline developers to find, summarise and use research about patient or public views that is already available in order to develop a guideline. The term ‘patient or public views’ (from this point referred to as ‘patient views’) covers several different terms currently in use, including values, preferences, experiences, perspectives, opinions and attitudes. There are many ways to gather information about patient views to inform the guideline development process and the evidence used to make decisions, including by engagement (see the chapters on how to conduct public and targeted consultation and how to recruit and support patients and the public, and overcome barriers to their involvement in guideline development). However, this chapter focuses on evidence from research that has already been conducted or published, whether in peer-reviewed journals or as research reports and other on-line documents. Methods for when and how to find evidence for patient views are relatively new, and we provide guidance based on what is currently known and being done, as well as references for more detailed guidance and other chapters in the toolkit.

This chapter answers the following questions:

- How can we plan for using research about patient views?
- At what stage of the guideline development process can research about patient views be used?
- What types of research can provide evidence about patient views?
- How can we search for research about patient views?
- How can the certainty of evidence on patient views be assessed?
- How can the research be summarised and presented for use?
- How can the research evidence be summarised in the guideline?

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- What to do when no methods are available?

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How can we plan for using research about patient views?

When making a plan on how to use research about patient views, you will need to balance resources, skills and time with the potential impact of that information on the guideline recommendations. Table 1 summarises the factors to balance when planning to use research about patient views.

Resources needed will depend on the evidence sources, and the amount and type of research available. Evidence about patient views can come from many sources (for example, journals, databases, websites, reports), consist of sparse individual studies or several reviews, span various study designs, and range in their relevance to the guideline topic. So, the plan could require a few to many resources to identify, synthesise, assess, present, and incorporate it into a guideline. The resources needed will also depend on whether the guideline group has capacity to use other methods to gather the evidence. If the existing evidence is limited in scope or relevance, guideline groups may decide to gather their own information about patient views through consultation with an advisory group, guideline panel members, or the general public. Or, they may gather information through primary research by conducting focus groups and interviews. Generally, consultation and primary research may provide evidence that is directly applicable to the guideline, whereas using research that has been previously conducted or published could not be as directly applicable.

In addition, the research could have limited or considerable impact on the guideline recommendations. If there is little debate about the value patients consistently place on the outcomes critical for decision making, meaning that it would be likely to have little impact on the final recommendation, a guideline group may determine that searching for this research evidence may not be an efficient use of resources.

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Table 1 Factors to balance when planning to use research about patient views

Resources	The time, budget, and expertise available to gather, synthesise, assess and present the research.
Impact	The research could have a large or small impact on the final recommendations.
Sources	Available sources of research may be different depending on the topic (for example, databases, websites, organisations).
Amount	The amount of research, which can range from sparse to many systematic reviews.
Relevance	How applicable the available research evidence may be to the guideline topic or specific recommendation.
Alternative sources	The capacity and resources to obtain patient views from other sources, such as by patient consultation or by conducting primary research.

At what stage of the guideline development process can research evidence about patient views be used?

Evidence about patient views and experiences can be used throughout the development of a guideline, including its recommendations. This section provides an overview of the development stages with a brief description relating using research on patient views to each stage. (The sections on how research can be summarised and presented for use, how research evidence can be summarised in the guideline, and what to do when no methods are available provide more detail about how to incorporate this evidence.) Each step in the guideline development process is illustrated in figure 1, from the GIN-McMaster Guideline Development Checklist (2014). Although research evidence can be used at all stages, most opportunities are in the inner area of the diagram (outlined by the black box and from Question Generation to Dissemination & Implementation), because many of the stages on the outer perimeter (including Priority Setting, Organisation, and Conflict of Interest Consideration) will be predetermined by macro- and organisational level decisions.

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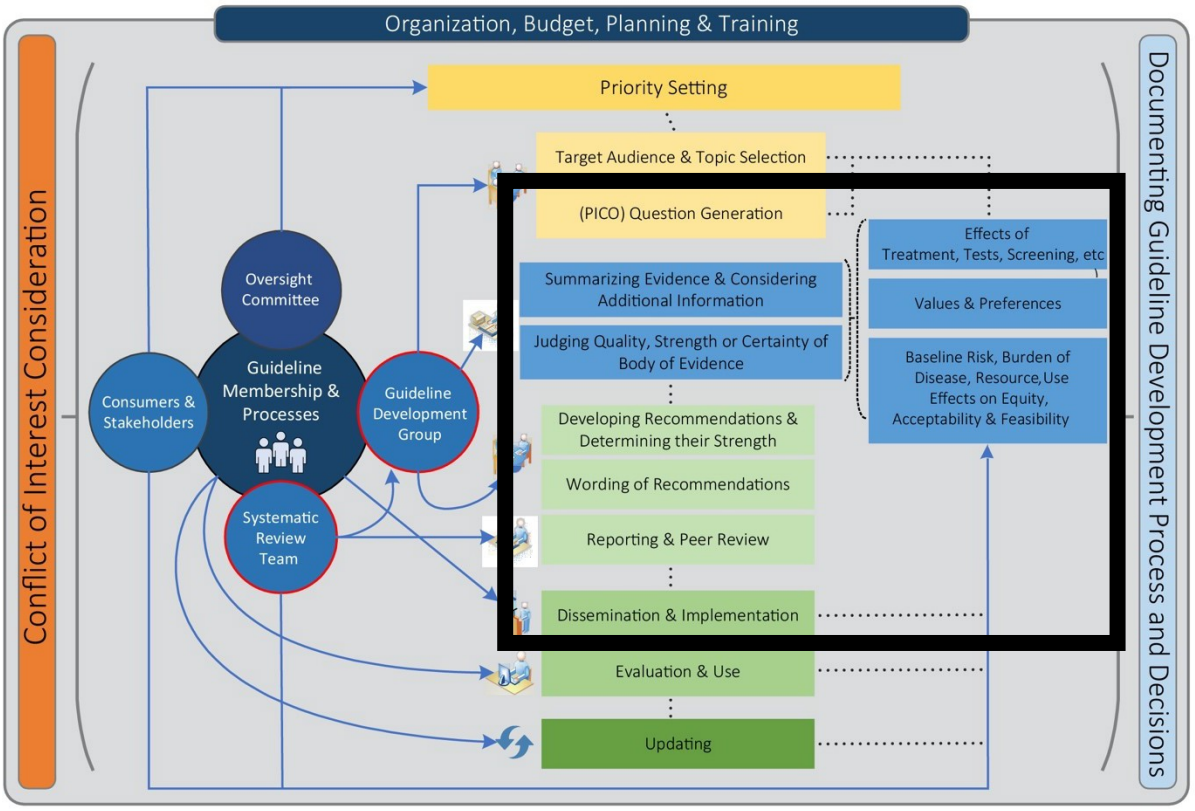

Figure 1 Diagram outlining stages of guideline development provided in the [GIN-McMaster Guideline Development Checklist]

One of the earliest and most important steps to ensure the usefulness of a guideline and its recommendations is answering **questions** that stakeholders (for example, practitioners, policy makers, patients and public) have about a topic. Typically, a guideline group will generate a list of questions about the interventions or tests that should be covered, and the **important outcomes** for which evidence is needed. The questions and the outcomes identified will in turn determine the direction of the systematic reviews to **summarise the evidence**. The group, however, may need to prioritise that list when there are many questions. Guideline developers can consult and conduct their own research with patients and the public, and key population groups, to determine what is important to them (see the chapter on how to conduct public and targeted consultation). However, before embarking on this research, developers may investigate what research is already available (published in

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traditional journals or in the grey literature in patient organisations and websites) to inform their own research and avoid conducting new research.

When **developing recommendations**, a guideline group will consider the evidence for benefits and harms of an intervention or test, and in doing so will need to consider the **magnitude of the benefit or harm** and the **value** placed on those outcomes. For example, suppose the question is about whether to recommend a new intervention to prevent cancer that may also have some side effects? The new intervention may reduce the risk of cancer by 5/100,000 over 20 years, but increase the risk of a debilitating stroke by 10/100,000. If the values placed on the risk of cancer and strokes are equal, then the new intervention may not be recommended because it increases strokes. However, if the value placed on the risk of cancer is greater than the value placed on a stroke, then the recommendation may be to provide the new intervention. This is because, although there are fewer cancers, reducing the risk of cancer has a greater weight than the risk of strokes. Another consideration is whether patients value outcomes differently from each other, which may also have an impact on weighing the benefits and harms. It is clear from this example, how important it is to consider the value placed on outcomes. But developers may not consider this information and, in particular, may not consider the value that patients place on those outcomes (Gärtner et al. 2019).

Considerations of the effects of interventions is 1 component of developing recommendations for which evidence should be summarised. But other factors, such as acceptability and burden of an intervention to stakeholders, costs and resource use, effects on equity, and feasibility, will also need to be considered. The Evidence to Decision framework can be used to help guideline groups move from evidence to making recommendations or /decisions by considering all of the factors (Alonso-Coello et al. 2016). To illustrate the importance of summarising and using this type of information, consider that there may be evidence that 1 intervention is more **acceptable** to (or preferred by) most patients because it involves less burden. For example, patients might prefer a single intramuscular injection every 6 months rather than a pill once daily. This preference could have an impact on whether

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1 intervention is recommended rather than another. In the same way, **costs and resources** may influence recommendations. If patients consider a new intervention

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to prevent cancer more costly compared with a currently used intervention, decision makers may decide to recommend against it. In another example, if an intervention is more **accessible** with good uptake by patients, for example, in poorly-resourced settings (potentially increasing **equity** as well), a guideline group may consider recommending it rather than less accessible treatments. Or the guideline group may consider how to make other treatments equally accessible.

Information from research on patient views about the challenges when **disseminating and implementing** recommendations may also be used to inform the guideline. Some research has indicated that the wording of recommendations can have an impact (Gagliardi et al. 2011). For example, the language used, if appropriate to the context of the specific patient population, may predict the success of implementation. Therefore, research on terminology and phrasing for patients on a topic or disease area may be helpful when **writing recommendations** (see more in chapter about how to develop information from guidelines for patients and the public)]. In addition, research evidence about different strategies to reach patients that is related to the guideline topic will also be useful when a guideline group is determining how to disseminate and implement their specific guideline and recommendations to the target population. Examples include use of decision aids, pamphlets, or social media. (See more in the chapter on involving patients and the public in guideline dissemination and implementation.)

What types of research can provide evidence about patient views?

Published and unpublished research about patient views can come from a single study or from a systematic review, and can include of a variety of study designs for different purposes:

- qualitative research, such as interviews and focus groups
- surveys
- comparative studies (non-randomised and randomised)
- studies providing utility and non-utility estimates for an outcome, and
- studies that determine minimally important differences (MIDs) in an outcome.

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Qualitative research studies

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Information about patient views will often come from qualitative research studies, such as interviews and focus groups. This evidence can highlight areas of concern to patients, which may inform the scope of the guideline, the significance of guideline questions, the relative importance of outcomes, and acceptability of interventions. In turn, these concerns can be considered by the guideline group when deciding which questions and outcomes to address, and when incorporating values and other factors into recommendations. For example, in a guideline about different care models for people with haemophilia, a qualitative study, consisting of interviews with patients and the results of a thematic analysis, was published (Lane et al. 2016). The study reported important aspects to patients related to different models of care, 2 of which were equal access to comprehensive models of care, and the perception that integrated care is better. Consequently, when making the recommendation for the integrated care model, the guideline panel included additional guidance about overcoming system level and patient level barriers to ensure equal access.

Surveys

Surveys can provide valuable information about patient views. In particular, surveys are often used to ascertain the important questions patients have about a topic. An example of a primary study is an online self-administered survey of members of the Canadian Osteoporosis Patient Network, who were asked what priority interventions should be covered in a new guideline for osteoporosis management (Morin et al. 2020). Over 1,000 people rated interventions, such as physical activity or nutrition, from ‘1 = not important’ to ‘5 = critical’. The ratings were used to prioritise topics for the new guideline. Published surveys can also be used to determine the important outcomes to review for a particular question. The Core Outcome Measures in Effectiveness Trials (COMET) initiative is a database of studies, including surveys, that identifies outcomes to measure and report in trials for different health conditions. The surveys can be used to inform guideline developers about which outcomes should be covered in the systematic reviews and should be weighed when making the recommendations.

Comparative studies

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Although quantitative research is typically used to determine the effects of interventions and tests, comparative studies can also include outcomes directly

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related to patient views. Acceptability of an intervention can be assessed in participants and compared between a group that receives the intervention and a group that does not. Whether patients experience barriers or other challenges because of costs, resources, equity or feasibility issues can also be measured and compared between groups. Both randomised controlled trials and comparative non-randomised studies may provide this evidence. For example, for a World Health Organization (WHO) guideline with recommendations on treatments for precancerous lesions, the guideline group was considering whether to recommend 1 surgical treatment (loop electrosurgical excision procedure) rather than another (cryotherapy). A randomised controlled trial measured important health outcomes with either treatment and also how many participants felt the procedure they received was acceptable (Chirenje et al. 2001). Acceptability was found to be similar and contributed to the decision of the guideline group to suggest treatment with either procedure.

In another WHO guideline, recommendations for treatment of chlamydia were made. Randomised controlled trials provided information about the difference in effects of various treatments and adherence to those treatments. The information about adherence was used to inform decisions about patient preference for single-dose compared with multi-dose regimens (Hillis et al. 1998)

Studies providing utility and non-utility estimates

Studies may also quantify the value placed on an outcome as utility and non-utility estimates. The use of these estimates in guideline development is relatively new and methods for incorporating this evidence are still being developed (Zhang et al. 2017) Essentially, studies will use different methods to measure utilities (such as Standard gamble or Time trade off) and report the utility of a health state (for example, a health outcome) on a scale from 0 (death) to 1 (perfect health). When comparing utilities for different outcomes, guideline groups could consider outcomes with lower utilities as an indicator of less desirable outcomes that may carry greater weight when balancing effects, and a wide range in a utility score as an indicator that patients may not value the outcome (or health state) similarly.

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Studies that determine MIDs

Another type of study related to patient experiences and views is a study that measures MIDs, defined as the smallest change, either positive or negative, that patients perceive as important (Schünemann and Guyatt 2005). This information can be used by guideline developers to interpret the magnitude of the effect of an intervention on an outcome. For example, in a guideline comparing a surgical procedure with non-operative treatment for shoulder pain, studies were available that determined the MIDs for instruments used to assess shoulder pain, function, and health-related quality of life (Hao et al. 2019). When the guideline panel had to decide how large the benefits of the surgery were and how large the harms were, they used the MIDs identified by patients. They determined that the magnitude of the benefits of surgery were less than the MIDs, and magnitude of the harms were greater than the MIDs, and therefore recommended against the surgery.

Systematic reviews

Finally, guideline groups can use the evidence from any of the above studies individually or synthesise such studies. If a systematic review of these studies is already available, that may be preferable because it reduces time and resources necessary to gather evidence about patient views. It could also save resources if there is a diverse or large body of evidence already available. When searching for systematic reviews, guideline groups should be aware that there is no standard for reviews of patient views, and groups will likely need to delve into the reviews for the details. Systematic reviews will have different purposes and therefore specific inclusion and exclusion criteria that guideline developers will need to assess as relevant before using the reviews. Systematic reviews may

- cover broad questions about patient views related to priority questions (see the series about how to use this type of review [Downe et al. 2019])
- cover all factors related to patient views, such as values, and acceptability and equity issues (see the series on how to use this type of review [Lewin et al. 2019])
- cover implementation issues (see the series about how to use a review for this topic [Glenton et al. 2019], and box 1 for an example), or

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- restrict types of study designs included, such as qualitative research (see the series on how to use this type of review [Lewin et al. 2019]).

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BOX 1: A systematic review of patient values and preferences

The American Society of Hematology developed guidelines for management of venous thromboembolism (VTE) disease. There are important trade-offs in VTE management, in particular, because interventions that reduce the risk of thrombosis increase the risk of bleeding. A systematic review of patient values and preferences related to VTE was conducted (Etxeandia-Ikobaltzeta et al. 2020). Multiple databases were searched for both quantitative and qualitative studies.

When summarising the data, the authors combined the results of quantitative and qualitative studies, and also conducted a separate analysis of the themes and quotes from the qualitative studies. The evidence from quantitative studies included utility estimates for outcomes (for example, deep vein thrombosis, gastrointestinal tract bleeding), and non-utility estimates about outcome priorities (for example, VTE risk reduction), willingness to accept a particular intervention (for example, treatment burden of vitamin K agonists), treatment method preference (for example, injection compared with oral medication), and testing method preference (for example, thrombophilia testing). The qualitative studies provided important information from patients related to disease treatment benefits and burden, healthcare provider communication and relationships, awareness and perceptions of risk, and day-to-day routines. Overall, the evidence suggested that patients put higher value on VTE risk reduction than on the potential harms of the treatment, and likely prefer oral medication rather than subcutaneous medication.

The guideline panel used this information to inform the:

- values placed on outcomes and whether the values are consistent across populations, and
- acceptability and feasibility of the interventions when making the recommendations and writing additional guidance about implementation.

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When systematic reviews are not available, a guideline group may decide to conduct their own systematic review. In this chapter, we do not provide details of how to conduct a systematic review, but we will describe some of the unique elements pertaining to syntheses of research about patient views in the next sections. For details about how to conduct systematic reviews that include a variety of different study designs, the resources in table 2 may be helpful.

Table 2 Resources for how to conduct systematic reviews

Type of systematic review	Guidance for conducting the review
Review of randomised and non-randomised studies	Cochrane Handbook
Synthesis of qualitative research	Cochrane Handbook: Chapter 21: Qualitative evidence Additional guidance – Cochrane Qualitative & Implementation Methods Group
Synthesis specific to quantitative patient values	General guidance: Zhang Y, Coello PA, Brożek J et al. (2017) Using patient values and preferences to inform the importance of health outcomes in practice guideline development following the GRADE approach. Health Quality Life Outcomes, 15: 52
Overviews of reviews	Cochrane handbook: Chapter 5: Collecting data
Rapid reviews	Cochrane Rapid Reviews Methods Group

How can we search for research about patient views?

Evidence for patient views and preferences may be found by searching traditional databases, such as Medline, Embase or the Cochrane Library. Other sources of this evidence may include:

- grey literature, such as health technology reports (whether indexed or not)
- patient organisation websites and forums
- professional organisation websites (in particular, in other guidelines), and
- research sites.

The James Lind Alliance website, for example, is dedicated to communicating research priorities and can inform questions about topics of interest to patients.

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Finding research about patient views in the published literature can be challenging, but some work has been done to create standard search strategies for key databases that can focus the search. The choice of strategy may often depend on the breadth of your topic area (for example, broad strategies may be appropriate in very specific diseases or conditions). Or the choice may depend on the expected types of studies conducted on the topic (for example, search strategies with specific terms for qualitative research or for studies measuring utilities are available). Guideline groups will need to consider their time and resources when choosing a strategy. A restricted search rather than a comprehensive search may be best if resources are limited (see table 3). When searching within specific organisation websites or in Google, for example, guideline groups could also consider using terms that are similar to those used in the strategies in table 3.

Table 3 Search strategies to find research in traditional databases related to patient views able

Search strategy	
Search strategy to systematically identify evidence addressing views and preferences with terms specific to different study designs	Selva A, Solà I, Zhang Y et al. (2017) Development and use of a content search strategy for retrieving studies on patients' views and preferences. Health and Quality of Life Outcomes 15(1):126
Search strategy from Scottish Intercollegiate Guidelines Network (SIGN) for publications related to 'patient issues'	SIGN search filters for patient issues
Further development of a search strategy for literature addressing patients' knowledge, views, and values based on the SIGN strategy	Wessels M, Hielkema L, van der Weijden T. How to identify existing literature on patients' knowledge, views, and values: the development of a validated search filter. Journal of the Medical Library Association 104(4):320–324
Search strategy available from the Health Information Research Unit for finding studies in qualitative research	Health Information Research Unit Qualitative – Medline

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Alternatively, a search for already published systematic reviews may be preferred if reviews are potentially available. If a guideline group has decided to search for

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systematic reviews (as opposed to individually published studies), groups can consider:

- adding a search filter for systematic reviews, such as the McMaster University Health Information Research Unit's Clinical Hedges database
- searching databases of systematic reviews, such as the Cochrane Library or Epistemonikos, or
- searching in other guidelines for synthesised evidence in the G-I-N International Guidelines Database or the TRIP database.

How can the certainty of evidence on patient views be assessed?

When thinking about the certainty of evidence, guideline groups will typically think about certainty or confidence in the evidence for benefits and harms. Consider a group making a recommendation who have been presented with the benefits and harms of an intervention from a systematic review of the literature. Drug X increases the number of people cured by 10 out of 100, and the risk of stroke increases by 5 out of 100 compared with no drug. The evidence that contributed to the estimates of the cures is very different from the evidence that contributed to the strokes. So, the certainty of the evidence is different. There is very low certainty that 10 more cures may occur, but high certainty that 5 more strokes could occur. Because of the certainty in the evidence, a guideline group may make a recommendation against the drug to avoid the 5 more strokes that could occur. In contrast, if the certainty was the other way around, that is, high certainty of 10 more cures, and very low certainty of 5 more strokes, the group may decide to suggest the drug as treatment because they are very uncertain about the increase in strokes. Assessing and presenting the certainty of evidence for benefits and harms is therefore important, and various systems do this, such as the GRADE approach (see the GRADE Handbook).

These systems can also be used to assess the evidence for patient views. If a guideline group is conducting a systematic review of research on patient views (using rigorous methods provided in table 2), the group should also convey the certainty of the results about those views. Consider a guideline group deciding

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whether to recommend a procedure with outcomes for precancerous cervical lesions and infertility. Research evidence about the value that couples place on fertility could

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be gathered. If evidence is certain that women who are trying to conceive place a very high value on avoiding infertility compared with preventing recurrence of a precancerous lesion, more so than women not trying to conceive, the guideline group may make a recommendation against the procedure for women trying to conceive, but a recommendation for the procedure in women not trying to conceive. In contrast, if the research evidence is very uncertain about the values, then the guideline group may make the same recommendation for both groups of women. In this way, the certainty of the evidence can have an impact on the recommendations that are made, and it is therefore important to assess the certainty of the research evidence about patient views.

One component of assessing the certainty of evidence is to judge the quality or limitations of the studies. For individual qualitative studies, there is no agreement on the best tool to use, but 2 have been more widely used:

- the CASP qualitative studies checklist
- an adapted version of the CASP tool (Atkins et al. 2008).

These tools continue to be developed as methods progress and as the debate persists about the impact of the assessment criteria, such as ethics approval, on the validity of a study. For now, either of these tools could be used to assess the limitations of each study that contributes information on patient views. However, assessing the limitations of studies is only 1 part of the overall assessment of evidence. There are other factors that need to be considered when evaluating the certainty of the evidence, and these factors depend on the study design contributing to the evidence.

To assess and present **confidence in the evidence from a review of qualitative research studies**, reviewers may use the GRADE-CERQual approach. GRADE-CERQual asks groups to assess 4 domains:

- quality or limitations of the studies
- whether the results from the studies are directly relevant to the recommendation

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question

- whether the results are coherent across the studies, and

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- whether the data from the studies is sufficiently rich or adequate.

Together, consideration of these domains determines the confidence in the conclusions from a review of qualitative research about patient views. For example, a systematic review of qualitative research was conducted to synthesise evidence about parents' and informal caregivers' views and experiences of how information about routine childhood vaccination is communicated (Ames, Glenton, and Lewin 2017). The authors found that scientific sources of vaccine information were seen to be more reliable than discussion forums or lay opinions. The review authors then assessed the certainty of the evidence using GRADE-CERQual. They had minor concerns with the limitations in the studies, no concern with coherence of the results across studies, but moderate concern with the setting of the original studies (being directly applicable to their question), and the richness of the data. They therefore had low confidence that scientific sources were seen as more reliable than discussion forums or lay opinions. Details about how to assess the confidence in qualitative research findings using the GRADE-CERQual approach can be found in a series of papers, each addressing how to assess 1 domain (Lewin et al. 2018).

To assess the **certainty of evidence specific to the importance of health outcomes**, a new method has been developed (Zhang et al. 2019a, Zhang et al. 2019b). The method is based on the GRADE approach in which evidence for patient values is assessed using the domains: risk of bias, inconsistency, indirectness, imprecision, publication bias, and others. Details are provided in the articles published by Zhang et al. 2019a and 2019b, but the concept for each domain is similar to what would be applied to a review of studies evaluating benefits and harms of an intervention. Of note is the consideration of inconsistency across study results. When research shows that values are variable, further exploration, for example by subgroups, is recommended in order to determine if there are true differences in how people value a health outcome. Differences in values would likely influence whether different recommendations are made for 1 group compared with another based on what they value most, or whether there should be a conditional rather than a strong recommendation (that is, a conditional recommendation requires shared decision

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making).

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For **evidence about patient views from a synthesis of studies, such as randomised controlled trials or non-randomised studies**, GRADE or other systems for assessing the certainty of evidence from these study designs should be used. For example, if there was a review of randomised controlled trials that reported the acceptability of 1 procedure compared with another. In this hypothetical review, the difference in how acceptable the 1 procedure is compared to how acceptable the other procedure was calculated from each study and then the differences from each study were pooled together to create 1 estimate of the difference. To express the certainty in such estimated differences, groups should assess the risk of bias of all the studies providing data, the number of participants providing data, the width of the confidence interval around the difference, the heterogeneity of the overall difference, and the applicability and risk of publication bias. Based on this assessment, the guideline group will know how certain to be in the difference from the review of studies.

Finally, in special circumstances when a guideline group is not using a standard approach to assess the evidence, there should be some description about how believable the overall conclusions are about the patient views and why they are believable. The following principles should be considered and communicated:

- whether the individual studies were well done
- how many studies (or participants) were included
- how relevant the studies are to the recommendation topic, and
- how consistent or coherent the results are across the studies.

How can the research be summarised and presented for use?

As explained in the section on the stage of the guideline development process at which research evidence about patient views can be used, research about patient views may contribute to multiple stages of a guideline and to many factors when making a recommendation. In this section, we provide several examples of how this research may be summarised and presented so it can be incorporated into guideline recommendations.

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A list of patient research priorities based on research

At the guideline development stage of generating questions to cover in a guideline, the guideline group may search the grey literature for research about what is important to key stakeholders. The James Lind Alliance website can be searched to find research about patients' top research priorities for a topic. Figure 2 shows the James Lind Alliance website's top 10 questions on diabetes and pregnancy (as well as information about how the research was conducted to inform the priorities). Presented this way, the guideline panel can easily incorporate this information when generating questions.

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Figure 2: Information from the James Lind Alliance website about priority questions related to diabetes and pregnancy

A thematic summary of patient views from evidence syntheses of qualitative research about acceptability presented narratively and in a table with rating of certainty

A synthesis of systematic reviews of qualitative research was conducted and informed the development of the WHO guideline: recommendations on digital interventions for health system strengthening (2019a). It includes recommendations on using digital health interventions for reproductive, maternal, newborn, child and adolescent health, in particular, for the use of telemedicine. An overview of systematic reviews of qualitative research on patient views of telemedicine was conducted. The evidence was summarised in themes and presented narratively and in tables, along with the confidence in the evidence. Figure 3 shows the research evidence on acceptability that was used to make the recommendation for using client-to-provider telemedicine (Glenton et al. 2019). The evidence statement 'Some clients believe that telemedicine has increased their independence and self-care, but some healthcare workers may be concerned about clients' ability to manage their own conditions (low confidence)' from the thematic text is reflected in the table item F7.

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Some clients see client-to-provider telemedicine services as offering reassurance and a sense of safety and appreciate the increased access, consistency and continuity of care (low confidence). Some clients appreciate the convenience of telemedicine as it saves time and money and reduces the burden of travel, although others may see it as difficult to engage with or too time consuming (low confidence). Some clients also appreciate being able to communicate with healthcare workers from their home environment, while others miss face-to-face contact (low confidence). Some clients believe that telemedicine has increased their independence and self-care, but some healthcare workers may be concerned about clients' ability to manage their own conditions (low confidence). Telemedicine services can give clients who speak minority languages access to providers who speak these languages. However, access may be difficult for others to achieve, for instance because of hearing impairments, poor computer literacy or technical issues (high confidence).

Summary of Qualitative Findings

Summary of overview finding		Reviews contributing to the overview finding	Methodological limitations	Relevance	Adequacy	Coherence	Overall CERQual assessment of confidence in the evidence
F7	Some clients may believe that telemedicine has increased their independence and self-care, but healthcare workers may be concerned about this transfer of responsibilities	Brewster 2013[1]; Cox 2017[2]; Raphael 2016[4]	No or very minor concerns	Moderate concerns because of partial relevance. Healthcare provider perspectives are from review of cancer patients only, while client perspectives are from COPD and from adults over 65.	Moderate concerns because of thin data	No or very minor concerns	**Low confidence** because of concerns about partial relevance and data adequacy

Figure 3: Narrative summary of the themes from the systematic reviews and summary in a table

A narrative summary of themes from a systematic review of qualitative research as evidence of benefits and harms

A systematic review of qualitative research was conducted for the Scottish Intercollegiate Guidelines Network (SIGN) guideline on managing long-term effects of COVID-19. Based on a search of bibliographic databases, grey literature and pre-print databases, 6 studies were included, and a thematic synthesis was done. Each of the themes was summarised and presented in the COVID-19 rapid evidence review. Managing the long-term effects of COVID-19: the views and experiences of patients, their families and carers (Healthcare Improvement Scotland 2020). One of the themes (Analytical theme 9) identified desirable features of healthcare services or service delivery, which in turn led to recommendations for health care

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professionals to perform person-centred assessments (figure 4).

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Analytical theme 9: desirable features of healthcare services/service delivery

Patients asked for face-to-face assessments; they talked about the need for one-stop clinics with multidisciplinary teams (MDT) who could look at their wide-ranging symptoms and treat them holistically. A case manager to oversee individual patients and ensure that all aspects of their care had been considered was suggested, along with meaningful referral pathways and criteria.

> "What would be most helpful is if all main hospitals could have a Covid clinic that had experts from respiratory, cardiology, rheumatology, neurology, physiotherapy etc, so you could go along for half a day and see people from these different departments, they can refer you for tests and you can get a plan in place, we are having such a range of symptoms that GPs are struggling to know what to do with you" (Maxwell, p17)[4]

> "... there was a view that it would be helpful if people living with Covid19 could have a 'quarter back' or case manager to oversee and coordinate investigations and support services across different medical specialities." (Maxwell, p17)[4]

When asked what features of healthcare delivery or services they would like to see, patients with long-term symptoms spoke about wanting to be listened to, to be believed and understood, and to be offered practical advice on coping.

> "... actually just the experience of being heard and feeling like somebody got it and was being kind about it, but you know it was okay that they couldn't do anything, I just kind of needed to know that I wasn't losing it really and it was real what I was experiencing, I think so that was really helpful." (Kingstone *et al*, p8)[2]

Figure 4: Example of a narrative summary of themes from qualitative research on the views and experiences of patients, their families and carers (Healthcare Improvement Scotland 2020)

A table summarising a synthesis of quantitative studies about patient acceptability and the certainty of that evidence along with other benefits and harms

A systematic review of randomised and non-randomised studies was conducted to inform recommendations for treatments, including thermal ablation or cryotherapy, to

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treat precancerous lesions in the WHO guideline on for the use of thermal ablation for cervical pre-cancer lesions (2019b). Acceptability was measured in the trials. The

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effects from the individual studies were pooled and presented along with the benefits and harms of the treatments in a Summary of Findings Table (Annex D Evidence to decision frameworks, page 43), shown in figure 5. The effect was that it was likely that there was little difference in acceptability between the 2 treatments.

Outcome N° of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Certainty
		Risk with cryotherapy	Risk with thermal ablation	Difference with thermal ablation	
Cure Nº of participants: 85 (1 RCT)	RR 1.14 (0.89 to 1.46)	Moderate			Moderate
		90.0%	100.0% (80.1 to 100.0)	12.6% more (9.9 fewer to 41.4 more)	
Cure Nº of participants: 157 (1 observational study)	RR 1.01 (0.89 to 1.14)	Moderate			Very low
		90.0%	90.9% (80.1 to 100.0)	0.9% more (9.9 fewer to 12.6 more)	
Cure Nº of participants: (23 case series)	not estimable	Moderate			Low
		90.0% (87 to 93)	92% (90 to 95) 2 probe: 95 (93 to 98) Not 2 probe: 85 (80 to 90)		
Pain immediately Nº of participants: 413 (4 RCTs)	RR 0.93 (0.76 to 1.15)	65.4%	60.8% (49.7 to 75.2)	4.6% fewer (15.7 fewer to 9.8 more)	Moderate
Pain immediately Nº of participants: (case series)	not estimable	Moderate			Low
		30.0% (19 to 41)	63% (42 to 83)	33% more	
Major bleeding Nº of participants: 817 (6 RCTs)	RR 0.62 (0.37 to 1.02)	1.7%	1.0% (0.6 to 1.7)	0.6% fewer (1.1 fewer to 0 fewer)	Moderate
Major bleeding Nº of participants: (case series)	not estimable	4 / 9941	9 / 4634		Low
Infection (including fever) Nº of participants: 816 (6 RCTs)	RR 0.81 (0.10 to 6.33)	0.3%	0.2% (0.0 to 1.6)	0.0% fewer (0.2 fewer to 1.3 more)	Moderate
Infections (including fever) (45 case series)	not estimable	60 / 8674	17 / 4082		Low
Acceptability – whether they would recommend it Nº of participants: 631 (3 RCTs)	Acceptability is likely not different between thermal ablation and cryotherapy. Risk Ratio 1.01 (0.99 to 1.02)				Moderate

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Figure 5: Summary of findings table including patient acceptability between 2 treatments (WHO 2019b)

A summary of quantitative and qualitative research about patient views related to equity using the Evidence to Decision framework to present the evidence

A systematic review of research was conducted for a recommendation comparing different models of care for people with haemophilia (Pai et al. I2016). The review included any quantitative or qualitative research, such as focus groups, interviews and surveys, about barriers to accessing an integrated model of care. The review provided evidence about the impact of the model on health inequities and was summarised by analysis of thematic areas. The evidence was presented to the guideline group in a section on Equity in the Evidence to Decision Framework and then used by the group to make the recommendation (see figure 6).

	Criteria	Judgements	Research evidence	Additional considerations
Equity	**What would be the impact on health inequities?**	○ Increased ○ Probably increased ○ Uncertain ● **Probably reduced** ○ Reduced ○ Varies	**Summary of the evidence** There are no randomized controlled trials or non-randomized studies comparing integrated care to non-integrated care for people with hemophilia There are 7 non-randomized studies which provided data from one group of people who received integrated care. Ethnicity/race • Baker 2013 analyzed data from the U.S. HTC network (129 HTCs) from 1990-2010. In 2010, 71% of HTC patients were White, 13% Hispanic, 9% Black and 7% 'Other' (this was slightly lower than U.S. population of 64% White, 16% Hispanic, 13% Black and 6% 'Other'). From 1990 to 2010, the numbers of HTC Hispanic and Black patients grew, but remained under represented. • Monahan 2011 analyzed data from >130 HTCs from 1998-2008 in boys with hemophilia and found that the racial/ethnic composition reflected general demographics. • Forsberg 2014 (supplemented by Aschman 2014) report survey of 4,004 households with people with hemophilia in HTCs in 2013. The odds of having 5 or more problems were twice as high for minority groups relative to Whites categories, and almost thrice as high for African Americans. Distance/access • Soucie 2000 analyzed data from 1993-1995 and found more people with severe hemophilia accessed HTCs than mild or moderate (and more than non-HTCs). • Zhou 2011 (from the HUGS study) interviewed 327 adults and parents with children with hemophilia. 14% reported barriers to HTC, which included distance. • Hacker 2006 conducted a survey from 1999-2001 of ~120 adults and parents with children hemophilia at an HTC. 32% had limited access to HTC often due to transportation, inconvenient times, or problems with staff. • Forsberg 2014 (supplemented by Aschman 2014) found that moderate or severe barriers included time off from work/school for appointments (11% moderate, 4% severe), and distance to HTC (14%, 4%). The odds of having 5 or more problems were twice as high for minority groups relative to Whites categories (African Americans almost 3 times). • Nugent 2015 (from the HERO study) surveyed people with and parents of children with hemophilia in 10 countries [supplementary data also was available]. In the U.S., 22% of people with hemophilia report that it is quite/very difficult to visit HTCs in the U.S. Accessibility was the key issue; 71% of 42 respondents cited the long distance to their HTC, and 45% cited long/expensive travel.	Core question: will we do away with equity problems if we do away with HTCs? Or will we introduce more inequity? General demographic data on PWH is scant. Further, the bulk of published data is from HTCs. Thus we don't know if inequity also exists in individuals outside of HTCs. The issue of capacity looms large – does it affect access issues? Panelists felt that the HTC system's capacity was not truly a problem, but that access is being limited by insurance companies. Modifiers of inequity may include telehealth, empowering local healthcare providers, broader access to HTCs (e.g. through more appropriate implementation of recommendations and optimized utilization).

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Figure 6: Equity section of an Evidence to Decision Framework with a summary of the studies by theme (Pai et al. 2016, see hae13008-sup-0003-AppendixS3-S4.docx)

A summary of a systematic review of research about values placed on outcomes

As described in box 1, a systematic review of patient values and preferences was conducted for the American Society of Hematology guidelines for management of venous thromboembolism (VTE) disease (Etxeandia-Ikobaltzeta et al. 2020) Multiple databases were searched for both quantitative and qualitative studies. The authors summarised the research from non-utility studies on which outcomes patients with cancer valued more (along with the certainty of that evidence). This information was used when deciding how much weight to put on the benefits and harms of the different treatments (see table 7).

Trade-off between treatment burden and benefits with LMWH (Cajfinger et al,[46] Noble et al[54])	Cancer patients place highest value on "the interference with cancer treatment," followed by "efficacy of the VTE treatment" and "risk for major bleeding." They place low value on monitoring through blood tests, frequency of administration, mistakes, and costs. 509 participants from 2 cross-sectional studies	⊕⊕⊕◯ Moderate certainty due to RoB[a]

Figure 7: Summary of non-utility studies about the value placed on different outcomes in the treatment of venous thromboembolism (in table 4 of Etxeandia-Ikobaltzeta et al. 2020)

How can research evidence be summarised in the guideline?

The previous evidence presentations are most useful to the guideline group when making recommendations. After the evidence has been used in the guideline process there are 2 options for how to write about patient views in the final guideline. Options can include:

- summarising the evidence on patient views across many recommendations in 1 section of the guideline
- providing the patient views for each recommendation.

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The choice may depend on how many recommendations are in the guideline. If there are few recommendations, then 1 summary may be appropriate because readers will

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be able to apply the summary easily to each recommendation. If there are many recommendations, readers may appreciate having a summary of the views and experiences for each recommendation. If the recommendations are closely related and the views and experiences are similar across those recommendations, then 1 summary is adequate. However, if views, values, and experiences differ from recommendation to recommendation, specific descriptions within each recommendation would be necessary. Finally, if it is expected that each recommendation may not be read, may be made into a stand-alone document, or be copied into other related guidelines (that is, not necessarily always together with the other recommendations) then including a summary with each recommendation is likely the better choice.

For an example of how to summarise patient views **across multiple recommendations in 1 section**, see the American Society of Hematology 2018 guidelines for management of venous thromboembolism.

For an example of how to summarise patient values and preferences **for a recommendation in a guideline**, see the CMAJ recommendation on screening for chlamydia and gonorrhea in primary care for individuals not known to be at high risk.

What to do when no methods are available?

This chapter has provided practical advice on how to incorporate research evidence about patient views in the guideline process using examples. There are many more examples and more detailed guidance available in the references. However, there are still gaps in these methods, and guideline developers may need to develop novel methods when there are gaps. We suggest the following if no guidance is available:

- **be transparent** about what was done or not done
- **document** in the guideline or evidence syntheses what was done
- determine if it is possible to **adapt** methods for including stakeholder views from other fields to methods for including patient views in guideline development
- **conduct research** into what does and does not work, and
- **share** experiences.

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Acknowledgements

The authors would like to thank the following for their contributions to this chapter:

Contributors to the 2012 version of this chapter: Loes Knaapen, Christopher J Colvin, Jane Cowl and Trudy van der Weijden

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How to recruit and support patients and the public, and overcome barriers to their involvement in guideline development

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Key messages

- Guideline developers can experience several barriers to recruiting and engaging patient and public members in guideline development work. These include the lack of a clear cost-effective recruitment strategy, the ability to achieve genuine representation, and members lacking the appropriate skills to conduct the work (for example, good communication or research knowledge).
- The patient and public member's role will influence the tasks, experiences and qualities required to perform in the guideline group. This might influence the number and type of patient and public members, such as patients, carers and advocates from patient organisations. Information outlining the role and person specification should be carefully planned from the outset and openly advertised to reduce barriers to recruitment and engagement.
- There are 2 types of recruitment methods: open recruitment and nomination through patient organisations. But each method has advantages and disadvantages that need to be considered, taking into account the developer's resources and availability of patient organisations for specific conditions. Whichever method is selected, the way it was implemented must be documented and transparent.
- Barriers to effective patient and public member engagement during guideline development can be overcome with careful planning and:
  - delivering practical support (for example, providing easy read versions of documents)
  - informal support (such as providing advice and support)
  - financial compensation for time and travel expenses

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  - co-learning (during guideline development in the form of presentations or seminars)
  - training, performance feedback and managing group dynamics.
- There are occasions when patient and public members cannot be included in guideline groups (for example, children) or it is difficult to recruit seldom heard groups (for example, people in secure settings). Alternative approaches to consider are reference groups, additional sources of data on patient and public views, patient expert testimony, and consultation using research methods.
- Very specific barriers to involvement will need to be considered when engaging seldom heard groups, such as children, people with learning disabilities, and people with severe mental illness. Such barriers include legislation, cognitive capacity, and illness fluctuations. The practical and informal support strategies will need to be very carefully considered, adapted and tailored to each individual.

Top tips

- Plan, develop and advertise a role description and person specification during the planning stage of the guideline. It should outline in advance, the roles, tasks, experiences and qualities, and the type and number of patient and public members to gain a broad representation needed for the guideline.
- Involve patient and public members from the start, and throughout development, to ensure the scope applies to the people who will use the guideline and to encourage ongoing engagement.
- Recruit at least 2 patient or public members, who might be patients, parents, carers or advocates from patient organisations, with a range of perspectives, experiences and characteristics to gain a breadth of representation.
- Recruit people based on their experiences and understanding of the issues that matter to people with the condition.
- Consider the open recruitment method to reach a large pool of people if your organisation has the time and resources to produce recruitment documents and conduct interviews.
- Consider the nomination process if you have less resources to conduct open recruitment and have access to relevant patient organisations for the topic of interest.

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- When openly recruiting, advertise opportunities through websites, patient organisations, health professionals and social media, which can help recruit from seldom heard groups.
- Assess practical and informal support needs, including training needs, from the outset and during guideline development in case needs change. Tailor support and training to each individual member.
- Provide initial training and implement co-learning in which the whole guideline group learns and shares knowledge on guideline development and research, using presentations, seminars, and discussions.
- Create and offer opportunities for new members to meet an experienced patient and public member ‘buddy’ to allow them to discuss their role and any concerns.
- Regularly assess the patient or public member’s performance and provide feedback to ensure ongoing learning and to address any issues that arise, such as feeling unable to contribute.
- Manage group dynamics through training for the chair to ensure patient and public members are treated equally and can contribute and feel valued.
- Carefully plan and tailor specific practical and informal support strategies when engaging seldom heard groups, such as children, people with learning disabilities and people with severe mental illness. Take into consideration legislation, cognitive capacity, and illness fluctuations.

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Aims of the chapter

This chapter provides guideline developers with advice on how to identify, recruit and support patients and members of the public as participants in guideline development groups. It will also explore how facilitators can overcome some of the main barriers to recruitment and effective involvement. Published literature has highlighted several barriers for involving patient and public members (Armstrong et al. 2017b; Légaré et al. 2011; Ocloo and Matthews 2016), including:

- the developer being unclear of recruitment strategy, including the number or type of patient or public members to recruit to achieve genuine representation
- the developer, patient or public member being unclear of their role in guideline development
- scheduling and planning issues, or having the resources to adequately engage patient and public members
- lack of relevance of the scope to patient and public members
- difficulties in gaining meaningful involvement or avoiding tokenism
- patient or public member not respected, not seen as equal, or feeling devalued
- achieving a breadth of perspective or adequate representativity of patients and the public
- recruitment difficulties
- lack of methodological expertise, skills or knowledge related to guideline development
- patient and public members feeling isolated or lacking in confidence to speak up in a large group of experts.

The 4 sections of this chapter will address these barriers. The first section focuses on the role of patient and public members, including the qualities, experience, type and number, and skills needed. The second section focuses on the recruitment process and strategies. Support, including practical and informal support, group dynamics, training and co-learning, and re-assessment and feedback procedures, is addressed in the third section. The fourth section focuses specifically on the barriers and solutions to recruiting people who might face barriers to participating, such as children, and outlines a series of alternative approaches. Practical examples will be

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provided, based largely on the expertise and best practice of guideline developers from around the world, These include the National Institute for Health and Care Excellence (NICE) in England, Ärztliches Zentrum für Qualität in der Medizin (ÄZQ) in Germany (or the German Agency for Quality in Medicine [AEZQ]), the Registered Nurses' Association of Ontario (RNAO) in Canada, and the Scottish Intercollegiate Guideline Network (SIGN) in Scotland. Reference is made to published research where relevant. The advice in this chapter will help guideline developers avoid tokenism, defined as the ‘difference between…the empty ritual of participation and having the real power needed to affect the outcome’ (Arnstein 1969).

The role of patient and public members

Research has found that a barrier to involving patients and the public in guideline development can occur when the role and required skills, experience and knowledge have not been clearly outlined (Armstrong et al. 2017b, Carroll et al. 2017). At the planning stage of a new guideline, developers need to have a clear understanding of the role requirements and expectations of the patient and public members. This helps developers carefully plan the offer of support, training and any additional resources needed, and ensures that only suitable members are recruited. The information will also help patient and public members to understand what is required of them, including the time commitment, which enables better engagement because they will be able to plan their work. This section will explore the factors that guideline developers should consider during the planning phase, including:

- the role and tasks of patient and public members
- the type and number of members
- gaining appropriate representation
- the required skills and experience.

The role and tasks of patient and public members

Developers should be clear of the purpose and rationale for patient and public involvement because the role will influence the tasks, skills, and the qualities that developers will need to recruit for. The role is defined as their function in a group, including being an equal partner in decision making during guideline development.

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Knaapen and Lehoux (2016) defined 3 models that might be useful to consider when developing roles based on the tasks to be achieved: consumerist, democratic, and expert. A consumerist model emphasises an individual's right to have autonomy in making choices in healthcare decision making and that healthcare improves when tailored to patients' needs and preferences. This model applies if the task is to identify patient preferences and develop decision aids. A democratic model refers to the 'rights of citizens (and taxpayers) to democratic decision making on a policy or collective level' (Knaapen and Lehoux 2016). This model applies if the tasks are to develop policy documents that influence the design or redesign of healthcare services. An expert model emphasises the patient and public's experiences and knowledge of a condition, treatment, and quality-of-life outcomes. So, it offers a different kind of expertise to that of health professionals and is useful when producing guidance.

Although the models might be a useful starting point to consider roles and tasks, they can be contradictory because patient and public members are sometimes required to perform multiple tasks. For example, formulating recommendations, synthesising knowledge, revising drafts and, occasionally, strategic decision making such as deciding committee membership, outlining the scope, and producing decision aids (Légaré et al. 2011). The type and range of tasks will influence the number and type of patient and public members to recruit.

It is also important to ensure that the patient and public members' role, ideally, spans every stage of the development process, including the scoping stage. This can help prevent patient and public members disagreeing with the topic scope and disengaging from the guideline group (van Wersch et al. 2001). When it is not feasible to involve members early on, or at all stages of the development process, an alternative is to invite additional representatives, to attend 1 meeting or contribute to a consultation (see the chapter on how to conduct targeted and public consultation).

Role and tasks in practice

NICE in England involves patient and public members throughout the guideline development process. They have the same role and tasks as health and social care professionals. Tasks include:

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- agreeing the review questions and protocol
- assessing and interpreting the evidence
- producing recommendations
- identifying relevant stakeholders for consultation
- contributing to draft documents
- producing information for the public.

The RNAO involves patients and members of the public in similar ways to NICE. For some topics, NICE recruits patients or carers early on to help develop the guideline scope, as part of a smaller scoping group, and possibly also to support the development of patient-decision aids. When patients or public members cannot be involved in all stages of the guideline development, SIGN in Scotland invites additional representatives, living with the condition, to specific meetings. Patient and public members might also be recruited for different types of roles and tasks. NICE in England, ÄZQ in Germany, and RNAO in Canada all involve patients and the public when developing quality standards and indicators, based on guidelines, which includes the rating and assessment process.

The type and number of patient or public members

What type of patient or public member should we recruit?

The guideline topic and role and tasks will influence the type of members to include. The members can include patients, carers, parents or advocates from patient organisations. A carer or parent might be important to include when relatives are affected by the condition, or they have an integral role in caring for the person with the condition (for example, dementia). Parents or carers can be recruited if it is difficult to involve a patient living with the condition, such as young children (for more information, see the section on overcoming barriers to involving those who are seldom heard, in this chapter). Developers may also consider an employee or volunteer from a patient organisation. Even if this person does not have personal experience of the condition, they can provide a broad perspective on the condition and population. It is important to note that a patient, carer or advocate from an organisation will have different perspectives and it can be helpful to include all types of perspectives.

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How many patient or public members should we recruit?

NICE advocates that at least 2 patient or public members should be recruited to any guideline group, who might be patients, parents, carers or advocates from patient organisations. More members could be recruited if the guideline covers multiple issues, a complex condition, or requires multiple roles and tasks. The advantages of this are that it:

- broadens the experiences of the group and ensures different aspects of the guideline are covered from the patient or public member's perspective
- can build confidence, provide social support and empower patients to contribute
- reduces feelings of isolation, which is a known barrier to patient engagement
- provides peers to work with other patient and public members.

Consideration can be given to socio-demographic representation, such as the age range, which is likely to influence how many patients and public members are needed. For example, for the NICE guideline on babies, children and young people's experience of healthcare that is in development (2020), NICE recruited6 members (out of 16), including 2 parents and 4 young people aged between 18 and 25, with experience of different aspects of healthcare.

Representing compared with representative

It is important to recruit patient and public members who represent the condition or issues of those affected by the guideline. A common barrier to effective involvement is the difficulty in recruiting people to the guideline group who can broadly represent the guideline without heavily focusing on their own individual subjective experience or agenda (Carroll et al. 2017, Légaré et al. 2011). The individuals should be able to represent the commonalities and different aspects of the condition in question. However, patient and public members cannot be representative of everyone or all the socio-demographic characteristics (for example, age, gender, ethnicity) that make up the population of concern. Therefore, developers need to consider multiple patient and public members, who might be patients, parents, carers or members of a patient organisation, to achieve such broad representation. Additional approaches to involvement should be considered to address gaps in representation (see the section on supporting individual patient and public members in this chapter).

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Guideline developers and patient organisations report that a barrier to achieving sufficient representation on guideline groups is the lack of interest from patient and public members to get involved in guideline development. Solutions can be to engage other patient organisations who are associated with the health topic of interest. Alternatively, engage organisations who focus on a different condition that produces similar symptoms or experiences to the condition of interest. For example, if the guideline topic covers blood pressure then consider engaging organisations associated with coronary heart disease.

The experience, knowledge and skills required

After the role, type and number of patient and public members have been defined, developers should consider creating plain language information outlining the role and person specification. An important attribute of patients and public members is their experience of the condition and this should be included in the role specification. Exclude people who do not have experience but have only an intellectual or professional interest in the condition. Outline additional skills required, such as communication and team working skills. Ideally, recruit people who will actively contribute to group discussions and be able to represent the views of a wider patient or public group, which could be gained through membership of a support group or patient organisation. Depending on the roles and tasks of the guideline group, developers might need to recruit for different types of skills or they might need to recruit multiple people to achieve such diversity. The role and person specification should explain such skill requirements, what the work entails, the time commitment, expenses or payment arrangements, and what support or training is available. The SIGN 100 handbook for patient and carer representatives provides an example of the roles and skills required to be involved in guideline development (2019) and an example role description from NICE can be found in resource file 1.

The role specification should not disqualify people who may be able make a highly valued contribution to the group. For example, asking for academic levels of attainment or research experience can present a barrier to achieving genuine lay representation (Boivin et al. 2009). At RNAO and NICE, persons with lived experience are not required to submit a curriculum vitae when applying but are required to describe their experience relevant to the topic. Developers could consider

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that certain knowledge or skills can be gained ‘on the job’ with adequate co-learning with project teams (for example, research terminology) or through formal training. Some courses exist online, either free or with a small charge (see resource file 2 for a list of training resources). A greater emphasis should be placed on ‘soft’ skills, experience or knowledge that cannot be learned in the role, such as having contact with other people living with the relevant condition and being able to reflect on their experiences.

To recruit 2 or more patient or public members with a range of experience, knowledge and skills, the following factors could be considered:

- relevant experience of the condition
- an understanding of the issues that matter to people with that condition
- the ability to reflect and advocate on the experiences of a wide group of people living with the condition gained from contact with people through patient organisations, forums or self-help groups
- the time and commitment to attend the meetings and complete associated work
- good communication and teamworking skills
- a commitment to maintain confidentiality
- declaration of interests, such as receiving funds from pharmaceutical companies.

Recruitment of patient and public members

Successful recruitment strategies are key to recruiting appropriate people with different skills and experiences (Boivin et al. 2010). Research suggests that a barrier to recruitment for clinical guideline developers is not having the resources to implement recruitment strategies (Armstrong and Bloom 2017b). Therefore, this section provides advice on a range of recruitment methods, some of which are cost neutral.

Nomination and open recruitment

There are 2 key methods of recruitment: open recruitment and nomination. In open recruitment, guideline developers advertise the post using the role and person specification. Applications are reviewed against criteria and the developer is responsible for selecting people who meet the criteria. Nomination is used when

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developers approach patient organisations to nominate someone who, in their opinion, can reflect and understand patient or public issues relevant to the guideline. With nomination, the patient organisation is responsible for recruiting and the developer should not have any input. It is possible to combine elements of both approaches, but whatever method is selected it should be an accepted, transparent, and justifiable approach that can be documented.

Advantages and disadvantages of each method

Each method has advantages and disadvantages to consider when deciding which to use. These are outlined in table 1. In summary, open recruitment enables a wider range of people to become involved and is transparent. It helps minimise bias by allowing developers to choose between people from different geographical locations, treatment centres, and groups in society. However, it can increase bias if the developer chooses people who appear to be more ‘compatible’ with the interests or culture of the guideline group. To help avoid that bias, involve a suitable person external to the guideline team in the selection and ratification process, such as a patient involvement specialist. Open recruitment can be costly in terms of human resources and time compared with nomination. Timescales should account for developing recruitment criteria, administering the recruitment process, and reviewing applications. Templates of application forms and person specifications can help speed up the process.

Alternatively, nomination is rapid but can narrow the pool of potential candidates. To prevent this, a predefined nomination process should be outlined from the outset and strategies should be implemented to ensure people are nominated from a broad pool of candidates. Sometimes patients and public members recruited from patient organisations can pursue their organisation’s agenda. This should be prevented through induction and training that emphasises that the individual is to represent their experiences and those of others living with the condition.

If developers choose nomination as a method, they need to consider how this might affect the status of the individual within the group if the professional members had to compete to ‘earn’ their place. Conversely, if health professionals are nominated there may be no perceived unfairness. Open recruitment can increase patient and public members’ confidence by knowing that they were selected from a pool of applicants.

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Regardless of the method selected, the way in which it was implemented needs to be documented and transparent.

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Table 1 Advantages and disadvantages of open and nomination recruitment methods

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-	Open recruitment	Nomination
Advantages	• Attracts a wider range of people • Reduces bias by recruiting people who are unknown to rest of guideline development group, which lowers the chance of people agreeing with group in fear of disagreeing with their own doctor • Phone interviewing shortlisted applicants helps screen out people with narrow perspectives and those who cannot reflect on broader patient issues. Advice from a patient and public involvement specialist can be helpful in eliminating unsuitable applicants • Attracts people with broader perspectives • Transparent - can answer questions about why certain people were recruited and demonstrate where procedures have followed equality legislation	• Less resource demanding • The guideline developer has no influence on the choice of the group members and so no risk of influencing group composition through selective recruitment • Could increase the chance of recruiting individuals who you might not have considered because of the joint expertise of patient organisations and people with specific aspects of a disease • In most cases, patients nominated by a patient organisation are trained in championing patient perspectives • Can be faster than open recruitment although it depends on how long it takes the patient organisation to respond • Can recruit patients with a background in user-led research or known ability to work well in groups • Assures that patient organisations decide themselves who is best to provide their perspective (respects patient autonomy) • May facilitate reaching specific seldom heard groups, especially if there are barriers to patients or public engagement

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-	Open recruitment	Nomination
Disadvantages	• Time consuming • Costs of advertising, if paying for advertising to be placed • Costs of preparing and processing paperwork and applications • Risk of biased choice, that is, a risk that the guideline developer actively influences group composition in a way that 'easy to handle' patients are recruited • Needs rigorous and transparent documentation of the selection process to avoid risk of bias or being selective • If relying on patient organisations to circulate the advert, this could be perceived as nomination • Risks of failed recruitment - if the condition is rare or the affected population is less likely to use recruitment channels like the internet • Ethical concerns if organisations persuade a vulnerable person to apply and they are unsuccessful	• Risk of missing people with a very unique expertise and experience • When nominating from patient organisations, there is a risk of recruiting people with biased perspectives, such as those who have only had negative experiences of healthcare systems • Can exclude patients who have not had experience of similar work, but might still be able to make valuable contributions • May introduce bias. In some countries, nominated members from patient organisations could be associated with teaching hospitals, pharmaceutical companies or campaign organisations, and have different experiences from those in rural areas or general clinics • Risk of narrow patient perspectives if patients with a background in lobbying on one aspect of a condition are nominated • For some guideline topics (for example, rare conditions or symptom-based topics) there may not be any relevant patient organisations who can nominate patients • Some patient organisations may not have the capacity to identify appropriate nominees

Selection of methods in practice

The method to choose will depend on the developer's requirements and resources. Local circumstances may dictate which approach would work best. For example, in

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countries with well-resourced or well-developed patient organisations, the nomination process can work well (especially for main condition areas like cancer). Open recruitment works well for well-resourced guideline development agencies with specialist patient or public involvement support (like NICE).

NICE uses open recruitment and has found that it leads to a range of individuals applying for the role, including many who are not associated with patient organisations. NICE advertises positions for patients and public members for 4 weeks thereby allowing patient organisations time to contact their members and for the advertisement to get maximum exposure through websites and other social networks.

The Dutch Institute for Healthcare Improvement (CBO) in the Netherlands, the German ÄZQ and SIGN in Scotland, recruit primarily through umbrella patient organisations, such as The Richmond Group of Charities or National Voices in the UK. The ÄZQ uses a predefined nomination method, which is outlined in detail in their manual (Sänger, 2008). It recruits from 4 umbrella organisations to ensure people are nominated from a broad pool of candidates. ÄZQ asks them to select all the patient organisations they think are appropriate for the condition in question, and then have a discussion with every organisation about the patients they want to nominate. This results in a list of members for the guideline development group for the developer, who then starts training and support for them. During the initial meeting, the guideline group is asked if there any expertise is missing from the group and the developer then seeks to fill any gaps in experience.

Advertising the role

Open recruitment works best when patient organisations, or healthcare professional organisations with public involvement functions, can inform their members of the vacancy by promoting it on their websites, through social media, email distribution or newsletters. Patient organisations can also provide advice on how to recruit people from seldom heard groups.

Healthcare professionals in the development group may also be able to support recruitment, either by advertising the opportunity through their networks or by nominating a patient. However, this can increase the likelihood of recruiting a patient

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or public member who is treated by the same health professional on the panel. This should be avoided because it can prevent the patient from speaking freely during discussions.

If using social media to advertise, developers can reach a larger audience who are invested in the guidance topic by 'tagging' relevant patient organisations in any social media posts. Developers can engage seldom heard groups, such as black, Asian, and minority ethnic groups (BAME), on Twitter, Facebook or patient forums. Permission should be obtained before sharing any opportunities. Starting online conversations with public members who express interest in the recruitment opportunity can increase applications by addressing any concerns or queries that arise. This approach is relatively cost effective although time is required to build online relationships with the public. Not everyone has easy access to the internet, so additional methods of publicising the vacancy should still be used to reduce inequalities in the recruitment process. If seldom heard groups are not active on one form of social media (for example, Twitter) then they might be more active on another channel, such as Facebook. If not, it will be difficult to engage them through this means.

When advertising the role, state explicitly the kinds of support that individuals can receive to encourage more people to apply. This should be realistic and deliverable in practice. The section on supporting individual patient and public members describes the types of support that can be provided.

Documents for recruitment

It is helpful to publish the role and person specification (in both open and nomination recruitment methods), either as a detailed advertisement or as additional information to help applicants decide if they are suitable for the role. The application or nomination form should be well structured, which will make it easier for people to provide the relevant information. NICE also includes an equality monitoring form for applicants in line with the UK's Equality Act (2010). Guidance on this act can be found in the further reading section. The form collects personal information, such as age and gender, and can be used to evaluate and review the diversity of membership. The form is processed separately from the main application form to ensure anonymity.

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To enable people with various disabilities to apply (for example, people with sight impairment), developers need to consider the accessibility of their information, such as ensuring documents can be read using a screen reader. Guideline developers should check government or organisation guidelines on accessibility for further information.

Interviewing candidates after open recruitment

Interviewing candidates after open recruitment can help overcome some of the known barriers to effective patient and public involvement. These include concerns over skills, breadth of experience and the ability to reflect on experience, objectively review the evidence, or work critically within a group. People who have had only negative experiences of care, or people who are opposed to the methodology behind evidence-based care, may not be appropriate candidates. Developers should consider how to interview people with specific health conditions or disabilities, or those who work full time. Interviewing over the phone or by video conference (for example, Skype or Zoom) are useful alternatives if some people cannot attend face-to-face interviews. Group interviews might also help assess communication and group working skills.

Making the appointment

Successful candidates should be notified in writing. Consider whether they should complete a declaration of interests form, to identify possible conflicts, and a contract. Some organisations designate alternate members at the interview stage in case the appointed member has a change in circumstance and cannot take up the role. But, in some cases, it may be better to re-advertise or get new nominations.

It is also important to ensure the recruitment process is fair and to document the process, including the reasons for who to recruit, to avoid any potential accusations about discriminatory practices. Unsuccessful candidates can be offered other involvement opportunities, such as being a peer reviewer. Candidates should have a named contact and details, so the developers know who contact for further information or to discuss the outcome of their application or interview.

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Supporting individual patient and public members

Appropriate and adequate support strategies play a large part in overcoming barriers and facilitating effective patient and public engagement during guideline development. According to Armstrong et al (2017a), these include:

- practical support (for example, making reasonable adjustments to support people who are ill or disabled)
- informal support (for example, listening, advice and emotional support)
- financial compensation
- co-learning and training
- managing group dynamics
- enabling re-assessment and feedback on the patient or public member's role.

Practical support

Qualitative research suggests that practical support can consist of providing multiple shorter meetings instead of full-day meetings, providing the premeeting papers in good time before a meeting, providing physical resources (for example, paper versions of documents), and agreeing mechanisms for soliciting opinions (Armstrong et al. 2017a). However, individuals might have various practical support needs associated with their work and provision should be made for 'reasonable adjustments' to respect those needs. This might include changes to the physical environment for the group's meetings (for example, accessibility of the rooms). How meetings are conducted should be considered (for example, with a hearing loop induction system or chairing techniques in a virtual meeting), and the communication used in the group (for example, avoiding jargon and titles such as doctor, explaining medical and research terms, and agreeing appropriate communication channels, such as email). The length of meetings might need to be altered, and breaks added, if a person's condition affcets their level of concentration (such as those with pain or some mental health conditions). Catering requirements should also be considered for those with diabetes or other conditions affected by diet. If conducting virtual meetings by tele- or video-conferencing, provide regular breaks.

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When to assess support needs

Patient and public members should have the opportunity to discuss their practical support needs at interview, on appointment, and throughout their role. This is because many physical and mental health conditions fluctuate, and additional needs might arise during guideline development. In some countries, the laws on disability discrimination or equality cover the provision of aspects of practical support. For example, the Accessibility for Ontarians with Disabilities Act (Thompson 2020) in Ontario outlines and enforces accessibility standards that developers would need to follow to remove barriers. This could include providing accessible formats on request.

Practical support examples

There are many examples of practical support for guideline developers to consider and include (but are not limited to):

- Making adjustments for people with sensory impairments, like providing large print documents, microphones in meetings, or a hearing induction loop system. An interpreter could attend guideline meetings to assist members who have hearing loss.
- Offering the chance to participate virtually by video call (for people with high-grade conditions that prevent them from leaving home, like late stage heart failure, or individuals who cannot attend a meeting in person).
- Providing hints and tips on having an effect in virtual meetings, such as keeping oneself on mute when not speaking and methods to get the chair's attention.
- Booking meeting rooms large enough for an electric wheelchair or other medical devices and stair-free access.
- Making adjustments for people who experience fatigue, such as longer breaks or having a room available in which people can rest.
- Adjusting the room lighting or lighting of screens, such as illumination levels, glare and direction.
- Providing chairs that meet the needs of individuals with musculoskeletal conditions.
- Creating a 'break out' room for young people, or anyone, to take a break if they find the meeting too emotional (for example, when discussing sensitive topics).

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- Providing documents on coloured paper for people who have an autism spectrum condition or those with dyslexia. Also, providing documents in plain language, or at very low-level language and offering support to explain these for people with low literacy or numeracy.
- Providing a dedicated toilet for people who need one.
- Providing financial support for care for a dependent relative if a carer has been recruited, or for childcare if someone has children.
- Providing financial information to ensure any payments do not adversely affect individual's state benefits.
- Ensuring any food provided meet people's dietary requirements.
- Texting a person with dementia or with memory problems half an hour before a pre-arranged telephone conversation or to remind them that support is available.
- Having a neutral support person (to minimise bias) highlight the most important sections of papers to read or comment on, or ask them specific questions with a patient or public focus.

For some topics, a patient organisation could offer practical support to individuals. For example, for the NICE guideline on tuberculosis (TB) among under-represented groups (NG33; NICE 2019), members who had experienced TB were involved and received additional practical support from a homeless charity. This included use of a permanent address for communications because they lived in temporary homeless shelters, and access to a computer for communications between meetings.

Valuing members

Patients and public members largely volunteer their time to be involved in guideline development activities so their time, effort and value should be acknowledged. At a G-I-N PUBLIC workshop, patients collectively stated that being welcomed and respected for their dedication was more important than financial compensation for their time. However, taking part in guideline development for some people can mean taking unpaid time off work or can incur costs. The advantages of offering compensation outlined by INVOLVE (2011) include:

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- Supporting equity of access, by compensating people for lost income if they must take time off work or arrange childcare, travelling costs, access to journals and technology, access to care or personal assistants and so on.
- Supporting equity of power in groups.
- Acknowledging the professionalism and contributions to public service of group members.

Types of compensation

As a minimum, G-I-N PUBLIC recommends providing expenses, such as travel costs or accommodation, and providing compensation for time and effort. Compensation might also cover carer or childcare responsibilities and should be fair and appropriate for their role. Compensation could be provided in other cases, such as for attending training events or other preparation work. Payment in kind, such as vouchers, can also be offered. This is likely to be governed by local and national policies. Whatever the type of compensation, developers should be transparent during recruitment about any compensation arrangements.

Lack of budget

Some organisations may rely on volunteers to conduct patient involvement. In this case, be clear in recruitment documents that volunteers are needed. A lack of funds to cover payment or reimbursement of expenses may affect the ability to recruit people, especially those from a lower socio-economic background. In rare cases, patient organisations may offer support. There may be policies or laws that govern unpaid work so check the local context.

Consideration for those receiving state benefits

In some cases, receiving a payment will qualify as paid work and could cancel any state benefits (unemployment or disability payments) received. Furthermore, payments may qualify as taxable income, which can affect members who are self-employed. In this case, expenses (for example, train tickets and accommodation) should be booked by the organisation and paid from organisational budgets, which should avoid the individual being taxed. There may be an organisation in your country who can advise on this. If so, get their advice before the recruitment stage so that enquiries from potential applicants can be answered.

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Compensation in practice

NICE's lay member payments and expenses provides an attendance fee for patient and public members that covers either a half-day or full-day rate (2020a). Travel, subsistence expenses, accommodation costs and contributions to carer costs (for example, childcare or carer arrangements) are covered. NICE will book and pay for any such expenses so that the members are not out of pocket while they wait for reimbursement. If the member is an employee from a patient organisation, then it is possible to reimburse or pay the attendance fee to their organisation rather than the individual.

Informal support

Informal support might consist of emotional support and building trust and rapport, which can make someone feel welcome in their role. The amount of informal support someone might need will vary so it will need to be tailored to the individual. Some individuals might have a strong background in patient advocacy, committee work and decision making, whereas other people might find guideline development group work a completely new experience.

Methods of informal support

Examples of informal support include:

- Providing individuals with a key contact person who can help if they need further information or encounter any difficulties, either with practicalities or with the personal effect of working in a group.
- Offering to contact a 'peer group' of other patients who have been involved in previous guideline panels. Additionally, developers can offer contact with a one-to-one 'buddy', who is an experienced patient or public member at your institution. It is usually advisable to have someone who is not another member of the same guideline development group. Another contact could be a guideline project manager.
- Contacting each individual before the group's first meeting. This will provide an opportunity to address any questions about the first meeting and assess any additional practical or informal support needs for the meeting. It is useful for a key

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contact person to introduce individuals to both the guideline group and the supporting staff.

- Following up each individual after the group's first meeting and any other key meetings. This will provide an opportunity to receive feedback of their experience and identify if anything can be improved for the next meeting.
- Making additional check-in calls or sending emails can be useful for specific tasks (for example, reviewing materials) to find out if any supports are needed.

Managing emotional impact

Taking part in a guideline development group can have an emotional impact for some individuals. They might become frustrated if they feel their ideas are not fairly considered, or they can become upset when the group discusses sensitive issues, for example. It is important that individuals discuss any difficulty they have early on. Guideline developers should make it clear that that these are normal reactions, not unprofessional, and they should identify any support networks and coping strategies if the need arises. If left unresolved, it could lead to patient members stepping down from the guideline group.

Informal support in practice

To provide informal support, NICE in England and the ÄZQ in Germany provide a key contact person for patient and public members, so that they know who to contact for support or to discuss any issues that arise. At NICE, the key person will contact the patient member before the first group meeting and this is an opportunity to confirm any additional support needs. They will also greet the member at the first meeting. After that, the key person makes contact by email after the first and second meeting and then every 3 months (for shorter guidelines) or 6 months by phone or email. NICE also provides the opportunity for new members to meet existing experienced patient and public members, either face-to-face or virtually, to discuss the guideline development process and their role. Individuals are also able to contact their key person at any point. Similarly, SIGN offers a buddy who can provide support on a one-off basis or throughout the guideline development process (SIGN 2019).

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Sometimes patient organisations or support groups can provide informal support, particularly for specialist groups. For example, when working with migrant groups, the ÄZQ works with migrant interest groups who could help or give support for certain conditions when possible, such as diabetes.

It is also particularly important to develop trust and rapport with certain groups and this can involve considering specific cultural norms and traditions. In Canada, when working with indigenous populations, RNAOs integrate traditional cultural ceremonies or practices, such as sharing a gift of traditional tobacco or smudging, into guideline development processes. Providing culturally relevant support demonstrates respectful engagement and can establish trust and rapport between the individuals with lived experiences and the developers.

Training and co-learning

A barrier to patient engagement is the concern over whether the patient or public member has the skills and knowledge associated with research and group working to participate effectively in the guideline development process (Armstrong et al. 2017). As previously discussed, it is not necessary or advisable to only recruit individuals who have existing research and technical skills. Furthermore, patient members fear that professional members will dominate the meeting with their knowledge and ideas (Shippee et al. 2015). Training and co-learning are useful strategies to overcome such barriers and can increase patient confidence by encouraging capacity building, which is a fundamental principle of patient and public involvement. However, there are also concerns that too much training may result in ‘professional’ patients who no longer bring their individual experience. Even basic training in evidence-based medicine can automatically exclude people with low numeracy skills. Therefore, training should be tailored to the needs of everyone. An explanation of the difference between training and co-learning follows.

Training

Training should improve members’ confidence about their roles and how to make an impact in the guideline development process. Training is more formal than co-learning and can consist of 1 or more days of structured learning with specific

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learning outcomes related to patient and public involvement in guideline development.

Training can include different topics, including:

- guideline development processes
- research methods and terminology
- technical skills
- critical appraisal skills
- specific guideline development knowledge (for example, GRADE)
- strategies for participating effectively in the group (for example, assertiveness)
- building positive working relationships
- managing group dynamics.

There are different formats for delivering training. It can be provided in-house, by an external organisation, patient organisation or international society (for example, the European Lung Foundation), or be self-directed (for example, online training). Large organisations might be better equipped to provide their own training either face-to-face or electronically, which might not be possible in smaller organisations. Organisations may choose to use external training events or courses covering research and critical appraisal skills. If neither internal nor external organisations can offer training, free online resources to support self-directed learning exist. Several organisations offer free online courses to patients and members of the public, including Cochrane and CUE – Consumer's United for Evidence-based healthcare. A list of courses and websites offering free training can be found in resource file 2.

Co-learning

One fundamental principle of effective patient and public involvement is co-learning (Nguyen et al. 2020). Co-learning differs from training because it is mainly informal and is an ongoing process that should occur throughout the entire guideline development process. It is the process by which patient and public members, professional members and the guideline developer team teach, learn and share research knowledge and skills together. The process also benefits professional members. There are several ways to encourage co-learning:

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- Providing training on guideline methods and processes, research strategies and overviews of the evidence retrieved from a review at the start of a meeting. This could be in the form of a presentation or verbal description by the technical team to the whole group, with an opportunity for the group to discuss their understanding. Presentations or learning resources can also be sent before the meeting when appropriate.
- Providing an online repository for all documents and sections for different working groups, which might include a specific section for patient group members.
- Avoiding jargon, explaining technical terms in the meeting, and having a glossary of medical, or guideline-related definitions and acronyms. Professional members should be aware that it is also their responsibility to explain medical acronyms and terms. Different professional groups may have different terms for the same concept or use the same term, but with a different meaning.
- Providing resources, in the form of toolkits or a ‘hints and tips’ document that informs the individuals about their role, the processes and resources to support their work.
- Holding lay-friendly seminars on specific topics, such as health economics.
- Offering networking opportunities with other patient and public members, which can be face-to-face or through an online forum.
- Providing free access to online journals.
- Providing regular contact with a key contact person to discuss ideas and any issues.
- Providing feedback on performance to encourage learning and development.

Co-learning is a valuable process to consider, especially if your organisation cannot offer formal training. Networking opportunities can be provided either before the start of a group or during development in the form of a lunch, an event, a workshop or by providing people with contact details for other patient and public members. New members can meet more experienced patient members and discuss the guideline development process or how to contribute effectively. During development, the patient and public members may be willing to support each other by sharing contact details but local data protection rules need to be followed and details should not be shared without permission.

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Training and co-learning in practice

NICE provides a formal full-day training event (either face-to-face or virtually through Zoom) for new patient and public members, including presentations and group exercises covering the following: research terminology, the guideline development process, critically appraising scientific research using the GRADE system, group working and skills, producing recommendations, and a chance to learn from experienced patient and public members. Similarly, the ÄZQ initially assesses patient and public member's training needs and provides them with reading materials, such as 'testing treatments' (Evans et al. 2011). If required, ÄZQ offers a full-training day, or shorter units, tailored to their training needs. Digital modules are also provided using software such as Microsoft PowerPoint with audio narrations.

In terms of co-learning, NICE's Public Involvement team delivers a presentation on patient and public involvement at the first group meeting. The developer team provides brief training on the guideline development process, the roles and responsibilities of staff, and health economics. Any learning materials are sent to members before meetings. Technical or research leads are available to answer any questions from all group members. Patient or public members are provided with a paper or digital toolkit of resources and information for working effectively. They are also given the chance to meet an experienced lay member before the start of some guidelines. Their key contact person will also provide knowledge, by telephone or email, on the various stages including consultation, publication, and action to support guideline implementation.

Re-assessment and feedback

Another strategy for enhancing co-development is through re-assessment of the roles and expectations and providing feedback on the patient and public members' performance throughout guideline development (Shippee et al. 2015). This process can identify areas for development, which can be addressed through further training and co-learning. It can also help to address barriers associated with performance, such as not contributing or attending, or advocating their own agenda, which undermines the guideline. The process can also highlight the need for additional practical support strategies and areas where the member is having the most impact.

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Providing feedback can ensure continual upskilling of the participants and is important to ensure meaningful and valuable involvement throughout the development process. For those with limited committee experience, it can increase confidence by confirming they are fulfilling the role to an acceptable standard and contributing effectively. Furthermore, it can ensure that the members feel supported and valued, which enhances engagement by empowering the individual. For some guidance programmes at NICE that are longer than 1 year, assessment of the role and feedback is provided every 6 months during telephone check-ins, or yearly for more formal feedback by the group's chair.

Managing group dynamics

There is a large body of psychological and sociological literature on how groups form and behave, including the factors that create productive groups and the effects of power dynamics and status on the productivity of groups (for example, Forsyth, 2019). Power dynamics can occur as a result of age, gender, race, culture and socio-economic status, which largely operate at the unconscious level through stereotypes (for example, as discussed in Guinote and Vescio 2010). There are many useful texts focusing on this topic, which go beyond the scope of this chapter, some of which are listed in the section on further reading.

Understanding group dynamics is important and can help guideline development groups operate effectively and ensure that patient and public members' insight is included. This responsibility largely lies with the chair or moderator of the group and some useful general strategies are:

- Highlight the importance of patient and public involvement: Consider delivering an early presentation to the guideline development group on the importance of patient and public involvement. Stress that these members have equal status with valuable contributions and provide examples of where patient and public members have had an impact on previous guidelines.
- Chair training: Brief the chair to discourage the use of medical and other jargon in meetings, which can exclude patients. Ensure they have the skills for running effective and inclusive meetings and understand the importance of meaningful patient or public involvement (see the chapter on how the chair can facilitate

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patient and public involvement). At NICE, chairs are assigned to topics in which they have no professional experience so that they remain objective and limit bias, rather than trying to contribute their own opinions.

- Management of the meeting: Patient and public members should not be seated in an isolated area of the meeting and should be able to get the chair's attention. The chair should be briefed to bring the patient and public member into conversations, and some groups find it helpful to have a specific agenda item on patient and public matters associated with the guideline.
- Relationship building: Encourage individuals to identify potential allies in the group who can be a source of support for patient and public members during meetings. Alternative methods should be considered if meetings are conducted virtually when individuals need to connect by email, telephone and other digital means of communication.

The upcoming chapter on how the chair can facilitate patient and public involvement has further information on this topic. It is important to reassure patient and public members that their experience may differ from other patients and public members. Confirm that this difference of opinion is encouraged, and they should share this with the guideline group.

Overcoming barriers to involving those who are seldom heard

Throughout this chapter, we have highlighted several generic barriers and facilitators that guideline developers can take into account when recruiting and encouraging meaningful involvement of patient and public members in guideline development. These barriers and facilitators are summarised in table 2. Although these can apply to all patient and public members, including those who are seldom heard, there are specific barriers and facilitators to be considered when guideline developers cannot recruit patient and public members or when specific groups of people might have very specific support needs because of:

- age, such as babies and children
- circumstance, such as those living in prisons and other secure settings, or

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- condition, such as people with learning (developmental) disabilities, or severe and complex mental or physical health conditions.

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Table 2 Summary of generic barriers and facilitators for recruiting and promoting effective patient and public involvement in guideline development

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Barrier	Facilitator
Developer unclear of recruitment strategy in terms of the number or type of patient or public members to recruit to achieve genuine representation	Consider open recruitment as opposed to nomination methods, including where to advertise. Recruit through patient organisations and social media (for example, Twitter, Facebook and other online patient or support forums). Recruit at least 2 patient or public members who might be patients, carers, parents or advocates from patient organisations. The organisations should represent a breadth of views and experiences associated with the guideline and other important socio-demographic (for example, age range) factors. Re-advertise the position if there are no suitable applicants. Consider other involvement methods.
Developer or patient or public member unclear of their role in guideline development	Plan the role and associated tasks early in the planning phase. Develop and advertise a role description and person specification. Consider patient demographics and characteristics. Provide induction materials and discuss the role requirements before the first group meeting.
Scheduling and planning, such as meetings clashing with personal commitments	Ensure meeting dates are planned and shared with all guideline group members in advance of the first meeting. This will allow patient and public members to plan and arrange any necessary time off work or childcare arrangement, for example. Any changes to meeting dates must be communicated and agreed with all group members and communicated as soon as possible.
Lack of relevance of the scope to patient and public members	Involve patient or public members early in guideline development and invite them to smaller scoping groups. If this is not feasible, then involve a patient advocate from a patient organisation to represent the views of patient and public members in scoping discussions.
Gaining meaningful involvement or avoiding tokenism	Interview applicants to ensure they have the right skills and experience and recruit early so they can contribute to the topic prioritisation or scope development stage. For meaningful engagement, include members in strategic decision making (for example, in developing the scope), development of decision aids, or implementation strategies.
Patient and public member not respected, not seen as equal, or feeling devalued	Make certain that the group's chair understands group dynamics and ensures equal power balance, including a right to vote to reach consensus and providing feedback on patient contributions. Include a specific slot for patient and public members to provide input during discussions. Encourage relationship building between patient and public members on the same group or with health professionals to build allies.
Achieving a breadth of perspective	Recruit members according to their personal experience of guideline topic, wider understanding of patient issues from patient networks or support groups, and soft skills (for example, communication skills).

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Barrier	Facilitator
Recruitment can be resource intensive or costly	Use nomination as a recruitment strategy through patient organisations, if possible. Use social media to advertise.
Lack of methodological expertise, skills or knowledge related to guideline development	Deliver or signpost to relevant training (for example, research methods and critical appraisal skills) and consider ongoing co-learning (for example, presentations in meetings) or regular feedback on performance.
Lack of confidence to speak up in a large group of experts	Consider including hints and tips in induction materials, training, and also in catch-up calls with a patient and public involvement specialist, or key support person. Peer support from other patient and public members from previous or different guideline groups can help.
Supporting people with a range of practical support needs	Assess support needs early in the recruitment phase and continue to re-assess throughout guideline development. Make reasonable adjustments and offer practical and informal support through. During development, conduct regular check-ins (by email, phone or video call) to identify issues or to assess ongoing support needs.
Lacking peer support	Recruit more than 1 patient and public member. Offer a 'buddy' or a chance to meet or talk to someone from a previous or different guideline group to discuss the role and any issues at the beginning and throughout guideline development.
Limited funds to re-imburse members	Consider vouchers (gift in kind), offer free training to upskill members to improve their curriculum vitae. If possible, pay travel expenses or offer virtual participation in meetings (for example, using video-conferences or tele-conferences).

The remainder of the chapter will discuss alternative approaches to involvement and specific considerations for different groups who are seldom heard, such as children or people with learning disabilities.

Alternative approaches

Specific groups of people might not be able to be full members of the guideline development group (for example, children or people with advanced dementia). In addition to involving parents, carers and advocates, there are alternative approaches to involving people with the condition or from the affected population. These include a reference group, additional sources of data on patient and public views, patient expert testimony, consultation using research methods.

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Reference groups

A reference group in this context, is a group of people who use the relevant services or experience a particular condition. They can help the guideline group identify patients' perspectives and priorities at key stages of guideline development. Reference groups have the advantage of generating a wider range of patient and carer views by including people with different experiences of the condition, treatment and care, or people from a specific socio-demographic background. For example, for the NICE guideline on child abuse and neglect (NG76; 2017), the developer commissioned an independent charity to recruit and facilitate a reference group to inform the guideline group's deliberations and development of recommendations (Fielding et al. 2018). If considering involving a reference group, guideline developers should carefully plan the work including:

- the objectives
- involvement methods
- time and costs
- travel arrangements and incentives or reward for participation
- demographics and other characteristics or experiences of the group
- ethical issues, such as safeguarding
- methods for presenting findings to the guideline development group.

The work of the reference group should be facilitated by people with expertise in facilitation and a track record in working with the group of interest.

Additional sources of data on patient and public views

In addition to using peer-reviewed literature, guideline developers may find relevant information on patient and public views and experiences in surveys conducted by stakeholder organisations. SIGN, in Scotland will contact relevant patient organisations and charities before starting the development of a guideline (SIGN, 2019). They are asked for their views on the important issues that they think the guideline should focus on. Their input on these issues could be based on data gathered through surveys or telephone helpline experience.

Patient and the public views and experiences can also be found on patient forums or patient-focused websites. For example, a UK-based reputable website, HealthTalk,

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covers many health conditions or groups, such as young people. It is informed by the Health Experiences Research Group at Oxford University's Department of Primary Care. The team uses rigorous qualitative research methods to capture the full range of patients' experiences associated with each health issue, condition, or intervention. Similar websites exist in other countries (for further information, see the section on consulting patient and public members using online engagement methods in the chapter on how to conduct public and targeted consultation).

Patient and public expert testimony

When there are gaps in the patient and public evidence, an alternative option is getting such evidence from the expert testimony of people in the affected population (in person, in writing or by video). Such expert testimony may be sought one or more times during guideline development because the need for expert testimony may only become apparent later in the process. It is important to support the individual providing the testimony. Support should include giving them information about the guideline group and what information is required, and preparing them for questions they may receive. Stakeholder organisations may also be able to support people providing a testimony. At NICE there is no minimum age for people providing expert testimony, but if they are under 16 years, or a vulnerable adult, they must be accompanied by an appropriate adult with responsibility for their welfare. When children or vulnerable adults contribute evidence to meetings, the testimony might need to be given through a video-recording or in a closed, confidential session if meetings are usually held in public.

Consultation using research methods

When important gaps in the evidence are unlikely to be filled through consultation with stakeholder organisations or using any of the above approaches, some guideline developers may consider consulting the affected population using research techniques. This is an exceptional option requiring additional resources. Types of methods and when to use research methods for consultation have been covered in detail in the chapter on how to conduct public and targeted consultation.

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Involving people who are seldom heard in guideline development

Developers are likely to produce guidelines for a range of topics where the barriers to involvement can be greater for certain people. This section considers 3 groups of people: children and young people, people with learning disabilities, and people with severe and complex mental health conditions.

Children and young people

The UN Convention on the Rights of the Child (UNICEF 2016) enshrines the rights of children to be involved in decisions that affect their lives and to be heard. In the UK, health researchers, policy makers and services have increasingly engaged children and young people in matters that affect their health and wellbeing. Qualitative research indicates that children can provide their views, including those who are less articulate because of age, ability or culture. It also suggests that most children are acutely aware of the way in which they are treated, and their perceptions do not mirror those of adults (Doorbar et al. 1999). However, guideline developers find involving children and young people difficult and have several questions concerning when and how to involve children and young people (Schalkers et al. 2017). Some strategies for addressing common questions follow.

When should children be included in guideline development?

There is consensus that developers should seek the views of children and young people when the guideline specifically looks at a condition that affects this group or when the treatment or disease affects children differently compared with adults (Schalkers et al. 2017). It is likely that their views and experiences will differ from adults around symptoms, treatments, side effects, recovery, and care. An addendum to guidance for adults could suffice if the experience of the disease for children does not differ that much from adults.

Developers may need to prioritise involving children and young people in certain guidelines over others. Schalkers et al (2017) list 14 criteria for supporting this decision, with the top 3 criteria being when:

- there is a clear expected health benefit for children
- professionals identify that guidance is needed for children

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- there is difference of opinion between professionals around the treatment of children.

The criteria that are least important in deciding whether to involve children are when the disease has high expected healthcare costs, the lack of availability of scientific evidence, and when the focus is on pharmacological treatments.

What is the minimum age of children for involvement in guideline development?

Developers can be concerned about the ability and competence of a child or young person to be able to understand, contribute to and engage in decision making. The UN Convention on the Rights of the Child defines a child as a person under 18 years (UNICEF 2016), as does UK child protection legislation. In the UK, a child is deemed competent to decide about their treatment without parental or guardian consent from 16 years. This is the minimum age for a young person to join a NICE guideline development group without being accompanied by an appropriate adult. However, mental capacity should be considered. Some young people aged 16 and over might have a specific vulnerability, such as a learning (developmental) disability, and would need to be accompanied by an appropriate adult. But a child under 16 years, who does not have a specific vulnerability, might demonstrate sufficient mental capacity, known as Gillick competence, and be able to contribute to decision making.

Qualitative health research has demonstrated that children as young as 6 can share their views and provide useful information (Gibson 2007). However, young children would be unable to participate in a guideline development group and additional approaches to elicit their views would be needed, such as focus groups or reference groups. There may be country-specific age thresholds and so developers should consider local legislation and policies on children and young people, and their mental capacity.

Should a parent or primary caregiver provide the views of children?

One debate that could arise is whether parents or caregivers should provide the views of the child younger than 16 years. At NICE, an appropriate adult would likely need to be involved in a guideline group if the child is under 16 years. Although NICE acknowledges that parents and carers can bring valuable insights, they should not

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be regarded as a proxy for children. If guideline developers have the available resources, it is useful to work with a specialist external organisation, or a stakeholder organisation, with expertise and access to appropriate networks to elicit views from children.

How do you recruit children and young people?

Strategies outlined in this chapter also apply here, particularly working with relevant patient organisations, charities or other voluntary and community organisations for children and young people. Advertising on social media can also be useful for parents to identify the involvement opportunity for themselves and their child.

How do you involve children and young people and what approaches can be used to elicit their views?

NICE has developed a systematic approach, outlined in the NICE manual for developing guidelines, to ensuring that the views of children and young people are included in guideline development for relevant topics (NICE 2020b). The approach also includes involving parents or other family members. There is much research in the social sciences on how to elicit the views from people of different age groups, and it highlights the need for age-appropriate techniques (see Gibson 2007). But it is likely that for working with young and very young children, specialist input and training from an external organisation will be needed. Some general strategies to consider when involving children and young people aged 16 to 25 years are:

- Involve children and young people in a meaningful way, setting out clear objectives and working with sensitivity and flexibility, especially if the topic is sensitive.
- Consider measures for protecting the safety and welfare of children, including following local ‘safeguarding’ policies.
- Make adaptations, such as providing age-appropriate training, ensuring the chair asks specific questions or provides opportunities to contribute during meetings, and allowing regular breaks.

SIGN involved children and young people in the development of its guideline on diagnosis and management of epilepsies in children and young people. Two young people were full members of the guideline development group. Young people,

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associated with Epilepsy Scotland, engaged in an interactive session to discuss the issues identified from a patient-focused literature search. They explored what the additional priorities were for them and whether there were any other issues that the guideline group should consider. For further information, the Royal College of Paediatrics and Child Health provides guidance on how to involve children and young people in committees (2018; see the section on further reading).

People with learning disabilities

People with learning disabilities and their carers are increasingly being involved in guideline development groups (Caldwell et al. 2008). Although it is important to follow the guidance in the sections on the role of patient and public members, their recruitment, and supporting individual patient and public members, guideline developers must consider very specific reasonable adjustments to meetings and practical support to encourage meaningful involvement. Table 3 lists several considerations and adjustments that have been documented in the literature and implemented in NICE guidelines on learning disabilities (Caldwell et al. 2008; Karpusheff et al. 2020). There is no exhaustive list of strategies, but they can be categorised into accessibility of meetings, communication adjustments, environmental adjustments, financial support, and transportation.

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Table 3 List of reasonable adjustments for supporting people with learning disabilities

Category	Adjustment strategy
Meeting accessibility	• Provide physically accessible meeting locations • Be aware of the pace of the meeting – not too fast • Provide opportunities for discussions and questions • Ensure members with learning disabilities have had the opportunity to give input by asking them what they think and making them feel comfortable to talk • Provide meeting papers a few days in advance of the meeting • Prepare the individual about the topic of meeting discussions in advance of the meeting
Communication adjustments	• Consider whether sign language interpreters are needed, as well as closed captioning services and amplified hearing devices • Create easy read versions of meeting documents, including large print, or use braille or disk formats. Avoid jargon and use simple language
Environmental adjustments	• Consider scent-free meeting environments or rooms with specific lighting
Financial support	• Consider paying expenses, and accommodation and travel costs upfront because some people with learning disabilities do not have the financial capacity to pay for costs upfront • Offer childcare support or cover costs of a carer, support worker or other advocate • Provide an honorarium or stipend if possible
Transportation	• Offer transportation options, such as a taxi or cab from and to home, train station, airport and bus station

Support and reasonable adjustments will need to be tailored and continually assessed throughout the guideline process through regular contact and feedback from the individual and the group's chair. At NICE, a key contact person was beneficial for supporting individuals with learning disabilities to formulate their ideas before and after the meeting.

People with severe or complex mental health conditions

People living with severe or complex mental health conditions (for example, psychosis, alcohol misuse or schizophrenia) still experience barriers to participating in guideline development (van der Ham et al. 2014). There are several specific

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barriers and facilitators to consider, which van der Ham et al. (2014 and 2016) have reviewed in detail. In summary, guideline developers could consider the following:

- Value and contribution: People living with mental health conditions may be perceived as unable to make valuable contributions or valid statements about different therapeutic treatments (medical or psychological) because of their impaired cognitive state. This can be an inaccurate assumption. A review of mental health guidelines in the Netherlands revealed that the number of patient members with mental health conditions on a guideline group ranged from 2 to 5 per guideline (van der Ham et al. 2014). For Norwegian guidelines on mental health, 5 user representatives had significant influence in scoping the topic and formulating recommendations (Helsedirektoratel [The Norwegian Directorate of Health] 2013).
- Recruitment and representation: Gaining sufficient representation across the different classifications of mental health conditions can be difficult if the guideline topic is broad. Recruiting through patient organisations can help but could lead to over-representation of a particular mental health condition, depending on the focus of the organisation. In this instance, multiple recruitments and additional involvement methods will help gain representation, including incorporating existing patient research, panel or dialogue meetings, questionnaires or user focus groups, case studies or personal narratives. However, depending on available funds and resources, guideline developers will need to find a balance between gaining in-depth insight that requires fewer participants (for example, case studies) and methods that give broad perspectives but require large numbers of respondents (for example, questionnaires). If the right level of perspective is not achieved, there is a risk that patient organisations will reject the guideline, which would prevent it from being implemented.
- Topic of interest and scope: Members with mental health conditions are likely to be less interested in traditional biomedical approaches and more interested in holistic approaches, social support, quality of life, and non-medical implications, for example, the ability to retain employment (van der Ham et al. 2014). Such factors should be considered in the scope of mental-health related guidelines, and their inclusion is achieved by inviting mental-health related patient organisations to scoping meetings at NICE.

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- Dropout and support: Dropout from a guideline group is a risk that developers will need to consider from the outset. Mental health can vary and fluctuate over time leading to patient members either joining the group late or resigning. Additionally, patient members might struggle to read lengthy guideline documentation. Solutions involve recruiting multiple patient members and providing and adapting specific content and process-related support. For example, documents should be summarised or discussed with the patient members before a meeting and a key contact person should have regular contact with the patient member throughout the guideline process. Developers could also consider enabling input for specific parts of the guideline that need the patient's perspective. For the NICE guideline on violence and aggression in mental health and community settings (NG10; 2015), the developer encouraged peer support by providing a room for 4 patient and public members to meet before and after meetings to support each other. Members often experienced fluctuations in their conditions resulting in non-attendance at meetings. Peer support empowered the members to share experiences, encouraged a healthy critical debate, and ensured opinions were voiced in meetings.

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Acknowledgements

The authors would like to thank the following for their contributions to this chapter:

Peer reviewers: Noriko Kojimahara, Kenneth McLean, and Erin Whittingham.

Contributors to the 2012 version of this chapter: Sarah Chalmers Page, Jane Cowl, Loes Knaapen, Alix Johnson, and Carol Sakala.

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Resources

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Resource file 1: Example role description

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What we're looking for and what's involved

What is a lay member?

We use the phrase 'lay member' to refer to a member of one of our committees who has personal experience of using health or care services. The phrase can also mean someone from a community affected by the committee's topic area or an advocate or unpaid carer.

What will the committee be doing?

The committee will look at the evidence that is available, and develop NICE guidance on Thyroid cancer: assessment and management. The NICE guidance will be written recommendations about the best types of treatment, support and services.

For more information about our committees and what they do, visit the committee area of our website.

What knowledge and experience will I need?

We're looking for people with an understanding of Thyroid cancer: assessment and management and the issues important to patients, people using services, unpaid carers, communities and the public.

As a lay member, you will have this understanding:

- through personal experience you have of treatment and care provided for you by the NHS
- as a relative or unpaid carer of someone who has used relevant health services
- as an advocate, volunteer, or officer of a relevant charity or organisation.

You will also have:

- good communication and team-working skills
- the ability to listen and take part in constructive debate, while being respectful of other people's views

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- knowledge of the experiences and needs of lots of people which gives you the ability to champion a range of different perspectives on this topic.

Who sits on the committee?

NICE committees develop our guidance. As well as lay members, committees are also made up of professional members. This includes people who work in health or social care, as well as a range of other roles.

Lay members have the same status and carry out the same functions as other committee members.

What does the role involve?

- attending committee meetings (see time commitment below for more information) and taking part in discussions to shape the guidance
- reading committee papers
- commenting on documents between meetings
- keeping the committee's work confidential.

What am I expected to do?

- Make sure the views, experiences and interests of patients or people who use health and social care services are taken into account by the committee.
- Identify areas of concern to people using NHS, public health or social care services.
- Review topic information and the draft guidance from a patient, service user, carer or community perspective. For instance, does the information address issues important to people affected by the guidance? Does the guidance take their views into account?
- Make sure the guidance considers people from different backgrounds.

How much time will I need to give and where?

It's important that you are available for the committee's meetings.

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- Meetings for this committee will take place from 1 May 2020
- Committee meetings will usually last for 1 day, but sometimes 2 day meetings are held
- The meetings will happen every 4-6 weeks for a period of 18 months
- The meetings will take place in central London
- If you are appointed, you will be invited to a training day in Central London on 12 May 2020

What's in it for me?

- You will be helping to make national and local health and social care services work better for patients, people who use services, carers or the public.
- Previous lay members have said they found their confidence improved, as well as developing other skills like public speaking and critical thinking.
- Being a member of a NICE committee shows you are an expert by experience. It also shows you are able to work in a team, as an equal contributor to the committee alongside healthcare and other professionals.

What support will I get?

A named member of the public involvement team will be available throughout your time working with us, to offer help and support.

You will be offered training and guidance to make sure you feel confident on the committee, as well as regular chats with your named contact.

If you have any special requirements, for example access or travel needs, we can discuss this with you and make adjustments where needed.

What happens after I apply?

The public involvement team passes on applications to the team running this committee. Your application is then shortlisted against the required skills and abilities set out in this document.

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If you are shortlisted you will be contacted for a phone interview to talk about the position, your application and what is involved before a formal invitation is offered to sit on the committee. The date for interviews has been set for the 14 and 17 February 2020. They will take place on the phone and will last no more than 30 minutes.

More information

For more information about becoming a member on this committee, read our additional information.

This gives more information about:

- payment and expenses, including how this could affect any benefits you receive
- how we can help you to apply if you have a disability
- how we monitor equality and diversity in NICE's work
- what we expect from our committee members
- what might prevent you from sitting on a NICE committee
- how we will use the personal information you give us
- what you can do if you're not happy with our recruitment process

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Resource file 2: List of training resources

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Title	Description	Website	Cost
Cochrane Evidence Essentials	Modules cover: Evidence-based medicine, randomised controlled trials, introduction to systematic reviews, and understanding and using systematic reviews	https://training.cochrane.org/essentials	Free, login required
CUE - Consumers United for Evidence-based Healthcare	Multiple educational resources and free courses covering: evidence-based healthcare, FDA and the regulation of healthcare interventions and advisory panel engagement resources. There is a video covering consumer involvement in guideline development.	http://consumersunited.org/education&training http://consumersunited.org/rrguideline	Free
EUPATI: Patient engagement through education	Toolkit of resources and a course on patient engagement and medicines research and development	https://eupati.eu/	Application process for course. Resources are free.

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Title	Description	Website	Cost
Coursera	Coursera is a platform that hosts free and paid courses offered from reputable institutions around the world. There is a range of courses on research methods, statistics, and quantitative and qualitative research methods. Many other courses are offered that might be relevant to specific guideline topics, such as public health courses.	https://www.coursera.org/	Most courses are free, unless you want a certificate. There is a fee for specialisations, which are a series of courses.
Future Learn	Future Learn is similar to Coursera and offers courses from reputable institutions covering many aspects of healthcare and medicine, science, psychology and mental health topics that might be relevant for specific guideline groups.	https://www.futurelearn.com/	Courses are free for 6 weeks with the option to pay a fee to upgrade.

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Title	Description	Website	Cost
Testing Treatments	A valuable resource on critically appraising treatment claims. The book is available for free in PDF and audiobook formats. The book is available in different languages. The website also includes an interactive toolkit of additional resources.	https://en.testingtreatments.org/	Free
The NICE glossary	NICE provides a glossary and definitions of the terms used in guidance development	https://www.nice.org.uk/glossary	Free
Bandolier	The website provides a free resource of journal articles related to evidence-based medicine. There is also a learning zone with free articles related to different aspects of trials, meta-analyses, statistics, guidelines and health economics. A glossary of terms is also provided.	http://www.bandolier.org.uk/ http://www.bandolier.org.uk/learnzone.html http://www.bandolier.org.uk/glossary.html	Free
HTA Glossary	A free glossary for members working in health technology assessments.	http://htaglossary.net/HomePage	Free

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資料21

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Role of the guideline committee chair in supporting patient and public involvement: recruitment, training and support

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Key messages

- When a guideline agency commits to involving patients and the public in its processes, its committee chairs need to be committed to this principle and to support guideline development committees with patient and public members.
- If the chair of a guideline committee is properly recruited, supported, and trained to be facilitative and inclusive, successful patient and public participation in the guideline's development is more likely. A skilled chair can improve group dynamics by empowering patient/public members, who can then contribute more meaningfully.
- A skilled and well-trained chair will ensure that their guideline committee is an integrated group in which all members are treated equally and can contribute to the best of their ability.
- Good chairing will lead to good group dynamics so that committee members feel able to challenge and discuss the evidence presented to them in a rigorous but respectful way.
- All guideline committee chairs, however skilled and experienced, need support, induction and training to ensure they understand the specific requirements of the guideline development agency. All newly recruited chairs should be encouraged to take advantage of any training on offer.
- In recruiting or identifying guideline committee chairs, facilitation skills are more important than topic expertise because others on the committee will have this knowledge.
- All chairs need to commit to developing guidelines within the framework of the guideline agency's established principles of working, methods and processes, and

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organisational culture. This might include use of language according to the agency's corporate style guide.

Top tips

- Recruit your chairs openly and transparently or be clear about how your chairs are identified and selected.
- Train and support your chairs, weaving in patient and public involvement rather than having it as a stand-alone training module.
- When inducting your chairs, make sure they have the opportunity to hear from someone who has previously chaired a guideline committee within your agency, which included patient/public members.
- Offer your chairs regular appraisal and feedback on their performance and encourage them to offer something similar to their committee members.
- Offer chairs reimbursement for their time or reimburse their employers for the time they take working on the committee.
- Consider patient/public chairs – they may have valuable expertise your agency could benefit from.

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Aims of the chapter

This chapter describes the method for recruiting, selecting and supporting the chairs of guideline committees (GCs), developed for the National Institute for Health and Care Excellence (NICE) in the UK. The model places particular emphasis on involving and engaging with patient/public members (known as 'lay members' at NICE) of GCs as an integral part of the overall responsibilities of chairs.

Interactive discussions throughout an induction session take account of this aspect of the chair's role, alongside other elements that NICE feels are important. The approach described has been developed over time, specifically tailored to the needs of the chairs of NICE GCs. Elements of the model will be generalisable to other organisations, even when the NICE guideline development process and methodology is not being used.

The context for the process described in this chapter is the NICE policy for including patients and/or members of the public on all of its standing and ad hoc advisory committees.

Readers of this chapter should gain an understanding of:

- key issues for inducting and supporting chairs of GCs
- a sample mechanism for recruiting and selecting GC chairs
- the inherent value in providing formal and structured induction for chairs of GCs
- particular issues for chairs of groups with patient/public members
- organisational and resource implications for adequately supporting and inducting GC chairs
- the barriers to effective chairing, and some potential solutions for overcoming them.

Terminology

Guideline committee

NICE uses the term 'guideline committee' to refer to the decision-making groups that develop its guidelines. Other agencies may use different terms such as 'guideline development group' or 'guideline panel'.

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Patient/public members

For the purposes of this chapter the term ‘patient/public members’ is used throughout to describe the people NICE terms as ‘lay members’. The patient/public members of NICE’s GCs are recruited as individuals with a breadth of knowledge and experience about a particular topic, population, disease, condition or disability. They are not considered ‘representative’ of any particular group, organisation or patient population. We recognise that other terms are in common use but in this context ‘patient/public member’ refers to people with personal experience of a disease, condition or service (patients, consumers, users), their carers or family members, and those representing a collective group of patients, people using services or carers (representatives or advocates).

NICE’s approach to inducting and supporting GC chairs

Background

A NICE GC is a multidisciplinary group, supported by a technical team (systematic reviewer, information specialist, health economist). It is an advisory group to NICE and sits independently. As a minimum, a GC comprises:

- healthcare professionals, and for relevant topics, public health or social care practitioners (both specialists in the topic and generalists)
- patients, carers or members of the public.

The role of a GC chair should be rooted in the cultural norms of an organisation in terms of its identity and the methodological approaches it takes to guideline development. The wider legislative and policy framework within which the guideline agency operates is also relevant to the chair’s role. For example, legislative and policy imperatives to promote equality. NICE’s GC chairs are responsible for running independent groups, but knowledge of the methodological and process expectations of NICE is crucial in ensuring the chairs can run a group effectively.

Chairs must focus on their main objective, delivering a high-quality guideline, within the resource and time constraints allowed. If a guideline developer has yet to establish explicit methods and processes, the chair should apply core principles that

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are recognised as key to good quality guideline development (such as the AGREE II criteria [Brouwers at al. 2010]).

We strongly believe that the underlying philosophy of involving patients and the public in guideline development is important. It may well support guidance development organisations when convening such groups, and in chairing them in a facilitative and inclusive manner.

Training for chairs

In May 2006, the World Health Organization (WHO) conducted a review of NICE's guidelines development programme (de Joncheere et al. 2006), and made several recommendations. One was that chairs of GCs should be recruited through a standard process, preferably through open advertising, and that NICE should develop standardised training for GC chairs.

The first of these recommendations was quickly adopted. NICE developed an 'induction' programme, discussed more fully in the section on NICE's chairs' induction programme. It addresses, among other things, the involvement of the patient/public members of the GC. This approach reflects the results of reviews carried out by NICE's Public Involvement Programme, which identify the role of the chairs of GCs as crucial to the success of the way the GCs function and how well GC patient/public members feel integrated into the group and its workings. GC patient/public members have variously described characteristics of 'good' chairs as:

- *'inclusive'*
- *'skilled'*
- *open'*
- *'honest'*
- *'able to influence'*
- *'encouraging healthy rivalry'.*

One patient/public member said of their chair *'He went to some length to draw out or ensure that the patient/lay view and information was given to the group, and that the patient/public members were on an equal footing to the professionals'.* Another said *'The Chairman was very accommodating to the patient/public members but not so*

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awfully PC [politically correct] that he was not averse to arguing with them; in short he behaved like a reasonable human being'.

The PIP's evaluations revealed that the patient/public members felt that the chairs could either be 'weak' or 'skilled'. This perception depended on how well they managed their guideline group and how well they offered appropriate support to the patient/public members of the group.

As found in studies of other kinds of small group work (such as in Elwyn et al. 2001), the PIP's evaluations found a relationship between the skills of the chair and the success of the group. The chair is clearly a key element determining how well a GC functions. Success, or otherwise, of a group rests on the skills of the chair.

Recruitment of chairs

Each guideline agency will have different models for chairing their GCs. NICE recruits external independent chairs whereas other agencies may recruit skilled moderators from the agency's staff or well-known topic experts. This section details NICE's approach to recruiting chairs.

To ensure transparency, NICE adopts an open recruitment process, whereby anyone with an interest can apply to chair a group. NICE's appointments to advisory bodies policy and procedure, a corporate recruitment policy, has been developed to support this (2020). Potential chairs must submit an application (as they would for a position of employment), and then a formal process for selection and recruitment follows.

Applicants are assessed against criteria in a 'role description', and then short-listed. Short-listed candidates are interviewed by a panel comprising senior staff members and a member of the NICE Board. Further information on vacancies for chairs of NICE groups can be found on NICE's join a committee webpage. GC chairs are most often health or social care professionals with extensive commitments, although NICE has experience of recruiting lay people to chair its committees.

This process, although transparent, carries a significant administrative burden, for drafting recruitment paperwork, short-listing the applicants, and the interview process itself. But, because this follows a standardised process, after the template

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recruitment documents have been developed, they only require minor amendments to tailor them to each new recruitment.

NICE's chairs' induction programme

Because of the WHO report and the subsequent reviews, a programme for inducting GC chairs was developed jointly by NICE's Centre for Guidelines and NICE's Public Involvement Programme. It was specifically tailored to NICE's needs and the context in which it works.

NICE operates a mixed model of guideline development in which many of its guidelines are developed by 2 external contractor organisations, according to methods and processes set out in the publicly-available NICE guidelines manual. A new chair is recruited for each GC addressing each new guideline topic but some chairs are recruited to a broad topic area, such as diabetes, obstetrics, weight management.

Alongside the work contracted externally, some of NICE's guideline development work is undertaken 'in-house'. These guidelines are developed by GCs with a pool of chairs who oversee the development of a variety of guidelines on different topics. NICE invites both newly recruited GC chairs and chairs from this pool to attend induction sessions with their peers.

The induction process for NICE's GC chairs is constantly reviewed and refined, reflecting the accumulated experience of GCs, their chairs and members, and, importantly, changes in the guideline development methods and processes. During the COVID-19 pandemic, NICE's chairs' training was adapted for the online environment.

At NICE, the chair's role in supporting the patient/public members of the GC is part of the overall induction programme, and discussion of this is woven into the different sessions. This emphasises that patient/public member involvement is an integral part of the guideline development process and of the work of the GC. If there were a separate section of the induction programme, specifically focusing on patient/public involvement, it might suggest that patient/public involvement is an 'added extra' and not an integral and essential part of the process.

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The day-long programme comprises a mix of presentations, discussions and interactive sessions, intended to introduce chairs to the NICE guideline development methods (NICE 2014). (During the COVID-19 pandemic this was reduced to a half-day videoconference session with training material sent in advance.) It also covers practical issues related to running GCs, such as declaring and managing interests (NICE 2021), good facilitation skills, the importance of NICE's duties under equalities legislation (see the NICE equality scheme), and the NICE policy on participation of patient/public members of GCs. The session also expands on the role of NICE as commissioner, and how that sits alongside and independently of the guideline development staff and GC. Presentations are given by methodological and process specialists, and patient and public involvement specialists, thereby reinforcing the importance of an inclusive approach to guideline development. Participants also benefit from the contribution of an experienced chair (someone who has chaired 1 or more NICE GCs) who discusses their experience and offers tips and strategies for effectively chairing a GC in the NICE context.

Overall objectives of the day are to:

- provide a specific opportunity for GC chairs and NICE staff to meet, share experiences and discuss the work of NICE in context
- provide an overview of key NICE processes and methods
- identify key resources and support.

The format is flexible and interactive, with structured presentations designed both to inform and to act as the basis for discussion. The day gives chairs the opportunity to work collaboratively with their peers, as well as with the guideline development professionals from NICE.

Additional resources

General information about the role of chairs in running groups on which patient/public members sit can be found in 2 key additional resources:

- Patient and Public Involvement Toolkit, Chapter 4 Building relationships (Cartwright and Crowe 2011)

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- Patient and public involvement in research groups - Guidance for chairs (TwoCan Associates for the UKCRC and NCRI 2010).

Other useful information to support the chair's role on guideline development groups:

- Supporting effective participation in health guideline development groups: The Guideline Participation Tool (Piggott et al. 2020)
- Checklist for Guideline Panel Chairs (Department of Health Research Methods, Evidence and Impact, McMaster University 2017)
- Groups. A guide to small group work in healthcare, management, education and research (Elwyn et al. 2001).

Resource and planning requirements

Inducting and supporting GC chairs needs to be planned and sufficient resources allocated. Some of these are financial, but the most significant is the staff time to deliver the induction and provide ongoing support.

Organisation of induction

Given the large number of guidelines that NICE develops at any one time, it can be difficult to identify suitable times and dates for induction sessions. NICE has therefore appointed a dedicated person within the Centre for Guidelines to lead and coordinate the chairs' induction.

Financial commitment

At NICE, either the chair's employing organisation is re-imbursed or payment is made directly to the chair for each GC meeting. In addition, travel and subsistence expenses are covered, according to NICE's non-staff reimbursement policy. It is a requirement for all GC chairs to attend the induction session (see section 3.7 of NICE's guidelines manual 2014). NICE does not provide remuneration for attending the induction, but other agencies might consider it worth doing to encourage attendance.

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Barriers and strategies to address them

This section outlines some of the key barriers to appropriately supporting and inducting GC chairs, and some proposed solutions, based on the NICE model. The section is presented as a series of questions and answers.

What is the relationship between a GC chair's facilitation skills and their topic expertise? Is there a potential for tension between these 2 functions?

Although there are clear advantages to recruiting GC chairs with highly developed facilitation skills, NICE recognises that these can sometimes go hand in hand with expertise in a particular topic area. However NICE's policy on declaring and managing interests does not generally support the recruitment of topic expert chairs. NICE's current position is that its chairs are recruited for their facilitation skills, and that a 'topic adviser' with expertise in the topic under discussion should be recruited to work alongside the chair. This ensures the chair is more likely to be objective about the evidence the committee considers.

To facilitate inclusive group dynamics and support lay members, there are distinct advantages in having a well-informed chair with highly developed facilitation skills, but one who is not an expert in the guideline topic. These advantages include:

- Being able to ask naive questions of the topic experts and technical staff in order to clarify things for everybody, especially the patient/public members. A topic expert chair will either not realise that there might be a problem understanding something or not be prepared to lose face by asking. These may be genuine questions because the non-expert chair does not understand or might be deliberately asked to help the patient/public members and other committee members.
- Non-expert chairs are less likely to engage in esoteric arguments with specialists about details of the condition or intervention, or the evidence, and forget their chairing responsibility of engaging everyone in the discussion.
- They are more likely to be seen as impartial and someone to whom the patient/public members can turn for support, advice and comment, either in the meeting or in breaks or other informal settings.

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We recognise that other guideline development organisations may wish to recruit chairs with expertise in the topic under discussion. The key to identifying an appropriate approach is to be clear about the role of the chair in running the GC. There will need to be measures in place for managing any conflicts of interest that arise for a ‘topic expert’ chair, because the goals for facilitating discussion and debate on the evidence within the group may not always coincide with the desire for a particular approach to the guideline topic.

Should induction for GC chairs be compulsory?

Chairs should be encouraged to take advantage of any induction or training on offer. NICE’s experience is that GC chairs who have been through the induction are more likely to run functional and successful groups.

The NICE guidelines manual states ‘Anyone appointed as a committee chair is required to attend the chairs ‘induction session’ (NICE 2014, section 3.7). But a strong recommendation from a senior member of the guideline organisation’s staff about the value of induction will encourage newly recruited chairs to attend them. It is also important to encourage chairs to attend refresher sessions if they have worked with the guideline agency for many years. This will ensure they are up to date with organisational processes, the policy context, and other relevant changes.

Is there a ‘one-size-fits-all’ approach to developing and delivering an induction programme for GC chairs from different guidance-producing organisations?

Induction programmes for chairs need to be tailored to the specific context, methods and processes of the guidance-producing organisation. Induction programmes also need to be constantly refined and modified in light of external changes (for example, political priorities and legislation), organisational changes, developments in guideline methods, and in response to feedback from participants. However, there are likely to be common themes that apply across differing processes for guideline development. See, for instance, the generic guidance listed in the Resources section.

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How do those offering the induction for GC chairs take account of the differences between guideline topics, between chairs, and between guideline groups?

There are inevitable differences between the topics, chairs and groups, and this variation is entirely appropriate.

The induction sessions include a lot of time for open discussion. This is an opportunity for participants to think about NICE's guideline development methodology, and their particular topic. For instance, in the presentation about NICE guideline methodology, the first section on scoping ends with time for participants to reflect on and discuss themes relevant for their particular guideline topic, using prompts such as those in Box 1:

BOX 1 Chairs' induction – discussion prompts

Each topic has unique characteristics

Will there be problems in managing the expectations of GC members about the limitations of scope, time, and resources?

Taking into account patient and public perspectives:

- are there some topics specific to this guideline? (information, psychosocial issues, support, alternative or complementary treatments)
- are there any population sub-groups of patients who might need specific consideration?

In the induction sessions, it is crucial to have input from someone with previous experience as a GC chair for the same guideline development organisation. Their experience of having been through the process enables them to provide practical tips for the newly recruited chairs on how to be an effective chair in this very specific environment. Feedback from GC chairs who have attended the NICE induction session consistently rate the session with an experienced GC chair as the most valuable aspect of the induction session.

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Will someone who is a good committee chair automatically be a good GC chair?

Not necessarily - the skills needed to chair a formal committee may not meet the requirements for chairing and facilitating a dynamic, reactive, and discursive GC. A skilled GC chair will be expected to run the practical aspects of the group (for example, keeping to time and process) and also to foster debate and discussion among group members. They will also need to be able to draw together discussions about research evidence into practical recommendations for practice, taking into account all group members' input.

What is the role of the chair in relation to GC processes and methodologies?

The GC chair needs to be familiar with the 'rules' (of methods and process). Induction sessions are an ideal opportunity for these rules and expectations to be clearly outlined. The GC chair needs to fully understand the methodology and the rules, and both champion and follow them during GC meetings. The induction session should be a chance not only to explain them but also to discuss them with methodologists and support staff.

Might the new chairs find the idea of an induction patronising?

This is quite possible and needs to be recognised. But it is very important that a new chair is able to successfully work with a small group that includes patient/public members, while following a specific methodology.

How do you address the fact that the GC chairs may or may not be used to working with patient/public members?

As part of the induction, there needs to be an exploration of the chairs' experience in working with groups, including patient/public members. Their questions and concerns about this can be addressed and shared in a safe environment. At NICE, experience of working with groups, including patient/public members, is now an expectation of a chair's experience and is explored as part of their recruitment.

Providing the chairs with good practice examples (such as those cited in Cartwright and Crowe [2011] and TwoCan Associates [2010]) can give them practical tips to

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help them support the patient/public members of the GC. It is important for them to understand and recognise that the individual patient/public members of the GC may have quite different knowledge, experience and self-confidence. Some may be very experienced professionals with specialist knowledge of a small topic area, but others may be working on a committee at a national level for the first time.

How do you ensure that the GC chairs get the best possible experience from the induction?

One of the key things that NICE has identified as enriching the induction experience for GC chairs, is to ensure the participation of more than one new chair at the induction session. This allows them to share their concerns and issues, and provides them with a small peer group with whom they can share experiences and discuss problems.

It should be possible for several guideline development organisations to pool resources for chairs' induction sessions, especially with the use of video-conferencing. But care would be needed to take account of different methodologies if these sessions involved the discussion of anything more than the involvement of patient/public members.

How do you address the issue of scheduling of inductions and the chairs' availability to attend?

The stage of the guideline development process at which the chairs have their induction is crucial. Ideally there needs to be enough time and resources available for chairs to have access to induction before their first GC meeting. But it may be difficult to arrange induction sessions with enough notice for chairs to attend, and also to convince some of the value of attending an additional meeting. Induction should be arranged at regular intervals to enable groups of newly appointed chairs access as early as possible. Details of these scheduled sessions should be included in recruitment materials in order to give a clear message that they are expected to attend and to allow them to plan. Other options are online training resources and induction sessions via videoconference.

Although chairs should ideally attend an induction session before their first GC meeting, it can be helpful to have people at different stages of the development

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process coming at the same time so that they can describe their different issues and experiences. A newly appointed chair might have chaired a previous GC and feel that an induction session would be a waste of time for them. However, because guidelines methodology and political circumstances are constantly changing, they should still be encouraged to attend.

How do you address the need to provide the chairs with ongoing and additional training opportunities throughout the guideline development process?

NICE offers its GC chairs the opportunity to attend a workshop specifically on the health economics aspects of guideline development. Staff supporting each committee also provide training to GC chairs and other GC members on specific methodological issues (for example, systematic reviewing, meta-analyses) as and when required. GC chairs are also offered the opportunity to contact NICE’s methodological and patient and public involvement specialists, or members of the technical team, if they have specific questions.

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Acknowledgements

The authors would like to thank the following peer reviewers for their contributions to this chapter:

Fergus Macbeth, Nichole Taske, Steven Barnes

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Appendix 1

Sample guideline committee chairs' induction session—NICE

Guideline Committee Chair Induction

24th Feb 2020

NICE London office, with video link to Manchester office

AGENDA

Time	Item	Presenter/lead
10:00	Arrival & tea/coffee	-
10:20	Welcome and introductions	Technical Advisor, NICE's Centre for Guidelines (CfG)
10:30	Overview of NICE	Senior Public Involvement Adviser, NICE
11:15	Guidance development processes at NICE	Senior Guideline Commissioning Manager, CfG
12:15	Guideline development methodology (evidence reviewing)	Technical Advisor, CfG
12:45	Lunch	-
13:15	Guideline development methodology (health economics)	Technical Advisor (Health Economics), CfG
13:45	Experience as a Guideline Chair (Manchester video link)	Chair, Depression guideline
14:25	Thoughts on effective chairing of Guideline Committees	Senior Public Involvement Adviser, NICE
14:50	Declaring interests	Senior Guideline Commissioning Manager, CfG
15:15	Research recommendations	Technical Analyst, Science Policy & Research, NICE
15:35	Editorial and publishing at NICE	Senior Medical Editor, Publishing, NICE
16:00	Meeting close	-

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Appendix 2

Sample guideline committee chairs' induction session slides - NICE

Slide 1 Different expertise - equal status

NICE National Institute for Health and Care Excellence

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Slide 2 Desired outcomes

Desired outcomes

✓**A good guideline**

- produced to time and useful to practitioners & people using services

✓**Effective, amicable group working**

- 'different expertise – equal status'
- inclusive – avoiding jargon, explaining necessary terms
- responds to evidence, uses collective experience where appropriate and uses consensus

✓**Needs or problems recognised, tackled early, and resolved**

- members feel able to raise issues – inside and/or outside meetings
- known or 'hidden' disabilities or desired working arrangements are recognised and catered for

NICE

2

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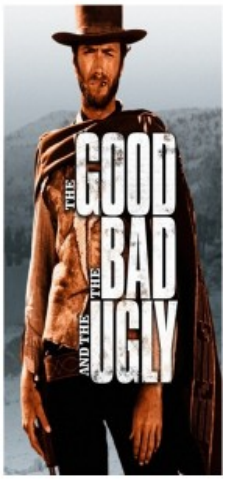
Slide 3 Lay members' feedback

Lay members' feedback

How easy did you find it to contribute to the work of your committee?

- "The Chair always made me feel my contribution was important."
- "I was treated with respect and as an equal member of the group. My views were given equal consideration to others."
- "A lot of medical terminology for a lay person to get used to."
- "I sometimes felt like the views of the lay members weren't taken seriously or given the same 'weight' as the academic or clinical members. This meant that after a while I was reluctant to contribute unless it was something I felt very strongly about."



NICE

4

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Slide 4 How lay members on your committee might feel

How lay members on your committee might feel

- The guideline I was involved with covered a lot of very technical discussions about drugs, of which I had limited knowledge. I found it difficult to contribute to these discussions. On other points it was easier to contribute."
- "As I was just a lay member, I felt very positive about each meeting and made to feel I was valued."
- "As a lay member you feel (or at least I do) that you need to have a pretty clear and marshalled argument before you open your mouth. Everyone else in the room has a very clear, gut understanding of diseases and/or how the NHS works - the lay member has neither of these. Consequently, being a lay member requires you to accept that from time to time you may look a fool but that if your point needs to be made that is the risk that you take."

NICE 5

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Slide 5 How lay members on your committee might feel continued

How lay members on your committee might feel

- "I usually feel able to express my views, even if they differ from expert members. I think it is useful to set aside specific agenda time to ensure lay members are able to have their say - I am happy to interject "as and when" but have been on committees where some members appear a little nervous of having their say."

- "The clinical experts may not have had service user experience however it was still an issue of confidence for me to speak out amongst professors etc. I'm not sure what the solution is but having an agenda item called 'service user concerns' did give us an opportunity but also felt a little patronising, I know this wasn't the intention and I don't how this could be rectified other than the chair having a little more liaison with the service users?"

NICE 6

Slide 6 Working with lay members

NICE

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Slide 7 Thoughts on facilitation and enhancing group dynamics

Thoughts on facilitation and enhancing group dynamics

- Preparation
  - clarity about work plan
  - agreeing mode of working with the staff team (and topic lead)
  - managing expectations of different committee members, considering issues which may arise (e.g. from scope)
- Establishing ground rules for working in the committee
  - open, honest communication
  - encouraging members to raise concerns early rather than late
- Observing group dynamics, being alert to problems
- Maintaining participation, managing conflict

NICE 7

Slide 8 Resources

Resources

- 'Good practice in chairing guide' – NICE
- 'A guide to maximising lay input on a committee - NICE
- 'Groups: A guide to small group work in heathcare, management, education, and research' – Elwyn, Greenhalgh & Macfarlane, Radcliffe Publishing, 2001

NICE 8

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Patient and public involvement in systematic reviews

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Key messages of this chapter

- Patient and public involvement (PPI) is important to ensure that systematic reviews are relevant and meaningful to people affected by a health condition and people using systematic reviews to inform health policy or practice.
- There is no set formula or single method of involving people in a systematic review, nor is there evidence that any one way of involving people in a review is any more or less impactful.
- Several different factors will influence the decision on the best approach for a specific systematic review, including (but not limited to) the aim of involvement, the people who are being involved, and the resources and time available for this.
- PPI may be useful at any (or all) stages of a systematic review.
- There should always be a clear aim associated with involvement of people within a systematic review. Often this aim will relate to decisions that need to be made within the systematic review process. Depending on the aim of involvement, people may be involved at 1 stage, at 2 or more stages, or they can be involved throughout the whole review.
- Involvement of people in a systematic review can be considered as a continuum, from more involvement and control, to less involvement and control. But there is no evidence of a hierarchical association between level, impact, benefit or success of involvement.
- Different levels and methods of involvement may be useful at different stages in a systematic review.
- PPI in a systematic review should be clearly reported.

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Terminology: systematic review

A systematic review is a type of research method that brings together evidence, generally from research studies, to answer a pre-defined research question.

Top Tips

- Plan PPI in a systematic review prior to working on the review protocol. This is because involving patients and the public in the protocol is a good way of making sure your final review addresses what is important to people with lived experience of a health condition.
- Planning should consider the project budget and payment of people's time or expenses, provision of training, and whether ethical approval is required. You should consider the availability of these resources when deciding who you can involve and how.
- Have a clear aim for involvement of patients and the public, and decide in advance what level of control that those involved will have over decision making within the review. Make sure that you communicate this clearly at the outset of the review.
- Good communication is a key to success when involving people in systematic reviews. This means it must be timely, use clear language, and use a method that suits the people involved.
- People can be involved at any (or all) stages in a review. When people are involved will depend on the aim of involvement. Involve people at:
  - the initial stages of the review (that is, protocol), to form the review question and scope
  - during the review, to contribute to searching, study selection, and collecting and analysing data
  - the final stages of the review, to support interpretation of the findings and dissemination of the review.
- Who you involve, and when and how you involve them, should be decided taking into account the topic of the review, the resources available, and the experience of the review team.

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- Have a conversation as early as possible with everyone involved about any resources they need, including financial payment for their time.
- For systematic reviews that are being planned and conducted as part of a guideline development, a top and tail approach could potentially fit efficiently within the guideline process.
- Adopting a formal research method or process can be useful when there is a clearly identified role, or aim, for the people involved.
- The ACTIVE framework and the GRIPP2 (Guidance for Reporting Involvement of Patients and the Public 2) checklist (Staniskewsa et al. 2017) can be helpful for describing the planned involvement and reporting the actual involvement.

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Aims of this chapter

This chapter aims to:

- highlight the importance of planning patient and public involvement (PPI) in a systematic review
- describe who you might involve in your review
- describe the stages when you might involve people
- describe the different levels of involvement you might have
- describe how people can be involved in a systematic review
- provide a framework for describing and reporting how you involved people
- signpost readers to a range of resources for further information.

Planning involvement in a systematic review

PPI and protocol development

A key stage in any systematic review is writing a detailed systematic review protocol. The protocol lays out details of the scope and design of the review, and the methods that will be used to conduct the review. Preferably, a systematic review protocol will be made freely available before the start of the systematic review. This lets people know what you are planning and helps avoid duplication of effort (that is, someone else carrying out the same, or very similar, systematic review).

Ideally, there will be PPI at the protocol development stage for the systematic review. It is good practice to have PPI contributors as core members of the review team. They play a key role in helping to plan how to involve additional PPI contributors throughout the review process.

The systematic review protocol should describe the planned PPI. In particular, the protocol should give details of:

- who will be involved, and how these people will be found or recruited
- when (at what stages) within the review process people will be involved, with a clear aim of the involvement at these stages
- how these people will be involved in order to meet the stated aim(s).

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It is important to consider the key principles for good practice in involving people at the planning stage. The following issues are central to PPI in any research activity, including a systematic review:

- supportive and positive relationships
- clear and timely communication
- the roles and expectations of everyone involved, which should be discussed and agreed in advance of any involvement
- skills, knowledge and training (of researchers as well as of the people they involve) needed
- clarity regarding time commitments and requirements.

The project budget and payment for people's time or expenses, provision of training, and whether ethical approval is required must also be considered. The availability of these resources will influence who you can involve and how.

The Cochrane Consumer Network has published a Statement of Principles for Consumer Involvement in Cochrane to guide PPI. It highlights the importance of equity, inclusion and partnership. Communication and organisation are central to successful PPI, and it is important for researchers to consider practical points, such as accessibility (of meetings and materials) and having a clear point of contact for the people who are involved.

Choosing who, when and how for your review

There is no set formula or single method of involving people in a systematic review. Factors that will influence decisions around the best method for a specific systematic review include the:

- Topic of the review, and the people who may be affected by the results of the review.
- Aims of involving people. There may be a very specific aim to be met by involving people, such as informing the review outcomes, or supporting the dissemination of review results.
- Time available to do the review.
- Money available to support the review and involvement of people in the review.

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- Expertise of researchers, and their experience of involving people in research.
- Preferences of the individuals involved.
- Desire for review findings to be locally, nationally or internationally generalisable. A review may focus on a topic of national importance, and consequently the methods of involvement could focus on gaining involvement across that individual nation. Alternatively, a review may be internationally relevant, so it may be appropriate to gain international views and opinions.

Although the research team commonly makes the decisions on the plan, there will ideally be PPI in reaching the plan for the methods of involvement in the review. It is essential to consider the views and perspectives of the individual people who get involved, and to be prepared to be flexible and adaptive to the needs and suggestions of the people involved. For example, although you may have pre-planned 1 large workshop to reach decisions on outcomes important to a review, this format may not be accessible to some people and you may need to adapt your plans. If you are asking people to read or comment on written documents it is important to find out whether any of the people involved have specific requirements to facilitate accessibility, such as larger font sizes or audio versions. When seeking people to get involved, you may consider circulating requests for involvement in a variety of formats to promote accessibility. For example, you could circulate an audio description alongside a written description of the project. Being flexible and responsive, and working in partnership with the people who get involved is important to ensure equity and inclusivity.

One review can use a variety of different methods, each of which have a different approach to involvement, with different role classifications, and different levels of involvement. The following sections discuss key things to think about when planning PPI in your systematic review.

Who to involve in a systematic review

It is important to consider who the stakeholders for your systematic review are, and to involve representatives of key groups of people. Key groups to consider include:

- patients and their family members

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- carers
- healthcare professionals
- health policy makers
- health funders
- decision makers working in the relevant field.

For a systematic review being conducted as part of a guideline development, the stakeholders for the review may be identical to the stakeholders for the guidelines. However, there may also be some differences. For example, if a systematic review is focused on a specific intervention or a population of people with a particular impairment or activity limitation, then it may be important to consider involving people with relevant specific lived experience.

The 7Ps framework (Concannon et al. 2012), shown in table 1, can be a useful framework for identifying who to involve. Although it has been developed for a US situation, and for involving people in identifying and prioritising outcomes for research on an intervention’s effectiveness, the principles can be applied in other parts of the world, and in other types of research.

Table 1 The 7Ps Framework to help identify who to involve in health research (Concannon et al. 2012 edited)

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Category	Description
Patients and the public	Current and potential consumers of patient-centred healthcare and population-focused public health, their caregivers, families, and patient and consumer advocacy organisations
Providers	Individuals (for example, nurses, physicians, mental health counsellors, pharmacists, and other providers of care and support services) and organisations (for example, hospitals, clinics, community health centres, community-based organisations, pharmacies, emergency medical services agencies, skilled nursing facilities, schools) that provide care to patients and populations
Purchasers	Employers, the self-insured, government and other entities responsible for underwriting the costs of healthcare
Payers	Insurers, Medicare and Medicaid, state insurance exchanges, individuals with deductibles, and others responsible for reimbursement for interventions and episodes of care
Policy makers	The White House, Department of Health and Human Services, Congress, states, professional associations, intermediaries, and other policy-making entities
Product makers	Drug and device manufacturers
Principal investigators	Other researchers and their funders

In deciding who to involve it is important to consider the aim of the PPI and, therefore, the range of perspectives that are needed to meet that aim. For example, if the aim is to have general oversight of the review conduct, then perhaps, people with a general perspective need to be involved. But if the aim is to identify the outcomes of greatest importance to people with lived experience of a particular health condition, then it will be essential to involve people with relevant lived experience. Often, for PPI, what is of greatest importance is that the people involved have a lived experience of a particular health condition. Generally, knowledge or familiarity with research methods and technical terms is not a requirement for involvement. It is good practice to write a role specification that describes, in plain language, the experience or attributes that people you involve should have. Also consider the potential benefits for people who volunteer to get involved in a systematic review, and make these clear. For example, these could include payment, authorship, acknowledgement, training, or impacting on an area of research that is important to them. The National Institute for Health Research (NIHR) webpage on people in research has examples of descriptions of people sought to involve in health research.

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How to recruit people

After identifying the key groups of people to involve, strategies are required to find relevant individuals to approach and invite to get involved. The chapter on how to recruit and support patients and the public, and overcome barriers to their involvement in guideline development highlights different ways of identifying and reaching out to patient and public groups. Two broad strategies commonly used to find people to be involved in systematic reviews are:

- An open recruitment strategy, in which opportunities for involvement are advertised to the general population, and anyone can volunteer to get involved (for example, advertising on the NIHR's People in research webpage). Open strategies can be:
  - Fixed: After a group has been formed, advertising ceases and no new members are added.
  - Flexible: Advertising for new members is ongoing and group membership can fluctuate. This may mean that a series of workshops has different group members, or some group members may attend more than once.
- A closed, or targeted, strategy, in which individual people, or individual groups, are invited to be involved. There are several strategies for recruiting a targeted group:
  - Invitation: People known by name (or reputation) to the researchers will be invited to get involved. This can also be described as 'nomination'.
  - Existing groups: Rather than recruiting specific named individuals, the membership of an existing group is invited to get involved. Because different groups vary in how they operate, this can impact on the membership. In some cases, a group may have closed membership (that is, the same individuals make up the group), and sometimes a group may have open membership (that is, the group membership changes over time).

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- Purposive sampling: A qualitative research framework is used for recruitment, generally aimed at getting representation of people with key pre-determined characteristics, experience or expertise. Although this results in a ‘targeted’ group, with closed membership, the strategies for identifying the population from which to sample can be similar to those for open involvement (that is, advertising).

How many people to involve

How many people you involve in your systematic review will depend on several factors. A key factor is the aim of PPI and, linked to the aim, how you are going to involve people (see the section on how to involve people in a systematic review). The factors listed in the section on choosing who, when and how for your review will also influence decisions about how many people to involve. The numbers to involve will also depend on the different groups of people that you want to have represented (see the section on who to involve in a systematic review). Work in partnership with the people you involve to ensure that they are comfortable with the number and range of people involved. When small numbers of people are involved, for example, as members of a steering or advisory group, ask them if they feel they can represent the different viewpoints, or whether additional input is required.

In an exploration of PPI in a range of systematic reviews, Pollock et al. (2018) found that for:

- face-to-face meetings, the number of people involved ranged from 2 to 27
- one-off events, often advertised as open to the general public, the number of people involved ranged from 15 to 81
- involvement that did not require a face-to-face meeting, for example using an electronic Delphi or survey, the numbers invited ranged from 29 to 340 people.

When to involve people in a systematic review

PPI at stages of the systematic review

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A systematic review is a process involving a series of different stages. The Cochrane review ecosystem illustrates 11 key stages of a systematic review, from developing the question through to writing and publishing the review. A final, 12th, stage is disseminating the results of the review. People can be involved at any (or all) of these stages. There should always be a clear aim or objective associated with involvement of people within a systematic review. Often the aim will relate to decisions that need to be made within the systematic review process. Depending on the aim of involvement, people may be involved at 1 stage, at 2 or more stages, or they can be involved throughout the whole review.

The Cochrane Involving People learning resource provides examples of systematic reviews that have involved people at the 12 different stages of a review process in order to meet a range of different aims. Table 2 provides some brief examples of PPI at different stages of systematic reviews, taken from the Involving People resource.

Table 2 Examples of involvement of people at different stages of systematic reviews (from the Cochrane Involving People learning resource)

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Stage of review	Example review (reference)	Aim of involvement	What happened?
1. Develop question	Edwards et al. (2015)	Clarify the review questions in a systematic review relating to complex mental health needs and services for children and adolescents in the UK	Edwards et al. (2015) used 2 different strategies. In 1 strategy, 6 young people who had been mental health inpatients, were interviewed, individually. The aim was to identify topics for the review to focus on. In the second strategy, healthcare professionals, young people and charity representatives met face to face to generate and rank topics of importance.
2. Plan methods	Pollock et al. (2015)	Clarify methods for a Cochrane review update relating to physiotherapy for people who had experienced a stroke, in particular the categorisation of interventions	Pollock et al. (2015) formed a stakeholder group of patients, carers and healthcare professionals. There were 2 meetings that focused on clarifying methods of the planned review. The stakeholder group's input generated a method for categorising interventions within the review. This method was used to structure the final review and also informed subgroup analyses.
3. Write and publish protocol	Liabo (2013)	Agree the protocol content for a review focused on interventions to support looked-after children in school	Liabo (2013) used a participatory approach to involve a group of young people throughout the review. At one of the meetings, participants were presented with a pre-prepared document with tick-box options for different alternatives within the protocol. The options had been generated from the discussions at previous meetings that focused on the review question. The text included in the final protocol reflected the views that had been collected during the tick-box exercise and associated discussion.
4. Develop search	Rees et al. (2004)	Advise on terminology for the search strategy, for a systematic review relating to HIV-related sexual health for men	Rees et al. (2004) involved a range of people in 3 meetings. In one of the meetings, the group specifically advised on terminology for the search strategy.

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Stage of review	Example review (reference)	Aim of involvement	What happened?
5. Run search	Harris et al. (2016)	Help identify unpublished papers, for a realist review relating to community-based peer support	Harris et al. (2016) established an advisory network of stakeholders. Communication with the advisory network occurred through a series of events, as well as less formal communication, including email. Harris et al. report that advisory network members helped to identify relevant unpublished papers during the searching phase.
6. Select studies	Vale et al. (2012)	Provide oversight to a Cochrane review of chemoradiotherapy for cervical cancer	Vale et al. (2012) formed a group of 'patient research partners' who provided continuous oversight for the review. The group was actively involved in several review tasks, including tracing the address details of trial investigators for studies selected for inclusion.
7. Collect data	Bayliss et al. (2016)	Co-produce a coding framework for the qualitative analysis in a qualitative systematic review focused on predictive testing for those at risk of developing a chronic inflammatory disease	Bayliss et al. (2016) had a group of 'patient research partners' who provided continuous oversight for the review. Three of the patient research partners volunteered to be involved in the qualitative analysis. They coded themes for a random selection of 3 papers and contributed to developing a co-produced coding framework in collaboration with the researchers. This was done through email correspondence. Written training documents were developed to support the volunteers with this involvement.
8. Assess risk of bias	-	-	There is little evidence of involvement of stakeholders in the process of assessing risk of bias. Liabo (2013) reported that 'none of the young people were interested in being involved in activities that required them to read the full studies'. As a result of this observation, these stakeholders were involved in 'a general discussion about research quality rather than aiming for them to take an active part in reading the studies and assessing them for quality'.

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Stage of review	Example review (reference)	Aim of involvement	What happened?
9. Analyse data	Bayliss et al. (2016)	Consider and comment on the qualitative themes generated for the qualitative synthesis	The patient research partners involved in the review of Bayliss et al. (2016) attended a face-to-face meeting to which all stakeholders were invited. They read all the included papers before the meeting. Bayliss et al. reported that this session aimed to help researchers draw on the perspectives of the patient research partners when interpreting and reflecting upon the data.
10. Interpret findings	Pollock et al. (2014, 2015)	Gain consensus on the clinical implications arising from the review	Pollock et al. (2014, 2015) held a stakeholder meeting at which the draft findings (results of meta-analyses) were presented. Stakeholders were asked to discuss the clinical implications of these findings. Through discussion, the group agreed the wording of a series of statements relating to clinical implications, with anonymous voting used to confirm agreement with the statements. The agreed statements were included with the published review.
11. Write review	Concannon et al. (2014)	Get feedback on drafts of a systematic review of methods of stakeholder engagement in research	Colcannon et al. (2014) held 2 face-to-face meetings with a group of stakeholders, who also participated by email and phone throughout the review process, including commenting on tables, figures and manuscript drafts. Colcannon et al. stated that 'stakeholders [at a second meeting] also helped us identify effective ways to communicate the findings in tables and figures for this manuscript. All stakeholders were invited to participate by email and phone throughout the research, including a review of the manuscript''.

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Stage of review	Example review (reference)	Aim of involvement	What happened?
12. Publishing the review and disseminating	Hyde et al. (2017)	Plan and contribute to disseminating the results of a review focused on factors affecting shared decision making around prescribing analgesia for musculoskeletal pain	Hyde et al. (2017) held 3 stakeholder meetings at different stages during the review. Group members were involved in 'planning how to share results' and 'agreeing dissemination of the results'. Consequently, 'results were targeted at practitioners, as [stakeholders] felt this was most important'. Hyde et al. reported that group members 'participated in dissemination of the review findings'. They also reported that they 'planned their own roles...including giving presentations and contributing the patient's perspective to discussions at conferences'.

Top and tail approach

Pollock et al. (2019) explored when systematic review authors had PPI in their reviews. They found that people were most commonly involved at the initial stages (stages 1 to 3: framing the question and planning the review) and the final stages (stages 10 to 12: interpretation, publication and dissemination of findings). It was less common for people to be involved during the middle stages (stages 4 to 9: conducting the review). Often people were involved at both the initial and final stages, but not in the middle – this has been termed a 'top and tail' approach (Pollock et al. 2019). A top and tail approach may involve the same group of people at the start and end of the review, or it may involve 2 different sets of people.

For systematic reviews being planned and conducted as part of the development of a guideline, a top and tail approach could potentially fit efficiently within the guideline process. However, there is no evidence to support this as being the 'best' approach, and decisions about when to involve people should be made based on the pre-determined aims of involvement for each individual systematic review.

How to involve people in a systematic review

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Approaches to involvement

There is no evidence to show that any one way of involving people in a review is more or less impactful. Several different factors will influence the decision on the best approach for a specific systematic review. These factors may include the topic of the review, time available, resources available, and expertise of the review team.

Two different approaches to involvement have been used for other systematic reviews:

- Continuous involvement – people are involved 'throughout' the review process, perhaps as a member of the review author team or an advisory group.
- One-time involvement – people are involved at a specific stage in a review in order to complete a specific task or address a specific aim. For example, a group of people might be involved in discussing and reaching consensus on the question for a review, or people might be involved in order to contribute to the writing a plain language summary.

The aims of the PPI will help determine which approach might be best for a specific review. For example, if a key aim is to ensure that the outcomes included in the review reflect those that matter most to people affected by a particular health condition, then a one-time involvement approach may be more advantageous. This could enable a group of people to come together and reach consensus on the outcomes for the review. However, if the aim of involving people is to provide general oversight to the review process and ensure that all stages of the review process consider the views of patients and the public, then continuous involvement may be more advantageous. Some systematic reviews combine both approaches. For example, they may have PPI input on an advisory group throughout the review process, and then also plan 1 or more one-time events to get additional input into key stages of the review.

Levels of involvement

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Involvement of people in a systematic review can be considered as a continuum, from more involvement and control, to less involvement and control. Pollock at al. (2019) explored the different tasks and activities in which patients and the public were involved in a range of systematic reviews. Using an iterative process, they developed a new taxonomy relating to the actions, responsibilities and tasks of those involved, called the 'ACTIVE continuum of involvement'. It describes people as leading, controlling, influencing, contributing or receiving (see table 3).

Table 3 The ACTIVE continuum of involvement (from Pollock et al. 2019)

Level of involvement	Tasks
Leading: Initiating the review; lead responsibility for carrying out and completion of review.	Tasks will include authorship of a review, and may include any activities associated with review completion, including key decisions relating to the methods and execution of the review.
Controlling: Working in partnership with researchers, with varying degrees of control or influence over the review process. Making decisions, controlling, or both, 1 or more aspects of the review process, in collaboration with or under the guidance of the review authors.	Tasks may include defining outcomes of interest, inclusion criteria, key messages arising from review findings and writing a plain language summary. In completing tasks people have control over final decisions, such as application of inclusion criteria, categorisation of interventions, or recommendations for clinical practice.
Influencing: Stating, commenting, advising, ranking, voting, prioritising, or reaching consensus. Providing data or information that should directly influence the review process, but without direct control over decisions or aspects of the review process.	Tasks may include assisting with review tasks, such as hand searching, screening, data extraction and assessment of risk of bias, possibly in a co-reviewer role. Tasks may include peer review, such as commenting on a protocol, systematic review or plain language summary.
Contributing: Providing views, thoughts, feedback, opinions or experiences. Providing data or information that may indirectly influence the review process. People may be participants in a research study (for example, focus groups or interviews).	Tasks may include sharing views or opinions, for example, within a focus group or interview. May include ranking, voting or prioritising as participants in a research study (for example, in a Delphi study).
Receiving: Receiving information about the systematic review, or results of the review.	Tasks may include attending events or reading or listening to information about the review. Although the results of a review may be discussed, these discussions do not influence the review process in any way.

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Although the level of involvement of people in a systematic review can be seen as a continuum, there is no evidence of a hierarchical association between level, impact, benefit or success of involvement. Indeed, current evidence and opinion suggests that different levels and methods of involvement may be useful at different stages in a systematic review. What is important is to consider the level of PPI involvement, and their level of control or influence over the process. Decisions about the level of control that people will have at various stages in the review process should be stated in advance, ideally within the systematic review protocol.

Format of involvement

Format of involvement means the ways in which people interact and communicate, such as through face-to-face meetings, events or workshops, individual or group telephone or video-calls, or email and written communication. The format of PPI in a systematic review will depend on several factors. These factors include (but are not limited to) the aim of involvement, the people who are being involved, and the resources and time available for this. In an exploration of the format of involvement adopted in a range of systematic reviews, Pollock et al. (2018) found that direct face-to-face interaction was the most common approach, and that this might comprise a small meeting, a larger workshop or public event, or a combination of these. In most cases, between 1 and 4 meetings or events were held throughout a review, although as many as 20 meetings had been held. Meetings varied in length from 1 hour to half a day. A small number of systematic reviews used electronic or remote methods to involve people. Most commonly, this was an electronic Delphi or survey method, usually involving 2 or 3 rounds of voting.

Research methods and processes

A range of different ways have been used when involving people in a systematic review. Often these methods and processes involve different ways of sharing thoughts and ideas, such as group discussions or written feedback. Several formal research methods have also been used when involving people. Adopting a formal research method or process can be useful when there is a clearly identified role, or aim, for the people involved. For example, the aim might be to reach consensus on the outcomes of relevance to the review, or to agree a way to synthesise the evidence so that it is accessible and understandable.

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Formal research methods and processes that have been used when involving people in systematic reviews include:

- Participatory research approaches: Include ‘action research’ and ‘participatory action research’ and are usually considered as ‘approaches’ to research, rather than methods. These approaches integrate PPI with qualitative research, with a joint process of knowledge production by researchers and patients or the public. Participatory research approaches have key tenets: a democratic impulse; iterative data collection and analysis, and simultaneous contributions to science, improvement and change.

Box 1 Example of a participatory research approach

For a realist review of community-based peer support, Harris et al. (2016) used participatory approaches to gain stakeholder involvement throughout the review. An advisory network was formed, comprising a range of different types of stakeholder. Recruitment to the advisory network took place throughout the review, and different individuals had varying levels of involvement, and at different stages. Some members contributed on multiple occasions and others on only a single occasion. A total of 12 meetings were held throughout the review, providing approximately 240 face-to-face contacts with around 120 stakeholders. In addition, there were also email discussions and opportunistic contact with researchers.

- Consensus decision-making techniques: Include using techniques for voting (that is, to make decisions about the review) and ranking (for example, to prioritise domains, such as outcomes, within a review). It also includes the nominal group technique, which involves a structured discussion and rounds of voting to reach consensus on a specific problem or issue, and the Delphi method, which involves several rounds of questionnaires or surveys to achieve consensus.

Box 2 Example of a consensus decision-making process

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For an update of a Cochrane review relating to physiotherapy for people who had a stroke, Pollock et al. (2014, 2015) formed a stakeholder group comprising physiotherapists, stroke survivors and carers. During a series of 3 meetings, stakeholders made several decisions relating to the review. Decisions were made using the nominal group technique. In each case, the stakeholder group members first discussed a topic or statement for an agreed amount of time. Then each stakeholder group member individually ranked their agreement with that topic or statement and noted their reasons for this. The 'voting' sheets were anonymous, but were then collected and counted in front of the group members in order to see whether or not there was consensus on a topic. Further rounds of discussion and voting took place when needed.

- Group process: Often the process of involving people within a systematic review entails a group meeting, which may be called a meeting, workshop or conference. These meetings commonly involve discussion and debate, perhaps supplemented with formal methods such as consensus decision-making techniques. The content and processes within these group meetings are often poorly reported. However, evidence suggests that these meetings do often combine careful planning and use of techniques known to enhance the group process. The planning and approach to running group meetings provides a way of addressing many of the general issues identified as important to involvement, such as effective communication, clarity, expectations, respect and trust.

Box 3 Resource on group process

The Agency for Healthcare Research and Quality Practice's Facilitator's Guide to Running Effective Meetings provides a guide to key issues associated with planning and facilitating a group meeting.

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- Qualitative research methods: These methods, such as interviews or focus groups, have been used to elicit views and opinions of patients and the public in relation to systematic reviews. The purpose has most commonly been to ‘contextualise’ the findings of a systematic review to a particular population or area. These data have then been analysed using methods for analysis of qualitative data, such as thematic analysis (Bunn et al. 2015, Martin et al. 2015). In such cases, the involvement of people has occurred after completion of the systematic review. However, it could be argued that the involvement relates to the final stages of a systematic review process (such as dissemination and translation of evidence into practice). The level of involvement is one of ‘contribution’ and, in these examples, the people involved could arguably be described as ‘participants’ in research.

Describing and reporting PPI within a systematic review

It is good practice to report who, when and how people have been involved in a systematic review, and to reflect on the impact that this had on decision making and the final outputs of the review. This section presents 2 ways to aid reporting on PPI.

The ACTIVE framework

The ACTIVE framework (Pollock et al. 2019) provides a way of describing how and when people were involved in a systematic review. The framework, mentioned in the section on levels of involvement and shown in table 4, lists a series of framework constructs that should be reported and proposes categories for classifying how people were involved.

Table 4 ACTIVE framework for describing involvement of people in a systematic review (adapted from Pollock et al. 2019)

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Framework constructs	Categories	Notes
Who is involved?	• Patients, carers and their families • Patients, carers and their families, and other stakeholders • Other stakeholders only	The ACTIVE framework provides a way of categorising who is involved, using 3 broad categories. A written description should also be provided, giving numbers of people, and key information (for example, length of time with the health condition).
How are people recruited?	• Open, fixed • Open, flexible • Closed, invitation • Closed, existing group • Closed, purposive sampling	The ACTIVE framework provides a way of categorising the way in which people were recruited, using a series of categories based on the method of recruitment. A written description should also be provided, describing the targeted individuals or organisations, as well as where those recruited came from.
When are people involved?	1. Develop question 2. Plan methods 3. Write and publish protocol 4. Develop search 5. Run search 6. Select studies 7. Collect data 8. Assess risk of bias 9. Analyse data 10. Interpret findings 11. Write and publish review 12. Knowledge translation and impact	EACH stage at which people are involved should be clearly stated. The aim of involvement at each stage should be clearly stated.
When are people involved?	Top and tail approach?	If a top and tail approach is used this should be clearly stated, again stating the level of involvement at each point at which people are involved.
How are people involved? Approach?	• One-time involvement • Continuous involvement • Combined involvement (that is, both one time and continuous)	The categorisation of the approach to involvement gives a simple way of summarising what happened in terms of involving people in the review. Further details about what happened at each different stage at which there is involvement should also be provided, as outlined in the row on how people are involved, level of involvement.

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Framework constructs	Categories	Notes
How are people involved? Level of involvement?	• Leading • Controlling • Influencing • Contributing • Receiving	For each stage at which people are involved, the level of involvement or control should be stated (see the ACTIVE Continuum in table 3 for definitions of levels and descriptions of tasks completed within each level). The level of involvement may vary at different stages in the review process.
How are people involved? Format and methods?	• Direct interaction • No direct interaction	The categorisation of the **format of involvement** gives a simple way of showing the format of the involvement. It is important to also provide a description of what happened during any interaction. Details of the number and length of the interactions should also be reported. Note whether any **formal research methods and processes** have been used, and if so, what these were.

Several icons have also been developed, which may be useful for 'labelling' the PPI within systematic reviews. These icons are shown in table 5.

Table 5 Icons relating to the ACTIVE framework for describing involvement of people in a systematic review

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Framework constructs	Categories	Icon
Who is involved?	Patients, carers and their families	
Who is involved?	Patients, carers and their families, and other stakeholders	
Who is involved?	Other stakeholders only	
How are people recruited?	Open, fixed	
How are people recruited?	Open, flexible	
How are people recruited?	Closed, invitation	
How are people recruited?	Closed, existing group	
How are people recruited?	Closed, purposive sampling	
When are people involved?	Top and tail approach?	
How are people involved? Approach?	One-time involvement	
How are people involved? Approach?	Continuous involvement	
How are people involved? Approach?	Combined involvement (that is, both one time and continuous)	
How are people involved? Approach?	Direct interaction	
How are people involved? Format and methods?	No direct interaction	

The GRIPP2 checklist

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The GRIPP2 (Guidance for Reporting Involvement of Patients and the Public 2) checklist (Staniszewska et al. 2017) is a guideline for reporting PPI in health and social care research. It is not specific to systematic reviews, and it aims to capture reflections relating to the impact of involvement, in addition to the methods, and other components. There is a long and short-form version. The long form includes 34 items on aims, definitions, concepts and theory, methods, stages and nature of involvement, context, capture or measurement of impact, outcomes, economic assessment, and reflections. It is suitable for studies in which the main focus of the manuscript is PPI. The short form includes 5 items on aims, methods, results, outcomes, and critical perspective and is suitable for studies in which PPI is a secondary focus (for example, to briefly describe the PPI approach used within the manuscript describing the broader study). Although not specific to systematic reviews, the GRIPP2 checklist may provide a helpful guide for reporting the methods and impact of PPI and could be applied to a systematic review.

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Resources for planning and conducting PPI in systematic reviews

Cochrane's Involving People

A resource for systematic review editors and authors to support them in getting people involved in producing reviews. It is open access with a free Cochrane account.

Stakeholder Engagement in Evidence Synthesis

Open access resources related to engaging with stakeholders during planning, conducting and communicating evidence syntheses.

Cochrane's Consumer involvement training

A collection of resources for those who want to involve consumers in producing systematic reviews.

Webinars from the International Network for Patient and Public Involvement

A series of open access recordings of webinars about engagement and involvement in an international context, including Stakeholder Involvement in Evidence Synthesis, by Dr Neal Haddaway.

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Acknowledgements

The authors would like to thank the following for their contributions to this chapter:

Peer reviewers: Kenneth McLean, Lucía Prieto Remón, Noriko Kojimahara

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How to develop information from guidelines for patients and the public

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Key messages of this chapter

- There are many patient-directed knowledge tools available for presenting recommendations to patients and the public. Guideline developers should consider the purpose of these tools when producing such recommendations. Purposes include informing or educating, providing recommendations, supporting decision making and engaging in shared decision making.
- Involving patients and the public in the development of patient information derived from guidelines (that is, guideline-based information) promotes readability and assures the information is relevant for readers.
- Ensuring high quality of information produced for patients and the public is essential. Tools such as The Patient Education Materials Assessment Tool (PEMAT) and the DISCERN questionnaire can be used to assess various aspects of patient information, such as understandability and actionability of patient information.
- Qualitative research suggests patients and the public want the following information to be available in guideline-based information:
  - Context: who is the information for?
  - Background information about the condition:
    - What are the risk factors?
    - How will the condition progress?
    - How long will the condition last?
    - What is the risk of other problems arising from the condition?
  - Information about how to live with a disease and the treatment interventions:
    - What are the treatments, including the alternatives?
    - What are the risks associated with treatments?
  - What can I do for myself (for example, self-management)?

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  - Where can I find more help (for example, phone numbers and websites for sources of support)?
  - How are guidelines produced?
- When prioritising recommendations for inclusion in guideline-based information, it is important to consider the purpose of the information. For example, if the purpose of the information is to promote self-management, recommendations about self-management are the ones to prioritise.
- It is extremely important to communicate the rationale behind guideline recommendations to patients and the public. It is helpful if the strength of recommendations is communicated using both qualitative text and symbols. The use of symbols should be tested with the target audience.
- When presenting information about benefits and harms, evidence shows that people's understanding of risk can be improved by presenting them with absolute numbers rather than words. Even where people say they prefer words, giving them both improves understanding.
- The choice of format for information will depend on the purpose of the information, target audience, the topic, and budget available. If the audience is segmented into different groups, it may be beneficial to have multiple formats to ensure accessibility. Accessibility may mean adapting information (including web-based materials) for people who have low health literacy, translating the information into other languages, as well as making versions available as easy read documents, large print, audio or video.
- People like information presented in layers, which means that they can read as much, or as little as they want. A useful approach is to have short paper versions and longer electronic versions, with the latter in particular using a layered approach.
- Personalisation of guideline-based information, for example 'Who is this information for', is useful because it makes it easier for people to think about how the information is relevant to them.
- Guideline-based information should be easy to find by both healthcare professionals and patients. It may be helpful to provide the patient version along with the guideline itself to ensurethat healthcare professionals who look up the guideline will also find the patient version.

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Top tips

- Involve patient and public members of guideline development groups in developing information for the public.
- Include those recommendations in patient information that patients can directly influence or that can empower them to make care and treatment choices.
- Clearly state how the information was produced and by which organisation.
- When developing guideline-based information, consider signposting to other reputable and high-quality sources of information, including organisations and websites.
- The format for patient information should take into account the needs of the target audience. Consider producing multiple formats to promote accessibility.
- Statistical information should be kept simple. Use visuals such as bar graphs, pictograms or tables when possible.
- When summarising evidence on treatment options for patients and the public, simple tabular format (with questions and answers) allows easy comparison and improves comprehension of treatment benefits and harms.
- Use words and symbols to communicate the strength of recommendations to patients and the public.
- Guidelines may use different systems to present uncertainty, and if not intuitive, it may be helpful to include a description of what the system means in information for patients and the public.
- Use colour to distinguish between information from the evidence and information from other sources, for example, patient experience.

Aims of the chapter

This chapter describes strategies and methods to directly communicate all or some of the recommendations contained in guidelines to patients and the public. The guidance in the chapter is based on current best evidence from qualitative research on how to produce useful guideline-based materials for the public and patients, and options for when evidence does not exist. It gives an overview of:

- why producing information for patients and the public may add value to guidelines and foster implementation

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- what should be included in guideline-based material for patients and the public
- how to communicate information and strength of recommendations
- how to describe treatment options
- how to ensure material adheres to more general quality criteria for patient and public information.

The chapter also offers best practice examples for developing guideline-based materials for patients and the public.

Communicating guidelines to patients and the public

Many recommendations in guidelines directly affect care for patients and the public. Therefore, efforts should be made to produce knowledge tools for patients (that is, patient-directed knowledge tools) to facilitate patient participation in decision making about care and treatment. There are many ways in which patient-directed knowledge tools can present care and treatment options to patients and the public, including:

- a plain language summary as described in Glenton et al. (2010)
- an interactive summary of findings tables as described in the DECIDE interactive summary of findings table
- a patient version of a guideline, as highlighted in Schafer et al. (2015)
- promotion of single recommendations, as in the Association of the Scientific Medical Societies in Germany (2020)
- interactive patient decision aids, as done by the Ottawa Hospital Research Institute (2020) or 1-page tabular decision aids such as The Dartmouth Institute's Option Grids
- decision boxes, as highlighted in Giguere et al. (2012)
- facts boxes, as shown in Schwartz et al. (2007).

No single approach has proven to work substantially better than another, although interactive and tabular formats have generally been well received, according to DECIDE's work with patients and public. Whichever format is used, it is important to involve people from the target audience for the patient-directed knowledge tool when selecting and developing the tool (DECIDE patients and public, Stacey et al. 2014, Stacey et al. 2019).

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Table 1 presents Dreesens et al.'s (2019) framework with the various tools and their purposes. The first part of the framework describes the tools' purposes and the second focuses on the tools' core elements.

Table 1 A conceptual framework for patient-directed knowledge tools to support patient-centred care (based on Dreesens et al. 2019)

Type of tool	Purpose: inform or educate	Purpose: provide recommendations	Purpose: support decision making	Purpose: engage in shared decision making
Patient information and educational material	+	-	-	-
Decision tree	-	+	+	-
Independent or pre- and post-encounter patient decision aid	+	-	+	-
Patient version of clinical practice guideline	+	+	+	-
Encounter patient decision aid	+	-	+	+

Patient decision aids

A Cochrane review on decision aids described them as an intervention designed to support patients' decision making by providing information about treatment or screening options and their associated outcomes compared with usual care and alternative interventions (Stacey et al. 2014). Decision aids inform patients clearly about their options and prepare them to participate in decisions about their care and treatment. Information on shared decision-making tools can be found in the upcoming chapter on guidelines and shared decision making.

Decision aids, such as Option Grids and Facts boxes, are based on the best evidence and input from patients and healthcare professionals. They are easy to

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read and use. They can ensure decisions are well informed and made carefully considering patients' views (The Dartmouth Institute, Giguere et al. 2012).

Patient information

Patient information, such as leaflets, can empower patients to ask questions about decisions on diagnostic and treatment interventions. A patient leaflet may include one or a few recommendations from guidelines on a specific topic to help with decision making. Initiatives such as Choosing Wisely, produce materials to promote conversations with healthcare professionals and patients and about what is appropriate and necessary treatment.

Patient versions of guidelines

Patient versions of guidelines are tools that 'translate' guideline recommendations and their rationales so patients and the public can easily understand them. Patient versions of guidelines can support individual decision making and help to foster a trustworthy patient clinician relationship in that they provide understanding about how, based on the evidence, clinicians should treat a condition. In turn, people may feel reassured and confident in their care. In situations where they are not offered care options recommended in a guideline, patients may intervene thus supporting guideline implementation (see the upcoming chapter on dissemination and implementation for further information). Box 1 describes the purposes of patient versions.

Box 1 Purpose of patient versions of guidelines

- Allow priorities to become clear to patients.
- Highlight to patients the benefits and harms of interventions to support decision making.
- Identify interventions for which there is good evidence that harms do outweigh the benefit, potentially reducing the use of or demand for unproven interventions.
- Point out other uncertainties and emphasise when a patient's own values and preferences are especially important for making a treatment choice.

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- Identify lifestyle interventions and ways in which the patient can take steps to manage their condition.

It is important that patient versions are derived from guidelines that have recommendations based on a high-quality systematic approach and a formal consensus process. Recommendations for or against interventions will involve the guideline development group's value judgements, which may be the wrong choice for individual patients. Hence, the adequate application of a guideline does not only imply strict adherence to guideline recommendations but also reasonable non-adherence because of a patient's individual preferences or circumstances. It is crucial that guidelines convey this idea to both healthcare professionals and patients, and provide information to facilitate decision making.

Although the word 'translate' suggests using a different language, producing a helpful patient version is about more than tailoring the language to patients and the public. It involves:

- the selection of recommendations and outcomes to present
- how to present the strength of the recommendations and uncertainty in the evidence
- how to present the options available to a patient, and
- decisions about general formatting because patient versions may vary widely in format, length and content.

Ensuring high-quality patient-directed knowledge tools

The quality of materials produced for patients and the public is key to making the information desirable (DECIDE patients and public). Guideline developers therefore require quality criteria to use when developing patient-directed knowledge tools. The International Patient Decision Aid Standards (IPDAS) collaboration has also developed validated quality criteria specific for patient decision aids. One example of national consensus-based quality criteria for development, content and governance of patient-directed knowledge tools is that produced by the National Healthcare Institute of the Netherlands (van der Weijden et al. 2019).

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The Patient Education Materials Assessment Tool (PEMAT) is a systematic method to evaluate and compare the understandability and actionability of patient education materials (Shoemaker at al. 2013). It is designed as a guide to help determine whether patients will be able to understand and act on information. Separate tools are available for use with print and audiovisual materials.

We have developed a checklist for ensuring good-quality guideline-based information, shown in box 2. The information gives the essential requirements for producing such health information for the public (DISCERN, Shoemaker at al. 2013).

Box 2 Checklist for producing good-quality information for the public

The material:

- Makes its aims and purpose clear.
- Provides details on funding, who produced the information, when it was produced, and what sources were used to compile it.
- Follows a logical format and uses everyday language. Medical terms are defined when used.
- Clearly presents information on treatment options, what will happen if no treatment is used and about the certainty of the evidence. Language reflects potential uncertainty.
- Provides the information in chunks. Uses boxes, tables and bullets to break up text.
- Provides easy to understand numbers.
- Provides visual aids to promote understanding, for example, a picture of a healthy portion size.
- Gives easy to read online information and spoken words can be clearly heard and understood, for example, pace is appropriate. Language is non-directive and non-persuasive.
- Uses an active voice in written and online information.
- Clarifies the actions for people to take.
- Signposts to other sources of information.

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Process for developing patient-directed knowledge tools

Ideally, patient-directed knowledge tools should be developed towards the end of the guideline development process, after confirmation of the full set of recommendations and their rationales. Recommendations change throughout the guideline development process and this will avoid having to revise the information each time. Patient-directed knowledge tools should preferably be produced by the patients and healthcare professionals who have already been involved in developing the guideline on which the information is based. During the guideline development process, the group can systematically prioritise situations that require in-depth conversations between healthcare professionals and patients (Association of the Scientific Medical Societies in Germany 2020).

The guideline group can also discuss content beyond that to be included in the guideline, which could or should be covered by patient-directed knowledge tools. So, it is helpful to have the tools in mind when starting the guideline to inform the process of tool development. Patient or consumer organisations may also produce patient-directed knowledge tools, such as educational materials and patient versions of guideines, all of which can then be reviewed by the healthcare professionals and patients who developed the guideline. Developing information for patients and the public together with them helps promote readability and ensures that information is relevant to its readers.

The case study in table 2 shows how the Scottish Intercollegiate Guidelines Network (SIGN) developed the patient version of their guideline on migraine.

There are many ways to ensure that the information in the patient version reflects patients' needs and experiences. Although collaboration of clinicians and patients during the whole development process of the patient version is desirable, it may be more feasible to have collaboration at particular stages of the process, for example at the planning and consultation stages (Schafer et al. 2017).

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Table 2 Development of the patient version of the SIGN guideline on migraine

When did SIGN start developing the patient version and what was the timescale?	SIGN started developing the patient version when the guideline was at the editorial stage of the guideline development process. The production process for the patient version took 7 months, including consultation and editorial stages.
Who did SIGN involve in the development process?	Two clinicians and 2 patients from the guideline group were invited to participate in a subgroup responsible for producing the patient version of the guideline. This made it easier to make the guideline and patient version complementary. A volunteer member of the public was also invited to join this group to provide an objective user perspective. Members of the guideline group provided quality assurance checks on the patient version to make sure it accurately reflected recommendations in the guideline.
How were recommendations selected for inclusion in the patient version of the guideline?	The group held face-to-face meetings to select recommendations that patients would find helpful and could influence, for example choice of medication. Patient-important outcomes, patient values and preferences for a recommendation, and the need to consider these in the patient version, were discussed with the full guideline group during development of the guideline. The group agreed how much information on medication and side effects would be useful to help with decisions. The group discussed what other information would be required in the patient version to help with understanding the recommendations.
How did SIGN include information that was important to patients but not recommended in the guideline?	There were a few ideas for content from patients and the member of the public that did not come directly from the guideline. It was decided that these were important to include. So they were presented differently from recommendations, for example, not in recommendation boxes, to make this clear to the information users.
How did SIGN gather feedback on the patient version of the guideline?	The draft patient version was available for consultation for 4 weeks. The full guideline group, voluntary organisations and members of SIGN's patient and public involvement network were invited to provide feedback. Feedback was compiled into a consultation report and shared with the group responsible for developing the patient version. Feedback was used to improve the booklet.

How to select recommendations for inclusion in patient-directed knowledge tools

Patient-directed knowledge tools should prioritise the recommendations that patients can influence or discuss with their healthcare professional. For example, a

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recommendation about how a pathologist should prepare a biopsy would not be helpful because patients would never be able to discuss this with the pathologist. Research conducted by DECIDE with patients and the public has shown that people would like recommendations about managing their own care. The challenge with this is finding a sensible way of selecting the recommendations that should be presented in patient-directed knowledge tools. The best way of doing this is to involve patients, their carers and the public in the selection of recommendations, either from within the guideline development group or through a parallel group working on patient-directed knowledge tools (SIGN 100 2019, van der Weijden 2019). Box 3 summarises the questions that can be used to aid selection of recommendations for inclusion in patient-directed knowledge tools. The case study in table 2 shows how recommendations were selected for inclusion in SIGN's guideline on migraine.

Being clear on the intended target group and situation, that is, when patients will receive patient versions of guidelines, is important because this will influence which recommendations should be included and how they should be presented. For example, will they receive it before a hospital appointment? Will they have the opportunity to discuss it with a healthcare professional? If a condition has been diagnosed before they get a patient version, it may not be helpful to include recommendations on diagnostics or risk factors.

Box 3 Questions to ask when choosing recommendations

- Do they highlight options for interventions or care?
- Do they assess harms and benefits of the intervention in question and empower patient to make informed decisions?
- Do they assess harms and benefits of the treatment intervention in question and empower patients to make informed decisions?
- Do they recommend lifestyle interventions and ways in which the patient can take steps to manage their condition?
- Do they identify treatments that have no evidence of benefit?
- Can the recommendations help patients to understand their own condition?

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- Do patients and the healthcare professional see a need for intensive conversation?
- Do they address relevant situations of over- or underuse? (this is extremely relevant in the context of diagnostic or screening recommendations)
- Do they address adherence?
- Are there barriers to the implementation of the recommendation, that could be resolved through discussion with the patient (for example, safe use of medicines)?

After the development group has selected recommendations to be included in patient-directed knowledge tools, they should be translated into plain language to allow them to be easily understood by a wide audience. If further information is needed to understand the recommendations (like anatomy, physiology or other information), it should be provided either along with the recommendation or in specific sections or paragraphs.

Content for patient-directed knowledge tools

The information in patient-directed knowledge tools should reflect what is in the guideline. Only diagnostic and care options provided in the guideline should be included (SIGN 100 2019, van der Weijden 2019).

A series of focus groups and other qualitative work with patients and the public (DECIDE patients and public, SIGN 100 2019, Cronin et al. 2018) found that the following issues are considered important when using information from guidelines :

- Context: who is the information for?
- Background information about the condition:
  - What are the risk factors?
  - How will the condition progress?
  - How long will the condition last?
  - What is the risk of other problems arising from the condition?
- Information about the diagnostic and treatment interventions:

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  - What are the treatments, including the alternatives?
  - What are the risks associated with treatments?
  - What can I do for myself (that is, self-management)?
- Where can I find more help (for example, phone numbers and websites for sources of support)?
- How are guidelines produced?

Patient-directed knowledge tools, such as patient versions of guidelines, should highlight that there may be other well-known treatment options available but that they are not covered and thus not recommended by the guideline. This may be either because of lack of evidence, lack of resources and prioritisation or because they are outdated. This helps to clarify for patients that there are other options available but they have not been recommended by the guideline because of lack of evidence.

Additional information may be included in patient versions of guidelines if it helps to foster an understanding of the recommendations or supports self-management. Including information not directly linked to recommendations is of value and allows people to participate in shared decision making. If there is content in the patient version that is not in the guideline, this has to be made explicit. Furthermore, the guideline panel should check this type of information for consistency with the guideline. How the information was generated should be documented transparently (for example, based on patient experience, systematic search or qualitative research). The case study in table 2 explains how information that was important to patients but not recommended in SIGN's guideline was included in the patient version.

Tick boxes or other interactive tools are useful formats for information not linked to recommendations (DECIDE patients and public). Guideline producers committed to providing patient versions will need to consider each guideline individually to determine the intended purpose of the patient version and then decide on the content (van der Weijden et al. 2019).

Who is this information for?

Research has shown that people will often ignore health information if it does not seem to apply to their individual circumstances. Therefore, patient-directed

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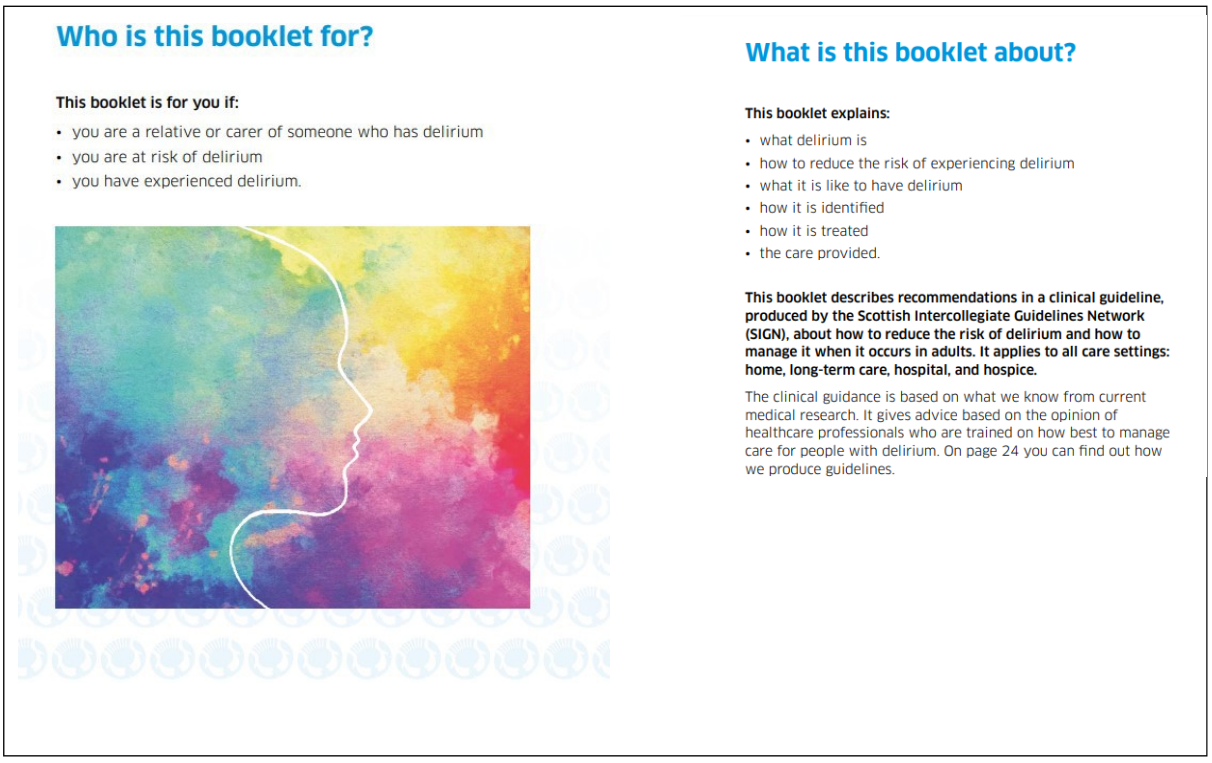
knowledge tools, such as patient versions of guidelines, should be clear about who the information is for. Making the applicability of a patient version of a guideline clear, using text such as ‘what does this have to do with me?’, is essential (DECIDE patients and public, Cronin et al. 2018, Loudon 2014, van der Weijden et al. 2019). However, around only half of current patient versions in the English language do this (Santesso et al. 2016). Figure 1 provides a simple example of how this can be done. It shows the information from a patient version in SIGN’s patient booklet on delirium, which explains who the booklet is for and what it is about. The context for using the booklet is clear; the information in the leaflet adds to the information provided by the people involved in a person’s care. Although written for patients, the booklet acknowledges that family members and carers may also read it.

If treatment recommendations apply only to a specific type of disease, it is helpful to make it clear that only patients with this specific diagnosis will benefit from the information. For instance, a guideline for the treatment of exocrine pancreatic cancer will not be relevant to patients diagnosed with endocrine pancreatic cancer, although they themselves will not be aware of this difference. If there are subgroups that have a larger or lesser benefit from interventions, this should also be made clear in the patient version or knowledge tool.



Who is this booklet for?

This booklet is for you if:

- you are a relative or carer of someone who has delirium
- you are at risk of delirium
- you have experienced delirium.

What is this booklet about?

This booklet explains:

- what delirium is
- how to reduce the risk of experiencing delirium
- what it is like to have delirium
- how it is identified
- how it is treated
- the care provided.

This booklet describes recommendations in a clinical guideline, produced by the Scottish Intercollegiate Guidelines Network (SIGN), about how to reduce the risk of delirium and how to manage it when it occurs in adults. It applies to all care settings: home, long-term care, hospital, and hospice.

The clinical guidance is based on what we know from current medical research. It gives advice based on the opinion of healthcare professionals who are trained on how best to manage care for people with delirium. On page 24 you can find out how we produce guidelines.

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Figure 1 Information from SIGN's patient version of the guideline on delirium

Downloading material from a guideline developer's website, or using an online tool, supports patients in discussing their care with healthcare professionals (Cronin et al. 2014, Utranker et al. 2018). Guideline producers should consider how the document might be used and word it accordingly.

Background information about the condition

Patients and the public have wider information needs than knowing the treatment options available for a particular condition or problem. When asked, many people thought guidelines could be a simple tool to provide health information, as well as recommendations (DECIDE patients and public). Focus group and user-testing work also found that participants had information needs that were more general than treatment recommendations. These included questions about whether the condition could be prevented, how it would progress, and would it lead to anything else. In particular, knowledge of progress and natural history of a condition may help to assess benefits and harms of different treatment options (DECIDE patients and public). Circumstances of the technical delivery of treatment options may influence the decision-making process (such as, weekly delivery instead of a single intervention, and inpatient instead of outpatient treatment or another arrangement).

Guidelines generally don't provide much of this sort of information as part of the standard guideline production process. For example, the information for the public in the National Institute for Health and Care Excellence (NICE) guideline on depression in adults (CG90 2009) contains little background information on depression. Guideline producers may have to make a choice between not providing information (even though patients and the public may want it) or doing extra work because their standard guideline production process does not routinely generate this information. Taking the former route may lead to information that is less useful than it could be. If taking the latter route, guideline producers may limit the need for extra work by asking patients on the guideline development group what information matters to them, especially those who are representing a wider group of patients. In the NICE depression guideline it was important to describe mild, moderate and severe depression because different recommendations are made for each type of depression. Some of this additional information may be sourced from the appropriate

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patient information groups for use in patient-directed knowledge tools. Links to local sources of support for patients and the public can also be provided.

What are the treatments and risks associated with them?

Similar to in the section about background information, guideline producers will need to balance the amount of information to provide and what is available in the original guideline document. Again, producers may consider background information about the treatments or interventions that will assist people in understanding the recommendations and treatment implications (DECIDE patients and public, SIGN 100 2019).

What can I do for myself?

The importance of presenting recommendations that relate to self-management is one of the strongest messages coming from research with patients and the public (DECIDE patients and public). It also emerged in a review of patient and public attitudes to guidelines as one of the purposes of patient versions (Loudon et al. 2014). Relatively few patient versions of guidelines in the English language currently meet this need (Santesso et al. 2016). German patient versions have a mandatory section called living with the disease, in which recommendations for self-management are addressed.

Presenting recommendations linked to self-management are therefore ones to prioritise when deciding which recommendations to cover in guideline-based information. Guideline producers may also want to consider whether to provide additional information about how people could apply the recommendations in their daily lives. When presenting additional information alongside recommendations, it should be clear that this information is not evidence based and is based on patient or expert opinion. The guideline group should check that additional information is consistent with the guideline. However, additional information may be very helpful for other patients if based on patient experience (Schaefer et al. 2015). Guidelines rarely address issues that matter most to patients like treatment burden or the impact that a condition has on daily life and how to deal with that. Information reporting patient experience must be carefully checked to ensure that it contains no effectiveness claims regarding treatments.

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The case in table 3 is based on a German guideline on gastric cancer. It shows an example of when patient knowledge and experience led to including additional information in a patient version that was more valuable for users than the guideline recommendations.

Table 3 Integrating patient experience in the German patient guideline on gastric cancer

What kind of patient experience did the patient guideline include?	There was a complete lack of evidence on what patients who had had surgery for gastric cancer should eat. The guideline did not address this question. However, the patient organisation involved stated that, based on their counselling experience, most patients reported that was the most important issue and barrier in their daily life and had much impact on their wellbeing.
How was this experience-based knowledge retrieved?	Based on collective experience retrieved through discussions in self-help groups, feedback from counselling (patient hotlines), and chats in patient forums, a patient group compiled a list of foods that seemed to be beneficial for patients after gastric surgery, and food that might be intolerable. They also provided experience-based strategies on how to start eating after surgery, and how to adapt nutrition to individual needs. This list was forwarded to the nutrition experts involved in developing the clinical practice guideline (CPG) and checked for plausibility.
How was the information presented in the guideline?	The patient version contained a chapter on nutrition. The introduction stated that the following information was not derived from the guideline but from patient experience. Important strategies and the lists of foods were presented. Information specialists checked that the wording was not directive but always reflected that the information was based on experience. For example, instead of writing ‘Do not drink coffee’ they suggested ‘some patients have reported a bad experience with drinking coffee’.
How was this chapter received?	Patients reported that for them, this section contained the most helpful information of the whole patient version. This is especially important because this information was not in the CPG, indicating that information that truly helps patients may partly differ from guideline content.

Where can I find more help?

Many patient-directed knowledge tools provide links or contact information, such as telephone numbers for additional information and support, a need that has been highlighted by patients and the public (DECIDE patients and public). Those

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developing guideline-based patient information should consider highlighting other sources of information including:

- contact details of relevant organisations
- relevant websites, including those focusing on financial benefits and returning to work
- other useful publications.

The sites or organisations listed in information should be reputable and assessed as providing high-quality support or information. Tools, such as the DISCERN questionnaire and the PEMAT, are a valid and reliable way for guideline developers to assess the quality of information provided by other organisations (DISCERN, Shoemaker et al. 2013).

Patient versions of guidelines might also provide practical advice, such as what to think of before an appointment with a doctor, or suggest questions to ask when talking to healthcare professionals. Patients involved in developing the patient version can compile their own experiences and offer tips on how to deal with the condition in daily life. For example, a patient version on diabetic foot problems could provide information on what to think of when buying shoes. This is an issue unlikely to be addressed by the guideline but which matters a lot to patients with diabetic foot syndrome. Also, patients involved in developing patient versions, as well as those involved in any wider consultation, can use their own experience and judgement to highlight further information they think would be important to other patients and information that goes beyond the information covered by the guideline. It should be clear in the patient version that further information is based on the experience of patients and not on a systematic search and appraisal of the evidence.

How are guidelines produced?

Patients and the public have very limited awareness of guidelines (Loudon et al. 2014, Sentell et al. 2013). When they are aware of them, they often think they are intended to restrict or ration the care available (van der Weijden at al. 2019). Research shows that some patients worry that guidelines might impair the relationship with their healthcare professionals by suggesting reduced confidence in them (Loudon et al. 2014). A patient version of a guideline is an opportunity to allay

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these fears but care is needed to avoid providing too much, complex information about how the guidelines were developed. Some, but not all, people are interested in this information (DECIDE patients and public).

People have found process diagrams, such as the one in figure 2, useful and can help them to understand how information was produced. Although there are some differences in opinion, there is preference for this information to be at the back of the patient version. This is to ensure that the information that most people are interested in comes first, and those who want to can still navigate straight to the information on the guideline process (DECIDE patients and public). Nevertheless, patients taking part in German focus groups expressed a need to have this information at the beginning, because it would allow them to understand the extent to which the information that followed was reliable (Schaefer et al. 2015).

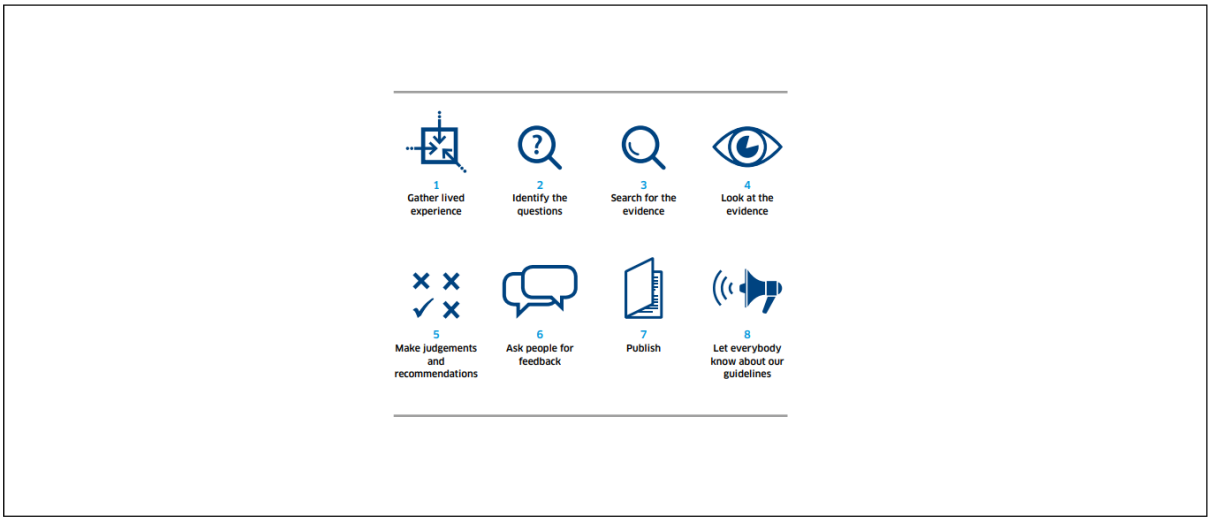

Figure 2 Example of a process diagram used by SIGN

Communicating the strength of a recommendation in patient-directed knowledge tools

Various standards for how to present recommendations advise that the strength of the recommendation and the level of evidence be presented separately (for example, a strong recommendation based on moderate quality evidence). The quality of evidence does, of course, affect the strength of the recommendation.

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To enable patients to understand the strength of recommendations in patient versions, we suggest using several strategies, for example, using words and symbols. Some work has also indicated that people want to know why a recommendation is strong or not. Therefore, providing the reasons for a recommendation and what to consider may help.

Conveying the strength of the recommendation in words

Typically, guideline producers will use qualitative text to convey the strength of a recommendation in the original guideline document. For example, strong recommendations may be ‘recommended’ and weaker recommendations may be ‘suggested’. Different guideline producers may use different labels to convey the strength of the recommendation. When using the GRADE approach, recommendations are labelled as ‘strong’, ‘weak’ or ‘conditional’ (Guyatt et al. 2008). It may be helpful, regardless of the system being used, to include a legend in the patient version for the definitions of the terms used (Ottawa Hospital Research Institute 2020).

Research, in particular with healthcare professionals, has indicated that words are interpreted differently (Nast et al. 2013). To minimise misunderstanding, guideline developers should include symbols, other labels and or reasons for the strength of the recommendation. The reasons may be based on the certainty of the evidence, the differences in people’s preferences, resources or other issues, such as feasibility, accessibility or equity.

Using symbols to convey the strength of recommendations

Symbols were used in the WHO’s guideline on health worker roles in maternal and newborn health (see figure 3). The guideline was aimed at a range of stakeholders (although not the public). The symbols were well received.

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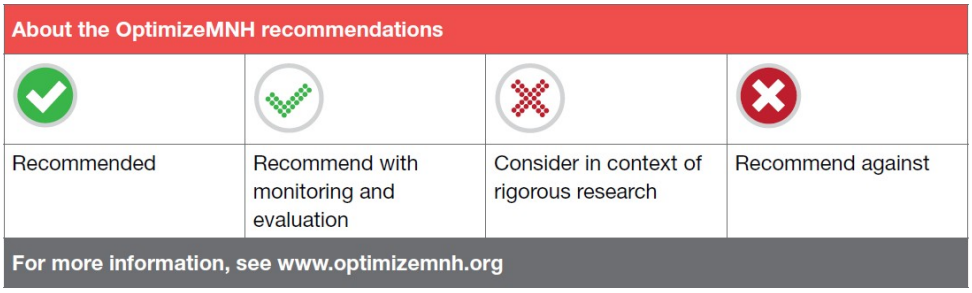

Figure 3 Symbols in WHO's guideline on health worker roles in maternal and newborn health that were tested with the target audience

The solid green ticks are strong recommendations in favour of the intervention, and solid red crosses are strong recommendations against the intervention. The dotted ticks and crosses are weak recommendations for and against the intervention, respectively.

Having learned from work with patients and the public (Ottawa Hospital Research Institute 2020), SIGN uses a system of icons with text to flag recommendations and their evidence level. The symbols in figure 4 were adopted for SIGN's autism booklet for patients, carers and families of children and young people, which is the public version of the autism guideline.

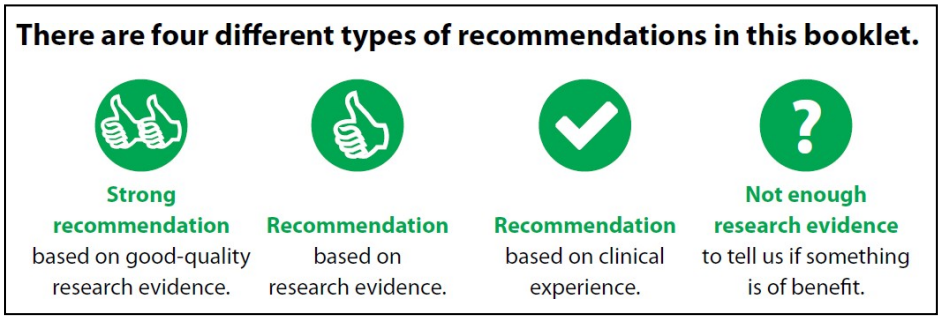

Figure 4 symbols tested with parents and carers for SIGN's autism booklet

Use of symbols to express strength of evidence needs to be tested with the target audience. For example, parents and carers taking part in user testing of the symbols in figure 4, found the thumbs up, tick and question mark symbols clear and easy to understand. However, the response to the underlying 4 levels of evidence was mixed. Some parents appreciated the level of detail offered by the grades of evidence and recommendations, and others thought it would be sufficient simply to

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know that SIGN recommended an intervention (DECIDE patients and public). The parents understood the essential message of the evidence levels, which is that one intervention is strongly recommended and another one less strongly recommended. But most did not understand why it is necessary to have these different levels of recommendation. Similarly parents found the not enough evidence icon disconcerting. Although they understood that the question mark and text was meant to convey uncertainty, they did not like this message, or understand why guideline producers would need to use it (DECIDE patients and public).

Presenting treatment options and communicating their risks and harms in patient-directed knowledge tools

Structuring the presentation

Structured presentations (especially with question and answer approaches) for presenting treatment options were well received and understood in work with patients and the public (DECIDE patients and public, Santesso et al. 2015). When summarising evidence on treatment options for patients and the public, a simple tabular format, as shown in figure 5, allows easy comparison and improves comprehension of treatment benefits and harms (DECIDE patients and public, Glenton et al. 2010, Loudon et al. 2014, Santesso et al. 2015, Santesso et al. 2016). ‘No treatment’ (doing nothing) should be considered and presented as an option to help people understand the benefits and risks of interventions. Presenting the benefits and harms for each option allows patients and the public to weigh these options against their personal values and preferences and can support conversations with healthcare professionals, something patients and the public have asked for (Santesso et al. 2016). It should be clear that information presented on the benefits and harms of treatment options is based on a systematic search and appraisal of the evidence.

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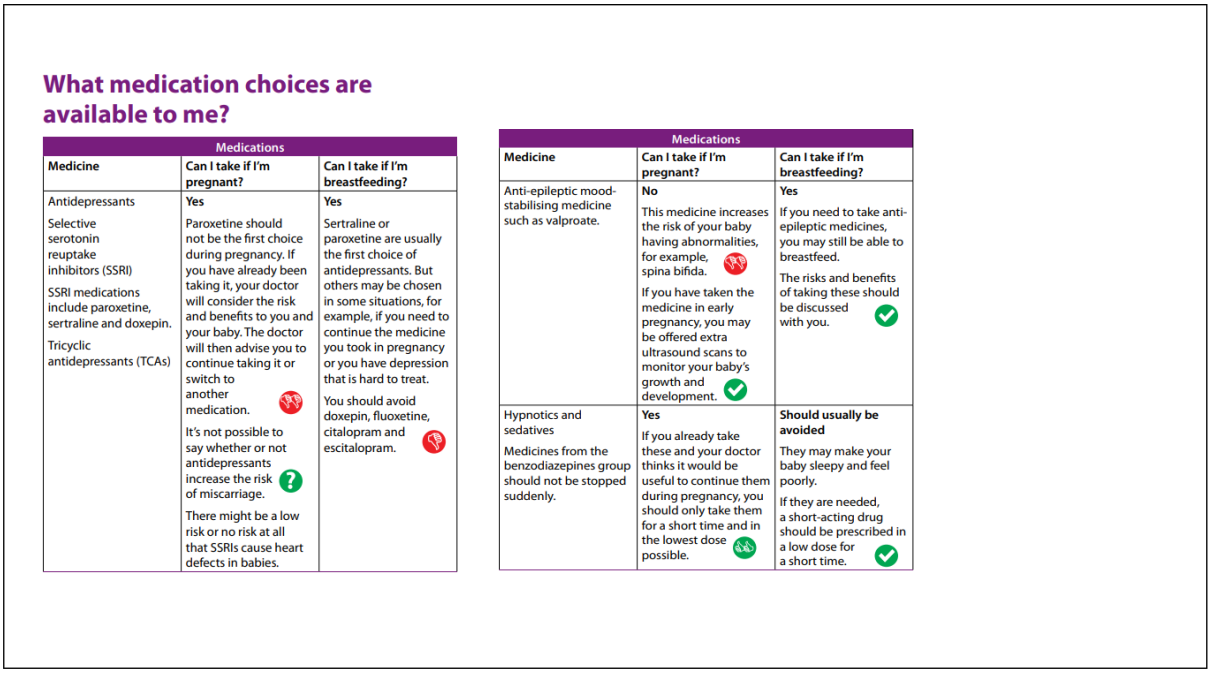

What medication choices are available to me?

Medications		
Medicine	**Can I take if I'm pregnant?**	**Can I take if I'm breastfeeding?**
Antidepressants Selective serotonin reuptake inhibitors (SSRI) SSRI medications include paroxetine, sertraline and doxepin. Tricyclic antidepressants (TCAs)	**Yes** Paroxetine should not be the first choice during pregnancy. If you have already been taking it, your doctor will consider the risk and benefits to you and your baby. The doctor will then advise you to continue taking it or switch to another medication. It's not possible to say whether or not antidepressants increase the risk of miscarriage. There might be a low risk or no risk at all that SSRIs cause heart defects in babies.	**Yes** Sertraline or paroxetine are usually the first choice of antidepressants. But others may be chosen in some situations, for example, if you need to continue the medicine you took in pregnancy or you have depression that is hard to treat. You should avoid doxepin, fluoxetine, citalopram and escitalopram.

Medications		
Medicine	**Can I take if I'm pregnant?**	**Can I take if I'm breastfeeding?**
Anti-epileptic mood-stabilising medicine such as valproate.	**No** This medicine increases the risk of your baby having abnormalities, for example, spina bifida. If you have taken the medicine in early pregnancy, you may be offered extra ultrasound scans to monitor your baby's growth and development.	**Yes** If you need to take anti-epileptic medicines, you may still be able to breastfeed. The risks and benefits of taking these should be discussed with you.
Hypnotics and sedatives Medicines from the benzodiazepines group should not be stopped suddenly.	**Yes** If you already take these and your doctor thinks it would be useful to continue them during pregnancy, you should only take them for a short time and in the lowest dose possible.	**Should usually be avoided** They may make your baby sleepy and feel poorly. If they are needed, a short-acting drug should be prescribed in a low dose for a short time.

Figure 5 Example of presenting treatment options in SIGN's patient version of mood disorders in pregnancy

Using qualitative and quantitative statements about benefits and harms

Existing patient versions in the English language generally say little about potential benefits and harms of treatment options, and very few provide numerical information (Santesso et al. 2016). There is evidence that people's understanding of risk can be improved by presenting them with numbers rather than words and even when people say they prefer words, giving them both improves their understanding (Büchter et al. 2014, Knapp et al. 2014, Natter and Berry 2005). For numerical information, using absolute numbers, rather than relative numbers, and natural frequencies (for example, '50 of 100 people') are easiest to understand and are less confusing (Büchter et al. 2014, DECIDE patients and public, Knapp et al. 2014, Natter and Berry 2005). Evidence shows that patients and consumers overestimate risks when probabilities are presented in verbal terms. Using numbers results in more accurate estimates of risk (Büchter et al. 2014, Knapp et al. 2014, Natter and Berry 2005, Santesso et al. 2015, Trevana et al. 2013). There is good evidence, that presenting relative risk reduction alone leads to overestimation of treatment effects, so this should be avoided (Trevena et al. 2013). Although there is currently no certain way to present numerical information from guidelines to patients and the public, we

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recommend guideline producers present information on benefits and harms and consider adding numerical information. Many people, although not all, would like to see such information on benefits and harms. Numerical information presented as a statement has been found to be more helpful than pictograms, but any numerical information should be tested with the target audience (Ottawa Hospital Research Institute 2020).

For qualitative text statements, standard text such as that shown in figure 6 provides consistency and includes both the size of the effect (for example, will not decrease, will decrease, probably decreases, may decrease, will not lead to more side effects) and the certainty and quality of the evidence (Büchter et al. 2014, Knapp et al. 2014, Natter and Berry 2005, Santesso 2015).

What happens to people who take vitamin C

This table provides more detail about what happens to people who take vitamin C. These numbers are based on the results of the research, when available. The quality of the evidence is either ranked as high, moderate, low or very low. The higher the quality, the more certain we are about what will happen.

What happens	Not taking Vitamin C	Taking Vitamin C (1 to 2 g per day)	Quality of evidence
Probably will not decrease how long the cold lasts if vitamin C taken as soon as the cold starts	The cold lasts **84 hours or 3 ½ days**	The cold lasts **2 fewer hours** (9 fewer to 4 more hours) *	⊕⊕⊕◯ Moderate
Will decrease how long the cold lasts if vitamin C taken before the cold	People at normal risk The cold lasts **84 hours or 3 ½ days**	The cold lasts **7 fewer hours** (3 to 11 fewer hours)	⊕⊕⊕⊕ High
Probably decreases how long the cold lasts if vitamin C taken before the cold	People at high risk The cold lasts **134 hours or 6 days**	The cold lasts **19 fewer hours** (8 to 30 fewer hours)	⊕⊕⊕◯ Moderate
Will not decrease the chance of catching a cold	People at normal risk **50 per 100 people**	**49 per 100 people** (48 to 50 per 100)	⊕⊕⊕⊕ High
May decrease the chance of catching a cold	People at high risk **70 per 100 people**	**35 per 100 people** (27 to 46 per 100)	⊕⊕◯◯ Low
Will not lead to more side effects	**6 per 100 people**	**6 per 100 people**	⊕⊕⊕⊕ High

Quality of evidence: The quality of the evidence is either ranked as high, moderate, low or very low. The higher the quality, the more certain we are about what will happen.
*The numbers in brackets show the range where the actual effect may be.

Figure 6 Format for presenting information from a Cochrane review of the effect of Vitamin C on the common cold in plain language (Hemillä et al. 2007)

Information about benefits and harms should refer to patient-relevant outcomes. Reporting on benefits could include controlling or getting rid of symptoms, prevention of recurrence, and eliminating the condition both short term and long term. Reporting on risks could include side effects, complications and adverse reactions to treatment, both short term and long term. Note that the harms of an option extend beyond clinical risks. For example, to make a treatment choice between radiation therapy and brachytherapy for prostate cancer, it may be important for some people that one

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treatment is non-invasive and requires several sessions whereas the other is invasive and performed at a single session. If the effect of treatments on morbidity or mortality is unknown, this should be stated.

Presenting uncertainty

Patients and the public do want to know about uncertainty (Knapp et al. 2009). For example, how sure are we that X in 100 of those affected will have pain? This information can be understood if well presented. Most guideline producers will have a system to evaluate the quality or certainty of the evidence. Different systems such as symbols, words and letters may be used, and if not intuitive, it may be helpful to include a description of what the system means in the patient version.

In addition, if reference is made to treatments for which there is no or very low quality research, this should be made clear. It should not be confused with a treatment in which evidence has shown that the treatment has little to no effect. Figure 7 is an example of how SIGN has presented such information.

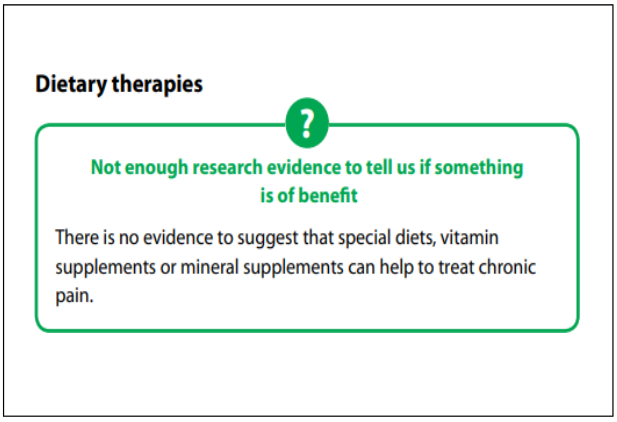

Figure 7 Example from SIGN on presenting information about a treatment which is not supported by the evidence

Using graphical approaches to present information

Focus groups and user testing with patients and the public found that patients and the public liked graphics to break up the text, but that graphics and charts should be kept simple (DECIDE patients and public). Those who used numerical information to increase their understanding of the risks and benefits indicated a preference for the

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information to be presented in pie charts. Evidence from a low-quality randomised controlled trial suggests that bars, pictographs and tables tend to be efficient tools to present numerical information (Trevena et al. 2013). The authors found that information seemed clearer when presented in this format. Simple bar charts were easily understood although they don't convey uncertainty. Graphs should present benefits and harms on the same scale and alternative treatment options should be reported for the same outcomes.

Formatting and style of patient-directed knowledge tools

There are many potential formats for patient information derived from guidelines and the format used should take account of the target audience. In addition to this, the choice of format will depend on the topic and budget available.

There is no one-size-fits-all approach to developing guideline-based patient information (DECIDE patients and public). But consider the information in the sections on using a layered approach, personalisation, accessibility, and colour, fonts and graphics.

Using a layered approach for presentation of information

The length of patient versions produced by different organisations varies, with them ranging from 2 to 3 pages to 40 or more pages. Patients and the public accessing information in guidelines don't want to be overwhelmed by the amount of information (Cronin et al. 2018, DECIDE patients and public, Loudon et al. 2014, Utrankar et al. 2018). A German qualitative study on a plain language version of a breast cancer screening guideline found that people consider a brochure of 15 or more pages as 'long' and that it makes no difference for readers if this 'long' brochure has 15 or 150 pages (Frauenselbsthilfe nach Krebs [Womens Health Coalition] 2012). People like information presented in layers, which means that they can read as much or as little as they want. A useful approach is to have short paper versions and longer electronic versions, with the latter in particular using a layered approach (Ottawa Hospital Research Institute 2020). However, people with chronic conditions may appreciate longer booklets that can be read and reread time after time, thereby accompanying them through the whole process of care (Frauenselbsthilfe nach Krebs [Womens Health Coalition] 2012). Exactly how much information should be

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provided depends on the target group and may be discussed early in the development process.

The concept of layered presentation, that is, the most important information in the first layer, less important in the next layer, is one of the strongest findings on work with patients and the public (DECIDE patients and public). For paper documents, patients and the public could select the recommendations for inclusion in the document. In the German National Disease Management Guidelines Program, the most important information is presented in a short information 2-page leaflet. The leaflet then refers to a comprehensive brochure that provides in-depth information. An example is their patient-information.de portal webpage on coronary heart disease. If necessary, more than 1 leaflet on different topics can be derived from a sinlge guideline. For example, SIGN's patient publications on the management of asthma present information from the guideline in various booklets, including a smaller booklet specifically on asthma in pregnancy. The flow of information in digital documents can be controlled by asking readers, who want more information on a topic, to click on text that has a link to another webpage or website.

Personalising the information

Many patient versions attempt to personalise the information provided. Participants in UK focus groups and user testing found personalisation useful because it makes it easier to think how the information is relevant to them. The same has been found in other fields (DECIDE patients and public, Glenton et al. 2010). The degree of personalisation that is possible and appropriate will be context specific.

The simplest personalisation is to have a statement at the beginning of the patient version saying to whom the information applies (see the section who this information is for). Some patient versions use the words 'you' or 'I' in text or headings to refer directly to the reader. For example, a heading could be 'What you need to know', or 'How much fibre do I need?'

Other ways to personalise information include personal stories, or narratives, of people with the same problem (Hartling et al. 2010). But, personal stories are not without problems, particularly regarding how to select stories for inclusion. For example, should the aim be to provide balance, to downplay problems, or to

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emphasise benefits? Selection of patient stories has proved difficult in decision-support work (Winterbottom et al. 2008). Evidence also suggests that personal stories may influence risk perception and lead to over or underestimation of treatment effects (Betsch et al. 2011, Betsch et al 2013, Winterbottom et al. 2008). So, if treatment or test options are presented in personal stories, it may be important to select the number of stories in proportion to their potential benefit. Furthermore, highly emotional narratives seem to have a greater impact on the perceived risk (Winterbottom et al. 2008).

In reality, it may be difficult to find the best story but readers do need to be able to connect with how information in patient versions affects them. Online websites focusing on patient views have been increasingly accessed and it might be helpful for guideline developers to signpost readers to popular websites, such as healthtalk.org or patientslikeme. These websites could provide personal stories for patient versions of guidelines.

Using quotations from people who have the condition may also be a useful way to personalise the information in patient versions and to engage readers (Loudon et al. 2014). Work with patients and the public highlights that patients find quotations useful, helping them to relate to the material (DECIDE patients and public). The use of quotations has the same challenge as using patient stories in terms of deciding which quotes to select. It may be difficult to find quotations that are consistent with the evidence base presented within the patient version. Figure 8 provides an example of quotations that SIGN used to personalise information in its guideline on managing diabetes.

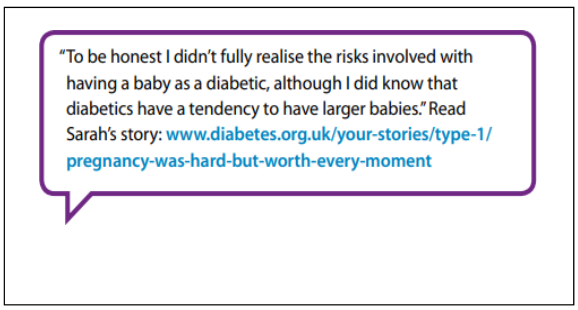

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Figure 8 Quotation to personalise information in SIGN's guideline on managinging diabetes

Ensuring accessibility

If the audience is segmented into different groups, it may be beneficial to have multiple formats to maximise accessibility and findability. This includes the availability of hard copies as well as online versions of the material, such as access through mobile phone application, patient portal and access, and social media (Cronin et al. 2018, DECIDE patients and public, Utrankar et al. 2018). More and more patients, including older people, search for health information on the internet.

It has also been suggested that information for patients and the public linked to guidelines could be embedded within the guideline itself. This would allow healthcare professionals to more easily access it when having conversations with their patients (DECIDE patients and public).

According to Santesso et al. (2016), about half of existing patient versions are intended to be printed (although they are also available as pdfs) and half are intended to be read on-screen (although they can also be printed). Increasing accessibility of these may mean translating the patient version into other languages, as well as making versions available in large print, as audio or video. For example, SIGN produced information from a guideline on perinatal exposure to alcohol in the form of a booklet for parents andcarers and a YouTube video animation for young people on perinatal exposure to alcohol.

Guideline developers providing information in the form of web-based materials should ensure they are accessible for all. Careful consideration should be given to colour contrasts and making text clearer. Adding descriptions to images, which screen readers can then interpret, can give people access to all the information from guidelines. By adding descriptions to different command buttons, patients can more easily navigate the online information.

Patient information derived from guidelines should be easy to find. In Santesso et al.'s review (2016), the easiest patient versions to find were ones from a guideline organisation that also had a dedicated patient website. Of course not all guideline

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producers can have a whole website, although it is still possible to make it easy to find patient versions. For example, by having a dedicated section of the guideline producer's website to list patient versions of guidelines. If the patient version is on another organisation's website, it should be easy for people to find it when searching for help on their condition. For example, NHS Inform (Scotland's single source of quality-assured health information) provides links to patient versions of guidelines on their website to help people to find them when searching for information on conditions. Evaluation of German patient versions has suggested that patients wanted healthcare professionals to forward the patient version to them (Schaefer et al. 2015).

If the patient version is designed for healthcare professionals to use in their conversations with patients, or to hand a printed copy to them, then it should also be simple for healthcare professionals to access. Therefore, it may be helpful to provide the patient version along with the guideline itself to ensure that healthcare professionals who look up the guideline will also find the patient version. Incentives for healthcare professionals to provide the patient version of the guideline may foster implementation. For example, a German survey found that most patients learned about patient versions of guidelines from their physicians (Schaefer et al. 2015).

Patients and the public have very low awareness of guidelines (Loudon et al 2014, Utramker et al. 2018), so it is likely that most people will not be looking specifically for guideline-related material when using, for example, internet search engines to find materials. Guideline producers may need to get professional help to assist them in getting 'hits' so that they reach their target audiences, and to ensure that the patient versions are indexed to their best advantage to allow search engines to find them. Patient organisations and other voluntary organisations should also be encouraged to promote patient versions of guidelines on their websites.

Patient information derived from guidelines should also be easy to read. Easy read is one form of accessible information. They use short, simple sentences and pictures to explain topics. For example, easy read documents provided by Mencap on keeping clean and handwashing help explain guidance during the Covid-19 outbreak.

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The amount and level of technical terms that people are confronted with in patient versions of guidelines should be carefully considered (DECIDE patients and public) Health literacy varies and depends especially on socioeconomic status, education and ability to speak the language the patient version is written in, with lower levels of health literacy being associated with poorer health outcomes (Berry et al. 2010, Wolf et al. 2005). Plain language should be used, unless it is absolutely essential to use specialist language, so as to not exclude some of your audience. Using terms like ‘lymphadenctomy’ or ‘types of pharmacological treatments’ will make a leaflet or a brochure difficult to understand for many (perhaps most) of the people expected to read the material. On the other hand, these are the expressions patients may hear during their conversations with healthcare professionals. Health forums may also provide some indication of words that are presently being used by patients and the public. Current patient versions have provided terms and defined them in an understandable way, for example, in brackets after the term, separately in a box, or as part of a short glossary at the end of the document (both NICE and the German National Disease Management Guidelines Program do the latter for their guidelines).

Colour, fonts and graphics

The text size and colours used in graphics must be appropriate for the target audience (DECIDE patients and public).

Colours

Poor choice of colours can make a document hard to read; avoid using light text on light backgrounds and dark text on dark backgrounds. Some colour combinations may work better (or worse) on computer screens than in print.

Colour blindness affects about 1 in 8 men and 1 in 200 women, so should be considered when selecting colours for use in patient versions. Common types of colour blindness are:

- red/green colour blindness
- blue/yellow colour blindness

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Avoid using these combinations of colours together. Similarly, the use of pale pastel colours is not helpful for people with visual impairments (DECIDE patients and public).

The use of colour can also convey meaning, which may not be what is intended. Black can sometimes be associated with death and red can be seen as highlighting danger (DECIDE patients and public). Inconsistent use of colour in documents can be confusing (DECIDE 2011 – 2015). Colour coding recommendations can be problematic and are required to take into account people's pre-existing associations with colour, for example, red for stop, green for go (DECIDE patients and public). The way that colour is used to differentiate between recommendations needs to be clear in patient versions of guidelines (DECIDE patients and public).

Fonts

A font with a clear design should be used to ensure accessibility. Use a minimum font size of 12 pt for standard versions and a minimum font size of 16 pt or larger for large print.

Graphics

Give careful thought to the use of graphics. Patients and the public like the text to be broken up (DECIDE patients and public), but the graphic should carry useful information, not simply be a decorative element.

The way information is presented can affect perceptions of its trustworthiness. Using cartoons in a physical activity patient version, for example, meant that people had less trust in the information it contained; indeed it led people to question whether adults were the target audience at all (Berry et al. 2010, Loudon et al. 2014). However, cartoons have been helpful when addressing people with learning disabilities. Logos can help if these are a recognised 'brand' for patients and the public, but too many becomes overwhelming and may be counter productive (DECIDE patients and public).

Table 4 provides some tips for using graphics.

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Table 4Tips for using graphics in patient versions

Use	Avoid
• Graphics relevant to the topic to illustrate what the patient version is about • Annotated diagrams to explain conditions • Images to break up the text to make the patient version patient friendly • Metaphorical images such as a blocked pipe to illustrate blood clot	• Graphics that may be upsetting or patronising • Complex, technical diagrams • Cartoons, because these are difficult for patients to identify with • Too many logos, which can be confusing for patients and distracting

Ensuring transparency in patient-directed knowledge tools

The authors and organisations producing patient-directed knowledge tools should declare their financial and intellectual conflicts of interest (COI). This includes patient or consumer representatives and their organisations. It should be clear what influence, if any, individuals and organisations had, or could be perceived to have had, on the content of the patient version. The same COI declaration forms as used for guideline development groups may be used, showing that patient versions are linked to the guideline not only in terms of content but also in terms of methods and transparency. If all authors of the patient version have already been part of the guideline panel, a new declaration of COI might not be necessary.

Evaluating patient-directed knowledge tools

Users of patient-directed knowledge tools should be encouraged to provide feedback on the information. Feedback should be collected and considered when updating the information. Ways to collect feedback may include a structured questionnaire at the end of the information, tests with focus groups, or surveys. It can also be useful to ask for feedback from other stakeholder groups, because they might be able to assess the extent to which the patient-directed knowledge tool helped their patients who are members.

Getting feedback on patient versions of guidelines

Asking a wider group of patients and public for input and feedback on the patient version can help ensure it is accessible to the target audience (SIGN 2019, van der

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Weijden et al. 2019). The chapter on how to conduct public and targeted consultation provides more details. The purpose of collecting feedback is to ensure the patient version:

- Provides useful information that helps patients make decisions.
- Provides patients with further experience and support regarding coping strategies or other issues that are not covered by the guidelines, but may matter to patients in their daily life. These can be provided directly in the patient version or indirectly through links to sources of further information and support.
- Is seen as relevant to patients and consumers.
- Has a useful layout that patients can effectively navigate.
- Uses appropriate language, fonts and graphics.

Various methods can be used to obtain feedback, depending on the intended audience and the intended goals. For example, an open consultation can help to foster ownership and transparency, whereas workshops can help to obtain specific feedback on relevance to readers and their level of understanding. Other methods include:

- Circulation of the document to guideline developers' own patient or consumer networks and voluntary organisations for written comment.
- Use of discussion groups to provide feedback, for example a discussion group with children and young people may be more effective than written consultation.
- Consulting patient organisations who have broad experience with patient counselling and collect data on individual experiences.

An example of questions guideline developers may want to ask patients and consumers is given in appendix 6.1. To ensure transparency, the methodology and process of development should be well documented. The case study in table 2 shows how SIGN gathered feedback on their patient version of the migraine guideline.

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Acknowledgements

The authors would like to thank the following for their contributions to this chapter:

Peer reviewers: Lyndsay Howitt, Kenneth McLean and Trudy van der Weijden

Contributors to the 2012 version of this chapter: Karen Graham, Shaun Treweek, Nancy Santesso, Corinna Schaefer

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Resources: appendix 6.1

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Consultation on patient version of guideline on xxxxxxxx

Name:

Job title (if applicable):

City/Town:

Presentation (Please tell us what you think of the way the booklet is presented)

Is the layout easy to read?

Are the images and diagrams appropriate and meaningful?

Writing Style (please tell us what you think of the way the booklet is written)

Do you think that the language and tone is appropriate?

Content (please tell us what you think of the content)

How useful is the content?

Does the content help patients and carers understand what the latest evidence supports around:

- diagnosis
- treatment
- self-care

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How to foster shared decision making through guidelines

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Key messages of this chapter

- Healthcare professionals (HCP) have the responsibility of enabling shared decision making (SDM). Guidelines guide HCPs to make clinical decisions. To foster shared SDM in clinical practice, guidelines have to reflect this concept in their structure, wording, content and tools.
- For a patient-centered guideline approach, it may be helpful to combine goal setting, goal-based SDM, the consideration of contextual factors, and the continuous evaluation of treatment goals, treatment burden, and barriers to adherence.
- Strategies to enable SDM through guidelines include:
  - use of wording that supports discussion between the patient or service user and health or social care professional about their care
  - presentation of options and their harms and benefits in a way that enables risk communication and discussion of options
  - systematic identification and prioritisation of recommendations and clinical situations that are most relevant to SDM
  - provision of a generic chapter on SDM
  - provision of guideline-based decision tools
  - integrating SDM aspects and decision aids into the guideline, recommendations and algorithms.

Top tips

- Implementing SDM-enhancing strategies in guidelines needs strategic planning from the very beginning, including scoping, formulation of review questions, and

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evidence selection or interpretation. A clear responsibility within the guideline production team for including SDM is helpful.

- The guideline team may not have all the expertise needed, or at its disposal, for implementing SDM-enhancing strategies (for example, medical writers or information specialists to design decision support tools for patients). Check beforehand what expertise might be needed and seek collaboration.
- If resources are scarce, it is helpful to prioritise clinical situations or recommendations in which SDM is of high importance when creating additional tools for decision support.
- The guideline group should review and approve all additional tools (patient information or decision support tools) to ensure consistency with the recommendations.

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Aims of this chapter

This chapter provides a rationale for harmonising guidelines with shared decision making (SDM) and discusses strategies for fostering SDM through guidelines. It does not discuss the concept of SDM, the underlying evidence or the different types of decision aids in use, nor does it provide evidence on their effects and how these can be measured. Information on these topics can be found elsewhere, for example National Institute for Health and Care (2021a) and Stacey et al. (2017). Instead, this chapter focuses on the guideline developer's perspective and aims to provide practical support that is mostly based on experience from various guideline development processes.

Rationale: SDM and guidelines

Theory and practice: definition of clinical practice guidelines

Guidelines can be understood as tools to support clinical decision making. In its 2011 standard reference work, 'Clinical practice guidelines we can trust', the US Institute of Medicine (2011) states:

'Rather than dictating a one-size-fits-all approach to patient care, [clinical practice guidelines] should aid clinician and patient decision-making by clearly describing and appraising the evidence and reasoning regarding the likely benefits and harms related to specific clinical recommendations.'

SDM is a key element of the clinical encounter as reflected in patients' views. Its importance, and the need for input from healthcare professionals (HCPs) when making a treatment choice, were recurrent findings in DECIDE research (Fearns et al. 2016). The Institute of Medicine's definition emphasises that guidelines can support HCPs in guiding patients through the SDM process.

However, some considerations and insights from guideline research suggest that clinicians' misconception of the underlying evidence, the format of many guidelines, and the wording of their recommendations might be a barrier to individual SDM:

- Evidence from a large sample of various guideline groups and a review of qualitative evidence (Carlsen et al. 2007) suggest that some clinicians may

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misinterpret guideline recommendations as absolute do's or don'ts that are opposed to SDM. This seems to apply especially to recommendations in favour of interventions.

- The development of guideline-based performance measures and pay-for-performance models may plausibly lead to clinicians following recommendations rather than discussing options with their patients, especially when these impact on either certificates or reimbursement (Legaré and Witteman 2013). The same may apply to the increasing role that guidelines have in legal contexts, that is, malpractice claims (Mackey and Liang 2011).
- A survey among physicians indicated that stronger and weaker guideline recommendations may be perceived as equally binding (Nast et al. 2013).
- In the literature, guidelines have been largely criticised for not providing guidance for individual situations that may need to go beyond the generalisation of a given guideline recommendation. This may be especially so when patients have comorbidities or multimorbidity (Elwyn et al. 2016; Young et al. 2015).

Key to success: harmonising guidelines with SDM

Guidelines, in a widely cited definition (Institute of Medicine 2011), are described as facilitators of clinical decision making. However, their potential to impede patient-centred decision making has to be taken into account.

In their Guidance manual, the German Association of the Scientific Medical Societies addressed this issue by explicitly stating:

‘Guidelines can be understood as "treatment and decision corridors” which can or should be deviated from in justified cases. The applicability of a guideline or individual guideline recommendations should be reviewed in individual situations in the individual encounter according to the principles of shared decision-making.’ (German Association of the Scientific Medical Societies 2012)

Therefore, guideline adherence truly means meticulously considering whether to deviate from a recommendation in the care of an individual person and discussing this with them (Kühlein and Schaefer 2020). To support clinicians in doing so, it is most important to integrate tools and elements into the guideline that facilitate talking about these options and SDM. This is why guidelines and decision tools have been

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stated as maintaining an ‘inevitable relationship’ (van der Weijden et al. 2012). Such a relationship seems crucial, because the format of many guidelines does not provide even basic elements that enable HCPs to present options and their probabilities to patients (Morgott et al. 2019).

The patients’ view seems to support this. Qualitative evidence from the DECIDE project indicated that patients need health information that enables them to choose between treatment options, including information about harms (Fearns et al. 2016). They would like help with making such choices from HCPs, especially general practitioners. Hence, guidelines have an important role here because they are mainly aimed at HCPs.

The following sections provide some guidance about different tools and strategies guideline that developers may use to enable and support SDM through guidelines.

Strength of the recommendation – a trigger for SDM?

Before presenting different enablers for SDM in guidelines, we will discuss whether or not SDM is more applicable for some recommendations than others. We will also discuss whether the strength of a recommendation has a role in deciding this.

Some models that assess the potential for SDM in guidelines suggest that weak recommendations are most appropriate for sharing decisions. This applies especially to the GRADE framework: ‘*When a recommendation is weak, clinicians and other health care providers need to devote more time to the process of shared decision-making by which they ensure that the informed choice reflects individual values and preferences.’* (Andrews et al. 2013)

However, in their DECIDE work, Fearns et al. found that weak recommendations triggered strong negative reactions from members of the public (2016). Although they understood that a weak recommendation was less strongly endorsed, they often interpreted it as the intervention not being effective.

Weak recommendations are made when there are different options, including no intervention, that are equally sensible and choices may differ largely among individual patients depending on their individual situations. Therefore, without any

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question, SDM applies here. However, SDM may be equally important in relation to strong recommendations, if the situation is appropriate (that is, it is not an emergency situation). It is assumed for strong recommendations that most informed people would decide in favour of the recommendation. But this raises the question of who makes that assumption. The experience, concerns and preferences of the guideline developers may not be shared by all patients. Several people may decide differently, in the context of their particular circumstances. These circumstances are characterised by the International classification of functioning, disability and health's (ICF) contextual factors and may present good reasons for deciding against a well-established, evidence-based intervention (World Health Organization [WHO] 2001).

These contextual factors include:

- environmental factors: factors that are not within the person's control, such as family, work, government agencies, laws, and cultural beliefs
- personal factors: factors such as race, gender, age, educational level, coping styles, health status, and risk attitudes, which vary widely among individuals and cultures.

Offering SDM enables patients to make a decision that best suits their individual and environmental conditions. Box 1 provides an example of a guideline panel deciding to provide a decision aid for a strong recommendation.

Box 1 Case study of decision support for a decision on taking statins for coronary artery disease in the German national disease management guideline on chronic coronary artery disease (Bundesärztekammer 2019)

Background

High grade evidence for statins in patients with coronary artery disease (CAD) shows consistent effects on mortality and morbidity and only rare adverse events. However, myalgia has often been reported under statin use, although randomised control trials showed no difference between intervention and control groups therefore suggesting a nocebo effect. Most

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guidelines give a strong recommendation in favour of statins for patients with CAD.

Rationale

Based on clinical experience, the large multidisciplinary guideline panel identified that the decision to start or continue statins was a key situation for SDM, mainly for 2 reasons:

- they assumed there was considerable overtreatment in older patients on polypharmacy, and
- according to their clinical experience, some patients refuse to take statins because of the false belief that these caused muscle pain.

Intervention

A decision support tool was designed, based on the results of the systematic review for the guideline, that provided a drugs fact box for statins and additional plain language information, which clearly explained why myalgia was most probably not caused by the medication. It was formatted so that it could be printed and handed out to patients (as a short leaflet) as well as being used online. The tool underwent formal consensus and was integrated into and published with the guideline. It was provided to clinicians (through the guideline and the webpage for physicians), but was directly and freely accessible for patients (though the patient webpage). Evaluation showed that physicians thought such tools were helpful in the clinical encounter and that most would use them with their patients (Schwarz et al. 2019).

Preference sensitivity

It is widely recognised that SDM is a concept to tackle preference sensitive decisions (Elwyn et al. 2009). As indicated by the above ‘GRADE’ definition, a considerable group of guideline developers and methodologists assume that weak recommendations indicate such preference sensitive decisions. However, not all guideline groups are consistent in their choice of the grade of recommendation for

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identical clinical questions. Every recommendation is not only based on the underlying evidence but on the collective value judgement of a specific group, influenced by, among others, their experience, academic interests and professional background. Hence, although there is some overlap between preference sensitive situations and situations where guideline panels make weak recommendations, they are not totally congruent. The concept of preference sensitivity needs to be operationalised to help identify situations where SDM is most appropriate. An example of operationalisation is shown in box 2.

Box 2 Case study on operationalisation of 'preference sensitivity' to guide the development of decision support tools for guideline developers

The National Institute for Health and Care Excellence (NICE) uses an operationalised concept of preference sensitivity in its process guide for decision aids. The concept is used to determine whether or not a decision point in a guideline needs more support to enable SDM, and has characterised those decisions as follows:

'Preference-sensitive decision points are points where the person's values and preferences are particularly important. They occur when either:

- There are 2 or more options for investigation, treatment or care that deliver similar outcomes but:
  - they have different types of harms and benefits which people may value differently, or
  - the likelihood of the harms or benefits may differ, or
  - the practicalities of the options are different (for example, the choice is between medicine and surgery, or the requirements for monitoring differ), or
  - people may consider the overall risks of harms for any of the options outweigh the overall benefits compared with no treatment or
- The choice between an investigation, treatment or care option and the option of 'no treatment' is finely balanced.' (NICE 2018c)

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Strong recommendations against interventions – providing rationales, not options

Strong recommendations against interventions are rare and usually made when a panel is sure that an intervention provides no benefit but substantial harm. It is hard to imagine that any reasonable and informed person would choose an option that does them no good, but instead, puts them at risk of serious harm. SDM requires commitment from patients and for some it may even be hard work discussing options with their doctor, reading, understanding the evidence, weighing up the benefits and harms, and making a decision. It is reasonable to ask whether the commitment, time and resources are necessary when there is no sensible alternative, and if patients and HCPs might rather need another type of information in these situations, that is, information that explains and supports a recommendation instead of offering options. Evidence from DECIDE indicates that when making a decision, patients want an honest explanation of the rationale behind such a recommendation (Fearns et al. 2016).

For example, imaging for low back pain is not recommended in the absence of red flags indicating a serious condition. Evidence has shown that imaging does not lead to better outcomes but may cause unnecessary treatment and increase the risk of the problem becoming chronic (Chou et al. 2011). Most guideline panels make a strong recommendation against imaging for low back pain. However, research indicates that patient expectation may be a driver of unnecessary testing because of the false belief that imaging is beneficial, and because patients may feel uncomfortable and not acknowledged when not getting a test or a treatment (Warner et al. 2016, Parmar 2016, Pathirana et al. 2017).

The idea that recommendations against interventions need transparent communication is reflected in the concept of ‘Choosing Wisely’. In the US, the Choosing Wisely programme is collaborating with Consumer Reports to provide patient leaflets for all Choosing Wisely recommendations. However, these recommendations seem to not have been implemented very well (Hong et al. 2012). They have also been shown to not adhere to international quality standards (Legaré et al. 2016). This indicates that information supporting negative recommendations:

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- needs to be provided to patients and physicians at the same time, and
- has to be designed carefully and respect patients' autonomy.

In the NICE guideline on dementia (NG97; NICE 2018a) a strong recommendation is made against routine enteral feeding for people living with severe dementia. A decision support tool on enteral (tube) feeding for people living with severe dementia was developed to guide discussions between HCPs and patients, their carers and relatives (NICE 2018b). Although being called a decision aid, the tool clearly explains the certainty of the evidence regarding harms and the lack of evidence for any benefit, thereby being strongly supportive of the recommendation.

In conclusion, we strongly suggest that:

- strong recommendations **in favour of interventions** (if not addressing emergency situations) be carefully considered for SDM with decision tools provided
- strong recommendations **against interventions** need careful discussion with the patient, supported by information that explains the rationale rather than offering options.

Strategies to foster SDM in guidelines

In the following paragraphs, we present some strategies that might help to harmonise guideline recommendations with SDM. However, developing a guideline in a way that enables and promotes SDM will require strategic planning by a guideline team who is committed to this concept, oversees the whole guideline production process, and creates a guideline format that is most appropriate to enable SDM for the specific condition or topic in question.

Strategic planning and the provision of additional guideline-based knowledge and decision tools also need resources and expertise. Not every guideline group will be able to adopt all the strategies suggested in this section and they will not be suitable for every recommendation in a guideline. Therefore, the group will need to prioritise which strategies to use and which recommendations to choose. Some suggestions on how to identify such recommendations are given at the end of this chapter.

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Based on qualitative interviews with guideline and SDM experts and group discussions with international participants, a team of experts developed a framework of suggestions on how guidelines could be adapted to enable SDM. They characterised these strategies as those:

- aimed at HCPs or patients, or
- generic or aimed at a specific recommendation (see table 1; van der Weijden et al. 2013).

Table 1 Strategies for implementing SDM in guidelines (adapted from van der Weijden et al. 2013)

Strategies within the guideline, aimed at the HCP	**Strategies within the guideline, aimed at the HCP**	**Strategies linked to or within the guideline, aimed at the patient**	**Strategies linked to or within the guideline, aimed at the patient**
Generic strategies	*Recommendation-specific strategies*	*Generic strategy*	*Recommendation-specific strategies*
• Separate chapter on SDM • Language that involves patients	• Cluster 1: Structuring options to increase option awareness • Cluster 2: Structuring the deliberation process	• Patient version of a guideline	• Cluster 3: Providing patient support tools linked to or within the guideline

Some of the suggested elements have generally been shown to be effective, such as decision aids (Stacey et al. 2017); others lack direct evidence and are based on reasoning, experience and expert opinion. The list of strategies is not complete and they should be understood as suggestions that have been found to be helpful and feasible, based on experience in various guideline groups.

In the following sections, we discuss generic strategies and then move on to those aiming at a specific recommendation or topic.

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Changing the wording in recommendations

A very simple strategy that highlights the importance of patient-HCP interaction is using wording that encourages discussion and engagement in SDM. For example, using ‘offer’ or ‘recommend’ instead of ‘perform’, and ‘discuss with the patient’ instead of ‘do’. Currently, it seems that several guidelines have adopted this wording, as shown in an investigation of 2 national guideline programmes in Germany (Schaefer et al. 2015).

The GRADE wording of ‘we recommend’ and ‘we suggest’ reflects this idea, although some guideline groups were not altogether comfortable with ‘suggest’ always indicating a weak recommendation. This might not offer enough guidance, because it does not allow differentiation between options that are poorly investigated, and options that have high-grade evidence showing benefit outweighing harms, but with a risk profile or treatment burden such that individual choices are likely to be highly preference sensitive.

Presenting options and their benefit–harm profile in the guideline

This strategy aims to present the options discussed in the guideline in a way that enables HCPs to adequately discuss them with patients. The presentation should also include evidence-based options that may be viewed as second best by professionals (for example, because they are deemed to be less effective), but that may be embraced by patients (for example, because of less intense side effects).

It seems a promising strategy because evidence suggests that some physicians have difficulties in understanding relative risks and adequately communicating those (Wegwarth et al. 2012). It includes:

- listing all the options including no intervention in a comparable format, ideally in tables or graphs
- providing the benefit–risk profile with important outcomes, including treatment burden (Dobler et al. 2018) that allows comparisons of options by:
  - providing absolute effect sizes rather than relative reductions
  - using the same framing for all options and outcomes presented

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- avoiding wording that suggests a value judgement (such as ‘dramatic reduction’ or ‘minimal increase’)
- highlighting uncertainty (in wording and effect size, with confidence intervals).

For evidence on some of these options see the systematic reviews in Lühnen et al. (2017).

However, a study investigating international guidelines on cardiovascular disease and diabetes found that the vast majority did not provide absolute risk reductions or the numbers needed to treat for interventions (Morgott et al. 2019). Therefore, they did not allow HCPs to grasp the relevance and effect size of the options in question and compare them.

Providing a generic chapter on SDM in guidelines or developing a guideline on this topic

The rationale for a generic chapter on SDM in guidelines is that it could potentially raise awareness of SDM among HCPs, address perceived enablers and barriers to SDM expressed by HCPs, and offer solutions (van der Weijden et al. 2013). There are different examples of such chapters in various guidelines, and they differ in length, content and format. To our knowledge, to date, none of these chapters has been evaluated or tested with guideline users. Therefore, their impact on guideline users remains unclear. Potential downsides of this approach are that:

- its impact may be limited if it is not referred to in the diagnostic and treatment recommendations
- it may easily be ignored by guideline users if it stands separately, and
- it may only be read carefully by those who are already aware of the importance of SDM.

We suggest that if this strategy is adopted, the chapter should not be designed as a textbook. Instead, it should offer practical examples on how to integrate SDM and patient centeredness into treatment planning and evaluation and the examples should be referred to in all relevant recommendations. Discussing treatment goals and planning or evaluating treatment is a core principle of health care provision. Therefore, the concept of goal-based SDM may provide a valuable link between

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guideline structure and SDM (Elwyn et al. 2020). Box 3 provides an example of a comprehensive generic SDM chapter and its content.

Box 3 Case study on a generic chapter on SDM and treatment planning in the German national disease management guideline on the treatment of type-2 diabetes (Bundesarztekammer 2021b)

Background: Among specialty societies, such as the American Diabetes Association (2020), it is largely accepted that optimal treatment of diabetes requires discussion of individualised disease-specific treatment goals (HbA1c, blood pressure, cholesterol), and continuous evaluation and adjustment of treatment strategies and goals. The German national disease management guideline (GNDMG) on type-2 diabetes provides, to our knowledge, the first model on how to integrate treatment planning and SDM in a guideline.

Content: The chapter was structured to highlight the close relationship between goal setting, SDM and evaluation. The guideline panel made consensus-based recommendations and offered practical advice on the following topics:

- Agreement on and continuous evaluation of treatment goals:
  - considering and prioritising fundamental, functional and disease-specific goals (Elwyn 2020).
- Risk communication on diagnostic and treatment options:
  - principles of adequate risk communication in the context of the clinical encounter (Elwyn et al. 2006, German Network for Evidence-based Medicine 2015).
- SDM:
  - presentation of the SDM-Model and suggestion of questions and phrases to enable HCPs' engagement in SDM (Bieber et al. 2016, Elwyn et al. 2017).
- Assessment of contextual factors that may influence prognosis, goals, treatment burden and adherence:

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  - before prioritising goals and planning therapy, assess and consider contextual personal and environmental factors (WHO 2001).
- Continuous evaluation of goals, treatment burden and adherence:
  - if goals are not met, before changing treatment strategies:
    - ◊ assess contextual factors as potential reasons and offer solutions, and
    - ◊ evaluate if individual goals are still valid, and if not, agree new goals.

The guideline underwent public consultation. Comments on the SDM chapter highlighted its importance and that it was very helpful. However, others indicated that they felt that, although helpful, it was too complex. (Bundesärztekammer 2021b)

Recently, the NICE guideline on shared decision making (NG197; NICE 2021) issued the first ever, to our knowledge, clinical practice guideline on SDM (see box 4). Many of the advantages and limitations discussed earlier may apply equally to this guideline. However, it has already demonstrated its potential to raise awareness and it is unique in addressing system-related factors that may enable or hinder SDM in practice, referring to the concept of organisational health literacy.

Box 4 Case study on development of a specific guideline on SDM (NICE, NG197, 2021)

Background: Every NICE guideline includes a statement emphasising that it is not mandatory to apply the recommendations and that, although professionals and practitioners should take the guideline fully into account, they should also consider individual's needs, preferences and values, and make decisions in consultation with them and their families and carers or guardian. NICE has also recommended SDM in several general guidelines, such as on patient experience in adult NHS services (CG138, NICE 2012), medicines optimisation (NG5, NICE 2015) and multimorbidity (NG56, NICE 2016). Topic-specific guidance also often explicitly recommends SDM for

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specific decisions. But because SDM is not yet routinely practised in the National Health Service (NHS), NICE was asked to produce guidance about facilitating SDM and embedding it in everyday practice.

Content: The NICE guideline on shared decision making (2021a) addresses the 'three legged stool' of the implementation challenge for SDM: engaging and empowering patients and people who use services; engaging and supporting individual HCPs; and engaging senior managers to embed SDM into healthcare organisations and systems. The guideline covers:

- Embedding SDM at an organisational level, including:
  - making a senior leader accountable for embedding SDM within healthcare organisations
  - identifying senior HCPs and service users as champions for SDM
  - developing an organisation-wide improvement plan to put SDM into practice
  - ensuring that training and development for HCPs in SDM includes specific components
  - promoting SDM to people who use services.
- Putting SDM into practice, including:
  - supporting SDM by offering interventions at different stages, including before, during and after interactions in which a healthcare decision might be made.
  - giving guidance on what that support should include.
- Patient decision aids (PDAs), including:
  - how HCPs can make best use of PDAs
  - how organisations can facilitate use of PDAs by HCPs.
- Communicating risks and benefits, including
  - discussing consequences in the context of each person's life and what matters to them
  - giving specific recommendations on how to discuss numerical information with service users.

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The guideline generated a large number (more than 1,100) of comments at public consultation. These were generally supportive. Regarding the development of the guideline, NHS England and NHS Improvement commissioned the development of the NICE Standards framework for shared-decision-making support tools, including PDAs (NICE 2021c). This will help users assess the usefulness and quality of a PDA and help PDA developers conduct a self-assessment of the quality of their tools and processes. To support implementation of the guideline, Keele University and NICE worked in partnership to develop a free online SDM learning package (NICE 2021b).

Systematically identifying and prioritising situations needing SDM support in the guideline

Some clinical situations described in a guideline will be essential for supporting SDM, but others may be of lesser importance. It may be helpful to systematically identify and prioritise such situations. This helps with structuring the guideline process, raising the guideline groups' awareness of emphasising SDM in the guideline, and assigning resources to the clinical situations that are key for decision support. The aim is to highlight throughout the guideline those recommendations that are most important when providing recommendation-specific decision support tools.

For setting up a structured process, it is important that a guideline group includes HCPs and patients or lay persons. It may be achieved through a criteria-based group rating or other consultation methods (see the chapter on how to conduct public and targeted consultation). For example, the German Association of the Scientific Medical Societies has systematically developed a very elaborate process to identify recommendations suitable for Choosing Wisely, based on rating criteria with a 4-point Likert scale (German Association of the Scientific Medical Societies 2020). This process can easily be adapted to identify SDM-priority recommendations. Nevertheless, simple surveys among the guideline group or other consultation methods can be equally helpful.

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Developing guideline-based patient-directed knowledge or decision tools

When a situation with specific need for decision support has been identified, respective tools should be provided. Van der Weijden et al. (2013) suggested a patient version of the guideline, although awareness of other information formats for patients that may accompany a guideline has increased over time. For more information on patient versions of guidelines, see chapter on how to develop information from guidelines for patients and the public.

However, the concept of patient versions of guidelines is not well implemented. For example, a structured analysis of the German Guideline registry indicated that only 35% of all guidelines provided patient versions (Ollenschläger 2018). Furthermore, many providers use patient versions to give specific information in an easy-to-read manner rather than as a tool that the patient and health care provider can use through an SDM process.

A group of researchers recently presented a framework to characterise and categorise the various patient-directed knowledge tools, including those that may be suitable to supporting clinical decisions (Dreesens et al. 2019). For a detailed description of this framework, see the chapter on how to develop information from guidelines for patients and the public.

Furthermore, quality criteria regarding the production of guideline-based patient-directed knowledge tools have been formulated (van der Weijden et al. 2019). They should inform the development process

Among the suggested formats to support decision making, the framework presented by Dreesens et al. (2019) lists decision trees, pre- or post-encounter patient decision aids, patient versions of guidelines, and encounter decision aids (see table 2). But only encounter decision aids are labelled as engaging SDM, based on the existing evidence (Coleywright et al. 2014, Wyatt et al. 2014):

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Table 2 Patient-directed knowledge tool types (adapted from Dreesens et al. 2019)

Purpose	Patient information and educational material	Decision tree	Independent/ pre- & post-encounter PDA	Patient version of guideline	Encounter-PDA
To inform or to educate	+	-	+	+	+
To provide recommendation(s)	-	+	-	+	-
To support decision-making	-	+	+	+	+
To engage in SDM	-	-	-	-	+

Encounter decision aids are short tools designed to be used during consultation ('point of care' tools). They may vary in format and may be presented, for example, as Option Grid decision aids, drug facts boxes (Schwartz and Woloshin 2013), or interactive online tools, such as tools for GPs.

The International Patient Decision Aid Standard (IPDAS) Collaboration and NICE (2021c) have published advice and quality criteria for SDM support tools, including PDAs.

Decision aids have proven to be effective. A Cochrane review found high to moderate quality evidence that decision aids improved a variety of outcomes, such as knowledge or risk perception and reduced decisional conflicts (Stacey et al. 2017). However, a follow-up study of this review showed that many of the decision aids included in the Cochrane review, that had been rigorously developed, tested and proven to be effective, were not implemented in routine care (Stacey et al. 2019). The most commonly reported barriers were lack of funding, outdated PDAs, and clinicians disagreeing with use of the PDA. Enablers included design for and integration into the care process. The authors suggested that '*to improve subsequent use, researchers should codesign decision aids with end users to ensure fit with clinical practice.'* (Stacey et al. 2019). This shows how involving the guideline panel may be helpful in the development of decision aids. The panel would be able to provide a broad range of clinical expertise and practical experience from different

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health care professions and patients. This would ensure that the guideline and the decision support tools are consistent and complement one another, and encourage uptake of both.

There are several ways to provide decision support tools alongside a guideline. Some possible approaches are described here.

Check out what already is out there

For some situations, high quality decision tools may exist. For example, see the Ottawa Hospital Research Institute's repository for English language decision aids and the Option Grids decision aids list. If there is consensus, a guideline panel can recommend suitable decision tools and provide a link to them instead of producing new ones.

Production by an external team

A team of information specialists, researchers and patients can develop decision tools for prioritised situations after the guideline has been published, using its systematic searches and evidence tables as basis for the decision tools. Ideally, members of the guideline group should review the draft for consistency with the guideline and the underlying evidence. The tools should be available for patients but also for HCPs, and be linked to the guideline documents (NICE 2018c).

Content management system-based semi-automated production

Guideline development tools and content management systems, such as MAGICapp or GRADE Pro, enable guideline groups to produce semi-automated electronic decision aids for use in the clinical encounter (Agoritsas et al. 2015, Vandvik et al. 2013). These are produced directly from the datasets of the systematic review and critical appraisal for each guideline recommendation or the underlying clinical question and are available directly through the app or other front ends, and so are linked to the guideline itself. Although representing a helpful tool to support the discussion between patient and clinician, a patient decision aid also needs input from patients or patient representatives, because they can shape the value elicitation statements or narratives that are needed to turn it into a decision support tool.

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Production during the guideline development process

After having identified relevant situations for SDM, guideline groups can develop decision tools for the guideline. They can be published as print, PDF, and web- or app-based or interactive online tools.

An advantage of these decision tools is that they are directly linked to the guideline and use the same body of evidence. However, they remain separate tools with additional features for interested guideline users, and do not necessarily raise awareness of SDM among guideline users in general. Only if integrated into and referred to by the guideline itself, do these tools gain importance and awareness, as explained in the next section).

Integration of SDM and decision aids in guideline algorithms and recommendations and provision of SDM tools as part of the guideline

Probably the best way to harmonise guidelines with SDM is to integrate all processes and develop a product that reflects the need for clinical guidance as well as the need for sharing decisions. This means integrating SDM in guideline recommendations and algorithms and putting decision tools at the heart of the guideline itself.

Integrating decision tools into the guideline

Decision tools for clinical encounters can be integrated into the guideline by:

- publishing them as integral part of the guideline rather than separately (for example, as an appendix or supplement)
- cross-referencing and referring to the decision tools in the context of the recommendations in question (either in the recommendation itself or the background information)
- a formal consensus process for all decision tools, indicating formal approval of the guideline panel and therefore the same level of credibility and relevance as recommendations or other guideline elements.

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Recommending the use of decision aids

Guidelines make recommendations for HCPs. In clinical situations with high relevance, the use of decision aids can be part of a recommendation. For example, based on expert consensus, the GNDMG on CAD recommends:

'Before receiving cardiac catheterisation, we strongly recommend the use of the respective patient decision aid (see annex). The consultation and use of the decision aid has to be documented.' (Bundesärztekammer 2019)

An encounter decision aid was developed for this recommendation, presenting the risks and benefits of all treatment options (medical treatment, stenting, coronary artery bypass grafting) in the form of an option grid. The decision, aid as well as the recommendation, underwent formal consensus. This recommendation was reflected and referred to in the treatment algorithm.

Similarly, in its guideline on urinary incontinence and pelvic organ prolapse in women, NICE (2019a, 2019b) recommends:

'If a woman is thinking about a surgical procedure for stress urinary incontinence, use the NICE patient decision aid on surgery for stress urinary incontinence to promote informed preference and shared decision making.'

The PDA referred to is a longer format PDA because of the complexity of the decision. It was developed by members of the guideline committee (including patient members) and PDA specialists and was formally consulted on.

Other recommendations that include the use of a decision aid might cover issues such as agreeing on individual treatment goals or evaluating treatment strategies.

Algorithms or decision trees

Algorithms provide a concise and dense overview of clinical decisions on the diagnosis or treatment of a condition. They are among the most cited and best implemented elements of clinical practice guidelines (Vader et al. 2020). The GNDMG on type-2 diabetes (Bundesärztekammer 2021a) provides a treatment algorithm that asks for SDM and the evaluation treatment goals before initiating and before modifying treatment (see figure 1). This is expressed through the symbol of

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speech bubbles indicating: '*agreement on treatment goals and therapy strategy using shared decision-making*'.

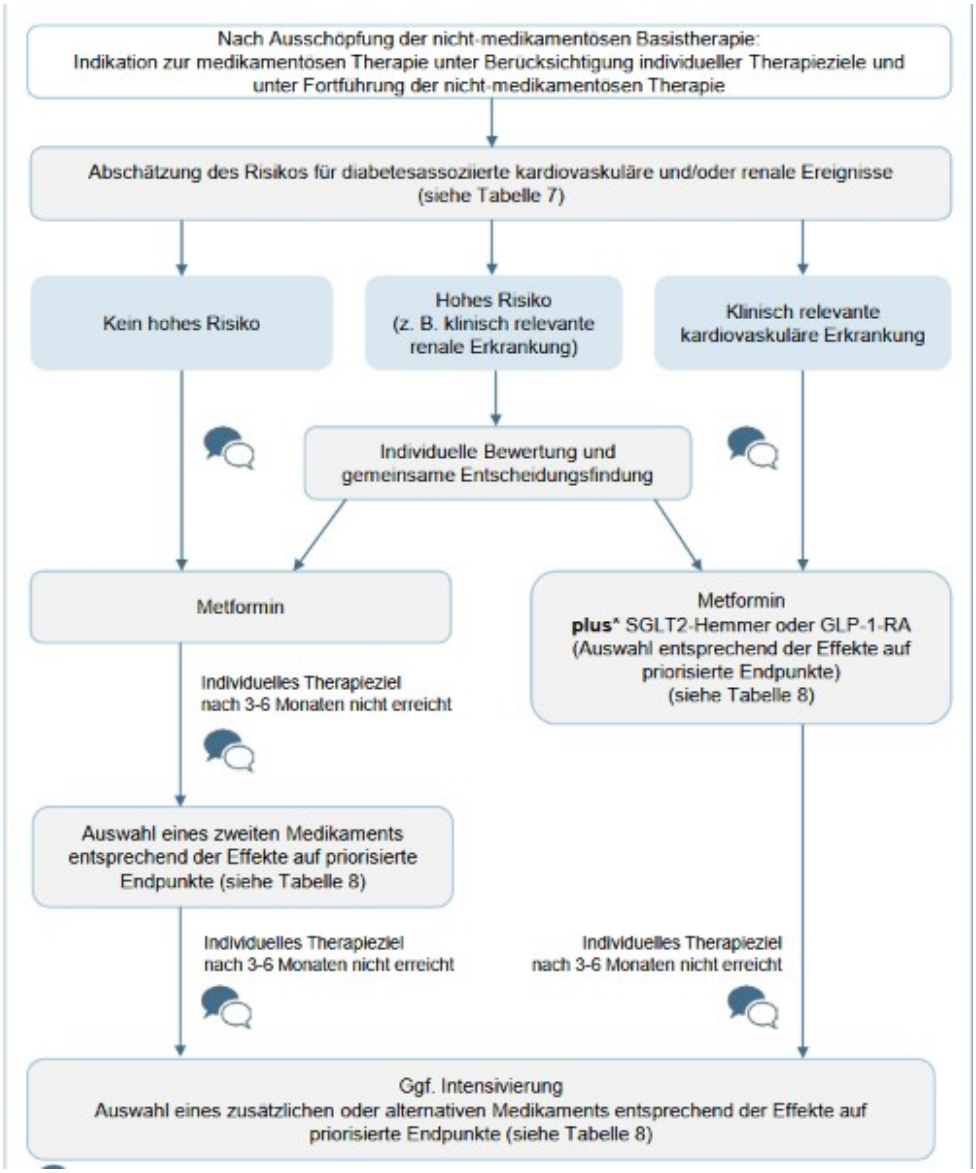

Figure 1 Treatment algorithm for type-2 diabetes based on SDM (Bundesärztekammer 2021a)

Shaping guidelines as unique tools to enable SDM – going beyond recommendations

The Canadian PEER initiative proposes an even more radical approach: They advise the use of so called 'simplified guidelines' that do not offer treatment recommendations. Instead, they suggest thresholds for discussing different treatment options with patients, therefore being designed to guide the patient-

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clinician encounter rather than providing guidance for clinicians only (Allen et al. 2017). So far, guidelines for lipid management in primary care, management of opioid use disorder, and prescription of cannabis in primary care have been developed. The idea that guidelines do not provide general guidance but enable individual conversations challenges the concept of guidelines as understood by most guideline developers and users. Giving it serious consideration might pave the way for future patient-clinician decision support tools that could address some shortcomings of actual guideline development. However, these tools may not be appropriate for all clinical situations and conditions. There will be some indications for which more concrete guidance is needed, and other situations in which enabling discussion is more than adequate.

Conclusion

So far, robust evidence on which strategies are most effective in supporting SDM through guidelines is lacking. Therefore, the content of this chapter is mostly based on experience and expert opinion. To the best of our knowledge, there are no experimental studies on the performance of SDM in practice, in which a guideline with SDM strategies is compared with a guideline with ‘classic’ recommendations. However, because SDM is widely regarded as an ethical obligation to assure patient autonomy (Steckelberg et al. 2011), we strongly recommend the use of practices supporting SDM that align with a guideline developer’s resources and goals.

SDM for individual patients can be promoted through population-level guidelines using a broad range of methods. These comprise interventions aimed at patients (providing decision support tools) and at HCPs (increasing awareness, encouraging engagement in SDM, enabling adequate communication). Some of the strategies are rather simple and do not require much planning or resources (consider wording that encourages discussion); some are moderately resource demanding (presenting information on options, developing generic chapters, highlighting situations with specific demand for SDM, production of semi-automated decision aids); but some entail a lot of additional work (producing decision tools for the guideline and assuring their visibility in the whole guideline context, formulating recommendations on the use of decision aids, on SDM and goal setting). Guidelines are produced in various settings. Some are very constrained, others have broad opportunities and resources.

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See table 3 for a summary of the strategies to encourage SDM that are presented in this chapter.

Therefore, not every intervention presented in this chapter will be helpful in all settings. However, even small changes in guideline production may contribute to the aim of enabling SDM through guidelines.

Table 3 Summary of proposed strategies to encourage SDM

Intervention	When	Who	Resource demanding
Revise wording of recommendations	During guideline production	Guideline group	–
Present options and their benefit–harm profile in the guideline	During guideline production	Guideline Group, content management system support possible	+/-
Identify and systematically prioritise clinical situations needing SDM support	During guideline production	Guideline group	+
Provide either a generic chapter on SDM in guidelines or a specific SDM-guideline	Before or during guideline production	Guideline group or former guideline groups	+/++
Provide guideline-based decision support tools	During production or after publication	External teams, information specialists and medical writers, guideline group	+/++
Integrate SDM and decision aids into guideline algorithms and recommendations and provide SDM-tools as an integral part of the guideline	During guideline production	Guideline group, possibly supported by medical writers or others	++

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Acknowledgements

The authors would like to thank the following for their valuable contributions to this chapter and their peer review:

Karen Graham, Laura Norburn, Lucia Prieto Ramon, Trudy van der Weijden

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Involving patients and the public in guideline dissemination and implementation

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Key messages of this chapter

- Patient and public involvement in dissemination strategies is valuable for developing educational materials, online resources and implementation tools that public and professional audiences find useful, understandable and convincing.
- A combination of strategies for involving patents and the public is essential when disseminating guideline recommendations to patients and the public. This includes media releases, digital tools, distributing patient versions of guidelines, and appointing community champions.
- Patient organisations and charities can promote the guideline (and its patient version) to patients and the public through various routes. These include social media, their newsletter, at conferences, by hosting it on their website, and including it in the information packages provided to their members.
- Providing patients and the public with information about conditions or procedures recommended in guidelines can help them to understand the care and treatment choices available to them based on the evidence. It can also support shared decision making about their own health. This can help with implementing guideline recommendations.
- Patient organisations and charities can promote guideline recommendations to professionals through educational materials, educational meetings such as conferences, and mass media information.
- Attitudes of healthcare professionals and lack of agreement with recommendations can act as barriers to implementation. Patients, the public, and patient organisations can play a key role in addressing these problems by becoming involved with implementation strategies.

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Top tips

- Patients and the public may have conflicting views about recommendations, and these need to be understood and resolved during the guideline development process.
- Think about how patients and the public can be involved in dissemination and implementation plans during the development of guidelines and not at the end of the process.
- Focus on developing implementation strategies in which patients and the public can play an active role.
- Provide patients and the public with access to guideline recommendations and their rationales by using patient versions of guidelines and other decision-making tools to promote awareness of them and encourage their use in people’s own care.
- Encourage and support patients to become involved in developing dissemination and implementation strategies for self-management recommendations.
- Raise awareness of tools with patients and the public to promote decision making about care and treatment, thereby helping with implementation of guideline recommendations.
- Patient and public members of guideline groups who become involved with dissemination and implementation strategies should be trained and supported.
- Provide a named contact for patients, the public, and organisations to contact.

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Aims of this chapter

This chapter focuses on ways in which recommendations from guidelines can be promoted to maximise impact on patient care. It describes ways that patients, the public and organisations can be involved in guideline dissemination and implementation strategies. It aims to describe who to involve in this process and how they can be involved in planning and delivery of dissemination and implementation strategies. It does not give guidance or advice on how to implement guidelines.

The chapter highlights a wealth of examples from guideline developers and other organisations on involving patients and the public in the dissemination and implementation of guidelines.

Dissemination of guidelines

Dissemination of guidelines is about raising awareness among the public, patients and professionals of the existence and content of the guideline. Dissemination plans are ideally developed in parallel with developing recommendations (SIGN 2019). Dissemination plans are needed to clarify at the start of the guideline development process the target audience, which will determine the scope, objectives, format, style and wording of the recommendations as well as the tools for dissemination (NICE 2020, Schipper et al. 2016, Armstrong et al. 2018).

Patient and public involvement in dissemination strategies is valuable to develop educational materials, online resources and implementation tools that public and professional audiences find useful, understandable and convincing. This is demonstrated in case studies 1 and 2.

Case study 1

On publication of their epidermolysis bullosa (EB) psychosocial guideline in 2019, DEBRA International circulated the news to:

- 45 member patient support groups
- 3,422 social media followers

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- 400 members of the DEBRA International Research Involvement Network
- 530 members of the international EB clinical network (EB-CLINET), and
- 407 members of the clinical practice guideline network.

DEBRA International also gave presentations on the guideline at the annual congress in Switzerland (2018) and the first EB World Congress 'EB 2020' (2020), attended by 690 delegates representing 215 organisations from 54 countries.

Patient support groups involved with DEBRA International are patient-founded and led (many people within the clinical practice guideline network are also affiliated with these groups). They further supported dissemination in the following ways:

- recirculating news about the guideline to their members and signposting to the document hosted on the DEBRA International website
- hosting the guideline on their own websites
- presenting the guideline at events, such as national patient and clinical meetings, study days, and forums
- presenting real-life patient stories to complement the guideline content
- liaising with organisers of other groups to promote it, for example, following discussions with DEBRA Norway, it was included in the programme of the European Rare Disease Day (2019).

At EB 2020, DEBRA International launched 3 patient versions of the guideline to support adults with EB, parents of children with EB, and both caregivers and patients in understanding the multidisciplinary team involved in their care processes. These are hosted on the DEBRA International website, circulated by the same means, and freely available. Currently, DEBRA Belgium is translating these into Dutch, and there have been requests for Turkish versions.

DEBRA International started a programme to develop EB infographics for low-resource countries to help EB patients, their families, and doctors in

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countries without a DEBRA group. EB infographics are more pictorial ensuring key guideline recommendations remain consistent no matter where people live. For the EB Psychosocial guideline, the ‘Healthy mind and control’ EB infographics are currently being developed.

Case study 2

The Scottish Intercollegiate Guidelines Network (SIGN) produced the first UK guideline on children and young people exposed prenatally to alcohol. The guideline is also accompanied by downloadable information for individuals having assessment for fetal alcohol spectrum disorder (FASD) and information for clinicians to support individuals and their carers before, during and after the assessment process. To raise awareness of the guideline, there was extensive coverage on social media with retweets from various charities including NOFASD-UK, Scottish Drugs Forum, Alcohol Awareness, FASD Network UK, and Adoption UK. This was to endorse the impact of the SIGN guideline on patients and carers in Scotland. SIGN involved a young person living with FASD in the production of a YouTube video animation on FASD that used their story to increase awareness of the condition and the guideline recommendations with both professionals and the public. This was a different approach, which suited audiences with different learning styles and allowed access to new audiences on a wider platform. The video received 930 views within the first 6 months of publication and supported social media promotion of the guideline recommendations.

Strategies for disseminating guidelines to patients and the public

To ensure patients and the public are aware of guideline recommendations, a combination of strategies is essential (Schipper et al. 2016). One strategy is to disseminate guideline recommendations and their rationales using patient and public versions of guidelines in various formats and other decision-making tools (DECIDE

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patients and public, Schaefer et al. 2015, Santesso et al. 2016, Utrankar et al. 2018). Details on the development of these and how patients and the public are involved in the process is provided in the chapter on how to develop information from guidelines for patients and the public.

When disseminating guideline recommendations through patient and public versions of guidelines, the involvement of patients and the public in multiple dissemination strategies outlined below have been found to be effective (Schipper et al 2016). These include:

- media releases involving patients and the public
- digital tools, such as websites and apps
- providing copies of the patient and public version to public places such as libraries
- using community champions to disseminate patient versions of guidelines to patients.

Media releases

Involving individual patients, the public, and carers in media releases provides a useful platform to highlight their personal stories and can help to raise awareness of guideline recommendations. Patients, carers and members of the public, who have helped develop guidelines, should be supported to be involved in media releases to highlight the importance of making diagnosis and treatment decisions based on the latest evidence. Patients and the public can also help promote awareness that patients helped develop the guideline to ensure that the needs of users shaped the recommendations. Consent should be collected from the patient, carer or member of the public to share personal experiences of care in media releases. The individual's contact details should not be shared, and comments should be sent to the guideline organisation. Any criticism should be responded to directly by the guideline organisation. Media releases shared via social media should be shared from the guideline organisation's social media account.

Digital tools

The use of digital tools, such as apps and websites, can help to raise awareness of guideline recommendations. Web-based self-management programmes can serve

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as a tool for healthcare professionals to share evidence-based information to help patients to successfully manage their conditions (Brosseau et al. 2012).

Community champions

People living with particular conditions have expert knowledge to become community champions, and it is both feasible and effective to involve them in adaptation of information from guidelines for patients, for example self-management guides (Campbell at al. 2018). Patient, public, and carer members of guideline development groups can act as champions for change. Together with other patient champions, they are in a good position to communicate to others the importance of the evidence when making decisions about their own care.

Providing support and training for patients and members of the public to become community champions is one approach that guideline developers can take to disseminate patient versions of guidelines to patients and the public. This is highlighted in SIGN 50's guideline developers handbook. Community champions educate and raise awareness of guidelines by organising stalls, talks and presentations at various places where patients and the public are likely to be. Examples include health conferences, community groups and local festivals. Patients and members of the public can also be supported to participate in virtual events, such as conferences and webinars, to raise awareness of guideline recommendations. Case study 3 highlights how patient and public members of guideline groups can be trained and supported to become community champions to assist with dissemination of guidelines.

Case study 3

SIGN appointed patient members of guideline groups and members of the public to become Awareness Volunteers (Community Champions). In addition to patients who were members of guideline development groups, others were recruited through patient groups, charities, voluntary organisations and volunteer centres.

Expectations of the role were clarified. The role included contributing to advertising materials, exhibiting at events, conferences and community

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hospitals, and delivering talks to patient and community groups about SIGN and patient versions of guidelines. In addition to this, Awareness Volunteers delivered talks to student nurses to raise awareness of guidelines and patient versions of guidelines.

SIGN provided training and support, which included:

- training on guideline development processes
- practical tasks to develop communication and presentation skills
- a named contact for individuals, who could support them in their role
- availability of a buddy for people new to the role.

Resources at the organisational level needed to successfully involve patients and members of the public in dissemination groups included:

- staff time to recruit, train and supervise patient and public members (see the chapter on recruitment)
- sufficient finances to reimburse out-of-pocket expenses, including travel expenses, childcare expenses and carer allowance (see the chapter on recruitment)
- sufficient finances for publicity materials
- possibly, financial compensation for patient and public representatives' time and work.

Patient organisations and networks of patients

Patient organisations and charities can promote the guideline (and its patient version) through social media, in their newsletter, at their annual conference, hosting it on their website (see case study 4), and including it in the information packages provided to their members.

The benefits of organisations and charities promoting guidelines include that:

- they have an established and engaged membership base

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- patients and the public may be more likely to access information through their channels when searching for information
- they are a trusted source of information for the public, and
- their knowledge of the patient and public group can enable them to pick out and phrase the most relevant recommendations for their audience.

Patient organisations can organise events where people share their experiences and take part in training and education (Schipper et al. 2016). Recommendations from guidelines can be disseminated at these events organised for patients and the public, for example, through posters, pocket cards, handouts and summaries. Discussions can take place on how patients can use them to help them take part in shared decision making (see the chapter on how to develop information from guidelines for patients and the public). Patient organisations may also provide telephone advice based on guideline recommendations.

Networks or 'virtual panels' of patients and the public can aid the dissemination of recommendations from guidelines as shown in SIGN 100's handbook for patient and carer representatives. SIGN's Patient Network members are alerted when new guidelines or patient versions of guidelines are published. Network members can raise awareness of them by circulating them to patients and other patient organisations.

Case study 4

Patient organisations promoting NICE guidelines:

Mind provides links to NICE guidance in their treatment and support sections of topics. For example, in schizoaffective disorder.

The MND Association created patient friendly resources to support the NICE guideline on motor neurone disease (NG42 2016). These include a pocket guide containing a summary of what you should expect from your care and an animated video setting out key aspects of the guideline.

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Strategies for disseminating guidelines to professionals

The involvement of patients and the public in dissemination plans can be crucial in increasing awareness of the guideline, not only among patients and the public, but also among healthcare professionals. Various strategies exist for disseminating guidelines to professionals, including educational materials, educational meetings such as conferences, and mass media information. Evidence shows that when multiple strategies for dissemination and implementation of guidelines are used, significant improvements in knowledge, practice and patient outcomes are likely (Fischer et al. 2016, Schipper et al. 2016).

Many patient organisations, charities and their networks include close connections with health and social care professionals in their disease area. They can thus promote the guideline to professionals through social media, on their websites, and at events and workshops that are attended by both professionals and patient organisations. Patient organisations and charities also send members to attend conferences aimed at (and organised by) healthcare professionals, to promote their own organisations and learn about new developments concerning their condition. Patient and public representatives from guideline groups can also be trained and supported by guideline organisations to speak at relevant conferences to raise awareness of the guideline with healthcare professionals. Case study 3 provides details of support and training for this role.

Patients and the public who have been involved with the development of guidelines can be supported to take part in media releases aimed at professionals to raise awareness of guideline recommendations (see case study 5).

Case study 5

SIGN published its guideline on risk reduction and management of delirium on World Delirium Awareness Day. To help raise awareness of the guideline, the patient representative from the guideline development group was involved in a media release. They were supported to share their experience of delirium and how the guideline could improve care in a blog and video.

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Recruiting patients and members of the public as community champions can also help to raise awareness of guidelines with health and social care professionals (see case study 3).

Implementation of guidelines

Barriers to implementation of guidelines by healthcare professionals include lack of awareness and lack of familiarity with the guideline and its recommendations. Attitudes of healthcare professionals and lack of agreement with recommendations can also act as barriers to implementation (Fischer et al. 2016). Patients and patient organisations can play a key role in addressing this problem by becoming involved with implementation strategies (SIGN 2019). Structured implementation can improve adherence to guideline recommendations.

Implementation of guidelines includes developing additional tools, documents or campaigns to encourage awareness and use of the guidelines. These can be designed either for patients and the public, or for professionals. Patients and public members of guideline development groups can be involved in both the design, testing and promotion of such implementation strategies.

After implementation tools have been developed, patient and public members and organisations can help promote and distribute these tools. This is usually alongside the dissemination of the guideline itself, using dissemination strategies such as those described in this chapter.

Implementation tools can include web-based resources for health and social care professionals or patients to help implement the guideline recommendations, for example, podcasts and video presentations. They can also include the development of more- or less-extensive public awareness campaigns and strategies. Case studies 6, 7, 8, 9, 10 and 11 demonstrate the various strategies and tools that can support implementation of guideline recommendations.

Case study 6

> As part of implementation of the SIGN glaucoma guideline a poster was created highlighting key recommendations for use with community

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optometrists. A patient representative on the guideline group was involved with the design of these and dissemination.

Case study 7

Patient organisations can promote guidelines in their training for patients and professionals to encourage a change in practice. To help with implementing SIGN's guideline on children and young people exposed prenatally to alcohol (SIGN156), Adoption UK Scotland highlights recommendations from the guideline in training they provide for professionals to help support families.

Information from guidelines for patients and the public

Information for patients and the public, such as patient versions of guidelines and plain language summaries, give patients, carers and members of the public access to recommendations in guidelines. This can help with implementation (see the chapter on how to develop information from guidelines for patients and the public). Patient information about conditions or procedures can help people to understand the care and treatment choices available to them based on the evidence and can support shared decision making about their own health (Bradley et al. 2019). Information from guidelines can help patients to evaluate their own care because they can monitor whether their own care is in line with options recommended in guidelines. It allows patients to discuss recommended treatment options with healthcare professionals and to find out why they are not being offered recommended treatments. Providing patients with this information can help to change the behaviour of the healthcare professionals caring for them. Case study 8 demonstrates this.

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Case study 8

The National competence service for simultaneous substance misuse and mental illness in Norway has produced a wide range of resources for patients and professionals, which they publish on their website. These resources include a 'recommendation card' for patients that highlights the 10 most important recommendations so that patients and relatives have increased knowledge of what kind of assessment, treatment and follow-up to expect from their healthcare professionals.

Example

The Norwegian guideline for assessment, treatment and follow-up of people with substance abuse and mental illness was developed by the Norwegian National Directorate of Health, medical associations, the Knowledge center for dual diagnosis and 10 user organisations. A user version of the guideline was developed by the Knowledge center for dual diagnosis in collaboration with several user and relatives organisations. They have also developed and published several other resources:

- Video collection of examples on how assessment tools and motivational interviews can be used in clinical work, as well as videos with representatives from user organisations that address several important topics.
- Web page with an introduction to motivational interview (MI), with clinical examples of how the various MI techniques can be used, as well as videos that show how the method can be used in clinical work. Care givers and patients can order free cards on assessment of drug use and MIs.
- Dual-diagnosis TV consisting of continuous lectures, interviews and other short snippets.
- Contact information for the Expert Council, a group where the National knowledge center for dual diagnosis, user organisations, social entrepreneurs, and professional organisations share experiences and

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discuss key topics within the drug or substance misuse and mental health field.

A web resource for users with:

- information about follow-up and treatment
- guideline and guidance documents from the authorities
- links to all user organisations, foundations, and social entrepreneurs in the area of substance abuse and mental health
- user rights
- digital self-help programmes or guidance
- helplines and humanitarian organisations to contact for practical help.

In addition to equipping patients with information about treatment options, raising awareness of guideline recommendations can promote their involvement in other areas, such as implementation of recommendations in relation to healthcare-associated infections. Raising patient's self-awareness on the risks and transmission of infections is one method to promote their involvement in infection prevention and control interventions. Involving patients as partners can promote conversations with professionals about infection control, for example, the patient can remind healthcare professionals to wash their hands (Fernandes Agreli et al. 2019).

Self-management tools

Self-management is an important component of care for patients with chronic conditions. Research shows that patients view guidelines as potential sources of self-management support (DECIDE patients and the public, Vernooij et al. 2016). It is therefore crucial that every effort is made to develop implementation strategies in which patients can play an active role. One example is online education tools that promote shared decision making. Brosseau et al. 2012 found that an online evidence-based educational programme delivered through Facebook could improve the knowledge, skills, and self-efficacy of patients with arthritis in relation to evidence-based self-management rehabilitation interventions. Facebook offers a way

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for healthcare professionals to interact with their patients and share guideline recommendations to promote shared decision making.

Involvement of patients in innovative implementation strategies for self-management recommendations can increase their feeling of having control over their life. For example, self-monitoring, the use of short message services (SMS), diaries, reminders and action plans can serve as tools to support self-management for patients with conditions, such as cancer pain, asthma and diabetes. In patients with cancer pain, SMS alerts and interactive voice response (through a mobile phone) can be used to report and assess pain, allowing patients to be more involved with their pain management. In patients with asthma, action plans can encourage patients to be in more control of their asthma. The use of such tools may be a way to encourage patient empowerment because the patient's role in managing their condition becomes more active, thus aiding the implementation of self-management recommendations (te Boveldt et al. 2012, Vernooij et al. 2016). Case study 9 provides an example of how patient organisations can support implementation of self-management recommendations.

Case study 9

A UK patient organisation, the National Rheumatoid Arthritis Society, developed a framework of supported self-management for people with newly diagnosed rheumatoid arthritis with the aim of improving patient outcomes. The Right Start service and resources supports the implementation of recommendations on self-management in the NICE guideline on rheumatoid arthritis in adults: management (NG100 2018) and related quality standard (QS33 2013). Right Start outcomes are being independently evaluated as part of a quality improvement programme and national audit.

Development of apps and web-based resources

Often apps and web-based resources are developed for health and social care professionals and patients to help with implementing guideline recommendations.

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Examples of patients and public members being involved in developing such implementation materials are highlighted in case studies 10 and 11.

Case study 10

To help with implementation of the NICE guidelines, patients or service users were involved in developing podcasts.

NICE has worked with patient organisations, such as the British Lung Foundation, Prostate Cancer UK and the British Skin Foundation, to develop podcasts. Examples include:

- Why you should get the flu jab – with the British Lung Foundation
- How is prostate cancer managed and treated? - with Prostate Cancer UK
- What is melanoma and how can I prevent it? – with the British Skin Foundation and a patient.

Individual patients or service users were also involved in developing the following podcasts:

- Care of women and their babies during labour and birth
- Which contraceptive method is best for me?

Case study 11

To help with implementing the guideline developed by SIGN, NICE and Royal College of GPs on managing the long-term effects of COVID-19 (2020), an app is in development for patients and the public. A patient who was involved in developing the guideline was involved with this at both the planning stage and early user testing stage of the app development. Interactive content is being developed to support self-management. Further user testing with patients and the public is planned.

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Public awareness-raising campaigns

Patient organisations and charities can be involved in using a guideline to develop education programmes for patients or people at high risk of a condition. Informing patients and the public about a condition and how best to prevent, diagnose and treat it can support the implementation of a guideline by encouraging patients to seek care in accordance with the guideline. It also ensures that professionals treat conditions in patients in accordance with the new, updated or existing guidelines. In addition to being organised or co-developed by patient organisations or charities, patients can be involved in delivering such education programmes.

Individual patients and members of the public can be involved in raising awareness of public health messages, based on evidence. Case study12 provides an example of this.

Case study 12

World Antibiotic Awareness Week (WAAW) is a global campaign held each year in mid-November. The Scottish Antimicrobial Prescribing Group (SAGP) and Health Scotland lead activities in Scotland to support WAAW and work closely with colleagues in Public Health England and professional groups to coordinate activities and share feedback. The aim is to raise awareness among health and social care staff, patients and the public about the need to use antibiotics more wisely to stop antimicrobial resistance. Since 2019, the campaign slogan has been ‘Keep Antibiotics Working’ and SAPG has promoted key messages using social media, the SAPG website, and radio adverts. Health Scotland has supported the campaign using posters in community pharmacies, GP practices and other community settings. Antimicrobial Management Teams in Scotland lead their Health Board campaign and local activities are supported by SAPG communications and resources. Public partners (volunteers) play an important role in these local activities through promoting the key messages and engaging healthcare staff and members of the public in discussions about the campaign.

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Evaluating service provision and commissioning

Patient organisations and charities can evaluate the quality and provision of services using guidelines as a measure. They can develop research projects and frame questions about the availability and quality of provision to evaluate if services and experiences are aligned with published guidance.

Patient organisations and charities can then use guidelines to develop or scrutinise service improvement plans, to ensure they align with the evidence of what is effective and good value care. Case studies 13 and 14 provide examples.

Case study 13

Healthwatch Bucks in England wanted to find out about the experiences of people treated in the hospital emergency department after a self-harm injury. They wanted to see if the NICE clinical guideline on self-harm in over 8s (CG16 2004) was being followed. They worked with a mental health charity, Buckinghamshire MIND, who carried out interviews with service users. As a result of the project, Healthwatch Bucks made recommendations aimed at supporting implementation of the NICE guideline. Local health service organisations responded by producing a joint action plan that implemented several recommendations, including those around privacy and consent.

Case study 14

Pancreatic Cancer UK worked with University Hospital Birmingham to develop a project to deliver fast track pancreatic cancer surgery.

The patient organisation worked in partnership with the hospital to implement NICE guideline recommendations to improve access to services and reduce waiting times. The project enabled patients to have surgery in 16 days rather than 65 days, increased the number of those having surgery

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by more than a fifth, and achieved a cost–saving benefit of £3,200 per patient.

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Acknowledgements

The authors would like to thank the following for their contributions to this chapter.

Provision of case studies: Kattya Mayre-Chilton, Marion Pirie, Mark Rasburn

Peer reviewers: Jane Cowl, Kenneth McLean, Mark Rasburn

Contributors to the 2012 version of this chapter: Karen Graham, Sara Twaddle, Carrie M Davino-Ranaya, Loes Knaapen

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Beyond guidelines – tools to support patient involvement in health technology assessment

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Key messages of this chapter

- Health technology assessment (HTA) considers patient involvement as both patient participation (such as committee membership and submissions) and research into patient aspects (such as patients' needs, preferences, expectations and experiences) using robust scientific methods. This is similar to patient involvement in clinical guideline development.
- As in clinical guideline development, patient involvement in HTA plays an essential role with patient input and research into patient aspects helping to identify what the traditional scientific evidence means for patient communities. It can also address gaps and uncertainties in that evidence.
- Choosing the approach to patient involvement and tools to use depends on the goal for involvement and context of implementation.

Top tips

- Start with a clear goal(s) agreed by guideline developers, staff within the organisation and patient groups, communities and key patients.
- In patient involvement, earlier is better, so begin by developing involvement processes with patient groups, communities and key patients.
- Manage expectations about what can and can't be achieved with patient involvement – explaining the purpose of the process and how decisions are made.
- Consider the ethical consequences – including harm and burden to patients and their representatives – and develop strategies with patient groups to manage them.
- Develop values and quality standards for patient involvement in guidelines internationally and encourage GIN members to adopt and enact them.

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- Learn from the experiences of others and document and share your own experiences.

Aims of this chapter

This chapter gives an overview of tools to support patient involvement in health technology assessment (HTA). It begins by explaining the parallels and differences between HTA and clinical guideline development. It then discusses the barriers to patient involvement in HTA, outlines how patients participate in the HTA process, and how patient-based evidence is used. It presents tools developed to support patient involvement in HTA that may be adapted to suit the needs of clinical guideline development.

The HTA context

HTA can be defined as

'a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.' (O'Rourke et al. 2020.)

HTA is deployed in more than 30 countries, using robust scientific evidence and deliberation to guide policy decisions about medicines, devices, interventions, procedures, and other health technologies. HTA often seeks to determine the value of a new health technology based on clinical and cost effectiveness evidence. However, when HTA was first described by the US Office of Technology Assessment in 1976 it was envisioned as a means of considering all the implications of introducing a new health technology. As such, wider societal aspects – including the impact for patients and their families, legal and ethical issues, and the environment – were considered essential to any assessment of the consequences of the way a health technology was or was not used. In some HTAs, this wider consideration of consequences continues to inform the determination of value and has important implications for the evidence considered and deliberative frameworks used.

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One of the accompanying footnotes to O'Rourke at al.'s definition of HTA, Note 3, recognises that value has many dimensions and the overall value of a health technology 'may vary depending on the perspective taken, the stakeholders involved, and the decision context' (2020). As such, it appears to support a view that the evidence base for HTA is robust but not neutral. Determining value depends on your perspective, which shapes the questions you ask in an HTA, the evidence you consider, and how you interpret it. This understanding of value determination has implications for the goals of patient involvement and subsequent use of research into patient aspects (known as patient-based evidence) and approach to patient participation. For example, patient-based evidence and participation may be used in recognition that traditional scientific evidence (such as randomised controlled trials) may not capture the outcomes that are most important to patients. It needs to be interpreted in the light of patients' needs, preferences, expectations and experiences, especially for application in the local healthcare context. As such, it often provides an important opportunity for those with lived experience of a condition to challenge assumptions made about patients and to direct inquiry to more relevant issues. Thus, patient involvement in HTA can be viewed as a means to patient-centred healthcare policy, 'ensuring fair and transparent allocation of resources informed by the needs, preferences and experiences of patients' (Facey et al. 2018).

There are many parallels between clinical guideline development and HTA in terms of scientific rigour and fair processes to translate international evidence into improvements in healthcare at a national or regional level. However, there is a difference in the way the evidence flows into decision making. Although clinical guidelines inform improvement in the whole care pathway and are focused on informing clinicians of best practice (provider decision making), HTA focuses more on decisions about a specific item in the care pathway and may be linked directly to reimbursement (payer decision making). HTA is often described in 3 steps:

- Assessment: critical review of published or submitted evidence about the clinical effectiveness or cost effectiveness of a health intervention.
- Appraisal: wider consideration of the evidence in the local context with value judgements about value and appropriate use.

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- Decision making: decisions about whether health interventions are made available, and to whom, in a health system - access or reimbursement decisions. (Garrido et al. 2008.)

Bodies that undertake HTA vary widely and may be responsible for assessment, appraisal or both, but all seek to inform decision making in some way. Furthermore, many of the HTA bodies are part of larger organisations that undertake a range of evidence-based work in the health system and this often includes clinical guideline development. Hence sharing approaches, while recognising differences, seems appropriate.

As HTA has become increasingly associated with treatment reimbursement and access issues, it has become more contentious. In some countries this has resulted in strong patient advocacy challenges and political drives to involve patients in the processes. Some HTA bodies have responded by creating transparent processes for patient participation in the HTA process and developing approaches for obtaining patients' needs, preferences, expectations and experiences (Facey et al. 2010). However, this involvement is not widespread or consistent. Some HTA bodies are reticent about involving patients or including their perspectives, especially when a health technology's value is seen as scientifically determined and patient involvement considered a source of bias rather than evidence and perspective. If such concerns are not satisfactorily explored and resolved within an HTA body (and its stakeholders), patient involvement is unlikely, or may at best be tokenistic because of its perceived threat to the credibility and legitimacy of HTA rather than improving the robustness of HTA. Without careful consideration of an HTA body's beliefs and norms before committing to shared goals for patient involvement, HTA bodies risk setting up unrealistic expectations for patient communities. As a result, patient input and patient-based evidence will be perceived to have little or no consequence because of implicit or explicit barriers.

Hence guidance was needed to provide practical ways in which patients could contribute to HTA and decision making with credibility and legitimacy (Boivin et al. 2014). Clarification was also needed about the complementary but different roles for evidence generated from research into patients' needs, preferences and experiences using robust, scientific methodology and insights gained from patient participation in

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HTA processes. Such participation includes patient input from written submissions and committee membership.

Barriers to patient involvement in the HTA process

Beyond organisational beliefs about HTA and patient involvement, a variety of barriers to involvement need consideration to operationalise it and avoid the features of tokenism, such as lack of transparency in decision making, lack of influence, and lack of inclusivity. In 2005, Hailey identified common themes that had been reported about consumer (patient and public) involvement in health research relevant to HTA. Facey updated this table in 2017 (Chapter 5). Table 1 presents a summarised version of Hailey and Facey's work. with some recent literature additions.

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Table 1 Barriers to patient participation in HTA (adapted from Hailey [2005] and Facey [2017])

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Challenge	Issues
Interaction of patients and researchers	• Time needed to develop a trusting, productive relationship
Resources	• Administrative, financial, staff support
Mechanisms of participation	• Lack of a comprehensive approach that sets the goals of participation for each stage of HTA (Gauvin et al. 2015) • Often chosen by the decision maker, who shapes it in a specific manner and so has control over the participation (Boivin et al. 2014)
Identifying a 'patient position'	• Recognising that there are differing values, expectations, environment, culture, genetics, and experience of the health system, and that it is not possible to canvass all
Nature and extent of patient representation	• Difficulty defining which patients should be involved • Questions about representativeness • Concerns about conflicts of interest and influence of health technology developers • Difficulty reaching marginalised populations
Technical demands	• Lack of knowledge, power, credentials or skills in scientific process and health care policy options
Training and education	• Lack of education and training developed specifically for consumers
Time demands and remuneration	• Time commitments, working to tight timetables, payments that should be made to patients
Balancing information from researchers, the literature, and patients	• Lack of concordance between issues that patients regard as important and those in which research has been conducted • Concern about methodology to balance qualitative and quantitative evidence and the role of costs, including questions about credibility of patient-based evidence • Devaluing patient-based evidence in evidence hierarchies (Gauvin et al. 2015)

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Challenge	Issues
Use of patient input	• Unsure what to do with patients or how to involve them • Concern of tokenism • Impact on timelines • Poorly moderated discussions preventing patient contribution (Facey et al. 2010) • Researchers' or clinicians' concerns that scientific debate is softened by including patient perspectives • Possible distortion of funding decisions because of patients' biases • Selection bias – processes may be inaccessible to many patients and ignore, or aim to eliminate bias, rather than valuing the unique perspective of individual patient participants and developing more accessible and appealing processes (Vanstone et al. 2019) • Patient group concerns about how evidence from different sources is handled, weighed and valued, and that others have more influence • Power differences between patients and professionals (Boivin et al. 2014) – processes value clinical and economic evidence over lived experience and patient-based evidence (Vanstone et al. 2019)
Lack of awareness of HTA processes	• The implications of HTA processes for healthcare systems (including beyond yes or no funding decisions) are not understood • Patients do not know how HTA is used or how to participate
Few evaluations of patient input	• Absence of good quality research to show that patient involvement makes a difference • No demonstration that patient involvement improves quality of assessments
Burden, benefit or risk	• Poor consideration of the impact on patients or patient groups of involvement, including poor management of expectations • Benefit (for example, capacity building, learning, system change) should outweigh risk (for example, physical, emotional, spiritual, economic harm; Vanstone et al. 2019)

Although the research reflected in table 1 was initially done in the first decade of this millennium, many of these barriers still exist. They are probably applicable not only to HTA, but also to clinical guideline development.

Similarly, the variation in type and level of patient involvement in HTA identified by a European Patients' Forum (EPF) survey in 2011 remains a feature in this field. It

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reflects the different rationale, motivation and approach applied in each country. The EPF confirmed that few HTA bodies and decision-making bodies involve and integrate patients' perspectives in their reports or conduct formal evaluation of the impact of patient involvement in HTA. Moreover, when there is some form of patient involvement this is often not done in a systematic, comprehensive and meaningful way. Apart from financial resource constraints, the main challenges were perceived to be the lack of capacity, time and good methodologies to involve patients. (EPF 2013.)

The first book in this field, Patient involvement in health technology assessment (Facey et al. 2017), sought to address the need for information about good methodologies and approaches to patient involvement in HTA. It drew on the expertise and experience of 80 authors from around the globe. In addition to providing case studies, the book aimed to be a cohesive guide to the field. It set out the rationale and detailed recognised approaches to participation and evaluation, and appropriate scientific methodologies for research into patients' needs preferences and experiences. The latter included the use of qualitative evidence synthesis, discrete choice experiments (DCEs), analytical hierarchy process (AHP), patient-reported and relevant outcome measures, ethnography field work, deliberative methods, and social media analysis.

Importantly, the book also sought to clarify issues that had arisen because of inconsistent terminology in the field and the resulting inappropriate use and treatment of patient involvement in HTA. Building on the work of the Health Technology Assessment international (HTAi) Patient and Citizen Involvement in HTA Interest Group (PCIG) in 2010, which described the 2 distinct but complementary approaches of patient involvement, that is, participation and robust evidence about patients' perspectives (Facey et al. 2010), the book expanded on the different roles and considerations for each. Participation was defined as a form of dialogue for shared learning and problem solving that can aid value judgements throughout the HTA process. Described as a mosaic of approaches selected according to the goal(s), participation is often sought to address gaps and uncertainty in the evidence and recognised for its role in interpreting evidence for real-world implementation. It commonly takes the form of patient input, such as written submissions and

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committee membership, which is characterised by its source (patients and patient groups gathering and presenting information to aid decision making). Whereas evidence about patients' perspectives, known as patient-based evidence, is intended to provide evidence of patients' needs, preferences and experiences in a form that can be critically assessed, as are other forms of scientific evidence. Table 2, by Staniszewska and Werkö (2017), summarises key differences between the 2 approaches.

Table 2 Summary of the differences between patient-based evidence and input from patient participation in the HTA process (Staniszewska and Werkö 2017)

Patient-based evidence	Patient participation in the HTA process
Produced through research, generally published in peer-reviewed journals	Originates in perspectives of individuals, groups of patients or organisations
Draws on a range of methodologies	Does not necessarily use or need a specific methodology
Draws on robust scientific methods whose strengths and limitations are known, and provides a robust conclusion that can be clearly interpreted	The quality of the methods used to gather inputs may be unclear or not considered as important
Depends on appraisal of quality, including formal critical assessment and peer review	The concept of quality may depend on factors such as authenticity or diversity of perspectives
Research is based on research genres and specific research questions, and takes time to generate from either primary or secondary research	Patient participation can be used at any point in the HTA process, and may be in the form of a dialogue to enable immediate reaction to an emerging issue
May be more limited in accounting for context of the HTA, depending on whether studies have considered context	Can consider the context of the HTA question
Can be based on a synthesis of studies, which means a comprehensive, unbiased view of a patient issue can be summarised very effectively	Provides a selection of perspectives that may not be comprehensive but are informative
Research directly addresses questions of bias and balance, which provides some assurance of quality	Bias in relation to patient input is a complex concept that requires exploration in the future

In addition to clarifying these distinctions and describing appropriate methodologies and approaches, Facey at al. (2017) drew on the work of Abelson et al. (2016) and the OHTAC Public Engagement Subcommittee (2015) to suggest that patient involvement begins with defining the goals for involvement, which should then guide

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decisions about approaches, methods and evaluation within the framework of the HTAi Values and Quality Standards for Patient Involvement in HTAi (see the section on HTAi Values and Quality Standards for Patient Involvement in HTA for more information). These goals may be instrumental, democratic, scientific or developmental (OHTAC Public Engagement Subcommittee 2015).

The editors and many of the authors of the book were active members of the HTAi PCIG. This interdisciplinary group, formed in 2005, promotes awareness of patient and citizen involvement, encourages methodological development, shares best practice, and supports jurisdictions seeking to introduce or develop involvement. PCIG has been active in developing tools for HTA bodies and patient groups to adapt for local involvement activities. Some of these tools may be suitable for adaptation for clinical guideline development. Key tools are described in the next section and further tools can be found on PCIG's web pages.

HTAi Values and Quality Standards for Patient Involvement in HTA

Increased awareness of and interest in patient involvement in HTA has led to calls for guidance around 'best practice' from many stakeholder communities, including those comprising patients and families. In response, the PCIG produced HTAi Values and Quality Standards for Patient Involvement in HTA. These values and standards, shown in table 3, were developed through an international 3-round Delphi process. They can be applied or developed to suit the clinical guideline setting.

Table 3 HTAi Values and Quality Standards for Patient Involvement in HTA (2014)

Values	• Relevance: Relevance refers to the fact that patients and families hold important knowledge and a unique perspective, which can only be obtained through 'lived' experiences with a particular disease or condition. Both are essential to the generation of HTA evidence that is comprehensive and captures the value of a technology to those directly affected by its use. • Fairness: Fairness relates to the need to create opportunities for patients to be engaged in the HTA process that are equivalent to those already available to other stakeholder communities, such as healthcare providers and industry. Therefore, patient involvement is

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	viewed as a basic 'right' of patients and families affected by HTA-informed decisions. • Equity: Equity is often defined as the absence of avoidable differences among groups within a population. Patient involvement in HTA helps to ensure that HTA evidence reflects an in-depth understanding of the diverse needs of various groups of patients. This information can reduce the risk of creating inequities in health status when healthcare systems are required to distribute health resources fairly among all users. • Legitimacy: Legitimacy refers to the acceptance of HTA-informed recommendations or decisions by affected individuals through appropriate patient involvement. Engagement of patients and families in HTA contributes to the transparency, accountability, and credibility of HTA-informed decision-making processes, which, in turn, enhances their legitimacy. • Capacity building: In general, adoption of formal mechanisms for involving patients in HTA not only addresses existing barriers to their engagement, but also provides an opportunity to build capacity for patients, families and HTA organisations to work together in a productive way.
Quality Standards: **General HTA process**	1. HTA organisations have a strategy that outlines the processes and responsibilities for those working in HTA and serving on HTA committees to effectively involve patients. 2. HTA organisations designate appropriate resources to ensure and support effective patient involvement in HTA. 3. HTA participants (including researchers, staff, HTA reviewers and committee members) receive training about appropriate involvement of patients and consideration of patients' perspectives through the HTA process. 4. Patients and patient organisations are given the opportunity to participate in training to empower them so that they can best contribute to HTA. 5. Patient involvement processes in HTA are regularly reflected on and reviewed, taking account of the experiences of all those involved, with the intent to continuously improve them.

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Quality Standards: Individual HTAs	The remaining 5 standards apply to specific steps followed during the assessment and formulation of a recommendation or decision about a particular health technology. 6. Proactive communication strategies are used to effectively reach, inform, and enable a wide range of patients to participate fully in each HTA. 7. Clear timelines are established for each HTA with advance notice of deadlines to ensure that appropriate input from a wide range of patients can be obtained. 8. For each HTA, HTA organisations identify a staff member whose role is to support patients to contribute effectively to HTA. 9. In each HTA, patients' perspectives and experiences are documented and the influence of patient contributions on conclusions and decisions are reported. 10. Feedback is given to patient organisations who have contributed to an HTA, to share what contributions were most helpful and provide suggestions to assist their future involvement.

In developing these values and quality standards, the PCIG stressed that patient involvement should be seen as a journey. Every HTA body starts in a different place and the high requirements of the values and quality standards are intended to encourage them to take a step on the journey to involve patients in their processes. Those who already do, should evaluate what they do and make improvements. Since their publication in 2014, several HTA bodies have endorsed the Values and Quality Standards and used them to review their own processes. For example, CADTH has used it for their Framework for patient engagement in health technology assessment (2019).

Participation throughout the HTA process

Technology or topic selection

Most HTA bodies established to inform reimbursement or coverage recommendations review all new drugs and therefore do not need processes for identifying and selecting technologies for assessment. However, some jurisdictions require a sponsor to make a submission to trigger the assessment. Usually, the manufacturer is the sponsor. But when manufacturers do not submit a drug for assessment, other stakeholders, such as patient groups, may seek to make a submission so that patients can access the drug. Some HTA bodies, such as the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia, accept

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submissions from the public and patient groups. In practice this is rare because of the complexity of the technical process, but PBAC has supported and considered 1 submission from a patient group, Rare Cancers Australia.

However, HTA bodies with a mandate for assessing non-drug technologies do need processes for identifying and selecting technologies for assessment. For example, the Swedish Agency for HTA and Assessment of Social Services (SBU) and the Scottish Health Technologies Group (SHTG) accept topic proposals from patient groups and other stakeholders. Patient organisations have the right to request Germany's Joint Federal Committee (G-BA) for a decision on non-medicine technologies. This means that not only can they propose a topic, but a request must be discussed, and if it meets the conditions for an HTA, G-BA must conduct the HTA. Instead of using a form, a specialist team, available to patient organisations regardless of funding, skills or size, helps with drafting the request (Haefner and Danner 2017).

Additionally, IQWiG (Germany's Institute for Quality and Efficiency in Healthcare programme) ThemenCheck Medizin (TopicsCheck Medicine) allows anyone to propose a topic for an HTA. IQWiG uses a 2-stage selection process to determine up to 5 citizen proposed topics each year. Usually completing proposal forms can be challenging for any stakeholder even with support from the HTA body. However, IQWiG has developed a simple online process designed to enable people without medical or research knowledge submit a question.

In terms of prioritisation of work, SBU has involved patients and carers in prioritisation methods. Its process is based on work by the James Lind Alliance and is used to identify the 10 most important uncertainties for condition areas with many uncertainties (Werkö and Andersson 2017).

However, most HTA bodies need to develop opportunities for patient input into decisions around which technologies to assess. This may include the participation of patients and their families in the development of criteria used to select technologies for HTA.

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Scoping

Patients and patient groups may be involved in scoping, which generally uses the PICO (population, intervention, comparator, outcome) framework. For example, the National Institute for Health and Care Excellence (NICE) elicits patient input by publishing its draft scoping documents for comment and then publishes all the comments and the new scope. An examination of the NICE's public involvement webpage reveals patient groups provide important input, particularly about patient subgroups, comparators and outcomes that matter.

Another example may be found in Australia's Medical Services Advisory Committee's (MSAC) PICO Advisory Sub-Committee. This group circulates the scope and a consultation survey to targeted patient groups.

EUnetHTA is a network of European agencies that collaborate in the joint production of HTA reports. The network uses the HTAi template (described in the section on HTA tools for patient input) to involve patients in EUnetHTA's patient input in Relative Effectiveness Assessments (reports that assess clinical effectiveness). The intention is to gain patient input to inform the development of the PICO table and provide the assessment team with insights into patient experiences.

Patient input at scoping has been shown to be valuable for highlighting outcomes that matter to patients and identifying appropriate comparators for HTA submissions.

HTA tools for patient input

With the adoption of more rapid HTAs, especially for drugs, many HTA bodies began accepting submissions in the form of a written template. Some, for example the Centre for Drug Evaluation (Taiwan), the National Committee for Health Technology Incorporation (CONITEC, Brazil), and PBAC and MSAC (Australia), accept submissions from any member of the public, including patient groups. Whereas others, such as NICE (England and Wales), the Scottish Medicines Consortium (SMC) and CADTH (Canada), apply criteria that usually limit submissions to patient groups and include a declaration of funding basis. Submissions contain insights from the lived experiences of patients and their families that may challenge assumptions or address gaps and uncertainties. Templates generally ask questions about the daily lives of patients and families affected by the particular condition or illness,

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current treatment options and their impact, as well as the experiences of those who have had the technology being assessed.

The PCIG has worked with HTA bodies and patient organisations to review patient group submission forms. They have developed 3 standardised HTAi patient group submission templates for medicines, non-medicines and diagnostics. These tools have been consulted upon internationally and translated from English into French, Spanish and Mandarin. The template for patient group submissions to the non-medicine's HTA could be adapted for clinical guidelines. This is accompanied by a cover note for HTA bodies, which stresses the need to adapt the template to suit their own circumstances, processes and the technology being assessed. In 2021, the EC-funded IMPACT HTA project used the HTAi work to develop a new patient group submission template for re-appraisal after data collection. This aims to document patients' experiences during the data collection period and identify unexpected effects not captured in the clinical evidence.

The HTAi templates highlight the information that is valued by decision makers but patients need to be well supported by training, guidance and feedback to realise their value. This is because patients may not know which areas of their lived experience knowledge are being assumed, misunderstood or missing in the evidence. Some HTA bodies have dedicated staff who provide support to patient organisations during the completion of submissions. SMC, for example, provides feedback on draft submissions and CADTH gives feedback in a letter after the assessment.

The PCIG has adapted a guide developed by CADTH's pan-Canadian Oncology Drug Review that helps patients complete a patient group input submission template. The HTAi's guidance for providing patient input using the templates helps patient groups understand what kind of information will have most impact and gives guidance on how to undertake surveys and conduct interviews with patients and report findings. Recognising that patient groups usually conduct this work without an ethics committee review, the PCIG also developed an HTAi short guide and a long guide on ethical issues for patient groups to consider when collecting and reporting information for HTA submissions.

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Additionally, in 2020 the PCIG released a Summary of Information for Patients template and guidance based on a research project and SMC's experience in providing information to patient groups from the sponsors about the medicine being assessed. The rationale for the template is that people, especially those in smaller or less HTA-experienced patient groups, require information about the product being assessed to target their input. The PCIG intends that HTA bodies will adapt the template.

Patient input in submissions has helped HTA bodies understand:

- the trade-offs patients might make
- the consequences of variations in service provision
- the potential real-world value of small clinical benefits to patients
- the consequences of treatment pathways
- how a treatment is administered for patient subgroups not identified in clinical trials.

Berglas et al. (2016) studied how patient input was integrated in 30 assessments by CADTH's Common Drug Review. They found that CADTH reviewers used patient insights about health status achieved, progress of recovery, and longer-term consequences of illness and treatment to frame the assessment. The CADTH Canadian Drug Expert Committee uses these insights to aid the interpretation of evidence. They also found patient input identified outcomes that are important to patients, but which may not be measured in clinical trials.

Committee membership

Patients and their representatives may be included on advisory and appraisal committees. To overcome ongoing confusion about the roles of patient and public members, Street et al. (2020) found identifying members by the interest and values they are tasked to represent provided clarity. They defined a patient member as someone 'who has been selected to support the inclusion of the interests of patients in HTA processes on a committee', whereas a public member 'supports the inclusion of the interests of the society at large'. Patient members may be nominated for a committee to give specific expertise based on their lived experience. As committee members, they can also present the wider experiences and perspectives of their

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patient communities on a particular condition or issue. Furthermore, patient and public members play an important role in ensuring that patient involvement processes are appropriately enacted, can reflect on improvements, and provide training to those providing patient input. G-BA appraisal committees are an example of HTA bodies using this approach. They include patient representatives throughout the appraisal process and in all sessions of the committee.

Hearings

Australia's PBAC conducts consumer hearings when there is greater uncertainty in interpreting benefit and harm evidence, such as some medicines for rare diseases. In Brazil, public hearings are legally provided for and the first hearing took place in March 2021. It was for spinal muscular atrophy. The intention is that public hearings be held before the final decision is taken for cases in which the secretary of the Ministry of Health's Secretariat of Science, Technology and Strategic Inputs determines that the relevance of the matter justifies a hearing. The hearings are envisaged as a face-to-face consultative mechanism open to anyone and participants will have the opportunity to speak. (Silva et al. 2019.)

Consultation

Several HTA bodies, including the Italian National Agency for Regional Healthcare Services (AGENAS), CONITEC (Brazil) and NICE (England and Wales), publish consultation reports to seek feedback from a wider range of stakeholders, including patients and patient groups. Because these reports can be quite technical, patient involvement is better supported if patient-friendly versions are prepared and workshops or meetings are held to discuss the issues with relevant patient communities.

Dissemination

HTA bodies use patient-friendly versions of HTA reports and recommendations to communicate how recommendations were formed and what this means for patients. For example, working with Health Improvement Scotland's public partners and drawing on the guidance from the DECIDE project, the SHTG produced a patient guide to its HTA on wound dressings.

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Beyond individual HTAs

The use of patient participation beyond individual HTAs is less described in the literature. Examples include the formation of advisory groups at SMC, NICE and Health Technology Wales who involve patients in developing and reviewing patient involvement processes. Another example is CADTH's involvement of patients in shaping and contributing to the agenda of its key capacity building activity, that is, its annual symposium. PCIG is currently undertaking a study to describe patient participation at the organisational level and may develop tools to support this area if a need is identified.

PCIG's resources to involve patient groups and individual patients in HTA, include the HTAi Online Resource Directory. The directory aims to make it easier to locate useful resources shared by HTA bodies, not-for-profit organisations and other relevant organisations.

Use of patient-based evidence

HTA bodies that perform their own literature reviews, such as SBU, DEFACTUM (part of Corporate Quality in Central Denmark Region), AGENAS, CADTH, RedETS (the Spanish Network of Health Technology Assessment Agencies and Benefits of the National Health System) and SHTG, may undertake specific literature searches to determine patient issues. They use iterative processes to identify issues of importance to patients, and then search for literature (often qualitative research studies) that describes patients' perspectives and experiences about those issues. Such studies provide evidence of how people, including patients, carers and family members, perceive and experience a condition and its treatment. They are in a form that can be critically reviewed and is explicit about the strengths, limitations and bias of its methods. Systematic processes, such as qualitative evidence synthesis, can be used to critically appraise such qualitative research and synthesise it using methodologies from social and humanistic research (Swedish Council on HTA 2013). If evidence is lacking, primary research can be commissioned and reported as part of the HTA (Danish National Board of Health 2007).

EUnetHTA's HTA Core Model Online (2017) includes a patient and social aspects domain that focuses on patients' and their significant others' considerations, worries

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and experiences before, during and after the implementation of the technology. The EUnetHTA HTA Core Model Handbook provides guidance on conducting research into patients' perspectives that could be used for a variety of needs. In such processes, patient groups or patient experts can also:

- provide helpful input to the protocol that defines the research questions
- identify outcomes that matter most to patients
- provide important consultation comments on the draft guideline and recommendations.

In recognition of the increasing use of rapid assessments, Health Improvement Scotland has produced 3 resources, which they are trialling. See the HTAi website for the guide to conducting rapid qualitative evidence synthesis for HTA, the methodology and the coding template.

In addition to qualitative research, patient preference methodologies, such as DCEs and AHPs, may provide a useful additional source of evidence to inform HTA recommendations. Some HTA bodies are exploring these methodologies. Patient preference research may be especially useful when a technology is being compared with a standard treatment that has different features, such as mode, ease of administration, side effects, and the risk of serious side effects (Bouvy et al. 2020). However, further research is needed to ascertain its optimal use in HTA and the health technology development lifecycle (Danner and Gerber-Grote 2017). Limitations associated with stated preference methods, such as participant innumeracy, hypothetical bias, variation among subgroups, and inert or flexible preferences need to be considered. A PCIG project subcommittee is investigating these issues.

IQWiG conducted 2 preference elicitation studies – one using DCE and one using AHP - in which patients valued the importance of treatment outcomes in different indications. It found the studies had potential to generate weights or prioritise outcome-specific HTA results. The AHP study demonstrated that patients valued different outcomes to clinicians and the DCE study in lung cancer identified important alternative endpoints (Egbrink and IJzerman 2014).

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Impact

Inconsistent terminology, limited goal descriptions, and poor documentation of patient involvement's use and influence have made it challenging to evaluate their impact. Despite this, the need to evaluate the impact of patient involvement is increasingly recognised, especially to improve practice. Evaluation has been used to determine if and how patient insights were integrated into assessment reports, and if the presence of written patient statements are associated with positive reimbursement decisions. It has also been used to assess the impact of written statements (Mason et al. 2020). The number of sources of evidence and variables in an HTA make such evaluations problematic. An alternative approach to understanding the impact of patient involvement in HTA is case studies in the form of stories (for example, as described by Single et al. 2019). The PCIG has developed this work using their Patient Involvement Impact Perspectives template (see Stakeholders perspectives of impact of patient involvement in HTA (Impact Project)) to collect further case studies or stakeholders' experiences of patient involvement in HTA. Such information could provide reflections on the perceived impact of patient involvement from the perspective of anyone involved in an HTA, including patients and people working in HTA or industry.

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Acknowledgements

The authors would like to acknowledge and thank Dr Tania Stafinski (HTPU, Health Policy and Management, School of Public Health, University of Alberta, Edmonton, Canada), who co-authored the 2015 version of the chapter, on which this 2020 version is based.

Peer reviewers: Lucía Prieto Remón, Maria Jose Vicente Edo

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Ⅱ．研究成果の刊行に関する一覧表

書籍（該当なし）

著者氏名	論文タイトル名	書籍全体の編集者名	書　籍　名	出版社名	出版地	出版年	ページ

雑誌（該当なし）

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年