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

医療安全対策の最新のエビデンスと今後の政策課題についての研究

平成 29 年度　総括・分担研究報告書

研究代表者　長谷川友紀

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医療安全対策の最新のエビデンスと今後の政策課題についての研究

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研究要旨

医療安全向上のため、過去の施策の成果を評価し、今後優先度の高い施策を特定することは、エビデンスに基づく医療政策実現に有効である。本研究は、医療安全の諸施策を制度・病院・臨床現場の 3 レベルに分け、各施策の過去の貢献度や各病院での実施状況、今後推進する上で想定される費用、効果、優先順位を明らかにすること、および、主要国の医療安全施策の状況のほか、全国の病院の医療安全管理体制・活動状況を明らかにすることを目的とした。

平成 29 年度は 5 つの調査を実施した。①医療安全の専門家 25 人を対象とした Delphi 法による調査では、医療安全の諸施策の過去の貢献度、今後進める上での費用・効果・優先度を明らかにした。②全国 3215 病院の代表者・医療安全管理者を対象にした郵送法によるアンケート調査では、病院の医療安全管理体制、活動のほか、諸施策の実施状況、今後進める上での優先度を明らかにした。③OECD 加盟する 35 ヵ国の医療安全政策担当者を対象にした電子メールによるアンケート調査では、各国の医療安全施策の現状を明らかにした。④ 海外の医療安全政策についての調査では、米国 ASHRM の年次大会に参加し、米国の取り組みについて情報収集した。⑤医療安全に関する 3 件の文献調査を試行し、文献検索方法や取りまとめ方を検討した。

①より、費用対効果の高い施策として「処置・手術のチェックリスト」「周術期の投薬方法の標準化」「患者・部位・手技等の照合方法の標準化」が挙げられ、今後の優先度が高い施策として「医療職の教育・訓練」「業務量に応じた人員配置」「患者が服薬中の薬剤の定期的な評価・見直し」が挙げられた。②より、病院における専従・専任の医療安全管理者の配置状況や各種医療安全管理活動の実施状況を明らかにしたほか、今後の優先度が高い施策として「医療事故やヒヤリ・ハットの報告・管理の仕組み」「転倒・転落の予防方法の標準化」「手指衛生の取り組み」が挙げられた。③より、OECD 加盟国における病院機能評価、医療安全管理者の配置、医療安全に関する臨床指標の報告制度、有害事象の報告制度等の現況を取りまとめた報告書を作成し、第 3 回閣僚級世界患者安全サミット（平成 30 年 4 月 13 日～14 日、東京）において参加者に配布した。④より、米国 ASHRM の提供するリスクマネジメントと医療安全に関する教育プログラムや認定制度、及び米国で現在注目されている話題、活動等が明らかにされた。⑤より、医療安全に関する活動はエビデンスレベルの高い研究が少なく、文献調査の費用対効果について検討する必要があること、重要な内容に絞って丁寧に調査すべきであること等が挙げられた。

本研究により、さまざまな医療安全施策・活動について、その費用対効果や優先度を評価することができた。また、諸外国の医療安全施策について、わが国でも参考にできるものを特定することができた。

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A．研究目的

1990 年代後半に医療安全が世界的に大きな関心事になって以降、医療安全向上を目指した種々の活動が実施されてきた。日本では、医療安全推進総合対策（2002）により国として医療安全にどのように取り組むかの方向性が明らかにされるとともに、種々の施策が行われてきた。10 年以上を経過し、医療安全向上への取り組みがどのような成果を上げてきたか、今後、優先度の高い課題としてはどのようなものが考えられるかを明らかにすることは、エビデンスに基づく医療政策実現に有効である

本研究では、制度・病院・臨床現場の 3 レベルについて、①医療安全の諸施策について文献調査により、有効性、エビデンスレベルを明らかにする（平成 29 - 30 年度）。②日本及び海外の専門家を対象にした調査により、諸施策のうち医療安全に貢献した事項、今後推進する上で想定される費用、効果、優先順位を明らかにする。③主要国においてどのような政策が優先して進められているかを明らかにする（平成 29 - 30 年度）。④病床規模により層別化抽出した約 3000 病院を対象にしたアンケート調査により、院内における医療安全体制、活動状況を明らかにし、あわせて前記事項（病院・臨床現場レベルについては実施状況を含む）の貢献度合い、推進に当たっての優先順位を明らかにする（平成 29 年度）。

B．研究方法

本研究は以下から構成される。

1. 日本の医療安全の専門家を対象にした Delphi 法による調査（専門家調査）

Delphi 法は定量的な予測が困難な事柄に対して、専門家に対して回答を求め、その結果を回答者にフィードバックし再度回答を求めることを繰り返すことにより、集団の意見や知見を集約し、統一的な見解を得る手法である。医療制度に関わる諸施策について、①過去の医療安全への貢献度、②今後推進するにあたっての費用、効果、優先度、最適な施策の組み合わせについて、医療安全の専門家の意見を集約した。研究班が 25 名の専門家を有意抽出し、3 回の調査を実施した（2017/7/18～25、8/28～9/5、9/25～10/6）。1 回目の調査は郵送法を用い、2・3 回目の調査は電子メールを用いた。

2. 全国の病院の代表者・医療安全管理者を対象にしたアンケート調査（全国調査）

全国の病院（n=8,438）から、病床規模で層化抽出した病院（n=3,215）を対象にした郵送法によるアンケート調査を実施した（2017/10/30～11/14）。回答者は病院の代表者もしくは医療安全管理の担当者とした。調査項目は、院内における医療安全体制、活動状況および諸施策（病院・臨床現場レベルについては実施状況を含む）の過去の貢献度合い、推進に当たっての障害因子、優先順位とした。なお、院内体制、活動状況については、過去に研究代表者らが実施した調査結果と比較検討が可能なように、調査項目

の整合を図った。調査期間は 2017/10/30～11/14 とした。

3. OECD 加盟国を対象にしたアンケート調査（国際調査）

OECD 諸国（n=35）の医療安全政策担当者を対象にした電子メールによるアンケート調査を実施した（2017/12/4～12/20）。厚生労働省から各国のカウンターパートに対し電子メールで調査票を送付した。各国のカウンターパートは、各国の医療安全政策に詳しい専門家等に調査票への回答を求めた。回答票は厚生労働省あるいは東邦大学に電子メールで返送された。調査項目は、各国の医療安全施策、制度、組織、活動に関する項目とした。

4. 海外の医療安全政策についての調査（海外調査）

ASHRM （The American Society for Healthcare Risk Management） 2017 Annual Conference （米シアトル、2017/10/15～10/18）に参加し、関連する情報を収集した。

5. 医療安全についての文献調査（文献調査）

文献調査の方法および取りまとめ方について検討した。

（倫理面への配慮）

本研究の研究計画は、東邦大学医学部倫理委員会の審査を受け、承認された（申請番号：A17025）。

C．研究結果

詳細は分担研究報告書で報告する。

1. 専門家調査

調査対象は医療安全の専門家 25 名（医師 15 名、看護師 5 名、薬剤師 2 名、その他 3 名）とした。回収率は 96%（24/25）であった。42 個の医療安全施策の多くについて、専門家の意見の集約が見られた。効果の評価点が費用の評価点を上回る施策を費用対効果の高い施策と定義すると、費用対効果の高い施策として「処置・手術のチェックリスト」「周術期の投薬方法の標準化」「患者・部位・手技等の照合方法の標準化」が挙げられた。優先度の評価点の高い施策は、評価点の高い順に「医療職の教育・訓練」「業務量に応じた人員配置」「患者が服薬中の薬剤の定期的な評価・見直し」であった。

2. 全国調査

回収率は 19%（603/3,215）であった。配置されている医療安全管理者は、100 床以上の急性期病院は専従が主体であり、100 床未満の急性期病院と、療養型病院、精神科病院は専任が主体であった。医療事故とヒヤリ・ハットの院内報告の件数（中央値）は約 3 件/床/年であり、病床規模の大きい急性期病院で多く、療養型病院や精神科病院で少ない傾向が見られた。42 個の医療安全施策うち、優先度の高い施策は、評価点の高い順に「2.2 医療事故やヒヤリ・ハットの報告・管理の仕組み」「3.14 転倒・転落の予防方法の標準化」「2.11 手指衛生の取り組み」であった。

3. 国際調査

回収率は 51%（18/35）であった。OECD 加盟国では、病院に対し病院機能評価の受審を義務化している国は少なく、多くは任意であること、医療安全管理者の配置を義務化したり配置に対してインセンティブを与えたりしている国は非常に少ないこと、病院が医療安全に関する臨床指標を政府あるいは第三者機関に任意で報告する仕組みを有する国が多いこと、病院が有害事象を政府や第三者機関に任意あるいは義務として報告する仕組みをほぼ全ての国が有していること等が明らかにされた。それらの結果を取りまとめた報告書を作成し、第 3 回

閣僚級世界患者安全サミット（平成 30 年 4 月 13 日～14 日、東京）において参加者に配布した。

4. 海外調査

ASHRM 2017 Annual Conference では、医療安全関連のテーマとして、Human Factors、RCA、Wrong-Site Surgery、a Culture of Patient Safety 、 Accountable Care Organization、a Disclosure Program、HRO Journey などに関するテーマが並んでおり、現場からの取り組み報告、いわゆる Champion 報告や、基本を進化させた方法論に関する報告が多かった。他にも、Transgender、Cyber Risk、Webcare、Social Media 、 Telemedicine 、 Data Science Techniques、an Aging Population といったテーマが取り上げられていた。また、Medical Marijuana は米国におけるタイムリーなテーマであり、シンポジウムでも取り上げられていた。

5. 文献調査

施設間の Handover、中心静脈カテーテルの超音波ガイド下挿入、WHO 手術安全チェックリストの医療安全に関するエビデンスについて、医中誌 WEB および PubMed を用いた文献調査を試行した。施設間の Handover に関する文献調査では、地域連携パスと患者手帳の効果が認められたが、エビデンスレベルの高いデザイン・アウトカムの研究は少なかった。

D．考察

専門家調査では、施策の費用対効果と優先度の評価は必ずしも一致しないことが確かめられた。電子カルテや人員配置など、費用対効果の評価は低いが、優先度の評価が高い施策について、今後の推進方法を検討する必要がある。また、施策の優先度がどのような要素によって決定づけられるのかについて検討を進める必要があると考えられた。

全国調査では、全国の病院の医療安全管理の現状と医療安全施策の優先度について、全国の病院代表者または医療安全管理の担当者の評価を明らかにできた。医療安全管理体制・活動の状況は、病床規模の大きい急性期病院で充実していた。医療安全管理体制・活動の状況は、その詳細について更なる解析が必要である。医療安全施策の中でもっとも優先度が高かったのが「2.2 医療事故やヒヤリ・ハットの報告・管理の仕組み」であった。施策の優先度は病院の規模・機能により異なることが予想されるため、各施策の優先度と病院の規模・機能との関連について更なる解析が必要である。

国際調査では、OECD 諸国の取り組みから、我が国も参考にできる多数の医療安全施策を明らかにすることができた。今後はそれらの導入可能性について検討する必要がある。

海外調査では、米国でもわが国と同じようなテーマが注目されていることが明らかにされた。Transgender、Cyber Risk、Webcare、Social Media、Telemedicine、Data Science Techniques 、 an Aging Population など、社会の動きに敏感に反応し、新たなテーマとして積極的に取り組んでいることが特徴的であり、わが国でも参考にできると考えられた。

試行した文献調査では、医療安全に関する施策・活動の効果については、エビデンスレベルの高い研究が少ないことが明らかになり、推奨度を低く設定せざるを得ない施策が多くなると予想された。今後は、文献調査の費用対効果も考慮し、文献調査のテーマを絞り込む必要があると考えられた。

E．結論

本研究により、さまざまな医療安全施策・活動について、その費用対効果や優先度を

評価することができた。また、諸外国の医療安全施策について、わが国でも参考にできるものを特定することができた。今後は、得られたデータについて更なる解析を進める必要がある。

Ｆ．健康危険情報

本研究では被験者への介入を行わないため、被験者への健康被害は発生しない。

Ｇ．研究発表

1. 論文発表

なし

2. 学会発表

なし

Ｈ．知的財産権の出願・登録状況

1. 特許取得

なし

2. 実用新案登録

なし

3. その他

なし

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）
分担研究報告書

医療安全管理の専門家を対象とした調査（専門家調査）

研究要旨

本研究は、医療安全に関する専門家の知見に基づき、医療安全のための諸施策の費用対効果と今後の優先度を明らかにすることを目的とした。

医療安全管理の専門家 25 名を対象に、Delphi 法を用い、3 回のアンケート調査を実施した。42 個の施策の過去の貢献度、現在の普及度合、今後進めるにあたって期待される効果、費用、緊急性、優先度について、5 段階のリッカートスケールで回答を求めた。

3 回の調査の回収率はいずれも 96%（24/25）であった。多くの項目で専門家の意見の集約が見られた。費用対効果の高い施策として「3.8 処置・手術のチェックリスト」「3.10 周術期の投薬方法の標準化」「3.18 患者・部位・手技等の照合方法の標準化」が挙げられた。優先度の評価点の高い施策は、評価点の高い順に「1.5 医療職の教育・訓練」「2.8 業務量に応じた人員配置」「3.1 患者が服薬中の薬剤の定期的な評価・見直し」であった。

施策の費用対効果と優先度は必ずしも一致しないことが確かめられた。電子カルテや人員配置など、費用対効果の評価は低いが、優先度の評価が高い施策について、今後の推進方法を検討する必要がある。また、施策の優先度がどのような要素によって決定づけられるのかについて検討を進める必要があると考えられた。

A．研究目的

医療安全が 1990 年代後半より世界的に注目されるようになり、各国において種々の試みがなされた。2017 年に OECD は発表した報告書「The economics of patient safety - strengthening a value-based approach to reducing patient harm at national level」では、医療安全のための諸施策の費用対効果が明らかにされた。しかし、施策の費用対効果はその国の医療制度や各施策の普及度により異なると考えられる。また、今後推進すべき医療安全施策は費用対効果だけで決まるものではなく、わが国のさまざまな状況を勘案して優先度を決めなければならない。本研究は、医療安全に関する専門家の知見に基づき、医療安全のための諸施策の費用対効果と今後の優先度を明らかにすることを目的とした。

B．研究方法

医療安全管理の専門家の医療安全施策に対する意見を、Delphi 法を用いて取りまとめた。Delphi 法は、定量的な予測が困難な事柄に対して、専門家に対して回答を求め、その結果を回答者にフィードバックし、再度回答を求めることを繰り返すことにより、集団の意見や知見を集約し、統一的な見解を得る手法である。

研究班が国内の医療安全管理の専門家 25 名を有意抽出した。抽出された専門家に対し依頼文と調査票を郵送し、回答後に東邦大学へ返送していただいた（1 回目調査）。1 回目調査の集計後、1 回目調査に回答のあった専門家に対し、集計結果と共に同じ調査票を電子メールで送付した（2 回目調査）。専門家には、1 回目調査の集計結果を見たうえで、再度同じ調査票に回答し、電子メールで東邦大学に返送することを求めた。2 回目

調査の集計後、2 回目調査に回答のあった専門家に対し、集計結果と共に同じ調査票を電子メールで送付した（3 回目調査）。専門家には、2 回目調査の集計結果を見たうえで、再度同じ調査票に回答し、電子メールで東邦大学に返送することを求めた。

調査期間は、1 回目調査が 2017/7/18～7/25、2 回目調査が 2017/8/28～9/5、3 回目調査が 2017/9/25～10/6 とした。

調査項目は、2017 年の OECD の報告書「The economics of patient safety - strengthening a value-based approach to reducing patient harm at national level」に準じた。同報告書には、全国/制度レベルの施策が 10 個、病院レベルの施策が 14 個、臨床現場レベルの施策が 18 個挙げられ、各施策を完全に導入し維持する「費用」（1：低い～5：高い）と、施策が導入され定着した場合の死亡や傷害の低減「効果」（1：低い～5：高い）についてそれぞれ 5 段階で評価した。本研究では、同じ計 42 個の施策について、過去の医療安全への貢献度（1：小さい～5：大きい）、現在の普及度合（1：低い～5：高い）、今後進めるにあたって期待される効果（1：小さい～5：大きい）・費用（1：安い～5：高い）・緊急性（1：低い～5：高い）・優先度（1：低い～5：高い）について、それぞれ 5 段階の評価を求めた。また、1 回目調査のみ、上記の 42 個の施策の他に評価すべき施策があれば列挙するように求め、2・3 回目調査ではそれらの施策についても同様に評価することを求めた。

回答者へのフィードバックに用いた集計結果は、各施策の評価項目別に、5 段階の各選択肢の度数（人数）を集計し、中央値と四分位範囲が判別できるように色付けした。

施策の費用対効果は、各施策の費用と効果の評価点の平均値を求めたうえで、効果の評価点を費用の評価点で除算した「効果費用比」を算出した。効果費用比が 1 を上回る施策は費用対効果が高く、1 を下回る施策は費用対効果が低いと判定した。優先度の評価点は平均値を求めた。

（倫理面への配慮）

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C．研究結果

3 回の調査の回収率はいずれも 96％（24/25）であった。回答者の職種別内訳は、医師が 15 人、看護師が 4 人、薬剤師が 2 人、患者代表を含むその他が 3 人であった。24 人の専門家の回答を資料 1 に示す。1～3 回目の回答の分布の変化と、1 回目と 3 回目の回答を比較した結果を表 1-1 に示す。42 個の施策の普及度、効果、費用、緊急度、優先度（42 個×5 項目）のうち、12%の項目で、中央値を選択する者が有意に増加した。特に、「3.18 患者・部位・手技等の照合方法の標準化」の優先度は、Delphi 法を用いたことにより、専門家達の回答の分布と中央値が変化し、中央値を選択する者の割合が増加した。

施策の効果費用比と優先度を表 1-2 に示す。効果費用比に基づき、費用対効果の高い施策として「3.8 処置・手術のチェックリスト」「3.10 周術期の投薬方法の標準化」「3.18 患者・部位・手技等の照合方法の標準化」が挙げられた。優先度の評価点の高い施策は、評価点の高い順に「1.5 医療職の教育・訓練」「2.8 業務量に応じた人員配置」「3.1 患者が服薬中の薬剤の定期的な評価・見直し」であった。

D．考察

Delphi 法を用いたことにより、医療安全施策に対する専門家の意見を集約することができた。費用対効果と優先度の双方が高

い施策として「2.11 手指衛生の取り組み」や「2.6 患者情報の伝達方法の標準化と訓練」があり、これらの施策は積極的に推進すべきであると考えられた。一方で、優先度は高いが、費用対効果が低い施策として「2.8 業務量に応じた人員配置」や「2.7 情報技術を用いた医療安全対策」があり、これらの施策は費用の問題が解決されない限り積極的に推進するのは難しいと考えられた。費用対効果と優先度の双方が低い施策として、「1.2 医療安全指標に基づくデータの収集と公表」や「1.1 認定・認証における医療安全基準」が挙げられた。国・制度レベルの施策の費用対効果の評価は低く、臨床現場レベルの施策は費用対効果が高いという点では、OECD が 2017 年に実施した調査と同じ結果が示された。優先度は、費用対効果だけでなく、これまでの貢献度や現在の普及度、緊急度など、さまざまな要素を勘案したうえで選択されていると考えられる。今後は、施策の優先度がどのような要素によって決定づけられるのかについて検討を進める必要があると考えられた。

Ｅ．結論

本研究により、費用対効果の評価が高い医療安全施策と、優先度の評価の高い医療安全施策を特定することができた。

Ｆ．研究発表

1. 論文発表

なし

2. 学会発表

なし

Ｇ．知的財産権の出願・登録状況

1. 特許取得

なし

2. 実用新案登録

なし

3. その他

なし

表 1-1　Delphi 法による回答の変化

(P 値)

番号	施　策		現在の普及度合	今後進めるにあたっての			
				期待される効　果	費　用	緊急性	優先度
1.1	認定・認証における医療安全基準	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	0.04	n.s.
1.2	医療安全指標に基づくデータの収集と公表	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	<0.01	n.s.
1.3	医療事故の院外への強制報告制度	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	0.04	n.s.	n.s.	n.s.	n.s.
1.4	医療安全に対する診療報酬の支払い	1～3 回目の分布を比較(Friedman 検定)	n.s.	0.02	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	0.02	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
1.5	医療職の教育・訓練	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	0.02	0.04
1.6	電子化した診療情報の施設を越えた共有(Electronic Health Record：医療情報連携基盤)	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
1.7	医療事故に対する無過失補償制度	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	0.03	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
1.8	一般人を対象とした医療・健康・患者参加等の教育	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
1.9	医療安全に関する特定のテーマについて、政府が医療機関に取り組みを促す	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
1.10	国全体の医療安全を管掌する公的機関(ナショナルセンター)の設置	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
2.1	医療安全を含めたガバナンスと説明責任の確立	1～3 回目の分布を比較(Friedman 検定)	<0.05	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	0.04
2.2	医療事故やヒヤリ・ハットの報告・管理の仕組み	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	0.02	n.s.	n.s.	n.s.
2.3	患者・家族による医療事故・苦情・意見等の報告の仕組み	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
2.4	医療安全指標のモニタリングと現場へのフィードバック	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
2.5	患者参加の取り組み	1～3 回目の分布を比較(Friedman 検定)	n.s.	0.01	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
2.6	患者情報の伝達方法の標準化と訓練	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	0.04	0.03	n.s.	0.02
2.7	情報技術を用いた医療安全対策	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
2.8	業務量に応じた人員配置	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.

番号	施　策		現在の普及度合	今後進めるにあたっての			
				期待される効　果	費　用	緊急性	優先度
2.9	医療安全文化の醸成	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	0.04	n.s.	n.s.	n.s.	n.s.
2.10	院内感染の検知・報告・サーベイランスの仕組み	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	<0.01	n.s.	n.s.	n.s.	0.02
2.11	手指衛生の取り組み	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	0.02	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
2.12	抗菌剤の適正使用	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	0.04	n.s.	n.s.	n.s.	n.s.
2.13	輸血用血液製剤の管理方法の標準化	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
2.14	医療器具の滅菌方法の標準化	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
3.1	患者が服薬中の薬剤の定期的な評価・見直し	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	0.02	n.s.	n.s.	n.s.	n.s.
3.2	転記・読み取りミスを減らす対策	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	0.02
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	0.04	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
3.3	医療安全面の機能を充実させた輸液ポンプ・シリンジポンプ(スマートポンプ)の導入	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
3.4	無菌操作法や感染予防対策の標準化	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	0.04
3.5	尿道カテーテルの使用・挿入方法の標準化	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	0.02	n.s.	n.s.	n.s.
3.6	中心静脈カテーテルの挿入方法の標準化	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
3.7	人工呼吸器関連肺炎の予防方法の標準化	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
3.8	処置・手術のチェックリスト	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	0.03	n.s.	n.s.	0.04
3.9	手術室内の情報の統合・一覧性の向上	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
3.10	周術期の投薬方法の標準化	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	0.04	n.s.	n.s.
3.11	深部静脈血栓の予防方法の標準化	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	<0.05
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
3.12	主要な疾患の治療方法の標準化	1～3 回目の分布を比較(Friedman 検定)	n.s.	0.02	0.04	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	0.03	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
3.13	褥瘡の予防方法の標準化	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	0.03	<0.05	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.

番号	施　策		**現在**の普及度合	**今後**進めるにあたっての			
				期待される効　果	費　用	緊急性	優先度
3.14	転倒・転落の予防方法の標準化	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	n.s.
3.15	せん妄・認知機能障害の管理	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	n.s.	n.s.	n.s.	0.02
3.16	患者の状態悪化への対応	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	<0.01	n.s.	n.s.	n.s.	n.s.
3.17	患者の水分・栄養管理の基準	1～3 回目の分布を比較(Friedman 検定)	n.s.	<0.01	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	0.02	n.s.	n.s.	n.s.
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	0.01	n.s.	n.s.	n.s.	n.s.
3.18	患者・部位・手技等の照合方法の標準化	1～3 回目の分布を比較(Friedman 検定)	n.s.	n.s.	n.s.	<0.01	<0.01
		1 回目と 3 回目の中央値を比較(Wilcoxon 符号付き順位検定)	n.s.	n.s.	n.s.	0.02	0.01
		1 回目と 3 回目の中央値の選択割合を比較(カイ二乗検定)	n.s.	0.04	n.s.	n.s.	0.04

表 1-2 医療安全施策の費用対効果と優先度

		効果費用比† (効果の評価点/ 費用の評価点)	優先度†† (平均値)
1.1	認定・認証における医療安全基準	0.92	3.17
1.2	医療安全指標に基づくデータの収集と公表	0.95	3.17
1.3	医療事故の院外への強制報告制度	0.96	3.42
1.4	医療安全に対する診療報酬の支払い	1.02	4.08
1.5	医療職の教育・訓練	1.16	4.25
1.6	電子化した診療情報の施設を越えた共有(Electronic Health Record:医療情報連携基盤)	0.81	3.54
1.7	医療事故に対する無過失補償制度	0.77	3.42
1.8	一般人を対象とした医療・健康・患者参加等の教育	1.07	3.00
1.9	医療安全に関する特定のテーマについて、政府が医療機関に取り組みを促す	1.11	3.13
1.10	国全体の医療安全を管掌する公的機関(ナショナルセンター)の設置	0.91	3.33
2.1	医療安全を含めたガバナンスと説明責任の確立	1.20	3.67
2.2	医療事故やヒヤリ・ハットの報告・管理の仕組み	1.26	3.29
2.3	患者・家族による医療事故・苦情・意見等の報告の仕組み	1.08	2.78
2.4	医療安全指標のモニタリングと現場へのフィードバック	1.11	3.48
2.5	患者参加の取り組み	1.20	3.65
2.6	患者情報の伝達方法の標準化と訓練	1.27	3.91
2.7	情報技術を用いた医療安全対策	0.86	4.04
2.8	業務量に応じた人員配置	0.88	4.25
2.9	医療安全文化の醸成	1.16	3.58
2.10	院内感染の検知・報告・サーベイランスの仕組み	1.09	3.71
2.11	手指衛生の取り組み	1.31	4.00
2.12	抗菌剤の適正使用	1.26	3.79
2.13	輸血用血液製剤の管理方法の標準化	1.21	3.48
2.14	医療器具の滅菌方法の標準化	1.08	3.21
3.1	患者が服薬中の薬剤の定期的な評価・見直し	1.16	4.22
3.2	転記・読み取りミスを減らす対策	1.07	3.96
3.3	医療安全面の機能を充実させた輸液ﾎﾟﾝﾌﾟ・ｼﾘﾝｼﾞﾎﾟﾝﾌﾟ(ｽﾏｰﾄﾎﾟﾝﾌﾟ)の導入	0.85	3.58
3.4	無菌操作法や感染予防対策の標準化	1.01	3.62
3.5	尿道カテーテルの使用・挿入方法の標準化	1.22	3.04
3.6	中心静脈カテーテルの挿入方法の標準化	1.10	3.71
3.7	人工呼吸器関連肺炎の予防方法の標準化	1.17	3.52
3.8	処置・手術のチェックリスト	1.42	3.79
3.9	手術室内の情報の統合・一覧性の向上	1.02	3.46
3.10	周術期の投薬方法の標準化	1.33	3.74
3.11	深部静脈血栓の予防方法の標準化	1.18	3.78
3.12	主要な疾患の治療方法の標準化	1.23	3.65
3.13	褥瘡の予防方法の標準化	1.17	3.17
3.14	転倒・転落の予防方法の標準化	0.98	3.43
3.15	せん妄・認知機能障害の管理	1.22	3.91
3.16	患者の状態悪化への対応	1.10	3.91
3.17	患者の水分・栄養管理の基準	1.11	3.04
3.18	患者・部位・手技等の照合方法の標準化	1.54	3.79

†:効果費用比は、1.0より大きければ費用対効果が高く、小さければ費用対効果が低い

††:優先度は、数値が高いほど優先度が高い

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分担研究報告書

全国の病院を対象とした調査（全国調査）

研究要旨

本研究は、全国の病院の医療安全管理体制・活動の現状を明らかにすることに加え、医療安全向上への取り組みがどのような成果を上げてきたか、今後、優先度の高い課題としてはどのようなものが考えられるかを明らかにすることを目的とした。

全国の病院から病床規模で無作為に層化抽出した病院（n=3,215）を対象に、郵送法によるアンケート調査を実施した。調査期間は 2017 年 10 月 30 日～11 月 14 日とした。アンケートでは、各病院の医療安全管理体制・活動の現状と、42 個の医療安全施策の病院での実施状況、過去の貢献度、今後の優先度について回答を求めた。

回収率は 19%（603/3,215）であった。配置されている医療安全管理者は、100 床以上の急性期病院は専従が主体であり、100 床未満の急性期病院と、療養型病院、精神科病院は専任が主体であった。医療事故とヒヤリ・ハットの院内報告の件数（中央値）は約 3 件/床/年であり、病床規模の大きい急性期病院で多く、療養型病院や精神科病院で少ない傾向が見られた。42 個の医療安全施策うち、優先度の高い施策は、評価点の高い順に「2.2 医療事故やヒヤリ・ハットの報告・管理の仕組み」「3.14 転倒・転落の予防方法の標準化」「2.11 手指衛生の取り組み」であった。

今後は、各施策の優先度と病院の規模・機能との関係、優先度が高い施策について優先度が高いと評価された理由、それらの施策を推進するうえで障害となっているもの等を明らかにする必要があるほか、専門家調査の結果と併せた解析を進める必要がある。

A．研究目的

2002 年の医療安全推進総合対策により、国としての医療安全に対する取り組みの方向性が示され、制度・病院・臨床現場の各レベルにおいて、種々の施策が行われてきた。しかし、それらの効果は十分に評価されていない。本研究は、全国の病院の医療安全管理体制・活動の現状を明らかにすることに加え、医療安全向上への取り組みがどのような成果を上げてきたか、今後、優先度の高い課題としてはどのようなものが考えられるかを明らかにすることを目的とした。

B．研究方法

全国の病院を対象とした郵送法による無記名自記式のアンケート調査を実施した。対象は、全国の病院（n=8,438）から、病床規模で層化抽出した病院（n=3,215）の代表者もしくは医療安全管理の担当者とした。対象病院は、一般病床数が 100 床未満の病院の 25%（n=1,460）、100～299 床の病院の 50%（n=842）、300 床以上の病院の 100%（n=912）を無作為に抽出した。調査期間は 2017 年 10 月 30 日～11 月 14 日とした。調査項目は、院内における医療安全体制、活動状況および諸施策（病院・臨床現場レベルについては実施状況を含む）の過去の貢献度合い、推進に当たっての障害因子、優先順位とした。優先順位等を評価した諸施策は、専門家調査と同様に、2017 年の OECD の報告書「The economics of patient safety - strengthening a value-based approach to

reducing patient harm at national level」に挙げられた 42 個の施策とした。なお、院内体制、活動状況については、過去に研究代表者らが実施した調査結果と比較検討が可能なように、調査項目の整合を図った。

本研究では、一般病床が 50%以上を占める病院を急性期病院、療養病床が 50%以上を占める病院を療養型病院、精神科病床が 50%以上を占める病院を精神科病院、いずれにも該当しない、もしくは病床数が不明の病院をその他病院と定義した。病院の機能・規模で各設問をクロス集計した。

（倫理面への配慮）

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C．研究結果

回収率は 19%（603/3,215）であった。調査の全集計結果を資料 2 に示す。回答病院の機能・規模別の内訳を表 2-1 に示す。

専従の医療安全管理者は、300 床以上の急性期病院では 97%、100-299 床の急性期病院では 58%が配置していた（図 2-1）。100 床未満の急性期病院と 100 床以上の療養型病院では、専従を配置する病院は 1 割に満たないが、専任を配置する病院は 4 割を超えていた。一方で、精神科病院と 100 床未満の療養型病院は、他と比べて専任または専従を配置する病院の割合が低い傾向が見られた。

医療事故とヒヤリ・ハットの 1 病床当りの年間報告件数（院内報告）を表 2-2 に示す。全体では、1 病床当り年間約 3 件の医療事故とヒヤリ・ハットが院内で報告されていた。報告件数は病床規模の大きい急性期病院で多く、療養型病院や精神科病院で少ない傾向が見られた。

最近 3 年以内の患者が死亡または重篤な後遺障害を残すような医療事故の経験の有無を図 2-2 に示す。重大な医療事故の経験は、病床規模の大きい急性期病院で多く、療養型病院で少ない傾向が見られた。精神科病院の約 4 割も重大な医療事故を経験していた。

医療安全施策の優先度の評価点の平均値を図 2-3 に示す。優先度の評価点の高い施策は、評価点の高い順に「2.2 医療事故やヒヤリ・ハットの報告・管理の仕組み」「3.14 転倒・転落の予防方法の標準化」「2.11 手指衛生の取り組み」であった。

医療安全施策の優先度は、専門家調査と全国調査の双方で同じ項目に評価を求めた。専門家調査と全国調査における施策の優先度の評価点を図 2-4 に示す。全国/制度レベルの施策の多くは、専門家調査と全国調査の双方で優先度の評価が低い傾向が見られた。専門家調査と全国調査の双方で優先度の評価が高かった施策は、「1.5 医療職の教育・訓練」「2.8 業務量に応じた人員配置」「2.11 手指衛生の取り組み」「3.1 患者が服薬中の薬剤の定期的な評価・見直し」の 4 つであった。

D．考察

全国の病院の医療安全管理の現状と医療安全施策の優先度について、全国の病院代表者または医療安全管理の担当者の評価を明らかにできた。医療安全管理体制・活動の状況は、病床規模の大きい急性期病院で充実していた。医療安全管理体制・活動の状況は、その詳細について更なる解析が必要である。

医療安全施策の中でもっとも優先度が高かったのが「2.2 医療事故やヒヤリ・ハットの報告・管理の仕組み」であった。300 床以上の急性期病院における院内報告の件数は 4.4 件/床/年であったが、精神科病院では 1.4 件/床/年、100 床未満の療養型病院では

1.9 件/床/年であり、2〜3 倍の差が認められた。提供する医療の内容や患者の重症度が異なるため、報告件数を単純に比較することはできないが、「2.2 医療事故やヒヤリ・ハットの報告・管理の仕組み」の施策の優先度も病院の規模・機能により異なることが予想された。今後、各施策の優先度と病院の規模・機能との関連について更なる解析が必要である。

専門家調査と全国調査の比較により、病院の代表者または医療安全管理の担当者は、専門家と比べ、病院レベルの施策および臨床現場レベルの施策の優先度を高く評価する傾向が見られた。専門家調査と全国調査の双方で優先度が高いと評価された 4 つの施策については、今後更なる解析を行い、優先度が高い理由や、それらの施策を推進するうえで障害となっているものを明らかにして行く必要がある。

Ｅ．結論

全国の病院の医療安全管理の現状と、全国の病院の代表者または医療安全管理の担当者の考える優先度の高い医療安全施策を明らかにすることができた。今後更にデータの解析を進め、具体的な施策の提言に繋げてゆく必要があると考えられた。

Ｆ．研究発表

1. 論文発表

なし

2. 学会発表

なし

Ｇ．知的財産権の出願・登録状況

1. 特許取得

なし

2. 実用新案登録

なし

3. その他

なし

図 2-1 医療安全対策加算の取得状況

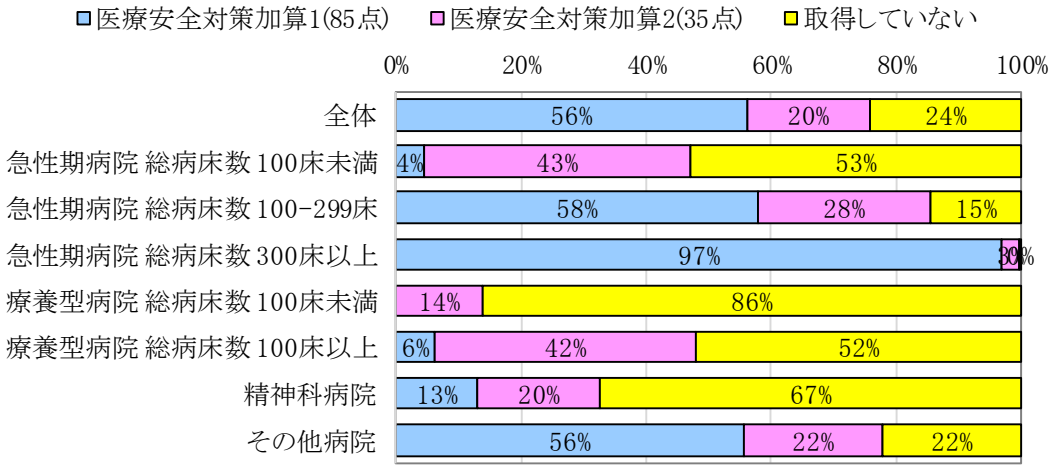


図 2-2 最近 3 年以内の患者が死亡あるいは重篤な後遺障害を残すような医療事故の経験

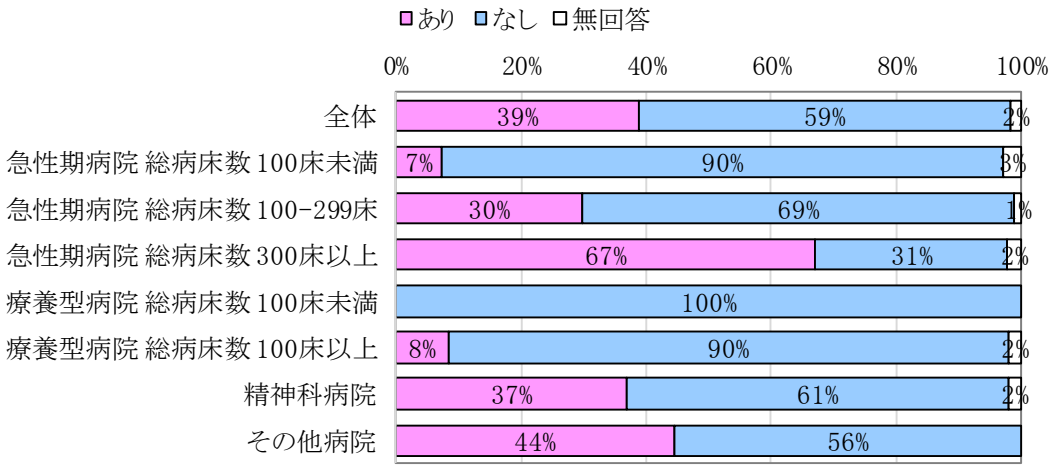
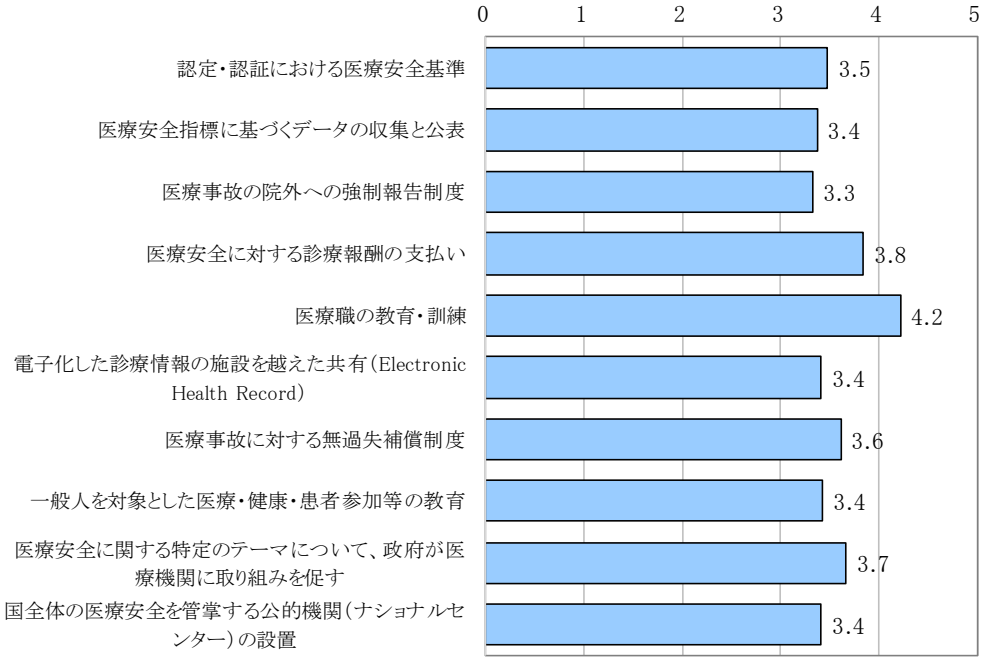


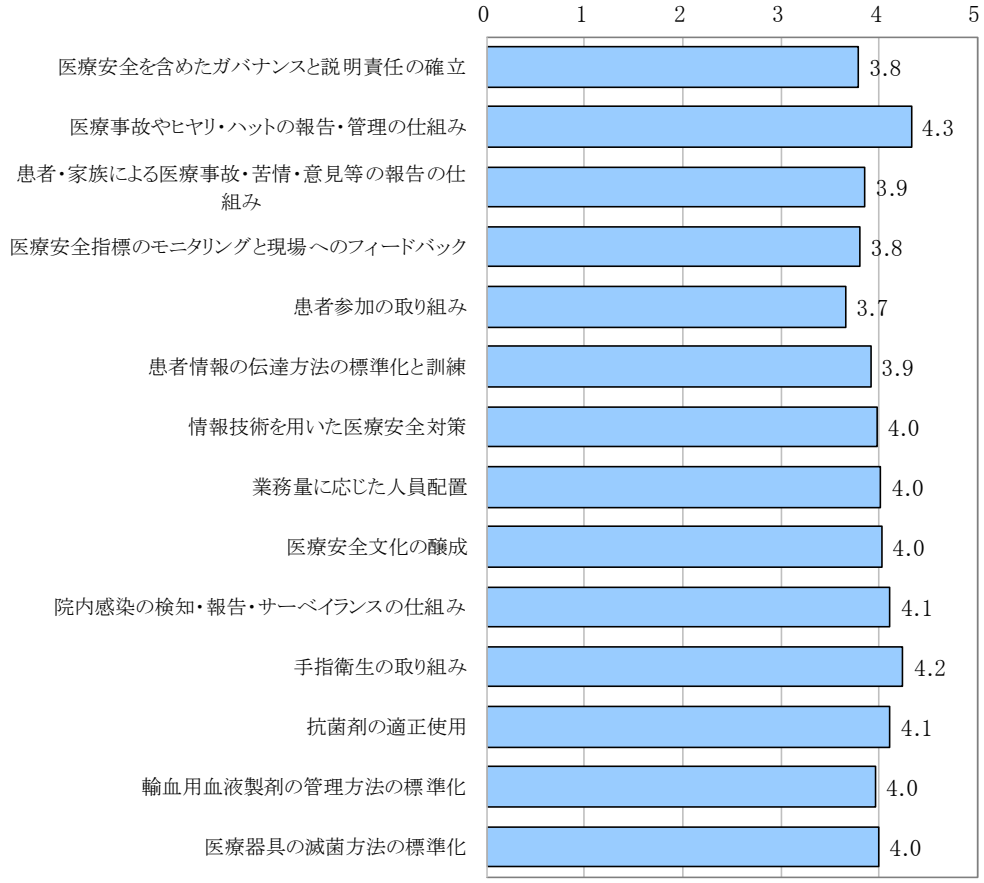
図 2-3 医療安全施策の今後の優先度

（1：低い～5：高い、平均値（点））

＜全国/制度レベルの施策＞



＜病院レベルの施策＞



＜臨床現場レベルの施策＞

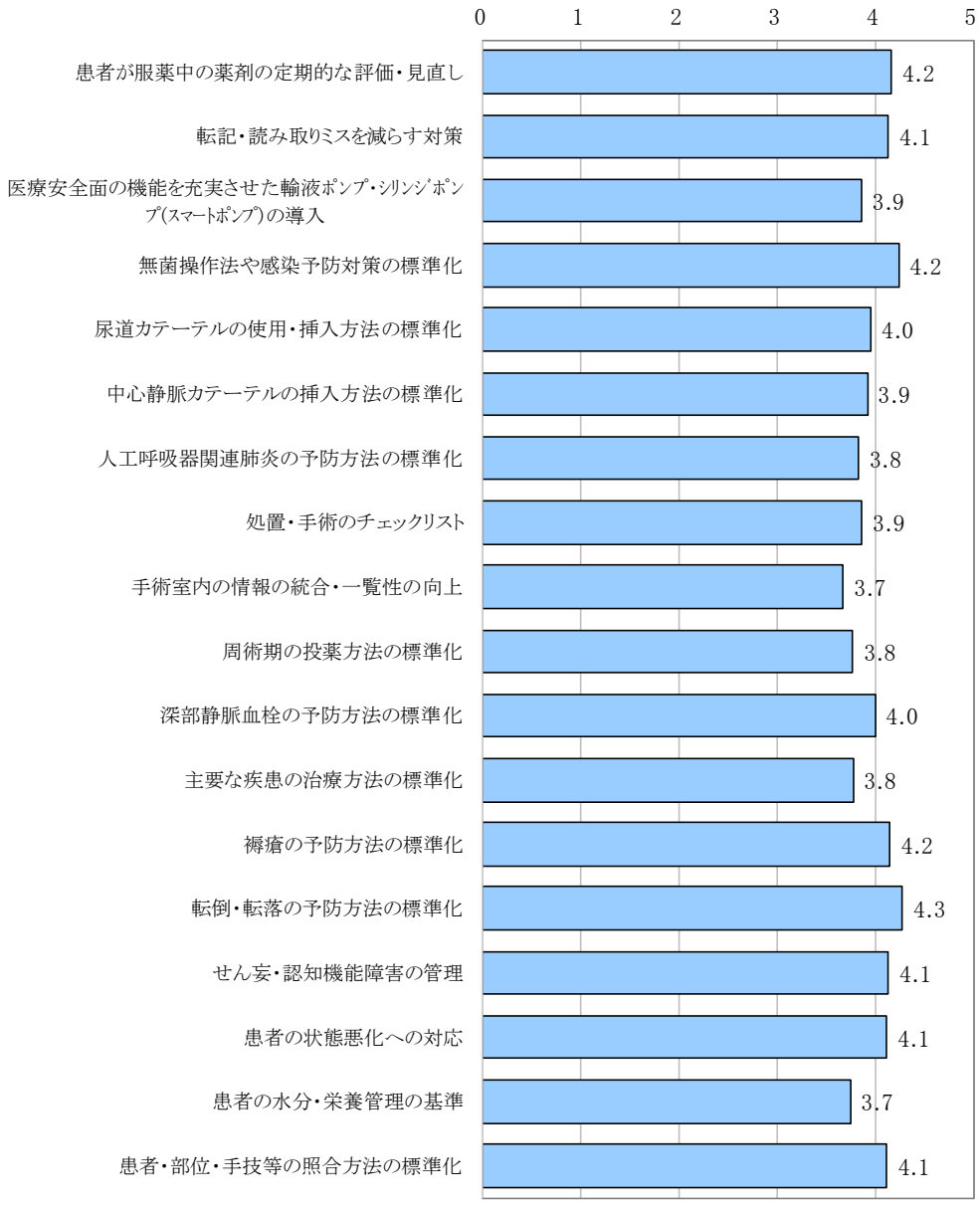

0
1
2
3
4
5
患者が服薬中の薬剤の定期的な評価・見直し
4.2
転記・読み取りミスを減らす対策
4.1
医療安全面の機能を充実させた輸液ポンプ・シリンジポンプ(スマートポンプ)の導入
3.9
無菌操作法や感染予防対策の標準化
4.2
尿道カテーテルの使用・挿入方法の標準化
4.0
中心静脈カテーテルの挿入方法の標準化
3.9
人工呼吸器関連肺炎の予防方法の標準化
3.8
処置・手術のチェックリスト
3.9
手術室内の情報の統合・一覧性の向上
3.7
周術期の投薬方法の標準化
3.8
深部静脈血栓の予防方法の標準化
4.0
主要な疾患の治療方法の標準化
3.8
褥瘡の予防方法の標準化
4.2
転倒・転落の予防方法の標準化
4.3
せん妄・認知機能障害の管理
4.1
患者の状態悪化への対応
4.1
患者の水分・栄養管理の基準
3.7
患者・部位・手技等の照合方法の標準化
4.1

図 2-4 専門家調査と全国調査による医療安全施策の優先度

（プロットのラベルは施策の番号を示す。施策の内容は表 1-2 を参照。）

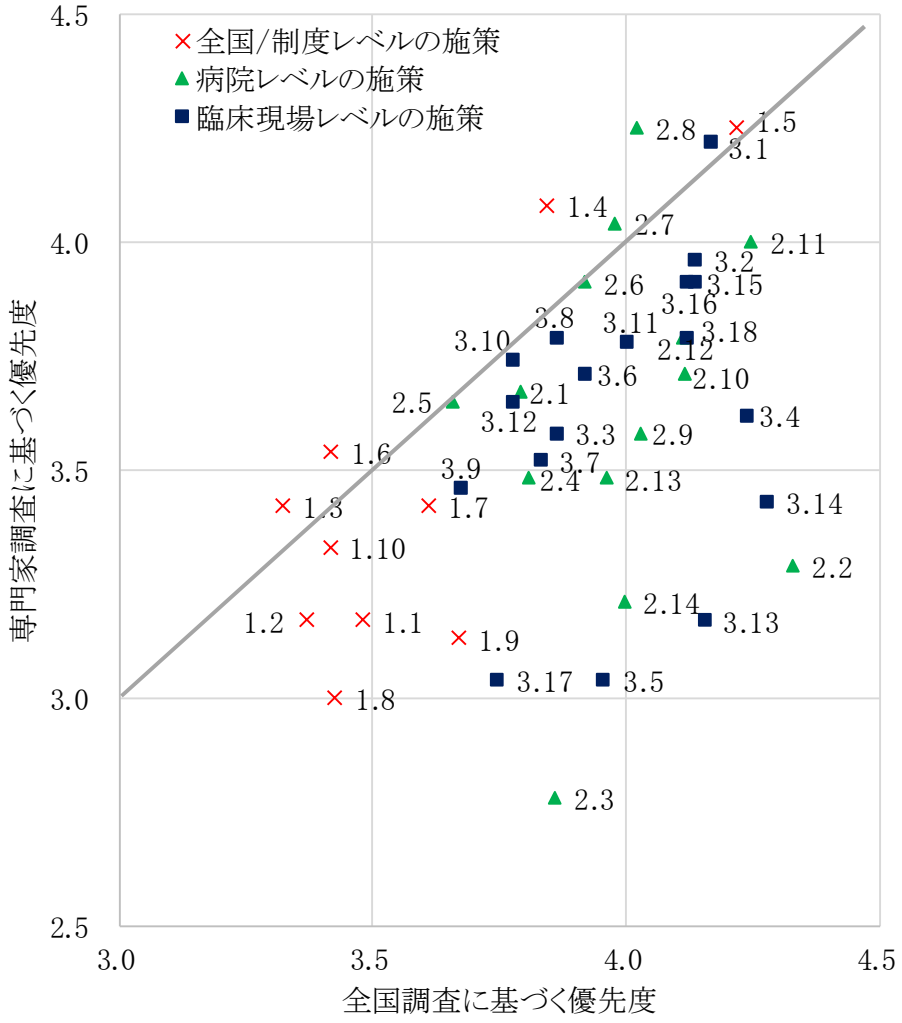


表 2-1 回答病院の内訳

			病院数
全　体			603
急性期病院	総病床数	100 床未満	68
		100-299 床	178
		300 床以上	225
療養型病院	総病床数	100 床未満	29
		100 床以上	48
精神科病院			46
その他病院			9

表 2-2 医療事故及びヒヤリ・ハットの院内報告の件数

			報告件数（中央値）（件/床/年）
全 体			3.4
急性期病院	総病床数	100 床未満	3.0
		100-299 床	3.2
		300 床以上	4.4
療養型病院	総病床数	100 床未満	1.9
		100 床以上	2.3
精神科病院			1.4
その他病院			1.8

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）
分担研究報告書

OECD 加盟国の医療安全政策担当者を対象とした調査（国際調査）

研究代表者　長谷川友紀　東邦大学医学部・教授
研究分担者　藤田　茂　東邦大学医学部・講師

研究要旨

本研究は、諸外国の医療安全政策の現状と、各施策の効果と優先度を明らかにすることを目的とした。

経済協力開発機構（OECD）に加盟する国（n=35）の医療安全政策担当者を対象にした電子メールによるアンケート調査を実施した。

回収率は 51%（18/35）であった。OECD 加盟国では、病院に対し病院機能評価の受審を義務化している国は少なく、多くは任意であること、医療安全管理者の配置を義務化したり配置に対してインセンティブを与えたりしている国は少ないこと、病院が医療安全に関する臨床指標を政府あるいは第三者機関に任意で報告する仕組みを有する国が多いこと、病院が有害事象を政府や第三者機関に任意あるいは義務として報告する仕組みをほぼ全ての国が有していること等が明らかにされた。

医療安全に関する各国の施策は、それぞれ特徴的な部分があり、わが国でも参考にできる部分が見られた。次の施策はわが国でも導入の可能性を検討してもよいと考えられた。

A．研究目的

世界各国でさまざまな医療安全政策が進められているが、それらの情報は十分に共有されておらず、政策担当者が参考にできるような情報源は限られている。本研究は、第 3 回閣僚級世界患者安全サミットの開催に際し、諸外国の医療安全政策の現状と、各施策の効果と優先度を明らかにし、医療安全の政策担当者が政策決定の参考にできるようなデータベースを提供することを目的とした。

B．研究方法

経済協力開発機構（OECD）に加盟する国（n=35）の医療安全政策担当者を対象にした電子メールによるアンケート調査を実施した（2017/12/4～12/20）。厚生労働省から各国のカウンターパートに対し電子メールで調査票を送付した。各国のカウンターパートは、各国の医療安全政策に詳しい専門家等に調査票への回答を求めた。回答票は厚生労働省あるいは東邦大学に電子メールで返送された。調査項目は、各国の医療安全施策、制度、組織、活動に関する項目と、各施策の効果と優先度に対する 5 段階の評価とした。優先度の平均点を算出し、点が高い施策ほど優先度の高い施策であると判断した。

C．研究結果

回収率は 51%（18/35）であった。OECD 加盟国では、病院に対し病院機能評価の受審を義務化している国は少なく、多くは任意であること、医療安全管理者の配置を義務化したり配置に対してインセンティブを与えたりしている国は少ないこと、病院が医

療安全に関する臨床指標を政府あるいは第三者機関に任意で報告する仕組みを有する国が多いこと、病院が有害事象を政府や第三者機関に任意あるいは義務として報告する仕組みをほぼ全ての国が有していること等が明らかにされた。

効果の評価点が高い施策は、平均点の高い順に、「病院に対する医療安全指針の策定の義務化」「病院に対する医療安全管理の組織設立の義務化」「病院に対する医療安全管理の担当者配置の義務化」「病院に対する有害事象とヒヤリ・ハットの院内報告システム構築の義務化」であった。優先度の評価点が高い施策は、平均点の高い順に、「病院がヒヤリ・ハットやニアミスを政府機関あるいは第三者機関に対し自発的に報告する仕組み」「病院に対し有害事象を政府機関あるいは第三者機関に対し報告することを要求する仕組み」「患者安全に関する臨床指標など、患者安全の測定・評価方法を定めることを病院に対し義務化」であった。

上記の結果を取りまとめた報告書を作成し、第3回閣僚級世界患者安全サミット（平成30年4月13日～14日、東京）において参加者に配布した。

（厚生労働省：第３回閣僚級世界患者安全サミット、http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000204000.html、アクセス平成30年5月8日）

D．考察

医療安全に関する各国の施策は、それぞれ特徴的な部分があり、わが国でも参考にできる部分が見られた。次の施策はわが国でも導入の可能性を検討してもよいと考えられた。

1. 病院の医療の質に基づいて診療報酬の支払い額を増額する(P4Q)（ベルギー、フランス、スペイン）
2. P4Q の仕組みに病院機能評価の認定の有無を入れる（ベルギー）
3. 病院機能評価の認定を取得していない病院は診療報酬の支払い額が減額される（スロベニア）
4. 患者満足度など、患者による医療サービスの評価を全国規模で実施する仕組みを構築する（カナダ他）
5. 病院に対し患者満足度の定期的な測定を義務化する（ベルギー）
6. 患者団体と協力して患者満足度調査を実施する（スロベニア）
7. 病院に対し医療安全文化の定期的な測定を義務化する（ポルトガル）
8. 病院に対し特定の医療の質と安全の臨床指標の公表を義務付ける（フランス、ドイツ）
9. 患者が有害事象や苦情を報告できる国レベルの仕組みを構築する（韓国、スロバキア）
10. 患者・家族への謝罪が過失を認めたと解釈されないことを保証する法律を制定する（カナダ、アイルランド）
11. 自発的な院内報告や施設横断的な報告システムのデータは、一部の例外を除き、裁判に利用できないことを法律に定める（ドイツ）
12. 医療の質や安全に関する収集データに対する訴訟目的の開示請求を認めないことを法律に定める（カナダ）
13. 医事紛争の早期解決を目的とした ADR のための法律と組織を作る（韓国）
14. 分娩に関連して発症した重度脳性麻痺だけでなく、一定の条件に合致する妊産婦死亡や死産についても無過失補償制度で補償する（韓国）
15. ロンドンプロトコル（日本版の RCA に近い）を用いて医療事故の原因分析を行う（スペイン、スイス）

16. 医療事故の当事者となった医療従事者に対する標準的な支援プログラムを開発する（カナダ、スペイン）
17. 手術、麻酔、癌に関する一部の症例のM&Mカンファレンスを義務化する(フランス)
18. 病院で行われる病理解剖に財政的なインセンティブを与える（ドイツ）
19. 各病院に院内死亡検討委員会を設ける（スペイン）
20. 病院に対し小児の院内死亡は全例院内で検討することを義務化する（イギリス）
21. 病院に対し医療安全に関するPDCAサイクルを確立することを義務化する（ドイツ）
22. 高齢者施設における警鐘事例や有害事象をモニタリングする仕組みを導入する（スロベニア）
23. 患者安全週間に医療安全に関するノンフィクションのドラマを作成しWEB上で公開する（カナダ、フランス）

Ｅ．結論

国際調査により、我が国も参考にできる多数の医療安全施策を明らかにすることができた。今後はそれらの導入可能性について検討する必要がある。

Ｆ．研究発表

1. 論文発表
なし
2. 学会発表
なし

Ｇ．知的財産権の出願・登録状況

1. 特許取得
なし
2. 実用新案登録
なし
3. その他
なし

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）
分担研究報告書

米国の医療安全管理活動の現況に関する調査（海外調査）

研究分担者　鮎澤純子　九州大学大学院医学研究院・准教授

研究要旨

本邦における医療安全に関連する専門職育成の参考になるよう、米国 ASHRM（The American Society for Healthcare Risk Management）が提供するリスクマネジメントに関する教育・認定システムを紹介するのに加え、ASHRM で現在注目している活動・話題について紹介する。

ASHRM 2017 Annual Conference(October15-18、Seattle、Washington)へ参加し、医療の安全・質管理、リスクマネジメントおよび米国の医療システムに関する情報を収集した。

ASHRM はリスクマネジメントだけでなく医療安全に関する広範な教育プログラムを提供していた。ASHRM には 4 つの認定制度（HRM Certificate Program、Patient Safety Certificate Program、ERM Certificate Program、Risk Financing Certificate Program）があり、ASHRM の提供する研修会に参加することで、リスクマネジャーの資格認定を得ることができる。また、それらの研修会への参加は、看護師等の生涯研修の単位としても認められていた。

ASHRM 2017 Annual Conference では、医療安全関連のテーマとして、Human Factors、RCA、Wrong-Site Surgery、a Culture of Patient Safety、Accountable Care Organization、a Disclosure Program、HRO Journey などに関するテーマが並んでおり、現場からの取り組み報告、いわゆる Champion 報告や、基本を進化させた方法論に関する報告が増えていた。他にも、Transgender、Cyber Risk、Webcare、Social Media、Telemedicine、Data Science Techniques、an Aging Population といったテーマが取り上げられていた。また、Medical Marijuana は米国におけるタイムリーなテーマであり、シンポジウムでも取り上げられていた。

米国とは医療システムや医療環境が異なるが、ASHRM において注目されているテーマは、本邦でも同様に注目されているものが多かった。

A．研究目的

本稿では、本邦における医療安全に関連する専門職育成の参考になるよう、ASHRM の活動の概要と、ASHRM の教育プログラム、教育システム、クレジット、教科書、認定制度、称号付与制度について紹介する。また、本邦における医療安全の取り組みの参考になるよう、ASHRM 2017 Annual Conference について、Annual Conference の概要と、開催されたセッションの概要について報告する。

B．研究方法

ASHRM 2017 Annual Conference (October15-18、Seattle、Washington)へ参加し、医療の安全・質管理、リスクマネジメントおよび米国の医療システムに関する情報を収集した。また、関連情報は ASHRM のウ

ェブサイト（http://www.ashrm.org）より取集した。

（倫理面への配慮）

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Ｃ．研究結果

（１）ASHRM の活動の概要

ASHRM （ The American Society for Healthcare Risk Management） は、AHA （American Hospital Association ）に所属する領域団体のひとつで、1980 年に設立された。現在約 6000 人の会員がおり、会員の専門領域は、risk management を中心に、patient safety、healthcare operation、insurance、law、finance など、多岐にわたっている。

ASHRM は、実効あるリスクマネジメントの実施と革新的リスクマネジメントの実現と、リスクマネジメントに関連する専門職の職能の向上のために、医療機関や関連団体・関係省庁などと連携しながら、会員向けの教育活動を中心に、アドボカシー、ネットワーキングなど、リスクマネジメントに関するさまざまな活動を行っている。

ASHRM は医療現場におけるさまざまなリスクを対象としているが、1990 年後半から、IOM の報告書「To Err is Human」を起爆剤としながら patient safety が世界的な課題となるなかで、safe and effective patient care practices に大きく重心を移すことになった。

2000 年に入ってからは、変化する医療環境に対応すべく、ERM（Enterprise Risk Management）というコンセプトをかかげて、新しい医療環境における新たな今日的リスクに対応していくためのリスクマネジメントの在り方を模索、提唱している。

いまなお patient safety は活動の core competency の一つに位置付けられているが、patient safety については、年月を経るなかで取り組みが進み、個人・医療機関・関連団体・行政における取り組みのスキームがそれなりにできあがってきたこと、また、医療環境が急速に変化するなか、新たなリスクとそのリスクへの対応策が求められていることから、そろそろ patient safety も数あるリスクの一つとしていいのではないか、という声もある。

ASHRM が掲げるビジョン、ミッションは以下の通りである。

- Vision : ASHRM is the leader in advancing safe and trusted healthcare through enterprise risk management.
- Mission : To advance patient safety, reduce uncertainty and maximize value through management

主な活動は以下の通りである。

①ネットワーキング

- Online Member Directory：会員情報を共有することによってネットワークの活用が図られている。
- Local Chapters：３１の州に支部があり、地域の活動拠点となっている。
- ASHRM Exchange:会員間の情報交換の場である。実務に関する Q&A や意見交換なども行われる。リクルート情報の共有にも活用されている。

②リスクマネジメントに携わる会員のレベルアップのためのサポート

- CPHRM （Certified Professional in Healthcare Risk Management） :ASHRM は AHA の運営のもと、ヘルスケアリスクマネジメントに係る、いわゆるヘルスケアリスクマネジャーの資格認定制

度を設けている。試験に合格すると、ASHRM 及び AHA の認定の資格である CPHRM が与えられる（詳細は次項を参照）。

- CPHRM Exam Prep Materials：CPHRM の試験に合格するために必要な事項を学習するための教材も開発されている。教科書に該当する体系的なテキストも提供されている。
- DFASHRM（Distinguished Fellow of the American Society for Healthcare Risk Management）と FASHRM（Fellow of the American Society for Healthcare Risk Management）：一定の基準を満たすことで称号が付与される（詳細は次項を参照）。
- Certificate Program：HRM Certificate Program、Patient Safety Certificate Program、ERM Certificate Program、Risk Financing Certificate Program を開催している（詳細は次項の参照）。
- Career Center：リクルートのための情報サイト。必要な書類作成の方法なども紹介されている。
- Advocacy：ヘルスケアリスクマネジメントに関連する重要事項に関するアドボカシーとして活動する。主な活動先として挙げられているのは the Department of Health and Human Services、Joint Commission、州の行政機関及びその代理機関などである。なお、アドボカシーの活動事項の例として挙げられているのは、patient safety、HIPAA、disaster preparedness などである。
- Healthcare Risk Management Week：毎年６月を Healthcare Risk Management Week として、さまざまなイベントを企画するとともに、現場のリスクマネジメントの啓蒙活動を推進している。２０１８年は６月１８－２２日である。

③最新の教育や情報を提供するためのサポート

- Annual Conference & Exhibition：年に一回開催される学術集会である。教育活動と最新情報の共有、ネットワーキングに焦点があてられている。
- ASHRM Academy：基本的にオンサイトで運営されている教育システムである。
- ASHRM University：基本的にオンラインで運営されている教育システムである。
- Webinars：原則として最新の情報を提供する方法としてウェブによるさまざまなセミナーが準備されている
- Publications：CPHRM の教材も含み、リスクマネジメントの領域に関するさまざまなテキストが出版されている
- Journal of Healthcare Risk Management：いわゆる学会誌である。リスクマネジメント関連の論文などが査読付きで掲載される。
- e-News：会員向けに毎週金曜日に最新のニュースが配信される。
- Forum Newsletter：会員向け情報誌である。
- Enterprise Risk Management Playbook：ASHRM が推進する Enterprise Risk Management に関する、理論の習得と実践に至るまでのガイドブック。
- Pearls Pocket Guide Series：リスクマネジメントや医療安全に関するテキ

スとト。薬剤の安全、インフォームド・コンセントなど、現在３５種類が発行されている。
- Tool Kits：リスクマネジメントや医療安全に関する現場の実践に役立つツール。
- White Papers：いわゆる白書である。近年の医療安全の取り組みへの高まりから、Data for Safety、Patient Safety に関するものが数多く作成されてきた。新しいものでは「Enterprise Risk Management: A Framework For Success (2014)」「Healthcare Risk Management: The Path Forward (2014)」などもある。

過去に発表された主な「White Papers」のテーマは以下の通りである。
- Tackling patient safety taxonomy: A must for risk managers (2008)
- Modernization of patient safety event reporting: Surveillance and benchmarking (2008)
- Turning lessons learned into actionable knowledge (2008)
- Serious Safety Events: A Focus on Harm Classification - Deviation in Care as Link Getting to Zero™ White Paper Edition No. 2 (2014)
- Serious Safety Events: Getting to Zero™ White Paper Edition No. 1 (2012)
- Disclosure of Unanticipated Events (2013)
- Thought Leader Forum: Workplace Intimidation - Summary of Findings (2011)
- Different roles, same goal: Risk and quality management partnering for patient safety (2007)
- Perspectives in advance directives (2006)
- A call for federal immunity to protect health care employers, and patients (2005)
- The growing role of the Patient Safety Officer: Implications for risk managers (2004)
- Strategies and tips for maximizing Failure Mode Effect Analysis in your organization (2002)

（２）ASHRM の教育プログラム、教育システム、教科書、認定制度、クレジット、称号付与制度

卒後のキャリアのなかで専門性を確立していくヘルスケアリスクマネジャーという職種の育成と活躍を支援するために、ASHRM は教育と資格認定を活動の重要な柱にしている。

①ASHRM が提供する教育プログラム

現在 ASHRM は、教育プログラムとして４つの Certificate Program(HRM Certificate Program 、 Patient Safety Certificate Program、ERM Certificate Program、Risk Financing Certificate Program) を提供している。

１）HRM Certificate Programs

ヘルスケアリスクマネジャーの基本的なプログラムで、３つのモジュールで構成されている。CPHRM 受験に向けて基本的な事項を学習するための教育プログラムでもある。

モジュール１はいうなれば基本コースで、ERM のフレームワークをはじめリスクマネジメントの基本を学習する。モジュール２は中級コースで、関連法規、コンプライアンスなどについても学習する。モジュール３は上級コースで、ケーススタディなども織り込みより実践的な内容を学習する。

モジュールはいずれも13時間のオンサイト学習で、合計で39時間（13時間×3モジュール）のオンサイト学習を受講することになる。

２）Patient Safety Certificate Program

医療安全に焦点をあてプログラムで、以下のような内容で構成されている。

- Patient Safety Past, Present and Future
- Patient Safety Infrastructure
- Patient Safety Science/Foundations
- Patient Safety Data
- Root Cause Analysis
- Disclosure
- Human Factors
- Communicating for Patient Safety
- Building Patient Safety into Organizations
- Maintaining Personal Energy

医療安全の経緯、取り組みの体制、医療安全に関する科学、医療安全の基礎、医療安全に関するデータマネジメント、RCA、事故事例の開示、ヒューマンファクターズ、コミュニケーション、組織体制の構築といった見慣れた項目が並ぶ。最後に、「Maintaining Personal Energy」として医療安全に取り組む者の熱意の継続といった項目があることは、消耗職（バーンアウトすることが多い職種）と言われることが多い職種のプログラムとして興味深い。

プログラムは、５時間のオンライン学習とオンライン学習終了後の１３時間のオンサイト学習で構成されている。

なお、医療安全については、Patient Safety Core Topics and tipsという、the American Hospital Association (AHA)/Health Research & Education Trust (HRET)と Hospital Engagement Network (HEN)との協働プログラムが進んでいる。以下の１０項目について、入院患者の傷害の４０％を減らし、再入院を２０％減らそうとするものである。プログラムではそうした具体的な改善の取り組みについても学習する。

プログラムのなかで学習することになる主な内容な以下の通りである。

- Adverse Drug Events
- Catheter-Associated Urinary Tract Infections (CAUTI)
- Central Line Associated Blood Stream Infections (CLABSI)
- Injuries from Falls and Immobility
- Obstetrical Adverse Events
- Pressure Ulcers
- Preventable Readmissions
- Surgical Site Infections
- Venous Thromboembolisms
- Ventilator Associated Event/ Ventilator Associated Pneumonia

３）ERM Certificate Program

このプログラムは、ERM について、concepts を理解し、それぞれの組織で ERM を導入する strategies をたて、組織に application することができるようになるための、実践的な学習をするプログラムである。

プログラムは以下の内容で構成されている。ビッグデータなどが取り上げられているところも今日的である。

- Overview
- An Introduction to ERM
- Decision Analytics
- Risk Identification and Assessment
- Diagnostic and Assessment Tools
- Evaluation and Monitoring
- Big Data
- Preparing for On-Site Application
- Wrap Up

４）Risk Financing Certificate Program

リスクマネジメントの手法の一つであるRisk Financingについて学ぶプログラムである。医療職からのキャリアアップとして選択されるヘルスケアリスクマネジャーにとって、リスクマネジャーの専門的知識として学ばなければならない領域として「難関」といわれるのが、Risk Financingであるといわれている。ちなみに、Risk Financing をしっかり修得したヘルスケアリスクマネジャーのなかには、一般産業界のリスクマネジャーに転じるケールもある。

②教育プログラムを提供する教育システム

教育プログラムを提供する教育システムとしてASHRM UniversityとASHRM Academyがある。

１）ASHRM University

ASHRM Universityはリスクマネジャーに必要とされるさまざまな「科目」をオンラインによる受講を原則として提供している。

最近提供された科目と受講料は以下の通りである。

- Identity Theft in the Workplace （盗難防止、特にデータの盗難防止について焦点をあてた科目）Member $79.00, Non-Member $99.00
- Not Too Quick, Not Quick Enough: Getting Cesarean Delivery Safety Right （帝王切開のタイミングに関する科目）Member $49.00, Non-Member $99.00
- CPHRM Exam Prep Series (CPHRMの認定試験準備セミナー)Member $300.00, Non-Member $325.00
- How to Keep Lawyers from Circling your Practice(訴訟防止をテーマにした科目)Member $79.00, Non-Member $99.00
- Minimizing Liability Risks of Robotic Surgery: A Proactive Approach （ロボット支援手術の賠償責任の最小化に関するセッション)Member $79.00, Non-Member $99.00
- More than a Signature: Informed Consent Reframing informed consent as a process of communication and shared decision-making-- not just a document.（意思決定のプロセスという観点からインフォームド・コンセントを見直そうとする科目)Member $79.00, Non-Member $99.00
- Investigations Complete Module Set(事故調査に関する包括的な科目)Member $149.00, Non-Member $199.00
- Creating a Sepsis Management Plan （褥瘡に関する科目）Member $79.00, Non-Member $99.00
- Safer Sign Out: Establishing a Higher Standard for Physician Handoffs and Team Communication（医師及びチームのコミュニケーションに焦点をあてた科目）Member $79.00, Non-Member $99.00
- Discharge of the Homeless: Valuing Care and Identifying Risks （ホームレスの受診・退院に焦点をあてた科目）Member $49.00, Non-Member $69.00

２）ASHRM Academy

ASHRM Academyは、ASHRMが提供するHRM Certificate ProgramsとPatient Safety Certificate Program、ERM Certificate Program、Risk Financing Certificate Program のプログラムに加え、CPHRM （Certified Professional in Healthcare Risk Management ）の資格試験に関して必

要な研修をオンサイトとオンラインを併用して提供している。

全米各地で開催される ASHRM Academy は、概ね４日間程度で、その間に、上記のプログラムが集中して開催される。スケジュールによっては、複数のプログラムを受講することもできる。

③受講のクレジット

ASHRM University における科目と ASHRM Academy の受講プログラムについては、それぞれクレジットが定められており、FASHRAM や DASHRAM の資格申請の条件となる。また、これらのクレジットは科目や受講プログラムによって、他の医療職の専門職のクレジットとしてみなすこともできるようになっている。例えば、Patient Safety Certificate Program の１８単位は、そのまま Continuing Nursing Education (CNE)として、the American Nurses Credentialing Center の１８単位とみなすことができるようになっている。

④教科書

ASHRM はさまざまな出版活動も熱心に行っているが、そのなかには、ヘルスケアリスクマネジメントを体系的にまとめた、いわゆる教科書がある。ASHRM が提供する教育プログラムは教科書と整合した内容で構成されるとともに、認定試験のなかで出題される問題も教科書と整合する問題が出題されている。受験のための問題集なども出版されているが、その解説には、教科書のどこを読めばいいかといったことも丁寧に示されている。

⑤資格認定制度

ASHRM は AHA の運営のもと、ヘルスケアリスクマネジメントに係る、いわゆるヘルスケアリスクマネジャーの資格認定制度を設けている。受験資格として設定されている要件を満たし、試験に合格すると、CPHRM (Certified Professional in Healthcare Risk Management)を名乗ることができる。CPHRM であることは、後述の ASHRM が付与する二つの称号の前提となるものであり、CPHRM の取得は、ヘルスケアリスクマネジャーとしてのキャリアの第一歩ということになる。「AHA-CPHRM-handbook (CPHRM 受験のための手引き書)」については添付資料を参照のこと（資料 4-1）。

CPHRM

⑥称号付与制度

ASHRM にはリスクマネジメントの専門職を対象とする称号付与制度がある。前述の DFASHRM (Distinguished Fellow はof the American Society for Healthcare Risk Management) と FASHRM (Fellow of the American Society for Healthcare Risk Management) である。CPHRM を取得していることを前提に、Member for years、Designations、Continuing Education Credits、Employment Experience、Contributions to the field：Leadership/Publishing/Lecturing の領域でそれぞれ設定されている基準を満たすことが条件になる。DFASHRM は FASHRM の上位の称号であり、基準もより厳しくなる。例えば、会員在籍期間は、DFASHRM が 10 年であるのに対し FASHRM は 5 年、Continuing Education Credits における必要クレジットは、DFASH が 10 年で 150 時間であるのに対し FASHRM は 5 年で 75 時間とされている。申請の要件

は資料 4-2 に示す。

（３）ASHRM 2017 Annual Conference の全体像

例年４日間のカンファレスの前には「PRE-CONFERENCE」として、教育プログラムや試験が実施される。その年のカンファレンスによってどの教育プログラムが選ばれるかは、年によって異なる。2017 年は以下の教育プログラムが実施された。

- HRM Certificate Program：「HRM 1: Essentials in HRM」「HRM 2: Applications in HRM」
- 「HRM 3: Advanced Forum in HRM」
- ERM Certificate Program
- Patient Safety Certificate Program
- CPHRM Prep Course

この「PRE-CONFERENCE」間に、学会認定のヘルスケアリスクマネジャーの資格試験が実施される。続く 4 日間のカンファレンスの初日と最終日には、特別講演、教育講演、シンポジウムなどが行われ、2 日間で、6 領域（Claims & Litigation、Clinical /Patient Safety、Leadership、Legal & Regulatory、Risk Financing、Performance Outcome & Quality）をレベル別（foundation、Practitioner、Advanced）に整理して、毎年 60～70 の教育的セッションが、60 分～120 分で行われる。セッションの形式は、講義形式・ワークショップ形式などさまざまである。また、セッションの演者も、領域の専門職、医療機関の実務家、行政職、またその合同プレゼンテーションなどさまざまである。関連する展示もあり、多くのリスクマネジメント関連企業・関連団体が参加している。

（４）教育的セッションで取り上げられたテーマ

特別講演、教育講演、シンポジウムなどに加え、2 日間にわたり、計 65 のセッションが開催された。教育的セッションで取り上げられたテーマを資料 4-3 に示す。

Psychiatric & Behavioral Health Patients、Safe Obstetrical Transitions of Care Between Providers、ED、the Ambulatory Care Setting、Products Liability、Violence、End-of-Life Care、the Credential、Diagnostic Error など、いわゆるハイリスクな領域や事項に関するテーマは、オーソドックスなテーマとして取り上げられている。ただし、キーワードとしてはオーソドックスではあるが、近年の法改正や診療報酬の制度改正、また判例などのトピックスに照らしたプレゼンテーションが行われている。近年の医療環境の変化のなかでは考え方やアプローチを進化させていかなければならない、端的に言えば、これまでと同じ対応をしていることこそがリスクであるという認識にたたなければならないということが共通して説かれている。

医療安全関連のテーマとしては、Human Factors、RCA、Wrong-Site Surgery、a Culture of Patient Safety、Accountable Care Organization、a Disclosure Program、HRO Journey などに関するテーマが並んでいる。ただし、現場からの取り組み報告、いわゆる Champion 報告や、基本を進化させた方法論に関する報告が増えているのが特徴である。また、リスクマネジメントと医療安全との関係を考えるという意味で、ERM、The Bridge Between Risk Management and Patient Safety なども取り上げられている。

今日的なテーマとしては、Transgender、Cyber Risk、Webcare、Social Media、Telemedicine、Data Science Techniques、an Aging Population といったテーマが目立っている。米国とは医療システムや医療環境が異なるとはいうものの、これらのテーマは本邦においてもすでに重要なテーマである。なお Medical Marijuana は米国に

おけるタイムリーなテーマであり、シンポジウムでも取り上げられていた。

学会として継続して取り上げているテーマとして、保険会社と組んで実施している医療過誤訴訟の動向の結果(2017 Aon/ASHRM Hospital and Physician Professional Liability Benchmark Study)とリスクマネジメント関連の法改正のポイント(Legislative & Regulatory Update 2017)のセッションが設けられていた。また、学会が医療機関と協力して行った調査である「Joining the Communication and Resolution Revolution: Lessons from the First 100 Hospitals (An ASHRM/Collaborative for Accountability and Improvement Reciprocal Session)」についての報告も行われた。うまくいっている組織に共通する特徴(とともにうまくいっていない組織に共通する特徴)なども指摘されている。

医療安全に関連するテーマとして、訳すと「マスクの向こうは誰?」ということになる Who's Behind the Surgical Mask? Limiting Liability Beyond the Credential では、整形外科を例にとり、surgeon、surgical assistant、surgical technologist、anesthesiologist、circulator というさまざまな職種がマスクをして手術関係者となる米国において、さまざまな教育システムがあるなかそれぞれの職種の知識と技量をどのように担保するか、それぞれの職種において許される手技の範囲をどのように定めるか、患者にはどのようなインフォームド・コンセントが必要になるか、などが論じられている。本邦においても、看護師の特定医行為が認められるようになるなど、タスク・シフティングが進もうとしているなか、参考になるものであった。また、Closing the Loop with Health I.T. Risk Management は診断エラーにどのように取り組むかを取り上げたセッションであった。タイトルに「I.T.」とあるように、診断エラーの防止に IT が大きな役割を果たすであろうこと、その活用の可能性を論じつつ、その IT そのものが新たなリスクになる可能性についても指摘されていた。

(参考文献)

- ASHRM ウェブサイト: http://www.ashrm.org
- ASHRM 2017 Annual Conference 配布資料、配信資料

Ｅ．結論

米国とは医療システムや医療環境が異なるが、ASHRM において注目されているテーマは、本邦でも同様に注目されているものが多かった。

Ｆ．研究発表

1. 論文発表
   なし
2. 学会発表
   なし

Ｇ．知的財産権の出願・登録状況

1. 特許取得
   なし
2. 実用新案登録
   なし
3. その他
   なし

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分担研究報告書

医療安全管理活動のエビデンスに関する文献調査（文献調査）

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研究要旨

本研究は、医療安全の諸施策について、文献調査により有効性とエビデンスレベルを明らかにすることを目的とする。その準備として、平成 29 年度は文献調査の手法と結果の取りまとめ方、その他の課題を明らかにすることを目的とした文献調査を試行した。

医中誌 Web および PubMed を用い、医療安全施策の有効性とエビデンスレベルを明らかにする文献調査を実施した。文献調査の対象として、①施設間の Handover、②中心静脈カテーテルの超音波ガイド下挿入、③WHO 手術安全チェックリストを選択した。

試行した文献調査の結果、医療安全に関する施策・活動の効果については、エビデンスレベルの高い研究が少ないことが明らかになり、推奨度を低く設定せざるを得ない施策が多くなると予想された。今後は、文献調査の費用対効果も考慮し、文献調査のテーマを絞り込む必要があると考えられた。

A．研究目的

医療安全にかかわる事項について文献調査を実施し、有効性をエビデンスレベルとともに明らかにする試みは、不定期に実施されている。しかし、最近数年間では実施されてないほか、対象となる事項の多くは臨床現場での活動に限定されている。本研究は、医療安全の諸施策について、文献調査により有効性とエビデンスレベルを明らかにすることを目的とした。

平成 29 年度は、文献調査の手法と結果の取りまとめ方、その他の課題を明らかにし、平成 30 年度に主要な施策に関する文献調査を実施する。

B．研究方法

医中誌 Web および PubMed を用い、医療安全施策の有効性とエビデンスレベルを明らかにする文献調査を実施した。文献調査の対象として、①施設間の Handover、②中心静脈カテーテルの超音波ガイド下挿入、③WHO 手術安全チェックリストを選択した。対象ごとにフリーワードを用いて関連文献を探し、見つけた文献のシソーラス／MeSH を用いて再検索するなどして、適切なシソーラス／MeSH を探索した。特定されたシソーラス／MeSH を用いて文献を再検索し、エビデンスレベルの高い研究デザインに絞るなどした。その後、文献のタイトルと抄録を基に文献を絞り込んだ上で、文献の原本をすべて取り寄せた。取り寄せた文献の本文を読み、さらに文献を絞り込んだ上で、文献の内容を下記の項目に従って評価した。

文献検索に用いたシソーラス／MeSH、検索式、検索の実施日を記録した。

1. 文献の評価項目

・ 執筆者、題名、雑誌・書籍名、出版日

・ 研究デザインのレベル
・ 介入の内容
・ 対象者
・ アウトカムのレベル
・ アウトカムの指標
・ 主な結果
・ 活動・対策の短所
・ 費用
・ その他

2. 研究デザインのレベル
・ レベル 1A:システマティックレビューまたはメタアナリシス
・ レベル 1：無作為化比較試験
・ レベル 2：非無作為化比較試験
　対照群のある前向き研究であり、対象者の選択基準とアウトカムが事前に定義されていた研究
・ レベル 3：対照群のある観察研究
　介入の前後を比較した後ろ向き研究、症例対照研究、対照群のあるコホート研究、交絡の調整を行った各種研究（横断的研究を含む）
・ レベル 4：対照群のない観察研究
　対照群のないコホート研究、ケースシリーズ

3. アウトカムのレベル
・ レベル 1：臨床アウトカム
　罹患率、死亡率、有害事象
・ レベル 2：代替アウトカム
　発見されたエラーの件数、有害事象と密接な関係のある検査値など
・ レベル 3：その他の測定可能なアウトカムのうち、安全と間接的に関係するもの、あるいは安全との関係が証明されていないもの
　教育・研修の前後に行ったテストの点数、異なる環境下での自己評価の点数
・ レベル 4：エラーや有害事象の減少に寄与するアウトカムがない
　患者満足度のみを測定した研究、エラーの検知方法について述べているが、何も結果を測定していない研究

（倫理面への配慮）

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C．研究結果

1. 施設間の Hand Over（資料 5-1）

地域連携パスと患者手帳の効果が認められたが、エビデンスレベルの高いデザイン・アウトカムの研究は少なかった。

医中誌 Web および PubMed の文献検索により、和文論文 51 件、英文論文 7 件（英文論文は件数が多かったため過去 3 年分の文献に限定）が得られた。

和文論文では、エビデンスレベルの高い文献が少なく、研究のアウトカムに臨床上の指標を用いた文献が少ないことが明らかにされた。大腿骨近位部骨折の連携パスの使用群は、未使用群と比較し、退院後の反対側の骨折の発生率が有意に低いこと等が確認されているが、他の地域連携パスまたは連携手帳については、在院日数の短縮は認められるものの、臨床上のアウトカムの改善との関連を示すものは見当たらなかった。

英文論文では、Transitional care interventions の導入群は、非導入群と比較し、死亡率や再入院率、救命受診率が有意に低いことが確認された。また、施設間のテレビ会議と診療情報提供書の項目別記載率についても、死亡率と関連していることが確認された。英文論文では、施設内の患者情報共有に関する研究が多く、施設間の患者情報共有に関する研究は少なかった。

2. 超音波ガイド下中心静脈カテーテル挿入（資料 5-2）

医中誌の文献検索より和文論文 5 件、PubMed の過去 5 年間の文献検索より英文論文が 20 件得られた。英文論文にはシステマティックレビューやメタ解析の文献も複数認められた。

英文論文では、システマティックレビューや無作為化比較試験などエビデンスレベルが高い研究デザインで、尚且つアウトカムとして動脈穿刺の発生率、合併症率、カテーテル留置の成功率、穿刺回数等を用いた文献が多く認められた。Lalu（2015）のシステマティックレビューでは、超音波ガイド下群は、ランドマーク法群よりも合併症発生率が低いことが認められ、超音波の使用を支持している。

和文論文では、エビデンスレベルの高い文献が少ないものの、研究のアウトカムに合併症発生率などの臨床アウトカム、カテーテル留置の成功率、穿刺回数、インシデント発生率などの代替アウトカムが用いられていた。超音波ガイド下穿刺群は、ランドマーク法群と比較して、合併症の発生率・動脈穿刺の発生率が有意に低いこと、CVC 挿入行為の認定制度の導入の前後比較ではインシデント発生率が減少したこと等を報告した研究が認められた。

3. WHO 手術安全チェックリスト（資料 5-3）

医中誌 Web および PubMed を用いて過去 10 年間の文献を検索した結果、和文論文 3 件、英文論文 76 件が得られた。英文論文には複数のシステマティックレビューが存在し、WHO Surgical Safety Checklist（SSC）導入効果等が報告されていた。

Cadman（2016）は、システマティックレビューの結果、SSC の導入効果として死亡率減少、コミュニケーションとチームワークの改善、手術時間の短縮等が確認されたと報告している。また、de Jager（2016）は、SSC は外科的有害事象の減少と関連しており、その効果は発展途上国においてより大きいことを報告している。英文論文では、死亡率や在院日数といった臨床アウトカムを用いて SSC の導入効果を測定した研究がみられたほか、SSC の順守状況等を明らかにしている研究もみられた。

和文論文では、単一施設において SSC 導入前後の医師、看護師の誤認防止等といった安全意識の変化を報告した研究がみられたほか、SSC 導入と術後合併症発生率との関係を報告した研究等がみられた。

D．考察

一定の手法に基づいて医療安全施策の効果に関する文献調査を試行した。研究デザインと研究のアウトカム指標について EBM に基づいて評価した結果、医療安全に関する施策・活動の効果については、エビデンスレベルの高い研究が少ないことが明らかにされた。関連する文献を漏れなく検索するには適切なシソーラス／MeSH を用いることが要求されるが、そのシソーラス／MeSH の特定と検索結果の絞り込みには多大な労力を必要とした。労力をかけて収集した文献についても、エビデンスレベルの高い研究が少ないため、多くの施策が推奨度を低く設定せざるを得ないと予想された。

今後は、文献調査の費用対効果も考慮し、文献調査のテーマを絞り込む必要があると考えられた。また、EBM に基づく施策の推奨度の設定は難しいと考えられるため、文献調査の結果は施策の効果を定量的に把握できる情報の一覧を作成するに留めるべきと考えられた。

E．結論

EBM に基づいた文献調査を実施するうえでの課題を整理することができた。平成 30 年度は、研究班の専門家の意見を踏まえ、文

献調査のテーマを慎重に選択する必要があ
ると考えられた。

Ｆ．研究発表

1.　論文発表

なし

2.　学会発表

なし

Ｇ．知的財産権の出願・登録状況

1. 特許取得

なし

2. 実用新案登録

なし

3. その他

なし

Ⅲ．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

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
藤田茂、長谷川友紀	医療安全施策の費用対効果－OECD の調査報告書から	患者安全推進ジャーナル	No. 51	52-54	2018 年 3 月

その他（報告書）

Hasegawa T, Fujita S: Patient Safety Policies - Experiences, Effects and Priorities; Lessons from OECD Member States -, Third Global Ministerial Summit on Patient Safety, 厚生労働省, 2018.4

資料1. 専門家調査の集計結果

(1)医療安全に関する全国/制度レベル・病院レベル・臨床現場レベルの各種施策について、下記の項目を1～5段階で評価してください。

集計結果(n=24人)　中央値に濃い色(例:■)、四分位範囲(25パーセンタイルと75パーセンタイル)に薄い色(例:■)をつけました。

番号	施策	調査回	過去の医療安全への貢献度 1:小さい～5:大きい						現在の普及度合 1:低い～5:高い						今後進めるにあたっての(現状を踏まえ、追加的な措置を講じる場合の) 期待される効果						費用						緊急性						優先度						各施策へのご意見
			1	2	3	4	5	無	1	2	3	4	5	無	1	2	3	4	5	無	1	2	3	4	5	無	1	2	3	4	5	無	1	2	3	4	5	無	
1	**全国/制度レベルの施策**																																						
1.1	認定・認証における医療安全基準	①	1	4	5	11	3	0	0	4	6	9	5	0	0	2	8	11	3	0	0	2	8	7	7	0	3	5	10	6	0	0	0	4	11	7	2	0	継続的な質評価に対する診療報酬への適応が必要。診療報酬で直接的に評価すべきである。JCIの普及は正の影響を与える可能性がある。医療者の理解の向上が望まれる。普及はしているが自主性は高くないのでは。基準のクリアのみで実効性の疑い。
		②	–	–	–	–	–	–	0	3	7	12	2	0	0	0	10	11	3	0	0	2	7	8	7	0	1	5	13	5	0	0	0	4	13	5	2	0	
		③	–	–	–	–	–	–	0	1	6	15	2	0	0	1	6	14	3	0	0	1	3	12	8	0	2	1	17	4	0	0	2	0	15	6	1	0	
1.2	医療安全指標に基づくデータの収集と公表	①	1	8	11	2	1	1	2	8	10	3	0	1	0	4	11	7	1	1	0	2	12	9	0	1	2	6	7	8	0	1	0	4	12	6	1	1	データの活用が課題。病院団体に限定されず、規模別などでもっと共有し合えるものを望む。データの信頼性確保が重要。報告義務病院からの報告が少ない。あまり活用できていない。真に実態を反映していない可能性。医療機関間の差があるのではないか。データベース項目の検討必要。
		②	–	–	–	–	–	–	1	9	10	3	0	1	0	3	13	6	1	1	0	0	14	9	0	1	1	2	16	4	0	1	1	1	15	5	1	1	
		③	–	–	–	–	–	–	1	7	13	2	0	1	0	1	15	7	0	1	0	0	14	8	1	1	1	0	20	2	0	1	1	0	17	4	1	1	
1.3	医療事故の院外への強制報告制度	①	2	4	8	8	2	0	1	5	9	6	3	0	0	3	10	9	2	0	1	3	13	6	1	0	1	4	13	4	2	0	0	6	7	8	3	0	報告義務対象医療機関の拡大が望まれる。まだまだ外部表出できていないと感じる。法的義務であり、必要性が高い。病院によって温度差あり。取りあえずは普及しているが、今後の在り方は要検討。強制的報告の限界あり。
		②	–	–	–	–	–	–	0	5	11	7	1	0	0	4	11	8	1	0	0	1	16	5	2	0	2	4	16	2	0	0	2	3	9	9	1	0	
		③	–	–	–	–	–	–	0	1	17	6	0	0	1	1	12	9	1	0	0	0	13	11	0	0	1	2	15	6	0	0	1	1	10	11	1	0	
1.4	医療安全に対する診療報酬の支払い	①	2	3	8	5	6	0	3	2	8	5	6	0	0	0	3	13	8	0	1	2	10	5	6	0	0	0	8	9	7	0	0	0	8	9	7	0	効果は大きいが現実的ではない。支払いが低すぎる。医療安全にもっと加算をつけてほしい。やっていることへの評価を。人物金時間を投入しない限り安全確保は困難である。最も行動を規制しうる。効果は大きいと考えるが、経済メリットの追求の側面が強すぎるのが欠点。チーム医療の評価を進める必要あり。医療安全にもっとお金が必要。
		②	–	–	–	–	–	–	0	6	9	6	3	0	0	0	4	14	6	0	0	2	9	9	4	0	0	0	9	6	9	0	0	0	6	8	10	0	
		③	–	–	–	–	–	–	0	7	9	6	2	0	0	1	4	17	2	0	0	1	7	13	3	0	0	0	9	11	4	0	0	0	6	10	8	0	
1.5	医療職の教育・訓練	①	1	4	4	12	3	0	0	6	7	10	1	0	0	0	7	10	7	0	2	2	13	7	0	0	0	3	7	8	6	0	0	1	7	6	10	0	次世代のリーダー養成に力を注ぐことが重要。基礎教育にもっと取り入れてほしい。各団体で実施している。内容の充実が求められる。恒常的に取り組むもの。取りあえずは普及しているが研修の拡大が必要。医学生・病院職員・実習を含めた研修必要。
		②	–	–	–	–	–	–	0	3	10	11	0	0	0	0	5	13	6	0	0	2	12	10	0	0	0	1	5	11	7	0	0	1	4	9	10	0	
		③	–	–	–	–	–	–	0	2	10	11	1	0	0	0	6	14	4	0	0	1	14	8	1	0	0	1	2	17	4	0	0	0	2	14	8	0	
1.6	電子化した診療情報の施設を越えた共有(Electronic Health Record:医療情報連携基盤)	①	5	14	3	1	1	0	6	13	5	0	0	0	1	2	8	6	7	0	0	0	2	7	15	0	1	3	10	6	4	0	1	2	7	7	7	0	開発を望む。地域限定。今後期待できるが投資が必要。地域包括ケアの基盤だが現行のHISは診療報酬中心で設計されている。以前から言われているが電子化情報共有は困難。
		②	–	–	–	–	–	–	3	17	4	0	0	0	0	3	6	8	7	0	0	0	0	10	14	0	0	2	9	10	3	0	0	2	8	11	3	0	
		③	–	–	–	–	–	–	2	17	5	0	0	0	1	2	6	9	6	0	0	0	0	10	14	0	0	2	10	10	2	0	1	1	8	12	2	0	
1.7	医療事故に対する無過失補償制度	①	3	9	4	7	1	0	4	10	5	5	0	0	1	3	8	8	4	0	0	0	7	7	10	0	2	3	7	10	2	0	2	2	9	8	3	0	医療安全への貢献度という視点？現場での医療安全の取り組みとの兼ね合い？産科医療補償制度は限定的である。医療全般に拡げるには、費用が掛かる。産科領域においては一定の貢献あり。国民的議論により、産科領域を超えた制度の創設が望まれる。産科以外の領域拡大をどう図るかが課題ではないか。産科のみでなく医療事故補償制度へ。
		②	–	–	–	–	–	–	3	14	5	2	0	0	0	4	9	8	3	0	0	0	4	10	10	0	0	3	11	7	3	0	0	3	13	6	2	0	
		③	–	–	–	–	–	–	5	17	2	0	0	0	0	4	8	10	2	0	0	0	1	11	12	0	0	2	9	11	2	0	0	2	12	8	2	0	
1.8	一般人を対象とした医療・健康・患者参加等の教育	①	6	11	6	0	1	0	6	12	6	0	0	0	2	7	5	8	2	0	1	6	12	3	2	0	1	7	7	8	1	0	2	5	10	4	3	0	もっと積極的に広報をすべき。患者参加の意味が不明確。効果を感じたことはない。正しい知識の普及をどう図るかが課題。今後必要。
		②	–	–	–	–	–	–	4	15	5	0	0	0	0	8	9	5	2	0	0	4	17	2	1	0	1	6	9	8	0	0	2	4	12	6	0	0	
		③	–	–	–	–	–	–	1	18	5	0	0	0	0	6	12	4	2	0	0	6	16	1	1	0	1	5	11	7	0	0	1	3	15	5	0	0	
1.9	医療安全に関する特定のテーマについて、政府が医療機関に取り組みを促す	①	3	4	8	8	1	0	0	4	9	10	1	0	0	1	12	8	3	0	0	3	17	3	1	0	0	5	14	3	2	0	1	4	14	2	3	0	特に医師に対する政府の取り組みを望む。診療報酬での評価が必要。法の遵守を促す必要がある。コスメティックになりがち。処分とつながる仕組みでは、本来の医療安全の動機を育てにくい。国の介入の在り方は要検討。保険加算・罰則等困難もある。
		②	–	–	–	–	–	–	0	4	11	9	0	0	1	4	8	10	1	0	0	3	16	5	0	0	1	0	20	3	0	0	1	0	20	3	0	0	
		③	–	–	–	–	–	–	0	4	15	5	0	0	0	3	7	13	1	0	0	2	16	6	0	0	0	2	18	4	0	0	0	2	17	5	0	0	
1.10	国全体の医療安全を管掌する公的機関(ナショナルセンター)の設置	①	1	6	5	8	4	0	0	6	9	8	1	0	0	4	4	11	5	0	1	1	6	8	8	0	1	5	10	6	2	0	2	3	7	9	3	0	機能を整理し一元化する検討を始める時期。分担ではなく統合の必要あり。分散しているので統括があると良いと思う。現組織の体制整備で十分。シンボル的だが、強制力が弱い。役割が分担されていることによる医療機関の負担軽減を図るべきではないか。医療事故調査制度を少し経過を見てから。
		②	–	–	–	–	–	–	0	6	12	6	0	0	1	1	6	13	3	0	0	0	7	10	7	0	1	1	15	7	0	0	1	1	11	10	1	0	
		③	–	–	–	–	–	–	0	6	15	3	0	0	0	1	5	17	1	0	0	1	3	12	8	0	0	2	13	9	0	0	0	2	12	10	0	0	

番号	施策	調査回	**過去**の医療安全への**貢献度** 1:小さい～5:大きい						**現在**の**普及度合** 1:低い～5:高い						**今後**進めるにあたっての（現状を踏まえ、追加的な措置を講じる場合の）																		各施策へのご意見
															期待される**効果**						**費　用**						**緊急性**						**優先度**						
			1	2	3	4	5	無	1	2	3	4	5	無	1	2	3	4	5	無	1	2	3	4	5	無	1	2	3	4	5	無	1	2	3	4	5	無	
2	**病院レベルの施策**																																						
2A	組織全体の取り組み																																						
2.1	医療安全を含めたガバナンスと説明責任の確立	①	1	9	8	4	2	0	0	7	7	8	2	0	0	2	3	13	6	0	0	7	12	5	0	0	0	3	7	8	6	0	0	2	7	8	7	0	ある程度は普及済。重要だが、ガバナンスを正確に理解できていない。病院毎のバラツキが大きい。実績を上げるには、時間がかかる。施設間格差があるのではないか。形式はつくれるが内容を伴わない。
		②	–	–	–	–	–	–	0	6	13	5	0	0	0	1	3	15	5	0	0	4	16	4	0	0	2	1	4	15	2	0	2	1	3	12	6	0	
		③	–	–	–	–	–	–	0	7	12	5	0	0	0	2	2	20	0	0	0	3	15	6	0	0	0	3	5	15	1	0	1	2	3	16	2	0	
2.2	医療事故やヒヤリ・ハットの報告・管理の仕組み	①	2	1	4	14	3	0	0	1	4	11	8	0	0	0	12	7	5	0	0	2	18	4	0	0	1	6	10	5	2	0	0	5	10	5	4	0	全体としては院内の管理は不十分。分析が不十分である。恒常的に取り組むべきだが、活用方法にバラつき有り。再発防止につながらなくても、報告すること自体に意義が大きい。報告システムは普及しているが結果が活用されているか。報告文化と非懲罰性を病院レベルで徹底必要。
		②	–	–	–	–	–	–	0	0	7	8	9	0	0	0	5	16	3	0	0	2	18	4	0	0	0	1	16	7	0	0	0	2	14	7	1	0	
		③	–	–	–	–	–	–	0	0	5	12	7	0	0	0	6	16	2	0	0	2	19	3	0	0	0	2	15	7	0	0	0	1	15	8	0	0	
2.3	患者・家族による医療事故・苦情・意見等の報告の仕組み	①	1	9	9	4	1	0	1	7	7	6	3	0	0	9	11	3	1	0	4	5	14	1	0	0	1	9	11	2	1	0	0	10	11	2	1	0	患者への安全教育も併せて行う必要あり。患者家族の意見もよいが、医療者の取り組みが重要。患者の声は重要だが、事故防止には直接繋がらない。建設的な結果に結びついていない。
		②	–	–	–	–	–	–	0	9	9	4	1	1	0	9	12	0	2	1	2	8	12	1	0	1	0	8	12	3	0	1	0	8	14	1	0	1	
		③	–	–	–	–	–	–	0	9	9	5	0	1	0	7	11	4	1	1	2	3	17	1	0	1	0	5	15	3	0	1	0	6	16	1	0	1	
2.4	医療安全指標のモニタリングと現場へのフィードバック	①	3	5	11	4	0	1	3	5	9	6	0	1	1	1	7	11	3	1	0	4	14	5	0	1	1	1	11	7	3	1	1	1	9	10	2	1	分析と改善が必要。ノウハウがまだまだ身についていない。何を測るかが重要。何を指標とするかが問題。どのようにフィードバックを図るのかが課題。効果に疑問。
		②	–	–	–	–	–	–	1	7	11	4	0	1	0	1	9	13	0	1	0	3	14	6	0	1	0	1	12	9	1	1	0	0	11	12	0	1	
		③	–	–	–	–	–	–	0	11	8	4	0	1	0	1	8	14	0	1	0	2	15	5	1	1	0	0	16	7	0	1	0	1	10	12	0	1	
2.5	患者参加の取り組み	①	3	10	6	3	1	1	3	8	8	4	0	1	0	0	8	10	5	1	0	7	10	6	0	1	0	4	7	9	3	1	0	3	7	9	4	1	国民の医療安全文化が醸成されていない中での「参加」は慎重であるべき。患者参加の意味が不明確。患者教育が重要。内容にバラつき有り。形式的には普及しているが質の評価が必要。今後絶対必要。
		②	–	–	–	–	–	–	2	10	11	0	0	1	0	1	10	10	2	1	0	8	13	2	0	1	0	3	9	11	0	1	0	3	8	10	2	1	
		③	–	–	–	–	–	–	0	14	9	0	0	1	0	0	11	10	2	1	0	4	15	4	0	1	0	2	11	10	0	1	0	2	6	13	2	1	
2.6	患者情報の伝達方法の標準化と訓練	①	3	5	10	4	2	0	0	9	9	5	1	0	0	1	3	14	5	1	0	7	10	4	2	1	0	1	6	13	3	1	0	1	4	13	5	1	いかに本格的に導入できるかが鍵。取りあえず普及していると思われるが。
		②	–	–	–	–	–	–	0	8	10	5	0	1	0	1	1	19	2	1	0	2	18	3	0	1	0	1	3	16	3	1	0	1	2	18	2	1	
		③	–	–	–	–	–	–	0	9	12	2	0	1	0	1	1	21	0	1	0	2	18	3	0	1	0	0	6	17	0	1	0	0	2	21	0	1	
2.7	情報技術を用いた医療安全対策	①	3	5	8	6	2	0	0	6	9	8	1	0	0	2	5	8	8	1	0	0	0	6	17	1	1	1	5	7	9	1	0	2	4	6	11	1	ITに起因する不具合の検討が必要。電子カルテメーカーとの協働が求められる。画像や病理診断において、癌の診断が多いので、読影支援システムの充実が望まれる。情報システムの評価を行う必要があるのではないか。チェックのみで内容までのチェックは高度な対応必要。
		②	–	–	–	–	–	–	1	3	10	9	1	0	0	0	4	13	7	0	0	0	0	8	16	0	0	2	2	10	10	0	0	2	2	10	10	0	
		③	–	–	–	–	–	–	0	3	13	7	1	0	0	1	4	12	7	0	0	0	0	7	17	0	0	2	2	12	8	0	0	2	2	13	7	0	
2.8	業務量に応じた人員配置	①	1	8	12	2	1	0	1	11	8	4	0	0	1	0	5	10	7	1	1	0	3	5	14	1	1	0	6	6	10	1	1	0	5	8	9	1	適切の定義が必要。費用対効果が重要。業務の視覚化・整理を先行させる必要あり。施設間格差がおおきいのではないか。どこも人手不足。必要量の推定困難。
		②	–	–	–	–	–	–	1	13	8	2	0	0	0	0	8	13	3	0	0	0	4	9	11	0	0	1	7	10	6	0	0	1	6	6	11	0	
		③	–	–	–	–	–	–	1	15	7	1	0	0	0	0	7	14	3	0	0	1	2	9	12	0	0	0	6	13	5	0	0	0	4	10	10	0	
2.9	医療安全文化の醸成	①	3	4	10	6	1	0	1	4	9	9	1	0	0	1	6	13	4	0	0	5	13	6	0	0	0	3	10	8	3	0	0	1	9	10	4	0	病院の規模、地域性、リーダーシップによっても差が大きい。医師が非協力的であり、政策を望む。恒常的な取り組み。取りあえずはできていると思われるが。すでに行われている。
		②	–	–	–	–	–	–	0	4	12	7	1	0	0	0	8	15	1	0	0	3	17	3	1	0	0	2	15	6	1	0	0	0	8	15	1	0	
		③	–	–	–	–	–	–	0	3	17	3	1	0	0	0	11	12	1	0	0	1	20	3	0	0	0	1	15	8	0	0	0	0	10	14	0	0	
2B	特定の分野での取り組み																																						
2.10	院内感染の検知・報告・サーベイランスの仕組み	①	1	3	5	9	6	0	0	4	5	7	8	0	0	1	7	11	5	0	0	1	9	12	2	0	0	4	8	7	5	0	0	5	7	6	6	0	現状継続及び新型感染症への取り組み。専門外で不明だが、効果を上げているように見える。質の向上が課題ではないか。明かな目的・分野で効果大。
		②	–	–	–	–	–	–	0	1	4	14	5	0	0	1	4	15	4	0	0	0	12	12	0	0	0	0	12	9	3	0	0	0	8	12	4	0	
		③	–	–	–	–	–	–	0	0	6	17	1	0	0	0	4	18	2	0	0	0	10	14	0	0	0	0	10	12	2	0	0	0	8	15	1	0	
2.11	手指衛生の取り組み	①	1	3	9	7	4	0	0	4	8	7	5	0	0	0	5	13	6	0	2	8	8	6	0	0	0	3	6	11	4	0	0	4	5	10	5	0	タイミング、質的なモニタリング。まぁいいかがなくならない。永遠の課題である。何を測定するかが重要。取りあえず普及していると思われる。すでに行われている。
		②	–	–	–	–	–	–	0	1	9	11	3	0	0	0	3	14	7	0	2	6	15	1	0	0	0	3	5	13	3	0	0	2	2	15	5	0	
		③	–	–	–	–	–	–	0	1	9	12	2	0	0	0	3	16	5	0	0	7	8	8	1	0	0	2	7	12	3	0	0	1	2	17	4	0	
2.12	抗菌剤の適正使用	①	3	5	6	9	1	0	2	4	11	6	1	0	0	0	1	16	7	0	2	4	13	4	1	0	0	0	7	12	5	0	0	2	5	11	6	0	使用量の増加、クリニカルパス。かなり実施されている。徐々に普及してきた？施設内のみならず地域での評価が必要。専門部門必要。
		②	–	–	–	–	–	–	1	3	13	6	1	0	0	0	3	16	5	0	1	2	17	3	1	0	0	1	8	11	4	0	0	1	4	14	5	0	
		③	–	–	–	–	–	–	0	2	19	3	0	0	0	2	1	19	2	0	0	6	12	4	2	0	0	1	6	15	2	0	0	1	5	16	2	0	
2.13	輸血用血液製剤の管理方法の標準化	①	1	3	4	10	5	1	0	1	7	10	5	1	0	2	5	11	5	1	2	3	13	4	1	1	1	4	7	10	1	1	2	3	7	9	2	1	医療機関による差がある。かなり実施されている。それでもまだ完全ではない。施設毎のバラツキが起きい。取りあえず普及していると思われる。すでに行われている。
		②	–	–	–	–	–	–	0	0	3	14	6	1	0	1	5	11	6	1	2	2	15	4	0	1	0	3	8	10	2	1	1	1	9	8	4	1	
		③	–	–	–	–	–	–	0	0	6	13	4	1	0	2	5	12	4	1	0	3	14	6	0	1	0	3	8	11	1	1	0	2	10	9	2	1	
2.14	医療器具の滅菌方法の標準化	①	1	3	6	9	5	0	0	2	7	9	6	0	0	1	7	8	8	0	2	2	10	7	3	0	1	2	12	7	2	0	1	2	11	6	4	0	単回使用。かなり実施されている。専門外のため現状不明。取りあえず普及していると思われる。すでに行われている。
		②	–	–	–	–	–	–	0	0	7	12	5	0	0	0	7	9	8	0	2	0	11	9	2	0	0	4	12	6	2	0	1	4	10	6	3	0	
		③	–	–	–	–	–	–	0	0	7	11	6	0	0	2	7	10	5	0	0	2	11	9	2	0	0	5	13	5	1	0	0	4	13	5	2	0	

番号	施策	調査回	**過去**の医療安全への**貢献度** 1:小さい～5:大きい						**現在**の**普及度合** 1:低い～5:高い						**今後**進めるにあたっての（現状を踏まえ、追加的な措置を講じる場合の）																		各施策へのご意見
															期待される**効果**						**費　用**						**緊急性**						**優先度**					
			1	2	3	4	5	無	1	2	3	4	5	無	1	2	3	4	5	無	1	2	3	4	5	無	1	2	3	4	5	無	1	2	3	4	5	無	
3	**臨床現場レベルの施策**																																						
3A	薬剤に関連した有害事象対策																																						
3.1	患者が服薬中の薬剤の定期的な評価・見直し	①	2	12	1	7	1	1	1	10	5	5	2	1	0	0	2	12	9	1	2	0	9	6	6	1	0	1	4	13	5	1	0	1	1	14	7	1	病棟薬剤師の役割の標準化は急ぐべき。病棟薬剤師の介入が有効。推進が望まれる。以前に比べれば普及したが、今後更なる質の向上が必要。薬剤部に新たな人員必要。
		②	–	–	–	–	–	–	0	6	12	5	1	0	0	0	2	14	8	0	1	2	7	9	5	0	0	2	3	16	3	0	0	2	2	12	8	0	
		③	–	–	–	–	–	–	0	5	14	4	0	1	0	1	1	15	6	1	0	2	10	7	4	1	0	1	3	15	4	1	0	1	1	13	8	1	
3.2	転記・読み取りミスを減らす対策	①	1	8	4	6	4	1	0	5	11	6	1	1	0	1	4	12	6	1	0	3	5	11	4	1	0	2	9	9	3	1	0	2	7	10	4	1	持参薬の情報を転記することがある。手書きによるエラーは減少。推進が望まれる。情報システムとの兼ね合い。すでに基本は行われている。
		②	–	–	–	–	–	–	0	3	10	10	1	0	0	1	3	13	7	0	0	2	7	10	5	0	0	2	7	10	5	0	0	1	4	13	6	0	
		③	–	–	–	–	–	–	0	3	11	10	0	0	0	1	3	15	5	0	0	2	6	12	4	0	0	2	3	15	4	0	0	1	3	16	4	0	
3.3	医療安全面の機能を充実させた輸液ポンプ・シリンジポンプ（スマートポンプ）の導入	①	2	7	6	6	3	0	2	4	13	4	1	0	0	2	2	14	6	0	1	1	1	10	11	0	1	2	10	8	3	0	1	2	8	10	3	0	機器はモデルチェンジするため行政の介入が必要。費用対効果。病院の経営事情などに左右される。モノの面から一層の改善の余地ありと考える。機種の統一化が課題。すでに現行の中では機器側は充実、運用に問題。
		②	–	–	–	–	–	–	0	5	14	4	1	0	0	1	3	16	4	0	1	1	0	8	14	0	1	2	6	13	2	0	1	2	6	14	1	0	
		③	–	–	–	–	–	–	0	6	15	2	1	0	0	3	4	15	2	0	0	2	0	10	12	0	0	3	6	13	2	0	0	3	5	15	1	0	
3B	感染制御																																						
3.4	無菌操作法や感染予防対策の標準化	①	1	3	4	7	8	1	0	1	7	10	5	1	0	1	5	11	6	1	1	1	9	7	5	1	1	3	7	7	5	1	1	4	6	6	6	1	継続して強化する。継続必要。質の向上と徹底が必要。すでに行われている。徹底の部分必要。
		②	–	–	–	–	–	–	0	1	4	16	3	0	0	0	2	16	6	0	0	3	3	11	7	0	1	2	9	9	3	0	0	3	6	11	4	0	
		③	–	–	–	–	–	–	0	1	5	16	2	0	0	1	2	17	4	0	0	1	4	14	5	0	0	2	8	12	2	0	0	3	5	14	2	0	
3.5	尿道カテーテルの使用・挿入方法の標準化	①	2	5	6	6	4	1	1	2	7	9	4	1	1	1	8	9	4	1	2	5	10	4	2	1	1	3	14	4	1	1	2	2	13	5	1	1	使用しない方向で。閉鎖式のものを使用する。恒常的取り組み。一応普及していると思われる。すでに行われている。徹底の部分必要。
		②	–	–	–	–	–	–	0	2	6	14	1	1	1	0	6	15	1	1	1	4	11	6	1	1	1	2	14	5	1	1	1	2	15	4	1	1	
		③	–	–	–	–	–	–	0	0	8	14	1	1	0	1	3	18	1	1	0	3	14	6	0	1	0	2	15	6	0	1	0	3	16	4	0	1	
3.6	中心静脈カテーテルの挿入方法の標準化	①	1	3	6	10	4	0	0	2	8	12	2	0	0	0	3	13	8	0	0	2	7	10	5	0	0	3	8	10	3	0	0	1	8	11	4	0	定期的な研修会の実施が必要。専門家の協力必要。実技研修の普及が課題。いまだに事故多くシミュレーション等必要。
		②	–	–	–	–	–	–	0	0	11	12	1	0	0	1	4	15	4	0	0	1	8	12	3	0	0	2	7	12	3	0	1	2	5	14	2	0	
		③	–	–	–	–	–	–	0	1	12	9	2	0	0	1	1	19	3	0	0	0	11	11	2	0	0	2	6	15	1	0	0	2	4	17	1	0	
3.7	人工呼吸器関連肺炎の予防方法の標準化	①	1	4	9	8	1	1	0	4	8	9	2	1	0	0	6	14	3	1	1	2	13	4	3	1	1	3	8	9	2	1	1	1	10	9	2	1	専門外のため不明。一応普及していると思われる。すでに行われている。徹底のみ。
		②	–	–	–	–	–	–	0	4	10	9	1	0	0	0	8	14	2	0	1	2	13	8	0	0	0	2	14	6	2	0	0	3	11	9	1	0	
		③	–	–	–	–	–	–	0	2	13	8	0	1	0	1	4	16	2	1	0	2	13	8	0	1	0	1	14	7	1	1	0	1	10	11	1	1	
3C	周術期の安全																																						
3.8	処置・手術のチェックリスト	①	1	3	7	8	4	1	0	4	7	10	2	1	0	1	5	12	5	1	6	3	11	2	1	1	1	3	7	9	3	1	1	1	6	10	5	1	普及にバラつき有り。一応普及していると思われる。すでに行われている。徹底のみ。
		②	–	–	–	–	–	–	0	0	7	15	2	0	0	0	3	16	5	0	3	5	14	2	0	0	0	1	8	13	2	0	0	2	5	13	4	0	
		③	–	–	–	–	–	–	0	0	11	10	3	0	0	1	1	20	2	0	1	4	18	1	0	0	0	1	7	16	0	0	0	1	4	18	1	0	
3.9	手術室内の情報の統合・一覧性の向上	①	2	8	7	4	3	0	1	9	9	5	0	0	0	1	4	14	5	0	3	2	7	4	8	0	1	2	8	10	3	0	1	1	10	8	4	0	RFIDを使用した機器管理。ITの改良が必要。予算に余裕があれば。手術室の機能が複雑になっていることから、情報の統合は重要。機器の発展、表示の標準化が必要。機器の種類、新製品への交換等、現状では不可。
		②	–	–	–	–	–	–	0	8	14	2	0	0	0	0	4	19	1	0	1	2	6	7	8	0	0	1	11	10	2	0	0	1	11	9	3	0	
		③	–	–	–	–	–	–	0	6	16	2	0	0	0	1	5	17	1	0	0	2	10	6	6	0	0	1	12	10	1	0	0	2	9	13	0	0	
3.10	周術期の投薬方法の標準化	①	1	6	7	7	2	1	0	5	8	9	1	1	0	1	2	15	5	1	4	7	6	5	1	1	1	1	4	13	4	1	1	2	3	13	4	1	エビデンスあることは推進すべき。周術期への薬剤師関与を高める必要あり。投薬の手順はごく基本以外個別。一部統一しても効果なし。
		②	–	–	–	–	–	–	0	2	11	10	0	1	0	0	2	21	0	1	1	5	10	7	0	1	0	2	4	17	0	1	0	3	2	18	0	1	
		③	–	–	–	–	–	–	0	3	13	7	0	1	0	1	2	19	1	1	1	4	14	4	0	1	0	1	6	16	0	1	0	1	4	18	0	1	
3D	その他の分野の対策																																						
3.11	深部静脈血栓の予防方法の標準化	①	2	2	8	7	4	1	0	3	7	11	2	1	0	0	5	13	5	1	1	2	12	6	2	1	0	2	7	13	1	1	0	2	8	12	1	1	エビデンスあることは推進すべき。徹底方法が課題。すでに行われている。新しい標準が必要。
		②	–	–	–	–	–	–	0	1	6	15	1	1	1	0	2	18	2	1	1	1	12	9	0	1	0	1	7	15	0	1	0	1	5	16	1	1	
		③	–	–	–	–	–	–	0	0	8	14	1	1	0	0	3	18	2	1	0	2	11	10	0	1	0	2	4	17	0	1	0	1	3	19	0	1	
3.12	主要な疾患の治療方法の標準化	①	2	1	12	6	2	1	0	3	12	7	1	1	0	0	3	15	5	1	3	7	8	4	1	1	1	1	8	12	1	1	1	0	8	13	1	1	エビデンスあることは推進すべき。標準化の一層の推進が必要。標準化の普及が課題。すでに行われている。
		②	–	–	–	–	–	–	0	2	15	5	1	1	0	1	5	17	0	1	1	2	13	7	0	1	0	0	8	15	0	1	0	0	8	15	0	1	
		③	–	–	–	–	–	–	0	1	16	5	1	1	0	2	2	19	0	1	0	5	12	6	0	1	0	2	5	16	0	1	0	2	4	17	0	1	
3.13	褥瘡の予防方法の標準化	①	1	2	11	6	3	1	0	1	7	10	5	1	0	1	7	12	3	1	2	7	9	4	1	1	1	7	10	4	1	1	1	6	8	7	1	1	マットレスの変更、評価・ポジショニングのスキル。介護施設との連携が必要。エビデンスあることは推進すべき。標準化の普及が課題。すでに行われている。
		②	–	–	–	–	–	–	0	0	10	13	0	1	0	0	8	14	1	1	1	1	14	7	0	1	0	2	12	9	0	1	0	0	17	6	0	1	
		③	–	–	–	–	–	–	0	0	7	16	0	1	0	2	5	15	1	1	0	2	16	5	0	1	0	3	13	7	0	1	0	3	13	7	0	1	
3.14	転倒・転落の予防方法の標準化	①	2	3	9	6	2	2	0	2	7	9	4	2	0	4	9	6	3	2	1	3	4	8	6	2	1	4	5	8	4	2	0	5	6	8	3	2	対応の標準化を国レベルで行ったらその遵守に重きをおく。患者が「転ばないこと」を評価とするのは無理がある。医療界の施策の不足、全体の問題になっていない。外来患者への定期的評価が遅れている。効果が正確に視覚化されていない印象有り。標準化の普及が課題。すでに行われている。
		②	–	–	–	–	–	–	0	1	10	9	3	1	0	2	16	4	1	1	1	0	9	10	3	1	0	5	9	7	2	1	0	2	10	9	2	1	
		③	–	–	–	–	–	–	0	2	8	11	2	1	0	1	12	8	2	1	0	1	9	12	1	1	0	2	13	8	0	1	0	1	12	9	1	1	
3.15	せん妄・認知機能障害の管理	①	2	5	11	4	0	2	0	8	9	4	1	2	0	2	6	11	3	2	1	4	9	6	2	2	0	2	4	10	6	2	1	1	6	9	5	2	むしろ看護師の労務管理上重要。抗精神薬の最新の使い方の知識を普及する必要性が大きい。手順の標準化・普及が課題。今後増大か。
		②	–	–	–	–	–	–	1	8	11	3	0	1	0	1	7	14	1	1	1	2	14	5	1	1	0	1	5	12	5	1	0	2	3	14	4	1	
		③	–	–	–	–	–	–	0	9	12	2	0	1	0	1	7	14	1	1	0	4	15	4	0	1	0	1	4	16	2	1	0	1	2	18	2	1	

番号	施　策	調査回	**過去**の医療安全への**貢献度** 1:小さい～5:大きい						**現在**の**普及度合** 1:低い～5:高い						**今後**進めるにあたっての（現状を踏まえ、追加的な措置を講じる場合の）																		各施策へのご意見
															期待される**効果**						**費　用**						**緊急性**						**優先度**					
			1	2	3	4	5	無	1	2	3	4	5	無	1	2	3	4	5	無	1	2	3	4	5	無	1	2	3	4	5	無	1	2	3	4	5	無	
3.16	患者の状態悪化への対応	①	1	6	10	5	0	2	1	7	5	8	1	2	0	0	5	12	5	2	1	1	6	8	6	2	1	1	5	12	3	2	1	1	5	12	3	2	費用対効果。実現可能な病院少ない。専門医師の協力必要。RRS(Rapid Response SYstem)の普及が望まれる。人員問題。すでに行われている。
		②	–	–	–	–	–	–	0	8	12	4	0	0	0	0	7	13	4	0	1	2	10	6	5	0	0	0	7	13	4	0	0	0	5	16	3	0	
		③	–	–	–	–	–	–	0	5	16	2	0	1	0	0	5	17	1	1	0	2	10	9	2	1	0	0	4	17	2	1	0	0	4	17	2	1	
3.17	患者の水分・栄養管理の基準	①	1	6	12	3	0	2	0	5	11	5	1	2	0	0	13	7	2	2	1	5	15	1	0	2	0	4	13	4	1	2	0	3	11	7	1	2	スクリーニングとそれに基づくNSTの介入。エビデンスあるなら推進すべき。普及・徹底をどう図るかが課題。現在の基準・治療の中で行われる。今さら必要ない。
		②	–	–	–	–	–	–	0	1	20	2	1	0	0	0	17	6	1	0	1	2	20	1	0	0	0	1	17	5	1	0	0	0	19	4	1	0	
		③	–	–	–	–	–	–	0	0	20	3	0	1	0	1	18	4	0	1	0	4	19	0	0	1	0	2	18	3	0	1	0	2	18	3	0	1	
3.18	患者・部位・手技等の照合方法の標準化	①	1	3	3	13	2	2	0	1	6	11	4	2	0	2	7	8	5	2	6	8	7	0	1	2	1	2	8	9	2	2	1	2	8	8	3	2	遵守がまだ不足。国内で手順を標準化すべき。標準化の普及が課題。すでに徹底されていると思われる。
		②	–	–	–	–	–	–	0	2	4	14	4	0	0	0	6	13	5	0	7	9	6	1	1	0	2	0	4	15	3	0	2	0	3	16	3	0	
		③	–	–	–	–	–	–	0	0	5	15	4	0	0	1	3	17	3	0	3	9	9	2	1	0	0	2	5	14	3	0	0	2	3	17	2	0	
4	**その他の施策（1回目調査で回答者が追加的に評価すべきと回答した施策）**																																						
4.1	病院管理者への教育啓発	①	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	
		②	–	–	–	–	–	–	4	14	3	3	0	0	0	1	7	13	3	0	0	5	14	5	0	0	0	0	4	19	1	0	0	0	3	15	6	0	
		③	–	–	–	–	–	–	3	16	2	3	0	0	0	0	4	16	4	0	0	5	15	4	0	0	0	2	3	17	2	0	0	2	1	17	4	0	
4.2	医療安全に関する院内教育・研修の標準化	①	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	
		②	–	–	–	–	–	–	4	12	4	4	0	0	0	1	7	15	1	0	0	1	9	12	2	0	0	0	11	10	3	0	0	0	8	11	5	0	
		③	–	–	–	–	–	–	1	16	4	1	1	1	1	0	7	15	0	1	0	1	7	11	4	1	1	0	8	11	3	1	1	0	7	10	5	1	
4.3	専従または専任の医療安全管理者の配置	①	0	0	0	1	1	0	0	0	1	0	1	0	0	0	0	1	1	0	0	0	1	1	0	0	0	0	1	1	0	0	0	0	1	1	0	0	医師の専従・専任化は効果あり
		②	–	–	–	–	–	–	0	1	9	9	5	0	0	0	4	15	5	0	0	0	9	14	1	0	1	1	6	13	3	0	1	0	4	14	5	0	
		③	–	–	–	–	–	–	0	2	8	11	3	0	0	1	3	16	4	0	0	0	7	15	2	0	1	1	4	15	3	0	1	1	3	14	5	0	
4.4	電子カルテ等情報システムの標準化	①	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	1	0	0	ベンダー間の差が大きい。人間中心設計を進めるべき。診療報酬請求目的から正確な医療記録を残すシステムへの転換が必要。
		②	–	–	–	–	–	–	2	9	9	3	1	0	0	0	2	14	8	0	0	0	1	6	17	0	0	1	7	9	7	0	0	1	6	10	7	0	
		③	–	–	–	–	–	–	1	12	8	2	1	0	0	1	4	13	6	0	0	0	1	7	16	0	1	1	5	10	7	0	1	1	4	11	7	0	
4.5	薬物療法の標準化	①	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	
		②	–	–	–	–	–	–	1	6	13	3	0	1	0	1	5	15	2	1	0	1	19	2	1	1	0	1	8	14	0	1	0	1	7	15	0	1	
		③	–	–	–	–	–	–	0	8	13	2	0	1	0	1	4	17	1	1	0	1	19	2	1	1	0	0	9	14	0	1	0	0	8	15	0	1	
4.6	新薬の患者モニタリング	①	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	医療機関・薬局の連携が課題
		②	–	–	–	–	–	–	0	7	13	3	0	1	0	1	10	9	3	1	0	2	11	9	1	1	0	1	12	10	0	1	0	1	10	12	0	1	
		③	–	–	–	–	–	–	1	6	14	2	0	1	1	1	9	11	1	1	0	1	14	8	0	1	1	1	15	6	0	1	1	2	11	9	0	1	
4.7	医療対話推進者の養成	①	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	1	0	0	
		②	–	–	–	–	–	–	4	11	7	2	0	0	0	3	6	10	5	0	1	2	8	9	4	0	0	5	8	11	0	0	0	4	10	10	0	0	
		③	–	–	–	–	–	–	2	15	5	2	0	0	0	1	9	11	3	0	0	1	12	10	1	0	0	4	10	9	1	0	0	3	10	11	0	0	
4.8	院内事故調査の実務研修	①	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	0	0	1	0	
		②	–	–	–	–	–	–	2	18	2	2	0	0	0	2	6	10	6	0	0	2	8	13	1	0	0	2	9	4	9	0	0	1	10	7	6	0	
		③	–	–	–	–	–	–	1	19	1	2	1	0	1	1	8	9	5	0	0	0	10	12	2	0	1	1	8	8	6	0	1	1	10	7	5	0	

(2) 上記の施策の中で、相乗効果が見込まれる組み合わせがあれば、その組み合わせを施策の番号で回答してください。

1.1-1.4,	1.6-2.4-2.7-3.9,	2.1-2.9,
1.1-1.5-2.8,	1.6-2.6-2.7-4.1,	2.5-2.6,
1.1-3.18,	1.6-2.7,	2.10-2.11-2.12,
1.2-2.1-2.4,	1.8-2.5,	2.10-3.4,
1.3-1.7-2.1-2.2,		2.14-3.4,
1.3-2.1,		3.1-4.2-4.3,
1.4-1.7,		3.1-3.10,
1.4-1.9,		3.8-3.18,
1.4-2.9-4.3,		3.9-3.18,
1.4-3.14,		3.14-3.15,
1.4-3.3,		4.8-4.10,

資料2 全国調査の集計結果

2018年3月

医療安全管理と病院情報システムに関する調査 集計結果
（全国の病院から病床規模で層化抽出された病院）

平成29年度厚生労働科学研究
医療安全対策の最新のエビデンスと今後の政策課題についての研究 研究班
研究代表者
東邦大学医学部教授 長谷川友紀
全日本病院協会 医療の質向上委員会
委員長 飯田修平

本調査の目的:

1 医療安全向上への取り組みがどのような成果を上げてきたか、今後、優先度の高い課題としてはどのようなものが考えられるかを明らかにする。

2 病院情報システムとその運用体制、ITを利用した遠隔医療、地域連携ネット等への各病院の関わり状況やサイバーセキュリティ対策等を明らかにする。

対 象:

全国の病院(n=8,438)から、病床規模で層化抽出した病院(n=3,215)と、層化抽出から漏れた全日本病院協会の会員病院(n=1,576)。

	一般病床の病床数	母数(2017)	抽出率	配布数
層化抽出病院	100床未満	5,843	25%	1,461
	100-299床	1,683	50%	842
	300床以上	912	100%	912
	小 計	8,438	-	3,215
	(内、全日病会員病院)	(2,499)		(923)
層化抽出から漏れた全日本病院協会 会員病院				1,576
合 計				4,791

期 間: 2017年10月30日(発送)～11月14日(投函期限)

回収率:
全体 18.1%(868/4791)
層化抽出病院 18.8%(603/3215)
全日本病院協会 会員病院 18.0%(449/2499)

定 義:

急性期病院	一般病床が50%以上を占める病院
療養型病院	療養病床が50%以上を占める病院
精神科病院	精神科病床が50%以上を占める病院
その他病院	上記に該当しない病院

※以下は層化抽出された病院の調査結果(n=603)をまとめたものです。

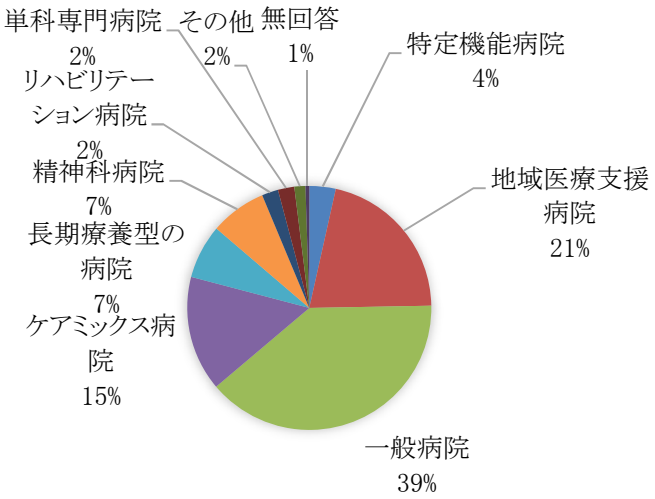
第1部 医療機関の基礎的な情報について

回答病院の内訳
1. 病床数
2. 病床稼働率
3. 平均在院日数

			n (病院数)	病床稼働率(%)		平均在院日数(日)	
				平均値	中央値	平均値	中央値
全 体			603	83	85	81	16
急性期病院	総病床数	100床未満	68	71	72	31	18
		100-299床	178	82	84	46	16
		300床以上	225	83	84	14	13
療養型病院	総病床数	100床未満	29	85	85	164	121
		100床以上	48	91	92	182	89
精神科病院			46	90	92	455	282
その他病院			9	78	83	71	25

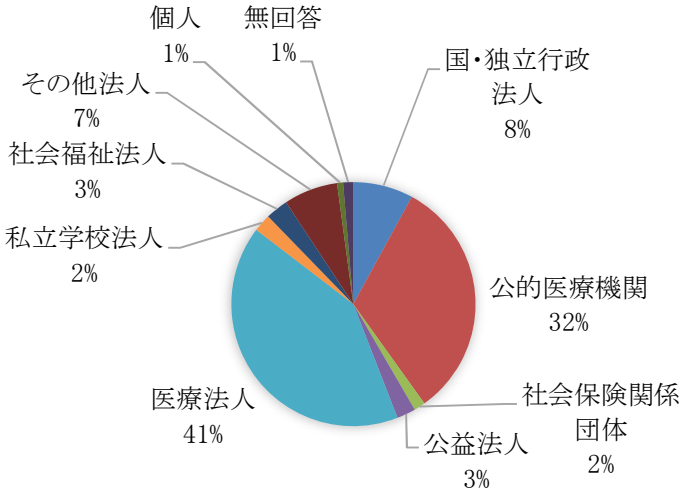
4. 施設機能としてもっとも当てはまるものを1つを選んでください。

n=603



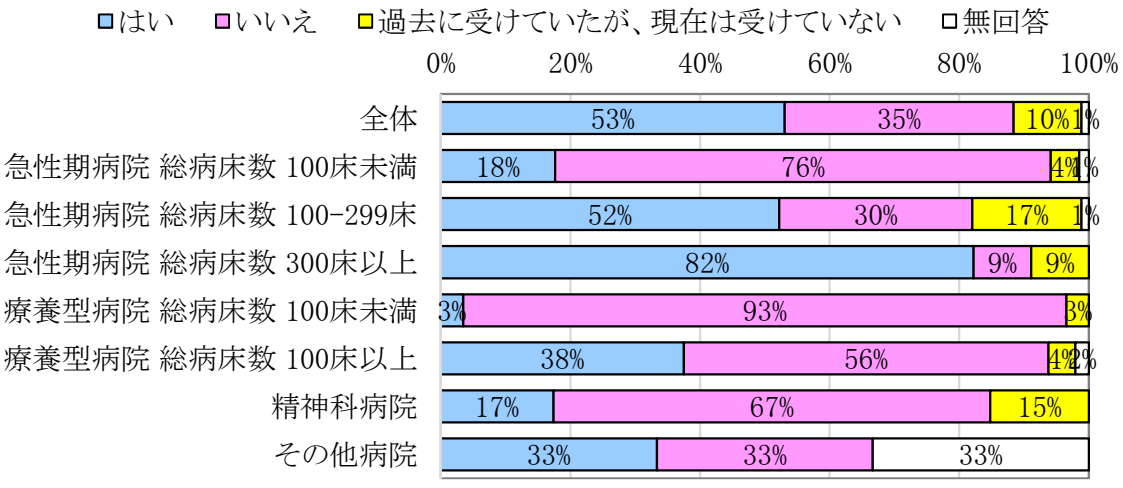
5. 開設主体を選択してください。

n=603

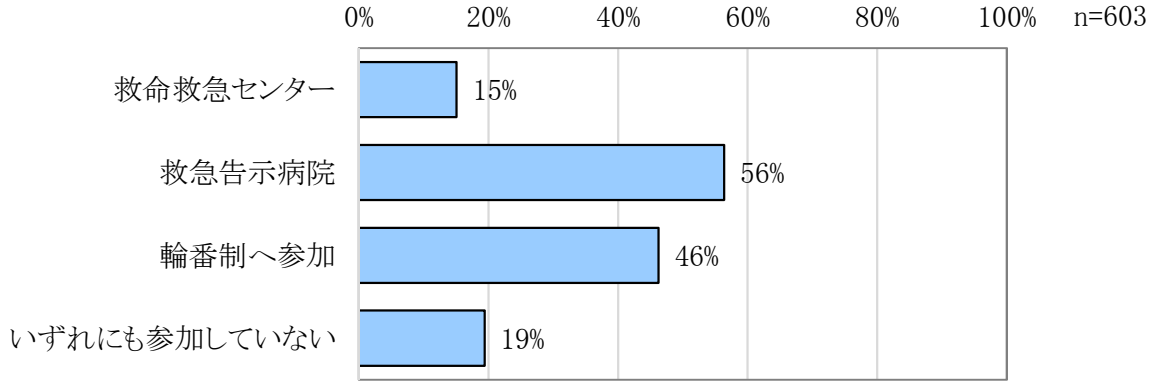


6. 日本医療機能評価機構による認定を受けていますか。

n=603



7. 救急医療体制には参加していますか。(当てはまるもの全て選択)



8. 職員数(常勤換算)

平均(人)

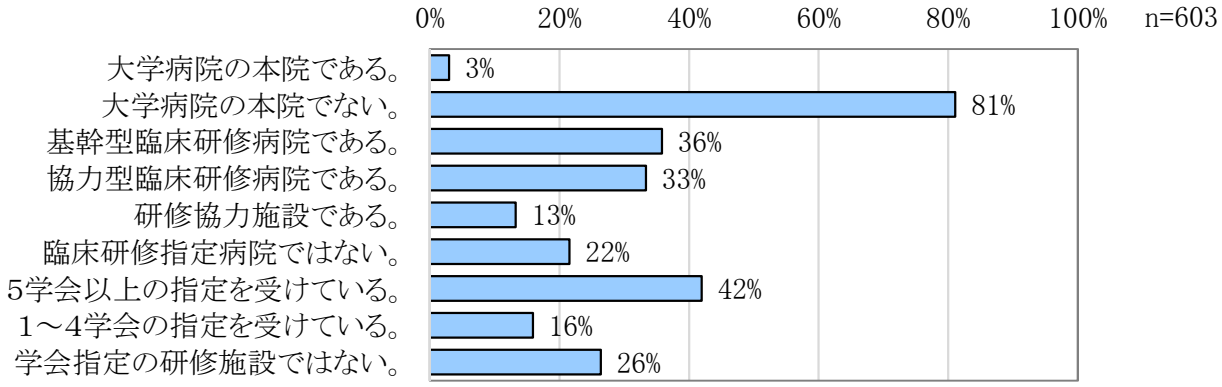
			n (病院数)	医師	研修医	看護師	薬剤師	その他	総職員数
全 体			603	62	9	246	14	187	519
急性期病院	総病床数	100床未満	68	8	0	41	3	58	112
		100-299床	178	27	2	142	8	139	317
		300床以上	225	134	22	480	28	306	972
療養型病院	総病床数	100床未満	29	5	0	29	2	38	79
		100床以上	48	9	0	70	4	142	223
精神科病院			46	12	1	94	4	115	226
その他病院			9	14	0	90	4	109	218

9. 年間退院患者数および死亡退院患者数はそれぞれ何人ですか。

平均(人)

			n (病院数)	退院患者数	うち死亡退院患者数
全 体			603	4947	216
急性期病院	総病床数	100床未満	68	825	33
		100-299床	178	2771	154
		300床以上	225	10337	395
療養型病院	総病床数	100床未満	29	259	55
		100床以上	48	546	106
精神科病院			46	416	40
その他病院			9	1139	89

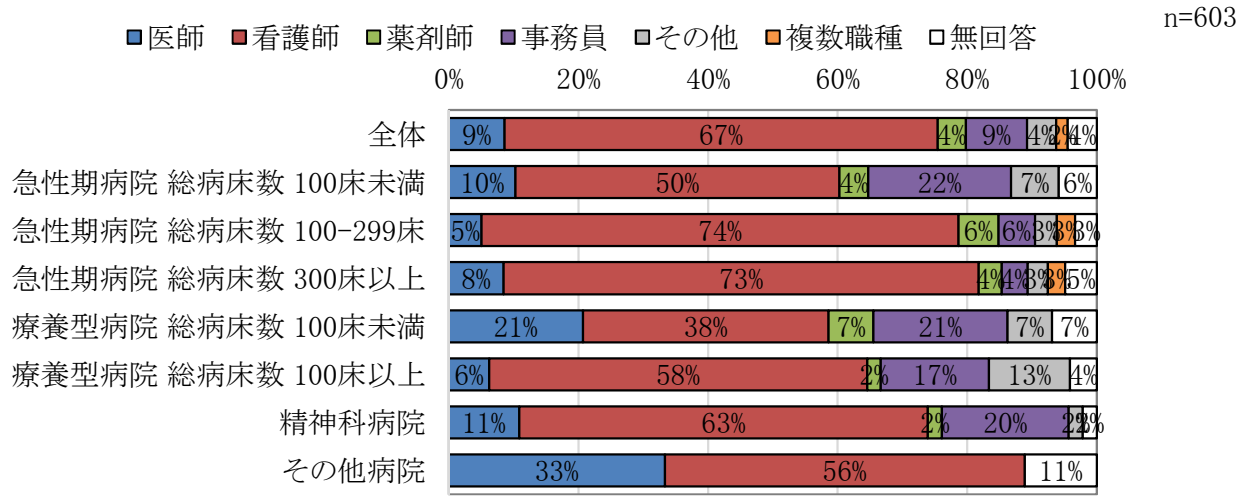
10. 卒前・卒後教育の状況についてそれぞれ回答してください。(当てはまるもの全て選択)



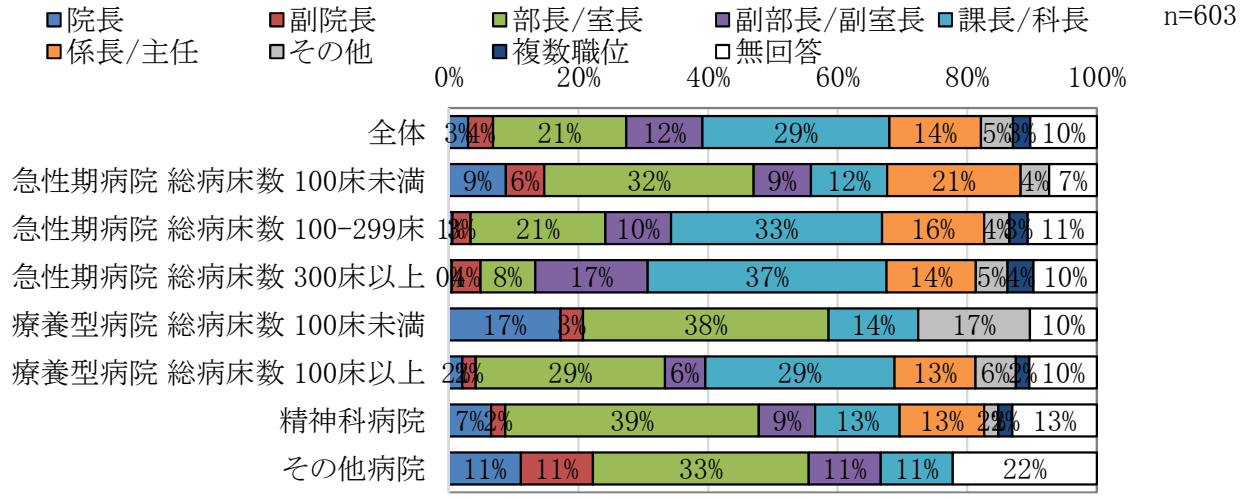
第2部　医療安全管理の体制と施策の評価について

11. 本調査(第2部)に主にご回答いただく方の院内でのお立場をお教えください。(当てはまるもの全て選択)

＜職　種＞

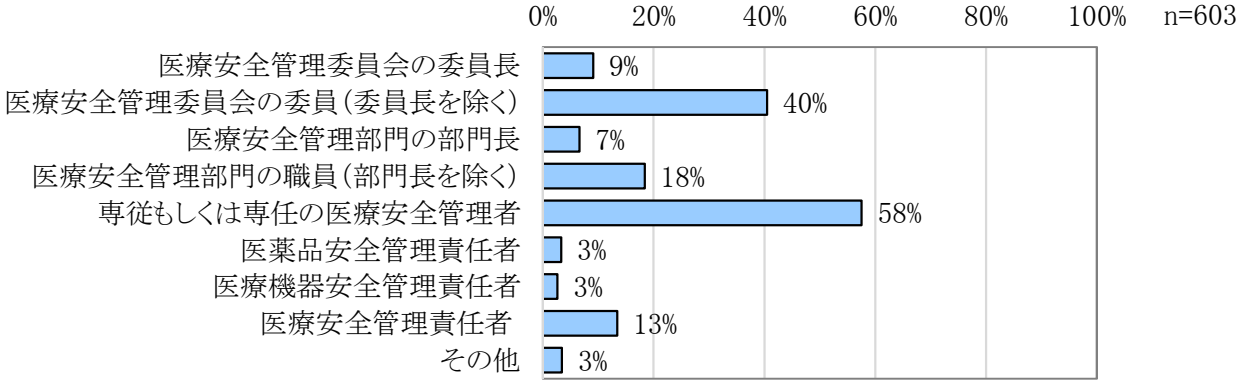


＜職　位＞



(注:師長は「課長/科長」に分類)

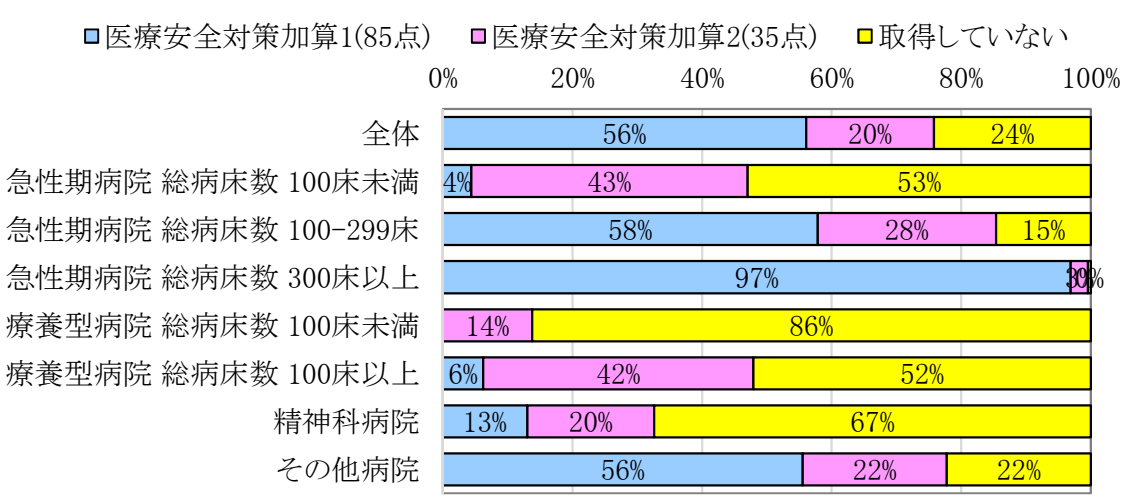
＜医療安全管理の役割＞(当てはまるもの全て選択)



＜医療安全管理の体制＞

12. 診療報酬で医療安全対策加算を取得していますか。

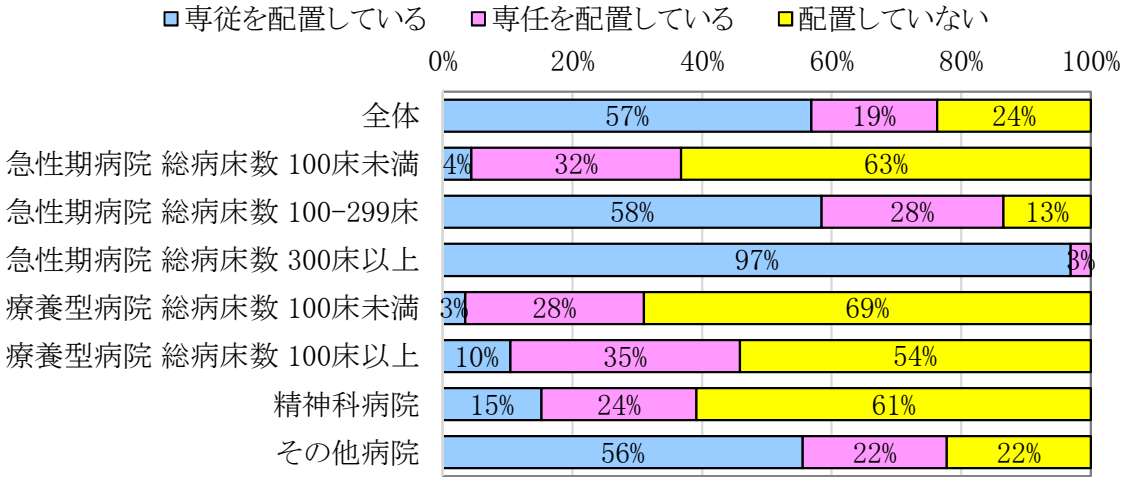
n=603



13. 専従または専任の医療安全管理者を配置していますか。

ただし、専従と専任は次の定義に従う者とします。
専従:他の業務を行わず、医療安全の業務に就業時間の8割以上従事している者
専任:他の業務への従事の有無を問わず、医療安全の業務に就業時間の5割以上従事している者

n=603



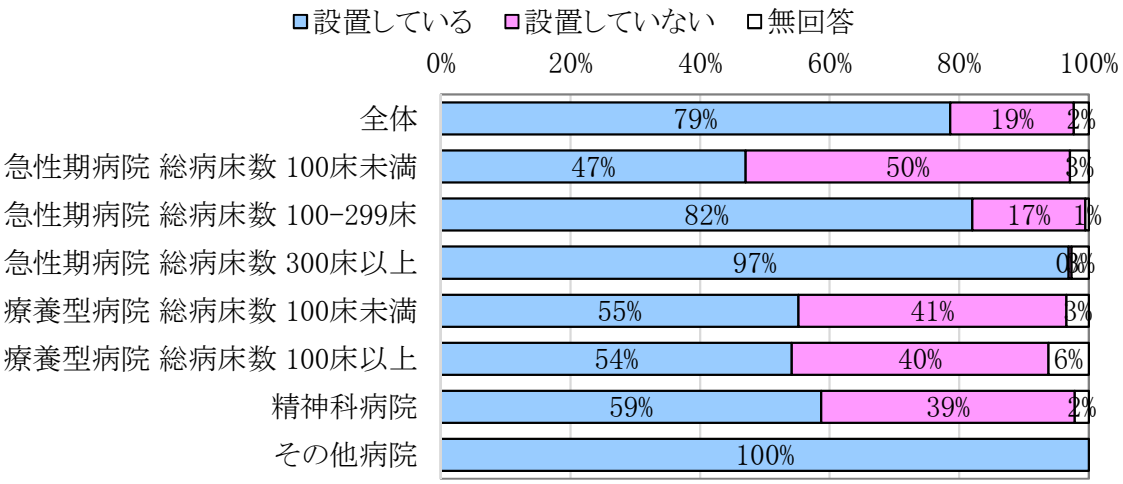
14. 問13で「配置している」と回答した場合、職種別の配置人数を教えてください。

中央値(人)

		専従配置病院(n=343)					専任配置病院(n=117)				
		医師	看護師	薬剤師	事務員	その他	医師	看護師	薬剤師	事務員	その他
全 体		0	1	0	0	0	0	1	0	0	0
急性期病院 総病床数	100床未満	0	1	0	0	0	0	1	0	0	0
	100-299床	0	1	0	0	0	0	1	0	0	0
	300床以上	0	1	0	0	0	0	1	0	0	0
療養型病院 総病床数	100床未満	0	0	0	0	1	1	1	0	1	0
	100床以上	0	1	0	0	0	0	1	0	0	0
精神科病院		0	1	0	0	0	0	1	0	0	0
その他病院		0	2	0	0	0	0	1	0	0	0

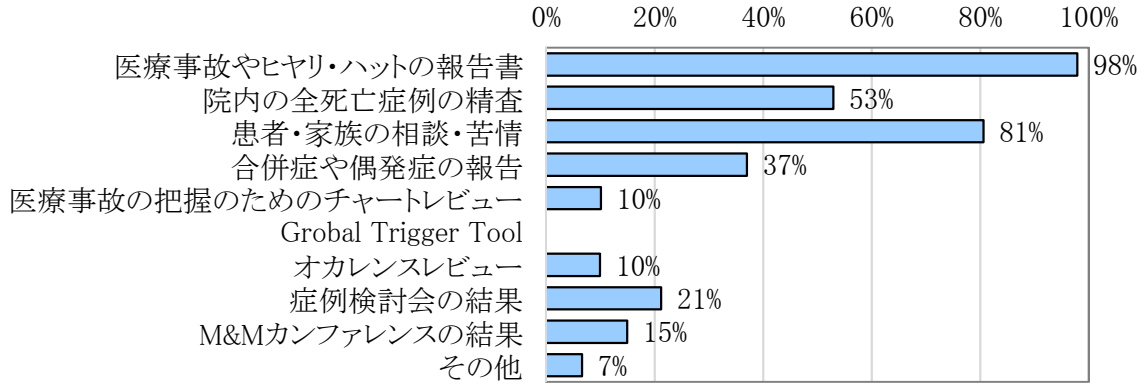
15. 医療安全管理のための部署を設置していますか。

n=603



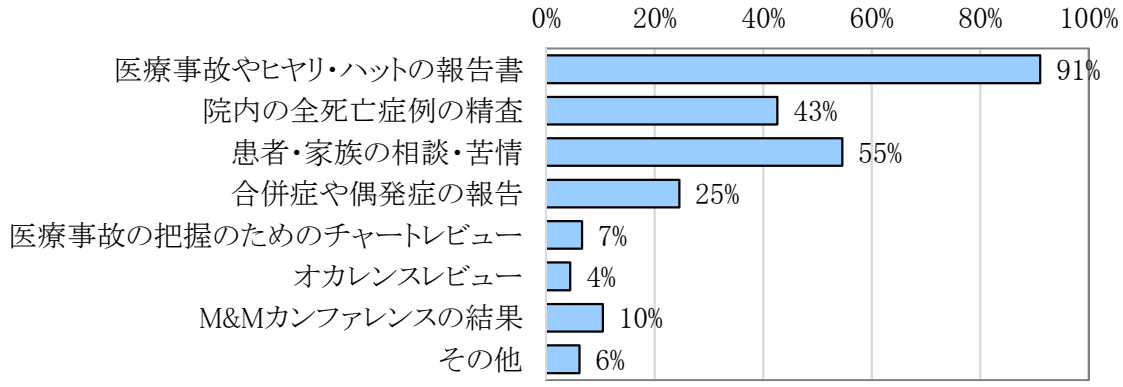
16. 医療安全管理の担当者が、院内で発生した医療事故やヒヤリ・ハットを把握するために、どのような方法を用いていますか。(当てはまるもの全て選択)

n=603



上記の10個の方法のうち、特に重視しているものを**3つ**選んでください。

n=603



17. 問16で「05 医療事故の把握のためのチャートレビュー」を用いていると回答した場合、入院患者の何%がその対象になっていますか。

			n (病院数)	中央値 (%)	平均値 (%)
全 体			61	3.7	9.4
急性期病院	総病床数	100床未満	4	7.0	11.5
		100-299床	20	10.0	7.1
		300床以上	26	2.5	13.7
療養型病院	総病床数	100床未満	4	6.0	8.0
		100床以上	3	5.0	3.7
精神科病院			3	3.4	4.8
その他病院			1	1.0	1.0

18. 問16で「06 Grobal Trigger Tool」を用いていると回答した場合、レビューチームの組織体制、対象患者の範囲、症例の抽出方法・件数など、具体的な運用方法を記載してください。

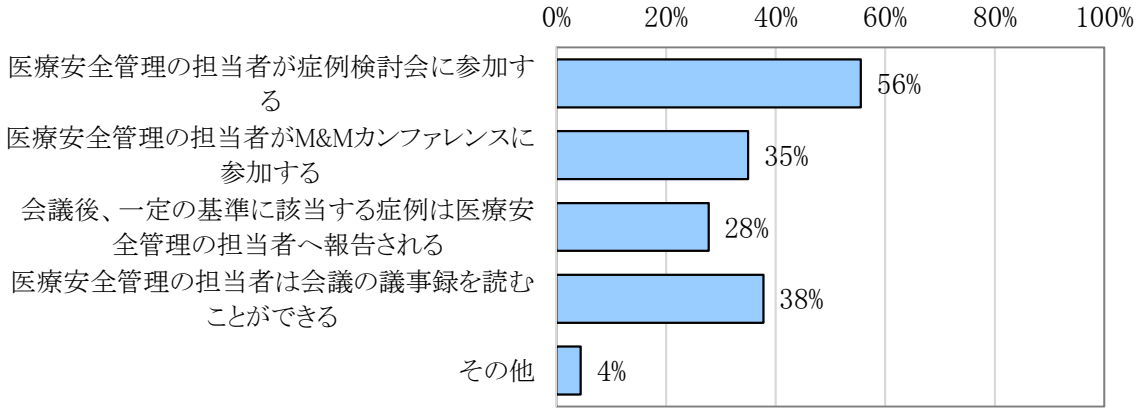
なし

19. 問16で「07 オカレンスレビュー」を用いていると回答した場合、症例の抽出基準を記載してください。

省略

20. 問16で「08 症例検討会の結果」または「09 M&Mカンファレンスの結果」を用いていると回答した場合、医療安全管理の担当者はそれらの情報をどのような方法で把握していますか。(当てはまるもの全て選択)

n=180



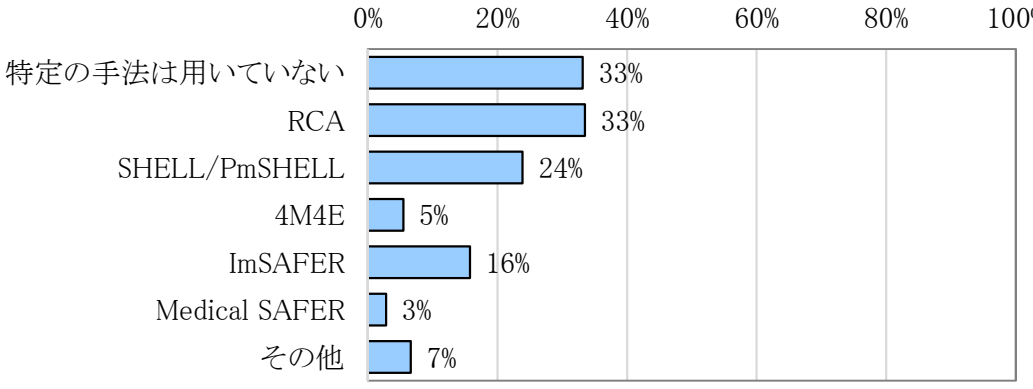
21. 医療安全管理を目的とした**院内報告の件数**は、年間(昨年もしくは昨年度)およそ何件ですか。
(1事例に対し複数の報告がある場合は、延べ報告件数を回答してください。)

n=603

			中央値(件) 医療事故 (レベル3a↑)	ヒヤリ・ハット (レベル2↓)	医療事故とヒヤリ・ハットの合計
全 体			64	695	800
急性期病院	総病床数	100床未満	9	151	158
		100-299床	43	488	557
		300床以上	142	1792	1943
療養型病院	総病床数	100床未満	14	90	115
		100床以上	32	395	442
精神科病院			62	318	423
その他病院			25	342	350

22. 報告された事例(医療事故やヒヤリ・ハット)の分析にどのような手法を用いていますか。(当てはまるもの全て選択)

n=603



08 複数の手法を用いている場合、それらをどのような基準で使い分けていますか。

省略

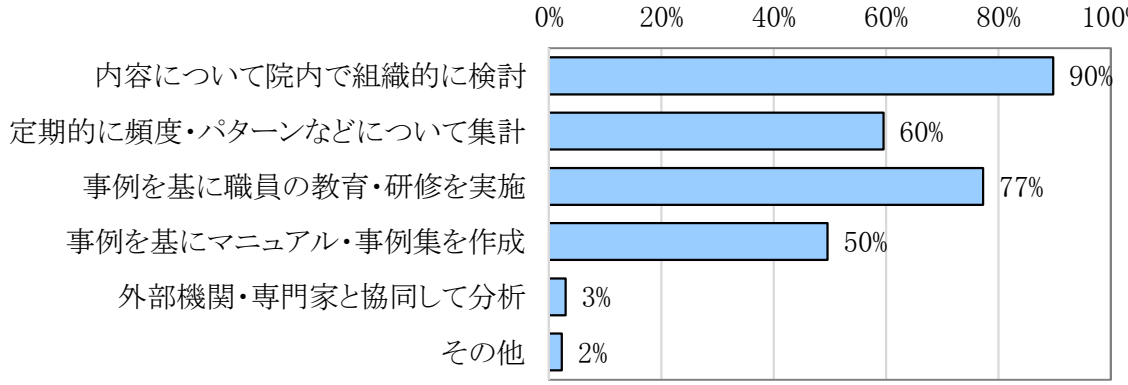
23. RCAやImSAFER、PmSHELLモデル等の手法を用いて分析した件数は、年間（昨年もしくは昨年度）およそ何件ですか。（類似事例をまとめて分析している場合には、まとめて1件とします。）

n=403

			中央値（件） 医療事故（レベル3a↑）	ヒヤリ・ハット（レベル2↓）
全　体			3	8
急性期病院	総病床数	100床未満	2	2
		100-299床	3	6
		300床以上	4	10
療養型病院	総病床数	100床未満	3	2
		100床以上	1	6
精神科病院			2	7
その他病院			6	1

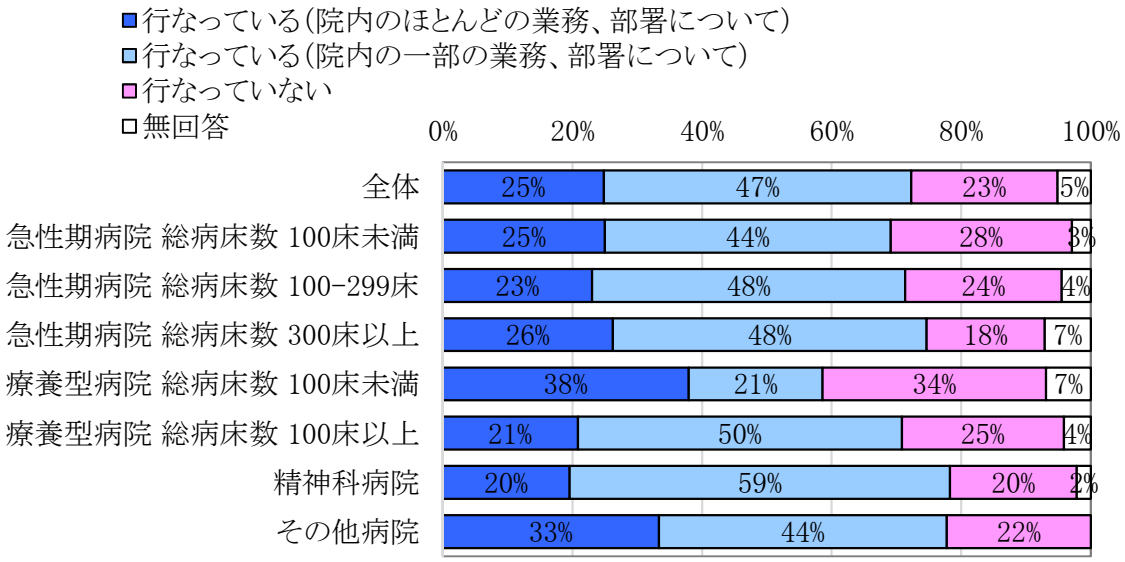
24. 報告された事例・情報をどのように活用していますか。（当てはまるもの全て選択）

n=603

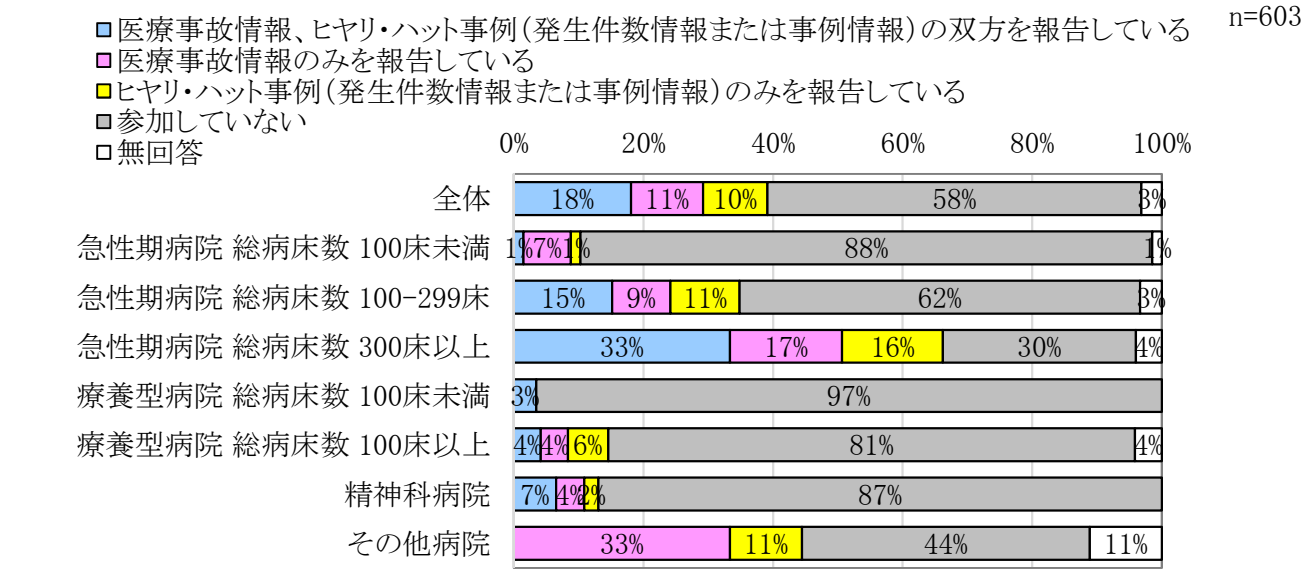


25. 生じやすい医療事故等についてリスク評価を実施していますか。

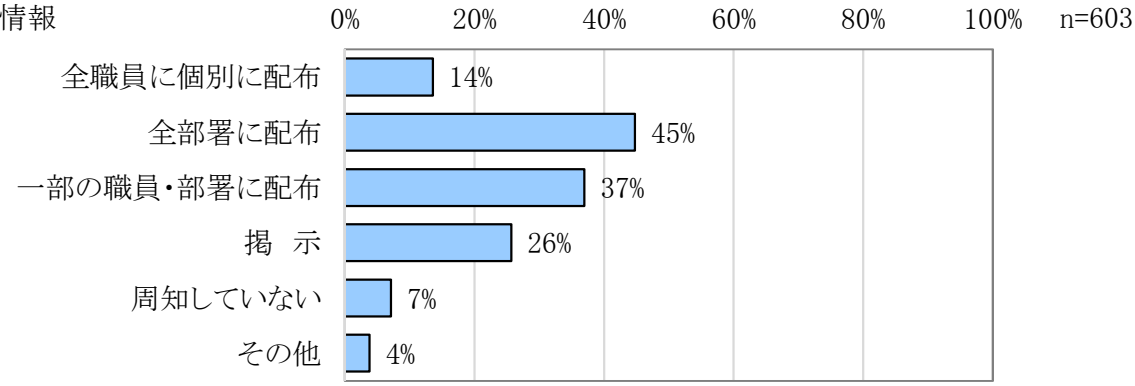
n=603



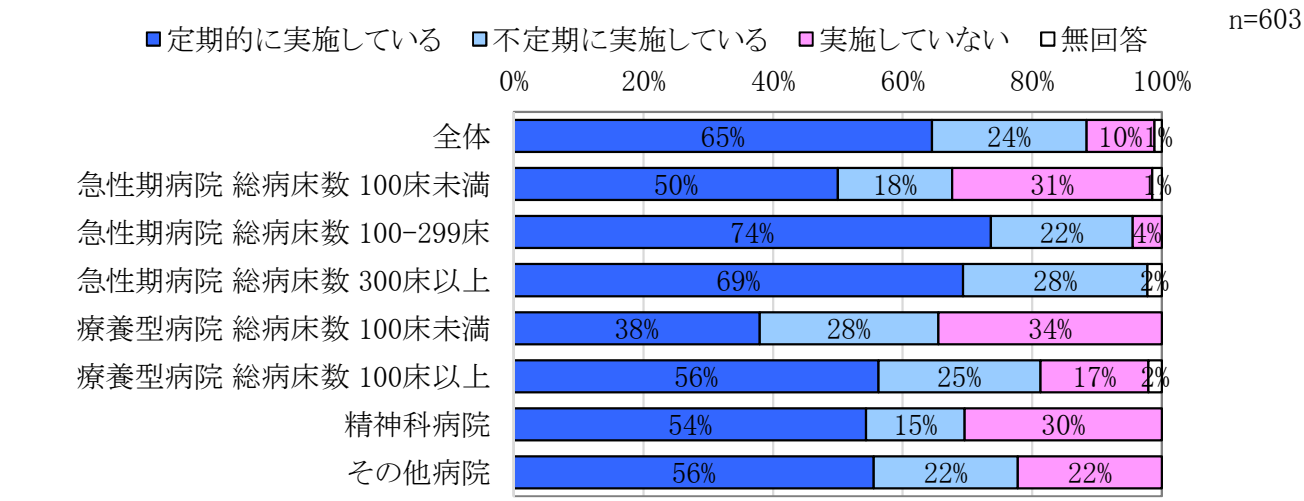
26. 日本医療機能評価機構の医療事故情報収集等事業に参加していますか。



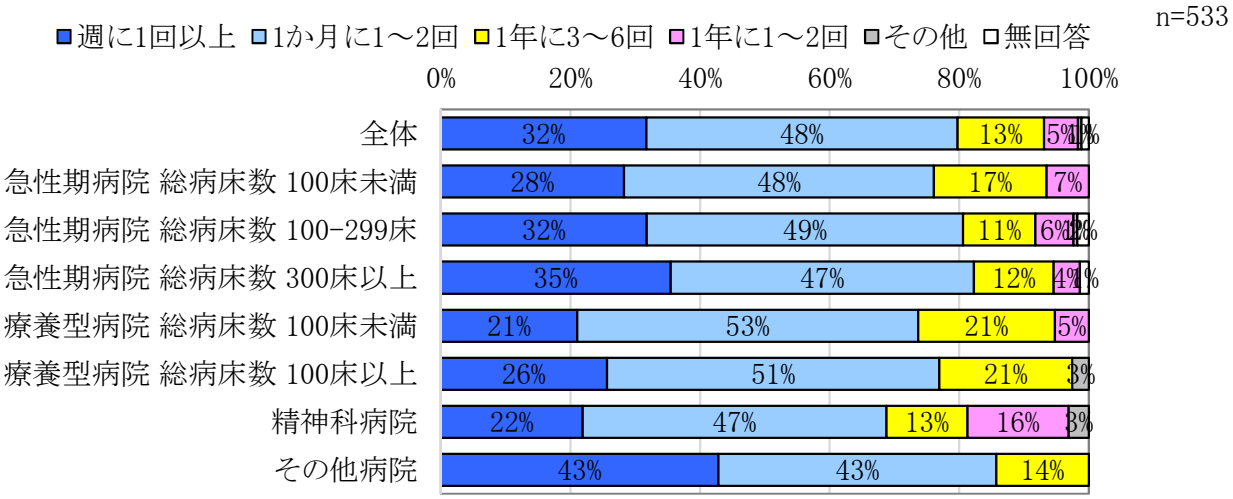
27. 日本医療機能評価機構の医療安全情報を院内で周知していますか。（当てはまるもの全て選択）



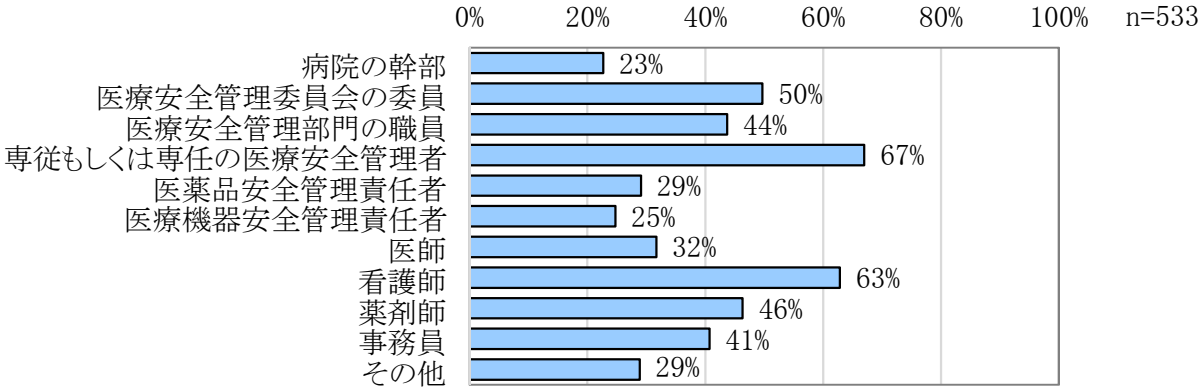
28. 医療安全管理を目的とした職場巡視を実施していますか。



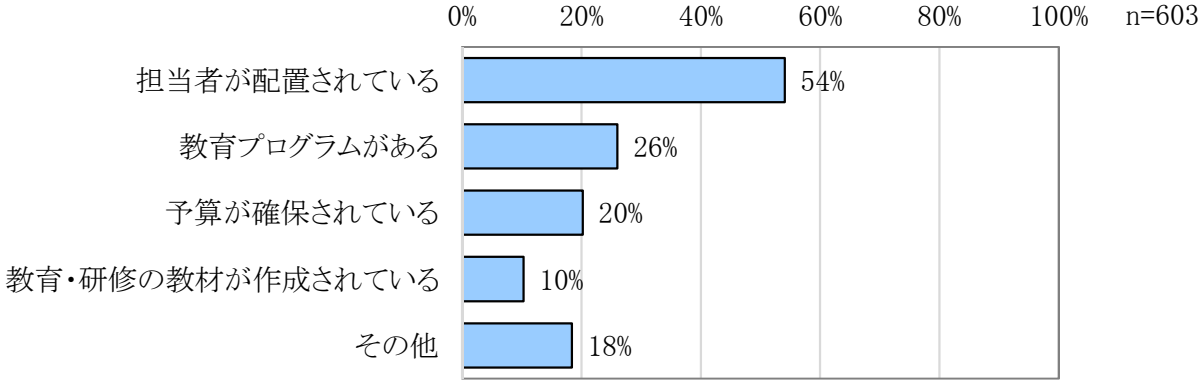
29. 問28で「実施している」と回答した場合、その頻度をお答えください。



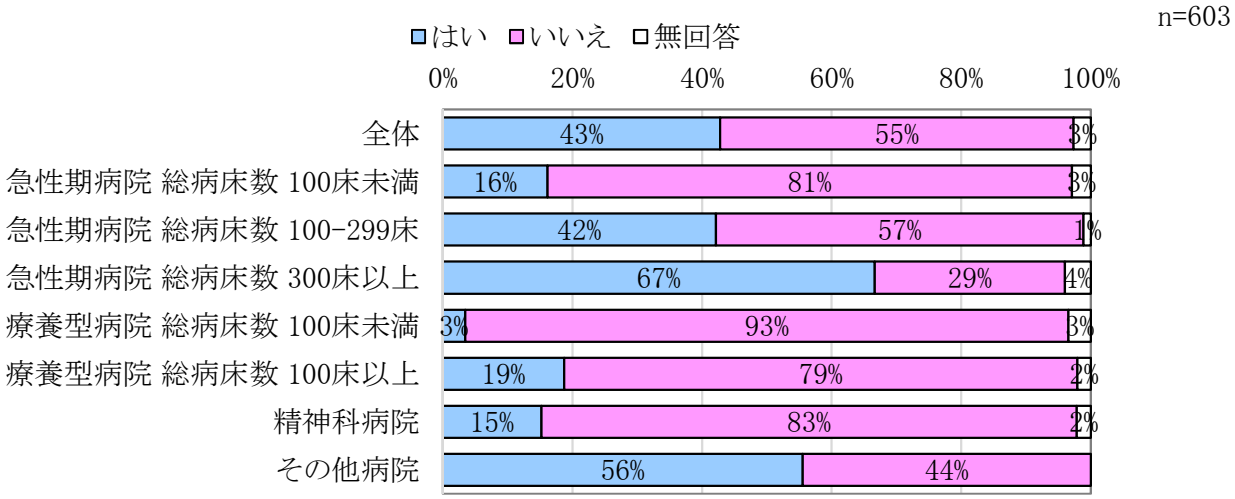
30. 問28で職場巡視を定期的または不定期に「実施している」と回答した場合、その参加者をお答えください。（当てはまるもの全て選択）



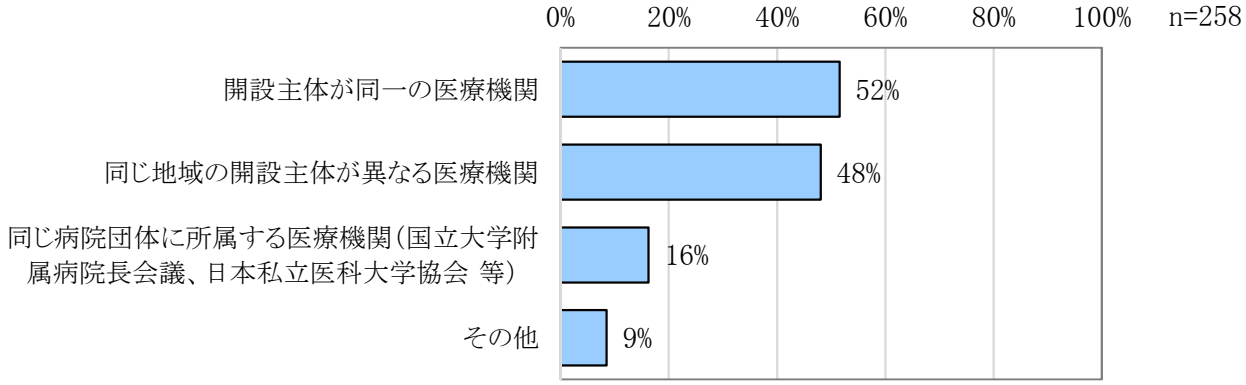
31. 医療安全管理に関する教育・研修の現状についてお答えください。（当てはまるもの全て選択）



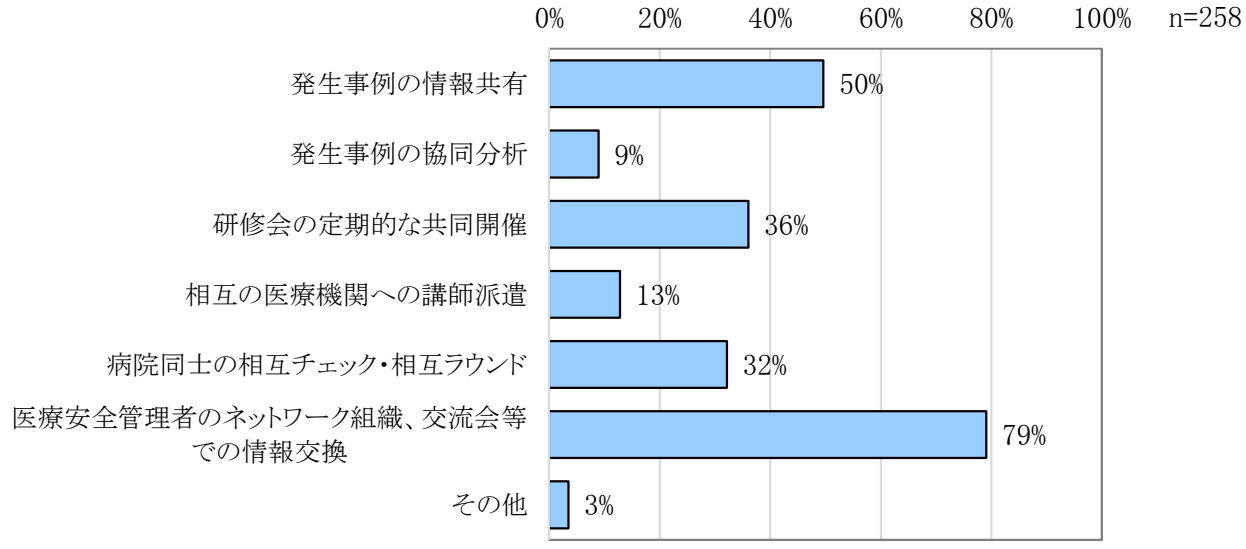
32. 医療安全を目的として、継続的に他の医療機関と協働して活動していますか。



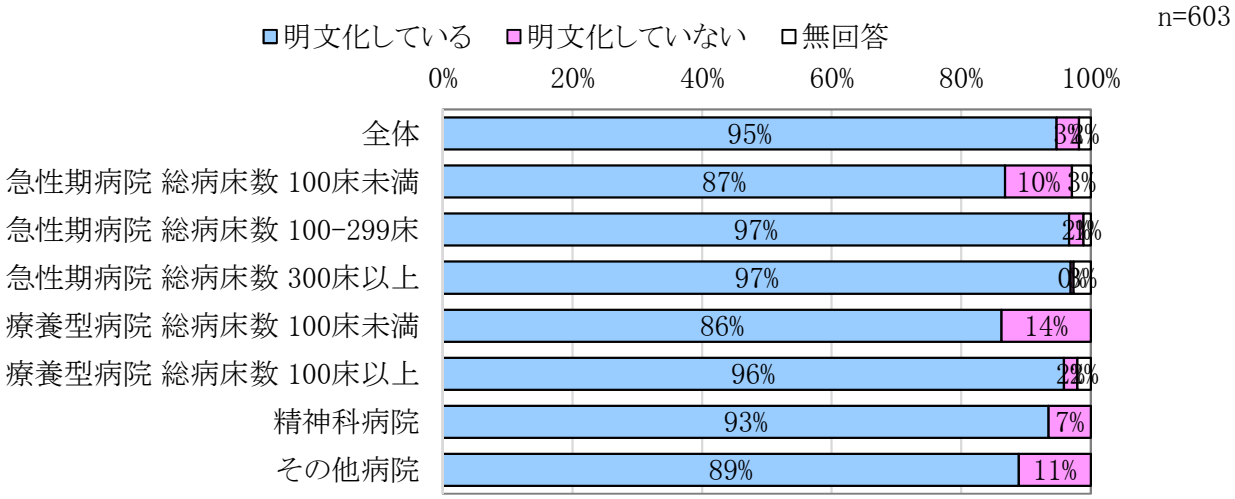
33. 問32で「はい」と回答した場合、どのような医療機関と協働していますか。（当てはまるもの全て選択）



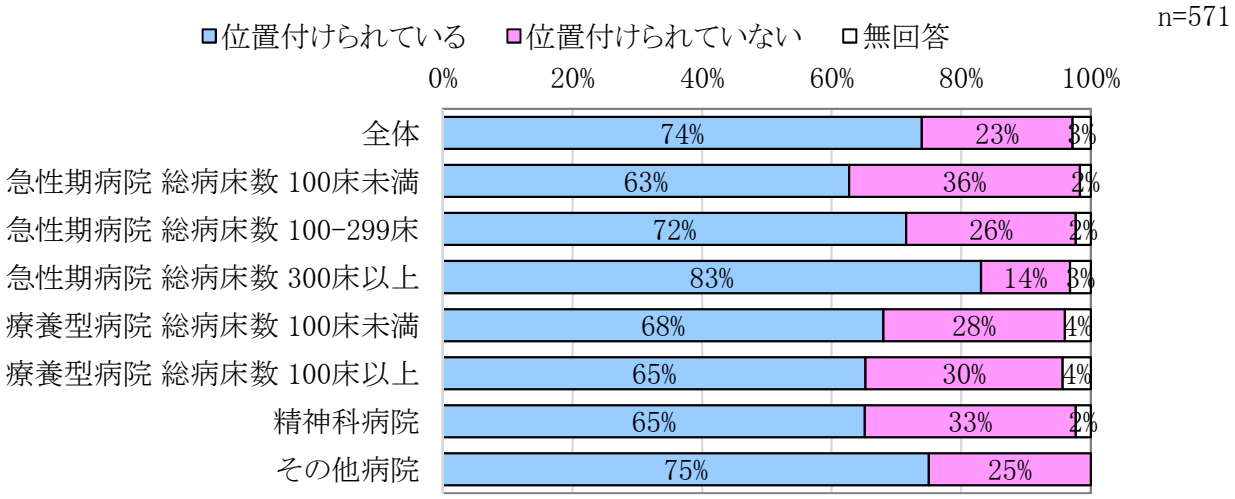
34. 問32で「はい」と回答した場合、協働している内容を具体的にお答えください。（当てはまるもの全て選択）



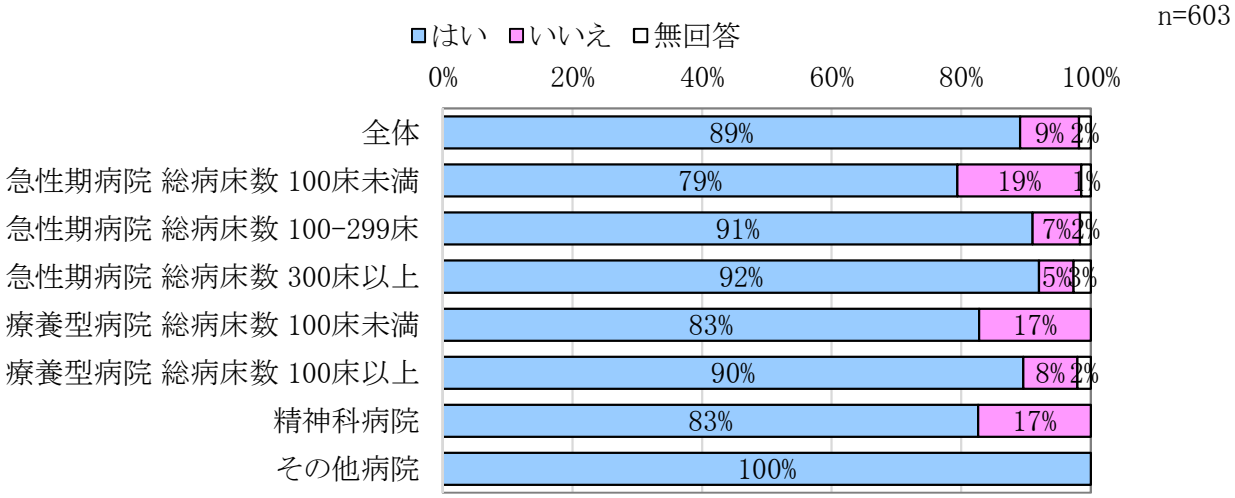
35. 病院の経営理念・目標等を明文化していますか。



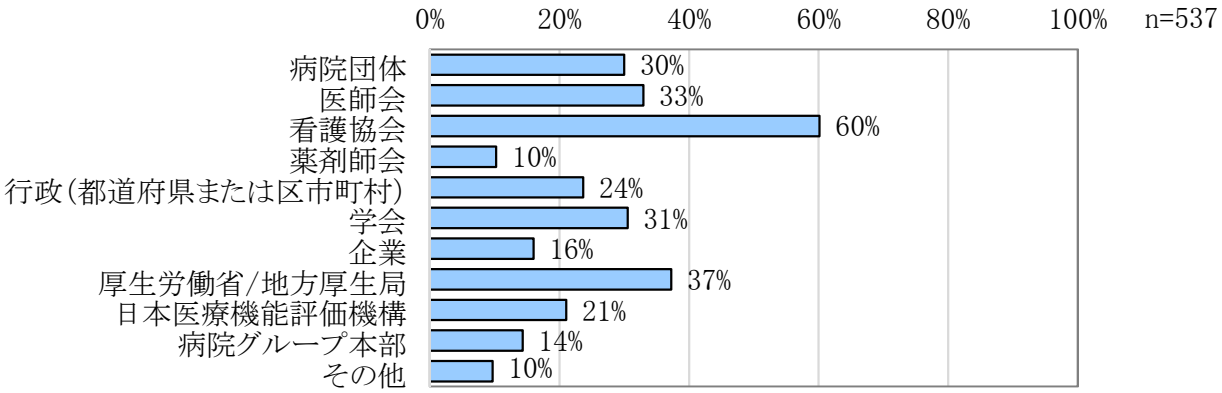
36. 問35で「明文化している」と回答した場合、その中に院内の医療安全管理が位置付けられていますか。



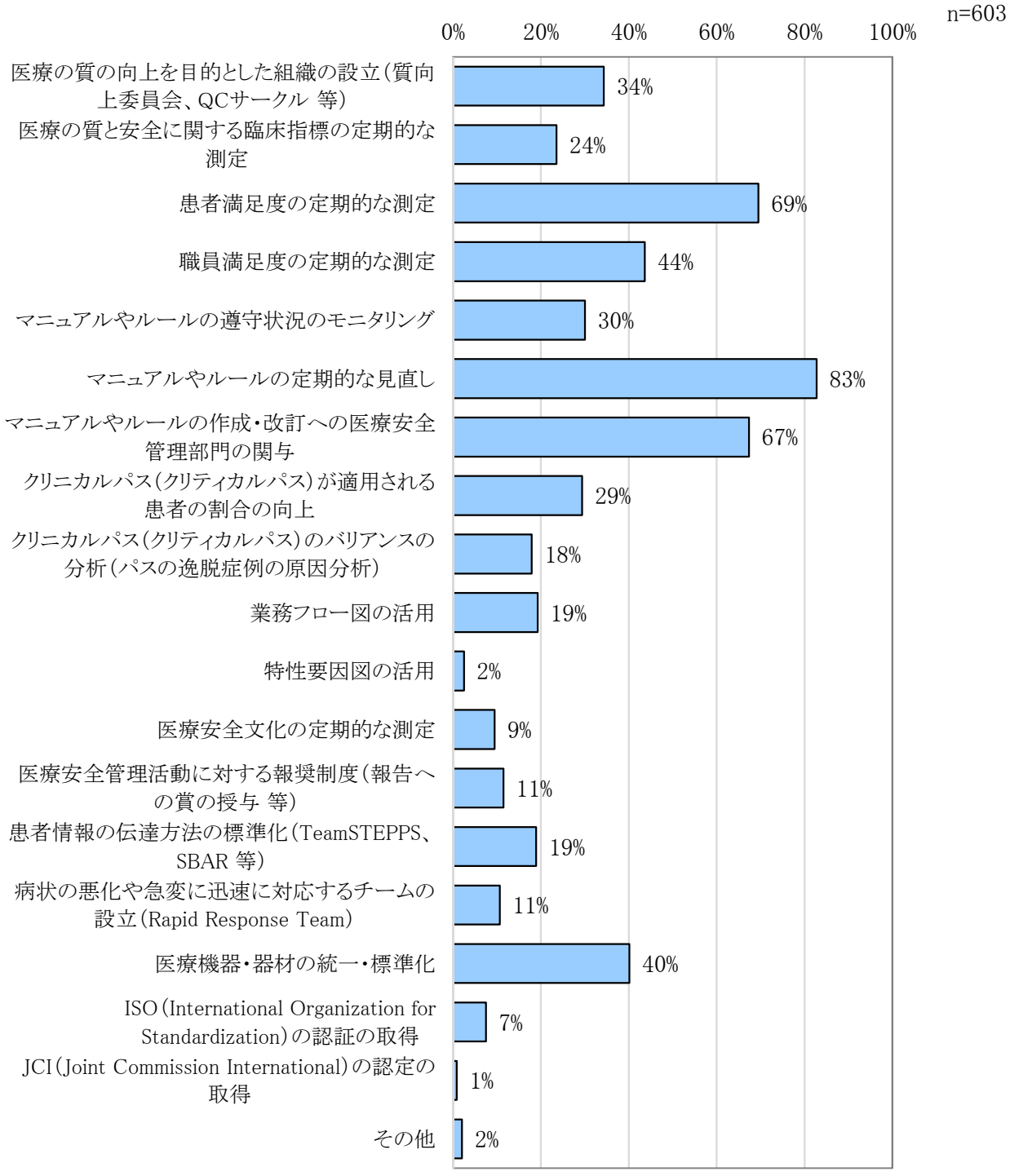
37. 過去1年以内に、外部機関による医療安全に関する教育・研修を、貴院の幹部や医療安全の実務担当者が受けましたか。



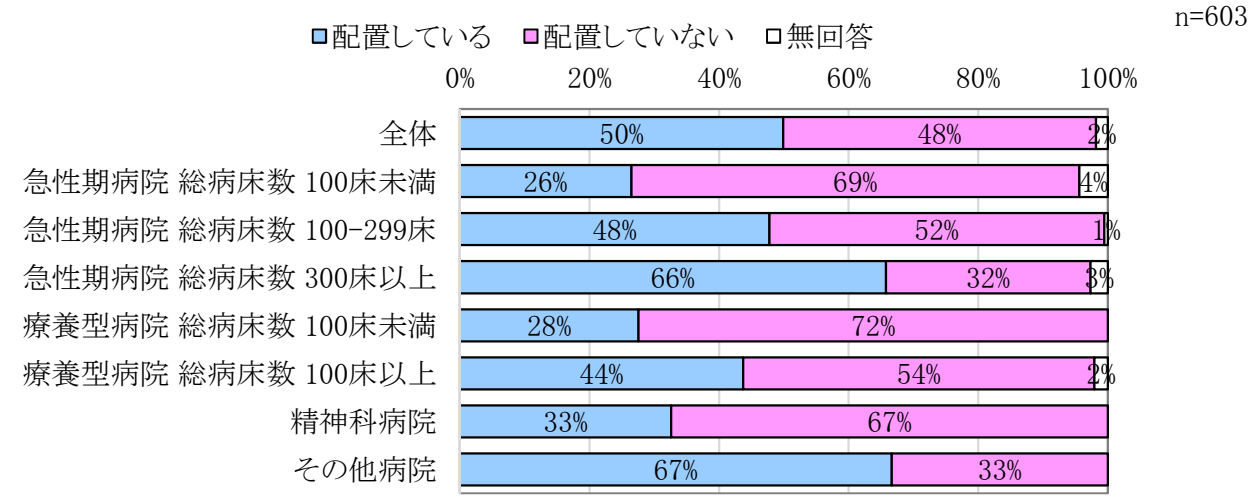
38. 問37で「はい」と回答した場合、その医療安全に関する教育・研修を主催している団体は何でしたか。（当てはまるもの全て選択）



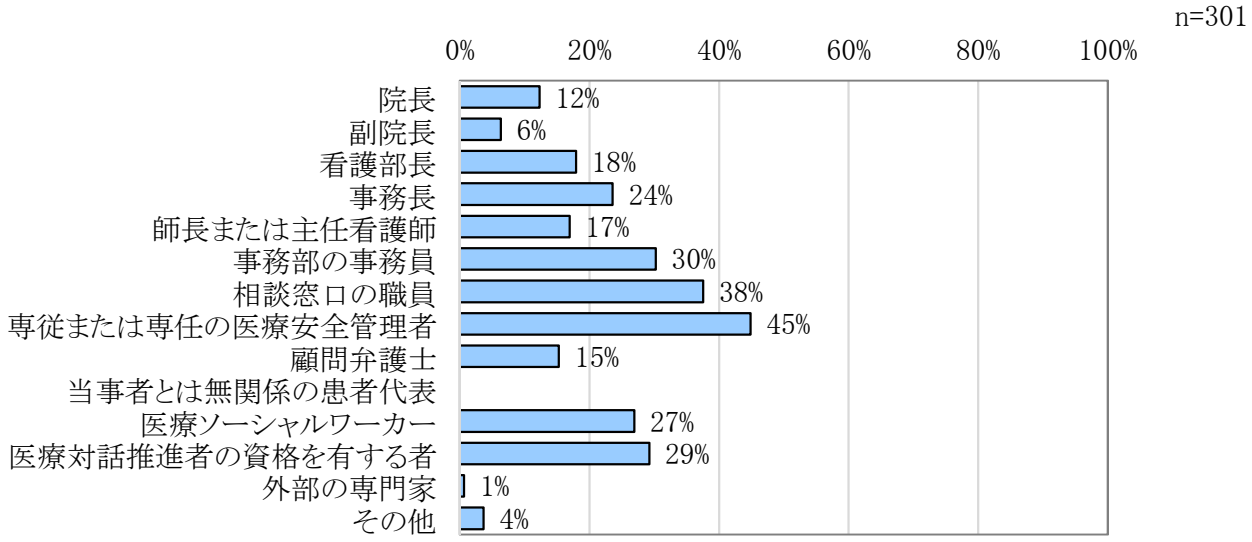
39. 貴院で実施されている医療の質向上を目的とした取組みを回答してください。（当てはまるもの全て選択）



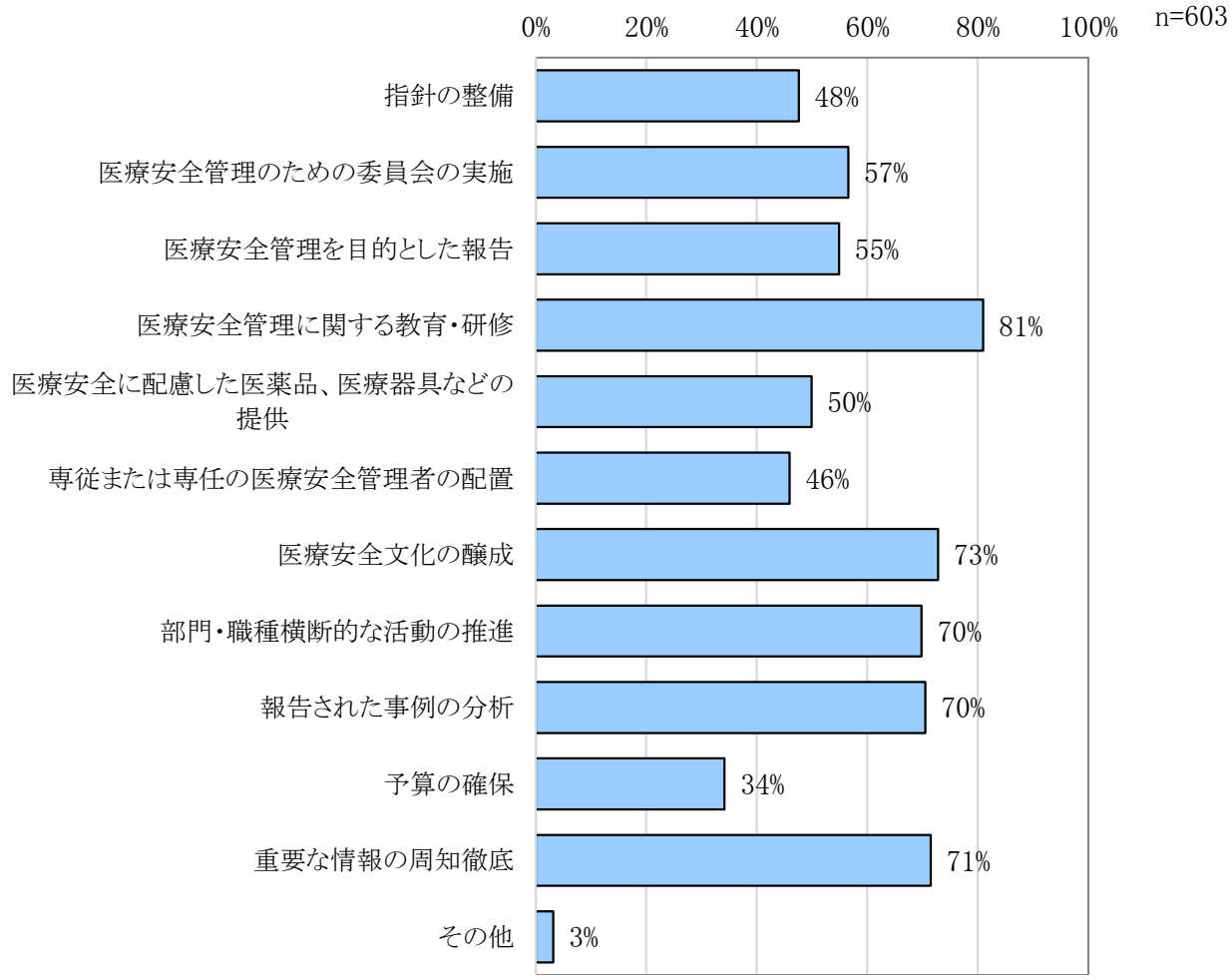
40. 医療紛争が起きた際、当事者である患者と医療者の対話を促進する役割を担う者（医療対話推進者等）を配置していますか。



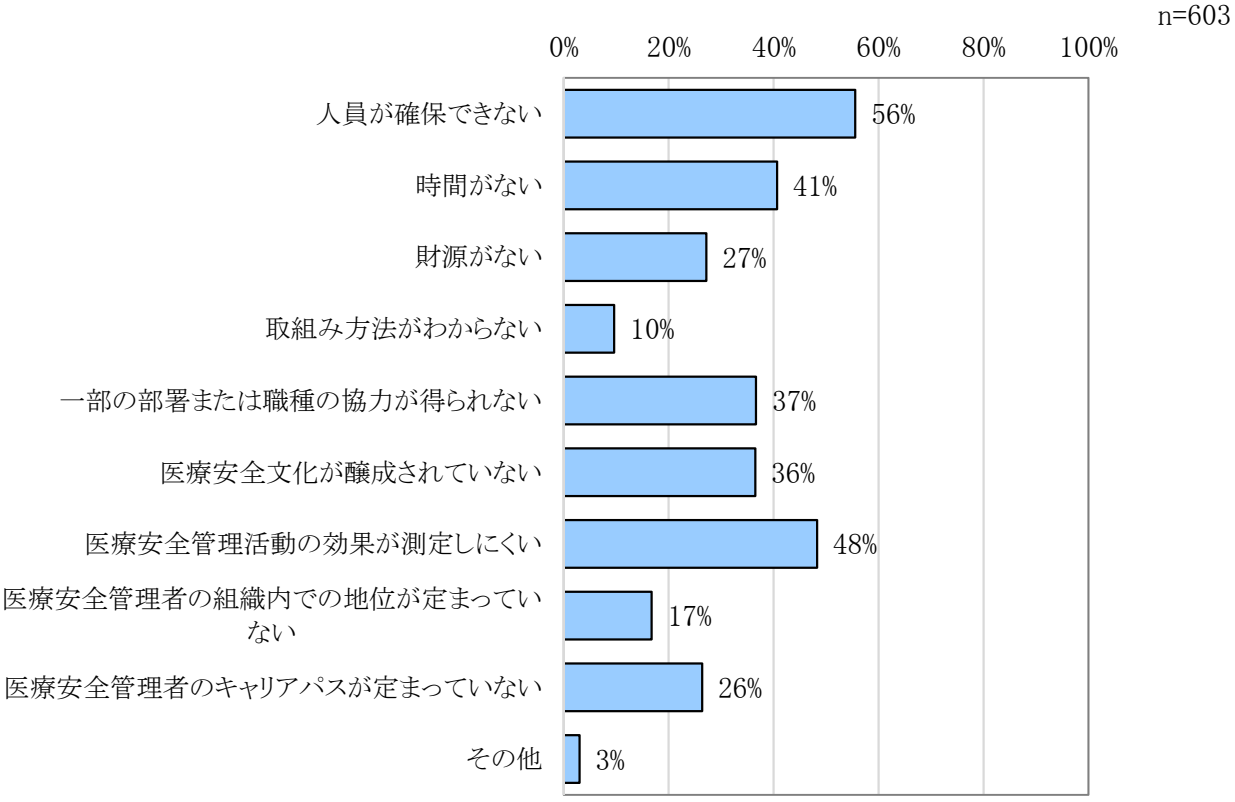
41. 問40で「配置している」と回答した場合、それはどのような立場の方ですか。（当てはまるもの全て選択）



42. 貴院として、医療安全のために特に重要と考えられる事項は何ですか。（当てはまるもの全て選択）



43. 貴院で安全確保のための方策を実施するにあたっての問題点は何ですか。（当てはまるもの全て選択）



44. 貴院の医療安全管理活動により、医療安全の向上に効果があったと思われる事例がありましたら、下の例にならってその内容をお教えください。

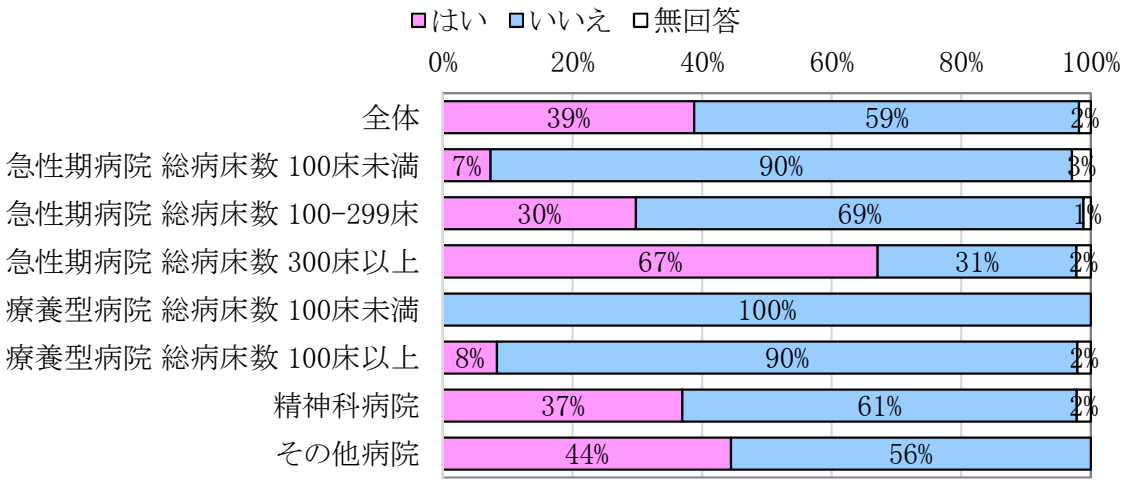
	部門／部署	内　容
例	*病棟*	*デバイスの変更により、ラインの誤接続がなくなった。*
01 事例	省略	省略
02 事例	省略	省略

＜医療事故への対応＞

45. <u>最近3年以内に</u>、患者さんが死亡し、あるいは重篤な後遺障害を残すような医療事故を経験しましたか。†

（†国立大学医療安全管理協議会による分類でレベル5またはレベル4bに該当する症例）

n=603



「はい」の場合、それは何件ですか。

中央値（件）

			n（病院数）	死亡症例	重篤な後遺障害が残った症例
全　体			234	1.0	1.0
急性期病院	総病床数	100床未満	5	1.0	0.0
		100-299床	53	1.0	0.0
		300床以上	151	2.0	1.0
療養型病院	総病床数	100床未満	0	－	－
		100床以上	4	1.0	0.0
精神科病院			17	2.0	0.0
その他病院			4	4.0	2.0

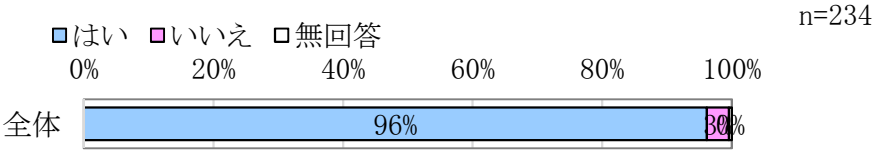
そのうち、院内医療事故調査委員会等により、原因究明し、その結果を報告書等にとりまとめたのは何件ですか。

中央値（件）

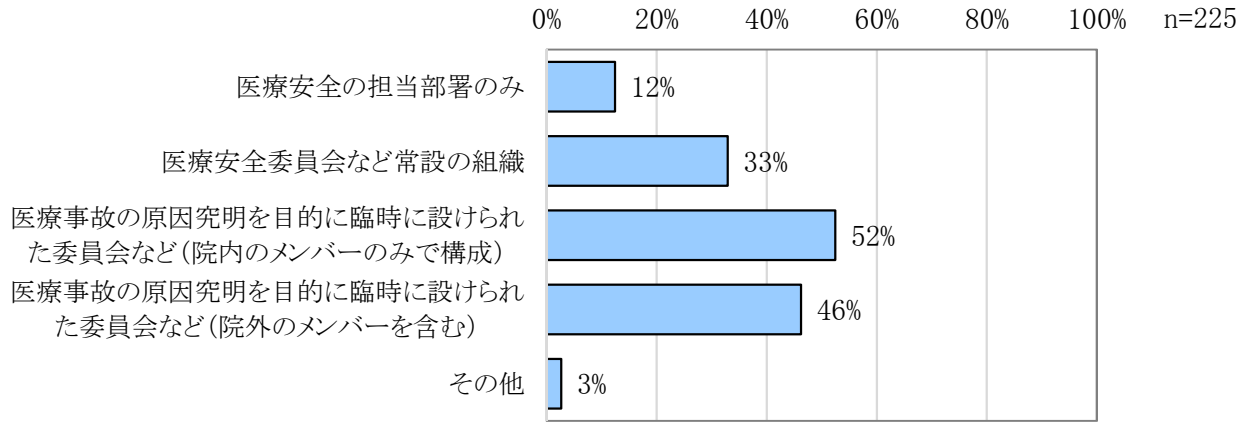
			n（病院数）	原因究明・報告書作成した症例
全　体			234	1.0
急性期病院	総病床数	100床未満	5	1.0
		100-299床	53	1.0
		300床以上	151	1.0
療養型病院	総病床数	100床未満	0	－
		100床以上	4	3.5
精神科病院			17	1.0
その他病院			4	1.0

問45で「はい」と回答された場合、その医療事故の原因究明の方法や事故報告書の取り扱い等についてお聞きします。もし、2例以上の重大な医療事故（死亡あるいは重篤な後遺障害が残った事例）を経験された場合には、**もっとも最近のもの**について回答して下さい。

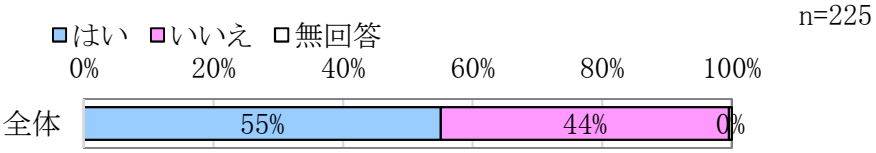
46. 医療事故の原因究明を行ないましたか。



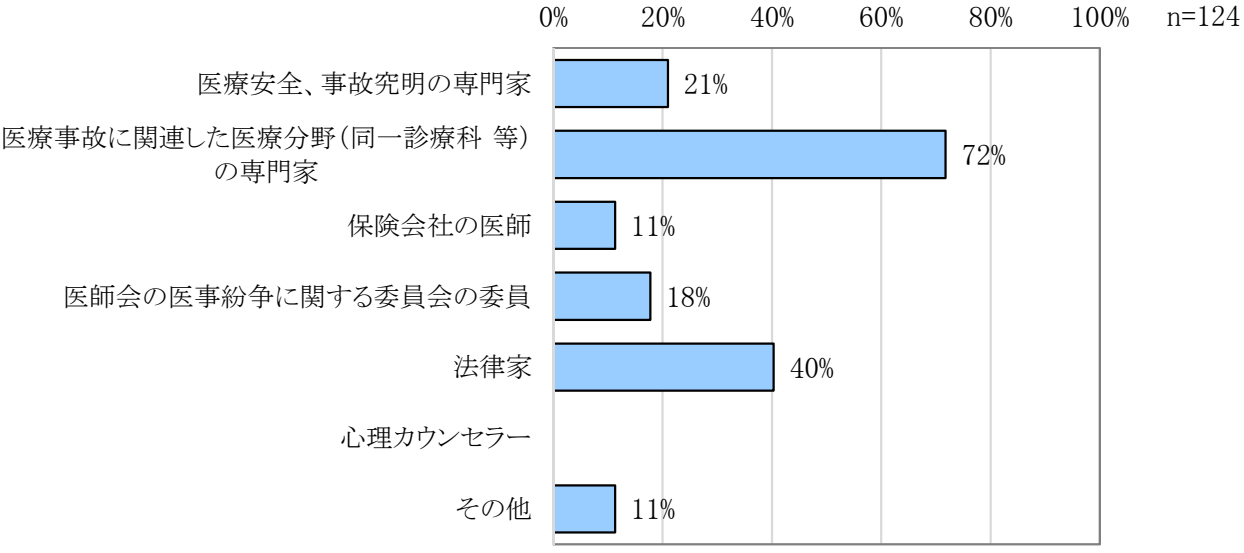
47. 原因究明はどのような組織で行ないましたか。（当てはまるもの全て選択）



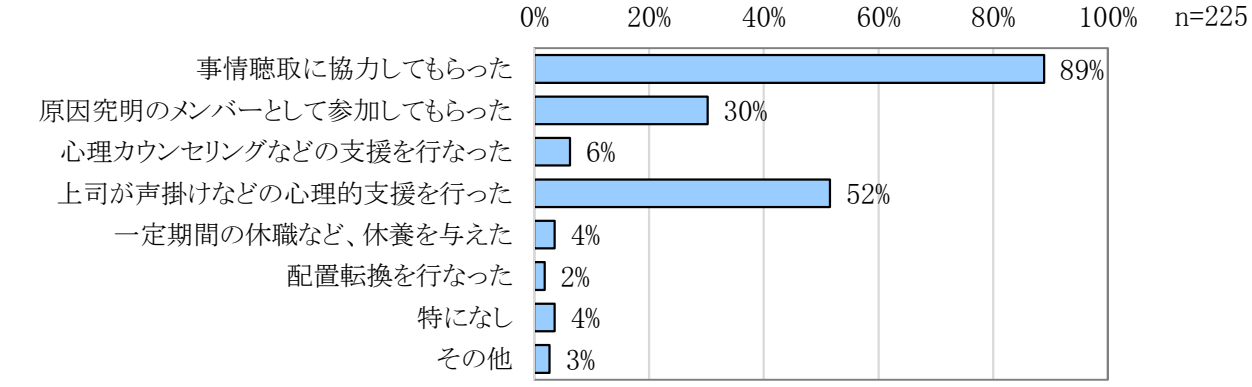
48. 原因究明にあたって外部の専門家の支援を受けましたか。



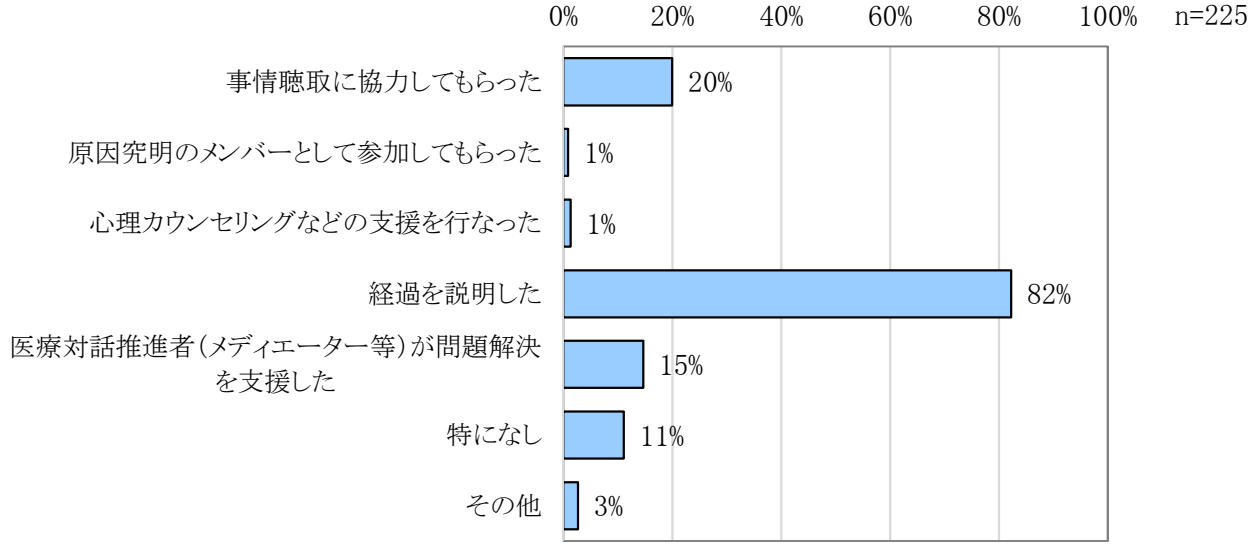
49. 問48で「はい」と回答した場合、それはどのような方ですか。（当てはまるもの全て選択）



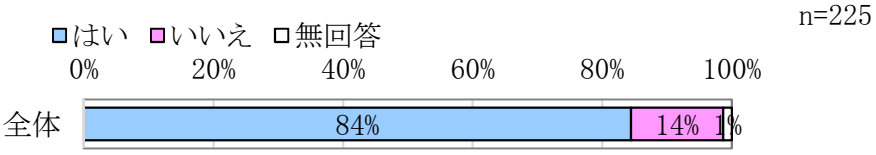
50. 原因究明にあたって当事者の職員への対応はどうしましたか。（当てはまるもの全て選択）



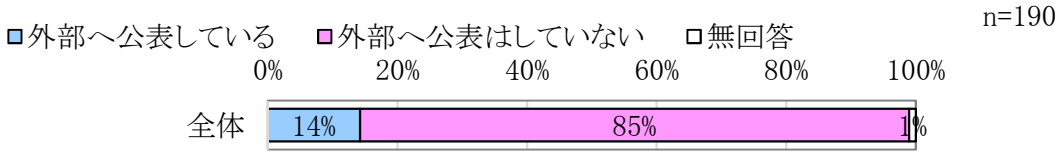
51. 原因究明にあたって患者・家族への対応はどうしましたか。（当てはまるもの全て選択）



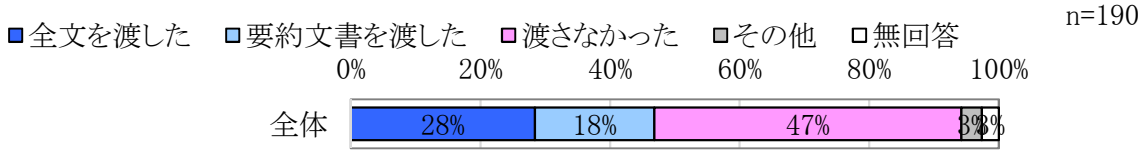
52. 事故報告書は作成しましたか。



53. 問52で事故報告書を作成したと回答した場合、その報告書は誰でも閲覧可能な形で外部へ公表していますか。



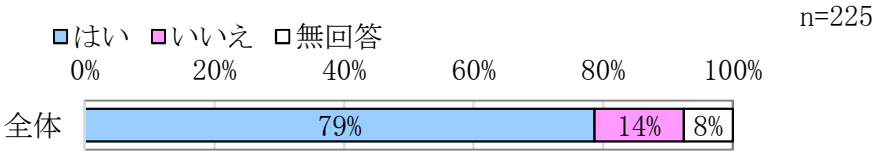
54. 問52で事故報告書を作成したと回答した場合、その事故報告書は患者・家族に渡しましたか。



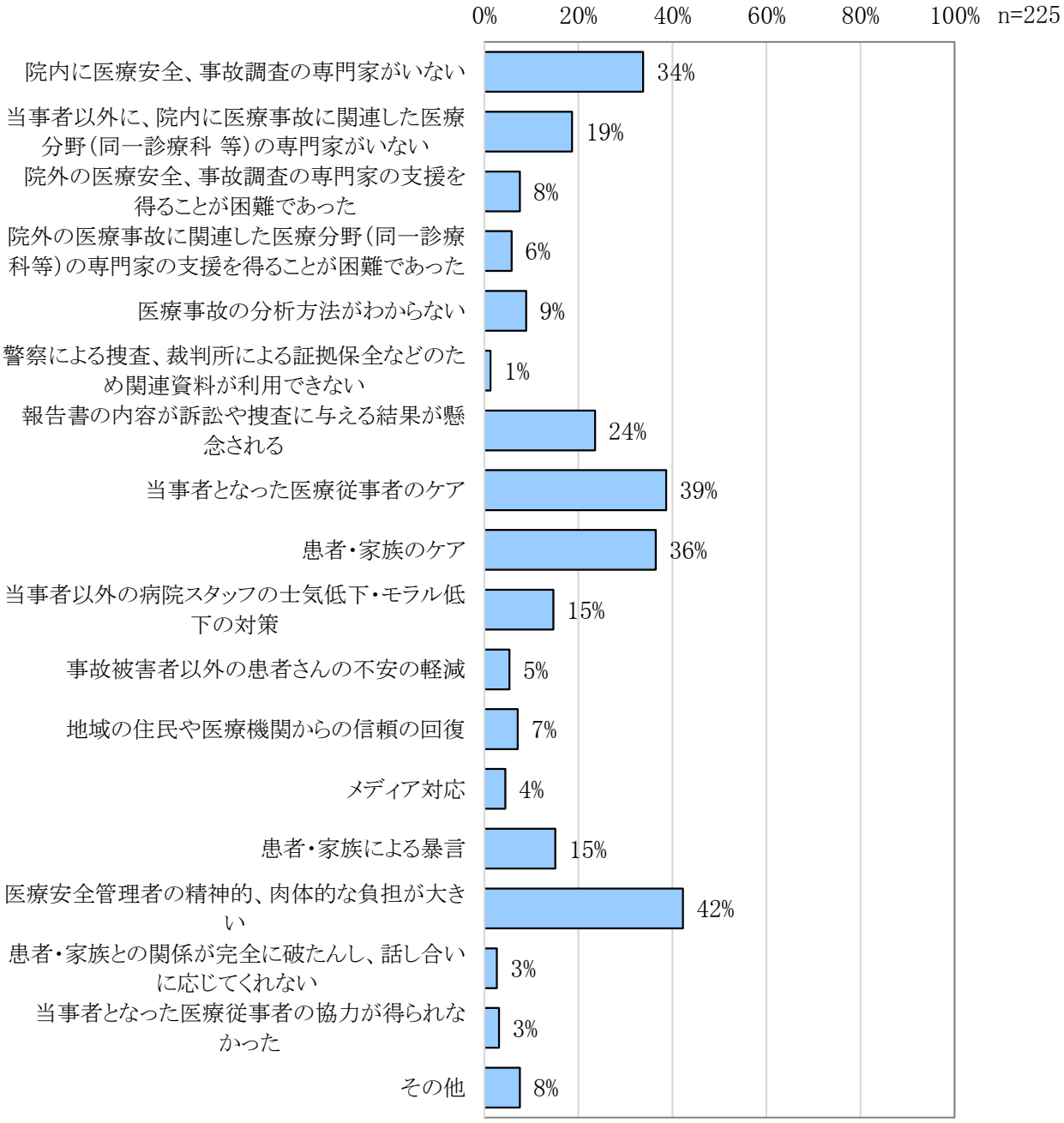
55. 問54で「全文を渡した/要約文書を渡した/渡さなかった/その他」を選択した理由は何ですか。

（省略　　）

56. 原因究明の結果について患者・家族へ説明しましたか。



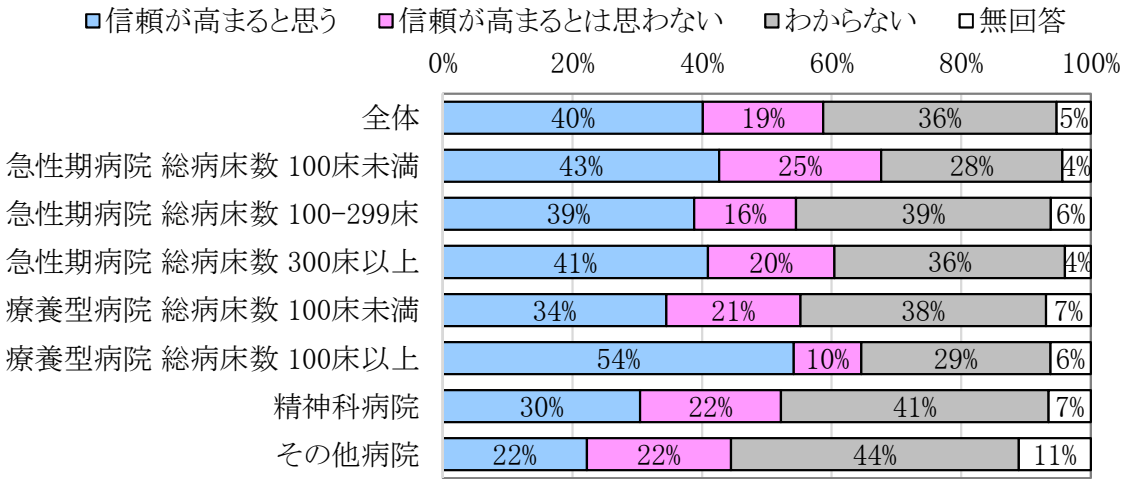
57. 原因究明全般にあたって困ったことは何ですか。（当てはまるもの全て選択）



58. 患者・家族に医療事故が起きた事を説明することにより、患者・家族の医療機関への信頼が高まると思いますか。

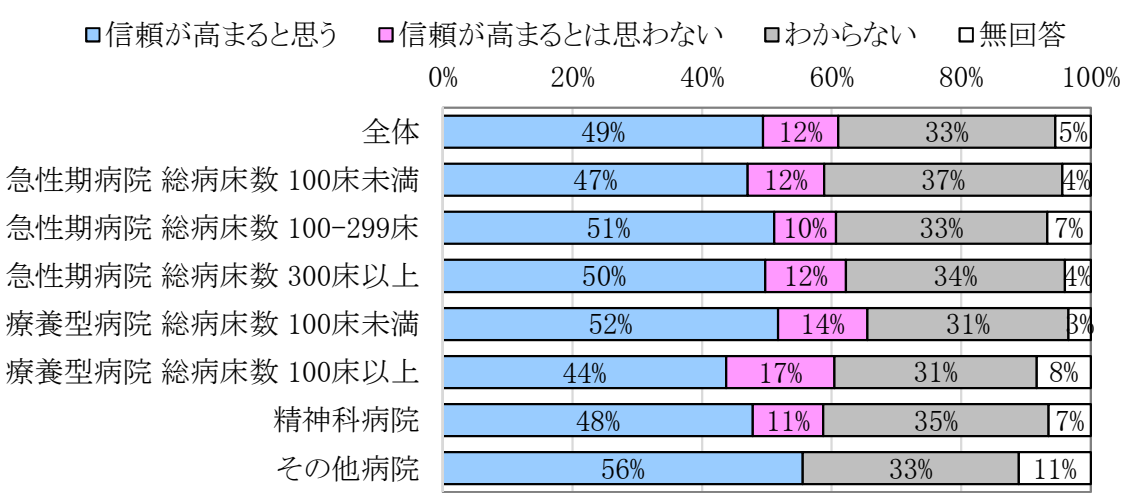
＜患者に健康被害が**あった**場合＞

n=603



＜患者に健康被害が**なかった**場合＞

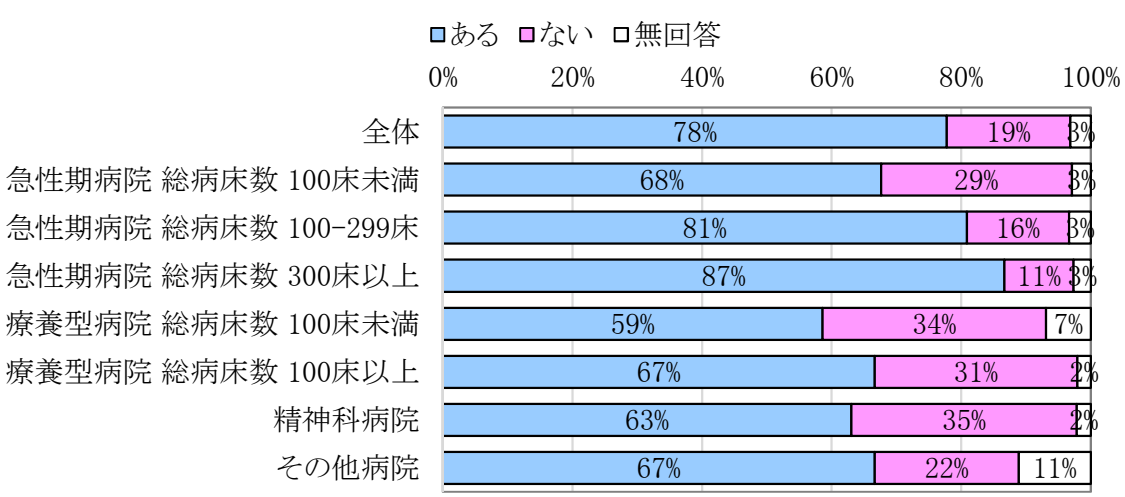
n=603



＜医療事故調査制度＞

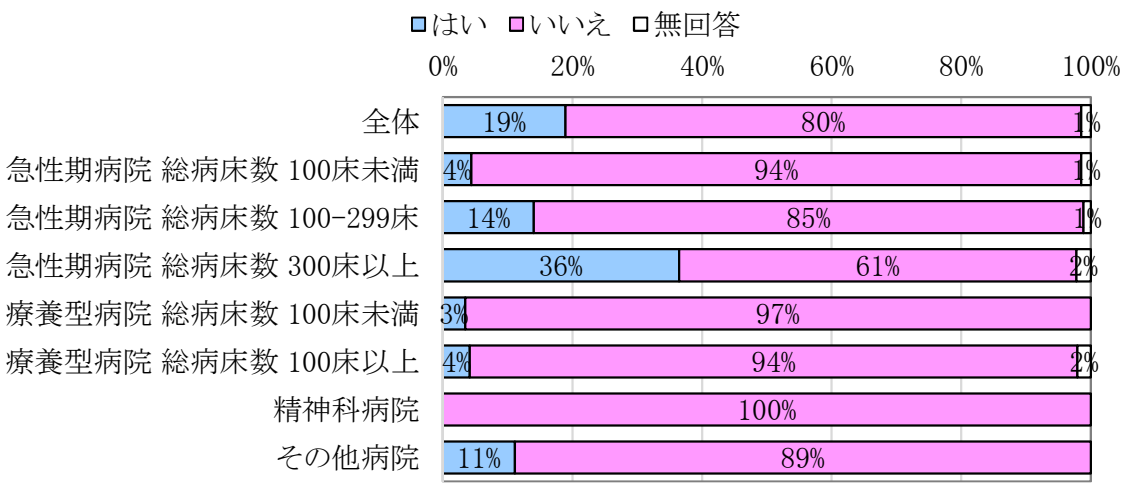
59. 医療事故調査・支援センターへの報告が必要な医療事故が発生した際の調査方法について定めた指針やマニュアルはありますか。

n=603



60. 医療事故調査制度の開始後(2015年10月以降)に、医療事故調査・支援センター(日本医療安全調査機構)へ医療事故の届け出をしましたか。

n=603



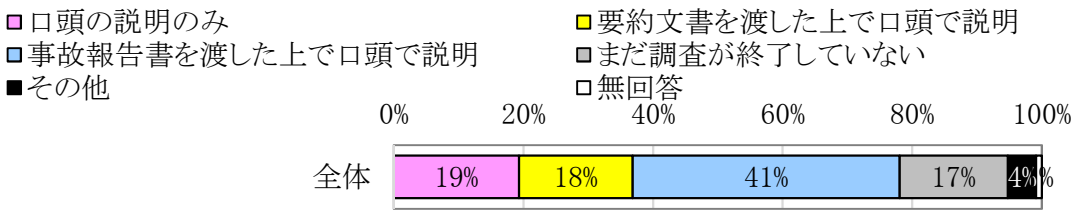
「はい」の場合、届け出たのは何件ですか。

中央値(件)

			n (病院数)	届出件数
全　体			114	1
急性期病院	総病床数	100床未満	3	1
		100-299床	25	1
		300床以上	82	1
療養型病院	総病床数	100床未満	1	-
		100床以上	2	1
精神科病院			0	-
その他病院			1	1

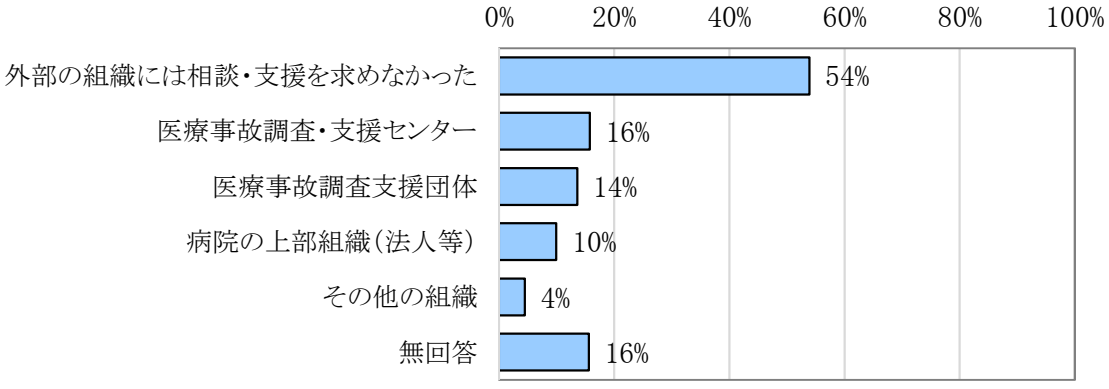
61. 問60で「はい」と回答した場合、遺族への説明はどのように行いましたか。

n=114

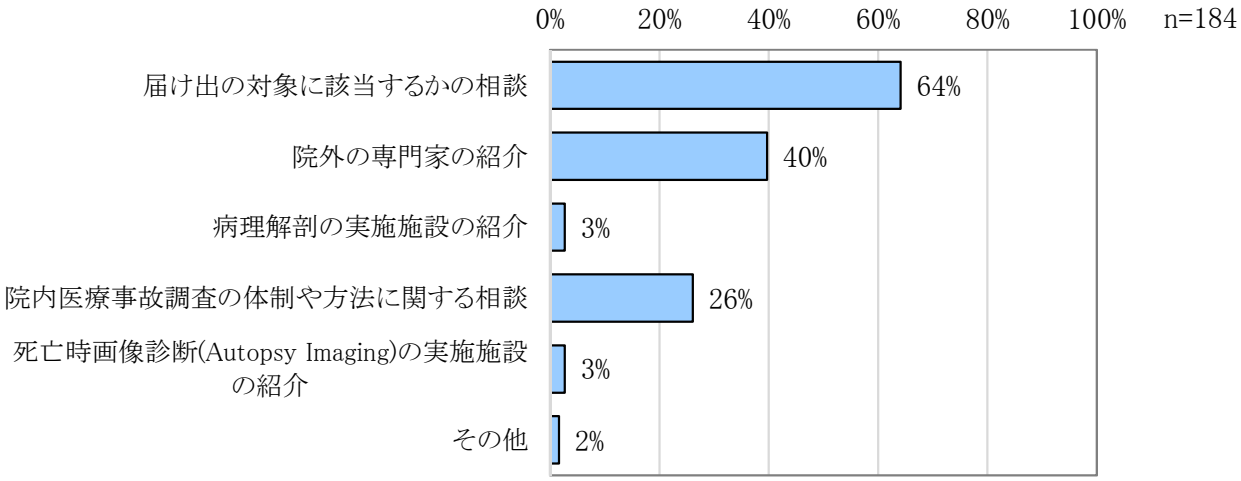


62. 医療事故の届け出の判断や原因究明にあたり、次の組織に相談したり支援を求めたりしましたか。(当てはまるもの全て選択)

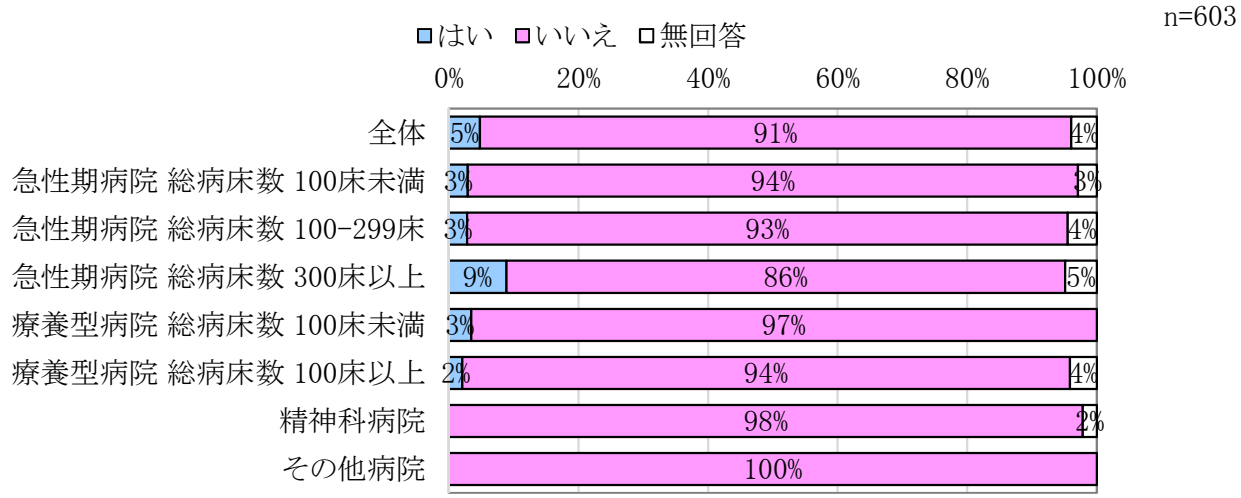
n=603



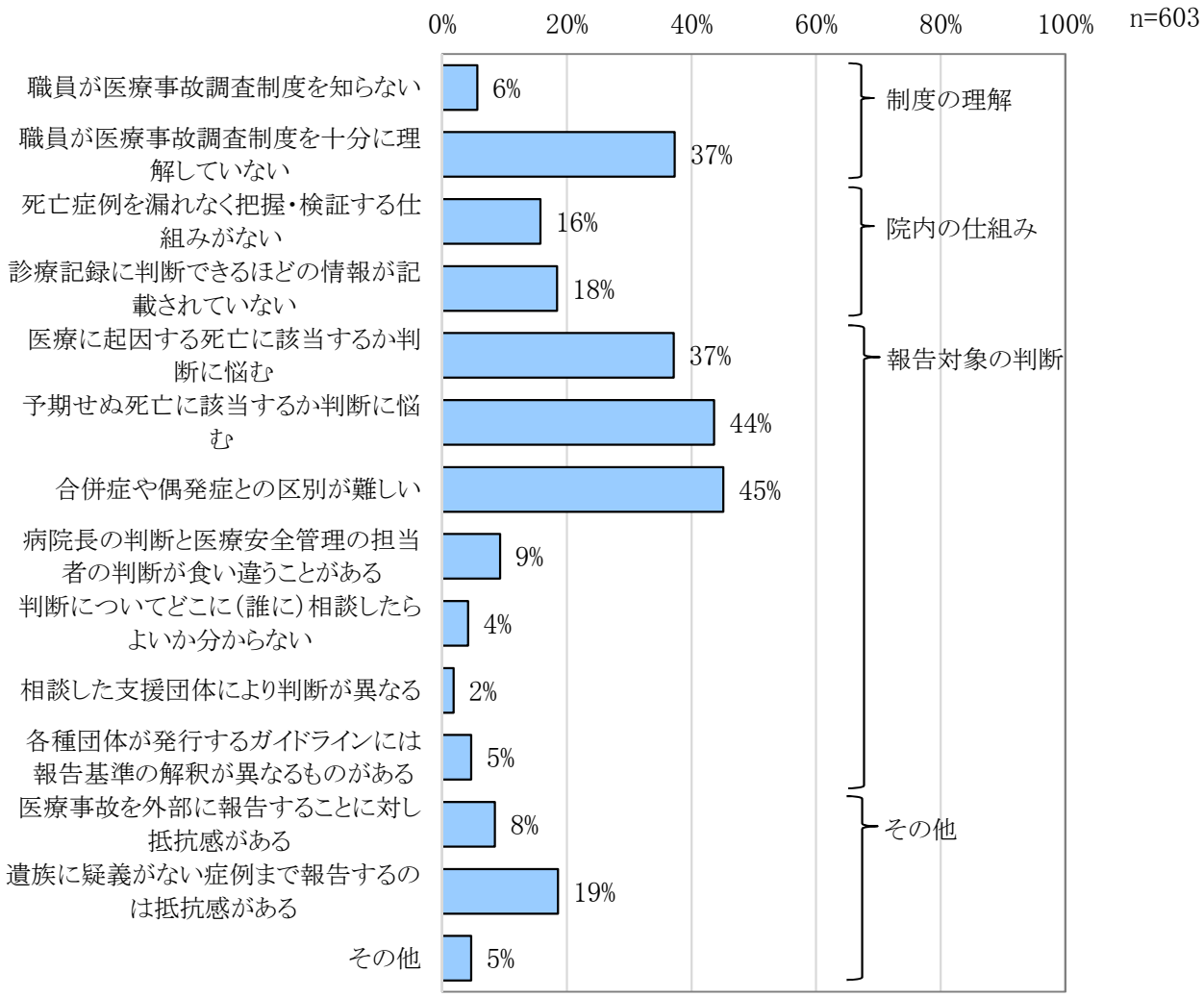
63. 問62でいずれかの組織に相談・支援を求めたと回答した場合、どのような相談または支援を求めましたか。(当てはまるもの全て選択)



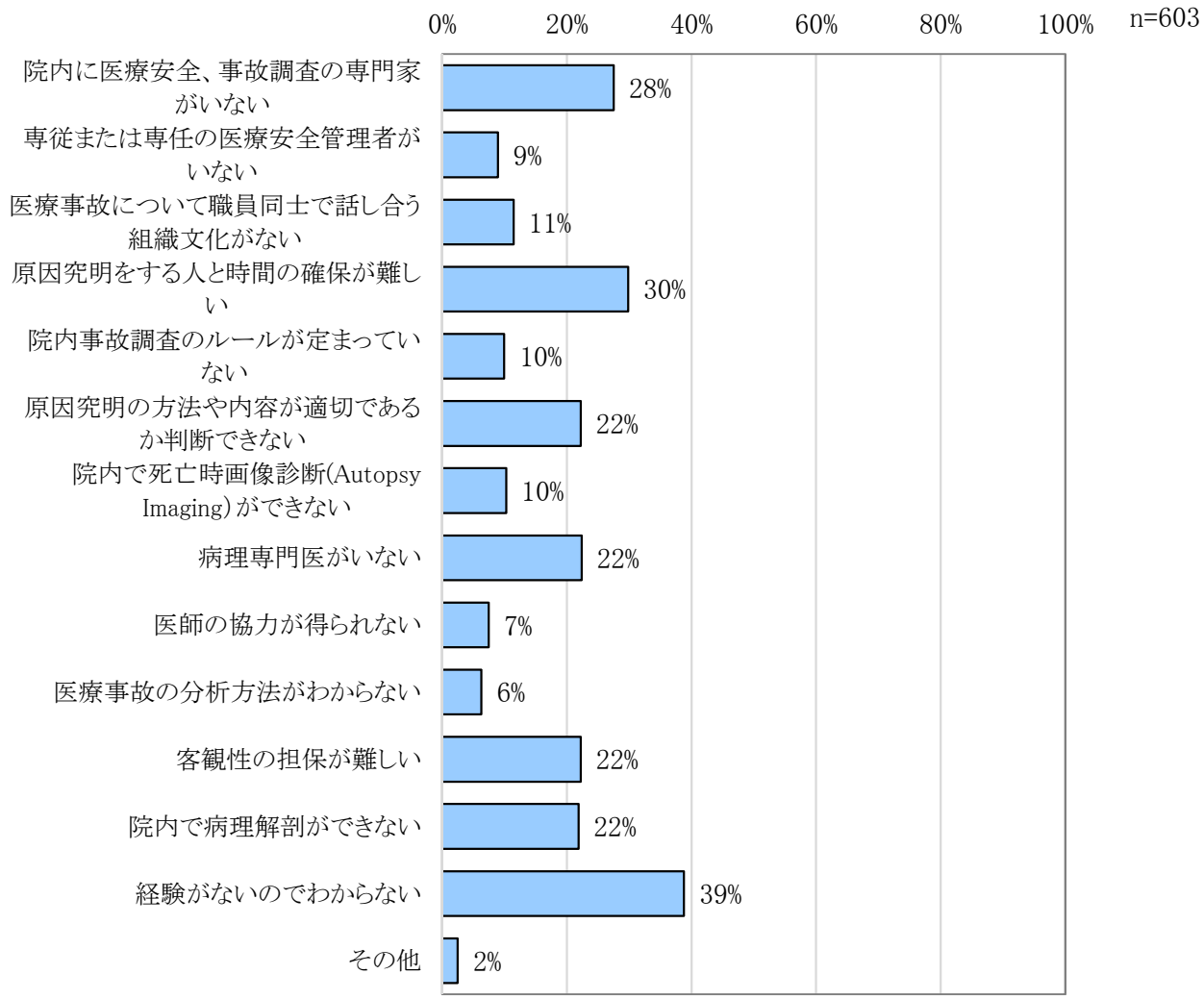
64. 遺族から、医療事故調査・支援センターへの届け出の要請または死亡原因究明の要請を受けたことがありますか。



65. 医療事故調査・支援センターへ医療事故を報告するか否かの判断をするうえで、障害となっているのは何ですか。（当てはまるもの全て選択）



66. 医療事故調査・支援センターへの報告が必要な医療事故の原因究明をするうえで、障害となっているのは何ですか。（当てはまるもの全て選択）



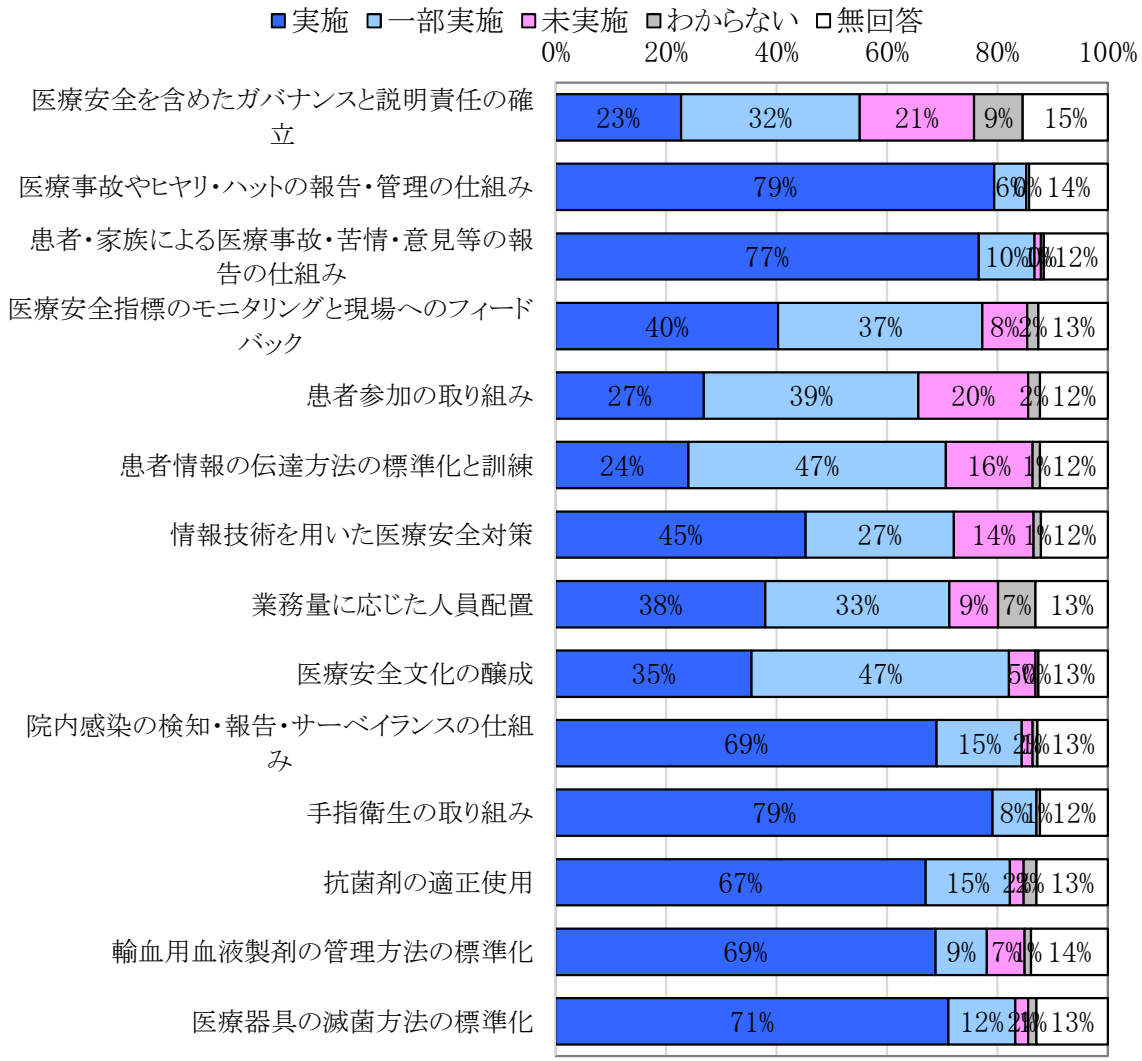
＜医療安全の各種施策の評価＞

以下にこれまでに行われた医療安全に関する主な施策を示します。医療安全に関する全国/制度・病院・臨床現場レベルの各種施策について、下記の項目を評価してください。（1～5の数字に○をつけてください。）

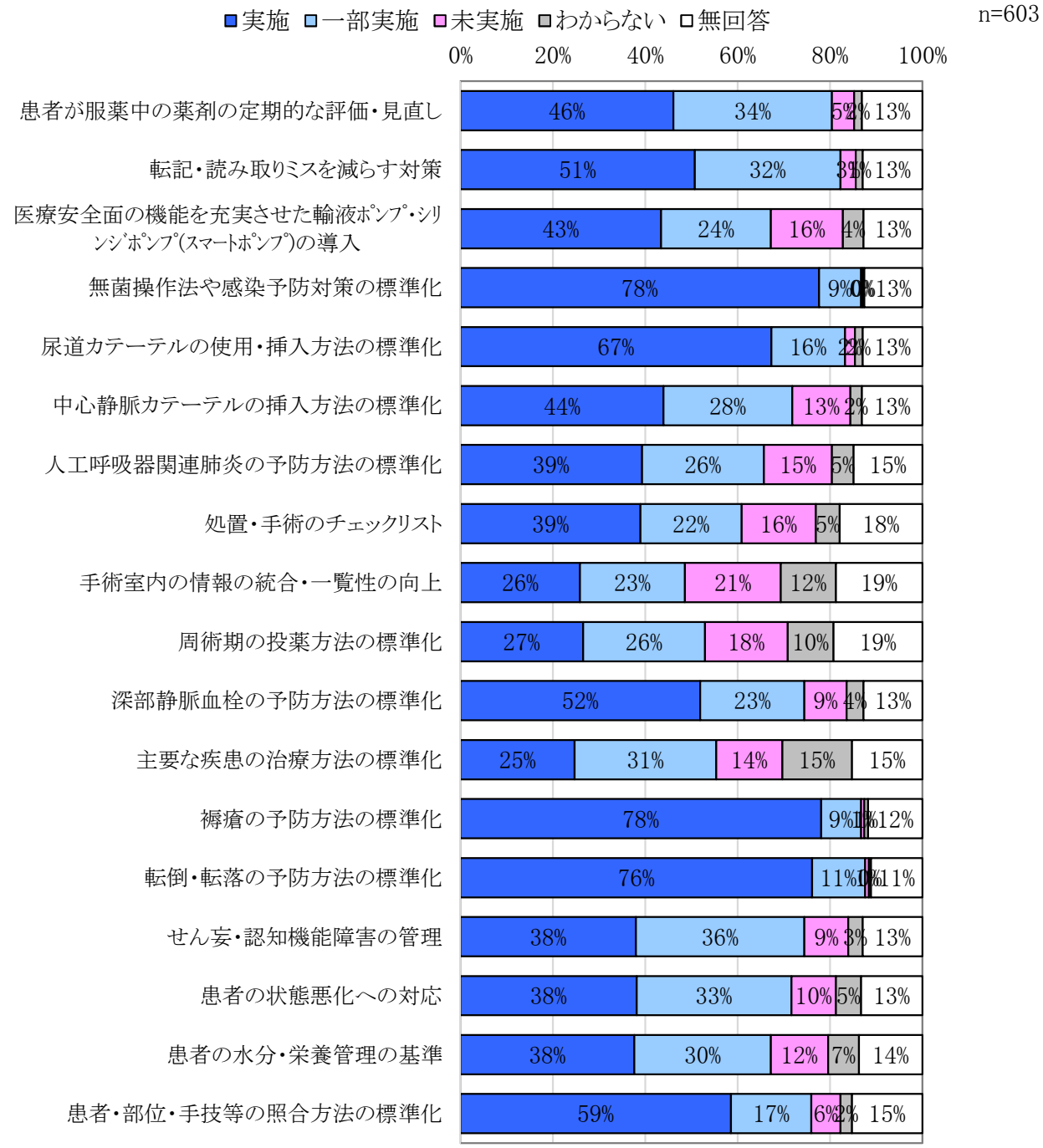
n=603

■貴院での実施状況

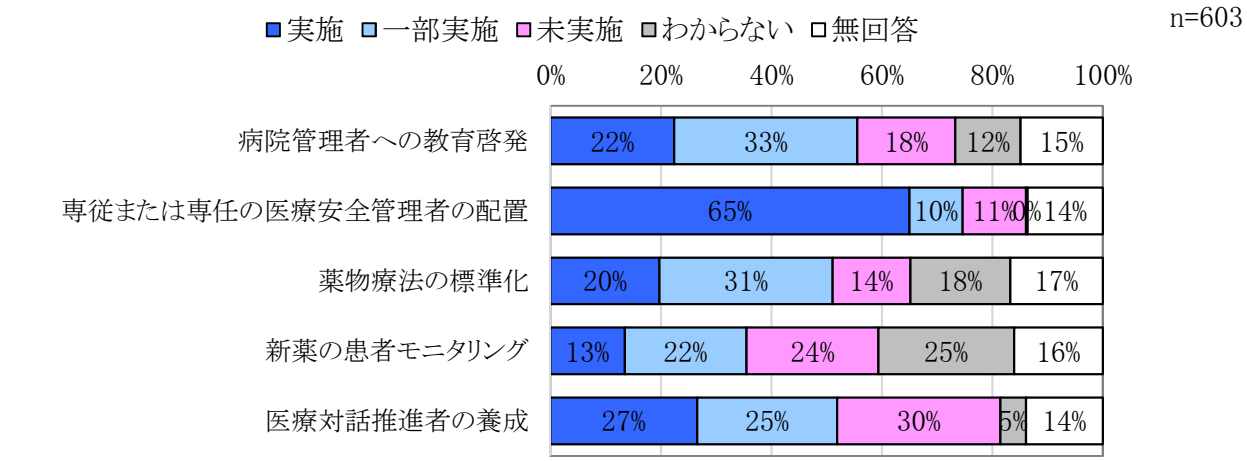
●病院レベルの施策



●臨床現場レベルの施策

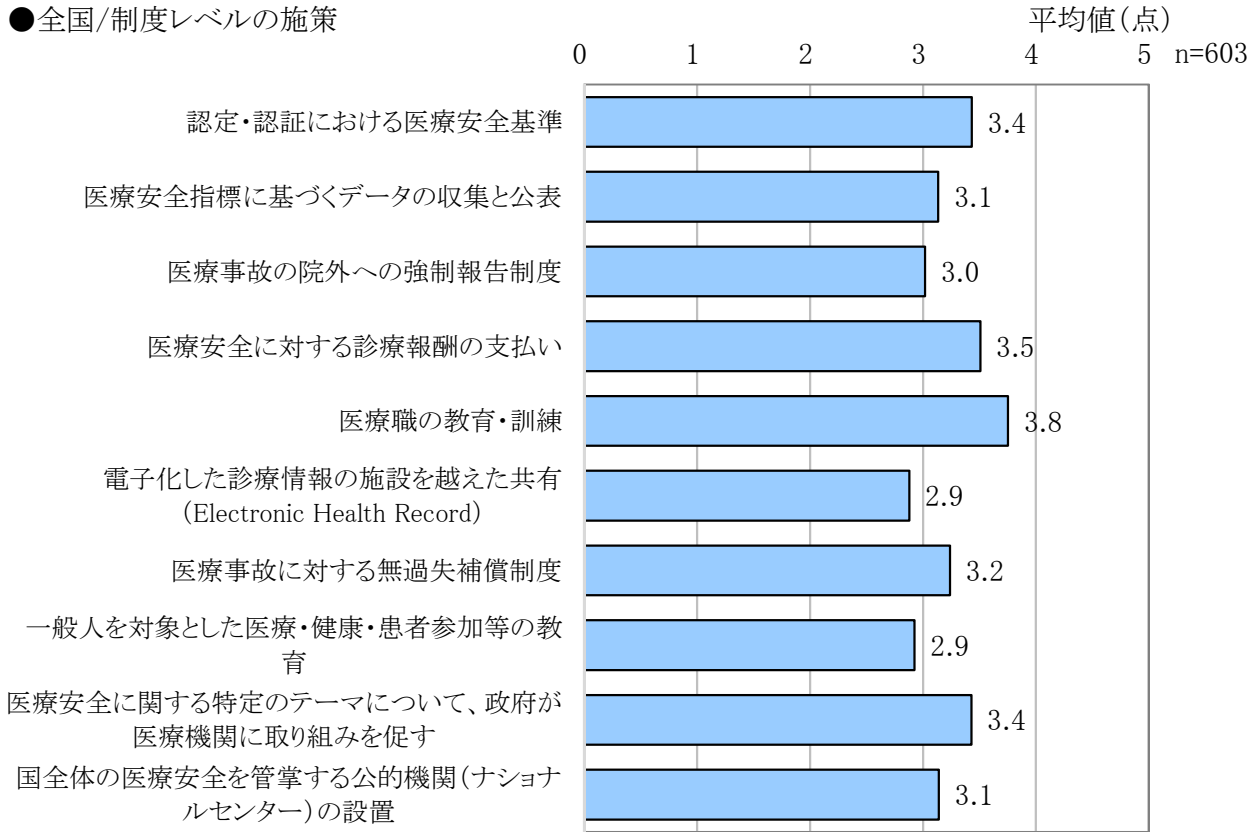


●その他の施策

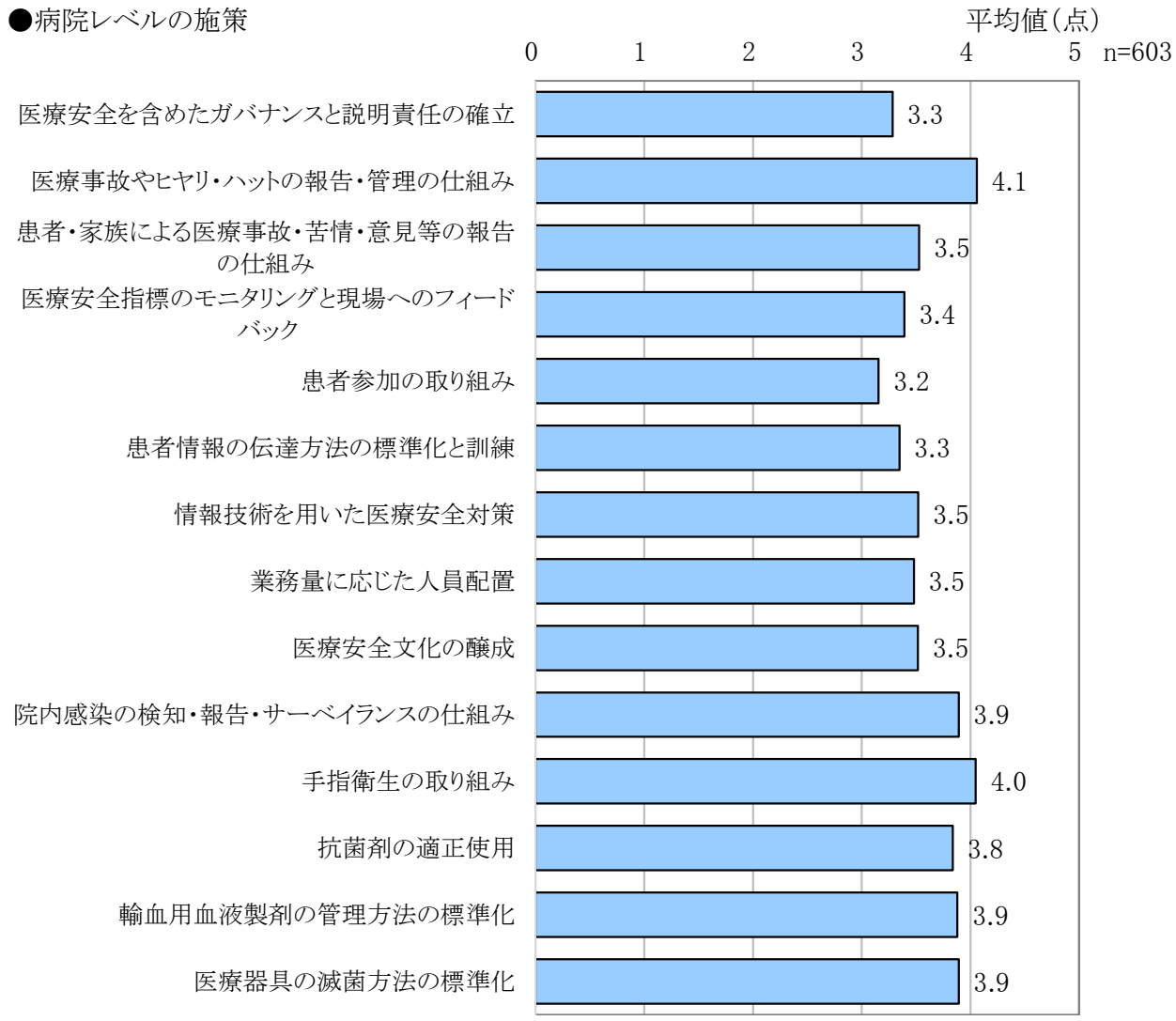


■過去の医療安全への貢献度(1:小さい～5:大きい)

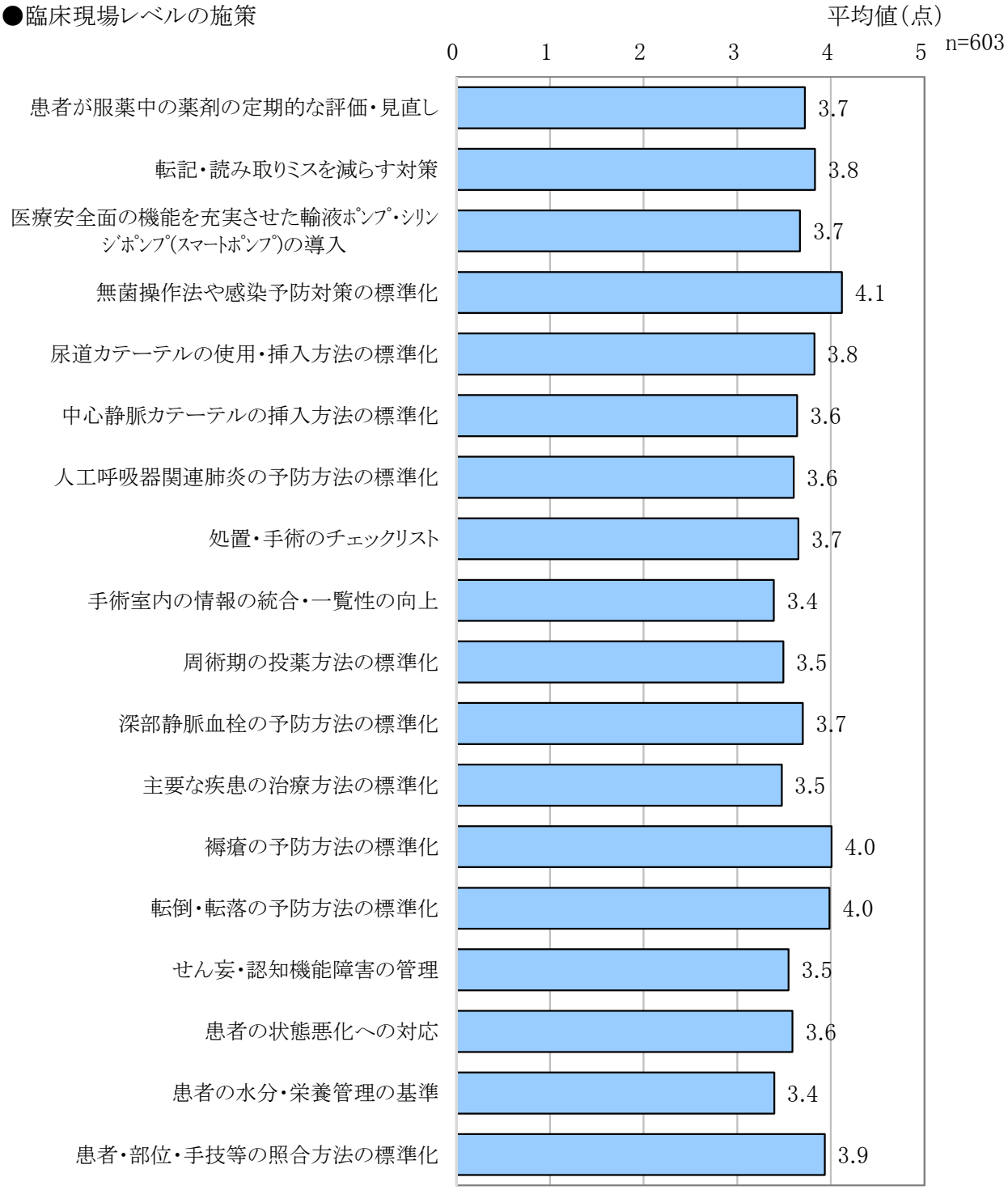
●全国/制度レベルの施策



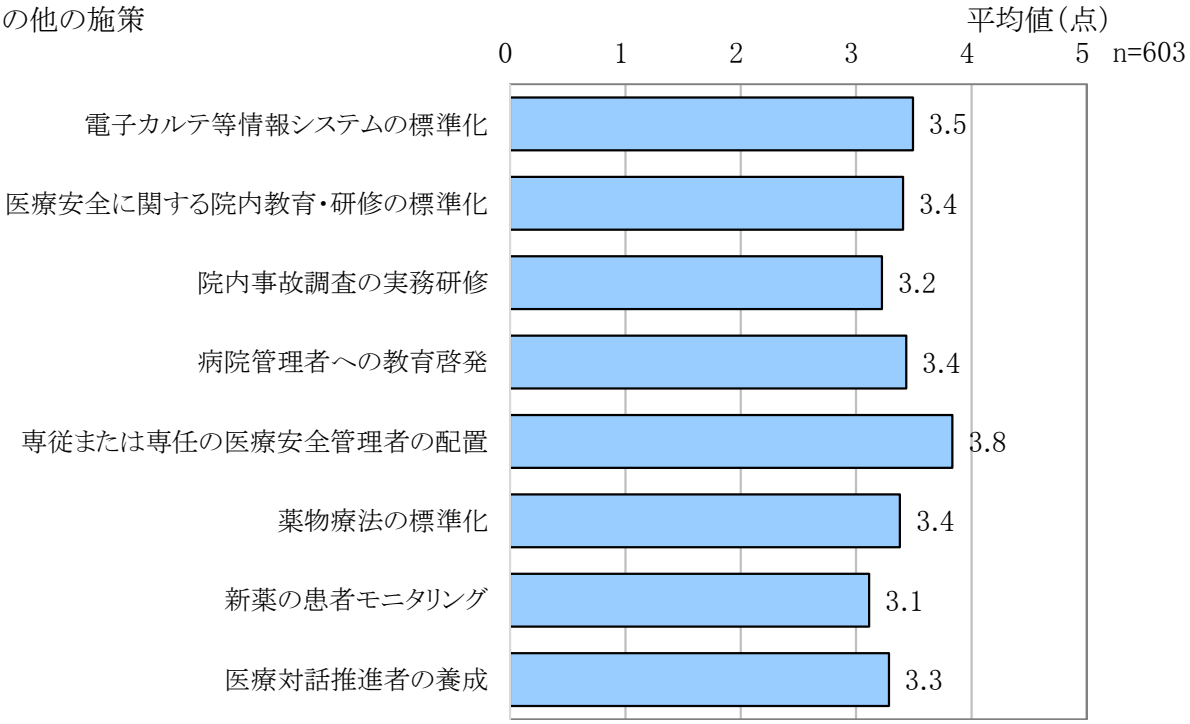
●病院レベルの施策



●臨床現場レベルの施策

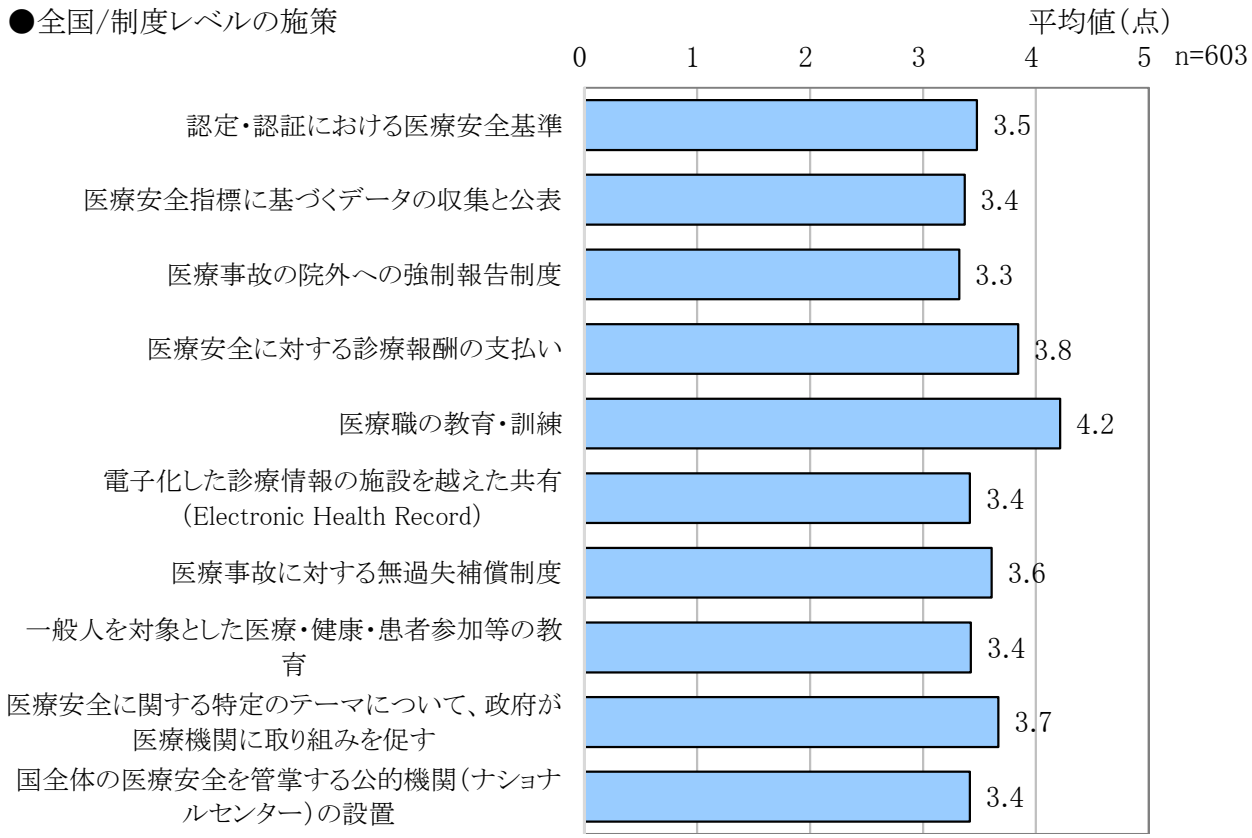

平均値（点）
n=603
0
1
2
3
4
5
患者が服薬中の薬剤の定期的な評価・見直し
3.7
転記・読み取りミスを減らす対策
3.8
医療安全面の機能を充実させた輸液ﾎﾟﾝﾌﾟ・ｼﾘﾝｼﾞﾎﾟﾝﾌﾟ(ｽﾏｰﾄﾎﾟﾝﾌﾟ)の導入
3.7
無菌操作法や感染予防対策の標準化
4.1
尿道カテーテルの使用・挿入方法の標準化
3.8
中心静脈カテーテルの挿入方法の標準化
3.6
人工呼吸器関連肺炎の予防方法の標準化
3.6
処置・手術のチェックリスト
3.7
手術室内の情報の統合・一覧性の向上
3.4
周術期の投薬方法の標準化
3.5
深部静脈血栓の予防方法の標準化
3.7
主要な疾患の治療方法の標準化
3.5
褥瘡の予防方法の標準化
4.0
転倒・転落の予防方法の標準化
4.0
せん妄・認知機能障害の管理
3.5
患者の状態悪化への対応
3.6
患者の水分・栄養管理の基準
3.4
患者・部位・手技等の照合方法の標準化
3.9

●その他の施策

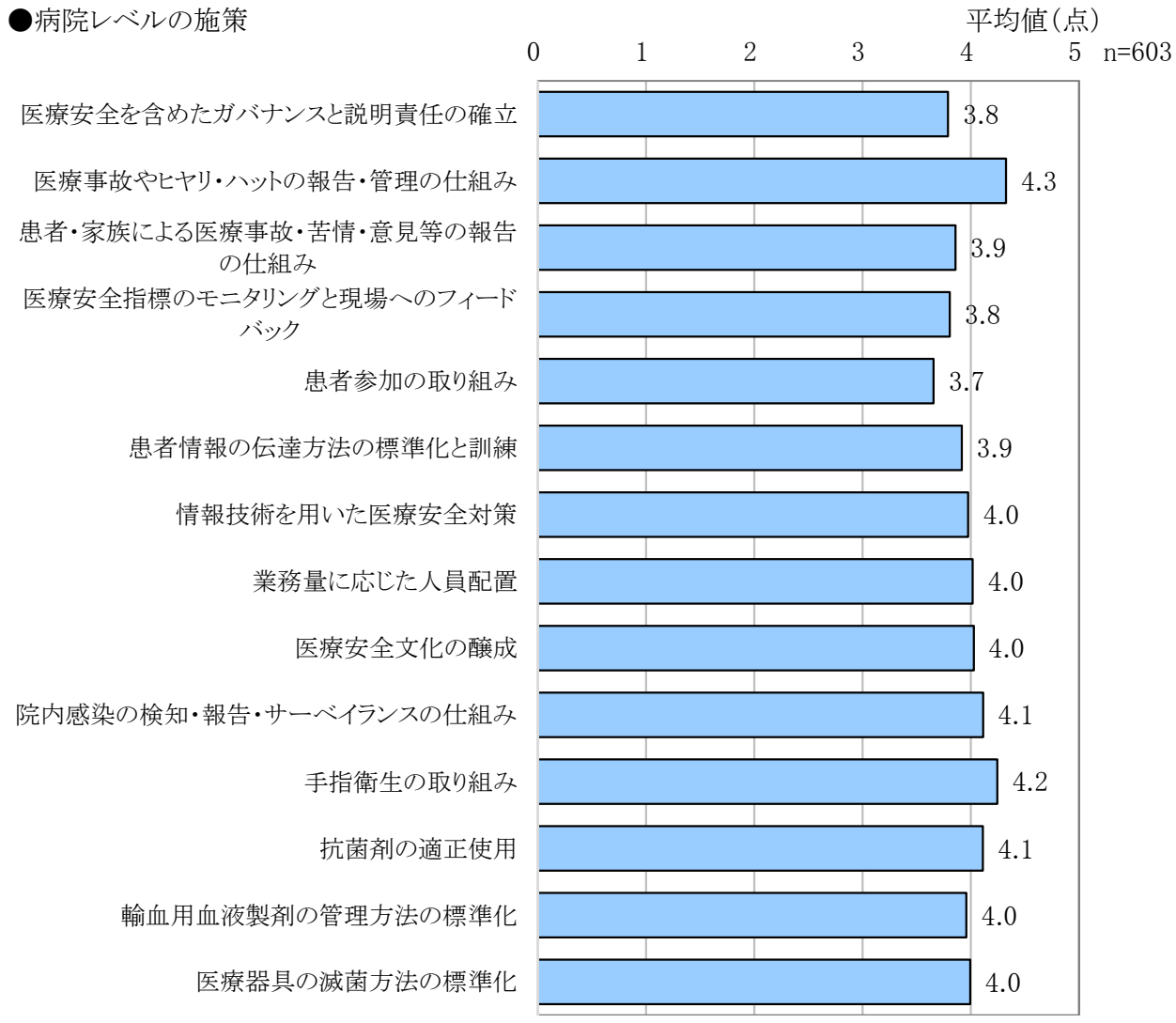

平均値(点)
0
1
2
3
4
5
n=603
電子カルテ等情報システムの標準化
3.5
医療安全に関する院内教育・研修の標準化
3.4
院内事故調査の実務研修
3.2
病院管理者への教育啓発
3.4
専従または専任の医療安全管理者の配置
3.8
薬物療法の標準化
3.4
新薬の患者モニタリング
3.1
医療対話推進者の養成
3.3

■今後進めるにあたっての優先度(1:低い～5:高い)

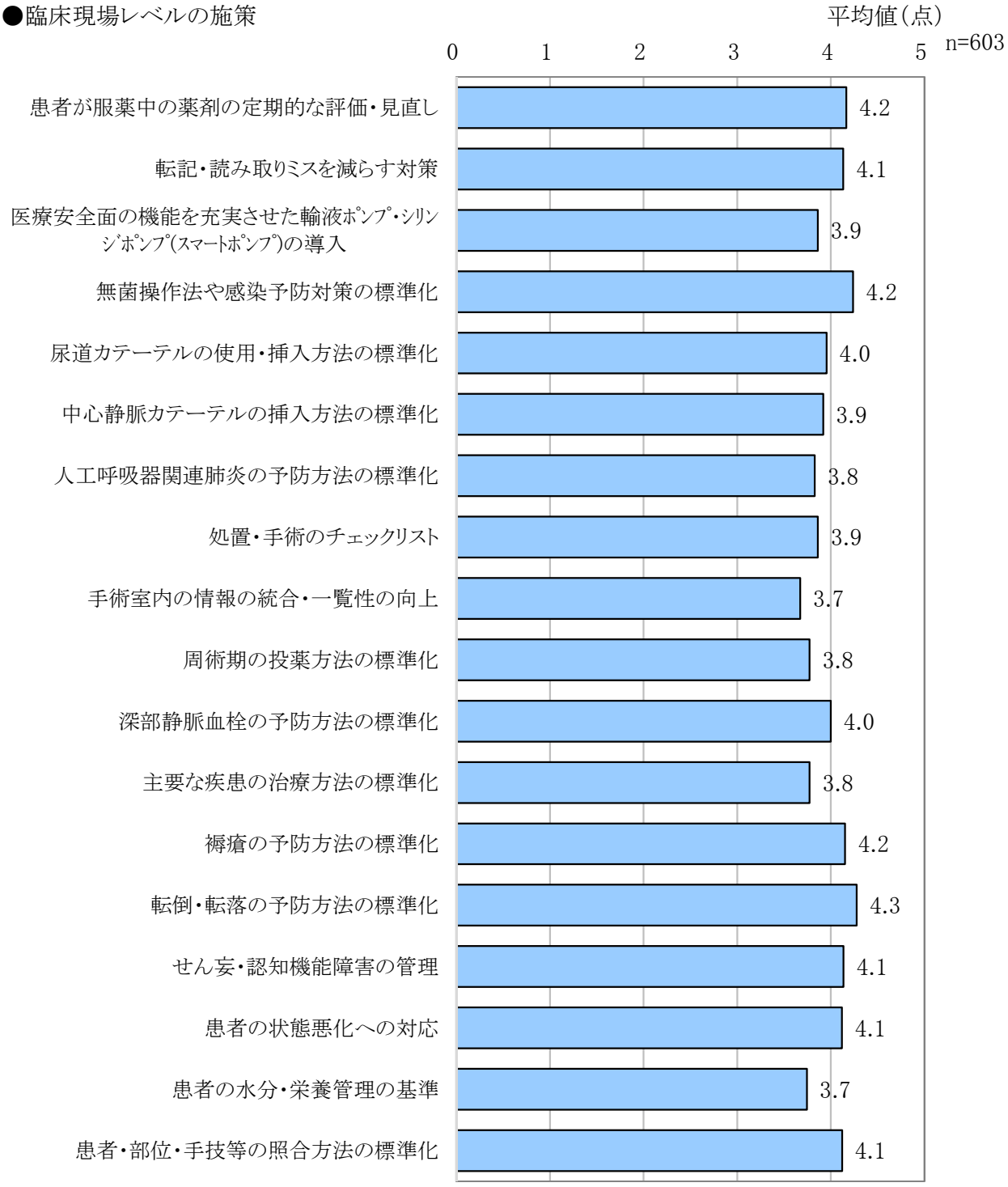
●全国/制度レベルの施策



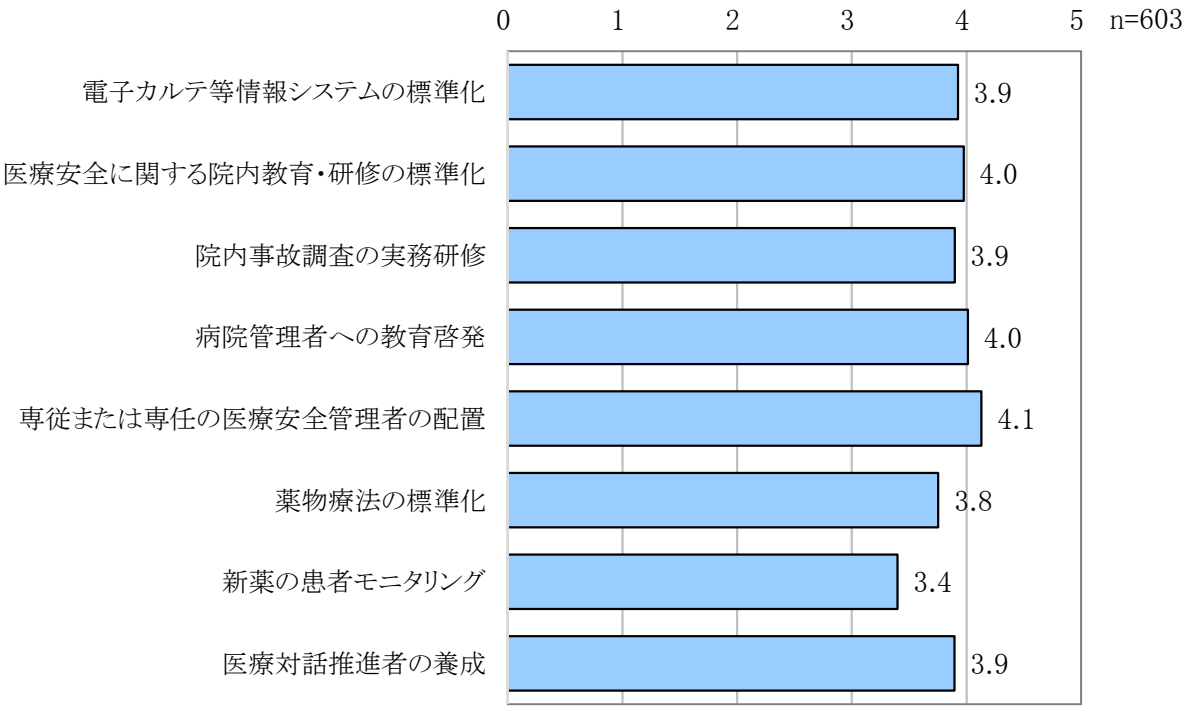
●病院レベルの施策



●臨床現場レベルの施策


平均値（点）
n=603
0
1
2
3
4
5
患者が服薬中の薬剤の定期的な評価・見直し 4.2
転記・読み取りミスを減らす対策 4.1
医療安全面の機能を充実させた輸液ﾎﾟﾝﾌﾟ・ｼﾘﾝｼﾞﾎﾟﾝﾌﾟ(ｽﾏｰﾄﾎﾟﾝﾌﾟ)の導入 3.9
無菌操作法や感染予防対策の標準化 4.2
尿道カテーテルの使用・挿入方法の標準化 4.0
中心静脈カテーテルの挿入方法の標準化 3.9
人工呼吸器関連肺炎の予防方法の標準化 3.8
処置・手術のチェックリスト 3.9
手術室内の情報の統合・一覧性の向上 3.7
周術期の投薬方法の標準化 3.8
深部静脈血栓の予防方法の標準化 4.0
主要な疾患の治療方法の標準化 3.8
褥瘡の予防方法の標準化 4.2
転倒・転落の予防方法の標準化 4.3
せん妄・認知機能障害の管理 4.1
患者の状態悪化への対応 4.1
患者の水分・栄養管理の基準 3.7
患者・部位・手技等の照合方法の標準化 4.1

●その他の施策

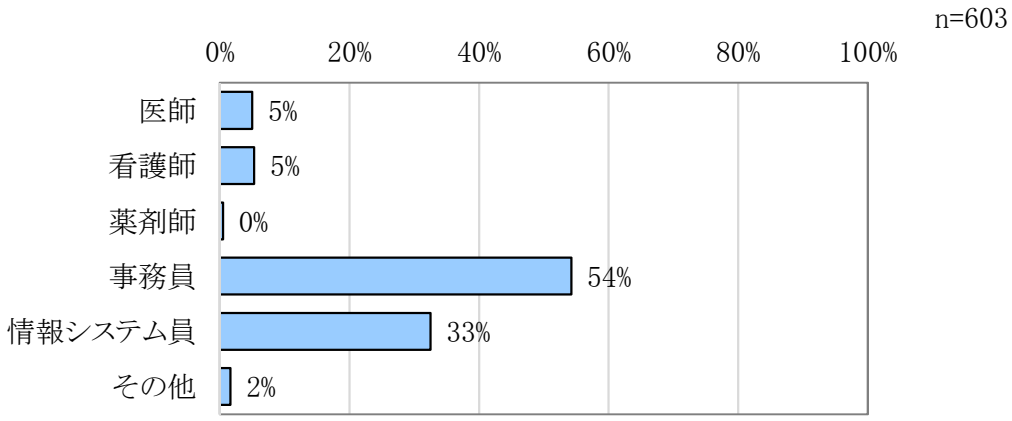


上記の施策の他に、評価すべき施策がありましたら列挙してください。
117 省略

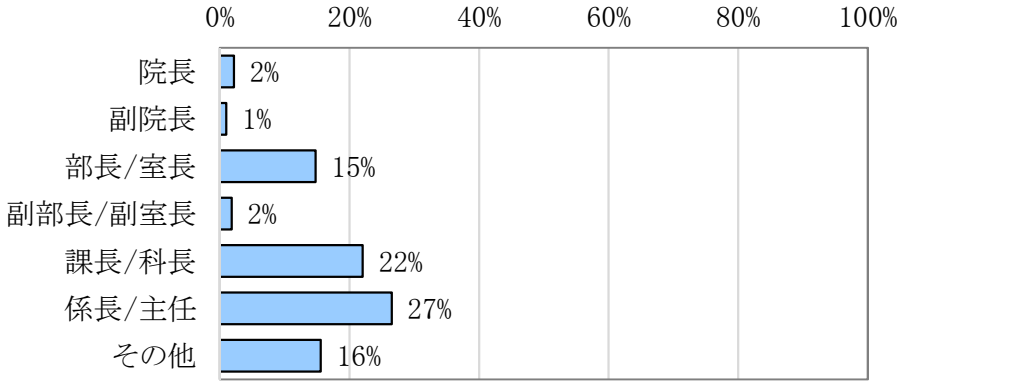
第3部　病院情報システムについて

118. 本調査(第3部)に主にご回答いただく方の院内でのお立場をお教えください。(当てはまるもの全て選択)

＜職　種＞

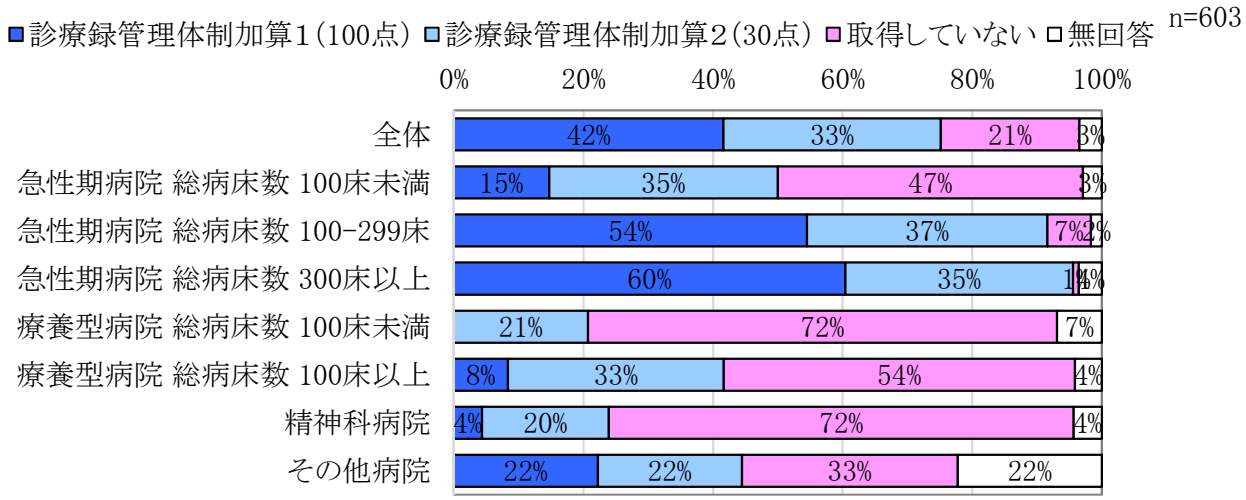


＜職　位＞

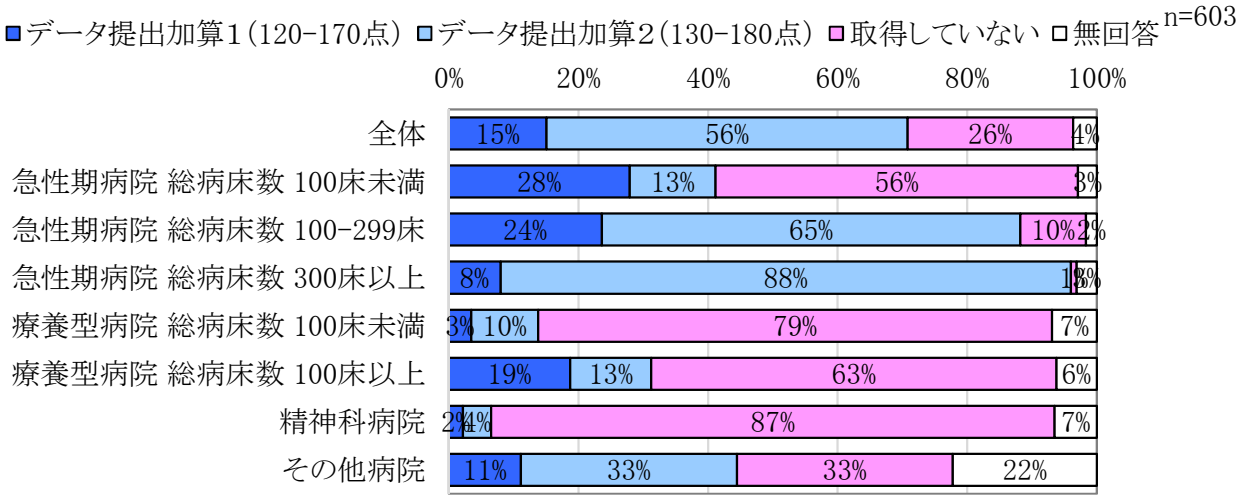


＜ITに関連した診療報酬について＞

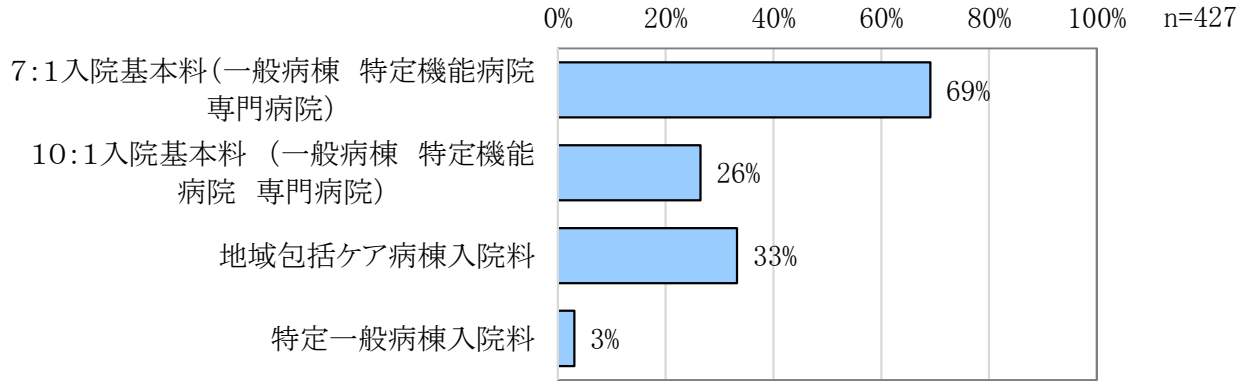
119. 診療録管理体制加算を取得していますか。



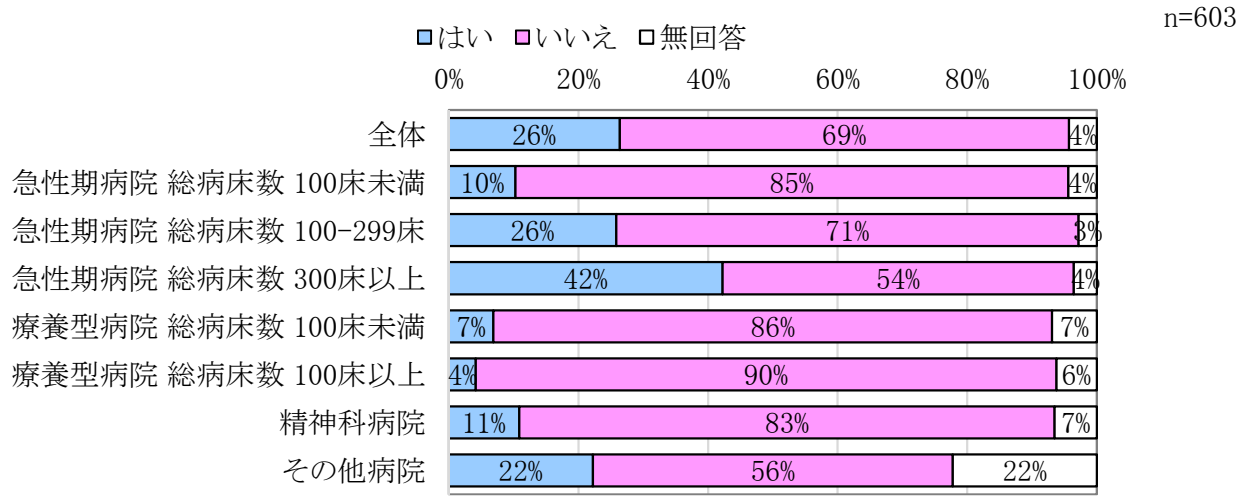
120. データ提出加算を取得していますか。



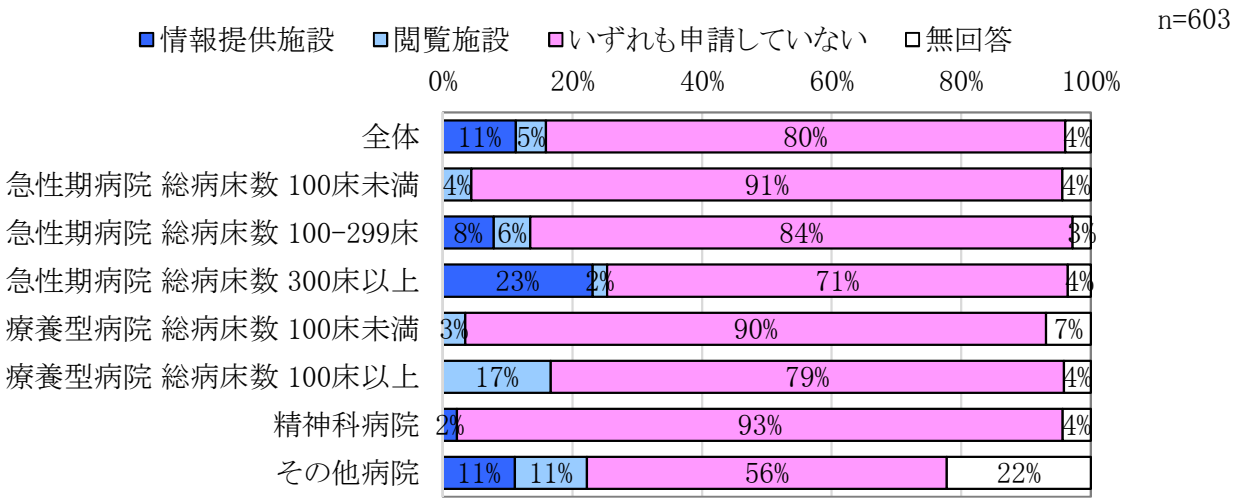
121. データ提出加算を取得している病院にお聞きします。その場合の入院基本料はどれですか。(当てはまるもの全て選択)



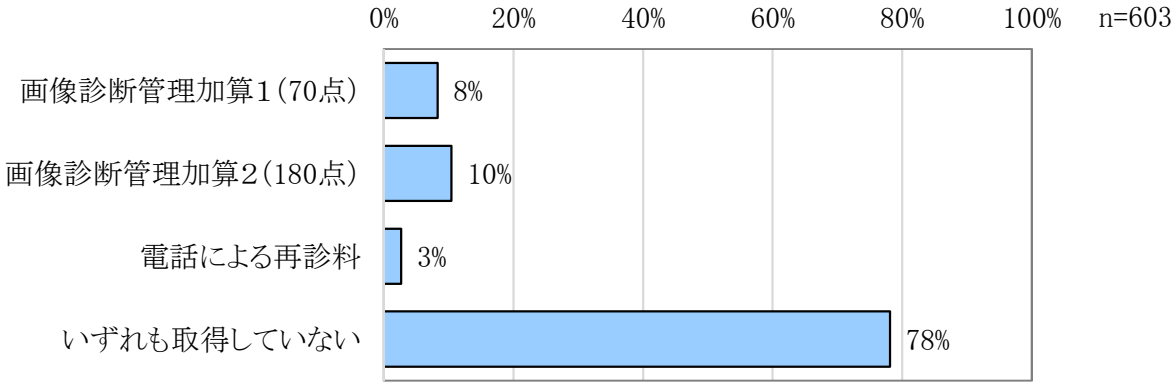
122. 地域連携に関して、検査・画像情報提供加算を取得していますか。



123. 地域連携に関して、電子的診療情報評価料を申請していますか。



124. 遠隔医療に関して、画像診断管理加算を取得していますか。(当てはまるもの全て選択)



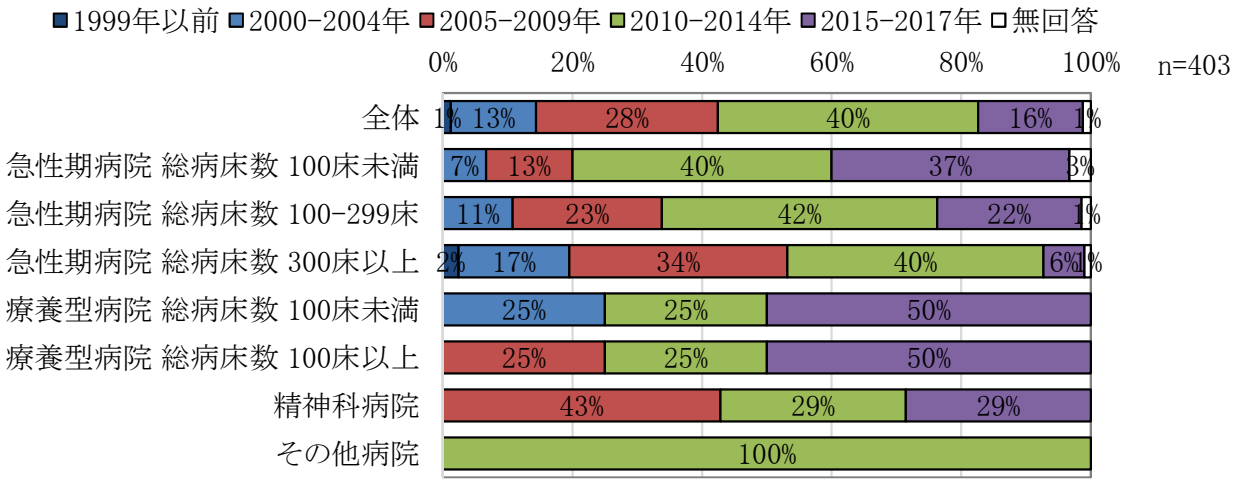
＜病院情報システムの導入状況について＞

125. 病院情報システムの導入状況をご回答ください。(当てはまるもの全て選択)

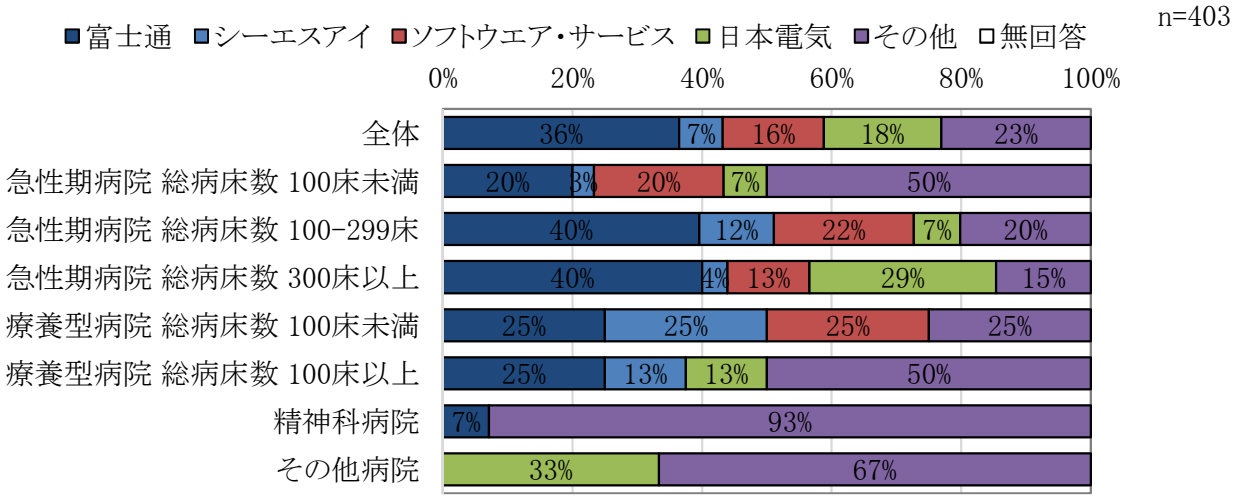
		n (病院数)	電子カルテ	オーダーエントリーシステム	バーコード認証システム	インシデント報告システム	左記はいずれも導入していない
全　体		603	67%	11%	50%	50%	16%
急性期病院　総病床数	100床未満	68	44%	10%	19%	16%	38%
	100-299床	178	78%	16%	57%	49%	3%
	300床以上	225	91%	5%	78%	80%	0%
療養型病院　総病床数	100床未満	29	14%	10%	3%	10%	62%
	100床以上	48	17%	10%	10%	15%	56%
精神科病院		46	30%	22%	7%	13%	35%
その他病院		9	33%	33%	11%	44%	11%

電子カルテを導入されていない場合、第3部のアンケートはここで終了です。
以下の設問は、電子カルテを導入されている場合にご回答ください。

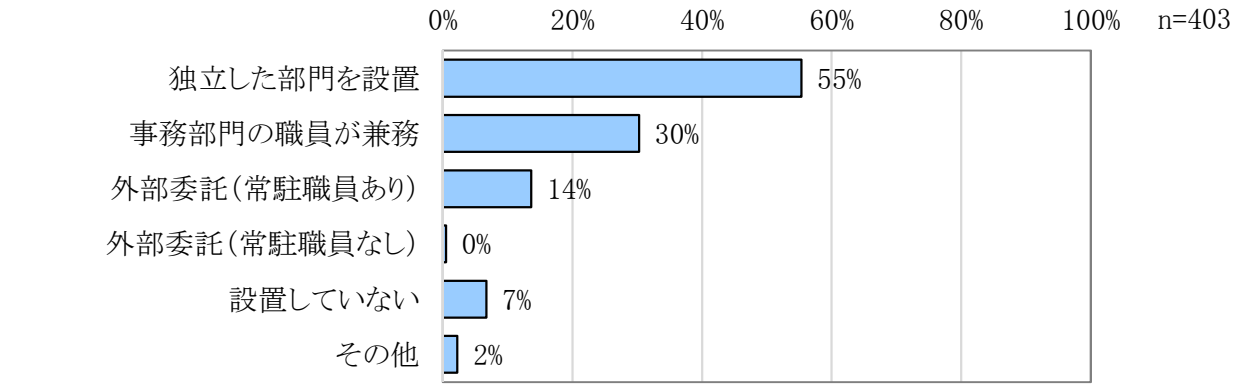
126. 電子カルテの導入時期はいつですか。



127. 現在採用されているベンダはどれですか。



128. 院内に情報システム部門を設置していますか。

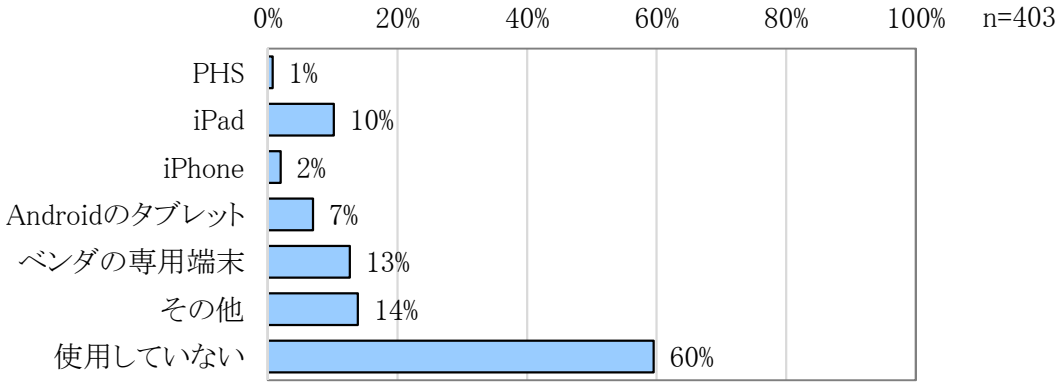


129. 情報システム部門に担当者を何名配置していますか。(データウエアハウス部門は含みません)
130. 電子カルテ用のパソコンはおよそ何台ありますか。

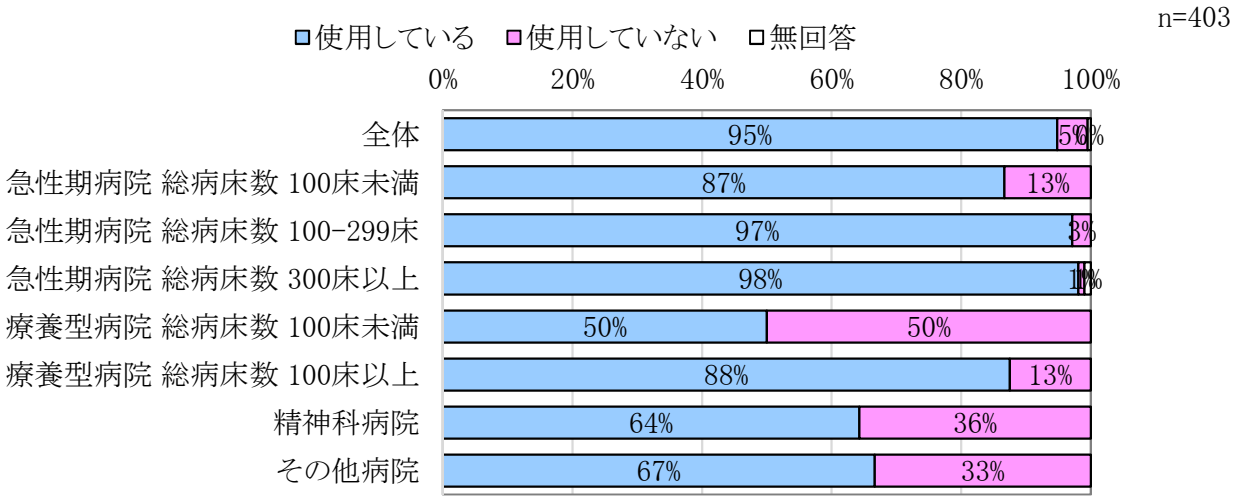
平均値

		n (病院数)	担当者(人)		電子カルテ用のパソコン(台)	
			専従	兼任	デスクトップ	ノート型
全　体		403	3	1	348	177
急性期病院　総病床数	100床未満	30	1	1	62	35
	100-299床	139	1	1	164	82
	300床以上	205	4	1	539	273
療養型病院　総病床数	100床未満	4	1	1	41	4
	100床以上	8	2	1	56	56
精神科病院		14	1	1	116	57
その他病院		3	0	1	262	93

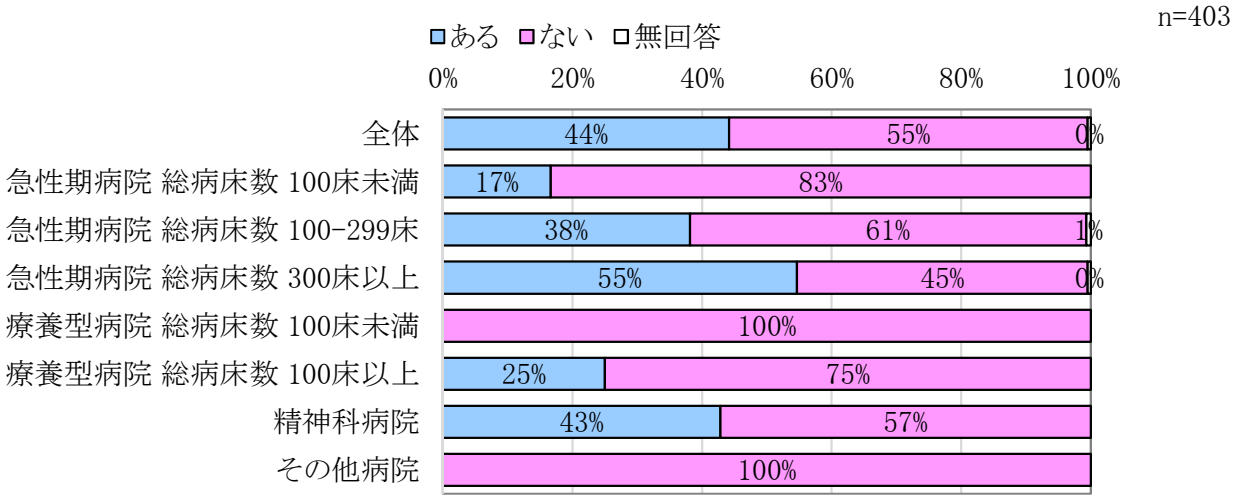
131. 電子カルテと連動した携帯端末を使用していますか。(当てはまるもの全て選択)



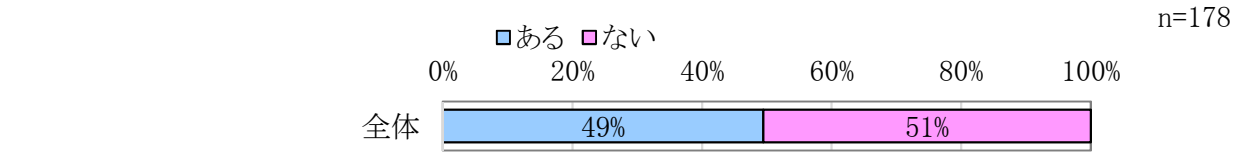
132. 院内無線LANを使用していますか。



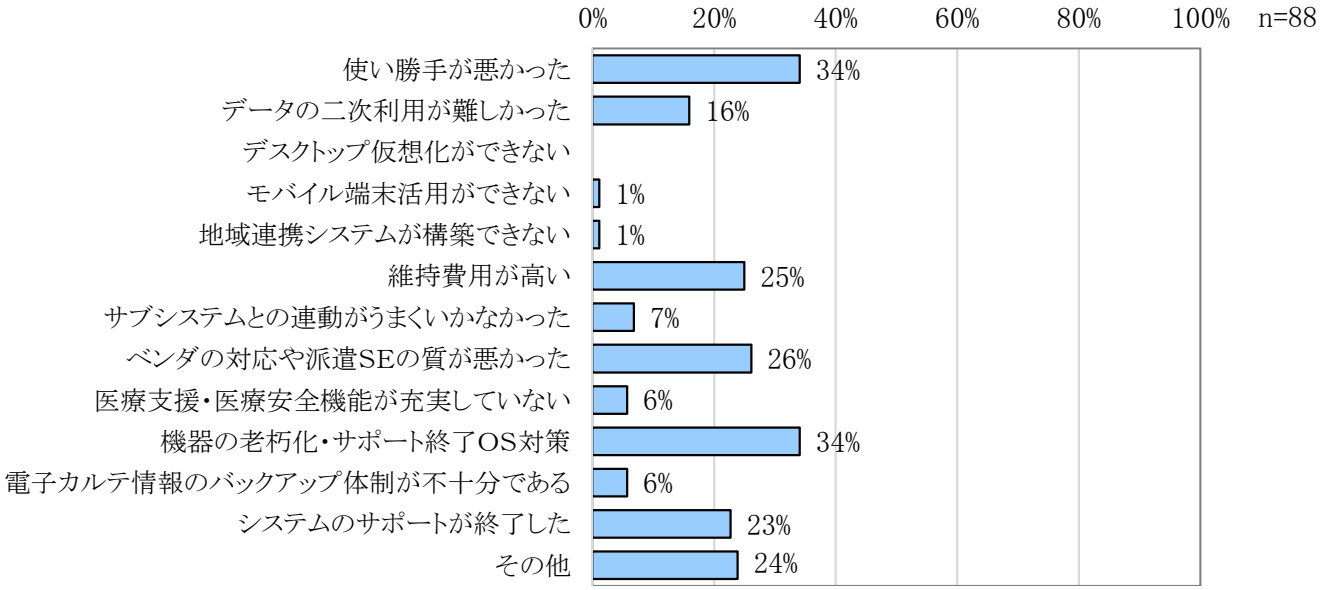
133. システムのインタフェースが大きく変更されるような、大規模なシステム更新の経験はありますか。



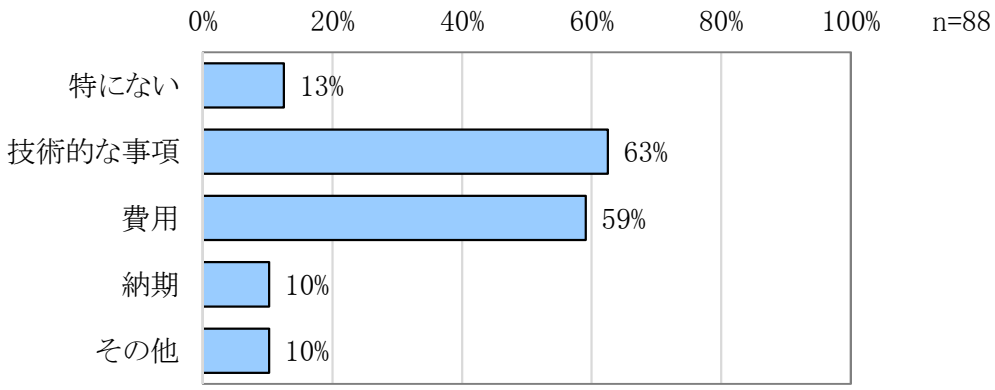
134. 問133で「ある」と回答した場合、システム更新時にベンダを変更した経験はありますか。



135. 問134でベンダを変更した経験があると回答した場合、その理由は何ですか。（当てはまるもの全て選択）

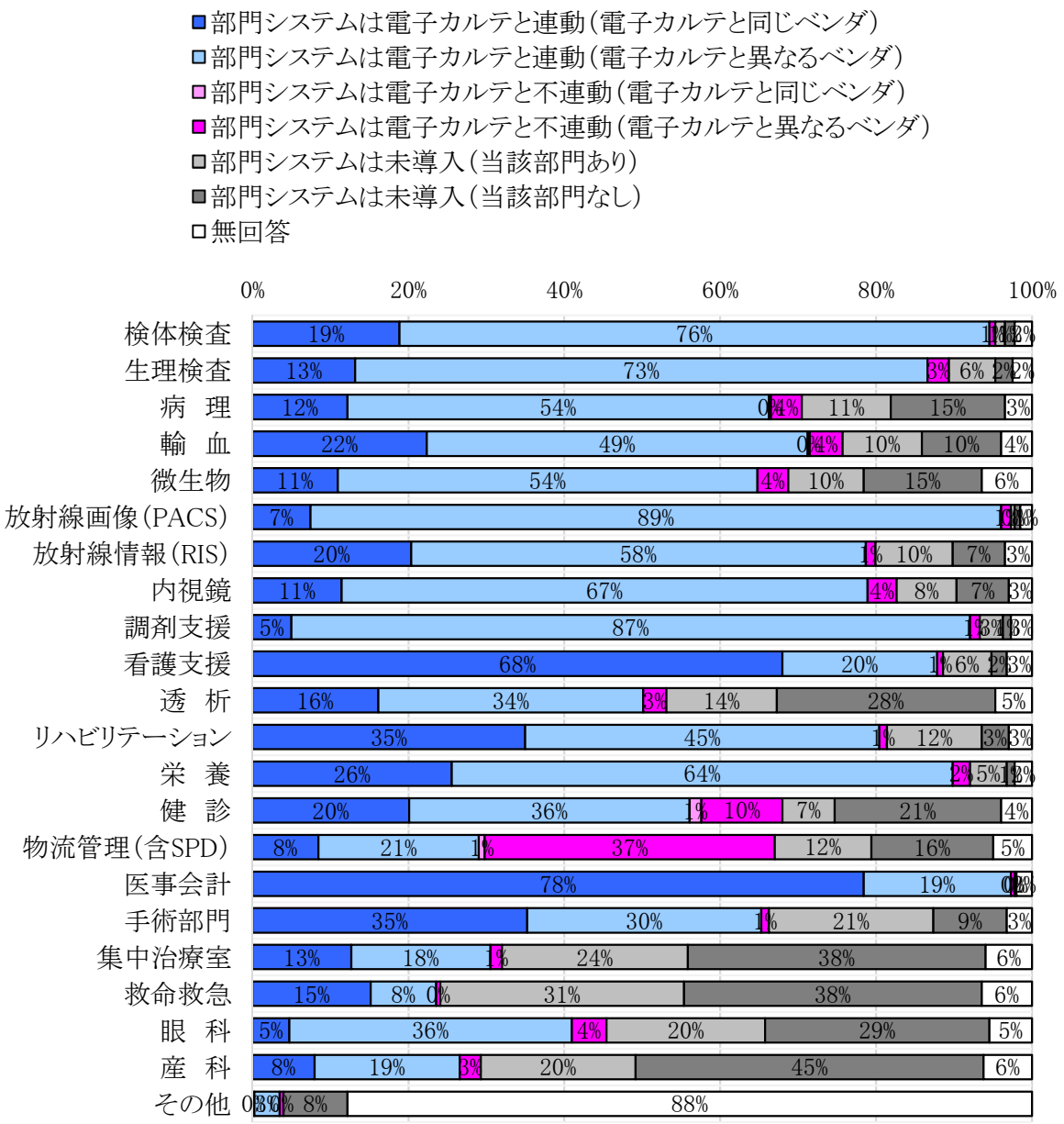


136. 問134でベンダを変更した経験があると回答した場合、変更時のデータ移行で問題となったものを選択してください。（当てはまるもの全て選択）



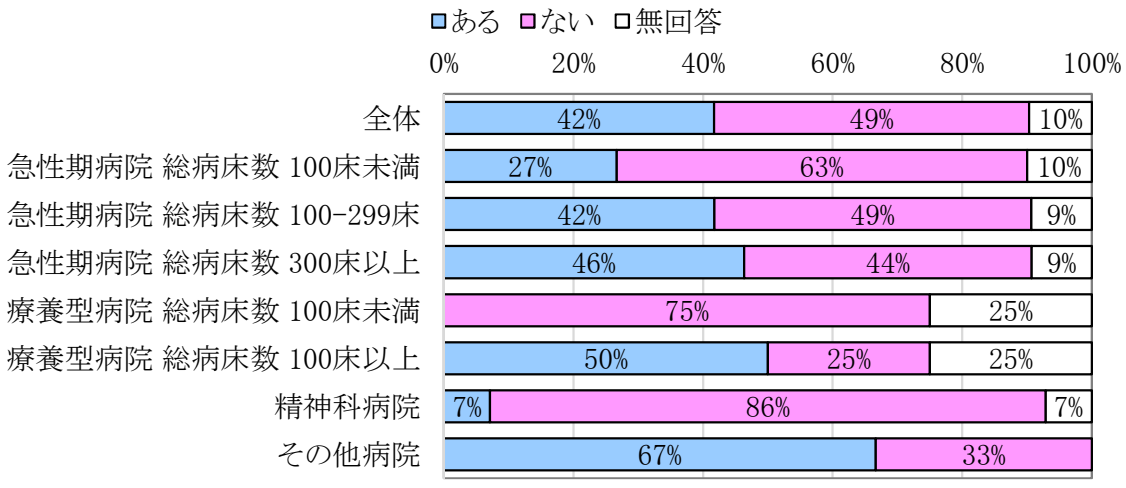
137. 次に示す部門システム(サブシステム)について、導入状況と、電子カルテ(基幹システム)との連動の有無、ベンダの違い等についてお答えください。

n=403



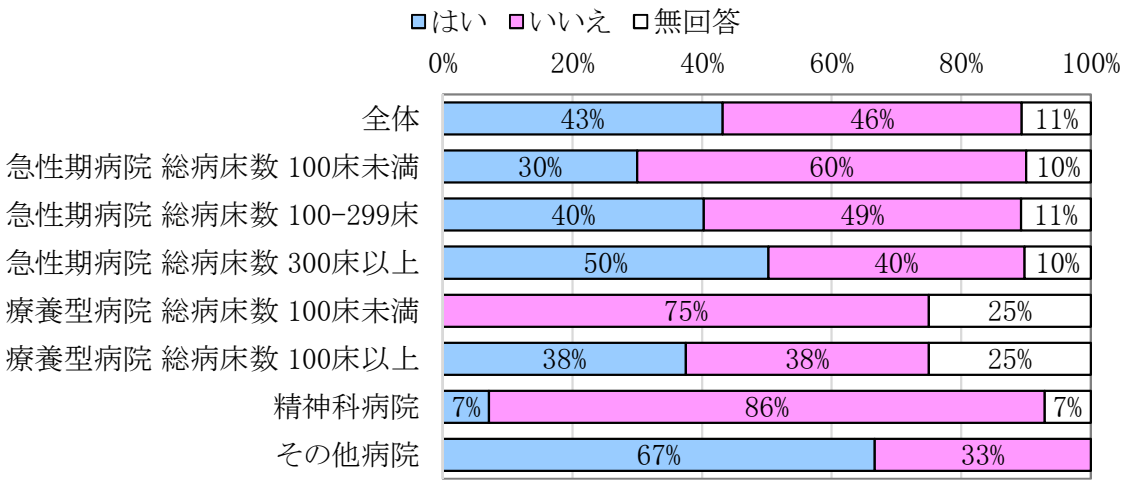
138. 生体情報モニタ(心電図・心拍数、血圧、体温等を測定・記録する機器)のアラームの設定を患者の状態に合わせて変更するためのマニュアルや取決めがありますか。

n=403



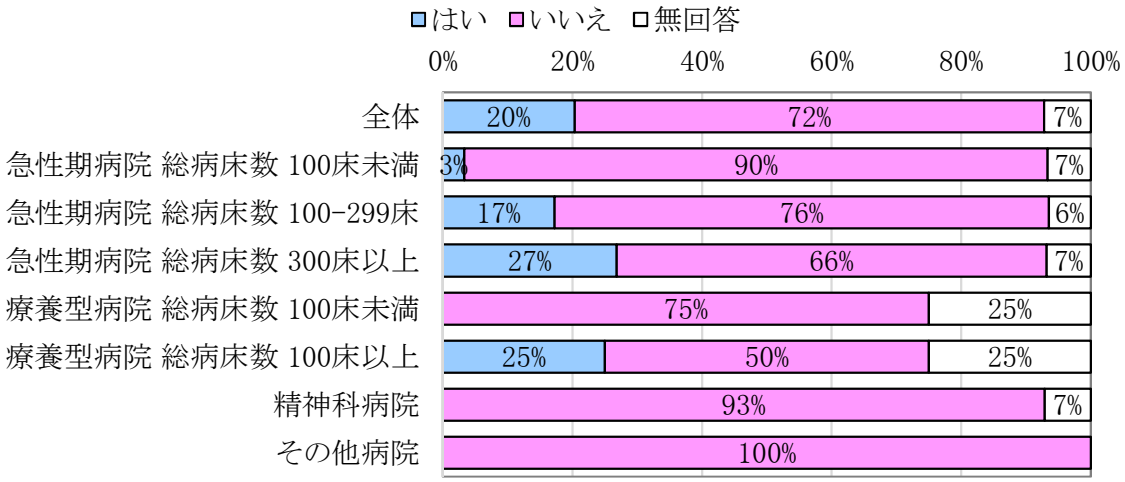
139. 生体情報モニタのアラームの放置を減らすために何らかの組織的な取り組みをしていますか。

n=403



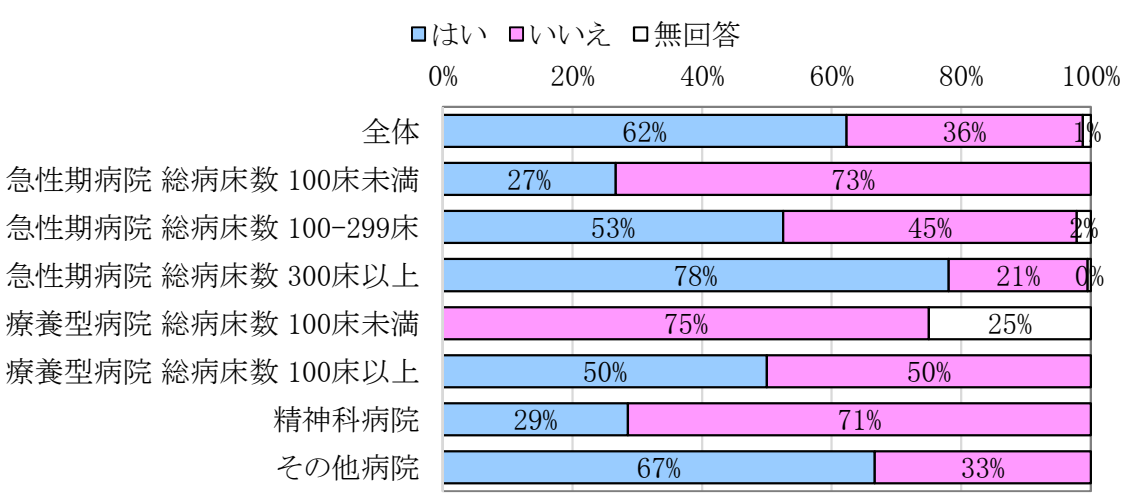
140. 生体情報モニタや人工呼吸器等に連結したナースコールシステムを採用していますか。

n=403

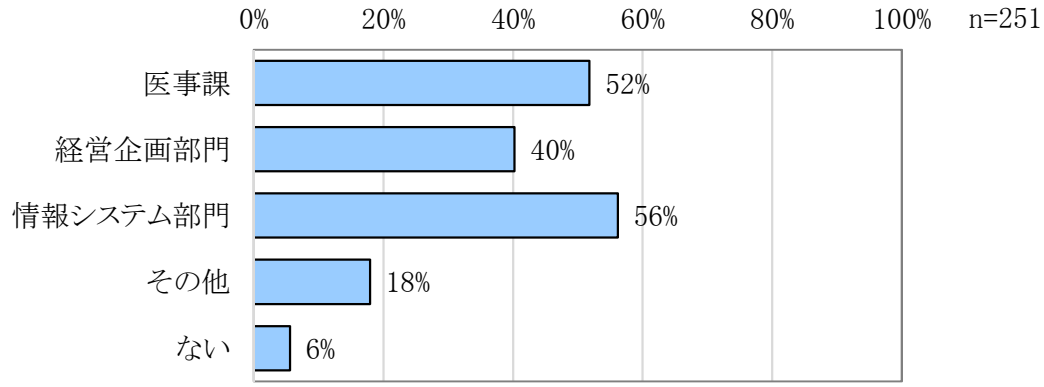


141. データウエアハウス(電子カルテやDPC等の院内のデータを統合・蓄積した、情報分析と意思決定に用いるデータベース)を構築していますか。

n=403



142. 問141でデータウエアハウスを構築していると回答した場合、そのデータを収集・分析する担当部署はありますか。(当てはまるもの全て選択)

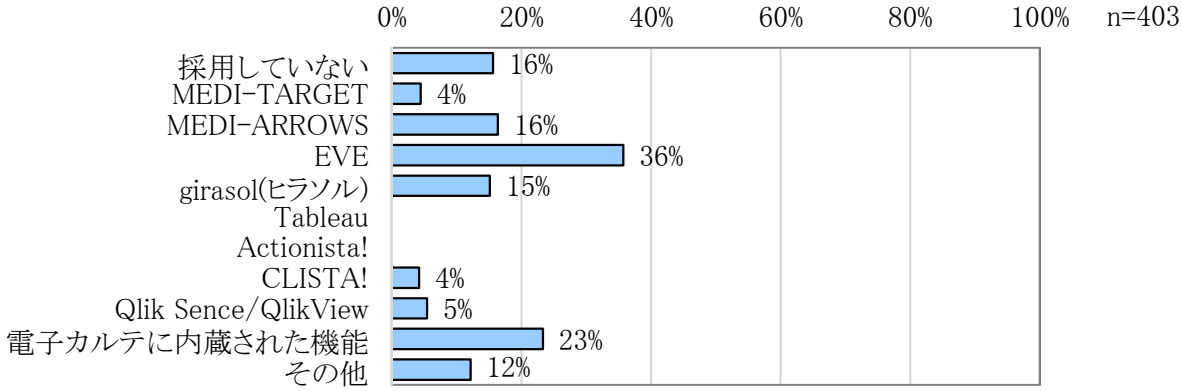


143. 問141でデータウエアハウスを構築していると回答した場合、そのデータ収集・分析担当者は何人ですか。

専従	0.9	人	(平均値)
兼任	2.8	人	

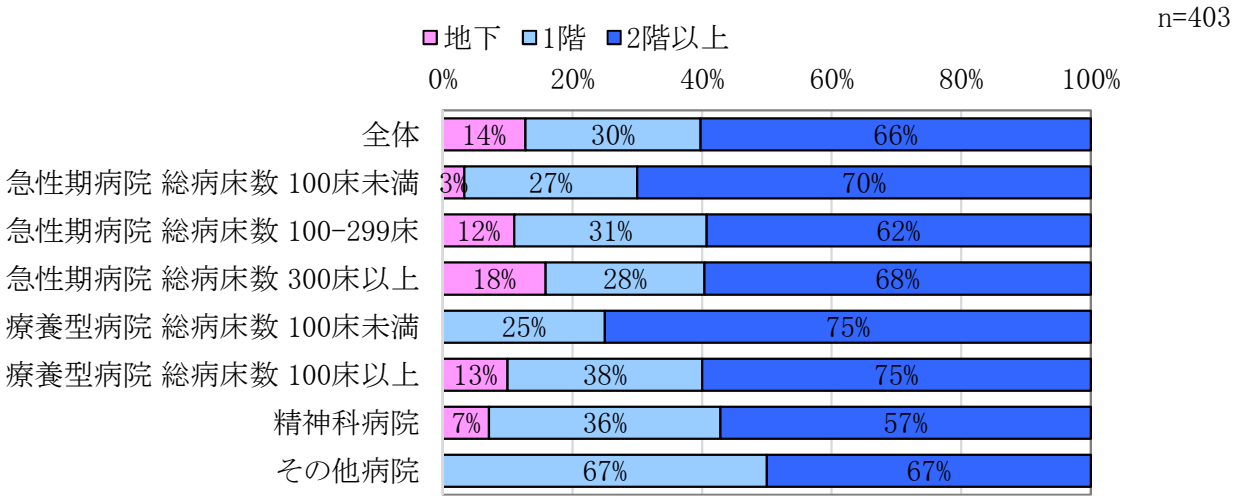
n=251

144. DPCデータを含む院内データの分析ではどのようなデータ分析ツールを採用していますか。(当てはまるもの全て選択)

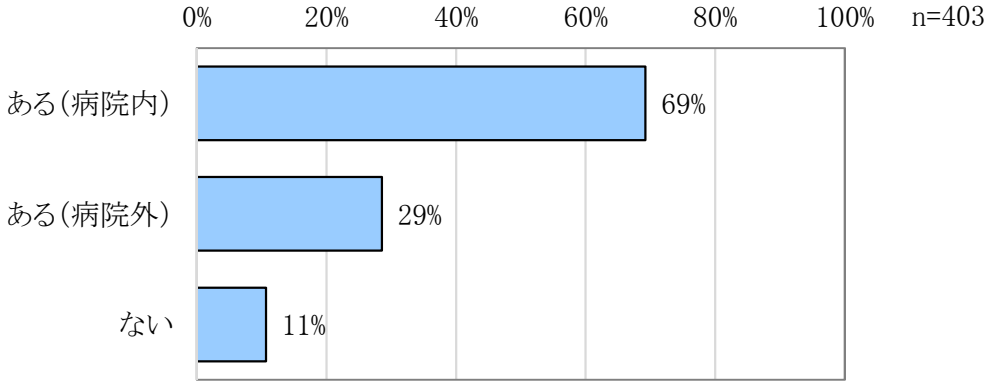


＜サイバーセキュリティなどについて＞

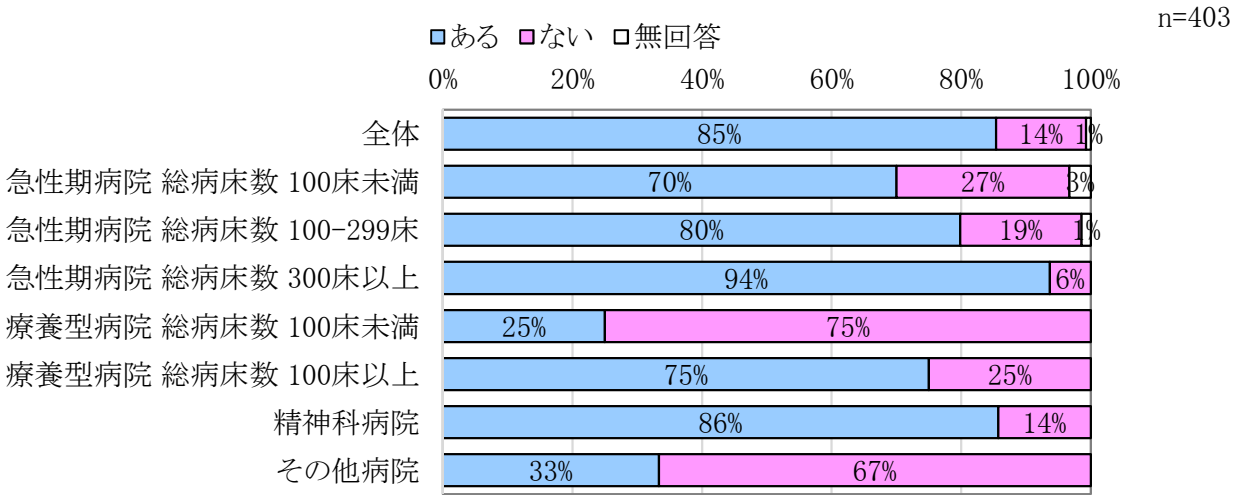
145. サーバは何階に設置していますか。(当てはまるもの全て選択)



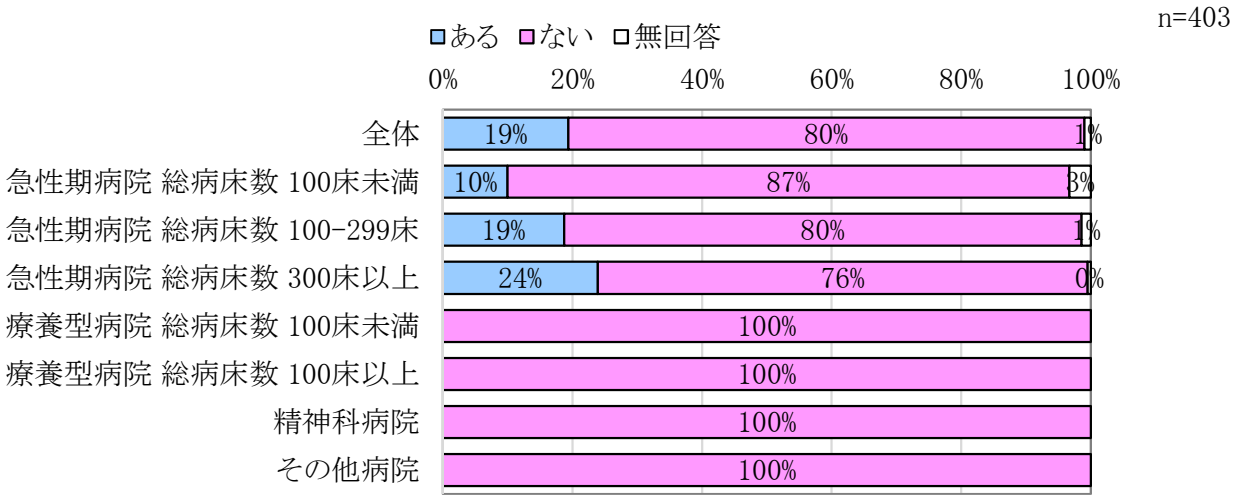
146. 災害時やサイバー攻撃に備えたデータのバックアップ体制はありますか。



147. システムダウン時の病院としての対応マニュアルはありますか。

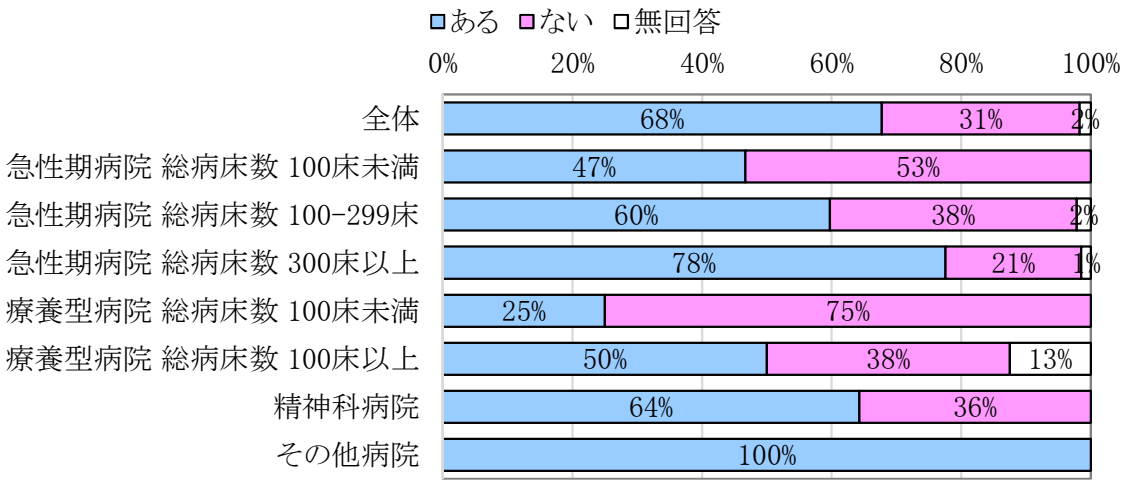


148. サイバー攻撃を受けたときの対応マニュアルはありますか。



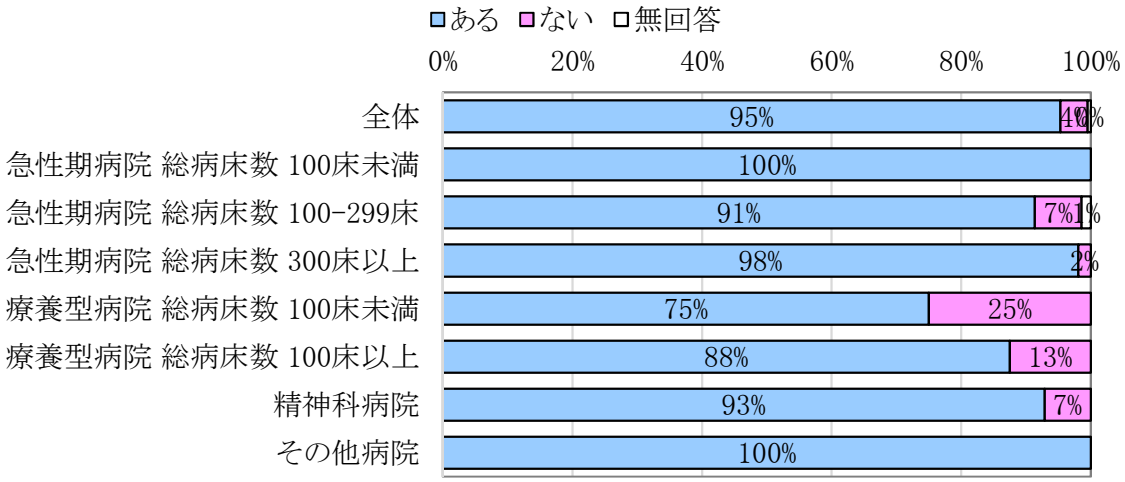
149. 職員の電子カルテ操作に関する教育プログラムはありますか。

n=403



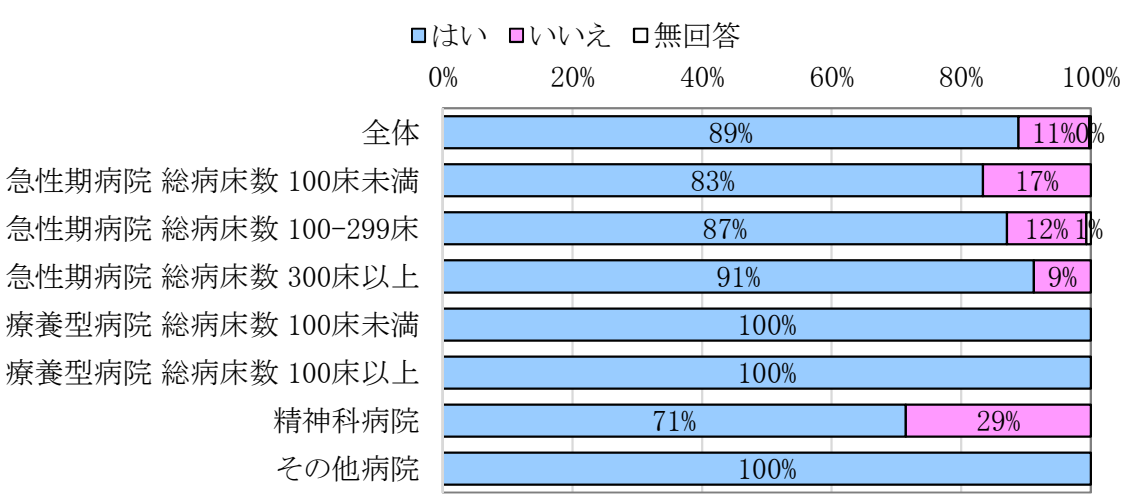
150. 職員のID、パスワード発行手順はありますか。

n=403



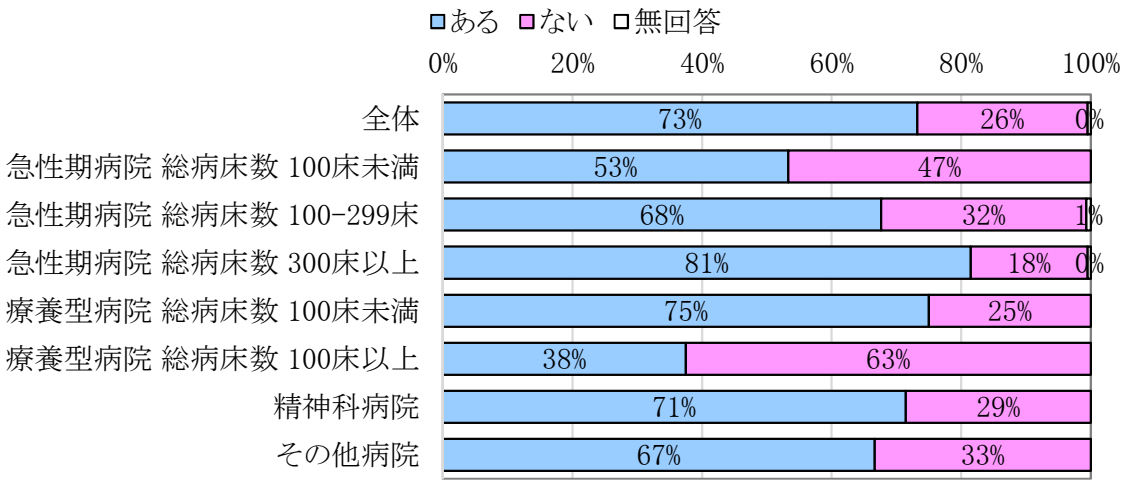
151. 電子カルテのログインパスワードの定期的な更新を義務化していますか。

n=403



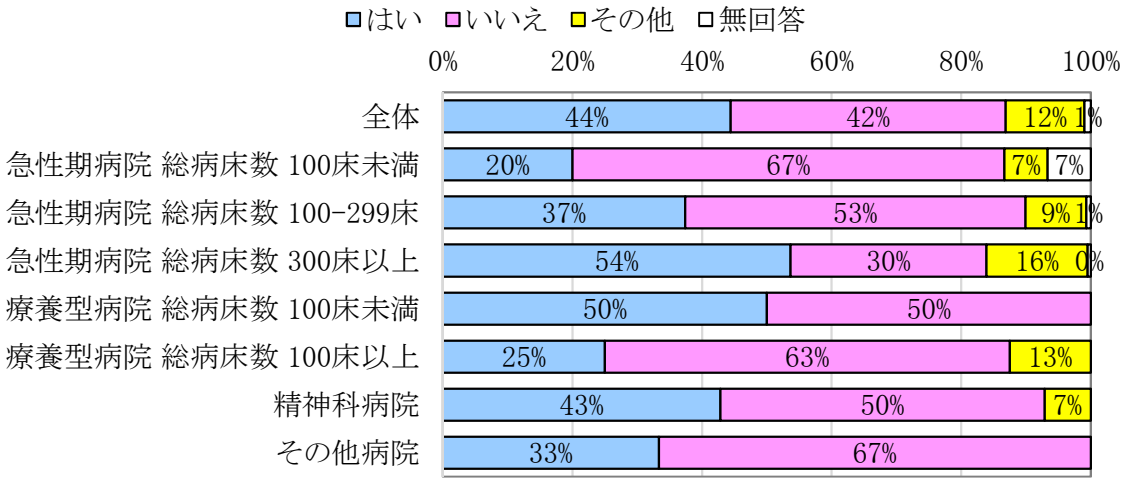
152. 診療記録の不適切な閲覧（診療に関係しない興味本位な閲覧）を制限する取り決めがありますか。

n=403



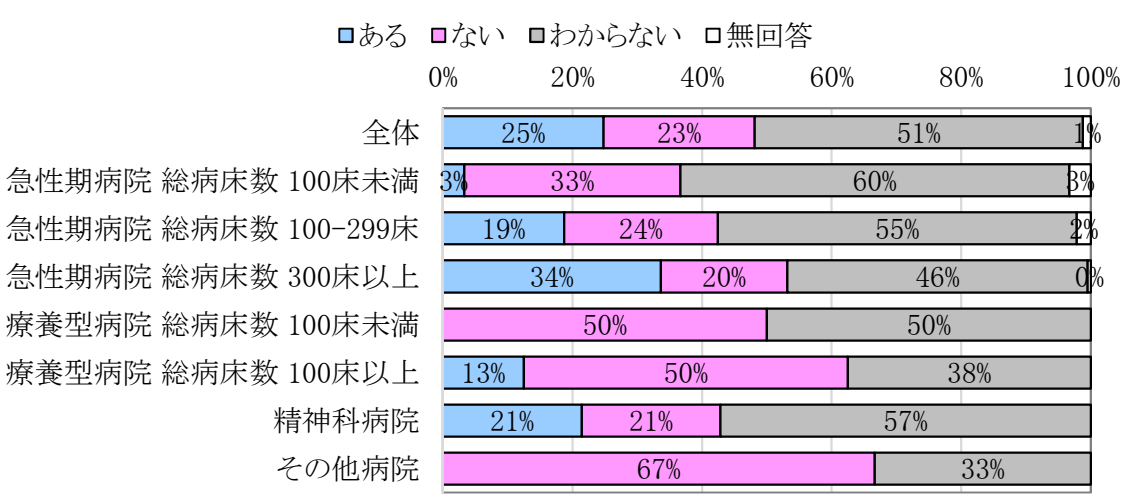
153. 職員による診療記録の閲覧状況を監査していますか。

n=403



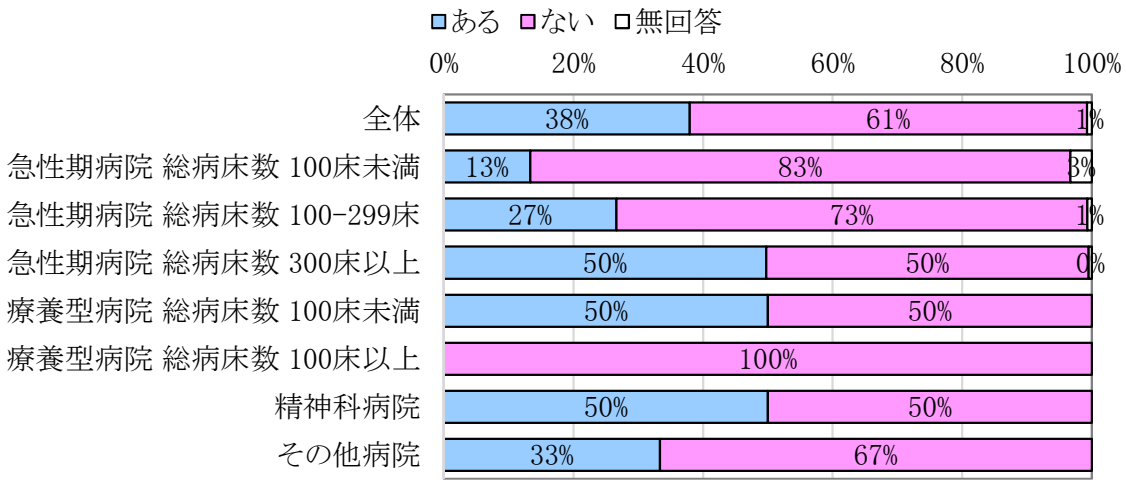
154. 有名人や職員が入院した際、当該患者の診療記録の閲覧が増加したことがありますか。

n=403



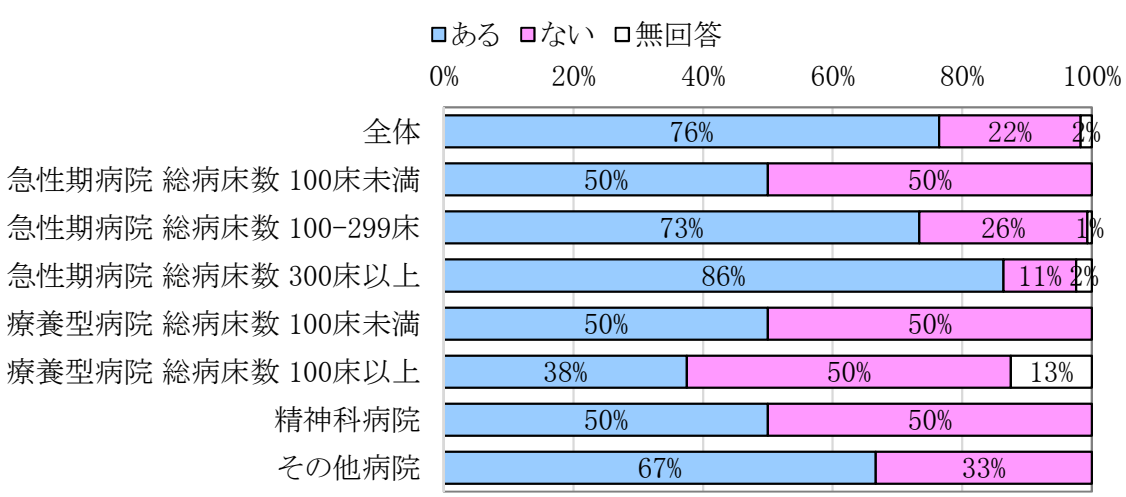
155. 有名人や職員が入院した際、当該患者の診療記録に電子的な閲覧制限をかけることがありますか。

n=403



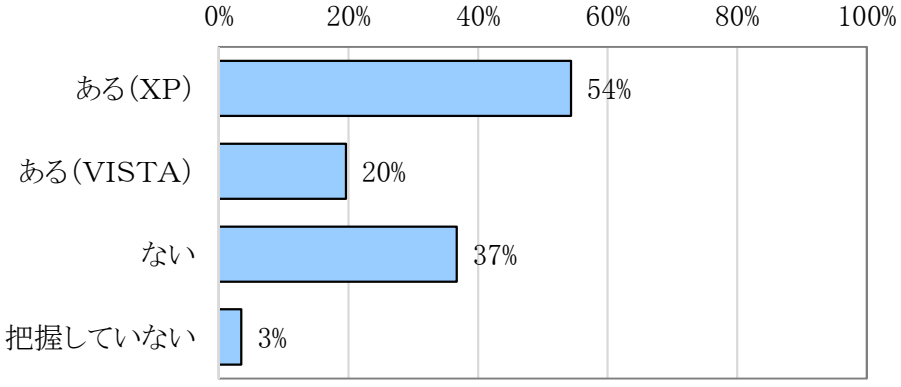
156. 診療以外の研究等を目的とした、診療情報の使用申請手順・基準はありますか。

n=403



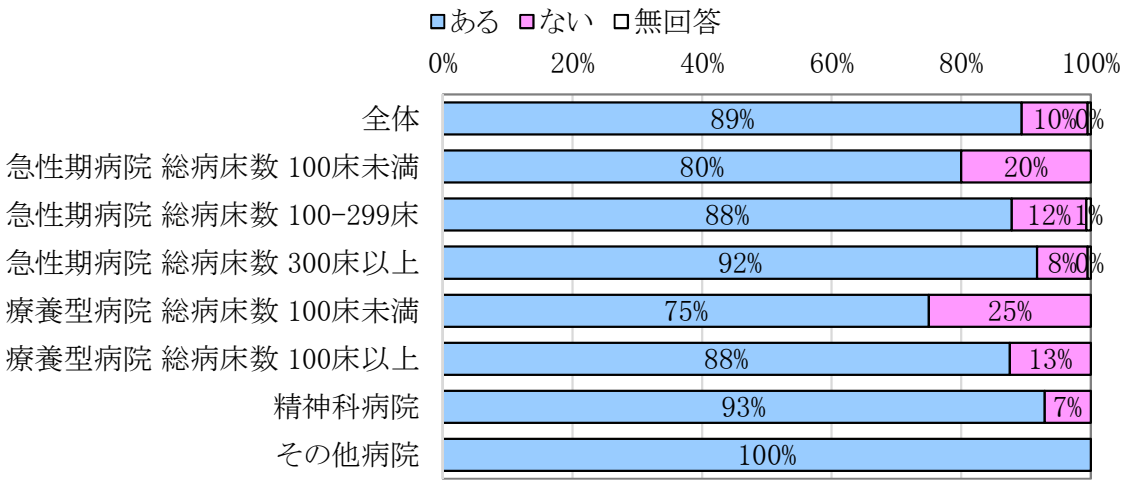
157. Microsoftのサポートが終了したOSを搭載したパソコンが院内にありますか。（当てはまるもの全て選択）

n=403



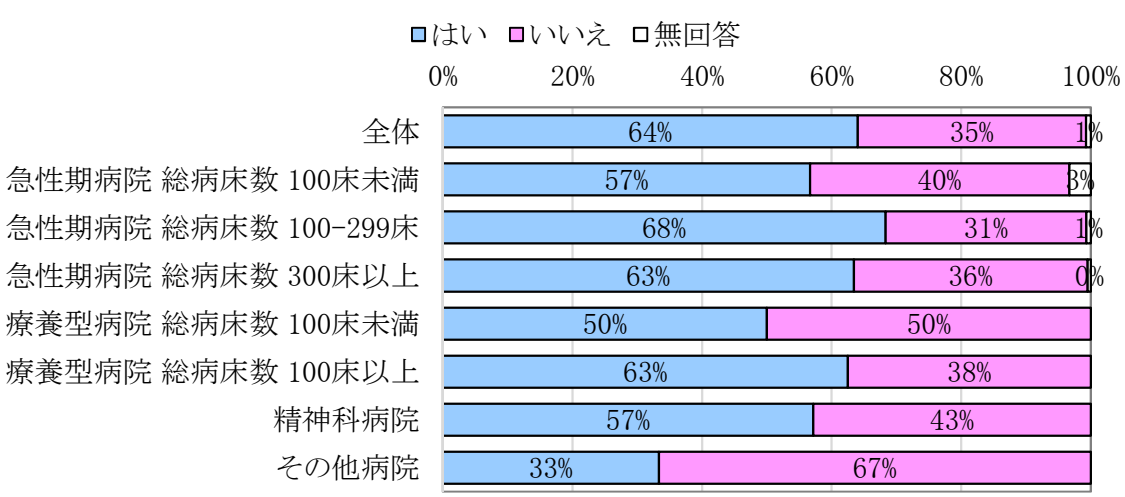
158. 職員がフラッシュメモリ(USBメモリ)を使用する際の取り決めはありますか。

n=403



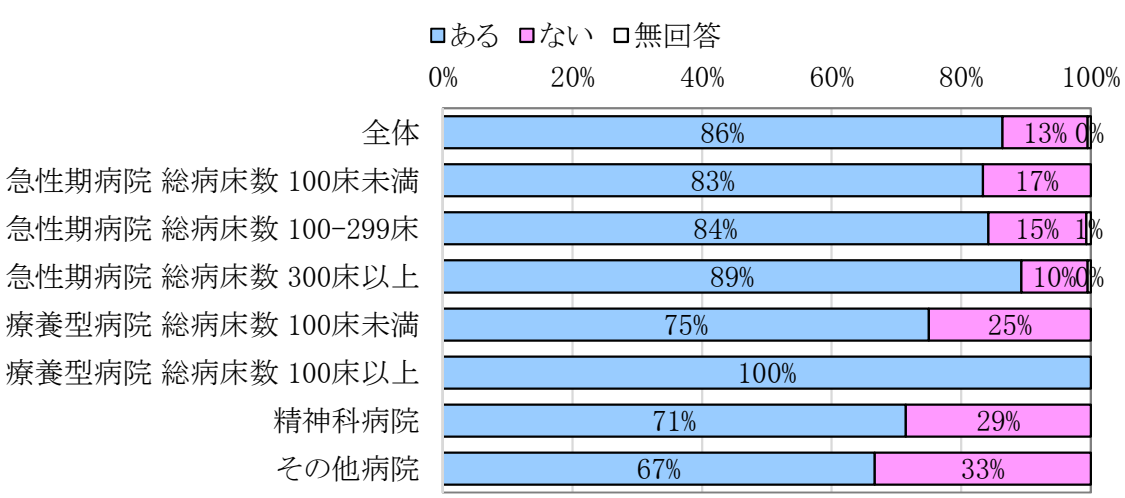
159. パソコンのソフトウエアに定期的に修正プログラムを適用していますか。

n=403



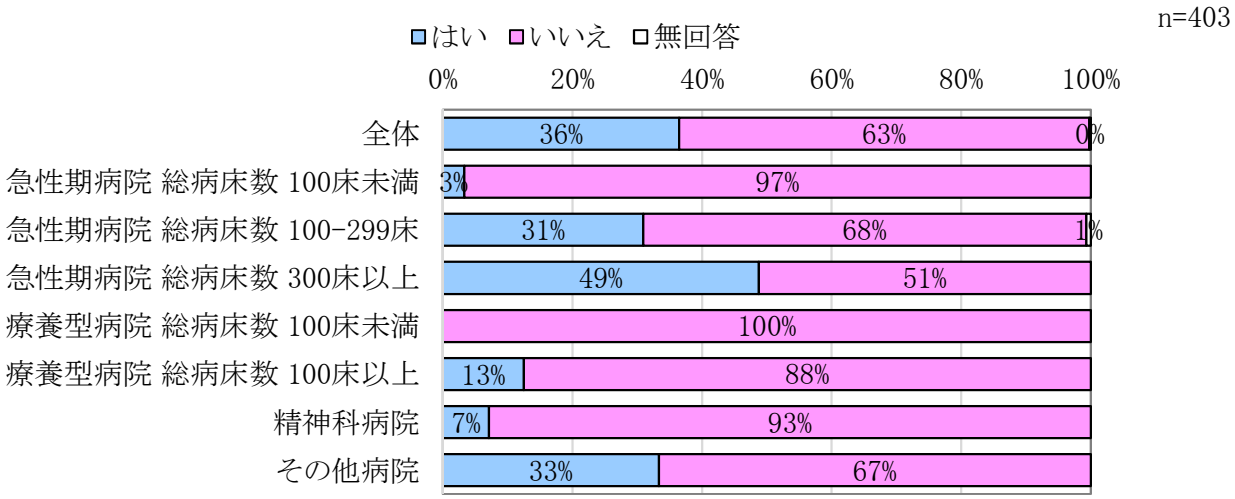
160. 電子カルテ、院内LAN端末のインターネット接続に関する取り決めはありますか。

n=403

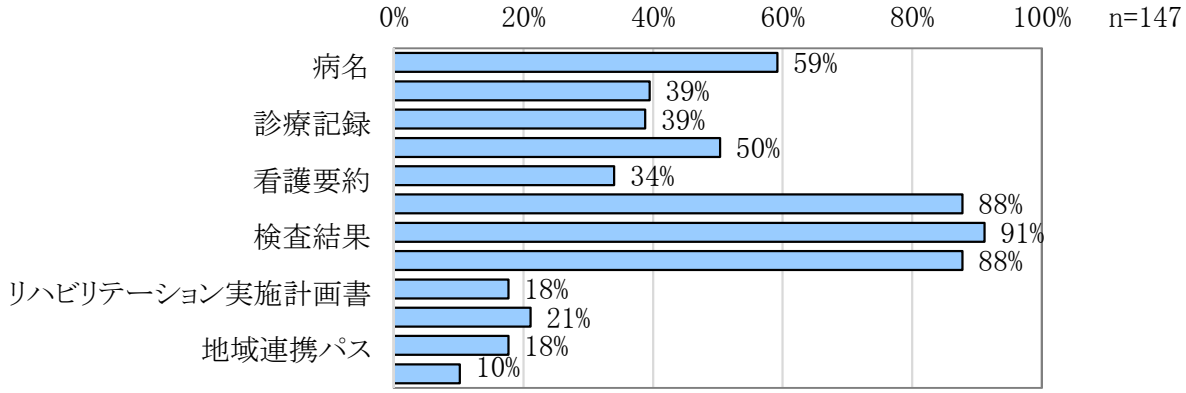


＜地域連携システムについて＞

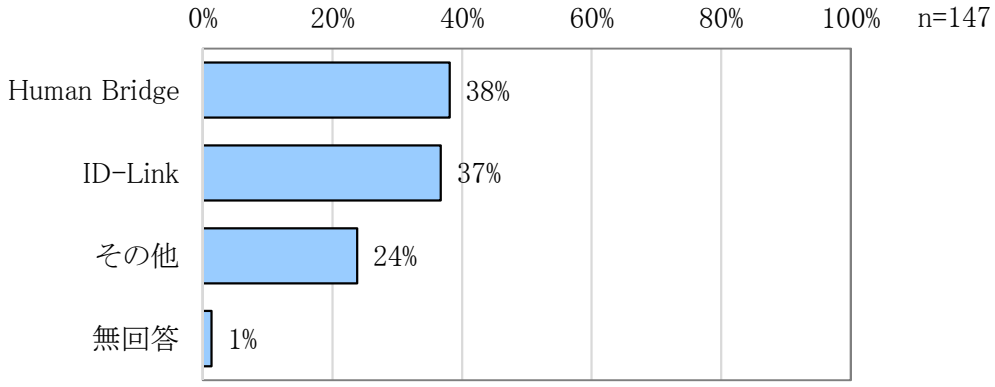
161. 電子カルテシステムを地域連携システムに接続していますか。



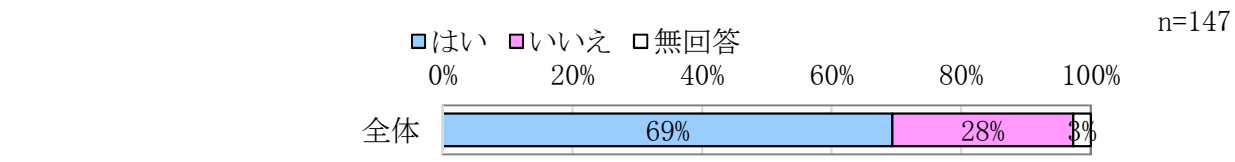
162. 情報交換している内容は何ですか。(当てはまるもの全て選択)



163. 地域共通の患者IDを管理するのに使用しているシステムは何ですか。



164. 情報交換に統合用SS-MIX(SS-MIX2を含む)を使用していますか。

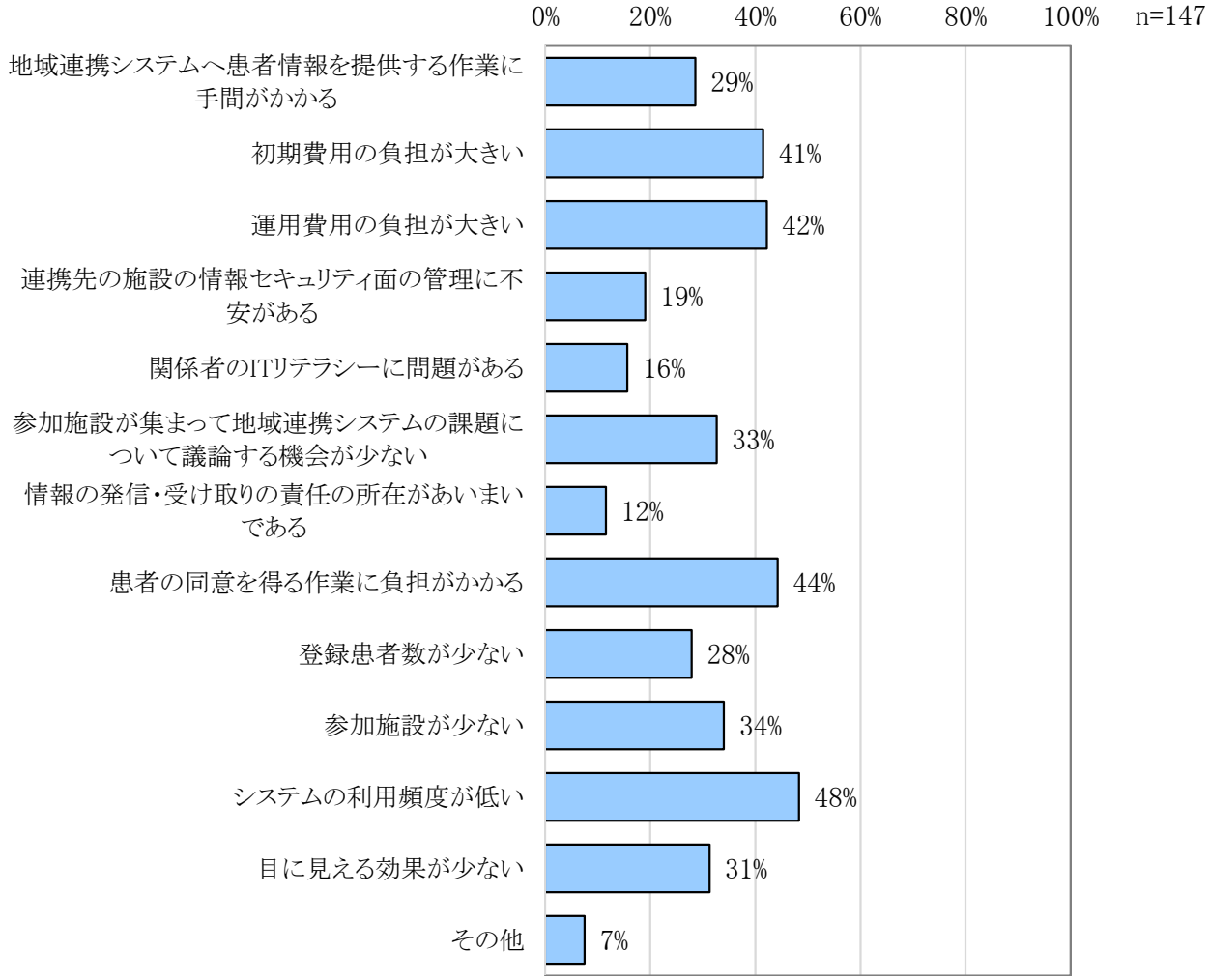


165. 地域連携システムに参加している施設の種類と数をお答えください。(当てはまるもの全て記入)

n=147

		平均値	中央値
01	病院	38 ヵ所	14 ヵ所
02	診療所	140 ヵ所	46 ヵ所
03	保険薬局	44 ヵ所	7 ヵ所
04	介護施設	13 ヵ所	2 ヵ所
05	訪問看護ステーション	10 ヵ所	3 ヵ所

166. 地域連携システムについて困ったことはありますか。(当てはまるもの全て選択)



167. 病院情報システムの機能、管理、運用等について、研究班によるヒアリング調査にご協力いただけますか。

電子カルテ導入済みの病院のうち、「はい」と回答した病院数は次の通り。

層化抽出された病院	全日本病院協会の非会員	53
	全日本病院協会の会員	34
層化抽出から漏れた全日本病院協会の会員		24
合 計		111

以上

資料3

ひと、くらし、みらいのために
厚生労働省
Ministry of Health , Labour and Welfare

Patient Safety
Global Ministerial Summit 2018

Patient Safety Policies
– Experiences, Effects and Priorities;
Lessons from OECD Member States –

April 2018

Third Global Ministerial Summit on Patient Safety

Patient Safety Policies – Experiences, Effects and Priorities; Lessons from OECD Member States –

Authors: Tomonori Hasegawa, Shigeru Fujita

SUMMARY

Patient safety involves various aspects at three levels: health policy (system), in-hospital (organizational), and clinical practice. All of them are profoundly related to establishing a database for benchmarking, sharing information, staff training, monitoring of patient safety indicators, detection of adverse events, investigation, introduction of protective methods, compensation, patient/employee satisfaction, patient safety culture, and proper funding. In the last 20 years, many countries have learned that patient safety is a complex, composite issue which reflects the maturity and achievement of society. In an aging society, the mainstream of healthcare is moving from acute care hospitals to the community care setting, including home health care and nursing homes. In the latter, there are fewer resources available for ensuring patient safety, and so a more cost-effective and convincing patient safety system needs to be established. Such a system could be used in developing countries with limited resources.

This report examines the latest state of major policies related to patient safety in various countries, to serve as a reference for policymakers. A questionnaire survey was conducted in December 2017, targeting policymakers concerning patient safety in OECD member states.

In spite of the limited time, 18 of the 35 states (51%) answered the questionnaire, providing precious information for member states to share. More than half of responding states have a law that requires hospitals to establish a patient safety management system. Most accreditation systems are on a voluntary basis, but all hospitals are obligated to be accredited in the United Kingdom, and some provincial/territorial governments in Canada require hospitals to be accredited according to each law. How best to promote accreditation and standardization is an issue that needs to be addressed, since accredited hospitals accounted for less than 50% in most states. The assignment of personnel responsible for patient safety management (patient safety managers) in hospitals is reimbursed only in Japan and Korea, and the effects need to be investigated.

Most hospitals are submitting data using clinical indicators relating to patient safety. Most data submission systems are on a voluntary basis. The number of required indicators is 238 in Germany, and about 150 in Switzerland. The collected data are made public in such a way that the hospital can be identified in more than half of the states. A pay-for-performance scheme according to reported clinical indicators has been introduced in France, Korea, and Portugal. As a driver of quality improvement, benchmarking with a reference database seems to be more popular than pay-for-performance schemes. In most states, hospitals are requested to report serious adverse events to the government. Patients or family members are also able to report events to the national system only in Korea and Portugal. Alerts or aggregated data of reported adverse events are published in each state.

Regarding screening of adverse events, investigation of in-hospital deaths is obligated in some states. In France, in-hospital deaths that relate to surgery, anesthesiology or cancerology have to be reviewed by morbidity-mortality conferences. In Japan, all in-hospital deaths have to be reviewed irrespective of whether the case meets the reporting criteria of the Adverse Event Investigation System or not. In Spain, there are hospital mortality commissions in each hospital. In Germany, there is a financial incentive for post-mortem examination. Not only an autonomous reporting system but also other screening systems may be needed to identify problems, because low sensitivities or under-reporting by healthcare workers may conceal problems in the hospital.

In the case of adverse events, hospitals are expected to conduct an in-hospital investigation. In some states,

in addition to in-hospital investigation, external investigation by a third-party organization has been introduced. Attempts have been made to standardize the method of in-hospital investigation in most states with guidelines and recommended methods. A support system is also available in some states.

No-fault compensation has been introduced in several states. It is sometimes difficult to specify the cause of adverse events, and this system helps to support patients and establish good relationships between patients and healthcare organizations, and to encourage them to cooperate in establishing effective prevention methods. A no-fault compensation scheme for extensive adverse events has been introduced in Denmark, Finland, France, and Portugal. The scheme in Belgium, Japan and Korea covers some adverse events. The establishment of a no-fault compensation scheme for extensive adverse events may be a big challenge, but a scheme that focuses on limited areas, such as adverse drug events or newborns with cerebral palsy, may be easier to introduce as a first step.

The work was supported by Research on Region Medical of Health, Labour and Welfare Sciences Research Grants (H29-IRYO-IPPAN-004). The opinions and statements expressed in this report do not necessarily reflect the official views of each government.

ACKNOWLEDGEMENTS

With the support of academic researchers, this work was undertaken by the Ministry of Health, Labour and Welfare of Japan to provide a brief report for the 3rd Global Ministerial Summit on Patient Safety in Tokyo, April 2018.

The authors would like to thank the respondents for providing precious information from Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Japan, Korea, Mexico, Portugal, Slovakia, Slovenia, Spain, Switzerland and the United Kingdom. We would like to acknowledge a project team of the summit for their suggestions on the survey. Within the Health Policy Bureau in the Ministry of Health, Labour and Welfare of Japan, we are very grateful to Kiwamu Nagoshi, Ogusa Shibata, Miyako Otsuka, Kaoru Katata, and Mika Kakuta for their support and management of the survey.

TABLE OF CONTENTS

INTRODUCTION

In the early 21st century, major states recognized that patient safety is an urgent threat to the society and should be regarded as the cornerstone of health policy following several serious adverse events in renowned hospitals. Patient safety methods can be classified into three levels: health policy (system), in-hospital (organizational), and clinical practice. Most studies on patient safety belong to the in-hospital and clinical practice levels. Policymakers who are responsible for patient safety issues sometimes struggle to find information on the possible options and their effects.

At the last Global Ministerial Summit on Patient Safety in Germany, the OECD distributed a report entitled "The Economics of Patient Safety – Strengthening a value-based approach to reducing patient harm at national level". The report estimated the cost of patient harm, and outlined a strategy for policymakers and healthcare leaders to improve patient safety with limited resources. This information was very useful for policymakers in each state.

In April 2018, the 3rd Global Ministerial Summit on Patient Safety will be held in Tokyo. The Japanese Government, as the host, plans to provide the latest information on patient safety policies in OECD member states. This report clarifies the latest major policies related to patient safety in each state; we hope that it is helpful for policymakers in each state.

METHODS

The authors drew up a questionnaire that asked about major policies related to patient safety in each state and asked respondents to estimate the effectiveness and priorities of those policies. The effectiveness concerns the expected reduction of morbidity and mortality by introducing the policy, while the priority concerns the allocation of resources in each state in the near future. The questionnaire was revised several times based on comments from a project team of the Tokyo Summit and several experts on patient safety. Items in the questionnaire are shown in the Appendix.

The questionnaire survey was conducted in December 2017, targeting policymakers concerning patient safety in OECD member states. The questionnaire was distributed by e-mail by the Ministry of Health, Labour and Welfare of Japan to the delegates of OECD member states, transferred to the key persons involved in patient safety policies in each state, and collected by e-mail. We compiled the results of the questionnaire into a report on patient safety policies in each state. The respondents rated the effectiveness and priority of patient safety policies using a Likert scale of 1 (low) to 5 (high). For convenience, a favorable policy is defined as one that was rated high in effect ($\geq$3.5) and in priority ($\geq$4), and an unfavorable policy as one that was rated low in effect ($<$3) and in priority ($<$3). The evaluation depends on the mean values of the ratings for each policy.

RESULTS

The response rate of the survey was 51% (18/35). Most of the respondents or the counterparts of the survey were policymakers of the Ministry of Health in each state.

1. Safety standards

Hospitals are required to establish a patient safety system by law in 9 states. Among them, all hospitals are required to establish the system in 6 states. The contents of requirements vary, but guiding principles, organization, patient safety manager, in-hospital reporting system or staff training on patient safety were commonly cited. Measurements of patient safety and participation of patients and caregivers are defined in some states, and may be the subject of discussion.

1.1 Requirement for hospitals to establish a patient safety management system by law

All hospitals are required: CZE, FIN, FRA, ITA, JPN, PRT, GBR

Some hospitals are required: CAN, KOR, ESP

Not required: BEL, IRL, SVK, SVN, CHE

Others: DNK, DEU, MEX

1.2 Actions required for hospitals

		CAN	CZE	DNK	FIN	FRA	DEU	ITA	JPN	KOR	MEX	PRT	ESP	GBR
1.2.1	To define the guiding principles (or guidelines) for patient safety program	+	+	−	+	+	+	+	+	+	−	+	+	+
1.2.2	To define the organization for patient safety management	+	+	+	+	+	+	+	+	+	−	+	+	+
1.2.3	To define who is assigned in charge of the patient safety management	−	+	+	+	+	+	+	+	+	−	+	+	+
1.2.4	To define the in-hospital reporting system for adverse event and close calls (near misses)	+	+	−	+	+	+	+	+	−	+	+	+	+
1.2.5	To define procedures for identification, investigation and prevention of adverse events	+	+	+	+	+	+	+	+	+	+	+	+	+
1.2.6	To define the staff education and training for patient safety	+	+	+	+	+	+	+	+	+	−	−	+	+
1.2.7	To define patient and caregiver participation in patient safety efforts	+	+	−	−	−	+	−	−	+	−	+	+	+
1.2.8	To define the measurement and evaluation of methods for patient safety (including patient safety indicators)	+	+	−	+	+	+	−	−	+	−	+	+	−

+; Yes/A requirement/Exist, −: No/Not a requirement/Not exist, ±; Others, N/A; Not applicable

1.3 Details in each country

Canada

Law

Canada has legislation specific to patient safety, but due to Canada's decentralized health system, patient safety legislation and management varies across jurisdictions and is managed at the provincial/territorial health system level. Provincial/territorial health ministries may describe guidelines or requirements for the establishment of patient safety management systems for hospitals. For example, it is required by law in Quebec: S-4.2 - Loi sur les services de santé et les services sociaux. Ontario has The Excellent Care for All Act, and Newfoundland has the Patient Safety Act.

Guiding principles (or guidelines)

Hospitals - with their Regional Health Authority (RHA) and/or provincial/territorial Health Ministries - are required to define guidelines for their patient safety program including: patient safety education; reporting and tracking systems for patient safety incidents; all elements of incident management including guidelines for disclosure and support to patients, families and clinicians; risk management; investigation; and follow up reports and surveillance.

Organization

In Quebec, the law S-4.2 requires hospitals to establish a Risk Management Committee that oversees all Patient Safety related investigations, projects and strategic priorities. The Law further outlined the role and composition of the committee. Otherwise, hospitals define which department within the hospital manages patient safety activities.

Ontario's Excellent Care for All Act (ECFAA) requires every health care organization to establish a quality committee responsible for monitoring and reporting on quality issues at the hospital.

Person in charge of patient safety management

This is not specified by law. Guidelines exist that describe the competencies and experiences required for this role. Each hospital/health region has a quality/patient safety/risk management department or lead who is in accountable for managing the comprehensive processes needed to ensure patient safety.

In-hospital reporting system

In some provinces, this is described at a higher level, for example by the regional or provincial level. Reporting systems for adverse events vary by province in Canada but within a province, consistency across sites allows clinicians and patients to become familiar and comfortable with reporting processes.

In Quebec, the law S-4.2 defines in-hospital reporting system for adverse events and near misses, requiring a central reporting of adverse events.

Procedures for identification, investigation and prevention of adverse events

This process varies across provinces and territories. Within institutions, strategies for identifying adverse events include self-reporting, use of trigger tools, audits, insurer collected information, and other methods; most rely on an examination of past harms. Investigation processes may range by province but can include a privileged process consisting of interviews, research, chart reviews, and the creation of a summary document. Others may use the LEAN method to do a systematic review focused on improvements that can be quickly and easily implemented to prevent future harm. Decision making for what type of investigation to do may be aided by the use of a severity and impact matrix. The Quebec Law S-4.2 requires the establishment of policy and procedure for incident reporting, analysis and disclosure.

Staff education and training

Patient Safety staff education and training is required for accreditation purposes (and all Canadian hospitals and most other health care facilities are accredited). There may be leadership regionally or provincially, but

typically every health authority or hospital creates their own patient safety education program. This includes general patient safety awareness for all staff at orientation, information on how to report an incident, what the best practices are in patient safety in hospitals, current hospital improvement activities aimed at improving patient safety, and where to get more information.

Patient and caregiver participation

Patient and family engagement in patient safety is also an accreditation requirement for Canadian Hospitals. This is, however, defined locally. There are various ways for patients and caregivers to be involved in improvement efforts, including: having patients participate on LEAN improvement teams; supporting a patient, family and caregiver advisory council; and hearing patient stories at board meetings, events and during patient safety week. To some extent, the direction may come from a regional health authority and in fact, they may also have regional-level activities and efforts to improve patient safety that include patient and caregiver participation. There are various sources across Canada that define patient and family participation in patient safety. These include:

- Engaging Patients in Patient Safety - a Canadian Guide, developed by the National Patient Safety Consortium.
- Accreditation Canada's accreditation program has embedded client and family centered care in all their standards, and included patient representatives in the accreditation team.
- Patients For Patient Safety Canada (PFPSC) is a patient-led program of CPSI. PFPSC is the voice of the patients and brings the patient's safety experiences to help improve patient safety at all levels in the health system.

Measurement and evaluation

Ontario and Quebec have province-wide requirements and require the reporting of various types of patient safety indicators such as rates of nosocomial infections, wait times for surgeries, etc. Except for indicators of nosocomial infections, Ontario indicators include a rate for Surgical Safety Checklist Compliance.

Czech Republic

Law

Act no. 372/2011 Coll.

Bulletin 16/2015 Coll. Minimum requirements for the establishment of an internal system of quality assessment and safety of provided health services.

Denmark

Law

Government provides national system.

Organization

It is required locally.

Person in charge of patient safety management

It is required locally.

Finland

N/A

France

Law

The 2009 law about "Hospital reform and concerning patients, health and territories" (2009-879 dated 21 07

2009) states in its first article that healthcare quality, patient safety and management of risks, including their prevention and control, are a policy target for all healthcare structures, whatever type of care they provide, whatever public or private status they are.

The ministerial decree, 2010-1408 dated 12 11 2010, established further obligations for this patient safety policy in hospitals. This decree states:

a) what is a healthcare adverse event in hospitals,
b) that the director and the president of the medical community of the hospital are both liable for the management of patient safety in the structure and for its operational framework for which
c) they assign a dedicated professional,
d) what are the targets of this organization: patient safety culture, coordination, expertise, putting up a program and its yearly evaluation, on-going training, etc.

These policy lines have been disseminated in a more operational and detailed document called "instruction".

Patient and caregiver participation

This specific theme is integrated in the National Patient Safety Program 2013-2017. Its first target (out of 4) is dedicated to partnership with patient and patients' representatives. It includes deliverables for both professionals and patients, and also for their representatives. All deliverables aim at a better communication and partnership.

Germany

Law

There is no specific law related to patient safety. However, the Social Code Book Five (SGB V), that is a law for statutory health insurance, obligates the Federal Joint Committee to define measures for the improvement of patient safety and to establish minimal standards for risk management systems and Critical Incident Reporting System (CIRS). The respective regulation of the Federal Joint Committee (Gemeinsamer Bundesausschuss: G-BA) that are binding for all parties in the statutory health insurance is the Quality Management Guideline (§§1-4 Qualitätsmanagement-Richtlinie: QM-RL).

Guiding principles (or guidelines)

In accordance with the QM-RL, the mandatory quality management achieves to define general methods for securing and developing the quality of the health care including patient safety (§3 QM-RL).

Organization

Structures of the organization, responsibilities, competences and decision responsibilities are to be established in a written form (§4(1)3 QM-RL).

In-hospital reporting system

Hospitals are obliged to establish an internal Critical Incident Reporting System (CIRS). Required features are a low threshold access for all levels and professions of staff and a customer friendly layout (§4(1)14 QM-RL). In addition, there is an incentive for hospitals to engage in multi-center Critical Incident Reporting System (CIRS) programs in accordance with Hospital Financing Act (§17b (1a(4))). The engagement is voluntary.

Procedures for identification, investigation and prevention of adverse events

The risk management system in a hospital is mandatory to establish. A systematic risk management strategy includes the systematic recognition, estimation, processing and oversight of risks as well as the analysis of critical and undesired events, damages and, finally, the elaboration and realization of preventive measures (§4 (1)13 QM-RL).

Staff education and training

Participation of all staff in trainings and educations that relate to their occupation is compulsory (§4(1)7 QM-RL). However, there is no special regulation to make patient safety a topic of these trainings and educations.

Patient and caregiver participation

According to the QM-RL (§4(1)13), the patient-and staff-perspectives are explicitly to be considered, but the elaboration of specific measures for patient participation is left up to the hospital.

Measurement and evaluation

According to QM-RL (§2), internal goals in each institution are to be elaborated in a systematic process that includes systematic planning, implementation, revision and, if necessary, improvement (so called PDCA-plan – plan, do, check, act). Quantitative and qualitative indicators are used to evaluate the benchmarks internally and to foster implementation.

Ireland

Law

The Irish Government has approved the General Scheme of Patient Safety (Licensing) Bill. This Bill is being progressed and all hospitals will be required to hold a license to operate. This license will require hospitals to meet core patient safety standards and have clinical governance frameworks in place.

Italy

Guiding principles (or guidelines)

The Italian Ministry of Health defines the guidelines, and the hospitals adapt these guidelines to their context.

Person in charge of patient safety management

Every hospital has a risk manager who is responsible of Patient Safety at hospital level.

Procedures for identification, investigation and prevention of adverse events

The MoH published a guide on the analysis systems with the aim of facilitating identification, investigation and actions for the prevention of similar events.

Japan

Law

Patient safety management in hospitals is requested by the Medical Care Act that covers broad contents concerning hospital management and standards. Under the Medical Care Act and the Ordinance for Enforcement of the Medical Care Act, all healthcare organizations including hospitals and clinics are required to establish patient safety policies, to organize a patient safety management committee, and to provide patient safety training for employees every year.

Person in charge of patient safety management

Special function hospitals, such as university hospitals that provide advanced medical care, are required to assign patient safety managers responsible for patient safety management. For other hospitals, assignment of patient safety managers is not mandatory, but is encouraged by financial incentives: hospitals with patient safety managers can receive more money from public medical insurance. Most acute care hospitals have already assigned patient safety managers.

All hospitals are required to designate a person responsible for pharmaceuticals safety and a person responsible for medical device safety. Those personnel are required to establish procedure manuals regarding medication, dispensing or medical device management, and to monitor alerts from related organizations.

In-hospital reporting system

All healthcare organizations are required to implement an in-hospital reporting system for incidents and accidents.

Korea

Law

Patient Safety Act

Guiding principles (or guidelines)

Patient safety standards (Article 9 of the Patient Safety Act; and Article 6 of the Enforcement Decree of the Patient Safety Act)

Organization

Tertiary hospitals (general hospitals) and hospital-level medical institutions with 200+ beds are required to establish and operate a patient safety committee within hospital. (Article 11 of the Patient Safety Act; and Article 6-7 of the Enforcement Rule of the Patient Safety Act)

Person in charge of patient safety management

Tertiary hospitals (general hospitals) and hospital-level medical institutions with 200+ beds are required to deploy personnel dedicated to patient safety within hospital (Article 12 of the Patient Safety Act; and Article 9 of the Enforcement Rule of the Patient Safety Act).

Patient and caregiver participation

Paragraph 2/Article 5 of the Patient Safety Act states the responsibility of patients and their guardians to participate in patient safety activities.

Measurement and evaluation

It is mandatory to develop and disseminate assessment standards (patient safety indicators) which can measure performance on patient safety and the quality of care (Article 10 of the Patient Safety Act; and Article 4 of the Enforcement Rule of the Patient Safety Act).

Mexico

Law

In September 2017, the General Health Council, published in the Official Federal Diary the Essential Actions for Patient Safety, this document is not considered a law, but it has a mandatory character to all hospitals in Mexico. The implementation of this actions will be supervised by the accreditation process that is necessary to be eligible to receive funds from the "Seguro Popular".

Organization

The hospital committee for quality and patient safety convenes at least 3 times a year, to analyze all potential risks in patient safety. All sentinel events must be analyzed by the quality and patient safety committee.

In-hospital reporting system

The Adverse Event report system is mandatory according to Essential Actions for Patient Safety.

Portugal

Law

The Ministry of Health published

(1) The National Plan for Patients' Safety 2015-2020 (Order nº 1400-A/2015) to establish the national patient safety strategic goals and

(2) the Quality and Safety Commissions Order (Order nº 3635/2013) to determine the creation of Commissions that have to implement the National Strategy for Quality in Health (Order nº 5613/2015) as well as the National Plan for Patient's Safety. These Commissions also have to submit an annual report of the activities developed and the action plan for the next year.

Organization

According to Order nº 3635/2013, all healthcare institutions (hospitals and primary healthcare units) are obliged to have Quality and Safety Commissions, and its president must be designated by the board of director of the Institution.

Slovakia

Law

There is not specific law oriented toward patient safety management, only partial topics are covered e.g. the regulation No. 553/2007 Coll., or quality systems ISO 9001:2000 and ISO 14001:2004. Legislation is in process of preparation. Separately system is required to establish for the purposes of clinical testing of the medicines too.

Slovenia

Law

This area is partly regulated in the Patients' Right Act. The Law on Infectious Diseases is also important. They apply to all healthcare organizations, not only for hospitals. The Quality and Safety Act is the process of preparation. This is an important part of the government project "Šilih". The project represents a government commitment to improve the quality and safety of healthcare.

Spain

Law

Some Health Regions have some patient safety requirements for authorizing healthcare centers. Others have specific laws on PS for all the healthcare centers, but the effects have not been evaluated yet. In addition to that, the national strategy of PS recommends to the Regions to have PS management systems in their healthcare centers (hospitals & primary care). Guideline varies by the Regions.

United Kingdom

N/A

2. Audits and accreditation of hospitals

Periodic audits of patient safety conditions by the government are a common policy in most states, but the audit items vary among states. Hospital accreditation systems and bodies vary among states. The proportion of accredited hospitals is high in Canada, Italy, Slovenia and the United Kingdom. Most accreditation systems are on a voluntary basis, but all hospitals are obligated to be accredited in the United Kingdom, and some provincial/territorial governments in Canada require hospitals to be accredited based on local law. Half of the respondent states have some systems or incentives to encourage hospitals to undergo hospital accreditation. Denmark stopped accreditation in 2015. The effects of accreditation on patient safety are not yet established, and how best to promote accreditation is an issue that needs to be addressed since the proportion of accredited hospitals in most states is less than 50%.

2.1 System of audit and accreditation for hospitals

			BEL	CAN	CZE	DNK	FIN	FRA	DEU	IRL	ITA	JPN	KOR	MEX	PRT	SVK	SVN	ESP	CHE	GBR
2.1.1	Periodic audit for patient safety conditions by the government		+	+	+	+	+	+	±	+	+	+	−	+	+	±	+	+	−	+
2.1.2	Hospital accreditation system by an independent third-party organization		+	+	+	−	−	+	+	±	+	+	+	±	+	±	+	+	−	+
2.1.3	Systems or incentives to support hospitals to undergo hospital accreditation		+	±	+	−	−	−	−	−	+	−	+	+	+	±	+	+	N/A	±
2.1.4	Accredited hospitals	No.	30	N/A	208	N/A	N/A	N/A	N/A	N/A	N/A	2181	1688	3997	74	N/A	28	150	N/A	N/A
		%	16	97	N/A	N/A	N/A	N/A	40	N/A	95	26	44	18	33	N/A	100	33	N/A	100

+; Yes/A requirement/Exist, −: No/Not a requirement/Not exist, ±; Others, N/A; Not applicable

2.2 Name(s) of the accreditation body(ies)

Belgium

Joint Commission International (JCI)

Netherlands Institute for Accreditation in Health Care (Nederlands Instituut voor Accreditatie Ziekenhuizen: NIAZ) - Qmentum

ACI

Canada

Accreditation Canada

Conseil Québécois d'agrement

Commission on Accreditation of Rehabilitation Facilities Canada

Canadian Association for Laboratory Accreditation

etc.

Czech Republic

Joint accreditation committee
Czech Republic Association for accreditation in Healthcare
e-ISO, a.s.
Tcert, s.r.o
EURO CERT CZ, a.s.
LL-C (Certification) Czech Republic a.s.
DNV GL Business Assurance Czech Republic s.r.o.
Czech Republic Quality Union

Denmark

N/A

Finland

N/A

France

Nuclear Safety and Radiation Protection (Haute Autorité de Santé and Autorité de sûreté nucléaire)

Germany

Co-operation for transparency and quality in the hospital (KTQ)
International Organization for Standardization (ISO)

Ireland

N/A

Italy

Regions

Japan

Japan Council for Quality Health Care (JQ)
International Organization for Standardization (ISO)
Joint Commission International (JCI)

Korea

Korea Institute for Healthcare Accreditation (KOIHA)

Mexico

General Directorate of Quality and Healthcare Education (Dirección General de Calidad y Educación en Salud: DGCES)

Portugal

ACSA
Joint Commission
CHKS

Slovakia

International Organization for Standardization (ISO)
Slovak National Accreditation Service (SNAS)
The Czech Society of Clinical Biochemistry
The Reference Laboratory for Clinical Biochemistry in the Czech Republic

Slovenia

Join Commission International (JCI)
Accreditation Canada (AC)
Det Norse Veritas GLAS (DNV)-NIAHO
American Accreditation Commission International (AACI)
Slovenian Independent Organization

Spain

Ministry of Health, Social Services and Equality (MSSSI)
Andalusian Agency of Quality
Cataluya Region, etc
Joint Commission (JC)
International Society for Quality in Healthcare (ISQua)

Switzerland

N/A

United Kingdom

The Care Quality Commission

2.3 Details in each country

Belgium

Audit by government

Only the Flemish government audit patient safety conditions in the Flemish region.
A thematic inspection on specific patient groups whereby safety components are inspected (e.g. high risk medication, patient identification, safe surgery checklist).

Accreditation by a third-party organization

Accreditation in Belgian hospitals is still an ongoing process (in Brussels and Walloon region the accreditation process is initiated only recently). Close to all Belgian hospitals who do not have a certificate yet, are in preparation and will obtain one in the next year(s).
Between 2012 and 2017, there was a financial support for hospitals that participated in a national patient safety program relating to topics of accreditation such as patient identification, safe surgery, high risk medication, integrated care, leadership, communication, patient empowerment, or safety management. From 2018, in a scheme of P4Q for acute hospitals, accredited hospitals will get points and a financial incentive.

Canada

Accreditation by a third-party organization

Hospitals in Canada and most other health care facilities are accredited regularly against defined quality and

safety standards. In most jurisdictions, accreditation is voluntary (exception Quebec where it is required by law, in Alberta where it is required under a directive from the Ministry of Health, and in all Canadian teaching hospitals, where in order to maintain teaching status from Canadian medical regulatory colleges, the hospitals much be accredited, which means that almost every hospital by default must be accredited).
The Quebec Law S-4.2 requires Quebec hospitals to be accredited. The health ministry then requires hospitals who received recommendations in the accreditation process to report to the government on their follow-up improvement activities.

Czech Republic

Audit by government

Adverse events and 8 National safety goals (patient identification, safety in the use of medicinal products, surgical procedures, procedures of hand hygiene, transfer of patients, etc.) are inspected by the government.

Accreditation by a third-party organization

It is not an obligation, but most of the hospital is accredited by independent third-party organizations.

Denmark

Audit by government

Risk based supervision (regulation) with all care units

Accreditation by a third-party organization

It ceased in 2015.

Finland

Audit by government

Patient outcomes/diagnoses are inspected by the government.

France

Audit by government

Inspections are organized on both national and regional levels (the national "Inspection générale des affaires sociales" has a branch in each of the 17 Regional Health Agencies [Agences régionales de santé]). These inspection departments perform the necessary inspections and controls:

a) conformity of settings, equipment and qualifications to existing regulation and
b) on the spot inspections in case of claims, proven risks, defective answers to patient's unexplained death or other difficult situations, and any other situation they consider at high risk.

Accreditation by a third-party organization

Accreditation of hospitals has been launched in 1999 (and ever since named "certification"). It is an external and compulsory process of quality assessment imposed on every healthcare structure, including autonomous plastic surgery settings. It is led by healthcare experts (medical and non-medical peers) appointed by an independent body, Haute Autorité de santé, and carried out every 4 to 6 years in each HC structure.

Germany

Audit by government

It is not a responsibility of the federal government to provide on-site medical care. It is regulated individually at state level. The Joint Commission (G-BA) put the Institute for Quality Assurance and Transparency (IQTIG) in charge of developing recommendations for establishing and explaining the state of quality management;

including the use of representative sample surveys (§ 6 QM-RL). So far, hospitals are obliged to report the state of their quality management and Critical Incident Reporting System (CIRS) in their annual "quality reports" (§§ 136a(3)2 and 136b(6)V).

Accreditation by a third-party organization

There is no compulsory accreditation of hospitals. However, many hospitals opt for a voluntary certification by an independent organization for their quality management. There are no official numbers of accredited hospitals because ISO does not publish them. It is estimated that 40% of the 1900 hospitals underwent certification.

Ireland

Audit by government

Via the Health Information and Quality Authority which is a service regulator under the aegis of the Department of Health. Hospitals follow the National Standards for Safer Better Healthcare (2012). Themes include maternity, hygiene, nutrition, and medication safety. Disability and social care services are regulated as designated centres under specific HIQA Standards.

Accreditation by a third-party organization

International accreditation systems are used by private hospitals. This is not prescribed by the government however it is required by health insurers.

Italy

Accreditation by a third-party organization

The accreditation process is performed by Regions. All the public hospitals are accredited. Private hospital can ask for accreditation with the National Health System. A small group of private health facilities are not accredited with the NHS.

Japan

Audit by government

Under the Medical Care Act, the prefectural government audits hospitals by an on-the-spot inspection every year.

Accreditation by a third-party organization

Accreditation is not mandatory. For some hospitals such as university hospitals and teaching hospitals, accreditation is recommended by the government. The Japan Council for Quality Health Care (JQ) is the biggest third-party accreditation body. Activities of the JQ include: (1) hospital accreditation, (2) clearinghouse of clinical practice guidelines, (3) nation-wide medical incident and accident reporting system, and (4) no-fault compensation of cerebral palsy babies.

Korea

N/A

Mexico

Audit by government

Through the accreditation and certification process, all facilities from the public and private sector need to prove that they comply with patient safety conditions. The General Health Council certificates the medical facilities. The medical facilities voluntarily request the certification. This process evaluates patient safety conditions, and is performed up to every 5 years.

The inspected items are the essential actions for patient safety measure: 1. patient identification, 2. effective communication, 3. correct medication process, 4. correct procedures, 5. control of healthcare associated infections 6, control of patient falls, 7. adverse events reports, 8. patient safety culture.

Accreditation by a third-party organization

The accreditation is performed by the General Directorate for Quality and Healthcare Education, and the certification is performed by the General Health Council, both are public entities. The accreditation is necessary for medical facilities to be eligible to receive funds from the "Seguro Popular".

Portugal

Audit by government

There is a protocol signed by the Ministry of Health and by the Portuguese Medical Association to audit regularly national guidelines. The annual plan for audits is defined by the Ministry of Health for specific national guidelines or specific clinical areas (Examples: prescription of antimicrobials and diabetes, WHO safety surgery checklist, etc.).

Accreditation by a third-party organization

ACSA accredits 54 hospitals and services; Joint Commission accredits 9 hospitals; CHKS accredits 11 hospitals. Portugal also have an accreditation of the Primary Care Units (42). The ACSA model is a no-profit Ministerial accreditation program.

Slovakia

Audit by government

There is no regular governmental audit system for patient safety conditions.

Accreditation by a third-party organization

Hospitals can use the ISO on a voluntary basis. It is regarding Integrated Quality Management and Environmental Management according to ISO 9001: 2000 and ISO 14001: 2004 standards. We do not have information about number of all certificated hospitals.

There is an external independent accreditation system for the medical or clinical laboratories only.

Slovenia

Audit by government

There are regular professional control and counseling. The regular surveillance program is public available. Administrative controls are also carried out. The Medical Chamber and the Health Care Chamber also obtained a public authorization to carry out inspections. The control is carried out for a particular area (health care, physiotherapy, etc.) or for a particular provider.

Protocol:

- verification of the adequacy of professional development and organization of work,
- checking the implementation of quality and safety in the field of expertise,
- checking the continuous tracking of the development of the profession,
- checking and complying with doctrines and guidelines in the field of work,
- verification of the performance of professional activities in accordance with professional and ethical codes,
- checking the appropriate staffing,
- consultations on the basis of the findings of expert supervision,
- team work.

Accreditation by a third-party organization

Certification and accreditation processes vary in Slovenia. All hospitals in Slovenia are accredited. For hospitals without accreditation, the pay activity was reduced by 0.3%.

Spain

Audit by government

The government audits patient safety condition for teaching hospitals and reference centers. Hand hygiene, patient identification, management of high risk medication, protocols of medication reconciliation and Reporting and Learning System (R&LS) are inspected.

Accreditation by a third-party organization

Some hospitals accredited in some of the Regions. The MSSSI accredited 150 teaching hospitals, and this figure refers only to public hospitals (451 in total). In Spain, there are 791 public and private hospitals in total. Incentives for accreditation varies by region, including funding by the Healthcare Region.

Switzerland

N/A

United Kingdom

Audit by government

The UK Care Quality Commission inspects all Hospitals and rates their performance against 5 key indicators, one of which is safety. This indicator includes information regarding safe staffing levels, patient monitoring, capability to investigate mistakes, cleanliness and contingency planning.

Accreditation by a third-party organization

Accreditation is a mandatory requirement.

3. Data submission requirements by hospitals

Most data submission systems of clinical indicators are on a voluntary basis. The number of required indicators is 238 in Germany, and about 150 in Switzerland. The collected data are made public in such a way that the hospital can be identified in more than half of the states. A pay-for-performance scheme according to reported clinical indicators has been introduced in France, Korea, and Portugal. As a driver of quality improvement, benchmarking with a reference database seems to be more popular than pay-for-performance schemes.

In most states, hospitals are requested to report serious adverse events to the government. Patients or family members are also able to report events to the national system only in Korea and Portugal. Alerts or aggregated data of reported adverse events are published in each state, and such information should be shared across the states.

A system to exempt liability for an adverse event when it is reported to the government or other organizations has been introduced only in Finland, Germany and Korea. According to newly introduced legislation in Ireland, open disclosure and apology cannot be regarded as admission of liability and cannot be used in litigation against the person making the disclosure.

3.1 System of data submission

		BEL	CAN	CZE	DNK	FIN	FRA	DEU	IRL	ITA	JPN	KOR	MEX	PRT	SVK	SVN	ESP	CHE	GBR
3.1.1	Requirement for hospitals to submit data of clinical indicators concerning patient safety to the government or an independent third entity	±	+	+	+	+	+	±	+	±	±	+	+	+	±	+	+	+	±
3.1.2	No. of required indicators	1	Varies	8	Varies	N/A	24	238	11	5	Varies	27	8	56	21	4	50~60	150	5
3.1.3	Patient reported outcomes or experiences in the reporting indicators	−	+	+	+	−	+	−	±	−	±	−	−	+	−	−	±	+	N/A
3.1.4	Publication of the collected clinical indicators	+	+	+	+	+	+	+	+	−	±	−	+	+	+	±	+	+	+
3.1.5	Publication of the collected clinical indicators in a manner that identifies the hospital	+	+	−	−	−	+	+	+	−	±	−	+	+	−	−	−	+	+
3.1.6	A system to reward or penalize hospitals based on the reported data	+	−	−	−	−	+	+	−	−	−	+	−	−	−	−	+	−	−
3.1.7	Requirement for hospitals to report adverse events to the government or an independent organization	−	+	+	+	+	+	−	+	+	+	−	+	+	±	+	−	−	N/A

		BEL	CAN	CZE	DNK	FIN	FRA	DEU	IRL	ITA	JPN	KOR	MEX	PRT	SVK	SVN	ESP	CHE	GBR
3.1.8	Voluntary reporting system of adverse events to the government or an independent organization	−	+	−	−	N/A	+	+	+	+	+	+	+	+	+	+	+	+	+
3.1.9	Voluntary reporting system of close calls/near misses to the government or an independent organization	−	+	−	−	N/A	+	+	+	−	+	+	+	−	+	±	+	+	+
3.1.10	Periodical publication of sentinel events based on reported adverse events and close calls	−	+	+	+	−	±	±	+	+	+	+	±	−	−	−	+	−	+
3.1.11	A system to exempt criminal or civil liability of adverse events when the case is reported to the government or the independent organization	−	−	−	+	+	−	+	±	±	−	+	−	−	+	−	−	−	−

+; Yes/A requirement/Exist, −: No/Not a requirement/Not exist, ±; Others, N/A; Not applicable

3.2 Name of organization that collects the information of adverse events or close calls

Belgium

N/A

Canada

Some jurisdictions, MedEffect Canada, National System for Incident Reporting, safemedicationuse.ca (ISMP Canada) etc.

Czech Republic

Institute of Health Information and Statistics of the Czech Republic

Denmark

The Danish Patient Safety Authority

Finland

National Institute for Health and Welfare, Finnish Medicines Agency, National Supervisory Authority for Welfare and Health

France

Nuclear Safety Authority (L'Autorité de sureté nucléaire)

Germany

Association of Statutory Health Insurance Physicians, Chamber of Surgeons, German Hospital Federation

Ireland

N/A

Italy

Ministry of Health

Japan

Japan Council for Quality Health Care (JQ), Japan Council for Patient Safety Investigation

Korea

Korea Institute for Healthcare Accreditation (KOIHA)

Mexico

General Directorate of Quality and Health Education (DGCES)

Portugal

Directorate General of Health, National Institute of Pharmacy and Medicine (Instituto Nacional da Farmácia e do Medicamento: INFARMED)

Slovakia

National State Institute for Drug Control (Štátny ústav pre kontrolu liečiv)

Slovenia

Ministry of Health

Spain

Reporting and Learning System for Patient Safety (SiNASP)

Switzerland

Patient Safety Switzerland

United Kingdom

Care Quality Commission

3.3 Details in each country

Belgium

Data submission of clinical indicators concerning patient safety

Several initiatives collect indicators but there is no systematic and coherent approach on national level. Hospitals participate on a voluntary basis. The data is made public partially.

The P4Q-program starts in 2018, and it uses a structural indicator on coding patient safety incidents bases on the ICPS of the WHO. Hospitals will not be penalized but will not get a financial incentive for bad results on

the structural indicator on coding patient safety incidents.

Public reporting of adverse events or close calls

Hospitals notify incidents on a voluntary basis but notification is highly supported by the Belgian government. However, notifications are not required by the government. Radiotherapy incidents and blood transfusion incidents are required to be notified to specific bodies.

Canada

Data submission of clinical indicators concerning patient safety

Some provinces and territories mandate indicator submissions (ex. Ontario, Quebec, Nova Scotia) or cooperation with provincial health quality councils who assess health care system performance, but most do not. Provincial governments where applicable (ex. Ontario, Quebec) review hospital performance based on the indicator reports and incident reporting. Where indicated, the provincial government may request a follow-up action plan from the healthcare organization. In addition, several provinces have independent health quality organizations with mandates to report publicly on and to support efforts to improve patient safety in that jurisdiction.

Some national organizations, for example, the Canadian Institute for Health Information (CIHI) collects indicator data from provincial governments but participation in its processes is not mandatory. CIHI maintains a suite of patient safety indicators through its administrative databases, including measures related to Hospital Harm (a composite measure of 31 specific clinical groups), obstetrical safety, patient falls, infections, pressure ulcers, and the inappropriate use of antipsychotics.

Summary reports of collected data are produced and posted on websites (ex., Ontario, Quebec, Manitoba). CIHI maintains the publicly facing, searchable database "Your Health System" which includes many of their safety indicators. Hospitals are identified in some situations, and other times, the data is rolled up to a regional/provincial level.

Patient reported outcomes or experiences are not collected regularly, but efforts are underway in Canada to do so more frequently. CIHI is now collecting data from Patient Reported Outcome Measures (PROMS): PROMs are measurement instruments that patients complete to provide information on aspects of their health status that are relevant to their quality of life, including symptoms, functionality and physical, mental and social health. CIHI also collects and administers the Canadian Patient Experiences Survey - Inpatient Care. In addition, in Canada, many jurisdictions conduct patient experience surveys using a variety of tools and data collection methods. To support pan-Canadian comparisons of patient experience, CIHI worked with representatives from Canadian jurisdictions and other leading experts in the field to develop a standardized questionnaire. This enables patients to provide feedback about the quality of care they experienced during their most recent stay in a Canadian acute care hospital.

Public reporting of adverse events or close calls

Mandatory reporting of critical incidents is required in some jurisdictions:

Manitoba requires to report critical incident that is defined as "an unintended event that occurs when health services are provided to an individual and results in a consequence to him or her that is serious and undesired." Anybody can report a critical incident, including patients, family members or health care providers.

Quebec requires the reporting of incidents, accidents and near misses. 481,000 events were reported between April 1, 2014 and March 31, 2015. Among the events reported, 86% are accidents (adverse events), and 14% are incidents (near misses).

Saskatchewan requires to report critical incident that is defined as "a serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function related to a health service provided by, or a program operated by, a health care organization."

In 2014, the Government of Canada put in place the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law). Vanessa's Law introduced amendments to the Food and Drugs Act that will improve Health Canada's ability to collect post-market safety information, and take appropriate action when a serious risk to health is identified. These amendments include the mandatory reporting of serious adverse drug reactions and medical device incidents by healthcare institutions.

Voluntarily reporting system for medication safety administers by MedEffect Canada, National System for Incident Reporting, safemedicationuse.ca (ISMP Canada) Individual Practitioner Reporting System, etc.

Nova Scotia publishes quarterly reports on the Serious Reportable Events, but the system varies among provinces, territories and respective health authorities. According to the critical incident reporting, Patient Safety Alerts are published by Manitoba and Saskatchewan government. The Canadian Patient Safety Institute (CPSI) is working to support sharing across jurisdictions via the Global Patient Safety Alerts that is a growing repository of alerts and recommendations from around the world meant to support the identification of risks and solutions to prevent harm.

Ontario's Excellent Care for All Act (2010) legislates that hospital annual quality improvement plans must be developed, having regard to its aggregated critical incident data as compiled based on disclosures of critical incidents pursuant to regulations made under the Public Hospitals Act (PHA). In addition, as of January 1, 2011, the PHA Regulation 965 was amended to ensure that the administrator provides aggregated critical incident data to the quality committee at least two times per year.

Exemption system of liability of adverse events

There is no system to exempt criminal or civil liability of adverse events, but some protection does exist for some situation, and varies by jurisdiction. Legislative protection which prevents release of information concerning quality reviews from subsequent disclosure in the context of legal proceedings now exists in all Canadian provinces. For example, the Manitoba Evidence Act. In addition, almost all provinces have Apology Acts, whereby care providers can apologize to a patient or a family for a safety incident or undesirable outcome without that apology being taken as an admission of guilt in a court of law.

Czech Republic

Data submission of clinical indicators concerning patient safety

Bulletin 16/2015 Coll. Minimum requirements for the establishment of an internal system of quality assessment and safety of provided health services and Act no. 372/2011 Coll. There is no reward or penalization for the reporting.

Public reporting of adverse events or close calls

There is no voluntary system and we have obligatory system which is on high priority. Since 2018, all inpatient healthcare facilities will be obligated to report adverse events to the Ministry of Health and the Institute of Health Information and Statistics (IHIS). The Central system for adverse event reporting (CAERS) is serving rather as methodological support for quality of care improvement, sharing knowledge system and platform for methodological guidance production and implementation. On the national platform for CAERS, a part of sentinel event is published, but the portal is available only to certified person.

Exemption system of liability of adverse events

Criminal or civil liability AE are evaluated on local level of each hospital or facility. There are anonymous aggregated data reported to the government and IHIS.

Denmark

Data submission of clinical indicators concerning patient safety

The aggregated data is made public.

Public reporting of adverse events or close calls

All adverse events are mandatory to report.

Finland

Exemption system of liability of adverse events

According to Criminal Act, there is a system to exempt liability of adverse events.

France

Data submission of clinical indicators concerning patient safety

Every hospital has to publish (display on its website and on the hospital lobby walls) the results of a list of patient safety and quality indicators. The Ministry of Health specifies this list of indicators every year. The results of all hospitals are open to the public on both the Haute Autorité de Santé website (scope sante) and the Ministry website with other information and results, "certification", for example. For 2018, 24 indicators are listed and will be published. They are process indicators (22) and patient satisfaction (2).

There is a system to enhance hospital quality, called Incitation financière à l'amélioration de la qualité (IFAQ). It is based on the results of the above indicators and consists of rewards only (min 50 000 € and max 500 000 € for one hospital), as long as the hospital meets definite requirements of quality or has made a positive step towards better quality.

Public reporting of adverse events or close calls

Hospitals are required to declare serious adverse events related to health care to their Health Regional Agency. Since March 2017, a nationwide web-based adverse events reporting system has been provided to both HC professionals (hospital, in-town and elderly care) and patients. This reporting system integrates all regulated vigilances (medication, material such as medical devices, blood derived products, cosmetics, etc.) and is meant to enhance collaboration between the professionals who provide the specialized expertise in each of them.

The serious adverse events are reported in 2 times by professionals or organizations: at once when it occurs, and then within 3 months in order to allow the professionals to perform their analysis and put up corrective measures. The serious adverse event reports, once they are considered dealt with by the Regional Health Authority, are anonymized and transferred to the Haute Autorité de Santé, in charge of an annual report about the facts and issue the necessary recommendations to prevent those events. The first global report on declared serious adverse events is due by HAS in 2018.

There is a voluntary system for at-risk specialist doctors, called "accreditation des médecins des spécialités à risques" based on the reporting of 3 "risk baring events" each year but it is so far mostly implemented in primary care only. The specialists report to the Haute Autorité de Santé which is in charge of the whole process.

L'Autorité de sureté nucléaire provides extended information on the prevention and management of risks derived from interventional radiology, nuclear medicine, radiotherapy, etc. This information is based on a principle of shared reporting and feedback.

Germany

Data submission of clinical indicators concerning patient safety

According to "Social Code Book Five (SGB V) Statutory health insurance -§135a(2)1", hospitals are obligated to participate in cross-institutional measurements for quality assurance. The details are written in the Guideline on Quality Assurance Measures in Hospitals (Richtlinie über Maßnahmen der Qualitätssicherung in Krankenhäusern: QSKH-RL) that is published by the Joint Commission (G-BA). According to the QSKH-RL, that is a framework of external quality assurance, the Joint commission (G-BA) obligates hospitals to report 238 indicators including sentinel-event-indicators such as mortalities in obstetrics. In addition, the Joint

Commission (G-BA) deals with the hospitals which reported suspicious quality results. If a suspicious hospital does not manage to improve the quality, several measures are prescribed. Those include professional training, inspections of the hospital, or setting of milestones that lead to improve the quality.
According to "§136b (1)1.3", hospitals are obligated to publish annual quality reports, that contain patient safety indicators such as sentinel-event-indicators and information on risk management and Critical Incident Reporting System (CIRS). The quality reports of individual hospital publish 216 out of the 238 reported indicators. Many search engines and comparison websites make use of this data. The Institute for Quality Assurance and Transparency (IQTIG) publishes annual quality reports that include a summary of de-identified data.
In accordance with the Hospital Restructuring Act (Krankenhausstrukturgesetz), that was enacted in January 2016, the Joint Commission was ordered to identify services that are suitable for quality adjusted incentives and disincentives as well as the measures to introduce them.
As for patient reported outcomes or experiences, patient interviews are not part of the external quality assurance measures. However, the Joint Commission (G-BA) instructed the IQTIG to develop such patient interviews. Therefore, the external quality assurance will include such patient reported outcomes in the near future.

Public reporting of adverse events or close calls

There is an incentive for hospitals to engage in multi-center Critical Incident Reporting System (CIRS) programs. However, it is not a legal requirement.
There are multiple voluntary reporting systems that are established and run by non-government bodies. Publication rules of reported adverse events vary with the registry.

Exemption system of liability of adverse events

It is written in a law as follows:
"Reports and data from in-hospital and cross-institutional risk management and error reporting systems shall not be used in legal relations to the detriment of the reporting person. This does not apply if they are necessary to prosecute a criminal offence that carries a maximum penalty of more than five years of imprisonment, if it is a particularly serious case, and if it would be impossible or would be much harder to investigate the case or the whereabouts of the offender." (Social Code Book Five (SGB V) Statutory health insurance - §135a(3))

Ireland

Data submission of clinical indicators concerning patient safety

The first National Patient Experience Survey was completed for all adult inpatients in the month of May with 61 internationally validated questions.

Public reporting of adverse events or close calls

Serious Reportable Events (SREs) are reported to HIQA. SREs are a defined list of serious incidents, many of which may result in death or serious harm (e.g. wrong site surgery). All hospitals are required to report adverse events on the National Incident Management System. The Department requires all hospitals to publish a monthly patient safety statement. Reported events are published in the Health Service Executive (HSE) Performance Report on a monthly basis.
Maternal deaths are required to be reported to the National Women and Infant's Programme.

Exemption system of liability of adverse events

Legislation for Open Disclosure provisions due to be enacted early 2018 provides protections for staff who conduct open disclosure in line with the legislation. The open disclosure and any apology cannot be interpreted as admission of liability and cannot be used in litigation against the person making the disclosure.

Italy

Data submission of clinical indicators concerning patient safety

The hospitals are not required to submit PS indicators, nevertheless regions have to send data to the Ministry.

Public reporting of adverse events or close calls

Only the serious adverse events which defined as Sentinel Events are required to report to the Ministry of Health. The MoH defined 16 sentinel events. We are approaching to collect data on adverse events and also on near misses. Other adverse events and near misses will be collected in the next future by the agency Agenas.

Exemption system of liability of adverse events

The government approved in March 2017 a new law on the responsibility of health professionals.

Japan

Data submission of clinical indicators concerning patient safety

It is not mandatory. Hospital associations and organizations such as the National Hospital Organization collect data using clinical indicators, and publish summary reports of collected data. For example, the All Japan Hospital Association collects data from 42 hospitals using 22 clinical indicators, and the Japan Hospital Association collects data from 350 hospitals using 32 clinical indicators and publishes an annual report in which hospitals can not be identified. The National Hospital Association collects data from 64 national hospitals using 25 clinical indicators, and publishes an annual report in which hospitals can be identified. The Government encourages the standardization of clinical indicators (i.e. definition, calculation methodology).

Public reporting of adverse events or close calls

Based on the Medical Care Act, national hospitals and special function hospitals such as university hospitals (276 hospitals in total) are required to report serious adverse events to the Japan Council for Quality Health Care (JQ). In 2016, they reported 3,428 adverse events. The JQ also collects near-miss data from 608 hospitals on a voluntarily basis. The database of anonymized case reports is open to the public on the website of the JQ. The database contains more than 75,000 reports and the number is increasing every year.

In addition, another reporting system named the Adverse Event Investigation System was introduced in 2016, where every healthcare organization must report an unexpected patient death due to medical service to the Adverse Event Investigation & Support Center, which is administered by the Japan Council for Patient Safety Investigation (a third-party non-profit organization). According to the system, hospitals are required to conduct an institutional review of the adverse event, and to submit a final report of the investigation to the organization. In 2017, hospitals reported 370 patient deaths to the organization.

The JQ also administers a national reporting system from pharmacies. Among 68,000 pharmacies, about 7,000 are voluntarily reporting adverse events and near misses to the JQ.

The JQ publishes Medical Safety Information monthly, which provides alerts based on reported adverse events and near misses. The Ministry of Health, Labour and Welfare publishes Pharmaceuticals and Medical Devices Safety Information almost monthly. The Pharmaceuticals and Medical Devices Agency publishes PMDA Medical Safety Information almost monthly.

Korea

Data submission of clinical indicators concerning patient safety

Tertiary hospitals are required to submit data of clinical indicators to the Health Insurance Review & Assessment Service (HIRA). The data is used to determine the amount of government funding for care quality assessment, which goes to healthcare institutions showing excellent performance.

Public reporting of adverse events or close calls

In accordance with the Patient Safety Act, we operate the adverse event reporting & learning system, which is based on voluntary reporting. Korea Institute for Healthcare Accreditation (KOIHA) is commissioned by the Ministry of Health and Welfare to establish and operate the adverse event reporting & learning system (Article 8 of the Enforcement Decree of the Patient Safety Act; Article 15 of the Patient Safety Act; and Public Notice No. 2016-141 by the Ministry of Health and Welfare).

Patients are possible to report adverse events to the national learning system on adverse event reporting (Article 14 of Patient Safety Act; and Article 12 of the Enforcement Rule of the Patient Safety Act).

In accordance with Article 16, warnings are issued when there are legitimate reasons: if an adverse event is new or may cause serious harm. Analysis documents on adverse events, including annual statistics on patient safety are scheduled for announcement.

Exemption system of liability of adverse events

In accordance with Article 14 of the Patient Safety Act, if the person responsible for causing an adverse event reports the case, administrative dispositions may be mitigated or exempted.

Mexico

Data submission of clinical indicators concerning patient safety

INDICAS II is a system managed by the General Directorate of Quality and Healthcare Education (DGCES), and include 4 HAS indicators and 4 Nursing Indicators. The collected data is made public in a website of DSCES.

Public reporting of adverse events or close calls

According to the Essential Actions for Patient Safety published in September 2017 by the General Health Council, the adverse events must be reported in the Adverse Event Report System managed by the DGCES. Up to December 2017, there were more than 11,000 reports from more than 450 hospitals in Mexico. This system encompasses all adverse events, close calls /near misses and never ever events, and it allows a comprehensive study of the incidence, frequency of all events, sorted by work shift, personnel type, place in the facility, etc. Adverse Events Report System gives reports to the users on the frequency and incidence of adverse events, by type of event, personnel type, work shift, preventability, etc. The use of the system to report adverse events is mandatory for all medical facilities, but the report itself is voluntary to all healthcare personnel.

Portugal

Data submission of clinical indicators concerning patient safety

Hospital are required to submit data to the Ministry of Health regarding the Ministerial Order nº 3635/2015 and Ministerial Order nº 5739/2015 and by the financing procedures (GDH and Contratualization Contract).

All data is published at the official portal of the Ministry of Health “Portal da Saúde” and at the official websites of the institutions of the Ministry of Health (Directorate-General of Health and Hospitals).

Public reporting of adverse events or close calls

NHS Hospitals are required to report adverse events to the Ministry of Health.

The Ministry of Health developed a National Reporting and Learning System and issued National Guidelines to support the investigation of adverse events and health risk management. Adverse events and near misses are reported voluntarily to National Incident Reporting System and National System on Adverse medication reaction. The National Incident Reporting System is anonymous and not punitive. The national reporting and learning system also includes notifications from patients. The Patient’s Complaints and Suggestions are analyzed and action’s plan are developed accordingly.

Slovakia

Data submission of clinical indicators concerning patient safety

Only partial data are submitted (e.g. Indictors of Quality for hospitals) to the national Health Care Surveillance Authority (Úrad pre dohľad nad zdravotnou starostlivosťou: HCSA) and the National State Institute for Drug Control (Štátny ústav pre kontrolu liečiv: NSIDC).

There are 18 indicators of Quality and 3 Indicators for public health (§52 par. 5 letters A, F, and G of the Act of the National Council of the Slovak Republic no. 355/2007 Z.z. on the Protection, Promotion and Development of Public Health and on Amendments to Certain Acts).

Public reporting of adverse events or close calls

All health care providers are obligated to report adverse events during the process of the clinical testing of the medicines only. The NSIDC is an independent body for the adverse events reporting in the area of medicinal products.

Patients in Slovakia are able to report complaint for hospitals to the HCSA. The patients reported 1652 complaints to the HCSA in 2016. The patients are able to get expertize from the HCSA.

Slovenia

Data submission of clinical indicators concerning patient safety

The data on falls, pressure ulcers, MRSA and hand hygiene are reported to the Ministry of Health. The data are partially accessible to the public at the website of the Ministry of Health. A system to reward or penalize hospitals based on the reported data is not exist yet. Efforts are going in this direction.

In Slovenia, we started the projects of Patient Reported Experience Measures (PREMs) and Patient Reported Outcome Measures (PROMs) with the support of the European Commission Structural Reform Support Service. We also participate in the Paris project working group.

Public reporting of adverse events or close calls

The Ministry of health has established the Reporting and Learning System on adverse/sentinel events for Hospitals in 2002. The instructions and reporting forms were prepared and are published on the website of the Ministry of Health. Report from hospitals to the Ministry of Health is mandatory. The Ministry of Health requires hospitals to report seven of the most serious dangerous adverse events: unexpected death, major permanent loss of bodily functions, the suicide of a patient in a medical institution, the switching of newborn babies, haemolytic transfusion reactions after the transfusion of blood or blood products due to the incompatibility of the main blood groups, surgical intervention on the wrong patient or on the wrong part of the body and the suspicion of a crime. In 2016, eight hospitals reported 18 cases that included 12 unexpected patient's deaths, 4 patient's suicides in the hospital, and 2 reports on an event which was not the subject of reporting to the Ministry of Health. As for the reported adverse events, there is an upward trend in the number of sudden death of a patient, and a downward trend in the number of reports which are not the subject of reporting to the Ministry of Health. The highest number of reported events on an annual level was 25.

The publishing system of reported events will be established as part of the update.

Exemption system of liability of adverse events

The Quality and Safety Act will attempt to establish a system to exempt criminal or civil liability of adverse events.

Spain

Data submission of clinical indicators concerning patient safety

The hospitals have to submit data of PS clinical indicators to the Health Regions because it´s included in their

annual objectives, and the Regions send some of these data to the MSSSI. The indicators include medication, HCAI, surgery and other PSI indicators. Patient reported outcomes are included in indicators in some Regions (mainly satisfaction), but not yet at national level. The Regions have their systems to reward hospitals that reach the objectives proposed on PS.
Only aggregated data are made public. Data by hospital/Region are restricted to the teamwork.

Public reporting of adverse events or close calls
Adverse events reporting to the government is not mandatory.
As for voluntary reporting system, the MSSSI promotes a Reporting and Learning System (R&LS) that is used by 10/17 Regions (SiNASP). The others have their own R&LS (Vallejo-Gutiérrez P, et al: Lessons learnt from the development of the Patient Safety Incidents Reporting an Learning System for the Spanish National Health System: SiNASP. Rev Calid Asist. 2014 Mar-Apr;29(2):69-77).
Annual report is published in the web page of MSSSI.

Exemption system of liability of adverse events
The R&LS are separate from judicial proceedings. However, if a judge requires information, there is no national/regional regulation that prevents it.

Switzerland

Data submission of clinical indicators concerning patient safety
All cantons (member states of the Swiss Confederation) require participation on quality indicators measurements. Hospitals are required approx. 150 indicators mostly through administrative data. Some cantons have additional quality requirements. Mortality rates and case load for approx. 50 conditions and interventions such as surgical site infections, falls, bedsores, potentially avoidable rehospitalizations and reoperations. Most indicators are made public.
Patient reported outcomes or experiences are included in the reporting indicators in mental health.

Public reporting of adverse events or close calls
There is no mandatory nationwide reporting system, but one canton requires it.
The Patient Safety Switzerland is an independent foundation, and provides a voluntary reporting system. Its focus is on promoting and developing safety in medical and nursing activities. It is funded by the federal government, the cantons and other sponsoring agencies, as well as by attracting third party funding and selling its services.

United Kingdom

Public reporting of adverse events or close calls
There are a number of methods for reporting of incidents, depending on the cause. These include the National Reporting and Learning System; the Serious Incident Framework; and the legal requirement to publish data on the number of deaths thought more likely than not to have been due to problems in care.
When reported to a service, such as the National Reporting and Learning System, recommendations are published

4. Personnel responsible for patient safety management (Patient safety manager)

Training for personnel responsible for patient safety management is offered in most states, but the program varies among states or educational organizations. The competencies of personnel are also defined in some states.

There is no national certification system for personnel. The assignment of personnel in hospitals is reimbursed only in Japan and Korea. The assignment of a person responsible for patient safety management in a hospital should be encouraged with incentives, although the effects of the assignment may need to be established.

4.1 System regarding personnel responsible for patient safety management

		BEL	CAN	CZE	DNK	FIN	FRA	DEU	IRL	ITA	JPN	KOR	MEX	PRT	SVK	SVN	ESP	CHE	GBR
4.1.1	The personnel regarded as a professional focus in patient safety management	+	+	+	+	+	±	±	+	+	+	+	+	+	−	±	+	+	+
4.1.2	Standard educational programs for training the personnel	+	+	+	−	+	+	−	−	−	±	+	−	+	−	−	±	−	N/A
4.1.3	Organizations that offer education or training for the personnel	+	+	+	+	+	+	+	+	+	+	+	−	+	−	±	+	+	N/A
4.1.4	National or other certification system for the personnel	−	+	+	−	−	−	−	−	−	±	−	N/A	−	N/A	−	+	−	N/A
4.1.5	Incentives to promote assignment of the personnel in each hospital	+	−	+	+	+	+	−	±	−	+	+	−	−	−	+	−	−	N/A
4.1.6	Networks which promote information sharing among personnel across hospitals	+	+	+	+	+	+	+	+	+	+	−	+	+	−	−	+	+	N/A

+; Yes/A requirement/Exist, −: No/Not a requirement/Not exist, ±; Others, N/A; Not applicable

4.2 Major educational background of the personnel

		BEL	CAN	CZE	DNK	FIN	FRA	DEU	IRL	ITA	JPN	KOR	MEX	PRT	SVK	SVN	ESP	CHE	GBR
4.2.1	Medical doctor	+	+	±	+	+	+	±	±	N/A		+	+	N/A		+	+	±	+
4.2.2	Nurse	+	+	±	+	+	+	±	±	N/A	+	+	+	N/A		+		±	
4.2.3	Other healthcare professionals	+	+	±			+	±	±	N/A		+		N/A	±			±	

+; Yes/A requirement/Exist, −: No/Not a requirement/Not exist, ±; Others, N/A; Not applicable

4.3 Details in each country

Belgium

Organizations that offer education or training for the personnel

Federal government, universities, private initiatives

Major challenges in training or the assignment of personnel in each hospital

Involvement of hospital management, clinical leaders and implementation of safety practices at the bed side

Canada

Assignment of personnel responsible for patient safety management

Often a master's level trained healthcare professional with a clinical or healthcare management background with training in quality improvement and patient safety.

Standard educational programs for training the personnel

The Canadian Patient Safety Institute offers education to healthcare providers and healthcare educators: The Patient Safety Officer Course, The Incident Management Education Program and the Patient Safety Education Program.

The Patient Safety Officer Course provides an overview of the fundamentals of patient safety and equips health care professionals and leaders with information, tools and techniques. The Patient Safety Education Program is a conference based education program which uses a train-the trainer curriculum-driven approach to teach both content and how to disseminate it. The Effective Governance for Quality and Patient Safety program supports boards in their efforts to improve governance for quality and patient safety. Advancing Safety for Patients in Residency Education is geared towards medical educators and residents with a keen interest in teaching and implementing patient safety and quality improvement initiatives.

Organizations that offer education or training for the personnel

- Canadian Patient Safety Institute - National Organization Focused on Patient Safety
- ISMP Canada- National Organization Focused on Medication Safety
- Ontario Hospital Association - Member Association that represents hospitals in Ontario
- Health Quality Council of Alberta- Alberta based organization that promotes and works to improve patient safety and health service quality
- HealthCareCAN- National Organization that is the voice of healthcare organizations and hospitals to improve health of Canadians through evidence based and innovative healthcare systems
- Royal College of Physicians and Surgeons - National organization that works to improve health by leading in medical education, professional standards, physician competence and continuous enhancement
- Canadian Medical Protective Association
- Universities are also offering graduate programs in quality improvement and patient safety. The Centre for Quality Improvement and Patient Safety/ University of Toronto/ The University of Montreal.

National or other certification system for the personnel

The Canadian Patient Institute offers the Patient Safety Officer Course as a certification program but this is a voluntary program. There isn't a requirement for certification. Such decisions to certify Patient Safety Leaders would be local in nature.

Incentives to promote assignment of the personnel in each hospital

Incentives may be in the nature of the position being a management level position, thus the benefits (part of leadership team, salary, regular work hours, etc.) that would accompany of such a position.

Networks promoting information sharing among the personnel across hospitals

Each jurisdiction would have its own network that meet regularly either virtually or face to face.

Major challenges in training or the assignment of personnel in each hospital

Limited resources for training due to reduced budgets. Budget cuts limit training to those available locally, or those available virtually (eLearning). Budget cuts also reduce number of administrative positions or reduce hours available to staff in them to focus on safety.

Czech Republic

Organizations that offer education or training for the personnel

Institute for Postgraduate Medical Education, National Center of Nursing and Non-Medical Health Care

National or other certification system for the personnel

Certified courses and also one master degree program at College of Polytechnics Jihlava (Quality in Healthcare for non-medical staff).

Major challenges in training or the assignment of personnel in each hospital

Number of workers, especially non-medical staff - overburden, low interest in medical personnel in some AE which they recognize as nursing sensitive problems.

Denmark

Organizations that offer education or training for the personnel

A professional patient safety society/local operator

Incentives to promote assignment of the personnel in each hospital

Reporting is mandatory, resources must be allocated.

Networks promoting information sharing among the personnel across hospitals

There is a significant number of networks.

Major challenges in training or the assignment of personnel in each hospital

That personnel range from vocationally trained to highly specialized.

Finland

Organizations that offer education or training for the personnel

National Institute for Health and Welfare

Incentives to promote assignment of the personnel in each hospital

Honorary or monetary award from the employer

Major challenges in training or the assignment of personnel in each hospital

Usually not the main task of the person, hence lack of time

France

Assignment of personnel responsible for patient safety management

The 2010-1408 ministerial decree and its following instruction states that a coordinator of risk management has to be assigned in every hospital. Hospital “certification” checks if the assignment is fulfilled and how efficiently the management of risks operates in the hospital.

Standard educational programs for training the personnel

There are numerous diplomas open to most healthcare professionals. In order to provide all health care givers with a common doctrine including the human factor component, The National patient safety program 2013-2017 enabled the translation of the WHO Patient safety curriculum guide (multi-professional edition). An e-learning tool has been made out of it (2017) and a MOOC is to follow (2018).

Organizations that offer education or training for the personnel

Universities and institutions provide education. They also provide on-the-job training, together with insurance companies and private training organizations.

Major challenges in training or the assignment of personnel in each hospital

The hospital management (director and head of the medical community) must support the person responsible for risk management and place this person next to them in the hospital organizational chart. This requirement is progressively better understood and fulfilled.

Germany

Assignment of personnel responsible for patient safety management

It differs from hospital to hospital. There are continuing education programs for patient safety and risk management. Many hospitals opened a position of patient safety officer.

Standard educational programs for training the personnel

There are many programs but no binding standard.

Organizations that offer education or training for the personnel

There are many organizations but no standardized programs. Most of organizations are non-government organizations or institutions of the self-administration.

Incentives to promote assignment of the personnel in each hospital

It is a responsibility of each hospital.

Networks promoting information sharing among the personnel across hospitals

German Coalition for Patient Safety; partially National Quality Conference; German Network for Quality in Care; German Physicians Congregation (Deutscher Ärztetag)

Major challenges in training or the assignment of personnel in each hospital

To convince hospital management to invest in patient safety measures including the training and assignment of personal

Ireland

Assignment of personnel responsible for patient safety management

These are designated posts such as 'Quality and Safety', 'risk managers' or 'complaints managers'.

Standard educational programs for training the personnel

Patient safety is taught by a number of bodies within undergraduate and postgraduate education.

Italy

Organizations that offer education or training for the personnel

Public and private organizations organize courses on Patient Safety.

National or other certification system for the personnel

The new law establishes that everybody with five years of experience in this field can be responsible of patient safety.

Major challenges in training or the assignment of personnel in each hospital

Guarantee and maintain levels of competencies

Japan

Assignment of personnel responsible for patient safety management

Almost all acute care hospitals with >300 beds have already assigned patient safety managers who have a medical license. Most of them are nurses.

Standard educational programs for training the personnel

The Ministry of Health, Labour and Welfare has created a guideline for training programs.

Organizations that offer education or training for the personnel

Hospital associations, the Japan Nursing Association and other healthcare organizations.

Incentives to promote assignment of the personnel in each hospital

Hospitals are paid more money from public medical insurance when they assign patient safety managers.

Networks promoting information sharing among the personnel across hospitals

There is no professional society of patient safety managers. There are some informal networks; some of them are established by nearby hospitals, hospitals belonging to the same group, etc. The annual conference of the Japanese Society for Quality and Safety in Healthcare may be an occasion to communicate with each other.

Major challenges in training or the assignment of personnel in each hospital

The challenges include: (1) no concrete evidence of the positive effects on patient safety of assigning a patient safety manager, (2) continuous training, and (3) development of a model career path of patient safety managers.

Korea

Assignment of personnel responsible for patient safety management

The Patient Safety Act requires hospitals to deploy personnel dedicated to patient safety. There is no penalty, but it is a legal requirement.

Hospitals with dedicated patient safety personnel report details on the personnel deployment to the organization (Korea Institute for Healthcare Accreditation) responsible for operating the adverse event reporting & learning system.

Standard educational programs for training the personnel

Personnel dedicated to patient safety are required to regularly take courses on patient safety, if they work for tertiary hospitals (general hospitals) and hospital-level medical institutions with 200+ beds (Article 13 of the Patient Safety Act: and Article 10-11 of the Enforcement Rule of the Patient Safety Act).

- New course: Dedicated personnel are required to complete 24 hours of training within 6 months after deployment.
- Refresher course: Dedicated personnel are required to complete at least 12 hours of training per year.

Organizations that offer education or training for the personnel

Korean Hospital Association

Incentives to promote assignment of the personnel in each hospital

Long-term care services are reimbursed if tertiary hospitals (general hospitals) and hospital-level medical institutions with 200+ beds perform patient safety activities (including deployment of dedicated patient safety personnel, and establishment and operation of a patient safety committee). (1 time per day of hospital stay for inpatients)

Major challenges in training or the assignment of personnel in each hospital

Shortages of clinical nurses, and lack of incentives such as financial support for deploying dedicated patient safety personnel.

Mexico

Major challenges in training or the assignment of personnel in each hospital

There is a high level of rotation of the personnel in charge of patient safety implementation and supervision, both at the facilities and state level. Hospitals have a Quality Manager, who is in charge all quality strategies,

including Patient Safety. This position is usually occupied by personnel without the proper training for patient safety.

Portugal

Standard educational programs for training the personnel

The Ministry of Health approved a training program on patient safety.

Organizations that offer education or training for the personnel

Universities and Health Professionals Associations

Slovakia

Assignment of personnel responsible for patient safety management

There are no specific personnel for patient safety management.

Standard educational programs for training the personnel

There are not educational programs. There are only short seminars, workshops, lectures or presentations and courses.

Organizations that offer education or training for the personnel

Slovak Medical Chamber in cooperation with national Health Care Surveillance Authority, "Úrad verejného zdravotníctva Slovenskej republiky" (National Public Health Authority) as a competent body for the working conditions and internal process of patient safety in health care providers and safety of used equipment

Incentives to promote assignment of the personnel in each hospital

It is not a systematically regulated process in each hospital.

Networks promoting information sharing among the personnel across hospitals

Information is promoted and shared by only individual efforts of professionals in the hospitals. Information sharing process is not systematically led by the local chiefs in the hospitals or regional/national authorities.

Slovenia

Assignment of personnel responsible for patient safety management

In Slovenia, we have representatives of the quality management, such as assistant director of quality, assistant to chief doctor and chief nurse for quality, coordinators of the quality, coordinators of the quality management. Security officers have been operating since 2009. The tasks they perform are usually related to the quality and safety of health care. These are jobs that have a slightly higher initial payment grade.

Standard educational programs for training the personnel

There is no specific educational program. Organizations offer individual content. The initiatives to regulate this area are strong.

Organizations that offer education or training for the personnel

Prosunt operates in this area. It is a private company.

Incentives to promote assignment of the personnel in each hospital

According to the Health Care and Health Insurance Act, there are incentives that are provided by the Health Insurance Institute of the Republic of Slovenia. The financial resources provided by the MoH to ensure patient safety are limited. Our position: "Establishing a system means saving in practice".

Networks promoting information sharing among the personnel across hospitals

Some integration activities run within the Association of Health Care Institutes. They created a Quality

Commission in health care institutions. The purpose of the commission is to achieve development in this field and to act as an advisor and a link with the Ministry of Health.

Major challenges in training or the assignment of personnel in each hospital
Find the right people for this job. Make sure to report all sentinel and other adverse events.

Spain

Assignment of personnel responsible for patient safety management
In general, this person is also responsible of quality improvement in the hospital. Most of them are specialist in preventive medicine.

Standard educational programs for training the personnel
Each Region has its own educational program.

Organizations that offer education or training for the personnel
The MSSSI was in charge of this standard education, in collaboration with some universities, until 2014. There are several universities and other organizations offering masters and specific courses on PS.

National or other certification system for the personnel
Andalusia has a certification system for healthcare professionals.

Networks promoting information sharing among the personnel across hospitals
There is a national network around PS as well as regional level promoting information sharing and PS good practices.

Major challenges in training or the assignment of personnel in each hospital
Lack of resources and leadership.

Switzerland

Organizations that offer education or training for the personnel
Patient Safety Foundation and one more organization in the French speaking part of Switzerland

Networks promoting information sharing among the personnel across hospitals
There is a network only for quality officers, who are also responsible for patient safety.

Major challenges in training or the assignment of personnel in each hospital
Sensibilisation for patient safety not high enough. Patient safety officers are considered a “nice to have” and still not mandatory

United Kingdom

N/A

5. System for dispute resolution and compensation concerning patient harm

No-fault compensation has been introduced in several states. It is sometimes difficult to specify the cause of adverse events, and this system helps to support patients and establish good relationships between patients and healthcare organizations, and to encourage them to cooperate in establishing effective preventive methods. A no-fault compensation scheme for extensive adverse events has been introduced in Denmark, Finland, France, and Portugal. The scheme in Belgium, Japan and Korea covers some adverse events. The establishment of a no-fault compensation scheme for extensive adverse events may be a big challenge, but a scheme that focuses on limited areas, such as adverse drug events or newborns with cerebral palsy, may be easier to introduce as a first step. The number of cases of compensation is the largest in Finland. The annual amount of compensation is 759 million Danish kroner in Denmark. In Spain, the amount of compensation is calculated at present according to the scale of traffic accident, but the government is planning to present a law regarding a compensation scale for adverse events in 2018. In Japan. babies with cerebral palsy can receive 30 million yen from a private insurance scheme run by the Japan Council for Quality Health Care.

Systems of alternative dispute resolution (ADR) are classified into two types: one is run by national institutions and the other is an in-hospital system. In France, hospitals are required to involve patients' representatives for dealing with quality and safety issues, and the patients' representatives are able to serve as mediators if the patient requests. In Japan, hospital staff serve as mediators in many hospitals. Hospitals with trained mediators are paid more by public medical insurance.

5.1 No-fault compensation scheme for adverse events

Exist: BEL, CAN, DNK, FIN, FRA, JPN, KOR, PRT

Not exist: CZE, DEU, IRL, ITA, MEX, SVK, SVN, CHE, GBR

Others: ESP

5.2 Name of the administrative entity of the no-fault compensation scheme

Belgium

Fund for medical accidents

Canada

Healthcare Insurance Reciprocal of Canada (HIROC)

direction des assurances du réseau de la santé et des services sociaux in Quebec (DARSSS or AQESSS)

Denmark

The Patient Compensation Association

Finland

Finnish Patient Insurance Centre

France

Office national d'indemnisation des accidents médicaux (ONIAM)

Japan

Japan Council for Quality Health Care (JQ)

Korea

Korea Medical Dispute Mediation and Arbitration Agency

Portugal

National Health Service

Spain

Ministry of Health, Social Services and Equality (MSSSI)

5.3 Definition of adverse events which are compensated by the scheme

Belgium

The damage which has occurred since 2 April 2010, which is results of medical dispensation, and which meet one of the criteria as follows:

- a permanent disability of 25% or more
- temporary incapacity for at least 6 consecutive months or 6 non-consecutive months over a period of 12 months
- particularly severe damage, also economically, for the living conditions of the patient
- death of the patient

Canada

See websites of HIROC and DARSSS.

Denmark

All areas in the Danish healthcare system and all private authorized health professionals are covered by a publicly funded compensation scheme. The Patient Compensation Association determines whether a patient should be compensated, but the regions pay the compensation. The same is true of medicine injuries, for which the Ministry of Health and Prevention pays the compensation.

The scheme covers following injuries:

- Injuries which could have been avoided, because an experienced specialist in the same situation would have acted differently.
- Injuries due to failure or malfunction of technical devices and the like.
- Injuries which could have been avoided by another equally effective treatment, technique or method.
- Injuries which are very rare and serious in relation to the illness the patient is being treated for, and which exceed what one can reasonably be expected to tolerate.

Finland

As defined by the Finnish law

France

Damage caused by a medical accident or damage attributable to an activity of biomedical research, an iatrogenic condition (or side effect of medical treatment) or one nosocomial infection (or infection in a health care facility).

Japan

A no-fault compensation system for cerebral palsy babies was introduced in 2009. The insurance system is run by the Japan Council for Quality Health Care, and healthcare facilities are strongly encouraged by academic societies to buy the insurance; almost 100% of facilities dealing with delivery buy the insurance. Patients can receive 30 million yen if they are diagnosed with cerebral palsy; about 400 patients receive this payment each year. According to the Supreme Court, the number of lawsuits in the field of obstetrics and gynecology decreased dramatically after the introduction of this system.

Korea

Applies to only adverse events related to child delivery performed after April 8, 2013

- Cerebral palsy cases among newborns which occurred during child delivery or due to unusual reasons related to child delivery
- Deaths of mothers during child delivery or due to unusual reasons related to child delivery
- Deaths of unborn children during child delivery or due to unusual reasons related to child delivery

Portugal

Clinical execution error or clinical planning error

Spain

There is a compensation system for adverse events managed by assurance companies that try to mediate between the hospital and the patient/family. However, the government is planning to present a law regarding a compensation scale for adverse events in 2018.

5.4 Number of cases that were compensated by the scheme during the past year

Belgium

600

Canada

N/A

Denmark

N/A (In 2016, there were 11,212 claims, and 759 million Danish kroner was given as compensation to patients and their relatives)

Finland

2166

France

654 (with an average of 87,515€ paid to the claimer per case)

Japan

314 (30 million yen is paid per case)

Korea

11

Portugal

N/A

Spain

N/A

5.5 Alternative dispute resolution (ADR)

		BEL	CAN	CZE	DNK	FIN	FRA	DEU	IRL	ITA	JPN	KOR	MEX	PRT	SVK	SVN	ESP	CHE	GBR
5.5.1	Availability of an alternative dispute resolution (ADR) for resolving medical disputes	±	+	N/A	−	−	+	±	+	−	+	+	+	+	±	+	+	−	+
5.5.2	Organizations that provide or help to find a mediator or an arbitrator for the ADR	N/A	+	N/A	N/A	N/A	+	+	+	N/A	−	+	+	+	±	+	+	N/A	+
5.5.3	Standard educational program to train mediators or arbitrators for medical disputes	N/A	+	N/A	N/A	N/A	+	−	+	N/A	+	−	−	+	−	+	±	N/A	N/A

+; Yes/A requirement/Exist, −: No/Not a requirement/Not exist, ±; Others, N/A; Not applicable

5.6 Details of ADR in each country

Belgium

N/A

Canada

Organizations that provide or help to find a mediator or an arbitrator

HIROC and DARSSS

Czech Republic

N/A

Denmark

N/A

Finland

N/A

France

Scheme of ADR

Every hospital has to organize a procedure to answer patients' claims. The administrative manager is assisted by a medical and a paramedical mediator. The law n° 2002-303 dated 4th of March 2002 "relative aux droits des malades et à la qualité du système de santé" (loi Kouchner) has organized the system, including the creation of a

Commission des Usagers in every hospital, where patients' representatives deal with the management on quality and safety issues. Since the ministerial decree of July 1st 2016 this Commission has gained new prerogatives.

Standard educational program to train mediators or arbitrators for medical disputes

Patients' representatives in hospital are trained for their missions in the Commission des usagers (see 5,5) and may be consulted as mediators, if the claimer wishes it. Most of their training comes from the Union nationale des associations agréées d'usagers du système de santé (approx. 70 patient associations are represented in this Union nationale).

Germany

Scheme of ADR

It is not at a centralized level. However, there are dispensaries where patients can apply to if they suspect a treatment error (Schlichtungsstellen der Ärztekammern). Health insurances support patients as well.

Organizations that provide or help to find a mediator or an arbitrator

Independent patient counselling (Unabhängige Patientenberatung Deutschlands: UPD)
Health insurances are obliged to support the members in cases of treatment errors.

Ireland

Scheme of ADR

The Mediation Act (2017). Its objective is to provide a wide ranging statutory framework to promote a resolution of disputes through mediation as an alternative to court proceedings. The legislation requires that legal practitioners advise parties about mediation as a means of resolving difficulties and the Courts may invite parties to consider mediation. The Act contains general principles for the conduct of mediation by qualified mediators.

Standard educational program to train mediators or arbitrators for medical disputes

The Mediators' Institute of Ireland is the not-for profit professional association for mediators in Ireland. It has approved a range of training programs and CPD courses, which are not specific to medical disputes.

Italy

N/A

Japan

Scheme of ADR

ADR (not limited to healthcare) is recommended by the ADR Encouragement Act. Hospitals are encouraged to assign hospital staff as mediators, and hospitals with mediators are paid more by public medical insurance.

Korea

Scheme of ADR

In accordance with the "Act on Remedies for Injuries from Medical Malpractice and Mediation of Medical Disputes", the Korea Medical Dispute Mediation and Arbitration Agency undertakes the deliberation and resolution of medical disputes arising from adverse events.

Organizations that provide or help to find a mediator or an arbitrator

Korea Medical Dispute Mediation and Arbitration Agency

Mexico

Scheme of ADR

When a patient has a complaint regarding medical treatment, the patient is referred to the National Commission for Medical Arbitration that is in charge of resolution between medical staff and patients.

Organizations that provide or help to find a mediator or an arbitrator

National Commission for Medical Arbitration

Portugal

Organizations that provide or help to find a mediator or an arbitrator

Medical Association

Slovakia

Scheme of ADR

Except the compensation via court resolution, the patient can use the system of mediators on the base of mutual voluntary agreement.

Organizations that provide or help to find a mediator or an arbitrator

The help to find mediators is not needed because they are well-known.

Slovenia

Organizations that provide or help to find a mediator or an arbitrator

Some healthcare providers, especially among public health institutions, have established their own mediation referral services that offer mediation as a method of peaceful dispute resolution between their employees, patients and other users of health services. Tenderness to mediation and understanding of its importance is already strongly present in some healthcare providers, as they offer their patients free participation in the mediation process.

Standard educational program to train mediators or arbitrators for medical disputes

There are several providers of mediator education and training. As a rule, these are two strands: basic and continuing education. Runs Association of Mediators (NGO), which seeks to provide all the information in one place.

Spain

Scheme of ADR

Lawyers, experts and forensic doctors calculate compensation in cases of medical malpractice based on the scale of traffic accidents.

Standard educational program to train mediators or arbitrators for medical disputes

Not a national level

Switzerland

N/A

United Kingdom

N/A

6. Investigation of adverse events

In the case of adverse events, hospitals are expected to conduct an in-hospital investigation. In some states, in addition to in-hospital investigation, external investigation by a third-party has been introduced. Attempts have been made to standardize the method of in-hospital investigation in most states with guidelines and recommended methods. A support system is also available in some states. Reports of investigations are disclosed in limited cases in most states. In Japan, a nationwide reporting system has been introduced, and data on more than 75,000 anonymized cases are available on the website of the Japan Council for Quality Health Care. These reports contain useful information for preventing recurrence, and need to be shared among healthcare professionals.

6.1 Investigation by third-party organizations

6.1.1 Third-party organizations that investigate the causes of adverse events

Exist: FIN, IRL, JPN, PRT, ESP, GBR

Not exist: BEL, DNK, ITA, KOR, MEX, SVK, SVN, CHE

Others: CAN, CZE, FRA, DEU

6.1.2 Name of the administrative entity for patient harm investigations

Canada

Health Quality Council of Alberta etc.

Czech Republic

N/A

Finland

National Supervisory Authority for Welfare and Health

France

N/A

Germany

Chambers of Physicians (Ärztekammern)

Ireland

Health Information and Quality Authority (HIQA)

Japan

Japan Council for Patient Safety Investigation

Portugal

General Inspection of Activities in Health (IGAS)

Healthcare Regulation Authority (ERS)

Portuguese Medical Association

Spain

The insurance company

United Kingdom

Healthcare Safety Investigations Branch (HSIB)

6.1.3 Details of the investigation by the third-party organizations in each country

Belgium

The analysis and the resulting actions improvement must be done and formulated by the hospitals themselves.

Canada

Some areas have quality/safety organizations that have mandates from the provincial government to investigate specific or systemic issues that lead to patient safety incidents. For instance, the Health Quality Council of Alberta can lead public inquiries and system reviews when requested by the government.
In addition, health professionals have their practice of care overseen by regulatory colleges in Canada who have investigative authority as part of their ability to grant, restrict or withdraw license to practice in each jurisdiction.

Czech Republic

The CAERS is not serving as entity for patient harm investigation.

Finland

N/A

France

N/A

Germany

N/A

Ireland

N/A

Japan

According to the Adverse Event Investigation System in Japan introduced in 2015, every hospital is required to report an unexpected patient death due to medical service to the Adverse Event Investigation & Support Center, which is administered by the Japan Council for Patient Safety Investigation. Hospitals are required to conduct an institutional review of the adverse event, and to submit a final report of the investigation to the Center. In addition, hospitals and patients can request an external investigation by the Japan Council for Patient Safety Investigation. About 400 cases were reported, and external investigations were conducted for 7 cases at the request of hospitals, and for 32 cases at the request of bereaved families in 2017.

Portugal

N/A

Slovenia

There is no special body. From the hospitals, sentinel events are reported to the Ministry of Health. The new law foresees the establishment of a special body for these purposes.

Spain

It depends on the Region.

United Kingdom

The Healthcare Safety Investigations Branch (HSIB) is newly established. The aim is to review up to 30 serious cases per year, and HSIB also hold responsibility for investigating perinatal deaths.

6.2 Autonomous in-hospital investigation

6.2.1 System of autonomous in-hospital investigation

		BEL	CAN	CZE	DNK	FIN	FRA	DEU	IRL	ITA	JPN	KOR	MEX	PRT	SVK	SVN	ESP	CHE	GBR
6.2.1.1	Guidelines for in-hospital investigation of adverse events	+	+	+	−	+	+	±	+	+	±	−	+	+	−	+	+	−	+
6.2.1.2	Requirement for hospitals to involve an external person in the in-hospital investigation team deliberations for guaranteeing fairness and transparency	−	−	+	−	−	−	−	+	−	±	−	−	+	−	−	±	−	−
6.2.1.3	Recommended methods for investigating adverse events (e.g. root cause analysis)	+	+	+	−	+	+	+	+	+	−	−	+	+	−	+	+	+	+
6.2.1.4	External supporting systems for in-hospital investigation	+	−	±	−	−	+	±	+	−	+	−	+	+	−	+	+	−	+
6.2.1.5	Disclosure of the reports of adverse event investigations	−	±	−	−	−	+	±	+	−	−	−	−	+	+	−	−	−	+

+; Yes/A requirement/Exist, −: No/Not a requirement/Not exist, ±; Others, N/A; Not applicable

6.2.2 Recommended methods for investigating adverse events

Belgium

Root Cause Analysis, PRISMA, BowTie

Canada

Incident Analysis (concise, comprehensive or multi-incident analysis), critical incident review committee procedures, use of LEAN methodology for ex rapid improvement events, and others.

Czech Republic

Root Cause Analysis

Denmark

N/A

Finland

N/A

France

N/A

Germany

Mortality and morbidity conferences, Case analyses

Ireland

N/A

Italy

N/A

Japan

There is no recommendation, but Root Cause Analysis is widely used.

Korea

N/A

Mexico

Root Cause Analysis

Portugal

National Guideline nº 11/2012

Slovakia

N/A

Slovenia

Root Cause Analysis

Spain

Root Cause Analysis (London protocol)

Switzerland

Root Cause Analysis (London protocol)

United Kingdom

N/A

6.2.3 Standardized items that are included in the investigation report

Belgium

N/A

Canada

When used by jurisdictions or facilities, the Canadian Incident Analysis Framework and the Patient Safety and Incident Management Toolkit include templates and examples for the incident report. The key components include: information about the incident (date, type, severity of harm, outcome, date, etc.), summary, background and context, scope of the analysis/ terms of reference, methodology (type of analysis, legislative framework), summary of findings, recommended actions, appendices (timeline, diagrams, implementation, evaluation and communication plan, references). Patient perspective and engagement in incident analysis is also discussed.

Czech Republic

N/A

Denmark

N/A

Finland

N/A

France

N/A

Germany

N/A

Ireland

Depending on the level and method of review, review reports may contain:

- the terms of reference
- the membership of the review team
- the methodology applied to the review process and the rationale for why the decision to use this methodology was made
- a summary of the background to the incident
- any actions taken immediately following identification of the incident and during the review process
- what happened during the incident or incidents
- why it happened
- any incidental findings
- an apology or expression of regret to all those affected
- the recommendations and actions identified for implementation
- a section relating to responsibility for implementing recommendations and arrangements for sharing the learning with other services nationally
- and a glossary of key terms used in the report.

Italy

N/A

Japan

Date, time and place of the event/ Clinical department/ Name of healthcare facility/ Address/ Contact address/ Name of administrator/ Gender and age of the patient/ Items and method of investigation/ Clinical course/ Results of investigation to determine the cause of event/ Measures to prevent a recurrence if possible/ Responses and comments from family members of the patient

Korea

N/A

Mexico

24 items

Portugal

Causes, corrective measures, conclusions

Slovakia

N/A

Slovenia

11 items

Spain

It depends on the Region/Hospital.

Switzerland

The London Protocol - Systems analysis of clinical incidents
(Developed by Sally Taylor-Adams & Charles Vincent at the Clinical Safety Research Unit of the Imperial College London)

United Kingdom

Dependent on the type of investigations

6.2.4 Details of autonomous in-hospital investigation in each country

Belgium

External supporting systems for in-hospital investigation

The federal government Public Health

Disclosure of the reports of adverse event investigations

Impact is questionable and depends on the patient safety culture.

Canada

Guidelines for in-hospital investigation of adverse events

The Canadian Incident Analysis Framework, available through CPSI, includes a recommended incident analysis process which focuses on system improvement.

HIROC also offers an in-depth risk resource guide with evidence-informed practical advice on managing critical incidents and multi-patient events that covers the organization response; support for families, patients, and staff; and performing an impactful impact analysis.

An incident management toolkit is available from the Canadian Patient Safety Institute. It provides an integrated set of resources focused on immediate and ongoing actions following patient safety incidents (including near misses). Incident analysis guidelines, tools and resources curated from across Canada (including the Canadian Incident Analysis Framework) are available in this toolkit and presented as part of the patient safety and incident management processes.

Requirement for hospitals to involve an external person in the in-hospital investigation team deliberations for guaranteeing fairness and transparency

Hospitals are not required to involve them, although some hospital based investigations may also involve a regional health authority investigator on their review team.

Disclosure of the reports of adverse event investigations

Some provinces have a legislated obligation to disclose patient safety events. For example, both Manitoba and Quebec have statutes (respectively the Regional Health Authorities Act, C.C.S.M., c. R34, s. 53.2(2) and an Act Respecting Health Services and Social Services (R.S.Q., c. S-4.2) which require health authorities or health institutions to disclose adverse events (in the case of Manitoba "critical incidents" as defined in the Act) to those impacted by the adverse event. However, these statutes fall short of requiring health professionals themselves from disclosing such incidents and do not encompass reporting to the general public. The Manitoba statute goes further and also requires disclosure centrally to the relevant regional health authority (section 53.3(4) of the Act) and to the Manitoba Minister of Health (section 53.3(5) of the Act).

Some organizations disclose this information publicly, in a de-identified way, while others do not. It is recommended that a summary report is made available to staff and the family or patient involved in the incident as well as merged in the organization's reporting and learning system (where analysis reports, coroner reports, patient complaints/complements and other relevant information is collected) to allow for the identification of trends and systemic actions to improve safety.

Czech Republic

Guidelines for in-hospital investigation of adverse events

Guidance are presented on National portal for each type of AE (for prevention, actions for planning interventions, checklists etc.).

Denmark

N/A

Finland

N/A

France

Guidelines for in-hospital investigation of adverse events

Haute Autorité de santé has provided two guides.

External supporting systems for in-hospital investigation

Hospitals can be accompanied in their own analysis of causes and corrective measures by expert bodies, specialized in quality of care and patient safety (medical, paramedical and management of risk staff). Since a ministerial decree dated Nov 25th 2016, every Regional Health authority is required to select a structure to perform this assistance to health care organizations and professionals that would ask for it, be there from primary care, hospital or elderly care. These structures are also meant to bring their expertise to the Regional Health Authorities, should they need it. These structures are NOT ADMINISTRATIVE. They are called Structures régionales d'appui à la qualité des soins et à la sécurité des patients. The system is currently being built up in every region. These structures do NOT "investigate" (the Regional Health Authority does the investigation if necessary) but they provide support in analyzing and dealing with risk management.

Disclosure of the reports of adverse event investigations

Some Regional Healthcare Agencies publish cases of (serious) adverse events with their feedback.

Germany

Guidelines for in-hospital investigation of adverse events

There are no binding regulations. The Alliance for Patient Safety published recommendations. Internal guidelines might be a part of the hospital quality management system.

Ireland

Guidelines for in-hospital investigation of adverse events

HIQA and the Mental Health Commission have published 'Standards for the Conduct of Review of Patient Safety Incidents'.

Requirement for hospitals to involve an external person in the in-hospital investigation team deliberations for guaranteeing fairness and transparency

Depends on level of investigation required.

Italy

N/A

Japan

Guidelines for in-hospital investigation of adverse events

Several healthcare associations publish guidelines for in-hospital investigations.

Requirement for hospitals to involve an external person in the in-hospital investigation team deliberations for guaranteeing fairness and transparency

As for in-hospital investigations based on the Adverse Event Investigation System, the Ministry of Health, Labour and Welfare strongly encourages hospitals to assign an external specialist. As for other in-hospital investigations, hospitals can decide whether or not to assign an external specialist.

External supporting systems for in-hospital investigation

Academic societies, hospital associations, medical associations and other healthcare organizations registered as supporting bodies for the Adverse Event Investigation System can recommend specialists at the request of a hospital which finds it difficult to identify an appropriate specialist.

Disclosure of the reports of adverse event investigations

In the Adverse Event Investigation System, hospitals are required to explain the results of the investigation to

the bereaved family and are also able to give the report to the bereaved family, but the report is not disclosed to the public.
In the Project to Collect Medical Near-Miss/Adverse Event Information, the reports from hospitals are anonymized and disclosed to the public on the website of the Japan Council for Quality Health Care (JQ). Anyone can browse more than 75,000 reports including not only adverse events but also near misses.

Korea

N/A

Mexico

Guidelines for in-hospital investigation of adverse events
Root Cause Analysis Guidelines

Portugal

Guidelines for in-hospital investigation of adverse events
The Ministry of Health developed a National Reporting and Learning System and issued National Guidelines to support the investigation of adverse events and health risk management.
National Guidelines nº 11/2012 and nº 15/2014.

Disclosure of the reports of adverse event investigations
Those decided by IGAS (General Inspection of Activities in Health), ERS (Healthcare Regulation Authority) and the Portuguese Medical Association.

Slovakia

N/A

Slovenia

Requirement for hospitals to involve an external person in the in-hospital investigation team deliberations for guaranteeing fairness and transparency
The hospital can initiate for an extraordinary external control with counseling.

External supporting systems for in-hospital investigation
Control of quality and safety takes place within the framework of professional control with counseling on the basis of the Health Care Services Act and the Medical Services Act.
In accordance with the Rules on the implementation of expert control with consulting for individual groups of healthcare professionals not organized in professional chambers or professional associations with a public mandate.

Disclosure of the reports of adverse event investigations
Case studies will be created from the documentation, and the identity of the person involved will not be disclosed.

Spain

Guidelines for in-hospital investigation of adverse events
There are guidelines in some Regions. At national level, we are working on a national guideline

Requirement for hospitals to involve an external person in the in-hospital investigation team deliberations for guaranteeing fairness and transparency

In some hospitals.

External supporting systems for in-hospital investigation

Supports by the Health Region

Switzerland

N/A

United Kingdom

Requirement for hospitals to involve an external person in the in-hospital investigation team deliberations for guaranteeing fairness and transparency

It is not a stipulated requirement, rather described as best practice. In certain investigations, independent scrutiny is mandated, such as coronial investigations.

Disclosure of the reports of adverse event investigations

The general findings and recommendations are shared with the system, and, depending on the type of review, also made public.

7. Other efforts

In most states, hospitals are required to measure patient satisfaction regularly. Measurements of employee satisfaction and patient safety culture vary among states.

Regarding screening of adverse events, investigation of in-hospital deaths is obligated in some states. In France, in-hospital deaths that relate to surgery, anesthesiology or cancerology have to be reviewed at morbidity-mortality conferences. In Japan, all in-hospital deaths have to be reviewed irrespective of whether the case meets the reporting criteria of the Adverse Event Investigation System or not. In Spain, there are hospital mortality commissions in each hospital. Not only an autonomous reporting system but also other screening systems may be needed to identify problems, because low sensitivities or under-reporting by healthcare workers may conceal problems in the hospital.

More than half of states make efforts to provide emotional support to the staff involved in adverse events. Most of them are voluntary efforts in each hospital, but a standardized program is offered in Belgium, Canada and Spain. Second victims may be able to use the scheme easily if there is a standardized program.

Legislative protection which prevents the release of information concerning quality reviews from subsequent disclosure in the context of legal proceedings exists in all Canadian provinces. Stipulating protection against lawsuits is an interesting effort, as healthcare professionals will be able to discuss adverse events freely when protected.

7.1 Systems of other efforts

		BEL	CAN	CZE	DNK	FIN	FRA	DEU	IRL	ITA	JPN	KOR	MEX	PRT	SVK	SVN	ESP	CHE	GBR
7.1.1	Requirement for hospitals to measure patient satisfaction regularly	±	+	+	−	+	+	±	+	+	±	+	+	+	±	−	+	+	+
7.1.2	Requirement for hospitals to measure employee satisfaction regularly	±	−	+	+	+	−	±	−	−	±	+	−	+	−	−	±	−	+
7.1.3	Requirement for hospitals to measure patient safety culture regularly	+	+	+	−	−	−	−	+	−	−	−	+	+	−	−	+	−	+
7.1.4	Requirement for hospitals to offer education or training concerning patient safety for their staff	+	+	+	−	+	−	−	−	−	+	+	+	+	−	−	+	−	±
7.1.5	Requirement for hospitals to have a dedicate team that is available to respond to a deterioration or a sudden change of condition of patients	−	+	+	+	+	−	±	±	+	−	−	−	+	−	+	+	−	+
7.1.6	Requirement for hospitals to carry out periodic inspections for patient safety	±	+	±	+	+	−	±	−	+	−	−	+	+	−	−	+	−	±
7.1.7	Requirement for hospitals to investigate in-hospital deaths	±	+	±	−	+	+	±	±	+	±	−	+	+	+	−	+	−	±

		BEL	CAN	CZE	DNK	FIN	FRA	DEU	IRL	ITA	JPN	KOR	MEX	PRT	SVK	SVN	ESP	CHE	GBR
7.1.8	Standardized education/training programs for patient safety	+	+	+	−	+	+	±	−	−	−	−	−	+	−	−	+	+	+
7.1.9	Medical equipment/ device certification that is taken into account patient safety/ human factors concerns	±	+	+	−	+	N/A	±	−	−	+	+	+	+	+	+	±	−	±
7.1.10	Financial incentives for hospitals to support introducing electronic medical records	+	+	±	−	−	+	−	−	±	±	−	−	+	±	−	+	−	−
7.1.11	Efforts to standardize the way of sharing patient information across different facilities	+	+	+	+	+	±	+	+	+	±	+	−	+	+	−	+	−	+
7.1.12	Efforts to provide emotional support for the staff involved in adverse events	+	+	+	−	+	+	−	+	+	−	−	−	−	±	+	+	−	+
7.1.13	Safety standards for nursing homes or retirement homes	±	+	+	+	+	N/A	±	+	+	−	+	−	+	−	+	+	−	+

+; Yes/A requirement/Exist, −: No/Not a requirement/Not exist, ±; Others, N/A; Not applicable

7.2 Details in each country

Belgium

Periodic measurement

Almost all hospitals measure patient satisfaction, but it is not required. In the Flemish region, employee satisfaction is required to measure. Patient safety culture measurement is supported by the federal government and measured in 2007-2011-2015. Hospitals could participate at a benchmark study in collaboration with university.

Rapid response team

In 2015-2016, the federal government supported a scientific implementation study of the Rapid Response Team.

Investigation of in-hospital deaths

Hospitals are stimulated to analyze unexpected deaths and sentinel events.

Efforts to provide emotional support for the staff involved in adverse events

Program on second victim has been elaborated.

Safety standards for nursing homes or retirement homes

Nursing homes are the responsibility of the regions.

Canada

Periodic measurement

Client satisfaction is part of accreditation requirements for hospitals that choose to be accredited. Most regions and hospitals have a system with tools in place to gather patient/client experience feedback and use the responses as one crucial input informing quality improvement initiatives in hospitals. Many hospitals perform

employee engagement surveys, but it is not necessarily a requirement. Patient safety culture survey is required for those who are accredited by Accreditation Canada.

Education or training concerning patient safety for staff

Most hospitals will offer primary education on patient safety education to all staff at mandatory hospital orientations when they begin to work there. There will also be ongoing training that is provided, which may or may not be mandatory depending on the person's role in the organization. This is in addition to patient safety training provided in Canada's medical education programs (e.g. medical or nursing schools).

Rapid response team

All hospitals have a rapid response team to address medical emergencies, many have patient/family activated response teams.

Financial incentives for hospitals to support introducing electronic medical records

At the national level, Canada Health Infoway is funded to support the efforts of the provinces and territories to significantly increase the adoption of digital health technologies including use of electronic medical records (EMR). This includes:

- Supporting jurisdictions' EMR programs, which incent physicians and nurse practitioners to implement, adopt and use EMRs in their offices, primary care centres and out-patient clinics
- Upgrading and connecting EMRs so they are interoperable with the jurisdiction's electronic health record (EHR) components
- Helping clinicians achieve increased clinical value through the advanced use of EMRs, such as managing patient populations

To date, Infoway has invested in over 15,000 EMR systems in partnership with provincial and territorial governments. These investments leverage electronic health record (EHR) investments by making existing patient health information such as lab results, prescribed drugs, diagnostic images and selected hospital reports available to all clinicians. Provincially, there are several organizations also dedicated to the adoption of digital health solutions (ex., E-Health Ontario) which can provide incentives (often financial but sometimes tied to requirements of practice) to adopt and use EMRs.

Efforts to standardize the way of sharing patient information across different facilities

For non-safety specific information, aggressive Canadian efforts has been accompanied to link electronic health systems (EHRs) and to make all systems within a region/area interoperable, although this work is not yet optimal in Canada.

Efforts to provide emotional support for the staff involved in adverse events

There are formal processes such as Critical Incident Stress Management that can be used soon after the event, as well as more informal strategies such as conversation with one's manager and peer support for staff. Staff are encouraged to utilize their hospital's Employee and Family Assistance Plan, which offer free counselling and psychological support in most major health facilities.

Safety standards for nursing homes or retirement homes

Varies by province and by accreditation program, which currently set their own standards against which facilities are accredited.

Other systems for patient safety at the national level

■ Approval and post-market surveillance for pharmaceuticals and medical devices

As Canada's regulator of pharmaceuticals, medical devices and health technologies, Health Canada has considerable systems in place to determine when to provide regulatory approval of those things. In addition, it conducts post-market surveillance and analysis, which can lead to changes in the approval if required.

Its Marketed Health Products Directorate is also responsible for

(a) collecting, monitoring and analyzing adverse reaction, medical device and medication incident data,
(b) conducting benefit-risk assessments of marketed health products
(c) communicating product-related risks to health care professionals and the public
(d) overseeing the advertising regulatory requirements of health products
(e) providing policies to effectively regulate marketed health products.

In addition, The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.

■ Education for each professional based on defined competencies

Early in its mandate, CPSI prioritized health professional education and competency related to patient safety as a key enabler in patient safety improvement. Prepared through collaboration of CPSI with the Royal College of Physicians and Surgeons of Canada (RCPSC) and several Canadian experts, the Safety Competencies Framework (2008) is a foundational publication that has supported curriculum development, patient safety practices, and health professional standards and competency assessments across Canada and beyond.

The Safety Competencies Framework has been integrated into the RCPSC CanMEDS 2015 revised Physician Competency Framework which guides licensing and credentialing requirements for all physicians in Canada.

CPSI and the RCPSC developed the Advancing Safety for Patients in Residency Education (ASPIRE) program, a national faculty development certificate program for physicians on teaching patient safety and quality improvement. This has been embedded in every post-graduate medical residency training program across Canada.

The Canadian Association of Schools of Nursing (CASN) has adopted new accreditation standards for nursing education in Canada that strengthen patient safety, and incorporate key elements drawn from the Safety Competencies.

The Association of Faculties of Pharmacy of Canada has mapped their educational outcomes to the Framework, and the National Association of Pharmacy Regulatory Authorities of Canada has included the domains of the Framework into their professional competencies for Canadian pharmacists and pharmacy technicians at entry to practice.

The Paramedics Association of Canada has integrated the Competencies into the National Occupational Competency Profile for paramedics and emergency medical technicians.

■ Legislative protection of information against a request for disclosure

The legislative protection which prevents release of information concerning quality reviews from subsequent disclosure in the context of legal proceedings now exists in all Canadian provinces. Protection of quality of care information generated by specified types of committees is often found in the provincial or territorial Evidence Acts. However, protection of this information may also be found in standalone legislation (e.g. Ontario's Quality of Care Information Protection Act), or legislation governing other aspects of health services (e.g. Quebec's Act respecting health services and social services).

Ontario's Quality of Care Information Protection Act provides that quality of care information may only be disclosed to management if the committee considers it appropriate for the purposes of improving or maintaining the quality of health care provided in a facility. The information may also be disclosed if it will eliminate or reduce a significant risk to a person or group of persons.

Generally, statutes require that a committee's activity be motivated by the desire to improve health-care services in order to receive protection. For example, for committees to be established and protected under Ontario's Quality of Care Information Protection Act, they must have a view to improve or maintain: 1) the quality of

health care; or 2) the level of skill, knowledge, or competence of the health-care provider. Under Quebec's Act Respecting Health Services and Social Services, an institution must establish a risk management committee that seeks, develops, and promotes ways to identify and analyze incident or accident risks to ensure the safety of users.

Czech Republic

Periodic measurement

Patient satisfaction: Bulletin 16/2015 Coll. minimum requirements for the establishment of an internal system of quality assessment and safety of provided health services (empowerment in Act no. 372/2011 Coll.)

Periodic self-inspections for patient safety in each hospital

The internal system of quality assessment and safety of provided health services are inspected.

Standardized education/training programs for patient safety

MoH certified course in the field. Patient Safety in Health Services was developed in accordance with the WHO Multi-Professional Patient Safety Curriculum Guide.

Financial incentives for hospitals to support introducing electronic medical records

Electronic records in inpatient facilities is common standard, there is no incentives as far as we know.

Efforts to standardize the way of sharing patient information across different facilities

Portal of Quality of Safety; booklets publication Patient's Guide, Ministry of Health - Patient Rights Support Unit

Efforts to provide emotional support for the staff involved in adverse events

Mostly at local level (the hospital level) it is based on local policy for each healthcare facility.

Denmark

Education or training concerning patient safety for staff

It is voluntarily, but most units do.

Investigation of in-hospital deaths

Only when unexpected

Efforts to provide emotional support for the staff involved in adverse events

It is not systematically.

Finland

N/A

France

Periodic measurement

Patient safety culture measurement is not required, but the promotion of patient safety culture measurements is an item of the National patient safety program 2013-2017.

Education or training concerning patient safety for staff

It is not required, but very much spread out.

Rapid response team

It is not required, but frequently put up.

Investigation of in-hospital deaths

Hospital morbidity-mortality reviews have been compulsory in some cases since 2010: in surgery, anesthesiology, cancerology.

Standardized education/training programs for patient safety

In order to provide all health care givers with a common doctrine regarding risk management and patient safety including the human factor component, the National patient safety program 2013-2017 enabled the French translation of the WHO Patient safety curriculum guide (multi-professional edition) and promotes its use. An e-learning tool has been made out of it (2017) and a MOOC is to follow (2018). Medical studies (3rd cycle) underwent a reform in 2016-2017 which made patient safety one of the 3 topics taught to all medical interns, whatever specialty they opt for. Patient safety has also been notably reinforced during the 2nd cycle of medical studies (reform issued in 2013) as well as communication/collaboration with other staff and with patients.

Financial incentives for hospitals to support introducing electronic medical records

A full strategy is implemented by the Ministry of Health. In order to make information systems more efficient, particularly in terms of quality and safety of care, the General Directorate for the Provision of Care (DGOS) launched the Digital Hospital Program in November 2011. The Digital Hospital Strategy defines a plan for the development and modernization of hospital information systems and aims to set priorities and objectives at 6 years. To support them in this process, a specific financing plan is proposed.

Efforts to standardize the way of sharing patient information across different facilities

On a person to person level, the national patient safety program 2013-2017 has promoted a better communication between professionals and patients such as letter of referral or SBAR [SAED in French]. SBAR is currently taught in some paramedical schools.

Other systems for patient safety at the national level

■ Approval for pharmaceuticals and medical devices

Medical equipment authorizations are a compulsory procedure for a number of care activities (conformity of settings, devices and staff qualifications to regulation requirements). They highly contribute to keep safety standards high.

Germany

Periodic measurement

There is no legal requirement. Hospitals undertake such measurements as a frequent part of quality management systems, especially when they are needed for certifications.

Rapid response team

Hospitals are required to be equipped with emergency equipment according to their patient and service spectrum (§4 QM-RL). This encompasses emergency equipment, competence and training. Whether special teams are established lies in the responsibilities of the hospital.

Periodic self-inspections for patient safety in each hospital

According to QM-RL (§2), hospitals are required to establish PDCA-Cycle that includes frequent check-ups of patient safety measures.

Investigation of in-hospital deaths

There is no explicit legal requirement to investigate each case. However, such investigations are generally an important part of the risk management.

There is a financial incentive for clinical dissections according to the Hospital Restructuring Act (Krankenhausstrukturgesetz, §9(1a)3).

Efforts to standardize the way of sharing patient information across different facilities
It is included in the digitalization strategy of the Federal Ministry of Health.

Safety standards for nursing homes or retirement homes
There is no legal requirement. Details unknown.

Other systems for patient safety at the national level
National Action Plan on Medications Safety. Widespread initiatives to fight AMR, nosocomial infections and sepsis.

Ireland

Periodic measurement
The first National Patient Experience Survey was completed for all adult inpatients in the month of May with 61 internationally validated questions. This will be repeated annually. An HSE annual staff survey occurs.

Rapid response team
The Department of Health has published a National Clinical Guideline for detection of the deteriorating patient - early warning systems.

Investigation of in-hospital deaths
Deaths in hospitals are covered by the Coronor's Act (1962).

Medical equipment/ device certification that is taken into account patient safety/ human factors concerns
HPRA role.

Efforts to standardize the way of sharing patient information across different facilities
The implementation of the EU General Protection Regulation (effective from 25 May 2018) directly affects the sharing between health services providers of patient identifiable information for patient care and safety across the health system. The planned Health Information and Patient Safety Bill provides a further legislative opportunity to address information sharing in the health system, including for patient safety.

Safety standards for nursing homes or retirement homes
HIQA Standards

Italy

Education or training concerning patient safety for staff
Hospitals can organize internal courses. Health professionals can attend also external courses.

Periodic self-inspections for patient safety in each hospital
Hospitals perform visits in the different wards in order to ascertain and guarantee quality levels.

Investigation of in-hospital deaths
Depending on the conditions of the patients and on the type of deaths.

Financial incentives for hospitals to support introducing electronic medical records
It is strongly recommended.

Efforts to provide emotional support for the staff involved in adverse events
A support is offered from the organization to the third victim of adverse events.

Japan

Periodic measurement

It is not mandatory, but most hospitals measure patient satisfaction regularly, and some hospitals measure employee satisfaction.

Education or training concerning patient safety for staff

According to the Medical Care Act and the Ordinance for Enforcement of the Medical Care Act, hospitals are required to provide training sessions for hospital staff concerning patient safety twice a year.

Periodic self-inspections for patient safety in each hospital

According to the Medical Care Act and the Ordinance for Enforcement of the Medical Care Act, hospitals are requested to have a patient safety committee. One of the activities of the committee is to perform an inspection tour through the hospital regularly.

Investigation of in-hospital deaths

According to the Medical Care Act and the Ordinance for Enforcement of the Medical Care Act, special function hospitals such as university hospitals are required to review all in-hospital deaths whether they are related to adverse events or not.

In the Adverse Event Investigation System, all hospitals are required to report unexpected patient deaths due to medical service to the Japan Council for Patient Safety Investigation. All hospitals are required to review all in-hospital deaths whether or not they meet the reporting criteria of the Adverse Event Investigation System.

Financial incentives for hospitals to support introducing electronic medical records

The Ministry of Health, Labour and Welfare provides the budget for developing healthcare facilities to each prefecture, and each prefecture is able to use the budget for introducing EMR in hospitals.

Efforts to standardize the way of sharing patient information across different facilities

There is no authorized standardized way of sharing patient information across different facilities, although care coordination among different facilities is regarded as an essential part of the Integrated Community Health System in an aged society. Electronic health records, which enable the exchange of patient information across facilities, have been introduced in several areas, but the systems are developed independently. Exchange of patient information among different systems is not guaranteed.

The regional cooperation pathway (pathway from acute to rehabilitation care) is usually paper-based, and is used to share patient information across different facilities. The pathway enables the sharing of patient information via a common format among different healthcare facilities in a certain area. A pathway for femur fracture is widely used for cooperation among acute care hospitals and rehabilitation centers, because use of the pathway is paid by public medical insurance.

Safety standards for nursing homes or retirement homes

Patient safety in facilities with fewer resources than acute care hospitals can become a serious matter. There are no standards or data for patient safety in nursing homes and retirement homes.

Other systems for patient safety at the national level

■Approval and post-market surveillance for pharmaceuticals and medical devices

The Pharmaceuticals and Medical Devices Agency (PMDA) provides approval and post-market surveillance for pharmaceuticals and medical devices. Companies and healthcare professionals are required to report adverse drug reactions, infections caused by use of pharmaceuticals and medical devices and adverse events caused by medical devices to the agency. The agency also provides compensation for death or health damage requiring hospitalization caused by appropriately used, prescribed and purchased drugs and by infections from appropriately used biological products.

Korea

Periodic measurement

Accredited healthcare institutions are required to monitor indicators on patient satisfaction. The Health Insurance Review and Assessment Service (HIRA) is working on introducing a patient experience-based hospital assessment system to tertiary hospitals with 500+ beds. Accredited healthcare institutions are required to monitor indicators on employee satisfaction. Patient safety culture measurement is recommended but optional.

Efforts to standardize the way of sharing patient information across different facilities

The Health Insurance Review and Assessment Service is piloting a project on patient referral and transfer. This pilot project aims to facilitate the sharing of patient information between primary and secondary healthcare institutions through an intermediate system, which will enable rapid and accurate patient referral and transfer. Moving forward, we plan to develop and implement a model that can be linked with EMR.

Safety standards for nursing homes or retirement homes

In accordance with the Welfare of Older Persons Act, safety standards are included in the facility standards for nursing homes.

Other systems for patient safety at the national level

In accordance with Article 12 of the Patient Safety Act, the job responsibilities of personnel dedicated to patient safety include healthcare personnel training on the prevention of new and repeated adverse events.

Mexico

Periodic measurement

All hospitals measure patient satisfaction of hospital personnel and representatives of the community that are called “Aval Ciudadano” in parallel, and the results are then compared in order to establish their credibility. This results are publicly presented to all hospital users and personnel.

The General Directorate of Quality and Healthcare Education coordinates the implementation of the patient safety culture survey, and 12,525 doctors and nurses answer this survey in 2017.

Education or training concerning patient safety for staff

It is not mandatory.

Other systems for patient safety at the national level

The General Directorate of Quality and Healthcare coordinates specific actions such as a national survey in quality perception and a national survey in hand hygiene in accordance with the multimodal strategy form the world health organization.

Portugal

Periodic measurement

The Ministry of Health (Directorate-General of Health) also measures patient satisfaction every two years and the hospitals also do it according to the National Strategy for Quality in Health. Hospitals are required to measure patient safety culture since 2013 (Guideline nº 25/2013) and according to the 1st Strategic Goal of the National Plan for Patient Safety.

Periodic self-inspections for patient safety in each hospital

According to the National Plan for Patient Safety, the National Guidelines and the Ministerial Order nº 3635/2013.

Standardized education/training programs for patient safety
The Minister of Health approved training programs on Patient Safety.

Efforts to standardize the way of sharing patient information across different facilities
Ministerial Order nº 2783/2013 and National Guideline nº01/2017.

Safety standards for nursing homes or retirement homes
These units participate in HALT - Healthcare-associated infections in long-term care facilities study developed by ECDC and the national guidelines of the multimodal strategy for Infection Control also apply to these units.

Other systems for patient safety at the national level
The Ministry of Health published "The National Plan for Patients' Safety 2015-2020 (Order nº 1400-A/2015)" to establish 9 national patient safety strategic goals. For each strategic goal, there are national guidelines with national indicators. Furthermore, the Ministry of Health also issued Order nº5739/2015 publishing the national indicators for quality monitoring (including Safety).
The national program "Health education, literacy and self-care" was created by ministerial order nº 3618-A/2016. In 2017, this program was merged with the program: "Prevention and Management of Chronic Illness" and a new program was created: "Health Literacy and Integration of Care" (ministerial order nº 6429/2017).

Slovakia

Periodic measurement
The Ministry of Health requires state hospitals to measure patient satisfaction voluntarily.

Investigation of in-hospital deaths
If the bereaved families agree, yes.

Financial incentives for hospitals to support introducing electronic medical records
It is in the process of national action plan.

Efforts to provide emotional support for the staff involved in adverse events
The Modrý anjel (Blue Angel, NGO) provides the support based on a request of the staff.

Slovenia

Periodic measurement
Measuring the quality and safety of health care is not yet fully equivalent to the interconnected planned interdependent activities and measures at all levels and segments of healthcare.
As for patient satisfaction, we started the PREMs and PROM project with the support of the European Commission Structural Reform Support Service.
Employee satisfaction is not automatically monitored in public health facilities. The system was established only in some hospitals. It is partially established at the primary level in family medicine practices.
A patient safety culture survey was conducted in 13 hospitals in 2011. The results were not good. In upgrading the monitoring system of sentinel and other adverse events is one of the important points is to improve the safety culture.

Education or training concerning patient safety for staff
The internal education system is well established only in some hospitals.

Rapid response team
Hospitals have a dedicate team which are available to respond to a deterioration or a sudden change of condition of patients.

Periodic self-inspections for patient safety in each hospital

The hospitals are performing regular security rounds.

Control of quality and safety takes place within the framework of professional supervision with counseling on the basis of the Health Care Services Act. The amendment to the Health Care Act, adopted on 19 September 2017, as an important novelty introduces systemic control and, in some other forms of supervision, emphasizes the possibility of control over quality and safety.

Standardized education/training programs for patient safety

Training for health professions is carried out in accordance with Directive 2005/36 / ES and Directive 2013/55 / EU (for full-time and part-time studies). Quality and safety is part of compulsory professional training of health professionals. Modules for the development of skills and skills for inter-professional cooperation are being introduced.

Medical equipment/ device certification that is taken into account patient safety/ human factors concerns

The area is partially regulated by the Rules on minimum sanitary health conditions for the provision of hygienic care and other similar activities. In some parts, the areas also touch on the provisions of the Law on safety and health at work.

Financial incentives for hospitals to support introducing electronic medical records

eHealth is a project at national level. Training of contractor was carried out. The facility of a national system is financially supported. The development of internal systems is in the domain of individual hospitals.

Efforts to provide emotional support for the staff involved in adverse events

This is primarily available in psychiatric hospitals, in others, depending on hospital management and the willingness of psychiatrists or clinical psychologists to work in hospitals, supervision is not provided to workers in health care.

Safety standards for nursing homes or retirement homes

Patient safety systems in homes for elderly people are partially established. The system for monitoring and implementing measures for sentinel and other adverse events in Slovenia are only established in some major public institutes, less in private institutions.

Other systems for patient safety at the national level

■ Continuing education for licensed professionals

The Rules on Medical Licenses and Regulations on the Register and Licenses of Performers in Nursing or Midwifery Care are important. Professional training in addition to the contents from the narrower field of expertise in which the worker performs his work, also includes compulsory contents from the quality and safety in health care, in the scope of 6 hours. The healthcare professional will have to complete the above mentioned contents at least once every seven years.

■ Contribution of patient associations

Cooperation takes place through patient associations (NGO Network 25 x 25), answering patients' questions, by completing questionnaires on satisfaction with services provided.

Spain

Periodic measurement

The Regions normally assess patient satisfaction annually. Employee satisfaction is not measured in general. The National PS strategy recommends to assess patient safety culture regularly.

Periodic self-inspections for patient safety in each hospital

It conducts in the framework of accreditation programs as well as some specific programs regarding PS good practices.

Investigation of in-hospital deaths

There are hospital mortality commissions in each hospital.

Standardized education/training programs for patient safety

There are standard programs in some Regions.

Medical equipment/ device certification that is taken into account patient safety/ human factors concerns

It is a responsibility of the National Medication and Medical Device Agency.

Financial incentives for hospitals to support introducing electronic medical records

The MSSSI provides specific budget to implement electronic clinical records nationwide.

Efforts to standardize the way of sharing patient information across different facilities

Annual national and Regional meetings to share the results of specific indicators among hospitals.

Efforts to provide emotional support for the staff involved in adverse events

There are supports in some Regions/hospitals. Also the MSSSI is working with experts and Universities to design a national program regarding this issue.

- Mira JJ et al.: Lessons learned for reducing the negative impact of adverse events on patients, health professionals and healthcare organizations. Int J Qual Health Care. 2017 Aug 1;29(4):450-460
- Mira JJ, et al.: The Second Victim Phenomenon After a Clinical Error: The Design and Evaluation of a Website to Reduce Caregivers' Emotional Responses After a Clinical Error. J Med Internet Res. 2017 Jun 8;19(6): e203
- Mira Solves JJ, et al.: In case of an adverse event don´t forget to say sorry. An Sist Sanit Navar. 2017 Aug 31;40(2):279-290

Safety standards for nursing homes or retirement homes

There are standards in some Regions/hospitals.

Switzerland

Periodic measurement

Patient safety culture has not measured regularly yet, but it is in consideration to be made mandatory (clarifications ongoing).

Standardized education/training programs for patient safety

Only in the French speaking cantons.

Safety standards for nursing homes or retirement homes

In some specific cantons.

Other systems for patient safety at the national level

National Breakthrough Programms (Safe surgery WHO checklist), Safe Medication (medication reconciliation), Safety in urinary catheters, Medication safety in nursing homes). Methodology: IHI Breakthrough Collaboratives

United Kingdom

Education or training concerning patient safety for staff

Factors taught in medical education curriculum

Periodic self-inspections for patient safety in each hospital

The Care Quality Commission independently inspects hospitals on a regular basis, in addition to when responding to incident notification.

Investigation of in-hospital deaths

Providers are required to investigate deaths thought to have been due to problems in care under the National Guidance on Learning from Deaths. The learning from investigations or reviews must then be published, alongside the steps that the provider will take in response. Additionally, the deaths of all children must be reviewed under the national guidance on Child Death Review.

Medical equipment/ device certification that is taken into account patient safety/ human factors concerns

Medicines and Healthcare Products Regulatory Agency advise that manufacturers take human factors into account, and assess these factors when reviewing new devices.

Efforts to standardize the way of sharing patient information across different facilities

NHS Digital are leading on a project to make patient records available for investigative purposes.

8. National Patient Day/Week

More than half of the states already have a national patient day or week that aims to promote patient safety activities in healthcare organizations and societies. Not only posters but also videos, games and quizzes are provided in Canada and France. World Patient Safety Day would be welcomed to promote patient safety activities worldwide.

8.1 National Patient Day/Week

Exist: BEL, CAN, FRA, DEU, JPN, SVN, CHE

Not exist: CZE, FIN, IRL, ITA, KOR, PRT, ESP, SVK

Others: DNK, MEX, GBR

8.2 Activities on the Patient Day/Week

Belgium

Third week of November is a patient safety week.

Symposium and hospitals are asked to develop activities focused on patient safety during that week.

Canada

Canadian Patient Safety Week is a national, annual campaign that started in 2005 to inspire extraordinary improvement in patient safety and quality. As the momentum for promoting best practices in patient safety has grown, so has the participation in Canadian Patient Safety Week. Canadian Patient Safety week is relevant to anyone who engages with our healthcare system: providers, patients, and citizens. Working together, thousands help spread the message to Ask. Listen. Talk.

During the most recent Canadian Patient Safety Week, the following activities occurred:

- A quiz related to medication safety which was tailored to both patients and providers
- A podcast series entitled PATIENT which explores medication safety through a non-fiction medical drama.
- A contest entitled - Question Your Meds Catchy Phrase Contest which brought attention to the 5 Questions to Ask Medication Safety Tool.
- A National Conversation Webinar around Implementing Safer, More Efficient Care.

Denmark

N/A

France

Patient safety Week nationally hold every year since 2011.

Numerous activities are organized by the Ministry of Health, by the Regional Health Authorities, by the regional “structures d’appui à la qualité des soins et à la sécurité des patients”, by other experts’ bodies at national, regional or local levels (expert bodies for infections, for the safety of medication, etc.), by almost every hospital and in a number of elderly care structures. Events, symposiums and workshops are organized, talks, trainings, contests, etc. Videos, serious games, posters are displayed.

Germany

September 17th (International Day of Patient safety, celebrated in D, AUT, CH, LIE, LUX, CRO, BRA)
German Alliance for Patient Safety (Aktionsbündnis Patientensicherheit) sets a topic each year for outreach events that involve patients and all stakeholders of the health care system. An annual topic is chosen.

Japan

The week including November 25th is Patient Safety Week.
The Ministry of Health, Labour and Welfare makes a poster for Patient Safety Week and holds a symposium. Many healthcare organizations also hold symposiums or workshops around this week.

Korea

Starting from 2018, Patient Safety Day/Week will be celebrated.

Mexico

May 5th is the international day for hand hygiene, in accordance with the International Hand Hygiene strategy promoted by the WHO.
There is a nationwide campaign to promote Hand Hygiene with social media events, education programs, etc. All states in Mexico must elaborate a continuous improvement plan form the results of the Hand Hygiene multimodal survey.

Slovakia

Slovak day of oncology patients (Deň narcisov), Slovak day of obesity (Slovenský deň obesity), National week of antibiotic use and AMR (November) and others
Collecting donation of citizens for medical equipment, and informational campaigns about the illness

Slovenia

February 11 is World Patient Day.
Many events take place on that day. Chambers and professional associations make public statements, and civil associations of patients are active. In 2017, respect for the dignity of patients was the topic.

Switzerland

It is led by Patient Safety Foundation. Presentations in many hospitals, media contacts etc.

United Kingdom

N/A

9. Effectiveness and priorities of patient safety policies

The mean values of ratings of all items are shown in Figure 1 and in the Appendix. Ten policies were identified as favorable policies, six of which were related to the reporting and investigation of adverse events. Policymakers may consider establishing a public reporting system and standardizing the system for investigating adverse events. Two policies were identified as unfavorable policies. The effect of accreditation for patient safety or the certification of personnel responsible for patient safety management may be controversial issues that need further investigation.

9.1 Favorable policies

(1: low --- 5: high)

Questions		Effect of the policy		Priority in near future in your country	
		Mean	SD	Mean	SD
1.2.5	(Requirement for hospitals) To define procedures for identification, investigation and prevention of adverse events	4.0	0.9	4.2	1.2
1.2.7	(Requirement for hospitals) To define patient and caregiver participation in patient safety efforts	3.7	1.1	4.0	1.1
1.2.8	(Requirement for hospitals) To define the measurement and evaluation of methods for patient safety (including patient safety indicators)	4.0	0.9	4.3	1.0
3.7	Are the hospitals required to report adverse patient events to the government or an independent organization?	3.8	1.0	4.3	0.9
3.8	Is there a system for hospitals to report VOLUNTARILY adverse events to the government or an independent organization?	3.5	1.0	4.2	1.1
3.9	Is there a system for hospitals to report VOLUNTARILY close calls/near misses to the government or an independent organization?	3.8	0.9	4.4	0.9
6.4	Are there guidelines for in-hospital investigation of adverse events?	3.9	1.1	4.2	1.1
7.1.7	Are hospitals required to investigate in-hospital deaths?	3.7	1.0	4.1	1.1
7.2.3	Is there financial incentive support for hospitals to introduce electronic medical records?	3.6	0.9	4.1	0.8
7.3.1	Are there efforts to standardize the way of sharing patient information across different facilities?	3.8	1.1	4.0	0.9

9.2 Unfavorable policies

(1: low --- 5: high)

Questions		Effect of the policy		Priority in near future in your country	
		Mean	SD	Mean	SD
2.6	If “yes” in 2.3, are there any systems or incentives to support hospitals to undergo hospital accreditation?	2.4	1.1	2.8	1.7
4.6	If “Yes” in 4.4, is there a national or other certification system for personnel responsible for patient safety management?	2.3	1.6	2.6	1.5

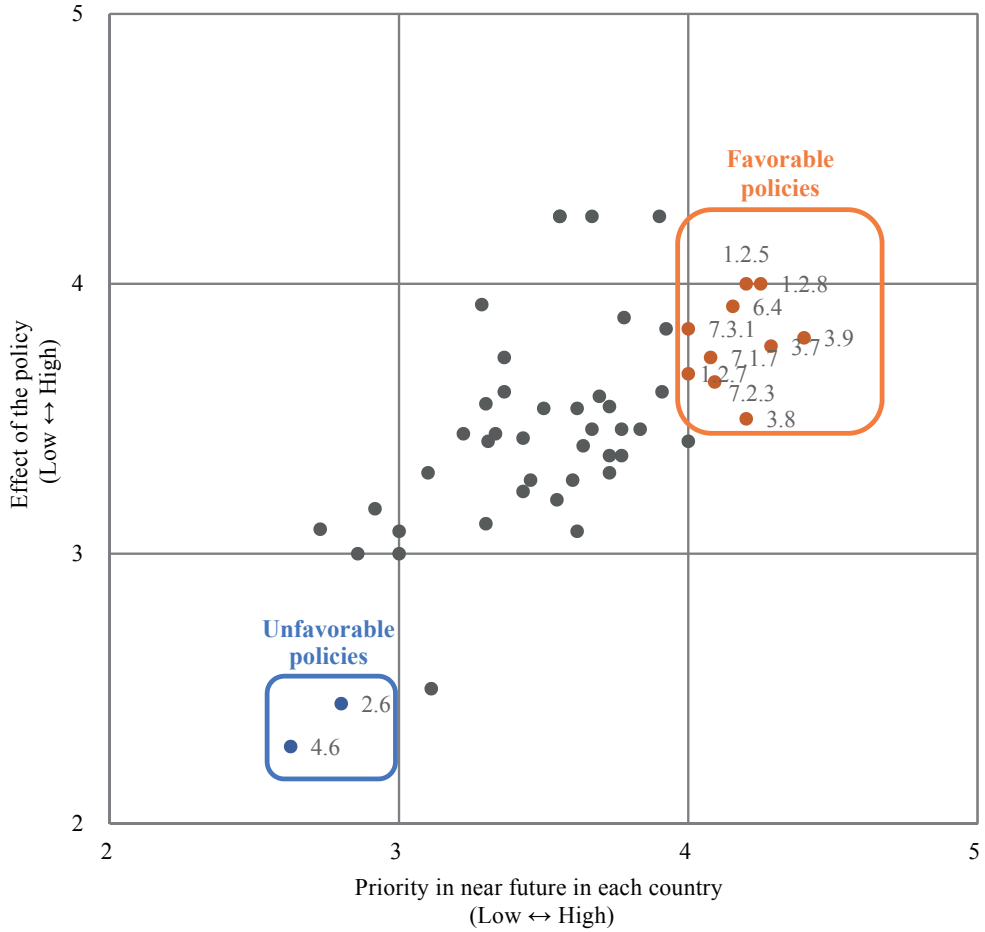


Figure 1 Distribution of ratings of all items

APPENDIX

Table. Ratings of effects and priorities of each policy

Questions		Effect of the policy		Priority in near future in your country	
		Mean	SD	Mean	SD
1	Safety standards				
1.1	Are hospitals required to establish a patient safety management system by law?	3.9	1.1	3.3	1.5
1.2	If "yes" in 1.1, choose the actions required by hospitals.				
1.2.1	To define the guiding principles (or guidelines) for patient safety program	4.3	0.8	3.6	1.3
1.2.2	To define the organization for patient safety management	4.3	0.8	3.6	1.3
1.2.3	To define who is assigned in charge of the patient safety management	4.3	0.8	3.7	1.4
1.2.4	To define the in-hospital reporting system for adverse event and close calls (near misses)	4.3	1.0	3.9	1.3
1.2.5	To define procedures for identification, investigation and prevention of adverse events	4.0	0.9	4.2	1.2
1.2.6	To define the staff education and training for patient safety	3.9	1.1	3.8	1.4
1.2.7	To define patient and caregiver participation in patient safety efforts	3.7	1.1	4.0	1.1
1.2.8	To define the measurement and evaluation of methods for patient safety (including patient safety indicators)	4.0	0.9	4.3	1.0
2	Please describe the required audits and accreditation of hospitals with focus on patient safety				
2.1	Does the government audit patient safety conditions regularly?	3.5	1.3	3.5	1.5
2.2	If "yes" in 2.1, what conditions or actions are inspected?				
2.3	Is there a hospital accreditation system by an independent third body organization?	3.7	0.9	3.4	1.1
2.4	If "yes" in 2.3, please provide the name(s) of the accreditation body(ies).				
2.5	If "yes" in 2.3, please provide the number and/or the proportion of accredited hospitals in your country.				
2.6	If "yes" in 2.3, are there any systems or incentives to support hospitals to undergo hospital accreditation?	2.4	1.1	2.8	1.7
3	Please describe the patient safety data submission requirements by hospitals				
3.1	Are hospitals required to submit data of clinical indicators concerning patient safety to the government or an independent third entity?	3.4	1.0	3.4	1.2
3.2	If "Yes" in 3.1, how many patient safety indicators are required?				
3.3	If "Yes" in 3.1, are patient reported outcomes or experiences included in the reporting indicators?	3.3	1.4	3.7	1.4
3.4	If "Yes" in 3.1, is the collected data made public?	3.6	1.0	3.7	1.2
3.5	If "Yes" in 3.1, is the collected data made public in a manner that identifies the hospital?	3.4	1.2	3.3	1.3
3.6	If "Yes" in 3.1, is there a system to reward or a penalize hospitals based on the reported data?	2.5	1.2	3.1	1.7
3.7	Are the hospitals required to report adverse patient events to the government or an independent organization?	3.8	1.0	4.3	0.9
3.8	Is there a system for hospitals to report VOLUNTARILY adverse events to the government or an independent organization?	3.5	1.0	4.2	1.1

	Questions	Effect of the policy		Priority in near future in your country	
		Mean	SD	Mean	SD
3.9	Is there a system for hospitals to report VOLUNTARILY close calls/near misses to the government or an independent organization?	3.8	0.9	4.4	0.9
3.10	If you answered "Yes" in any questions from 3.7 to 3.9, please provide the name of organization that collects the information of adverse events or close calls.				
3.11	Is there a system to exempt criminal or civil liability of adverse events when the case is reported to the government or the independent organization?	3.1	1.2	2.7	1.4
3.12	Are the sentinel events published regularly based on reported adverse events and close calls?	3.3	1.1	3.6	1.5
4	What training or experience is required for hospital staff responsible for patient safety management?				
4.1	Are personnel responsible for patient safety management regarded as a professional focus in patient safety management?	3.5	1.2	3.8	1.3
4.2	What is the major educational background among personnel responsible for patient safety management?				
4.3	Are there standard educational programs for training personnel responsible for patient safety management?	3.5	1.2	3.8	1.2
4.4	Are there organizations that offer education or training for personnel responsible for patient safety management?	3.5	1.5	3.6	1.3
4.5	If "Yes" in 4.4, what kind of organizations offer education or training for personnel responsible for patient safety management?				
4.6	If "Yes" in 4.4, is there a national or other certification system for personnel responsible for patient safety management?	2.3	1.6	2.6	1.5
4.7	Are there incentives to promote assignment of personnel to be responsible for patient safety management in each hospital? If so, can you elaborate?	3.1	1.6	3.0	1.7
4.8	Are there networks which promote information sharing among personnel responsible for patient safety management across hospitals?	3.2	1.4	3.4	1.4
4.9	What are the major challenges in training or assignment of a personnel responsible for patient safety in each hospital?				
5	Please describe the system for dispute resolution and compensation concerning patient harm in your country				
5.1	Is there a no-fault compensation scheme for adverse events?	3.4	1.3	3.2	1.5
5.2	If "Yes" in 5.1, please answer the name of the administrative entity of the no-fault compensation scheme.				
5.3	If "Yes" in 5.1, please provide the definition of adverse events which are compensated by the scheme. (e.g. the type or severity of adverse events, etc.)				
5.4	If "Yes" in 5.1, how many cases were compensated by the scheme during the past year?				
5.5	Is an alternative dispute resolution (ADR) available to resolve medical disputes?	3.2	1.2	2.9	1.4
5.6	If "Yes" in 5.5, are there organizations that provide or help to find a mediator or an arbitrator?	3.4	0.7	3.3	1.1
5.7	If "Yes" in 5.5, is there a standard educational program to train mediators or arbitrators for medical disputes?	3.0	0.6	3.0	1.0
6	Please define the standard methods for investigation of adverse events				
	(External organization)				
6.1	Are there third body organizations that investigate the causes of adverse events?	3.6	1.4	3.4	1.7

Questions		Effect of the policy		Priority in near future in your country	
		Mean	SD	Mean	SD
6.2	If "Yes" in 6.1, please provide the name of the administrative entity for patient harm investigations.				
6.3	If "Yes" in 6.1, how many cases were investigated by the third body organizations during the past year?				
	(Autonomous in-hospital investigation)				
6.4	Are there guidelines for in-hospital investigation of adverse events?	3.9	1.1	4.2	1.1
6.5	Are hospitals required to involve an external person in the in-hospital investigation team deliberations for guaranteeing fairness and transparency?	3.6	1.5	3.3	1.6
6.6	Are there recommended methods for investigating adverse events? (e.g. root cause analysis)	3.8	1.1	3.9	1.4
6.7	Are there external supporting systems for in-hospital investigation?	3.2	1.3	3.5	1.6
6.8	What standardized items are included in the investigation report?				
6.9	Are the reports of adverse event investigations disclosed to the public?	3.0	1.4	2.9	1.4
7	Others				
7.1	Requirements				
7.1.1	Are hospitals required to regularly measure patient satisfaction?	3.5	1.2	3.7	1.1
7.1.2	Are hospitals regularly required to measure employee satisfaction?	3.3	1.2	3.1	1.4
7.1.3	Are hospitals required to regularly measure patient safety culture?	3.6	1.3	3.9	1.3
7.1.4	Are hospitals required to offer education or training concerning patient safety for their staff?	3.5	1.2	3.7	1.3
7.1.5	Are hospitals required to have a dedicate team that is available to respond to a deterioration or a sudden change of condition of patients? (e.g. rapid response team, METS, etc.)	3.4	1.1	4.0	1.1
7.1.6	Are hospitals required to carry out periodic inspections for patient safety?	3.4	1.0	3.8	1.2
7.1.7	Are hospitals required to investigate in-hospital deaths?	3.7	1.0	4.1	1.1
7.2	Promotion of standardization in hospital				
7.2.1	Are standardized education/training programs for patient safety provided?	3.4	1.2	3.6	1.0
7.2.2	Are patient safety/human factors concerns taken into account when certifying medical equipment/device?	3.3	1.2	3.5	1.3
7.2.3	Is there financial incentive support for hospitals to introduce electronic medical records?	3.6	0.9	4.1	0.8
7.3	Others				
7.3.1	Are there efforts to standardize the way of sharing patient information across different facilities?	3.8	1.1	4.0	0.9
7.3.2	Are there efforts to provide emotional support for the staff involved in adverse events? If yes, please provide details.	3.1	1.1	3.3	0.8
7.3.3	Are there safety standards for nursing homes or retirement homes?	3.4	1.0	3.7	0.7
7.3.4	Describe other systems for patient safety at the national level, and please explain briefly.				
8	National Patient Day				
8.1	Is there a National Patient Day/Week?	3.1	1.4	3.6	1.4
8.2	If Yes in "8.1", what kind of activities are provided on the Patient Day/Week?				

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資料4-1

Certified Professional in Healthcare Risk Management

American Hospital Association

CANDIDATE HANDBOOK AND APPLICATION

Conducted by the American Hospital Association Certification Center
Effective June 2017

For questions regarding the certification programs, contact:

AHA Certification Center (AHA-CC)
155 N. Wacker Drive, Suite 400
Chicago, IL 60606
Phone: 312-422-3702
Fax: 312-422-4575
Email: certification@aha.org
Website: www.AHACertificationCenter.org

For questions regarding the examination application and administration, contact:

PSI Candidate Services
18000 W. 105th St.
Olathe, KS 66061-7543
Phone: 888-519-9901
Fax: 913-895-4651
Email: info@goAMP.com
Website: www.goAMP.com

TABLE OF CONTENTS

This Candidate Handbook provides information about the Certified Professional in Healthcare Risk Management (CPHRM) program, including the exam administration policy and process as well as the CPHRM Examination Application. Keep this Candidate Handbook until after the CPHRM Examination is completed. Additional copies of this Candidate Handbook may be obtained by downloading a copy from www.AHACertificationCenter.org. *The most current version of the Candidate Handbook is posted here and supersedes any other version.*

THE AHA-CC

The American Hospital Association Certification Center (AHA-CC) is a division of the American Hospital Association (AHA). Its mission is to create, facilitate and administer the healthcare industry's premier certification programs.

The AHA-CC Board of Directors is charged with governance of Certification Programs conducted by the AHA-CC. Board members are appointed to represent AHA's professional Certification Program stakeholders.

Each Certification Program in development or operation with the AHA-CC has a Certification Program Committee that serves as content expert, program resource, and consultant to the AHA-CC regarding program development, CPHRM Examination content, test development, test administration and evaluation. Members are appointed by the AHA-CC Board of Directors.

Statement of Nondiscrimination

The AHA-CC does not discriminate among candidates on the basis of age, gender, race, color, religion, national origin, disability or marital status.

AHA-CC CERTIFICATION PROGRAM EXAMINATIONS

The AHA-CC conducts certification examinations for programs in the following fields of health care:

- Facility Managers
- Constructors
- Environmental Services
- Human Resources
- Materials and Resource Management
- Risk Management

The AHA-CC also provides contracted project management and quality assurance services to the American Organization of Nurse Executives (AONE) in support of its certification programs for nurse executives and nurse managers.

Each certification examination is designed to test a well-defined body of knowledge representative of professional practice in the discipline. Successful completion of a certification examination is an indicator of broad-based knowledge in the discipline being tested. Certification examinations conducted by the AHA-CC are independent of each other. Each leads to a certification credential in a healthcare discipline.

Content of each examination was defined by a national role delineation study. The study involved surveying practitioners in the field to identify tasks that are performed routinely and considered important to competent practice. Each edition of a certification examination is developed through a combined effort of qualified subject matter experts and testing professionals, who construct the examination in accordance with the Examination Content Outline.

Testing Agency

The AHA-CC contracts with PSI Services to assist in the development, administration, scoring, score reporting and analysis of its CPHRM Examination.

CPHRM CERTIFICATION PROGRAM

The CPHRM certification program promotes healthcare risk management through certification of qualified individuals and the following program elements:

- Recognizing formally those individuals who meet the eligibility requirements of the AHA-CC and pass the CPHRM Examination
- Requiring certification renewal through continued personal and professional growth in the practice of healthcare risk management
- Providing a national standard of requisite knowledge required for certification; thereby assisting employers, the public and members of health professions in assessing healthcare risk managers

Definition of a Healthcare Risk Management Professional

The Healthcare Risk Management Professional's primary duties include the prevention, reduction, and control of loss to the healthcare organization, its patients, visitors, volunteers, physicians, other healthcare professionals and employees. Regardless of the healthcare delivery system in which the individual works, the Healthcare Risk Management Professional interfaces with a number of healthcare professionals in the accomplishment of these objectives. Duties may include incident investigation and analysis, tracking, trending and evaluation, risk financing and claims management.

CPHRM Eligibility Requirements

Candidates meeting the CPHRM eligibility requirements fully and passing the CPHRM Examination attain the CPHRM designation. The AHA-CC reserves the right, but is not obligated, to verify the accuracy of eligibility information supplied by or on behalf of a candidate.

To be eligible for the Certified Professional in Healthcare Risk Management (CPHRM) Examination, a candidate must fulfill one (1) of the following requirements for education/healthcare experience ***and*** meet the requirement for risk management experience.

Education/Healthcare Experience

- Baccalaureate degree or higher from an accredited college or university plus five (5) years of experience in a healthcare setting or with a provider of services to the healthcare industry
- Associate degree or equivalent from an accredited college plus seven (7) years of experience in a healthcare setting or with a provider of services to the healthcare industry.
- High school diploma or equivalent plus nine (9) years of experience in a healthcare setting or with a provider of services to the healthcare industry.

Risk Management Experience

- 3,000 hours or 50 percent of full-time job duties within the last three years dedicated to healthcare risk management in a healthcare setting or with a provider of services (e.g. consultant, broker, or attorney) to the healthcare industry.

CPHRM EXAMINATION

The CPHRM Examination is structured as follows:

- Composed of 110 multiple-choice questions. A candidate's score is based on 100 of these questions. Ten (10) items are "trial" or "pretest" questions that are interspersed throughout the Examination and are not scored.
- A candidate is allowed two (2) hours in which to complete the CPHRM Examination.
- The CPHRM Examination is based on the five (5) major content areas listed in the Content Outline.
    - Each content area is further defined in the Content Outline by a list of tasks representative of that job responsibility.
    - The number of CPHRM Examination questions devoted to each major content area is included in the Content Outline.

- Generally, the Examination questions are categorized by the following cognitive levels:
  - Recall: The ability to recall or recognize specific information
  - Application: The ability to comprehend, relate or apply knowledge to new or changing situations
  - Analysis: The ability to analyze and synthesize information, determine solutions and/or evaluate the usefulness of a solution

CPHRM Examination Content Outline

For the CPHRM Examination Content Outline for the current CPHRM Examination, refer to the following pages.

1. Clinical/Patient Safety: 35 items *(Recall: 7, Application: 10, Analysis: 18)*

A. Assess the current state of patient safety and staff awareness within the organization.
B. Collaborate on proactive patient safety initiatives (e.g., FMEA, RCA, Safety Culture/Just Culture).
C. Design, implement, and maintain educational programs on risk management and patient safety related topics.
D. Promote a culture of patient safety through education, policy development, and standardization of processes.
E. Educate providers, staff, employees, patients and families on the role of patients and families in improving patient safety and reducing risk.
F. Coach physicians, leaders, managers, and staff on appropriate disclosure methods and processes.
G. Participate in critical incident debriefing.
H. Participate in the development of corrective action plans and supervise follow-up of recommended improvements stemming from risk assessments, audits and investigations (e.g., sentinel events, reported events/incidents, FMEA and Root Cause Analysis).
I. Provide guidance to staff regarding a:
    1) disruptive patient.
    2) verbally disruptive family member.
J. Design a management data collection and analysis system and timely reporting including elements of written incidents reports.
K. Design a management data collection and analysis system and timely reporting including elements of patient complaints and/or satisfaction surveys.
L. Design a management data collection and analysis system and timely reporting including elements of clinical indicators.

2. Risk Financing: 10 items *(Recall: 2, Application: 6, Analysis: 2)*

A. Assist General Counsel with administration of all aspects of the Self-Insured Retention (SIR) program.
B. Implement a program for control of contractual risk by recommending/implementing modifications to address identified risks.
C. Oversee the investigation of accidents or circumstances that could lead to financial loss (e.g., professional, institutional, general liability, and product liability).
D. Participate in due diligence/research potential liability assessment for new services or delivery models, acquisitions or construction (e.g., line of service, new products in the delivery of care).
E. Assess liability and probability of legal action resulting from adverse events, complaints, and regulatory actions.
F. Analyze professional liability historical loss experience.
G. Develop comprehensive risk financing strategies to address the organization's areas of exposure (e.g., general liability (GL), professional liability (PL), privacy and security liability).
H. Respond to risk management concerns about insurance coverage from organization personnel and staff members.

3. Legal and Regulatory: 24 items *(Recall: 5, Application: 14, Analysis: 5)*

A. Promote compliance with state-specific legislation through policy development, guidance, or education.
B. Promote compliance with federal and state laws and regulations governing patient confidentiality through policy development, guidance, or education including protected health information (PHI).
C Promote compliance with state reporting requirements through policy development, guidance, or education (e.g., abuse of vulnerable populations).
D. Promote compliance with state reporting requirements governing violence in the workplace through policy development, guidance, or education.
E. Educate staff on regulatory issues related to risk management.
F. Promote compliance with state regulations regarding the investigation and resolution of patient complaints or grievances through policy development, guidance, or education.
G. Collaborate with other departments by preparing and conducting quality and/or risk assessments to maintain a constant state of accreditation readiness.
H. Promote compliance with regulations governing involuntary detention of patients through policy development, guidance, or education.

I. Manage a vendor liability program to catalog evidence of vendor licensure, required insurance limits, permits, etc.
J. Promote compliance with state agencies governing the reporting of specific events through policy development, guidance, or education.
K. Promote compliance with the requirements of the following federal acts/regulations through policy development, guidance, or education:
    1) Americans with Disabilities Act (ADA).
    2) Anti-Kickback Statute.
    3) Centers for Medicare and Medicaid Services (CMS).
    4) Emergency Medical Treatment and Active Labor Act (EMTALA/COBRA).
    5) Food and Drug Administration (FDA).
    6) Health Care Quality Improvement Act (HCQIA).
    7) Health Insurance Portability and Accountability Act (HIPAA).
    8) National Practitioner Data Bank (NPDB).
    9) Occupational Safety and Health Administration (OSHA).
    10) Patient Self-Determination Act (PSDA).
    11) Safe Medical Device Act (SMDA).
    12) Stark Law.
L. Provide guidance to staff regarding:
    1) consent for care.
    2) false identification provided by a patient.
    3) illegal drugs in the patient's possession.
M. Design a management data collection and analysis system and timely reporting including elements of:
    1) device reporting and tracking logs.
    2) recall notices.
    3) regulatory inquiries.
N. Ensure that appropriate policies, procedures, and mechanisms exist to reflect current practice and are routinely updated to reflect relevant legislation and regulations.
O. Provide ongoing consultation to other departments to promote compliance with accreditation standards.
P. Collaborate in the development of the organization's regulatory compliance plan.
Q. Promote compliance with The Joint Commission (TJC) Sentinel Event reporting requirements.
R. Promote compliance with private accrediting organizations.
S. Assure compliance with The Joint Commission (TJC) Patient Safety Standards.
T. Develop and implement policies in response to regulatory mandates from The Joint Commission (TJC).
U. Maintain awareness of patient safety activities occurring locally and nationally (e.g., The Joint Commission (TJC), Institute for Healthcare Improvement (IHI), National Quality Forum (NQF)).
V. Advise on questions related to patient self-determination and advance directives.
W. Ensure HIPAA compliant business partner agreements are in place and current for all insurers, attorneys and others involved in the claims process that will have access to PHI.
X. Ensure processes and programs are in place (e.g., Advance Directives, cultural sensitivity, organ donation).
Y. Provide risk management consultation for specific ethical dilemmas (cases).
Z. Provide education/in-service for staff, patients, families, communities on patient's rights (e.g., end of life decisions).
AA. Ensure organizational compliance with disclosure of unanticipated outcomes.
BB. Ensure programs that address provider and staff behavioral issues are culturally, legally and psychologically sound and non-discriminatory.
CC. Develop responses to inquiries from regulatory and licensing agencies.

4. Healthcare Operations: 26 items (Recall: 5, Application: 16, Analysis: 5)

A. Ensure that processes are in place for compliance with federal and state community initiatives for emergency preparedness and business continuity including natural, man-made, and biologic disaster readiness.
B. Provide guidance to staff regarding a physically disruptive family member.
C. Conduct risk assessments to identify exposures related to new and existing services.
D. Collaborate with public relations in the preparation of responses to the media/external inquiries regarding incidents/occurrences.
E. Design a management data collection and analysis system and timely reporting including elements of:
   1) security reports.
   2) general liability incidents (e.g., sexual misconduct by or against staff, patients).
F. Design a management data collection and analysis system and timely reporting including elements of referrals by staff, committees, departments, other facilities.
G. Design a management data collection and analysis system and timely reporting including elements of medical record requests.
H. Develop and maintain communications and relationships across the continuum of care.
I. Communicate with key committees, including the governing body.
J. Promote appropriate procedures for retention, access, and destruction of medical records and other key business records.
K. Supervise risk management staff.
L. Conduct risk assessments to identify exposures related to enterprise-wide services.
M. Develop/maintain department policies and procedures and modify as required.
N. Prepare risk management department budgets.
O. Develop enterprise risk management philosophy including the organizational response to errors.
P. Coordinate enterprise risk management activities for the institution/committees.
Q. Develop annual institutional goals for enterprise risk management program/department.
R. Train risk management staff.
S. Develop enterprise risk management plan for institution.
T. Evaluate the effectiveness of risk management activities.
U. Develop policies and procedures for acceptance of legal documents (e.g., summons, complaints, subpoenas, court orders).
V. Support patient safety committee meetings by collecting and formulating relevant information to facilitate decision-making process.
W. Participate in professional association activities.
X. Assess enterprise risk management plan for effectiveness on an annual basis.
Y. Develop statistical and qualitative enterprise risk management reports.
Z. Analyze information technology liability risk exposure (e.g., risk assessment, general IT control audits/reviews).

5. Claims and Litigation: 5 items (Recall: 2, Application: 3, Analysis: 0)

A. Design a management data collection and analysis system and timely reporting including elements of reports of Potential Compensatory Events (PCEs).
B. Design a management data collection and analysis system and timely reporting including elements of open and closed claims and loss runs.
C. Notify carriers and/or claims and litigation department of potential or actual claims.
D. Participate in claims management activities (e.g., setting loss reserves, discovery requests/interrogatories, preparation for trials, evidence/record preservation and management).
E. Ensure that administration is kept informed of high exposure cases and aggregate claims experience, including its impact on the risk financing program.
F. Secure and evaluate all pertinent medical, billing, and other records related to individual liability claims.
G. Ensure chain-of-custody for all potential evidence related to individual liability claims.
H. Ensure legal case files are maintained in such a way to protect discoverability.
I. Manage the response to service of process and notify appropriate parties of such service.

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Sample Examination Questions

1. Which of the following is NOT a valid reason for selecting a particular defense attorney or firm?

   A. referral from the hospital's Board of Directors
   B. the firm's track record in medical malpractice litigation
   C. the degree of responsiveness to, and cooperation with, the healthcare organization's Risk Manager
   D. the firm's compliance with procedural requirements included in the insured's "defense attorney guidelines"

2. What type of primary malpractice insurance policy is necessary to purchase "tail"/prior acts coverage when changing carriers?

   A. excess
   B. umbrella
   C. occurrence
   D. claims made

3. Which insurance coverage is designed to protect individuals serving in a governance role from liability claims arising out of errors in judgment, breach of duty, and other wrongful acts?

   A. crime
   B. fiduciary
   C. directors' and officers'
   D. Workers' Compensation

4. Which of the following should be considered when establishing a risk management budget?

   1 salaries
   2 office supplies
   3 job description
   4 indemnity/expense

   A. 1, 2, and 3 only
   B. 1, 2, and 4 only
   C. 1, 3, and 4 only
   D. 2, 3, and 4 only

5. Which of the following would NOT be considered a sentinel event?

   A. suicide
   B. patient rape
   C. infant abduction
   D. medical record alteration

6. A Risk Manager receives interrogatories that include several questions to which he/she intends to ask the defense counsel to object. Which of the following objections, while appropriate, must be accompanied by detailed reasons?

   A. The interrogatory is inapplicable to the instant case.
   B. The interrogatory is unduly burdensome and time consuming.
   C. The information sought is in the possession of the party requesting it.
   D. The information sought is a matter of public record and equally applicable to both parties.

7. A systematic approach to ethics consultation and decision making will help ensure that risk management goals and ethical principles are served. A systematic approach includes all of the following EXCEPT

   A. verification of the facts.
   B. unanimous agreement among participants.
   C. documentation of the rationale for the decision.
   D. identification of the potential legal and ethical problems.

8. Which of the following is required as part of the sentinel event process of The Joint Commission?

   A. fish bone diagram of the causal factors
   B. pareto chart outlining the problems identified
   C. action plan listing the steps for improvement
   D. flowchart listing the responsibility of each of the departments involved

9. The Safe Medical Device Act requires that a device related death be reported to the

   A. Food and Drug Administration.
   B. Office of Management and Budget.
   C. Centers for Medicare and Medicaid Services.
   D. Occupational Safety and Health Administration.

10. Which of the following is a notice to the defendants named in a complaint indicating that an action has been filed against them, and that they are required to answer on a specified date and at a specified place?

    A. subpoena
    B. summons
    C. court order
    D. notice of intent

ANSWER KEY	
1. A	6. B
2. D	7. B
3. C	8. C
4. B	9. A
5. D	10. B

CPHRM EXAMINATION PREPARATION

The method of preparation and amount of time spent preparing for the AHA-CC certification Examinations can be driven by the candidate's preferred study style, level of professional experience or academic background. Some methods of preparation may include but are not limited to the following methods.

Review the Content

Candidates who have passed the AHA-CC certification examinations report that study should begin by reviewing the Examination Content Outline. Review the content categories and related tasks. Identify and focus review on tasks that you do not perform regularly or with which you are not familiar. Remember that all questions in the CPHRM Examination are job-related/experience-based and test the application and analysis of information, not just the recollection of isolated facts.

Complete the CPHRM Self-Assessment Examination (SAE)

A Self-Assessment Examination (SAE) for the CPHRM Examination is an online tool created by the AHA-CC to simulate the CPHRM Examination. This tool is available for purchase at www.AHACertificationCenter.org.

The 100-question online practice test was developed using the same procedures as the CPHRM Examination, and conforms to CPHRM Examination specifications in content, cognitive levels, format and difficulty. Feedback reports from the SAE provide an opportunity to evaluate and remedy less-than-desirable performance before taking the CPHRM Examination. The questions presented in the SAE are different from the questions contained on the CPHRM certification Examination. Performance on the CPHRM SAE is not necessarily an indicator of performance on the CPHRM certification Examination.

Use Other Study Resources

The AHA-CC recommends that review for the CPHRM Examination focus on references and programs that cover the information summarized in the CPHRM Examination Content Outline. It should not be inferred that questions in the CPHRM Examination are selected from any single reference or set of references, or that study from specific references guarantees a passing score on the CPHRM Examination. For information about references, study guides and review sessions offered by the American Society for Healthcare Risk Management (ASHRM), visit www.ashrm.org.

CPHRM EXAMINATION ADMINISTRATION

The CPHRM Examination is administered in the following ways:

- On computers at PSI Test Centers
- During special administrations at conferences, meetings or other specially-arranged sessions
- Outside of the U.S. on request

In accordance with the Americans with Disabilities Act (ADA), special arrangements can be made for candidates with a disability.

Computer Administration at PSI Test Centers

The primary mode of delivery of the CPHRM Examination is via computer at over 190 PSI Test Centers geographically distributed throughout the United States and typically located in H&R Block offices. For PSI Test Center locations, detailed maps and directions, go to www.AHACertificationCenter.org, click on "CPHRM" and then on "Testing Centers."

For computer administrations at PSI Test Centers, a candidate who meets eligibility requirements for the CPHRM Examination may submit an application and fee at any time. A candidate must make an appointment to take the CPHRM Examination within ninety (90) days from confirmation of eligibility from PSI. The CPHRM Examination is administered by appointment only Monday through Saturday at 9:00 a.m. and 1:30 p.m., with the exception of some holidays. Candidates are scheduled on a first-come, first-served basis.

If PSI is contacted by 3:00 p.m. CST Time on...	*Depending upon availability, the examination may be scheduled as early as…*
Monday	Wednesday
Tuesday	Thursday
Wednesday	Friday/Saturday
Thursday	Monday
Friday	Tuesday

The CPHRM Examination is *not* offered on the following holidays.

- New Year's Day
- Martin Luther King, Jr. Day
- Memorial Day
- Independence Day (July 4)
- Labor Day
- Thanksgiving Day and the following Friday
- Christmas Eve Day
- Christmas Day

Special Administration – Laptop or Paper-and-Pencil

The CPHRM Examination may be offered on laptop or in paper-and-pencil format during conferences or meetings. A candidate who meets the CPHRM eligibility requirements and submits a CPHRM Examination application and fee for receipt by the posted deadline is allowed to take the CPHRM Examination. Online application is not available for special administrations. Dates of special administrations and deadlines for receipt of applications are posted on www.AHACertificationCenter.org. For the Special Administration application, go to www.goAMP.com.

International Testing

Candidates who are eligible for the CPHRM Examination and wish to take the CPHRM Examination outside of the U.S. may email AMPIntlExamServices@goAMP.com for more information or to begin the international scheduling process.

Special Arrangements for Candidates with Disabilities

The AHA-CC complies with applicable provisions of the Americans with Disabilities Act (ADA) and strives to ensure that no individual with a disability is deprived of the opportunity to take the CPHRM Examination solely by reason of that disability. Through its agents, the AHA-CC will provide reasonable accommodation for a candidate with a disability who requests accommodation by completing and timely submitting the two-page Request for Special Examination Accommodations form included in this Candidate Handbook to PSI.

Wheelchair access is available at all PSI Test Centers. Candidates must advise PSI at the time of scheduling that wheelchair access is necessary.

A candidate with a visual, sensory or physical disability that prevents taking the CPHRM Examination under standard conditions may request special accommodations and arrangements. For either a computer or a special administration of a CPHRM Examination, complete the two-page Request for Special Examination Accommodations form included in this Candidate Handbook and submit it with a CPHRM Examination application and fee at least 45 days prior to the CPHRM Examination date desired.

ADHERING TO PROFESSIONAL STANDARDS OF CONDUCT

The AHA-CC is responsible to its candidates, certificants, employers, the profession and the public for ensuring the integrity of all processes and products of its Certification Programs. As such, the AHA-CC requires adherence to these *Professional Standards of Conduct* by all who have achieved certification through successful completion of its programs. A candidate's signature on the CPHRM Examination Application attests to ongoing agreement to adhere to the following *Professional Standards of Conduct.*

Professional Standards of Conduct. A certificant who is awarded certification by the AHA-CC agrees to conduct himself/herself in an ethical and professional manner. This includes demonstrating practice-related behavior that is indicative of professional integrity. By accepting certification, the certificant agrees to the following:

- Maintain professional competence
- Demonstrate work behavior that exemplifies ability to perform safely, competently and with good judgment
- Conduct professional activities with honesty and integrity
- Avoid discriminating against any individual based on age, gender, race, color, religion, national origin, disability or marital status
- Avoid conflicts of interest
- Abide by the laws, rules and regulations of duly authorized agencies regulating the profession
- Abide by rules and regulations governing programs conducted by the AHA Certification Center
- Not to misrepresent the credential and to adhere to the Guidelines for Use of the Certification Marks as posted on the AHA-CC website.

Infraction of the Professional Standards of Conduct is misconduct for which granting of a certification or renewal of a certification may be delayed or denied, or for which a certification may be revoked by the AHA Certification Center.

Reporting Violations. To protect the national credentials and to ensure responsible practice by its certificants, the AHA-CC depends upon its candidates and certificants, professionals, employers, regulatory agencies and the public to report incidents that may be in violation of these *Professional Standards of Conduct*. A certificant who has violated these *Standards* should voluntarily surrender his/her certification.

Written reports of infraction of these *Standards* may be sent to: AHA Certification Center, 155 N. Wacker Drive, Suite 400, Chicago, IL 60606. Only signed, written communication will be considered.

The AHA-CC will become involved only in matters that can be factually determined, and commits to handling any situation as fairly and expeditiously as possible. During its investigation and decision, the AHA Certification Center will protect the confidentiality of those who provide information to every possible extent. The named individual will be afforded a reasonable opportunity to respond in a professional and legally defensible manner, in accordance with policies established by the AHA-CC.

CPHRM EXAMINATION APPLICATION AND SCHEDULING PROCESS

CPHRM Examination Application Fee Schedule

After fulfilling the CPHRM eligibility requirements, a candidate may apply to PSI for the CPHRM Examination in one of the following ways.

- Online Application (available at www.goAMP.com; requires credit card payment for fees.)
- Paper Application (included in this Candidate Handbook)

Documentation of eligibility does *not* need to be submitted with a CPHRM Examination Application. The AHA-CC reserves the right, but is not obligated, to verify the accuracy of information supplied by or on behalf of a candidate. If selected for an audit, the candidate may be asked to submit documentation as proof of meeting the eligibility requirements.

To apply for the CPHRM Examination, an eligible candidate must submit the appropriate fee (see below) with a complete CPHRM Examination Application to PSI.

Member of ASHRM or other AHA Personal Membership Group…. $275

Nonmember……... $425

- Payment may be made by credit card (VISA, MasterCard, American Express or Discover) or by company check, cashier's check or money order made payable to PSI Services. Cash and personal checks are not accepted.
- Examination-related fees are nonrefundable and nontransferable.
- Up to two (2) business days prior to a scheduled administration, the application may be transferred to a future CPHRM Examination date by requesting PSI to reschedule a new date. The examination date may be rescheduled *once* without incurring an additional fee. This date must be within your original 90 days eligibility window of PSI confirming receipt of your CPHRM Examination application. Each additional rescheduling of a CPHRM examination date is subject to a $100 rescheduling fee.
- Credit card transactions that are declined are subject to a $25 handling fee. A certified check or money order for the amount due, including the handling fee, must be submitted to PSI to cover declined credit card transaction.
- Candidates who fail a CPHRM Examination and apply to retake the CPHRM Examination must pay the full CPHRM Examination fee as listed above.

Online Application and Scheduling

For computer administrations at PSI Test Centers only

Complete the CPHRM Examination application and scheduling process in one online session. Visit http://www.AHACertificationCenter.org, click on "CPHRM," click on "Online Application and Scheduling", and then follow the online instructions.

If you are a current member of an AHA Personal Membership Group (PMG), you are eligible for the reduced AHA member rate for CPHRM Examination fee. Click on "Member," and enter your membership number, name and address *exactly* as they appear in AHA's membership database. Your preferred mailing and email addresses designated in AHA's membership database are used for all records and communications. For information on your membership record, please contact ASHRM at 312-422-3980 or AHA's Member Services Center at 312-422-2765. ***NEW MEMBERS must wait at least five business days after new membership to apply online. If the membership number is not accepted, you may submit the paper application to receive the membership discount.*

After completing the CPHRM Examination application and submitting credit card payment information (VISA, MasterCard, American Express, Discover), PSI confirms the candidate's certification of eligibility, and the candidate is prompted to schedule a CPHRM Examination appointment or supply additional eligibility information. The candidate must schedule a CPHRM Examination date within the assigned 90 day eligibility window.

Paper Application

For all administrations

Complete and submit to PSI a CPHRM Examination application with the appropriate fee. You may complete the two-page paper application included in this Candidate Handbook or obtained by one of the following ways:

- Downloading copy from www.AHACertificationCenter.org
- Contacting PSI at 888-519-9901

A written request must be submitted for an incomplete online CMRP Examination Application fee to be returned to the candidate (less a $50 processing fee). For eligibility, a CPHRM Examination application requires::

- Information provided is legible and accurate.
- All of the following required information is provided:
  - Personal Information
  - Examination Type. For the application for a specific special administration, go to www.goAMP.com.
  - Application Status
  - Membership Status. Eligibility for the Member rate of the CPHRM Examination Application fee requires recording your membership number, name, and address *exactly* as they appear in AHA's membership database. For information on your member record, contact ASHRM at 312-422-3980 or AHA's Member Service Center at 312-422-2765.
  - Method of payment for the applicable fee
  - Demographic information
  - Signature
- The candidate is eligible for the CPHRM Examination and can provide evidence if requested to do so.
- Appropriate fee accompanies the application (credit card, company check, cashier's check or money order).

If you are an AHA Personal Membership Group (PMG) member, you must provide your member number to PSI.

If ***special accommodations*** are required, complete and submit to PSI the two-page *Request for Special Examination Accommodations* form included in this Candidate Handbook and submit with the CPHRM Examination application and fee to PSI at least 45 days prior to the desired testing date.

Application Processing and CPHRM Examination Scheduling

Generally, in about two (2) weeks of PSI receiving the application, PSI processes it, confirms the candidate's certification of eligibility, and sends an email and postcard confirmation notice with a toll-free phone number and website address at which a testing appointment can be scheduled. For ***special administrations,*** approximately ten (10) business days after PSI's receipt of application, a notice is sent by email to the candidate stating the application has been received and approved. If the application is ineligible, a letter will be sent to the candidate listing the deficiency. Generally, candidates receive their admission letter to the testing about two (2) to three (3) weeks prior to the CPHRM special administration date. The notice includes the date, location and check-in time for the CPHRM Examination. ***If a confirmation notice is not received within four (4) weeks of mailing your application, contact PSI at 888-519-9901.***

When scheduling a ***CPHRM Examination at a PSI Test Center***, be prepared to provide your assigned identification number and confirm a location and a preferred date and time for testing.

For a computer administration at a PSI Test Center, a candidate's application is valid for 90 days from the date of eligibility. The candidate must schedule an appointment and take the CPHRM Examination within this 90-day period. A candidate who fails to schedule an appointment within the 90-day period forfeits the application and all fees paid to take the CPHRM Examination. A complete application and full examination fee are required to reapply for CPHRM Examination.

A candidate is allowed to take only the CPHRM Examination for which application is made and confirmation from PSI is received. Unscheduled candidates (walk-ins) are not allowed to take the CPHRM Examination.

Rescheduling a CPHRM Examination

Although CPHRM Examination application fees are nonrefundable, a candidate who is unable to take the CPHRM Examination has the following options to reschedule a CPHRM Examination:

- A candidate ***may reschedule the CPHRM Examination once at no charge*** online at www.goAMP.com or by calling PSI at 888-519-9901 at least two (2) business days prior to a scheduled administration date. The CPHRM Examination must be rescheduled within your original ninety (90) day eligibility window.
- A candidate may ***reschedule a second or additional time*** by submitting to PSI a written request including their name, address, identification number and the ***$100 rescheduling fee.*** A new CPHRM Examination application is not required. The CPHRM Examination must be rescheduled *within 90 days* of the originally scheduled CPHRM Examination date. For payment by credit card, the credit card number, expiration date and 3-digit security code must be included.
- A candidate who wants to ***reschedule a CPHRM Examination or cancel the examination after the 90-day period*** forfeits the application and all fees paid to take the exam. A new, complete application and *full* exam fee are required to reapply for the CPHRM Examination.

ON THE DAY OF THE CPHRM EXAMINATION

Reporting for the CPHRM Examination

Bring with you the ***confirmation notice*** provided by PSI. It contains the unique identification number required to take the test and is required for admission to the testing room.

For a computer administration, report to the PSI Test Center no later than the scheduled testing time. After entering the H&R Block office, for some locations, follow the signs indicating PSI Test Center Check-In.

For a special administration (laptop or paper-and-pencil), report to the designated testing room at the time indicated on the confirmation notice. The CPHRM Examination will begin after all scheduled candidates are checked-in and seated and no more than one hour after the scheduled registration begins. Follow the signs provided in the hotel/convention center to locate the testing room.

Failing to Report for the CPHRM Examination

A candidate who arrives more than fifteen (15) minutes after the scheduled testing time is not admitted.

- A candidate who is not admitted due to late arrival must reschedule the CPHRM Examination for a new date that is within ninety (90) days from the originally scheduled testing date and remit the $100 rescheduling fee. To schedule a new appointment for the exam, the candidate must submit to PSI a written request including their name, address, identification number and rescheduling fee. For payment by credit card, the credit card number, expiration date and 3-digit security code must be included. A new examination application is not required.
- A candidate who does not reschedule a CPHRM Examination session that is within the ninety (90)-day period forfeits the application and all fees paid to take the exam. A complete application and full exam fee are required to reapply for the exam.

On-site Security

The AHA-CC and PSI maintain CPHRM Examination administration and security standards that are designed to assure that all candidates are provided the same opportunity to demonstrate their abilities. The testing environment at PSI Test Centers is continuously monitored by audio and video surveillance equipment or CPHRM Examination personnel. Candidates may be subjected to a metal detection scan upon entering the examination room.

Identity Verification

To gain admission to the PSI Test Center or a testing room, the candidate must present two (2) forms of identification. The primary form must be government issued, current, and include the candidate's name, signature and photograph. The candidate will also be required to sign a roster for verification of identity. A candidate without proper identification will not be permitted to take the CPHRM Examination.

- Examples of valid primary forms of identification are current driver's license with photograph, current state identification card with photograph, current passport, or current military identification card with photograph.
- The secondary form of identification must display the candidate's name and signature for the candidate's signature verification. (e.g., credit card with signature, social security card with signature, employment/student ID card with signature, etc.)
- If the candidate's name on the registration list is different than it appears on the forms of identification, the candidate must bring proof of the name change (e.g., marriage license, divorce decree, or court order).
- No form of temporary identification will be accepted.

Use of Calculators

Some CPHRM Examination questions may require calculations. Use of a silent, nonprogrammable calculator without paper tape-printing capability or alpha keypad is permitted during the CPHRM Examination. Use of a computer or a cell phone is not permitted. Calculators will be checked for conformance with this regulation before candidates are allowed admission to the PSI Test Center or testing room. Calculators that do not comply with to these specifications are not permitted in the PSIT Test Center or testing room.

Inclement Weather or Emergency

In the event of inclement weather or unforeseen emergencies on the day of the CPHRM Examination, the AHA-CC, in concert with PSI, will determine whether circumstances warrant the cancellation and subsequent rescheduling of a CPHRM Examination. If testing personnel are able to conduct business, the CPHRM Examination usually proceeds as scheduled.

Every attempt is made to administer a CPHRM Examination as scheduled; however, should a CPHRM Examination be canceled, the scheduled candidate will receive notification following the CPHRM Examination regarding a rescheduled CPHRM Examination date or reapplication procedures. In the case of cancellation, no additional fee is required to take the CPHRM Examination.

For computer administrations at PSI Test Centers, candidates may visit www.goAMP.com prior to the CPHRM Examination to determine if any PSI Test Centers have been closed.

In the event of a personal emergency on the day of the CPHRM Examination, a candidate may request consideration of rescheduling the CPHRM Examination without additional fee by contacting the AHA-CC in writing within 30 days of the scheduled testing session. A description of the emergency and supporting documentation are required. Rescheduling without additional fee will be considered on a case-by-case basis.

TAKING THE CPHRM EXAMINATION

After identity of the candidate has been verified and his/her calculator has been approved, the candidate is directed to a testing carrel for a computer administration or an assigned seat for a special administration. For computer-based testing, including laptop administrations, each candidate is provided one sheet of scratch paper for calculations that must be returned to the CPHRM Examination proctor at the completion of testing.

For a ***paper-and-pencil administration***, the candidate is provided oral and written instructions about the CPHRM Examination administration process.

For a ***computer administration at a PSI Test Center or a laptop administration***, the candidate is provided instructions on-screen. First, the candidate is instructed to enter his/her unique identification number. Then, the candidate's photograph is taken and remains on-screen throughout the CPHRM Examination session. Prior to attempting the CPHRM Examination, the candidate is provided a short tutorial on using the software to take the CPHRM Examination. Tutorial time is NOT counted as part of the two (2) hours allowed for the CPHRM Examination. Only after a candidate is comfortable with the software and choses to do so does the CPHRM Examination begin.

The ***computer monitors the time spent on the CPHRM Examination***. The CPHRM Examination terminates at the two-hour mark. Clicking on the ***TIME*** button in the lower right portion of the screen reveals a digital clock that indicates the time remaining. The ***TIME*** feature may also be turned off during the CPHRM Examination.

Only one (1) CPHRM Examination question is presented at a time. The question number appears in the lower right portion of the screen. The entire CPHRM Examination question appears on-screen (stem and four options labeled A, B, C and D). Select an answer either by entering the letter of the option (A, B, C or D) or using the mouse to click on the option. The letter of the selected option appears in the window in the lower left portion of the screen. To change an answer, enter a different option by pressing the A, B, C or D key or by clicking on the option using the mouse. An answer may be changed multiple times.

To move to the next question, click on the forward arrow (**>**) in the lower right corner of the screen. This action allows the candidate to move forward through the CPHRM Examination question by question. To review a question or questions, click the backward arrow (**<**) or use the left arrow key to move backward through the CPHRM Examination.

A CPHRM Examination question may be left unanswered for return later in the testing session. Questions may also be bookmarked for later review by clicking in the blank square to the right of the ***TIME*** button. Click on the hand icon to advance to the next unanswered or bookmarked question on the CPHRM Examination. To identify all unanswered or bookmarked questions, repeatedly click on the hand icon.

When the CPHRM Examination is completed, the number of CPHRM Examination questions answered is reported. If fewer than 110 questions were answered and time remains, return to the CPHRM Examination and answer the remaining questions. Be sure to answer each CPHRM Examination question before ending the CPHRM Examination. There is no penalty for guessing.

Candidates may provide comments about a test item. Comments will be reviewed, but individual responses will not be provided.

- For a ***computer administration***, online comments may be provided for any question by clicking on the button displaying an exclamation point (!) to the left of the ***TIME*** button. This opens a dialogue box where comments may be entered.
- For a ***paper-and-pencil administration***, comments may be provided on the answer sheet on the day of the CPHRM Examination.

Rules for CPHRM Examination

All CPHRM Examination candidates must comply with the following rules during the CPHRM Examination administration:

1. No personal items (including watches, hats, and coats), valuables or weapons should be brought into the testing room. Only keys, wallets, and items required for medical needs are permitted. Books, computers, or other reference materials are strictly prohibited. If personal items are observed in the testing room after the examination is started, the exam administration will be forfeited. PSI is not responsible for items left in the reception area.
2. Pencils will be provided during check-in. No personal writing instruments are allowed in the testing room.
3. CPHRM Examinations are proprietary. CPHRM Examination questions may not be recorded or shared with any individual in any manner. No cameras, notes, tape recorders, pagers, cellular/smart phones, or other recording devices are allowed in the testing room. Possession of a cellular/smart phone or other electronic devices is strictly prohibited and will result in dismissal from the CPHRM Examination.
4. Eating, drinking, and smoking is not permitted in the testing room.
5. No documents or notes of any kind may be removed from the testing room. Each CPHRM candidate will be provided one sheet of scratch paper that must be returned to the CPHRM Examination proctor at the completion of testing.
6. No questions concerning the content of the CPHRM Examination may be asked of anyone during the CPHRM Examination.
7. Permission from the CPHRM Examination proctor is required to leave the testing room during the exam. No additional time is granted to compensate for time lost.
8. No guests, visitors, or family members are allowed in the testing room or reception areas.

Candidates observed engaging in any of the following conduct during the CPHRM Examination may be dismissed from the CPHRM Examination session, their score on the CPHRM Examination voided and the CPHRM Examination fees forfeited. Evidence of misconduct is reviewed by the Appeal Board of the AHA-CC

to determine whether the CPHRM candidate will be allowed to reapply for CPHRM Examination. If re-examination is granted, a complete CPHRM Examination application and full CPHRM Examination fee are required.

- Gaining unauthorized admission to the CPHRM Examination
- Creating a disturbance, being abusive or otherwise uncooperative
- Displaying and/or using electronic communications equipment including but not limited to pagers, cellular/smart phones, etc.
- Talking or participating in conversation with other CPHRM Examination candidates
- Giving or receiving help or being suspected of doing so
- Leaving the PSI Test Center or testing room during the CPHRM Examination
- Attempting to record CPHRM Examination questions in any manner or making notes
- Attempting to take the CPHRM Examination for someone else
- Having possession of personal belongings
- Using notes, books, or other aids without it being noted on the roster
- Attempting to remove CPHRM Examination materials or notes from the PSI Test Center or the testing room

Copyrighted CPHRM Examination Questions

All CPHRM Examination questions are the copyrighted property of the AHA-CC. It is forbidden under federal copyright law to copy, reproduce, record, distribute or display these CPHRM Examination questions by any means, in whole or in part. Doing so may result in severe civil and criminal penalties.

FOLLOWING THE CPHRM EXAMINATION

CPHRM Examination Score Reports

Score reports are issued by PSI, on behalf of the AHA-CC. Scores are reported in written form only, in person or by U.S. mail. Scores are not reported over the telephone, by electronic mail or by facsimile.

- A candidate who takes the CPHRM Examination in ***paper-and pencil format*** receives his/her score report from PSI by mail generally about three (3) to five (5) weeks after the CPHRM Examination.
- A candidate who takes the CPHRM Examination ***on a computer at a PSI Test Center or on laptop*** receives his/her score report before leaving the testing center except when the CPHRM Examination program is in a provisional score report mode.

The score report indicates a "Pass" or "Fail", which is determined by the raw score on the CPHRM Examination. The score report also includes raw scores for each of the major categories of the CPHRM Examination Content Outline. A raw score is the number of questions answered correctly. Responses to individual CPHRM Examination questions will not be disclosed to the candidate. Even though the CPHRM Examination consists of 110 questions, the CPHRM Examination score is based on 100 questions. Ten (10) questions are "pretest" questions and do not impact the candidate's score. The minimum passing score for the CPHRM Examination is posted on http://www.AHACertificationCenter.org/index.shtml .

Recognition of certification and information about certification renewal are issued from the AHA-CC generally about four (4) to six (6) weeks of successfully completing the CPHRM Examination. This package is mailed to the address contained in the AHA member database.

How the CPHRM Examination passing score is set

The methodology used to set the initial minimum passing score is the Angoff method in which expert judges estimate the passing probability of each question on the CPHRM Examination. These ratings are averaged to determine the preliminary minimum passing score (i.e., the number of correctly answered questions required to pass the CPHRM Examination). This method takes into account the difficulty of the CPHRM Examination. The preliminary minimum passing score is validated by the performance of candidates. The passing standard is applied consistently across all candidates who take the same form of the CPHRM Examination.

When new forms of the CPHRM Examination are introduced, a certain number of CPHRM Examination questions in the various content areas are replaced by new CPHRM Examination questions. These changes may cause one form of the CPHRM Examination to be slightly easier or harder than another form. To adjust for these differences in difficulty, a procedure called "equating" is used. For equated CPHRM Examinations that have different passing scores, the equating process helps ensure that the levels of examinee knowledge are equivalent on the various CPHRM Examination forms.

Passing the CPHRM Examination

An eligible candidate who passes the CPHRM Examination is awarded the Certified Professional in Healthcare Risk Management (CPHRM) credential. Generally about four (4) to six (6) weeks after the candidate passes a CPHRM Examination, the AHA-CC mails to the candidate a certificate of recognition, a pin and information about CPHRM certification renewal requirements. The name on the certificate and the address to which the package is mailed is based on information in the candidate's membership record. It is the candidate's responsibility to keep current this information.

The AHA-CC, in concert with the personal membership group (PMG), reserves the right to recognize publicly any candidate who has successfully completed the CPHRM Examination. Recognition is awarded so as not to embarrass any candidate who is not successful in achieving certification.

Name, address, telephone number and email address of a candidate who passes the CPHRM Examination will be shared with the PMG. *Scores are never reported*. If you do NOT wish to have your personal information shared, please opt out by contacting the AHA-CC in writing via e-mail at certification@aha.org or fax at 312-422-4575.

Failing the CPHRM Examination

If a candidate does not pass the CPHRM Examination, the score report includes a shortened application form to apply for retaking the exam.

- To schedule a ***retake of the CPHRM Examination***, a candidate may apply by using the online application and scheduling feature on www.AHACertificationCenter.org or by submitting the re-application form included with the score report. To use this shortened application form, the completed application and full CPHRM Examination fee must be submitted and a CPHRM Examination scheduled within the 90-day period following the failed CPHRM Examination.
- A candidate who wishes to retake the CPHRM Examination after 90 days following the failed CPHRM Examination date must submit a completed full-length application (in this CPHRM Handbook or on-line at goAMP.com) and full examination fee.

Every retake requires submitting a CPHRM Examination application and the *full* CPHRM Examination fee. There is no limit to the number of times an individual may take the CPHRM Examination.

CPHRM Examination Scores Cancelled by the AHA-CC

The AHA-CC and PSI are responsible for maintaining the integrity of the scores reported. On occasion, occurrences such as computer malfunction or misconduct by a candidate may cause a score to be suspect. The AHA-CC is committed to rectifying such discrepancies as expeditiously as possible. The AHA-CC may void CPHRM Examination results if, upon investigation, violation of CPHRM Examination regulations is discovered.

CPHRM Examination Score Confidentiality

Information about a candidate for testing or renewal of certification and CPHRM Examination results is considered confidential; however, the AHA-CC reserves the right to use information supplied by or on behalf of a candidate in the conduct of research. Studies and reports concerning candidates contain no information identifiable with any candidate, unless authorized by the candidate.

Demographic information about a candidate is shared only when beneficial to the candidate. Scores are never reported to anyone other than the candidate, unless the candidate directs such a request in writing.

Administrative Matters

Duplicate CPHRM Examination score report

Duplicate score reports are available from PSI up to one year from the testing date. The fee is $25 per copy payable by cashier's check or money order to PSI Services. The request must include the candidate's name, unique identification number, mailing address, telephone number, and date the CPHRM Examination was completed. After receipt of the request, a duplicate score report is generally mailed within three (3) weeks.

Score verification request

Candidates who do not pass the CPHRM Examination may request a manual verification of the computer scoring. Requests for manual scoring must be submitted to PSI in writing with a $25 hand scoring fee (cashier's check or money order made payable to PSI Services) within one year following the CPHRM Examination date. The request must include your name, unique identification number, mailing address, CPHRM Examination date, and a copy of your score report. Please allow 10 business days for processing your request. Candidates close to passing are discouraged from a handscore request. PSI routinely samples examinations of candidates who score near passing to ensure correct reporting of results. These CPHRM Examinations are automatically handscored before results are mailed as a quality control measure. Thus, it is unlikely any CPHRM Examination results will change from "fail" to "pass" after a requested handscore.

Name and address change

Certificants are responsible for keeping current all contact information. The AHA-CC is not responsible for communication not received due to incorrect contact information. To update any contact information, please contact ASHRM at 312-422-3980 or the AHA Member Services Center at 312-422-2765.

RENEWAL OF CPHRM CERTIFICATION

Achieving certification is an indication of mastery of a well-defined body of knowledge at a point in time. Periodic renewal of the certification is required to maintain certified status and to demonstrate ongoing commitment to remain current in the field. Initial certification or renewal of CPHRM certification is valid for three (3) years.

Eligible candidates who successfully complete the CPHRM Examination are provided information about certification renewal requirements in a certification package sent by the AHA-CC. ***The CPHRM Certification Renewal Application may be submitted to the AHA-CC up to one (1) year prior to the expiration date. For an additional nonrefundable fee of $50, certification renewals may be submitted up to 30 days past the expiration date.***

As a courtesy, the AHA-CC sends notices to certificants of their pending certification expiration. ***Certificants are responsible for keeping their contact information accurate.*** The AHA-CC is not responsible for communications not received due to incorrect contact information in a certificant's record.

The current CPHRM Certification Renewal Application and fees are available at www.AHACertificationCenter.org.

A certificant shall renew the CPHRM credential through one of the following two ways:

- **Successful re-examination.** To renew this way, successfully pass the CPHRM Certification Examination no more than one (1) year prior to expiration of your CPHRM certification (subject to usual fees and provisions for testing). Submit to the AHA-CC the CPHRM Certification Renewal Application and a copy of your passing CPHRM Examination score report. ***An additional Certification Renewal Application fee is not required if a candidate selects this way to renew the CPHRM designation.***
- **Completion of 45 contact hours of eligible continuing professional education** over the three (3)-year period and payment of the renewal fee. To renew this way, submit a completed CPHRM Certification Renewal Application with the appropriate fee and report all eligible continuing professional education activities that you completed during your renewal period. Eligible activities include attending or teaching academic courses, completing on-line course, attending professional organization conferences and completing AHA-CC CPHRM Self Assessment Examinations, among other activities. Some activities have limitation on maximum allowable hours. Refer to the current CPHRM Certification Renewal Application for a description of eligible activities and other provisions for renewing your certification.

CPHRM Certification Renewal Application processing is generally about two (2) weeks from receipt of application. Certificants who meet the renewal requirements receive in the mail (at the address in their membership record) a new certificate of recognition. Certificants are afforded an opportunity to remove deficiencies. Certificants are responsible for keeping current contact information in their membership record.

Failing to Renew CPHRM Certification

A certificant who fails to renew his or her CPHRM certification will receive written notification that he/she is no longer considered certified and may not use the CPHRM credential in professional communications including but not limited to letterhead, stationery, business cards, directory listings and signatures. To regain certification, the individual must retake and pass the CPHRM Examination (subject to the usual fees and provisions for testing).

APPEALS

A candidate who believes he or she was unjustly denied eligibility for CPHRM Examination, who challenges results of a CPHRM Examination or who believes he/she was unjustly denied renewal of certification may request reconsideration of the decision by submitting a written appeal to the AHA Certification Center, 155 N. Wacker Drive, Suite 400, Chicago, IL 60606. The candidate for certification or renewal of certification must provide evidence satisfactory to the Appeal Board that a severe disadvantage was afforded the candidate during processing of an application for CPHRM Examination or renewal of CPHRM certification or prior to or during administration of a CPHRM Examination. The appeal must be made within 45 days of receipt of a score report or any other official correspondence related to certification or renewal of certification from the AHA-CC or its agents. The written appeal must also indicate the specific relief requested. The appealing candidate is required to submit a $100 fee (payable to the AHA-CC) with the written appeal. The fee will be refunded to the candidate if deemed justified through action of the Appeal Board. For additional regulations related to the appeal process, contact the AHA-CC.

Checklist for becoming certified

- Meet the CPHRM Certification Examination Eligibility Requirements.
- Prepare for the CPHRM Certification Examination.
- Read the CPHRM Candidate Handbook fully. Use the CPHRM Examination Content Outline to focus study efforts.
- Apply for the CPHRM Examination by one of the following two ways:
  - Mail or fax the complete CPHRM Examination Application to PSI as directed on the form. Include the CPHRM Examination fee, sign the application, and submit both pages of the application. When confirmation of eligibility is received from PSI, make an appointment to take the CPHRM Examination.
  - Apply online for the CPHRM Examination and schedule an appointment to test on computer at a PSI Test Center. Visit www.AHACertificationCenter.org, click on "CPHRM," "Online Application and Scheduling", and then follow the online instructions.
- Appear on time for the CPHRM Examination on the date and at the time and location selected. Bring the confirmation notice provided by PSI and identification as described in the CPHRM Candidate Handbook.

AMERICAN HOSPITAL ASSOCIATION CERTIFICATION CENTER

CERTIFIED PROFESSIONAL IN HEALTHCARE RISK MANAGEMENT (CPHRM)

***To apply for the CPHRM Examination**, complete this two-page application and return it with the examination fee to:*

PSI, AHA-CC Examination, 18000 W. 105th St., Olathe, KS 66061-7543
FAX: 913-895-4651 PHONE: 888-519-9901

CANDIDATE INFORMATION

(First Name) (Middle Initial) (Last Name) Former name if exam was taken previously under a different name.

List name as you wish to be printed on your certificate.
Titles and designations will not be printed on the certificate.

Name of Facility/Company/Organization Title

Preferred Mailing Address (Street Address, City, State/Province, Zip/Postal Code, Country)

Preferred Telephone Number Email Address

EXAMINATION TYPE. Place a checkmark next to the type of exam administration for which you are applying. Select only one.

☐ Computer administration at a PSI Test Center

☐ Special domestic administration (*For scheduled dates, see www.AHACertificationCenter.org.)* Scheduled date and location: _____

☐ International administration (*For Request for International Examination Administration form, see www.AHACertificationCenter.org*)

ELIGIBILITY REQUIREMENTS

To be eligible for the Certified Professional in Healthcare Risk Management (CPHRM) Examination, a candidate must fulfill one (1) of the following requirements for education/healthcare experience **AND** meet *the requirement for risk management experience. By checking a box below, a candidate certifies to the AHA-CC that he or she satisfies the eligibility requirement*. Check the one that applies.

Education/Healthcare Experience

☐ Baccalaureate degree or higher from an accredited college or university plus five (5) years of experience in a healthcare setting or with a provider of services to the healthcare industry

☐ Associate degree or equivalent from an accredited college plus seven (7) years of experience in a healthcare setting or with a provider of services to the healthcare industry.

☐ High school diploma or equivalent plus nine (9) years of experience in a healthcare setting or with a provider of services to the healthcare industry.

Risk Management Experience

☐ 3,000 hours or 50 percent of full-time job duties within the last three (3) years dedicated to healthcare risk management in a healthcare setting or with a provider of services (e.g. consultant, broker, attorney) to the healthcare industry.

APPLICATION STATUS

Check one of the following.

☐ I am applying as a new candidate.

☐ I am applying as a re-applicant, i.e., *retaking the exam.*

☐ I am applying for renewal of CPHRM certification.

MEMBERSHIP STATUS

If you are a current member of ASHRM or other AHA Personal Membership Group (PMG), you are eligible for the reduced CPHRM Examination fee. *Please provide your 10-digit membership number below.*

For information on joining the American Society for Healthcare Risk Management (ASHRM), visit www.ASHRM.org. Membership must be obtained before application for examination at the reduced fee can be honored.

If you have applied for membership but have not yet received your membership number, enter "NEW" below.

Membership Number: _____

CPHRM EXAMINATION FEES

Payment may be made by credit card, company check, cashier's check or money order made payable to PSI Services.
Indicate the type and amount of fees enclosed:

☐ Member of ASHE or other AHA PMG……..…....$275

☐ Nonmember:……...…..…..…....$425

☐ Rescheduling Fee……...$100

☐ Member Voucher…….$0

** Note: If you are paying with a Member Voucher, the original voucher is required. Copies will not be accepted.

For payment by credit card, complete the following.

Select type of credit card being used:

☐VISA ☐MasterCard ☐American Express ☐Discover

Credit Card Number Expiration

Date

Your Name as it Appears on the Card

Signature

AMERICAN HOSPITAL ASSOCIATION CERTIFICATION CENTER

CERTIFIED PROFESSIONAL IN HEALTHCARE RISK MANAGEMENT (CPHRM)

SPECIAL ACCOMMODATIONS. Do you require special disability related accommodations during testing?

☐ No ☐ Yes *If yes, please complete the two-page Request for Special Examination Accommodations form included in this Candidate Handbook and submit it with an application and fee at least 45 days prior to the desired testing date.*

DEMOGRAPHIC INFORMATION. The following demographic information is requested.

1. How many years of experience do you have in healthcare risk management?
   - ☐ 0-5 years
   - ☐ 6-10 years
   - ☐ 11-15 years
   - ☐ 16-20 years
   - ☐ 21-25 years
   - ☐ 26-30 years
   - ☐ More than 30 years

2. What is the highest academic level you have attained?
   - ☐ High school diploma or equivalent
   - ☐ Associate's degree
   - ☐ Baccalaureate degree
   - ☐ Master's degree
   - ☐ Doctoral degree

3. Professional designations earned (select all that apply):
   - ☐ ABHRM
   - ☐ AIC
   - ☐ ALCM
   - ☐ ARM
   - ☐ AU
   - ☐ CHEM
   - ☐ CHSP
   - ☐ CPA
   - ☐ CPCU
   - ☐ CPHQ
   - ☐ CSP
   - ☐ RN
   - ☐ RPLU
   - ☐ Other: _____

4. The majority of formal training you received in risk management was through:
   - ☐ College Courses
   - ☐ Professional Development (e.g., ARM, CPCU)
   - ☐ ASHRM Seminars/Certificate Programs
   - ☐ Other: _

5. Current primary job function (select all that apply):
   - ☐ Acute Care Medical Center
   - ☐ Academic Medical Center
   - ☐ Multi-Hospital System
   - ☐ Specialty (e.g., pediatric, psychiatric, rehab.)
   - ☐ Long Term Care
   - ☐ Military/Federal/VA
   - ☐ Ambulatory Care
   - ☐ Insurance Company/Captive/Trust
   - ☐ Law Firm
   - ☐ Medical Group Practice
   - ☐ Home Healthcare Agency
   - ☐ Risk Management Consultant
   - ☐ Other: _____

6. Current job title (Select one):
   - ☐ CEO/COO/CMO/CNO/CFO
   - ☐ Vice President/Chief Risk Officer
   - ☐ Medical Director
   - ☐ Risk Manager (e.g., coordinator, director, corporate)
   - ☐ Quality Assurance Manager (e.g., coordinator, director, corporate)
   - ☐ Patient Safety Officer
   - ☐ Claims Manager (e.g., coordinator, director, corporate)
   - ☐ Insurance Manager (e.g. coordinator, director, corporate)
   - ☐ Consultant
   - ☐ Attorney
   - ☐ Compliance Officer
   - ☐ Other: _____

NOTE: *Name, address, telephone number and email address of candidates who pass the CPHRM Examination are with ASHRM. Scores are never reported. If you do NOT wish to have your personal information shared, please opt out by contacting the AHA-CC in writing via e-mail at certification@aha.org or fax to 312-422-4575.*

SIGNATURE. I certify that I have read all portions of the CPHRM Candidate Handbook and agree to abide by regulations contained therein. I certify that I am eligible to take the CPHRM Examination and the information I have submitted in this application is complete and correct to the best of my knowledge and belief. I understand that, if the information I have submitted is found to be incomplete or inaccurate, my application may be rejected or my CPHRM Examination results may be delayed or voided.

Name (please print): _____

Signature: _____ Date: _____

REQUEST FOR SPECIAL EXAMINATION ACCOMMODATIONS

If you have a disability covered by the Americans with Disabilities Act (ADA), please complete this form and provide the Documentation of Disability-Related Needs on the next page so your accommodations for testing can be processed efficiently. The information you provide and any documentation regarding your disability and your need for accommodation in testing will be treated with strict confidentiality. Please return this form with your CPHRM Examination application and fee to PSI at least 45 days prior to the desired testing date.

CANDIDATE INFORMATION

First Name _____ Middle Initial _____ Last Name _____

Name of Facility/Company _____ Title _____

Preferred Mailing Address (Street Address, City, State/Province, Zip/Postal Code, Country _____

Preferred Telephone Number _____ Email Address _____

ASHRM or other AHA Personal Membership Group Member (PMG) Number _____

☐ I am not a member of an AHA PMG.

SPECIAL ACCOMMODATIONS

I request special accommodations for the _____ examination.

Please provide (Check all that apply):

_____ Reader
_____ Extended testing time (time and a half)
_____ Reduced distraction environment
_____ Large print test (paper-and-pencil administration only)
_____ Circle answers in test booklet (paper-and-pencil administration only)
_____ Other special accommodations (Please specify.)

_____

_____

_____

Comments _____

_____

_____

PLEASE READ AND SIGN: I give my permission for my diagnosing professional to discuss with PSI staff my records and history as they relate to the requested accommodation.

Signed: _____ Date: _____

Return this form with your examination application and fee to:
PSI, 18000 W. 105th St., Olathe, KS 66061-7543

If you have questions, call PSI Candidate Services at 888-519-9901 or fax to 913-895-4651.

DOCUMENTATION OF DISABILITY-RELATED NEEDS

Please have this section completed by an appropriate professional (education professional, physician, psychologist, psychiatrist, etc.) to ensure PSI is able to provide the required CPHRM Examination accommodations. The information provided will be treated with strict confidentiality. Return this form with the Request for Special Examination Accommodations form and your CPHRM Examination application and fee to PSI at least 45 days prior to the desired testing date.

PROFESSIONAL DOCUMENTATION

I have known_____ since_____/_____/____ in my capacity as a
Examination Candidate Date

_____.
Professional Title

The candidate discussed with me the nature of the examination to be administered. It is my opinion that, because of this candidate's disability described below, he/she/ should be accommodated by providing the special arrangements as described on the Request for Special Examination Accommodations form.

Description of disability: _____

_____

_____

_____

_____

Signed:_____ Title: _____

Printed Name:_____ Date: _____

License Number (if applicable) _____

Address: _____
(Street Address, City, State/Province, Zip/Postal Code, Country)

_____

Telephone Number:_____ Fax Number: _____

Email: _____

Return this form with your CPHRM Examination application and fee to:
PSI, 18000 W. 105th St., Olathe, KS 66061-7543

If you have questions, please call PSI Candidate Services at 888-519-9901 or fax to 913-895-4651.

資料4-2

ASHRM AMERICAN SOCIETY FOR HEALTHCARE RISK MANAGEMENT

safe and trusted healthcare

A personal membership group of the American Hospital Association

ASHRM Professional Recognition Checklist

FASHRM	DFASHRM
Application Form ☐	**Application Form** ☐
Application Fee* ☐	**Application Fee*** ☐
Member for at least 5 years ☐	**Member** for at least 10 years ☐
Designations – minimum of 2 ☐ CPHRM ☐ Additional Designation	**Designations** – minimum of 3 ☐ CPHRM ☐ Additional Designation ☐ Additional Designation
Continuing Education Credits ☐ Continuing education form complete ☐ 75 hours ☐ Within past 5 years ☐ Copies w/ o Name of program o Date of program o # of contact hours o Content code (1-6) Contact hour = 60 minutes of educational experience	**Continuing Education Credits** ☐ Continuing education form complete ☐ 150 hours ☐ Within past 10 years ☐ Copies w/ o Name of program o Date of program o # of contact hours o Content code (1-6) Contact hour = 60 minutes of educational experience
Employment Experience ☐ 5 years minimum experience ☐ Current job description ☐ 2 letters of reference ☐ Typed summary of RM experience (ie: resume or CV) indicating growth of responsibility/authority	**Employment Experience** ☐ 10 years minimum experience ☐ Current job description ☐ 2 letters of reference ☐ Typed summary of RM experience (ie: resume or CV) indicating growth of responsibility/authority
Contributions to the field ALL REQUIREMENTS in 2 categories <u>Leadership</u> ☐ 2 examples totaling 4 years (each at least 1 year in duration) ☐ W/in past 10 years ☐ Dates of service ☐ Activities performed ☐ Written verification of title/leadership position held provided by the organization ☐ Examples not work related	**Contributions to the field** ALL REQUIREMENTS in ALL 3 categories <u>Leadership</u> ☐ 2 examples totaling 4 years (each at least 1 year in duration) ☐ W/in past 10 years ☐ Dates of service ☐ Activities performed ☐ Written verification of title/leadership position held provided by the organization ☐ Examples not work related

Publishing ☐ Copy of book chapter (as primary or co-author) OR ☐ 2 articles published in journals/periodicals with circulation of 1000 readers or more (as primary author of at least one of the submissions) ☐ Published w/in 5 years of date of application ☐ Related to the field of risk management ☐ Articles or book chapters must bear the publication's name and date of publication ☐ Publications not work related Lecturing ☐ 2 examples as speaker or faculty for risk management programs o One must be national/state o One must offer continuing educational credit ☐ Conducted w/in 5 years of application ☐ Documentation verifying purpose or occasion of the presentation (program brochure or correspondence from program sponsors) ☐ Presentation is not work related	Publishing ☐ Copy of book chapter (as primary or co-author) OR ☐ 2 articles published in journals/periodicals with circulation of 1000 readers or more (as primary author of at least one of the submissions) ☐ Published w/in 5 years of date of application ☐ Related to the field of risk management ☐ Articles or book chapters must bear the publication's name and date of publication ☐ Publications not work related Lecturing ☐ 2 examples as speaker or faculty for risk management programs o One must be national/state o One must offer continuing educational credit ☐ Conducted w/in 5 years of application ☐ Documentation verifying purpose or occasion of the presentation (program brochure or correspondence from program sponsors) ☐ Presentation is not work related

*Application Fee
(One-time, nonrefundable):

Distinguished Fellow (DFASHRM)

- $125—First time applicants to designation process
- $50—Applicants with current FASHRM status

Fellow (FASHRM)

- $100

Reapplication After One Year

- $50*
- *Unsuccessful applicants who reapply for either designation within 12 months of the decision are exempt from the application fee.

資料 4-3

Concurrent Sessions

Claims & Litigation track presented by Beazley Group

Monday, October 16

Session	Title	Room	Track	Level
9:00-10:00 AM				
M-01	Improving End-of-Life Care: Strategies and Best Practices	605-607	Claims & Litigation	Advanced
M-02	Transgender Patient Safety: Advanced Concepts	608-610	Clinical/Patient Safety	Foundation
M-03	The Power of One: Working with Collaboratives	619-620	Leadership	Foundation
M-04	Risks Associated with Facility and Group Practice Mergers and Acquisitions	611-612	Legal & Regulatory	Advanced
M-05	Managing Cyber Risk in an Evolving Landscape	615-617	Healthcare Operations	Practitioner
M-06	A Peek Behind the Underwriting Curtain (an ASHRM/Bermuda Reciprocal Session)	613-614	Risk Financing	Practitioner
M-07	Closing the Loop with Health I.T. Risk Management	602-604	Performance Outcomes & Quality	Practitioner
9:00-11:15 AM				
M-08	Communicating with Confidence Workshop*	4C	Leadership	Foundation
10:15-11:15 AM				
M-11	Handling and Defending Sepsis Related Claims	615-617	Claims & Litigation	Practitioner
M-12	Improving Patient Safety in the Ambulatory Care Setting	602-604	Clinical/Patient Safety	Practitioner
M-13	The Power of Storytelling: Using Case Studies to Understand Communication Failures	605-607	Leadership	Advanced
M-14	Cops and Docs - Responding to Law Enforcement Requests	608-610	Legal & Regulatory	Practitioner
M-15	ERM: Get ready, set, GO!	619-620	Healthcare Operations	Foundation
M-16	Two Faces of Risk: When Healthcare Risk Meets Sub-capitation Risk	613-614	Risk Financing	Advanced
M-17	Peer Review Best Practices - Limiting Exposure in the Age of Technology	611-612	Performance Outcomes & Quality	Practitioner
1:45-2:45 PM				
M-21	High Times: An Update on Medical Marijuana and the Changing Landscape in Healthcare	611-612	Claims & Litigation	Foundation
M-22	Incorporating Human Factors Engineering into a Comprehensive Credible RCA - a Healthcare System's Approach	605-607	Clinical/Patient Safety	Advanced

資料 4-3

M-23	A Self Assessment for Your Risk Management Program	608-610	Leadership	Practitioner
M-24	Managing Risk for an Aging Population	615-617	Legal & Regulatory	Foundation
M-25	ERM 2.0: Practical Applications of the Theory	613-614	Healthcare Operations	Practitioner
M-26	Leveraging Data Science Techniques to Bring Modern Analytics to Health Institutions	619-620	Risk Financing	Practitioner
M-27	Don't Just Think, Understand: Lessons Learned Tackling a Solvable Problem, Wrong-Site Surgery	602-604	Performance Outcomes & Quality	Advanced
M-28	The Adapt Strategy: a New Way to Address High Exposure Damages*	4C-4	Claims & Litigation	Practitioner
3:00-4:00 PM				
M-31	Patient Safety at Our Fingertips; Lessons from a Real Case Study	611-612	Claims & Litigation	Practitioner

M-32	Safe Obstetrical Transitions of Care Between Providers	619-620	Clinical/Patient Safety	Practitioner
M-33	Building a Culture of Patient Safety	605-607	Leadership	Foundation
M-34	Legislative & Regulatory Update 2017	608-610	Legal & Regulatory	Practitioner
M-35	Enterprise Risk Management: Benchmarking Data and Implementation Strategies	615-617	Healthcare Operations	Advanced
M-36	Show Me the Money: Creating Value Through Proactive Risk Assessment	602-604	Risk Financing	Practitioner
M-37	Planning to Commit Violence? Not at Our Facility!	613-614	Performance Outcomes & Quality	Foundation
M-38	So You Think You're Covered: Analyzing and Understanding Different Coverage Options*	4C-4	Risk Financing	Foundation

Tuesday, October 17

Session	Title	Room	Track	Level
10:30 AM-11:30 AM				
T-01	2017 Aon/ASHRM Hospital and Physician Professional Liability Benchmark Study	605-607	Claims & Litigation	Practitioner
T-02	Who's Behind the Surgical Mask? Limiting Liability Beyond the Credential	619-620	Clinical/Patient Safety	Practitioner
T-03	The Bridge Between Risk Management and Patient Safety	608-610	Leadership	Foundation
T-04	Webcare: Management and Response to Patient Posts Online	602-604	Legal & Regulatory	Practitioner
T-05	Healthcare's ERM Success Stories: A Journey to ERM	613-614	Healthcare Operations	Advanced
T-06	Emerging Best Practices in Obstetrics	611-612	Risk Financing	Practitioner

資料 4-3

T-07	Accountable Care Organization: Why Value-based Reimbursement Should Thrill You—and Scare You Silly	615-617	Performance Outcomes & Quality	Practitioner
T-08	Secrets of Successful Risk Management Projects*	4C-4	Clinical/Patient Safety	Foundation
2:00-3:00 PM				
T-11	Building a Disclosure Program - Let's Start at the Very Beginning	611-612	Claims & Litigation	Practitioner
T-12	Truly High Reliable: Practical Tools to Help Your Organization Take Ownership of Their HRO Journey	613-614	Clinical/Patient Safety	Practitioner
T-13	Authentic Leadership Without an Agenda -- the Hidden Skills of a Successful Risk Manager	608-610	Leadership	Practitioner
T-14	Psychiatric & Behavioral Health Patients in the ED: Avoiding Liability	605-607	Legal & Regulatory	Advanced
T-15	What's the Alternative? Managing Unusual Risks in Unconventional Settings	602-604	Healthcare Operations	Practitioner

T-16	Products Liability & Hospitals: A New Area of Risk	615-617	Risk Financing	Foundation
T-17	Minimizing Risk and Liability for Waterborne Pathogens	619-620	Performance Outcomes & Quality	Practitioner
2:00-4:15 PM				
T-18	Difficult Conversations: Strategies for Addressing What Feels Impossible to Address*	4C-4	Leadership	Practitioner
3:15-4:15 PM				
T-21	Evolving Social Media Pitfalls and Management Strategies for Providers	608-610	Claims & Litigation	Practitioner
T-22	The Behavioral Health Patient in the Physician Practice Setting	611-612	Clinical/Patient Safety	Foundation
T-23	Joining the Communication and Resolution Revolution: Lessons from the First 100 Hospitals (An ASHRM/Collaborative for Accountability and Improvement Reciprocal Session)	615-617	Leadership	Practitioner

T-24	Colliding Worlds: Medical Necessity Versus Medical Quality Review	619-620	Legal & Regulatory	Practitioner
T-25	Telemedicine: Eight Questions to Ask Before Diving In	605-607	Healthcare Operations	Advanced
T-26	Bad Bugs: Managing Enterprise Risks Surrounding Pandemic Infections	613-614	Risk Financing	Practitioner
T-27	Retained Surgical Items: What the Data is Telling Us	602-604	Performance Outcomes & Quality	Foundation

*** Ticketed Workshop - Limited Capacity**

施設間のHand Over(施設間の患者情報の伝達)

資料5-1

＜和文論文＞

シソーラスの探索

①	「患者の引き継ぎ」で検索し、得られた論文のシソーラスを抽出
②	得られたシソーラスで再検索し、関連のあるシソーラスを抽出
③	②を繰り返し、500件以上の文献のタイトルと抄録から約100件の関連しそうな文献を抽出
④	③で得られた約100件の文献が、3つのシソーラス(患者の引き継ぎ、地域社会ネットワーク、多機関医療協力システム)で抽出できることを確認

医療連携、病病連携、地域連携等のフリーワードは、すべて「地域社会ネットワーク」または「多機関医療協力システム」に紐づいている。地域連携パスは「地域社会ネットワーク」に紐づけられることが多い。

検索式と絞り込みの過程

	検索式	件数	検索日
医中誌WEB	**(患者の引き継ぎ/TH)** and (PT=会議録除く)	16	2017/10/20
	(地域社会ネットワーク/TH) and (PT=会議録除く)	20878	2017/10/20
	(多機関医療協力システム/TH) and (PT=会議録除く)	14649	2017/10/20
	(患者の引き継ぎ/TH or 地域社会ネットワーク/TH or 多機関医療協力システム/TH) and (PT=会議録除く)	31406	2017/10/20
	(患者の引き継ぎ/TH or 地域社会ネットワーク/TH or 多機関医療協力システム/TH) and ([メタアナリシス]/TH or [システマティックレビュー]/TH or [ランダム化比較試験]/TH or [準ランダム化比較試験]/TH or [観察研究]/TH or RD=メタアナリシス,ランダム化比較試験,準ランダム化比較試験,比較研究) and (PT=症例報告除く) and (PT=会議録除く) and CK=ヒト	782	2017/10/20
絞り込み	タイトルと抄録	79	
	本文	51	

「観察研究/TH」には、前向き研究、後ろ向き研究、症例対照研究、コホート研究、断面研究等が含まれる。

研究デザインとアウトカムのレベル

		アウトカムレベル				
		1:臨床アウトカム	2:代替アウトカム	3:安全と間接的に関係するその他の測定可能なアウトカム	4:エラーや有害事象の減少に寄与するアウトカムがない	計
研究デザインレベル	1A:システマティックレビューまたはメタアナリシス	0	0	1	0	1
	1:無作為化比較試験	0	0	0	0	0
	2:非無作為化比較試験	0	2	0	0	2
	3:対照群のある観察研究 #	7	12	29	0	48
	4:対照群のない観察研究	0	0	0	0	0
	計	7	14	30	0	51

#:コホート研究 3本、症例対照研究 16本、前後比較研究 22本、横断的研究 7本

介入の内容と研究デザインレベル

		論文数	1A:システマティックレビューまたはメタアナリシス	2:非無作為化比較試験	3:対照群のある観察研究
地域連携パス	地域連携パス(大腿骨近位部骨折)	27	0	0	27
	地域連携パス(脳卒中)	5	0	0	5
	地域連携パス(大腿骨近位部骨折)の説明用パンフレットの使用	2	0	0	2
	地域連携パス(胃癌術後S-1補助化学療法)	1	0	0	1
	地域連携パス(血液浄化用長期留置カテーテル管理)	1	0	0	1
	地域連携パス(骨粗鬆症)	1	0	0	1
	地域連携パス(糖尿病)	1	0	0	1
	地域連携パス(脳梗塞)	1	0	0	1
	地域連携パス(慢性腎臓病)	1	0	0	1
	地域連携パス(PCI後)	1	0	0	1
	地域連携パス(虚血性心疾患)	1	0	0	1
	地域連携パス(乳がん検診)	1	0	0	1
連携手帳	連携手帳(糖尿病)	3	0	0	3
	連携手帳(糖尿病眼)	1	0	0	1
その他	地域連携の専門部署の設置	1	1	0	0
	急性期病院間の合同カンファレンスの有無	1	0	1	0
	病院から診療所への患者紹介の有無	1	0	1	0
	連携治療または院内完結治療	1	0	0	1
合計		51	1	2	48

介入の内容とアウトカムのレベル

		論文数	アウトカムのレベル			アウトカムの指標		
			1:臨床アウトカム	2:代替アウトカム	3:安全と間接的に関係するその他の測定可能なアウトカム	1:臨床アウトカム	2:代替アウトカム	3:安全と間接的に関係するその他の測定可能なアウトカム
地域連携パス	地域連携パス(大腿骨近位部骨折)	27	3	3	21	再骨折	ADL、移動能力、FIM	在院日数、在宅復帰率、骨粗鬆症薬の処方率　等
	地域連携パス(脳卒中)	5	0	4	1		FIM、FIM利得、mRS	在院日数、リハの実施単位数、診療情報提供書の項目別記載率　等
	地域連携パス(大腿骨近位部骨折)の説明用パンフレットの使用	2	0	0	2			説明に対する患者の理解度、患者の転院に対する不安感　等
	地域連携パス(胃癌術後S-1補助化学療法)	1	1	0	0	薬剤有害事象発生割合		S-1の治療継続性
	地域連携パス(血液浄化用長期留置カテーテル管理)	1	1	0	0	感染症、カテ閉塞	入院	患者のメール相談件数
	地域連携パス(骨粗鬆症)	1	1	0	0	新規脆弱性骨折発生率	骨粗鬆症治療薬服薬継続率、骨塩量の変化	
	地域連携パス(糖尿病)	1	1	0	0	悪性腫瘍発症率、大血管障害発症率		
	地域連携パス(脳梗塞)	1	0	1	0		mRS	在院日数
	地域連携パス(慢性腎臓病)	1	0	1	0		病期・腎機能・尿蛋白/尿Cr値の変化、血圧	
	地域連携パス(PCI後)	1	0	1	0		TC、LDL-C、L/H比	
	地域連携パス(虚血性心疾患)	1	0	0	1			虚血性心疾患に対する各種指導の実施有無
	地域連携パス(乳がん検診)	1	0	0	1			患者満足度
連携手帳	連携手帳(糖尿病)	3	0	1	2		HbA1cの数値、網膜症の程度	患者がHbA1c・血圧等を把握する割合、眼科・歯科を定期受診する割合
	連携手帳(糖尿病眼)	1	0	0	1			医師の眼手帳の認知度、医師の診療連携の改善感
その他	地域連携の専門部署の設置	1	0	0	1			相談数、在院日数、h測員の意識、在宅復帰率
	急性期病院間の合同カンファレンスの有無	1	0	1	0		mRS	在院日数
	病院から診療所への患者紹介の有無	1	0	1	0		HbA1c値、網膜症・腎症の進行割合	患者満足度
	連携治療または院内完結治療	1	0	1	0		FIM	在院日数、在宅復帰率
合計		51	7	16	28			

＜英文論文＞

MeSH termsの探索

①	″Community Networks″、″Multi-Institutional Systems″、″Patient Handoff″で検索し、得られた論文のMeSH termsを抽出
②	先行研究のPatient handoffに関する文献レビューで使用された検索式を用いて再検索し、得られた論文のMeSH termsを抽出
③	①②で得られたMeSH termsで再検索し、関連のあるMeSH termsを抽出
④	①②③を繰り返し、300件の文献のタイトルと抄録から19件の関連しそうな文献を抽出
⑤	④で得られた文献から26個のMeSH termsを得
⑥	⑤で得られたMeSH termsについて、ツリー構造を勘案し、26個を13個に絞り込んだ
⑦	⑥で得られた13個のMeSH termsで④の文献が抽出できることを確認

検索式と絞り込みの過程

※論文数が多いため、直近3年間の論文をレビューの対象にした。

	検索式	件数(直近3年間)※	検索日
PubMed	Multi-Institutional Systems	104	2017/10/26
	Case Management	799	2017/10/26
	Critical Pathways	934	2017/10/26
	Patient Discharge	4156	2017/10/26
	Patient Handoff	400	2017/10/26
	Patient Transfer	1102	2017/10/26
	Health Communication	668	2017/10/26
	Residential Facilities	3903	2017/10/26
	Community Health Services	24012	2017/10/26
	Rehabilitation Centers	964	2017/10/26
	Hospitals	23430	2017/10/26
	Physicians' Offices	86	2017/10/26
	Primary Health Care	21470	2017/10/26
	上記を全てORで連結	70293	2017/10/26
	<Pathways group> ″multi-institutional systems″[MeSH Terms] OR ″Case Management″[MeSH Terms] OR ″Critical Pathways″[MeSH Terms] OR ″Patient Discharge″[MeSH Terms] OR ″Patient Handoff″[MeSH Terms] OR ″Patient Transfer″[MeSH Terms] OR ″Health Communication″[MeSH Terms]	7904	2017/10/26
	<Facilities/providing systems group> ″residential facilities″[MeSH Terms] OR ″community health services″[MeSH Terms] OR ″rehabilitation centers″[MeSH Terms] OR ″hospitals″[MeSH Terms] OR ″physicians' offices″[MeSH Terms] OR ″primary health care″[MeSH Terms]	68393	2017/10/26
	上記の<Pathway group>と<Facilities/providing system group>をANDで連結	6004	2017/10/26
	研究デザインを加えてさらに絞り込み		
	<最終的な検索式> ((″multi-institutional systems″[MeSH Terms] OR ″Case Management″[MeSH Terms] OR ″Critical Pathways″[MeSH Terms] OR ″Patient Discharge″[MeSH Terms] OR ″Patient Handoff″[MeSH Terms] OR ″Patient Transfer″[MeSH Terms] OR ″Health Communication″[MeSH Terms]) AND (″residential facilities″[MeSH Terms] OR ″community health services″[MeSH Terms] OR ″rehabilitation centers″[MeSH Terms] OR ″hospitals″[MeSH Terms] OR ″physicians' offices″[MeSH Terms] OR ″primary health care″[MeSH Terms])) AND (″Meta-Analysis as Topic″[Mesh] OR ″Controlled Clinical Trials as Topic″[Mesh] OR ″Case-Control Studies″[Mesh] OR ″Cohort Studies″[Mesh] OR ″Cross-Sectional Studies″[Mesh] OR ″Observational Studies as Topic″[Mesh] OR Meta-Analysis[ptyp] OR systematic[sb] OR Controlled Clinical Trial[ptyp] OR Observational Study[ptyp] OR Comparative Study[ptyp]) AND ″humans″[Mesh] AND (″2014/10/26″[PDAT] : ″2017/10/26″[PDAT])	3124	2017/10/26
絞り込み	タイトルと抄録	140	
	本文	7	

研究デザインとアウトカムのレベル

		アウトカムレベル				
		1:臨床アウトカム	2:代替アウトカム	3:安全と間接的に関係するその他の測定可能なアウトカム	4:エラーや有害事象の減少に寄与するアウトカムがない	計
研究デザインレベル	1A:システマティックレビューまたはメタアナリシス	1	1	0	0	2
	1:無作為化比較試験	0	0	0	0	0
	2:非無作為化比較試験	1	0	0	0	1
	3:対照群のある観察研究 #	1	2	1	0	4
	4:対照群のない観察研究	0	0	0	0	0
	計	3	3	1	0	7

#:症例対照研究 1本、前後比較研究 2本、横断的研究 1本

介入の内容と研究デザインレベル

		論文数	1A:システマティックレビューまたはメタアナリシス	1:無作為化比較試験	2:非無作為化比較試験	3:対照群のある観察研究
地域連携パス	Transitional care interventions (programs)(退院計画作成、患者教育、退院後のフォローアップ、退院後のケアの調整、薬剤の整理・調整等)	5	2	0	0	3
	病院とナーシングホーム間でのテレビ会議	1	0	0	1	0
	診療情報提供書の項目別記載率	1	0	0	0	1
合計		7	2	0	1	4

介入の内容とアウトカムのレベル

		論文数	アウトカムのレベル			アウトカムの指標		
			1:臨床アウトカム	2:代替アウトカム	3:安全と間接的に関係するその他の測定可能なアウトカム	1:臨床アウトカム	2:代替アウトカム	3:安全と間接的に関係するその他の測定可能なアウトカム
地域連携パス	Transitional care interventions (programs)(退院計画作成、患者教育、退院後のフォローアップ、退院後のケアの調整、薬剤の整理・調整等)	5	1	3	1	死亡率	再入院(率)、救命受診率	入院から後方連携施設に連絡を入れるまでの日数等
	病院とナーシングホーム間でのテレビ会議	1	1	0	0	死亡率	再入院率	入院医療費、平均在院日数
	診療情報提供書の項目別記載率	1	1	0	0	死亡率、有害事象		
合計		7	3	3	1			

Hand Over(施設間の患者情報の伝達) 文献一覧

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
＜和文論文＞											
1	急性期病院における地域連携を推進するための専門部署に関する文献的考察(原著論文) Author:上田 雅子(神戸市看護大学), 叶谷 由佳, 佐藤 千史 Source: 神戸市看護大学紀要 (1342-9027)8巻 Page45-57(2004.03)	1A:システマティックレビューまたはメタアナリシス	システマティックレビュー	地域連携の専門部署の設置	医中誌Webで最新過去5年分(1998-2003年)で「地域連携室」「地域医療室」「看護相談室」「療養指導室」「地域医療連携室」「総合相談室」「医療連携室」「医療社会福祉部」のキーワードで検索、61件の文献	3:安全と間接的に関係するその他の測定可能なアウトカム	部署設置目的、役割、業務、連携先、院内の業務、退院支援をする患者の特徴、部署設置効果、活動上の問題点、今後の課題	部署設置の効果については、相談数の増加、連携がスムーズ・在院日数の短縮、院内職員の意識変化、相談窓口が明確になり相談しやすい、社会資源の活用率や在宅へ退院する患者の増加、チーム医療の向上、情報の共有化 などがあげられていた。			フリーワード検索。解説や症例報告、会議録を含む。研究デザインやアウトカムレベルについて検討なし。
2	地域中核病院を中心とした糖尿病病診連携の取り組みと長期経過 大垣病診連携研究(原著論文) Author:鈴木 厚(大垣市民病院 糖尿病・腎臓内科), 藤谷 淳, 清田 篤志, 山内 雅裕, 柴田 大河, 青木 孝彦, 傍島 裕司 Source: 糖尿病 (0021-437X)50巻5号 Page303-311(2007.05)	2:非無作為化比較試験	非無作為化比較試験	病院から診療所への患者紹介の有無	病院外来糖尿病教育終了後1年以上糖尿病治療を継続し、HbA1Cが8%未満で安定した患者の中で、診療所の一般医に紹介された患者78人、同時期に病院で診療を継続した64人	2:代替アウトカム	紹介後4年間のHbA1c値、患者満足度、等	介入群(診療所紹介群)と対照群(病院診療継続群)の患者属性に偏りなし。介入群のうち52例が4年後まで毎月の診療所の受診と半年に1回の病院の定期受診を継続した。介入群52例のHbA1cは紹介1年後から有意に上昇(紹介時6.21、紹介1年後6.50、P<0.01)、その後も上昇を続けた(紹介4年後6.95、紹介時と比較しP<0.01)。紹介時点のHbA1cは介入群と対照群で有意差がなかったが(6.21、6.18、P=0.57)、4年後は介入群の方が高かった(6.95、6.61、P=0.047)。網膜症や腎症の進行した割合は両群でほぼ同等であった。			

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
3	地域完結型と病院完結型脳卒中診療態勢の比較(原著論文) Author:藏元 聖子(熊本大学医学部附属病院 神経内科), 平野 照之, 橋本 洋一郎, 米原 敏郎, 内野 誠 Source: 脳卒中 (0912-0726)25巻2号 Page245-251(2003.06)	2:非無作為化比較試験	非無作為化比較試験	急性期病院間の合同カンファレンスの有無	脳卒中の治療を行った患者。合同カンファレンスを行っている3病院に入院した806人、それ以外の2病院に入院した217人	2:代替アウトカム	急性期在院日数、急性期退院時・退院1年後mRS、等	カンファ群と非カンファ群で、入院時の患者年齢、入院時重症度(NIHSS)、退院時移動能力、退院時・退院後1年のmRSに有意差なし。臨床病型の分布は差があり。急性期在院日数は、カンファ群が非カンファ群より短かった(17.3日、38.1日、P<0.01)。			
4	糖尿病地域連携パスにおける悪性腫瘍と大血管障害の発症(原著論文) Author:高田 裕之(富山赤十字病院), 若林 祐介, 篠崎 洋, 川原 順子, 平岩 善雄 Source: 糖尿病 (0021-437X)58巻5号 Page342-345(2015.05)	3:対照群のある観察研究	症例対照研究	地域連携パス(糖尿病)	パス適用者168名、パス非適用者105名(性・年齢・罹患期間をマッチ)	1:臨床アウトカム	悪性腫瘍発症率、大血管障害発症率	パス適用群と非適用群で、悪性腫瘍発症率と大血管障害発症率に有意差なし。ただし、悪性腫瘍発症率は、適用群(5.4%)が非適用群(1.0%)よりも高い傾向(P=0.10)が見られた。パスは定期的精査を通して合併症の早期発見に役立つ可能性			
5	大腿骨近位部骨折地域連携パスの構築と予後調査　浜松方式(原著論文) Author:田中 久重(田中整形外科医院), 藤野 圭司, 森 諭史, 岩瀬 敏樹, 藤島 一郎, 静岡県西部広域大腿骨近位部骨折地域連携パス委員会 Source: 日本臨床整形外科学会雑誌 (1881-7149)39巻1号 Page76-	3:対照群のある観察研究	コホート研究	地域連携パス(大腿骨近位部骨折)	急性期病院、回復期病院を退院後、連携パスで診療所に通院した14人、通院しなかった93人	2:代替アウトカム	急性期病院退院1年後のADL評価点(独自評価票)	診療所を継続受診しなかった者は、継続した者よりも、ADLが低下した(検定なし)。退院後に診療所に通院すると、退院時のADLが維持される。	連携パスに則って診療所に通院する患者が少ない		
6	骨粗鬆症検診を起点とする地域連携パスの成果と意義(原著論文) Author:黒川 正夫(済生会吹田病院 整形外科), 藤井 敏之, 平田 正純, 高宮 尚武, 阪尾 敬, 酒井 亮, 山田 尚武, 山田 学 Source: Osteoporosis Japan (0919-6307)22巻3号 Page518-521(2014.07)	3:対照群のある観察研究	前後比較研究	地域連携パス(骨粗鬆症)	2004-2008年に市の検診で骨粗鬆症要精検とされ当該病院を受診した412人	1:臨床アウトカム	服薬開始後5年間の骨粗鬆症治療薬服薬継続率、骨塩量の変化、新規脆弱性骨折の頻度	服薬継続率はパスの導入後に有意に増加した(2004-6年:51.9-73.7%、2007-8年:86.4-91.3%、P<0.05)。骨塩量の変化、新規脆弱性骨折の頻度は有意差なし。			

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
7	大腿骨地域連携パスのデータベース構築　データベースの運用結果と課題(原著論文) Author:池田 昇(聖隷浜松病院 地域医療連携室), 森 論史, 田中 健太郎, 二宮 太志, 藤野 圭司 Source: 運動器リハビリテーション (2187-8420)24巻4号 Page415-420(2013.12)	3:対照群のある観察研究	コホート研究	地域連携パス(大腿骨近位部骨折)	連携パスに基づき治療され回復期病院を退院した患者205人(退院後パス通り診療所と連携して骨粗しょう症治療とリハビリを実施した42人、診療所と連携しなかった163人)	1:臨床アウトカム	再骨折の発生、日常生活機能評価点数、要介護度	診療所連携群は再骨折が0件(0%)、非連携群は4件(2.5%)(検定なし)。回復期病院退院時から調査時までの日常生活機能評価の低下(点数の減少)は、連携群が非連携群より小さかった(-0.22点、-1.07点)(検定なし)。連携群は要介護度の高い患者の割合が減少傾向にあり、非連携群では増加傾向にあった。			比較に検定を用いていない。
8	地域連携パスによる大腿骨近位部骨折治療の検証　両側発生頻度の検討(原著論文) Author:山崎 薫(磐田市立総合病院 整形外科), 森本 祥隆, 猿川 潤一郎, 鈴木 大輔, 錦野 匠一, 小川 高志 Source: 中部日本整形外科災害外科学会雑誌 (0008-9443)56巻4号 Page1009-1010(2013.07)	3:対照群のある観察研究	前後比較研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療を行った患者。パス導入前の140人、導入後の192人	1:臨床アウトカム	退院後の反対側の大腿骨近位部骨折の発生率	退院後の反対側の大腿骨近位部骨折の発生率は、導入前群と導入後群で差が無かった(10.5%、14.9%、P=0.33)。			
9	静岡県西部広域における大腿骨近位部骨折地域連携パス報告　病診連携の実態と課題(原著論文) Author:池田 昇(聖隷浜松病院 地域医療連携室), 竹内 利之, 森 論史, 二宮 太志, 静岡県西部広域地域連携パス委員会大腿骨近位部骨折部会 Source: Osteoporosis Japan (0919-6307)21巻2号 Page337-340(2013.04)	3:対照群のある観察研究	横断的研究	地域連携パス(大腿骨近位部骨折)	腿骨近位部骨折で入院治療し1年以上が経過した患者176人(回収後、診療所連携群13人、非連携群57人)	1:臨床アウトカム	再骨折の発生、日常生活機能評価	検定なし。再骨折発生率は連携群が0%、非連携群が5.2%。連携群では、回復期退院時と予後調査時点で日常生活機能評価の点数が横ばいであったが、非連携群では低下傾向にあった。			比較に検定を用いていない。
10	地域連携クリニカルパスによる胃癌術後S-1補助化学療法の認容性とアウトカム(原著論文) Author:岸本 朋乃(堺市立堺病院 外科), 今村 博司, 川端 良平, 木村 豊, 福永 睦, 大里 浩樹 Source: 癌と化学療法 (0385-0684)40巻4号 Page489-492(2013.04)	3:対照群のある観察研究	前後比較研究	地域連携パス(胃癌術後S-1補助化学療法)	胃癌術後にS-1補助化学療法を行った患者44人(パス導入前の26人、導入後の18人)	1:臨床アウトカム	S-1の治療継続性、1年間S-1を服用できた症例のRP値[S-1の実際総投与量/予定総投与量(%)]、有害事象発現割合	パス導入前と導入後で全て有意差なし。			

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11	透析療法における血液浄化用長期留置カテーテル管理パス作成と地域における運用(原著論文) Author:野口 隆司(東葛クリニック病院 臨床工学部), 松金 隆夫, 宮内 裕希, 桜井 裕之, 内野 敬, 東 仲宣 Source: 日本クリニカルパス学会誌(2187-6592)12巻2号 Page116-121(2010.06)	3:対照群のある観察研究	症例対照研究	地域連携パス(血液浄化用長期留置カテーテル管理)	当該病院において他施設から依頼され透析用長期カテを挿入した患者。パス適用群9人、非適用群4人	1:臨床アウトカム	感染、閉塞、電話・メールでの相談件数	検定なし。パス適用群は感染0件、閉塞1件、入院0件、相談3-5件/月。非適用群は感染1件、閉塞2件、カテ切断1件、入院4件、相談0件。パス導入群はカテの異常を早期発見・相談でき、入院に至るような有害事象は発生しなかった。非適用群は有害事象が発生してから受診し、全例入院した。			サンプル数が少ない。比較に検定を用いていない。
12	大阪府豊能圏域糖尿病地域医療連携の取り組みと成果(原著論文) Author:津川 真美子(市立池田病院), 飯田 さよみ, 嶺尾 郁夫, 火伏 俊之, 黒田 耕平, 多田 勇介, 鷲見 誠一, 西本 明文, 松山 辰男, 天羽 康雄, 木村 好美, 吉政 康直, 三谷 一裕, 中田 信輔, 見野 比左夫, 中村 圭子, 大西 宏昭, 飯沼 恵子, 山本 雅代, 前田 和恵, 岸本 一郎 Source: 日本医師会雑誌 (0021-4493)144巻2号 Page311-317(2015.05)	3:対照群のある観察研究	横断的研究	連携手帳(糖尿病)	保険薬局に来た糖尿病の患者858人	3:安全と間接的に関係するその他の測定可能なアウトカム	HbA1c値・収縮期血圧値・LDLコレステロール値の把握度、眼科・歯科の定期受診割合	HbA1c値を把握している者の割合は、連携手帳所持者(91%)が非所持者(84%)よりも有意に高かった(P<0.01)。収縮期血圧は両群で把握割合が高く、有意差なし。LDLコレステロールは両群とも約半数が把握しており有意差なし。眼科を定期受診する割合は所持群(7割)が非所持群(5割)より有意に高かった(P<0.01)。歯科定期受診割合は有意差なし。3つの値そのものは、交絡要因で調整すると、所持群と非所持群で有意差なし。			
13	大阪府豊能医療圏における糖尿病実態と連携手帳所持率調査(原著論文) Author:岸本 一郎(国立循環器病研究センター 糖尿病・代謝内科), 芦田 康宏, 大森 洋子, 西 洋壽, 萩原 泰子, 藤本 年朗, 槇野 久士, 大畑 洋子, 岩根 光子, 飯沼 恵子, 前田 和恵, 佐藤 滋 Source: 糖尿病 (0021-437X)56巻8号 Page543-550(2013.08)	3:対照群のある観察研究	横断的研究	連携手帳(糖尿病)	大阪府豊能の2次医療圏にある約350の保険薬局に糖尿病薬の処方箋を持参した患者1138人	3:安全と間接的に関係するその他の測定可能なアウトカム	HbA1cの把握の有無、眼科の定期受診、他	多変量解析で糖尿病連携手帳の所持は、HbA1cの把握の有無、眼科の定期受診と関連が認められた。糖尿病連携手帳の所持は糖尿病入院歴(r=0.22、P<0.01)と相関が認められた。			

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14	内科と眼科における糖尿病連携手帳運用の実態と効率的な利用方法の検討(原著論文) Author:武田 美佐(徳島県立中央病院 眼科), 白神 敦久 Source: 徳島県立中央病院医学雑誌 (0913-5103)33巻 Page13-16(2012.03)	3:対照群のある観察研究	コホート研究	連携手帳(糖尿病)	初回の眼科受診時に糖尿病連携手帳を交付し、交付後に眼科の再診があった患者42人(うち手帳持参が22人、持参なしが20人)	2:代替アウトカム	HbA1c値、網膜症の程度等	再診時に手帳を持参した患者と、持参しなかった患者で、HbA1cに有意差なし。継続的に連携手帳を利用する患者の特徴を明らかにした。			
15	大腿骨近位部骨折者の移動能力と日常生活活動の回復調査(原著論文) Author:高橋 忠清(公立置賜総合病院) Source: 山形理学療法学 (1880-8166)8巻 Page14-17(2012.03)	3:対照群のある観察研究	前後比較研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療を行った患者。パス導入前に自院でリハビリまで完結した49人、導入後の52人	2:代替アウトカム	総在院日数、PT終了時の移動能力、等	自院でリハビリまで完結した群は、連携パスにより他院でリハビリまで完結した群と比較し、総在院日数が短かったが(25.4日、46.5日、P<0.01)、PT終了後の移動能力は連携群の方が高い(独歩や杖歩行の割合が高い)傾向にあった。			
16	脳卒中地域連携パスの機能的評価(原著論文) Author:関 幸恵(脳血管研究所附属美原記念病院 リハビリテーション科), 常田 康司, 内田 智久, 美原 盤 Source: 群馬医学 (0285-0656)93号 Page159-163(2011.08)	3:対照群のある観察研究	前後比較研究	地域連携パス(脳卒中)	脳卒中の患者で、急性期病棟から回復期リハ病棟へ転棟した患者。連携パス導入前の57人、導入後のパス適用症例の22人、導入後のパス非適用症例の35	2:代替アウトカム	急性期在院日数、回復期在院日数、総在院日数、転棟時と退院時のFIM、自宅復帰率	パス導入前群と導入後パス適用群は、いずれのアウトカムも有意差なし。			
17	脳卒中医療における施設完結型と病院間連携の臨床的質および効率性に関する比較(原著論文) Author:常田 康司(脳血管研究所附属美原記念病院 リハビリテーション科), 関 幸恵, 内田 智久, 美原 盤 Source: 群馬医学 (0285-0656)93号 Page153-157(2011.08)	3:対照群のある観察研究	症例対照研究	連携治療または院内完結治療	脳卒中の患者で、当該病院の急性期病棟から回復期リハ病棟へ転棟した患者82人、他の急性期病院から当該病院の回復期リハ病棟に転院してきた患者43人	2:代替アウトカム	急性期在院日数、回復期在院日数、総在院日数、転棟時と退院時のFIM、自宅復帰率	当該病院内で完結した群は、他院から回復期リハ病棟に転入した群よりも、急性期在院日数が短く(14日、27日、P<0.01)、総在院日数が短かった(55日、76日。P<0.01)。しかし、回復期在院日数とFIM点数、自宅復帰率に有意差なし。			

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
18	回復期リハビリテーション病棟におけるソーシャルワーカーの連携パス強化に向けた取り組み(原著論文) Author:加藤 充子(脳血管研究所附属美原記念病院 地域医療連携室), 狩野 悠, 岩崎 恭大, 新井 ゆきね, 田中 奈緒, 相澤 勝健, 美原 盤 Source: JMC: 日本慢性期医療協会機関誌 19巻4号 Page88-94(2011.10)	3:対照群のある観察研究	症例対照研究	地域連携パス(脳卒中)	他の急性期病院から当該病院の回復期リハ病棟へ入院した脳卒中患者466人(内、連携パスに則って入院した患者119人、パスを利用せずに入院した患者347人)	2:代替アウトカム	急性期在院日数、回復期在院日数、総在院日数、回復期入院1日当たりのFIM利得((退院時FIM-入院時FIM)/回復期在院日数)、自宅復帰率	パス群は非パス群より、急性期在院日数が短かった(32.0日、42.8日、P<0.01)。しかし、回復期在院日数(60.1日、66.8日)、1日当たりのFIM利得(0.35点、0.34点)、自宅復帰率(87%、85%)は有意差無し。			
19	慢性腎臓病(CKD)地域連携パスの取り組み　熊本県上天草地区(原著論文) Author:白井 純宏(済生会熊本病院 救急総合診療センター), 具嶋 泰弘, 前原 潤一, 町田 健治, 井上 浩伸, 町田 二郎, 小妻 幸男, 多田 修治, 副島 秀久, 藤岡 正導, 宮崎 正史, 山内 穣滋, 中村 修, 杉本 啓介 Source: 日本クリニカルパス学会誌(2187-6592)13巻2号 Page107-114(2011.06)	3:対照群のある観察研究	症例対照研究	地域連携パス(慢性腎臓病)	慢性腎臓病の治療を行った患者。連携パスを用い専門医とかかりつけ医が連携して診療した患者39人、専門医だけで外来診療した患者24人	2:代替アウトカム	病期の変化、腎機能の変化、尿蛋白/尿Cr値の変化、血圧	連携群と専門医のみの群で、各指標に差は認められない(検定なし)。			サンプル数が少ない。比較に検定を用いていない。
20	府中市循環器疾患連絡協議会での新しい連携の取り組み(原著論文) Author:長山 雅俊(榊原記念病院), 齋藤 佳子, 新村 郁子, 石井 典子, 藁谷 恵美子, 角口 亜希子, 熊谷 由美子, 鈴木 紫水香, 田城 孝雄, 住吉 徹哉, 村上 保夫 Source: 東京都医師会雑誌(0040-8956)64巻4号 Page473-478(2011.05)	3:対照群のある観察研究	症例対照研究	地域連携パス(PCI後)	PCI後に連携パスを適用した患者31人、連携パスを適用せずに開業医へ紹介・逆紹介した患者30人	2:代替アウトカム	TC、LDL-C、L/H比	連携パス適用群と非適用群でTC、LDL-C、L/H比に有意差なし(PCI入院時と確認カテ時のデータのうち、どれをどのように比較したのか記載なし)。			結果の記載が不十分であり、評価できない。

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
21	地域ネットワークにおける脳卒中地域連携クリニカルパスの影響(Influence of liaison clinical pathway for stroke patients in regional networks)(英語)(原著論文) Author:Osawa Aiko(埼玉医大国際医療センター 運動・呼吸器リハビリテーション科), Maeshima Shinichiro, Ishihara Shoichiro, Morikawa Eiharu, Sato Akira, Tanahashi Norio Source: 埼玉県包括的リハビリテーション研究会雑誌 (1882-8345)9巻1号 Page9-11(2009.11)	3:対照群のある観察研究	前後比較研究	地域連携パス(脳卒中)	脳卒中の治療を行った患者。パス導入前の176人、導入後の255人	2:代替アウトカム	急性期在院日数、退院時FIM・mRS	パス導入前と比較し、導入後は在院日数が延長した(20.7日、25.7日、P<0.01、考察なし)。パス導入前と導入後で、退院先別に、退院時FIM・mRS、在院日数を比較すると、有意差を認めなかった。			パス導入後に在院日数が延長したが、何も考察されていない。
22	回復期リハ病棟における脳卒中患者のADL改善に関する調査 地域連携パス導入前後の比較および地域連携パス参加病院とそれ以外の病院との比較(原著論文) Author:徳永 誠(熊本機能病院 リハビリテーション科), 桑田 稔丈, 渡邊 進, 中西 亮二, 園田 茂, 橋本 洋一郎 Source: Journal of Clinical Rehabilitation (0918-5259)18巻7号 Page663-668(2009.07)	3:対照群のある観察研究	前後比較研究	地域連携パス(脳卒中)	脳卒中により回復期リハ病棟に入院した患者。パス導入前132人、導入後142人	2:代替アウトカム	回復期在院日数、1日当たりリハ単位数、回復期入院時・退院時FIM、FIM利得、等	パス導入前と導入後を比較し、1日当たりリハ単位数が増加し(4.1単位、4.5単位、P<0.01)、認知FIM利得が増加した(3.3点、4.4点、P<0.05)。回復期在院日数、入院時・退院時FIM、運動FIM利得に有意差なし。			
23	脳卒中連携医療の見直しと地域連携クリティカルパス(原著論文) Author:佐治 直樹(兵庫県立姫路循環器病センター 神経内科), 時本 清己, 小寺 正人, 今脇 節朗 Source: 日本医療マネジメント学会雑誌 (1881-2503)9巻3号 Page444-450(2008.12)	3:対照群のある観察研究	前後比較研究	地域連携パス(脳梗塞)	急性期病院で脳梗塞の治療が行われ、回復期病院に転院した患者。地域連携パス導入前の12人、導入後の19人	2:代替アウトカム	転院時mRS、回復期病院退院時mRS、急性期在院日数、回復期在院日数、総在院日数	パス導入前と導入後で比較すると、回復期退院時mRSが低下した(2.8点、1.9点、P<0.05)。転院時mRS、各種在院日数(短縮傾向あり)に有意差なし。			サンプル数が少ない。

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
24	大腿骨頸部骨折地域連携クリニカルパス導入の効果と問題点(原著論文) Author:竹前 貴志(総合リハビリテーションセンターみどり病院 リハビリテーション科), 佐藤 豊, 曽川 裕一郎, 宮尾 益尚, 塩崎 浩之, 遠藤 直人 Source: 新潟整形外科研究会会誌(0914-6636)24巻1号 Page35-38(2008.02)	3:対照群のある観察研究	前後比較研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療後に回復期病院に転院してきた患者。パス導入前の5人、導入後の17人	2:代替アウトカム	回復期入院時・退院時FIM、急性期在院日数、回復期在院日数、患者1人当たりの診療報酬点数、患者1人当たりのリハ単位数	パス導入前と導入後を比較すると、急性期在院日数が短縮し(31.0日、22.7日、P<0.05)、患者1人当たりのリハ単位数が増加し(150.6単位、248.7単位、P<0.05)、患者1人・1日当たりのリハ単位数が増加した(2.5単位、3.3単位、P<0.05)。回復期在院日数、患者1人当たりの診療報酬点数に有意差なし。導入前後でFIMに有意差なし。			サンプル数が少ない。
25	大腿骨頸部骨折地域連携パスの運用状況の比較(原著論文) Author:侭田 敏且(地域医療機能推進機構東京山手メディカルセンター 脊椎脊髄外科), 飯島 卓夫, 徳山 周, 伊藤 直美, 水野 清, 柳田 千尋, 園田 恭子 Source: 日本クリニカルパス学会誌(2187-6592)17巻3号 Page294-299(2015.09)	3:対照群のある観察研究	症例対照研究	地域連携パス(大腿骨近位部骨折)	大腿骨頸部骨折で手術した214例	3:安全と間接的に関係するその他の測定可能なアウトカム	当該病院の在院日数と術後在院日数、当該病院と連携先のリハ病院も含めた総在院日数	連携パスを使用してリハビリ病院へ転院した群と、連携パスを使用せずに転院した群を比較した。当該病院の在院日数、術後在院日数、リハ病院を含めた総在院日数は、連携パス適用群の方が有意に短かった。ただし、導入直後の3年間のデータでは有意差が認められたものの、その後の3年間のデータではいずれも有意差が認められなかった。連携パスの適用率が上昇し、連携パスを使用しないでリハビリ病院へ転院した症例数が少なくなったことが要因。			
26	大腿骨近位部骨折地域連携パスによる治療において急性期を担う医療機関が骨粗鬆症薬を処方する効果の検証(原著論文) Author:一ノ瀬 初美(磐田市立総合病院 整形外科), 山崎 薫, 功刀 さおり, 長谷 奈那子 Source: Osteoporosis Japan(0919-6307)23巻1号 Page41-45(2015.01)	3:対照群のある観察研究	症例対照研究	地域連携パス(大腿骨近位部骨折)	急性期から維持期までの連携を完結した115人	3:安全と間接的に関係するその他の測定可能なアウトカム	骨粗鬆症薬処方の有無	維持期医療機関で骨粗鬆症薬が処方される割合は、急性期病院で同薬が処方されていた場合の方が、処方されていなかった場合よりも高い(68.6%、46.9%、P=0.02)。急性期病院で骨粗鬆症薬を処方すれば、維持期医療機関でも骨粗鬆症薬が継続して処方される可能性が高まる。(同薬の処方を連携パスに組み込む前に、自院の院内パスに組み込んだ。)			

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
27	大腿骨近位部骨折地域連携パス導入の有用性　在院日数の比較から(原著論文) Author:大泉 みどり(JA北海道厚生連帯広厚生病院 看護部), 佐藤 千秋, 鼻和 真由美, 金元 信子 Source: 北海道農村医学会雑誌 (1341-4666)46巻 Page64-68(2014.03)	3:対照群のある観察研究	前後比較研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の術後に回復期病院に転院した患者。パス導入前の70人、導入後の113人(内パス適用76人、非適用37人)	3:安全と間接的に関係するその他の測定可能なアウトカム	平均在院日数	パス導入前と導入後(パス適用群)で、平均在院日数が短縮した(37.2日、31.1日、P<0.05)。パス導入前と導入後もパス非適用の群は有意差なし。	受け入れ施設側の空き状況に影響される。		
28	当院における大腿骨近位部骨折に対する地域連携パスを利用した治療の検討(原著論文) Author:一ノ瀬 初美(磐田市立総合病院 整形外科), 山崎 薫, 森本 祥隆, 猿川 潤一郎, 鈴木 大輔, 錦野 匠一 Source: 中部日本整形外科災害外科学会雑誌 (0008-9443)57巻1号 Page33-34(2014.01)	3:対照群のある観察研究	前後比較研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療を行った患者。パス導入前の139人、導入後の169人	3:安全と間接的に関係するその他の測定可能なアウトカム	平均在院日数、手術から退院までの日数、退院後急性期病院で経過観察した日数、退院時の骨粗しょう症薬処方頻度	パス導入前と導入後で、平均在院日数(43.2日、25.6日、P<0.01)、手術から退院までの日数(36.6日、18.9日、P<0.01)、退院後急性期病院で経過観察した日数(6.9か月、3.5か月、P<0.01)が短縮した。退院時の骨粗しょう症薬の処方率が減少した(13%、5%、P<0.05)。			
29	大腿骨近位部骨折における地域連携クリニカルパスの有用性(原著論文) Author:井出 浩一郎(静岡市立静岡病院 整形外科), 佐野 倫生, 松原 隆将, 松下 聡, 青木 健太郎, 清水 朋彦 Source: 中部日本整形外科災害外科学会雑誌 (0008-9443)57巻1号 Page31-32(2014.01)	3:対照群のある観察研究	前後比較研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療を行った患者。パス導入前の238人、導入後の742人	3:安全と間接的に関係するその他の測定可能なアウトカム	在院日数、手術待機日数、包括点数、整形外科医の仕事量(年間手術件数等)	パス導入前と導入後で、在院日数(33.2日、25.7日、P<0.01)、包括点数(61000点、51000点、P<0.01)が減少した。手術待機日数に有意差なし。年間平均手術件数と延入院件数は増加したが、整形外科医1人・1日当たりの入院患者数は7.1人から6.1人に減少した(検定なし)。	病床回転率は上昇するが、病床稼働率は低下する。		
30	当院における大腿骨近位部骨折地域連携パス導入効果の評価判定(原著論文) Author:盛房 周平(洛和会丸太町病院 整形外科), 原田 智久, 末原 洋, 牧 昌弘 Source: 京都医学会雑誌 (0453-0039)60巻1号 Page5-8(2013.06	3:対照群のある観察研究	前後比較研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療を行った患者。パス導入前の69人、導入後の78人	3:安全と間接的に関係するその他の測定可能なアウトカム	在院日数	パス導入前と導入後で比較し、在院日数は短縮した(68.5日、26.0日、P<0.01)。			

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
31	地域連携クリティカルパスを使用した乳がん診療における患者満足度(原著論文) Author:丹内 智美(千葉県がんセンター 地域医療連携室), 浜野 公明, 佐々木 美奈子, 比江島 欣慎, 坂本 すが Source: 日本医療マネジメント学会雑誌 (1881-2503)14巻1号 Page2-8(2013.05)	3:対照群のある観察研究	横断的研究	地域連携パス(乳がん検診)	がん診療連携拠点病院で乳がん手術を受けた患者385人(回収後、拠点病院継続群151人、地域連携群86人)	3:安全と間接的に関係するその他の測定可能なアウトカム	患者満足度	地域連携群は拠点病院継続群と比較し、通院時間が短く、診察待ち時間が短く、通院頻度が多く、通院しやすさの満足度が高く、乳がん以外の診療を受けている割合が高く、診療に対する満足度が高かった。多変量解析により、乳がん診療総合的満足度の点数は、地域連携パスを用いた地域連携と有意な関係を認めた。			
32	大腿骨近位部骨折地域連携パス導入効果の評価(原著論文) Author:盛房 周平(洛和会丸太町病院 整形外科), 原田 智久, 末原 洋, 牧 昌弘 Source: 洛和会病院医学雑誌 (1341-1845)24巻 Page47-50(2013.03)	3:対照群のある観察研究	前後比較研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療を行った患者。パス導入前の69人、導入後の78人	3:安全と間接的に関係するその他の測定可能なアウトカム	在院日数	パス導入前と導入後を比較すると在院日数が短縮した(68.5日、26.0日、P<0.01)。			
33	虚血性心疾患・地域連携クリティカルパス使用がかかりつけ医の患者指導に及ぼす効果(原著論文) Author:川本 俊治(国立病院機構呉医療センター 循環器科), 松田 守弘, 田村 律, 渡辺 弘司 Source: 日本医療マネジメント学会雑誌 (1881-2503)13巻4号 Page180-184(2013.03)	3:対照群のある観察研究	横断的研究	地域連携パス(虚血性心疾患)	呉市医師会員のうち内科を標榜している医師235人(回収後、パスを持参した患者を診療した経験のある医師が33人、診療経験のない医師が45人)	3:安全と間接的に関係するその他の測定可能なアウトカム	虚血性心疾患に対する各種指導の実施の有無	パスを持参した患者を診療した経験のある医師は、経験のない医師より、コレステロール値や血糖値の目標値の指導、肉や酪農製品の制限の指導、魚介類の摂取の指導等を実施する頻度が高い傾向にあった。(経験ありは経験数により3群に分けられているが、経験なしとの多重比較は無し。)			統計手法に問題あり。
34	当院における大腿骨近位部骨折の状況　地域連携パスの導入前後を比較して(原著論文) Author:浅川 俊輔(山梨県立中央病院 整形外科), 藤原 三郎, 千野 孔三, 瀬戸 宏明, 岩瀬 弘明, 佐久間 陸友, 分島 智子, 伊坂 陽, 原田 将太 Source: 山梨医学 (0912-2958)40巻 Page114-116(2012.10)	3:対照群のある観察研究	前後比較研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療を行った患者。パス導入前の63人、導入後の62人	3:安全と間接的に関係するその他の測定可能なアウトカム	術前待機日数、入院日数、術後入院日数	パス導入前と導入後を比較し、術前待機日数は短縮したが(4.6日、3.1日、P=0.02)、入院日数と術後入院日数は有意差が認められなかった。			

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
35	八重山地域における地域連携パス導入の効果　大腿骨頸部骨折パス導入後1年を経過して(原著論文) Author:東嘉彌真 愛子(沖縄県立八重山病院), 次呂久 睦子, 滝 綾子, 平良 美江 Source: 沖縄県看護研究学会集録(1882-4986)26回 Page107-110(2010.12)	3:対照群のある観察研究	前後比較研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療を行った患者。パス導入前の65人、導入後の76人	3:安全と間接的に関係するその他の測定可能なアウトカム	平均在院日数、転院調整日数、等	検定なし。パス導入前と導入後を比較すると、平気在院日数は短縮傾向(47.4日、36.1日)、転院調整日数は短縮傾向(13.7日、8.8日)であった。			
36	当院の大腿骨近位部骨折症例における地域連携クリニカルパスの運用状況(原著論文) Author:白木 誠(佐賀県立病院好生館 整形外科), 野口 康男, 久保 祐介, 泉 政寛, 永野 賢, 井口 貴裕, 佐々木 宏介, 前 隆男, 佛坂 俊輔, 力丸 俊一 Source: 整形外科と災害外科(0037-1033)60巻3号 Page483-487(2011.09)	3:対照群のある観察研究	症例対照研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療を行った患者。パスを適用した226人、パス非適用の225人	3:安全と間接的に関係するその他の測定可能なアウトカム	在院日数	パス適用群は非適用群よりも在院日数が短かった(26.5日、31.7日、P<0.01)。骨接合群と人工骨頭置換術で層別化しても同様の結果であった。			
37	当院における大腿骨近位部骨折・地域連携クリティカルパス活用状況の検討(原著論文) Author:藤井 淳一(尾道市立市民病院 整形外科), 廣岡 孝彦, 小瀬 靖郎, 東條 好憲, 井代 愛 Source: 中部日本整形外科災害外科学会雑誌 (0008-9443)53巻3号 Page621-622(2010.05)	3:対照群のある観察研究	前後比較研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療を行った患者。パス導入前1年間の126人、導入後1年間の161人、導入後2年目の136人	3:安全と間接的に関係するその他の測定可能なアウトカム	急性期在院日数	急性期在院日数は、導入前が27.8日、導入後1年目が23.7日、導入後2年目が24.9日であった(検定なし)。			比較に検定を用いていない。
38	大腿骨頸部骨折地域連携パス導入の効果(原著論文) Author:上田 康博(福井県立病院 整形外科), 松井 貴至, 三崎 智範, 山内 健輔, 野村 一世, 村田 淳 Source: 日本臨床整形外科学会雑誌 (1881-7149)35巻1号 Page163-166(2010.04)	3:対照群のある観察研究	前後比較研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療を行った患者。パス導入前の99人、導入後の125人(内、連携パス適用は52人)	3:安全と間接的に関係するその他の測定可能なアウトカム	術後転院までの日数、総在院日数、等	比較できるデータの提示なし。パス導入前のアウトカムは術式で分けていないが、導入後のアウトカムは術式で分けたものしか提示されていない。検定なし。			結果の記載が不十分であり導入効果を評価できない。比較に検定を用いていな

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39	脳梗塞患者における回復期リハビリテーション病院への診療情報提供書の記載情報　地域連携パスの導入前後の比較(原著論文) Author:木村 怜子(熊本機能病院 作業療法課), 徳永 誠, 桑田 稔丈, 木原 誓子, 米村 美樹, 中島 雪彦, 橋本 洋一郎 Source: 総合リハビリテーション (0386-9822)38巻2号 Page179-182(2010.02)	3:対照群のある観察研究	前後比較研究	地域連携パス(脳卒中)	脳梗塞の治療を受けた患者。パス導入前125人、導入後78人	3:安全と間接的に関係するその他の測定可能なアウトカム	急性期病院から回復期病院への診療情報提供書の記載項目(臨床病型、責任病巣、MRI結果、頸部血管エコー検査結果、ホルター心電図結果、心エコー結果、PT-INR結果)	診療情報提供書の項目別の記載割合をパス導入前と導入後で比較すると、ホルター心電図(35.2%、65.4%、P<0.01)、心エコー(35.2%、80.8%、P<0.01)、PT-INR(64.3%、96.6%、P<0.01)の記載率が上昇した。			
40	糖尿病眼手帳の5年間推移(原著論文) Author:船津 英陽(東京女子医科大学附属八千代医療センター 眼科), 堀 貞夫, 福田 敏雅, 宮川 高一, 山口 直人 Source: 日本眼科学会雑誌 (0029-0203)114巻2号 Page96-104(2010.02)	3:対照群のある観察研究	前後比較研究	連携手帳(糖尿病眼)	10道県の眼科医2907人、内科医3432人	3:安全と間接的に関係するその他の測定可能なアウトカム	医師の眼手帳の認知度、診療連携の改善感、等	2003年と2008年のアンケートの結果を病院/診療所、眼科/内科別に比較。病院の内科医を除き、眼手帳の認知度が上昇した。眼手帳により診療連携が改善したと回答する割合は、診療所の眼科医のみで増加した。眼手帳により眼科受診中断・放置が減少したと感じる割合は、診療所の眼科医、内科医では増加したが、病院の眼科医、内科医は有意差がなかった。	眼手帳ではなく、健康手帳を利用する医師が少なくない。眼手帳を患者が持参しないので利用されない。		
41	大腿骨近位部骨折地域連携クリニカルパス導入における急性期リハビリテーションの変化(原著論文) Author:高橋 勇二(聖隷浜松病院), 大野 綾, 西村 立, 中野 淳子, 竹内 利之 Source: 聖隷浜松病院医学雑誌 (1346-9045)9巻2号 Page1-5(2009.12)	3:対照群のある観察研究	前後比較研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療を行った患者。パス導入前の安定型の患者15人、人工骨頭置換術の患者12人、導入後の安定型の患者24人、人工骨頭置換術の患者20人	3:安全と間接的に関係するその他の測定可能なアウトカム	急性期在院日数、術後入院日数、患者1人当たりの実施リハビリ単位数、9か月間の総実施リハビリ単位数	パス導入前と導入後を比較すると、安定型群、置換術群とも総在院日数が短縮した(30.9日、19.0日、P<0.01)(31.6日、20.2日、P<0.01)。術後入院日数も同様の結果。患者1人当たり実施リハビリ単位数は、両群とも減少した(28.8単位、17.1単位、P<0.01)(24.8単位、18.0単位、P<0.01)。	導入前と導入後で、9か月間の総実施リハビリ単位数は増加傾向にある(730単位/27人→770単位/44人)。回転率が上昇し、リハ科の業務量が増加した。		

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42	大腿骨近位部骨折の病診連携パスとリハビリの問題点 地域連携クリニカルパスによる大腿骨近位部骨折の治療予後の検討と骨粗鬆症治療の現状(原著論文) Author:大西 和友(聖隷浜松病院 骨・関節外科), 森 諭史, 近藤 尚, 中山 崇, 竹内 利之, 池田 昇, 小松 由樹, 花木 ひとみ Source: Osteoporosis Japan (0919-6307)17巻3号 Page428-431(2009.07)	3:対照群のある観察研究	症例対照研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療を行った患者。パス適用98人、非適用70人	3:安全と間接的に関係するその他の測定可能なアウトカム	急性期在院日数、総在院日数、在宅復帰率、等	パス適用群は不適用群よりも急性期在院日数が短かったが(16.4日、32.6日、P<0.01)、総在院日数は有意差がなかった(53.0日、56.0日)。在宅復帰率は両群で有意差なし(86.1%、76.8%)。			
43	大腿骨近位部骨折における早期退院の方策 大腿骨近位部骨折患者への地域連携クリティカルパス導入の入院期間への効果(原著論文) Author:大はた 武夫(東住吉森本病院 整形外科), 久保 隆彦, 乾 健太郎, 多田 昌弘 Source: Hip Joint (0389-3634)34巻 Page81-83(2008.11)	3:対照群のある観察研究	症例対照研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療を行った患者のうち受傷前が独歩または杖歩行であった患者。パス適用14人(認知症、内科合併症なし)、非適用187人(それ以外)	3:安全と間接的に関係するその他の測定可能なアウトカム	急性期在院日数	急性期在院日数は、パス適用群が24.1日、非適用群が36.1日であった(検定なし)。			
44	骨粗鬆症地域連携クリティカルパスを組み合わせた大腿骨頸部骨折に対する地域医療ネットワークの構築(原著論文) Author:山口 徹(足利赤十字病院 整形外科), 本庄 宏, 浦部 忠久 Source: 日本医療マネジメント学会雑誌 (1881-2503)9巻4号 Page535-540(2009.03)	3:対照群のある観察研究	前後比較研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療を行った患者。パス導入前の511人、導入後の92人(内、パス適用は26人)	3:安全と間接的に関係するその他の測定可能なアウトカム	急性期在院日数	パス導入前と導入後を比較すると、急性期在院日数が短縮した(38日、32日、P<0.05)。リハビリ目的の転院が増加傾向にあった(16.6%、31.5%、検定なし)。			
45	地域連携パスに伴う家族の不安に対するパンフレットの有効性の検討(原著論文) Author:児玉 美由紀(山口県済生会下関総合病院), 加藤 留美, 萩原 尚美 Source: 日本看護学会論文集: 看護総合 (1347-815X)39号 Page284-285(2008.12)	3:対照群のある観察研究	横断的研究	地域連携パス(大腿骨近位部骨折)の説明用パンフレットの使用	大腿骨近位部骨折の治療を行った患者の家族。従来通りパスを用いて口頭説明した家族16人、パスとパンフレットを用いて説明した家族9人	3:安全と間接的に関係するその他の測定可能なアウトカム	説明の理解度、転院時期の適切さ、転院の説明時期の適切さ、転院への不安感統への家族の評価	従来説明群とパンフレット使用群を比較すると、パンフレット使用群の方が転院への不安が軽減されていた(評価点が有意に高かった)。			サンプル数少ない。統計手法に問題あり。

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
46	大腿骨頸部骨折地域連携パスの使用実績(原著論文) Author:小久保 吉恭(武蔵野赤十字病院 整形外科), 山崎 隆志, 佐藤 茂, 山内 真恵 Source: 日本クリニカルパス学会誌 (2187-6592)10巻2号 Page85-90(2008.06)	3:対照群のある観察研究	症例対照研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療後に転院した患者。パスを適用した19人、パス非適用の51人	3:安全と間接的に関係するその他の測定可能なアウトカム	急性期在院日数	急性期在院日数は、パス適用者が非適用者よりも短かった(19.5日、29.3日、P<0.01)。			
47	大腿骨頸部骨折における地域連携クリニカルパスの有用性(原著論文) Author:酒井 清司(富山赤十字病院 整形外科), 清水 一夫, 山上 亨, 中村 宏, 田原 徳人, 八野田 純 Source: 骨折 (0287-2285)30巻1号 Page154-156(2008.02)	3:対照群のある観察研究	症例対照研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療を行った患者。パスを適用した99人、非適用の51人	3:安全と間接的に関係するその他の測定可能なアウトカム	術後在院日数	術後在院日数は、パス適用群が21日、非適用群が25日であった(検定なし)。			
48	地域連携パス使用に伴う患者・家族の不安に対してパンフレットを用いた効果(原著論文) Author:萩原 尚美(済生会下関総合病院), 松江 麻希, 加藤 留美, 児玉 美由紀 Source: 済生会下関総合病院院内看護研究集録 平成19年度 Page17-21(2007.12)	3:対照群のある観察研究	横断的研究	地域連携パス(大腿骨近位部骨折)の説明用パンフレットの使用	大腿骨近位部骨折の治療を行った患者の家族。従来通りパスを用いて口頭説明した家族16人、パスとパンフレットを用いて説明した家族9人	3:安全と間接的に関係するその他の測定可能なアウトカム	説明の理解度、転院時期の適切さ、転院の説明時期の適切さ、転院への不安感統への家族の評価	従来説明群とパンフレット使用群を比較すると、パンフレット使用群の方が転院への不安が軽減されていた(評価点が有意に高かった)。			サンプル数少ない。統計手法に問題あり。(45番と同じ内容(重複投稿))
49	当院における大腿骨近位部骨折に対する地域連携クリティカルパスの経験(原著論文) Author:大はた 武夫(東住吉森本病院 整形外科), 久保 隆彦, 前田 剛, 多田 昌弘, 乾 健太郎, 恵木 丈 Source: 中部日本整形外科災害外科学会雑誌 (0008-9443)50巻5号 Page895-896(2007.09)	3:対照群のある観察研究	症例対照研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療を行った患者。パスを適用した8人、非適用の86人	3:安全と間接的に関係するその他の測定可能なアウトカム	急性期在院日数、在宅医療への移行率、等	検定なし。急性期在院日数は、パス適用群が28.0日、非適用群が34.7日であった。在宅医療への移行率は、パス適用群が87.5%、非適用群が45.4%であった。			

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
50	大腿骨近位部骨折の地域連携クリニカルパスの試み(原著論文) Author:野口 康男(佐賀県立病院好生館 整形外科), 佛坂 俊輔, 前隆男, 江頭 惠美子, 長尾 照子, 古賀 ひとみ, 重富 順子, 橋本 広子, 松本 尚子 Source: 日本クリニカルパス学会誌(2187-6592)9巻2号 Page135-141(2007.05)	3:対照群のある観察研究	症例対照研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の術後に転院した患者。パスを適用した17人、非適用の26人	3:安全と間接的に関係するその他の測定可能なアウトカム	急性期在院日数	パス適用群は非適用群より急性期在院日数が短かった(28.5日、37.1日、P<0.05)。			
51	地域連携パスを用いた大腿骨近位部骨折の治療成績(原著論文) Author:西田 公明(済生会熊本病院 整形外科), 川谷 洋右, 岩本 克也, 國武 克彦, 堤 康次郎, 山田 正寿 Source: 骨折 (0287-2285)30巻1号 Page151-153(2008.02)	3:対照群のある観察研究	症例対照研究	地域連携パス(大腿骨近位部骨折)	大腿骨近位部骨折の治療を行い、リハビリ病院へ転院した患者。連携パスA群(回復期病棟あり)85人、連携パスB群(回復期病棟なし)115人、パス非適用群84人	3:安全と間接的に関係するその他の測定可能なアウトカム	総在院日数、在宅復帰率、等	人工骨頭置換術の総在院日数は、3群間で有意差なし。骨接合術の総在院日数は、A群がパス非適用群より長かった(88日、64日、P<0.05)。在宅復帰率は、A群がB群より高かった(96%、78%、P<0.05)。			

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
＜英文論文＞											
1	Le Berre M, Maimon G, Sourial N, Guériton M, Vedel I. Impact of Transitional Care Services for Chronically Ill Older Patients: A Systematic Evidence Review. J Am Geriatr Soc. 2017 Jul.	1A:システマティックレビューまたはメタアナリシス	メタアナリシス	Transitional care interventions (① elements aimed at providing coordination and continuity of care; ② pre-arranged structured post-discharge follow-up (e.g., home visits, phone calls); ③ at least one follow-up starting within 30-days post-discharge)	From 10,234 references, 92 studies were included.	1:臨床アウトカム	Mortality rate, rate of ED visits, rate of readmissions.	Compared to usual care, significantly better outcomes were observed: ① a lower mortality at 3, 6, 12 and 18 months post-discharge ② a lower rate of ED visits at 3 months ③ a lower rate of readmissions at 3, 6, 12 and 18 months ④ a lower mean of readmission days at 3, 6, 12 and 18 months	None.	None.	None.
2	Kansagara D, Chiovaro JC, Kagen D, Jencks S, Rhyne K, O'Neil M, Kondo K, Relevo R, Motu'apuaka M, Freeman M, Englander H. So many options, where do we start? An overview of the care transitions literature. J Hosp Med. 2016 Mar	1A:システマティックレビューまたはメタアナリシス	システマティックレビュー	Transitional care interventions (① discharge planning, ② hospital-at-home interventions, ③ medication reconciliation intervention, ④ postdischarge follow-up calls, ⑤ postdischarge monitoring)	17 systematic reviews PubMed and Cochrane Database of Systematic Reviews (January 1950-May 2014), reference lists, nd technical advisors.	2:代替アウトカム	Hospital readmission.	Among 10 reviews of mixed patient populations, there was consistent evidence that enhanced discharge planning reduced readmissions. Among 7 reviews in specific patient populations, transitional care interventions reduced readmission in patients with congestive heart failure and general medical populations. In general, interventions that reduced readmission addressed multiple aspects of the care transition extended beyond hospital stay, and had the flexibility to accommodate individual patient needs.	None.	None.	None.

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
3	Moore AB, Krupp JE, Dufour AB, Sircar M, Travison TG, Abrams A, Farris G, Mattison MLP, Lipsitz LA. Improving Transitions to Postacute Care for Elderly Patients Using a Novel Video-Conferencing Program: ECHO-Care Transitions. Am J Med. 2017 Oct	2:非無作為化比較試験	非無作為化比較試験	Weekly video-conference sessions between the hospital and skilled nursing facility care teams	All patients discharged in 2014 from the hospital to a skilled nursing facility for short-term rehabilitation. there were 148 patients in the intervention group and 214 in the comparison group, such that a total of 362 individuals were eligible for analyses.	1:臨床アウトカム	Thirty-day readmission rates, 30-day total health care cost, average length of stay,30-day mortality rate.	1. Thirty-day readmission rates were significantly lower in the intervention group (odds ratio 0.57, P 0.04), 2. 30-day total health care cost was significantly lower in the intervention group($2602.19 lower, P <.001) 3. average length of stay at the skilled nursing facility (P <.001)	None.	It was estimate that yearly operational costs of the program are $300 per patients.	None.
4	Karapinar-Çarkıt F, van der Knaap R, Bouhannouch F, Borgsteede SD, Janssen MJA, Siegert CEH, Egberts TCG, van den Bemt PMLA, van Wier MF, Bosmans JE. Cost-effectiveness of a transitional pharmaceutical care program for patients discharged from the hospital. PLoS One. 2017 Apr 26.	3:対照群のある観察研究	前後比較研究	A transitional care program that consists of medication reconciliation, patient counselling at discharge, and communication to healthcare providers in primary care	Total 319 patients (168 patients COACH and 151 patients usual care). Usual care patients were included during an eight months period (April 2009-November 2009). During the next 3.5 months the intervention was implemented (December 2009-March 2010). Intervention patients were included during a nine months period from March 2010 to December 2010.	2:代替アウトカム	Unplanned rehospitalisations.	There was no significant difference in the proportion of patients with unplanned rehospitalisations and in QALYs. Total costs for the COACH program were non-significantly lower than usual care.	None.	Based on a gross mean year salary of €50.000, assuming 46 annual working weeks and an efficiency rate of 70%, the labour costs for the intervention were € 41.04/patient.	None.

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
5	542: Usher MG, Fanning C, Wu D, Muglia C, Balonze K, Kim D, Parikh A, Herrigel D. Information handoff and outcomes of critically ill patients transferred between hospitals. J Crit Care. 2016 Dec	3:対照群のある観察研究	症例対照研究	Handoff documentation completeness	335 patients directly transferred to RobertWood Johnson University Hospital (RWJUH) ICU from outside hospital critical care units or emergency departments (EDs) between December 1, 2011, and December 31, 2012	1:臨床アウトカム	In-hospial mortality, adverse events	Transfer documentation was frequently absent with overall completeness of 58.3%. Adverse events occurred in 42% of patients within 24 hours of arrival, with an overall in-hospital mortality of 17.3%. Higher documentation completeness was associated with reduced in-hospital mortality (OR=0.07; P = 0.002), reduced adverse events (P< 0.001), and reduced duplication of labor (OR=0.19; P = 0.033) when controlling for severity of illness.	None.	None.	None.
6	1014: Hamar B, Rula EY, Wells AR, Coberley C, Pope JE, Varga D. Impact of a scalable care transitions program for readmission avoidance. Am J Manag Care. 2016 Jan	3:対照群のある観察研究	コホート研究	A transitional care program (CTS) that consists of patient education, discharge planning/preparation, post-dischage follow-up and care coordination	All patients (4638) admitted to 1 of the 14 evaluated hospitals during January to July 2013 and diagnosed to have at least AMI, HF, COPD or pneumonia. 3900 patients were matched study population. 560 in the treatment group and 3340 in the comparison group.	2:代替アウトカム	30 day readmission and all readmissions occurring within 6 months.	Significantly lower rates of all readmissions (p=0.006) and 30 day readmission (p=0.01) in the intervention group.	None.	None.	None.

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
7	Ulin K, Olsson LE, Wolf A, Ekman I. Person-centred care - An approach that improves the discharge process. Eur J Cardiovasc Nurs. 2016 Apr	3:対照群のある観察研究	前後比較研究	A transitional care program (gPCC) that consists of discharge planning and providing sufficient information to the municipal home care service or to the primary healthcare service	248 hospitalized Swedish patients with chronic heart failure (CHF) during the period of February 2008 to April 2010 were included, 123 in the usual care group and 125 in the gPCC intervention.	3:安全と間接的に関係するその他の測定可能なアウトカム	The number of days from admission to the communication with the municipal home care service or the primary healthcare service	During hospitalization, the number of days from admission to notices to the patients' municipal home-care services and/or round-the-clock home nursing care services for confirmed discharge planning conferences decreased significantly (p=0.03) in the per-protocol gPCC group compared with the usual care group. The proportion of patients who were able to return to independent living was increased in the per-protocol gPCC group (95.9%) compared with the usual care group (90.6%) at discharge from hospital. The length of stay in hospital and the time to the third notification to the patients' municipal home-care services and/or round-the-clock home nursing care services were significantly decreased: 6.77 days in the per-protocol gPCC group compared with 9.22 days in the usual care group ($p<0.01$), and 11 days in the per-protocol gPCC group compared with 35 days in the usual care group (p=0.01), respectively.	None.	None.	None.

超音波ガイド下中心静脈カテーテル挿入(Ultrasound guidance for central catheterization)

資料5-2

＜和文論文＞

シソーラスの探索

①	中心静脈カテーテルと超音波診断を検索し、該当する用語を抽出
②	得られたシソーラスで再検索し、関連のあるシソーラスを抽出
③	②を繰り返し、文献のタイトルと抄録からシソーラスを確認し、「中心静脈カテーテル法」「超音波診断」が文献に含まれていることを確認

検索式と絞り込みの過程

	検索式	件数	検索日
医中誌WEB	**(中心静脈カテーテル法/TH)** and (PT=会議録除く)	2,822	2018/1/22
	(超音波診断/TH) and (PT=会議録除く)	97,773	2018/1/22
	(中心静脈カテーテル法/TH and [超音波診断]/TH) and (PT=会議録除く)	318	2018/1/22
	(中心静脈カテーテル法/TH and [超音波診断]/TH) and (PT=症例報告除く) and (PT=会議録除く) and CK=ヒト	58	2018/1/22
絞り込み	タイトルと抄録	10	
	本文	5	

研究デザインとアウトカムのレベル

		アウトカムレベル				
		1:臨床アウトカム	2:代替アウトカム	3:安全と間接的に関係するその他の測定可能なアウトカム	4:エラーや有害事象の減少に寄与するアウトカムがない	計
研究デザインレベル	1A:システマティックレビューまたはメタアナリシス	0	0	0	0	0
	1:無作為化比較試験	0	0	0	0	0
	2:非無作為化比較試験	0	0	0	0	0
	3:対照群のある観察研究	2	3	0	0	5
	4:対照群のない観察研究	0	0	0	0	0
	計	2	3	0	0	5

介入の内容と研究デザインレベル

		論文数	1A:システマティックレビューまたはメタアナリシス	2:非無作為化比較試験	3:対照群のある観察研究
	CV挿入(超音波ガイド法とランドマーク法の比較)	3	0	0	3
	CV挿入(認定医制度導入前後の比較)	1	0	0	1
	CV挿入(超音波導入前後の比較)	1	0	0	1
合計		5	0	0	5

介入の内容とアウトカムのレベル

		論文数	アウトカムのレベル			アウトカムの指標		
			1:臨床アウトカム	2:代替アウトカム	3:安全と間接的に関係するその他の測定可能なアウトカム	1:臨床アウトカム	2:代替アウトカム	3:安全と間接的に関係するその他の測定可能なアウトカム
	CV挿入(超音波ガイド法とランドマーク法の比較)	3	1	2	0	合併症発生率	カテーテルの位置異常率、カテーテル留置の成功率	平均所要時間
	CV挿入(認定医制度導入前後の比較)	1	0	1	0		インシデント発生率、穿刺回数	超音波ガイド下施行率、CV挿入に要した時間
	CV挿入(超音波導入前後の比較)	1	1	0	0	合併症	穿刺回数	挿入所要時間
合計		5	2	3	0			

＜英文論文＞

MeSH termsの探索

①	"Catheterization"、"Catheters, indwelling"、"Ultrasonography"で検索し、得られた論文のMeSH termsを抽出
②	先行研究のAHRQ、コクランレビューで使用されている、論文のMeSH termsを抽出
③	①②で得られたMeSH termsで再検索し、関連のあるMeSH termsを抽出
④	③で得られたMeSH term13個について、ツリー構造を確認し、6個に絞り込んだ。

検索式と絞り込みの過程

	検索式	件数	検索日
PubMed	"catheterization"[MeSH Terms]	183,974	2018/3/1
	"catheters, indwelling"[MeSH Terms]	17,557	2018/3/1
	"ultrasonography"[MeSH Terms]	393,052	2018/3/1
	"jugular veins"[MeSH Terms]	10,753	2018/3/1
	"subclavian vein"[MeSH Terms]	4,326	2018/3/1
	"femoral vein"[MeSH Terms]	7,875	2018/3/1
	上記を全てORで連結	577,842	2018/3/1
	<Catheters> ((((("catheterization"[MeSH Terms]) OR "catheters, indwelling"[MeSH Terms]) AND "jugular veins"[MeSH Terms]) OR "subclavian vein"[MeSH Terms]) OR "femoral vein"[MeSH Terms]	14,672	2018/3/1
	<Ultrasonography> "ultrasonography"[MeSH Terms]	393,052	2018/3/1
	上記の<Catheters>と<Ultrasonography>をANDで連結	2,179	2018/3/1
	絞り込み		
	((((("catheterization"[MeSH Terms] OR "catheters, indwelling"[MeSH Terms]) AND "jugular veins"[MeSH Terms]) OR "subclavian vein"[MeSH Terms]) OR "femoral vein"[MeSH Terms]) AND "ultrasonography"[MeSH Terms] AND ("humans"[MeSH Terms] AND English[lang])	1,784	2018/3/1
	研究デザインを加えてさらに絞り込み		
	((((("catheterization"[MeSH Terms] OR "catheters, indwelling"[MeSH Terms]) AND "jugular veins"[MeSH Terms]) OR "subclavian vein"[MeSH Terms]) OR "femoral vein"[MeSH Terms]) AND "ultrasonography"[MeSH Terms] AND ("humans"[MeSH Terms] AND English[lang]) AND ("Meta-Analysis as Topic"[Mesh] OR "Controlled Clinical Trials as Topic"[Mesh] OR "Case-Control Studies"[Mesh] OR "Cohort Studies"[Mesh] OR "Cross-Sectional Studies"[Mesh] OR "Observational Studies as Topic"[Mesh] OR Meta-Analysis[ptyp] OR systematic[sb] OR Controlled Clinical Trial[ptyp] OR Observational Study[ptyp] OR Comparative Study[ptyp])	814	2018/3/1
	※過去5年に絞って検索（Cochrane Library のシステマティックレビュー論文が2013年までを対象として実施しており、それ以降の文献における知見について検討） ((((("catheterization"[MeSH Terms] OR "catheters, indwelling"[MeSH Terms]) AND "jugular veins"[MeSH Terms]) OR "subclavian vein"[MeSH Terms]) OR "femoral vein"[MeSH Terms]) AND "ultrasonography"[MeSH Terms] AND ("humans"[MeSH Terms] AND English[lang]) AND ("Meta-Analysis as Topic"[Mesh] OR "Controlled Clinical Trials as Topic"[Mesh] OR "Case-Control Studies"[Mesh] OR "Cohort Studies"[Mesh] OR "Cross-Sectional Studies"[Mesh] OR "Observational Studies as Topic"[Mesh] OR Meta-Analysis[ptyp] OR systematic[sb] OR Controlled Clinical Trial[ptyp] OR Observational Study[ptyp] OR Comparative Study[ptyp]) AND ("2013/03/1"[PDat] : "2018/03/2"[PDat])	195	2018/3/1
絞り込み	タイトルと抄録	33	2018/3/1
	本文	20	2018/3/1

研究デザインとアウトカムのレベル

		アウトカムレベル				
		1:臨床アウトカム	2:代替アウトカム	3:安全と間接的に関係するその他の測定可能なアウトカム	4:エラーや有害事象の減少に寄与するアウトカムがない	計
研究デザインレベル	1A:システマティックレビューまたはメタアナリシス	2	2	0	0	4
	1:無作為化比較試験	0	7	0	0	7
	2:非無作為化比較試験	0	0	0	0	0
	3:対照群のある観察研究	3	6	0	0	8
	4:対照群のない観察研究	0	1	0	0	1
	計	4	16	0	0	20

介入の内容と研究デザインレベル

		論文数	1A:システマティックレビューまたはメタアナリシス	1:無作為化比較試験	2:非無作為化比較試験	3:対照群のある観察研究
	CVC(US vs LM)	19	4	7	0	8
合計		19	4	7	0	8

*US: Ultrasound, LM: Landmark

介入の内容とアウトカムのレベル

		論文数	アウトカムのレベル			アウトカムの指標		
			1:臨床アウトカム	2:代替アウトカム	3:安全と間接的に関係するその他の測定可能なアウトカム	1:臨床アウトカム	2:代替アウトカム	3:安全と間接的に関係するその他の測定可能なアウトカム
	CVC(US vs LM)	19	4	15	0	Incidence of accidental arterial puncture, Cmplication rate, Inadvertent arterial puncture, Rate of total complication	Correct placement, Rate of real time US, Access time, Success rate, Number of attempt	None
合計		19	4	15	0			

超音波ガイド下中心静脈カテーテル挿入(Ultrasound guidance for central catheterization) 文献一覧

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
＜和文論文＞											
1	中心静脈カテーテル挿入に伴うインシデント発生防止を目指した中心静脈カテーテル挿入施行医認定制度の導入 舛形 尚(香川大学医学部附属病院 医療安全管理部), 豊嶋 克美, 筧 善行, 松本 佐和子, 岡野 圭一, 横見瀬 裕保, 千田 彰一 医療の質・安全学会誌(1881-3658)9巻2号 Page119-123(2014.04)	3:対照群のある観察研究	前後比較研究	CVC挿入施行医認定制度の導入 医師免許取得後6年未満の医師は、1)医療安全管理部などが主催する実技研修の受講、2)CVC挿入介助の経験3回、3)診療科長の推薦を満たすものと定めた(研修医は取得後も指導医のもとで行うことが義務付けられた)。 取得後6年以上の医師は、診療科長の推薦書提出のみでCVC挿入を許可されるものと定めた。 同時に超音波ガイド下中心静脈穿刺を推奨、院内のME機器管理センターに携帯型中心静脈穿刺用超音波装置を設置し、病棟などでのCVC挿入に用いるように推奨した。	導入前6か月のCVC挿入224件、導入後1年間のCVC挿入件数391件	2:代替アウトカム	インシデント発生率、CVC挿入部位、超音波ガイド下施行率、CVC挿入に要した時間・穿刺回数	本制度導入により、インシデント発生率(導入前4.9% vs. 導入後1.3%,p=0.026)、3bインシデント(発生率導入前2.2%、導入後0.3%、p=0.015)とともに低下した。 CVC挿入部位は、内頸静脈穿刺が増加し、鎖骨下静脈穿刺が減少した。超音波ガイド下施行率は、導入前7%、導入後64%に増加したが(p<0.001)、CVC挿入に要した穿刺時間や穿刺回数は変わらなかった。 本制度導入によって穿刺部位に変化が生じたことは、インシデント減少の一因と考えられた。 CVC挿入施行医認定制度の導入はCVC挿入に伴うインシデント減少に有用であった。	不明	なし	
2	リアルタイム超音波ガイド下鎖骨下・腋窩静脈穿刺法の安全性の検討 持田 崇(新潟県立中央病院 麻酔科), 清野 豊, 松田 敬一郎, 芳賀 美奈子, 山本 豪, 森平 貴, 渡辺 逸平 麻酔(0021-4892)63巻1号 Page57-61(2014.01)	3:対照群のある観察研究	症例対照研究	鎖骨下・腋窩静脈への中心静脈カテーテルの留置(リアルタイム超音波ガイド下穿刺法(U群)、ランドマーク法(J群)	2008年1月から2012年3月まで局所麻酔下に鎖骨下・腋窩静脈に中心静脈カテーテル留置を行った355症例	1:臨床アウトカム	合併症の発生率、カテーテル留置の成功率、カテーテル留置不成功の原因、平均手術時間	合併症発生率は、U群1.9%、L群8.7%とU群で有意に少なかった(P=0.005)。動脈穿刺の発生率は、U群1.9%、L群7.2%でU群で有意に低かった。オッズ比は0.200(95%CI 0.058-0.696)であった。RUSG穿刺法は、鎖骨下・腋窩静脈でも機械的合併症が抑えられる。 合併症の内訳は、U群では全て動脈穿刺であり、L群では動脈穿刺の他に気胸や神経損傷などより重篤な合併症が発生していた。 カテーテル留置成功率、手術時間は両群間で有意差はなかった。同方法は、手技の習熟を前提に安全に施行できる。	不明	なし	
3	小児患者におけるリアルタイム超音波ガイド下内頸静脈内挿管の時間消費リスク 従来の2種の技法との比較 (Time-consumption risk of real-time ultrasound-guided internal jugular vein cannulation in pediatric patients: comparison with two conventional techniques)(英語) Yoshida Hitoshi(弘前大学 医学研究科麻酔科学講座), Kushikata Tetsuya, Kitayama Masatou, Hashimoto Hiroshi, Kimura Futoshi, Niwa Hidetomo, Ishihara Hironori, Hirota Kazuyoshi Journal of Anesthesia(0913-8668)24巻4号 Page653-655(2010.08)	3:対照群のある観察研究	症例対照研究	リアルタイム超音波ガイド(USG)、解剖学的指標(AL)、audio-Dopplerガイド(ADG)での挿入	小児の心血管手術を受ける患者の11年間にわたるCV挿入	2:代替アウトカム	挿管の成功率と麻酔導入から挿管までの時間	リアルタイム超音波ガイド(USG:90%)による成功率は、解剖学的指標(AL:76%)あるいはaudio-Dopplerガイド(ADG:74%)より良好で、所要時間はUSG(35.0±13.6分)と、AL(26.7+11.2分)やADG(29.2±8.9分)より長かった。しかし、USGは低体重(5kg未満)の患者の処置時間内で、他の方法より高い成功率を収めた。USGは有意な時間遅延を伴うものの、IJV挿管の最も高い成功率をもたらし、低体重群では時間遅延もなく最も有用であった。	不明	なし	

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
4	当科における中心静脈ライン挿入の臨床的検討 里見 貴史(東京医科大学 口腔外科学講座), 長谷川 温, 渡辺 正人, 三木 保, 千葉 博茂 日本口腔科学会雑誌(0029-0297)58巻4号 Page147-150(2009.09)	3:対照群のある観察研究	前後比較研究	CV挿入術はガイドワイヤーを用いて行い、穿刺の際は、ポータブル血管穿刺用超音波装置を使用。	2004年10月1日から2008年5月31日までのCVライン挿入を行った6913例(2004年10月1日から2005年7月30日までを導入前、2005年8月1日から2008年5月31日までを導入後とした)	1:臨床アウトカム	合併症、穿刺回数、挿入所要時間	合併症(大腿動脈穿刺)については、導入前は、病院全体で9.4%、口腔外科で38.9%であり、導入後は、病院全体で4.2%、口腔外科で4.8%であった。穿刺回数は、導入前平均2.05回、導入後1.73回であった。CV挿入の所要時間は、20分未満が導入前は83%、導入後は74%、21-30分が導入前11%、導入後19%であった。	不明	なし	
5	中心静脈カテーテル先端の正確な設置を確認するための携帯式超音波装置の使用(Use of hand-held ultrasonography to confirm the correct placement of a central venous catheter tip)(英語) Ohta Tomoyuki(聖マリアンナ医科大学附属病院 超音波センター), Tsujimoto Fumio, Nakajima Yasuo, Ohyama Akihiro, Sakamoto Maho, Kishino Akiko, Hamasuna Kazumitsu, Ohno Giichiro, Tsugu Atsushi Journal of Medical Ultrasonics(1346-4523)34巻1号 Page69-72(2007.03)	3:対照群のある観察研究	症例対照研究	中心静脈カテーテル(大腿静脈)を通常の方法(通常群)と、超音波誘導法(超音波群)での挿入。	2003年12月から2005年5月までの大腿静脈へ中心静脈カテーテルの挿入を行った94例。	2:代替アウトカム	カテーテルの位置異常率	超音波群では2名(6.9%)、通常群では19名(29.2%)が位置異常であった。超音波誘導と通常のカテーテル挿入の相対リスクの比は0.23であった。リアルタイム超音波モニタリングは、大腿静脈から挿入した中心静脈カテーテルの位置異常を避けるのに有用と思われた。	不明	なし	

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
＜英文論文＞											
1	Single-Operator Ultrasound-Guided Central Venous Catheter Insertion Verifies Proper Tip Placement. Galante O, Slutsky T, Fuchs L, Smoliakov A, Mizrakli Y, Novack V, Brotfein E, Klein M, Frenkel A, Koifman L, Almog Y. Crit Care Med. 2017 Oct;45(10):e994-e1000. doi: 10.1097/CCM.0000000000002500.	3:対照群のある観察研究	Prospective observational study with historical controls.	Ultrasound-assisted right-sided central venous catheterization or unassisted central catheter insertion	Adult ICUs. 64 consecutive patients undergoing ultrasound-assisted right-sided central venous catheterization compared with 92 serial historic controls who had unassisted central catheter insertion at the same sites.	2:代替アウトカム	Correct placement of the catheter tip determined by postprocedural chest radiography.	The tip was accurately positioned in 59 of 68 patients (86.7%) in the ultrasound-assisted group compared with 51 of 94 (54.8%) in the control group ($p < 0.001$). The median time from end of the procedure to catheter utilization after chest radiography approval was 2.4 hours. A single-operator ultrasound-guided central venous catheter insertion is effective in verifying proper tip placement and shortens time to catheter utilization.	Unknown	None	
2	Accidental arterial puncture during right internal jugular vein cannulation in cardiac surgical patients. Maddali MM, Arun V, Wala AA, Al-Bahrani MJ, Jayatilaka CM, Nishant AR. Ann Card Anaesth. 2016 Oct-Dec;19(4):594-598. doi: 10.4103/0971-9784.191568.	3:対照群のある観察研究	Prospective observational study	USG was used for the right internal jugular vein cannulation or USG was not used	255 consecutive adult and pediatric cardiac surgical patients were included. In Group I (n = 124) USG was used for the right internal jugular vein cannulation and in Group II (n = 81) it was not used. There were 135 adult patients and 70 pediatric patients.	1:臨床アウトカム	Iincidence of accidental arterial puncture during right internal jugular vein (RIJV) cannulation with and without ultrasound guidance (USG) if USG improves the chances of successful first pass cannulation and if BMI has an impact on incidence of arterial puncture and the number of attempts that are to be made for successful	The overall incidence of accidental arterial puncture in the entire study population was significantly higher when ultrasound guidance was not used (P< 0.001). In subgroup analysis, incidence of arterial puncture was significant in both adult (P = 0.03) and pediatric patients (P< 0.001) without USG. First attempt cannulation was more often possible in pediatric patients under USG (P = 0.03). In adult patients USG did not improve first attempt cannulation except in underweight patients. USG helped in the avoidance of inadvertent arterial puncture during RIJV cannulation and simultaneously improved the chances of first attempt cannulation in pediatric and in underweight adult cardiac surgical patients.	Unknown	None	
3	Real-time ultrasonography for placement of central venous catheters in children: A multi-institutional study. Gurien LA, Blakely ML, Russell RT, Streck CJ, Vogel AM, Renaud EJ, Savoie KB, Dassinger MS; Pediatric Surgery Research (PedSRC) Collaborative.. Surgery. 2016 Dec;160(6):1605-1611. doi: 10.1016/j.surg.2016.05.019. Epub 2016 Jul 25.	3:対照群のある観察研究	Retrospective cohort study	Landmark technique(LM) vs real-time ultrasonography(RTUS)	Using data gathered from 14 institutions, patients <18 years old who underwent central venous catheter placement. Patient demographics and operative details were collected. n=1134(total) , n=774(LM) and n=360(RTUS)	1:臨床アウトカム	The rate of mechanical complications, The procedural success rates on first-site attempt,	Real-time ultrasonography was less likely to be used for subclavian vein (odds ratio = 0.002; P < .0001) and more likely to be used when coagulopathy (international normalized ratio >1.5) was present (odds ratio = 11.1; P = .03). The rate of mechanical complications was 3.5%. Real-time ultrasonography use was associated with greater procedural success rates on first-site attempt, but also with a greater risk of hemothorax. Pediatric surgeons access preferentially the subclavian vein for central venous access, yet are less likely to use real-time ultrasonography at this site. Real-time ultrasonography was superior to the landmark techniques for the first-site procedure success, yet was associated with greater rates of hemothorax.	Unknown	None	
4	Ultrasound-guided cannulation of the femoral vein in electrophysiological procedures: a systematic review and meta-analysis. Sobolev M, Shiloh AL, Di Biase L, Slovut DP. Europace. 2017 May 1;19(5):850-855. doi: 10.1093/europace/euw113. Review.	1A:システマティックレビューまたはメタアナリシス	Systematic review and meta-analysis	Ultrasound group vs palpation group	A comprehensive literature search of Medline, Embase, Google Scholar, and the Cochrane Central Register of Controlled Trials was performed. Five years of conference abstracts from the Heart Rhythm Society, European Heart Rhythm Association, and European Cardiac Arrhythmia Society were reviewed. Four trials, with a total of 4065 subjects, were included in the review, with 1848 subjects in the ultrasound group and 2217 subjects in the palpation group.	2:代替アウトカム	Data were extracted on study design, study size, operator and patient characteristics, use of anticoagulation, vascular complication rates, first-pass success rate, and inadvertent arterial puncture.	Ultrasound guidance for femoral vein cannulation was associated with a 60% reduction of major vascular bleeding (relative risk, 0.40; 95% confidence interval, 0.28-0.91). Additionally, there was a 66% reduction in minor vascular complications (relative risk, 0.34; 95% confidence interval, 0.15-0.78). The use of real-time 2D ultrasound guidance for femoral vein cannulation decreases access-related bleeding rates and life-threatening vascular complications.	Unknown	None	

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
5	Ultrasound guided internal jugular venous cannulation: comparison with land-mark technique. Riaz A, Shan Khan RA, Salim F. J Coll Physicians Surg Pak. 2015 May;25(5):315-9. doi: 05.2015/JCPSP.315319.	1:無作為化比較試験	Randomized controlled trial	Real-time ultrasound-guided technique or land-mark technique.	A total of 200 patients who required internal jugular vein cannulation	2:代替アウトカム	Access time, number of attempts until successful cannulation, complications and the demographics of each patient were recorded.	Access time was significantly less in real-time ultrasound group (34.95 ± 11.47 vs. 146.59 ± 40.20 seconds, p < 0.001). Cannulation was performed in first attempt in 99% of patients in ultrasound group as compared to 89% of landmark group. Complication rate was significantly higher in the land-mark group than in the ultrasound-guided group. Carotid artery puncture rate (9% vs. 1%) and haematoma formation (7% vs. 0%) were more frequent in the land-mark group than in the ultrasound-guided group. Brachial plexus irritation was also more in land-mark group (6% vs. 0%). Access time, failure rate and procedure related complications are reduced when real-time ultrasonography is used to cannulate internal Jugular vein.	Unknown	None	
6	Ultrasound-Guided Subclavian Vein Catheterization: A Systematic Review and Meta-Analysis. Lalu MM, Fayad A, Ahmed O, Bryson GL, Fergusson DA, Barron CC, Sullivan P, Thompson C; Canadian Perioperative Anesthesia Clinical Trials Group.. Crit Care Med. 2015 Jul;43(7):1498-507. doi: 10.1097/CCM.0000000000000973. Review.	1A:システマティックレビューまたはメタアナリシス	Systematic Review and Meta-Analysis.	Ultrasound compared to landmark technique for subclavian catheterization	Medline, Embase, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and CINAHL (from inception to September 2014). Six hundred and one studies were reviewed and 10 met inclusion criteria (n = 2,168 participants). Six used dynamic 2D ultrasound (n = 719), one used static 2D ultrasound (n = 821), and three used Doppler-guided insertion techniques (n = 628).	2:代替アウトカム	Outcomes of interest included safety and failure of catheterization	Overall complication rates were reduced with ultrasound use compared to the landmark group (odd ratio, 0.53; 95% CI, 0.41-0.69). Subgroup analysis demonstrated that dynamic 2D ultrasound reduced inadvertent arterial puncture, pneumothorax, and hematoma formation. No difference in failure of catheterization was noted between the ultrasound group and the landmark method (risk ratio, 0.85; 95% CI, 0.48-1.51). Subgroup analysis of dynamic 2D ultrasound demonstrated a significant decrease in failed catheterization (risk ratio, 0.24; 95% CI, 0.06-0.92). Ultrasound-guided subclavian catheterization reduced the frequency of adverse events compared with the landmark technique. Our findings support the use of dynamic 2D ultrasound for subclavian catheterization to reduce adverse events and failed catheterization.	Unknown	None	
7	Ultrasound guidance versus anatomical landmarks for subclavian or femoral vein catheterization. Brass P, Hellmich M, Kolodziej L, Schick G, Smith AF. Cochrane Database Syst Rev. 2015 Jan 9;1:CD011447. doi: 10.1002/14651858.CD011447. Review.	1A:システマティックレビューまたはメタアナリシス	Systematic Review	Ultrasound (US)- or Doppler ultrasound (USD)-guided puncture techniques for subclavian vein vs anatomical landmarks	We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (2013, Issue 1), MEDLINE (1966 to 15 January 2013), EMBASE (1966 to 15 January 2013), the Cumulative Index to Nursing and Allied Health Literature (CINAHL) (1982 to 15 January 2013), reference lists of articles, 'grey literature' and dissertations. An additional handsearch focused on intensive care and anaesthesia journals and abstracts and proceedings of scientific meetings. We attempted to identify unpublished or ongoing studies by contacting companies and experts in the field, and we searched trial registers. We reran the search in August 2014. We will deal with any studies of interest when we update the review. Altogether 13 studies enrolling 2341 participants (and involving 2360 procedures)	1:臨床アウトカム	Inadvertent arterial puncture, haematoma formation, complications, number of attempts until success or first-time) success rates or time taken to insert the catheter	The quality of evidence was very low (subclavian vein N = 3) or low (subclavian vein N = 4, femoral vein N = 2) for most outcomes, moderate for one outcome (femoral vein) and high at best for two outcomes (subclavian vein N = 1, femoral vein N = 1). Most of the trials had unclear risk of bias across the six domains, and heterogeneity among the studies was significant.For the subclavian vein (nine studies, 2030 participants, 2049 procedures), two-dimensional ultrasound reduced the risk of inadvertent arterial puncture (three trials, 498 participants, risk ratio (RR) 0.21, 95% confidence interval (CI) 0.06 to 0.82; P value 0.02, I^2 = 0%) and haematoma formation (three trials, 498 participants, RR 0.26, 95% CI 0.09 to 0.76; P value 0.01, I^2 = 0%). No evidence was found of a difference in total or other complications (together, US, USD), overall (together, US, USD), number of attempts until success (US) or first-time (US) success rates or time taken to insert the catheter (US).For the femoral vein, fewer data were available for analysis (four studies, 311 participants, 311 procedures). No evidence was found of a difference in inadvertent arterial puncture or other complications. However, success on the first attempt was more likely with ultrasound (three trials, 224 participants, RR 1.73, 95% CI 1.34 to 2.22; P value < 0.0001, I^2 = 31%), and a small increase in the overall success rate was noted (RR 1.11, 95% CI 1.00 to 1.23; P value 0.06, I^2 = 50%). No data on mortality or participant-reported outcomes were provided. On the basis of available data, we conclude that two-dimensional ultrasound offers small gains in safety and quality when compared with an anatomical landmark technique for subclavian (arterial puncture, haematoma formation) or femoral vein (success on the first attempt) cannulation for central vein catheterization. Data on insertion by inexperienced or experienced users, or on patients at high risk for complications, are lacking. The results for Doppler ultrasound techniques versus anatomical landmark techniques are uncertain.	Unknown	None	

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
8	Ultrasound guidance versus anatomical landmarks for internal jugular vein catheterization. Brass P, Hellmich M, Kolodziej L, Schick G, Smith AF. Cochrane Database Syst Rev. 2015 Jan 9;1:CD006962. doi: 10.1002/14651858.CD006962.pub2. Review.	1A:システマティックレビューまたはメタアナリシス	Systematic Review	(imaging ultrasound (US) or ultrasound Doppler (USD)) guided puncture techniques for insertion of central venous catheters via the internal jugular vein vs anatomical landmarks	Central Register of Controlled Trials (CENTRAL) (2013, Issue 1), MEDLINE (1966 to 15 January 2013), EMBASE (1966 to 15 January 2013), the Cumulative Index to Nursing and Allied Health Literature (CINAHL) (1982 to 15 January 2013), reference lists of articles, 'grey literature' and dissertations. An additional handsearch focused on intensive care and anaesthesia journals and abstracts and proceedings of scientific meetings. We attempted to identify unpublished or ongoing studies by contacting companies and experts in the field, and we searched trial registers. We reran the search in August 2014. We will deal with identified studies of interest when we update the review.	1:臨床アウトカム	Rate of total complications	On the basis of available data, we conclude that two-dimensional ultrasound offers small gains in safety and quality when compared with an anatomical landmark technique for subclavian (arterial puncture, haematoma formation) or femoral vein (success on the first attempt) cannulation for central vein catheterization. Data on insertion by inexperienced or experienced users, or on patients at high risk for complications, are lacking. The results for Doppler ultrasound techniques versus anatomical landmark techniques are uncertain.	Unknown	None	
9	Ultrasound assistance for central venous catheter placement in a pediatric emergency department improves placement success rates. Gallagher RA, Levy J, Vieira RL, Monuteaux MC, Stack AM. Acad Emerg Med. 2014 Sep;21(9):981-6. doi: 10.1111/acem.12460.	4:対照群のない観察研究	Retrospective cohort study	CVC using US assistance or CVC without US assistance	168 patients undergoing CVC placement attempts.	2:代替アウトカム	Success rate of CVC placement.	The proportion of successful placement attempts was significantly higher when using US assistance (96 of 98) compared to those without (55 of 70; 98% vs. 79%, odds ratio [OR] = 13.1, 95% confidence interval [CI] = 2.9 to 59.4). When controlling for patient- and physician-specific factors, success rates remained significantly higher. Ultrasound assistance was associated with greater likelihood of success in CVC placement in a pediatric ED.	Unknown	None	
10	Guidance and examination by ultrasound versus landmark and radiographic method for placement of subclavian central venous catheters: study protocol for a randomized controlled trial. Perbet S, Pereira B, Grimaldi F, DualéC, Bazin JE, Constantin JM. Trials. 2014 May 20;15:175. doi: 10.1186/1745-6215-15-175.	1:無作為化比較試験	Randomized, controlled two-arm trial	Ultrasound real-time guidance and examination or landmark guidance and radiographic examination.	Investigators screen consecutive patients who are admitted to the ICU and require a central venous line. Inclusion criteria are requirement for SCV catheterization, age >18 years and informed consent from the patient or his/her nextof-kin. Exclusion criteria are patient refusal, femoral or internal jugular catheterization, and impossibility of obtaining good echogenicity.	2:代替アウトカム	The primary outcome is the time between the beginning of the procedure and control of the catheter. Secondary outcomes include the times required for the six components of the total procedure, the occurrence of complications (pneumothorax, hemothorax, or misplacement), failure of the technique and occurrence of central venous catheter infections.	The SUBGEUS trial is the first randomized controlled study to investigate whether ultrasound real-time guidance and examination for SCV catheter placement reduces all procedure times and the rate of complications.	Unknown	None	

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
11	Comparison of an ultrasound-guided technique versus a landmark-guided technique for internal jugular vein cannulation. Dolu H, Goksu S, Sahin L, Ozen O, Eken L. J Clin Monit Comput. 2015 Feb;29(1):177-82. doi: 10.1007/s10877-014-9585-3. Epub 2014 May 18.	1:無作為化比較試験	RCT	Landmark-guided technique to the ultrasound-guided technique for internal jugular vein cannulation	One hundred cardiovascular surgery patients, of whom 65 were male and 35 were female with ages ranging from 22 to 65, who had internal jugular cannulation between December 2010-March 2011 in our clinic were investigated prospectively	2:代替アウトカム	The number of attempts until successful catheterization, the time required for successful catheterization, arising complications, the demographics and the duration of catheterization were recorded for each patient.	The number of attempts for successful catheterization was statistically lower in group U (1.1±0.5) than in group A (2.2±1.6). The time required for successful catheterization was statistically lower in group U (109.4±30.4) than in group A (165.9±91.5). There were no significant differences found in the total complications of the two groups (p=0.092). Four patients had an arterial punction [group U (n=0) and group A (n=4)] and two patients had a hematoma [group U (n=1) and group A (n=1)]. Arterial punction complication was increased significantly in landmark group (p=0.041). The findings of this study indicate that internal jugular vein catheterization guided by real-time ultrasound results in a lower access time and a lower rate of attempts.	Unknown	None	
12	Ultrasound- versus landmark-guided femoral catheterization in the pediatric catheterization laboratory: a randomized-controlled trial. Law MA, Borasino S, McMahon WS, Alten JA. Pediatr Cardiol. 2014 Oct;35(7):1246-52. doi: 10.1007/s00246-014-0923-5. Epub 2014 May 16.	1:無作為化比較試験	RCT	US- versus landmark (LM)-guided femoral vascular access	A single operator randomized 95 patients (201 vessels) to undergo either LM- or US-guided vascular access.	2:代替アウトカム	The primary end point was the access success rate. Number of attempts, inadvertent access, time to sheath placement, and complications also were compared between the two groups.	No difference was seen in the overall access success rate: 98 % with US versus 93 % with LM (p = 0.17). The success rate for the targeted vessel was higher with US (89 %) than with LM (67 %) (p = 0.012). US facilitated fewer attempts (1.1 ± 0.4 vs 1.4 ± 0.9; p = 0.048) and improved the first-attempt success rate (87 vs 77 %; p = 0.049). The time to access did not differ significantly between the two groups (US 2:55 ± 4:03 vs LM 3:37 ± 2:54; p = 0.28). No differences in complication rates were noted. The benefits of US were accentuated in the subgroup weighing less than 10 kg. In this study, US access in the pediatric catheterization laboratory did not improve overall success. However, US improved accuracy and reduced the number attempts necessary for access without prolonging the access time of the procedure. Small children realized the greatest benefit of US-guided access.	Unknown	None	
13	Pre-procedure ultrasound increases the success and safety of central venous catheterization. Schummer W, Köditz JA, Schelenz C, Reinhart K, Sakka SG. Br J Anaesth. 2014 Jul;113(1):122-9. doi: 10.1093/bja/aeu049. Epub 2014 Mar 18.	3:対照群のある観察研究	Observational non-randomized study	Pre-procedure US and landmark (LM) methods	606 of ~1300 procedures, that is, 200 patients were treated under pre-procedure US and 406 under LM [pathfinder (PF) n=202, direct cannulation (DC) n=204].	2:代替アウトカム	First needle pass success rate, success rate after the third attempt, and the cannulation time.	Pre-procedure US was associated with more successful attempts and shorter cannulation times. Under pre-procedure US, 88% of first attempts were successful and 100% of third attempts. The median (range) cannulation time was 39 (10-330) s. Under PF, only 56% of first, and 87% of third, attempts were successful with a median (range) cannulation time of 100 (25-3600) s. Under DC, 61% of first and 89% of third attempts were successful; the median (range) cannulation time was 70 (10-3600) s. Remarkably, inexperienced operators using pre-procedure US (n=38) were significantly faster than experienced operators using PF or DC (n=343) (cannulation time: median 60 s, range 12-330, for inexperienced; 60 s, range 10-3600, for experienced). First puncture success rates were higher (pre-procedure US, inexperienced 84%, PF or DC, experienced 57%). Pre-procedure US for IJV catheterization is safe, quick, and superior to LM.	Unknown	None	
14	The influence of the direction of J-tip on the placement of a subclavian catheter: real time ultrasound-guided cannulation versus landmark method, a randomized controlled trial. Oh AY, Jeon YT, Choi EJ, Ryu JH, Hwang JW, Park HP, Do SH. BMC Anesthesiol. 2014 Feb 28;14:11. doi: 10.1186/1471-2253-14-11.	1:無作為化比較試験	Prospective randomized controlled study	real-time ultrasound-guided infraclavicular subclavian venous cannulation or landmark method.	Sixty adult patients who required subclavian venous catheterization for neurosurgery	2:代替アウトカム	Incidence of unsuccessful guidewire placement, unsuccessful guidewire placements, the incidence of misplacement	The incidence of unsuccessful guidewire placement was lower in the ultrasound group than in the landmark group (13% vs. 47%, P=0.01). Among the unsuccessful guidewire placements, the incidence of misplacement were comparable between the groups and were all located in the ipsilateral internal jugular vein (7% vs. 7%). However, the incidence of advancement failure was significantly higher in landmark group (40% vs. 7%, P=0.005). There were no complications such as pneumothorax or hemothorax. The proper placement of guidewire was less influenced by the direction of the guidewire J-tip with ultrasound-guided subclavian venous cannulation than with the landmark approach.	Unknown	None	

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
15	Residents learning ultrasound-guided catheterization are not sufficiently skilled to use landmarks. Maizel J, Guyomarc'h L, Henon P, Modeliar SS, de Cagny B, Choukroun G, Slama M. Crit Care. 2014 Feb 23;18(1):R36. doi: 10.1186/cc13741.	3:対照群のある観察研究	Prospective observational study	Ultrasound-guided (UG) technique or landmark (LM) placement	During the first three months of their rotation in our ICU, residents inexperienced in CVC used only the real-time UG technique. During the following three months, residents were allowed to place CVC by means of the LM technique when authorized by the attending physician.	2:代替アウトカム	Success rate, complication rate,	A total of 172 procedures (84 UG and 88 LM) were performed by the inexperienced residents during the study. The success rate was lower (72% versus 84%; P=0.05) and the complication rate was higher (22% versus 10%; P=0.04) for LM compared to UG procedures. Comparison between the five last UG procedures and the first five LM procedures performed demonstrated that the transition between the two techniques was associated with a marked decrease of the success rate (65% versus 93%; P=0.01) and an increase of the complication rate (33% versus 8%; P=0.01). After 10 LM procedures, residents achieved a success rate and a complication rate of 81% and 6%, respectively. Residents who only learn the UG technique will not be immediately able to perform the LM technique, but require specific training based on at least 10 LM procedures. The question of whether or not the LM technique should still be taught when an ultrasound device is not available must therefore be addressed.	Unknown	None	
16	Ultrasound-guidance can reduce adverse events during femoral central venous cannulation. Powell JT, Mink JT, Nomura JT, Levine BJ, Jasani N, Nichols WL, Reed J, Sierzenski PR. J Emerg Med. 2014 Apr;46(4):519-24. doi: 10.1016/j.jemermed.2013.08.023. Epub 2014 Jan 22.	3:対照群のある観察研究	Prospective, observational study	Ultrasound-guidance and landmark techniques.	143 patients who had femoral CVC in our institution.	2:代替アウトカム	CVC site, ultrasound usage, CVC indication, and mechanical complications (e.g., pneumothorax, arterial puncture, failed access, catheter misdirection, and hematoma).	Sixty CVCs (42%) were performed under ultrasound guidance, 83 (58%) via landmark technique (p = 0.0159); 3.3% of femoral central venous lines placed by ultrasound guidance had recorded adverse events compared with 9.6% for the landmark technique (p = 0.145). There was no statistically significant difference in complications between ultrasound-guidance and landmark techniques. Our data showed a trend toward decreased rates of arterial puncture and reduced cannulation attempts resulting in improved placement success. Our experience shows that ultrasound guidance for femoral CVC might decrease complications and improve placement success, although we cannot recommend this approach without additional data. We recommend a larger study to further evaluate this technique.	Unknown	None	
17	Achieving optimal clinical outcomes in ultrasound-guided central venous catheterizations of the internal jugular vein after a simulation-based training program for novice learners. Koh J, Xu Y, Yeo L, Tee A, Chuin S, Law J, Noor IB, Poulose V, Raghuram J, Verma A, Ng A. Simul Healthc. 2014 Jun;9(3):161-6. doi: 10.1097/SIH.0000000000000010.	3:対照群のある観察研究	Prospective, observational study	Simulation-based training program	32 residents participated in a formal training program, consisting of a simulation-based workshop and 5 supervised USG CVC insertions on patients.	2:代替アウトカム	Data on the overall success (OS), first pass success (FP) and mechanical complication (MC) rates were serially collected over 2 years, spanning 4 cohorts of residents.	None had performed USG CVC before. Results showed that residents improved in their OS, FP, and MC rates as they performed more USG CVC. Residents needed to perform 7 USG CVCs to achieve optimal clinical outcomes of high OS and FP as well as low MC rates. There was a significant improvement in OS, FP, and MC rates for the eighth and subsequent USG CVCs compared with the first 7 USG CVCs (82% vs. 99% [P < 0.001], 70% vs. 92% [P < 0.001] and 11% vs. 0%, respectively). After a formal training program consisting of a simulation-based workshop and 5 supervised USG CVCs on critically ill adults, residents were able to achieve optimal clinical outcomes after performing 7 procedures.	Unknown	None	
18	Ultrasound-guided central venous cannulation is superior to quick-look ultrasound and landmark methods among inexperienced operators: a prospective randomized study. Airapetian N, Maizel J, Langelle F, Modeliar SS, Karakitsos D, Dupont H, Slama M. Intensive Care Med. 2013 Nov;39(11):1938-44. doi: 10.1007/s00134-013-3072-z. Epub 2013 Sep 12.	1:無作為化比較試験	Prospective randomized single-center study.	Each inexperienced resident randomly inserted a central venous line using the UM, LM or UG technique. 118 patients requiring jugular or femoral central cannula placement.	A medical intensive care unit (ICU) of a university medical center.	2:代替アウトカム	The primary outcome was the success rate, and secondary outcomes were the placement time, number of attempts, mechanical complication rate, and catheter colonization rate	The mean age of patients included in the study was 65 ± 15 years, and the mean Simplified Acute Physiology Score 2 (SAPS2) was 57 ± 20. The success rate was higher in the UG group than in the LM and UM groups (100, 74, and 73 %, respectively; p = 0.01). The total number of mechanical complications was higher in the LM and UM groups than in the UG group (24 and 36 versus 0 %, respectively; p = 0.01). The number of attempts and the access time were higher in the LM group than in the UG group, but not compared with the UM group. No difference in terms of catheter colonization was observed between the three groups. Ultrasound-guided cannulation of the internal jugular or femoral vein by inexperienced residents appears to be more reliable than the LM or UM methods and was associated with a lower mechanical complication rate among ICU patients.	Unknown	None	

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
19	Ultrasound-guided cannulation of the internal jugular vein in robotic cardiac surgery. Wang Y, Wang G, Gao CQ. Chin Med J (Engl). 2013 Jul;126(13):2414-7.	3:対照群のある観察研究	Historical control study	Ultrasound-guided cannulation of the IJV vs landmark	296 adult patients undergoing ultrasound-guided right IJV cannulation during establishment of peripheral CPB in robotic cardiac surgery. landmark-guided method used for 302 historical control patients	2:代替アウトカム	Success rate, first attempt success rate, access time and the complication rate	The success rate and the frst attempt success rate in the ultrasound group were significantly higher than that in the landmark group (100% vs. 88.1%, P < 0.000 and 98.6% vs. 38.4%, P < 0.000). Average access time in the ultrasound group was shorter than that in the landmark group ((6.3 ± 13.6) seconds; interquartile range (4 - 62) seconds vs. (44.5 ± 129.5) seconds; interquartile range (5 - 986) seconds). The complication rate in the ultrasound group was significantly lower than that in the landmark group (0.3% vs. 8.3%, P < 0.000). Compared with the landmark-guided approach, ultrasound-guided cannulation of the right IJV significantly improves success rate, decreases access time and reduces complication rate during establishment of peripheral CPB in robotic cardiac surgery.	Unknown	None	
20	A prospective randomized trial of ultrasound- vs landmark-guided central venous access in the pediatric population. Bruzoni M, Slater BJ, Wall J, St Peter SD, Dutta S. J Am Coll Surg. 2013 May;216(5):939-43. doi: 10.1016/j.jamcollsurg.2013.01.054. Epub 2013 Mar 7.	1:無作為化比較試験	Randomized prospective study	Ultrasound-guided cannulation of the IJV vs landmark	150 children under 18 years of age undergoing tunneled central venous catheter placement was performed. Patient accrual was based on power analysis. Exclusion criteria included known nonpatency of a central vein or coagulopathy.	2:代替アウトカム	The primary outcomes measure was number of attempts at venous cannulation. Secondary outcomes measures included: access times, number of arterial punctures, and other complications.	There was no difference when comparing demographic data. Success at first attempt was achieved in 65% of patients in the ultrasound group vs 45% in the landmark group (p = 0.021). Success within 3 attempts was achieved in 95% of ultrasound group vs 74% of landmark group (p = 0.0001). Ultrasound reduced the number of cannulation attempts necessary for venous access. This indicates a potential to reduce complications when ultrasound is used by pediatric surgeons.	Unknown	None	

WHO手術安全チェックリスト

資料5-3

＜和文論文＞

シソーラスの探索

①	「世界保健機関 手術安全チェックリスト」で検索し、得られた論文のシソーラスを抽出
②	得られたシソーラスで再検索し、関連のあるシソーラスを抽出
③	②を繰り返し、770件の文献のタイトルと抄録から関連しそうな文献を抽出

検索式と絞り込みの過程

	検索式	件数	検索日
医中誌	**(世界保健機関/TH)** and (PT=会議録除く)	3844	2018/3/19
	(チェックリスト/TH) and (PT=会議録除く)	6702	2018/3/19
	(世界保健機関/TH) or (チェックリスト/TH) and (PT=会議録除く)	10489	2018/3/19
	(世界保健機関/TH) or (チェックリスト/TH) and (PT=会議録除く) and ([メタアナリシス]/TH or [システマティックレビュー]/TH or [ランダム化比較試験]/TH or [準ランダム化比較試験]/TH or [観察研究]/TH or RD=メタアナリシス,ランダム化比較試験,準ランダム化比較試験,比較研究) and (PT=症例報告除く) and (PT=会議録除く) and CK=ヒト	770	2018/3/19
絞り込み	タイトルと抄録	3	2018/3/19
	本文	3	2018/3/19

「観察研究/TH」には、前向き研究、後ろ向き研究、症例対照研究、コホート研究、断面研究等が含まれる。

研究デザインとアウトカムのレベル

		アウトカムレベル				
		1:臨床アウトカム	2:代替アウトカム	3:安全と間接的に関係するその他の測定可能	4:エラーや有害事象の減少に寄与するアウトカムが	計
研究デザインレベル	1A:システマティックレビューまたはメタアナリシス	0	0	0	0	0
	1:無作為化比較試験	0	0	0	0	0
	2:非無作為化比較試験	0	0	0	0	0
	3:対照群のある観察研究	0	0	0	0	0
	4:対照群のない観察研究	1	1	1	0	3
	計	0	0	0	0	0

＜英文論文＞

シソーラスの探索

①	「WHO Surgical Safety Checklist」で検索し、得られた論文のシソーラスを抽出
②	得られたシソーラスで再検索し、関連のあるシソーラスを抽出
③	②を繰り返し、3,600件以上の文献のタイトルと抄録から関連しそうな文献を抽出中（継続作業中）

検索式と絞り込みの過程

	検索式	件数	検索日
PubMed	**"World Health Organization"[Mesh]** AND ("2008/03/16"[PDat] : "2018/03/13"[PDat])	10913	2018/3/14
	"Checklist"[Mesh] AND ("2008/03/16"[PDat] : "2018/03/13"[PDat])	4736	2018/3/14
	"World Health Organization"[Mesh] OR "Checklist"[Mesh] AND ("2008/03/16"[PDat] : "2018/03/13"[PDat])	15483	2018/3/14
	("World Health Organization"[Mesh] OR "Checklist"[Mesh]) AND ("Meta-Analysis as Topic"[Mesh] OR "Controlled	3653	2018/3/14
絞り込み	タイトルと抄録	76	
	本文	76	

研究デザインとアウトカムのレベル

		アウトカムレベル				
		1:臨床アウトカム	2:代替アウトカム	3:安全と間接的に関係するその他の測定可能	4:エラーや有害事象の減少に寄与するアウトカムが	計
研究デザインレベル	1A:システマティックレビューまたはメタアナリシス	5	1	0	0	6
	1:無作為化比較試験	2	2	0	0	4
	2:非無作為化比較試験	0	0	0	0	0
	3:対照群のある観察研究	11	4	0	2	17
	4:対照群のない観察研究	4	37	0	8	49
	計	22	44	0	10	76

WHO Surgical Safety Checklist（WHO手術安全チェックリスト） 文献一覧

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
＜和文論文＞											
1	「手術安全チェックリスト」を導入しての安全意識に関する追跡調査 Author：葛西香菜紗, 眞弓祐子, 野村里織, 石井容子, 佐藤律子 Source： 川崎市立川崎病院院内看護研究集録 69回 Page8-11(2015.03)	4：対照群のない観察研究	前後比較研究	WHOSSCの使用	医師68名、看護師(手術室、ICU、外来、病棟)57名、助産師20名、放射線技師4名、臨床工学技師5名	3：安全と間接的に関係するその他の測定可能なアウトカム	職員の安全意識	チェックリスト導入の2年後に医師と看護師を対象に行った今回と同様の調査と比較した結果、チーム全体として誤認防止への安全意識が向上しており、チェックリストが誤認防止に有効であることが確認できた。			
2	手術安全チェックリストの運用と課題　手術部運営効率化の観点から Author：釈永清志, 飯塚真理子, 木本久子, 山崎光章 Source： 日本手術医学会誌 (1340-8593)36巻1号 Page65-68(2015.02)	4：対照群のない観察研究	前後比較研究	WHOSSCの使用	麻酔科管理の手術症例7126例	2：代替アウトカム	麻酔導入時間、手術準備時間、手術時間、麻酔時間、麻酔覚醒時間	手術安全チェックリスト運用開始後群では平均麻酔導入時間が有意に延長し、平均麻酔覚醒時間は有意に短縮したが、平均手術準備時間に有意差は認めなかった。また、運用開始後は日勤帯のすべての時間帯で手術室稼働率が改善した。			
3	臨床と研究「手術室チェックリスト」が術後合併症の発生率に与える影響の検討 Author：太田裕之, 塚山正市, 藤岡重一, 望月慶子, 村上眞也, 川浦幸光 Source： 外科 (0016-593X)75巻10号 Page1104-1107(2013.10)	4：対照群のない観察研究	前後比較研究	WHOSSCの使用	手術室チェックリスト導入前施行手術350例、導入後施行手術319例	1：臨床アウトカム	術後30日以内の手術関連死亡、合併症発生率、術後感染症発症率	1)術後30日以内の手術関連死亡は導入前2例(0.6%)、導入後3例(0.9%)で、合併症発生率は導入前7.3%、導入後4.4%といずれも有意差は認められなかった。2)術後合併症のうち術後感染症は手術部位感染と遠隔感染の肺炎の合計でみた発生率はチェックリスト導入前の5.3%から導入後2.2%と有意に減少していた。			

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
＜英文論文＞											
1	Haynes AB, Edmondson L, Lipsitz SR, Molina G, Neville BA, Singer SJ, Moonan AT, Childers AK, Foster R, Gibbons LR, Gawande AA, Berry WR. Mortality Trends After a Voluntary Checklist-based Surgical Safety Collaborative. Ann Surg. 2017 Dec;266(6):923-929. doi: 10.1097/SLA.0000000000002249. PubMed PMID: 29140848.	3：対照群のある観察研究	前後比較研究	The Safe Surgery 2015 South Carolina program.	Fourteen hospitals.	1：臨床アウトカム	Postoperative mortality rates.	Before program launch, there was no difference in mortality trends between the completion cohort and all others (P = 0.33), but postoperative mortality diverged thereafter (P = 0.021). Risk-adjusted 30-day mortality among completers was 3.38% in 2010 and 2.84% in 2013 (P < 0.00001), whereas mortality among other hospitals (n = 44) was 3.50% in 2010 and 3.71% in 2013 (P = 0.3281), reflecting a 22% difference between the groups on difference-in-differences analysis (P = 0.0021).	N.A.	N.A.	
2	White MC, Peterschmidt J, Callahan J, Fitzgerald JE, Close KL. Interval follow up of a 4-day pilot program to implement the WHO surgical safety checklist at a Congolese hospital. Global Health. 2017 Jun 29;13(1):42. doi: 10.1186/s12992-017-0266-0. PubMed PMID: 28662709; PubMed Central PMCID: PMC5492505.	4：対照群のない観察研究	前後比較研究	A four-day pilot SSC training course.	A single hospital centre in the Republic of Congo.	4：エラーや有害事象の減少に寄与するアウトカムがない	SSC implementation.	Over 50% of participants using the SSC at 15 months, positive changes in learning, behaviour and organisational change, but less impact on hierarchical culture.	N.A.	N.A.	
3	Bartz-Kurycki MA, Anderson KT, Abraham JE, Masada KM, Wang J, Kawaguchi AL, Lally KP, Tsao K. Debriefing: the forgotten phase of the surgical safety checklist. J Surg Res. 2017 Jun 1;213:222-227. doi: 10.1016/j.jss.2017.02.072. Epub 2017 Mar 6. PubMed PMID: 28601318.	4：対照群のない観察研究	コホート研究	なし	An academic children's hospital	4：エラーや有害事象の減少に寄与するアウトカムがない	SSC adherence.	Despite slight increases annually in overall compliance to the debriefing checklist, only half of all checklists were completed in full.	N.A.	N.A.	

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4	Yu X, Huang Y, Guo Q, Wang Y, Ma H, Zhao Y; Relaunch and Implementation of Operating Room Surgical Safety Checklist (RIORS) study group. Clinical motivation and the surgical safety checklist. Br J Surg. 2017 Mar;104(4):472–479. doi: 10.1002/bjs.10446. Epub 2017 Feb 3. PubMed PMID: 28158915.	4：対照群のない観察研究	前後比較研究	Revision of the SSC	Four academic/teaching hospitals	4：エラーや有害事象の減少に寄与するアウトカムがない	Completion rates of SSC	Completion rates of all stages reached over 80·0 per cent at all sites. There was a significant change in doctors who participated. The rates of hasty or casual checking decreased to less than 6·0 per cent overall.	N.A.	N.A.	
5	Gillespie BM, Marshall AP, Gardiner T, Lavin J, Withers TK. Impact of workflow on the use of the Surgical Safety Checklist: a qualitative study. ANZ J Surg. 2016 Nov;86(11):864–867. doi: 10.1111/ans.13433. Epub 2016 Jan 7. PubMed PMID: 26748669.	4：対照群のない観察研究	質的研究（インタビュー等）	なし	70 participants from nursing, medicine and the community.	4：エラーや有害事象の減少に寄与するアウトカムがない		Within the domain, seven categories illustrated the causal conditions which determined the ways in which workflow influenced checklist use.	N.A.	N.A.	
6	El Boghdady M, Tang B, Tait I, Alijani A. The effect of a simple intraprocedural checklist on the task performance of laparoscopic novices. Am J Surg. 2017 Aug;214(2):373–377. doi: 10.1016/j.amjsurg.2016.07.019. Epub 2016 Aug 16. PubMed PMID: 27773378.	1：無作為化比較試験	症例対照研究	(control group) receiving paper feedback (checklist group) receiving paper feedback and the checklist	Twenty novices	2：代替アウトカム	Errors	2,341 errors were detected during the 5 stages. During the first stage, the errors were not significantly different between the 2 groups. The checklist group committed significantly fewer errors as compared with the control group during all the later 4 stages (P < .01).	N.A.	N.A.	
7	Gitelis ME, Kaczynski A, Shear T, Deshur M, Beig M, Sefa M, Silverstein J, Ujiki M. Increasing compliance with the World Health Organization Surgical Safety Checklist–A regional health system's experience. Am J Surg. 2017 Jul;214(1):7–13. doi: 10.1016/j.amjsurg.2016.07.024. Epub 2016 Aug 16. PubMed PMID: 27692671.	3：対照群のある観察研究	症例対照研究	電子カルテと連動するWHOSSCの使用	NorthShore University HealthSystem	2：代替アウトカム	Compliance rate, risk events, LOS, 30–day readmissions.	Compliance increased from 48% (n = 167) to 92% (n = 1,037; P < .001) after the SSC was integrated into the electronic health record. Surgeons (91% vs 97%; P < .001), anesthesiologists (89% vs 100%; P < .001), and nurses (55% vs 93%; P < .001) demonstrated an increase in compliance. A comparison between risk events in the pre– and post–rollout period	N.A.	N.A.	

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8	Martis WR, Hannam JA, Lee T, Merry AF, Mitchell SJ. Improved compliance with the World Health Organization Surgical Safety Checklist is associated with reduced surgical specimen labelling errors. N Z Med J. 2016 Sep 9;129(1441):63-7. PubMed PMID: 27607086.	3:対照群のある観察研究	前後比較研究	WHOSSCの使用	Five operration rooom, A total of 9,825 specimen	2:代替アウトカム	specimen labelling errors	There were 19 errors in 4,760 specimens (rate 3.99/1,000) and eight errors in 5,065 specimens (rate 1.58/1,000) before and after the change in SSC administration paradigm (P=0.0225).	N.A.	N.A.	
9	Torres-Manrique B, Nolasco-Bonmati A, Maciá-Soler L, Milberg M, Vilca AN, López-Montesinos MJ, González-Chordá VM. Cultural analysis of surgical safety checklist items in Spain and Argentina. Rev Gaucha Enferm. 2016 Aug 25;37(3):e56359. doi: 10.1590/1983-1447.2016.03.56359. English, Spanish. PubMed PMID: 27579844.	3:対照群のある観察研究	質的研究（インタビュー等）	なし	Two hospitals in Spain and Argentina.	4:エラーや有害事象の減少に寄与するアウトカムがない	Percentage of agreement	There was a greater percentage of classifications in fields related to the prevention of critical events. The category ″clinical processes and procedures″ was mentioned most frequently in both lists.	N.A.	N.A.	
10	Epiu I, Tindimwebwa JV, Mijumbi C, Ndarugirire F, Twagirumugabe T, Lugazia ER, Dubowitz G, Chokwe TM. Working towards safer surgery in Africa; a survey of utilization of the WHO safe surgical checklist at the main referral hospitals in East Africa. BMC Anesthesiol. 2016 Aug 11;16(1):60. doi: 10.1186/s12871-016-0228-8. PubMed PMID: 27515450; PubMed Central PMCID: PMC4982013.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	The main referral hospitals in each East Africa Community country., Of the 86 anaesthetists contacted and interviewed, 85 responses were analysed.	2:代替アウトカム	Availability, knowledge and usage of the surgical checklist	Only 25 % regularly used the WHO surgical checklist. None of the anaesthetists in Mulago (Uganda) or Centre Hospitalo-Universitaire de Kamenge (Burundi) used the checklist, mainly because it was not available, in contrast with Muhimbili (Tanzania), Kenyatta (Kenya), and Centre Hospitalier Universitaire de Kigali (Rwanda), where 65 %, 19 % and 36 %, respectively, used the checklist.	N.A.	N.A.	
11	Putnam LR, Anderson KT, Diffley MB, Hildebrandt AA, Caldwell KM, Minzenmayer AN, Covey SE, Kawaguchi AL, Lally KP, Tsao K. Meaningful use and good catches: More appropriate metrics for checklist effectiveness. Surgery. 2016 Dec;160(6):1675-1681. doi: 10.1016/j.surg.2016.04.038. Epub 2016 Jul 26. PubMed PMID: 27473370.	4:対照群のない観察研究	前後比較研究	SSCの使用	Multifaceted interventions aimed at the preincision checklist and 5 prospective audits.	4:エラーや有害事象の減少に寄与するアウトカムがない	Implementation of a systematic checklist.	Implementation of a systematic checklist program resulted in significant and sustainable improvement in performance.	N.A.	N.A.	

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12	Diego LA, Salman FC, Silva JH, Brandão JC, de Oliveira Filho G, Carneiro AF, Bagatini A, de Moraes JM. Construction of a tool to measure perceptions about the use of the World Health Organization Safe Surgery Checklist Program. Braz J Anesthesiol. 2016 Jul-Aug;66(4):351-5. doi: 10.1016/j.bjane.2014.11.011. Epub 2016 May 1. PubMed PMID: 27343783.	4:対照群のない観察研究	その他	麻酔科医を対象としたWHOSSC使用状況測定ツールに関するアンケート調査	459 participants who join the 59th CBA in BH/MG.	2:代替アウトカム	Attitudes of respondents on various aspects of the checklist applicability and usefulness.	There was a statistically significant difference between the groups of anesthesiologists who reported using the instrument in less or more than 70% of patients, indicating that the attitude questionnaire discriminates between these two groups of professionals.	N.A.	N.A.	
13	Cadman V. The impact of surgical safety checklists on theatre departments: a critical review of the literature. J Perioper Pract. 2016 Apr;26(4):62-71. Review. PubMed PMID: 27290755.	1A:システマティックレビューまたはメタアナリシス	システマティックレビュー	WHOSSCの使用	Databases utilised were CINAHL Complete, MEDLINE and Scopus.	1:臨床アウトカム	morbidity and mortality etc.	The evidence found shows that use of the checklist reduces patient morbidity and mortality, improves communication and teamwork, reduces operating time and can reduce theatre costs.			
14	Lacassie HJ, Ferdinand C, Guzmán S, Camus L, Echevarria GC. World Health Organization (WHO) surgical safety checklist implementation and its impact on perioperative morbidity and mortality in an academic medical center in Chile. Medicine (Baltimore). 2016 Jun;95(23):e3844. doi: 10.1097/MD.0000000000003844. PubMed PMID: 27281092	3:対照群のある観察研究	前後比較研究	WHOSSCの使用	チリ都市部の学術医療機関1施設	1:臨床アウトカム	In-hospital mortality rate, Length of stay.	In-hospital mortality rate was 0.82% [95% CI, 0.73-0.92] before and 0.65% (95% CI, 0.57-0.74) after checklist implementation [odds ratio (OR) 0.73; 95% CI, 0.61-0.89]. The median length of stay was 3 days [interquartile range (IQR), 1-5] and 2 days (IQR, 1-4) for the pre and postchecklist period, respectively (P<0.01).	N.A.	N.A.	
15	GlobalSurg Collaborative. Mortality of emergency abdominal surgery in high-, middle- and low-income countries. Br J Surg. 2016 Jul;103(8):971-988. doi: 10.1002/bjs.10151. Epub 2016 May 4. Erratum in: Br J Surg. 2017 Apr;104(5):632. PubMed PMID: 27145169.	3:対照群のある観察研究	コホート研究	WHOSSCの使用	357 centres in 58 countries	1:臨床アウトカム	Mortality at 30 days.	Surgical safety checklist use was less frequent in low- and middle-income countries, but when used was associated with reduced mortality at 30 days.	N.A.	N.A.	

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16	Lyons VE, Popejoy LL. Time-Out and Checklists: A Survey of Rural and Urban Operating Room Personnel. J Nurs Care Qual. 2017 Jan/Mar;32(1):E3-E10. PubMed PMID: 27270848.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	rural and urban operating rooms.	4:エラーや有害事象の減少に寄与するアウトカムがない	checklist use	Although checklist use has been adopted in many organizations, use is inconsistent across both settings.	N.A.	N.A.	
17	de Jager E, McKenna C, Bartlett L, Gunnarsson R, Ho YH. Postoperative Adverse Events Inconsistently Improved by the World Health Organization Surgical Safety Checklist: A Systematic Literature Review of 25 Studies. World J Surg. 2016 Aug;40(8):1842-58. doi: 10.1007/s00268-016-3519-9. Review. PubMed PMID: 27125680; PubMed Central PMCID: PMC4943979.	1A:システマティックレビューまたはメタアナリシス	システマティックレビュー	WHOSSCの使用	25 studies were included.	1:臨床アウトカム	The total complication rate, Mortality rates, Length of admission, Surgical site infections, Rates of deep vein thrombosis and/or pulmonary embolism, Total infection rates.	The effects of the checklist were largely inconsistent. Postoperative complications were examined in 20 studies; complication rates significantly decreased in ten and increased in one. Eighteen studies examined postoperative mortality.	N.A.	N.A.	
18	O'Leary JD, Wijeysundera DN, Crawford MW. Effect of surgical safety checklists on pediatric surgical complications in Ontario. CMAJ. 2016 Jun 14;188(9):E191-8. doi: 10.1503/cmaj.151333. Epub 2016 Mar 14. PubMed PMID: 26976960; PubMed Central PMCID: PMC4902710.	3:対照群のある観察研究	前後比較研究	WHOSSCの使用	116 acute care hospitals in Ontario.	1:臨床アウトカム	perioperative complications.	The proportion of children who had perioperative complications was 4.08% (95% confidence interval [CI] 3.76%-4.40%) before the implementation of the checklist and 4.12% (95% CI 3.80%-4.45%) after implementation. After we adjusted for confounding factors, we found no significant difference in the odds of perioperative complications after the	N.A.	N.A.	

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19	Sendlhofer G, Lumenta DB, Leitgeb K, Kober B, Jantscher L, Schanbacher M, Berghold A, Pregartner G, Brunner G, Tax C, Kamolz LP. The Gap between Individual Perception and Compliance: A Qualitative Follow-Up Study of the Surgical Safety Checklist Application. PLoS One. 2016 Feb 29;11(2):e0149212. doi: 10.1371/journal.pone.0149212. eCollection 2016. PubMed PMID: 26925579; PubMed Central PMCID: PMC4771169.	4：対照群のない観察研究	横断的研究	WHOSSCの使用	875 operating team members.	4：エラーや有害事象の減少に寄与するアウトカムがない	healthcare professionals' individual perception of, as well as satisfaction and compliance with the SSC.	Despite healthcare professionals confirming the importance of the SSC, compliance was moderate.			
20	Santana HT, de Freitas MR, Ferraz EM, Evangelista MS. WHO Safety Surgical Checklist implementation evaluation in public hospitals in the Brazilian Federal District. J Infect Public Health. 2016 Sep-Oct;9(5):586-99. doi: 10.1016/j.jiph.2015.12.019. Epub 2016 Feb 26. PubMed PMID: 26924253.	3：対照群のある観察研究	前後比較研究	WHOSSCの使用	ブラジリア連邦直轄区所在の公的医療機関3施設	1：臨床アウトカム	Four important measures for theprevention of SSI, Adherence to the checklist, Frequency of surgical complications, Length of stay.	WHO checklist implementation as an intervention tool showed good adherence to the majority of the items on thelist. Complications and deaths were low in pre and post periods.	N.A.	N.A.	
21	Bock M, Fanolla A, Segur-Cabanac I, Auricchio F, Melani C, Girardi F, Meier H, Pycha A. A Comparative Effectiveness Analysis of the Implementation of Surgical Safety Checklists in a Tertiary Care Hospital. JAMA Surg. 2016 Jul 1;151(7):639-46. doi: 10.1001/jamasurg.2015.5490. PubMed PMID: 26842760.	3：対照群のある観察研究	前後比較研究	WHOSSCの使用	a public, regional, university-affiliated hospital in Italy.	1：臨床アウトカム	all-cause 90- and 30-day mortality rates.	Ninety-day all-cause mortality was 2.4% (129 patients) before compared with 2.2% (118 patients) after the SSC implementation, for an adjusted odds ratio (AOR) of 0.73 (95% CI, 0.56-0.96; P= .02). Thirty-day all-cause mortality was 1.36% (74 patients) before compared with 1.32% (70 patients) after the SSC implementation, for an AOR of 0.79 (95% CI, 0.56-1.11; P=.17).			

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22	Gagné JF, Labidi M, Turmel A. Internal Audit of Compliance with a Perioperative Checklist in a Tertiary Care Neurosurgical Unit. Can J Neurol Sci. 2016 Jan;43(1):87–92. doi: 10.1017/cjn.2015.308. PubMed PMID: 26786640.	4：対照群のない観察研究	前後比較研究	WHOSSCの使用	171 neurosurgical cases.	2：代替アウトカム	compliance with and completeness of the three steps in the perioperative checklist:	Compliance with the Sign–in, Time–out and Sign–out steps was 82%, 99% and 93% respectively. On average, 92% of the Time–out elements were verified. The emergent nature of a surgery was the only factor that caused a statistically significant reduction in compliance with the checklist.			
23	Ong AP, Devcich DA, Hannam J, Lee T, Merry AF, Mitchell SJ. A 'paperless' wall–mounted surgical safety checklist with migrated leadership can improve compliance and team engagement. BMJ Qual Saf. 2016 Dec;25(12):971–976. doi: 10.1136/bmjqs–2015–004545. Epub 2015 Dec 30. PubMed PMID: 26717990.	4：対照群のない観察研究	前後比較研究	introducing a wall–mounted paperless WHOSSC.	111 operations.	2：代替アウトカム	team engagement and compliance.	Improvements in team engagement and compliance with administering checklist items followed introduction of migrated leadership of checklist administration and a wall–mounted checklist	N.A.	N.A.	
24	Robert MC, Choi CJ, Shapiro FE, Urman RD, Melki S. Avoidance of serious medical errors in refractive surgery using a custom preoperative checklist. J Cataract Refract Surg. 2015 Oct;41(10):2171–8. doi: 10.1016/j.jcrs.2015.10.060.	3：対照群のある観察研究	コホート研究	WHOSSCの使用	Consecutive patients who had primary or enhancement laser vision correction.	2：代替アウトカム	medical errors	Although there were 2 (0.07%) serious errors in the prechecklist cohort, none occurred following implementation of the safety checklist protocol (P = .23).	N.A.	N.A.	
25	Overdyk FJ, Dowling O, Newman S, Glatt D, Chester M, Armellino D, Cole B, Landis GS, Schoenfeld D, DiCapua JF. Remote video auditing with real–time feedback in an academic surgical suite improves safety and efficiency metrics: a cluster randomised study. BMJ Qual Saf. 2016 Dec;25(12):947–953. doi: 10.1136/bmjqs–2015–004226. Epub 2015 Dec 11. PubMed PMID: 26658775; PubMed Central PMCID: PMC5256234.	1：無作為化比較試験	無作為化比較試験(RCT)	Remote video auditing with real–time provider feedback on checklist compliance	23–operating room (OR) suite.	2：代替アウトカム	compliance.	Remote video auditing with feedback improves surgical safety checklist compliance for all cases, and turnover time for scheduled cases, but not for unscheduled cases.	N.A.	N.A.	

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26	Rönnberg L, Nilsson U. Swedish Nurse Anesthetists' Experiences of the WHO Surgical Safety Checklist. J Perianesth Nurs. 2015 Dec;30(6):468-475. doi: 10.1016/j.jopan.2014.01.011. Epub 2014 Dec 6. PubMed PMID: 26596382.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	A university hospital and a community hospital in Sweden, A total of 68 RNAs(registered nurse anesthetists) were eligible for participation, and 47 (69%) answered the questionnaire.	2:代替アウトカム	Response rate	There was a statistically significant lower compliance to "Sign-in" compared with the other two parts, "Timeout" and "Sign-out." The RNAs expressed that the checklist was very important for anesthetic and perioperative care. They also expressed that by confirming their own area of expertise, they achieved an increased sense of being a team member.	N.A.	N.A.	
27	Dixon JL, Mukhopadhyay D, Hunt J, Jupiter D, Smythe WR, Papaconstantinou HT. Enhancing surgical safety using digital multimedia technology. Am J Surg. 2016 Jun;211(6):1095-8. doi: 10.1016/j.amjsurg.2015.08.023. Epub 2015 Oct 22. PubMed PMID: 26547406.	3:対照群のある観察研究	症例対照研究	implementation of a multimedia time-out, including a patient video.	Hospital staff.	4:エラーや有害事象の減少に寄与するアウトカムがない	clarity of patient identification, operative laterality.	The multimedia time-out allows improved participation by the surgical team and is preferred to a standard time-out process.			
28	Melekie TB, Getahun GM. Compliance with Surgical Safety Checklist completion in the operating room of University of Gondar Hospital, Northwest Ethiopia. BMC Res Notes. 2015 Aug 19;8:361. doi: 10.1186/s13104-015-1338-y. PubMed PMID: 26285824; PubMed Central PMCID: PMC4544783.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	282 patients undergoing elective and emergency surgery.	2:代替アウトカム	Compliance and completeness rate with implementation of Sign-in, Time-out, and Sign-out domains.	The overall compliance and completeness rate were 39.7 and 63.4% respectively. The sign-in, time-out and sign-out were missed in 30.5% (273/896), 35.4 % (436/1,232) and 45.7% (307/672) respectively.	N.A.	N.A.	

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29	Toor AA, Farooka MW, Ayyaz M, Sarwar H, Malik AA, Shabbir F. Pre-operative antibiotic use reduces surgical site infection. J Pak Med Assoc. 2015 Jul;65(7):733-6. PubMed PMID: 26160082	3:対照群のある観察研究	前後比較研究	WHOSSCの使用	Mayo Hospital, Lahore, Pakistan	1:臨床アウトカム	Adherence of optimal administration of antibiotic, and other sefety protocols, Rate of post-operative infection, Length of stay.	Adherence of optimal administration of antibiotic increased from 114(37.6%) to 282(91%) (p<0.001). The rate of post-operative infection fell from 99(32.7%) to 47(15.2%) (p<0.001). Mean hospital stay was reduced from 7.8±5.7 days to 6.5±5.6 days (p<0.001).	N.A.	N.A.	
30	Bergs J, Hellings J, Cleemput I, Vandijck D; Flemish Safe Surgery Consortium. The World Health Organisation's Surgical Safety Checklist in Belgian Operating Theatres: a Content-Driven Evaluation. Acta Chir Belg. 2015 Mar-Apr;115(2):147-54. PubMed PMID: 26021949.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	Belgian hospitals (n=36)	2:代替アウトカム	Response rate	Based on self-report, 69.4% (n=25) of hospitals reported to use all WHO items. The expert panel determined that 17.1% (n=6) of checklists included all WHO items. Inclusion ranged from 7 to 22 items (mean=16.6, Std. Dev.=4.48).	N.A.	N.A.	
31	Kim RY, Kwakye G, Kwok AC, Baltaga R, Ciobanu G, Merry AF, Funk LM, Lipsitz SR, Gawande AA, Berry WR, Haynes AB. Sustainability and long-term effectiveness of the WHO surgical safety checklist combined with pulse oximetry in a resource-limited setting: two-year update from Moldova. JAMA Surg. 2015 May;150(5):473-9. doi: 10.1001/jamasurg.2014.3848. PubMed PMID: 25806951.	3:対照群のある観察研究	前後比較研究	WHOSSCの使用	A total of 637 patients undergoing noncardiac surgery were included in the long-term follow-up group were compared with 2106 patients who underwent surgery shortly after implementation in the short-term follow-up group	2:代替アウトカム	Change in Surgical Complication Rates	Between the short- and long-term follow-up groups, the complication rate decreased 30.7% (P=.03). Surgical site infections decreased 40.4% (P=.05). The mean (SD) rate of completion of the checklist items increased from 88% (14%) in the short-term follow-up group to 92% (11%) in the long-term follow-up group (P<.001).	N.A.	N.A.	

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
32	Mayer EK, Sevdalis N, Rout S, Caris J, Russ S, Mansell J, Davies R, Skapinakis P, Vincent C, Athanasiou T, Moorthy K, Darzi A. Surgical Checklist Implementation Project: The Impact of Variable WHO Checklist Compliance on Risk-adjusted Clinical Outcomes After National Implementation: A Longitudinal Study. Ann Surg. 2016 Jan;263(1):58-63. doi: 10.1097/SLA.0000000000001185. PubMed PMID: 25775063.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	6714 patients at 5 academic and community hospitals.	1:臨床アウトカム	The primary endpoint was any complication, including mortality, occurring before hospital discharge.	Checklist completion did not affect mortality reduction, but significantly lowered risk of postoperative complication (16.9% vs. 11.2%), and was largely noticed when all 3 components of the checklist had been completed (odds ratio = 0.57, 95% confidence interval: 0.37–0.87, P < 0.01).	N.A.	N.A.	
33	Oak SN, Dave NM, Garasia MB, Parelkar SV. Surgical checklist application and its impact on patient safety in pediatric surgery. J Postgrad Med. 2015 Apr–Jun;61(2):92-4. doi: 10.4103/0022-3859.150450. PubMed PMID: 25766340; PubMed Central PMCID: PMC4943428.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	3000 consecutive surgeries	2:代替アウトカム	major peri-operative errors and events, near missed catastrophe	No major perioperative errors were noted. The patient identification tag was missing in four (0.1%) patients. Mention of the side of procedures was missing in 108 (3.6%) cases. In 0.1% (3) of patients there was mix up of the mention of side of operation in the case papers and consent forms.	N.A.	N.A.	
34	Lepänluoma M, Rahi M, Takala R, Löyttyniemi E, Ikonen TS. Analysis of neurosurgical reoperations: use of a surgical checklist and reduction of infection-related and preventable complication-related reoperations. J Neurosurg. 2015 Jul;123(1):145-52. doi: 0.3171/2014.12.JNS141077. Epub 2015 Feb 27. PubMed PMID: 25723297.	3:対照群のある観察研究	前後比較研究	WHOSSCの使用	Turku University Hospital, Finland	1:臨床アウトカム	Operations leading to complication-related reoperations, Preventable complications leading to reoperation, Rate of infection-related reoperations	The overall rate of preventable complication-related neurosurgical reoperations decreased from 3.3% (95% CI 2.7%–4.0%) to 2.0% (95% CI 1.5% –2.6%) after the checklist implementation. All infection-related reoperations proportioned to all neurosurgical operations (2.5% before vs 1.6% after checklist implementation) showed a significant reduction (p = 0.02) after the implementation of the checklist.	N.A.	N.A.	

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35	Helmiö P, Blomgren K, Lehtivuori T, Palonen R, Aaltonen LM. Towards better patient safety in otolaryngology: characteristics of patient injuries and their relationship with items on the WHO Surgical Safety Checklist. Clin Otolaryngol. 2015 Oct;40(5):443–8. doi: 10.1111/coa.12396. PubMed PMID: 25704536.	4：対照群のない観察研究	コホート研究	WHOSSCの使用	Claim record study of national patient insurance charts in Finland.	1：臨床アウトカム	patient injuries	Patient injuries in otolaryngology are strongly related to operative care. The WHO checklist is one suitable tool for error prevention.			
36	Chaudhary N, Varma V, Kapoor S, Mehta N, Kumaran V, Nundy S. Implementation of a surgical safety checklist and postoperative outcomes: a prospective randomized controlled study. J Gastrointest Surg. 2015 May;19(5):935–42. doi: 10.1007/s11605-015-2772-9. Epub 2015 Feb 18. PubMed PMID: 25691114.	1：無作為化比較試験	無作為化比較試験(RCT)	WHOSSCの使用	700 consecutive patients	1：臨床アウトカム		Postoperative wound-related (p＝0.04), abdominal (p＝0.01), and bleeding (p＝0.03) complications were significantly lower in the checklist group compared to the control group.			
37	Biskup N, Workman AD, Kutzner E, Adetayo OA, Gupta SC. Perioperative Safety in Plastic Surgery: Is the World Health Organization Checklist Useful in a Broad Practice? Ann Plast Surg. 2016 May;76(5):550–5. doi: 10.1097/SAP.0000000000000427. PubMed PMID: 25664411.	3：対照群のある観察研究	前後比較研究	WHOSSCの使用	Loma Linda University Medical Center, A total of 2166 patients were operated on before list implementation and a total of 2310 patients after checklist implementation.	1：臨床アウトカム	morbidity and mortality	The most common complications were wound related, including infection, seroma and/or hematoma, dehiscence, and flap-related complications. No significant decrease in the measured complications, neither total nor each specific complication, occurred after the implementation of the SSC.	N.A.	N.A.	

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38	Jammer I, Ahmad T, Aldecoa C, Koulenti D, Goranović T, Grigoras I, Mazul-Sunko B, Matos R, Moreno R, Sigurdsson GH, Toft P, Walder B, Rhodes A, Pearse RM; European Surgical Outcomes Study (EuSOS) group. Point prevalence of surgical checklist use in Europe: relationship with hospital mortality. Br J Anaesth. 2015 May;114(5):801-7. doi: 10.1093/bja/aeu460. Epub 2015	3:対照群のある観察研究	横断的研究	WHOSSCの使用	45,591 patients from 426 sites were included in the primary analysis	1:臨床アウトカム	The use of a surgical checklist, hospital mortality.	There were wide variations in exposure to surgical checklist use between European nations. Exposure was associated with a lower hospital mortality after adjustment for risk factors, which may differ between hospitals and countries.	N.A.	N.A.	
39	Myers JW, Gilmore BA, Powers KA, Kim PJ, Attinger CE. The utility of the surgical safety checklist for wound patients. Int Wound J. 2016 Oct;13(5):848-53. doi: 10.1111/iwj.12391. Epub 2015 Jan 14. PubMed PMID: 25585543.	4:対照群のない観察研究	前後比較研究	WHOSSCの使用	233 patients.	2:代替アウトカム	the frequency of changes in patient care resulting from the use of a SSC.	The number of patients whose management was modified as a result of the checklist was 113 (48%) out of 233. The total number of changes made was 132, and 18 patients had more than one modification made to their care plan.	N.A.	N.A.	
40	Rodrigo-Rincon I, Martin-Vizcaino MP, Tirapu-Leon B, Zabalza-Lopez P, Zaballos-Barcala N, Villalgordo-Ortin P, Abad-Vicente FJ, Gost-Garde J. The effects of surgical checklists on morbidity and mortality: a pre- and post-intervention study. Acta Anaesthesiol Scand. 2015 Feb;59(2):205-14. doi: 10.1111/aas.12443. Epub 2014 Dec 5. PubMed PMID: 25476578; PubMed Central PMCID:	3:対照群のある観察研究	前後比較研究	WHOSSCの使用	A tertiary teaching hospital.	1:臨床アウトカム	Mortality and surgical adverse events (AEs).	The overall AE rate did not decrease significantly between the two periods. However, the rate of infectious AEs and overall AEs in patients with non-elective admissions had statistically significant reductions. Mortality rate at 30 days decreased from 1.5% to 0.9% (P =0.35).	N.A.	N.A.	

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41	Russ S, Rout S, Caris J, Mansell J, Davies R, Mayer E, Moorthy K, Darzi A, Vincent C, Sevdalis N. Measuring variation in use of the WHO surgical safety checklist in the operating room: a multicenter prospective cross-sectional study. J Am Coll Surg. 2015 Jan;220(1):1-11.e4. doi: 10.1016/j.jamcollsurg.2014.09.021. Epub 2014 Oct 12. PubMed PMID: 25456785.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	5 English hospitals	2:代替アウトカム	Variability in How the WHO Checklist Was Used at Time-Out / Sign-Out.	A bespoke Checklist Usability Tool (CUT) for assessment of variation in checklist use was developed. On average, two-thirds of the items were checked, team members were absent in more than 40% of cases, and they failed to pause or focus on the checks in more than 70% of cases. Information sharing could be improved across the entire operating room (OR) team. Sign-out was not completed in 39% of cases, largely due to uncertainty about when to conduct it.	N.A.	N.A.	
42	Patel J, Ahmed K, Guru KA, Khan F, Marsh H, Shamim Khan M, Dasgupta P. An overview of the use and implementation of checklists in surgical specialities - a systematic review. Int J Surg. 2014 Dec;12(12):1317-23. doi: 10.1016/j.ijsu.2014.10.031. Epub 2014 Oct 28. Review. PubMed PMID: 25448652.	1A:システマティックレビューまたはメタアナリシス	システマティックレビュー	WHOSSCの使用	The literature search found 916 potentially relevant articles. A final total of 16 studies were identified that observed the use of checklists in various surgical specialties	1:臨床アウトカム	Compliance of the WHO Checklist, Percentage decrease in post-operative complication rate and mortal rate.	The positive impact of the WHO surgical safety checklist on patient outcomes and post-operative complications can be seen in several studies. It is thought that the use of checklists in surgery can reduce the incidence of wrong site surgery, as well as reduce complications, something which has been mentioned in various studies. There is a general consensus amongst surgical staff that the WHO checklist is beneficial, and as a result has been widely accepted.	N.A.	N.A.	

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43	Russ SJ, Sevdalis N, Moorthy K, Mayer EK, Rout S, Caris J, Mansell J, Davies R, Vincent C, Darzi A. A qualitative evaluation of the barriers and facilitators toward implementation of the WHO surgical safety checklist across hospitals in England: lessons from the "Surgical Checklist Implementation Project". Ann Surg. 2015 Jan;261(1):81-91. doi: 10.1097/SLA.0000000000000793. PubMed PMID: 25072435.	4:対照群のない観察研究	質的研究(インタビュー等)	WHOSSCの使用	A longitudinal interview study with operating room personnel was conducted across a representative sample of 10 hospitals in England.	4:エラーや有害事象の減少に寄与するアウトカムがない	Checklist implementation	Most barriers to implementation were specific to the checklist itself (eg, perceived design issues) but also included problematic integration into preexisting processes.	N.A.	N.A.	
44	Cullati S, Licker MJ, Francis P, Degiorgi A, Bezzola P, Courvoisier DS, Chopard P. Implementation of the surgical safety checklist in Switzerland and perceptions of its benefits: cross-sectional survey. PLoS One. 2014 Ju 18;9(7):e101915. doi: 10.1371/journal.pone.0101915. eCollection 2014. PubMed PMID: 25036453; PubMed Central PMCID: PMC4103799.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	Surgeons and anaesthetists working in Swiss hospitals and clinics	2:代替アウトカム	Perceptions of the SSC	the SSC has been largely implemented in many Swiss hospitals and clinics. Both surgeons and anaesthetists perceived the SSC as a valuable tool in improving intraoperative patient safety and communication among health care professionals, with lesser importance in facilitating teamwork	N.A.	N.A.	
45	van Schoten SM, Kop V, de Blok C, Spreeuwenberg P, Groenewegen PP, Wagner C. Compliance with a time-out procedure intended to prevent wrong surgery in hospitals: results of a national patient safety programme in the Netherlands. BMJ Open. 2014 Jul 3;4(7):e005075. doi: 10.1136/bmjopen-2014-005075.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	Operating rooms of 2 academic, 4 teaching and 12 general Dutch hospitals	2:代替アウトカム	Compliance of time-out procedure	Large differences in compliance with the TOP were observed between participating hospitals which can be attributed at least in part to the type of hospital, surgical specialty and patient characteristics.	N.A.	N.A.	

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
46	Putnam LR, Levy SM, Sajid M, Dubuisson DA, Rogers NB, Kao LS, Lally KP, Tsao K. Multifaceted interventions improve adherence to the surgical checklist. Surgery. 2014 Aug;156(2):336–44. doi: 10.1016/j.surg.2014.03.032. Epub 2014 Jun 16. PubMed PMID: 24947646	4：対照群のない観察研究	横断的研究	Safety council was created. Safety workshops, Checklist modification, Stakeholder audit and feedback.	Children's Memorial Hermann Hospital (Texas)	2：代替アウトカム	Adherence to checklist.	Adherence to the checklist significantly improved. Interventions targeted to improve the culture of safety, local engagement of stakeholders, and comprehension of the checklist significantly improved checklist adherence from 30% to 96% over the course of 2 years.	N.A.	N.A.	
47	Haugen AS, Søfteland E, Almeland SK, Sevdalis N, Vonen B, Eide GE, Nortvedt MW, Harthug S. Effect of the World Health Organization checklist on patient outcomes: a stepped wedge cluster randomized controlled trial. Ann Surg. 2015 May;261(5):821–8. doi: 10.1097/SLA.0000000000000716. PubMed PMID: 24824415	4：対照群のない観察研究	横断的研究		2 hospitals in Norway; a tertiary teaching hospital (1,100 beds) and a central community hospital (300 beds).	2：代替アウトカム	Major and minor complications and in-hospital mortality up to 30 days after surgery, Length of stay.	A total of 2212 control procedures were compared with 2263 SCC procedures. The complication rates decreased from 19.9% to 11.5% ($P < 0.001$), with absolute risk reduction 8.4 (95% confidence interval, 6.3–10.5) from the control to the SSC stages.	N.A.	N.A.	
48	Gillespie BM, Chaboyer W, Thalib L, John M, Fairweather N, Slater K. Effect of using a safety checklist on patient complications after surgery: a systematic review and meta-analysis. Anesthesiology. 2014 Jun;120(6):1380–9. doi: 10.1097/ALN.0000000000000232. Review. PubMed PMID: 24845919.	1A：システマティックレビューまたはメタアナリシス	システマティックレビュー	WHOSSCの使	Of the 207 intervention studies identified, 7 representing 37,339 patients	1：臨床アウトカム	Complication rate, Mortality	The use of checklists in surgery compared with standard practice led to a reduction in any complication and wound infection and also reduction in blood loss. There were no significant reductions in mortality	N.A.	N.A.	
49	Bergs J, Hellings J, Cleemput I, Zurel Ö, De Troyer V, Van Hiel M, Demeere JL, Claeys D, Vandijck D. Systematic review and meta-analysis of the effect of the World Health Organization surgical safety checklist on postoperative complications. Br J Surg. 2014 Feb;101(3):150–8. doi: 10.1002/bjs.9381. Review. PubMed PMID: 24469615.	4：対照群のない観察研究	横断的研究	WHOSSCの使用	The Cochrane Library, MEDLINE, Embase and CINAHL were searched. Seven of 723 studies identified met the inclusion criteria.	2：代替アウトカム	Complication, surgical-site infection (SSI) and mortality.	Risk ratios for any complication, mortality and SSI were 0·59 (95 per cent confidence interval 0·47 to 0·74), 0·77 (0·60 to 0·98) and 0·57 (0·41 to 0·79) respectively. There was a strong correlation between a significant decrease in postoperative complications and adherence to aspects of care embedded in the checklist (Q = 0·82; P =	N.A.	N.A.	

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50	Lepänluoma M, Takala R, Kotkansalo A, Rahi M, Ikonen TS. Surgical safety checklist is associated with improved operating room safety culture, reduced wound complications, and unplanned readmissions in a pilot study in neurosurgery. Scand J Surg. 2014 Mar;103(1):66-72. doi: 10.1177/1457496913482255. Epub 2013 Dec 17. PubMed PMID: 24345978.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	From structured questionnaires delivered to operating room personnel, answers were analyzed during 89 and 73 neurosurgical operations before and after the checklist implementation, respectively.	2:代替アウトカム	Communication between the surgeon and the anesthesiologist, safety-related issues, Wound complications	Communication between the surgeon and the anesthesiologist was enhanced, and safety-related issues were better covered when the checklist was used. Unplanned readmissions fell from 25% to 10% after the checklist implementation ($p = 0.02$). Wound complications decreased from 19% to 8% ($p = 0.04$).	N.A.	N.A.	
51	Vasconcelos H, Bomfim CC, Mello MJ, Borges PS, Couceiro TC, Orange FA. Is the anesthesiologist actually prepared for loss of airway or respiratory function? A cross-sectional study conducted in a tertiary hospital. Rev Assoc Med Bras (1992). 2014 Jan-Feb;60(1):40-6. PubMed PMID: 24918851.	4:対照群のない観察研究	前後比較研究	WHOSSCの使	87 patients aged 18 to 60 years	2:代替アウトカム	Compliance	It was found that in 87.4% of patients, the airway was not evaluated using the Mallampati classification and in 51.7% of cases, preoperative fasting was not confirmed	N.A.	N.A.	
52	McDowell DS, McComb SA. Safety checklist briefings: a systematic review of the literature. AORN J. 2014 Jan;99(1):125-137.e13. doi: 10.1016/j.aorn.2013.11.015. Review. PubMed PMID: 24369977.	1A:システマティックレビューまたはメタアナリシス	システマティックレビュー	WHOSSCの使用	23 studies conducted in 17 countries	2:代替アウトカム	The studies used a variety of methodologies and outcome measures.	Common themes in the studies included enhanced patient safety, improved compliance over time, and increased communication among team members when checklists were used.	N.A.	N.A.	
53	Pickering SP, Robertson ER, Griffin D, Hadi M, Morgan LJ, Catchpole KC, New S, Collins G, McCulloch P. Compliance and use of the World Health Organization checklist in U.K. operating theatres. Br J Surg. 2013 Nov;100(12):1664-70. doi: 10.1002/bjs.9305. PubMed PMID: 24264792.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	One district general hospital, three teaching hospitals and one tertiary referral centre.	2:代替アウトカム	The attempt rate of time-out and sign-out, the median time taken to perform a time-out	The time-out section of the WHOSSC was usually attempted, but the sign-out section was not.	N.A.	N.A.	

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54	Saturno PJ, Soria-Aledo V, Da Silva Gama ZA, Lorca-Parra F, Grau-Polan M. Understanding WHO surgical checklist implementation: tricks and pitfalls. An observational study. World J Surg. 2014 Feb;38(2):287-95. doi: 10.1007/s00268-013-2300-6. PubMed PMID: 24142333.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	A regional network of nine Spanish hospitals	2:代替アウトカム	SSC compliance was assessed overall and by item.	In the retrospective evaluation the SSC was present in 83.1 % of cases, fully completed in 28.4 %, with 69.3 % of all possible items checked. Recorded SSC compliance may be widely unreliable and higher than actual compliance, particularly when recording is facilitated by using an electronic format.	N.A.	N.A.	
55	Boaz M, Bermant A, Ezri T, Lakstein D, Berlovitz Y, Laniado I, Feldbrin Z. Effect of Surgical Safety checklist implementation on the occurrence of postoperative complications in orthopedic patients. Isr Med Assoc J. 2014 Jan;16(1):20-5. PubMed PMID: 24575500.	4:対照群のない観察研究	前後比較研究	WHOSSCの使用	The records of 760 patients (380 in each group) hospitalized during this 12 month period were analyzed.	1:臨床アウトカム	Postoperative f	Postoperative fever occurred in 5.3% versus 10.6% of patients with and without the checklist respectively (P = 0.008). Significantly more patients received only postoperative prophylactic antibiotics rather than both pre-and postoperative antibiotic treatment prior to implementation of the	N.A.	N.A.	
56	Papaconstantinou HT, Smythe WR, Reznik SI, Sibbitt S, Wehbe-Janek H. Surgical safety checklist and operating room efficiency: results from a large multispecialty tertiary care hospital. Am J Surg. 2013 Dec;206(6):853-9; discussion 859-60. doi: 10.1016/j.amjsurg.2013.08.016. Epub 2013 Oct 8. PubMed PMID: 24112671.	4:対照群のない観察研究	前後比較研究	WHOSSCの使用	All operations at one large multispecialty tertiary care hospital	2:代替アウトカム	operating room time, operation time, first starts on time, and same-day cancellations, etc.	A total of 35,570 operations were reviewed: 17,204 pre-SSC and 18,366 post-SSC. There was no difference between groups for operating room time (P = .93), operation time (P = .66), first starts on time (P = .15), and same-day cancellations (P = .57). The mean OR disposable cost was significantly lower ($70/operation) for the post-SSC group (P < .01).	N.A.	N.A.	

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
57	Sparks EA, Wehbe-Janek H, Johnson RL, Smythe WR, Papaconstantinou HT. Surgical Safety Checklist compliance: a job done poorly! J Am Coll Surg. 2013 Nov;217(5):867-73.e1-3. doi: 10.1016/j.jamcollsurg.2013.07.393. Epub 2013 Aug 21. PubMed PMID: 23973104.	4:対照群のない観察研究	前後比較研究	WHOSSCの使用	One institution	2:代替アウトカム	compliance score etc.	Mean overall compliance score was 27.7 (± 5.4 SD) of 40 possible points (69.3% ± 13.5% of total possible score; n = 671) and did not change over time. Although completion scores were high (16.9 ± 2.7 out of 20 [84.5% ± 13.6%]), accuracy was poor (10.8 ± 3.4 out of 20 [54.1% ± 16.9%]). Overall compliance score was significantly associated with case start-time ($p < 0.05$), and operative time and case complexity showed no association.	N.A.	N.A.	
58	Hannam JA, Glass L, Kwon J, Windsor J, Stapelberg F, Callaghan K, Merry AF, Mitchell SJ. A prospective, observational study of the effects of implementation strategy on compliance with a surgical safety checklist. BMJ Qual Saf. 2013 Nov;22(11):940-7. doi: 10.1136/bmjqs-2012-001749. Epub 2013 Jul 9. PubMed PMID: 23840072.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	An original WHO pilot study centre (Hospital 1) with that at a similar neighbouring hospital (Hospital 2) that independently integrated the SSC with preexisting practice.	2:代替アウトカム	Domain compliance	Domain compliance at Hospital 1 and Hospital 2, respectively, was: 96%and 31% ($p<0.0005$) for Sign In; 99%and 48%($p<0.0005$) for Time Out and 22%and 9% ($p=0.008$) for Sign Out. Engagement of two or more teams during Sign In and Time Out occurred more frequently at Hospital 2 than at Hospital 1.	N.A.	N.A.	
59	Haugen AS, Søfteland E, Eide GE, Sevdalis N, Vincent CA, Nortvedt MW, Harthug S. Impact of the World Health Organization's Surgical Safety Checklist on safety culture in the operating theatre: a controlled intervention study. Br J Anaesth. 2013 May;110(5):807-15. doi: 10.1093/bja/aet005. Epub 2013 Feb 12. PubMed PMID: 23404986; PubMed Central PMCID: PMC3630285.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	a single Norwegian university hospital.	2:代替アウトカム	Norwegian version of the Hospital Survey on Patient Safety Culture.	Significant positive changes in the checklist intervention group for the culture factors 'frequency of events reported' and 'adequate staffing'. Overall, the intervention group reported significantly		N.A.	

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60	Cullati S, Le Du S, Raë AC, Micallef M, Khabiri E, Ourahmoune A, Boireaux A, Licker M, Chopard P. Is the Surgical Safety Checklist successfully conducted? An observational study of social interactions in the operating rooms of a tertiary hospital. BMJ Qual Saf. 2013 Aug;22(8):639-46. doi: 10.1136/bmjqs-2012-001634. Epub 2013 Mar 8. PubMed PMID: 23476070.	4:対照群のない観察研究	前後比較研究	WHOSSCの使用	Geneva University Hospitals	2:代替アウトカム	Validation of the items, etc.	Items were mostly confirmed during the Time Out (range 100-72%) but less often during the Sign Out (range 86-19%). Validation of the items was far from optimal: only 13% of Time Outs and 3% of Sign Outs were properly checked (all items validated).	N.A.	N.A.	
61	Poon SJ, Zuckerman SL, Mainthia R, Hagan SL, Lockney DT, Zotov A, Holt GE, Bennett ML, Anders S, France DJ. Methodology and bias in assessing compliance with a surgical safety checklist. Jt Comm J Qual Patient Saf. 2013 Feb;39(2):77-82. PubMed PMID: 23427479.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	A single observer group made up of medical students and nurses recorded compliance with each of the 11 standardized items of the time-out.	2:代替アウトカム	Compliance.	One item (procedure to be performed) achieved > 95% compliance. Three items (surgical site; availability of necessary blood products, implants, devices; and start of antibiotics) achieved 80%-95% compliance. Of the 11 items on the time-out being evaluated, there was a statistically significant difference between medical student and nursing observations for 10 items ($p < .05$).			
62	Fudickar A, Hörle K, Wiltfang J, Bein B. The effect of the WHO Surgical Safety Checklist on complication rate and communication. Dtsch Arztebl Int. 2012 Oct;109(42):695-701. doi: 10.3238/arztebl.2012.0695. Epub 2012 Oct 19. Review. PubMed PMID: 23264813; PubMed Central PMCID: PMC3489074.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	The 20 studies that we analyzed included a single prospective random ized trial concerning the effect of the WHO checklist on safety-related behavior in the operating room.	2:代替アウトカム	Effects on perioperative morbidity and mortality, Effects on safety culture, Practical implementation, Acceptance in the operating room	The two surgical outcome studies documented a relative improvement of perioperative mortality by 47% in one study (from 56 in 3733 cases [1.5%] to 32 in 3955 cases [0.8%]) and by 62% in the other (from 31 in 842 cases [3.7%] to 13 in 908 cases [1.4%]), as well as a relative improvement of perioperative morbidity by 36% in one study (from 411 in 3733 cases [11.0%] to 288 in 3,955 cases [7.3%]) and by 37% in the other (from 151 in 842 cases [17.9%] to 102 in	N.A.	N.A.	

	執筆者、題名、雑誌・書籍名、出版日	研究デザインのレベル	研究デザイン	介入の内容	対象者	アウトカムのレベル	アウトカムの指標	主な結果	活動・対策の短所	費用	その他
63	Mohammed A, Wu J, Biggs T, Ofili-Yebovi D, Cox M, Pacquette S, Duffy S. Does use of a World Health Organization **obstetric safe surgery checklist** improve communication between obstetricians and anaesthetists? A retrospective study of 389 caesarean sections. BJOG. 2013 Apr;120(5):644-8. doi: 10.1111/1471-0528.12041. Epub 2012 Nov 27. PubMed PMID: 23190321.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	a Teaching hospital in London, 195 caesarean sections before introduction ofthe WHO safe surgery checklist and 194 caesarean sections afterchecklist introduction were studie	2:代替アウトカム	Differences in grading	WHO Obstetric Safe Surgerychecklist improves the communication of caesarean section grade(urgency) between obstetricians and anaesthetists.	N.A.	N.A.	
64	Romain B, Chemaly R, Meyer N, Brigand C, Steinmetz JP, Rohr S. Value of a preoperative checklist for laparoscopic appendectomy and cholecystectomy. J Visc Surg. 2012 Dec;149(6):408-11. doi: 10.1016/j.jviscsurg.2012.10.001. Epub 2012 Nov 17. PubMed PMID: 23164526.	4:対照群のない観察研究	前後比較研究	WHOSSCの使用	Laparoscopic procedures	1:臨床アウトカム	The number of incidents etc.	The risk of at least one incident to occur during the procedure was increased 3-fold ([1.36 vs. 6.64], P=0.007) when the checklist was not used compared to when the preoperative checklist was used. Likewise, the number of incidents increased 2.4-fold ([1.15; 5.01], P=0.02), compared to when the preoperative checklist was used. The checklist significantly reduced the proportion of incidences during which time was lost from 22%	N.A.	N.A.	

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65	Borchard A, Schwappach DL, Barbir A, Bezzola P. A systematic review of the effectiveness, compliance, and critical factors for implementation of safety checklists in surgery. Ann Surg. 2012 Dec;256(6):925–33. doi: 10.1097/SLA.0b013e3182682f27. Review. PubMed PMID: 22968074.	1A：システマティックレビューまたはメタアナリシス	システマティックレビュー	WHOSSCの使用	Medline including Premedline (OvidSP), Embase, and Cochrane Collaboration Library, hand search, a search of reference lists of key articles, and tables of content.	1：臨床アウトカム	Mortality, etc.	With the use of checklists, the relative risk for mortality is 0.57 [95% confidence interval (CI): 0.42–0.76] and for any complications 0.63 (95% CI: 0.58–0.67). The overall compliance rate ranged from 12% to 100% (mean: 75%) and for the Time Out from 70% to 100% (mean: 91%).	N.A.	N.A.	
66	Levy SM, Senter CE, Hawkins RB, Zhao JY, Doody K, Kao LS, Lally KP, Tsao K. Implementing a surgical checklist: more than checking a box. Surgery. 2012 Sep;152(3):331–6. doi: 10.1016/j.surg.2012.05.034. Epub 2012 Jul 6. PubMed PMID: 22770952.	4：対照群のない観察研究	横断的研究	WHOSSCの使用	One hospital. A total of 142 pediatric surgical cases were observed.	2：代替アウトカム	Compliance.	Hospital reported data demonstrated 100% compliance with the preincision phase of the checklist for these cases. None of the cases completely executed all items on the checklist, and the average number of checklist items performed in the observed cases was 4 of 13. The most commonly performed checkpoint were the confirmation of patient name and procedure (99%) and the	N.A.	N.A.	
67	Yuan CT, Walsh D, Tomarken JL, Alpern R, Shakpeh J, Bradley EH. Incorporating the World Health Organization Surgical Safety Checklist into practice at two hospitals in Liberia. Jt Comm J Qual Patient Saf. 2012 Jun;38(6):254–60. PubMed PMID: 22737776.	4：対照群のない観察研究	横断的研究	WHOSSCの使用	two hospitals in the resource–limited setting of Liberia, 232 consecutively enrolled patients who were undergoing surgery.	2：代替アウトカム	Overall surgical processes and surgical outcomes.	The introduction of the checklist was associated with significant ($p < 0.05$) improvements in terms of overall surgical processes and surgical outcomes.	N.A.	N.A.	

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68	Pérez-Guisado J, de Haro-Padilla JM, Rioja LF. Implementation of the World Health Organization surgical safety checklist in plastic and reconstructive patients. Plast Reconstr Surg. 2012 Mar;129(3):600e-602e. doi: 10.1097/PRS.0b013e3182419b1c. PubMed PMID: 22374042.	4：対照群のない観察研究	横断的研究	WHOSSCの使用	n=1684 patients; 719 operations under general anesthesia and 965 operations under local anesthesia	2：代替アウトカム	Surgical Safety Checklist Item Implementation	Results were better for operations performed under local anesthesia (resident surgeons in charge) when compared with operations performed under general anesthesia (94.87 percent versus 83.63 percent).	N.A.	N.A.	
69	Berrisford RG, Wilson IH, Davidge M, Sanders D. Surgical time out checklist with debriefing and multidisciplinary feedback improves venous thromboembolism prophylaxis in thoracic surgery: a prospective audit. Eur J Cardiothorac Surg. 2012 Jun;41(6):1326-9. doi: 10.1093/ejcts/ezr179. Epub 2011 Dec 26. PubMed PMID:	4：対照群のない観察研究	前後比較研究	WHOSSC (time out) の使用	959 patients of 990 (96.8%) undergoing thoracic surgery.	2：代替アウトカム	Errors.	After a lag period of 15 months, during which the team underwent human factors training, introduced debriefing and escalated VTE prophylaxis to regular departmental meetings, VTE prophylaxis errors were substantially reduced.	N.A.	N.A.	
70	van Klei WA, Hoff RG, van Aarnhem EE, Simmermacher RK, Regli LP, Kappen TH, van Wolfswinkel L, Kalkman CJ, Buhre WF, Peelen LM. Effects of the introduction of the WHO "Surgical Safety Checklist" on in-hospital mortality: a cohort study. Ann Surg. 2012 Jan;255(1):44-9. doi: 10.1097/SLA.0b013e31823779ae. PubMed PMID: 22123159.	4：対照群のない観察研究	横断的研究	WHOSSCの使用	The University Medical Center Utrecht (The Netherlands), 11,151 patients	2：代替アウトカム	In-hospital mortality within 30 days after surgery.	After checklist implementation, crude mortality decreased from 3.13% to 2.85% (P = 0.19). After adjustment for baseline differences, mortality was significantly decreased after checklist implementation (odds ratio [OR] 0.85; 95% CI, 0.73-0.98).	N.A.	N.A.	

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71	Takala RS, Pauniaho SL, Kotkansalo A, Helmiö P, Blomgren K, Helminen M, Kinnunen M, Takala A, Aaltonen R, Katila AJ, Peltomaa K, Ikonen TS. A pilot study of the implementation of WHO surgical checklist in Finland: improvements in activities and communication. Acta Anaesthesiol Scand. 2011 Nov;55(10):1206–14. doi: 10.1111/j.1399–6576.2011.02525.x. Epub 2011 Sep 26. PubMed PMID: 22092125.	4：対照群のない観察研究	横断的研究	WHOSSCの使用	Four university and teaching hospitals, Questionnaires were returned from 1748 operations, 901 before and 847 after checklist implementation.	2：代替アウトカム	Performance of safety checks and communication.	Patient's identity was more often confirmed and knowledge of names and roles among team members improved with the checklist. Anaesthesiologists and surgeons discussed critical events pre–operatively more frequently after the checklist.	N.A.	N.A.	
72	Vogts N, Hannam JA, Merry AF, Mitchell SJ. Compliance and quality in administration of a Surgical Safety Checklist in a tertiary New Zealand hospital. N Z Med J. 2011 Sep 9;124(1342):48–58. PubMed PMID: 21963925.	4：対照群のない観察研究	横断的研究	WHOSSCの使用	100 adult surgical cases were observed.	2：代替アウトカム	The rate (per 100 cases) of the checklist domain administration.	The mean (range) checklist item compliance was 56% (27–100%) for Sign In, 69% (33–100%) for Time Out, and 40% for Sign Out. Checklist items related to patient identity and surgical procedure were administered in 100% of Sign In	N.A.	N.A.	
73	Calland JF, Turrentine FE, Guerlain S, Bovbjerg V, Poole GR, Lebeau K, Peugh J, Adams RB. The surgical safety checklist: lessons learned during implementation. Am Surg. 2011 Sep;77(9):1131–7. PubMed PMID: 21944620.	1：無作為化比較試験	無作為化比較試験(RCT)	WHOSSCの使用	47 laparoscopic cholecystectomies.	1：臨床アウトカム	patient outcomes, case times, or technical proficiency	Participants in the intervention (checklist) group consistently rated their cases as involving less satisfactory subjective levels of comfort, team efficiency, and communication compared with those performed by surgeons in the control group.	N.A.	N.A.	
74	Panesar SS, Noble DJ, Mirza SB, Patel B, Mann B, Emerton M, Cleary K, Sheikh A, Bhandari M. Can the surgical checklist reduce the risk of wrong site surgery in orthopaedics?--Can the checklist help? Supporting evidence from analysis of a national patient incident reporting system. J Orthop Surg Res. 2011 Apr 18;6:18. doi: 10.1186/1749-799X-6-18. PubMed PMID: 21501466	4：対照群のない観察研究	横断的研究	WHOSSCの使用	The National Reporting and Learning Service (NRLS) database	2：代替アウトカム	WHOSSCの使用を想定した場合に防げた有害事象の割合	the checklist could have been prevented 28/133 [21.1% (95%CI 14.1 – 28.0%)] patient safety incidents.	N.A.	N.A.	

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75	Helmiö P, Blomgren K, Takala A, Pauniaho SL, Takala RS, Ikonen TS. Towards better patient safety: WHO Surgical Safety Checklist in otorhinolaryngology. Clin Otolaryngol. 2011 Jun;36(3):242-7. doi: 10.1111/j.1749-4486.2011.02315.x. PubMed PMID: 21481197.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	The Department of Otorhinolaryngology at the Helsinki University Central Hospital	2:代替アウトカム	Questions concerned patient-related safety checks, teamwork and communication.	The checklist improved verification of the patient's identity (P < 0.001). Awareness of the patient's medical history, medication and allergies increased (P < 0.001).	N.A.	N.A.	
76	Weiser TG, Haynes AB, Dziekan G, Berry WR, Lipsitz SR, Gawande AA; Safe Surgery Saves Lives Investigators and Study Group. Effect of a 19-item surgical safety checklist during urgent operations in a global patient population. Ann Surg. 2010 May;251(5):976-80. doi: 10.1097/SLA.0b013e3181d970e3. PubMed PMID: 20395848.	4:対照群のない観察研究	横断的研究	WHOSSCの使用	842 patients had urgent operations before checklist implementation and 908 after checklist implementation	2:代替アウトカム	Complication rate, Death rates	The complication rate was 18.4% (n = 151) at baseline and 11.7% (n = 102) after the checklist was introduced (P = 0.0001). Death rates dropped from 3.7% to 1.4% following checklist introduction (P = 0.0067). Adherence to 6 measured safety steps improved from 18.6% to 50.7% (P < 0.0001).	N.A.	N.A.	