厚生労働科学研究費補助金（医薬品・医療機器等レギュラトリーサイエンス政策研究事業）
分担研究令和２年度終了報告書

質の高い薬学管理・評価指標の検討

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研究要旨
諸外国の取り組み等を参考とし、質の高い薬学管理・評価指標の検討に向けた取り組みとして、本年度は、アドヒアランスに関するNICEガイドライン（CG76)、アドヒアランスの測定尺度であるBeliefs about Medicines Questionnaire（BMQ)、症例報告の書き方に関するガイドライン（CARE）について、日本での正式な使用に関する許可手続きと翻訳を実施した。

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A. 研究目的

フォローアップ業務の効果としては、様々考えられるが、有害事象・副作用および服薬の課題の発見、アドヒアランスへの支援等が期待される。

本分担研究では、諸外国での取り組みを参考にして、本邦の薬剤師によるフォローアップ業務の実施に伴う成果を国際的な取組みとも整合させ、その成果発表を国内のみならず海外にも発信できるようにすることで、更なる質の高い薬学管理や評価指標としていくことにつなげることも目的として実際する。

B. 研究方法

本年度は、アドヒアランスの関係と、有害事象・副作用報告や症例報告に対応すべく、服薬アドヒアランスを促進するための推奨事項を記載した英国の National Institute for Health and Care Excellence（NICE）ガイドライン（Clinical guideline 76：CG76)、アドヒアランスの測定尺度である Beliefs about Medicines Questionnaire（BMQ)、国際標準となる症例報告の書き方に関するガイドライン（CARE）について、本邦での正式な使用許可の手続き及び翻訳等について実施した。

1. NICE CG76について

(1) 選定方法

服薬アドヒアランスの重要性は国内外で強く認識されている。しかし、アドヒアランスに関する国際的な資料はNICEとWHOのも

のだけであり、NICE はガイドラインとして英文で公表しているため、諸外国にも影響が大きいと考えられる。

なお、CG76 の策定は 2009 年だが、2019 年にサーベイランスが実施されており、CG76 の推奨事項は現在においても有効で、その根底にある原則は変わっていないと結論付けられている。

(2) 本年度の実施状況

NICE にコンタクトし、CG76（別添 1）の全文翻訳と本邦での活用について、担当者と連絡を取り合った。また、CG76 を順翻訳した。

2. BMQ について

(1) BMQ とは

薬に関する信念（beliefs）を評価するために英国で Horne らが開発した尺度である。CG76 の full guideline では薬に関する信念を評価するツールとして BMQ が紹介されている。BMQ は BMQ-Specific と BMQ-General の 2 つの質問票で構成されており、前者は特定の薬に対しての信念を、後者は一般的な薬に対して抱いている信念を評価するものである。現在、世界中の研究で使用されており、本邦においてもアドヒアランス評価の一助となることが期待される。

(2) 本年度の実施状況

BMQ の開発者にコントクトし、BMQ の日本語版開発の許可を取った。また、研究協力者と研究チームを立ち上げた。BMQ-Specific と BMQ-General について、ISPOR の Good Practice に準じて翻訳を行なっている。

3. CARE について

(1) 症例報告の書き方に関するガイドラインの必要性について

CARE は CONSORT、STROBE と同様に EQUATOR network で公開されている報告のためのガイドラインである。CARE は症例報告の正確性、透明性などを向上させる目的で、国際的な専門家グループによって作成されたものであり、checklist、writing outline、e-learning 等のコンテンツが公開されている。これらのコンテンツは様々な言語に翻訳されており、CARE の checklist は複数の学術誌が投稿要件として採用している。本邦において、薬剤師が症例報告を書く際に参考にできる資料は限られている。薬剤師が報告する機会の多い、医薬品の有害事象・副作用に関する症例報告の質向上において CARE は有用であるため、翻訳を行うこととした。

(2) 本年度の実施状況

CARE の開発者にコントクトし、開発者より checklist（別添 2）、writing outline、e-learning の翻訳を提案され、翻訳許可を得た。CARE に関する翻訳チームを立ち上げ、ISPOR の Good Practice に準じて翻訳を行っている。

４．米国に関して

本事業に関連して、米国における服薬アドヒアランス、フォローアップ業務等に関する調査を 2021 年度に実施する予定であり、2020 度はその事前調査を行った。

（倫理面への配慮）

倫理面への配慮が必要となる内容は含まれていない。

C. 研究結果

1. NICE CG76 について

NICE の担当者との連絡の結果、本邦において CG76 の正式な使用の権利と受けることとなった。翻訳の内容は事前に NICE の確認を受けることとなっている。本年度は、NICE との契約及び順翻訳（仮訳）まで実施した。来年度は、順翻訳の修正、NICE による翻訳内容の確認を経て、本邦における CG76 の使用等について対応することとする。

2. BMQ について

研究協力者とともに BMQ-Specific 及び BMQ-General の順翻訳を作成した。順翻訳では英国独自の表現を日本語訳することに難渋したが、開発者からご意見を頂きつつ順翻訳を調整し、逆翻訳を行った。今後、順翻訳を見直し、認知的デブリーフィング及び validation study を行う。

3. CARE について

研究協力者とともに checklist、writing outline、e-learning の順翻訳を作成した。順翻訳に難渋した項目は、開発者からご意見を頂きつつ順翻訳を調整した。今後、逆翻訳を行い、最終的な日本語版を完成させ、翻訳コンテンツの公開と普及等について対応する。

4. 米国の状況について

米国では、オバマケアの一貫で、公的保険の医療費適正化等を目的に、2014 年より

Medication Therapy Management（以下、MTM）、Accountable Care Organization（以下、ACO）、HITECH 法（意味のある電子カルテの導入）を開始した。MTM は英国の MUR（Medicine User Review）に相当し、ACO は我が国の地域包括ケアシステムに類似する制度である。

MTM は、服薬アドヒアランス改善等 MTM 類似プログラムによって入院率と係る医療費が有意に低下すること示され、Medicare Part D（高齢者向け公的保険）の償還プログラムとして開始された。

その後、MTM は、医療サービスの全体最適化目的に制度化された ACO（地域全体医療費最適化とインセンティブ設計等）と統合化した運用が一部で試行されている。

2021 年度の調査では、米国 MTM や ACO 制度と現状、UCSF（University of California San Francisco）他医療機関での服薬アドヒアランスやフォローアップ業務事例等について調査し、取り纏める予定である。

D. 健康危機情報

総括研究年度終了報告書に記載。

E. 研究発表

本年度の発表は実施していない。

F. 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

NICE National Institute for Health and Care Excellence

NICE guideline

別添 1

Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence

Clinical guideline

Published: 28 January 2009
www.nice.org.uk/guidance/cg76

Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guideline is partially replaced by NG5.

This guideline is the basis of QS149.

Overview

This guideline covers medicines adherence in people aged 18 and over. It recommends how to encourage adherence to medicines by supporting and involving people in decisions about their prescribed medicines. It aims to ensure that a person's decision to use a medicine is an informed choice.

Who is it for?

- Healthcare professionals
- Adults receiving prescribed medicines and their families and carers

Introduction

It is thought that between a third and a half of all medicines[1] prescribed for long-term conditions are not taken as recommended. If the prescription is appropriate, then this may represent a loss to patients, the healthcare system and society. The costs are both personal and economic.

Adherence presumes an agreement between prescriber and patient about the prescriber's recommendations. Adherence to medicines is defined as the extent to which the patient's action matches the agreed recommendations. Non-adherence may limit the benefits of medicines, resulting in lack of improvement, or deterioration, in health. The economic costs are not limited to wasted medicines but also include the knock-on costs arising from increased demands for healthcare if health deteriorates.

Non-adherence should not be seen as the patient's problem. It represents a fundamental limitation in the delivery of healthcare, often because of a failure to fully agree the prescription in the first place or to identify and provide the support that patients need later on.

Addressing non-adherence is not about getting patients to take more medicines per se. Rather, it starts with an exploration of patients' perspectives of medicines and the reasons why they may not want or are unable to use them. Healthcare professionals have a duty to help patients make informed decisions about treatment and use appropriately prescribed medicines to best effect.

There are many causes of non-adherence but they fall into two overlapping categories: intentional and unintentional. Unintentional non-adherence occurs when the patient wants to follow the agreed treatment but is prevented from doing so by barriers that are beyond their control. Examples include poor recall or difficulties in understanding the instructions, problems with using the treatment, inability to pay for the treatment, or simply forgetting to take it. Intentional non-adherence occurs when the patient decides not to follow the treatment recommendations. This is best understood in terms of the beliefs and preferences that influence the person's perceptions of the treatment and their motivation to start and continue with it. It follows that to understand adherence to treatment we need to consider the perceptual factors (for example, beliefs and preferences) that influence motivation to start and continue with treatment, as well as the practical factors that influence patients' ability to adhere to the agreed treatment.

Applying this approach in practice requires:

- a frank and open approach which recognises that non-adherence may be the norm (or is at least very common) and takes a no-blame approach, encouraging patients to discuss non-adherence and any doubts or concerns they have about treatment
- a patient-centred approach that encourages informed adherence
- identification of specific perceptual and practical barriers to adherence for each individual, both at the time of prescribing and during regular review, because perceptions, practical problems and adherence may change over time.

This guideline makes recommendations about how healthcare professionals can help patients to make informed decisions by facilitating the involvement of patients in the decision to prescribe, and how they can support patients to adhere to the prescribed medicine. We have not made separate recommendations for carers and families. The principal relationship is between patient and healthcare professional, and the patient has a right to decide who should be involved in their care. With the patient's consent, carers should have access to appropriate levels of information and support.

An increasing number of healthcare professionals are now involved in the prescribing, dispensing and reviewing of medicines. It is not within the remit of a guideline to recommend which healthcare professional carries out these roles. All healthcare professionals should be aware of and work within legal and professional codes. Information and tools are available to support healthcare professionals.

[1] In this guideline 'medicines' is used as a general term to refer to prescribed medicines that are self-administered and includes tablets, syrups, ointments, eyedrops and suppositories.

Key principles

- Healthcare professionals should adapt their consultation style to the needs of individual patients so that all patients have the opportunity to be involved in decisions about their medicines at the level they wish.
- Establish the most effective way of communicating with each patient and, if necessary, consider ways of making information accessible and understandable (for example, using pictures, symbols, large print, different languages, an interpreter or a patient advocate).
- Offer all patients the opportunity to be involved in making decisions about prescribed medicines. Establish what level of involvement in decision-making the patient would like.
- Be aware that increasing patient involvement may mean that the patient decides not to take or to stop taking a medicine. If in the healthcare professional's view this could have an adverse effect, then the information provided to the patient on risks and benefits and the patient's decision should be recorded.
- Accept that the patient has the right to decide not to take a medicine, even if you do not agree with the decision, as long as the patient has the capacity to make an informed decision and has been provided with the information needed to make such a decision.
- Be aware that patients' concerns about medicines, and whether they believe they need them, affect how and whether they take their prescribed medicines.
- Offer patients information that is relevant to their condition, possible treatments and personal circumstances, and that is easy to understand and free from jargon.
- Recognise that non-adherence is common and that most patients are non-adherent sometimes. Routinely assess adherence in a non-judgemental way whenever you prescribe, dispense and review medicines.
- Be aware that although adherence can be improved, no specific intervention can be recommended for all patients. Tailor any intervention to increase adherence to the specific difficulties with adherence the patient is experiencing.
- Review patient knowledge, understanding and concerns about medicines, and a patient's view of their need for medicine at intervals agreed with the patient, because these may change over time. Offer repeat information and review to patients, especially when treating long-term conditions with multiple medicines.

1 Guidance

People have the right to be involved in discussions and make informed decisions about their care, as described in your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

The following guidance is based on the best available evidence. The full guideline gives details of the methods and the evidence used to develop the guidance.

Recommendation 1.4.2 has been replaced by recommendations in the NICE guideline on medicines optimisation.

These recommendations apply to all healthcare professionals who prescribe, dispense or review medicines or who have a role in making decisions about medicines with patients. Healthcare professionals are reminded of their duty under the Equality Act (2010) to make reasonable adjustments to ensure that all people have the same opportunity for health.

1.1 Patient involvement in decisions about medicines

Communication

Good communication between healthcare professionals and patients is needed for involvement of patients in decisions about medicines and for supporting adherence. Some patients may find it easier to communicate with their healthcare professional than others.

1.1.1 Healthcare professionals should adapt their consultation style to the needs of individual patients so that all patients have the opportunity to be involved in decisions about their medicines at the level they wish.

1.1.2 Consider any factors such as physical or learning disabilities, sight or hearing problems and difficulties with reading or speaking English, which may affect the patient's involvement in the consultation.

1.1.3 Establish the most effective way of communicating with each patient and, if

necessary, consider ways of making information accessible and understandable (for example, using pictures, symbols, large print, different languages, an interpreter or a patient advocate).

1.1.4 Encourage patients to ask about their condition and treatment.

1.1.5 Ask patients open-ended questions because these are more likely to uncover patients' concerns.

1.1.6 Be aware that the consultation skills needed for increasing patient involvement can be improved.

Increasing patient involvement

Patient involvement in the decision-making process requires that healthcare professionals acknowledge patients' views about their condition and its treatment, and that both healthcare professional and patient have a role in making decisions about treatment. Simple interventions to increase patient involvement do not necessarily increase the overall length of consultation and may be justified by benefits, particularly over the course of a long-term condition.

1.1.7 Offer all patients the opportunity to be involved in making decisions about prescribed medicines. Establish what level of involvement in decision-making the patient would like.

1.1.8 Discuss with the patient why they might benefit from the treatment. Clearly explain the disease or condition and how the medicine will influence this.

1.1.9 Explain the medical aims of the treatment to patients and openly discuss the pros and cons of proposed medicines. The discussion should be at the level preferred by the patient.

1.1.10 Clarify what the patient hopes the treatment will achieve.

1.1.11 Avoid making assumptions about patient preferences about treatment. Talk to the patient to find out their preferences, and note any non-verbal cues that may indicate you need to explore the patient's perspective further.

1.1.12 Healthcare professionals have a duty to help patients to make decisions about

their treatment based on an understanding of the likely benefits and risks rather than on misconceptions.

1.1.13 Accept that patients may have different views from healthcare professionals about the balance of risks, benefits and side effects of medicines.

1.1.14 Be aware that increasing patient involvement may mean that the patient decides not to take or to stop taking a medicine. If in the healthcare professional's view this could have an adverse effect, then the information provided to the patient on risks and benefits and the patient's decision should be recorded.

1.1.15 Accept that the patient has the right to decide not to take a medicine, even if you do not agree with the decision, as long as the patient has the capacity to make an informed decision and has been provided with the information needed to make such a decision.

1.1.16 Assess the patient's capacity to make each decision using the principles in the Mental Capacity Act (2005). To lack capacity patients must: (a) have an impairment of or disturbance or malfunction of brain and mind, and (b) demonstrate lack of capacity to:

- understand the information relevant to the decision
- retain information for long enough to use it in the decision
- use or weigh information as part of the process of making the decision
- communicate the decision (whether by talking, using sign language or any other means).

More information is available in NICE's guideline on decision-making and mental capacity.

1.1.17 If the patient has specific concerns, record a summary of the discussion, because this may be helpful in future consultations.

1.1.18 Encourage and support patients, families and carers to keep an up-to-date list of all medicines the patient is taking. The list should include the names and dosages of prescription and non-prescription medicines and herbal and nutritional

supplements. If the patient has any allergic or adverse reactions to medicines, these should be noted.

Understanding the patient's knowledge, beliefs and concerns about medicines

There is evidence that patients make decisions about medicines based on their understanding of their condition and the possible treatments, their view of their own need for the medicine and their concerns about the medicine.

1.1.19 Be aware that patients' concerns about medicines, and whether they believe they need them, affect how and whether they take their prescribed medicines.

1.1.20 Ask patients what they know, believe and understand about medicines before prescribing new treatments and when reviewing medicines.

1.1.21 Ask if the patient has any specific concerns about their medicines, whenever you prescribe, dispense or review medicines. These may include concerns about becoming dependent on medicines and concerns about adverse effects. Address these concerns.

1.1.22 Be aware that patients may wish to minimise how much medicine they take.

1.1.23 Be aware that patients may wish to discuss:

- what will happen if they do not take the medicine suggested by their healthcare professional
- non-pharmacological alternatives to medicines
- how to reduce and stop medicines they may have been taking for a long time, particularly those known to be associated with withdrawal symptoms
- how to fit taking the medicine into their daily routine
- how to make a choice between medicines if they believe they are taking too many medicines.

Providing information

Patients need information about their condition and possible treatments if they are to be involved

in making informed decisions about medicines. The format and content of the information provided should meet the needs of individual patients.

1.1.24 Offer patients information about medicines before the medicines are prescribed.

1.1.25 Offer patients information that is relevant to their condition, possible treatments and personal circumstances, and that is easy to understand and free from jargon.

1.1.26 Check that patients have any information they wish about medicines when the medicines are dispensed.

1.1.27 Discuss information on medicines with the patient rather than just presenting it. The discussion should take into account what the patient understands and believes about the condition and treatment.

1.1.28 Do not assume that the patient information leaflets (PILs)[2] that patients receive with their medicines will meet each patient's needs. Address concerns that patients may have after reading the standard PILs.

1.1.29 Patients differ in the type and amount of information they need and want. Therefore the provision of information should be individualised and is likely to include, but not be limited to:

- what the medicine is
- how the medicine is likely to affect their condition (that is, its benefits)
- likely or significant adverse effects and what to do if they think they are experiencing them
- how to use the medicine
- what to do if they miss a dose
- whether further courses of the medicine will be needed after the first prescription
- how to get further supplies of medicines.

1.1.30 Be careful not to make assumptions about a patient's ability to understand the

information provided. Check with the patient that they have understood the information. Information for patients should be clear and logical and, if possible, tailored to the needs of the individual patient.

1.1.31 Suggest where patients might find reliable information and support after the consultation: for example, by providing written information or directing them to other resources (for example, the NHS website).

1.1.32 Provide inpatients with the same information as patients in other settings. Information should include:

- what the medicine is
- how the medicine is likely to affect their condition (that is, its benefits)
- likely or significant adverse effects and what to do if they think they are experiencing them
- how to use the medicine
- what to do if they miss a dose
- whether further courses of the medicine will be needed after the first prescription
- how to get further supply after discharge.

1.2 Supporting adherence

Assessing adherence

Patients do not always take their medicines exactly as prescribed, and healthcare professionals are often unaware of how patients take their medicines. The purpose of assessing adherence is not to monitor patients but rather to find out whether patients need more information and support.

1.2.1 Recognise that non-adherence is common and that most patients are non-adherent sometimes. Routinely assess adherence in a non-judgemental way whenever you prescribe, dispense and review medicines.

1.2.2 Consider assessing non-adherence by asking the patient if they have missed any doses of medicine recently. Make it easier for them to report non-adherence by:

- asking the question in a way that does not apportion blame
- explaining why you are asking the question
- mentioning a specific time period such as 'in the past week'
- asking about medicine-taking behaviours such as reducing the dose, stopping and starting medicines.

1.2.3 Consider using records of prescription re-ordering, pharmacy patient medication records and return of unused medicines to identify potential non-adherence and patients needing additional support.

Interventions to increase adherence

Patients may need support to help them make the most effective use of their medicines. This support may take the form of further information and discussion, or involve practical changes to the type of medicine or the regimen. Any interventions to support adherence should be considered on a case-by-case basis and should address the concerns and needs of individual patients.

1.2.4 If a patient is not taking their medicines, discuss with them whether this is because of beliefs and concerns or problems about the medicines (intentional non-adherence) or because of practical problems (unintentional non-adherence).

1.2.5 Be aware that although adherence can be improved, no specific intervention can be recommended for all patients. Tailor any intervention to increase adherence to the specific difficulties with adherence the patient is experiencing.

1.2.6 Find out what form of support the patient would prefer to increase their adherence to medicines. Together, you and your patient should consider options for support.

1.2.7 Address any beliefs and concerns that patients have that result in reduced adherence.

1.2.8 Because evidence supporting interventions to increase adherence is inconclusive, only use interventions to overcome practical problems associated with non-adherence if a specific need is identified. Target the intervention to the need. Interventions might include:

- suggesting that patients record their medicine-taking
- encouraging patients to monitor their condition
- simplifying the dosing regimen
- using alternative packaging for the medicine
- using a multi-compartment medicines system.

1.2.9 Side effects can be a problem for some patients. If this is the case you should:

- discuss how the patient would like to deal with side effects
- discuss the benefits, side effects and long-term effects with the patient to allow them to make an informed choice
- consider adjusting the dosage
- consider switching to another medicine with a different risk of side effects
- consider what other strategies might be used (for example, timing of medicines).

1.2.10 Ask patients if prescriptions charges are a problem for them. If they are, consider possible options to reduce costs.

1.3 Reviewing medicines

Patients may use medicines long term. The initial decision to prescribe medicines, the patient's experience of using the medicines and the patient's needs for adherence support should be reviewed regularly. The patient's own list of medicines may be a useful aid in a medicines review.

1.3.1 Review patient knowledge, understanding and concerns about medicines, and a patient's view of their need for medicine at intervals agreed with the patient, because these may change over time. Offer repeat information and review to patients, especially when treating long-term conditions with multiple medicines.

1.3.2 Review at regular intervals the decision to prescribe medicines, according to patient choice and need.

1.3.3 Enquire about adherence when reviewing medicines. If non-adherence is identified, clarify possible causes and agree any action with the patient. Any plan

should include a date for a follow-up review.

1.3.4 Be aware that patients sometimes evaluate prescribed medicines using their own criteria such as their understanding of their condition or the symptoms most troubling to them. They may, for example, stop and start the medicine or alter the dose and check how this affects their symptoms. Ask the patient whether they have done this.

1.4 Communication between healthcare professionals

Patients may be under the care of healthcare professionals from different disciplines and specialties at the same time; responsibility for patients' care may be transferred between healthcare professionals, and medicines reviews may be carried out by healthcare professionals other than the prescriber. Therefore good communication between healthcare professionals is required to ensure that fragmentation of care does not occur.

1.4.1 Healthcare professionals involved in prescribing, dispensing or reviewing medicines should ensure that there are robust processes for communicating with other healthcare professionals involved in the patient's care.

1.4.2 This recommendation has been replaced by recommendations in section 1.2 in the NICE guideline on medicines optimisation.

1.4.3 Healthcare professionals involved in reviewing medicines should inform the prescriber of the review and its outcome. This is particularly important if the review involves discussion of difficulties with adherence and further review is necessary.

[2] Patient information leaflets (PILs) contain information for patients on how medicines should be used. It is a legal requirement that this information is included on the label or within the packaging of a medicine.

2 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future. The Guideline Development Group's full set of research recommendations is detailed in the full guideline (see section 5).

2.1 Developing effective, equitable interventions to support adherence to appropriate prescriptions

What are the most clinically effective and cost-effective methods for identifying and addressing the perceptual barriers (such as beliefs and concerns about medicines) that influence motivation to start and continue with treatment, and the practical barriers (such as limitations in personal capacity and resources) that limit an individual's ability to implement intentions to adhere to medicines?

Why this is important

The Guideline Development Group identified a priority for the systematic development of effective, realisable, efficient and equitable interventions to facilitate informed choice and optimal adherence to appropriately prescribed medicines.

Systematic reviews of adherence interventions show that although adherence can be improved, the effects were generally modest and there is considerable room for improvement. Few previous interventions have been developed systematically using appropriate theoretical models, and they have not been modelled and piloted with assessment of process variables as well as outcomes.

Interventions should be developed using an appropriate theoretical framework with a phased approach to testing that includes assessment of process (that is, the things that are targeted for change) as well as outcomes and a need for an individual approach[3].

2.2 Informed choice and shared decision-making

What are the most clinically effective and cost-effective ways of communicating the potential benefits and risks of medicines to promote informed choice and optimal adherence?

Why this is important

The principles of informed choice and shared decision-making have largely been developed from theoretical and conceptual models. The competencies listed for shared decision-making consist of a number of different skills, and patients have shown that they may value different aspects of shared decision-making. Although the right of patients to be involved in decision-making in regard to their own healthcare is accepted, the practice of shared decision-making may mean that healthcare professionals and patients play different roles than they have to date in healthcare consultations. This may have implications for legal and professional responsibility and accountability. Patients and professionals enter decision-making with very different levels of knowledge and access to information. Improving patient knowledge and information may require structural changes to health services and their delivery. Patient-reported outcomes also need to be included.

2.3 Support processes: prescribing-related consultations and medicines review

How can practitioners and patients be supported to improve the quality of prescribing-related consultations and medicines reviews so that they facilitate informed choice and optimal adherence to medicines?

What are the effects of medicines reviews by healthcare professionals other than the prescriber on patients, prescribers and outcomes? How can the process of medicines review be enhanced or improved to address issues of informed choice and adherence?

Why this is important

Non-adherence is often a hidden problem. Many patients are reluctant to express doubts and concerns about medicines because they fear that it will displease the healthcare professional. We need better methods for overcoming this problem and promoting honest and open discussions about medicines and adherence.

There are an increasing number of non-medical prescribers (such as pharmacists and nurses) This is a key context issue and there are a range of questions relating to patient perspectives on new prescribers and to new and existing prescribers' perceptions and skills. The effects of new prescribers on patient adherence to medicines should be included in any studies designed to evaluate new prescribers. The inclusion of formal procedures for medicines review within the Pharmacy Contract in England provides an opportunity for improved support for patients. We need a better understanding of the effects of non-prescriber reviews on medicines usage and outcomes,

and how reviews might be improved to benefit patients and society.

[3] Campbell NC, Murray E, Darbyshire J et al. (2007) Designing and evaluating complex interventions to improve health care. BMJ 334: 455–9.

Finding more information and resources

To find out what NICE has said on topics related to this guideline, see our web page on medicines management.

Update information

September 2019: Reference to Disability Discrimination Act (2005) changed to Equality Act (2010). Recommendation 1.1.16 amended to add cross-reference to the NICE guideline on decision-making and mental capacity (NG108).

March 2015: Recommendation 1.4.2 has been replaced by recommendations in section 1.2 in the NICE guideline on medicines optimisation.

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Accreditation

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CARE case report guidelines

CARE Checklist of information to include when writing a case report

Topic	Item	Checklist item description	Reported on Line
Title	**1**	The diagnosis or intervention of primary focus followed by the words “case report”	
Key Words	**2**	2 to 5 key words that identify diagnoses or interventions in this case report, including "case report"	
Abstract (no references)	**3a**	Introduction: What is unique about this case and what does it add to the scientific literature?	
	3b	Main symptoms and/or important clinical findings	
	3c	The main diagnoses, therapeutic interventions, and outcomes	
	3d	Conclusion—What is the main “take-away” lesson(s) from this case?	
Introduction	**4**	One or two paragraphs summarizing why this case is unique (**may include references**)	
Patient Information	**5a**	De-identified patient specific information	
	5b	Primary concerns and symptoms of the patient	
	5c	Medical, family, and psycho-social history including relevant genetic information	
	5d	Relevant past interventions with outcomes	
Clinical Findings	**6**	Describe significant physical examination (PE) and important clinical findings	
Timeline	**7**	Historical and current information from this episode of care organized as a timeline	
Diagnostic Assessment	**8a**	Diagnostic testing (such as PE, laboratory testing, imaging, surveys).	
	8b	Diagnostic challenges (such as access to testing, financial, or cultural)	
	8c	Diagnosis (including other diagnoses considered)	
	8d	Prognosis (such as staging in oncology) where applicable	
Therapeutic Intervention	**9a**	Types of therapeutic intervention (such as pharmacologic, surgical, preventive, self-care)	
	9b	Administration of therapeutic intervention (such as dosage, strength, duration)	
	9c	Changes in therapeutic intervention (with rationale)	
Follow-up and Outcomes	**10a**	Clinician and patient-assessed outcomes (if available)	
	10b	Important follow-up diagnostic and other test results	
	10c	Intervention adherence and tolerability (How was this assessed?)	
	10d	Adverse and unanticipated events	
Discussion	**11a**	A scientific discussion of the strengths AND limitations associated with this case report	
	11b	Discussion of the relevant medical literature **with references**	

	11c	The scientific rationale for any conclusions (including assessment of possible causes)	_____
	11d	The primary "take-away" lessons of this case report (without references) in a one paragraph conclusion	_____
Patient Perspective	**12**	The patient should share their perspective in one to two paragraphs on the treatment(s) they received	_____
Informed Consent	**13**	Did the patient give informed consent? Please provide if requested	**Yes** ☐ **No** ☐