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3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、本年度も引き続き、服薬アドヒアランスに関するNational Institute for Health and Care Excellence（NICE）ガイドライン（Clinical guideline 76: CG76)、医薬品に対する信念の測定尺度である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、日本語版の作成を実施した。

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A. 研究目的

薬剤師による患者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患者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施する。

B. 研究方法

本年度も引き続き、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支援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)、医薬品に対する信念の測定尺度である 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、日本語版の作成などを実施した。

1. NICE CG76 について

(1) 日本語版作成の背景

2020 年に日本薬剤師会が発出した「薬剤使用期間中の患者フォローアップの手引き」では、注意を要する患者例として、長期的なアドヒアランス維持が重要となる薬剤を使用している患者が挙げられている。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おり、ノンアドヒアランスが問題視されている。しかし、服薬アドヒアランスに関する国際的な資料は NICE と World Health Organization（WHO）のものだけである。NICE はガイドライン（CG76）として英文で公表しているが、本邦に類似のガイドラインはなく、日本語で参照可能な資料は限られている。本邦において CG76 は活用可能であると考え、日本語版を作成することとした。

(2) 本年度の実施状況

NICE の担当者と連絡を取り合い、CG76（別添１）の原文の意味などを確認しながら、CG76 の順翻訳および逆翻訳を行った。NICE に順翻訳と逆翻訳を提出し、NICE の校正者が日本語の校正を行った。また、CG76 日本語版の活用について専門家委員会で検討した。

2. BMQ について

(1) BMQ とは

医薬品に対する信念（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 では医薬品に対する信念の評価尺度として 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いる。前者は（処方された）特定の医薬品に対する信念を、後者は一般的な医薬品に対する信念を評価するものである。医薬品に対する信念は服薬アドヒアランスに関連することが知られており、現在、世界各国の研究で BMQ が使用されている。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 の開発者と連絡を取り合いながら、BMQ-Specific と BMQ-General について、International Society for Pharmacoeconomics and Outcomes Research（ISPOR)の Good Practice に準じて順翻訳、逆翻訳、および逆翻訳レビューを行った。

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（Case Report Writing Course）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 は有用であると考え、翻訳を行うこととした。

(2) 本年度の実施状況

CARE の開発者と連絡を取り合いながら、checklist（別添２)、writing outline（別添３)、e-learning について、ISPOR の Good Practice を参考に翻訳を行った。

（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

CG76 日本語版は NICE および専門家委員会の意見を反映し、修正を行っている。また、専門家委員会で検討した結果、本邦と英国における医療体制や法律の差異等を考慮する必要があると考えられたため、CG76 日本語版の補足資料を作成している。来年度は、NICE による CG76 日本語版の最終確認と、本邦における CG76 日本語版の活用等についての対応を継続することとする。

2. BMQ について

研究協力者とともにBMQ-SpecificおよびBMQ-Generalの日本語版の暫定版を作成した。今後、ISPORのGood Practiceに準じてBMQ-Specific と BMQ-General の認知的デブリーフィングを行い、日本語版を完成させる。

3. CAREについて

研究協力者とともに checklist、writing outline、e-learningの日本語訳を作成した。checklist と writing outline の日本語版、および e-learning の日本語字幕は Scientific Writing in Health and Medicine (SWIHM) のホームページで公開されている。今後、日本語版コンテンツの普及等について対応する。

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

CARE case report guidelines

症例報告を書く際に含めるべき情報の CARE チェックリスト
（CARE Checklist of information to include when writing a case report）

別添２

トピック（Topic）	項目（Item）	チェックリスト項目の説明（Checklist item description）	報告されているページと行の番号（Reported on Line）
タイトル（Title）	**1**	診断名（diagnosis）または主要な介入につづけて「症例報告」（case report）という文言	
キーワード（Key Words）	**2**	本症例報告の診断名または介入を特定できる 2〜5 個のキーワードで、「症例報告」を含む	
抄録（Abstract）	**3a**	はじめに：本症例の独自性（unique）、科学論文における新規性は何か？	
（参考文献なし）	**3b**	主な症状（symptoms）および / または重要な臨床所見	
	3c	主な診断（diagnoses）、治療的介入、アウトカム	
	3d	結論（conclusion）：本症例からの主な教訓は何か？	
はじめに（Introduction）	**4**	本症例の独自性について 1〜2 段落に要約（**参考文献を含めてもよい**）	
患者情報（Patient Information）	**5a**	匿名化された（de-identified）患者の個人情報（specific information）	
	5b	患者の主要な問題点（concerns）や症状	
	5c	病歴（medical history）、家族歴（family history）、心理社会的背景（psycho-social history）、関連する遺伝情報を含む	
	5d	関連する過去の介入とそのアウトカム	
臨床所見（Clinical Findings）	**6**	有意な身体所見（physical examination）と重要な臨床所見の記述	
タイムライン（Timeline）	**7**	本症例のケアに関する、過去から現在までの情報をタイムラインとして整理	
診断的評価	**8a**	診断検査（diagnostic testing）（身体診察 physical examination、臨床検査、画像検査、質問票など）	
（Diagnostic Assessment）	**8b**	診断上の課題（diagnostic challenges）（検査へのアクセスのしやすさ、経済的または文化的な課題など）	
	8c	診断名（他に考慮した診断名を含む）	
	8d	あてはまる場合は予後（prognosis）（がんの病期分類など）	
治療的介入	**9a**	治療的介入の種類（薬理学的、外科的、予防的、セルフケアなど）	
（Therapeutic Intervention）	**9b**	治療的介入の実施（administration）（用量、力価、期間など）	
	9c	治療的介入の変更内容（論拠とともに）	
フォローアップとアウトカム	**10a**	臨床家（clinician）と患者が評価したアウトカム（可能であれば）	
（Follow-up and Outcomes）	**10b**	重要なフォローアップ診断や他の検査結果	
	10c	介入のアドヒアランス（adherence）と忍容性（tolerability）（どのように評価したか？）	
	10d	有害事象（adverse events）や予期せぬ事象	
考察（Discussion）	**11a**	本症例報告に関連する強み（strengths）と限界（limitations）の科学的な考察	
	11b	関連する**医学論文を用いた**考察	
	11c	結論に対する科学的な論拠（可能性のある原因の評価を含む）	

	11d	本症例の主要な教訓（参考文献なし）を 1 段落にまとめる	_____
患者の見解（Patient Perspective）	**12**	患者が受けた治療について、1〜2 段落で患者の見解を記述するべきである	_____
インフォームドコンセント（Informed Consent）	**13**	患者のインフォームドコンセントを得たか？要求された場合は提供する	**はい** ☐ **いいえ** ☐

症例報告を書く著者のための執筆アウトライン
（CASE REPORT WRITING OUTLINE FOR AUTHORS）

一般的な注意事項　すべての患者データが匿名化されていることを確認し、必要に応じて、倫理委員会または施設内審査委員会からの承認を得ていることを確認する。

タイトル（Title）　タイトルに「症例報告」（case report）という文言を含める。最も関心のある現象を記述する。患者の状態（presentation）、診断名（diagnosis）、検査結果（test result）、介入（intervention）、アウトカム（outcome）のいずれでもよい。

抄録（Abstract）　関連があれば、以下の情報を約 200 語でまとめる。(1) 本症例を報告する論拠（rationale）、(2) 患者の問題点（concerns）の提示（主訴、症状、診断など）、(3) 介入（診断的、予防的、予後、治療の変更など）、(4) アウトカム、(5) 本症例報告から学ぶべき主な教訓。

キーワード（Key Words）　読者が本症例報告を検索して見つけやすくするために、2〜5 個のキーワードを提示する。

はじめに（Introduction）　本症例報告の背景（background）と文脈（context）を簡潔にまとめる。

問題点の提示（Presenting Concerns）　患者の特性（関連する人口統計学的な特性ー年齢、性別、人種、職業など）と、患者の問題点について、関連する過去の介入の詳細とともに記述する。

臨床所見（Clinical Findings）　以下の項目を記述する。(1) 病歴（medical history）、家族歴（family history）、心理社会的背景（psycho-social history）、生活習慣および遺伝情報を含む、(2) その他の関連する併存疾患（co-morbidities）および介入（セルフケアを含む他の治療）、(3) 重要な所見に焦点をあてた身体所見（physical examination）。

タイムライン（Timeline）　特定の日付と時間を含むタイムラインを表（table）、図（figure）、グラフ（graphic）として作成する。

診断の焦点と評価（Diagnostic Focus and Assessment）　以下の評価を提示する。(1) 診断方法（diagnostic methods）（臨床検査、画像検査の結果、質問票、紹介状の診断情報を含む）、(2) 診断上の課題（diagnostic challenges）（評価する能力の限界、患者の都合、文化的な課題など）、(3) 考慮された他の診断を含む診断推論（diagnostic reasoning）、(4) あてはまる場合は予後の特性（prognostic characteristics）（がんの病期分類など）。

治療の焦点と評価（Therapeutic Focus and Assessment）　以下の項目を記述する。(1) 介入の種類（薬理学的、外科的、予防的、生活習慣、セルフケアなど）、(2) 実施した介入とその強度（intensity）（用量、力価、期間、頻度を含む）。

フォローアップとアウトカム（Follow-up and Outcomes）　本症例の臨床経過（すべてのフォローアップ診察を含む）と、以下の項目を記述する。(1) 介入内容の変更、中断、中止およびその理由、(2) 介入へのアドヒアランス（adherence）とその評価方法、(3) 有害事象（adverse effects）または予期せぬ事象。以下の項目を記述する。(1) 患者報告アウトカム（patient-reported outcomes）、(2) 臨床家（clinician）が評価し、報告したアウトカム、(3) 重要な陽性（positive）、陰性（negative）の検査結果。

考察（Discussion）　症例マネジメントを含む本症例の強み（strengths）と限界（limitations）、および本症例に関連する科学・医学論文を記述する。考えられる要因や本症例の一般化可能性など、あなたの結論（conclusions）に対する論拠を考察する。最後に、本症例報告の主な知見は何か、伝えたいメッセージは何かを記述する。

患者の見解（Patient Perspective）　適切な場合はいつでも、本症例報告または付随した内容に患者のケアの体験をナラティブ（narrative）として記述するべきである。

インフォームドコンセント（Informed Consent）　本症例報告の公表について、患者からインフォームドコンセントを得たことを確認する。

「厚生労働科学研究費における倫理審査及び利益相反の管理の状況に関する報告について
（平成26年4月14日科発0414第5号）」の別紙に定める様式

2022年3月31日

厚生労働大臣
（~~国立医薬品食品衛生研究所長）~~殿
（~~国立保健医療科学院長~~）

機関名　東京薬科大学

所属研究機関長　職　名　学長

氏　名　平塚　明

次の職員の令和３年度厚生労働科学研究費の調査研究における、倫理審査状況及び利益相反等の管理については以下のとおりです。

１．研究事業名　令和３年度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)

２．研究課題名　薬剤師の職能発揮のための薬学的知見に基づく継続的な指導等の方策についての調査研究

３．研究者名　（所属部署・職名）薬学部　教授

（氏名・フリガナ）陳　惠一　チン　ケイイチ

４．倫理審査の状況

	該当性の有無 有	無	左記で該当がある場合のみ記入（※1） 審査済み	審査した機関	未審査（※2）
ヒトゲノム・遺伝子解析研究に関する倫理指針	□	☑	□		□
遺伝子治療等臨床研究に関する指針	□	☑	□		□
人を対象とする医学系研究に関する倫理指針（※3）	□	☑	□		□
厚生労働省の所管する実施機関における動物実験等の実施に関する基本指針	□	☑	□		□
その他、該当する倫理指針があれば記入すること（指針の名称：　　）	□	☑	□		□

（※1）当該研究者が当該研究を実施するに当たり遵守すべき倫理指針に関する倫理委員会の審査が済んでいる場合は、「審査済み」にチェックし一部若しくは全部の審査が完了していない場合は、「未審査」にチェックすること。

その他（特記事項）

（※2）未審査の場合は、その理由を記載すること。
（※3）廃止前の「疫学研究に関する倫理指針」や「臨床研究に関する倫理指針」に準拠する場合は、当該項目に記入すること。

５．厚生労働分野の研究活動における不正行為への対応について

研究倫理教育の受講状況	受講 ☑　未受講 □

６．利益相反の管理

当研究機関におけるＣＯＩの管理に関する規定の策定	有 ☑　無 □（無の場合はその理由：
当研究機関におけるＣＯＩ委員会設置の有無	有 ☑　無 □（無の場合は委託先機関：
当研究に係るＣＯＩについての報告・審査の有無	有 ☑　無 □（無の場合はその理由：
当研究に係るＣＯＩについての指導・管理の有無	有 ☑　無 □（有の場合はその内容：

（留意事項）　・該当する□にチェックを入れること。
・分担研究者の所属する機関の長も作成すること。

「厚生労働科学研究費における倫理審査及び利益相反の管理の状況に関する報告について
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３．研究者名　（所属部署・職名）薬学部　准教授

（氏名・フリガナ）川口　崇　カワグチ　タカシ

４．倫理審査の状況

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