

Appendix A

Guidelines scope

SCOPE

1 Guideline title

Medicines concordance and adherence: involving adults and carers in decisions about prescribed medicines

1.1 *Short title*

Medicines concordance

2 Background

- (a) The National Institute for Health and Clinical Excellence ('NICE' or 'the Institute') has commissioned the National Collaborating Centre for Primary Care to develop a clinical guideline on medicines concordance for use in the NHS in England and Wales. This follows referral of the topic by the Department of Health (see appendix). The guideline will provide recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness.
- (b) The Institute's clinical guidelines will support the implementation of national service frameworks (NSFs) in those aspects of care where a framework has been published. The statements in each NSF reflect the evidence that was used at the time the framework was prepared. The clinical guidelines and technology appraisals published by the Institute after an NSF has been issued will have the effect of updating the framework.
- (c) NICE clinical guidelines support the role of healthcare professionals in providing care in partnership with patients, taking account of their individual needs and preferences, and ensuring that patients (and their carers and families, where appropriate) can make informed decisions about their care and treatment.

3 Clinical need for the guideline

- a) The number of prescription items in the NHS increased from 686 million in 2004 to 720 million in 2005, an increase of 34 million, or 5.0%. Between 2004 and 2005, the net ingredient cost of prescription items dispensed fell by £143 million from £8080 million (1.8 per cent) to £7937 million, compared with an increase of 7.6 % in the previous year.
- b) Reviews conducted across disease areas and countries suggest that at least 30–50% of prescribed medication is not taken as recommended. This behaviour is often undisclosed by patients and unrecognised by prescribers, but may lead to worse health outcomes in terms of morbidity or mortality for the patient and to an increased economic burden on the healthcare system.
- c) The terminology using when discussing medication-taking behaviours is complex with three commonly used definitions. The terminology is explained as follows by Horne (2005)¹
- Compliance – ‘the extent to which the patient’s behaviour matches the **prescriber’s** recommendations’.
 - Adherence – ‘the extent to which the patient’s behaviour matches **agreed** recommendations from the prescriber’. Adherence emphasises the need for agreement and that the patient is free to decide whether or not to adhere to the doctor’s recommendation
 - Concordance – this is a recent term whose meaning has changed. It was initially applied to the consultation process in which doctor and patient agree therapeutic decisions that incorporate their respective views but now includes patient support in medicine taking as well as prescribing communication.

¹ Horne R (2005) Concepts and terminology. In: Horne R, Weinman J, Barber N et al, *Concordance, Adherence and Compliance in Medicine Taking – Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation Research and Development*, pp 27–37 www.sdo.lshtm.ac.uk.

Concordance reflects normative values but does not address medicine –taking and may not lead to improved adherence.

The NCCSDO recommended using the term adherence to describe patients' medicine taking behaviour. This scope will use the terms 'shared decision-making about medicines' to refer to the health professional – patient/carer consultation and the term 'adherence' to refer to patient's medicine taking behaviour.

- d) Medicines may not be taken as prescribed for many reasons. These include adverse effects, poor instructions, poor communication between healthcare professional and patient, poor memory, the effects of the illness, patients' disagreement with the need for treatment and their inability to buy the prescribed medication. Other reasons may be that patients are confused by what medicine they have been prescribed and its impact on their condition, a treatment regimen that does not fit in with the patient's daily activities has been prescribed, or the lack of a decision process that takes into account values and beliefs of the patient.
- e) Current methods to improve adherence in long-term conditions are quite complex and have little effect, as reported by the latest Cochrane review on interventions for enhancing medication adherence. Similarly, the scoping review commissioned by the National Co-ordinating Centre for NHS Service Delivery and Organisation Research and Development (2005) concluded that the evidence on interventions for adherence was limited. Both the reviews showed that there was little evidence on the effectiveness of interventions to improve adherence to medication for long-term conditions within the clinical setting. Despite this, the Service Delivery and Organisation report does give some suggestions about how to improve interventions in the future.
- f) There is evidence of significant differences in patterns of prescribing and of variation in application of recommended good

practice among healthcare practitioners: 'this not only relates to differences in what is prescribed for the same condition but also in the amount and level of information which is provided about prescribed medications'.²

4 The guideline

- a) The guideline development process is described in detail in two publications that are available from the NICE website (see 'Further information'). 'The guideline development process: an overview for stakeholders, the public and the NHS' describes how organisations can become involved in the development of a guideline. 'The guidelines manual' provides advice on the technical aspects of guideline development.
- b) This document is the scope. It defines exactly what this guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health (see appendix).
- c) The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

- a) People aged 16 years and older, including those with comorbidities, learning disabilities or language and/or cultural differences.

² O' Brien M (1997) Compliance among health professionals. In Baum A, Newman S, Weinman J et al. editors *Cambridge Handbook of Psychology, Health and Medicine*. Cambridge: Cambridge University Press
cited by Weinman J, Horne R (2005) Patient provider interaction and health care communication In: Horne R, Weinman J, Barber N et al, *Concordance, Adherence and Compliance in Medicine Taking – Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation Research and Development.*,pp 61–8.
www.sdo.lshtm.ac.uk

4.1.2 Groups that will not be covered

- a) Children and young people (younger than 16 years). However, the guideline recommendations may be considered for anyone younger than 16 years who is deemed competent to express a view on their prescription.

4.2 *Healthcare setting*

- a) All consultations with healthcare professionals in any NHS setting that relate to the initiation or review of prescribed medication.

4.3 *Areas that will be covered*

- a) Shared decision-making about medicines and medicine taking as reported by the patient or carer. The guideline will focus on the barriers (such as communication difficulties, cultural issues, low health literacy and physical limitations), facilitators (including structural or procedural factors), beliefs and health behaviours that influence decision-making and adherence.
- b) Shared decision-making about medicines and medicine taking as reported by the healthcare professional. The guideline will focus on the barriers (such as communication difficulties, cultural issues and time), facilitators (including structural or procedural factors), beliefs and health behaviours that influence decision-making and adherence.
- c) The effectiveness and cost effectiveness of interventions to facilitate the process of shared decision-making about medicines (looking at time of intervention – before, during, or after the consultation with the healthcare professional; and mode of delivery). The target of the intervention may be the patient, the carer, the prescriber, any healthcare professional providing ongoing support or a combination of these.
- d) The effectiveness and cost effectiveness of interventions to promote adherence in medicine taking (looking at time of

intervention – before, during, or after the consultation with the healthcare professional; and mode of delivery). The target of the intervention may be the patient, the carer, the prescriber, the dispenser or any other healthcare professional providing ongoing support or a combination of these.

- e) The evidence on single or multiple medications as it relates to issues around decision-making and adherence.
- f) The guideline development group will take reasonable steps to identify ineffective interventions and approaches to care. If robust and credible recommendations for repositioning the intervention for optimal use, or changing the approach to care to make more efficient use of resources, can be made, they will be clearly stated. If the resources released are substantial, consideration will be given to listing such recommendations in the 'Key priorities for implementation' section of the guideline.

Areas that will not be covered

- g) Situations where direct professional involvement is required for the use or administration of medicines. Administration is defined as giving a medicine by introduction into the body (for example, orally or by injection), or by external application (for example application of an impregnated dressing). It is expected that recommendations regarding decision-making about medicines would be relevant in these situations.

4.4 Status

4.4.1 Scope

This is the final draft of the scope.

4.4.2 Guideline

The development of the guideline recommendations will begin in March 2007.

5 Further information

Information on the guideline development process is provided in:

- 'The guideline development process: an overview for stakeholders, the public and the NHS'
- 'The guidelines manual'.

These booklets are available as PDF files from the NICE website (www.nice.org.uk/guidelinesprocess). Information on the progress of the guideline will also be available from the website.

Appendix: Referral from the Department of Health

The Department of Health asked the Institute to develop a guideline:

‘... on involving patients in decisions about prescribed medicines. The guideline should cover:

- approaches to achieving informed agreement between the prescriber and the patient on medicines to be taken
- communication with patients around medicine-taking, including the provision and use of medicines information
- dealing with poly-pharmacy and co-morbidity
- the skills and competencies required by prescribers
- medication review.’