

# Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes

NICE guideline

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## 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.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

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

Overview .....	4
Who is it for? .....	4
Introduction .....	5
The King's Fund definitions of polypharmacy .....	6
Safeguarding children .....	10
Medicines .....	11
Key priorities for implementation .....	12
Recommendations .....	14
1.1 Systems for identifying, reporting and learning from medicines-related patient safety incidents .....	14
1.2 Medicines-related communication systems when patients move from one care setting to another .....	16
1.3 Medicines reconciliation .....	19
1.4 Medication review .....	20
1.5 Self-management plans .....	22
1.6 Patient decision aids used in consultations involving medicines .....	23
1.7 Clinical decision support .....	25
1.8 Medicines-related models of organisational and cross-sector working .....	26
Terms used in this guideline .....	27
Recommendations for research .....	29
1 Medication review in children – suboptimal use of medicines and medicines-related patient safety incidents .....	29
2 Medication review – suboptimal use of medicines and patient-reported outcomes .....	31
3 Clinical decision support systems .....	34
4 Cross-organisational working .....	36
Finding more information and committee details .....	39
Update information .....	40

This guideline replaces PSG1.

This guideline partially replaces CG76.

This guideline is the basis of QS120 and QS149.

## Overview

This guideline covers safe and effective use of medicines in health and social care for people taking 1 or more medicines. It aims to ensure that medicines provide the greatest possible benefit to people by encouraging medicines reconciliation, medication review, and the use of patient decision aids.

NICE has also produced a [guideline on medicines adherence](#).

## Who is it for?

- Healthcare professionals
- Social care practitioners
- Commissioners and providers
- People taking 1 or more medicines and their families and carers

# Introduction

Getting the most from medicines for both patients and the NHS is becoming increasingly important as more people are taking more medicines. Medicines prevent, treat or manage many illnesses or conditions and are the most common intervention in healthcare. However, it has been estimated that between 30% and 50% of medicines prescribed for long-term conditions are not taken as intended (World Health Organization's world health report 2003). This issue is worsened by the growing number of people with long-term conditions. In 2012, the [Department of Health's long term conditions compendium of information: third edition](#) suggested that about 15 million people in England now have a long-term condition and the number of long-term conditions a person may have also increases with age: 14% of people aged under 40 years and 58% of people aged 60 years and over report having at least one long-term condition. The report defines a long-term condition as 'a condition that cannot, at present, be cured but is controlled by medication and/or other treatment/therapies'. When one or more non-curable long-term conditions are diagnosed, this is termed 'multimorbidity'. The number of people with multimorbidity in 2008 was 1.9 million, but this is expected to rise to 2.9 million by 2018. Twenty-five per cent of people aged over 60 years report having 2 or more long-term conditions.

Data from the [Health and Social Care Information Centre \(HSCIC\)](#) shows that between 2003 and 2013 the average number of prescription items per year for any one person in England increased from 13 (in 2003) to 19 (in 2013). When a person is taking multiple medicines this is called [polypharmacy](#), a term that has been used in health care for many years. With an increasing ageing population, polypharmacy has become more important to consider when making clinical decisions for individual people.

In 2013, [The King's Fund polypharmacy and medicines optimisation – making it safe and sound](#) paper outlined the view that polypharmacy was something to avoid, but proposed an alternative approach to the concept of polypharmacy: that it may have positive (appropriate) or negative (problematic) potential. Reducing the number of medicines a person is taking may not be the only factor to consider when reviewing polypharmacy.

## The King's Fund definitions of polypharmacy

### Appropriate polypharmacy

'Prescribing for an individual for complex conditions or for multiple conditions in circumstances where medicines use has been optimised and where the medicines are prescribed according to best evidence.'

### Problematic polypharmacy

'The prescribing of multiple [medicines] inappropriately, or where the intended benefit of the [medicines are] not realised.'

As the population ages and life expectancy increases, more people are living with several long-term conditions that are being managed with an increasing number of medicines. Maintaining a careful balance gets more difficult for people and health professionals, particularly when also trying to reduce health inequalities of the population.

Optimising a person's medicines is important to ensure a person is taking their medicines as intended and can support the management of long-term conditions, multimorbidities and polypharmacy. Medicines optimisation is defined as 'a person-centred approach to safe and effective medicines use, to ensure people obtain the best possible outcomes from their medicines. Medicines optimisation applies to people who may or may not take their medicines effectively. Shared decision-making is an essential part of evidence-based medicine, seeking to use the best available evidence to guide decisions about the care of the individual patient, taking into account their needs, preferences and values' ([Evidence based medicine: a movement in crisis Greenhalgh et al. 2014](#); [Evidence based medicine: what it is and what it isn't Sackett et al. 1996](#)).

An important part of shared decision-making is about health professionals understanding the person's desired level of involvement in decision-making about their medicines. When having these discussions it is often difficult for the person and the health professional to decide whether the medicines being taken are appropriate and the decision may be different for each individual person.

Involving people in decisions about their care and treatment is not a new concept. Over several years the UK government has supported an approach to change how the NHS

engages with patients. The [Department of Health's equality and excellence: liberating the NHS](#) outlined the government's vision of putting the public and patients first through shared decision-making. This White paper stressed that this would only happen by 'involving patients fully in their own care, with decisions made in partnership with clinicians, rather than by clinicians alone' and would be implemented by making shared decision-making the 'norm'. Subsequent to the government's White paper, [The King's Fund's making shared decision-making a reality: no decision about me, without me](#) aimed to outline the skills and resources needed by health professionals to use shared decision-making, and suggested tools that may help patients in decision-making when implementing this principle throughout the NHS.

The [NICE guidelines on patient experience in adult NHS services and service user experience in adult mental health](#) provide recommendations aiming to improve the experience of care for people using adult NHS and adult mental health services to create sustainable changes that aim to move the NHS towards a truly person-centred service. In relation to medicines, the [NICE guideline on medicines adherence](#) recommends that all patients have the opportunity to be involved in decisions about their medicines at the level they wish, through shared decision-making. Furthermore, [General Medical Council's good practice in prescribing and managing medicines and devices](#) also emphasises the need to take account of the patient's needs, wishes and preferences.

The safety of medicines is another important consideration when optimising medicines and can be a continual challenge. The Department of Health's [exploring the costs of unsafe care in the NHS](#) report found that 5% to 8% of unplanned hospital admissions are due to medication issues. This report focused on preventable adverse events which can be attributed to a specific error or errors. Incidents involving medicines have a number of causes, for example: lack of knowledge, failure to follow systems and protocols, interruptions (for example, during prescribing, administration or dispensing), staff competency, poor instruction, and poor communication. Organisations should have a standard approach to determine when a medicines-related incident or error should be referred to local safeguarding services. Effective systems and processes can minimise the risk of preventable medicines-related problems such as side effects, adverse effects or interactions with other medicines or comorbidities. The risk of people suffering harm from their medicines increases with polypharmacy.

The [Francis Report](#) (2013) emphasised the need to put patients first at all times, and that they must be protected from avoidable harm. In addition, the [Berwick report](#) (2013) recommended 4 guiding principles for improving patient safety, including:

- placing the quality and safety of patient care above all other aims for the NHS
- engaging, empowering, and hearing patients and carers throughout the entire system, and at all times.

Adverse events of medicines represent a considerable burden on the NHS and have a significant impact on patients (Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients Pirmohamed et al. 2004). When people transfer between different care providers, such as at the time of hospital admission or discharge, there is a greater risk of poor communication and unintended changes to medicines (Royal Pharmaceutical Society getting the medicines right). When people move from one care setting to another, between 30% and 70% of patients have an error or unintentional change to their medicines.

Patient safety in relation to medicines is not a new issue and several national initiatives exist to help improve patient safety. In 1964, the Medicines and Healthcare products Regulatory Agency (MHRA) and Commission on Human Medicines launched the national yellow card scheme for reporting side effects to medicines. The scheme is still in existence today and over 600,000 UK yellow cards have been received.

The National Reporting and Learning System (NRLS) was introduced in 2010 by the National Patient Safety Agency (NPSA) as a single, national reporting system for patient safety incidents in England and Wales. The NRLS staff reviewed all alerts to help NHS organisations understand patient safety incidents and why and how they happened, learning from these experiences and taking action to prevent future harm to people. In June 2012, the key functions and expertise for patient safety developed by the NPSA transferred to NHS England.

In 2014, NHS England and the MHRA issued a joint alert Patient safety alert improving medication error reporting and learning. The alerts aim to improve the quality of data reported by providers and introduce national networks to maximise learning and provide guidance on minimising harm relating to medication error reporting. NHS England also launched at this time a new National Patient Safety Alerting System (NPSAS) to strengthen the rapid dissemination of urgent patient safety alerts to healthcare providers via the Central Alerting System (CAS). The new system is a three-stage system to provide 'useful educational and implementation resources to support providers to put appropriate measures in place to prevent harm and encourage and share best practice in patient safety'.

To further support the patient safety agenda, the [NHS Safety Thermometer](#) was introduced by the Department of Health as a measurement tool to support an additional programme of work aimed at supporting patient safety and improvement. The tool is accessible to organisations across all healthcare settings, such as hospitals, care homes and community nursing, and allows them to measure, monitor and analyse patient harms and harm-free care at a local level to assess improvement over time.

Medicines use can be complex and how people can take their medicines safely and effectively has been a challenge for the health service for many years. The [Department of Health's liberating the NHS](#) emphasised the need to improve the outcomes of healthcare for all, to deliver care that is safer, more effective and provides a better experience for patients. Furthermore, the focus of health and social care to become a more integrated service, with person-centred care, has been made a priority after the Health and Social Care Act was passed in 2012. The Act aims to modernise the NHS, putting clinicians at the centre of commissioning and empowering patients. The [NHS Constitution](#) outlined the values and principles of the NHS in England and gave people the right to be involved in discussions and decisions about their health and care, and to be given information to enable them to do this. Patients with capacity have the right to make an informed decision and can refuse to take their medicines.

Before medicines optimisation, the term 'medicines management' was used which has been defined as 'a system of processes and behaviours that determines how medicines are used by the NHS and patients' (National Prescribing Centre 2002). Medicines management has primarily been led by pharmacy teams. Medicines management is an important enabler of medicines optimisation. The definition of 'optimise' is to 'make the best or most effective use of (a situation or resource)'. Medicines optimisation focuses on actions taken by all health and social care practitioners and requires greater patient engagement and professional collaboration across health and social care settings.

The [Royal Pharmaceutical Society's medicines optimisation: helping patients make the most of medicines](#) guide was produced to support the medicines optimisation agenda. This guide suggests 4 guiding principles for medicines optimisation, aiming to lead to improved patient outcomes:

- 'Aim to understand the patient's experience
- Evidence based choice of medicines
- Ensure medicines use is as safe as possible

- Make medicines optimisation part of routine practice'.

To further support the implementation of the guiding principles, the prototype [NHS England medicines optimisation dashboard](#) was launched. The dashboard aims to 'encourage Clinical Commissioning Groups (CCGs) and trusts to think more about how well their patients are supported to use medicines and less about focusing on cost and volume of drugs'. [NHS England's medicines optimisation supporting information](#) outlines the purpose of the dashboard.

Better use of data and technology can give people more control over their health and support the medicines optimisation agenda. The [National Information Board](#) (NIB) has been established by the Department of Health to bring together 'national health and core organisations from the NHS, public health, clinical science, social care and local government, together with appointed lay representatives'. The [National Information Board personalised health and care 2020: a framework for action](#) was published to support people using health and social care services and frontline health and social care practitioners to take better advantage the digital opportunity. Using the potential of information technology and data will help bridge the gaps between care services and enable people who use these services have access to their health care information, all of which can help optimise the use of medicines.

Striving towards a person-centred service through joint working across health and social care and cross-sector working (for example with commercial organisations) achieves the best possible outcomes for the person. This incorporates a patient's values and preferences and minimises harm, supporting effective medicines optimisation. This guideline reviews the evidence available to support health and social care practitioners, and health and social care organisations, in considering the systems and processes required to ensure safe and effective medicines optimisation.

In this guideline, the term 'medicines' covers all healthcare treatments, such as oral medicines, topical medicines, inhaled products, injections, wound care products, appliances and vaccines.

## Safeguarding children

Remember that child maltreatment:

- is common

Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes (NG5)

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- can present anywhere
- may co-exist with other health problems.

See [NICE's guideline on child maltreatment](#) for clinical features that may be associated with maltreatment.

## Medicines

The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

# Key priorities for implementation

The following recommendations have been identified as priorities for implementation. The full list of recommendations are in the [section on recommendations](#).

## **Systems for identifying, reporting and learning from medicines-related patient safety incidents**

- Organisations should consider using multiple methods to identify medicines-related patient safety incidents – for example, health record review, patient surveys and direct observation of medicines administration. They should agree the approach locally and review arrangements regularly to reflect local and national learning.

## **Medicines-related communication systems when patients move from one care setting to another**

- Health and social care practitioners should share relevant information about the person and their medicines when a person transfers from one care setting to another. This should include, but is not limited to, all of the following:
  - contact details of the person and their GP
  - details of other relevant contacts identified by the person, and their family members or carers where appropriate – for example, their nominated community pharmacy
  - known drug allergies and reactions to medicines or their ingredients, and the type of reaction experienced (see [NICE's guideline on drug allergy](#))
  - details of the medicines the person is currently taking (including prescribed, over-the-counter and complementary medicines) – name, strength, form, dose, timing, frequency and duration, how the medicines are taken and what they are being taken for
  - changes to medicines, including medicines started or stopped, or dosage changes, and reason for the change
  - date and time of the last dose, such as for weekly or monthly medicines, including injections

- what information has been given to the person, and their family members or carers where appropriate
  - any other information needed – for example, when the medicines should be reviewed, ongoing monitoring needs and any support the person needs to carry on taking the medicines. Additional information may be needed for specific groups of people, such as children.
- Consider sending a person's medicines discharge information to their nominated community pharmacy, when possible and in agreement with the person.

### **Medicines reconciliation**

- Organisations should ensure that medicines reconciliation is carried out by a trained and competent health professional – ideally a pharmacist, pharmacy technician, nurse or doctor – with the necessary knowledge, skills and expertise including:
  - effective communication skills
  - technical knowledge of processes for managing medicines
  - therapeutic knowledge of medicines use.

# Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in [NICE's information on making decisions about 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 prescribing medicines (including off-label use), 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.

## 1.1 Systems for identifying, reporting and learning from medicines-related patient safety incidents

Improving learning from medicines-related patient safety incidents is important to guide practice and minimise patient harm. Medicines-related patient safety incidents are unintended or unexpected incidents that are specifically related to medicines use, which could have or did lead to patient harm. These include potentially avoidable medicines-related hospital admissions and re-admissions, medication errors, near misses and potentially avoidable adverse events.

- 1.1.1 Organisations should support a person-centred, '[fair blame](#)' culture that encourages reporting and learning from medicines-related patient safety incidents.
- 1.1.2 Health and social care practitioners should explain to patients, and their family members or carers where appropriate, how to identify and report medicines-related patient safety incidents.
- 1.1.3 Organisations should ensure that [robust and transparent](#) processes are in place

to identify, report, prioritise, investigate and learn from medicines-related patient safety incidents, in line with national patient safety reporting systems – for example, the National Reporting and Learning System.

- 1.1.4 Organisations should consider using multiple methods to identify medicines-related patient safety incidents – for example, health record review, patient surveys and direct observation of medicines administration. They should agree the approach locally and review arrangements regularly to reflect local and national learning.
- 1.1.5 Organisations should ensure that national medicines safety guidance, such as patient safety alerts, are actioned within a specified or locally agreed timeframe.
- 1.1.6 Organisations should consider assessing the training and education needs of health and social care practitioners to help patients and practitioners to identify and report medicines-related patient safety incidents.
- 1.1.7 Health and social care practitioners should report all identified medicines-related patient safety incidents consistently and in a timely manner, in line with local and national patient safety reporting systems, to ensure that patient safety is not compromised.
- 1.1.8 Organisations and health professionals should consider applying the principles of the PINCER intervention to reduce the number of medicines-related patient safety incidents, taking account of existing systems and resource implications. These principles include:
- using information technology support
  - using educational outreach with regular reinforcement of educational messages
  - actively involving a multidisciplinary team, including GPs, nurses and support staff
  - having dedicated pharmacist support
  - agreeing an action plan with clear objectives

- providing regular feedback on progress
- providing clear, concise, evidence-based information.

1.1.9 Consider using a screening tool – for example, the STOPP/START tool in older people – to identify potential medicines-related patient safety incidents in some groups (STOPP, Screening Tool of Older Persons' potentially inappropriate Prescriptions; START, Screening Tool to Alert to Right Treatment). These groups may include:

- adults, children and young people taking multiple medicines (polypharmacy)
- adults, children and young people with chronic or long-term conditions
- older people.

1.1.10 Organisations should consider exploring what barriers exist that may reduce reporting and learning from medicines-related patient safety incidents. Any barriers identified should be addressed – for example, using a documented action plan.

1.1.11 Health and social care organisations and practitioners should:

- ensure that action is taken to reduce further risk when medicines-related patient safety incidents are identified
- apply and share learning in the organisation and across the local health economy, including feedback on trends or significant incidents to support continuing professional development. This may be through a medicines safety officer, controlled drugs accountable officer or other medicines safety lead.

## 1.2 Medicines-related communication systems when patients move from one care setting to another

Relevant information about medicines should be shared with patients, and their family

members or carers, where appropriate, and between health and social care practitioners when a person moves from one care setting to another, to support high-quality care. This includes transfers within an organisation – for example, when a person moves from intensive care to a hospital ward – or from one organisation to another – for example, when a person is admitted to hospital, or discharged from hospital to their home or other location.

Recommendations in this section update and replace recommendation 1.4.2 in [NICE's guideline on medicines adherence](#).

1.2.1 Organisations should ensure that robust and transparent processes are in place, so that when a person is transferred from one care setting to another:

- the current care provider shares complete and accurate information about the person's medicines with the new care provider **and**
- the new care provider receives and documents this information, and acts on it.

Organisational and individual roles and responsibilities should be clearly defined. Regularly review and monitor the effectiveness of these processes. See also [section 1.3](#) on medicines reconciliation.

Take into account the 5 rules set out in the [Health and Social Care Information Centre's guide to confidentiality in health and social care](#) when sharing information.

1.2.2 For all care settings, health and social care practitioners should proactively share complete and accurate information about medicines:

- ideally within 24 hours of the person being transferred, to ensure that patient safety is not compromised **and**
- in the most effective and secure way, such as by secure electronic communication, recognising that more than one approach may be needed.

1.2.3 Health and social care practitioners should share relevant information about the person and their medicines when a person transfers from one care setting to another. This should include, but is not limited to, all of the following:

- contact details of the person and their GP
  - details of other relevant contacts identified by the person and their family members or carers where appropriate – for example, their nominated community pharmacy
  - known drug allergies and reactions to medicines or their ingredients, and the type of reaction experienced (see [NICE's guideline on drug allergy](#))
  - details of the medicines the person is currently taking (including prescribed, [over-the-counter](#) and [complementary medicines](#)) – name, strength, form, dose, timing, frequency and duration, how the medicines are taken and what they are being taken for
  - changes to medicines, including medicines started or stopped, or dosage changes, and reason for the change
  - date and time of the last dose, such as for weekly or monthly medicines, including injections
  - what information has been given to the person, and their family members or carers where appropriate
  - any other information needed – for example, when the medicines should be reviewed, ongoing monitoring needs and any support the person needs to carry on taking the medicines. Additional information may be needed for specific groups of people, such as children.
- 1.2.4 Health and social care practitioners should discuss relevant information about medicines with the person, and their family members or carers where appropriate, at the time of transfer. They should give the person, and their family members or carers where appropriate, a complete and accurate list of their medicines in a format that is suitable for them. This should include all current medicines and any changes to medicines made during their stay.
- 1.2.5 Consider sending a person's medicines discharge information to their nominated community pharmacy, when possible and in agreement with the person.
- 1.2.6 Organisations should consider arranging additional support for some groups of

people when they have been discharged from hospital, such as pharmacist counselling, telephone follow-up, and GP or nurse follow-up home visits. These groups may include:

- adults, children and young people taking multiple medicines (polypharmacy)
- adults, children and young people with chronic or long-term conditions
- older people.

## 1.3 Medicines reconciliation

Medicines reconciliation, as defined by the Institute for Healthcare Improvement, is the process of identifying an accurate list of a person's current medicines and comparing them with the current list in use, recognising any discrepancies, and documenting any changes, thereby resulting in a complete list of medicines, accurately communicated. The term 'medicines' also includes over-the-counter or complementary medicines, and any discrepancies should be resolved. The medicines reconciliation process will vary depending on the care setting that the person has just moved into – for example, from primary care into hospital, or from hospital to a care home.

- 1.3.1 In an acute setting, accurately list all of the person's medicines (including prescribed, over-the-counter and complementary medicines) and carry out medicines reconciliation within 24 hours or sooner if clinically necessary, when the person moves from one care setting to another – for example, if they are admitted to hospital.
- 1.3.2 Recognise that medicines reconciliation may need to be carried out on more than one occasion during a hospital stay – for example, when the person is admitted, transferred between wards or discharged.
- 1.3.3 In primary care, carry out medicines reconciliation for all people who have been discharged from hospital or another care setting. This should happen as soon as is practically possible, before a prescription or new supply of medicines is issued and within 1 week of the GP practice receiving the information.
- 1.3.4 In all care settings organisations should ensure that a designated health

professional has overall organisational responsibility for the medicines reconciliation process. The process should be determined locally and include:

- organisational responsibilities
- responsibilities of health and social care practitioners involved in the process (including who they are accountable to)
- individual training and competency needs.

1.3.5 Organisations should ensure that medicines reconciliation is carried out by a trained and competent health professional – ideally a pharmacist, pharmacy technician, nurse or doctor – with the necessary knowledge, skills and expertise including:

- effective communication skills
- technical knowledge of processes for managing medicines
- therapeutic knowledge of medicines use.

1.3.6 Involve patients and their family members or carers, where appropriate, in the medicines reconciliation process.

1.3.7 When carrying out medicines reconciliation, record relevant information on an electronic or paper-based form. See [section 1.2](#) on medicines-related communication systems.

## 1.4 Medication review

Medication review can have several different interpretations and there are also different types which vary in their quality and effectiveness. Medication reviews are carried out in people of all ages. In this guideline medication review is defined as 'a structured, critical examination of a person's medicines with the objective of reaching an agreement with the person about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste'. See also [recommendation 1.6.3](#).

1.4.1 Consider carrying out a structured medication review for some groups of people

when a clear purpose for the review has been identified. These groups may include:

- adults, children and young people taking multiple medicines (polypharmacy)
- adults, children and young people with chronic or long-term conditions
- older people.

1.4.2 Organisations should determine locally the most appropriate health professional to carry out a structured medication review, based on their knowledge and skills, including all of the following:

- technical knowledge of processes for managing medicines
- therapeutic knowledge on medicines use
- effective communication skills.

The medication review may be led, for example, by a pharmacist or by an appropriate health professional who is part of a multidisciplinary team.

1.4.3 During a structured medication review, take into account:

- the person's, and their family members or carers where appropriate, views and understanding about their medicines
- the person's, and their family members' or carers' where appropriate, concerns, questions or problems with the medicines
- all prescribed, over-the-counter and complementary medicines that the person is taking or using, and what these are for
- how safe the medicines are, how well they work for the person, how appropriate they are, and whether their use is in line with national guidance
- whether the person has had or has any risk factors for developing adverse drug reactions (report adverse drug reactions in line with the yellow card scheme)
- any monitoring that is needed.

## 1.5 Self-management plans

Self-management plans can be patient-led or professional-led and they aim to support people to be empowered and involved in managing their condition. Different types of self-management plan exist and they vary in their content depending on the needs of the individual person. Self-management plans can be used in different settings. In this guideline self-management plans are structured, documented plans that are developed to support a person's self management of their condition using medicines. People using self-management plans can be supported to use them by their family members or carers who can also be involved when appropriate during discussions – for example, a child and their parents using a self-management plan.

1.5.1 When discussing medicines with people who have chronic or long-term conditions, consider using an individualised, documented self-management plan to support people who want to be involved in managing their medicines. Discuss at least all of the following:

- the person's knowledge and skills needed to use the plan, using a risk assessment if needed
- the benefits and risks of using the plan
- the person's values and preferences
- how to use the plan
- any support, signposting or monitoring the person needs.

Record the discussion in the person's medical notes or care plan as appropriate.

1.5.2 When developing an individualised, documented self-management plan, provide it in an accessible format for the person and consider including:

- the plan's start and review dates
- the conditions being managed
- a description of medicines being taken under the plan (including the timing)

- a list of the medicines that may be self-administered under the plan and their permitted frequency of use, including any strength or dose restrictions and how long a medicine may be taken for
- known drug allergies and reactions to medicines or their ingredients, and the type of reaction experienced (see the [NICE guideline on drug allergy](#))
- arrangements for the person to report suspected or known adverse reactions to medicines
- circumstances in which the person should refer to, or seek advice from, a health professional
- the individual responsibilities of the health professional and the person
- any other instructions the person needs to safely and effectively self-manage their medicines.

1.5.3 Review the self-management plan to ensure the person does not have problems using it.

## 1.6 Patient decision aids used in consultations involving medicines

Many people wish to be active participants in their own healthcare, and to be involved in making decisions about their medicines. Patient decision aids can support health professionals to adopt a shared decision-making approach in a consultation, to ensure that patients, and their family members or carers where appropriate, are able to make well-informed choices that are consistent with the person's values and preferences. More information is available in [NICE's guidelines on decision-making and mental capacity and shared decision making](#).

1.6.1 Offer all people the opportunity to be involved in making decisions about their medicines. Find out what level of involvement in decision-making the person would like and avoid making assumptions about this.

1.6.2 Find out about a person's values and preferences by discussing what is important

to them about managing their conditions and their medicines. Recognise that the person's values and preferences may be different from those of the health professional and avoid making assumptions about these.

- 1.6.3 Apply the principles of evidence-based medicine when discussing the available treatment options with a person in a consultation about medicines. Use the best available evidence when making decisions with or for individuals, together with clinical expertise and the person's values and preferences.
- 1.6.4 In a consultation about medicines, offer the person, and their family members or carers where appropriate, the opportunity to use a patient decision aid (when one is available) to help them make a preference-sensitive decision that involves trade-offs between benefits and harms. Ensure the patient decision aid is appropriate in the context of the consultation as a whole.
- 1.6.5 Do not use a patient decision aid to replace discussions with a person in a consultation about medicines.
- 1.6.6 Recognise that it may be appropriate to have more than one consultation to ensure that a person can make an informed decision about their medicines. Give the person the opportunity to review their decision, because this may change over time – for example, a person's baseline risk may change.
- 1.6.7 Ensure that patient decision aids used in consultations about medicines have followed a robust and transparent development process, in line with NICE's Standards framework for shared-decision-making support tools, including patient decision aids or the International Patient Decision Aid Standards criteria.
- 1.6.8 Before using a patient decision aid with a person in a consultation about medicines, read and understand its content, paying particular attention to its limitations and the need to adjust discussions according to the person's baseline risk.
- 1.6.9 Ensure that the necessary knowledge, skills and expertise have been obtained before using a patient decision aid. This includes:
- relevant clinical knowledge

- effective communication and consultation skills, especially when finding out patients' values and preferences
  - effective numeracy skills, especially when explaining the benefits and harms in natural frequencies, and relative and absolute risk
  - explaining the trade-offs between particular benefits and harms.
- 1.6.10 Organisations should consider training and education needs for health professionals in developing the skills and expertise to use patient decision aids effectively in consultations about medicines with patients, and their family members or carers where appropriate.
- 1.6.11 Organisations should consider identifying and prioritising which patient decision aids are needed for their patient population through, for example, a local medicines decision-making group. They should agree a consistent, targeted approach in line with local pathways and review the use of these patient decision aids regularly.
- 1.6.12 Organisations and health professionals should ensure that patient decision aids prioritised for use locally are disseminated to all relevant health professionals and stakeholder groups, such as clinical networks.

## 1.7 Clinical decision support

Clinical decision support software is a component of an integrated clinical IT system providing support to clinical services, such as in a GP practice or secondary care setting. These integrated clinical IT systems are used to support health professionals to manage a person's condition. In this guideline the clinical decision support software relates to computerised clinical decision support, which may be active or interactive, at the point of prescribing medicines.

- 1.7.1 Organisations should consider computerised clinical decision support systems (taking account of existing systems and resource implications) to support clinical decision-making and prescribing, but ensure that these do not replace clinical judgement.

- 1.7.2 Organisations should ensure that robust and transparent processes are in place for developing, using, reviewing and updating computerised clinical decision support systems.
- 1.7.3 Organisations should ensure that health professionals using computerised clinical decision support systems at the point of prescribing have the necessary knowledge and skills to use the system, including an understanding of its limitations.
- 1.7.4 When using a computerised clinical decision support system to support clinical decision-making and prescribing, ensure that it:
- identifies important safety issues
  - includes a system for health professionals to acknowledge mandatory alerts. This should not be customisable for alerts relating to medicines-related 'never events'
  - reflects the best available evidence and is up-to-date
  - contains useful clinical information that is relevant to the health professional to reduce 'alert fatigue' (when a prescriber's responsiveness to a particular type of alert declines as they are repeatedly exposed to that alert over time).

## 1.8 Medicines-related models of organisational and cross-sector working

The introduction of skill mixing of various health and social care practitioners to meet the needs of different groups of people has led to different types of models of care emerging across health and social care settings. Cross-organisational working further provides seamless care during the patient care pathway when using health and social care services. The type of model of care used will be determined locally based on the resources and health and social care needs of the population in relation to medicines.

- 1.8.1 Organisations should consider a multidisciplinary team approach to improve outcomes for people who have long-term conditions and take multiple medicines (polypharmacy).

- 1.8.2 Organisations should involve a pharmacist with relevant clinical knowledge and skills when making strategic decisions about medicines use or when developing care pathways that involve medicines use.

## Terms used in this guideline

### Adverse drug reaction

This is a response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility. See also [Medicines and Healthcare Products Regulatory Agency](#) for further information.

### Complementary medicine

Treatments that fall outside of mainstream healthcare. These medicines and treatments range from acupuncture and homeopathy to aromatherapy.

### 'Fair blame' culture

In health and social care, this enables open and honest reporting of mistakes that are treated as an opportunity to learn to improve care.

### Over-the-counter medicines

Medicines that can be bought without a prescription.

### Person's baseline risk

Patient decision aids illustrate the absolute benefits and risks of interventions, assuming a particular baseline risk. It is important to take into account the person's likely starting or baseline risk when using a patient decision aid. Even though the relative risk is the same regardless of the person's baseline risk, people with a lower baseline risk than that illustrated in a patient decision aid will have a lower absolute chance of benefiting and a lower residual risk. People with a greater baseline risk than that illustrated will have a greater absolute chance of benefiting but also a greater residual risk.

## **PINCER (pharmacist-led information technology intervention for medication errors)**

Method for reducing a range of medication errors in general practices with computerised clinical records.

## **Polypharmacy**

Use of multiple medicines by a person.

## **Preference-sensitive decision**

Decisions about treatment made based on the person's preferences and personal values of each treatment option presented. Decisions should be made only after patients have enough information to make an informed choice, in partnership with the prescriber.

## **Robust and transparent**

Robust and transparent processes, including sharing of information and appropriate collaboration with relevant stakeholders, aims to improve the consistency of decision-making about medicines and ensure that patient safety is not compromised. This should reduce inappropriate variation in patient care when decisions are made due to inconsistent, inadequate or unsafe processes and policies. However, even with robust and transparent processes in place, legitimate variation will remain. Organisations will make decisions within their local governance arrangements that are based on local priorities and the needs of their local population.

# Recommendations for research

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.

## 1 Medication review in children – suboptimal use of medicines and medicines-related patient safety incidents

Is a medication review more clinically and cost effective at reducing the suboptimal use of medicines and medicines-related patient safety incidents, compared with usual care or other interventions, in children?

The research should be carried out in children that use services where medication reviews can be carried out.

Study methodology can be based on other well-conducted randomised controlled trials (RCTs) that have been carried out in adults, the difference being the age of the population. Approval from ethics or other committees would be needed given the young age of the population. 'Usual care' or other interventions would be used as a comparator. 'Usual care' would need to be defined in the study. A follow-up period of 1–2 years or more would capture longer-term outcomes. The outcomes for this research question should be patient-centred and include suboptimal use of medicines, medicines-related patient safety incidents, patient-reported outcomes, clinical outcomes, medicines-related problems, health and social care resource use and cost effectiveness.

The study would need to take into account:

- the type of medication review carried out; the study needs to outline a framework of the medication review to help guidance developers to see the process used; they would then be better able to decide if it would affect clinical effectiveness of the intervention
- the health professional carrying it out
- child, parent and carer involvement as this may affect some outcome measures,

depending on their engagement level

- the frequency of medication review (this would impact on cost effectiveness of resource use).

## Rationale

The GDG recognised that the key focus of the medicines optimisation agenda is to make care person-centred. In line with this and to ensure the best use of NHS resources, the GDG agreed that research needs to be carried out in children to identify the benefit from them having medication reviews. There may be some longer-term gains with this approach, as from a young age the child would become more aware of the intervention, develop a relationship with the health professional and be encouraged to understand their medicines.

Research into this area will provide guidance to organisations who may want to, or already provide, medication reviews as part of their care and enable better use of resources (for example, health professional cost and time and health and social care resources). This information would be useful to commissioners who may consider whether or not to commission providers to carry out medication reviews.

## Proposed format of recommendations for research

Criterion	Explanation
Population	Children (this may also involve parents or carers where appropriate) taking medicines for 1 or more clinical conditions in the UK.
Intervention	Medication reviews. Defined in the review protocol as: 'a structured, critical examination of a patient's medicines with the objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste'. The framework of the medication review should be outlined in the method of the study. The medication review can be professional led or carried out by a multidisciplinary team.

Criterion	Explanation
Comparators	'Usual care' such as people who may not have a medication review or may have an 'ad hoc' review of their medicines. This may be provided in all settings. Other interventions, such as another type of medication review.
Outcome	The following outcomes should be considered: suboptimal prescribing medicines-related patient safety incidents patient-reported outcomes (for example, patient satisfaction and medicines adherence) quality of life clinical outcomes medicines-related problems (for example, medication errors) health and social care resource use. For results to be valid and reliable, outcomes should ideally be measured using validated tools, and where this is not possible the outcome measure should be detailed in the study. Quality of life should be assessed using an EQ-5D questionnaire so that a cost-utility analysis can be conducted.
Study design	Randomised controlled trial.
Timeframe	Follow-up outcomes of 1–2 years or more. This will enable assessment on the clinical and economic impact of medication reviews on long-term conditions and associated outcomes.

## 2 Medication review – suboptimal use of medicines and patient-reported outcomes

Is a medication review more clinically and cost effective at reducing the suboptimal use of medicines and improving patient-reported outcomes, compared with usual care or other intervention in the UK setting?

The study should consider the cost effectiveness of the health professionals carrying out the medication review.

The medication review should be carried out by a multidisciplinary team or be professional led by any health professional other than a community or hospital pharmacist to provide data to develop an economic model for cost effectiveness. There is already economic evidence available for community and hospital pharmacists.

Research can be carried out using an RCT. Study methodology can be based on other well-conducted RCTs that have been carried out looking at medication reviews. 'Usual care' or other interventions would be used as a comparator. 'Usual care' would need to be defined in the study. A follow-up period of 1–2 years or more would capture longer-term outcomes. Outcomes for this research question should be patient-centred and include the suboptimal use of medicines, patient-reported outcomes, clinical outcomes, medicines-related problems, health and social care resource use and cost effectiveness.

The study would need to take into account:

- the type of medication review carried out; the study would need to outline a framework of the medication review to help guidance developers to see the process used; they would then be better able to decide if it would affect clinical effectiveness of the intervention
- type of health professional carrying out the medication review
- the frequency of medication review (this would impact on cost effectiveness of resource use).

## Rationale

The GDG recognised that the key focus of the medicines optimisation agenda is to make care person-centred and to have services that support people in the optimal use of their medicines. Medication reviews can be offered to people by different health professionals at different levels, working in different settings. Resources (for example, staff and time) needed to enable routine medication review may vary locally depending on the setting and health professional availability.

Research into this area will provide guidance to organisations who may want to, or already provide, medication reviews as part of their care and enable better use of resources (for example, health professional cost and time and health and social care resources) and facilitate service delivery. This information would be useful to commissioners who may consider whether or not to commission medication reviews by providers.

### Proposed format of recommendations for research

Criterion	Explanation
Population	Children and adults taking medicines for 1 or more clinical conditions in the UK.
Intervention	<p>Medication reviews.</p> <p>Defined in the review protocol as: 'a structured, critical examination of a patient's medicines with the objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste'.</p> <p>The framework of the medication review should be outlined in the method of the study.</p> <p>Carried out by health professionals (including primary care pharmacists) other than community or hospital pharmacists.</p> <p>Carried out by a multidisciplinary team that can involve any health professional.</p>
Comparators	<p>'Usual care' such as people who may not have a medication review, or may have an 'ad hoc' review of their medicines. This may be provided in all settings.</p> <p>Other interventions, such as:</p> <ul style="list-style-type: none"> <li>• another type of medication review</li> <li>• a review carried out by health professionals other than those specified in the intervention, for example a nurse rather than a doctor.</li> </ul>

Criterion	Explanation
Outcome	<p>The following outcomes should be considered:</p> <ul style="list-style-type: none"> <li>• suboptimal prescribing</li> <li>• patient-reported outcomes (for example, patient satisfaction and medicines adherence)</li> <li>• medicines-related patient safety incidents</li> <li>• quality of life</li> <li>• clinical outcomes</li> <li>• medicines-related problems (for example, medication errors)</li> <li>• health and social care resource use.</li> </ul> <p>For results to be valid and reliable, outcomes should ideally be measured using validated tools; where this is not possible the outcome measure should be detailed in the study.</p> <p>Quality of life should be assessed using an EQ-5D questionnaire so that a cost-utility analysis can be conducted.</p>
Study design	Randomised controlled trial.
Timeframe	Follow-up outcomes of 1–2 years or more. This would enable assessment on the clinical and economic impact of medication reviews on long-term conditions and associated outcomes.

### 3 Clinical decision support systems

What is the clinical and cost effectiveness of using clinical decision support systems to reduce the suboptimal use of medicines and improve patient outcomes from medicines, compared with usual care, in the UK setting?

Randomised controlled trials should consider the use of clinical decision support systems to improve outcomes and safety for medicines in the UK setting compared with usual care. A follow-up period (ideally longer than 2 years) would capture longer-term outcomes. Outcomes for this research question should include patient-reported outcomes, clinical

outcomes, medicines-related problems and cost effectiveness. The research can be carried out in all populations that use services where clinical decision support systems can be used. The research could also look at process measures for using clinical decision support systems, for example the clinical effectiveness of such systems can depend on the end users of the system and their interpretation of the active information provided on the screen.

## Rationale

Clinical decision support systems (defined as 'an active, computerised intervention that occurs at the time and location of prescribing, to support prescribers with decision-making') are widely used in some primary care settings, such as in GP practices, but they may also be used in secondary care (in specialist units, for example renal units). There are many types of clinical decision support system available and they vary, from providing clinical decision support for general medicines use to highlighting specific drug interactions. As different types of clinical decision support systems are used already in some UK healthcare settings, the GDG agreed that research needs to be carried out to identify whether using clinical decision support systems is a clinically and cost effective intervention to reduce the suboptimal use of medicines and improve patient outcomes from medicines compared with usual care, in the UK setting.

### Proposed format of recommendations for research

Criterion	Explanation
Population	All people taking medicines.
Intervention	Clinical decision support systems. Defined in the review protocol as 'an active, computerised intervention that occurs at the time and location of prescribing, to support prescribers with decision-making'.
Comparators	Usual care. 'Usual care' in the primary care setting, for example in a GP practice, uses clinical decision support systems which may highlight for example choice of formulary medicines or drug interaction to the prescriber, however 'usual care' in secondary care settings may be different when such clinical decision support systems may or may not be available to use.

Criterion	Explanation
Outcome	<p>The following outcomes should be considered:</p> <ul style="list-style-type: none"> <li>• patient-reported outcomes (for example satisfaction, medicines adherence)</li> <li>• quality of life</li> <li>• clinical outcomes</li> <li>• medicines related problems (for example adverse drug reactions).</li> </ul> <p>An appropriate length of follow-up would be 2 years or more for the outcomes to be externally valid.</p> <p>Process measures may also be considered for this research question to see what impact clinical decision support systems have on the training on use of systems, updating systems, and 'alert fatigue'.</p>
Study design	Randomised controlled trial.
Timeframe	Follow-up outcomes of 2 years or more.

## 4 Cross-organisational working

What models of cross-organisational working improve clinical and cost effectiveness in relation to the suboptimal prescribing of medicines – for example, between NHS and social care, or primary and secondary care, or between NHS and commercial organisations?

Randomised controlled trials should consider models of cross-collaborative working to improve outcomes and safety for medicines, in the UK setting, compared with usual care. A follow-up period (ideally longer than 2 years) would capture longer-term outcomes. Outcomes for this research question should include patient-reported outcomes, clinical outcomes, medicines-related problems and cost effectiveness. The research should be carried out in all populations that use services across different sectors – for example, care (relating to the use of medicines) of people may be transferred from an NHS organisation to social care, from a secondary care organisation to primary care or within secondary care – for example, from one ward to another. The research could also identify benefits and challenges of cross-organisational working for suboptimal prescribing of medicines.

## Rationale

The GDG was aware of pockets of good practice that involve models of care consisting of cross-organisational working relating to medicines. However, no published evidence was found to show whether or not it improves patient-reported outcomes in relation to suboptimal prescribing. This research recommendation will help to provide evidence on whether or not cross-organisational working is a cost-effective model of care when improving patient-reported outcomes for suboptimal prescribing.

### Proposed format of recommendations for research

Criterion	Explanation
Population	All people taking medicines using the following care settings: <ul style="list-style-type: none"><li>• NHS</li><li>• social care</li><li>• pharmaceutical industry</li><li>• home care companies</li><li>• private providers of healthcare services.</li></ul>
Intervention	Model used to deliver cross organisational working, for example between NHS and social care, or primary and secondary care, or NHS and commercial organisations; working together using a model to deliver a service collaboratively for medicines.
Comparators	Routine care or usual care.

Criterion	Explanation
Outcome	<p>The following outcomes should be considered:</p> <ul style="list-style-type: none"> <li>• patient-reported outcomes (for example satisfaction, medicines adherence)</li> <li>• quality of life</li> <li>• clinical outcomes</li> <li>• medicines-related problems (for example adverse drug reactions, medicines discrepancies on records).</li> </ul> <p>An appropriate length of follow-up would be 2 years or more for the outcomes to be externally valid.</p> <p>Process measures may also be considered for this research question to see what impact cross-collaborative working has on resources such as time and staffing. Process measure outcomes may include:</p> <ul style="list-style-type: none"> <li>• time required to transfer medicines-related information from one care setting to another</li> <li>• training of staff required to solve any medicines-related queries.</li> </ul>
Study design	Randomised controlled trial.
Timeframe	Follow-up outcomes of 2 years or more.

## Finding more information and committee details

To find NICE guidance on related topics, including guidance in development, see the [NICE topic page on medicines management](#).

For full details of the evidence and the guideline committee's discussions, see the [full guideline](#). You can also find information about [how the guideline was developed](#), including details of the guideline committee.

NICE has produced [tools and resources to help you put this guideline into practice](#). For general help and advice on putting our guidelines into practice, see [resources to help you put NICE guidance into practice](#).

# Update information

## Minor changes since publication

**October 2021:** We added a link to NICE's guideline on shared decision making in section 1.6 on patient decision aids.

**June 2021:** In recommendation 1.6.7 we added a link to [NICE's Standards framework for shared-decision-making support tools, including patient decision aids](#).

**September 2019:** We updated links to guidance on confidentiality in recommendation 1.2.1, and added a link to our guideline on decision making and mental capacity in section 1.6.

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