NICE National Institute for Health and Care Excellence

NICE Pathways

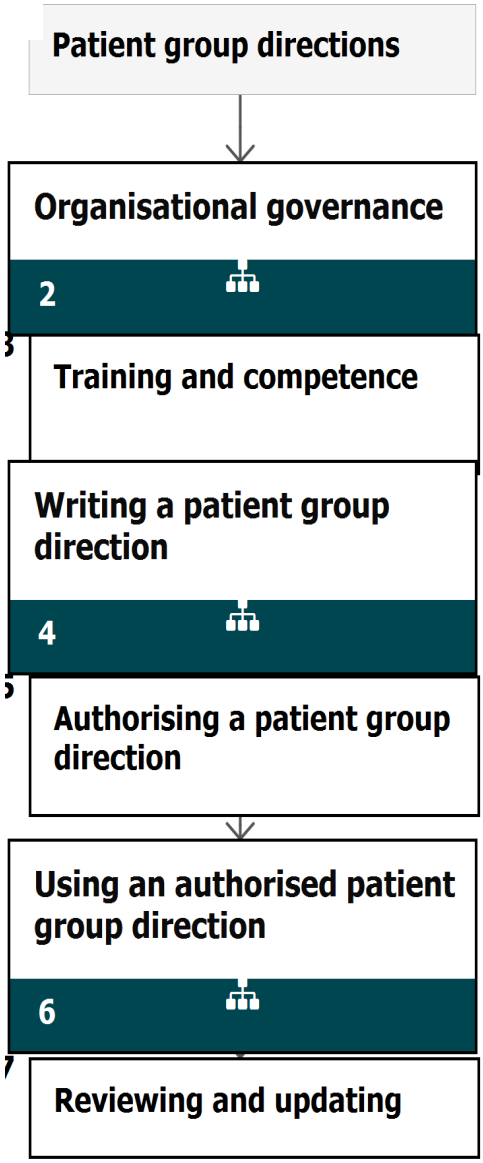
Patient group directions overview

NICE Pathways bring together everything NICE says on a topic in an interactive flowchart. NICE Pathways are interactive and designed to be used online.

They are updated regularly as new NICE guidance is published. To view the latest version of this NICE Pathway see:

http://pathways.nice.org.uk/pathways/patient-group-directions
NICE Pathway last updated: 27 March 2017

This document contains a single flowchart and uses numbering to link the boxes to the associated recommendations.



1 Patient group directions

No additional information

2 Organisational governance

See Patient group directions / Organisational governance for a patient group direction

3 Training and competence

Identify gaps in competency and establish a comprehensive and appropriate training programme for all people involved in considering the need for, developing, authorising, using and updating patient group directions.

Consider collaborating with other organisations and sharing existing educational materials to ensure a comprehensive approach.

Identify the senior person in each profession who is responsible for ensuring that only fully competent, qualified and trained health professionals use patient group directions.

Ensure that adequate educational materials are available to enable individual people and organisations to deliver safe and effective services in which patient group directions are used.

Ensure that training and re-training of health professionals using patient group directions incorporates a post-training assessment of competency.

4 Writing a patient group direction

See Patient group directions / Writing a patient group direction

5 Authorising a patient group direction

Patient group directions must be authorised only by an appropriate authorising body in line with the Human Medicines Regulations 2012.

When acting as a doctor, dentist or pharmacist signatory, establish that the clinical and

pharmaceutical content is accurate and supported by the best available evidence.

At an early stage, identify the appropriate person who will sign the patient group direction as a representative of any professional group(s) practising under the patient group direction. Consider their training and competency needs.

When signing a patient group direction on behalf of an authorising body, establish that:

- local processes and governance arrangements have been followed
- all legal requirements have been met (see organisational governance for a patient group direction).

Assess local needs and develop a communications plan to support the dissemination of patient group directions. Identify an appropriate person who is responsible for ensuring that this occurs.

For each patient group direction, the provider organisation should:

- identify a senior, responsible person from within the service to authorise named, registered health professionals to practise under the patient group direction (see considering the need for a patient group direction).
- ensure that authorised health professionals have signed the appropriate documentation (see before practicing under a patient group direction).

If the provider is not the authorising body, this responsibility would require a formal agreement between the commissioner and provider.

Publish final signed versions of patient group directions on an intranet.

Determine the expiry date for an individual patient group direction on a case-by-case basis, with patient safety paramount. Ensure that this date does not exceed 3 years from the date the patient group direction was authorised.

Ensure that an updated patient group direction is reauthorised, in line with the Human Medicines Regulations 2012. (See identifying who is responsible).

Ensure that an updated patient group direction is communicated and disseminated effectively to all relevant stakeholders.

6 Using an authorised patient group direction

See Patient group directions / Using an authorised patient group direction

7 Reviewing and updating

When reviewing the patient group direction, conduct an appropriate literature search to identify new evidence. Ensure that this evidence is evaluated to assess its relevance and validity.

When reviewing the patient group direction, determine whether the patient group direction remains the most appropriate option to deliver the service. This should be informed by local monitoring and evaluations, frequency of use of the patient group direction, views of health professionals working under the patient group direction and views of relevant stakeholders, such as patients or their carers.

When a patient group direction is updated, ensure all relevant documentation is also updated, including the record and signatures of health professionals authorised to practise under the patient group direction (see organisational records).

Establish a robust and transparent process for the unscheduled review and updating of a patient group direction, when the need for this has been identified. This should include responding to:

- changes in legislation
- important new evidence or guidance that changes the patient group direction, such as new NICE guidance
- new information on drug safety
- changes in the summary of product characteristics (SPC)
- changes to the local formulary.

Glossary

Appropriately labelled pack

in most cases, the pack to be issued under a PGD will need to be labelled to reflect the dose exactly as authorised in the PGD, as if it were being dispensed against a prescription. Separate requirements exist for prescription-only medicines (POMs) and for pharmacy (P) and general sales list (GSL) medicines. In practice, medicines supplied for use under a PGD are often in packs that are pre-labelled by a licensed manufacturing unit. These labels include all the standard labelling requirements, leaving a space on the pack for the patient's name, date of dispensing and address of the supplying service to be added at the time of supply. This is sometimes known as over-labelling

Authorising body

an organisation listed in the Human Medicines Regulations 2012 (and subsequent amendments) that is legally able to authorise a PGD. The commissioning and/or provider organisation may be an authorising body. In the NHS in England, these organisations are: clinical commissioning groups (CCGs), local authorities, NHS trusts or NHS foundation trusts, NHS England and Public Health England

Black triangle medicine

black triangle medicines are licensed medicines that are intensively monitored and subject to special reporting arrangements for adverse events

Commissioning organisation/commissioner

the organisation with which a contract or agreement for the provision of a service that may require the prescribing, supply or administration of medicines has been made

Off-label use

using a UK licensed medicine outside the terms of its marketing authorisation, such as outside defined indications, doses or routes of administration. For example, when amitriptyline, licensed for the treatment of depression, is used for neuropathic pain

Organisations

unless stated otherwise, use of the term 'organisation' includes authorising bodies and any other organisations (both NHS and non-NHS) who are considering the need for, developing, authorising, using and updating PGDs to provide public-funded services

Patient group direction

patient group direction (PGD) defined in Health Service Circular (HSC 2000/026) as 'Written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment'

Patient safety incident

any unintended or unexpected incident that could have or did lead to harm for 1 or more patients receiving healthcare. This includes clinical errors, medication errors, adverse events and near misses

Patient group direction approval group

a locally determined multidisciplinary group that considers proposals to develop a PGD to deliver a service. This group may also be involved at other stages of the process, depending on local arrangements. For example, the group may approve a final draft of the PGD before it is submitted for authorisation. The term 'PGD approval group' is used for the purpose of this guidance, but other names for the group may be used locally. The group may be an existing local medicines decision-making group, such as the drug and therapeutics committee, or subgroup

Patient group direction working group

a locally determined multidisciplinary group established for each individual PGD. The PGD working group is responsible for developing the PGD and its subsequent review and updating. The term 'PGD working group' is used for the purpose of this guideline, but other names for the group may be used locally

Provider organisation/provider

the organisation responsible for providing the commissioned service, which may require the prescribing, supply or administration of medicines. This may be an NHS organisation or a non-

NHS organisation providing public-funded service

Sources

Patient group directions (2013 updated 2017) NICE guideline MPG2

Your responsibility

Guidelines

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.

Technology appraisals

The recommendations in this interactive flowchart represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take these recommendations fully into account, alongside the individual needs, preferences and values of their patients. The application of the

recommendations in this interactive flowchart is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Commissioners and/or providers have a responsibility to provide the funding required to enable the recommendations to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so 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.

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.

Medical technologies guidance, diagnostics guidance and interventional procedures guidance

The recommendations in this interactive flowchart represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take these recommendations fully into account. However, the interactive flowchart does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the recommendations, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this interactive flowchart should be interpreted in a way that would be inconsistent with compliance 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.