

Putting NICE guidance into practice

Case scenarios for patient group directions

**Implementing the NICE guideline on patient group
directions (MPG2)**

Published: 2 August 2013

Last updated: 4 January 2018

These case scenarios accompany the [NICE guideline on patient group directions](#). Issue date: August 2013 [updated January 2018].

These case scenarios were developed in October 2013. They were updated in January 2018 to reflect the updated guideline on patient group directions. They are not formal NICE guidance.

Commissioners and providers are reminded that it is their responsibility to implement the guidance, 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 the guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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Introduction

NICE case scenarios

Case scenarios are an educational resource that can be used for individual or group learning. Each question should be considered by the individual or group before referring to the answers.

These 6 case scenarios were developed using common queries that were submitted to the [NHS Specialist Pharmacy Service website patient group directions \(PGD\) resources](#) and have been put together to improve your knowledge of PGDs and their application in practice. They illustrate how the recommendations from [NICE's guideline on patient group directions](#) can be applied to individual people and organisations involved with PGDs, with the aim of ensuring patients receive safe and appropriate care and timely access to medicines, in line with legislation.

These case scenarios were used at PGD implementation workshops on 8 October and 10 October 2013 to provide the opportunity for delegates to share learning and discuss common issues relating to PGDs.

You will need to refer to the NICE guideline while using these case scenarios, so make sure that users have access to a copy.

Each case scenario includes background information, and relevant recommendations from the NICE guideline are quoted in the text (at the end of each case scenario), with corresponding recommendation numbers.

Patient group directions

Patient group directions (PGDs) provide a legal framework that allows some registered health professionals to supply and/or administer a specified medicine(s) to a pre-defined group of patients, without them having to see a prescriber.

Supplying and/or administering medicines under PGDs should be reserved for situations in which this offers an advantage for patient care, without

compromising patient safety. For example, a PGD may be appropriate for supplying a medicine to a patient seeking treatment for a minor ailment in a community pharmacy or walk-in centre.

The current legislation for PGDs is included in [The Human Medicines Regulations 2012](#). This legislation was amended in April 2013 to reflect changes to NHS organisational structures in England (see [The National Treatment Agency \[Abolition\] and the Health and Social Care Act 2012 \[Consequential, Transitional and Saving Provisions\] Order 2013](#)).

Case scenarios for patient group directions

Case scenario 1: Reviewing the service

A community service is currently being reviewed to understand if a PGD is still the most appropriate method of medicines supply.

What needs to be considered when undertaking this review and who should be involved?

- Legislation – does it comply with legislation? See [section 1.2 of the full guideline](#).
- NICE guideline – is it in line with the medicines practice guideline? See recommendation 1.1.11.
- Governance – are appropriate local policies and governance arrangements in place? Are these arrangements being adhered to?
- Review of the service:
 - Is a PGD still necessary? Have additional prescribers qualified since the PGD was first in use? Can there be investment in prescribers to deliver the service?
 - Is it still the most appropriate method of supply for individual patients? What other options may be appropriate? Can the service be redesigned, for example, out of hours or community pharmacy?
 - Are other treatments appropriate? Newer treatments may need less service involvement.
 - Are adequate resources available?
 - Have there been any patient safety incidents such as medication errors or near misses? Are these reported and reviewed?
 - How often is the PGD used, such as once or twice a year versus many times a day?
 - How many patients are being referred elsewhere because they don't meet the criteria? Do the criteria meet patient needs?
 - What are the views of health professionals working under the PGD?
 - What are the views of relevant stakeholders, such as local authorities?
 - Has the commissioner changed following organisational restructures?

- Have patients or their carers been involved in the review? It may be an opportunity to ask what they need from the service; for example, patients accessing an emergency hormonal contraception service may also want a combined oral contraceptive supplied at the same time.
- Training and competency issues:
 - What are the training and competency needs of staff?
 - What prescriber involvement is needed?
 - Is there an opportunity for learning from others?
- Who should be involved? (See recommendation 1.6.4)
 - Commissioner and provider – governance arrangements should be clear about who is responsible for reviewing the service.
 - Health professionals working in the service.
 - Relevant stakeholders, such as clinical networks, service leads, local medicines decision-making groups, patients and the public.

Related recommendations

Recommendation 1.1.1

Provide the majority of clinical care involving supplying and/or administering medicines on an individual, patient-specific basis. Reserve patient group directions (PGDs) for limited situations in which this offers an advantage for patient care, without compromising patient safety, and where there are clear governance arrangements and accountability.

Recommendation 1.1.2

Explore all the available options for supplying and/or administering medicines in a specific clinical situation. Consider whether 1 option or a range of options is appropriate.

Recommendation 1.1.4

Consider investing in the training of additional non-medical prescribers to enable redesign of services if necessary, as part of a wider development or review of local medicines policy.

Recommendation 1.1.11

Do not include a medicine needing frequent dosage adjustments or frequent or complex monitoring in a PGD (for example, anticoagulants or insulin).

Recommendation 1.6.4

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

Recommendation 1.8.4

Ensure that patient safety incidents relating to PGD use are reported, collated and reviewed by the appropriate organisations in a planned programme, in line with national patient safety reporting systems.

Recommendation 1.8.5

Agree and undertake a planned programme of monitoring and evaluation of PGD use within the service.

Case scenario 2: Administering medicines under PGDs

A nurse works in a clinic using PGDs to supply injections for self-administration by the patient. A patient attends and asks if the district nurse can administer the injection that is supplied.

Can the clinic nurse make this supply? What needs to be considered?

- Registered health professionals using PGDs can only do so as named, authorised individuals and are not able to assign or delegate their responsibility to another person, regardless of their professional group or level of training.
- Delegation is not allowed under PGD medicines legislation.
- The injection has to be administered under the PGD by the nurse who supplies it, or it has to be self-administered by the patient themselves.
- The inclusion criteria of the PGD should clearly state that patients would only be included if they are competent to self-administer the medicine.
- If the patient cannot self-administer, they should be excluded from the PGD. An informal carer could assist, for example by opening the packaging and bringing the injection to the patient, but the administration must be under the control of the patient.
- Need to consider why the patient wants the district nurse to administer the injection.

A new nurse is recruited. Can they be supervised administering an injection under a PGD as part of their training and assessment of competency?

No, health professionals should be trained and assessed as fully competent before working under the PGD. They can be supervised to administer an injection, but this would need to be under the direction of a prescriber, such as using a patient-specific direction.

Related recommendations

Recommendation 1.5.3

When practising under a PGD, health professionals should:

- not delegate their responsibility
- ensure that they can determine that the patient meets the inclusion criteria as set out in the PGD
- ensure that they can determine that no exclusion criteria apply
- discuss alternative options for treating the patient's condition, when appropriate
- assess each individual patient's circumstances and preferences
- recognise when signposting or referral to another health professional or service is needed, as specified in the PGD
- understand relevant information about the medicine(s) included in the PGD, such as:
 - how to administer the medicine
 - how the medicine acts within the body
 - dosage calculations
 - potential adverse effects and how to manage them
 - drug interactions, precautions and contraindications
 - storage requirements, including maintenance of the 'cold chain'
 - follow-up arrangements
- be able to advise the patient or their carer about the medicine(s), as appropriate.

Recommendation 1.7.1

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

Recommendation 1.7.2

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 PGDs.

Case scenario 3: Developing PGDs

A commissioning support unit (CSU) wants to develop PGDs for several clinical commissioning groups (CCGs) in their area.

Can the CSU do this?

Yes, if they have the expertise and resources to do so. A CSU does not have the legal authority to authorise the PGD.

What are the benefits and risks of this approach?

Benefits:

- Utilises medicines management expertise and resources in CSUs.
- Avoids duplication of work.
- Develops skills of individuals who are developing PGDs frequently.
- Income generating for CSUs.
- Reduces risk of inexperienced individuals developing PGDs.
- May improve patient safety.

Risks:

- Requires collaboration across external organisations, for example, contract specifications, service level agreements and memorandum of understanding.
- Clear cross-organisational governance arrangements are needed that specify which organisation is responsible and accountable for all steps in the process, including:
 - reviewing and updating the PGD
 - signatories
 - training and competency
 - evaluation
 - record keeping
 - sharing information, for example on serious incident reports.
- Written processes agreed by the CCGs need to be followed.

How could several CCGs work together to develop a PGD?

- One CCG could take responsibility, on behalf of the other CCGs. However, clear processes and governance arrangements need to be in place, and there is a need to also consider the funding arrangements. Each CCG may still want to seek individual advice.
- A PGD working group could be established to develop a PGD, with membership that covers all CCGs. This could be a virtual working group or a face-to-face working group. There may be some challenges around the agreement of content across several CCGs.
- New models of working are emerging, and the [NHS Specialist Pharmacy Service \(SPS\) website PGD resources](#) can be used as a resource for examples of shared practice.
- Collaboration needs to be discussed and considered locally, depending on the services provided.

Related recommendations

Recommendation 1.3.1

Ensure that a named lead author has responsibility for developing a PGD, supported by a locally determined multidisciplinary PGD working group. Include a doctor (or dentist), pharmacist and representative of any other professional group(s) using the PGD. Define their roles and responsibilities, and consider their training and competency needs.

Recommendation 1.3.3

Seek views on draft PGDs and agree final draft PGDs with relevant stakeholders, including clinicians and local medicines decision-making groups.

Recommendation 1.8.1

For each PGD, the commissioning and provider organisation(s) should collaborate to firmly establish local governance arrangements with clear lines of responsibility and accountability.

Recommendation 1.8.2

Develop or review the organisational PGD policy and associated procedures to ensure that robust and transparent processes are documented. Ensure that the PGD policy is publicly available.

Recommendation 1.8.4

Ensure that patient safety incidents relating to PGD use are reported, collated and reviewed by the appropriate organisations in a planned programme, in line with national patient safety reporting systems.

Recommendation 1.8.5

Agree and undertake a planned programme of monitoring and evaluation of PGD use within the service.

Recommendation 1.8.6

Ensure that appropriate organisational records are maintained, stored securely and archived, in line with relevant legislation and the [Department of Health and Social Care's code of practice on records management](#). These records should include:

- patient safety incidents, such as medication errors, near misses and suspected adverse events
- terms of reference and minutes or notes of the PGD approval group
- a list of all PGDs in use within the organisation, including their review date and expiry date
- master authorised copies of PGDs
- expired versions of PGDs
- members of the PGD working group
- signatures of people signing a PGD
- a list of named, registered health professionals authorised to practise under each PGD used within the service
- training records
- results of monitoring and evaluation.

Case scenario 4: Authorising PGDs

A doctor working in an NHS trust has been asked to be the doctor signatory on some PGDs which have already been developed by a PGD working group.

What does the doctor need to consider?

- What are they signing for? Are they clear exactly what their responsibilities are?
- Is there a PGD policy? Are robust local processes and governance arrangements in place; has the process has been followed?
- Do they feel competent to undertake the role?
- If the above are not in place or are unclear, the doctor should not sign the PGD.

Other considerations:

- Do they have appropriate experience, such as working in a local medicines decision-making group?
- Do they have a clear knowledge of the legislation governing PGDs?
- Are they aware of the benefits and risks of the range of options for supplying and/or administering medicines, including the purpose and intention of PGDs?
- Do they have a good knowledge of the clinical speciality or service in which the PGD is to be used?
- Do they have sufficient knowledge of the medicines and conditions included in the PGD, including national guidance and policy?
- The [PGD competency frameworks](#) help to address these considerations.

Should the doctor signing the PGD have also been involved in developing the PGD?

This is not required by legislation.

- The [Health Service Circular \(HSC 2000/026\)](#) states that PGDs 'should be drawn up by a multidisciplinary group involving a doctor, a pharmacist and a representative of any other professional group expected to supply medicines under the PGD'.
- Therefore, a doctor should be involved at an early stage in developing the PGD, but this may or may not be the same doctor who signs the PGD.

- For example, in a large organisation, the medical director may sign PGDs, but it is not realistic for them to be involved in developing every PGD.

Related recommendations

Recommendation 1.4.2

Address barriers that may delay authorising PGDs, such as lack of clear leadership, ownership and understanding of legislation and governance arrangements.

Recommendation 1.4.3

At an early stage, identify the appropriate senior doctor (or dentist) and senior pharmacist who will sign the PGD, in line with [The Human Medicines Regulations 2012](#). Define the roles and responsibilities of these people and consider their training and competency needs.

Recommendation 1.4.4

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.

Recommendation 1.8.2

Develop or review the organisational PGD policy and associated procedures to ensure that robust and transparent processes are documented. Ensure that the PGD policy is publicly available.

Recommendation 1.8.3

Ensure that a designated person has overall organisational responsibility for PGDs.

Case scenario 5: Supplying medicines under PGDs

A PGD is being used to supply a medicine that is for children aged from 3 months to 12 years of age. A mother attends the clinic with her 2-month-old child. All criteria included in the PGD are met, except for the child's age.

Can the health professional make a clinical judgement to supply the medicine under a PGD? What's the reason for your answer?

No, this is not legal. The patient must meet the criteria exactly as stated in the PGD. The health professional cannot use their clinical judgement to determine that the medicine can be supplied.

What if the health professional working under the PGD was an independent prescriber? Can the medicine be supplied to the child in this case?

No, for the reasons stated above. If the health professional is working under the PGD, the PGD must be followed exactly, regardless of whether the health professional is an independent prescriber. If the health professional is an independent prescriber and competent to prescribe, they should not be working under a PGD.

What options are available to the health professional?

They should not supply the medicine. If the patient does not meet the criteria, or the health professional is not able to determine that they meet the criteria, the patient must be referred to another health professional or provider. It is a legal requirement that this referral information is included in the PGD. If the health professional is an independent prescriber and competent to prescribe, they should not be working under a PGD.

When reviewing your records, the health professional is concerned that a high proportion of patients presenting for treatment are referred to an

alternative provider because they don't meet the criteria of the PGD.

What should they do, and what options are available?

- The health professional should discuss this with colleagues and the lead author/PGD working group who developed the PGD.
- Has the PGD service been evaluated? Has this been considered within the evaluation?
- Is the PGD meeting patient's needs? Can you seek their views?
- Does the service need to be redesigned?
- Are there any staff training and competency issues that need to be considered?
- Can the inclusion and exclusion criteria be reviewed? Would a change compromise patient safety?
- Does the evidence underpinning the PGD need to be reviewed. When is the PGD due for review? Who is responsible?

Related recommendations

Recommendation 1.5.1

When supplying and/or administering a medicine under a PGD, health professionals should follow local organisational policies and act within their code(s) of professional conduct and local governance arrangements (see recommendations 1.8.1 and 1.8.2).

Recommendation 1.5.3

When practising under a PGD, health professionals should:

- not delegate their responsibility
- ensure that they can determine that the patient meets the inclusion criteria as set out in the PGD
- ensure that they can determine that no exclusion criteria apply
- discuss alternative options for treating the patient's condition, when appropriate
- assess each individual patient's circumstances and preferences
- recognise when signposting or referral to another health professional or service is needed, as specified in the PGD

- understand relevant information about the medicine(s) included in the PGD, such as:
 - how to administer the medicine
 - how the medicine acts within the body
 - dosage calculations
 - potential adverse effects and how to manage them
 - drug interactions, precautions and contraindications
 - storage requirements, including maintenance of the 'cold chain'
 - follow-up arrangements
- be able to advise the patient or their carer about the medicine(s), as appropriate.

Recommendation 1.6.4

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

Recommendation 1.8.5

Agree and undertake a planned programme of monitoring and evaluation of PGD use within the service.

Case scenario 6: Updating PGDs

A PGD was authorised for use before April 2013 by the local primary care trust (PCT) as the commissioner of the service. After April 2013, the local authority inherited the PGD as the new commissioner of the service. The PGD is due to expire in 2 months.

What options are available to the local authority for this PGD? What are the possible risks and benefits of each of these options?

Retain the PGD and extend the expiry date

Risks:

- PGD may be out of date
- important new evidence may not be identified
- should only consider in exceptional circumstances
- need assurances that the PGD will be reviewed and updated within an agreed short period of time.

Benefits:

- an expired PGD is not used
- gives time to review and update appropriately
- opportunity to review local governance arrangements.

Remove the PGD from use

Risks:

- service can't be delivered
- safety risk as patients won't have access to medicines they need.

Benefits:

- an expired PGD is not used
- no illegal supply or administration of medicines
- provides an opportunity to review service provision.

Review, update and reauthorise the PGD before it expires

Risks:

- reviewing and updating process may be rushed
- important new evidence may be missed
- service delivery may not be reviewed
- insufficient resources to deliver within the timeframe.

Benefits:

- an expired PGD is not used
- PGD will be fit for purpose and reflect current best evidence.

If the expiry date has already been extended once, can it be extended again without review?

Yes, this is allowable under the legislation, but the risks and benefits would need to be considered very carefully, and the decision must be justifiable. A decision to do this should be considered only in exceptional circumstances. Arrangements would need to be reviewed to determine why the PGD can't be reviewed and updated before the expiry date.

The local authority has no previous experience of developing and authorising PGDs, and does not have adequate expertise in-house. What are the legal and governance considerations?

- The local authority needs to be clear that supply and/or administration against an expired PGD is not legal.
- Need to consider transitional arrangements; for example, the local authority may 'inherit' a PCT-authorized PGD and continue to use it until it is updated or expires.
- The local authority may be the new authorising body, but they do not necessarily need to develop their own PGD, so they need to determine who is going to review and update the PGD.
- If the local authority does not have sufficient resources and expertise, they can consider the following options:
 - commission an external organisation
 - employ a pharmacist and/or other expertise

- collaborate with a local CCG medicines management team.
- The local authority needs to consider whether they have an individual with appropriate expertise to authorise the PGD on behalf of the local authority (the authorising body)
- Need robust local governance arrangements in place, for example if the provider takes responsibility for developing, reviewing and updating, and training, then this needs to be clear in the contract specification or service level agreement.
- The most appropriate option needs to be considered and determined locally, then need to devise an action plan to deliver.
- Consider the decisions to be made, and systems and processes to be put into place (see the [PGD baseline assessment tool](#)).

Related recommendations

Recommendation 1.6.1

Establish and manage a structured work programme for reviewing, updating and reauthorising PGDs. Ensure that sufficient resources are available to deliver the work programme.

Recommendation 1.6.2

Ensure that a named lead author has responsibility for reviewing and updating the PGD, supported by a locally determined multidisciplinary PGD working group. Include a doctor (or dentist), pharmacist and representative of any other professional group(s) using the PGD. Define their roles and responsibilities and consider their training and competency needs (see recommendation 1.3.1).

Recommendation 1.6.3

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

Recommendation 1.6.4

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

Recommendation 1.6.5

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

Recommendation 1.6.6

Ensure that an updated PGD is reauthorised, in line with [The Human Medicines Regulations 2012](#) (see recommendations 1.4.3 to 1.4.7).

Recommendation 1.6.7

When a PGD is updated, ensure all relevant documentation is also updated, including the record and signatures of health professionals authorised to practise under the PGD (see recommendation 1.8.6).

Recommendation 1.8.1

For each PGD, the commissioning and provider organisation(s) should collaborate to firmly establish local governance arrangements with clear lines of responsibility and accountability.

Recommendation 1.8.2

Develop or review the organisational PGD policy and associated procedures to ensure that robust and transparent processes are documented. Ensure that the PGD policy is publicly available.

Recommendation 1.8.3

Ensure that a designated person has overall organisational responsibility for PGDs.

Glossary

Authorising body

An organisation listed in the legislation 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
- Public Health England.

PGD 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 the guideline, but other names for the group may be used locally.

See the [terms used in the guideline section](#) in the medicines practice guideline for other terms not defined above.

Other implementation tools

NICE has developed tools to help organisations implement [NICE's guideline on patient group directions](#). These are available in the [tools and resources of the guideline](#):

- PGD template.
- PGD baseline assessment tool.
- Competency framework for people developing and/or reviewing and updating PGDs.
- Competency framework for people authorising PGDs.
- Competency framework for health professionals using PGDs.

[Resources on how to put NICE guidance into practice](#) are also available.