

Patient Group Directions and Patient Specific Directions in General Practice May 2015

There have been a number of regulatory and organisational changes within the NHS since the GPC last produced guidelines on Patient Group Directions (PGDs) and Patient Specific Directions (PSDs) in 2010. In particular there has been a NICE Guideline¹ published and subsequently revised on this matter, and as a consequence aspects of the original GPC advice have been updated. However, despite the passage of time and events many of the principles of PGDs remain the same. Note that this guidance is for England only, although there are links to guidance in Scotland and Wales at the end of the document.

[The Human Medicines Regulation 2012](#) does not permit nurses, or other registered practitioners, who are not qualified prescribers to administer or supply prescription only medicines (POMs) unless one of three types of instruction is in place:

1. A signed prescription
2. A signed Patient Specific Direction (PSD)
3. A Patient Group Direction (PGD)

If non-prescribing health care professionals administer medicine on the instruction of a GP, the GP must be able to show that they have authority for that administration via one of the above methods.

To summarise:

- PGDs should be used only where appropriate, suitable and legal. To check use the flow chart “to PGD or not to PGD”²
- PGDs can be **written** by anyone involved with their use but the group should include a doctor/dentist and a pharmacist who will sign it off
- PGDs can only be **approved** by certain bodies, in the cases relevant to general practice these are Clinical Commissioning Groups (CCGs), Local Authorities or NHS England.
- PGDs can only be used by certain registered health professionals – this excludes Health Care Assistants.
- A named GP in each practice should sign the PGD and should ensure that it is also signed by those who are to use it.
- There are certain categories of medicines for which a PGD should only be used with caution for example antibiotics, off license drugs, controlled drugs, or those subject to black triangles.

¹ <http://www.nice.org.uk/guidance/MPG2>

² <http://www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/>

1. Patient Specific Directions (PSDs)

In general, most of the occasions where a non-prescribing health care professional administers a POM they do so under the terms of a PSD. This is, in essence, *any instruction which can be either in written form with a signature or alternatively as an electronic instruction, made after considering that individual patient, and which constitutes an instruction to the practice nurse or other competently trained health care professional to administer that drug.*

There is no set protocol for PSDs written into the Legislation. As long as the prescriber (prescribing nurse or doctor) has considered that the individual patient and has, as a consequence, given an instruction to supply or administer a drug to that patient the PSD is sound. The PSD could also be a signed list of patients – such as in a flu or travel clinic. Practices must have protocols in place for their staff to follow to administer a POM using a PSD. There is no requirement for the instruction to be defined as a PSD in the notes.

2. Patient Group Directions (PGDs)

PGDs, can be used in *“limited situations in which this offers an advantage for patient care, without compromising patient safety, and where there are clear governance arrangements and accountability”*³

PGDs were introduced as a facilitative measure to allow non-prescribing health care professionals to take a decision to supply or administer a POM to a patient with an identified clinical condition without the patient needing to see a prescriber. This is useful in services where assessment and treatment follows a clearly predictable pattern (e.g. immunisation, family planning) or where a practice nurse has the experience and knowledge to make decisions on appropriate treatment (e.g. travel clinics). Because they are, in effect, giving someone without the legal ability to prescribe the right to supply or administer prescription only medication, they are instruments that should be subject to monitoring and checks.

Nurses using PGDs must have been assessed as competent to use them and must comply with the standards set by their professional regulatory body, the Nursing and Midwifery Council (*‘The Standards for Medicine Management’*⁴).

The NICE guidance document numerates a number of recommendations for PGDs. It is important that all who are going to use PGDs are appropriately trained and have access to advice and supervision.

³ Para 2.2.1 of NICE PGD guidance: <http://www.nice.org.uk/guidance/mpg2/chapter/2-recommendations>

⁴ Standards for Medicines Management (NMC, 2007)
<http://www.nmc-uk.org/Nurses-and-midwives/Regulation-in-practice/Medicines-management-and-prescribing/>

3. Particulars to be included in a Patient Group Direction

- (a) the period during which the Direction shall have effect;
- (b) the description or class of prescription only medicine to which the Direction relates;
- (c) whether there are any restrictions on the quantity of medicine which may be supplied on any one occasion, and, if so, what restrictions;
- (d) the clinical situations which prescription only medicines of that description or class may be used to treat;
- (e) the clinical criteria under which a person shall be eligible for treatment;
- (f) whether any class of person is excluded from treatment under the Direction and, if so, what class of person;
- (g) whether there are circumstances in which further advice should be sought from a doctor or dentist and, if so, what circumstances;
- (h) the pharmaceutical form or forms in which prescription only medicines of that description or class are to be administered;
- (i) the strength, or maximum strength, at which prescription only medicines of that description or class are to be administered;
- (j) the applicable dosage or maximum dosage;
- (k) the route of administration;
- (l) the frequency of administration;
- (m) any minimum or maximum period of administration applicable to prescription only medicines of that description or class;
- (n) whether there are any relevant warnings to note, and, if so, what warnings;
- (o) whether there is any follow up action to be taken in any circumstances, and, if so, what action and in what circumstances;
- (p) arrangements for referral for medical advice;
- (q) details of the records to be kept of the supply, or the administration, of medicines under the Direction.

Questions and Answers

1. Can nurses who are not qualified prescribers administer or supply a prescription only medicine?

Yes. A GP can instruct a named practice nurse to supply or administer medicines on his or her behalf. However, medicines may only be administered by a practice nurse if one of three types of instruction is in place:

1. A signed prescription
2. A signed Patient Specific Direction (PSD)
3. A Patient Group Direction (PGD)

[The Human Medicines Regulation 2012](#) does not permit nurses who are not prescribers to administer or supply POMs without a PSD or PGD in place or the item having been previously prescribed by a practitioner.

2. Can a nurse independent prescriber administer a POM without a PSD or PGD in place?

Yes. Nurse independent prescribers do not require a PSD or PGD in order to administer a POM. Under the [The Human Medicines Regulation 2012](#) a nurse independent prescriber is able to supply or administer any licensed medicine for any medical condition within their competence, including some controlled drugs for specified medical conditions.

3. When can PGDs be used in general practice?

In some circumstances, where assessment and treatment follows a clearly predictable pattern (for example where nurses are administering travel or childhood vaccinations to large groups of patients) practices may find it beneficial to have an agreed PGD in place so a GP does not have to give a specific instruction for each individual patient. A PGD enables a nurse to supply and/or administer prescription-only medicines to patients using his/her own assessment of patient need, in accordance with the criteria set out in Schedule 7, Part I of Statutory Instrument 2000 No. 1917 - The Prescription Only Medicines (Human Use) Amendment Order 2000⁵. The PGD must include this information.

Nurses using PGDs must have been assessed as competent to use them and must comply with the standards set by their professional regulatory body, the NMC, *'The Standards for Medicine Management'*⁶.

A selection of example PGDs including those for vaccinations are available on the NHS PGD website⁷.

⁵ <http://www.legislation.gov.uk/uksi/2000/2899/made>

⁶Standards for Medicines Management (NMC, 2008)

<http://www.nmc-uk.org/Nurses-and-midwives/Regulation-in-practice/Medicines-management-and-prescribing/>

⁷ <http://www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/Local-PGD-examples/>

4. What role do LMCs have in the development of PGDs?

LMCs should:

- Ensure that practice efficiency and workload is not affected by the failure of statutory organisations (e.g. CCGs) to approve appropriate PGDs
- Provide advice to practices on PGDs and PSDs.
- Provide advice to practices seeking to write their own PGDs
- Ensure that CCGs do not unreasonably withdraw PGDs or allow them to go out of date without renewal

5. Can non-prescribing nurses administer POMs without a PGD in place?

A PGD is, you will recall, just one of three methods of permitting administration. The other two, prescriptions or PSDs, are still available. Some employers of Community Nurses ask GPs to fill in administration charts before allowing a nurse to give a drug, although this must be viewed as discretionary as it is not a legal requirement if a prescription providing detailed instructions has been provided.

6. Do PGDs apply to Health Care Assistants (HCAs)?

No. HCAs are not registered healthcare professionals and can only administer prescription only medicines where they have either been prescribed or there is a Patient Specific Direction in place. [The Human Medicines Regulation 2012](#) does not allow HCAs to administer POMs under a PGD.

7. Can PGDs be used for all drugs?

No, there are limitations but they are unlikely to apply in General Practice. Unlicensed drugs; Specials; dressings; abortifacients; radiopharmaceuticals; and controlled drugs where used to treat addiction. In addition PGDs should be considered “carefully”¹ for antimicrobials, off licence black triangle, controlled, or self-administered drugs.

8. Can PGDs be used in General Practice to administer non-NHS treatment?

Under the [Human Medicines Regulation 2012](#) (Part 3, Chapter 12, paragraph 230) practices are not permitted to use PGDs to administer treatment in NHS GP practices in non-NHS circumstances, for example providing private travel vaccinations such as Yellow Fever, Rabies, Meningitis etc. Patient Specific Directions must be used in these circumstances.

9. Can PGDs be used for travel clinics?

PGDs are useful for NHS travel health services as in many practices these are delivered by practice nurses who have a special expertise in that field. However they can only be used for those treatments which are provided on the NHS and not for private treatment. This is further complicated where vaccines can be given in either manner. So where Hepatitis B vaccination is given for travel and the patient is charged, a PGD cannot be used - a PSD has to be used instead; only if it is given under the NHS then it can be administered using a PGD.

10. Can a GP sign off a PGD?

A PGD can only be signed off by an authorised body [CCGs, Local authorities, or NHS England] when it applies to an NHS practice. However GPs can sign off a PGD for a private practice or a private travel clinic even though they cannot do so for their own NHS practice or clinic.

11. Can a PCO demand that a practice adopts a PGD for a particular POM?

No. The practice can determine how it wishes to organise the administration of medicines.

12. What if the Authorised body withdraws PGDs for certain medicines?

There is nothing in the legislation that states that authorised bodies^{Error! Bookmark not defined.} have to develop PGDs, they merely have to authorise them. Therefore GP practices can develop their own PGDs and it would be difficult for a authorised bodies to justify not approving it if all the conditions listed above have been met and there is a clinical need for the service, as they would not be adhering to their obligations and duties to administer and provide health care to the public as set out in the NHS Act 2006.

Practices should, with LMC support, justify to the authorised body, in writing, the reasons why a PGD is needed, quoting the authorised body's duties under the NHS Act and the amendment to the Prescription Only Medicines (Human Use) Order 1997 The Prescription Only Medicines (Human Use) Amendment Order 2000⁵. Please contact the GPC (info.gpc@bma.org.uk) for assistance this. Note that if a PGD is not signed on behalf of the authorised body it is not valid.

If there are difficulties with the use of or production of PGDs then the practice can use patient specific directions where possible in order to continue providing the service.

13. Who in the practice needs to sign a PGD?

The authorising GP needs to sign a PGD naming the specific health care professionals (HCP) who the PGD will apply to. In addition, the GPC recommends that the HCP acting under the PGD should sign the PGD.

14. Can a nurse prescriber sign a PSD?

Yes nurses may prescribe from the formulary linked to their recorded qualification. Nurse prescribers may issue a PSD and instruct another health care professional to administer the medicine.

15. Can PGDs be used to administer Botox?

No. The administration of medicines (such as Botox[®], Vistabel[®] or Dysport[®]) to paralyse muscles which cause wrinkles requires assessment of individual patients' suitability and (if the administration is to be delegated to a nurse or other person) patient specific directions. PGDs or general directions which would apply to any patient with an appointment on a particular day are not sufficient⁸. In any case PGDs cannot be used for private services in an NHS practice.

⁸ *Supply and administration of Botox[®], Vistabel[®], Dysport[®] and other Injectable medicines in cosmetic procedures*, Medicines and Healthcare products Regulatory Agency, and *Medicines Matters - a guide to mechanisms for the prescribing, supply and administration of medicines*, Department of Health, 2006

Examples

Childhood Immunisation Clinics

When children have been called for vaccinations and non-prescribing nurses are immunising the children, practices have two options:

- i) The GP to prepare a PSD for each patient attending the clinic, in the form of a note in the patient record or a list of those attending the clinic signed by the GP. The note or list must specify which vaccination is due for each child.
- ii) The practice to have a PGD in place which allows the nurse to administer the POM.

If HCAs are to be administering the vaccinations note that a PGD cannot be used.

Vaccinations and Medicines for Travel

If a patient is attending a nurse appointment and requires an NHS vaccination for travel, the most straightforward solution would be for the nurse to be able to administer that vaccination under the authority of a PGD. The GPC would recommend in these circumstances that if a PGD is available and acceptable to the GP, it would be in the practice's interest to have a PGD in place. However a PGD cannot be used for private immunisations so Rabies, Yellow Fever, Japanese B encephalitis, and Tic Borne encephalitis cannot be administered under a PGD. This also applies to supply of anti-malaria chemoprophylaxis or for any other drugs supplied privately (such as, for example, antibiotics, acetazolamide) in case of disease arising abroad.

Opportunistic treatment

If a patient attends a nurse appointment and requires a prescription only medicine, the nurse can decide to administer that treatment under the authority of a PGD rather than requiring a specific instruction from a GP. The GPC would recommend in these circumstances that if a PGD is available, has been agreed and signed off by the Primary Care Organisation (PCO) and acceptable to the GP, it would be in the practice's interest to have a PGD in place. Examples where this might be appropriate include a sexual health clinic where the pill may be given or treatments for Sexually Transmitted Diseases are needed.

Instructions from secondary care

If a patient attends the practice for the administration of a drug specified in a letter from secondary care (e.g. Clexane, Zoladex) then the nurse may regard the signed hospital letter as a PSD and may administer the drug provided that she is satisfied that the letter contains sufficient detail of the drug and dosage.

Further Information and useful links

Medicines Act (1968)

http://www.opsi.gov.uk/RevisedStatutes/Acts/ukpga/1968/cukpga_19680067_en_1

Statutory Instrument (2000a) *The Prescription only Medicines (Human Use) Amendment Order 2000*. Statutory Instrument no.1917, London: The Stationery Office.

<http://www.opsi.gov.uk/si/si2000/20001917.htm>

Statutory Instrument (2000b) *The Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment (no.2) Regulations 2000*. Statutory Instrument no. 1918, London: The Stationery Office.

<http://www.opsi.gov.uk/si/si2000/20001918.htm>

Statutory Instrument (2000c) *The Medicines (Pharmacy and General Sale Exemption) Amendment Order 2000*. Statutory Instrument no. 1919, London: The Stationery Office.

<http://www.opsi.gov.uk/SI/si2000/20001919.htm>

HSC 2000/026

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/PublicationsAndStatistics/LettersAndCirculars/HealthServiceCirculars/DH_4004179

Medicines Matters - A guide to mechanisms for the prescribing, supply and administration of medicines (2006)

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_064326.pdf (sections 2 & 3)

Department of Health guidance

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Managingyourorganisation/Emergencyplanning/DH_4069610 (2011)

<https://www.gov.uk/government/publications/patient-group-directions> (2003)

NHS Patient Group Directions (PGD) website.

<http://www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/>

NICE medicines practice guidelines [MPG2] (2013)

<http://www.nice.org.uk/guidance/MPG2>

Medicines and Healthcare products Regulatory Agency (MHRA) PGD guidance

<http://www.mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribingsellingandsupplyingofmedicines/ExemptionsfromMedicinesActrestrictions/PatientGroupDirectionsintheNHS/index.htm>

NHS Education for Scotland guidance

<http://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/prescribing-and-patient-group-direction/patient-group-directions.aspx>

Practice Nurse information on NHS Wales website:

<http://www.wales.nhs.uk/sites3/page.cfm?orgid=739&pid=32198>