Patient Group Directions
Guidance and information for nurses
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Introduction

For the past decade nurses have found it useful to be able to supply and/or administer medicines using group protocol arrangements. This system was ratified by the first part of the second Crown Review (DH, 1998). This report laid out criteria for the correct drafting of group protocols and recommended that the new criteria be adopted wherever protocols are used.

In England, it became mandatory for all NHS and general practitioner services to follow this guidance in accordance with HSC 1998/051 (NHSE, 1998) and Wales and Scotland have also produced their own guidance (NAW, 2000; SE, 2001). The health service administration for Northern Ireland has yet to issue guidance but RCN advice it that nurses there adopt similar principles to those advised for the other UK countries.

Although the Crown recommendations were comprehensive and intended to ensure good practice, the legal basis for the use of group protocols has been uncertain with a lack of clarity as to how existing legislation – notably the Medicines Act 1968 – supported their use. A general consensus emerged that whilst properly drafted group protocols (i.e. according to the Crown recommendations) exemplified good practice, their use was illegal with the potential risk of prosecution for anyone supplying or administering prescription-only medicines using this system.

This situation was seen as unacceptable, particularly because of the widespread use of group protocols to deliver national immunisation services, and their use by a wide range of nurses in other settings, such as family planning clinics. Following sustained lobbying by the RCN, the changes required to make the use of group protocols legal were made and secondary legislation was introduced throughout the UK on 9 August 2000 (Statutory Instrument, 2000a,b,c). As a result of the legislative change, group protocols are now called Patient Group Directions (PGDs).*

What is a patient group direction (PGD)?

The legislation (Statutory Instrument, 2000a) states that 'Patient Group Direction means – in connection with the supply of a prescription only medicine… a written direction relating to the supply and administration of a description or class of prescription only medicine… or a written direction relating to the administration of a description or class of prescription only medicine, and which in the case of either is signed by a doctor… and by a pharmacist; and relates to the supply and administration, or to administration, to persons generally (subject to any exclusions which may be set out in the Direction).'

* All NHS organisations and non NHS organisations providing care to NHS patients, prison health care services, the defence medical services, police services and independent hospitals and clinics that are registered with the Healthcare Commission.
In practice this means that a PGD, signed by a doctor and agreed by a pharmacist, can act as a direction to a nurse to supply and/or administer prescription-only medicines (POMs) to patients using their own assessment of patient need, without necessarily referring back to a doctor for an individual prescription.

**When can PGDs be used?**

The law is clear that the majority of care should be provided on an individual, patient-specific basis, and that the supply and administration of medicines under PGDs should be reserved for those situations where this offers an advantage for patient care (without compromising safety), and where it is consistent with appropriate professional relationships and accountability.

The RCN interprets this to mean that PGDs should only be used to supply and/or administer POMs to homogeneous patient groups where presenting characteristics and requirements are sufficiently consistent for them to be included in the PGD. Examples of such groups are:

- infants and children requiring immunisation as part of a national programme
- adults requiring immunisation as part of a national programme
- those requiring immunisation for foreign travel
- those requiring contraceptive services including the use of emergency hormonal contraception
- those requiring analgesia prior to minor surgery or treatment of injury
- those requiring medication for common acute or chronic illness.

In determining the suitability of a PGD in meeting care needs, consider whether the patient’s needs can be dealt with as part of a homogeneous group or if they require an individual prescription to meet their specific needs.

**Which POMs can be supplied or administered under a PGD?**

PGDs can be used to supply and administer a wide range of POMs although there are currently legislative and ‘good practice’ restrictions in relation to controlled drugs, antimicrobials and black triangle drugs.

**Controlled drugs**

The use of controlled drugs continues to be regulated under the Misuse of Drugs Act 1971 and associated regulations made under that Act. The Home Office has agreed to allow the supply and administration of substances on Schedule 4 (with the exclusion of anabolic steroids) and all substances on schedule 5 to be included in PGDs.
Also the use of diamorphine (Schedule 2) under PGDs by specialist trained nurses in accident and emergency departments and in coronary care units. The relevant amendments to the Misuse of Drugs Regulations 2001 came into force on 15 October 2003.

**Antimicrobials**

Antimicrobial drugs can be included within a PGD but consideration must be given to the risk of increased resistance within the general community. When seeking to draw up a PGD for antimicrobials, a local microbiologist should be involved and approval sought from the drug and therapeutics committee or equivalent.

**Black triangle drugs and medicines used outside the terms of the Summary of Product Characteristics**

Black triangle drugs (i.e. those recently licensed and subject to special reporting arrangements for adverse reactions) and medicines used outside the terms of the Summary of Product Characteristics (SPC) – sometimes called ‘off label use’ (for example, as used in some areas of specialist paediatric care) may be included in PGDs. Their use should be exceptional and justified by best clinical practice, and a direction should clearly describe the status of the products. Black triangle drugs used in national immunisation programmes may be included in PGDs.

Where the medicine is for children, specific attention should be given to restrictions on age, size and maturity of the child. Each PGD should clearly state why the product is being used outside the terms of the SPC and the documentation should include the reasons why such use is necessary.

**How should PGDs be drawn up?**

The law (Statutory Instrument, 2000a) requires that PGDs should be drawn up by a pharmacist and the doctor who works with the nurses who will be using them. The relevant health authority should also ratify the PGD. In England, when PGDs are developed locally, HSC 2000/026 (NHSE, 2000) requires that a senior doctor and a senior pharmacist sign them off with authorisation from the appropriate health organisation, i.e. the trust, and that all nurses using the directions are specifically named within the PGD and signed by them (see SE, 2001 and NAW, 2000 for guidance in Scotland and Wales). The RCN acknowledges this as good practice and recommends the following steps be taken throughout the UK.

✦ Health authorities/boards/trusts should identify a designated team of people including a senior doctor, a senior pharmacist and a senior nurse who will take responsibility for PGD development in their area.
✦ The designated team should draw up a framework for PGDs that can be used at local level.

✦ Staff in each clinical environment where PGDs are to be used (including general practice) should be provided with guidance by the team as to how to draw up a PGD properly and how to identify circumstances in which a PGD might be necessary.

✦ Doctors and nurses using the PGDs should draft them according to national guidance and the framework made available to them by the designated team for their area.

✦ PGDs drawn up at local level should be submitted for approval to the designated team for the area.

✦ Teams are encouraged to disseminate their PGDs as examples of good practice.

What should go in a PGD?

The legislation (Statutory Instrument, 2000a) requires a series of key elements to be included within a PGD.

The name of the business to which the direction applies

This refers to the place in which the PGD will be used, for example, primary care or acute trust.

The date the PGD comes into force and the date it expires

The expiry date is particularly important. The legislation gives no time limit for a PGD to be reviewed although HSC 2000/026 (NHSE, 2000) requires a review every two years for England and the RCN recommends this as good practice throughout the UK (see SE, 2001 and NAW, 2000 for guidance in Scotland and Wales). It may be appropriate to review a PGD more frequently, depending on the medication(s) concerned, but this should be determined at the time of authorisation of use.

Review should take place at a local level where the PGD is in use. The review should consider whether the medication(s) listed has/have changed in any way (for example, a new name), whether the situation in which the direction is used is the same and if the staff named to use the direction are still the same. If the PGD remains satisfactory, the team (senior doctor/senior pharmacist/senior nurse) designated as responsible for that PGD should be notified and asked that it remains in force, or alternatively asked to sanction any changes needed.
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A description of the medicine(s) to which the direction applies

The name of the medicine(s) and its purpose should be indicated, for example, analgesic, laxative or oral contraceptives.

The class of health professional able to supply or administer the medicine

The legislation primarily allows the following health professionals to supply and administer medicines under PGDs: pharmacists, registered midwives, registered health visitors, registered nurses, registered ophthalmic opticians, state registered chiropodists, registered physiotherapists, registered radiographers and registered paramedics (NHSE, 2000). They can only do so as named individuals. The PGD should state which of these groups can use it.

Signature of a doctor or dentist, as appropriate, and a pharmacist

The legislation determines that only approved prescribers practising as doctors or dentists may authorise supply and administration of POMs via a PGD. Law now requires the additional safeguard of pharmaceutical expertise in drawing up a PGD.

Signature by a representative of an appropriate health organisation

A representative of the organisation in which the PGD is being used should indicate approval of its use, for example, the chief executive of a trust.

The clinical condition to which the direction applies

A description of the presenting problems of patients who are to be supplied with or to receive administered medication under the PGD.

A description of those patients excluded from treatment under the direction

By definition, a PGD should be used only when the characteristics of patients and appropriate treatment or care options are sufficiently similar. An individual with a complex medical history or a specific problem might need an approach suited to their unique requirements. The PGD should contain guidance on who it includes and in what circumstances an individual should be excluded and provided with an individual prescription.

A description of the circumstances in which further advice should be sought from a doctor (or dentist, as appropriate) and the arrangements for referral

A patient may meet the criteria for inclusion to the PGD, but sometimes, depending on the specifics of how they present, advice may be required from a doctor. Therefore, consideration should be given as to when those authorised to supply or administer medicines under the PGD might want to discuss their decisions with a medical colleague.
Details of the appropriate dosage and maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, and minimum or maximum period over which the medicine should be administered. Legal status of the drug should also be indicated

This is straightforward information required to ensure the correct medicine is used in the right dose for the appropriate length of time, whether this is a single administration or a course of medication.

Relevant warnings, including potential adverse reactions

As with any use of medicines, irrespective of how they might be prescribed, it is important to be aware of any contra-indications or potential adverse effects. This information will assist those deciding whether to supply or administer medicine(s) and help them to provide appropriate information to the patient.

Details of any necessary follow-up action and the circumstances

The use of medication via a PGD might be only one part of the treatment plan. A patient may need to be seen again to determine whether the medication has been effective or for additional care to be provided.

A statement of records to be kept for audit purposes

The PGD should indicate what records need to be kept in relation to its use. As a minimum, these should include full patient details, a record of the medicine concerned and details of dose, route, and time of supply or administration. Additional records may be required for specific conditions and medicines.
Summary of guidance

✦ The RCN fully supports the use of PGDs as a reasonable and practical way of recognising the ability of nurses to appropriately use medicines to the benefit of their patients.

✦ Nurses using medicines under the terms of a PGD should be sure of their competence to do so and act in accordance with the NMC’s Code of Professional Conduct (NMC, 2002) and Guidelines for the Administration of Medicines (NMC, 2000).

✦ A team comprising of a senior nurse, a senior doctor and a senior pharmacist should be responsible for ensuring appropriate PGDs are drawn up for a given practice area and that only fully competent, qualified and trained professionals operate within them.

✦ All those involved in the drawing up and use of PGDs should be familiar with the guidance within Appendix A of the first report of the second Crown Review (DH, 1998).

Note

This guidance replaces all previous RCN information concerning the supply and administration of medicines under group protocol arrangements. Those working in England, Scotland and Wales should also read their respective guidelines (NHSE, 2000; SE, 2001; NAW, 2000) which explain the requirements for each country.

All patient group directions should now comply with the legislative requirements described above. Failure to comply with the law could result in a criminal prosecution under the Medicines Act.
References


Useful websites

www.dh.gov.uk
Search here for Department of Health publications, including health circulars and reports and for NHS Executive publications and information.

www.hmso.gov.uk/acts.htm

www.nurse-prescriber.co.uk
Educational pages, forums, news and other resources available to health care professionals involved in prescribing and medicine management.

www.portal.nelm.nhs.uk/PGD/default.aspx
For a centrally-maintained archive of approved group protocols for the supply and administration of medicines.