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Best Practice Statement ~ *March 2006*

Patient Group Directions

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Copies of this best practice statement, and other documents produced by NHS QIS, are available in print format and on the website.

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Introduction

NHS Quality Improvement Scotland (NHS QIS) was set up by the Scottish Parliament in 2003 to take the lead in improving the quality of care and treatment delivered by NHSScotland.

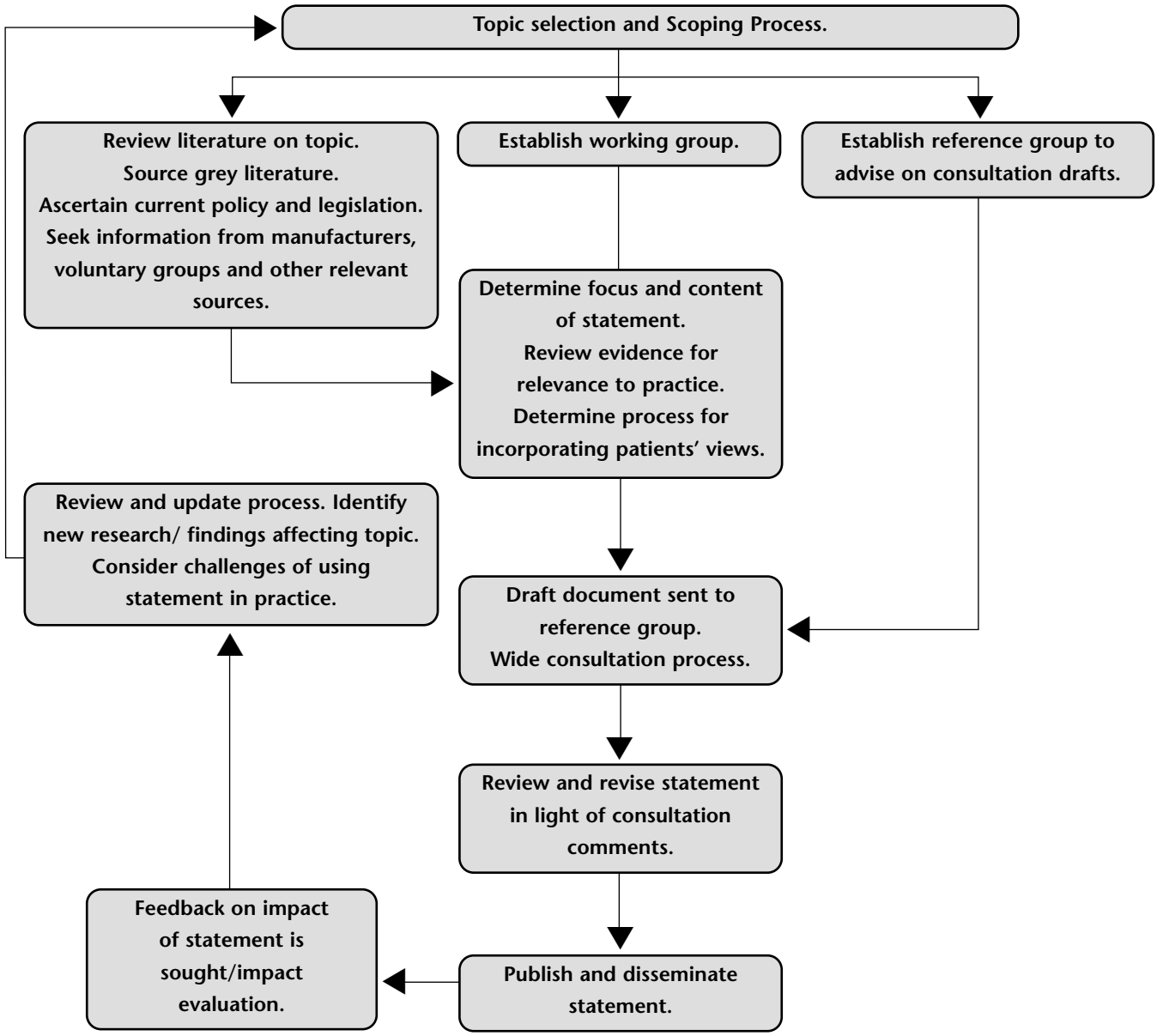
The purpose of NHS QIS is to improve the quality of healthcare in Scotland by setting standards and monitoring performance, and by providing NHSScotland with advice, guidance and support on effective clinical practice and service improvements.

A series of best practice statements has been produced within the Practice Development Unit of NHS QIS, designed to offer guidance on best and achievable practice in a specific area of care. These statements reflect the current emphasis on delivering care that is patient-centred, cost-effective and fair. They reflect the commitment of NHS QIS to sharing local excellence at a national level.

Best practice statements are produced by a systematic process, outlined overleaf, and underpinned by a number of key principles:

- They are intended to guide practice and promote a consistent, cohesive and achievable approach to care. Their aims are realistic but challenging.
- They are primarily intended for use by registered nurses, midwives, allied health professionals, and the staff who support them.
- They are developed where variation in practice exists and seek to establish an agreed approach for practitioners.
- Responsibility for implementation of these statements rests at local level.
- Best Practice Statements are reviewed, and, if necessary, updated after 3 years in order to ensure the statements continue to reflect current thinking with regard to best practice.

Key Stages in the development of best practice statements



Best Practice Statement: Patient Group Directions (PGDs)

The supply and administration of medicines is controlled by The Medicines Act 1968. Controlled Drugs are regulated by The Misuse of Drugs Act 1971. For the past decade healthcare professionals have found it useful to be able to supply and/or administer medicines using documentation in the form of 'group protocols.'

In 1998, a report on The Supply and Administration of Medicines under Group Protocols was published. The report recommended that the legal position of protocols was clarified, thus ensuring that the risks to patients of receiving treatment under such protocols was minimised and that the healthcare practitioners supplying or administering medicines under such a framework were protected.

On 9th August 2000, secondary legislation was introduced throughout the UK, which provided the framework for the supply and administration of medicines without the need for an individual prescription (Human Use Amendment Order 2000). This framework was that of Patient Group Directions (PGDs).

The best practice statement aims to help practitioners ensure that:

- PGDs are developed according to The Legal Framework (HDL2001(7))
- Good practice from throughout Scotland is shared
- Practitioners are trained to develop and operate under PGDs
- Practitioners are able to audit practice and review/revise the PGD accordingly, and
- Patients receive the best possible care when treated by a practitioner under a PGD.

The development of PGDs can be a lengthy process, involving several members of the multidisciplinary team. Challenges include:

- the provision of resources to provide leadership for the development and the updating/review of PGDs
- the provision of adequate resources to ensure that practitioners receive the underpinning knowledge and skills necessary for the development and use of PGDs, and
- the provision of resources to ensure that PGDs are audited on a regular basis.

The development process for the best practice statement began in May 2005 with collaboration between NHS QIS and NHS Education for Scotland. A multidisciplinary working group was set up with professional representation from across Scotland (Appendix 1).

The statement is in 3 sections covering:

Section 1: The development of Patient Group Directions.
Section 2: The provision of education for practitioners developing and operating under Patient Group Directions.
Section 3: The management and monitoring of Patient Group Directions.

Section 1: The development of Patient Group Directions

Key Points ~

1 Patient Group Directions are developed to improve access to treatment for patients according to a legal framework.

2 The development of a Patient Group Direction is to benefit patient care whilst ensuring patient safety at all times.

Statement	Reasons for statement	How to demonstrate statement is being achieved
1.1 **PGDs are developed in accordance with the legal framework** *SEHD HDL 2001 (7) Patient Group Directions.* The National Prescribing Centre March 2004: Patient Group Directions: A practical guide and framework of competencies for all professionals using patient group directions. (see www.nes.scot.nhs.uk/pgds/management and monitoring of PGDs for 'The PGD Screening Tool') (see www.nes.scot.nhs.uk/pgds/pgdexamples for sample PGDs)	The legal framework details that PGDs should only be developed according to certain criteria. The Health Department letter (7) of 2001 details the criteria and gives further guidance for the development of PGDs. 'The majority of clinical care should be provided on an individual patient specific basis.' *The National Prescribing Centre: March 2004: Patient Group Directions'* There must be a standard template for the development of PGDs within the organisation. The content of a PGD may be adopted by another organisation, however, the PGD must then be signed and approved for use within this further organisation as per the professionals detailed within the legal framework. The development of PGDs must be by a multidisciplinary group that includes a doctor, pharmacist and the relevant practitioner developing the PGD for use by their professional group, eg nurse, pharmacist, dietician, chiropodist. The development of a PGD must be to improve patient care, without compromising patient safety. Practitioners need to have policies/guidance/ processes for the development of PGDs. Such resources need to be readily available, to ensure that appropriate PGDs are developed within the constraints of the legal framework and that they are reviewed and approved at least 2 months prior to their expiry date.	Organisations will have an approval process for PGDs which ensures that the need for development of the PGD meets the criteria as detailed within the legal framework issued by The Scottish Executive. SEHD HDL2001 (7): Patient Group Directions. Organisations will have policy/guidance/processes for the development, approval, implementation, review, refreshment and re-approval (prior to the expiry date) of PGDs and records kept of each element.

Statement	Reasons for statement	How to demonstrate statement is being achieved
1.2 **All Patient Group Directions (PGDs) are underpinned by the best possible evidence base.** The actual printed evidence does not need to be included as part of the PGD but should be a basis for producing the PGD and should be referenced within the document. Sources of evidence should be referenced within the PGD.	The development of a PGD informs a pathway of care/treatment for a patient group. Such pathways need to be supported by published clinical evidence or local (eg formulary)/national guidelines or a reputable body of evidence. The evidence needs to demonstrate that the development of the PGD will be in the best interests of the patient. Where the medicine has UK Marketing Authorisation (a UK Product Licence) and is being supplied or administered according to this licence then the evidence base is assured. A clearly defined need for the development of the PGD will ultimately benefit patient care. In the majority of cases, patients should be prescribed treatment from an independent/supplementary prescriber on an individual patient basis. *SEHD HDL 2001 (7) Patient Group Directions.*	The evidence base will be referenced within the PGD, where appropriate.
1.3 **Each practitioner operating under a PGD has a duty of care to ensure that they understand their role and responsibility.** *SEHD HDL 2001(7) Patient Group Directions* *(see www.nes.scot.nhs.uk/pgds/guidance for sample processes within organisations)* *(see www.nes.scot.nhs.uk/pgds/guidance for sample forms for practitioners to sign indicating that they understand their role and responsibility)* *(The National Prescribing Centre 2004: Patient Group Directions: A practical guide and framework of competencies for all professionals using patient group directions)*	PGDs need to be developed by a multidisciplinary group that consists of a doctor, pharmacist and practitioner who requires the development of the PGD for use by their professional group eg nurse, pharmacist, dietician, chiropodist. PGDs are then operated by named individuals who have been trained in the legal aspects and the specific clinical area of the PGDs. Practitioners operating under a PGD need to be qualified practitioners who are registered with their relevant professional body. Professionals have a responsibility to act within their appropriate code of professional conduct	Organisations must have policy/guidance to ensure that practitioners operating under a PGD understand their role and responsibility. Standard documentation will detail the signatures of the practitioners authorised by the organisation to operate under the PGD. (Such documentation may be held centrally for ease of updating the information. The documentation will detail the name of the practitioner, the practitioner's signature, their professional qualification and their professional registration number. The form should also include a statement highlighting the responsibilities of the practitioner.

Statement	Reasons for statement	How to demonstrate statement is being achieved
	The National Prescribing Centre 2004: Patient Group Directions 2004. Practitioners need to be educated about PGDs, the legal framework, and their role and responsibility for patient care whilst operating under a PGD. Services using PGDs should ensure that appropriate training is available for healthcare professionals operating under PGDs. PGDs need to be regularly updated to ensure that the names of the practitioners operating under the PGD reflect current practice. *The National Prescribing Centre: March 2004: Patient Group Directions.*	Training that ensures that practitioners have knowledge of the legal framework and of the roles and responsibilities of staff who are authorised to operate under the PGD will be provided by the organisation. The organisation will have a policy/guidance for the updating of such controlled documentation to ensure that practitioners only operate under the most up to date version of the PGD.
1.4 **Clear and unambiguous criteria are defined within the PGD to guide the practitioner and ensure that the patient receives treatment via the most appropriate care pathway.** *The National Prescribing Centre March 2004: Patient Group Directions.*	Patient safety is of paramount importance. Should a patient be excluded from treatment under a PGD, they should be referred by the nurse/pharmacist/dietician to an independent prescriber. Practitioners must work in partnership with colleagues for the benefit of patients and must be confident and self-aware in their own ability to use PGDs.	There should be a record in the patient casenotes of the patient consultation with details of the treatment/referral provided. Should the patient be excluded from treatment under the PGD, the reasons for exclusion will have been recorded in the patient's case notes/record, with details of the independent prescriber/dental practitioner to whom the patient has been referred.
1.5 **Patients/patient representatives/carers should receive current and up to date patient information that concurs with legal and quality guidance.**	Patient safety is of paramount importance. Any risks to the patient need to be documented in the patient's casenotes and discussed with the patient/patient representative/carer.	Specific significant risks identified will be documented in the patient's casenotes/record. Such information should be available to the whole of the multidisciplinary team.

Statement	Reasons for statement	How to demonstrate statement is being achieved
When a medicine is *administered* to a patient a Patient Information Leaflet (PIL) should be available for the patient to read prior to treatment being administered. **Where a medicine is *supplied* to a patient for self-administration patient information should be available in a range of formats tailored to meet the needs of individuals eg those with learning disabilities.** *(see www.nes.scot.nhs.uk/pgds/guidance for sample risk assessments used within organisations prior to the administration/supply of medication)* *(The Royal Pharmaceutical Society of Great Britain. Patient Group Directions: A Resource Pack for Pharmacists)*	Such risks should be discussed using standard information eg a PIL, which should then be given to the patient. Where there is no PIL available from a manufacturer or for a specific patient group, a PIL should be specifically developed and approved as part of the 'PGD Approval Process' for the particular PGD. It is a legal requirement that the manufacturer's patient information leaflet is provided each time a medicine is supplied to a patient. Practitioners need to inform patients about treatment and should have copies of current specific product characteristics available for reference at the consultation. Patients/patients' representatives/carers need to be able to consent to treatment.	Patient information will be readily available in a variety of formats that are tailored to the needs of the patient. PILs will be readily available within the clinical area when practitioners are supplying or administering medication to a patient. The specific product characteristics will be readily available for practitioners during the consultation. (See 1.7 for further information required to be available for patients.) Practitioners will follow professional guidelines for patient's consent prior to treatment.
1.6 **Only medicines with UK Marketing Authorisation (a UK Product Licence) must be supplied or administered under a PGD.** In exceptional circumstances, PGDs may be required to be developed for indications/doses/patient groups that are not included in the UK Marketing Authorisation (UK Product Licence). Such an 'unlicensed use' of a medicine may be required for specific groups of patients eg paediatrics. Special care must be exercised when developing and approving a PGD for an indication/patient group that is not included in the UK Marketing Authorisation (UK Product Licence) documentation. The PGD should clearly highlight that the PGD has NOT been developed according to the UK Marketing Authorisation (UK Product Licence).	PGDs should only be developed for products that have an approved UK Marketing Authorisation (UK Product Licence). Where PGDs are required to be developed for indications/doses/patient groups not included in the UK Marketing Authorisation (UK Product Licence), organisations must have policies/guidance/processes to ensure that such PGDs clearly highlight that the medicine is NOT being used within the UK Marketing Authorisation (UK Product Licence) eg a statement may be annotated on the front cover of the PGD. Where the clinical indication/dose/ patient group is NOT included within the UK Marketing Authorisation (UK Product Licence), such use must be supported by a reputable body of evidence, that must be referenced within the PGD eg NICE/SIGN Guidelines and/or leading local clinical opinion.	PGDs developed for an indication/dose/patient group that is NOT included within the UK Marketing Authorisation (UK Product Licence) will have a statement within the PGD that highlights such use. The reasons for such use will also be justified within the PGD. Reference will be made to supporting evidence for such use within the PGD. Where a PGD has been developed for an indication/dose/patient group that is NOT included within the UK Marketing Authorisation (UK Product Licence) a specialist in the relevant field should have been involved in the development process of the PGD (eg paediatrics). Organisations will have policies/guidance/processes that advise on the development of PGDs for medicines that are not included in the UK Marketing Authorisation (UK Product Licence).

Statement	Reasons for statement	How to demonstrate statement is being achieved
A specialist in the relevant field must be involved in development of a PGD for use within specialist areas eg paediatrics. Should the Marketing Authorisation for the medicine change, the PGD will need to be 'suspended' whilst the PGD is revised and re-approved for use within the organisation. This may also apply if the medicine is temporarily unavailable and a medicine which does NOT have UK Marketing Authorisation (eg an imported medicine) is the only product available. *The Royal Pharmaceutical Society of Great Britain 2004: Patient Group Directions: A Resource Pack for Pharmacists.*	A PGD is a document that details a pathway of care for specified treatment of a group of patients. Should the treatment specified in the PGD not be be available on a temporary basis, practitioners need to have knowledge of organisational policy/guidance/processes for such a situation.	Organisations must have policies/guidance/processes that advise practitioners how to deal with situations where medication may be temporarily unavailable.
1.7 **When developing and approving a PGD for a newly marketed medicine, special care must be exercised. (such newly marketed medicines are highlighted by a black triangle (▲) in the British National Formulary).**	Patient safety is of paramount importance. The risks to patients from the supply/administration of medicines needs to be monitored. Newly marketed medicines are required to be monitored in case of adverse effects that will affect patient care. Any suspected adverse reactions resulting from a medicine is required to be reported nationally as 'A Suspected Adverse Drug Reaction' via 'The Yellow Card Reporting Scheme'. Any suspected adverse reactions resulting from a medicine is required to be reported locally, as per local organisational polices/guidance/processes. Patients need to be informed who to contact should they experience a suspected adverse drug reaction.	Organisations will have policies/processes/guidance that advise on the development of PGDs for newly marketed medicines. Organisations will have policies/guidance/processes advising practitioners the process for the reporting of adverse reactions due to medicines. Organisations will have documented evidence of any suspected adverse reactions that have occurred and details of how and when they were reported. Written details of who to contact in the event of a suspected adverse drug reaction should be readily available for patients.

Statement	Reasons for statement	How to demonstrate statement is being achieved
1.8 **When developing and approving a PGD for an anti-microbial, special care must be exercised.**	Due to resistance the use of anti-microbials is a public health concern. A microbiologist should be involved in the development of the PGD. In some instances an anti-microbial group may review the PGD, where this is the case the PGD should be signed by the Chair of the group.	The name and the signature of the microbiologist involved in the development/approval of the PGD will be annotated on the PGD. (This may be eg the Chair of the anti-microbial sub group depending on organisational processes for the development and approval of PGDs.)
1.9 **When developing and approving a PGD that involves a controlled drug, special care must be exercised.** **Only certain controlled drugs for certain clinical indications may be included in a PGD, for operation by certain practitioners as specified in the revised legislation.** (see www.nes.scot.nhs.uk/specificproductcharacteristics contains information about which controlled drugs are authorised at 2005, to be included in a PGD.)	Controlled drugs are regulated by The Misuse of Drugs Act 1971. Only certain controlled drugs are authorised by the legislation to be included in a PGD.	The originator will have documentation (copy of the legislation) indicating that the controlled drug is allowed to be included in the PGD.
1.10 **PGDs must be kept up to date and reviewed/refreshed in light of new legislation, current evidence, national/local policies, guidelines and practice.** **PGDs must be reviewed/refreshed and re-approved every two years and prior to their expiry date.** **When a PGD is reviewed/refreshed it should ideally be undertaken by members of the original multidisciplinary group, however this work should be led by a specific nominated individual from this group and communicated to members of the group.** **Controls should be in place to ensure that members of the group agree with any recommended changes to the PGD eg communication electronically that is then filed for consultation.**	Patient safety is of paramount importance. As legislation/practice/medicines information changes, practitioners need to refreshand update PGDs in light of the changes. A nominated individual/department needs to have responsibility for each PGD to ensure that PGDs are kept up to date. The content of the PGD should be reviewed immediately if there are evidence-base changes to clinical practice which affect the PGD.	Organisations will have policies/guidance that details processes for the revising/refreshing of PGDs in light of changes to legislation/medicines information/the PGD expiring. Organisations will have nominated individuals/departments with responsibility for ensuring that PGDs are kept up to date. The organisation will have filed copies of PGDs that have expired.

Statement	Reasons for statement	How to demonstrate statement is being achieved
	The PGD must be reviewed after development and implementation, but prior to the expiry date to ensure continuity of patient care. The National Prescribing Centre March 2004: Patient Group Directions.	Current PGDs will have the date of review/expiry date highlighted on the PGD.

Key Challenges ~

1 *Ensuring adequate leadership and resources for the development, updating, review and approval of PGDs across the various organisations.*
2 *Ensuring that the names of the practitioners operating under a PGD are updated on a regular basis.*
3 *Ensuring the development of PGDs for children when the majority of medicines are not licensed/approved for use in this group of patients.*
4 *Identification of those responsible for the approval of PGDs where care is provided across organisational boundaries eg direct access clinics to secondary care.*

Section 2: The provision of education for practitioners developing and operating under PGDs

Key Points ~

1 Practitioners need to understand the legal framework prior to developing a PGD.

2 Practitioners need to ensure that they continue to be competent to operate under the PGD.

Statement	Reasons for statement	How to demonstrate statement is being achieved
2.1 **There is a nominated individual who will ensure that training is available and provided for practitioners who are required to operate under a PGD.** (see 'The National Prescribing Centre March 2004: Patient Group Directions: A Competency Framework for assessment of training needs and recording of current competency.) (see www.nes.scot.nhs.uk/pgds/guidance to access the National Prescribing Centre document.)	All practitioners named on a PGD, and therefore required to operate under a PGD, need to have underpinning knowledge. Whilst it is the individual practitioner's responsibility to source such information, the organisation should provide education for practitioners prior to them operating under a PGD. Local managers and practitioners have a responsibility to ensure that adequate training records are maintained.	The name of the individual/title of the post holder with responsibility for training will be detailed within PGD. Records of attendance at training sessions will be held by a nominated individual/department for the organisation. A statement of completion should be made available to those who have attended training (eg a certificate). Organisations have local policy/guidance/processes for the assurance of continuing knowledge and competency. Practitioners operating under the PGD will have their competency reviewed, on a regular basis, as specified by the organisation.
2.2 **Practitioners have knowledge of the organisational policies/guidance/processes for the reporting of clinical incidents (including near misses) and in particular any incidents involving medication.** 'The practitioner needs to work within professional and organisational standards.' The National Prescribing Centre:2004:Patient Group Directions: Competency Framework Section 5.	Practitioners must have the knowledge and skills to ensure that any errors involving medicines are reported as per local policy. Practitioners must report any clinical incidents or near misses involving medicines according to local policy/guidance/processes.	The organisation will have a policy/guidance/process for the reporting of actual clinical incidents and 'near misses'. The organisation will have a record of any reported clinical incidents or 'near misses'. The clinical incidents/near misses will have been reported as per local policy/guidance and the reports will be available with the outcomes, for review by all practitioners operating under the PGD.

Statement	Reasons for statement	How to demonstrate statement is being achieved
2.3 **Practitioners are aware of any potential suspected adverse drug reactions that may be caused by the specific medicine, detailed within the PGD.**	Practitioners must have the knowledge and skills to ensure that patients experiencing any suspected adverse reaction to a medicine are reviewed within a clinically appropriate timescale. Practitioners must report any suspected adverse drug reactions according to local and national guidance. Whilst it is the individual practitioner's responsibility to ensure continuing competence, training should be provided to ensure that practitioners have knowledge of such policies.	The organisation will have a policy/guidance for the reporting of suspected adverse drug reactions that have occurred. The organisation will have a record of any reported suspected adverse drug reactions. The adverse drug reactions have been reported as per local policy/guidance and the reports will be available with the outcomes, for review/reflection by all practitioners operating under the PGD.
2.4 **Practitioners have the knowledge and skills to ensure that there are no significant potential drug interactions between current medication and newly supplied/administered medicines under the PGD.**	Practitioners need to undertake a comprehensive medical history prior to commencing a patient on 'new ' treatment under a PGD to ensure that there are no contra-indications or exclusion criteria that would prevent the patient receiving treatment under the PGD. Whilst it is the individual practitioner's responsibility to ensure continuing competence, training should be provided by the organisation, to ensure that practitioners have a knowledge of policy/guidance for the documentation of a patient's medication history.	The organisation will have a policy/guidance for the documentation of a patient's medical history. Any potential significant drug interactions must be specified within the PGD. A record of any medication currently taken by the patient will be documented within the patient's casenotes/records, by the practitioner operating under the PGD.

Statement	Reasons for statement	How to demonstrate statement is being achieved
2.5 **Practitioners need to ensure continuing competency of skills for operating under the PGD within the specific therapeutic area.** Practitioners need to have up to date clinical and pharmaceutical knowledge relevant to the scope of the PGD. *The National Prescribing Centre: March 2004: Competency Framework Section 5.*	Practitioners must be competent to operate under a PGD and work as per their code of conduct. They must have the knowledge and skills to operate under the PGD. Whilst it is the individual practitioner's responsibility to ensure continued competence, training should be provided to ensure that practitioners have knowledge of such policies. Competency must be reviewed on a regular basis with evidence of ongoing CPD by the practitioner within the relevant clinical area.	Practitioners may have completed competency frameworks available. Practitioners operating under the PGD will have their competency reviewed, on a regular basis, as specified by the organisation. The continuing competency of practitioners operating under the PGD is reviewed on a regular basis, as specified by the organisation. A review of a practitioner's competency should be included as part of the individual's Personal Development Plan (PDP) and Continuing Professional Development record (CPD). Individual practitioners' CPD records will detail any specific CPD undertaken to ensure competency for operating under a specific PGD. Local training records and practitioner's individual PDPs will contain information relating to the practitioner's CPD within the particular therapeutic/clinical area.

Key Challenges ~

1 *Ensuring that there are adequate resources for the provision of training that informs of the legal framework, the professional responsibility and accountability of practitioners.*

2 *Ensuring that there are adequate resources for the provision of training to ensure that practitioners have the clinical knowledge required for specific PGDs.*

Section 3: The management and monitoring of Patient Group Directions

Key Points ~

1 *PGDs need to be monitored, reviewed and revised on a regular basis to ensure that the PGD describes local and up-to-date practice.*

2 *Medicines transportation and storage is an important issue that needs to be considered at the development stage of the PGD and reviewed when the PGD is audited.*

Statement	Reasons for statement	How to demonstrate statement is being achieved
3.1 **The most current PGD must be readily available within the department/clinical area for reference by practitioners during the patient consultation.** The PGD may be available electronically, however consideration needs to be given to the protection/control of such documentation.	PGDs are controlled documents that allow named practitioners to treat patients without intervention from medical or dental practitioners. Practitioners need to ensure that reference is made to the PGD during patient consultations and that they follow the PGD when assessing patient's needs and administering/supplying treatment. PGDs must be updated and re-approved by the organisation should the practice or the specific product characteristics of the medicine change. A PGD must be reviewed in its entirety within 2 years of implementation of the PGD/the expiry date of the PGD.	The most up to date/current PGD(s) will be readily available within the clinical setting. The practitioner will be able to demonstrate a 'working knowledge' of the PGD. The current Specific Product Characteristics (SPC) for the medicine reflects the indications for inclusion/exclusion criteria as detailed within the PGD, unless this has been superseded by advice from a national/government body. The PGD available for reference is within its defined expiry date.
3.2 **The storage of medicines must comply with legislation and be stored safely and securely at all times.** *The Royal Pharmaceutical Society of Great Britain. January 2004: Patient Group Directions: A Resource Pack for Pharmacists* *(see www.nes.scot.nhs.uk/pgds/monitoring management of PGDs for further guidance).* *(see www.nes.scot.nhs.uk/pgds/guidance for samples of documentation used by organisations to monitor the supply of medication).*	Patient safety and practitioner safety is of paramount importance. Medicines must be stored according to The Medicines Act 1968 and The Misuse of Drugs Act 1971. The efficacy of the medicine must be guaranteed at all times. Guidance states that practitioners should be able to account for medicines that have been received from a supplier (pharmacy dept) and the actual medication supplied on an individual patient by patient basis.	Practitioners will be able to demonstrate that the storage of medicines for use under the PGD complies with local policy/guidance/procedures for the safe and secure handling of medicines, The Medicines Act 1968 and the Misuse of Drugs Act 1971. Organisations will have policy/guidance/processes to ensure that individual patients who have been supplied with medication can be identified eg in the event of product recall of the medication.

Statement	Reasons for statement	How to demonstrate statement is being achieved
		Practitioners will be able to demonstrate that there are policies/procedures in place to manage any risks when transporting the medication to or storing the medication within the clinical area eg maintaining the temperature of the medicine during transport and whilst being stored within the clinical area, should the medicine require refrigeration. Practitioners will be able to demonstrate the completion of a risk assessment should administration of the medicine be potentially hazardous to the patient or practitioner during administration eg resuscitation equipment.
3.3 **When treatment is administered to a patient the treatment must be documented.** **Should such treatment be declined or the patient excluded from being treated under the PGD then this needs to be documented.** *The Royal Pharmaceutical Society of Great Britain. January 2004: Patient Group Directions: A Resource Pack for Pharmacists.*	Patient safety is of paramount importance. Details of the treatment provided and any advice provided needs to be documented and made available to the clinical team to facilitate future clinical intervention. Details of the reasons for exclusion, and the action taken to ensure suitable care options, need to be documented and made available to the clinical team to facilitate future clinical intervention. Practitioners operating under a PGD need to inform the patient's GPs and other members of the healthcare team about medication supplied/administered, if appropriate.	Details of the medication administered to the patient during the consultation will be documented in the patient's casenotes/record. (eg: the name of the medicine, the strength, the dose, the dosage form, the frequency of dosing, the date, the time of administration, the route of administration, the clinical indication for treatment, the practitioner's name and signature, any warning or advice given to the patient, whether the patient required referral to a medical practitioner and details of any risk assessments eg a questionnaire completed prior to treating the patient under the PGD.) Details of the reasons for exclusion will be documented in the patient's casenotes and the actions taken in such circumstances will be documented.

Statement	Reasons for statement	How to demonstrate statement is being achieved
3.4 **Where a medicine is supplied to a patient to take away it must be labelled according to local and national labelling regulations.** **The medicine must be supplied appropriately labelled for the individual patient.** **Patient packs must, wherever possible, be prepared in advance and labelled under the supervision of a pharmacist eg a batch of 'pre- packed' tablets should be packed, labelled and checked under the supervision of a suitably qualified pharmacist.** **Details of the medication supplied must be documented in the patient's case notes/record.** *SEHD HDL 2001(7) Patient Group Directions (see www.nes.scot.nhs.uk/pgds/guidance for samples of documentation used by organisations to monitor the supply of medication).*	Patient packs supplied directly from the practitioner to the patient for self administration need to comply with the Medicines Act (1968) and with Para 3 of Schedule 5 of the Medicines For Human Use (Marketing Authorisations) Regulations 1994 (No 3144). Medicines supplied under PGD need to be suitably labelled and should be accompanied by a Patient Information Leaflet. (EU Labelling and Leaflet Directive 92/27.)	Patient packs available for direct supply to a patient by practitioners operating under a PGD, will be available labelled appropriately eg packs will be available as suitably labelled pack, in advance of the patient consultation. The use of patient packs should be encouraged. Organisations need to have policy/guidance/processes in place to enable medicines supplied to patients to be accounted for eg in the event of the medication being recalled by the manufacturer.
3.5 **Clinical incidents including near misses/suspected adverse reactions arising from medicines that are administered or supplied under a PGD must be reported as per local and national reporting systems.** **PGDs must include reference to organisational policy/guidance/processes for the reporting and monitoring of clinical incidents, near misses and suspected adverse drug reactions.** 'The practitioner needs to work within professional and organisational standards.' *The National Prescribing Centre: March 2004 Patient Group Directions: A Practical Guide and framework of competencies for all professionals using patient group directions.*	Practitioners must have the knowledge and skills to ensure that any errors involving medicines are reported as per local policy. Practitioners must report any clinical incidents or near misses involving medicines according to local policy/guidance/processes. Practitioners need to inform GPs and other healthcare practitioners re medication as appropriate. Practitioners must have the knowledge and skills to ensure that patients experiencing any suspected adverse reaction to a medicine are reviewed within a clinically appropriate timescale. Practitioners must report any suspected adverse drug reactions according to local and national guidance.	See section 2.2 and section 2.3 for demonstration of evidence by organisations

Statement	Reasons for statement	How to demonstrate statement is being achieved
3.6 **PGDs need to be audited on a regular basis eg annually.** **The PGD must reflect current local practice.** **Where medicines are administered or supplied to patients under a PGD the supply/administration needs to follow a suitable audit trail.**	A PGD is a legal framework, that allows practitioners to administer or supply medication to patients without the intervention of a medical or dental practitioner. Local practice must concur with the practice as detailed within the approved PGD. Practice must be audited on a regular basis to ensure that it concurs with the proposed practice detailed in the PGD.	Organisations will have a nominated individual with responsibility for ensuring that the PGD is audited on a regular basis. The lead practitioner for the PGD will be able to demonstrate that an audit has been undertaken, with the results of the audit available for review/sharing by all practitioners operating under the PGD.

Key Challenges ~

1 *Ensuring that there are adequate resources to audit PGDs.*

2 *Ensuring that there are adequate resources to ensure that PGDs are updated on a regular basis according to information and that they are re-approved every 2 years.*

3 *Ensuring that PGDs are kept up to date and that they are monitored and audited on a regular basis.*

Glossary

administration	The application of medication to patients.
amendment of a PGD	The process for updating a PGD.
anti-microbial	A drug that kills micro organisms.
approval/ authorisation	The process for ensuring that the PGD meets organisational standards, after which practitioners may operate under the PGD.
audit	The measuring and evaluation of practice against defined agreed standards with a view to improving practice and service delivery.
Black Triangle Drugs	New products and vaccines which are being intensively monitored in order to confirm the risk/benefit profile of the product. A black triangle ▲ indicates that the CSM and the MHRA are intensively monitoring the product. The symbol will be displayed in reference sources eg, The British National Formulary.
clinical incident reporting	The process within the organisation for the documentation and reporting of any untoward incidents.
clinical indication	The clinical reason for administering or supplying medication under a PGD.
Committee on the Safety of Medicines (CSM)	Body giving advice with respect to safety, quality and efficacy in relation to human use of any medicines and promoting the collection and investigation of information relating to adverse reactions for the purpose of enabling such advice to be given. Replaced, with effect from 30 October 2005, by a new body, Commission on Human Medicines.
competency	Maintains knowledge, skills and attitudes in a specific area.
Continuing Professional Development (CPD)	The ongoing commitment to learning in various forms, which maintains and enhances professional standards of work, and enhances the ability to recognise good practice.
evidence base	The best evidence available to help develop a PGD which best meets the needs of the patient group.
expiry date	The date (allocated by the manufacturer of a medicine), after which the medicine should not be administered or supplied to a patient.

frequency of dosing	The number of times that a medicine is administered to a patient within a 24-hour period.
Health Department Letter (HDL)	A formal communication from The Scottish Executive Health Department (SEHD) to the NHS within Scotland.
independent prescriber	A practitioner (generally a doctor or dentist) who can autonomously prescribe (write a prescription) for medication that will be dispensed by a pharmacist for a patient.
legal framework	SEHD HDL 2001(7) Patient Group Directions. The Health Department Letter issued from The Scottish Executive Department, detailing the requirements for the development and approval of PGDs. (Note: PGDs supersede Group Protocols)
medication error	An error/clinical incident that involves a medicine.
medication history	A detailed list of the medication that the patient is currently taking. The history is generally confirmed verbally between the practitioner and the patient.
Medicines and Healthcare products Regulatory Agency (MHRA)	A government body that enhances and safeguards the health of the public by ensuring that medicines and medical devices work and are acceptably safe.
microbiologist	A term used to describe a medical practitioner who has specialised in microbiology (the biology of micro-organisms).
multidisciplinary group	A group that consist of a range of professionals with a view to combining knowledge, skills and expertise.
National Prescribing Centre (NPC)	A health service organisation, formed in April 1996 by the Department of Health. Its aim is to promote and support high quality, cost-effective prescribing and medicines management across the NHS, and to help improve patient care and service delivery.
near miss	An error or clinical incident that was prevented and did not actually happen, but from which practitioners may learn how to prevent a potential error occurring in the future.

NHS Quality Improvement Scotland (NHS QIS)	NHS QIS has been established (January 2003) to lead in improving the quality of care and treatment delivered by NHSScotland. To do this it sets standards and monitors performance, and provides NHSScotland with advice, guidance and support on effective clinical practice and service improvements. Website: www. nhshealthquality.org
patient case notes/record	The casenotes or record card where details of the patient's treatment/consultation is recorded.
Patient Group Direction (PGD)	'A written instruction for the sale, supply and/or administration of named medicines in an identified clinical situation. It applies to groups of patients who may not be individually identified before presenting for treatment.' The National Prescribing Centre: Patient Group Directions March 2004
patient information leaflet (PIL)	Leaflet intended for the patient and included in the medicine's packaging.
Personal Development Plan (PDP)	Identifies the individual's learning and development needs and interests - the plan is jointly agreed between the individual and their reviewer.
PGD	See Patient Group Direction.
PGD Screening Tool	The Tool developed as part of the PGD Project to facilitate the development and the review of PGDs.
practitioner	Someone who practises a profession (eg pharmacy, nursing, physiotherapy).
re-approval of a PGD	The processes for the PGD to be approved after initial implementation, where there has been a change to practice or the information contained within the PGD that necessitates the original multidisciplinary group to amend the PGD and then seeking further approval of the PGD. Such a process will be defined by the organisation.
refer	The process for sending a patient to an independent prescriber (generally a doctor) for further care as the practitioner is unable to treat the patient under the PGD.

refreshment of a PGD	The process for updating a PGD where full re-approval is not required. This may be in instances where the change to the PGD is minor in nature and does not directly affect patient care (eg the change of name of a practitioner as opposed to the change in the UK Product Licence of a medicine).
resuscitation equipment	Equipment for reviving patients who are unconscious.
review of a PGD	The process for ensuring the content and accuracy of the information prior to submitting the PGD for approval for use within the organisation. It allows confirmation that the PGD covers all aspects as detailed within the legal framework. This process is generally undertaken by a multidisciplinary group and is independent from the group developing the PGD.
risk assessment	A document that guides the practitioner and facilitates the assessment of any undue risks that the patient or practitioner may be exposed to.
Scottish Executive Health Department (SEHD)	The Scottish Executive Health Department is responsible for health policy and the administration of NHSScotland. Website: www.show.scot.nhs.uk/sehd
Specific Product Characteristics (SPC)	Technical documents on a medicine, which help guide healthcare professionals on the best way to use a medicine.
supply	When medication is given to a patient to take away for self-administration.
suspected Adverse Drug Reaction (ADR)	An unintended reaction experienced by a patient to a drug, that is not the expected therapeutic action of the medicine.
suspension of a PGD	The process whereby the PGD ceases to be authorised for use within an organisation due to guidance from a government body. For example, where a drug is no longer available, due to a change in the UK Product Licence guidance, the Scottish Executive Health Department will issue information detailing the change.

UK Product Licence	Before a medicine can be prescribed or sold in the UK a number of licences are required. The product itself must have a licence called a 'Marketing Authorisation', formerly known as a Product Licence. The licence granted by The Medicines Health Care Regulatory Agency (MHRA) indicates that the medicine meets standards of safety, quality and efficacy.
unique patient identifier	A unique identifier allocated by the organisation that when accessed enables tracking of the patient throughout the organisation (eg patient CHI number).
unlicensed use of a medicine	Where the practitioner uses a medicine but does not follow the information contained within the UK Product licence as granted by the MHRA. For example, where a patient group is NOT listed within the UK Product Licence, then use within this patient group would be an 'unlicensed' use.
Yellow Card Reporting Scheme	A National Reporting Scheme, run by the MHRA and the Committee on The Safety of Medicines. The scheme is used to collect information from health professionals and patients on suspected adverse drug reactions (ADRs).

Appendix 1
Reference Group Membership

Project Leader

Mrs Fiona McMillan	Lead Pharmacist Clinical Governance, NHS Glasgow.
Mrs Elgin Schartau	Acting Associate Director of Nursing Midwifery & AHPs, NHS Education for Scotland

Working Group

Penny Bond	Professional Practice Development Officer NHS Quality Improvement Scotland
Mhairi Brandon	Superintendent Physiotherapist, Extended Scope Practitioner NHS Greater Glasgow
Jane Camp	Clinical Governance Practice Development Nurse, NHS Greater Glasgow
Diane Campbell	Associate Director of Nursing NHS Lanarkshire
Elaine Carnegie	Policy Officer Asthma UK, Scotland
Elaine Cockburn	Head of Midwifery Local Supervising Authority Off NHS Borders
Sandra Crawford	Drug Administration Co-ordinator NHS Lanarkshire
Jim Foulis	Lead Nurse Nursing & Patient Services NHS Tayside
George Lindsay	Chief Pharmacist NHS Lanarkshire
Billy Malcolm	Specialist in Pharmaceutical Public Health NHS Ayrshire & Arran
Dr John McKay	GP Associate Adviser NHS Education for Scotland

Toby Mohammed	Senior Nurse Practice Development NHS Glasgow
Audrey Murdoch	Head of Podiatry NHS Greater Glasgow
Rob Packham	Head of Allied Healthcare Professionals NHS Fife
Andrew Radley	Lead Principal Pharmacist NHS Tayside
Margaret Ryan	Head Prescribing Management NHS Argyll & Clyde
Derek Scott	Training Manager The Scottish Ambulance Service
Doreen Sharp	Practice Nurse NHS Argyll & Clyde
Linda Sinclair	Assistant Director of Nursing NHS Highland
John Stuart	Divisional Nurse, Clinical Services NHS Greater Glasgow
Garry Todd	Principal Pharmacist NHS Lothian Primary Care
Dr Mike Watson	Director of Medicine NHS Education for Scotland

Appendix 2

The PGD Screening Tool, for screening PGDs prior to approval by the authorising organisation.

Screening Tool for the development of PGDs

This screening tool is designed to facilitate the development of PGDs prior to approval by the authorised organisation. The tool may be used as guidance by the practitioner developing PGD or ideally as a tool to help those who are responsible for ensuring that PGDs meet the criteria as dictated by the legal framework, prior to approval by the organisation.

It is intended that the tool is used on up to five occasions to help review five separate PGDs.
The first section in **blue** details the basic requirements for a PGD that is being developed to meet the criteria laid out in the legal framework HDL 2001(7).

The second section in **green** enables practitioners to develop PGDs that encompass more than the basic information requirements. This section includes some best practice that was highlighted as part of The PGD Project.

Please note that this screening tool was developed in conjunction with The PGD Reference Group for the PGD Project.

Version 2 January 2006

BLUE SECTION CONFIRMATION THAT DEVELOPMENT OF A PGD IS APPROPRIATE

This section details the minimum legal requirements for the development of a PGD.
By using the checklist provided any omissions within a PGD should be easily identified.

(Please indicate if the PGD meets the standard by ticking ✓ the box.)

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
A: The PGD is for the 'supply' or 'administration' of a prescription only medicine (POM) or a Pharmacy medicine (P). • In the majority of cases patients should be reviewed by an independent or supplementary prescriber and medication prescribed on an individual basis. • PGDs should only be developed for conditions or situations where patients are unable to be identified prior to presentation for treatment eg for use in the emergency situation, for administration of vaccinations.	❑	❑	❑	❑	❑
B: Development of the PGD will improve patient care. • It is clear provision of care via a PGD will be advantageous for the patient and this is stated within the PGD. • Patient care will not be compromised by development of the PGD.	❑	❑	❑	❑	❑
C: The medicine has UK Marketing Authorisation (UK Product Licence) and the medicine is legally allowed to be 'supplied' or 'administered' under a PGD. • Medicines without UK Marketing Authorisation (a UK Product Licence) may NOT be supplied or administered under a PGD. • Medicines may be used outwith the UK Product Licence in justified circumstances. Where a medicine has Marketing Authorisation (a UK Product Licence) but the clinical indication of the PGD is NOT for an indication included in the licence, then this 'unlicensed use' should be stated within the PGD. • Where the PGD is for a newly marketed medicine (a black triangle medicine (▼)) the PGD should be developed with caution and the status of the medicine is clearly highlighted within the PGD (eg PGD for Unlicensed use of Medicine). • All suspected adverse drug reactions from medicines included in a PGD should be reported to the Committee for The Safety of Medicines.	❑	❑	❑	❑	❑

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
D: The medicine with the strength, form and legal classification (eg POM) are clearly defined within the PGD. • The duration of treatment, maximum total dosage, individual dosage, quantity to be supplied on one occasion, route, frequency of administration and the minimum or maximum period over which the medicine should be administered are all required to be stated as appropriate. • The specific product characteristics (SPC) for the product have been consulted. • Where there is a range of doses for the medicine, there is justification of the dose stated within the PGD.	❑	❑	❑	❑	❑
E: The patient group who will receive treatment under the PGD is clearly defined. • Where children are involved, doses are clearly defined by age, weight (kg) and where appropriate the maturity of the child. (Note: this may not be applicable for vaccines) • PGDs for specialist groups of patients, should be developed with the involvement of a local clinical specialist in the particular clinical area.	❑	❑	❑	❑	❑
F: The names of the clinical areas and the locations where the PGD will operate are clearly defined. • The speciality(ies)/locations where the PGD will operate need to be clearly defined eg Ward 8 XXXX, all acute medical receiving units within xxx. • The organisation authorising the PGD needs to be defined (eg the Hospital Division).	❑	❑	❑	❑	❑
G: The PGD has a start date and an expiry date (review date). • The start date and expiry/review dates are within 2 years or before, should new information become available.	❑	❑	❑	❑	❑

DETAILS OF THE PROFESSIONALS DEVELOPING THE PGD (Please indicate if the PGD meets the standard)

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
H: The practitioner group is defined within the legal framework as being: • An ambulance paramedic, chiropodist/podiatrist, dietician, health visitor, nurse, midwife, pharmacist, physiotherapist, optometrist, orthoptist, radiographer, or other professional as defined by the current legal framework (see www.opsi.gov.uk/legislation for updated legislation). • The practitioner needs to be currently registered with the appropriate professional body. • The PGD needs to include a statement to ensure that the practitioner is informed that they need to follow the appropriate code of conduct as defined by their professional body.	❑	❑	❑	❑	❑
I: The practitioners are required to be educated. • The basic education required by each practitioner, prior to operating under the PGD, is defined eg Level 1 registered nurse. • The need for practitioners to undertake CPD within the therapeutic area of the PGD is defined within the PGD. • The need for continuing competency and updating of knowledge is recognised within the PGD eg 'Refresher' Training after any initial training, should be provided on a regular basis by a local specialist in the relevant therapeutic/clinical area. • An individual/department is named within the PGD for the provision of this specific training (eg generally a clinical specialist to ensure continued knowledge of therapeutic area).	❑	❑	❑	❑	❑
J: A senior doctor/dentist has signed the PGD, indicating involvement in the development process. • When developing a PGD there must be medical staff/a dentist's involvement. The practitioner involved needs to have suitable experience and seniority within the organisation. Such individuals need to be registered within the UK and employed by the authorising organisation.	❑	❑	❑	❑	❑

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
K: A pharmacist has signed the PGD, indicating involvement in the development process. • When developing a PGD there must be the involvement of a pharmacist. • Such individuals need to be registered within the UK and employed by the authorising body. • The PGD is signed by a pharmacist, who has been involved in its development. • A 'senior pharmacist' should ensure that issues regarding medicine storage are regulated by The Medicines Act (1968) and that the facilities available to practitioners when operating under the PGD have been considered, eg availability of medicines required in case of anaphylaxis/the security of medicines whilst stored at a clinic.	❑	❑	❑	❑	❑
L: The senior professional practitioner employed by the organisation, has signed the PGD. • The senior professional head of the specific practitioner groups need to have signed the PGD eg a nurse developing a PGD, their senior professional colleague needs to approve the PGD. However, where PGDs are developed by a group of multi-professionals (eg for operation by more than one professional group) a senior professional may delegate this duty to one single senior professional from the various professional groups. In such instances the signatory needs to clearly understand their responsibilities for operation of the PGD.	❑	❑	❑	❑	❑
M: The name of the organisation within which the PGD will operate is clearly defined. • The organisation authorising the PGD needs to be defined (eg The Hospital Division).	❑	❑	❑	❑	❑
N: If the PGD is for an anti-microbial. • A microbiologist has been involved in the development of the PGD. • The PGD is signed by the microbiologist who has been involved in the development of the PGD. • Anti-microbial resistance is a serious public health issue and PGDs involving anti-microbials need to refer to local microbiological policies/guidelines.	❑	❑	❑	❑	❑

DETAILS OF THE CLINICAL INDICATION COVERED BY THE PGD (Please indicate if the PGD meets the standard)

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
O: The clinical condition(s) covered by the PGD are clearly defined.	❑	❑	❑	❑	❑
P: When further advice is sought from a medical practitioner/dentist the arrangements for this referral are defined within the PGD. • Some patients may be excluded from the PGD and need to be referred to an independent/supplementary prescriber.	❑	❑	❑	❑	❑
Q: If the PGD is for a child then any age restrictions and/or weight restrictions are clearly detailed within the PGD. • A clinical specialist should be involved in the review of PGDs for children. • Doses of medicines should be clearly defined by age, weight and where appropriate the maturity of the child assessed. (Note: this may not be applicable to vaccines) • The formulation of the medicine is suitable for administration to children.	❑	❑	❑	❑	❑
R: The inclusion criteria for patients to receive treatment under the PGD are clearly defined. • If several separate PGDs have been submitted for similar indications but for treatment with different medication practitioners need to be able to decide which PGD to follow (eg PGDs for psoriasis where a step-wise treatment plan is appropriate depending on the severity of the condition). • If there is more than one strength or form of the medicine being administered or supplied (to provide continuity of treatment), then when to administer or supply the different strengths/forms is clearly defined within the PGD.	❑	❑	❑	❑	❑

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
S: The exclusion criteria for patients NOT to receive treatment under the PGD are clearly defined. • The exclusion criteria should NOT just detail 'all those patients who do not meet the inclusion criteria'. • Pregnancy should be noted as an exclusion criterion, as appropriate. • The process for referral when patients are excluded from treatment needs to be clearly defined within the PGD. • A record of the reason for exclusion needs to be documented in the patient's case notes/record as a requirement of the PGD.	❑	❑	❑	❑	❑
T: If a patient declines treatment, the actions to manage the situation are defined. • Where a patient declines to receive treatment under a PGD, this decline of treatment should be documented with the patient's case notes/record as a requirement of the PGD. • The reasons for a patient declining treatment should be stated as a requirement within the PGD. • Referral of the patient to a medical practitioner/dentist should be stated as a requirement within the PGD.	❑	❑	❑	❑	❑
U: Relevant information that should be communicated to the patient, including any potential suspected adverse reactions need to be specified as a requirement within the PGD. • All risks to the patient should be minimised. The practitioner needs to ensure that specific questions are posed to the patient to ensure that the medicine can be administered/supplied safely without the risk of the medication interacting with medication currently taken by the patient. This needs to be stated as a requirement of the PGD. • Where feasible, a patient questionnaire (as a form of risk assessment) should be completed prior to the administration or supply of medication. Information given to patients should be available in a variety of different formats. Patient information leaflets developed as part of a PGD need to be approved as part of the authorisation process. Ideally commercially available	❑	❑	❑	❑	❑

PILs should be supplied with an original patient pack wherever possible. • The fact that a patient has received information needs to be documented in the patient's case notes/record. Such a requirement needs to be stated within the PGD. • Patients should be informed whom to contact, should they experience a suspected adverse drug reaction (ADR). Such a requirement needs to be stated within the PGD.					
V: Details of any follow up action and monitoring required should be noted.	❑	❑	❑	❑	❑

DETAILS OF THE PROFESSIONALS RESPONSIBLE FOR DEVELOPMENT AND APPROVAL OF THE PGD

(Please indicate if the PGD meets the standard)

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
W: The professionals who will operate under the PGD are named individually. • Within the PGD the individual practitioners have signed the PGD or a standard form, as agreed by the organisation, is used to record the practitioner's signature. • The individual practitioners have signed a form (eg a memorandum of understanding) that details their responsibilities and their understanding of the content of the PGD and their role and responsibility for the administration or supply of medication under the PGD.	❑	❑	❑	❑	❑
X:The PGD will be finally approved by a recognised multidisciplinary group. • PGDs need to be developed by a multidisciplinary group, the membership of which must include a doctor/dentist, pharmacist and a representative from the professional group developing the PGD. PGDs must then be authorised by a multidisciplinary group for use within the organisation eg the drug and therapeutics committee.	❑	❑	❑	❑	❑

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
Y: An individual with responsibility for clinical governance should finally sign and approve the PGD for use within the organisation. • The Medical Director usually has overall responsibility for clinical governance and therefore the final approval for PGDs within the organisation. • The Lead for Clinical Governance within the organisation may have delegated responsibility for approval to another member of the organisation.	❑	❑	❑	❑	❑

DETAILS OF THE DOCUMENTATION HELD FOR AUDIT PURPOSES (Please indicate if the PGD meets the standard)

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
Z: There is a clear audit trail for all paperwork/documentation for the medicines administered or supplied under the PGD. • A record of administration of the medicine under a PGD should be documented in the patient's case notes/record. • A record of the name of the practitioner involved, the signature of the practitioner, the name of the medicine, the strength of medication, the dosage form, the dosage frequency, the route of administration, the dose, the date and time of administration should be documented and this should be a requirement of the PGD. • Any clinical incidents/suspected adverse drug reactions should be documented.	❑	❑	❑	❑	❑
ZA: PGDs should be audited on a regular basis to ensure that local practice concurs with the defined practice detailed within the PGD. • PGDs should be audited at least 6 months after introduction to ensure that current practice concurs with the detail as defined in the PGD. This should be stated as a requirement within the PGD. • Random samples of PGDs should be 'audited' on an annual basis to ensure the adequate documentation and recording of information. This should be stated as a requirement within the PGD.	❑	❑	❑	❑	❑

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
ZB: Monitoring arrangements for the patient during and after treatment are clearly defined within the PGD. • Any communication with the GP/healthcare worker should be detailed in the patient's case notes/record, as appropriate. • Patients should be informed of contact details should they require further information following the administration/supply of medication. This should be stated as a requirement within the PGD.	❑	❑	❑	❑	❑

Green section <u>Examples of Good Practice For The Development of Patient Group Directions</u>

This section should only be consulted when the PGD has met all of the standards detailed in the blue section above. The detail within this section was identified as part of the scoping exercise for the PGD Project.

(Please indicate if the PGD meets the standard by ticking ✓the box.)

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
A: The template used to develop the PGD is an agreed standard template for the organisation. • The name, form and strength of the medication to be clearly stated on the front cover of the document. • The practitioner group that will operate under the PGD to be easily identified on the front cover of the document. • The start date and expiry date of the PGD to be easily identified on the front cover of the PGD.	❑	❑	❑	❑	❑
B: The names of the clinical areas and the locations where the PGD will operate are clearly defined. • The PGD (or standard paperwork as agreed within the organisation) details each hospital/clinical location where the PGD is authorised to operate.	❑	❑	❑	❑	❑
C: If the patient group treated under the PGD includes children. • A clinical specialist has been involved in the review of the PGD.	❑	❑	❑	❑	❑
D: The evidence base used to develop the PGD is detailed within the PGD. • Details of any literature review undertaken with references. • The information indicating that the PGD reflects best clinical practice. • Reference made to any national guidelines is reviewed (eg SIGN, NICE).	❑	❑	❑	❑	❑

E: If the medicine that will be administered or supplied under the PGD is a newly marketed medicine and requires close surveillance/ monitoring (eg a black triangle medicine) the status of the medicine is clearly defined within the PGD. • There is evidence to support the use of the medicine within the PGD. • The PGD clearly identifies the status of the medicine.	❑	❑	❑	❑	❑
F: Where the PGD includes a medicine which has UK Marketing Authorisation (a UK Product Licence), but the clinical indication for inclusion under the PGD is NOT included within the UK Marketing Authorisation, this status is clearly highlighted within the PGD. • Evidence to support the clinical indication is justified within the PGD.	❑	❑	❑	❑	❑
G: If the PGD is for an anti-microbial • Reference is made within the PGD to local antibiotic policies.	❑	❑	❑	❑	❑
H: If a patient is to be excluded from treatment under the PGD: • The process for referral to a medical/dental practitioner is defined within the PGD.	❑	❑	❑	❑	❑
I: The PGD details any form of risk assessment that has been undertaken prior to administration/supply of medication. • The risk assessment may take the form of a screening form/questionnaire eg prior to administration of vaccines, prior to supply of Emergency Hormonal Contraception (EHC). • The risk assessment tool may be appended to the PGD to enable regular review and updating of the information.	❑	❑	❑	❑	❑
J: The PGD refers to the process for receiving patient consent for treatment. Where the medicine is being used outwith the UK Product Licence patient consent must be sought as per the organisational policy/process and this needs to be defined as a criteria within such a PGD.	❑	❑	❑	❑	❑

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
K: Within the PGD there is a named individual/position within the organisation who will ensure that PGDs are kept up to date and that practitioners are educated prior to operating under the PGD. • The names and signatures of practitioners operating under the PGD need to be kept up-to-date. • Those operating under the PGD are suitably qualified/trained to do so.	❑	❑	❑	❑	❑
L: Where a medicine is supplied to a patient for self-administration the PGD details the process that will enable all medication to be accounted for ideally on a patient by patient basis. • The process will detail the controls in place to ensure that medication can be accounted for. • The process should inform that a unique patient identifier should be documented.	❑	❑	❑	❑	❑
M: Where a medicine is 'administered' under a PGD the practitioner will ensure that adequate information is recorded. • The name of the practitioner, the signature of the practitioner, the name of the medicine, the strength of the medicine, the dosage form, the dose, the dosage frequency, the route, the date and time of administration should be documented as a requirement of the PGD. • The PGD should detail that the practitioner needs to document that a medicine has been administered 'under a PGD' and they should sign and date the entry.	❑	❑	❑	❑	❑

STANDARD	PGD ref.	PGD ref.	PGD ref.	PGD ref.	PGD ref.
N: Part of the PGD includes a section that defines the role and responsibility of the practitioner. • The PGD may include an agreement of understanding that will be signed by each of the practitioners who will operate under the PGD. • This agreement of understanding may be part of the PGD or may be separate documentation that is held centrally within the organisation.	❑	❑	❑	❑	❑
O: The monitoring of the medicines at the site where the PGD is operational has been considered. • Cold chain issues (keeping any temperature labile medicines at the correct temperature during transport/within the clinical area), records of receipt, records of supply of the medication have been considered.	❑	❑	❑	❑	❑
P: There is a clear documented audit trail for all medication administered or supplied. • There is a named individual/position within the organisation with this responsibility and this is defined within the PGD.	❑	❑	❑	❑	❑
Q: The PGD details all of the clinical locations where the PGD will be held. • All operational sites. • At a central point within the organisation. • The originator of the PGD should keep the original signed copy of the PGD with other areas including pharmacy retaining a photocopy of the PGD.	❑	❑	❑	❑	❑

Appendix 3

AUDIT TOOL FOR PATIENT GROUP DIRECTIONS

This audit tool is designed to facilitate the self audit of developed PGDs.

The audit report should be sent to the relevant group or committee within the organisation that reviews PGDs.
Eg. PGD Group.

Ideally an audit should be undertaken 6 months after implementation/first operation of the PGD, to ensure that practice meets what is written within the PGD.

The scope of this audit is to determine if the medicines administered* /or supplied* (delete as appropriate)

under PGD……

follow the guidance according to HDL 2001 (7) and local practice.

The auditors carrying out the audit: 1……

2……

Date of audit:……..

1. Criteria: The PGD documentation is accessible and up to date.

Criteria	Standard Set	Standard at audit	Outcome
A: Of the practitioners surveyed it was confirmed that the PGD is routinely accessible for reference at consultations (eg min number surveyed 10% of signatories of PGD).	100%		
B: Hard copies/electronic copies of the PGD are located/able to be accessed in the locations where the PGD will operate. This information concurs with the locations detailed within the PGD.	100%		
C: The PGD is currently still in operation in the locations as stated within the PGD (eg it has not been 'suspended' from operation).	100%		
D: The PGD is still within the expiry date (valid) and is the most up to date current version.	100%		

2. Criteria: Local practice meets the standards detailed within the PGD.

Criteria	Standard Set	Standard at audit	Outcome
A: Patients are only being treated under the PGD for the clinical indications as stated within the PGD. (Number of patient records audited…….)	100%		
B: Patients excluded from treatment were documented and the reasons for exclusion were the exclusion criteria as stated within the PGD.	100%		
C: Patients are referred to medical practitioners eg if they are excluded from treatment. Details of the referral is	100%		

included in the documentation along with the reasons for exclusion.			
D: Where a patient declines treatment, the reasons for the decline of treatment is noted within the patient case notes/record and the referral to an independent/supplementary prescriber documented.	100%		
E: Following referral the independent/supplementary prescriber has documented in the patient case notes/record the outcome of the referral.	100%		
F: The practitioners operating under the PGD are as stated/named in the PGD or on documentation as agreed by the organisation. (eg surveyed 10% of signatories)	100%		

3. Criteria: The medicines for the PGD are stored safely and securely in accordance with local policies/guidance.

Criteria	Standard Set	Standard at audit	Outcome
A: The medicines are stored safely, securely and under the correct environmental conditions in the locations, as detailed in the PGD (Minimum sample 1 area).	100%		
B: Practitioners confirm that where medicines are transported to a clinical area, the medicines are transported according to the SPC for the medicine and as detailed in the PGD.	100%		

4. Criteria: The following information is recorded in the patient record, by the practitioners using the PGD when administering a medicine under the PGD.
(Min number of patient records survey as in criteria 1)

Criteria	Standard Set	Standard at audit	Outcome
A: The name of the practitioner	100%		
B: The signature of the practitioner	100%		
C: The name of the medicine administered	100%		
D: The strength of the medicine administered	100%		
E: The dosage form of the medicine administered	100%		
F: The route of the medicine administered	100%		
G: The dose of the medicine administered/supplied.	100%		
H: The dosage frequency of the medicine.	100%		
I: The clinical indication for the medicine.	100%		
J: The date and time when the patient received treatment/was supplied with treatment.	100%		

5. Criteria: Risks to the patient are minimised.
(Min number of patient records survey as in criteria 1)

Criteria	Standard Set	Standard at audit	Outcome
A: Any referrals to a medical practitioner are documented in the patient's case notes/record where appropriate.	100%		
B: Details of any risk assessment undertaken prior to treatment are recorded in the patient's case record.	100%		

C: Any formal patient information (eg PIL) given to the patient is the standard information as detailed in the PGD.	100%		

6. Criteria: Medicines can be accounted for at all times.
(Min number of patient records survey as in criteria 1 if PGD is for supply and not administration)

Criteria	Standard Set	Standard at audit	Outcome
A: Medicines 'supplied' to patients, can be accounted for.	100%		

7. Criteria: Supplies to patients for self-administration are documented.
(Min number of patient records survey as in criteria 1)

Criteria	Standard Set	Standard at audit	Outcome
A: The name of the practitioner			
B: The signature of the practitioner			
C: The name of the medicine	100%		
D: The strength of the drug			
E: The form of the drug			
F: The route of administration			
G: The dose of the drug			
H: The dosage frequency of the medicine			
I: The clinical indication for the medicine			
J: The patient's name and address	100%		
K: The unique identifier for the Patient eg CHI information	100%		
L: The amount of medicine supplied	100%		
M: The date and time the medicine was supplied			

8. Criteria: Suspected Adverse Reactions, Clinical Incidents and 'near misses' are documented
(Min number of patient records survey as in criteria 1)

Criteria	Standard Set	Standard at audit	Outcome
A: Any clinical incidents including 'near misses' have been reported via the local policy/guidance and there are reports/documents for review.			
B: Any suspected adverse drug reactions involving the medicine have been recorded via the local policy/guidance and there are reports/documents for review.	100%		
C: Any suspected adverse drug reactions involving the medicine have been reported via The National Yellow Card System and there are reports available for review.			

9. Criteria: PGDs are kept up to date.

Criteria	Standard Set	Standard at audit	Outcome
A: There is a mechanism/process in place to ensure that, if the specific product characteristics of the medicine change, the PGD is updated.	100%		
B: There is a mechanism/process in place to ensure that the PGD will be reviewed prior to the expiry date as detailed on the PGD.	100%		

10. Criteria: Practitioners are educated for operating under a PGD.

Criteria	Standard Set	Standard at audit	Outcome
A: There is an individual/position identified who is responsible for ensuring that practitioners are trained and competent. (NB: training records should be available for consultation)	100%		
B: Individual training records indicate that practitioners are ensuring that their competency is updated and individual CPD records indicate that practitioners are maintaining CPD within the specified therapeutic area (eg Min Sample 10% of signatories).	100%		

Action Plan		
Action required to be undertaken	**Timescale**	**Staff member responsible**

References/Bibliography/Further Reading

This section provides reference to all publications used to research the best practice statement, and may include recommended reading.

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