PATIENT GROUP DIRECTION (PGD) PROTOCOL
(CONSIDERING THE NEED, PROPOSING, DEVELOPING, AUTHORISING, USING, UPDATING AND MONITORING OF PGDS)

SUMMARY
This protocol, written with reference to NICE Medicines Practice Guidelines (MPG) for Patient Group Directions (PGDs) 2013, is aimed all managers and health professionals involved in considering the need for, developing, authorising, using, updating and monitoring PGDs within their service or directorate and when considering how patients may receive their medicines in new or re-designed services.

DOCUMENT DETAILS	
Document Type	Operational Protocol
Document name	Patient Group Direction Protocol - considering the need for, developing, authorising, using, updating and monitoring PGDs
Document location	Intranet folder, live version stored
Version	6
Effective from	June 14th 2018
Review date	June 14th 2021
Owner	Trust Drug & Therapeutics Committee (DTC)
Prepared by	Emma Williams
Approved by, date	Trust Drug & Therapeutics Committee
Related documents	**Codes of practice for:** • Safe Prescribing • Administration • Controlled Drugs • Supply, storage and disposal of medicines
Keywords	**PATIENT GROUP DIRECTIONS, PGD**
Relevant external law, regulation, standards	Human Medicines Regulations 2012 NICE Patient Group Directions (PGD) Medicines Practice Guidelines (MPG2) 2013.

Change History		
Date	Change details	Approved by
2014	Review and update of document to reflect NICE PGD MPG2 requirements 2013. Proposal stage – change in signatories/ streamlining of form Template change – change in signatories to reflect new post holders and change in organisational authorisation. Removal of detail of "duties" to specific individuals – these are often joint responsibilities and covered more generally in this document. Addition of Guidelines notes for Directorate Clinical Governance Committees.	DTC
2018	Amended to reflect NICE PGD MPG2 minor update	

CONTENTS

INTRODUCTION

The purpose of this Patient Group Direction (PGD) Protocol is to ensure compliance with NICE Medicines Practice Guidelines (MPG) recommendations for the systems and processes used when considering the need for, developing, authorising, using and updating Patient Group Directions (PGDs).

This also covers governance arrangements with the aim of ensuring patients receive safe and appropriate care and timely access to medicines, in line with legislation.

Significant dedicated resource is required from a number of highly qualified, competent staff when considering the need for, developing, authorising, using and updating PGDs.

The preferred way for patients to receive the medicines they need is for a prescriber to provide care for an individual patient on a one-to-one basis.

PGDs are NOT intended as a substitute for individual prescribing where there is an opportunity in the care pathway for a medicine or medicines to be prescribed i.e. where an episode of care is planned.

PGDs provide a legal framework that allows some registered health professionals to supply and/or administer a specified medicine(s) to a pre-defined group of patients, without them having to see a prescriber. However, supplying and/or administering medicines under PGDs should be reserved for situations in which this offers an advantage for patient care, without compromising patient safety.

Any practice requiring a PGD that fails to comply with the criteria falls outside of the Law and could result in criminal prosecution.

AUDIENCE

This protocol is aimed at all managers and health professionals involved in considering the need for, developing, authorising, using and updating PGDs within their service or directorate and when considering how patients may receive their medicines in new or re-designed services.

PROTOCOL LIMITATIONS

The protocol does not provide full details of the legal frameworks and national guidelines for PGDs but does provide links and signposting to relevant resources. See Reference resources.

ASSOCIATED TRUST POLICIES AND GUIDELINES

Refer to the current Trust Medicines Policy and associated Codes of Practice.
Refer to the current Trust Clinical Guidelines Submission Process
Refer to the current Trust Unlicensed Medicines Protocol
Refer to the current Trust Clinical Audit Policy

GLOSSARY

PGD Proposer – the person responsible for leading on consideration of a need for a PGD and subsequent proposal if appropriate. This is usually a representative of the professional group(s) who would practice under the PGD e.g. Head of Nursing/Professional Lead or a nominated nurse consultant, matron, specialist clinical lead etc.

PGD Working Group – a locally determined multidisciplinary group established for each individual PGD.

Members must include:

- A representative of the professional group(s) who would practice under the PGD should be involved. This person is usually nominated as "lead author" of the PGD by the Head of Nursing/Professional Lead of the Directorate.
- A senior doctor (or dentist) within the lead Directorate
- A senior clinical pharmacist afilliated with the lead Directorate

Co-authors should include (when relevant):

- Member of antimicrobial stewardship committee.
- Member of another health professional group who may be practising under the PGD in addition to the group represented by the lead author.
- Other consultants (medical or dental) whose patients may be treated under the PGD (particularly if the PGD is to be used across more than one clinical area of directorate)
- Other pharmacists if the PGD is to be used across more than one clinical area or directorate.
- Other lead practitioners if the PGD is to be used across more than one clinical area or directorate.

PGD Working Group members responsibilities are outlined in Appendix 1.

Compliance with the PGD Protocol by the PGD Working Group is essential to ensure that the legal and Trust requirements are met.

REFERENCE RESOURCES

NICE Medicines Practice Guidelines (MPG2) PGDs 2013
NICE Medicines Practice Guidelines (MPG2) PGDs - Implementation tools and resources
Specialist Pharmacist Service Website

SUMMARY

This protocol is written with reference to NICE Medicines Practice Guidelines PGDs 2013 (hereafter known as NICE PGD guidelines) and the associated recommendations at each stage in the process.

In accordance with NICE PGD guidelines, the Trust must provide the majority of clinical care involving supplying and/or administering medicines on an individual, patient-specific basis. It will reserve PGDs for limited situations in which this offers an advantage for patient care, without compromising patient safety, and where there are clear governance arrangements and accountability.

The PGD Protocol is divided into sections as follows:

- Section 1 Considering the need for a PGD and obtaining agreement to develop a PGD
- Section 2 Developing and submitting a PGD
- Section 3 Authorising a PGD
- Section 4 Authorising named, registered health professionals to use a PGD
- Section 5 Training and competency.
- Section 6 Using a PGD
- Section 7 Audit, review and updating a PGD

Each section provides a step-wise approach.

Sections 1-3 refer to PGD proposal, development, submission and authorisation.
Sections 4-7 refer to adoption of the PGD into the service following authorisation, ongoing management, monitoring and updating of PGDs.

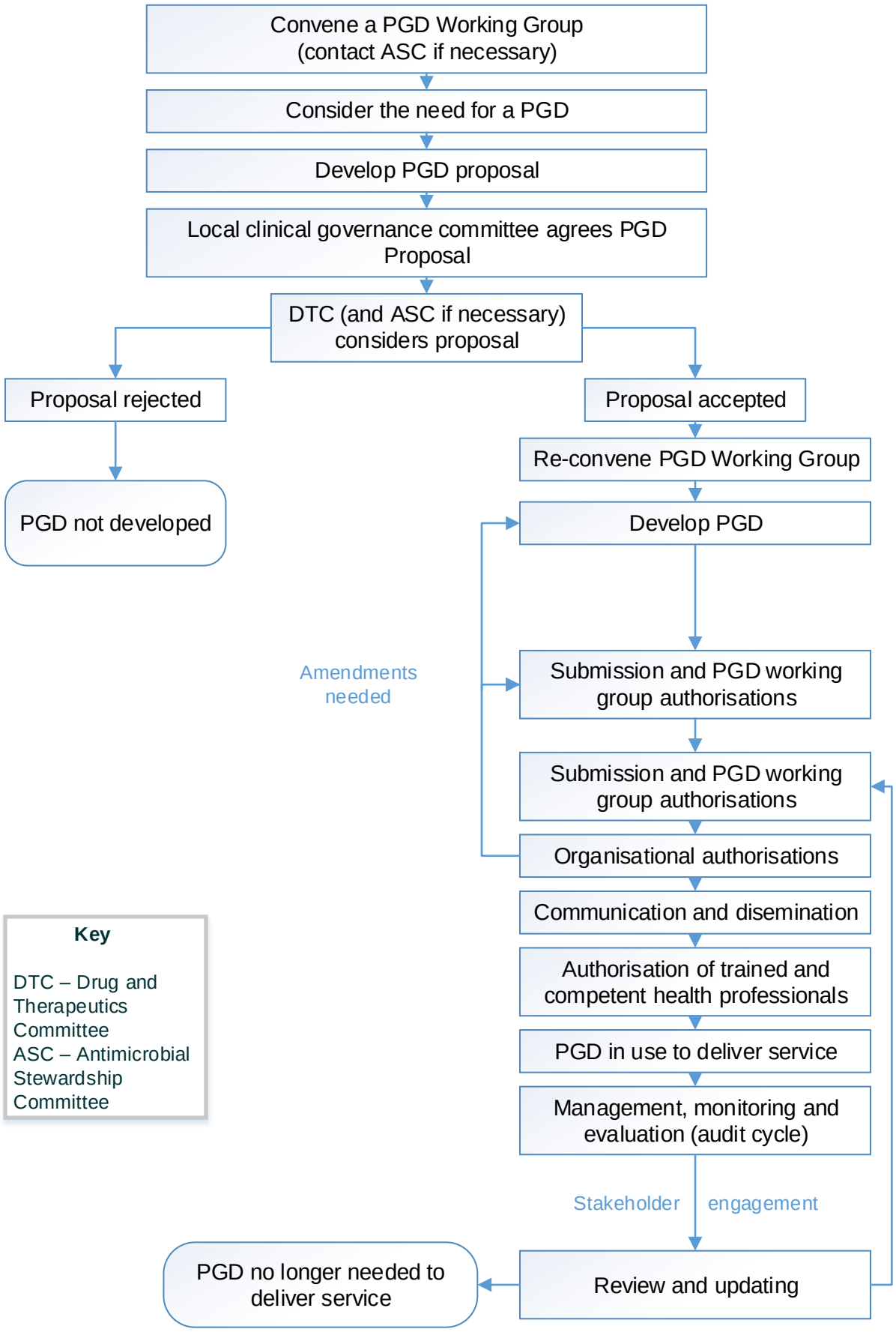
In line with NICE PGD guidelines, roles and responsibilities are defined in Appendices 1-3 for those considering the need, proposing, developing, authorising, using, updating and monitoring PGDs.

The PGD Protocol makes a number of references to the involvement of Directorate Clinical Governance Committees. Appendix 3 provides additional guidelines for these committees.

Pharmacy Clinical Governance can provide advice and guidelines to individuals and committees and a PGD Status report will be circulated on a quarterly basis to Directorate Clinical Governance Chairs and Facilitators where PGDs are in practice. This may be utilised as an agenda item for local Clinical Governance Committee meetings (See Appendix 3).

The PGD Protocol is summarised in Figure 1. This provides an overview of the process when considering the need for, developing, authorising, using and updating a PGD.

FIGURE 1: PGD PROTOCOL SUMMARY FLOW CHART



SECTION 1

1. Considering the need for a PGD and obtaining agreement to develop a PGD

1.1 Considering the need for a PGD

1.1.1 In accordance with NICE PGD guidelines, the Trust must provide the majority of clinical care involving supplying and/or administering medicines on an individual, patient-specific basis. It will reserve PGDs for limited situations in which this offers an advantage for patient care, without compromising patient safety, and where there are clear governance arrangements and accountability.

1.1.2 Before a PGD is written, all of the available options for supplying and/or administering medicines in a specific clinical situation must be considered. A comprehensive approach should include reviewing the care pathway and exploring all the options for prescribing, supplying and/or administering medicines. Consider whether one option or a range of options is appropriate.

1.1.3 When considering access to medicines via new care pathways, service re-design or a new service, patients and the public must be involved.

1.1.4 A PGD working group must be convened to consider the need for a PGD and to go on to develop a PGD proposal if they consider a PGD is appropriate.

1.1.5 PGD Working Group members responsibilities are outlined in Appendix 1.

1.1.6 If there is no specialist clinical pharmacist assigned to the speciality, the Head of Nursing/Professional Lead or their nominated deputy should contact the Chief Pharmacist to discuss support required. If there is no consultant assigned to the speciality, the Head of Nursing or their nominated deputy should contact the Chair of DTC to discuss.

1.1.7 The Antimicrobial Stewardship Committee (ASC) should be contacted if the discussion relates to the use of antimicrobials .

1.1.8 Use the PGD checklist and audit tool to consider whether a PGD is necessary or appropriate. For example, ensure that the health professional group being considered to practice under the PGD can legally do so. In addition, consider other options when exemptions in legislation allow medicine supply and/or administration without the need for a PGD.

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

1.2 Obtaining agreement to develop a PGD

1.2.1 A PGD proposal must be developed by PGD Working Group at Directorate level to support the case that a PGD is the most appropriate method to supply and/or administer the medicine. This case must ascertain that treatment cannot be delivered on an individual named basis and that a PGD is a legal method for supply and/or administration of this medicine in this care setting. Refer to "To PGD or not to PGD" and associated tools on the Specialist Pharmacy Service website for further information.

1.2.2 The following information must be considered:

- PGDs must only include medicines with a UK marketing authorisation, in line with legislation, i.e. no unlicensed medicines can be administered or supplied under a PGD
- Off-label use of a licensed medicine should be included in a PGD only when clearly justified by best clinical practice.
- Both licensed and off-label use must be approved for use on the local formulary.
- Black triangle medicines, (licensed medicines that are intensively monitored subject to special reporting for adverse effects) should only be included in a PGD when clearly justified by best clinical practice. The PGD should clearly indicate the black triangle status of the medicine.
- A controlled drug should only be included in a PGD when legally permitted and clearly justified by best clinical practice. The Trust CD Accountable Officer should be aware and agree in principle with the PGD Proposal
- The Antimicrobial Stewardship Committee (ASC) must be consulted if the proposed PGD includes an antimicrobial.
- A PGD should not include a medicine needing frequent dosage adjustments or frequent or complex monitoring (for example, anticoagulants or insulin)

- A PGD cannot be used to make dose adjustments to a medicine supplied under a PGD when the medicine is already in the patient's possession.
- Carefully consider the risks and benefits of including more than one medicine in a PGD on a case-by-case basis.
- A PGD should not be used for managing long-term conditions, such as hypertension or diabetes, or when uncertainty remains about the differential diagnosis.
- PGDs must be used only by named and authorised registered health professionals who can legally supply and/or administer medicines using a PGD.
- If the PGD is for supply of a medicine, availability of appropriately labelled packs. Health professional should not split packs.

1.2.3 After considering the need for a PGD and gaining agreement from colleagues that it is appropriate, the PGD Proposal checklist must be completed by the PGD proposer. The PGD Proposer will have gained agreement from their manager to undertake this role and will have had preliminary discussions considering the need for a PGD with colleagues who will have agreed to be involved as a member of the PGD Working Group.

1.2.4 The PGD Proposal Form and checklist should be completed to demonstrate that all legal and Trust requirements have been considered as follows:

- the title of the PGD
- details of the proposer and other individuals who would be involved in developing and authorising the PGD
- details of the service where the PGD will be used
- the setting where the PGD would be used
- the condition to be treated, considering patient inclusion and/or exclusion criteria
- benefits to patient care
- potential risks to patient safety

- details of medicine(s) to be supplied and/or administered, including dosage, quantity, formulation and strength, route and frequency of administration, duration of treatment and whether it is included in the local formulary
- details of any proposed use of the medicine outside of license i.e. off-label
- if the proposed PGD includes an antimicrobial, it is clinically essential and clearly justified by best clinical practice, such as Public Health England guidance.
- if the proposed PGD is a controlled drug, it is legally permitted and the Trust CD Accountable Officer is aware and agrees in principle with the PGD Proposal.
- health professional groups who would work under the PGD, including training and competency needs
- current and/or future service provisions for supplying and/or administering the medicine(s), including its position within the care pathway
- evidence to support the proposal
- resources needed to deliver the service
- a timescale for developing the PGD.

1.2.5 Proposals must be submitted to the Directorate clinical governance committee who are responsible for reviewing proposals to develop PGDs and must agree the proposal before it may be submitted to the Trust Drug and Therapeutics Committee (DTC). See Appendix 3

1.2.6 The PGD Proposer will send the completed, locally approved PGD proposal to Pharmacy Clinical Governance for DTC consideration.

1.2.7 DTC will only accept PGD proposal submissions once the Directorate Clinical Governance Committee have agreed with the proposal and when Pharmacy Clinical Governance has established that due process has been followed.

1.2.8 DTC will approve or reject the PGD Proposal within one month of receipt.

1.2.9 DTC will not accept any PGD submissions in the absence of a locally approved PGD Proposal checklist unless prior agreement has been granted by DTC to do so.

SECTION 2

2 Developing and submitting a PGD

2.1.1 A named lead author as identified on the approved PGD Proposal has responsibility for developing a PGD, supported by the PGD working group, as specified in the approved PGD Proposal.

2.1.2 The lead author should not work in isolation. Members of the PGD working group should be regularly involved at each stage of the process.

2.1.3 The most recently approved blank Trust PGD template must be used to write the PGD.

2.1.4 Refer to the Trust PGD template with guidance notes to ensure that requirements for writing a PGD are met.

2.1.5 All legally required information must be included in a PGD. The Trust PGD development checklist should be used to ensure that all of the Trust and legal requirements are met when developing the PGD. It may also be helpful to refer back to Section 1 to ensure that there is ongoing consideration about the appropriate use of a PGD.

2.1.6 Ensure PGDs are consistent with the relevant summary of product characteristics, unless the medicine is being used off-label or relevant national guidance is being followed.

2.1.7 Note that off-label use must have Joint Formulary Committee approval. Refer to the Trust Formulary webpage for further information. Clearly state that the medicine is being used outside the terms of the marketing authorisation on the PGD.

2.1.8 PGD Working Group should include in the PGD of the need to inform the patient or their carer that the use is off-label, in line with General Medical Council guidance. This information should be added under “Advice to Patient”.

2.1.9 Black triangle medicines (licensed medicines that are intensively monitored subject to special reporting for adverse effects) should only be included in a PGD when clearly justified by best clinical practice. The PGD should clearly indicate the black triangle status of the medicine.

2.1.10 If a PGD includes more than one medicine, ensure all legal requirements are met for each medicine.

2.1.11 Use the best available and up-to-date evidence, such as specific NICE guidance and other sources of high-quality information when developing PGDs. Include key references in an appendix to the PGD.

2.1.12 Seek views on the draft PGD with all relevant stakeholders, including clinicians and agree the final draft PGD with all members of the PGD Working Group.

2.1.13 Submit final draft PGD to Directorate Clinical Governance Committee and obtain approval.

2.1.14 Once local approval has been obtained, complete the online submission form and submit the final draft PGD to 'DTC PGD' via the online Clinical Guidelines system for authorisation.

SECTION 3

3 Authorising a PGD

3.1.1 After the PGD has been submitted onto the online clinical guidelines system, electronic authorisations (approvals) will be required from the PGD Working Group, all co-authors and relevant Directorate signatories named on the PGD. Electronic authorisations must be provided within the specified timescale as indicated by pharmacy clinical governance.

3.1.2 The lead author is responsible for liasing with members of the PGD Working Group who have not indicated their approval of the PGD within the timeframe provided by pharmacy clinical governance.

3.1.3 PGDs must be authorised by the Trust as the authorising body in line with legislation. The Chair (or Vice-Chair in their absence) of DTC is responsible for the organisational authorisation of all Trust PGDs. Trust PGD authorisation may not proceed until all other authorisations have been received.

3.1.4 The expiry date for an individual PGD will be considered on a case-by-case basis by DTC at the time of PGD authorisation, with patient safety paramount. PGDs

will normally be given an expiry date of three years from the date the PGD was authorised.

3.1.5 DTC will inform the PGD Lead author and Head of Nursing/Professional Lead when the PGD has the required organisational authorisation.

3.1.6 All Trust authorised PGDs are published on the online clinical guidelines system.

3.1.7 The Head of Nursing/Professional Lead will support the dissemination of PGDs to the appropriate service lead(s).

3.1.8 When a PGD is developed and authorised for use across more than one directorate, each Head of Nursing/Professional Lead remains responsible for the dissemination of PGDs to the appropriate service lead(s) within their directorate.

SECTION 4

4 Authorising named, registered health professionals to use a PGD

4.1.1 The Head of Nursing/Professional Lead will identify a senior, responsible person from within the service to authorise named, registered health professionals to practise under the PGD.

4.1.2 The senior person responsible for authorisation of named, registered health professionals to practise under the PGD will:

- ensure that authorised health professionals have signed the agreement to register as a practitioner to practise under the relevant PGD.
- maintain lists of authorised named registered health professionals to practise under the PGD who are currently employed by the Trust.
- provide all authorised named registered health professionals with a copy of the PGD and a copy of their individual authorisation.
- ensure that only fully competent, qualified and trained professionals operate within the PGD.
- remove the names of any authorised practitioners from the registered list for any of the following:
    - Failure to provide relevant CPD evidence when requested e.g. for compulsory training such as CPR.
    - Failure to successfully register with their professional body.
    - Audit results indicate poor professional standards.
    - Professional voluntary request.
    - Practitioner moves from the department or leaves the Trust.
- inform any relevant members of staff about any removal of practitioners from that list.
- plan a programme of monitoring and evaluation of PGD use within the service, including clinical audit (See Section 7).

SECTION 5

5 Training and competency

5.1.1 The Head of Nursing/Professional Lead will identify gaps in competency and establish a comprehensive and appropriate training programme for all people involved in considering the need for, developing, authorising, using and updating PGDs.

5.1.2 The Head of Nursing/Professional Lead will ensure that adequate educational materials are available to enable individuals to deliver safe and effective services in which PGDs are used.

5.1.3 The Head of Nursing/Professional Lead must ensure that training and re-training of health professionals using PGDs incorporates a post-training assessment of competency.

SECTION 6

6 Practising under Patient Group Directions

6.1.1 Health professionals practising under PGDs should refer to Appendix 2 for details of their responsibilities.

SECTION 7

7 Audit, review and updating Patient Group Directions

7.1.1 There should be a planned programme of monitoring and evaluation of PGD use within the service, including clinical audit.

7.1.2 The named lead author should ensure audit is undertaken and is responsible for reviewing and updating the PGD, supported by the PGD working group.

7.1.3 Any PGD submitted to DTC for re-authorisation will not be considered without an audit report. Failure to submit an audit report will result in the delay of re-authorisation of the PGD and risk the PGD being removed from practice.

7.2 Audit

7.2.1 Outcomes of audits must be considered when reviewing a PGD. Therefore audit should be completed ahead of commencement of the PGD review.

7.2.2 PGD audit must be completed at least once during the approved period of the PGD and no later than one year prior to PGD expiry, before PGD review takes place.

7.2.3 PGD Audit must conform with the Trust Clinical Audit Policy.

7.2.4 The Head of Nursing/Professional Lead may wish to ensure that all registered practitioners working under the PGD have their practice audited by an audit of records kept. For example: a sample of notes of those patients attending for treatment under a PGD, whether or not the medicine is supplied or administered, is audited.

7.2.5 Audits should capture practice of all registered practitioners including those who have been absent or on annual leave or where there has been lack of opportunity to supply and/or administer using PGDs e.g. by following up notes from specific clinics.

7.2.6 The Head of Nursing/Professional Lead for the relevant directorate in consultation with the Directorate Clinical Audit Lead will advise on any PGD audits to be undertaken. A Senior Clinical Pharmacist within the speciality and the lead author will support the audit. Proposals for audit of PGDs for antimicrobials must involve consultation with the Antimicrobial Stewardship Committee

7.2.7 The results will be reviewed by the Head of Nursing/Professional Lead and Directorate Clinical Audit Lead who together with an appropriate service lead e.g. Matron will provide recommendations for any changes in the PGD or its practice as necessary.

7.2.8 The results will highlight areas of best practice, may indicate whether PGD remains appropriate and may highlight areas of concern. The audit results will also form the basis of an ongoing training and development programme.

7.2.9 The following areas must be considered in any PGD audit:

- Reason for supplying and/or administering or reason for not supplying and/or not administering under the PGD
- Standard of written records and signature
- History of allergy recorded in notes
- Receipt of information including leaflet(s) by patients
- Clinical records such as date and time administered/supplied
- Clinical data such as correct indication/dose of medicine
- Clinical records such as reasons patients have been included and excluded
- Details of any adverse drug reaction and actions taken including documentation in the patient's medical record

7.2.10 Audits could also include:

- Signature/name of staff who administered or supplied the medication, and also, if relevant, signature/name of staff who removed/discontinued the treatment
- Referral arrangements (including self-care)
- Pharmaceutical information such as records of batch number and expiry dates. This is compulsory audit for immunisations, vaccinations and blood derived products such as immunoglobulins.
- Frequency of use of PGD

7.3 Review and updating

7.3.1 All reviewed and updated PGDs must be re-authorised by the Trust, in line with legislation.

7.3.2 Where review of a PGD results in no changes to practice, it must still be re-authorised when it is due to expire within the next six months. Amendments considered to be "minor" also require a PGD to be re-authorised.

7.3.3 Review of a PGD should commence NO LATER THAN six months before the PGD is due to expire or earlier if needed. The lead author, any member of the PGD Working Group or Head of Nursing/Professional Lead may suggest an earlier review where they have recognised a need to do so.

7.3.4 This should include responding to:

- changes in legislation
- important new evidence or guidance that changes the PGD, such as new specific NICE guidance or changes in national immunisation programme
- new information on drug safety
- changes in the summary of product characteristics
- changes to the local formulary.
- outcomes of audit

7.3.5 A reminder to the PGD Working Group will be sent by Pharmacy Clinical Governance six months prior to the expiry of the PGD.

7.3.6 The lead author should reconvene the PGD Working Group and existing membership should be reviewed to ensure that it remains appropriate and departing members are replaced.

7.3.7 When reviewing the PGD, the lead author and members of the PGD working group should:

- refer to the outcomes of PGD audit and agree if any changes to clinical practice under the PGD is required
- conduct an appropriate literature search to identify new evidence. Ensure that this evidence is evaluated to assess its relevance and validity.
- determine whether the PGD remains the most appropriate option to deliver the service. This should be informed by local monitoring and evaluations, frequency of use of the PGD, views of health professionals working under the PGD and views of relevant stakeholders, such as patients or their carers.

7.3.8 If it is decided that a PGD is no longer appropriate or necessary, the lead author should inform the Directorate Clinical Governance Committee and Pharmacy Clinical Governance. The Head of Nursing/Professional Lead should make arrangements to ensure that all practitioners are aware that the PGD is to be withdrawn from practice and that any associated changes in procedure are communicated appropriately.

7.3.9 When updating the PGD, the lead author must ensure that all legally required information is included in the PGD. The Trust PGD development checklist should be used to ensure that all Trust and legal requirements are met.

7.3.10 When updating the PGD, the lead author should amend the existing PGD using track changes to demonstrate where the PGD has been updated. They should also add information to the 'change history' textbox on the front page of the PGD.

7.3.11 When updating the PGD, the lead author should seek views on drafts and agree the final draft reviewed PGD with all members of the PGD Working Group.

7.3.12 The final draft reviewed PGD plus completed PGD development checklist should be submitted to the Directorate Clinical Governance Committee and approval obtained.

7.3.13 Once local approval has been obtained, the final draft reviewed PGD (with track changes) should be submitted to DTC via the online Clinical Guidelines system for re-authorisation. Refer to Section 3 for further information : Authorising a PGD.

7.3.14 All health professionals who will practice under the updated PGD must also be individually re-authorised to do so as outlined in Sections 3-5.

7.3.15 Head of Nursing/Professional Lead should make arrangements to ensure that all practitioners working under the updated PGD are made aware of any significant changes to practice.

APPENDIX 1

RESPONSIBILITIES OF INDIVIDUALS INVOLVED IN CONSIDERING THE NEED FOR, DEVELOPING, AUTHORISING AND UPDATING A PGD

Failure to adhere to these responsibilities may result in unnecessary delay to developing and delivering appropriate services.

General responsibilities of all members of the PGD Working group and Head of Nursing/Professional Lead

All members of the PGD Working Group must be employed on a permanent contract with the Trust and it is advised that they should not be involved if they are knowingly about to terminate employment within six months of the proposal or development of a PGD.

If a member of the PGD Working Group is not permanently employed by the Trust, this must be agreed and formally noted by the Directorate Clinical Governance Committee. The Clinical Director should ensure that the individual who is accepting this role understands the commitment and responsibilities as laid out in the Trust PGD Protocol.
The PGD Proposal should indicate such exceptions and indicate that there is evidence of a formally noted agreement.

The aim of the PGD Working Group is to ensure safe and effective practice under PGDs with consideration of clinical and management aspects at each stage.

All members of the PGD Working group and the Head of Nursing/Professional Lead should ensure considering the need, proposing, developing, authorising, using, updating and monitoring PGDs is according to the following policies and procedures:

- Guy's and St Thomas' NHS Foundation Trust Medicines Policy and associated Codes of Practice.
- Guy's and St Thomas' NHS Foundation Trust PGD Protocol including use of associated guidance notes, completion of the required documents and audit.

The PGD Working group and the Head of Nursing/Professional Lead will

ensure that they have the knowledge, skills and expertise required for developing and authorising PGDs and can demonstrate their competency.

- provide advice and support according to their speciality when considering the need for, developing, authorising, using and updating a PGD.

- provide any recommendations for change in practice and/or PGD content in a timely manner and in accordance with legislation and national guidelines.

- support any audit and provide any recommendations for change in practice and/or PGD content when the results of PGD audit are known.

- refer to their specific responsibilities as described below.

For further information refer to the PGD section on the Specialist Pharmacy Service website – Questions about signatories of PGDs or contact Pharmacy Clinical Governance PGDs by emailng DTC@gstt.nhs.uk.

2. Specific responsibilities

2.1 Clinical Director

- Ensures that the PGD Protocol is adhered to within the directorate when considering the need, proposing, developing, authorising, using, updating and monitoring PGDs to ensure safe and effective practice with consideration of clinical and management aspects at each stage.

- The Clinical Director should ensure that the processes are in place to ensure that individuals understand their commitment and responsibilities as laid out in the PGD Protocol.

- See Appendix 3 Guidance notes for Directorate Clinical Governance Committees

2.2 Head of Nursing/Professional Lead

- Discusses and agrees the need for a PGD with the PGD Working group prior to commencing the formal PGD proposal process.

- Ensures that a PGD is the most appropriate method of supply and/or administration of medicines for the clinical pathway, considering service delivery and skill mix.

- Identifies a suitably trained and competent PGD Proposer/Lead Author and ensures that the lead author has the necessary support and resource to carry out their responsibilities.

- If necessary, nominates a named deputy e.g. nurse consultant, matron or clinical nurse specialist who will be named within the PGD proposal documentation and the PGD. The nominated deputy may need to refer to Head of Nursing/Professional Lead responsibilities and associated duties within this protocol.

- Identifies a senior, responsible person from within the service to authorise named, registered health professionals to practise under the PGD.

- Where a lead author leaves the Trust, nominates a new lead author in the same or similar post to undertake relevant responsibilities and duties.

- Oversees monitoring and management of the PGD, including audit and review and ensures timeframes are met to achieve re- submission to DTC three months prior to the current expiry date of the PGD.

- Ensures that patient safety incidents relating to PGD use are reported, collated and reviewed in line with patient safety reporting systems.

- See Appendix 3 **–** Guidance notes for Directorate Clinical Governance Committees.

2.3 Lead author

The Lead Author will lead the PGD Working Group and:

- Is a representative of the professional group(s) who would practise under the PGD.
- Works closely with the PGD Working Group and with managers to ensure that all the requirements of PGD legislation and guidelines are met.
- Provides a comprehensive, completed proposal to DTC as evidence that treatment may not be delivered using a written instruction from an authorised prescriber on an individual named basis without significant disadvantage to delivery of patient care.
- Initiates and manages the development of the PGD within specified timeframes on receipt of the PGD Proposal approval from DTC.
- Submits PGDs for PGD approval and organisational authorisation within agreed timeframes.
- Liaises with the PGD Working Group to ensure signatories are provided for PGD approval within the given timeframe stipulated by Pharmacy Clinical Governance.
- Co-ordinates audit and review of the PGD according to a timetable agreed with the PGD workgroup to ensure timeframes are met to achieve re- submission to DTC three months prior to the current expiry date of the PGD.
- Ensures that any reviewed/updated PGDs comply with the latest Trust PGD Protocol and associated documents including the PGD blank template.
- Liaises with new post-holders or the relevant managers to discuss the PGD and any relevant responsibilities and duties where the doctor/dentist or pharmacist PGD signatory leaves the Trust. This may require review of the PGD by the new post-holders to ensure that it complies with their understanding of practice and is up to date.

2.4 Senior Clinical Pharmacist

The Senior Clinical Pharmacist will be a member of the PGD Working Group and will:

- Provide pharmacy advice and support to colleagues considering the need for, developing, authorising, using, updating and monitoring of PGDs.
- Provide pharmacy advice and support to ensure that the medicines content of the PGD is legal and accurate, with reference to the legal framework for PGDs and with reference to the Joint Medicines Formulary and associated medicines management.
- Establish that the clinical and pharmaceutical content of the PGD is accurate and supported by the best available evidence.
- Ensure that where a medicine is to be supplied to a patient to take away, appropriately labelled packs will be available.
- Alert the lead author if early PGD review is required due to changes in product availability, formulary changes or licence status or any other pharmaceutical matters e.g. availability or changes in cost of appropriately labelled packs.

2.5 Senior Doctor/Dentist

The Senior Doctor/Dentist will be a member of the PGD Working Group and will:

- provide medical/ dentistry advice and support to colleagues considering the need for, developing, authorising, using, updating and monitoring of PGDs
- provide medical/dentistry advice with reference to the most appropriate options for clinical care, associated clinical guidelines and with reference to the Joint Medicines Formulary.
- establish that the clinical and pharmaceutical content of the PGD is accurate and supported by the best available evidence.
- alert the lead author if early PGD review is required due to e.g. changes in best practice guidance

2.6 Co-Authors or reviewers

A co-author or reviewer will be a member of the PGD Working Group and will

- provide relevant advice with reference to the most appropriate options for clinical care and associated clinical guidelines to ensure specific issues are covered for that speciality or their area of practice e.g. antimicrobial stewardship.
- alert the lead author if early PGD review is required due to e.g. changes in best practice guidelines

APPENDIX 2

RESPONSIBILITIES OF HEALTH PROFESSIONALS USING PGDS

Before practising under a PGD, health professionals must ensure that they:

- have read and understood the context and content of the PGD
- have undertaken the necessary initial training and continuing professional development
- provide evidence that they meet in full the necessary competencies as specified in the PGD and are authorised to practise by a senior, responsible person from within the service
- have signed the individual practitioner agreement for the PGD
- are using a copy of the most recent and in date final signed version of the PGD, which may be found on the Trust Online Clinical Guidelines Database.

When practising under a PGD, health professionals must:

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

- ensure that the patient receives a manufacturer's patient information leaflet (PIL) with each medicine supplied. It is good practice to supply a PIL for medicines which are administered if practical to do so.

- report any patient safety incidents relating to PGD use in line with patient safety reporting systems

- document the following information about the clinical assessment and supply and/or administration of the medicine(s):
    - date and time of supply and/or administration
    - patient details, such as name, date of birth, allergies, previous adverse events and how the patient met the criteria of the PGD
    - details of medicine, such as name, strength, dose, frequency, quantity, route and site (if injection) of administration (record batch number and expiry date for vaccines, blood-derived products and other medicines if recommended by relevant national guidelines)
    - a statement that supply or administration is by using a PGD
    - name and signature (which may be an electronic signature) of the health professional supplying or administering the medicine
    - relevant information that was provided to the patient or their carer
    - whether patient consent to treatment was obtained
    - any other record that is specified in the PGD

APPENDIX 3
GUIDANCE NOTES FOR DIRECTORATE CLINICAL GOVERNANCE COMMITTEES

In accordance with NICE PGD Guidelines, PGDs will not be appropriate within most directorates within the Trust and patients will receive the medicines they need from a prescriber on a one-to-one basis.

Where PGDs are used, Chairs of Clinical Governance Committees and Heads of Nursing/Professional Leads will be sent periodic PGD status reports by Pharmacy Clinical Governance PGDs which lists PGDs due for review and due to expire. Directorate Clinical Governance Committees are responsible for addressing barriers that may delay PGD processes, such as lack of clear leadership, ownership and understanding of legislation and governance arrangements.

The Directorate Clinical Governance Committee should establish and manage a structured PGD work programme for ensuring adherence to the PGD Protocol.
Measures and resource required will depend on number of PGDs in the directorate.

A designated member of the committee will keep an up to date list of all PGD activity from proposal to development and practice within the Directorate with details of current status.

Where PGDs are in practice or are being considered, the Clinical Governance Committee should ensure that PGD Status is a regular item on the agenda. This includes discussion of considering need for PGDs, PGD proposals, PGD development, PGDs due for or under review and monitoring of practice under PGDs within the directorate. There may be a need to discuss and note any risks and actions taken or required, discussing with Pharmacy Clinical Governance PGDs when necessary.

The Directorate Clinical Governance Committee should be assured that:

- all legal and Trust requirements for PGDs can be met
- sufficient resources are available to deliver the PGD work programme.
- robust local processes and clear governance arrangements are in place
- the risks and benefits of all options for supplying and/or administering the medicine(s) are explored
- PGDs deliver effective patient care that is appropriate in a pre-defined clinical situation, without compromising patient safety
- the views of stakeholders, such as clinical groups, patients and the public, and the commissioning organisation are considered where relevant
- appropriate registered health professionals are available to use the PGD, and training and competency needs are addressed
- people who are developing, authorising, monitoring, reviewing and updating the PGD are identified, and training and competency needs are addressed
- the need for appropriately labelled packs and safe storage can be met
- adequate resources, such as finance, training, medicines procurement and diagnostic equipment are available
- adequate resources are available to ensure that processes are followed within any locally agreed timeframe
- decisions are aligned with local clinical commissioning frameworks.

APPENDIX 4 SUPPORTING DOCUMENTS

These supporting documents are provided separately and available via the links below:

4A PGD Proposal Form and checklist
4B PGD template with guidance notes – for reference only
4C PGD blank template
4D PGD development and submission checklist