Patient Group Direction Policy

Version number :	3.0
Consultation Groups	Senior Pharmacy Managers ELFT Policy Alignment Committee Nursing Steering Group
Approved by (Sponsor Group)	Medicines Committee
Ratified by:	Chairs Action, Dudley Manns
Date ratified:	9th August 2021
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Executive Director lead :	Chief Medical Officer (Dr Paul Gilluley)
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Services	Applicable to
Trustwide	√
Mental Health and LD	
Community Health Services	
Primary Care	

Version Control Summary

Version	Date	Author	Status	Comments
1.0	12 May 2014	Shameem Mir	Draft 1	
2.0	07 March 2018	Charity Okoli	Final	
3.0	July 2021	Charity Okoli	Final	Most sections of the policy including the introduction and the purpose were updated to reflect the current legislation and NICE guideline. Specific responsibilities for professionals added on page 6 On page 10, added a Process flow chart for the five key stages to consider before writing a PGD. Sections 4.1 to 4.5 (pages 10 to 13) updated with relevant and easy to follow information. Added Appendix 1 (PGD flow chart) on page 16 Added Appendix 2 (To PGD or NOT to PGD) on page 17 Added Appendix 3 (The Proposal form to develop PGD) on page 18 New PGD template added on page 20 Appendix 5- agreement for registered practitioner to act under PGD added Appendix 6 (Audit Tool Templates) added on page 25 to 29). Audit tool template 1 – Form for the audit of Compliance with governance processes of PGD or PGDs. Template 2- example of specific audit tool for some medications. Template 3 – Form for audit of completion of patients' record for supply or administration under the PGD The references updated as well, page 15

Contents

1. Introduction

Patient Group Directions (PGDs) provide a legal framework that allows some registered health professionals to supply and/or administer specified medicines to groups of patients who may not be individually identified before presentation of treatments without having to see a prescriber (eg doctor, dentist or Non-Medical Prescriber).

In August 2000 the Department of Health & Social Care issued a Health Service Circular (HSC) 2000/026 which outlines the legal requirements for the use of Patient Group Directions (PGDs).

The current legislation for PGDs is included in The Human Medicines regulations 2012.

It is important to note that the HSC 2000/026 states that the preferred method for patients to receive medicines is for an appropriately qualified prescriber to assess and prescribe on a on patient-specific basis. However, services may be able to increase the accessibility of treatment provided by the use of Patient Group Directions (PGD) without compromising patient safety.

This policy has been developed to ensure that the Trust has a framework for the use of PGDs which complies with legal requirements, and also safe for the patients.The supply and/or administration of medication should be done on a patient –specific basis in most cases. 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 and with a clear governance arrangements and accountability.

In August 2013, the Medicines Practice Guideline [MPG2] was published by NICE (National Institute for Health and Care Excellence) and this guideline covers good practice for developing, authorizing and using PGDs. This guideline was updated in March 2017, NICE with further recommendation that in developing any PGD that includes an antimicrobial, the team must liaise with a local specialist in microbiology who must agree that a PGD is needed and this must be clearly documented. This is to avoid jeopardising local and national strategies to combat antimicrobial resistance and healthcare associated infections.

Using a PGD is not a form of prescribing and PGDs do not allow professionals to use prescription forms to order medicines to be supplied by others.

Who Can Administer Medicines using PGDs?

The following registered health professionals may supply or administer medicines, as named individuals under a Patient Group Direction:

- chiropodists and podiatrists
- dental hygienists
- dental therapists
- dieticians
- midwives
- nurses
- occupational therapists

- optometrists
- orthoptists
- orthotists and prosthetists
- paramedics
- pharmacists
- physiotherapists
- radiographers
- speech and language therapists

Medications Exempted from PGDs:

Under a PGD the following items cannot be supplied:

- unlicensed medicines
- dressings, appliances and devices
- radiopharmaceuticals
- abortifacients, such as mifepristone.
- In accordance with NICE guidance, medicines needing frequent dosage adjustments or frequent or complex monitoring, should not be included in a PGD

All medicines supplied against a PGD must be in original packs.

Definition:

Patient Group Directions are written instructions which allow healthcare professionals to supply and/or administer specified medicines to pre-defined groups of patients who may not be individually identified before presentation for treatment.

2. Purpose of Policy

The purpose of this policy is to:

- define the processes and procedures for the proposal, development, approval, implementation, audit and review of PGDs in the Trust.
- offers guidance to help determine if PGD is required for a service setting and to understand that PGDs are not appropriate for all clinical situations.
- ensure there is consistency in the development and format of all the Trust PGDs and that the PGDs are reviewed as deemed appropriate.
- enable the delivery of effective patient care in a pre-defined clinical situation, without compromising patient safety, and without the need to see a prescriber.
- ensure that the Trust has a framework for the use of PGDs which complies with legal requirements, and also provide governance structure to protect patients and staff.

2.1 Targeted audience

Nurses, Doctors, Pharmacists, and all Clinical staff using PGDs, Audit staff and Team Managers.

2.2 Targeted Patient/Client/User group

This policy is relevant **to all service users who are prescribed, supplied or administered medicines under any** PGD.

2.3 Associated documents

This policy should be read in conjunction with the Trust Medicines Policy.

3. Specific responsibilities

3.1 Initiating Directorate 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.

- He/She should ensure that the processes are in place to support individual understanding of their commitment and responsibilities as laid out in the PGD Protocol.

3.2 Lead Nurse/Professional Lead

- Discusses and agrees the need for a PGD with the PGD Development 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. Clinical lead nurse, 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 Team Lead/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 PGD Development Group 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.

3.3 Lead author

The Lead Author will work with the PGD Development Group and:

- Is a representative of the professional group(s) who would practise under the PGD.
- Works closely with the PGD Development Group and with managers to ensure that all the requirements of PGD legislation and guidelines are met.
- Provides a comprehensive, completed proposal to the PGD Development Group 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 the PGD Development group.
- Submits PGDs for PGD approval and organisational authorisation within agreed timeframes.
- Liaises with the PGD Development Group to ensure signatories are provided for PGD approval within the given timeframe stipulated by Medicine Committee.
- Co-ordinates audit and review of the PGD according to a timetable agreed with the PGD Development group to ensure timeframes are met to achieve re-submission to Medicine Committee 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.

3.4 Senior Clinical Pharmacist or Directorate Pharmacist

The Directorate Pharmacist will be a member of the PGD Development 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 Trust Medicines Formulary including 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.

3.5 PGD Group Clinical Director (Senior Clinician)

The Senior Clinician/Dentist will be a member of the PGD Development Group and will:

- Provide medical 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 Trust 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.

3.6 Co-Authors or reviewers

A co-author or reviewer will be invited to the PGD Development 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.
- Alert the lead author if early PGD review is required due to e.g. changes in best practice guidelines.

3.7 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 intranet.

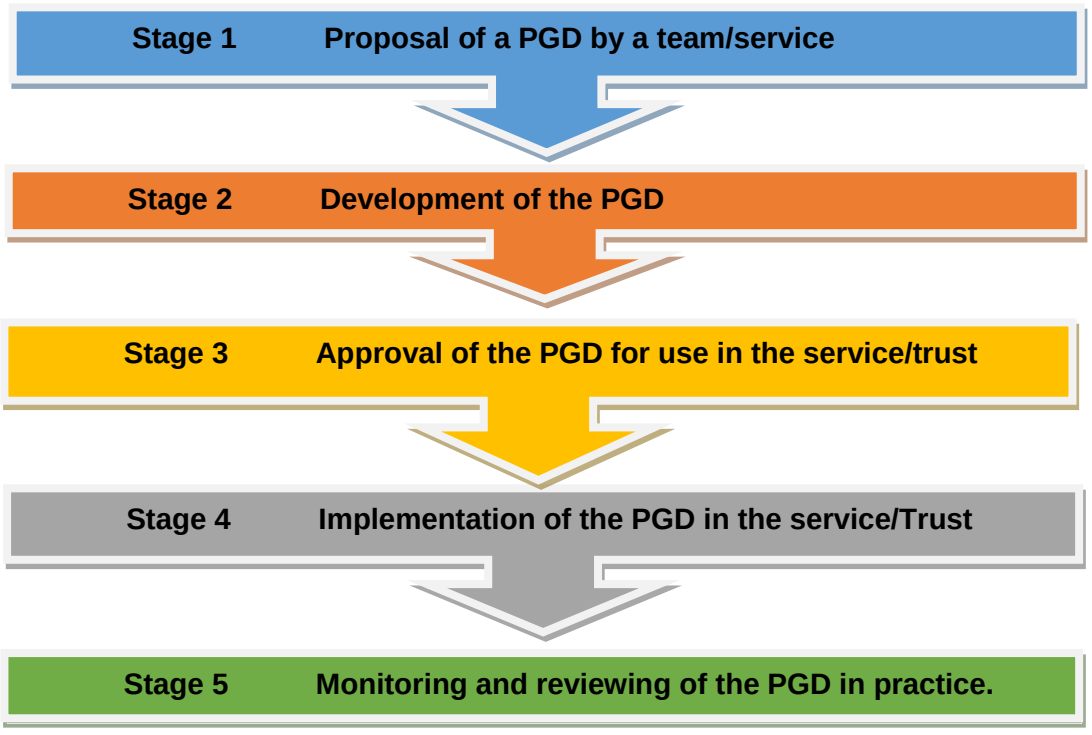
When practising under a PGD, health professionals must:

- 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 care professional supplying or administering the medicine
    - Relevant information that was provided to the patient or their carer and whether patient consent to treatment was obtained
    - Any other record that is specified in the PGD

4.0. Stages for Consideration:

There are five key stages to consider before writing a PGD as stated below:



Also see Appendix 1 for Map process

4.1 Stage 1: Proposal of the PGD

Before writing a PGD, the clinician must assess and establish the clinical need, use the national PGD guidance tools and seek agreement from a senior clinician to establish if PGD is needed. It is important to refer to section 1.1 of the NICE Medicines Practice Guideline March (2017) (https://www.nice.org.uk/guidance/mpg2) for more information. Team could also refer to Appendix 2 for more information on whether To PGD or not to PGD any medicines.

PGDs should not be used for medicines when exemptions in legislation allow their supply and/or administration without the need for a PGD.

Note: Unlicensed medicines cannot be included in a PGD. Off-label use of a licensed medication is only used in a PGD only when clearly justified by best clinical practice. Controlled drugs are only allowed for certain conditions therefore clinician should liaise with Senior Pharmacist in the Directorate who will seek approval from Trust Controlled Drugs Accountable Officer.

The summary of some points that should be considered when consulting on a PGD proposal are:

- Is the drug appropriate for inclusion in a PGD?
- Think first about finding the safest route for patient to receive their medications within the service.
- Have the risks and benefits to patients and staff been considered?
- What are the financial implications?
- Does the team have sufficient suitably competent staff members?
- What is the plan for monitoring compliance with the PGD?
- Who will lead the PGD development and implementation processes?

The PGD proposal form (see Appendix 3) needs to be completed and signed by the senior clinician. The proposal will then be submitted to the PGD Development group for approval at elftPGD@nhs.net

4.2 The PGD Development Group:

The Clinical Policies Alignment Committee which reviews, and initiates policies will double up as the PGD Development Group, with the Newham CHS Clinical Director in the role of the medical doctor in the group.

The **PGD development group** will ask pertinent questions as below:

- The PGD Development Group will need to consider the following:
- Does the drug have a UK marketing authorisation?
- Is the drug appropriate for inclusion in a PGD?
- Is a PGD an appropriate method for the supply of the drug?
- Has the PGD been approved for use in the team by the consultant or responsible clinician, head of nursing and senior or lead pharmacist of that team / directorate?
- Does the protocol present an unnecessary clinical risk to the patient or team?

- Is there a financial risk to the Trust in using the PGD?
- Does the team have sufficient numbers of competent staff to work in accordance with the PGD?
- Is there a plan for monitoring compliance with the PGD?
- Does the team agree to audit use of the PGD and present the results to the Medicines Committee at regular intervals?

It is important to provide a deadline for the development group to send comments within three months before the next Medicines Committee Meeting. This is to ensure there is enough time to develop the PGD and submit document for ratification by the Medicines committee.

4.3 Stage 2: Development of the PGD

1. When writing the PGD the lead author should consult and be advised by a multi-disciplinary group including a doctor, a pharmacist and a representative of any professional group expected to supply medicines under the PGD e.g nurses.
2. Special consideration must be given to the competencies of staff working in the service in relation to the supply/administration of the drug involved through training needs analysis.
3. Conduct an appropriate literature search to identify new evidence.
4. See appendix 4 for the Trust approved blank PGD template which needs to be completed.
5. Once completed, the PGD must be signed by the senior clinician or consultant and senior pharmacist for the team/service, both of whom should have been involved in developing the PGD.
6. PGD's must be consistent with the relevant summary of product characteristics.
7. Legally all sections on the PGD template must be completed., according to the Human Medicines Regulations 2012. e.g name of service who owns the direction

4.4 Stage 3: Approval of PGDs in the Trust

The Trust Medicines Committee is responsible for approving a PGD for use in East London NHS Foundation Trust.

A copy of the PGD and Stage 1 proposal checklist should be emailed to the Chair (Chief Medical Officer) and the Chief Pharmacist once the PGD Development Group has agreed and approved the proposal.

The Trust Medicines Committee meets once every 2 months therefore the PGD will be considered for approval at the next scheduled meeting. A member of the team/service proposing the PGD should attend the meeting to present the PGD.

Once approved the PGD must be signed by the senior clinician or consultant, Directorate pharmacist and the Chair of the Medicines Committee (Chief Medical Officer) and the Chief pharmacist. A copy of the PGD will also be made available on the Trust intranet.

4.5 Stage 4: Implementation of the PGD

Once the PGD is approved by the Medicines Committee, it is the responsibility of the consultant (or senior clinician), Lead nurse and pharmacist of the team/service to ensure that the:

- service has a list of named practitioners (and their signatures) who have been assessed and found competent with continuing professional development to supply/administer medication in line with the protocol of the PGD.
- service/team members are aware of the PGD
- service/team has a signed copy of the PGD
- patients consent to the supply/administration of the drug according to the PGD
- supplies of the medication are available in the service
- there is an adequate system for the safe storage of the medication
- There is ongoing review of the patient in terms of the effectiveness of medication on PGD.

4.6 Key Considerations for HCPs

- Healthcare professionals practicing under a PGD need to consider / ensure the following:
- Responsibility for administering of drugs / supply under the PGD should not be delegated.
- Ability to assess patients who meet the inclusion criteria for PGDs.
- When necessary, discuss alternative options available to treating the patient's condition.
- Ability to assess patient's circumstances and preferences.
- Ability to recognise when to refer/signpost to another healthcare service, as specified in the PGD.
- Understand the relevant information about the medication(s) included in the PGD. such as:
  - How to administer the medicine
  - The mechanism of action of the medicines
  - Any potential side effects and how they can be managed
  - condition including temperature of the medicine
  - Follow up arrangement
- Ensure medication packs are not split and supplied in full. Patient information leaflets should be provided.
- Healthcare professional should identify whether patients are exempt from NHS prescription charges. The appropriate prescription charge must be collected from patients who are not exempted by the pharmacy department dispensing the medicine except for medication that are free under PGDs e.g. flu vaccination.
- For each supply and/or administration of the medicine(s), the following documentation should be in place:
  - Date and time of supply/administration - Patient's details (Name, DOB, allergies, previous adverse events and how the patient met the criteria of the PGD)
  - Medication details (name, strength, form, frequency, quantity, route and site (if injection). Record Batch number and expiry date of vaccines, blood derived products and other medicines if recommended by relevant national guidance.
  - A statement that supply/administration is via a PGD

- Name and signature of the healthcare professional supplying and administering the medicines - whether patients consent to treatment was obtained-
- Any relevant information that was provided to the patient or their carer.

4.7 Stage 5: Monitoring and review of the use of the PGD

- Ensure that a named lead author has responsibility for reviewing and updating the PGD, supported by a locally determined multidisciplinary PGD Development Group which should include a doctor (or dentist), pharmacist, Nurses and or representative of any other professional group(s) using the PGD.
- Define roles and responsibilities and consider training and competency needs.
- Establish and manage a structured work programme for reviewing, updating and reauthorising PGDs.
- Ensure that sufficient resources are available to deliver the work programme.

When reviewing and creating the PGD:

- Conduct an appropriate literature search to identify new evidence.
- Determine whether the PGD remains the best way to deliver the service
- Determine the expiry date for an individual PGD on a case by case basis.
- Ensure this does not exceed 3 years from when the PGD was authorised.
- Remember to start reviewing the PGD at least six months before it expires.
- When a PGD is updated, ensure all relevant documentation is also updated, including the record and signatures of health professionals authorised to practice under the PGD
- Updated PGD's must be sent for ratification at the Trust Medicines Committee.
- It is the responsibility of the senior clinician, team leader, nurse and senior pharmacist in the team to ensure that each stage of the PGD is regularly audited and that records are kept for inspection
- See Appendix 6 for three different audit tools that could be useful

5.0 Disseminating / Monitoring:

Upon approval, this policy will be disseminated to the clinical teams through the Clinical leads and team leaders across the Trust and will be available on the Trust intranet. The policy will be reviewed every three years in line with Trust guidelines with research evidence, changes to National guidelines and policies. Regular audits will be undertaken to establish gaps in practice, with a view to mitigate risks through development and implementation of action plans.

References:

Medicines Health and Regulatory Agency. Patient Group Directions: Who Can Use Them. 4 Dec 2017. Available online: https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them [Last accessed 28.04.21]

National Institute of Health and Care Excellence. Patient Group Directions: Medicines Practice Guidelines [MPG2]. 2 Aug 2013 [Updated 27 Mar 2017]. Available online: https://www.nice.org.uk/guidance/mpg2 [Last Accessed: 28.04.21]

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Specialist Pharmacist Service. To PGD or Not to PGD? Jan 2018. Available online: https://www.sps.nhs.uk/wp-content/uploads/2020/12/To-PGD-v10-March-21.pdf [Last accessed 28.04.21]

Specialist Pharmacist Service: SPS Patient Group Direction Audit Tool. September 2020 https://www.sps.nhs.uk/articles/pgd-audit-tool-example [last accessed: 01.07.21]

The Human Medicines Legislation 2012. Schedule 16: Part 1. 2012. Available online: https://www.legislation.gov.uk/uksi/2012/1916/contents/made [last accessed: 28.04.21]

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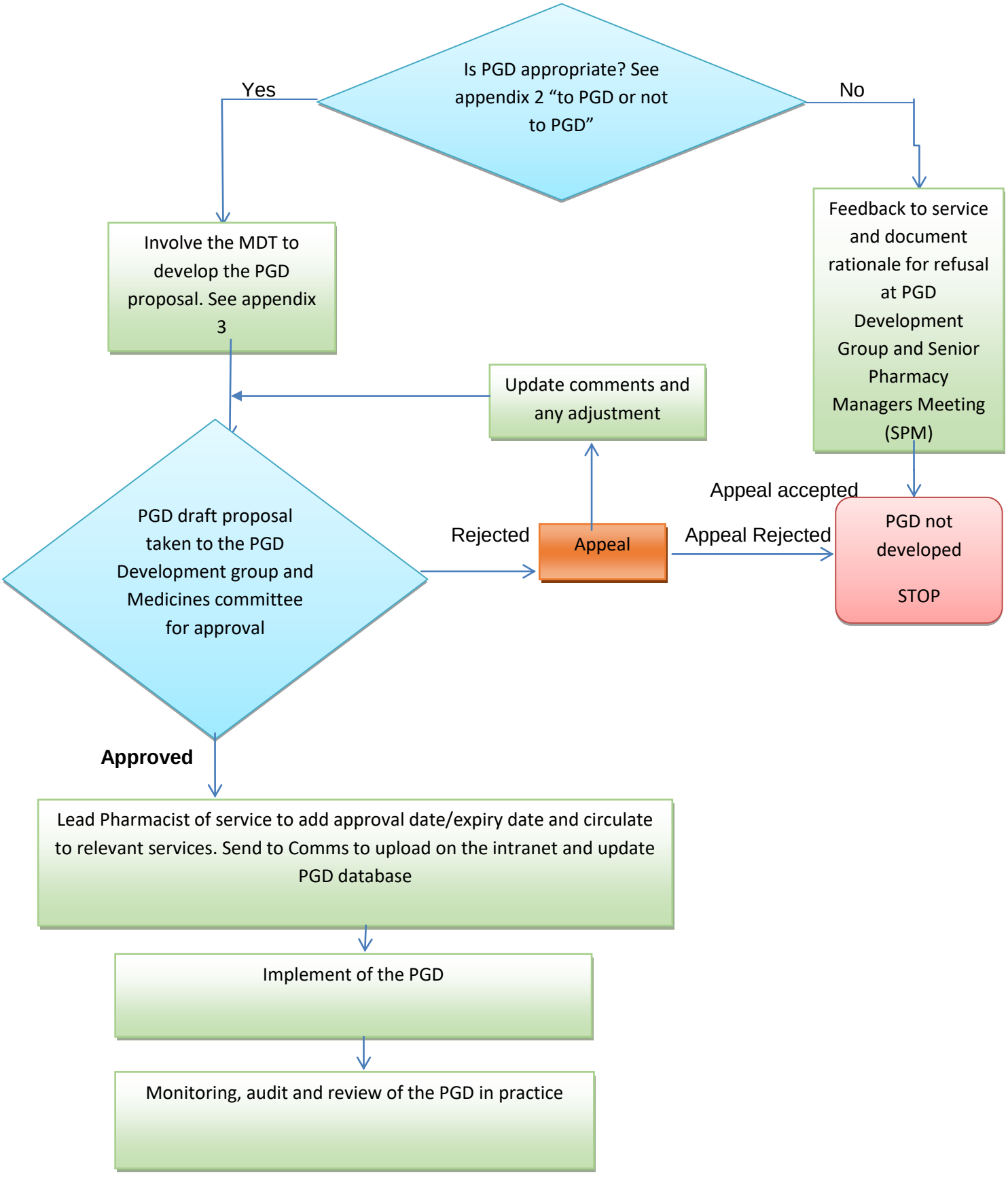
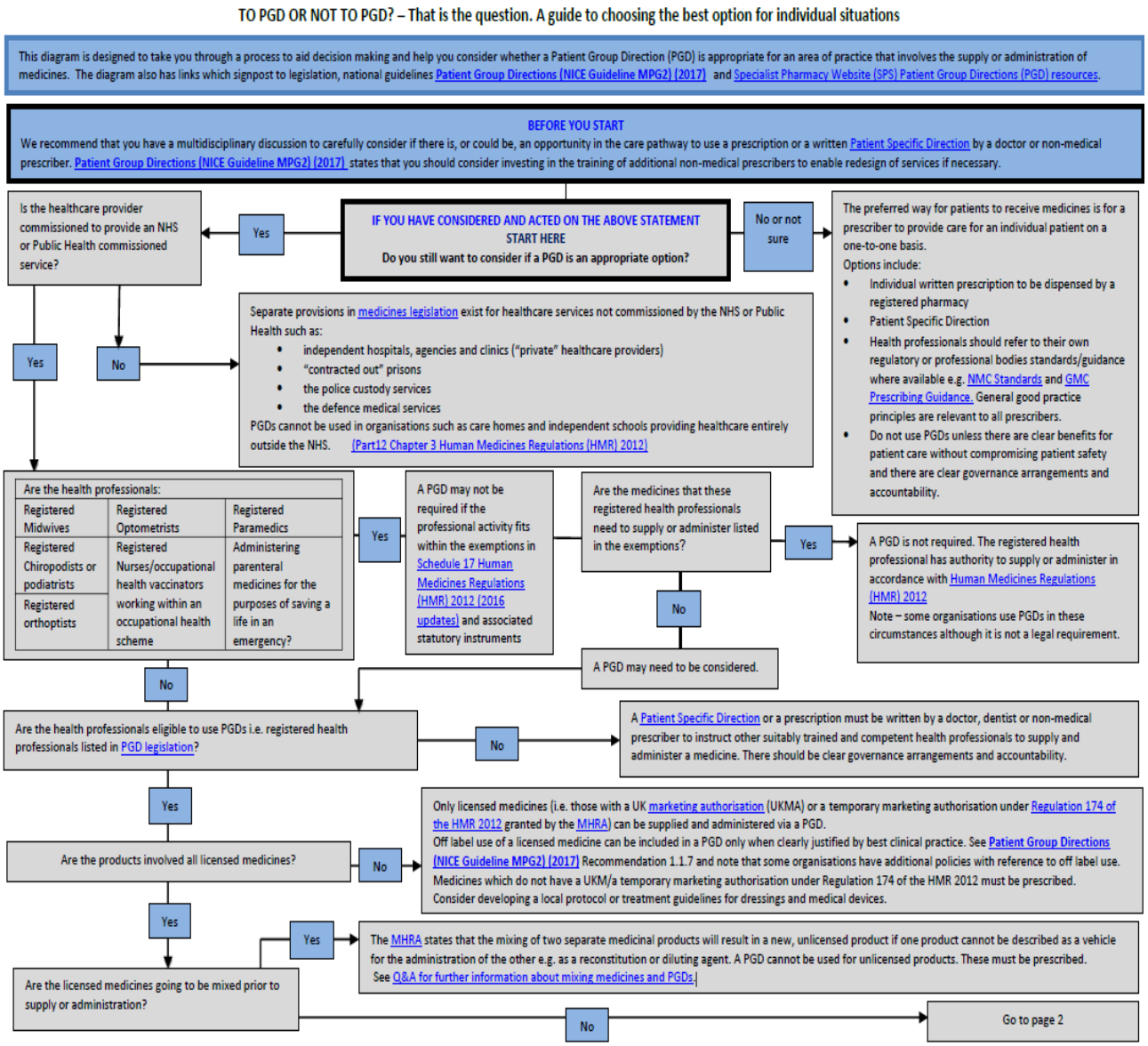
Appendix 1: PGD flowchart



Appendix 2: To PGD or NOT to PGD



To PGD or not to PGD Version 10. Update of links. Published by SPS PGDs (England) January 2018. THIS VERSION IS FOR ENGLAND ONLY. **Review due end 2021 (or earlier subject to legislation or other guidelines changes).** If you are referring to a hard copy of this document – please check the SPS website (England) www.sps.nhs.uk to make sure that you are using the most recent version.

Appendix 3: Proposal to Develop PGD template

Title of PGD:	
Details of the proposer:	
Names of others in developing and authorising the PGD:	
Team using the PGD:	
	Details of Patient Group
Condition to be treated:	
Patient inclusion Criteria	
Patient Exclusion criteria	
Benefits to patient care:	
Potential risk to patient Safety	
	Details of Medicine(s) to be Supplied and/or Administered
Name	
Dosage	
Quantity	
Formulation	

Strength	
Route	
Frequency of administration	
Duration of treatment	
	Details of Health Care Professional Group
Health professional groups who would work under the PGD	
What are their training needs	
What are their competency needs	
	Other Information
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	
Timescale for developing the PGD.	

Appendix 4: PGD Template

East London
NHS Foundation Trust

This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction

for the supply and/or administration of

Name of medicine

by registered health professional group(s) for

Condition/situation/patient group

in location/service/organisation

Version number:

Change history

Version number	Change details	Date

PGD development

Name		Job title and organization	Signature	Date
Lead author				
Senior Clinician				
Directorate pharmacist				
Representative of other professional group using PGD				
Signatures of the PGD Development Group	Chair			
	Clinical Director			
	Pharmacist			

Medicine Committee PGD Authorisation

Name	Job title and organisation	Signature	Date
Chief Medical Officer			
Chief Pharmacist			
Chief Nurse			
Clinical Directorate signatory when applicable			

PGD adoption by the provider

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

Training and competency of registered health professionals

	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	
Initial training	
Competency assessment	
Ongoing training and competency	

Clinical condition

Clinical condition or situation to which this PGD applies	
Inclusion criteria	
Exclusion criteria	
Cautions (including any relevant action to be taken)	
Arrangements for referral for medical advice	
Action to be taken if patient excluded	
Action to be taken if patient declines treatment	

Details of the medicine

Name, form and strength of medicine *Include ▼for black triangle medicines*	
Legal category (POM/P/GSL)	
Indicate any off-label use (if relevant)	
Route/method of administration	
Dose and frequency	
Warnings and Cautions	
Quantity to be administered and/or supplied	
Maximum or minimum treatment period	
Adverse effects	
Records to be kept	

Patient information

Written information to be given to patient or carer	
Follow-up advice to be given to patient or carer	

Record of Staff Authorised to Use this PGDs

Patient Group Direction for the Administration of:…….

Team:……

PGDs DO NOT REMOVE THE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

Note to Authorising Managers: Signing this document will be evidence that you are confirming that the authorised staff meets the criteria specified in the monograph and has undertaken the required training to use this PGD, that they have available a copy of the clinical content of the PGD and that they have signed a declaration of competence (adjustment of scope)

Staff listed below agree to have read and understood the Patient Group Direction and agree to only supply/administer this medicine in accordance with this PGD

Name of Professional	Signature of Professional	Name of Authorising Manager	Signature of Authorising Manager	Date

See Appendix 5 for Registered Health Practitioners' agreement to practise under the PGD

Appendix 5: Agreement by Registered Practitioner to act under PGD

Agreement by Registered Practitioner

Statement by practitioner agreeing to act under the PGD NAME within East London NHS Foundation Trust

I have received, read and fully understand the following documents:

1. The PGD Name within East London NHS Foundation Trust
2. The Drug Monograph(s) included in the PGD
3. Operational policy/policies Name
4. The East London NHS Foundation Trust Medicines Policy
5. The East London NHS Foundation Trust Policy for PGD Approval

I have received the training set out in the PGD which practitioners must undertake before being authorised to administer or supply any medicinal product under the PGD

I agree to act as a practitioner within the terms of the PGD and to administer and/or supply medicinal products in accordance with the PGD

In return, the Trust accepts vicarious liability for the practitioner acting under the terms of the PGD

I understand that by agreeing to act as a practitioner under the PGD, I am extending my role and job description. I understand that my acceptance of this extension of my role and job description has not been a compulsory requirement of East London NHS Foundation Trust

NAME OF PRACTITIONER: (*block capitals*).....

SIGNATURE OF PRACTITIONER:.....

DATE:.....

NAME OF DESIGNATED MANAGER; (*block capitals*).....

SIGNATURE OF DESIGNATED MANAGER:……

(TO CONFIRM THAT TRAINING HAS BEEN COMPLETED AND ATTAINED TO A SATISFACTORY STANDARD)

DATE:……

Appendix 6: Audit Tools

Audit Tool Template 1 of 3

This audit tool is to check compliance with the governance processes for PGD or PGDs Clinical or Service Lead to complete.

All New PGDs to be audited 6months after it is implemented and annually subsequently.

All PGDs should also be audited at least 6 months before they expire and a review completed

Name of service / clinical lead					
Service/Team					
Date of Audit					
Tick as appropriate. If 'no', state action required		Yes	No	NA	Action required
For all PGDs					
Does the service lead listed on the PGD hold a current list of authorised staff (as per the Managerial content of the PGD)					
Are all practitioners authorised to work under the PGD members of one of the health professions listed in the PGD?					
Have all staff working under the PGD signed the latest version of that PGD					
Is there an up-to-date clinical protocol in place for this					

PGD?				
Is the training specific to this PGD up to date for all staff named on it?				
Do all medicines administered/supplied under a PGD have a UK Marketing Authorisation?				
If the medication is antimicrobial, is there evidence that the antimicrobial PGDs have had an input from the local microbiology specialist?				
Have all medicines which have a current "black triangle" status been clearly indicated on the relevant PGD?				
Are all medicines supplied or administered under the PGD stored according to the PGD requirements?				
Are all medicine packs supplied in their original pack (or a licensed pre pack) when supplied under a PGD? (i.e. packs not split)				
Does the staff working under the PGD have a copy of the most current version of the PGD?				
Does the medicine require refrigeration?				
Is there a designated person responsible for ensuring that the cold chain is maintained?				
Is there a record that the fridge temperature has been monitored to required levels?				
Is there documentation of action taken if the temperature has fallen outside the required range?				
Any Additional Comments				

Audit Tool Template 2 of 3

Frequency of Audit:

- All PGDs to be audited once yearly.
- New PGDs to be audited after six months, then yearly subsequently.

Standards:

- 100% of administrations must be recorded as per policy
- 100% of supply where a medication is supplied for self-administration by patient must be recorded e.g. Medroxyprogesterone acetate SC injection
- 100% of administrations must be appropriate indications
- 100% of administrations must be STAT doses
- 100% of administrations must be by appropriately trained staff

Method:

- Review all charts, progress note entries and any records for all patients receiving medications during a specified time period for evidence of PGD use.

Suggested Audit Tool for some medications:

		Chlorphenamine			Ibuprofen			Lactulose			NRT			Paracetamol		
Recorded on Chart																
Recorded in notes																

Appropriate indication																
Dose or quantity supplied and/or administered																
Appropriate staff member																
Date																

Audit Tool Template 3 of 3

Clinical or service lead to complete

Form for audit of completion of Patient Records for supply or administration under this PGD

Take a sample of 10 records, ideally at least one from each of the named practitioners

If less than 10 records available for this PGD consider the need for the PGD/ use of alternative methods of supply

Questions		**Patient Record (initials only)**									
1	Was medication supplied/administered Y/N										
2	Was medicine supplied/administered according to the inclusion criteria Y/N										
3	Is the clinical indication (which is listed in the PGD's inclusion criteria) stated in the patient's record? Y/N										

4	Was the exclusion criteria checked? Y/N										
5	Was a drug history taken? Y/N										
6	Was allergy status documented? Y/N										
7	Is there a record of all of the following: patient's full name, date of birth, registered GP (where applicable) Y/N										
8	Was the medication strength and quantity given/supplied recorded? Y/N										
9	Was Injection site and route recorded Y/N or N/A										
10	Was expiry date and batch number recorded? Y/N										
11	Was the health professional's signature recorded? Y/N										
12	Was patient consent obtained? Y/N										
13	Is there a record of any written or verbal information/advice that was given to the patient when supplying/administering any medicine under any given PGD? Y/N										
14	Was the patient information leaflet										

	supplied to patient Y/N										
12	Did it state “given under pgd?” in the notes Y/N										
Comments											