Trust-wide Document

Great Western Hospitals NHS Foundation Trust

Administration of Medicines via a Patient Group Direction (PGD) Policy

Document No	D&O - 00066	**Version No**	1.0
Approved by	Policy Governance Group	**Date Approved**	26.06.18
Ratified by	Medicines Assurance Group	**Date Ratified**	23.08.18
Date implemented (made live for use)	11.10.18	**Next Review Date**	23.08.21
Status	LIVE		
Target Audience- who does the document apply to and who should be using it.	All employees using or managing employees that use Patient Group Directions (registered professionals only).		
Accountable Director	Chief Nurse		
Author/originator – Any Comments on this document should be addressed to the author	Non-Medical Prescribing Lead		
Division and Department	Diagnostics and Out-patients		
Implementation Lead	Non-medical prescribing lead		
If developed in partnership with another agency ratification details of the relevant agency	NA		

Equality Impact
Great Western Hospitals NHS Foundation Trust strives to ensure equality of opportunity for all service users, local people and the workforce. As an employer and a provider of health care, the Trust aims to ensure that none are placed at a disadvantage as a result of its policies and procedures. This document has therefore been equality impact assessed in line with current legislation to ensure fairness and consistency for all those covered by it regardless of their individuality. This means all our services are accessible, appropriate and sensitive to the needs of the individual.

Special Cases
No special cases.

Contents

1 Instant Information - Administration of Medicines via a Patient Group Direction (PGD) Policy

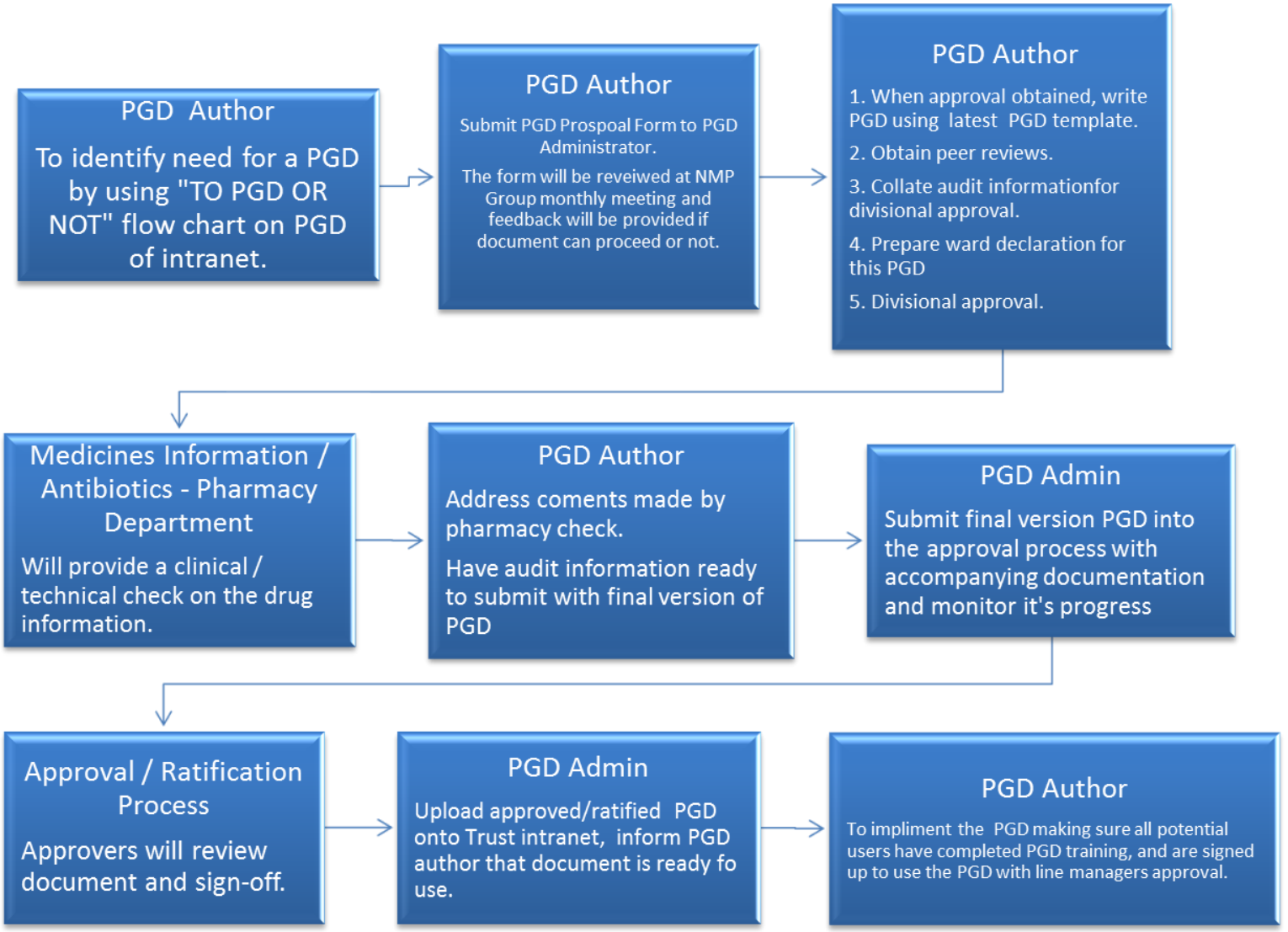
This policy is aimed at supporting employees with the administration of medication using a PGD. The policy covers the following aspects:

- Appropriateness and development of a PGD
- Review and renewal of a PGD
- Using a PGD in practice

Appropriateness and Development of a PGD.

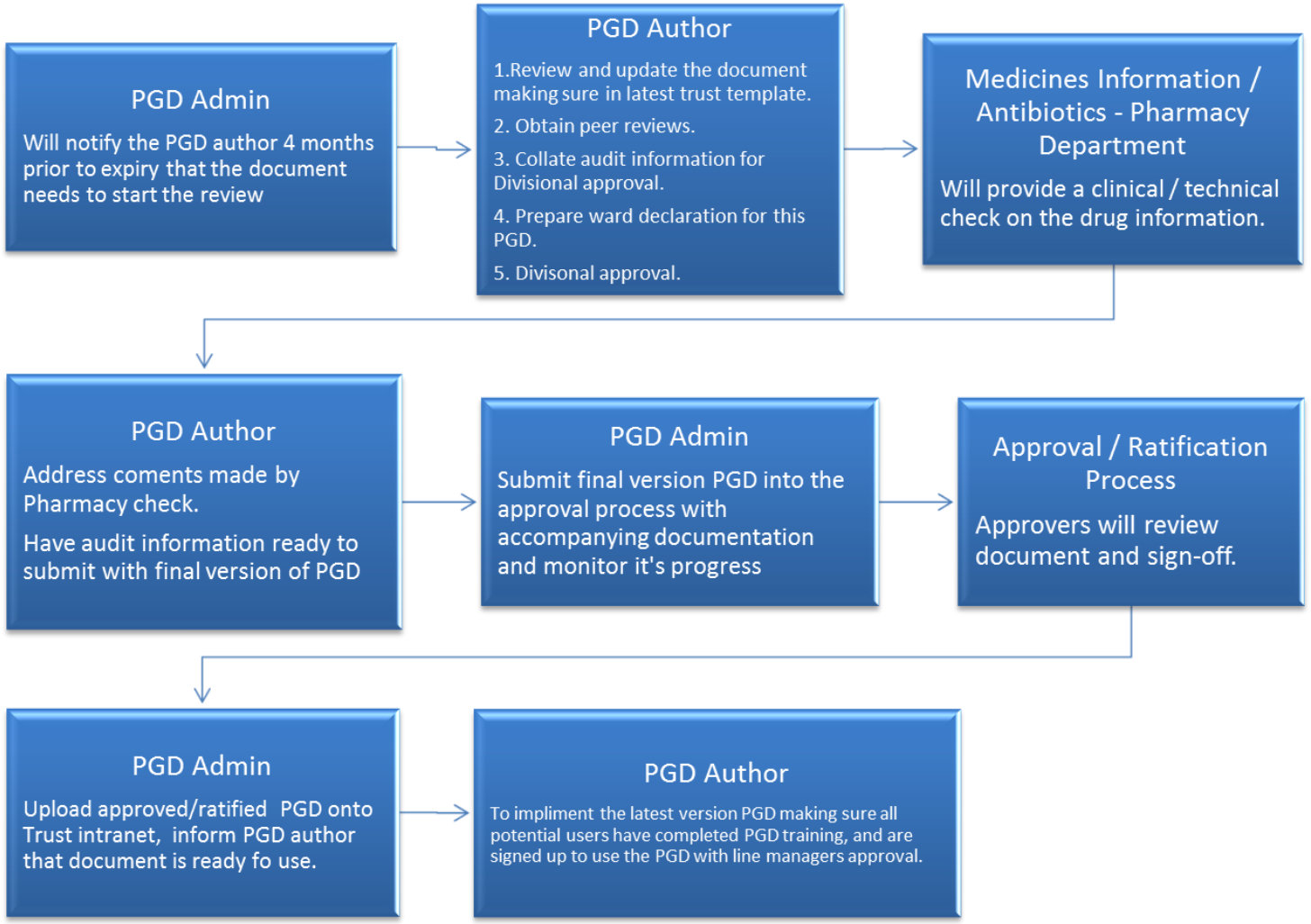
Before consideration of development of a PGD the employee must ensure that the medication being considered is suitable for usage under a PGD. Please follow the flow chart below and utilise the 'To PGD OR NOT' document (Appendix C) to support decision making.

PGD quick flow chart.



Review and renewal of a PGD.

Prior to expiry of the PGD an assessment should be undertaken to establish if the PGD is still required and should be reviewed and re-approved. Please follow the flow chart below and utilise the appropriate documentation to support review and re-approval.



Using a PGD in practice.

All employees using a PGD must ensure that all appropriate training has been completed and that they are working within their scope of professional practice.

2 Document Details

2.1 Introduction and Purpose of the Document

The legal definition of a Patient Group Direction (PGD) is "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 (Ref 28).

A PGD may be used to supply / administer licensed medicinal products to patients who fit certain clinical criteria, without the need for a prescription. As such they are ideal for use in situations where the conditions with which patients present are largely predictable and where individualised treatment is not required.

2.2 Glossary/Definitions

The following terms and acronyms are used within the document:

SOP	Standard Operating Procedure
POM	Prescription only medicine
PGD	Patient Group Direction
NMC	Nursing and Midwifery Council
NMP	Non-Medical Prescribing
NICE	National Institute for health and Clinical Excellence
NHS	National Health Service
MHRA	Medicines and Healthcare Products Regulatory Agency
Off label	Medicine being used in a way that is different to that described in the licence
EPMA	Electronic Prescribing and Medicines Administration
CKS	Clinical Knowledge Summary
CQC	Care Quality Commission

Supply: To provide a medicine to a patient/carer for administration. There is no legal distinction between 'dispense' and 'supply' although there are considerable differences in practice. The act of dispensing includes supply and also encompasses a number of other cognitive functions (e.g. checking the validity of the prescription, the appropriateness of the medicine for an individual patient, assembly of the product). In common usage, 'dispense' is usually reserved to the activity of pharmacists and 'supply' can be used for nurses, pharmacists and other healthcare professionals.

Competency: Competencies can be described as knowledge, skills, motives and personal traits. Competencies help practitioners (and their managers) analyse how they perform their role. A competency framework is a collection of those competencies that are thought to be central to effective performance. Development of competencies should help employees to improve their performance continually and to work more effectively.

3 Main Policy Content Details

3.1 Patient Group Directions – using in practice

The aim of this policy is to ensure that medicinal products supplied under a PGD are supplied legally, safely and appropriately for the benefit of patients, and that the employee has clear guidance on individual responsibilities with the PGD process.

The law is clear that the majority of care should be provided on an individual, patient-specific basis, and that the supply and administration of medicines under PGDs should be reserved for those situations where this offers an advantage for patient care (without compromising safety), and where it is consistent with appropriate professional relationships and accountability. This means that PGDs must only be used to supply and/or administer prescription only medicine (POM) to homogeneous patient groups where presenting characteristics and requirements are sufficiently consistent for them to be included in the PGD.

Practitioners using medicines under the terms of a PGD must have completed the PGD Training Tracker (Ref 10) and be in possession of a signed statement of competency to do so and act in accordance with their professional body.

A senior person in each clinical area will be designated with the responsibility to ensure that only fully competent, registered and trained professionals operate within PGDs.

Services using PGDs will ensure that appropriate training is undertaken via the Academy Training Tracker for healthcare professionals using PGDs, including bank workers. Any eligible professional using a PGD will be named and assessed as competent to do so before they can use one, this would also include bank workers, agency workers will only be permitted to use PGD if the following criteria is met:

- The staff member has worked a minimum of 10 shifts in the area where they intend to use PGDs.
- The staff member completes the training tracker.
- The staff member is assessed as competent by the senior sister/ward manager for each PGD used.
- Competence is not transferable to other departments.

Each clinical area has a signed record of individuals named as competent and authorised to supply/administer under each PGD. Each practitioner that is deemed competent to use PGDs is authorised using the appropriate form within the document. A photocopy of this will form part of the practitioner's portfolio.

It is important that all professional groups, and their line managers, understand the scope and limitations of PGD's as well as the wider context into which they fit when designing safe, effective services for their patients.

PGDs will be formally reviewed and re-authorised every two years, and the expiry date must be included in the PGD. If no changes are made the PGD will still be peer reviewed and re-authorised by the Non-Medical Prescribing Committee. The PGD is no longer valid after the expiry date. It is therefore a requirement that when each PGD is reviewed, the designated person will review all employees signed as competent to use that new reviewed PGD as it would be updated and may have been altered. All employees will also review their competency in line with this newly reviewed PGD.

The content of the PGD will be reviewed if there are evidence-based changes to clinical practice that affect the PGD, regardless of the expiry date. If any alterations result from this then the PGD will be ratified by the Non-Medical Prescribing Committee and all designated employees and those they oversee will be informed of the changes and have their competencies reviewed if required. A new signature list will be generated with the PGD review.

In addition to patient records (Ref 2 and 3) relating to the PGD, local arrangements will be in place to retain the master copies of the PGD, lists of authorised practitioners and records of version numbers.

A PGD cannot be used for mixing two licensed medicines, unless one is an agent for the other, such as water for injection. The Medicines and Healthcare Products Regulatory Agency (MHRA) (Ref 28) has advised that where two separate products are mixed together, this results in a new, unlicensed product and therefore cannot be administered under a PGD.

If a medicine is going to be supplied to the patient to take home, the availability and / or suitability of an appropriately labelled pack will need to be taken into account. Original packs are preferred, where available, and appropriate audit trails will always be in place.

When a medicine is supplied via a PGD as a take away pack it must legally be accompanied by the patient information leaflet – even in cases where the product is being used “off-label”. When a medicine is administered, it is good practice to provide the leaflet to the patient / carer at the time of administration, although this is not a legal requirement.

All PGD usage must be audit by the manager of the department using the PDG. Audit documentation will be submitted as part of the PGD renewal process.

PGD’s must not be used for the management of long-term conditions. IN this case patients must be referred back to a prescriber for management.

PGDs are used to supply or administer medicines by the following qualified health professionals, only as named individuals MHRA 2017 (Ref 28).

- Nurses.
- Midwives.
- Dieticians.
- Occupational therapists.
- Dental hygienists.
- Dental therapists.
- Optometrists.
- Pharmacists.
- Chiropodists.
- Radiographers.
- Orthotists and prosthetists.
- Physiotherapists.
- Orthoptists.
- Podiatrists.
- Speech and Language therapists
- Paramedics.

It must be noted that Midwives, Paramedics and Podiatrists are allowed to supply and administer medicines if the professional activity fits within the exemptions in the Human Medicines Act (2012) (Ref 14) and associated statutory instruments. They may do so without the need for a prescription or patient specific written direction from a medical practitioner. If a medicine is not included in midwifery

exemptions then a PGD or a prescription or a patient-specific written direction will be required Nursing and Midwifery Council (NMC) (Ref 5) when using a PGD this Policy must be complied with.

All administration of medicines must comply with the Medicines Control and Administration Policy (Ref 4).

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 by injection) of administration (record the batch number and expiry date for vaccines, blood-derived products and other medicines if recommended by relevant national guidance)
- 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, in line with the Department of Health's advice on consent (Ref 30).

3.2 Developing a New PGD

It is important to ensure that a PGD is the most appropriate mechanism for delivery of the service in question and all options have been considered (see 2.1). Refer to PGD flow chart found on PGD Intranet page for help and support. The PGD proposal form (Appendix D) provides the opportunity to discuss the proposed PGD before submitting to the approval process. The PGD template is also available and must be used for any PGD.

When a service recognises a potential need for the supply or administration of a medicinal product, consideration must first be given to:

- The situation in which the administration or supply may be required including the type of service being delivered (see paragraphs below).
- The clinical condition being investigated or treated.
- The urgency of the administration or supply.
- The healthcare professional who may be administering or supplying the medicinal product and any prescriber status they may have.
- The potential patient characteristics.
- The legal classification of the medicinal product concerned.

In the community, the contractual context in which the PGD is to operate must also be considered; otherwise the PGD might offer a route by which the Clinical Commissioning Group could unwittingly be providing or commissioning a service in a way which conflicts with its overarching strategy and commissioning policies.

When a PGD for a particular named medicinal product is being proposed, reference must be made to national and local guidance, including but not limited to the National Institute for Health (NICE) and local formularies.

A PGD will not contradict these unless there has been more recent evidence. Each new PGD will be developed by practitioners who will be using it and involve the clinical expertise of a multi-disciplinary

group drawn largely from the service(s) that will use it. The group will usually work using email and telephone conversations rather than face to face meetings.

This group must involve:

- A Doctor.
- A Pharmacist.
- A representative of any professional group expected to use the PGD.
- A Microbiologist (if the PGD is for an antimicrobial).

Legally, PGDs must contain the following elements (Ref 8 and 28).

According to the legal requirements, a PGD must include:

- The name of the business who owns the direction
- The start and end date of the PGD
- A description of the medicine(s)
- The class of the health professional who can supply or administer the medicine
- A signature of a doctor or dentist (as appropriate) and a pharmacist
- Authorisation by an appropriate organisation
- The clinical condition or situation to which the direction applies (eg the specified condition/conditions that can be treated)
- A description of patients excluded from treatment under the direction
- A description of when the employee must get more advice from a doctor (or dentist, as appropriate) and arrangements for referral
- Details of appropriate dosage, maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, and minimum or maximum period to administer the medicine
- Relevant warnings, including potential adverse reactions
- Details of any necessary follow-up actions
- A statement of the records to be kept for audit purposes

In addition to the above, legally required elements, a PGD must state:

- The clinical care pathway, Clinical Knowledge Summary (CKS), or similar document to which it relates if appropriate.
- Specific information about the status of the medication e.g. black triangle or where the medication is being used off-label if appropriate.
- Follow-up and action to be taken in the event of adverse effects.
- Interactions.
- The service or services that will be using the PGD

Medicines supplied or administered using PGDs must normally be used within the Manufacturing Authorisation (Product License). Occasionally, use of a medicine outside its license (off-label) may reflect clinical best practice; this will be reviewed on a case by case basis per PGD. Where a PGD is developed to which this applies, the fact that it is being used outside its license must be clear and the reason for such use must be stated. Patients supplied with or administered such medicines using a PGD will be informed of the fact, its meaning and the consequences of such use, and the reason why it is considered to be the best medicine for them. Their informed consent (which may be verbal) to such off-label treatment must be obtained and documented in the clinical record.

3.3 Renewing a PGD

Prior to renewal of any PGD the ward or department lead must ensure that all relevant supporting documentation has been collated (Appendix E). The supporting documentation provides assurance that the PGD has been used in line with the policy and that its on-going use is a requirement of the service.

Once the information has been collated and the PGD has been reviewed by all key must the PGD must then be submitted back through the PGD process for consideration and renewal. Refer to PGD flow chart found on PGD Intranet page for help and support.

It is the responsibility of the author to ensure that the PGD is submitted for renewal well in advance of expiry as the process can be lengthy. Once expired employees are not permitted to use expired PGD's. The PGD administrator will contact the PGD author three months prior to expiry.

4 Protected Characteristics Provisions

No special measures required.

5 Duties and Responsibilities of Individuals and Groups

5.1 Chief Executive

The Chief Executive is ultimately responsible for the implementation of this document.

5.2 Ward Managers, Matrons and Managers for Non Clinical Services

All Ward Managers, Matrons and Managers for Non Clinical Services must ensure that employees within their area are aware of this document; able to implement the document and that any superseded documents are destroyed.

Each ward Senior Sister / Charge Nurse will be responsible for managing PGD's at ward level.

- Check on the Great Western Hospitals NHS foundation Trust (the Trust) Intranet for an overview of PGD's that are used within the ward or department. Check the final live document on the T-drive, ensure that they are within date and do not require any changes or amendments. If the Senior Sister or Charge Nurse are not the author of the PGD they must please contact the PGD administrator for advice.
- If any changes / review are required, to ensure these are processed to ensure the PGD expiry date does not pass. PGDs cannot be used beyond expiry date.
- To ensure all relevant employees are competent in the use of PGDs. That yearly updates have been completed and evidence of training and education is documented in individuals training folder.
- To ensure that each PGD is signed by the employee and that the record sheet is stored within the PGD folder.
- To complete a ward assessment declaration form (Appendix F) and return this to the PGD administrator at the start of each financial year, detailing compliance with the policy.
- To comply with Electronic Prescribing and Medicines Administration EPMA in line with any Standard Operating Procedure SOP relating to PGD's.

5.3 Document Author and Document Implementation Lead

The document Author and the document Implementation Lead are responsible for identifying the need for a change in this document as a result of becoming aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local/national directives, and resubmitting the document for approval and republication if changes are required.

5.4 Target Audience – As indicated on the Cover Page of this Document

The target audience has the responsibility to ensure their compliance with this document by:

- Ensuring any training required is attended and kept up to date.
- Ensuring any competencies required are maintained.
- Co-operating with the development and implementation of policies as part of their normal duties and responsibilities.
- Assess use of PGD in line with scope of practice.
- Complete the training tracker and PGD competency.
- Discuss with line manager and ensure that competency has been signed off (initial assessment).
- Complete yearly update via training tracker.
- Provide evidence at appraisal and one to one of on-going professional development in relation to medicines management specific to the scope of practice.
- To sign each individual PGD within the master file to be kept at ward level.
- To ensure each PGD is referred to at the point of delivery.
- To ensure appropriate and contemporaneous documentation as per Clinical Record Keeping Policy (Ref 2) and NMC Code (Ref 6).
- To ensure that all supporting training is complete and up to date (e.g. anaphylaxis).

5.5 PGD Authorisation

NICE Guidance (Ref 13) states that: ‘A senior person in each profession should be designated with the responsibility to ensure that only fully competent, qualified and trained professionals operate within directions.

5.6 Lead Doctor

The role of the lead doctor when signing the PGD is to takes responsibility and accountability for the accuracy of the clinical content of the PGD.

5.7 Lead Pharmacist (Deputy Director of Pharmacy)

When signing the PGD, the pharmacist takes responsibility and accountability for the accuracy of the pharmaceutical content of the PGD.

5.8 Trust Lead (Director of Pharmacy)

The authorising lead at the Trust should establish that local processes and governance arrangements have been followed and that all legal requirements have been met.

5.9 Lead Nurse / Allied Health Professional

The lead professional has the responsibility of representing professional groups and how they practice under a PGD.

5.10 PGD non-clinical Administrator

The PGD Non Clinical Administrator will:

- Will administer all aspects of PGDs including monitoring of review dates and remind employees accordingly.
- Maintain the PGD website.
- Collate E mails for all appropriate groups.

5.11 Non-Medical Prescribing Committee

The Committee will be responsible for the final ratification of all PGDs. The Committee does not formally meet and as such correspondence and review of PGD's is via email or hard copy of the document.

6 Monitoring Compliance and Effectiveness of Implementation

The arrangements for monitoring compliance are outlined in the table below: -

Measurable policy objectives	**Monitoring / audit method**	**Monitoring responsibility** (individual / group /committee)	**Frequency of monitoring**	**Reporting arrangements** (committee / group to which monitoring results are presented)	**What action will be taken if gaps are identified?**
Annual review of PGD usage within each department for each current PGD	Ward/department on-going audit	PGD committee	At presentation for each new PGD or each renewal	Medicines Assurance Committee	Suspension of PGD until adequate audit evidence is supplied.

7 Review Date, Arrangements and Other Document Details

7.3 Review Date

This document will be fully reviewed every three years in accordance with the Trust's agreed process for reviewing Trust -wide documents. Changes in practice, to statutory requirements, revised professional or clinical standards and/or local/national directives are to be made as and when the change is identified.

7.4 Regulatory Position

- British Association of Occupational Therapists (Ref 15).
- British Association of Prosthetists and Orthotists.(Ref 16).
- British Dietetic Association (Ref 17).
- British Society of Dental Hygiene and Therapy (Ref 18).

- Chartered Society of Physiotherapists (Ref 19).
- College of Paramedics.(Ref 20).
- Department of Health (Ref 21).
- General Pharmaceutical Council (Ref 22).
- Nursing and Midwifery Council (Ref 23).
- Royal Pharmaceutical Society (Ref 24).
- Society of Chiropodists and Podiatrists (Ref 25).
- Society of Radiographers (Ref 26).
- The College of Optometrists.(Ref 27).
- CQC (Care Quality Commission) regulate the Trusts activity and its right to provide services.

7.5 References, Further Reading and Links to Other Policies

The following is a list of other policies, procedural documents or guidance documents (internal or external) which employees should refer to for further details:

Ref. No.	Document Title	Document Location
1	Health Records Operational Policy.	Trust-wide-documents
2	Clinical Record Keeping Policy	Trust-wide-documents
3	Retention of Records Policy	Trust-wide-documents
4	Medicines Control and Administration Policy	Trust-wide-documents
5	NMC Circular 06/2010	http://www.nmc.org.uk
6	NMC. The Code 2015	http://www.nmc.org.uk
7	NMC Standards for Medicine Management 2008	http://www.nmc.org.uk
8	Human Medicines Regulations	www.legislation.gov.uk
9	NPC Patient Group Directions 2009 A practical guide and framework of competencies for all professions using PGDs	Intranet/Internet www.npc.co.uk
10	PGD Training Tracker and Competency	Trust-wide-documents
11	National Institute for Health	https://www.nice.org.uk
12	Controlled Drug Policy	Trust-wide-documents
13	Patient Group Directions Medicines Practice Guideline	https://www.nice.org.uk
14	Human Medicine Act 2012	http://www.hpc-uk.org
15	British Association of Occupational Therapists	https://www.cot.co.uk
16	British Association of Prosthetists and Orthotists	http://www.bapo.com
17	British Dietetic Association	https://www.bda.uk.com
18	British Society of Dental Hygiene and Therapy	www.bsdht.org.uk
19	Chartered Society of Physiotherapists	www.csp.org.uk
20	College of Paramedics	https://www.collegeofparamedics.co.uk
21	Department of Health	https://www.gov.uk
22	General Pharmaceutical Council	www.pharmacyregulation.org/

Ref. No.	Document Title	Document Location
23	Nursing and Midwifery Council	www.nmc.org.uk
24	Royal Pharmaceutical Society	www.rpharms.com/
25	Society of Chiropodists and Podiatrists	www.scpod.org
26	Society of Radiographers	https://www.sor.org
27	The College of Optometrists	www.college-optometrists.org/
28	Medicines and Healthcare Products Regulatory Agency (MHRA)	https://www.gov.uk
29	Health Service Circular (HSC 2000/026)	http://webarchive.nationalarchives.gov.uk/
30	Reference guide to consent for examination or treatment	www.gov.uk
31	To PGD or not to PGD	www.sps.nhs.uk

7.6 Consultation Process

The following is a list of consultees in formulating this document and the date that they approved the document:

Job Title / Department	Date Consultee Agreed Document Contents
Divisional Director of Nursing (Nursing and Midwifery)	19th April 2018
Community Pharmacist	8th May 2018
End User – sister emergency department	28th Feb 2018
End User *anticoagulation practitioner*	26th Feb 2018
Director of Pharmacy	19th April 2018
Deputy Chief Nurse	8th March 2018
Trust Non-Medical Prescribing and PGD Lead.	22nd Feb 2018
Administration Lead for PGD	22nd Feb 2018
Deputy Director of Pharmacy	8th June 2018

Appendix A – Equality Impact Assessment

Equality Impact Assessment

Are we Treating Everyone Equally?

Define the document. What is the document about? What outcomes are expected?

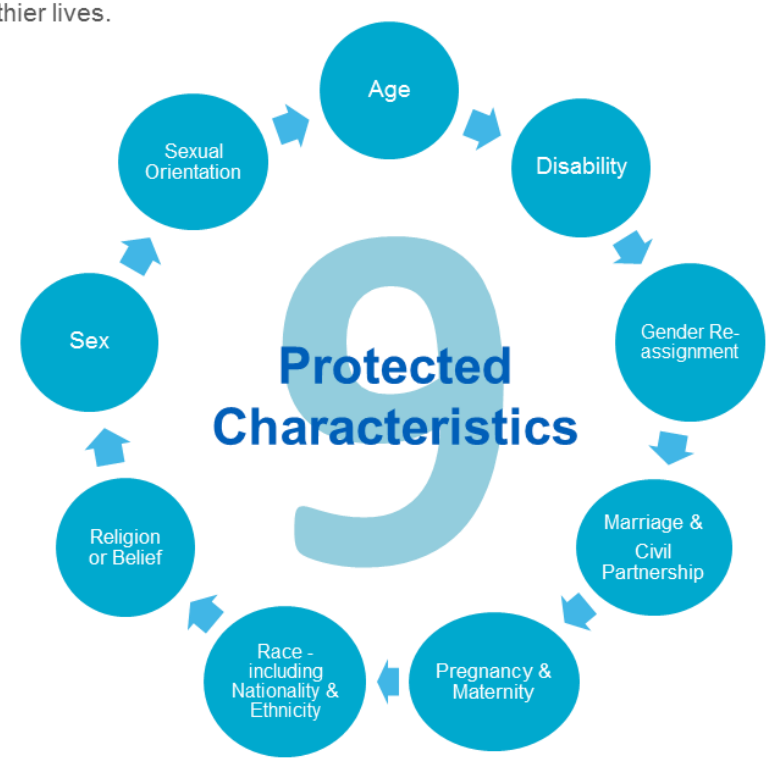
Consider if your document/proposal affects any persons (Patients, Employees, Carers, Visitors, Volunteers and Members) with protected characteristics? Back up your considerations by local or national data, service information, audits, complaints and compliments, Friends & Family Test results, Staff Survey, etc.

If an adverse impact is identified what can be done to change this? Are there any barriers? Focus on outcomes and improvements. Plan and create actions that will mitigate against any identified inequalities.

If the document upon assessment is identified as having a positive impact, how can this be shared to maximise the benefits universally?

Our Vision

Working together with our partners in health and social care, we will deliver accessible, personalised and integrated services for local people whether at home, in the community or in hospital empowering people to lead independent and healthier lives.



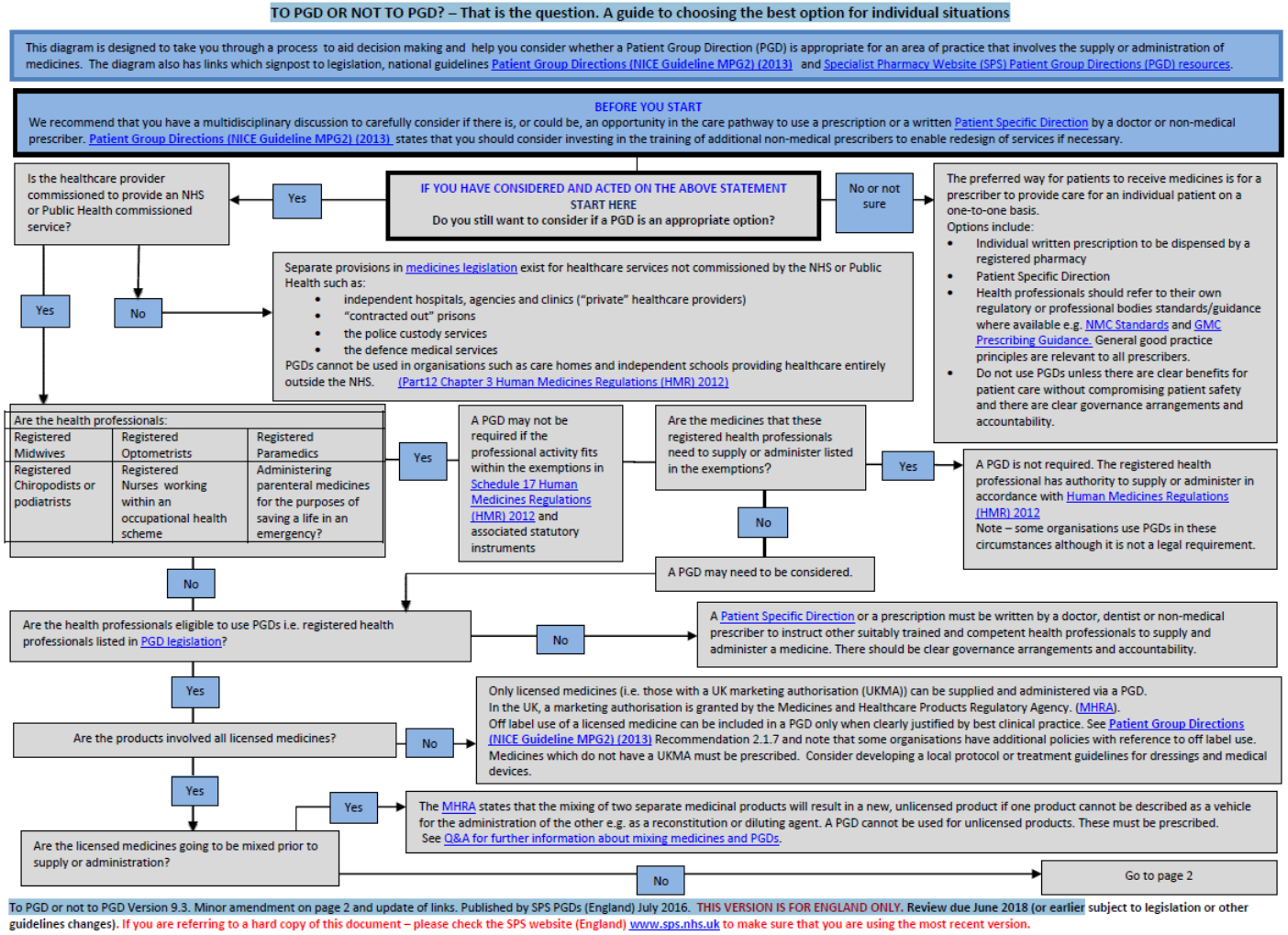
Trust Equality and Diversity Objectives

Better health outcomes for all	Improved patient access & experience	Empowered engaged & included staff	Inclusive leadership at all levels

Appendix B – Quality Impact Assessment Tool

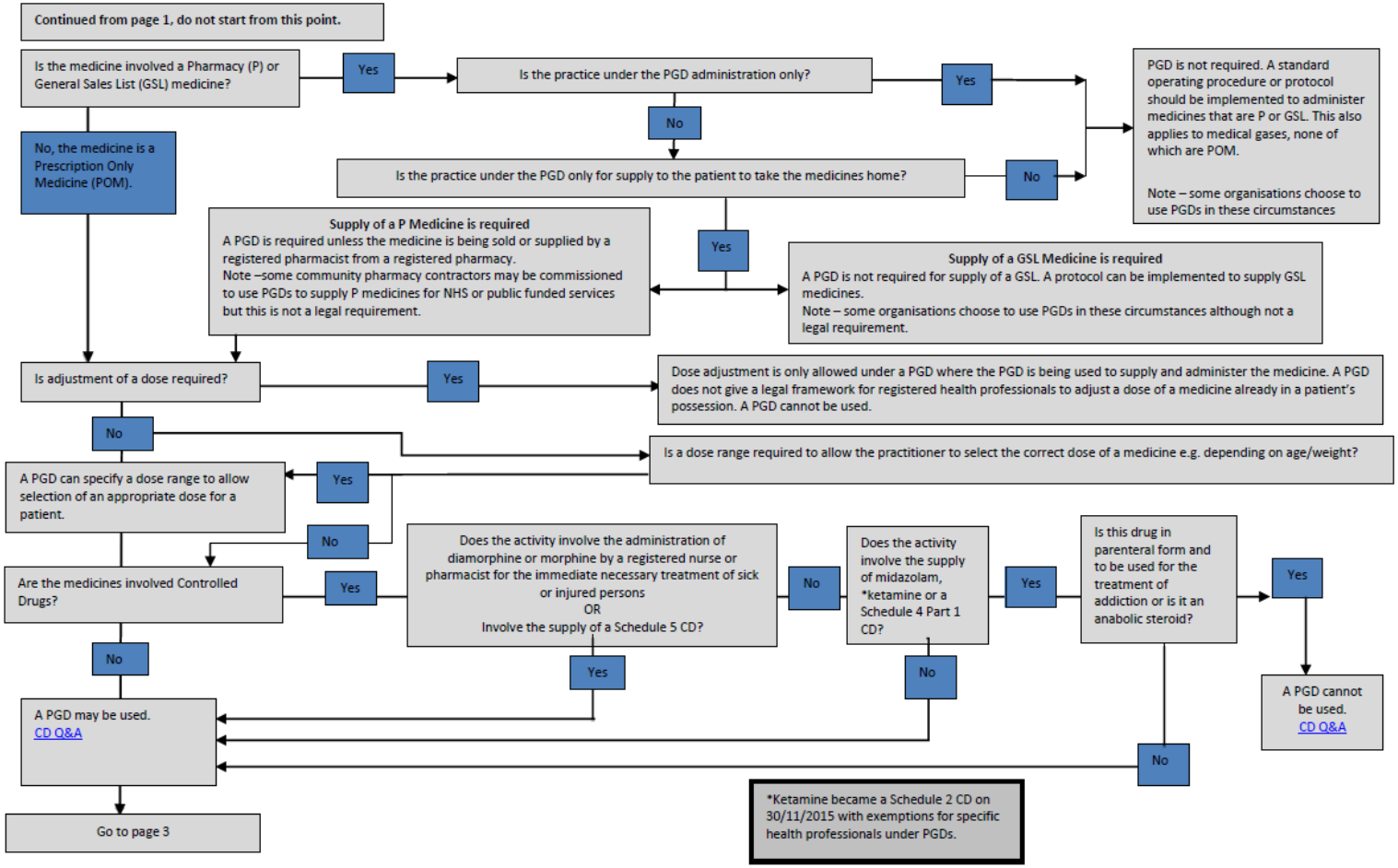
Purpose - To assess the impact of individual policies and procedural documents on the quality of care provided to patients by the Trust both in acute settings and in the community.		
Process -The impact assessment is to be completed by the document author. In the case of clinical policies and documents, this should be in consultation with Clinical Leads and other relevant clinician representatives. Risks identified from the quality impact assessment must be specified on this form and the reasons for acceptance of those risks or mitigation measures explained.		
Monitoring the Level of Risk - The mitigating actions and level of risk should be monitored by the author of the policy or procedural document or such other specified person. High Risks must be reported to the relevant Executive Lead.		
Impact Assessment Please explain or describe as applicable.		
1.	Consider the impact that your document will have on our ability to deliver high quality care.	The document is aimed at improving patient care through quicker access to treatment.
2.	The impact might be positive (an improvement) or negative (a risk to our ability to deliver high quality care).	Positive impact.
3.	Consider the overall service - for example: compromise in one area may be mitigated by higher standard of care overall.	Increase access to treatment meeting the needs of the patient.
4.	Where you identify a risk, you must include identify the mitigating actions you will put in place. Specify who the lead for this risk is.	Risk staff will inappropriate administer medication without proper training and education. Risk register number 1327
Impact on Clinical Effectiveness & Patient Safety		
5.	Describe the impact of the document on clinical effectiveness. Consider issues such as our ability to deliver safe care; our ability to deliver effective care; and our ability to prevent avoidable harm.	Increases ability to deliver safe effective care without delay.
Impact on Patient & Carer Experience		
6.	Describe the impact of the policy or procedural document on patient / carer experience. Consider issues such as our ability to treat patients with dignity and respect; our ability to deliver an efficient service; our ability to deliver personalised care; and our ability to care for patients in an appropriate physical environment.	Increase patient experience and satisfaction.
Impact on Inequalities		
7.	Describe the impact of the document on inequalities in our community. Consider whether the document will have a differential impact on certain groups of patients (such as those with a hearing impairment or those where English is not their first language).	No detrimental impact on any community services that adopt this policy.

Appendix C – To PGD or NOT PGD?



TO PGD OR NOT TO PGD? – That is the question. A guide to choosing the best option for individual situations

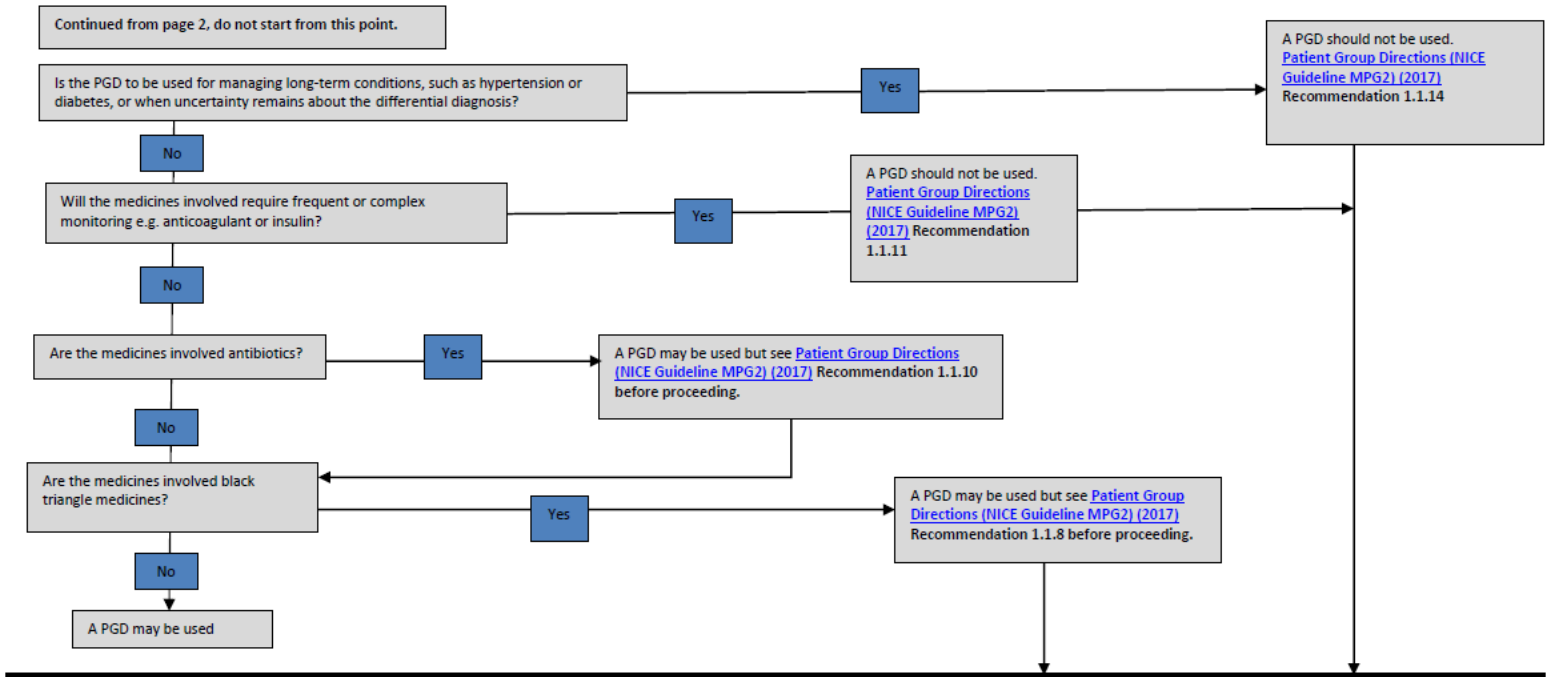
This diagram is designed to take you through a process to aid decision making and help you consider whether a Patient Group Direction (PGD) is appropriate for an area of practice that involves the supply or administration of medicines. The diagram also has links which signpost to legislation, national guidelines Patient Group Directions (NICE Guideline MPG2) (2017) and Specialist Pharmacy Website (SPS) Patient Group Directions (PGD) resources.



To PGD or not to PGD Version 9.5. Update of links. Published by SPS PGDs (England) January 2018. THIS VERSION IS FOR ENGLAND ONLY. Review due June 2018 (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.

TO PGD OR NOT TO PGD? – That is the question. A guide to choosing the best option for individual situations

This diagram is designed to take you through a process to aid decision making and help you consider whether a Patient Group Direction (PGD) is appropriate for an area of practice that involves the supply or administration of medicines. The diagram also has links which signpost to legislation, national guidelines Patient Group Directions (NICE Guideline MPG2) (2017) and Specialist Pharmacy Website (SPS) Patient Group Directions (PGD) resources.



This chart may not cover all situations proposed for using PGDs. The proposed activity should meet the principles stated in Patient Group Directions (NICE Guideline MPG2) (2017)
Supply or administration of medicines under PGD should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.

If having considered all of the above, you decide that a PGD may be an appropriate route to provide this clinical activity, also ensure that you consider other medicines legislation and clinical governance issues at each stage of the process. We recommend that you also refer to the following:

PGD Q&A – abortifacients
PGD Q&A - labelling of POMs supplied under PGD
PGD Q&A - delegation
PGD Q&A – trainee supervision
Quality PGDs -7 Steps to success and other resources such as PGD Q&As on the SPS website
Patient Group Directions (NICE Guideline MPG2) (2013) Pathway and Tools and Resources
PGD multi-disciplinary e learning package
Your local Medicines and PGD Policies

To PGD or not to PGD Version 9.5. Update of links. Published by SPS PGDs (England) January 2018. THIS VERSION IS FOR ENGLAND ONLY. Review due June 2018 (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 D – PGD Proposal Form

PGD PROPOSAL FORM

Please complete the form below electronically, which will be used to assess suitability for PGD development. The form should be completed by the intended primary author.

This form will be reviewed by the Non Medical Prescribing Committee to assess suitability for development. If approved, PGD template and relevant appendices will be sent to the primary author for completion. Do not leave any blanks on the form.

Once completed, return via e-mail to the PGD Administrator, details on the trust intranet page, please attached supporting information, electronically, that may support the PGD

Proposed Title	
Primary Author and Contact Details Name Job Title Email address	
Name of Doctor involved with PGD development Names Job Titles	
Proposed time-frame for development	

mm/yyyy for aim of completion	

Clinical Background and Medicine Details

What is the clinical situation that this PGD would be used in? State whether PGD for use to supply to patients to take home or for administration by the practitioner	
What is the current arrangement for administration or supply	
Where PGD will be used?	Setting Division
Which medications will be used? State British National Formulary (BNF) approved names(s) with strength or dose, form, frequency and treatment duration.	
Is there any written guidance supporting the medication use in the clinical area? Include brief details of local or national guidance, BNF guidance, NICE guidance	
Which patents will be included in treatment? Specify age	
Which patients will be excluded from treatment	
What is the potential number of patients that may be treated in a 6 month period Include previous audit data if known	

Supporting Information

Which professional group(s) will be using the PGD?	
How many practitioners may potentially be using this PGD?	
Are there any arrangements in place for obtaining stock and issuing the medication?	
Could the direction to administer or supply be made by a prescriber and a pharmacist? If not, why not?	
What are the perceived benefits to patient care that this PGD will provide? Attach any supporting information that will help support the proposal.	
What are the potential risks associated with this PGD? Please include any risk assessments already completed if known.	

Appendix E – PGD Audit and update Tool

Once completed, return via e-mail to the PGD Administrator, detail on the pharmacy intranet page. Pease attach any supporting information, electronically, that may be support the PGD review. Do not leave any blanks. When updates are reviewed, suitability to use a PGD in the particular clinical setting/division will also be reviewed.

A minimum of ten patient records must be audited. Records must be selected at random for sampling. Where a PGD is in use on multiple sites audit must be undertaken on each site.

Number of patients seen using this PGD	Sample Size Required
<100	A minimum of 10.
>100	5% - (minimum of 10 patients)

PGD Title PGD Number	
Date previous version of PGD approved	
Previous audit / update details	Date
	Lead Author
	Outstanding actions from previous audit
Has the lead author changed since the last version was approved?	
Lead Author and contact details	Name
	Job Title

	Email address
Audit and Update Tool completed by	Name
	Date
How many patients have been treated under this PGD since its last review	
Are all medicines being stored in accordance with the PGD?	

Authorised practitioner

	Yes / No / Please state	Supporting Information
Does the Department Manager hold a list of authorised practitioners permitted to use this PGD (appendix 1)		
How many practitioners have supplied or administered medication using this PGD since its last review.		
Has the list of practitioners that can use the PGD been reviewed?		
Are signatures up to date?		
Is a copy of the PGD available for reference when the PGD is in use?		
Have all authorised practitioner been competency assessed to use this PGD?		
Are records being completed on patient records?		

Audit of Patient Records (Complete with Y / N)

Patient Number	1 Insert No	2 Insert No	3 Insert No	4 Insert No	5 Insert No	6 Insert No	7 Insert No	8 Insert No	9 Insert No
Is the practitioner using this PGD authorised to do so?									
Has administration or supply of the medicines(s) been delegated to another practitioner									
Does the patient have a known/documented allergy to the medicines(s)									
Does the patient meet with inclusion criteria?									
Does the patient meet the exclusion criteria / contraindication?									
Was the consent obtained and clearly documented? For PGDs referring to Fraser guidelines, was this included in the consent process?									
Are there any drug interactions that were not considered resulting in the inappropriate use of the PGD									
Has the administration been documented clearly on the drug chart / EPMA / patient records? (dose, route, frequency)									
Is the in date and time of the administration and supply recorded in the notes / EPMA									
Has the supply been made using an appropriately label?									
Are details of the consultation clearly documented in the patents notes as per requirement outlined in PGD									
Is the practitioner using the PGD clearly identifiable from the entry made in the patients notes?									

Great Western Hospitals NHS
NHS Foundation Trust

Appendix F Ward/Department Declaration

Declaration to be completed by the Ward Manager / Clinical Service Manager

ANNUAL WARD / CLINICAL AREA ASSESSMENT PGD DECLARATION FORM

WARD / CLINICAL AREA ……..

CONFIRM IF PGDS DISCUSSED AT APPRISA ☐ WARD

CONFIRM IS PGDS ARE HELD ON THE ☐

PGD Number	PGD Title	PGD Expiry Date	Are all staff signed off and competent to use the PGD

Signed by…… Date ……

Print Name …… Designation ……..

ALL COMPLETED FORMS TO BE RETURNED THE
PGD ADMINISTRATOR, PHARMACY DEPARTMENT, GREAT WESTERN HOSPITAL, MARLBOROUGH ROAD, SWINDON