PATIENT GROUP DIRECTIONS (PGDs) POLICY

POLICY

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	X		
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Sponsor (Position)	Chief Nurse		
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Lead Division/ Directorate	Diagnostics & Outpatients		
Lead Specialty/ Service/ Department	Medicines Management (Pharmacy)		
Position of Person able to provide Further Guidance/Information	Clinical Pharmacy Services Manager		

Associated Documents/ Information	**Date Associated Documents/ Information was reviewed**
• Supplying medicines via Patient Group Directions (PGDs) in remote consultation SOP	May 2021
Published to Medicines Management/ Pharmacy intranet:	
• PGD Proposal Form	May 2021
• PGD Template	May 2021
• Guidance notes for producing a PGD	Oct 2017
• PGD Revalidation and monitoring framework	May 2021
Template control	June 2020

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1.0 INTRODUCTION

The preferred way for patients to receive medicines is for an appropriately qualified healthcare professional to prescribe for an individual patient on a one-to-one basis. The supply and/or administration of medicines under a PGD should be reserved for those limited situations where this offers an advantage for patient care, without compromising patient safety. The supply and/or administration of a medicine under a PGD is **NOT** a prescription or prescribing.

A Patient Group Direction (PGD) is defined as the written instruction for the supply and/or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. In simple terms, a PGD is the supply and/or administration of a specified medicine or medicines, by named, registered, authorised health professionals, to a well-defined group of patients requiring treatment for the condition described in the PGD.

Any practice requiring a PGD that fails to comply with the criteria outlined in Health Service Circular - HSC 2000/026 (and any subsequent Statutory Instruments) falls outside of the Law and could result in criminal prosecution under the Medicines Act. It is important that all staff involved with PGDs understand the scope and limitations of PGDs as well as the wider context into which they fit to ensure safe, effective services for patients.

2.0 POLICY STATEMENT

The aim of this policy is to provide a framework to ensure that development of and practice under PGDs complies with the requirement of HSC 2000/026, 9th August 2000, Patient Group Direction (England only) and associated Statutory Instruments. The current legislation for PGDs is included in The Human Medicines Regulations 2012. These outline the legal position regarding Patient Group Directions. Additionally, this policy aims to ensure compliance with Regulation 13 of the Health and Social Care Act (Regulated Activities) Regulations 2009.

The policy aims to encompass all necessary requirements for the proposal, development, review, approval and implementation of a PGD.

3.0 DEFINITIONS/ ABBREVIATIONS

Trust	Sherwood Forest Hospitals NHS Foundation Trust
Staff	All employees of the Trust including those managed by a third party on behalf of the Trust
PGD	Patient Group Direction
DTC	Drugs and Therapeutics Committee
CPD	Continuing Professional Development

4.0 ROLES AND RESPONSIBILITIES

Heads of Nursing/Section Heads/Matrons:

Development of PGD

- Considers the feasibility of a new PGD in discussion with the service lead, senior clinical pharmacist and/or clinical governance lead.
- Identifies and agrees a suitably competent Lead Author to develop a new PGD, who is a lead practitioner in the area in which the PGD is to be used and has at least 6 months experience within that area
- Ensures the completed PGD proposal form reflects what has been agreed in any multidisciplinary discussions
- Agrees final completed PGD proposal form and submits to divisional or specialty clinical governance committee (as appropriate) for approval.
- Informs Lead Author of clinical governance committee approval of proposal and facilitates submission of proposal to DTC.
- Provides adequate support to the Lead Author during the PGD development.
- Provides guidance to Lead Author on how appropriate monitoring of PGD will be undertaken
- Informs Clinical Pharmacy Services Manager of any change in Lead Author
- Ensures that the Lead Author has obtained full approval from all co-authors before draft PGD is submitted to DTC

Implementation and monitoring of PGD

- Once PGD is approved by DTC signs PGD on behalf of healthcare practitioners who will use it to confirm that use by the specified group of healthcare practitioners is appropriate and within their competence
- Distributes the approved, signed PGD to all clinical areas that will use it and ensures that ward/department leads take responsibility for training all staff using the PGD
- Ensures that monitoring of the use of the PGD is undertaken in all clinical areas using the PGD
- Discusses any areas of non-compliance with Lead Author and PGD work group and assists with development and implementation of an action plan to address such issues.
- Submits action plan to appropriate clinical governance committee for comment and approval
- Implements action plan

Lead Author:

Development of PGD proposal

- Agrees to lead on the development of the PGD and commence Stage 1 PGD Proposal
- Identifies members of the PGD work group and supports the PGD proposal process within specified time frames.
- Ensures that all members of the PGD work group are aware of the Trust PGD policy
- Checks the Trust intranet to identify whether a current PGD for the same medicine is available and considers adapting relevant content. This will help reduce duplication of effort and minimise any conflict in service delivery.
- Completes the PGD proposal in consultation with Head of Nursing/Section Head and PGD work group members who will support the development and implementation of the PGD.

- Provides sufficient detail in the PGD Proposal as evidence to DTC that a PGD is an appropriate method for supply and/or administration of this medicine in this care setting.
- Ensures completed PGD proposal form reflects what has been agreed in any multidisciplinary discussions
- Submits proposal to appropriate divisional/specialty clinical governance committee
- On receipt of approval from local clinical governance committee, submits proposal to DTC via Clinical Pharmacy Services Manager who acts as secretary to DTC
- On receipt of any comments from DTC about the proposal, consults with PGD work group and provides response to DTC on behalf of the group within one month of receipt of comments.
- On receipt of DTC approval proceeds to Stage 2 Development of PGD.

Development of full PGD

- Writes the PGD using the agreed template and following appropriate guidance with support of the PGD work group members. Ensures that all relevant guidance e.g. 'Green book' for vaccines, NICE has been considered
- Ensures the PGD meets with all requirements specified in the Trust Medicines Policy
- Ensures that any patient information leaflets developed alongside the PGD have Trust approval
- Liaises with Pharmacy to ensure that pre-packed medicines are available where necessary
- Submits draft PGD to DTC for approval
- Responds to any comments from DTC and ensures that any amendments requested are actioned in a timely manner
- Ensures that all members of the PGD work group are consulted at all stages.

Implementation and monitoring of PGD

- Monitors national/local guidance on ongoing basis to ensure that PGD is updated when necessary prior to expiry date
- Reviews monitoring results along with Head of Nursing/Section Head and PGD work group members. Assists in producing action plan to address any non-compliance.
- Completes revalidation review of PGD and amends PGD as necessary
- Submits updated PGD to DTC for revalidation

Senior Clinical Pharmacist

- Ensures the medicine(s) proposed for inclusion in the PGD has a full market authorisation and is consistent with local formulary and other medicines policies.
- Advises on completion of formulary request and/or off licence use of product and supporting Trust procedures where relevant
- If the medicine is going to be supplied as a pack to take out, advises on availability and/or suitability of an appropriately labelled pack and ascertains the financial viability based on potential quantities that will be used.
- Seeks advice from Pharmacy Clinical Governance Group if required.
- Supports lead author and comments on the proposal within agreed timeframes
- Ensures completed PGD proposal form reflects what has been agreed in any multidisciplinary discussions
- Provides pharmacy advice and support to ensure that the medicines content of the PGD is legal and accurate and that the framework for the supply and/or administration of the medicine is safe.
- Ensures that where a medicine is to be supplied to a patient to take away, appropriately labelled packs will be available.

- Advises on legality of PGD, seeking support from Pharmacy Clinical Governance Group when needed.
- Ensures a suitable manufacturer's PIL and/or a relevant Trust approved PIL is available for issue to the patient at the time of supply and/or administration of the medicine.
- Ensures PGD revalidation and monitoring framework is completed and PGD amended as required

Consultant Doctor

- Ensures that there has been full and careful consideration of all the potential methods of supply and/or administration of medicines, including prescribing by medical or nonmedical prescribers, before agreeing to the PGD proposal.
- Supports lead author to ensure all relevant clinicians are aware of the PGD proposal and are consulted during the proposal period as necessary.
- Comments on the proposal within agreed timeframes
- Ensures completed proposal form reflects what has been agreed in any multidisciplinary discussions
- Provides medical advice and support to ensure clinical accuracy of the PGD and that local and national guidelines are considered.
- Ensures PGD revalidation and monitoring framework is completed and PGD amended as required

Specialist co-authors

- Supports lead author to ensure all relevant clinicians are consulted during the proposal period.
- Comments on the proposal within agreed timeframes
- Ensures completed proposal form reflects what has been agreed in any multidisciplinary discussions
- Provides relevant advice and support to ensure clinical accuracy of the PGD and to ensure specific issues for that speciality or their area of practice are considered e.g. microbiology, virology.
- Ensures PGD revalidation and monitoring framework is completed and PGD amended as required

Trust Medicines Safety Officer:

- Reviews PGD proposals to ensure that all clinical governance arrangements have been considered
- Signs approved PGDs to verify that clinical governance arrangements are explicit and lines of accountability are clear

DTC chair:

- Signs all PGDs approved by DTC to verify that the clinical content is accurate, evidence based and safe for the patient group specified

DTC secretary:

- Ensures all PGD proposals are reviewed by DTC in a timely manner
- Informs Lead Author of approval or otherwise of PGD proposal
- Ensures all draft PGDs are reviewed by DTC in a timely manner
- Signs all PGDs approved by DTC to verify that all information relating to the specified medicine(s) is accurate, current and evidence based. All indications should be covered within the medicine SPC unless specifically stated within the PGD
- Informs Lead Author of DTC decisions regarding PGD approval

- Publishes all approved PGDs to the Trust intranet
- Ensures training records for staff using PGDs are maintained within Pharmacy
- Ensures PGD revalidation and monitoring framework has been completed before PGD is submitted to DTC for revalidation

DTC committee members:

- Review all proposals for new PGDs ensuring that they offer an advantage for patient care, without compromising patient safety, and that there are clear governance arrangements and accountability.
- Review all draft PGDs ensuring that all legal requirements are met and that all details relating to the medicine use are evidence based. Also ensure that
    - The practitioners specified on the PGD are legally allowed to use PGDs
    - The medicine specified is licensed in the UK
    - Any 'off label' use of a medicine or use of a black triangle medicine is within current best practice
    - Any controlled drugs are legally allowed on a PGD
    - Antimicrobials are only included when approved by microbiology
    - The medicine specified does not required frequent dose alterations e.g. insulin
    - The PGD is not being used to manage long term conditions e.g. hypertension

Ward/department lead:

- Ensures that all members of their staff using a PGD have completed the training specified in this policy
- Ensures that all trained members of staff have signed the PGD
- Countersigns their staff signatures on each PGD in use
- Ensures that evidence of successful completion of training is filed in the individual staff personnel files.
- Ensures that a copy of the signed PGD is available in all clinical areas where it will be used
- Ensures that any new members of staff are trained and that signatures on PGDs are updated as necessary
- Ensures that PGDs are not used past their expiry date
- Completes a revalidation and monitoring framework for each PGD in use in their clinical area one year prior to the expiry date of the PGD. This process will be led by the Head of Nursing/Section Head.

PGD user

- Read Trust Policy for the use of Patient Group Directions
- Read any guidance provided by relevant professional body on use of PGDs
- Complete PGD training & competency framework for all PGDs used and discuss with ward/dept leader
- Ensure that PGD is always in date before use. Never use a PGD past its expiry date

5.0 APPROVAL

This policy has been approved by the Trust's Drugs & Therapeutics Committee.

6.0 DOCUMENT REQUIREMENTS (POLICY NARRATIVE)

6.1. Consideration of the need for a PGD

You must consider how a patient will receive their medicines in the service or pathway and whether a PGD is safe and legal. A PGD should only be developed after careful consideration of all the potential methods of supply and/or administration of medicines, including prescribing by doctors, dentists or nonmedical prescribers.

PGDs are intended to allow improved access to medicines, particularly in the "see and treat" services, where there is a complete episode of unscheduled care e.g. family planning/sexual health clinics/Minor Injury Units. 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. A PGD must only be used in exceptional circumstances, where its use will lead to an improvement in patient care.

PGDs have very specific limitations to their use as well as advantages. Points to consider:

- Only medicines with a UK Marketing Authorisation can be supplied and/or administered under a PGD. Use of medicines outside of licensed indications i.e. off label is allowed in PGD legislation but must also have Trust approval.Not all healthcare professionals can supply and/or administer medicines using PGDs.
- The act of supply and/or administration cannot be delegated to another health professional under a PGD
- PGDs are not appropriate for the management of long-term conditions
- PGDs are not suitable for use in clinical areas with a high number of temporary/agency staff
- PGDs are not suitable for use in clinical areas where it will be difficult to monitor the use of the PGD
- Significant dedicated resource is required from a number of highly qualified, competent staff who should work as a multi-disciplinary team to propose, develop and review PGDs

For further information, and to help decide whether a PGD is the safest option, legal frameworks and associated guidance can be accessed via the national PGD website. This is an essential reference source and knowledge base for managers and clinicians alike. Use of the PGD website resources during development of a PGD will help ensure that PGD content and subsequent practice is appropriate and legal. Recommended tools to support decision making, particularly when considering if a PGD is appropriate include:

- To PGD or not to PGD?

6.2. Outline of the stages for the proposal, development, approval, implementation and review of PGDs

There are five stages to be considered within this policy.

- Stage 1 Proposal
- Stage 2 Development and submission
- Stage 3 Approval
- Stage 4 Implementation, management and monitoring
- Stage 5 Review and re-submission

These stages are summarised as a flow chart below.

Stage 1: Proposal Agree need for PGD within clinical area Identify work group to develop PGD including Lead Author Complete PGD Proposal Form Obtain clinical governance approval at appropriate level (Trust, division, specialty) Submit to DTC for approval Once DTC approval is obtained progress to next stage
Stage 2: Development & submission Lead Author works with PGD work group to develop draft of PGD using PGD Template Submit to DTC for approval
Stage 3: Approval DTC will discuss PGD PGD will either be approved with minor amendments or rejected if major amendments are required Rejected PGDs can be resubmitted once amendments have been made by Lead Author Approved PGDs will be amended and signed PGDs will be given a 2 or 3 year expiry
Stage 4: Implementation, Management & Monitoring Copies of signed PGD will be disseminated to all relevant wards/departments through Heads of Nursing/Section Heads Appropriate practitioners will be trained and authorised Completed competency frameworks will be returned to Pharmacy Admin with copy of signed PGD(s) PGD will be implemented into practice Plan will be developed for monitoring List of authorised practitioners will be maintained
Stage 5: Review & Resubmission Twelve months before expiry commence monitoring & review using PGD audits on AMaT https://sfh.amat.co.uk/login.php. Led by Head of Nursing/Section Head PGD working group should consider results of review & any appropriate actions needed Six months before expiry consider if PGD is still required If not, notify DTC secretary If yes, update PGD and submit to DTC four months before expiry with results of monitoring

6.3. PGD Development and Approval

There are three stages of PGD development and approval:

- Stage 1 Proposal – section 4.3.1
- Stage 2 Development and submission – section 4.3.2
- Stage 3 Trust Approval – section 4.3.3

6.3.1. Stage 1: Proposal

Before a PGD is written, a proposal must be developed 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. The feasibility of using a PGD should be considered by the Head(s) of Nursing/Section Head or their nominated deputy (e.g. nurse consultant, matron, specialist clinical lead), a specialist clinical pharmacist and/or the clinical governance lead prior to commencing the formal PGD proposal process. If the PGD is to be used across multiple divisions then representatives from all relevant divisions must be involved at all stages.

The Trust intranet should be checked for any PGDs for the same medicine(s) currently approved within the Trust. If similar PGDs are already approved, further discussions could take place to determine whether it is possible to review an existing PGD to include the new service rather than develop a new PGD. If this is the case, discuss how to proceed with the lead author and Head of Nursing of the existing PGD which may require review and re-approval. It may be necessary to develop a new PGD but it may be possible to use some of the clinical content of an existing PGD to save time and resource. In this case, proceed with PGD proposal stage. Once it is decided to proceed the Head of Nursing or Section Head should appoint a Lead Author to complete the PGD proposal form and subsequently develop the PGD. They should also assist the Lead Author to put together a PGD workgroup who will help complete the initial proposal form and once this is approved assist with developing the PGD.

The PGD workgroup can be as large or as small as required. Members of the PGD workgroup should consist of the following:

- Lead author
- Nominated deputy for Head of Nursing/Section Head
- Consultant doctor
- Senior Clinical Pharmacist
- Consultant Microbiologist - if PGD includes antibiotic/antiviral/vaccines.
- Other specialist co-authors who may be a registered healthcare professional to be involved in PGD development or practice whose profession is not represented by other authors (if required)

All members of the PGD workgroup should be employed on a permanent contract with the Trust and it is advised that they should not become involved if they are knowingly about to terminate employment within six months of the proposal. If there is no specialist clinical pharmacist assigned to the speciality, the Head of Nursing or their nominated deputy should contact the Clinical Pharmacy Services Manager to discuss support required.

Any extension to professional roles with regard to supply and/or administration of medicines must take into account the need to protect patient safety, ensure continuity of care and safeguard patient choice and convenience. It also has to be cost effective and bring demonstrable benefits to patient care.

Once the PGD proposal form is complete it should be submitted to the appropriate clinical governance committee (Trust, division or specialty) for approval and the clinical governance lead should sign the proposal form. It should also be signed by the lead author, lead consultant and Head of Nursing/Section Head. The form should then be submitted to the Clinical Pharmacy Services manager (DTC secretary) for submission to DTC for approval.

The DTC will use a designated checklist to ensure all PGD proposals are reviewed stringently. Ideally the lead author should attend DTC to put forward their proposal. The lead author will be informed of the DTC decision within two weeks of the meeting. If DTC rejects a PGD proposal the lead author can appeal the decision within three months. Further evidence must be provided in support of the proposal and the lead author must attend the DTC meeting when the appeal is discussed.

6.3.2. Stage 2 Development and Submission

It is the responsibility of the Head of Nursing/Section Head to oversee the implementation of Trust approved PGDs and to ensure they are developed, implemented and monitored according to this policy. A named nominated deputy may be designated to support this role e.g. nurse consultant, matron or clinical nurse specialist. This nominated deputy will have been named within the PGD proposal documentation and may need to refer to Head of Nursing/Section Head responsibilities and associated duties within this policy.

The responsibilities of management and each member of the multidisciplinary team (MDT) are listed above. Any practice requiring a PGD that fails to comply with the specified criteria could fall outside of the Law and could result in criminal prosecution under the Medicines Act.

Where a lead author leaves the Trust, the Head of Nursing/Section Head must nominate a new lead author in the same or similar post to undertake relevant responsibilities and duties. Where a co-author leaves the Trust, the lead author must liaise with the new post-holder or the relevant manager to discuss the PGD and any relevant responsibilities and duties. 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.

All authors should 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.

On receipt of the DTC approval of the PGD proposal the PGD work group should agree an action plan to fully develop the PGD and agree individual responsibilities within this plan. With the assistance of the work group the lead author should write the PGD using the template downloaded from the intranet or obtained from the Clinical Pharmacy Service Manager. Guidance notes to assist with this can also be found on the intranet. Any questions that the work group cannot resolve should be directed to the Clinical Pharmacy Services Manager.

Once the draft PGD is complete it should be submitted to the Clinical Pharmacy Services Manager who will ensure it is added to the next DTC agenda.

The PGD will either be approved with minor amendments or rejected if major amendments are required. Approved PGDs will be amended if necessary by the DTC secretary, signed and given a two or three year expiry date. If the PGD is rejected the lead author must review the PGD in light of the DTC comments and resubmit to the next DTC meeting.

6.3.3. Stage 3 Trust Approval

A PGD is not legal or considered to be Trust approved for use until all Trust signatures are obtained.

Pharmacy manages this stage and obtains all appropriate signatures on the approved PGD. The Lead Author will be informed in writing when the approved final document has been uploaded on the intranet for implementation.

Approved PGDs are allocated a DTC reference number and given an expiry date two or three years after the date of DTC approval. The approved PGD will also specify a review date which is the latest date by which the PGD must be submitted to DTC for re-approval if it is to remain in use.

6.4. PGD Implementation

PGDs must never be printed off the Trust intranet. Requests for signed copies must be made through Pharmacy.

On receipt of the signed PGD ward/department leads should ensure that all individuals who will use the PGD must complete appropriate training if not already done as described in section 5 below. Once the ward/department lead is satisfied that the individual has completed the training required in relation to the PGDs they will use they must ensure that the individual signs each PGD and they themselves must countersign the PGD to authorise that individual to use the PGD. Any training records should be kept in the individuals personnel file.

If a new PGD is implemented in a designated clinical area at a later date then all members of staff must be trained and assessed as competent against the new PGD using the process outlined above.

PGD implementation and training should also include consideration for supplying medicines via PGDs following remote patient consultation as per the relevant procedure.

6.5. PGD Monitoring and Review

The use of all PGDs must be monitored before revalidation of a PGD can be requested, using the PGD audit tools on The Audit Management and Tracking (AMaT) system (PGD staff records and PGD patient records) https://sfh.amat.co.uk/login.php . It is recommended that this process is commenced at least 12 months prior to the expiry date of the PGD. The Head of Nursing/Section Head should lead this process. Every clinical area using the PGD should complete the audit.

Every member of staff listed on the PGD must be evaluated within PGD staff records on AMaT.

In addition, a sample of ten sets of patient records must be reviewed for each PGD in use. These records can be collected consecutively for ease of data collection. This is known as 'convenient sampling'. All results must be entered into PGD patient records on AMaT.

Once these audits are completed the Head of Nursing/Section Head should be informed. The results should then be reviewed by the Lead Author and PGD work group members in discussion with the Head of Nursing/Section Head, and a clear action plan completed and put in place to deal with any areas of non-compliance. The action plan should be submitted to the appropriate clinical governance committee for approval. The PGD work group should then complete the 'Revalidation review' paperwork and any appropriate amendments made to the PGD prior to resubmission to the DTC for revalidation. The revalidation review form and amended PGD should then be submitted to the DTC for consideration. This should be done at least four months prior to the expiry date to allow time for discussion and sign off. If this is not done the PGD will be removed from use in that clinical area.

At this point it may be necessary to select new members for the PGD work group or even a new Lead Author if there have been staff changes. It is important that any such changes are noted on the updated PGD when it is submitted to the DTC.

6.6. Reissue of an updated PGD

Updated PGDs will be discussed, approved and implemented as described previously. A training pack does not need to be completed again for existing staff unless there are concerns around competence. New members of staff will require full training. As previously discussed once the ward/department lead has updated their staff the PGD should be signed by individuals and countersigned by the ward/department leader.

7.0 MONITORING COMPLIANCE AND EFFECTIVENESS

Minimum Requirement to be Monitored (WHAT – element of compliance or effectiveness within the document will be monitored)	Responsible Individual (WHO – is going to monitor this element)	Process for Monitoring e.g. Audit (HOW – will this element be monitored (method used))	Frequency of Monitoring (WHEN – will this element be monitored (frequency/ how often))	Responsible Individual or Committee/ Group for Review of Results (WHERE – Which individual/ committee or group will this be reported to, in what format (eg verbal, formal report etc) and by who)
Adherence to process specified in Policy for developing new PGDs	Clinical Pharmacy Services Manager	Completion of Trust PGD proposal by lead author	As needed	PGD proposal presented to Drug and Therapeutics Committee on designated paperwork. Outcome recorded in minutes
Adherence to process specified in Policy for approval of new PGDs	Clinical Pharmacy Manager	Completion of PGD template by lead author	As needed	PGD template presented to Drugs and Therapeutics Committee on designated paperwork. Outcome recorded in minutes.
Adherence to process for revalidation and review of existing PGDs	Dept/ward lead in all clinical areas using PGDs	Completion of Trust PGD review paperwork	Continuous. All PGDs have expiry of 2 or 3 years and are reviewed prior to that date.	PGD review presented to Drugs and Therapeutics Committee on designated paperwork. Outcome recorded in minutes.
Errors reported	All clinical staff using PGDs are responsible for reporting errors on Datix. Trust Medicines Safety Officer is responsible for raising such Datix reports with DTC.	Datix	As reported	Details of Datix reports will be presented to Drugs and Therapeutics Committee will review as they occur. Outcome of discussions will be recorded in minutes.

8.0 TRAINING AND IMPLEMENTATION

All staff involved in development, approval, implementation or monitoring of PGDs at any level must have completed the following and documented this within their CPD:

- Read the Trust Policy for the use of Patient Group Directions
- Read the Trust Medicines Policy, Section 5 Storage of Medicines and Section 11 Administration of Medicines
- Read any guidance issued by their relevant professional body e.g. General Pharmaceutical Council, Royal College of Nursing, Health and Care Professions Council

In addition the Lead author should demonstrate:

- Evidence of successful completion of Trust Drugs Administration Assessment.
- An understanding of the various service delivery options including prescribing and PGDs
- An understanding of the legal framework relating to PGDs
- An understanding of document and version control.

The Head of Nursing/Section Head is responsible for ensuring that the Lead Author has demonstrated an appropriate level of knowledge and competency.

All users of PGDs must complete the PGD training pack provided by the Trust. Evidence of successful completion will be kept in their personnel file. The individual will not be authorised to use the PGD until this has been completed. Ward/department leads will be responsible for ensuring the training is completed. This training is mandatory. Users must also complete any in-house training on the individual medicines specified in the PGD prior to use.

9.0 IMPACT ASSESSMENTS

- This document has been subject to an Equality Impact Assessment, see completed form at Appendix A
- This document is not subject to an Environmental Impact Assessment

10.0 EVIDENCE BASE (Relevant Legislation/ National Guidance) AND RELATED SFHFT DOCUMENTS

Evidence Base:

- Patient Group Directions. NICE Medicines Practice Guidance March 2017 https://www.nice.org.uk/guidance/mpg2
- National PGD website (hosted by specialist pharmacy services)
- MHRA Patient Group Directions in the NHS http://www.mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribingsellingandsupplyingofmedicines/ExemptionsfromMedicinesActrestrictions/PatientGroupDirectionsintheNHS/index.htm
- HSC 200/026: Patient Group Directions (England only); Department of Health, Health Service Circular 9th August 2000
- Human Medicines Regulations 2012 SI 1916
- Health and Social Care Act 2008 (Regulated Activities) Regulations 2009

Related SFHFT Documents:

- None

11.0 KEYWORDS

pharmacy; medicine; medication; SOP; supplying medicines in remote consultation; standard operating procedure

12.0 APPENDICES

- Appendix A – Equality Impact Assessment Form

APPENDIX A – EQUALITY IMPACT ASSESSMENT FORM (EQIA)

Name of service/policy/procedure being reviewed: Patient Group Directions (PGDs) Policy			
New or existing service/policy/procedure: Existing			
Date of Assessment: 24/05/2021			
For the service/policy/procedure and its implementation answer the questions a – c below against each characteristic (if relevant consider breaking the policy or implementation down into areas)			
Protected Characteristic	**a) Using data and supporting information, what issues, needs or barriers could the protected characteristic groups' experience? For example, are there any known health inequality or access issues to consider?**	**b) What is already in place in the policy or its implementation to address any inequalities or barriers to access including under representation at clinics, screening?**	**c) Please state any barriers that still need to be addressed and any proposed actions to eliminate inequality**
The area of policy or its implementation being assessed:			
Race and Ethnicity	None	None	None
Gender	None	None	None
Age	None	None	None
Religion	None	None	None
Disability	None	None	None
Sexuality	None	None	None
Pregnancy and Maternity	None	None	None
Gender Reassignment	None	None	None
Marriage and Civil Partnership	None	None	None
Socio-Economic Factors (i.e. living in a poorer	None	None	None

neighbourhood / social deprivation)			

What consultation with protected characteristic groups including patient groups have you carried out?

- This policy does not impact on any protected characteristic groups

What data or information did you use in support of this EqIA?

- None applicable

As far as you are aware are there any Human Rights issues be taken into account such as arising from surveys, questionnaires, comments, concerns, complaints or compliments?

- No

Level of impact

From the information provided above and following EQIA guidance document Guidance on how to complete an EIA (click here), please indicate the perceived level of impact:

Low Level of Impact

For high or medium levels of impact, please forward a copy of this form to the HR Secretaries for inclusion at the next Diversity and Inclusivity meeting.

Name of Responsible Person undertaking this assessment: Mark Clymer, Clinical Pharmacy Services Manager

Signature:

Date: 24/05/2021