Policy Number	SA50

COVID-19 DOCUMENT CHANGE FORM

NHS Mersey Care NHS Foundation Trust
Community and Mental Health Services

In light of the COVID-19 outbreak it has been necessary to make temporary changes to this Policy Document. Therefore when reading the policy document please take account of the changes highlighted in Part B and C of this form.

PART A – INFORMATION ABOUT THIS POLICY DOCUMENT

Policy Name	**The Management of Patient Group Directions**				**Reference No**	**SA50**	
Executive Lead *(Trust-wide policies)*	**Executive Director of Nursing and Operations**						
Chief Operational Officer *(Clinical Division policies)*							
Policy Document *(Tick only one)*	Trust-wide (Board approved)	☐	Trust-wide (Executive Director approved)	☒	Secure & Specialist Learning Disabilities Division	☐	
	Community Division	☐	Local Division	☐			
Type of Policy *(Tick only one)*	Clinical Policy	☒	Non-clinical Policy	☐			
Clinical Policy Only *(Tick only one)*	Minor Change *(Not referred to the Clinical Cell)*	☒	Major Change *(Referred to Clinical Cell, then to SCG for approval)*	☐			
Approving Body *(Tick only one)*	Board of Directors	☐	COVID-19 Strategic Coordination Group	☐	Community Division Tactical Coordination Group	☐	
	Corporate Division Tactical Coordination Group	☒	Local Division Tactical Coordination Group	☐	Secure & Specialist LD Division Tactical Coordination Group	☐	

PART B – CHANGES TO THE POLICY DOCUMENT

Section / Paragraph No	Outline of the information that has been amended in this policy document
Paragraphs 6.5 and 6.6	Normally the Patient Group Directions (PGD) Group meets monthly to consider and approve new or updated PGDs. In line with the *Arrangements and Principles for Governance Meetings* approved by the COVID-19 Strategic Coordinating Group, the meetings of the PGD Group will now be held virtually, including the review and authorisation of new or revised PGDs.

PART C – RATIONALE FOR CHANGES

Please explain why this document needs to be amended during the COVID-19 outbreak
Virtual meetings of the PGD Group will allow the virtual review and approval (where required) of the trust's Patient Group Directions In addition, the quoracy of PGD Group meetings is suspended and virtual authorisation will be sought by the PGD Lead Pharmacist from the signatories directly. These are temporary measures to facilitate the review and authorisation of PGDs, ensuring no disruption to services delivered via Patient Group Directions but maintaining full documentation and accountability of changes, record keeping and robust process as if the PGD meeting had taken place. This is to give assurances to organisation that risks of error have been minimised and that governance is maintained.

PART D – APPROVAL (for completion by officer loading policy document onto intranet / website)

Date Referred to the Clinical Cell *(Clinical Policies only)*	
Date Referred by the Clinical Cell to the SCG *(Clinical Policies only)*	
Date Approved by the Approving Body	14 April 2020
Date Circulated to Relevant Staff	14 April 2020
Date Published on the Divisional Intranet / Trust Website	14 April 2020

Policy Number	SA50

COVID-19 DOCUMENT CHANGE FORM

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NHS
Mersey Care
NHS Foundation Trust

Community and Mental Health Services

TRUST-WIDE NON-CLINICAL POLICY DOCUMENT

The Management of Patient Group Directions

Policy Number:	**SA50**
Scope of this Document:	**All Registered Staff**
Recommending Committee:	**PGD Group**
Approving Committee:	**Executive Committee**
Date Ratified:	**May 2019**
Next Review Date (by):	**May 2022**
Version Number:	**Version 2**
Lead Executive Director:	**Executive Director of Nursing & Operations**
Lead Author(s):	**PGD Lead**

TRUST-WIDE NON-CLINICAL POLICY DOCUMENT

2019 – Version 2

Striving for Perfect Care and a Just Culture

TRUST-WIDE NON-CLINICAL POLICY DOCUMENT

The Management of Patient Group Directions

Further information about this document:

Document name	**SA50 Management of Patient Group Directions**
Document summary	**To provide staff with direction and clarity around developing, reviewing, authorising and working to Patient Group Directions**
Author(s) Contact(s) for further information about this document	**Hillary Smith** **PGD Lead** **Telephone: 0151 295 3633** **Email: Hillary.Smith@merseycare.nhs.uk**
Published by Copies of this document are available from the Author(s) and via the trust's website	**Mersey Care NHS Foundation Trust** **V7 Building** **Kings Business Park** **Prescot** **Merseyside** **L34 1PJ** **Trust's Website www.merseycare.nhs.uk**
To be read in conjunction with	**SA03 Reporting, Managing & Review of Adverse Incidents** **SSCSD010 Overarching Medicines Policy** **SD06 Consent to Treatment Policy** **09 Vaccination and Immunisation Policy** **IT04 and IT06 Records Manual Policy** **126 WIC Handbook June 2016** **SOP130 PGD Completing PGD Training & Assessment** **SOP141 PGD Governance Reporting**
This document can be made available in a range of alternative formats including various languages, large print and braille etc	

Version Control:

		Version History:
Version 1	Original policy was a conversion from ratified guideline to give greater importance around implementation and legal aspects of Patient Group Directions	1/11/2017
Version 2	Transferred organisational ownership to Mersey Care, transfer to new template and review to ensure Trust-wide application included in document	1/2/2019

SUPPORTING STATEMENTS

This document should be read in conjunction with the following statements:

SAFEGUARDING IS EVERYBODY'S BUSINESS

All Mersey Care NHS Foundation Trust employees have a statutory duty to safeguard and promote the welfare of children and adults, including:

- being alert to the possibility of child / adult abuse and neglect through their observation of abuse, or by professional judgement made as a result of information gathered about the child / adult;
- knowing how to deal with a disclosure or allegation of child / adult abuse;
- undertaking training as appropriate for their role and keeping themselves updated;
- being aware of and following the local policies and procedures they need to follow if they have a child / adult concern;
- ensuring appropriate advice and support is accessed either from managers, *Safeguarding Ambassadors* or the trust's safeguarding team;
- participating in multi-agency working to safeguard the child or adult (if appropriate to your role);
- ensuring contemporaneous records are kept at all times and record keeping is in strict adherence to Mersey Care NHS Foundation Trust policy and procedures and professional guidelines. Roles, responsibilities and accountabilities, will differ depending on the post you hold within the organisation;
- ensuring that all staff and their managers discuss and record any safeguarding issues that arise at each supervision session

EQUALITY AND HUMAN RIGHTS

Mersey Care NHS Foundation Trust recognises that some sections of society experience prejudice and discrimination. The Equality Act 2010 specifically recognises the *protected characteristics* of age, disability, gender, race, religion or belief, sexual orientation and transgender. The Equality Act also requires regard to socio-economic factors including pregnancy /maternity and marriage/civil partnership.

The trust is committed to equality of opportunity and anti-discriminatory practice both in the provision of services and in our role as a major employer. The trust believes that all people have the right to be treated with dignity and respect and is committed to the elimination of unfair and unlawful discriminatory practices.

Mersey Care NHS Foundation Trust also is aware of its legal duties under the Human Rights Act 1998. Section 6 of the Human Rights Act requires all public authorities to uphold and promote Human Rights in everything they do. It is unlawful for a public authority to perform any act which contravenes the Human Rights Act.

Mersey Care NHS Foundation Trust is committed to carrying out its functions and service delivery in line the with a Human Rights based approach and the FREDA principles of **F**airness, **R**espect, **E**quality **D**ignity, and **A**utonomy

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1. PURPOSE AND RATIONALE

1.1 **Purpose** – a patient group direction is a legal document which allows a registered healthcare practitioner who is not a prescriber, to administer or supply a medicine flowing very specific criteria. Working outside these criteria would legally be classed as a criminal offence.

1.2 **Rationale** – PGDs allow organisations to make their services more efficient by utilising the skills of their staff and by reducing doctor consultations. They allow certain healthcare professionals who do not hold a relevant prescribing qualification to supply and/ or administer a specified medicine to a pre-defined group of patients without them having to see a prescriber.

2. OUTCOME FOCUSED AIMS AND OBJECTIVES

2.1 **Aim** - this policy is designed to provide comprehensive guidance to all staff about the processes involved in the development, review, authorisation, governance and use of patient group directions.

2.2 **Objectives** - to ensure patients receive a safe and equitable service delivery by using this document to:

a) Provide a standard for developing and implementing PGDs.
b) Provide guidance on situations when a PGD could be considered as a way of delivering services.
c) Provide a standard to staff on how to write and format PGDs, including details of criteria to be included in the document in order that the practice it supports is within the law.
d) Ensure that all documents are available as needed, are kept up to date and are duly ratified by the organisation.
e) Ensure that obsolete documents are clearly identified and archived in a way that prevents their unintended use.
f) Ensure all members of staff working for Mersey care are aware of their roles, responsibilities and limitations with respect to PGDs.

3. SCOPE

3.1 This policy is applicable to all staff working for Mersey care who are involved in the development, reviewing, authorising or monitoring of PGDs and those staff who use PGDs when in the process of patient care.

4. DEFINITIONS (Glossary of Terms)

4.1 The relevant terms and their definitions (within the context of this document) are outlined below:

Terms	Definition
Administer	To give a medication either by introduction into the body or by external application
Black Triangle Medicine	A licensed medicine which is intensively monitored and subject to special reporting arrangements for adverse reactions
Licensed medicine	A medicine that has a United Kingdom marketing authorisation
Off-label Use	Using a UK licensed medicine outside the terms of its marketing authorisation i.e. outside the defined indications, doses or routes of administration
Patient Group Direction (PGD)	A written instruction for the administration and/ or supply of a specified prescription-only (POM) or the supply of Pharmacy (P) medicines by a named, authorised, registered health professional to predefined groups of patients who may not be individually identified before presenting for treatment.
Patient Specific Direction (PSD)	A written instruction, signed by a doctor, dentist, or non-medical prescriber for a medicine to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis. Writing a PSD is a form of prescribing. PSDs can be used as an alternative to PGDs, for a group of patients, all of whom should be named on the direction. Patient Specific Directions are a direct instruction and do not require an assessment of the patient by the health care professional instructed to supply and/or administer
Staff Information Resource System (SIRS)	Is an online portal that facilitates communication across the organisation and allows staff to access and share key information that is held by the organisation such as: • Lessons learned • Best practice • Links to internal website and external websites and resources • Search functionality • Version control – a systematic way of managing changes to documents by multiple users • Alerts – alerting users when new documents have been uploaded or are due for review
Standard Operating Procedure (SOP)	Is a detailed description of a process referenced in a policy which can be used to demonstrate governance by requiring staff to sign up and agree to work by the process in order to do the procedure. It provides a legal framework for the organisation so that the liability insurance covers the actions taken.

5. DUTIES

5.1 Chief Executive

The Chief Executive has overall responsibility and accountability for ensuring that PGDs are produced and used in accordance with legislation. In Mersey Care this responsibility is delegated to a senior representative of the organisation who has **Clinical Governance** as part of their role.

5.2 Executive Director of Nursing and Operations

The Executive Director of Nursing and Operations has responsibility and accountability for ensuring that PGDs are produced and used in accordance with the Nursing & Midwifery Council's Guidelines. In Mersey Care this responsibility is delegated to the Deputy Director of Nursing.

5.3 PGD signatories

There will be 4 signatories: a senior doctor, a senior nurse, a senior pharmacist and a senior clinician whose job role includes governance. By signing the PGD, the Prescribing Doctor, the Professional Nurse lead, the Senior Medicines Management Pharmacist take accountability and responsibility for the accuracy and the correctness of the clinical and pharmaceutical content of the PGD. The Senior Clinician takes accountability and responsibility for the governance demonstrated within the document. The PGD signatories must also be members of the PGD Group.

5.4 Clinical Policies & Procedures Group

This Group is responsible for the scrutiny and approval of all clinical guidance documents produced internally and externally for use within the Trust.

5.5 PGD Group

The PGD Group has responsibility for development of new PGDs and review of existing PGDs. It will identify appropriate members of clinical teams to be involved in the multidisciplinary group to draw up the PGD once approval to proceed has been agreed or to review the PGD if it is still required.

5.6 PGD authors

The author of a PGD is accountable and responsible for their contribution to the development or review of the PGD and should have completed training around the PGD process to ensure they understand the legal implications and the boundaries of PGD use. Authors cannot sense check the final document, nor can they sign as authorised signatory.

5.7 Service Leads

a) It is the responsibility of the service or locality leads to ensure that only fully competent, qualified and trained professionals operate within PGDs. They must be assured that the individual meets the minimum requirements regarding training deemed necessary and is competent to use the PGD. The individual must have documented evidence of competence, training, knowledge, experience and continuing education relevant to the clinical conditions/situation to which the PGD applies.
b) The service lead must keep a list/database of all those authorised to practice under a PGD.

c) When a PGD is amended or updated, the service or locality lead will be responsible for ensuring that the new PGD is submitted for approval as soon as possible. All copies of the previous PGD should be destroyed and all practitioners authorised under the previous PGD should be advised of the changes and any additional training required under the new PGD. All practitioners should be provided with and sign a new copy of the PGD. It is best practice to always refer to the latest version available on the intranet as there is a risk that hard copies may be older versions which have been superseded.

5.8 Authorised Registered practitioners

a) Only a registered practitioner can work under a PGD (see Appendix 1).
b) Authorised practitioners must only undertake the extended role under PGDs in circumstances where they are competent to assess all relevant aspects of the patient's clinical condition and take responsibility for supply and administration and related decisions. They must be registered with their professional body and must always act within their professional code of conduct. They must be named and have documented evidence of competence, training, knowledge, experience and continuing education relevant to the clinical conditions/situation to which the PGD applies.
c) All authorised practitioners must understand and have read the content of the PGD and take responsibility for maintaining their clinical competencies and on-going training requirements to continue to use the PGD safely. By signing the PGD, they are acknowledging their responsibilities and stating their competencies in order to be able to work under the PGD.
d) All authorised practitioners must understand and have completed training around the PGD process to ensure they understand the legal implications and the boundaries of PGD use.
e) The extended role, with regard to administration and supply under PGDs, is not compulsory and each practitioner has the ability to exercise personal and professional judgement as to whether to accept the responsibility that the extended role will place upon them. If the authorised healthcare practitioner is in any doubt about their competency or training, they should not administer or supply in accordance with the PGD and should seek advice.
f) Supply cannot be delegated to any other person under a PGD, regardless of their profession or level of training because such delegation is not allowed by medicines legislation. If the medicine is to be administered immediately under a PGD e.g. intramuscular influenza vaccination, administration has to be by the same practitioner who has assessed the patient under the PGD.
g) Mersey Care Intranet will have the current version of the document.
h) Registered healthcare practitioners should always check that the signed copy of the PGD they are using for reference when supplying and/or administering a medicine is the current version.
i) Individuals need to assure themselves that there is adequate indemnity cover through their employer's indemnity arrangements. In law employers are vicariously liable for the actions of their staff and this also applies to NHS employees. This is a major reason behind the process of authorisation from the organisation where PGDs are being used. Essentially by 'signing

off' PGDs the organisation effectively accepts the vicarious liability that this incurs.

j) Any practitioner failing to comply with the criteria within the PGD falls outside of the Law and could result in criminal prosecution under the Medicines Act. Their actions will exclude them from the employer's indemnity arrangements as well.

5.9 PGD Group Administrator

a) Keeping accurate records contemporaneously.
b) Maintaining the files on the intranet to ensure all documents are in date.
c) Removing from use (i.e. intranet access) all documents which have expired or been superseded.
d) Preparing papers for the PGD Group monthly meetings.
e) Taking minutes of the PGD Group meeting.
f) Overall management of PGD Group meetings.

5.10 General Duties for all

a) It must be acknowledged by all members of staff that the interests and safety of every patient is paramount.
b) Until approval by the signatories, a PGD or amendments to an existing PGD are not legally valid.
c) The organisation accepts no responsibility for an authorised practitioner who acts in accordance with a PGD not yet approved or uses an expired PGD.
d) The organisation accepts no responsibility for the actions of an authorised practitioner who works outside the limits of the PGD.
e) The organisation accepts no responsibility for a practitioner who acts under a PGD they are not signed up.
f) The organisation accepts no responsibility for a practitioner whose training as specified in the PGD has expired.

6. PROCESS

6.1 Introduction

a) Health Service Circular (HSC 2000/026) states that the majority of clinical care should be provided on an individual patient-specific basis.
b) When this is not practical, supply and/or administration of medicine under PGDs should be considered for situations in which this offers an advantage for patient care without compromising patient safety and where there are clear governance arrangements and accountability.
c) A PGD is not meant to be a long-term means of managing a patient's clinical condition. This is best achieved by a health care professional prescribing for an individual patient on a one-to-one basis and the majority of clinical care should continue to be provided in this way.
d) A PGD is NOT an authorisation to prescribe.

e) A PGD allows a range (see Appendix 1) of specified health care professionals to supply and/or administer a medicine directly to a predefined group of patients without them having to see a prescriber. When a patient presents, the health care professional working within the PGD is responsible for assessing that the patient fits the criteria set out in the PGD.
f) The supply and administration of medicines under Patient Group Directions should therefore be reserved for those limited situations where this offers an advantage to patient care without compromising patient safety and must be consistent with appropriate professional relationships and accountability. For example in pre-defined clinical situations where clearly defined instructions for the supply and administration of medicines can be produced and where there are volumes of patients who present for treatment (e.g. vaccines). Such supply/administration must take into account the priorities of the organisation, be supported by appropriate training and must enable the highest standard of practice for each clinical situation to be achieved.
g) Only medicines with a UK marketing authorisation can legally be included in a PGD.

6.2 Proposal to develop a new PGD or revise an existing PGD

a) The Service Lead should complete the pro forma 'Proposal for the development of a PGD' and send it to medicines.management@merseycare.nhs.uk for inclusion at the next PGD Group meeting.
b) The proposal should clearly identify who should be involved in the PGD development group and what training will be required by the practitioner who will be using the PGD. The proposal should include consideration of other available options for the supply and/or administration of the medicine. The proposal will need to include how use of the PGD will be regularly audited and must also include estimated costs.
c) The PGD Group will consider the need for the PGD and, if in agreement with the proposal, will authorise the development of the PGD to proceed by the service. They will advise if other stakeholders need to be involved in the development or be consulted with.
d) If a PGD already exists that reflects the needs of the service, the proposal they submit can be that their service be added to an existing PGD.
e) The development group should be a multidisciplinary group which includes the input of a doctor, a pharmacist and a representative of the professional group(s) expected to give medicines under the proposed PGD.
f) All stakeholders in the development of the PGD should be identified by the development group and consulted on the development of the PGD.
g) There is a process of appeal when proposals are rejected. The revised proposal may be presented to the PGD Group **once** more.
h) The pro forma is available on SIRS as an electronic document to complete. It can be found on the PGD pages as a resource.

6.3 Developing a PGD

a) The PGD will be drafted to reflect the criteria in the proposal form, using the standard PGD template and with appropriate medical or dental input.

b) The nominated medicines management pharmacist will check the pharmaceutical and legal content of the drafted PGD.
c) If the PGD is for supply or administration of an antibiotic it must be in accordance with the current version of the Pan Mersey Antimicrobial Guidelines and Management of Common Infections in Primary Care, using the Antibiotic PGD template.
d) The templates are available from the PGD Administrator once proposal has been accepted.

6.4 **Competency Assessments for working under the PGD -** The PGD Group should consider and agree training and competency requirements for staff wishing to operate under the PGD, in line with the NICE competency framework for health professionals using PGDs, including:

a) Understanding of the requirements of individual PGDs.
b) Knowledge of pharmacology of the drug to be included in the PGD.
c) Knowledge of relevant legislation relating to use of the medicines and medical conditions and the content of the training will be agreed by the PGD working group.
d) Any additional training required in support of the procedure that the PGD may underpin i.e. suturing when local anaesthetic PGD has been used.

6.5 **Submission of Final Draft**

a) The final draft of the PGD will be submitted to the PGD Administrator via the Medicines Management mailbox at least **14 working days** before the next PGD Group meeting and at least **2 months** before its expiry date if it is a review.
b) The PGD Lead will then sense check the final draft and ensure that the document is presentable in an easy to read format i.e. tracking removed, and where necessary cross referenced for consistency against any other linked PGDs.
c) Documents completed in this way will be added to the agenda of the next PGD Group meeting.
d) Papers and agenda will be circulated to the members of the PGD Group no later than one week before the meeting as per TOR.

6.6 **Authorisation of the PGD**

a) The PGD will be presented at the PGD Group for consideration.
b) The PGD Administrator will record in the minutes if the signatories all agree approval of the PGD. This will be evidence authorising their signatures to be added to the final document.
c) The PGD Lead will forward the final document to the Governance signatory for authorisation to add their signature. The email response will be the evidence authorising their signature to be added to the final document.

6.7 Implementation

a) Once the PGD has been authorised by all four signatories, electronic signatures added and then saved as a PDF it will be uploaded to SIRS by the PGD Administrator.
b) The previous version of the PGD will be removed from SIRS and archived.
c) The relevant service lead(s) and ALL the practitioners who will use the PGD in the service will be informed directly by email by the PGD Administrator.
d) Service leads will direct each proposed practitioner to access the latest version of the PGD on-line and arrange for each practitioner to undertake any additional training specified in the PGD.
e) Once the practitioner has been deemed competent they will sign the master copy of the PGD to say that they have read and understood it and agree to supply the medication only in line with the PGD. The service lead/line manager must counter sign the PGD to authorise each practitioner to use it.
f) The service lead must give each Authorised Practitioner a photocopy of the completed authorisation sheet showing their authorisation to use the PGD.

6.8 Central Sign-up Register for PGDs

a) Each service using PGDs will have ownership of a sign-up register held on the intranet.
b) Only nominated administrators for each service will be allowed editing rights of these registers and it will be the responsibility of each service to ensure that these registers are kept up to date.
c) The level of sign-up will be traffic lighted on the registers and will be reported to the PGD Group each month by the PGD Lead (see SOP Governance Reporting).

6.9 Review Process

a) Each PGD will be given a review date of six months before the expiry date.
b) The expiry date on a PGD must be:
   - One Year for a new PGD
   - Three Years for an antibiotic PGD but needs to be responsive to any updates of the Pan Mersey Antimicrobial Guidelines which is usually a two year cycle
   - Three Years for all other PGDs
c) At the review date it is important for the service to assess whether there is a continued need for the PGD. If the PGD is needed, it must be reviewed at the review date following the process in Appendix 2, and re-approved for use before it expires.
d) The author(s) should ensure that the whole PGD is reviewed to ensure the information is still current and applicable.
e) Any changes, reference source or rationale for changes must be clearly indicated in the ‘change history’ section of the document.
f) The author(s) must maintain version control to avoid confusion when a PGD is being updated. The master word document and all subsequent versions will be held on record by PGD Group Administrator.

g) Once review of the PGDs is complete it should be submitted to the PGD Group for consideration and will be signed off following the same process described in section 6.4 above.
h) After the expiry date the PGD is not valid. **Medicines must not be supplied or administered under the authority of an expired PGD.**

6.10 **Extension of expiry dates**

a) The schedule plan allows six months for the review of a PGD so extension of an expiry date should only be in very exceptional circumstances.

b) Extension of expiry dates without review of a PGD is not without risk (e.g. license of medicine may have changed/national guidance may have changed) but the organisation may deem this necessary where it is in the interests of patient safety i.e. there may be a risk where withdrawing the PGD could result in significant service disruption and potential patient safety issues due to lack of access to medicines. The following ruling applies:

- Maximum of 1 month extension.
- Extended once only.
- To be approved by the authorising Senior Doctor, Pharmacist and Nurse Leads.

c) When an extension has been agreed, this must be formally noted by the PGD Group alongside an agreed action plan with timescales for review and re-approval of the PGD. The PGD Group will ensure that all service leads and practitioners working under the PGD are made aware of any expiry date extensions.
d) Practitioners who do not wish to practice under a PGD that has had an extended expiry should discuss concerns with their manager in the first instance.

6.11 **Interim Reviews -** Should there be any significant changes before the review date i.e. updates in practice and/or a change in the Summary of Product Characteristics (SPC) this should be notified to the PGD Group who will decide whether the PGD needs to be amended accordingly and submitted for re-approval. Once approved, the amended PGD will immediately supersede the previous PGD for that area of practice.

6.12 **USE OF A PATIENT GROUP DIRECTION criteria for the administration and/or supply of medicines**

Supply or administration of the medicine must be strictly in accordance with the PGD and appropriate for the clinical condition. Evidence-based treatment guidelines should be used by the healthcare professional to inform clinical decision-making. The patient must meet the eligibility criteria. Any variance from these criteria means that the patient must be excluded and alternative arrangements for referral made as per the PGD document. These should be documented.

6.13 **Patient Counselling -** The PGD should make clear the requirements to discuss with the patient:

a) Reason for the treatment.
b) Why the medicines are supplied or administered.
c) Counselling on correct use of the medicine according to the PGD and the label.
d) Supply patient information leaflet and discuss any queries.
e) Possible side effects, their management and when to seek medical help.
f) Caution with interacting medicines including over-the-counter medicines.
g) Advice on follow-up treatment and referrals.
h) Signposting to other services.

6.14 **Record keeping -** The following information must be recorded contemporaneously on the patient's electronic record. If access to the electronic records is at the time of the consultation then the information should be inputted prior to the administration or supply of a medicine using a PGD:

a) Clinical condition.
b) Patient details, name, condition presented, medical history.
c) Treatment and advice given; any adverse reactions.
d) Reasons for exclusion and referral.
e) Medicine supplied or administered:
   - Name
   - Form
   - Strength
   - Quantity
   - Batch number
   - Expiry date

   The above information is to be used for reconciliation of stocks.

f) Information and advice given.
g) Name and signature of healthcare professional providing treatment and supplying the medicine.
h) Records to be kept in patient's notes and sent to the GP if appropriate or as detailed in the individual PGD.

6.15 **Security and storage of medicines -**There must be comprehensive arrangements for the security, storage and labelling of all medicines in accordance with the Overarching Medicines Policy:

a) Storage must be appropriate to requirements for the medicine, e.g. refrigeration.
b) Internal and external medicines must be stored separately.
c) Flammables must be stored appropriately.
d) When a medicine is to be supplied to the patient, the labels should include specific directions. The only exception is "as directed" for oral contraceptives issued by the Sexual Health Services and where directions are complex e.g. Podophyllotoxin.
e) The medicine must be supplied in original packs or prepacks supplied by Mersey Care Medicines Distribution Service. Labelling of all supplies of medication including those supplied under PGDs should comply with

European Commission Directive 92/27. At the point of supply, the registered healthcare professional must add the following information to the label:

- Patient's name
- Date of issue

f) The manufacturers' patient information leaflets (PILs) must be provided each time a medicine is supplied to comply with European Council Directive 2004/27/EC.

g) There must be a secure system for recording and monitoring medicine use under a PGD to enable all stock receipts and all issues to individual patients to be reconciled. Names of the health professionals providing treatment, patient identifiers and medicine provided should all be recorded.

7. CONSULTATION

7.1 This policy was written in consultation with professional opinion sought from NHS Specialist Pharmacy Services.

7.2 Individuals involved in developing the policy:

Hillary Smith, PGD Lead.

7.3 This document was circulated for review to the PGD Group.

8. TRAINING AND SUPPORT

8.1 Training

a) Members of the PGD Group and staff developing, reviewing, authorising, working to a PGD or mentoring staff working to a PGD should have completed formal PGD training.

b) The training available is either:
   - On-line training package provided free of charge by external CPPE which records a score and issues a certificate of achievement
   - Classroom based training provided in-house followed by completing the NICE competencies related to use of PGDs which need to be signed off by a service lead/ mentor

c) Only staff working to a PGD can do the classroom based training. All others requiring training must complete the CPPE training package.

d) There is a Standard Operating Procedure (SOP) for PGD Training which explains in detail how to access and complete the training.

e) PGD Training is valid for 3 years.

f) Learning & Development Bureau hold the Central Register for PGD training and they must be informed directly of training status as the system only records attendance at the classroom session.

8.2 **Dissemination and Implementation**

a) This policy and any SOPs which underpin it will be disseminated by service leads.
b) New staff will be informed of policies relevant to practice at their local Induction.

9. MONITORING

9.1 National guidance recommends that care provided under a PGD must be audited. It is recommended that an audit of PGDs is undertaken annually.

9.2 It is a legal requirement to keep records of administration/supply under PGD for audit purposes.

9.3 It is the responsibility of the service lead to monitor and audit the use of PGDs within their service setting by retaining a list of named, registered health practitioners authorised to practice under each PGD used within their service.

9.4 The PGD Group will seek assurances from each service regarding audit conducted annually. Audit of both sign up to PGDs and adherence to criteria specified in a PGD will be necessary. Audit reports should be submitted to the PGD Group and any issues arising from audits will be built into on-going training and re-audited at a later date.

9.5 Such monitoring will ensure that PGDs are used appropriately and deliver safe and effective care that meets both patient and service needs.

10. EQUALITY AND HUMAN RIGHTS ANALYSIS

Title: Management of Patient Group Directions
Area covered: Registered Practitioners

What are the intended outcomes of this work?
The policy is applicable to all staff working for Mersey Care who are involved in the drafting, reviewing, authorising or monitoring of PGDs and those staff who use PGDs when in the process of patient care. It will underpin the on-going work of the PGD Group and set the standards of work undertaken. The outcome of a robust process to manage PGDs is that patients who require medicines or vaccinations when a service cannot be delivered by either a prescriber or a delegated Patient Specific Direction will still be able to receive them through a safe and equitable service.
Who will be affected?
Patient requiring vaccinations or treatment with medicines in the absence of a prescriber Registered practitioners who need a PGD to deliver a service using vaccinations or medicines when they do not have the legal qualification to prescribe

Evidence
What evidence have you considered? National guidance from the Department of Health, NICE, and the Royal College of Nursing Local guidance
Disability (including learning disability) None
Sex None identified
Race None identified
Age None identified
Gender reassignment (including transgender) None identified
Sexual orientation None identified
Religion or belief None identified
Pregnancy and maternity *Consider and detail (including the source of any evidence) on working arrangements, part-time working, infant caring responsibilities.* None identified
Carers *Consider and detail (including the source of any evidence) on part-time working, shift-patterns, general caring responsibilities.* None Identified
Other identified groups *Consider and detail and include the source of any evidence on different socio-economic groups, area inequality, income, resident status (migrants) and other groups experiencing disadvantage and barriers to access.* None identified
Cross Cutting *implications to more than 1 protected characteristic* None identified

Human Rights	Is there an impact? How this right could be protected? *Not applicable*
Right to life (Article 2)	*Not applicable*
Right of freedom from inhuman and degrading treatment (Article 3)	*Use supportive of a HRBA if applicable* *Not applicable*
Right to liberty (Article 5)	*Not applicable*
Right to a fair trial (Article 6)	*Not applicable*
Right to private and family life (Article 8)	*Not applicable*
Right of freedom of religion or belief (Article 9)	*Not applicable*
Right to freedom of expression **Note: this does not include insulting language such as racism (Article 10)**	*Not applicable*
Right freedom from discrimination (Article 14)	*Not applicable*

Engagement and Involvement *detail any engagement and involvement that was completed inputting this together.*
None

Summary of Analysis *This highlights specific areas which indicate whether the whole of the document supports the trust to meet general duties of the Equality Act 2010*
Eliminate discrimination, harassment and victimisation *This policy does not discriminate within the target populations who require immunisation or medicinal therapy*
Advance equality of opportunity NA
Promote good relations between groups NA

What is the overall impact? NA

Addressing the impact on equalities *There needs to be greater consideration re health inequalities and the impact of* each individual development /change in relation to the protected characteristics and vulnerable groups

NA

Action planning for improvement
Detail in the action plan below the challenges and opportunities you have identified. *Include here any or all of the following, based on your assessment* • *Arrangements for continued engagement of stakeholders.* • *Arrangements for continued monitoring and evaluating the policy for its impact on different groups as the policy is implemented (or pilot activity progresses)* • *Arrangements for embedding findings of the assessment within the wider system, other agencies, local service providers and regulatory bodies* • *Arrangements for publishing the assessment and ensuring relevant colleagues are informed of the results* • *Arrangements for making information accessible to staff, patients, service users and the public* • *Arrangements to make sure the assessment contributes to reviews of DH strategic equality objectives*

For the record **Name of persons who carried out this assessment:**
Hillary Smith
Date assessment completed:
3/1/19
Name of responsible Director:
Trish Bennett
Date assessment was signed:

11. ADDITIONAL APPENDICES

Appendix 1: Health professionals who can administer or supply medicines under a PGD

Currently, the following healthcare professional groups are able to use PGDs:

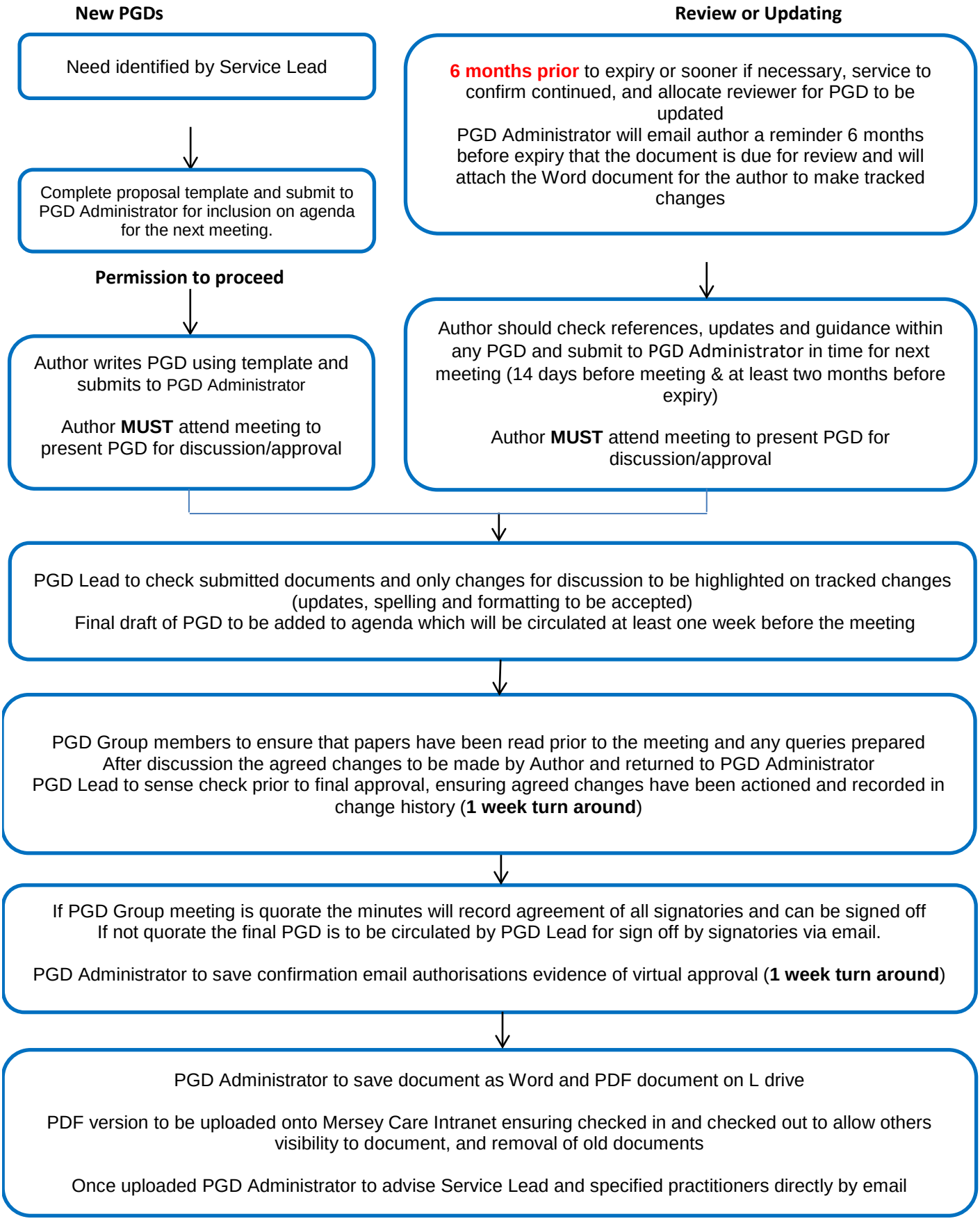
- Pharmacists
- Registered Chiropodists and podiatrists
- Registered Dental hygienists
- Registered Dental Therapists
- Registered Dieticians
- Registered Midwives
- Registered Nurses
- Registered Occupational Therapists
- Registered Optometrists
- Registered Orthoptists
- Registered Orthotists and prosthetists
- Registered Paramedics
- Registered Physiotherapists
- Registered Radiographers
- Registered Speech and Language Therapists

Individuals must be competent, qualified, trained and currently registered (or equivalent) members of their professional body and must be named and authorised to practice under a PGD. No other groups of health care workers, e.g. health care assistants, pharmacy technicians, auxiliaries etc., can use PGDs. This includes agency staff even if working for only one day in the organisation unless they have been assessed as competent and have signed the relevant PGD.

Authorised individuals are not able to delegate their responsibility to another person.

Appendix 2:

Process map for new, review or updating PGDs



Appendix 3: References

a) National Institute for Health and Care Excellence (NICE) Medicines Practice Guideline MPG2 on Patient Group Directions (Aug 2013 updated March 2017) http://www.nice.org.uk/guidance/mpg2

b) NICE MPG 2 Competencies https://www.nice.org.uk/guidance/mpg2/resources

c) NHS Patient Group Directions (PGD) website http://www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/

d) Health and Social Care Act 2008 (regulated Activities) Regulations 2009

e) Care Quality Commission (Registration) Regulations 2009

f) Royal Pharmaceutical Society (2005) A revision of the Duthie Report (1988)

g) Health Service Circular 2000/026 Patient Group Directions (England only) Health Service Circular (HSC 2000/026)

h) NMC (2018) The Code - Professional standards of practice and behaviour for nurses, midwives and nursing associates