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### 1 **Introduction**

This document sets out Torbay and South Devon NHS Foundation Trust’s (TSDFT) process for Patient Group Directions (PGDs). It provides a robust framework to ensure a consistent approach across the whole organisation, and incorporates the recommendations made in the Patient Group Directions NICE Guidelines (MPG2) August 2013 (updated March 2017) <https://www.nice.org.uk/guidance/mpg2/evidence/full-guideline-pdf-4420760941> (**accessed November 2019**)

The legislation enabling registered practitioners to operate under a PGD was outlined in the Health Service Circular (HSC 2000.026 – Appendix 1) this sets out the legal requirements to develop and operate under a PGD. <https://www.nice.org.uk/guidance/mpg2/evidence/full-guideline-pdf-4420760941> (**accessed November 2019**)

PGDs provide a legal framework that allows some registered health professionals (see 4.2.8) to supply and / or administer a specified medicine(s) to a pre-defined group of patients, without them having to see a doctor (or dentist). However, supplying and / or administering medicines under PGDs should be reserved for situations in which this offers an advantage for patient care without compromising patient safety. (Reference - Patient Group Directions NICE Guidelines (MPG2) August 2013 and reviewed 2017). <https://www.nice.org.uk/guidance/mpg2/evidence/full-guideline-pdf-4420760941> (**accessed November 2019**)

- 1.1 The preferred way for patients to receive the medicines they need is for a prescriber to provide care for an individual patient on a one-to-one basis, e.g. medical or non-medical prescriber.

It is important to consider whether other forms of prescribing / administration are more suitable before considering development of a PGD. To consider the appropriateness of a PGD please refer to “Whether to PGD or not to PGD” available at:

<https://www.sps.nhs.uk/wp-content/uploads/2017/11/To-PGD-v9.5-Jan-2018.pdf>  
(*accessed November 2019*)

- 1.3 This policy relates to all staff employed by TSDFT.

## 2 **Definitions**

### 2.1 Patient Group Direction

“A PGD is a specific written instruction for the supply or administration of a licensed named medicine including vaccines to specific groups of patients who may not be individually identified before presenting for treatment”.

Health Service Circular 2000

[https://webarchive.nationalarchives.gov.uk/20120503185443/http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_4012260.pdf](https://webarchive.nationalarchives.gov.uk/20120503185443/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012260.pdf)

(*accessed November 2019*)

### 2.2 Glossary

- POM (prescription only medicine) – patients can only obtain the medicine on prescription from a pharmacy.
- P (pharmacy medicine) – medicines can be sold in pharmacies by or under the supervision of a pharmacist.
- GSL (general sales list) – medicines can be sold in general shops as well as in pharmacies. GSL medicines can be sold directly to the public from any lockable business premises (for example, a petrol station, a supermarket) without any professional supervision. GSL medicines must be sold in defined quantities in an unopened manufacturers pack.

## 3. **Objective**

- 3.1 The aim of this policy is to set out the process for the identification, development, dissemination, implementation, monitoring, audit and review of Patient Group Directions (PGDs).

- 3.2 This policy will provide the framework for service, clinical and professional leads to assist in the identification of and outline the process for the development of PGDs.
- 3.3 This policy should be read in conjunction with supporting local and national policies, NICE guidelines, protocols and Standard Operating Procedures (SOPs).

#### **4. Roles & Responsibilities**

##### **4.1 Role of Medicines Governance Team**

- 4.1.1 The Medicines Governance Pharmacist is responsible for reviewing requests for the development of new PGDs for use within TSDFT and, if appropriate, for seeking approval from the Medicines Management Committee

##### **4.2 Role of Individual Line Managers, Professional and Clinical Leads**

- 4.2.1 Individual line managers, professional and clinical leads are responsible for informing staff of this policy and any associated policies, SOPs, guidelines and protocols.
- 4.2.2 Individual line managers, professional and clinical leads are responsible for the identification of appropriate registered staff who may operate under PGDs.
- 4.2.3 Individual line managers must ensure each new or revised PGD is signed by all appropriate registered staff.
- 4.2.4 Individual line managers, professional and clinical leads must ensure registered staff have the appropriate training and competencies to operate under PGDs.
- 4.2.5 Individual line managers, professional and clinical leads must ensure staff competencies are regularly reviewed and are up to date.
- 4.2.6 Individual line managers, professional and clinical leads must ensure that registered staff operating under PGDs have access to relevant protocols, guidelines and SOPs
- 4.2.7 Individual line managers, professional and clinical leads must ensure registered staff have the appropriate training and competencies outlined in the Patient Group Directions NICE Guidelines (MPG2) August 2013 – Competency Framework for Health Professionals using Patient Group Directions Implementing NICE good practice guidance on Patient Group Directions, published January 2014 reviewed 2017 <https://www.nice.org.uk/guidance/mpg2/resources> (*accessed November 2019*)
- 4.2.8 If the above criteria are met, the following registered professional staff groups may administer or supply medicines under a PGD:
- Chiropractors and Podiatrists
  - Dental Hygienists

- Dental Therapists
- Dieticians
- Midwives
- Nurses (band 5 and above)
- Occupational Therapists
- Optometrists
- Orthotists and Prosthetists
- Orthoptists
- Paramedics
- Pharmacists
- Physiotherapists
- Radiographers
- Speech and Language Therapists

### 4.3 Role of all Registered Staff using PGDs

- 4.3.1 Registered staff must ensure they have an up to date working knowledge of the medication they are supplying and / or administering under a TSDFT ratified PGD.
- 4.3.2 Registered staff are accountable for their own professional practice and must work within this policy and their respective professional codes. PGDs must not be used as a method for self-administration.
- 4.3.3 Registered staff **cannot delegate responsibility** of the supply or administration of a medicine to another person under a PGD.
- 4.3.4 Registered staff operating under a PGD must work within the relevant protocols identified within the PGD.
- 4.3.5 Registered staff operating under this policy will identify any training needs and attend required study sessions relating to this policy.
- 4.3.6 Professionals using a PGD must hold a current registration as identified within the PGD (see 4.2.8) and act within their appropriate professional codes of conduct.
- 4.3.7 Individual registered staff must be named and authorised to practice under a PGD.
- 4.3.8 Each new or revised PGD should be signed by all appropriate registered staff to ensure competencies are reviewed and up to date.
- 4.3.9 When supplying and/or administering a medicine under a PGD, registered health professionals should follow local organisational policies and act within their code(s) of professional conduct and local governance arrangements.

#### 4.4 Role of PGD Administrator

- Maintaining an up to date database of current and expired PGDs.
- Maintaining a PGD work plan
- Ensuring the PGD template is up to date and version control and history are accurate.
- Ensuring approved PGDs are ratified.
- Ensuring current PGDs are on the Trust's intranet
- Ensuring ratified PGDs are disseminated to appropriate line managers and / or service leads.

#### 5. Identifying the Need for a PGD

- 5.1 Reserve [patient group directions \(PGDs\)](#) for limited situations in which this offers an advantage for patient care, without compromising patient safety, and where there are clear governance arrangements and accountability.  
<https://www.nice.org.uk/guidance/mpg2/evidence/full-guideline-pdf-4420760941>  
(*accessed November 2019*)
- 5.2 Service leads identifying the need for a PGD must complete a PGD Development Request Form (Appendix 1) and send it to the Medicines Governance Group Pharmacist at ([tsdft.medicinesgovernance@nhs.net](mailto:tsdft.medicinesgovernance@nhs.net))
- 5.3 Requests for a new PGD received by the Medicines Governance Pharmacist will be considered to determine that the need for a PGD meets all the criteria for developing a PGD.
- 5.4 If a PGD is required and approval received from the Medicines Governance Pharmacist and the Medicines Management Committee to develop a PGD, then a pharmacist will be allocated to assist in the development of the PGD in conjunction with the clinical specialist.
- 5.5 The member of staff making the request to develop a PGD must identify an appropriate clinician to collaborate on the development of the PGD

#### 6. Clinical Protocols, Standard Operating Procedures or Guidelines Supporting PGDs

- 6.1 The development of associated protocols, standard operating procedures or guidelines must be completed prior to final PGD ratification.
- 6.2 It is advisable that work to produce a protocol, standard operating procedure or guideline to support the PGD is commenced in conjunction with the PGD.
- 6.3 A clinical protocol, standard operating procedure or guideline is to be produced by the clinical lead of the service to underpin each PGD.
- 6.4 A PGD will not be ratified without the supporting clinical protocol, standard operating procedure or guideline being ratified in advance or at the same time as the PGD.

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## 7. **Development, Authorising and Implementing PGDs**

- 7.1 PGDs must be developed, revised or updated by a multidisciplinary group involving a doctor, pharmacist and a representative of the professional group who will administer and/or supply medicines under the PGD.
- 7.2 Not all medicines are suitable to be included in a PGD and there are legal restrictions on others. Please seek advice from the Medicines Governance Pharmacist. For exclusions see Health Service Circular 2000.026 - pages 3 and 4  
<https://www.nice.org.uk/guidance/mpg2> (*accessed November 2019*)
- 7.3 If a PGD is for an antibiotic a microbiologist **must** be consulted in the PGD's production or review.
- 7.4 A clinical protocol **must** be developed and implemented in conjunction with the PGD (see Section 6).
- 7.5 The PGD will be informed by legislation, local and national frameworks, policies, guidelines, local formularies and other bodies with medicines expertise.
- 7.6 The PGD author(s) will ensure the draft PGD is put into the current PGD template (available from the Medicines Governance Team [tsdft.medicinesgovernance@nhs.net](mailto:tsdft.medicinesgovernance@nhs.net)) The current PGD template has been developed to comply with the legal requirements set out in HSC 2000/26 and should not be altered in any way. <https://www.nice.org.uk/guidance/mpg2> (*accessed November 2019*)
- 7.7 National PGDs from the Specialist Pharmacy Service (SPS) will be adopted by the Trust, if appropriate for use within the Trust.**
- 7.8 The Medicines Governance Team administrator will ensure PGD version control.
- 7.9 The PGD is to be approved and signed by the doctor, pharmacist and practitioner involved in developing the PGD. When the PGD authors have signed the PGD, the Medicines Governance Administrator will arrange for the PGD to be ratified.
- 7.10 Arrangements for sign off and ratifying of PGDs may diverge from the usual related processes during extraordinary circumstances, e.g. a pandemic situation, to ensure that PGDs remain within the legislation and that patient safety is protected.
- 7.11 The ratified PGD is to be forwarded by the Medicines Governance Team Administrator to the Clinical Effectiveness Department for uploading onto the Trust's website. The authorised and signed version will then be disseminated to the relevant professional / clinical leads, senior managers by the Medicines Governance Team Administrator.
- 7.12 Professional and clinical leads / senior managers will disseminate the ratified PGD to relevant registered staff. They will ensure that those who are going to operate under the

PGD have access to the document, have signed to operate under it and that any training needs have been identified and addressed.

7.13 Professionals using a PGD must hold a current registration as identified within the PGD and act within their appropriate professional codes of conduct.

7.14 Managers will retain a copy of the signed authorisation sheet at the back of each PGD and keep a record of staff who have signed up to the PGD. These records may be inspected by relevant bodies, e.g. CQC, Medicines Governance Team.

7.15 In the clinical setting where the PGD is used the following must be in place:

- a copy of the supporting protocol, or
- standard operating procedure, or
- guideline

7.16 PGDs will be reviewed every two years or before if necessary (see Appendix 3)

7.17 The expiry dates of current PGDs will only be extended if there is a justifiable delay in reviewing a PGD. It is the responsibility of the Professional Lead to conduct the review of their service's PGDs. PGDs that do not have their review completed within a year of their expiry date will be withdrawn from service.

<https://www.nice.org.uk/guidance/mpg2/evidence/full-guideline-pdf-4420760941>  
(**accessed November 2019**)

7.18 PGDs that are updated before their two year expiry will need to be re-ratified (see 7.7 and 7.8).

7.19 Each new or revised PGD should be re-signed by all appropriate registered staff to ensure competencies are reviewed and up to date.

7.20 Revised / out of date PGDs will be removed from the Trust's website.

7.21 Professional Leads and clinical leads / senior managers will be responsible for informing their registered staff of PGDs that are withdrawn from use.

7.22 PGD staff authorisation records **must** be kept by the relevant departments / wards for 8 years after the expiry date of the PGD if the PGD relates to adults only (10 years if it relates to an implant) <https://www.sps.nhs.uk/articles/retaining-pgd-documentation/>

7.23 PGD staff authorisation records **must** be kept by the relevant departments / wards for 25 years after the expiry date of the PGD if the PGD relates to children.  
<https://www.sps.nhs.uk/articles/retaining-pgd-documentation/>

7.24 The original ratified version of the PGD will be retained by the Medicines Governance team and kept for 8 years after the PGD expiry date if the PGD relates to adults only (10 years if

it relates to an implant) and 25 years if the PGD relates to children.  
<https://www.sps.nhs.uk/articles/retaining-pgd-documentation/>

7.25. In order to operate under a PGD a registrant must:

- Have a responsibility under their code of professional conduct to maintain their competence and identify any training needs required to safely operate under each PGD.
- Agree to operate under the PGD by signing each individual PGD authorisation sheet.

## 8. **Training**

8.1 There is no specific training to directly underpin this policy. However, resources can be accessed as follows:

- NICE PGD competency framework <https://www.nice.org.uk/guidance/mpg2/resources> (accessed December 2019)
- by contacting service leads in the first instance or the Medicines Governance team ([tsdft.medicinesgovernance@nhs.net](mailto:tsdft.medicinesgovernance@nhs.net)). The Medicines Governance team hold some resource materials

8.2 Specific training needs for individual PGDs must be identified by the Service Leads. Advice may be sought from the Medicines Governance team ([tsdft.medicinesgovernance@nhs.net](mailto:tsdft.medicinesgovernance@nhs.net)).

8.3 Records of training must be retained by the Service Lead / Line Manager.

## 9. **Audit of PGDs**

9.1 It is the responsibility of the service lead to monitor and audit the use of PGDs within their service setting. Information about how the audits are to be conducted are included in each individual PGD.

9.2 The service lead must retain a list of named, registered health professionals authorised to practise under each PGD used within their service.

9.3 Monitoring and evaluation of PGDs used within the Trust may be undertaken in conjunction with the CQC or the Medicines Governance team.

## 10. **References**

Medicines Policy [G0806](#)

Consent Policy [G0356](#)

NICE Guidance Patient Group Directions August 2013

<https://www.nice.org.uk/guidance/mpg2> (**accessed November 2019**)

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SPS (Specialist Pharmacy Service) PGD information

<https://www.sps.nhs.uk/articles/records-management-nhs-code-of-practice/>

(*accessed November 2019*)

<https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them> (*accessed November 2019*)

## 11. Appendices

[Appendix 1 - PGD Request Form](#)

[Appendix 2 - PGD Flowchart](#)

[Appendix 3 – Flowchart for Review of PGDs](#)

[Appendix 4 – A Practical Guide to Writing Patient Group Directions \(PGDs\)](#)

Appendix 1

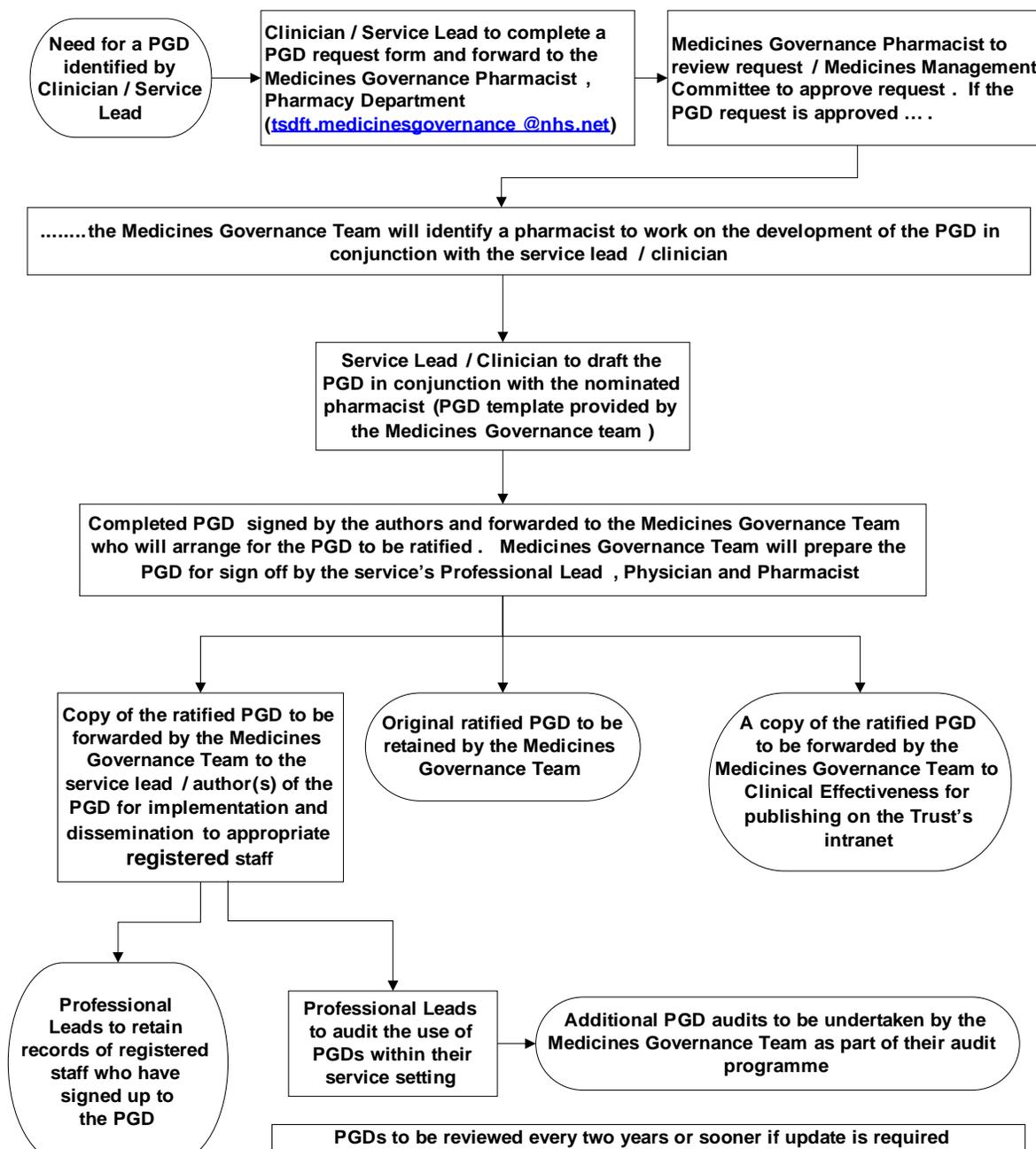
**REQUEST FOR THE DEVELOPMENT OF A PATIENT GROUP DIRECTION**

DETAILS OF THE PGD REQUESTED						
NAME OF THE MEDICATION						
Setting where the PGD will be used						
Condition to be treated (consider patient inclusion and/or exclusion criteria)						
Benefits to Patient Care						
Potential Risks to Patient Safety						
Are there arrangements in place for delivery of stock, storage, transportation YES <input type="checkbox"/> NO <input type="checkbox"/>						
If NO, what arrangements are to be made: .....						
Is a microbiologist required to be involved in the consultation (for antibiotic PGDs) YES <input type="checkbox"/> NO <input type="checkbox"/>						
DETAILS OF THE MEDICINE TO BE SUPPLIED/ADMINISTERED						
Dosage	Quantity	Formulation	Strength	Route	Frequency	Duration of Treatment
Is the appropriate formulation of medicine available. e.g. pre pack? YES <input type="checkbox"/> NO <input type="checkbox"/>						
If YES, is one already available YES <input type="checkbox"/> NO <input type="checkbox"/>						
Is the Medicine included in the local Joint Formulary (e.g. South Devon JF) ? YES <input type="checkbox"/> NO <input type="checkbox"/>						
DETAILS OF THE CLINICAL PROTOCOL / TRAINING AND RESOURCES TO SUPPORT THE PGD						
Has a protocol / standard operating procedure / guideline been developed to support the PGD and ratified by the Trust ? YES <input type="checkbox"/> NO <input type="checkbox"/>						
If NO, please state who will be responsible for writing this : .....						
If YES, will the current protocol / standard operating procedure / guideline require updating YES <input type="checkbox"/> NO <input type="checkbox"/>						
Which Registered Health Professional Groups will work under the PGD						
Detail training and competency needs						
What resources are needed to deliver the service						
What is the timescale for developing the PGD						
DETAILS OF AUDIT ARRANGEMENTS						
What audit arrangements will be in place to monitor administration / supply and use of this PGD: ..... .....						
DETAILS OF THE PROPOSER						
Name:						
Role within the Organisation:						
Contact Details (phone and email address):						
Name of Service Lead / Budget Holder if not the Proposer:						

Please attach any supporting evidence for this request to this form. Please complete the above and forward to the Medicines Governance team at: [tsdft.medicinesgovernance@nhs.net](mailto:tsdft.medicinesgovernance@nhs.net) OR Medicines Governance Team, Pharmacy Department, TSDFT, Lowes Bridge, Torquay TQ2 7AA

**DEVELOPMENT / REVIEW OF PGDS  
FLOWCHART FOR THE DEVELOPMENT, DISSEMINATION, IMPLEMENTATION,  
MONITORING, AUDIT AND REVIEW OF PATIENT GROUP DIRECTIONS (PGDs) WITHIN  
TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST  
(Licensed Medications Only)**

Link in flowchart ([tsdft.medicinesgovernance@nhs.net](mailto:tsdft.medicinesgovernance@nhs.net))



Appendix 3

REVIEW OF PGDS: FLOWCHART FOR THE REVIEW OF PGDS WITHIN  
TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST

(Links in flowchart: [tsdft.medicinesgovernance@nhs.net](mailto:tsdft.medicinesgovernance@nhs.net)) and  
<https://www.nice.org.uk/guidance/mpg2/chapter/recommendations#reviewing-and-updating-patient-group-directions>)

**FOUR** months before the PGD expiry date the Clinical Effectiveness and Medicines Governance Team will write to the Professional Lead to ask them to review their PGD

Does your service still use / need this PGD ?

Yes

The Professional Lead must review the **ENTIRE** content of the PGD and update information in line with current clinical practise, references, new guidance, changes to PGD audits and staff training, etc.

No

Let Medicines Governance know [tsdft.medicinesgovernance@nhs.net](mailto:tsdft.medicinesgovernance@nhs.net)  
The Professional Lead should withdraw all copies of the PGD from use and retain these copies in line with the Trust's policy for document retention. (See section 7 of the PGD Policy)

Send the updated PGD to [tsdft.medicinesgovernance@nhs.net](mailto:tsdft.medicinesgovernance@nhs.net) together with a summary of any amendments made to the PGD

The Medicines Governance team will arrange for a pharmacist to review the PGD

The Pharmacist will contact the PGD author if they have any queries

When the Pharmacist has reviewed the PGD the Medicines Governance Team will prepare the PGD for sign off by the service's Professional Lead, Physician and Pharmacist

**PLEASE NOTE: The expiry dates of current PGDs will only be extended if there is a justifiable delay in reviewing a PGD. It is the responsibility of the Professional Lead to conduct the review of their service's PGDs. PGDs that do not have their review completed within a year of their expiry date will be withdrawn from service.** (NICE guidance <https://www.nice.org.uk/guidance/mpg2/chapter/recommendations#reviewing-and-updating-patient-group-directions>)

## A Practical Guide to Writing Patient Group Directions (PGDs)

### Introduction

PGDs are complex legal documents. This level of complexity is necessary to fully meet the legal requirements placed on the supply and administration of medication to patients without an individually written independent prescriber's prescription. The document will take some time to write and will probably need amendment as part of the approval process.

### What is a PGD?

A PGD is a written instruction for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. It is drawn up locally by doctors, pharmacists and appropriate professionals, and approved by the employer, advised by the relevant professional advisory committees. It applies to groups of patients or other service users who may not be individually identified before presentation for treatment.

### Determining the need for a PGD

If you feel that a PGD is needed to improve the quality of patient care within the organisation this should be discussed with your service manager. If they are in agreement, then please proceed as detailed in [section 5](#) of this policy and complete [Appendix 1](#), which must include the following information:

- a. Title of PGD.
- b. Area of Trust in which PGD is to be used.
- c. Brief summary of the need to be met.
- d. Identification of appropriate storage facilities.
- e. Ensure that the precise dose form (pack size / labelling requirements etc.) is available and where pharmaceutical stock will be purchased from.
- f. Agree to provide audit data (see [section 9](#) of policy).
- g. Ensure the training needs have been considered (see [section 8](#) of policy).

### Writing a PGD

**Do not be daunted!** If this is the first PGD that you are writing make sure that you are clear about what you want to achieve and why. This will make the process much easier to follow.

Before you start you will need at least:

- A copy of the current treatment guidelines that support and will be incorporated in the PGD.
- A copy of the Trust's PGD template.
- A copy of the Trust Policy "Patient Group Directions Policy".
- A copy of the current BNF.

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There is a national website that gives nationally submitted examples of approved PGDs. [www.sps.nhs.uk](http://www.sps.nhs.uk) One of these may act as a starting point. However, each individual clinical setting may have slight variations that will require you to follow local policies and procedure. The PGDs published on this website cannot be used in TSDFT without local adaptation and in the Trust's PGD format.

There are no short cuts. If the document is not fully completed it will not be authorised. PGDs can only be put into clinical practice once full Trust authorisation has been obtained

### **Who should write the PGD?**

Please refer to [section 7](#) of this policy for guidance.

Usually the service lead / service specialist who is going to use the PGD, or a representative from their group, will be expected to collaborate with the medical lead and/or assigned pharmacist in the development of the PGD, who will ensure that the document meets acceptable professional standards.

### **The approval process**

This is contained within [section 7](#) of the policy. Please note that PGDs can only be used in clinical practice once the document has full Trust approval. [Section 7](#) explains the process.

### **Introduction of the PGD into clinical practice**

Please refer to [section 7](#) of this policy.

### **Review of PGDs**

PGDs will all be assigned a review date. Reminders will be sent to the appropriate service leads and they will be required to ensure that the necessary critical review of the PGD is performed in a timely manner. Once reviewed the PGD will be reissued with the new review date.

## Document Control Information

*This is a controlled document and should not be altered in any way without the express permission of the author or their representative.*

*Please note this document is only valid from the date approved below, and checks should be made that it is the most up to date version available.*

*If printed, this document is only valid for the day of printing.*

*This guidance has been registered with the Trust. The interpretation and application of guidance will remain the responsibility of the individual clinician. If in doubt contact a senior colleague or expert. Caution is advised when using clinical guidance after the review date, or outside of the Trust.*

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<b>Author:</b>	Governance Pharmacist and Medication Safety Officer		
<b>Directorate:</b>	Organisation Wide		
<b>Equality Impact:</b>	The guidance contained in this document is intended to be inclusive for all patients within the clinical group specified, regardless of age, disability, gender, gender identity, sexual orientation, race and ethnicity & religion or belief		
<b>Committee(s) approving the document:</b>	Clinical Director of Pharmacy Chief Nurse Medical Director Care and Clinical Policies Group		
<b>Date approved:</b>	3 March 2020		
<b>Links or overlaps with other policies:</b>	All TSDFT Trust Strategies, policies and procedure documents		

<b>Have you identified any issues on the Rapid (E)quality Impact Assessment. If so please detail on Rapid (E)QIA form.</b>	Yes <input type="checkbox"/>	
	Please select Yes      No	
<b>Does this document have implications regarding the Care Act?</b> <i>If yes please state:</i>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Does this document have training implications?</b> <i>If yes please state:</i>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Does this document have financial implications?</b> <i>If yes please state:</i>	<input type="checkbox"/>	<input type="checkbox"/>

<b>Is this document a direct replacement for another?</b> <i>If yes please state which documents are being replaced:</i>	<input type="checkbox"/>	<input type="checkbox"/>

### Document Amendment History

Date	Version no.	Amendment summary	Ratified by:
8 January 2016	1	New	Clinical Director of Pharmacy Clinical Governance Lead for Anaesthetics
22 April 2016	2	Revised	Clinical Director of Pharmacy Chief Nurse Medical Director
26 January 2018	2	Date change	Governance Pharmacist & Medication Safety Officer
28 July 2018	3	Revised	Clinical Care & Policies Group Medicines Management Group Chief Nurse Medical Director
7 August 2019	4	Revised addition of information regarding retention of PGD staff authorisation records	
13 March 2020	5	Revised	Clinical Director of Pharmacy Chief Nurse Medical Director Care and Clinical Policies Group
29 May 2020	6	Amendment (Point 7.10 added)	Clinical Director of Pharmacy

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## The Mental Capacity Act 2005

The Mental Capacity Act provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they lack capacity in the future. It sets out who can take decisions, in which situations, and how they should go about this. It covers a wide range of decision making from health and welfare decisions to finance and property decisions

Enshrined in the Mental Capacity Act is the principle that people must be assumed to have capacity unless it is established that they do not. This is an important aspect of law that all health and social care practitioners must implement when proposing to undertake any act in connection with care and treatment that requires consent. In circumstances where there is an element of doubt about a person's ability to make a decision due to 'an impairment of or disturbance in the functioning of the mind or brain' the practitioner must implement the Mental Capacity Act.

The legal framework provided by the Mental Capacity Act 2005 is supported by a Code of Practice, which provides guidance and information about how the Act works in practice. The Code of Practice has statutory force which means that health and social care practitioners have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves.

**“The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual's right to make decisions for themselves with their right to be protected from harm if they lack the capacity to make decisions to protect themselves”. (3)**

All Trust workers can access the Code of Practice, Mental Capacity Act 2005 Policy, Mental Capacity Act 2005 Practice Guidance, information booklets and all assessment, checklists and Independent Mental Capacity Advocate referral forms on iCare

<https://icon.torbayandsouthdevon.nhs.uk/areas/mental-capacity-act/Pages/default.aspx>

## Infection Control

All staff will have access to Infection Control Policies and comply with the standards within them in the work place. All staff will attend Infection Control Training annually as part of their mandatory training programme.

**Rapid (E)quality Impact Assessment (EqIA)** *(for use when writing policies)*

Policy Title (and number)		Version and Date	
Policy Author			
An (e)quality impact assessment is a process designed to ensure that policies do not discriminate or disadvantage people whilst advancing equality. Consider the nature and extent of the impact, not the number of people affected.			
Who may be affected by this document?			
Patients/ Service Users	<input type="checkbox"/>	Staff	<input type="checkbox"/>
Other, please state...		<input type="checkbox"/>	
Could the policy treat people from protected groups less favourably than the general population? <b>PLEASE NOTE: Any 'Yes' answers may trigger a full EIA and must be referred to the equality leads below</b>			
Age	Yes <input type="checkbox"/> No <input type="checkbox"/>	Gender Reassignment	Yes <input type="checkbox"/> No <input type="checkbox"/>
Race	Yes <input type="checkbox"/> No <input type="checkbox"/>	Disability	Yes <input type="checkbox"/> No <input type="checkbox"/>
Gender	Yes <input type="checkbox"/> No <input type="checkbox"/>	Pregnancy/Maternity	Yes <input type="checkbox"/> No <input type="checkbox"/>
Sexual Orientation			Yes <input type="checkbox"/> No <input type="checkbox"/>
Religion/Belief (non)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Marriage/ Civil Partnership			Yes <input type="checkbox"/> No <input type="checkbox"/>
Is it likely that the policy could affect particular 'Inclusion Health' groups less favourably than the general population? (substance misuse; teenage mums; carers <sup>1</sup> ; travellers <sup>2</sup> ; homeless <sup>3</sup> ; convictions; social isolation <sup>4</sup> ; refugees)			Yes <input type="checkbox"/> No <input type="checkbox"/>
Please provide details for each protected group where you have indicated 'Yes'.			
<b>VISION AND VALUES: Policies must aim to remove unintentional barriers and promote inclusion</b>			
Is inclusive language <sup>5</sup> used throughout?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
Are the services outlined in the policy fully accessible <sup>6</sup> ?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
Does the policy encourage individualised and person-centred care?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
Could there be an adverse impact on an individual's independence or autonomy <sup>7</sup> ?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
<b>EXTERNAL FACTORS</b>			
Is the policy a result of national legislation which cannot be modified in any way?			Yes <input type="checkbox"/> No <input type="checkbox"/>
What is the reason for writing this policy? (Is it a result in a change of legislation/ national research?)			
Who was consulted when drafting this policy?			
Patients/ Service Users	<input type="checkbox"/>	Trade Unions	<input type="checkbox"/>
Protected Groups (including Trust Equality Groups)		<input type="checkbox"/>	
Staff	<input type="checkbox"/>	General Public	<input type="checkbox"/>
Other, please state...		<input type="checkbox"/>	
What were the recommendations/suggestions?			
Does this document require a service redesign or substantial amendments to an existing process? <b>PLEASE NOTE: 'Yes' may trigger a full EIA, please refer to the equality leads below</b>			Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>ACTION PLAN: Please list all actions identified to address any impacts</b>			
Action	Person responsible	Completion date	
<b>AUTHORISATION:</b>			
By signing below, I confirm that the named person responsible above is aware of the actions assigned to them			
Name of person completing the form		Signature	
Validated by (line manager)		Signature	

**Please contact the Equalities team for guidance:**

For South Devon & Torbay CCG, please call 01803 652476 or email [marisa.cockfield@nhs.net](mailto:marisa.cockfield@nhs.net)

For Torbay and South Devon NHS Trusts, please call 01803 656676 or email [pf.d.sdhct@nhs.net](mailto:pf.d.sdhct@nhs.net)

**This form should be published with the policy and a signed copy sent to your relevant organisation**

Consider any additional needs of carers/ parents/ advocates etc, in addition to the service user

<sup>2</sup> Travelers may not be registered with a GP - consider how they may access/ be aware of services available to them

<sup>3</sup> Consider any provisions for those with no fixed abode, particularly relating to impact on discharge

<sup>4</sup> Consider how someone will be aware of (or access) a service if socially or geographically isolated

<sup>5</sup> Language must be relevant and appropriate, for example referring to partners, not husbands or wives

<sup>6</sup> Consider both physical access to services and how information/ communication is available in an accessible format

<sup>7</sup> Example: a telephone-based service may discriminate against people who are d/Deaf. Whilst someone may be able to act on their behalf, this does not promote independence or autonomy

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## Clinical and Non-Clinical Policies – Data Protection

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU General Data Protection Regulation (GDPR) and Data Protection Act 2018 (DPA 18) in mind, and therefore provides the reader with assurance of effective information governance practice.

The UK data protection regime intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy. Furthermore, data protection legislation requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data.

Does this policy impact on how personal data is used, stored, shared or processed in your department? Yes  No

If yes has been ticked above it is assured that you must complete a data mapping exercise and possibly a Data Protection Impact Assessment (DPIA). You can find more information on our [GDPR](#) page on ICON (intranet)

For more information:

- Contact the Data Access and Disclosure Office on [dataprotection.tsdf@nhs.net](mailto:dataprotection.tsdf@nhs.net),
- See TSDFT's [Data Protection & Access Policy](#),
- Visit our [Data Protection](#) site on the public internet.