Torbay and South Devon NHS
NHS Foundation Trust

Patient Specific Directions Policy

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Partners in Care

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Document Information

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Author:	Governance Pharmacist and Medication Safety Officer		
Owner:	Governance Pharmacist and Medication Safety Officer		
Directorate:	Organisation Wide		

Approval Route	
Approved By:	Date Approved:
Care and Clinical Policies Group	18 January 2017
Medicines Management Committee	19 January 2017
Chief Nurse	19 September 2017
Medical Director	26 September 2017

Links or overlaps with other policies:
1716 - Supervision, accountability and delegation of activities to skilled not registered staff
1782 - Patient Group Directions Policy

The Trust is committed to preventing discrimination, valuing diversity and achieving equality of opportunity. No person (staff, patient or public) will receive less favourable treatment on the grounds of the nine protected characteristics (as governed by the Equality Act 2010): Sexual Orientation; Gender; Age; Gender Reassignment; Pregnancy and Maternity; Disability; Religion or Belief; Race; Marriage and Civil Partnership. In addition to these nine, the Trust will not discriminate on the grounds of domestic circumstances, social-economic status, political affiliation or trade union membership.

The Trust is committed to ensuring all services, policies, projects and strategies undergo equality analysis. For more information about equality analysis and Equality Impact Assessments please refer to the Equality and Diversity Policy.

Amendment History

Issue	Status	Date	Reason for Change	Authorised
1	Ratified	2 October 2017	New	Care and Clinical Policies Group Medicines Management Committee Chief Nurse Medical Director
1		2 February 2018	Review date extended from 2 years to 3 years	

Contents

1. Introduction

1.1 This document sets out Torbay and South Devon NHS Foundation Trust's (TSDFT) process for development and review of Patient **Specific** Directions (PSDs). It provides a framework to ensure a consistent approach across the whole organisation mirroring some of the recommendations made in the Patient Group Directions NICE Guidelines (MPG2) August 2013.

The Human Medicines Regulations Act 2012 does not permit nurses, or other registered practitioners, who are not qualified prescribers to administer or supply prescription only medicines (POMs) unless one of three types of instruction is in place:

a. A signed prescription
b. A patient **specific** direction (PSD)
c. A patient group direction (PGD). See the TSDFT PGD Policy at **https://icon.torbayandsouthdevon.nhs.uk/corp_doc_mgmt/Clinical%20Effectiveness/G1782.pdf** *(last accessed May 2017)*

If non-prescribing health care professionals administer medicine on the instruction of a prescriber, the prescriber must be able to show that they have authority for that administration via one of the above methods.

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.

2. Definitions

2.1 A Patient **Specific** Direction (PSD) is the traditional written instruction, signed by a doctor, dentist, or non-medical prescriber for medicines to be administered to a named patient(s) after the prescriber has assessed the patient(s) on an individual basis.
www.rcn.org.uk/clinical-topics/medicines-optimisation/specialist-areas/patient-specific-directions-and-patient-group-directions *(last accessed May 2017)*

2.2 A PSD is individually tailored to the needs of a single or cohort of patients so more information may be required to enable safe administration of some medicines to manage identified risks.

2.3 A PSD is not:

- A Patient Group Direction (PGD)
- A verbal instruction
- An instruction applying to any patient who may be seen by a healthcare professional or who has an appointment on any particular day.

2.4 PSDs must be supported by approved procedures (Standard Operating Procedure) to support the safe administration of medicines under a PSD.

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 **Specific** Directions (PSDs).

3.2 This policy will provide the framework for service and clinical leads to assist in the identification and outline the process for the development of PSDs.

3.3 This policy should be read in conjunction with supporting policies, 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 ensuring that requests for the development of new PSDs for use within TSDFT are considered and approved, if appropriate.

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, Standard Operating Procedures (SOPs), guidelines and protocols (including Supervision, Accountability and Delegation of Activities to Skilled Not Registered Staff G1716).

4.2.2 Individual line managers, professional and clinical leads are responsible for the identification of staff who may administer medication under PSDs.

4.2.3 Individual line managers, professional and clinical leads must ensure staff have the appropriate training and competencies to administer medication under PSDs.

4.2.4 Individual line managers, professional and clinical leads must ensure staff competencies are reviewed and up to date.

4.2.5 Individual line managers, professional and clinical leads must ensure that staff administering medication under PSDs have access to the relevant protocols and/or Standard Operating Procedures.

4.3 Role of the Prescriber

4.3.1 The prescriber is responsible for assessment of the patient and the decision to administer the medicine(s) in question.

4.3.2 The prescriber must have adequate knowledge of the patient's health and be satisified that the medicine to be administered serves the individual needs of each patient on that list.

4.3.3 The prescriber has a duty of care and is professionally and legally accountable for the care he/she provides including tasks delegated to others.

4.3.4 The prescriber must be satisfied that the person to whom practice is delegated has the qualifications, experience, knowledge and skills to provide the care or treatment involved.

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4.3.6 The prescriber should include a start and finish date in the PSD to ensure it is acted on within a time frame following assessment which is appropriate to the needs of the patient(s).

4.3.7 A nurse or midwife independent prescriber may not prescribe remotely if they have not assessed the patient, except in life-threatening situations (Ref: https://www.**nmc**.org.uk) *last accessed May 2017*)

4.4 Role of Registered Staff Administering Medication under a PSD

4.4.1 Registered staff must ensure they have an up to date working knowledge of the medication they are administering under a TSDFT ratified PSD.

4.4.2 Registered staff are accountable for their own professional practice and must work within this policy and their respective professional codes.

4.4.3 Registered staff must act according to their level of competence and in accordance with the directions of the prescriber.

4.4.4 Registered staff operating under this policy will identify any training needs and attend required study sessions relating to this policy.

4.4.5 When administering a medicine under a PSD, health professionals should follow local organisational policies and act within their code(s) of professional conduct and local governance arrangements.

4.4.6 PSDs must not be used as a method for self administration.

4.4.7 Registered staff should ensure that the PSD includes:

- The name of the patient(s) and/or other individual patient identifiers
- Name, form and strength of medicine (generic or brand name where appropriate)

- Route of administration
- Dose
- Frequency
- Start and finish dates
- Signature of prescriber.

4.5 Role of Skilled Non-registered Staff Administering Medication under a PSD (Skilled Non registered staff refers only to Assistant Practitioners, Nursing Associates and Anaesthetic Practitioners)

4.5.1 Skilled Non-registered staff when administering medication are working under delegation from a registered professional. When delegating work to others, registered professionals have a legal responsibility and accountability to have determined the knowledge and skill level required to perform the delegated task.

4.5.2 The registered practitioner is accountable for delegating the task and the Skilled Non-registered staff are accountable for accepting the delegated task, as well as being responsible for their actions in carrying it out.

4.5.3 Assistant practitioners must have completed the Trust Medicines Administration Course and the competency framework for their specified area of practice. Standard Operating Procedures and supporting policies must be in place.

4.5.4 Non-registered staff must ensure they have an up to date working knowledge of the medication they are administering under a TSDFT ratified PSD.

4.5.5 Non-registered staff operating under this policy will identify any training needs and attend required study sessions relating to this policy.

4.5.6 Non-registered staff must act according to their level of competence and in accordance with the directions of the prescriber.

4.5.7 When administering a medicine under a PSD, non-registered professionals should follow local organisational policies, SOPs, guidelines and local governance arrangements.

4.5.8 Non-registered staff should ensure that the PSD includes:

- The name of the patient(s) and/or other individual patient identifiers
- Name, form and strength of medicine (generic or brand name where appropriate)
- Route of administration
- Dose
- Frequency
- Start and finish dates
- Signature of prescriber.

4.5.9 Non-registered staff **must not** administer or supply medication under a Patient Group Direction (PGD).

4.6 Role of PSD Administrator

– Maintaining an up to date database of current and expired PSDs.
– Retaining a PSD work plan
– Ensuring the PSD template is up to date and version control and history are accurate.

- Ensuring approved PSDs are ratified.
- Sending website versions of PSDs to Clinical Effectiveness Department for uploading on the Trust intranet
- Disseminating ratified PSDs to appropriate line managers and / or service leads.

5. Identifying the Need for a PSD

5.1 Service leads identifying the need for a PSD must complete a PSD Development Request Form in full (Appendix 1) and send it to the Medicines Governance Group Pharmacist at (tsdft.medicinesgovernance@nhs.net) *(last accessed May 2017)*

5.2 Request for a new PSD received by the Medicines Governance Pharmacist will be considered to determine that the need for a PSD meets all the criteria for developing a PSD.

6. Clinical Protocols / Standard Operating Procedures Supporting PSDs

6.1 The development of associated protocols / SOPs must be completed prior to final PSD ratification.

6.2 It is advisable that work to produce a clinical protocol and / or SOP to support the PSD is commenced in conjunction with the PSD.

6.3 A clinical protocol / SOP is to be produced by the clinical lead of the service to underpin each PSD.

6.4 A PSD will not be ratified without the supporting clinical protocol / SOP being ratified in advance or at the same time as the PSD.

7. Development, Ratifying and Implementing PGDs

7.1 PSDs and associated Standard Operating Procedures must be developed, revised or updated by a doctor / service lead and a representative of the professional group who will either prescribe or administer medicines under the PSD.

7.2 The PSD will be informed by legislation, local and national frameworks, policies, guidelines, local formularies and other bodies with medicines expertise.

7.3 The PSD author(s) will ensure the draft PSD is put into the current PSD template available from the Medicines Governance Team **tsdft.medicinesgovernance@nhs.net** *(last accessed May 2017).*

7.4 The draft PSD will be emailed to the Medicines Governance Team who will arrange for it to be ratified.

7.5 The Medicines Governance Team administrator will ensure version control.

7.6 The ratified PSD is to be forwarded by the Medicines Governance Team Administrator to the Clinical Effectiveness Department for uploading onto the Trust's intranet. The ratified version will be disseminated to the relevant professional / clinical leads, senior managers by the Medicines Governance Team Administrator.

7.7 Professional leads and clinical leads / senior managers will disseminate the ratified PSD to relevant staff. They will ensure that those who are going to operate under the PSD have access to the document and that any training needs have been identified and addressed.

7.8 In the area where the PSD is used the following must be in place:

– A copy of the protocol / SOP must be available in the clinical setting in which the care is provided.

– Staff should be provided with a copy of the PSD which includes the prescriber's name and signature and patient list.

7.9 PSDs and their associated protcols / SOPs will be reviewed every two years or before if necessary.

7.10 PSDs and associated protocols / SOPs that are updated before their two year expiry will need to be re-ratified.

7.11 The protocol / SOP should specify where the completed PSD will be stored and that a record of the administration should be made in the patient's notes.

7.12 Expired PSDs will be removed from the Trust's website.

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

7.14 Expired PSDs will be archived and stored in accordance with the guidelines issued by the Trust's Information Governance.

7.15 The original ratified version of the PSD will be retained by the Medicines Governance team.

8. Training

8.1 Specific training needs for individual PSDs must be identified by the Service Leads. Advice may be sought from the Medicines Governance team (tsdft.medicinesgovernance@nhs.net). *(last accessed May 2017)*

8.2 Where appropriate records of training must be retained by the Service Lead / Line Manager.

9. Audit of PSDs

9.1 It is the responsibility of the service lead to monitor and audit the use of PSDs within their service setting.

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

10. References

PGD Policy
Medicines Policy
Consent Policy
NICE Guidance Patient Group Directions August 2013
Specialist Pharmacy Service

https://www.sps.nhs.uk/articles/patient-specific-directions-qa/ *(last accessed May 2017)*

Specialist Pharmacy Service

https://www.sps.nhs.uk/wp-content/uploads/2013/03/PSDs_July2015.pdf *(last accessed September 2017)*

Royal College of Nursing

www.rcn.org.uk/clinical-topics/medicines-optimisation/specialist-areas/patient-specific-directions-and-patient-group-directions *(last accessed May 2017)*

Sue Mulvenna Head of Pharmacy NHS England SSW 12.4.16

www.england.nhs.uk/south/wp-content/uploads/sites/6/2016/04/patient-specific-directions.pdf *(last accessed May 2017)*

MHRA

http://webarchive.nationalarchives.gov.uk/20141205150130/http:/www.mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribingsellingandsupplyingofmedicines/Frequentlyraisedissues/PatientSpecificDirections/index.htm *(last accessed September 2017*

11. Distribution

Professional Leads.
Clinical Leads
Senior Managers

12. Appendices

Appendix 1 - PSD Request Form
Appendix 2 - PSD Flowchart

Appendix 1

(PATIENT SPECIFIC POLICY – version 1.0 August 2017)
REQUEST FOR THE DEVELOPMENT OF A PATIENT SPECIFIC DIRECTION

DETAILS OF THE PSD REQUESTED	
NAME OF THE MEDICATION	
Setting where the PSD 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 £ NO £
If NO, what arrangements are to be made: .....

DETAILS OF THE MEDICINE TO BE ADMINISTERED						
Dosage	Quantity	Formulation	Strength	Route	Frequency	Duration of Treatment

Is the appropriate formulation of medicine available. e.g. pre pack? YES £ NO £
If YES, is one already available YES £ NO £

Is the Medicine included in the local Joint Formulary (e.g. South Devon JF) ? YES £ NO £

DETAILS OF THE CLINICAL PROTOCOL / TRAINING AND RESOURCES TO SUPPORT THE PSD

Has a SOP or protocol been developed and ratified by the Trust ? YES £ NO £

If NO, please state who will be responsible for writing the protocol / SOP: .....
If YES, will the current protocol / SOP require updating YES £ NO £

Which Registered / Non-Registered staff will work under the PSD	
Detail training and competency needs	
What resources are needed to deliver the service	
What is the timescale for developing the PSD	

DETAILS OF AUDIT ARRANGEMENTS

What audit arrangements will be in place to monitor administration / supply and use of this PSD:
.....
.....

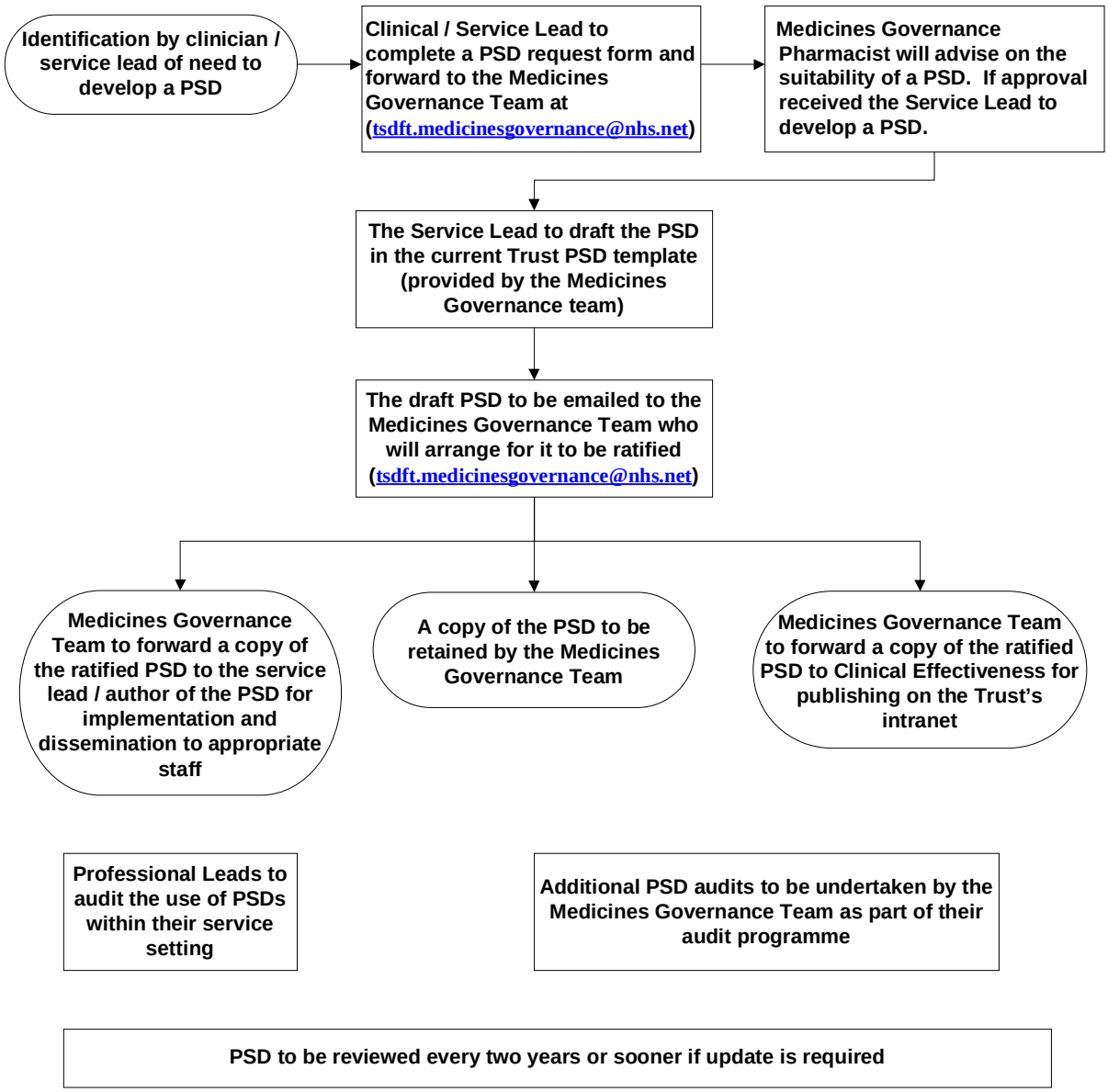
DETAILS OF THE PROPOSER

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 OR Medicines Governance Team, Pharmacy Department, TSDFT, Lawes Bridge, Torquay TQ2 7AA

Appendix 2

DEVELOPMENT / REVIEW OF PATIENT SPECIFIC DIRECTIONS FLOWCHART FOR THE DEVELOPMENT, DISSEMINATION, IMPLEMENTATION, MONITORING, AUDIT AND REVIEW OF PATIENT SPECIFIC DIRECTIONS (PSDs) WITHIN TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST



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

http://icare/Operations/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.

NHS South Devon and Torbay Clinical Commissioning Group

Torbay and South Devon NHS
NHS Foundation Trust

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 ☐	Staff ☐	Other, please state… ☐

Could the policy treat people from protected groups less favorably than the general population?
PLEASE NOTE: Any 'Yes' answers may trigger a full EIA and must be referred to the equality leads below

Age	Yes ☐ No☐	Gender Reassignment	Yes ☐ No☐	Sexual Orientation	Yes ☐ No☐
Race	Yes ☐ No☐	Disability	Yes ☐ No☐	Religion/Belief (non)	Yes ☐ No☐
Gender	Yes ☐ No☐	Pregnancy/Maternity	Yes ☐ No☐	Marriage/ Civil Partnership	Yes ☐ No☐

Is it likely that the policy could affect particular 'Inclusion Health' groups less favorably than the general population? (substance misuse; teenage mums; carers[1]; travellers[2]; homeless[3]; convictions; social isolation[4]; refugees)	Yes ☐ No☐

Please provide details for each protected group where you have indicated 'Yes'.

VISION AND VALUES: Policies must aim to remove unintentional barriers and promote inclusion

Is inclusive language[5] used throughout?	Yes ☐ No☐ NA ☐
Are the services outlined in the policy fully accessible[6]?	Yes ☐ No☐ NA ☐
Does the policy encourage individualised and person-centred care?	Yes ☐ No☐ NA ☐
Could there be an adverse impact on an individual's independence or autonomy[7]?	Yes ☐ No☐ NA ☐

EXTERNAL FACTORS

Is the policy a result of national legislation which cannot be modified in any way?	Yes ☐ No☐

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 ☐	Trade Unions ☐	Protected Groups (including Trust Equality Groups) ☐
Staff ☐	General Public ☐	Other, please state… ☐

What were the recommendations/suggestions?

Does this document require a service redesign or substantial amendments to an existing process? ***PLEASE NOTE: 'Yes' may trigger a full EIA, please refer to the equality leads below***	Yes ☐ No☐

ACTION PLAN: Please list all actions identified to address any impacts

Action	Person responsible	Completion date

AUTHORISATION:
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

For Torbay and South Devon NHS Trusts, please call 01803 656676 or email pfd.sdhct@nhs.net
This form should be published with the policy and a signed copy sent to your relevant organisation.

[1] Consider any additional needs of carers/ parents/ advocates etc, in addition to the service user
[2] Travelers may not be registered with a GP - consider how they may access/ be aware of services available to them
[3] Consider any provisions for those with no fixed abode, particularly relating to impact on discharge
[4] Consider how someone will be aware of (or access) a service if socially or geographically isolated
[5] Language must be relevant and appropriate, for example referring to partners, not husbands or wives
[6] Consider both physical access to services and how information/ communication in available in an accessible format
[7] 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