Naloxone Supply for Use in Overdose by Opiate Drug users	
Ref 2040 Version 2	
Standard Operating Procedure (SOP)	
Prepared by: Recovery Coordinator/Adult Nurse	
Presented to: **Care & Clinical Policies Sub-group** **Clinical Director of Pharmacy**	**Date:** **20 June 2018** **16 July 2018**
Ratified by: **Care and Clinical Policies Sub Group** **Clinical Director of Pharmacy**	**Date:** **20 June 2018** **23 July 2018**
	Review date: 27 July 2021
Relating to policies: **0806 – Medicines Policy for Wards and Departments at Torbay Hospital**	

Purpose of this document:

The aim of this standard operating procedure is to reduce drug related deaths associated with opioid overdose with the use of Naloxone.

Torbay and South Devon NHS Foundation Trust (TSDFT) will provide Overdose Awareness and use of Naloxone training to staff, service users, family members, hostel workers and others in line with local and national guidelines to reduce the numbers of drug related deaths from opioid overdose.

Britain continues to have a high number of drug-related deaths with opiate overdose remaining a major cause of death among injecting drug users. In England and Wales 765 deaths were registered in 2013 in which heroin or morphine were mentioned on the death certificate: an average of two every day, and a significant increase of 32% compared to those registered in 2012. This increase brings the number of deaths relating to heroin and/or morphine to similar levels to 2010. Naloxone is a drug which temporarily reverses the effects of opioids such as heroin, methadone and morphine. For many years, Naloxone has been used within emergency medical settings to reverse the effects of opioid overdose and prevent death. UK Guidelines on Clinical Management of Drug Misuse fully endorses the use of Naloxone in overdose management and prevention.

On the first of October 2015 The Human Medicines (Amendment) (No. 3) Regulations 2015 (2015/1503) came into force. This allows Naloxone to be supplied by:

Persons employed or engaged in the provision of drug treatment services provided by, on behalf of or under arrangements made by one of the following bodies– a) an NHS body; (b) a local authority;(c) Public Health England; or(d) Public Health Agency.

It can be supplied to anyone in the course of lawful drug treatment services and only where required for the purpose of saving life in an emergency.

For explanatory memorandum see: PHE take-home Naloxone
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/669475/phetake-homenaloxoneforopioidoverdoseaug2017.pdf
(date last accessed 02/03/16.)

Scope of this SOP: -

This standard operating procedure (SOP) outlines the process for the supply of Naloxone to service users, family members, hostel staff, carers and other groups for the purpose of temporarily reversing opioid overdose. This procedure is intended as a framework for the supply of Naloxone injections by Trust employees and partner agencies within specialist substance misuse services. This procedure applies to all staff volunteers and peers within Substance Misuse services that have direct contact with clients.

This SOP is for Torbay and South Devon NHS Foundation Trust staff working within Torbay Drug and Alcohol Service and linking substance misuse partners.

Competencies required:

Staff competence

Staff supplying Naloxone should have been appropriately trained (minimum requirement Substance Misuse Management Good Practice (SMMGP) online learning package and Torbay and South Devon NHS Foundation Trust Overdose Awareness and use of Naloxone training package) and have been signed off as competent by the Clinical Lead of the team. The Clinical Lead or nominated deputy will also be responsible for keeping a register of appropriately trained staff /volunteers with the supply of Naloxone.

It is recommended that staff complete annual refresher training via the SMMGP online learning module in order to maintain skills in the training and provision of Naloxone.

Procedure / Steps:

One Naloxone pre-filled syringe/pack for intramuscular use will be supplied. Should there be an identified need for more than one pack this should be discussed and agreed with the Clinical Lead. Each pack will include one Naloxone injection 1mg/ml as a 2ml pre –filled syringe. Each 2ml syringe is marked out with 5 x 0.4mg doses. 0.4mg is the minimum effective dose which can be given in an attempt to reverse the effects of opioid overdose.

Collection and audit

The supply of Naloxone must be recorded using the Torbay Drug and Alcohol Service (TDAS) Naloxone register & record in the clinical notes. **(Appendix 1)**, When a supply is made under this procedure a record shall be made of the supply, including to who it was supplied, the batch number of the product, the expiry date and the name of the person supplying the pack. If the supply is made as a replacement, client and administration details must be recorded on the Administration of Naloxone Feedback form **(see Appendix 2)**. This will give important information about the use of the Naloxone pack, the situation in which it was used and identify any further training needs to improve service provision and patient outcomes. A spread sheet of this data should be held at the Torbay Drug Service under the supervision of the Team Lead.

Supply, storage and stock control

In November 2015, Naloxone was reclassified under article 7 of Prescription Only Medicines Order, by Parliament. Naloxone is now on the list of prescription only medicines that can be administered parentally (by injection) by anyone for the purpose of saving a life.

Take home Naloxone will be supplied as pre-packed Naloxone pack containing:

- 1 x 2ml pre-filled syringe (Naloxone Hydrochloride 1mg/1ml)
- 2 x 23G 1.25” needles for intramuscular injection
- Product instruction sheet/s

Naloxone must be stored at room temperature (i.e. between 15 to 25^{o}C) and protected from light. Inappropriate storage and handling may shorten the shelf life. All persons issued with Naloxone must be advised to keep the take home Naloxone out of reach of children and pets and encouraged to return for a replacement pack should it have been administered, lost, damaged, or passed its expiry date. All persons issued with Naloxone must be advised on the safe disposal of needles following the use of the take home Naloxone. Naloxone has a low potential for misuse. However, authorised service users should be discouraged from opening the packs to use needles for other purposes.

Storage of Naloxone on Trust premises needs to be in line with the Trust Medicines Management policy, i.e., in approved medicines cabinets. Medicine cabinets need to remain locked and kept together on one key ring kept solely for these keys.
Stock received and supplied should be recorded in the Naloxone Register **(see Appendix 1).**

Expired supplies

Naloxone has a maximum shelf life of 3 years from the date of manufacture. When Naloxone is supplied this should be explained to all persons issued with Naloxone and the expiry date noted. The recipient should be encouraged to return the Naloxone to the service before the expiry date to collect a further supply. Expired packs will need to be disposed of appropriately, via the Trust Hospital pharmacy, located at Torbay Hospital.

Training Service users, carers and identified others in overdose management

Training on how to recognise opioid overdose, overdose management, and administration of Naloxone injection must be given before Naloxone is supplied. The training may be delivered on an individual or group basis. The training is not time consuming, taking five to ten minutes, but must cover recognition of an opioid overdose and that the procedure is to:

- Ensure personal safety first
- Call an ambulance
- Place the patient in the recovery position if breathing, place patient on their back if not breathing.
- If not breathing, commence basic life support, 2x rescue breaths, then 30 chest compressions.
- Inject 1x dose of Naloxone into the thigh or upper arm muscle. Repeat every 2-3 minutes until patient is responsive or ambulance arrives.
- If patient is not breathing repeat breaths and chest compressions until breathing commences.
- If patient's breathing is shallow, intermittent or fewer than 12 breaths per minute, commence rescue breathing 1 breath per 5 seconds. **Trainers must advise rationale for rescue breathing but that it is not expected if mouth-to-mouth resuscitation mask unavailable due to risks such as blood borne virus transmission. This will be at person's own risk.**
- Wait with the patient until the ambulance arrives and safely dispose of the Naloxone pack to paramedics

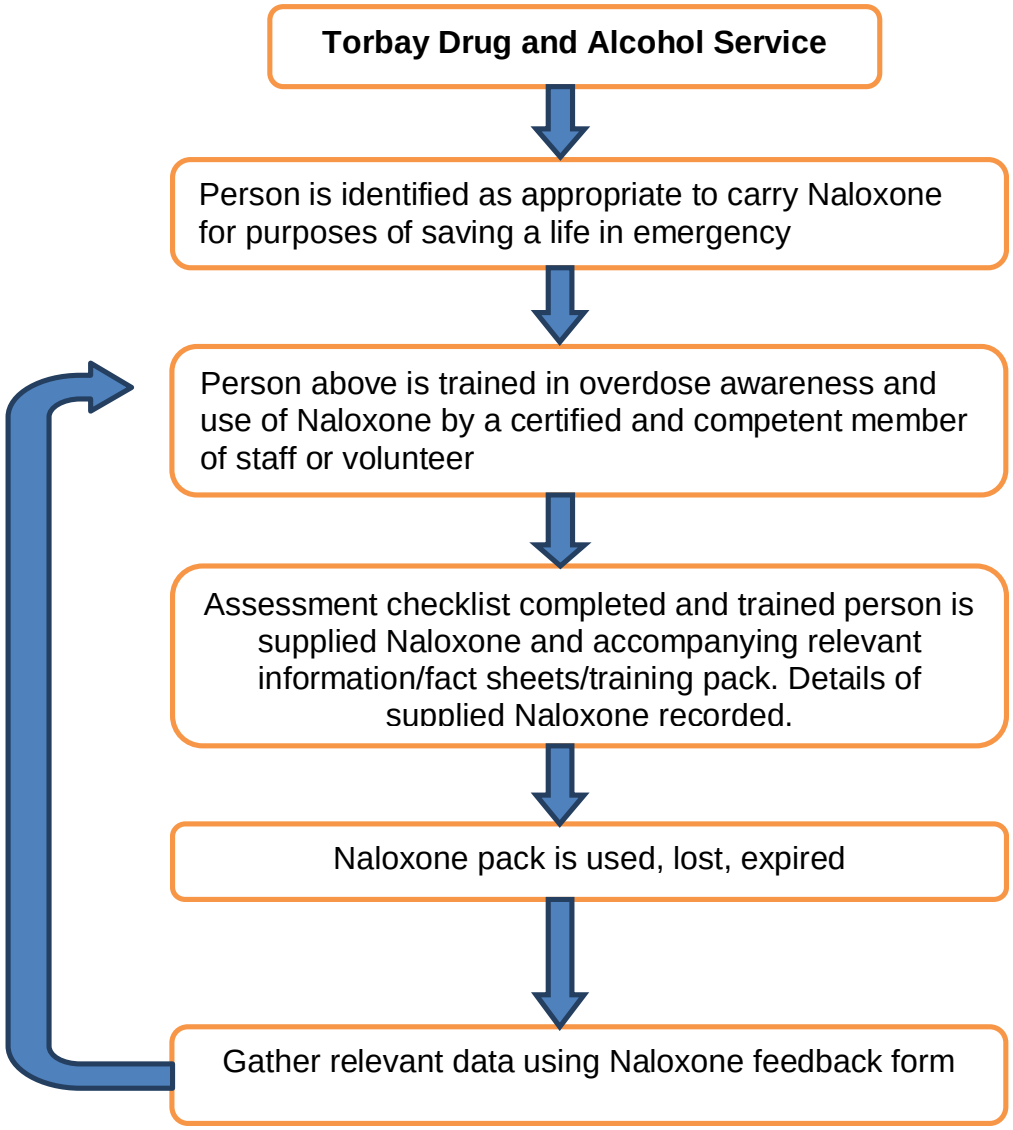
The process of using the Naloxone pack must be explained and demonstrated and an assessment checklist **(see Appendix 3)** must be carried out post training to ensure understanding. This should be done each time a pack is given out or replaced.

It's important to recognise that the primary issue for overdose is respiratory depression and not cardiac arrest. Therefore it's important that rescue breathing is discussed as part of training provision **(see Appendix 4).**

Torbay and South Devon NHS Foundation Trust Pharmacy will ensure that Naloxone orders are processed in a timely manner.

TDAS will ensure that the Naloxone is stored and ordered as per Medicines Management Policy.

Flowchart


Torbay Drug and Alcohol Service
Person is identified as appropriate to carry Naloxone for purposes of saving a life in emergency
Person above is trained in overdose awareness and use of Naloxone by a certified and competent member of staff or volunteer
Assessment checklist completed and trained person is supplied Naloxone and accompanying relevant information/fact sheets/training pack. Details of supplied Naloxone recorded.
Naloxone pack is used, lost, expired
Gather relevant data using Naloxone feedback form

1. Monitoring tool:

Standards:

Item	%	Exceptions
All clients using opiates or opiate substitute medication will be offered Naloxone.	100%	Nil
Records of all Naloxone supplied.	100%	Nil
All persons issued with Naloxone will have received overdose awareness first aid training.	100%	Nil
Feedback from resupply requests	75%	Declined to feedback/lost to service.

Equality Statement.
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

References:
Trust Medicines Policy – Ref 0806

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/669475/phetake-homenaloxoneforopioidoverdoseaug2017.pdf

Appendix:

Flowchart
Appendix 1 – Naloxone Register
Appendix 2 – Naloxone Feedback Form
Appendix 3 – Overdose and use of Naloxone Training Checklist
Appendix 4 – Training Provision

Amendment History

Issue	Status	Date	Reason for Change	Authorised
1	New	7 March 2016	Implementation of Naloxone Supply	Care and Clinical Policies Group

2	Ratified	27 July 2018	Revised	Care and Clinical Policies Group Clinical Director of Pharmacy

Appendix 1

Naloxone Register

Team:

Date	Staff member (name and Signature)	Quantity received	Quantity issued	Patient Initials & HALO number or initials and carer/hostel etc	Balance	Balanced checked by & date (weekly?)

Torbay and South Devon NHS
NHS Foundation Trust

Appendix 2

Administration of Naloxone Feedback

Client's name: ……

Date: ……

Naloxone kit used on: **CLIENT** or **SOMEONE ELSE**

How much was given (0.4mg per black line – total 2mg):

1 DOSE or **2 DOSES** or **3 DOSES** or **4 DOSES** or **ALL**

What was the outcome: ……

Was the ambulance called: **YES** or **NO**

If NO can you please state why: ……

How was the used pack disposed of: ……

Has a new pack been given: **YES** or **NO**

Would you like to tell us anything else about their experience of using Naloxone/ any further training needs to improve use in the future:

Staff name: ……

Appendix 3

Overdose and use of Naloxone Training Checklist

Client name:…… Date of birth:……..

Representative name (if applicable):……

Evidence of understanding	Assessor' signature
What are the signs and symptoms of suspected opioid overdose? Unconscious, not responding to touch or noise, breathing difficulties, heavy snoring, rasping sounds, pinned pupils, blue tinge to lips, nose, fingertips.	
How and when would you call an ambulance? Dial 999. Naloxone is not an alternative to calling an ambulance.	
Describe the recovery position.	
Describe what Naloxone is and how it works? Opioid antagonist, antidote to heroin, reverses effects of heroin temporarily, does not reverse alcohol or benzodiazepine, quick acting 2-8 min.	
When would you inject Naloxone? When the patient will not wake, shows signs of overdose and they have been put into the recovery position. Call ambulance first.	
How do you inject Naloxone? Assemble the injection as shown on the leaflet provided. Inject 0.4ml (up to the first black line) into the muscle of the outer thigh or upper arm. Repeat another 0.4ml dose every 2-3 minutes until the patient wakes up or the ambulance arrives.	
How long do the effects of Naloxone last? 20 – 30 minutes. Overdose may return after this, especially if the patient uses opioids again.	
Are you aware of the importance of staying with the person and handing over to the paramedics when they arrive? Tell the paramedics what the patient has taken if you know, hand the Naloxone pack to the paramedics.	

Torbay and South Devon NHS
NHS Foundation Trust

I confirm that the above named client and/or representative has had Naloxone training, has demonstrated sufficient understanding of overdose and using Naloxone and has been provided with a Naloxone pack and Naloxone information:

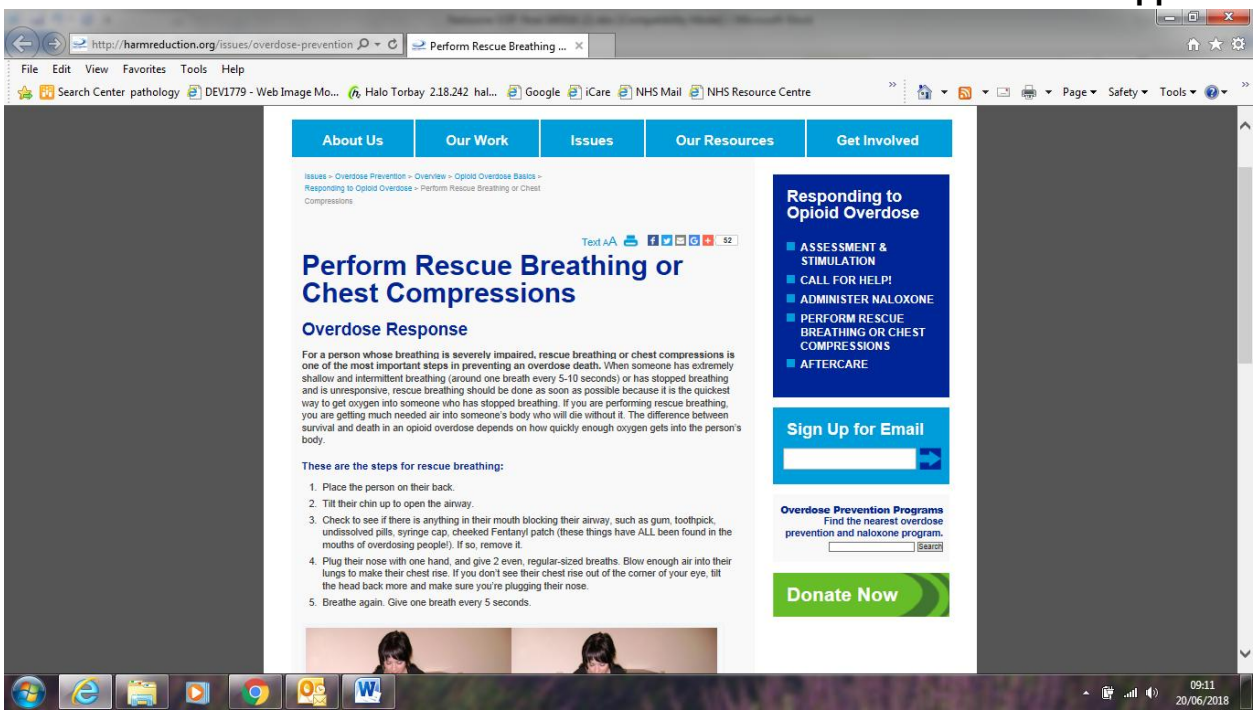
Staff sign:……Recipient sign:……

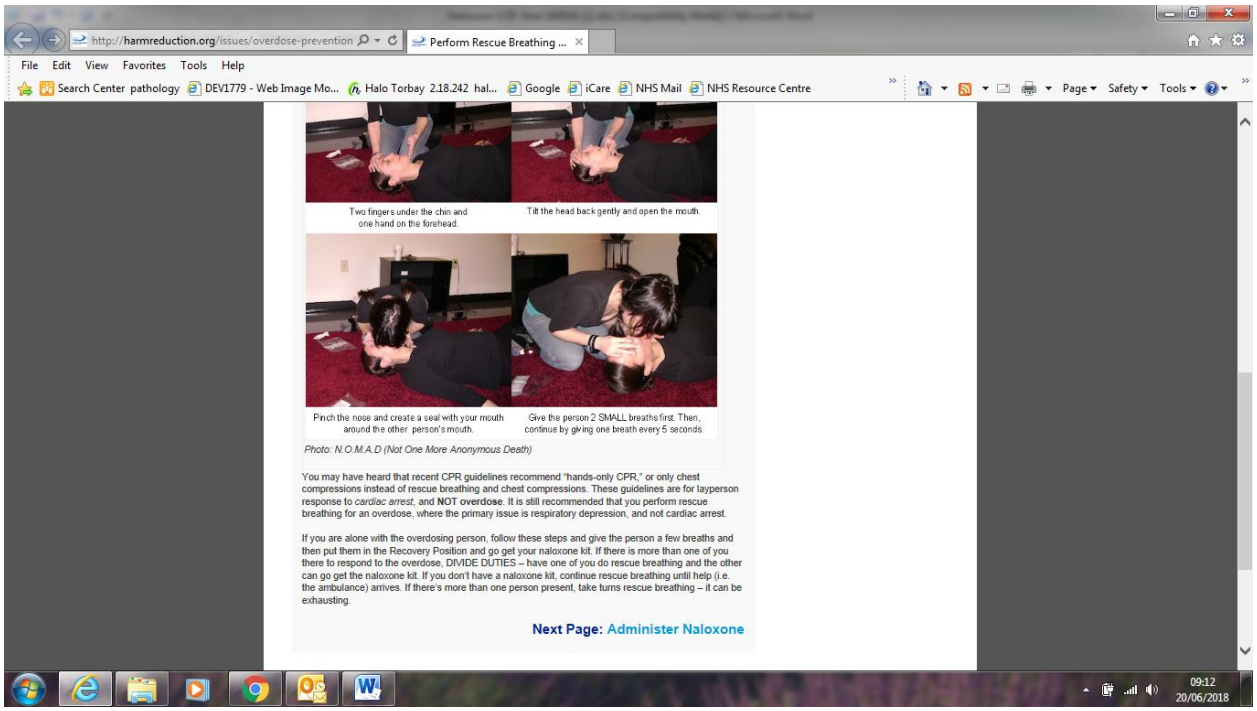
Staff name:……Recipient name:……..

Date:……Date:……

Batch no:……Expiry date:……

Appendix 4


http://harmreduction.org/issues/overdose-prevention
Perform Rescue Breathing ...
File Edit View Favorites Tools Help
About Us
Our Work
Issues
Our Resources
Get Involved
Perform Rescue Breathing or Chest Compressions
Overdose Response
For a person whose breathing is severely impaired, rescue breathing or chest compressions is one of the most important steps in preventing an overdose death. When someone has extremely shallow and intermittent breathing (around one breath every 5-10 seconds) or has stopped breathing and is unresponsive, rescue breathing should be done as soon as possible because it is the quickest way to get oxygen into someone who has stopped breathing. If you are performing rescue breathing, you are getting much needed air into someone's body who will die without it. The difference between survival and death in an opioid overdose depends on how quickly enough oxygen gets into the person's body.
These are the steps for rescue breathing:
1. Place the person on their back.
2. Tilt their chin up to open the airway.
3. Check to see if there is anything in their mouth blocking their airway, such as gum, toothpick, undissolved pills, syringe cap, cheeked Fentanyl patch (these things have ALL been found in the mouths of overdosing people!). If so, remove it.
4. Plug their nose with one hand, and give 2 even, regular-sized breaths. Blow enough air into their lungs to make their chest rise. If you don't see their chest rise out of the corner of your eye, tilt the head back more and make sure you're plugging their nose.
5. Breathe again. Give one breath every 5 seconds.
Responding to Opioid Overdose
ASSESSMENT & STIMULATION
CALL FOR HELP!
ADMINISTER NALOXONE
PERFORM RESCUE BREATHING OR CHEST COMPRESSIONS
AFTERCARE
Sign Up for Email
Overdose Prevention Programs
Find the nearest overdose prevention and naloxone program.
Donate Now


http://harmreduction.org/issues/overdose-prevention
Perform Rescue Breathing ...
Two fingers under the chin and one hand on the forehead.
Tilt the head back gently and open the mouth.
Pinch the nose and create a seal with your mouth around the other person's mouth.
Give the person 2 SMALL breaths first. Then, continue by giving one breath every 5 seconds.
Photo: N.O.M.A.D (Not One More Anonymous Death)
You may have heard that recent CPR guidelines recommend "hands-only CPR," or only chest compressions instead of rescue breathing and chest compressions. These guidelines are for layperson response to cardiac arrest, and NOT overdose. It is still recommended that you perform rescue breathing for an overdose, where the primary issue is respiratory depression, and not cardiac arrest.
If you are alone with the overdosing person, follow these steps and give the person a few breaths and then put them in the Recovery Position and go get your naloxone kit. If there is more than one of you there to respond to the overdose, DIVIDE DUTIES – have one of you do rescue breathing and the other can go get the naloxone kit. If you don't have a naloxone kit, continue rescue breathing until help (i.e. the ambulance) arrives. If there's more than one person present, take turns rescue breathing – it can be exhausting.
Next Page: Administer Naloxone

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 favourably 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

Clinical and Non-Clinical Policies – New Data Protection Regulation (NDPR)

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 New Data Protection Regulation (NDPR) in mind and therefore provides the reader with assurance of effective information governance practice.

NDPR 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, NDPR 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. The most effective way of being open is through data mapping. Data mapping for NDPR was initially undertaken in November 2017 and must be completed on a triannual (every 3 years) basis to maintain compliance. This policy supports the data mapping requirement of the NDPR.

For more information:

- Contact the Data Access and Disclosure Office on dataprotection.tsdft@nhs.net,
- See TSDFT's Data Protection & Access Policy,
- Visit our GDPR page on ICON.