

Duty of Candour	
Standard Operating Procedure (SOP)	
Ref No: 2159	
Version: 3	
Prepared by: Patient Safety Lead	
Presented to: Quality Improvement Group	Date: 14 March 2017
Ratified by: Quality Improvement Group	Date: 14 March 2017
	Review date: 16 February 2021
Relating to policies: This Standard Operating Procedure (SOP) should be read in conjunction with: 0898 Duty of Candour Policy; 0848 Incident Policy 2146 Incident Reporting SOP	

Contents

1.	Introduction	Page 2
2.	Purpose	Page 2
3.	Scope	Page 2
4.	Process for Implementing Duty of Candour	Page 2
5.	Process for Monitoring Compliance and Effectiveness.	Page 3
6.	Definitions	Page 3

Appendix A	Investigation Template Letter
Appendix B	No Investigation Template Letter
Appendix C	Template Letter (outcome of investigation)

1. Introduction

Duty of Candour (DoC) is a legal requirement. It places a formal obligation on providers of Health and Social Care to be open and honest with their patients when they suffer moderate harm or above (see definitions) related to their care or treatment provided by the Trust.

2 Purpose

This SOP has been developed to ensure a simple and robust processes in respect to the implementation of DoC and to ensure that openness, transparency and candour are complied with.

3. Scope

This SOP applies to all Health and Social Care staff working within the Trust, including those employed on a bank, agency or locum basis.

There is a statutory Duty of Candour on registered healthcare professionals to inform their employer where they believe or suspect that treatment has caused death or serious injury and it is a criminal offence for any registered medical practitioner, or nurse to fail to do so.

4. Process for Implementing Duty of Candour

All staff must ensure that any patient/service user safety incident is reported on the [Datix reporting system](#), (accessed off the intranet home page under the Incident icon) as soon as possible after making the patient/situation safe.

- If the patient/service user has suffered an injury or clinical incident whilst receiving NHS or Social Care thought to be due to a lapse in care, that is of a level of harm moderate or above, the team leader/ manager/ relevant other must speak to the patient and offer an apology and explain the event will be investigated and a SPOC will be identified. Subsequently, should the event, upon investigation be found to be due to a lapse in care the DoC must be followed.

The SPOC will ask what specific questions the patient/service user wants answering, be a formal contact point and ask how they would like the investigation to be fed back to them e.g. via a meeting or by sending a copy of the investigation to them.

This will be followed up with a letter sent to the patient/service user – Appendix A and appendices thereafter are templates that can be modified to accurately reflect the situation and Trusts response. These letters must be attached to the Datix system under the corresponding incident.

- If the patient/service user has suffered severe permanent disability or death or lacks capacity– DoC will be implemented by the investigating lead as a part of the serious incident process through the next of kin (NOK) or legal guardian (LG).
- If the patient/service user does not wish to be part of the investigation or DoC process (the patient has capacity) then a letter confirming the discussion should be completed (Appendix B) and sent. A copy should be attached to the health record.
- Similarly, if the patient/service user lacks capacity and the NOK or LG does not wish to be part of the investigation or DoC process then a letter confirming the discussion should be completed (Appendix B) and sent. A copy should be attached to the health record

- If the service user/carer is not satisfied with the outcome of the investigation they should be offered local resolution via further communications. However, It is the right of the patient/service user, should they wish to, to lodge a complaint via the normal processes.
- If more clarity on a specific incident is needed re the harm level, outcome etc., then a meeting with the Medical Director and or Chief Nurse should be convened and the proceedings recorded and attached to the incident recorded on Datix

Please note: All documentation sent to the service user/carer must be in a format which is easy to understand, free from medical jargon and acronyms.

5. Process for Monitoring Compliance and Effectiveness

Monitoring of the implementation of this procedure will be through the Datix system.

6. Definitions

- Harm Levels:
 - Moderate**, Any unexpected or unintended incident that resulted in a moderate increase in treatment e.g. continuous prolonged pain or psychological harm likely to last more than 28 days, an unplanned return to theatre, an unplanned admission, a prolonged episode of care, cancelling of treatment, or transfer to another area (e.g. such as Intensive Care), and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care
 - Severe** Any unexpected or unintended incident that appears to have resulted in permanent harm to one or more persons
 - Death** Any unexpected or unintended incident that directly resulted in the death of one or more persons.
- Lapse in Care – where an act or omission is as a result of care etc. given by the trust and its employees
- National Reporting and Learning System (NRLS) – The Department of Health’s repository of all clinical incidents that occur within England
- Specific Point of Contact – SPOC. A person assigned to liaise with the patient/carer
- Trust – Torbay & South Devon NHS Foundation Trust

Amendment History

Issue	Status	Date	Reason for Change	Authorised
1	Ratified	18 May 2017	New	Quality Improvement Group
2	Ratified	7 July 2017	Amendment to include lapse of care under point 4 bullet 1 Definitions point 4 amended. Point 6 amended	Patient Safety Lead
2		2 February 2018	Review date extended from 2 years to 3 years	
3	Ratified	16 February 2018	Amendments to Appendices A, B and C	Patient Safety Lead

****THIS IS A TEMPLATE LETTER - PLEASE AMEND AS
APPROPRIATE****

(Insert name & address)

Dear *(Insert title & name)*

As part of the Trust's ongoing work to monitor all patient/service user safety incidents, we are reviewing an episode of care relating to you/your *[insert relationship and name]* care at the Trust on *[insert date or interval range if not known]*.

On behalf of the Trust I am sorry that this incident occurred and for the distress caused to you and your family as a result.

This outcome was not what was expected and, as a Trust, we are committed to being open with patients and carers when events such as this occur, and in undertaking a robust review so that we gain a shared understanding of what happened.

My reason for writing to you now is to explain how the review will proceed and to ascertain if, and how, you would like to be involved in the review, in the feedback of the results and any actions arising.

Either

I am aware that a member of the clinical team *[insert name and role of the SPOC/ or clinical team member]* has already discussed the incident with you *[delete if not appropriate]*

Or

Staff member, *[insert name]*, is acting as your lead contact for the duration of the review. He/She can be contacted by email at *[insert email address]*, or on telephone number *[insert number]*.

The incident involving you/your *[insert name]* has been recorded on the Trust's incident reporting system and a review has started. The review will seek to identify the circumstances which resulted in the incident, together with any other contributing factors. You may have some specific questions you would like to be included in the review. If you have not already had the opportunity to put forward any questions, please contact *[insert name]* as soon as possible to discuss them. Please also indicate how you would like us to feedback our findings to you.

There is an independent Health Complaints Advocacy Service available to support and assist you if you would like this. They can be contacted on tel. 0330 440 9000.

Yours sincerely

Appendix B

****THIS IS A TEMPLATE LETTER - PLEASE AMEND AS APPROPRIATE****

(Insert name & address)

Dear *(Insert title & name)*

I am writing to follow up on the conversation we had on *[insert date]* when you agreed you were satisfied with the explanation provided and declined to be part of a review and the Duty of Candour process.

Again, I would like to express my sincere apologies that you/ your *[insert relationship/name]* has been involved in a patient/service user safety incident whereby *[provide appropriate factual details here]*.

As a Trust we are committed to being open with patients and carers when events such as these occur so that we gain a shared understanding of what happened and what we can do to prevent such an incident occurring again in the future. The incident involving you/*[insert name]* has been recorded on the Trust's incident reporting system and a review has started. The Trust will continue to review the occurrence of incidents to ensure any learning can be shared and changes made.

If you would like to meet with a member of staff to discuss this, please let me know within the next two weeks, and we will arrange a mutually convenient time and place to meet.

There is an independent Health Complaints Advocacy Service available to support and assist you if you would like this. They can be contacted on tel. 0330 440 9000.

Staff member *[insert name]* is acting as your lead contact for this incident and s/he can be contacted by email at *[insert email address]* or on telephone number *[insert number]*.

Yours sincerely

****THIS IS A TEMPLATE LETTER - PLEASE AMEND AS
APPROPRIATE****

(Insert name & address)

Dear *(Insert title & name)*

I am writing to let you know that we have now conducted the review, which is known as a Root Cause Analysis, into *[give details of the incident]*.

Either

As discussed earlier, we have arranged to meet on *[insert date & time]*. The meeting will be taking place at *[insert venue]*. I would be grateful if you could contact *[insert name]* on telephone number *[insert number]*, email *[insert email address]* or at the address above to confirm that you are still able to attend. *[insert name]* can also explain who will be present at the meeting. You may also wish to consider whether you would like to bring a friend or family member with you.

Or

I would therefore like to invite you/your *[insert relationship/name]* to meet with me to discuss the findings of the review and would be grateful if you would contact *[insert name]* on telephone number *[insert number]*, at email *[insert email address]* or at the above address, so that we can organise an appropriate day, time & venue should you wish to meet. *[insert name]* can also explain who would be present at the meeting. You may also wish to consider whether you would like to bring a friend or family member with you.

If, however, you do not wish to attend a meeting, I can arrange for the final report to be sent directly to you.

Finally, on behalf of myself and the staff at Torbay & South Devon NHS Foundation Trust, we are very sorry for any suffering and distress caused as a result of this incident. I wish to assure you that we have learnt from the events surrounding your / *[insert name]* care and have agreed / or are in the process of changing *[insert relevant information here]*.

Yours sincerely

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.

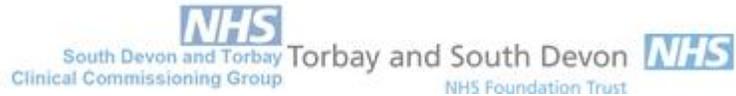
“The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual's right to make decisions for themselves with their right to be protected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



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 favorably than the general population? <i>PLEASE NOTE: Any 'Yes' answers may trigger a full EIA and must be referred to the equality leads below</i>			
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 favorably than the general population? (substance misuse; teenage mums; carers ¹ ; travellers ² ; homeless ³ ; convictions; social isolation ⁴ ; refugees)			Yes <input type="checkbox"/> No <input type="checkbox"/>
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 <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
Are the services outlined in the policy fully accessible ⁶ ?			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 ⁷ ?			Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
EXTERNAL FACTORS			
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? <i>PLEASE NOTE: 'Yes' may trigger a full EIA, please refer to the equality leads below</i>			Yes <input type="checkbox"/> No <input type="checkbox"/>
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 is 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.tsdf@nhs.net,
- See TSDFT's [Data Protection & Access Policy](#),
- Visit our [GDPR](#) page on ICON.