NHS
West Suffolk
NHS Foundation Trust

Trust Policy and Procedure **Document ref. no: PP(22)197**

Being Open and The Duty of Candour

For use in (clinical areas):	All areas of the Trust
For use by (staff groups):	All staff involved in patient care
For use for :	All patients, carers, relatives or staff affected by an adverse incident
Document owner:	Patient Safety team
Status:	Approved

1. Introduction

Staff work hard to provide services which are safe and of a high quality. However, it is a fact that despite this, sometimes things do go wrong and incidents will occur. When this happens, the organisation will respond quickly and positively to ensure the wellbeing of patients, staff and the public. More details can be found in PP015 Incident reporting and management.

Being Open

All healthcare professionals have a **professional** responsibility to be open and honest with patients when things go wrong. Evidence suggests that openness is welcomed by patients who are more likely to forgive errors when they are discussed fully in a timely and thoughtful manner and that being open can decrease the trauma felt following an incident.

All healthcare organisations have a **statutory** duty to support their staff to report adverse incidents, and to support staff to be open and honest with patients if something goes wrong with their care.

Being open supports a culture of openness, honesty and transparency, and includes apologising and explaining what happened. Being open is a process rather than a one off event and is about being open, honest and transparent with patients in a compassionate and respectful way if something goes wrong with their treatment or care that causes or has the potential to cause harm and distress.

The 10 key principles of Being Open are set out in Appendix A

Duty of Candour (DoC)

The Duty of candour is a **contractual obligation** that requires NHS provider organisations to implement and measure the principles of being open.

The **CQC regulation** Duty of candour is a general duty to be open and transparent with people receiving care. It applies to every health and social care provider that CQC regulates and is described in Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

DoC **must** be undertaken for ‘notifiable safety incidents’ which meet the harm threshold of moderate or above however a Being open conversation can be undertaken for any incident regardless of actual or potential severity.

Regulation 20 defines ‘notifiable safety incidents’ and specifies how registered persons must apply DoC if these incidents occur (see section 5).

The DoC regulations require the conversation to be ‘*as soon as reasonably practicable’*.

Saying Sorry

A crucial part of the duty of candour is the apology. Apologising is not an admission of liability. In many cases it is the lack of timely apology that pushes people to take legal action. To fulfil the duty of candour, you must apologise for the harm caused, regardless of fault, as well as being open and transparent about what has happened.

An ‘apology’ is an expression of sorrow or regret in respect of a notifiable safety incident. It is not an admission of guilt.

NHS Resolution is the organisation that manages clinical negligence claims against the NHS. Their ‘Saying Sorry’ leaflet confirms that apologising will not affect indemnity cover

Saying sorry is:

- always the right thing to do
- not an admission of liability
- acknowledges that something could have gone better
- the first step to learning from what happened and preventing it recurring.

“*We have never, and will never, refuse cover on a claim because an apology has been given.*”
Helen Vernon, Chief Executive, NHS Resolution (2017)

‘As soon as reasonably practicable’

Duty of candour should be carried out as soon as possible to ensure good communication and openness – however, it is important to treat each case individually, taking the current clinical situation into consideration.

For example – a duty of candour conversation may require a delay to enable a patient to recover from a serious procedure so as to be able to fully comprehend and recall the apology. Equally, if an incident is only identified after the fact (e.g. following a notification from another health provider) then there will be a delay between the event and the apology.

Where there is a delay between the two events (incident and apology) it is important to document the reasons for this within the Datix record.

As there is no quantitative measure for ‘*as soon as reasonably practicable’* the trust uses, as a proxy, a standard of 10 working days to measure the key performance indicator (KPI) of timely verbal DoC. This measure is based on the original timeframe stated in the national NHS standard contract at the time of DoC becoming statute although this absolute measure was subsequently removed from the national contract. This should absolutely **not** be seen as a target (not acceptable to say “*I have ten days to do DoC*”).

2. Purpose of this Policy

This policy has been developed to ensure that staff are aware of the processes and steps to follow in supporting patients and carers following an incident meeting the requirements for provision of DoC. It sets out specific requirements to follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology.

The organisation recognises that undertaking a DoC conversation can be stressful and/or traumatic for the clinician involved particularly in events involving a patient's death or serious harm and seeks to offer support and guidance to minimise that. Further information is available in the trust policy PP198 *Supporting staff involved in an incident ,complaint or claim.*

The policy provides guidance to staff on how to undertake DoC and support mechanisms available where staff are unsure how to proceed or require support. It also describes how and where to record the initial and ongoing communication with the patient and/or their representative.

The background and history of the development of this policy and the national Being open and DoC frameworks are set out in Appendix B.

3. Scope of this Policy

The Trust's *Incident Reporting and Management Policy* (PP105) encourages staff to report all patient and service user safety incidents, including those where there was no harm or it was a 'near miss' event.

The trust meets its statutory duty by requiring DoC to be undertaken for all patient safety incidents resulting in moderate / major or catastrophic harm (including psychological harm). See Appendix C for the national definitions of harm.

4. Responsibilities

All staff who identify a patient safety incident

- Responsible for reporting the incident on the Trust Datix incident reporting system according to the Trust's policy PP105.
- Documenting any conversation with the patient or other relevant person relating to the reported incident in the patient's health record.
- Any conversation undertaken prior to the incident being reported on Datix should also be noted within the incident description narrative.

Senior Professional Lead

This is the senior professional responsible for undertaking the initial DoC conversation. Who this is will be dependent on the specific incident type, location where the incident took place and who is available to enable the conversation to take place as soon as reasonably practicable.

- Responsible for providing an apology to the patient or other relevant person following a reported notifiable incident according to the principles of the DoC.
- Documenting any conversation with the patient or other relevant person relating to the reported incident in the patient's health record.
- Ensuring the incident has been reported on Datix
- Ensuring the patient's consultant (or GP / senior clinical lead in the community) is aware of the incident if they are not the senior professional lead undertaking the initial Duty of candour conversation

In most circumstances the senior professional lead will also

- Provide a written notification to the patient or other relevant person.
- Maintain ongoing conversation / update with the patient or other relevant person as required
- Provide timely communication with the patient safety team to enable an accurate record of compliance on the Datix record.

It is possible in some circumstances that the senior professional lead undertaking initial DoC at the time may pass the responsibility for these latter processes to another individual, however they retain the responsibility until that handover has been confirmed. Examples may include:

- An incident being investigated central by the organisation's patient safety incident investigators
- An incident identified in another speciality (e.g. in an outpatient clinic or following a readmission where the initial verbal apology is undertaken by the clinician present at the time)

Divisional Patient Safety & Quality Manager

- Ensuring the senior professional lead is aware of the notifiable incident and their responsibility to provide an apology and written notification if not already completed.
- Recording completion of the DoC process using the relevant section of the Trust Datix incident reporting system.
- Ongoing communication with the senior professional lead to enable completion of an accurate record of compliance including dates on the Datix record
- Escalation to divisional senior leadership of any instance where the DoC process has not been adhered to.

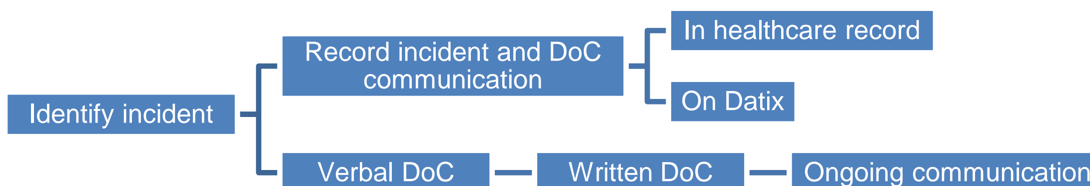
Divisional senior leadership

- Responsible for allocation of senior professional lead where there is lack of clarity following initial reporting of the notifiable incident
- Ensuring completion of DoC for any instance escalated by the Divisional Quality & Safety Manager where the DoC process has not been adhered to.

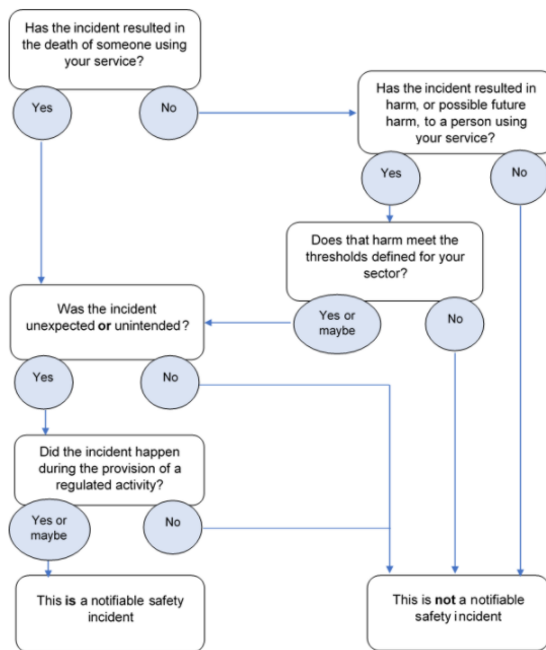
Head of Patient Safety & Quality

- Responsible for the oversight and management of the Trust's DoC process including reporting to the Trust Board and monitoring adherence to the policy.

5. Process for undertaking Duty of Candour (DoC)



Identifying a notifiable safety incident



- "*Your service*"

= Care provided by WSFT

- "*Thresholds defined for your sector*"

= Severity of outcome on Datix

Negligible (minimal injury requiring no treatment)
Minor (injury requiring minor treatment)
Moderate
Major (injury leading to long-term incapacity / disability)
Catastrophic (incident leading to death / multiple patients with major injuries))

- "*Regulated activity*" = Patient care provided by WSFT
- "*unexpected **or** unintended*".

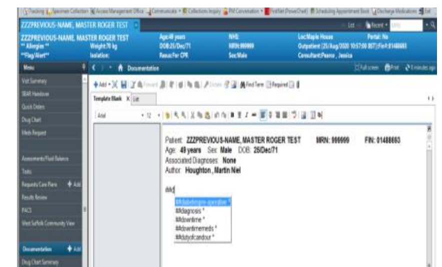
E.g. if a frail elderly man, known to be at risk of falling had a further fall. This might not be 'unexpected'. But it would be 'unintended'.

https://www.cqc.org.uk/guidance-providers/all-services/duty-candour-notifiable-safety-incidents

Record keeping

Throughout the DoC process it is important to record discussions with the patient or other relevant person in the health record.

eCare has a form which can be created using the *##dutyofcandour* (found under Documentation) and it can also be written up as a note in SystemOne or other clinical system.



Duty of Candour	
DoC lead	
DoC complete	
DoC extra details	No YES verbal only YES verbal and written N/R
DoC due date	
DoC Verbal done date	
DoC method	
DoC written notification date	

Datix also contains a section to record timeframes and responsibilities for completion of DoC and is used to monitor the compliance with the trust's statutory responsibility.

The 'Due date' records a 10 working day indicator which is the trust's local KPI to provide a measure for "*As soon as reasonably practicable*". This should not be seen as a target.

Verbal and written DoC

CQC regulation 20 states that you must:

1. Tell the relevant person, face-to-face, that a notifiable safety incident has taken place.
2. Apologise.
3. Provide a true account of what happened, explaining whatever you know at that point.
4. Explain to the relevant person what further enquiries or investigations you believe to be appropriate.
5. Follow up by providing this information, and the apology, in writing* and providing an update on any enquiries.
6. Keep a secure written record of all meetings and communications with the relevant person.

** A written notification is one given or sent (e.g. by letter or email) containing the information provided in any initial notification made in person, details of any enquiries to be undertaken, advise of any appropriate enquiries to be undertaken by the registered person, the results of any further enquiries into the incident, and an apology (as defined above).*

It is advantageous to maintain a central copy of the written notification and any further correspondence on the Datix record for that incident. This can be uploaded directly by the professional lead or a member of their team or submitted to the patient safety team.

6. Incidents not identified at the time of the event

On occasion, incidents are identified some considerable time after the event. This is most commonly found through the review of a complaint, clinical negligence claim or a coronial inquest but can also occur when an incident is reported to the organisation by another service provider.

If an incident is identified as part of a complaint, the complaint response will acknowledge that there will be an incident investigation and there will be a duty of candour on behalf of the Trust as part of the complaint acknowledgement. A point of contact for the ongoing communication will be established between the patient experience and patient safety team.

If an incident is identified as part of the Inquest process a duty of candour will be undertaken by the lead investigator. Ongoing dialogue with the NOK of the deceased will be managed by the Lead Investigator, supported by the Patient Safety Team.

The clinical negligence claim process includes a letter of apology, if appropriate, from the Chief Executive. This will highlight the investigation and any failings; it will also acknowledge and reference the length of time taken from incident to completion of the investigation.

7. When Duty of Candour is not required

There is one circumstance in which DoC can be omitted. It is important that the Datix record should contain sufficient detail to enable confirmation that the exemption criterion has been met.

1. Regulation 20(5)[1] of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 sets out that it is acceptable not to undertake Doc in the following circumstance:

If the relevant person cannot be contacted in person or declines to speak to the representative of the registered person

- *The provider must make every reasonable attempt to contact the relevant person through all available means of communication. All attempts to contact the relevant person must be documented.*
- *If the relevant person does not wish to communicate with the provider, their wishes must be respected and a record of this must be kept.*
- *If the relevant person has died and there is nobody who can lawfully act on their behalf, a record of this should be kept.*

[1] Guidance for providers on meeting the regulations Health and Social Care act 2008 (Regulated activities) Regulations 2014 (Part 3) (as amended) http://www.cqc.org.uk/content/regulation-20-duty-candour#guidance

8. Monitoring

The Trust uses the Trust Datix incident reporting system to monitor the progress of the DoC and a monthly status update is provided in the *Integrated Quality and Performance report* (IQPR). On a bi-monthly basis, more details on DoC completion is provided in the (closed board) *Serious incidents, complaints, claims and inquest report.*

Current measures are as follows:

Measure	Target
Number of verbal DoC still outstanding at month end (for relevant month and earlier)	Target = 0
Number of written DoC notifications still outstanding at month end (for incidents that have had a verbal DoC)	Target = 0
% of incidents that have had verbal DoC completed within 10 working days of incident reporting on Datix (note this is a local proxy measure for 'as soon as reasonably practicable')	Target = 100%
Incident requiring DoC where a decision was made not to undertake	Review of each case for reasonableness

9. Document configuration information

Field	Details
Author(s):	Head of Compliance & Effectiveness and Head of Patient Safety & Quality
Other contributors:	Head of Deteriorating Patients, Duty of candour task and finish group
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Equality Assessed	Yes

Appendix A: Key Principles of Being Open

1. Principle of acknowledgement

- All patient and service user safety incidents should be acknowledged and
reported as soon as they are identified in accordance with the Incident Reporting and Management Policy

2. Principle of truthfulness, timeliness and clarity of communication

- Information about a patient or service user safety incident must be given to the individual and/or their carers in a truthful and open manner by an appropriately nominated person.
- Communication should also be timely: patients, service users and/or their carers should be provided with information about what happened as soon as practicable.
- Patients, service users and/or their carers should receive clear, unambiguous information and be given a single point of contact for any questions or requests they may have. They should not receive conflicting information from different members of staff, and using medical jargon which they may not understand should be avoided.

3. Principle of apology

- Patients, service users and/or their carers should receive an apology as soon as possible
- Both verbal and written apologies should be given. Verbal apologies are essential because they allow face-to-face contact between the patient, service user and/or their carers and the health or social care team.
- A written apology, which clearly states the health/social care organisation is sorry for the suffering and distress resulting from the incident, must also be given.

4. Principle of recognising patient, service user and carer expectations

- Patients, service users and/or their carers should receive a full explanation of what led up to the patient/service user safety incident in a face-to-face meeting.
- They should be provided with support in a manner appropriate to their needs.
- Confidentiality should be maintained at all times.

5. Principle of professional support

- Staff should feel supported throughout the incident investigation process.
- Staff should be encouraged to seek support from relevant professional bodies such as the General Medical Council, Royal Colleges, the Medical Protection Society, the Medical Defence Union and the Nursing and Midwifery Council, General Social Care Council.
- Staff should be made aware of the Whistleblowing policy and procedure.

6. Principle of risk management and systems improvement

- Root cause analysis (RCA), significant event audit (SEA) or similar techniques should be used to uncover the underlying causes of a patient or service user safety incident.
- Investigations should focus on improving systems of care, which will then be reviewed for their effectiveness.

7. Principle of multidisciplinary responsibility

- Communication with patients, service users and/or carers following an adverse incident should reflect the multi disciplinary nature of the treatment received.
- Senior managers, clinicians and health and social care leaders should champion the *Being Open* process.

8. Principle of clinical governance

- *Being Open* is part of the overall quality and governance frameworks.

9. Principle of confidentiality

Policies and procedures for *Being Open* should give full consideration to the confidentiality of the patient, service user, carer and member of staff.

Details of a patient safety incident should at all times be considered confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient.

10. Principle of continuity of care

Patients and service users should expect to continue to receive all usual treatment / care and continue to be treated with respect and compassion.

If a patient or service user expresses a preference for their health or social care needs to be taken over by another team, the appropriate arrangements should be made for them to receive treatment or care elsewhere.

Appendix B – History of Being Open and the Duty of Candour legislation

In September 2005 the National Patient Safety Agency (NPSA) issued a *Safer Practice Notice* calling on all NHS organisations to develop local '*Being Open'* policies. The aim was to provide a framework for communicating patient and service user safety incidents that lead to moderate or severe harm to the patients, service users and/or their carers.

In November 2009 the NPSA updated the guidance with the issue of Patient Safety Alert NPSA/2009/PSA003. This alert required all organisations commissioning and providing healthcare to implement actions set out in the revised NPSA *Being Open* framework.

The National NHS Contract for 2013/14 introduced a contractual Duty of Candour for patient safety incidents that resulted in moderate harm, severe harm or death (using the national definition see Appendix C) that are reported to local risk management systems. This required an apology to be provided using the principles set out in '*Being Open'*.

In November 2014 a statutory Duty of Candour was introduced for all Secondary care providers registered with CQC in England as set out in Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

The introduction of Regulation 20 is a direct response to recommendation 181 of the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust, which recommended that a statutory Duty of Candour be introduced for health and care providers. This is further to the contractual requirement for candour for NHS bodies in the standard contract, and professional requirements for candour in the practice of a regulated activity.

The regulation and its implementation reflect the approach proposed by the Dalton/Williams review, including explaining notifiable safety incidents across different sectors.

In April 2015 this became law for all providers registered with the CQC to achieve a verbal Duty of Candour for moderate harm or above as soon as reasonably practicable and to follow this up with a written notification.

Appendix C – National definitions of harm, how to record on Datix and the requirements for Duty of Candour

Note: More details including a full FAQ can be found at
https://www.england.nhs.uk/wp-content/uploads/2019/10/NRLS_Degree_of_harm_FAQs_-_final_v1.1.pdf

1. No harm

This has two sub-categories:

1.1 No harm (Impact prevented) – *Any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care. This may be locally termed a **'near miss'**.*

DoC not required. Principles of Being Open still apply

* Outcome (result) of incident
What was the actual harm caused by the incident

Actual harm resulted from this incident
No harm - incident occurred but did not result in harm
Near miss - the incident was avoided

* Actual Severity

None (no harm caused)

1.2 No harm (impact not prevented) - *Any patient safety incident that ran to completion but no harm occurred to people receiving NHS funded care.*

DoC not required. Principles of Being Open still apply

* Outcome (result) of incident
What was the actual harm caused by the incident

Actual harm resulted from this incident
No harm - incident occurred but did not result in harm
Near miss - the incident was avoided

* Actual Severity

None (no harm caused)

2. Harm (includes psychological harm)

* Outcome (result) of incident
What was the actual harm caused by the incident?

- Actual harm resulted from this incident
- No harm - incident occurred but did not result in harm
- Near miss - the incident was avoided

Note: This is broken down into four levels nationally however on WSFT Datix it is picked from one of five options (this is because it is also used by the Risk register matrix which requires a 5 x 5 matrix). The actual terms used differ from the national terminology, again because the system is used for the risk register and to record non-patient safety incidents.

2.1 Low

Any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons receiving NHS-funded care.

- Negligible (minimal injury requiring no treatment)
- Minor (injury requiring minor treatment)
- Moderate
- Major (injury leading to long-term incapacity / disability)
- Catastrophic (incident leading to death / multiple patients with major injuries))

DoC not required. Principles of Being Open still apply

2.2 Moderate

Any unexpected or unintended incident that resulted in a moderate increase in treatment, possible surgical intervention, cancelling of treatment, or transfer to another area, and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.

- Negligible (minimal injury requiring no treatment)
- Minor (injury requiring minor treatment)
- Moderate
- Major (injury leading to long-term incapacity / disability)
- Catastrophic (incident leading to death / multiple patients with major injuries))

DoC required.

2.3 Severe

Any unexpected or unintended incident that appears to have resulted in permanent harm to one or more persons.

- Negligible (minimal injury requiring no treatment)
- Minor (injury requiring minor treatment)
- Moderate
- Major (injury leading to long-term incapacity / disability)
- Catastrophic (incident leading to death / multiple patients with major injuries))

DoC required.

2.4 Death

Any unexpected or unintended incident that directly resulted in the death of one or more persons.

- Negligible (minimal injury requiring no treatment)
- Minor (injury requiring minor treatment)
- Moderate
- Major (injury leading to long-term incapacity / disability)
- Catastrophic (incident leading to death / multiple patients with major injuries))

DoC required.