Shropshire Community Health
NHS Trust

Duty of Candour and Being Open

Trust Policy on communicating patient safety incidents with patients and their carers

Document Details	
Title	Duty of Candour and Being Open
Trust Ref No	1537-30812
Main points this document covers	The Health and Social Care Act 2008 Regulations 2014: Regulation 20 outlines providers requirements and circumstances when this applies. This policy will cover the main points and how this will be applied throughout Shropshire Community Health NHS Trust (SCHT)
Who is the document aimed at?	All Staff
Author	Head of Patient Safety (Daniel Redfern)
Approval Process	
Approved by	Quality and Safety Committee
Approval Date	21/07/2022
Initial Equality Impact Screening	No
Full Equality Impact Assessment	No
Lead Director	Director of Nursing and Workforce
Category	Clinical and Non-Clinical
Sub Category	Risk Management and Patient Safety
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Distribution	
Who the policy will be distributed to	All clinical staff
Method	Electronically to senior staff and via the Trust intranet for all clinical staff
Document Links	
Required by CQC	Yes
Other	

Amendments History		
No	Date	Amendment
1	June 2012	Minor amendments made as required by the Operational Quality and Safety Group.
2	June 2014	Statement about Duty of Candour added
3	December 2014	Reference made to the Duty of Candour requirement of the Health and Social Care Regulations
4	May 2016	Minor amendments made
5	May 2022	Complete policy revision and author change

1 Introduction and Scope

This policy is designed to ensure that Shropshire Community Health NHS Trust (SCHT) complies with the 2014 statutory Duty of Candour, it's contractual requirements as-well as meeting its obligations to patients, relatives and the public by ensuring a culture of being open and honest about mistakes throughout the provision of care to patients.

Promoting a culture of openness is a prerequisite to improving patient safety and the quality of healthcare systems. It involves apologising and explaining what happened to patients who have been harmed as a result of their healthcare treatment. It ensures communication is open and honest and occurs as soon as possible following an incident. It encompasses communication between healthcare organisations, healthcare teams and patients and/or their carers.

This policy is aimed at any healthcare staff responsible for ensuring the infrastructure is in place to support openness between healthcare professionals and patients and/or their carers following an incident. This document provides advice and guidance on communicating with patients and/or their carers/relatives following harm.

This policy is based on:

Regulation 20: Duty of Candour, Health and Social Care Act 2008 (regulated activity) Regulations 2014, Care Quality Commission. It aligns with the NHS standard contract as well as being based on guidance from:

National Patient Safety Agency (NPSA), *Being open: communicating patient safety incidents with patients and their carers (NPSA, 2009)* and the

National Health Service Resolution (NHSR) Strategy 2022

NHS Resolution is an arm's length body of the Department of Health and Social Care (formally National Health Service Litigation Authority - NHSLA), they provide expertise to the NHS on resolving concerns and disputes fairly, sharing learning for improvement and preserving resources for patient care

These encourage staff to apologise to patients harmed as a result of healthcare provision and explain an apology is not an admission of liability.

The latest guidance from CQC outlines the two types of candour: Professional and Statutory. Both have similar aims – to ensure those providing care are open and transparent with the people using their services, whether or not something has gone wrong.

This policy covers the statutory Duty of Candour, which regulates the statutory duty while professional duty is overseen by specific health-care regulated bodies such as General Medical Council (GMC) and Nursing and Midwifery Council (NMC).

'If a patient under your care has suffered serious harm, through misadventure, or for any other reason, you should act immediately to put matters right, if that is possible. You should explain fully to the patient what has happened and the likely long and short-term effects. When appropriate, you should offer an apology. If the patient is under sixteen and lacks the maturity to consent to treatment, you should explain the situation honestly to those with parental responsibility for the child.'

The Trust encourages staff to report patient safety incidents that were prevented (i.e. near-misses) no harm and low harm incidents along with incidents that have caused moderate, severe harm or

death. It is not however a requirement of this policy that near-miss and no-harm incidents are discussed with patients.

2 Purpose and Overview

The purpose of this document is to ensure that patients, their families, carers and staff feel supported when patient safety events occur or things go wrong, ensuring staff act in an open and transparent way.

This document also aims to improve the quality and consistency of communication with patients, their families and carers in the event a patient safety event occurs, so that they promptly receive the information they need to enable them to understand what happened; that a meaningful apology is offered; and they are informed of the action the organisation will take to try and ensure that a similar type of patient safety event does not recur.

2.1 Finally this document aims to provide clear guidance to staff on what they must do when they are involved in a patient safety incident. This includes notifying the relevant person and providing support in relation to the incident including the notification requirements. In addition this document details the support available for both patients, families and staff.

3 Duty of Candour

From 2014 all NHS providers registered with the Care Quality Commission (CQC) are required to comply with a new statutory Duty of Candour, Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20 Duty of Candour.

3.1 Contained within the NHS Standard Contract Particulars there is a requirement for the Trust to comply with the statutory Duty of Candour, failure to do so may lead to financial costs levied against the Trust.

3.2 Duty of Candour is

- Recognising when an incident occurs that impacts on a patient in terms of harm.
- Notifying the patient that something has occurred.
- Apologising to the patient.
- Supporting the patient further
- Following up with your patient as the investigation evolves.
- Documenting the above discussions and steps

3.3 The principles of being open for all staff can be found in Appendix 1

4 Professional and Statutory Requirements – when they duty applies

The professional Duty of Candour is a responsibility of all health care professionals to be open and honest when things go wrong with their treatment or care and has the potential to cause harm or distress. All staff have a duty to report this to their line manager via the incident reporting system (DATIX).

4.1 The statutory Duty of Candour must be enacted where actual harm has occurred to a patient that has been measured as moderate, serious or death.

There may be occasions where it is appropriate to embrace openness beyond the statutory Duty of Candour definitions (for example, where there is a significant near-miss, however this is not a statutory obligation and is covered by being open).

4.2 As soon as reasonably practicable and within 48 hours of the incident being identified the relevant manager and/or senior person must notify the patient and/or relative verbally and provide

reasonable support. This must be followed up in written format within 10 days. Template letters can be found in Appendix 3

4.3 Guidance on the principles of apology can be located from NHS Resolution (formerly known as the NHS Litigation Authority) providing a useful leaflet: Saying-sorry-leaflet-2019.pdf (resolution.nhs.uk)

4.4 A record must be kept in writing of the above and included within the completion of DATIX and Electronic Patient Record (e.g. RiO).

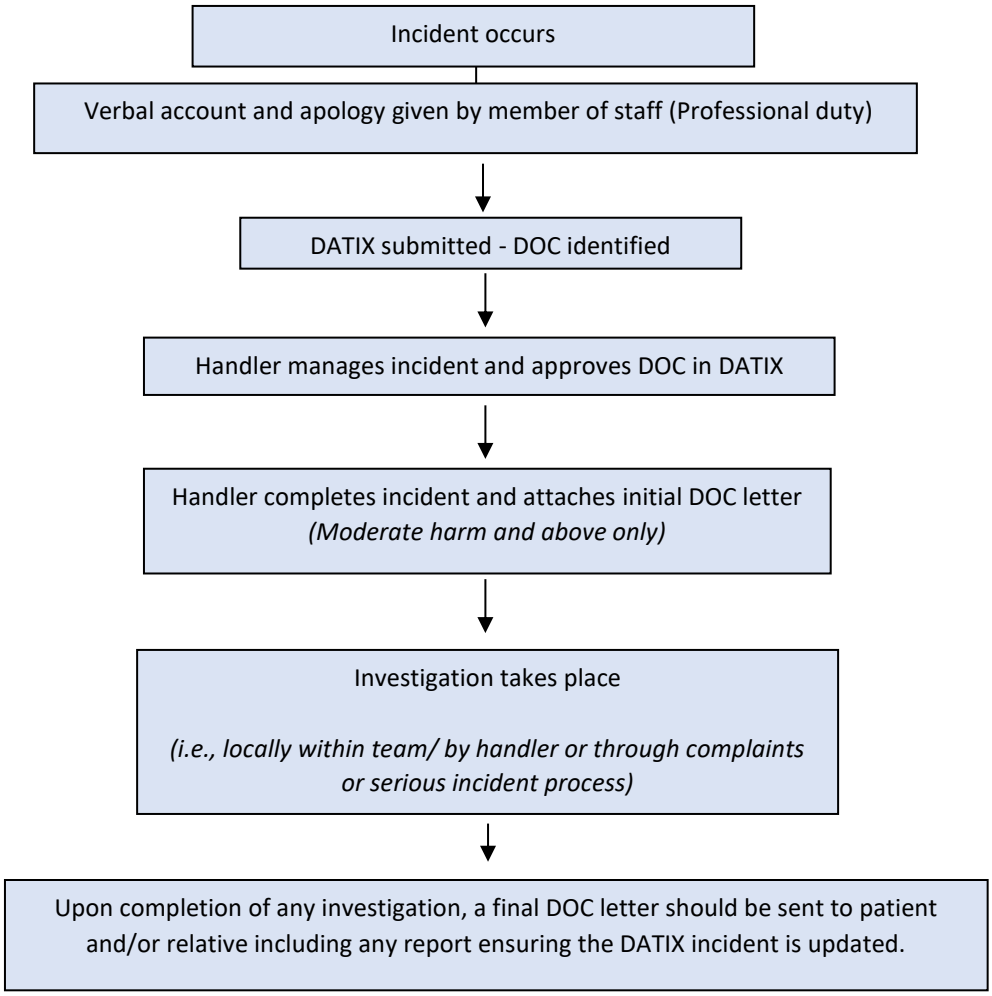
The relevant person would normally be the patient or where they have died, are under 16 or do not have capacity, their legal representative or nominated individual i.e. relative/carer.

4.5 Once an incident and/or investigation is complete, the relevant manager should produce a final Duty of Candour letter to the patient and/or relative to summarise their findings and what necessary actions are being undertaken by the trust, along with giving the opportunity to view any final report as a result.

5 Recording the information

The Datix incident form (Dif2) for handlers/managers includes “Duty of Candour”. All handlers must update this section when reviewing an incident. If Duty of Candour does not apply, the mandatory field tab section will need to be completed to detail reasons.

5.1 The incident form includes fields for recording the verbal notification and the date the written notification was sent. In some instances the former field can be filled on by the reporter. Where the verbal notification is given after the incident form is completed the fields will need to be completed by the approving manager. The approving manager will also need to complete the date field for the written notification and must attach a copy to the documents section of the form. The flowchart below illustrates the process:



5.2 If the patient lacks capacity and/or is deceased, the next of kin/carer should be informed. If these details are not easily obtainable, written notification should be addressed in bold **"To the next of kin of:"** in order to ensure we remain open. This should be clearly documented in the DATIX incident.

In cases where patients and/or relatives decline to receive further information/correspondence, this must be recorded within the incident.

5.3 There will be occasions where the incident or the degree of harm caused may not be identified for some time. The requirements of the Duty of Candour will still apply and should be followed as soon as the incident is identified. It is also likely that on occasions incidents will be identified by means other than the incident reporting e.g. complaints. In this circumstance, these will be reviewed as part of the ROSI group (Review of Significant Incidents) and identified if any further actions are required.

5.4 The Complaints, Risk, Patient Safety and Quality Teams will provide support to staff and managers with the process where required.

6 Incident Detection or Recognition

The Being Open process begins with the recognition that a patient has suffered harm or has died as a result of a patient safety incident. A patient safety incident may be identified by:

- A member of staff at the time of the incident.
- A member of staff retrospectively when an unexpected outcome is detected.
- A patient and/or their carers who expresses concern or dissatisfaction with the patient's healthcare either at the time of the incident or retrospectively.
- Incident detection systems such as incident reporting or medical records review.
- Other sources such as detection by other patients, visitors or non-clinical staff.

As soon as a patient safety incident is identified, the main priority is to ensure the patient is safe and prevent further harm. Where additional treatment is required this should occur whenever reasonably practicable after a discussion with the patient and with appropriate consent. The Incident Reporting Policy should be implemented and would include:

- Acknowledgement and an apology, where applicable, from an appropriate member of staff and as part of the Being Open process.
- An incident form being completed.
- An investigation being undertaken using appropriate methodology.

7 Patient safety incidents occurring elsewhere

A patient safety incident may have occurred in another organisation. The individual who identifies this should complete an incident through the trust incident reporting system for further escalation through NHS-to-NHS concerns.

The Being Open process and the investigation and analysis of a patient safety incident should normally occur in the healthcare organisation where the incident took place.

8 Criminal or intentional unsafe act

Patient safety incidents are almost always unintentional. However, if at any stage following an incident it is determined that harm may have been the result of a criminal or intentional unsafe act and/or neglect, the relevant manager or senior manager on call should be notified immediately.

9 Initiating the Being Open and Duty of Candour process

The Multidisciplinary Team, where applicable, including the most Senior Health Professional and the Manager involved in the patient safety incident, should be consulted as soon as possible after the event to:

- Establish all clinical and other facts.
- Assess the incident to determine the level of immediate response.
- Identify who will be responsible for discussion with the patient and/or their carers.
- Consider the appropriateness of engaging patient support at this early stage. This includes the use of a facilitator, a patient advocate or a healthcare professional that will be responsible for identifying the patient's needs and communicating them back to the healthcare team.
- Identify immediate support needs for the healthcare staff involved.
- ensure there is a consistent approach by all team members around discussions with the patient and/or their carers.

In addition to this, it will be an advantage to provide facilities for formal and informal debriefing of the clinical team involved in the patient safety incident, where appropriate, as part of the support system and separate from the requirement to provide statements for the investigation. Staff may also benefit from individual feedback about any outcome of the patient safety incident investigation, if appropriate.

Managers should also provide information on the support systems currently available for staff involved by patient safety incidents. These include counselling services offered by professional bodies, Occupational Health Services and access to the Trust's Independent Counselling Service.

10 Initial assessment to determine level of response

All incidents should be initially assessed by the reporting individual to determine the level of response required and then discussed with their line manager. The line manager will handle the incident and confirm/alter the level of harm as necessary once further information is available.

Incidents will be reviewed frequently and where necessary flagged to be reviewed weekly at the ROSI (Review of Significant Incidents) group. Duty of Candour is reviewed as part of this group.

Definitions on level of harm can be found in Appendix 2.

11 Timing

The Duty of Candour should occur as soon as possible after recognition of a patient safety incident. There are no key timeframes for professional Duty of Candour but this is expected to take place almost immediately. The statutory element should be completed:

- A verbal apology should be given as soon as possible once the incident has been identified and within 48 hours.
- Written notification of apology within 10 days.

12 Communication with patient and/or relative

The healthcare professional who informs the patient and/or their carers about a patient safety incident should be the most senior person responsible for the patient's care and/or someone with

experience and expertise in the type of incident that has occurred, for example this could be the patient's consultant, specialist nurse, manager or any other healthcare professional who has a designated caseload of patients. The following considerations should be made:

- If at all possible the individual be known to the patient, their family and carers.
- Have a good understanding of the incident and any facts already known.
- Be senior enough or have sufficient experience and expertise in relation to the type of patient safety incident to be credible to patients, carers and colleagues.
- Have excellent interpersonal skills, including being able to communicate with patients and/or their carers in a way they can understand and avoiding excessive use of medical jargon.
- Be willing and able to offer an apology, where indicated, reassurance and feedback to patients and/ or their carers.
- Be able to maintain a medium to long term relationship with the patient and/or their carers, where possible, and to provide continued support and information.
- Be culturally aware and informed about the specific needs of the patient and/ or their carers.

13 Involving healthcare staff when things go wrong

It's acknowledged that healthcare staff are amongst those affected by patient safety incidents. Staff affected will be supported by their line manager, in the first instance.

Staff involved in patient safety incidents, shall not be blamed and will be treated in a consistent, constructive and fair approach. The Just-Culture Guide produced by NHS England and Improvement can support managers when individuals may require further support or intervention to work safely when a patient safety incident occurs. The guide should not be used routinely and reflects best current understanding on how to apply in practice. The just-culture guide is available in Appendix 4.

14 Documentation

The communication of patient safety incidents must be recorded. The required documentation includes:

- A copy of relevant medical information, which should be filed in the patient's medical records.
- Incident reports, which should not be filed in the patient's notes
- Records of the investigation and analysis process.
- The incident report and record of the investigation and analysis process will be recorded on Datix, the local risk management system.
- The initial incident will be reported using the procedures detailed within the Incident Reporting Policy and will be recorded on Datix and reported to the National Patient Safety Agency (NPSA) through the National Reporting and Learning System (NRLS).

There should be documentation of:

- The time, place, date, as well as the name and relationships of all attendees.
- The plan for providing further information to the patient and/or their carers.
- Offers of assistance and the patient's and/or carer's response.
- Questions raised by the family and/or carers or their representatives and the answers given.
- Plans for follow-up as discussed.

- Progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient and/or their carers.
- Copies of letters sent to patients, carers and the GP for patient safety incidents not occurring within Primary Care.
- Copies of any statements taken in relation to the patient safety incident.
- A copy of the incident report.

Details of the verbal and written notification should be recorded/attached to the Datix incident form.

15 Supporting Staff

When a patient safety incident occurs, healthcare professionals involved in the patient's clinical care may also require emotional support and advice. To support healthcare staff involved in patient safety incidents, the organisation should:

- Actively promote Just-culture, ensuring an open and fair approach that fosters peer support and discourages the attribution of blame. This organisation shall work towards a culture where human error is understood to be a consequence of healthcare systems, not necessarily the individual.
- Ensure healthcare staff are made aware about Being Open and ensure that they understand that apologising to patients, their families and carers is not an admission of liability.
- Provide facilities for formal and informal debriefing of the clinical team involved in the patient safety incident, where appropriate and separate from the requirement to provide statements for the investigation.
- Healthcare staff may also benefit from individual feedback about the about the final outcome of the patient safety incident investigation.
- Provide information on the support systems available for staff distressed by patient safety incidents.

16 Monitoring Compliance

Monitoring the process of being open will be done through a number of ways:

- ROSI (Review of Significant Incidents).
- Audit.
- Investigation reports.

Further assurance will be sought from Service Delivery Groups Quality and Safety meetings on compliance and any appropriate actions reported to Patient Safety Committee.

17 Consultation

The following have been consulted in line with this policy:

- Deputy Director of Nursing
- Deputy Director for Safety, Quality and Improvement
- Service Delivery Group Manager
- Clinical Quality Leads
- Quality Facilitator
- Head of Governance and Risk

18 References

- General Medical Council (GMC) (2013) Good Medical Practice. http://www.gmc-uk.org/guidance/good_medical_practice.asp
- National Patient Safety Agency (2009) Patient Safety Alert Being Open: Communicating with patients, their families and carers following a patient safety incident, NPSA, London. http://www.nrls.npsa.nhs.uk/beingopen/?entryid45=83726
- NHS Standard Contract https://www.england.nhs.uk/nhs-standard-contract/16-17/
- Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, Part 3 Section 2: Fundamental Standards, Regulation 20: Duty of Candour http://www.cqc.org.uk/content/regulation-20-duty-candour
- Open and honesty when things go wrong (2022): General Medical Council (GMC), Nursing Midwifery Council (NMC) Openness and honesty when things go wrong: the professional duty of candour (nmc.org.uk)
- The Duty of Candour: guidance for providers (2021): Care Quality Commission (CQC), The duty of candour: guidance for providers (cqc.org.uk)
- Learning from Patient Safety Events (LFPSE) (2022): harm definitions, NHS England and Improvement (2022).
- Delivering fair resolution and learning from harm (2022): NHS Resolution Strategy, NHS-Resolution-Our-Strategy-to-2022.pdf
- Saying Sorry (2019): NHS Resolution, Saying-sorry-leaflet-2019.pdf (resolution.nhs.uk)

19 Associated Documentation

- Shropshire Community Health NHS Trust Incident Reporting Policy

Appendix 1

The Principles of Being Open

The following ten principles underpin Being Open. It is the responsibility of all staff to follow these principles at all times during the Being Open process.

Principle of Acknowledgement

All patient safety events should be acknowledged and reported as soon as they are identified. In cases where the patient, their family and carers inform healthcare staff that something has happened, their concerns must be taken seriously and should be treated with compassion and understanding by all staff. Denial of a person's concerns will make future open and honest communication more difficult.

Principles of Truthfulness, Timeliness and Clarity of Communication

Information about a patient safety incident must be given to patients and/or their carers in a truthful and open manner by an appropriately nominated person. Patients want a step-by-step explanation of what happened, that considers their individual needs and is delivered openly.[1]

Communication should also be timely: patients and/or their carers should be provided with information about what happened as soon as practicable. It is also essential that any information given is based solely on the facts known at the time. Healthcare staff should explain that new information may emerge as an incident investigation is undertaken, and patients and/or their carers should be kept up-to-date with the progress of an investigation.

Patients 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.

Principle of Apology

Patients, their families and carers should receive a meaningful apology - one that is a sincere expression of sorrow or regret for the harm that has resulted from a patient safety event. This should be in the form of an appropriately worded agreed manner of apology, as early as possible. Both verbal and written apologies should be given. Saying sorry is not an admission of liability and it is the right thing to do. Verbal apologies are essential because they allow face to face contact. A written apology, which clearly states the organisation is sorry for the suffering and distress resulting from patient safety events, must be given.

Principle of Recognising Patient and Carer Expectations

Patients, their families and carers can reasonably expect to be fully informed of the issues surrounding a patient safety event and its consequences, in a face to face meeting with representatives from the organisation. They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times.

Patients, their families and carers should also be provided with support in a manner to meet their needs. This may involve an independent advocate or an interpreter. Information on the Patient Advice and Liaison Service (PALS) and other relevant support groups should be given as soon as possible.

Principle of Professional Support

The organisation must create an environment in which all staff are encouraged to report patient safety events. Staff should feel supported throughout the patient safety event investigation process; they too may have been traumatised by the patient safety event. Where there are concerns about the performance of

individual doctors, dentists or pharmacists the National Clinical Assessment Service (NCAS) can be contacted for advice. Where there is reason for the healthcare organisation to believe a member of staff has committed a punitive or criminal act, the organisation should take steps to preserve its position and advise the member(s) of staff at an early stage to enable them to obtain separate legal advice and/or representation. Staff should be encouraged to seek support from relevant professional bodies.

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 patient safety events. This investigation should focus on improving systems of care, which will be reviewed for their effectiveness. This Being Open policy should be integrated into local patient safety event reporting and risk management policies and processes.

Principles of Multi-Disciplinary Responsibility

The Being Open policy applies to all staff who have key roles in patient care. Most healthcare provision involves multi-disciplinary teams. This should be reflected in the way that patients, their families and carers are communicated with when things go wrong. This will ensure that the Being Open process is consistent with the philosophy that patient safety events usually result from system failures and rarely from actions of an individual. To ensure multi-disciplinary involvement in the Being Open process, it is important to identify clinical, nursing and managerial leaders who will support it. Both senior managers and senior clinicians must participate in the patient safety event investigation and clinical risk management.

Principles of Clinical Governance

Being Open requires the support of patient safety and quality improvement through clinical governance frameworks, in which patient safety events are investigated and analysed, to find out what can be done to prevent their recurrence. It also involves a system of accountability through the chief executive to the board to ensure that these changes are implemented and their effectiveness reviewed. These findings should be disseminated to staff so they can learn from patient safety events. Audits should be developed to monitor the implementation and effects of changes in practice following a patient safety event.

Principle of Confidentiality

Details of a patient safety event 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. Where this is not practicable or an individual refuses consent to the disclosure, disclosure may still be lawful if justified in the public interest or where those investigating the patient safety event have statutory powers for obtaining information. Communications with parties outside of the clinical team should also be on a strictly need to know basis and, where practicable, records should be anonymous. It is good practice to inform the patient, their family and carers about who will be involved in the investigation before it takes place and give them the opportunity to raise any objections.

Principle of Continuity of Care

Patients are entitled to expect that they will continue to receive all usual treatment and continue to be treated with respect and compassion. If a patient expresses a preference for their healthcare needs to be taken over by another team, the appropriate arrangements should be made for them to receive treatment elsewhere.

Appendix 2

Level of Harm Definitions

Physical Harm

No Physical Harm / Near-miss
Incident prevented – any patient safety incident that had the potential to cause harm but was prevented, and no harm was caused to patients receiving NHS-funded care. Incident not prevented - any patient safety incident that occurred but no harm was caused to patients receiving NHS-funded care.

Low Physical Harm
Any incident that did not or is unlikely to:

- Affect a patient's independence.
- Need further healthcare beyond a single GP, community healthcare professional, emergency department or clinic visit.
- Need further treatment beyond simple dressing changes or short courses of oral medication.
- Affect the success of treatment for existing health conditions.

Moderate Physical Harm
Any incident when at least one of the following apply:

- Has, or is likely to limit the patient's independence, but for less than 6 months.
- Has, or likely to need treatment beyond a single GP, community healthcare professional, emergency department or clinic visit and beyond simple dressing changes or short course of medication, but less than 2 weeks additional in-patient care and/or less than 6 months of further treatment and did not need immediate life-saving intervention.
- Has affected, or likely to affect the success of treatment, but without meeting the criteria for reduced life expectancy or accelerated disability described under severe harm.

Severe Physical Harm
Any incident when at least one of the following apply:

- Needed, or likely to need additional inpatient care of more than 2 weeks and/or more than 6 months of further treatment.
- Likely to have reduced patient's life expectancy.
- Needed immediate life-saving intervention.
- Has, or is likely to have, reduced the chances of preventing or delaying disability from their existing healthcare conditions.
- Has limited or is likely to limit the patient's independence for 6 months or more.

Fatal / Death
You should select this option if the patient has died and there is at least a slight possibility the incident that you are recording may have contributed to the death, including stillbirth or pregnancy loss. You will have the option later to estimate to what extent a patient safety incident contributed to this fatal outcome.

Psychological Harm

No Psychological Harm / Near-miss
As detailed above in physical harm definition

Low Psychological Harm
Any incident when at least one of the following apply:

- Distress that did not or is unlikely to affect the patient's normal activities for more than a few days.

- Distress that did not or is unlikely to need extra treatment beyond a single GP, community healthcare professional, emergency department or clinic visit.
- Distress that did not or is unlikely to result in a new mental health diagnosis or a significant deterioration in an existing mental health condition

Moderate Psychological Harm
Any incident when at least one of the following apply:

- Distress that did not or is unlikely to affect the patient's normal activities for more than a few days.
- Distress that did not or is unlikely to need extra treatment beyond a single GP, community healthcare professional, emergency department or clinic visit.
- Distress that did not or is unlikely to result in a new mental health diagnosis or a significant deterioration in an existing mental health condition.

Severe Psychological Harm
Any incident when at least one of the following apply:

- Distress that did or is likely to affect the patient's normal activities or ability to live independently for more than six months.
- Distress that did or is likely to need a course of treatment or therapy sessions that continues for more than six months.
- Distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, and recovery is not expected within six months.

Appendix 3 Initial Duty of Candour Letter – Templates

Appendix 3a Initial Standard Letter

Shropshire Community Health
NHS Trust

Private & Confidential

Service Name
Service Address
Service Address
Service Address
Service Postcode

Patient / Relative Name
Patient Address

Tel:

[or] **Sent via e-mail to:**

Website: www.shropscommunityhealth.nhs.uk

Our Ref: *[DATIX ref]*

Date:

Dear,

I'm writing to express my sincere regret that *[you/your relative…]* has/have been involved in an event/incident whereby *[Please provide narrative of incident/describe event – further guidance support can be sought from Patient Safety/Quality & Risk teams]*

Please accept my sincere apologises; our commitment is to be open and help patients and/or their relatives receive accurate, truthful information from their healthcare provider when things don't go to plan. All NHS organisations have a legal duty to provide candour to their patients and relatives when things go wrong during their care and treatment, and this is why I am writing to you following our earlier discussions.

As a priority we will make sure you receive any care that you need, and that you are safe. Once you are comfortable, one of our healthcare professionals involved in your care will contact you and discuss the incident with you, if required. They will also explain any investigation process. We also report incidents to senior medical and nursing staff along with our patient safety team. Their role is to ensure any lessons identified are learnt to prevent future occurrence where possible and act upon throughout all our services.

Again, please accept my sincere apologies for any distress caused as a consequence and my assurance that any lessons learnt identified will be acted upon and the learning shared widely.

If you need to contact me for any reason or discuss further, please don't hesitate to use the contact details at the top of this letter.

Yours sincerely,

[Insert Name]

[Job Title]

Shropshire Community Health
NHS Trust

Private & Confidential

Patient / Relative Name
Patient Address

[or] **Sent via e-mail to:**

Service Name
Service Address
Service Address
Service Address
Service Postcode
Tel:

Website: www.shropscommunityhealth.nhs.uk

Our Ref: *[DATIX ref]*

Date:

Dear,

I'm writing to express my sincere regret that *[you/your relative…]* has/have been involved in an event/incident whereby *[describe event].*

Please accept my sincere apologies; our commitment is to be open and help patients and/or their relatives receive accurate, truthful information from their healthcare provider when things don't go to plan. All NHS organisations have a legal duty to provide candour to their patients and relatives when things go wrong during their care and treatment, and this is why I am writing to you following our earlier discussions.

I will be acting as your lead contact for the duration of the process. As an NHS Trust we aim to provide high quality, safe services, however sometimes things go wrong. I am sorry that *[you/r [relation]* was involved and we are sorry for any undue distress caused.

We encourage the involvement of families and carers when something is thought to have gone wrong. Regardless of the extent of your involvement in the investigation, once it has been completed, I will contact you again to arrange to discuss this with you and share our findings and recommendations. Should you wish, you will be involved in our investigation, receive a copy of our findings, and have the opportunity to discuss this with us.

When an investigation is conducted, we look at what went wrong, how it happened, and how we can learn lessons to prevent it happening again. This incident has also been reported to the local clinical commissioning group (CCG). Their role is to make sure the investigation is carried out properly and any lessons learned are acted upon throughout all our services.

At this stage, it is not possible to provide any timescale; *[provide further narrative if waiting for external information/or delete]* Please be assured we will keep in touch with you of any and all updates, as and when these become available. I would be grateful if you could let me know how you/your relative would like to be addressed in our investigation report.

If you need to contact me for any reason, please don't hesitate using the contact details at the top of this letter. I will be in touch in the coming weeks to update you on any progress.

Yours sincerely,
[Insert Name]

[Job Title]

Nuala O'Kane – Chair

Patricia Davies – Chief Executive

Shropshire Community Health
NHS Trust

Private & Confidential

Patient / Relative Name
Patient Address

[or] **Sent via e-mail to:**

Service Name
Service Address
Service Address
Service Address
Service Postcode
Tel:

Website: www.shropscommunityhealth.nhs.uk

Our Ref: *[DATIX ref]*

Date:
Dear,

Following my previous letter dated *[insert date]* in relation to *[incident description]* I'm writing following conclusion of our investigation.

As outlined in my previous letter, our commitment is to be open and help patients and/or their relatives receive accurate, truthful information from their healthcare provider when things don't go to plan. All NHS organisations have a legal duty to provide candour to their patients and relatives when things go wrong during their care and treatment.

In investigating, we have liaised with *[insert relevant teams/external organisations as required]*

The key points are summarised *[and highlight the improvements we are making]:*

A copy of the final report is enclosed, if you need to discuss this in any detail, please don't hesitate to ask and we can arrange a suitable appointment.

Again, please accept my sincere apologies and if you have any queries, please get in touch.

Yours sincerely,

[Insert Name]

[Job Title]

Appendix 4

NHS England Just Culture guide

NHS

A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate - most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should **not** automatically be examined using this *just culture guide*, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action. The guide highlights important principles that need to be considered before formal management action is directed at an individual staff member.

An important part of a just culture is being able to explain the approach that will be taken if an incident occurs. A just culture guide can be used by all parties to explain how they will respond to incidents, as a reference point for organisational HR and incident reporting policies, and as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made. As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to treat wider patient safety issues as individual issues.

Please note:

- **A just culture guide** is not a replacement for an investigation of a patient safety incident. Only a full investigation can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- **A just culture guide** can be used at any point of an investigation, but the guide may need to be revisited as more information becomes available.
- **A just culture guide** does not replace HR advice and should be used in conjunction with organisational policy.
- **The guide** can only be used to take one action (or failure to act) through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

Start here - **Q1. deliberate harm test**

1a. Was there any intention to cause harm?

→ **Yes** — **Recommendation:** Follow organisational guidance for appropriate management action. This could involve: contact relevant regulatory bodies, suspension of staff, and referral to police and disciplinary processes. Wider investigation is still needed to understand how and why patients were not protected from the actions of the individual. — **END HERE**

No go to next question - **Q2. health test**

2a. Are there indications of substance abuse?

→ **Yes** — **Recommendation:** Follow organisational substance abuse at work guidance. Wider investigation is still needed to understand if substance abuse could have been recognised and addressed earlier. — **END HERE**

2b. Are there indications of physical ill health?

2c. Are there indications of mental ill health?

→ **Yes** — **Recommendation:** Follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier. — **END HERE**

if **No to all** go to next question - **Q3. foresight test**

3a. Are there agreed protocols/accepted practice in place that apply to the action/omission in question?

3b. Were the protocols/accepted practice workable and in routine use?

3c. Did the individual knowingly depart from these protocols?

→ **If No to any** — **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. — **END HERE**

if **Yes to all** go to next question - **Q4. substitution test**

4a. Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances?

4b. Was the individual missed out when relevant training was provided to their peer group?

4c. Did more senior members of the team fail to provide supervision that normally should be provided?

→ **If Yes to any** — **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. — **END HERE**

if **No to all** go to next question - **Q5. mitigating circumstances**

5a. Were there any significant mitigating circumstances?

→ **Yes** — **Recommendation:** Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. — **END HERE**

if **No**

Recommendation: Follow organisational guidance for appropriate management action. This could involve individual training, performance management, competency assessments, changes to role or increased supervision, and may require relevant regulatory bodies to be contacted, staff suspension and disciplinary processes. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. — **END HERE**

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Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree

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Appendix 5

Communication Guidance – For Managers

Patients, carers/relatives and those close to the patient can be included in discussions and decision making with permission from the patient, where appropriate.

The patient, relatives and/or carers should be given the opportunity to ask questions. There should be an expression of genuine sympathy, regret and an apology for the harm that has occurred.

The patient and/or their carers should be informed that an incident investigation is being undertaken to establish all facts. In cases where a disciplinary process has been instigated, this will run separately and concurrently. All matters of any disciplinary proceedings will remain confidential.

It should be made clear to the patient and/or their carers that new facts may emerge as the incident investigation proceeds.

The patient's and/or carer's understanding of what happened should be taken into consideration, along with any questions.

There should be consideration and formal noting of the patient's and/or carer's views and concerns, and demonstration that these are being heard and acted upon.

Appropriate language and terminology should be used. For example, using the terms 'patient safety incident' or 'adverse event' and use of abbreviations should be avoided. If a patient's and/or their carers require any adaptations due to language or disability their needs must be addressed along with providing information how they wish to receive it.

An explanation should be given on next steps and any short or long term treatment plans, along with incident findings. Patients and/or relatives should be given the opportunity to be involved.

Some patients may not wish to know every detail of an incident. They should be reassured that if they change their minds, this information will be made available to them.

The patient and/or relative/carer should be given the contact details of one member of staff who will act as a contact point for them. Their role will be to provide both practical and emotional support in a timely manner.

It should be explained to patients that they are entitled to continue to receive all usual treatment and continue to be treated with respect and compassion. If a patient expresses a preference for their healthcare needs to be taken over by another team, the appropriate arrangements should be made for them to receive treatment elsewhere wherever this is possible.

Patients/carers should be given information on the complaints procedure and offered assistance if they wish to make a complaint.

It should be recognised that patients and/or their carers may be anxious, angry and frustrated even when the Being Open discussion is conducted appropriately - It is essential that the following does not occur:

- Speculation.
- Attribution of blame.
- Denial of responsibility.
- Provision of conflicting information from different individuals.