Duty of Candour Policy

Policy Number	CGP004
Version:	V2
Purpose:	To ensure that the infrastructure in in place to support all colleagues to be open and honest with patients and their families following an incident, complaint or claim.
Consultation:	Operations Colleagues, Associate Director of Quality Assurance & Clinical Compliance, Deputy Medical Director, Clinical Policy Group
Approved by:	Clinical Policy Group, Improving Care Group
Date approved:	5th October 2021
Author:	Duty of Candour Assurance Lead
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Review date:	October 2024
Audience:	All Trust Colleagues
Dissemination:	This policy is available to all colleagues via the Trust intranet
Impact Assessments:	This Policy has been subjected to an Equality Impact Assessment. This concluded that this policy will not create any adverse effect or discrimination on any individual or particular group and will not negatively impact upon the quality of services provided by the Trust.

Version History

Version	Date	Reason for Change
V1	October 2019	New Policy
V2	October 2021	To incorporate the most up to date Care Quality Commission (CQC) guidance which was published in March 2021, to exclude reference to organisations that have disbanded such as the National Patient Safety Agency (NPSA), to include examples of best practice of initial and final DoC letters.

SUMMARY

It is the Trust's policy to:

- Promote a culture that encourages and supports candour, openness and honesty at all levels of the organisation.
- Acknowledge, apologise and explain when things have gone wrong to patients and their families.
- Conduct objective and comprehensive investigations into "notifiable safety incidents" which provide assurance to patients, their families, and all stakeholders

that the Trust is committed to learn from and reduce the risk of reoccurrence of similar incidents.

- Engage and empower patients and their families in the investigation process leading to co-production and co-design of services.
- Respect the wishes of patients and their families in the event that they do not want to be involved with any stage of the investigative process.
- Provide support for all colleagues involved with "notifiable safety incidents" in accordance with a "just culture." Sign post and encourage colleagues to engage with proactive services such as the Trust's Occupational Health Department – "Working Well;" the "Freedom to Speak Guardian" and "Paul's Open Door."

Comply with statutory and professional duty of candour regulations.

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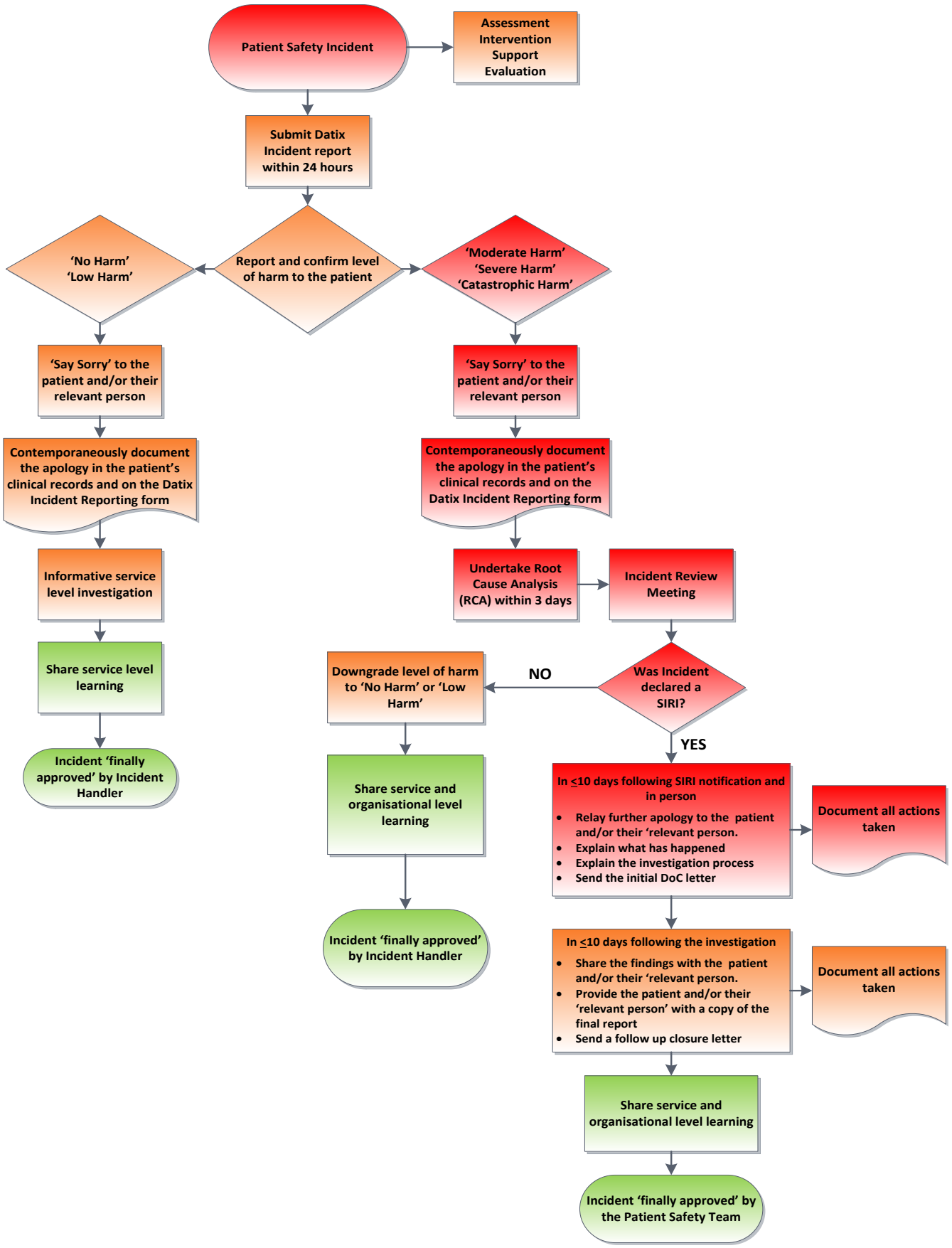
The Duty of Candour Process



1. INTRODUCTION

What is Duty of Candour?

1.1 Duty of candour is the act of being honest with patients and their families when avoidable harm has happened in our care. It underpins a safety culture which exonerates blame and focuses on learning leading to improved patient outcomes and patient experience.

1.2 In 2008, Regulation 20 of the Health and Social Care Act stated that:

"Registered persons must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity."

1.3 Following the Francis Inquiry in 2013, which found serious failings in openness and transparency at Mid Staffordshire NHS Foundation Trust, the statutory duty of candour was brought into law in 2014 for all NHS Trusts, and 2015 for all other providers of health and social care.

1.4 The statutory duty of candour is fundamentally linked to the concepts of openness and transparency that often policies and procedures related to it have come to be known by colleagues by other names such as "Being Open", "Saying Sorry", and "Just Culture."

1.5 The Care Quality Commission (CQC) oversee the statutory requirements for duty of candour through Regulation 20.

1.6 In March 2021, the CQC published their updated guidance following a public consultation in 2018. People shared examples of positive and negative experiences surrounding duty of candour. They referred to "cover ups" – whether real or perceived, and that the lack of an apology compounded the level of harm that they had experienced following the initial incident. This is frequently cited as "secondary trauma" in related literature.

1.7 However, when the duty of candour had been carried out well, people felt that they had received a "heartfelt apology", that the care provider had been "honest from the outset", that "it was not a tick-box exercise", and there was learning assurance that measures had been put in place to prevent the incident from happening to others.

1.8 There is also a professional duty of candour which is regulated by professional bodies including the General Medical Council (GMC), the General Dental Council (GDC) and the Nursing and Midwifery Council (NMC).

1.9 Duty of candour is strongly aligned to "The Seven Principles of Public life" which were set out by Lord Nolan in his report to the Committee on Standards in Public life in 1995. They outline the ethical standards for those people working in the public sector and are expected to be adhered to. The seven principles are:

- Selflessness
- Integrity
- Objectivity

- Accountability
- Openness
- Honesty
- Leadership

1.10 ***It is advised that this policy is read and implemented in conjunction with the Incidents Policy including Serious Incidents (Clinical Governance Policy CGP001) as they are closely aligned.***

2. PURPOSE

To ensure that the infrastructure in in place to support all colleagues to be open and honest with patients and their families following an incident, complaint or claim.

3. SCOPE

The duty of candour policy applies to colleagues working for Gloucestershire Health and Care NHS Foundation Trust. There are no limitations regarding its' circulation within the Trust and wider NHS community. The policy is available to patient's, their families and members of the public upon request.

4. DUTIES

4.1 Responsibility for the development, maintenance and review of this document lies with the Quality Assurance and Clinical Compliance Directorate. The Director of Nursing, Therapies & Quality has Board-level responsibility for the development of this document and may delegate this responsibility to a nominated senior colleague.

4.2 The Trust Board

The Trust Board is responsible for actively championing the Duty of Candour Policy by promoting an open and just culture that fosters peer support and discourages the attribution of blame.

4.3 Chief Executive

The Chief Executive is responsible for ensuring the infrastructure is in place to support openness between colleagues, patients, their families, carers or representatives.

4.4 Director of Nursing, Therapies and Quality

The Director of Nursing, Therapies and Quality has responsibility for ensuring that an appropriate support mechanism is in place for all colleagues involved in clinical patient safety incidents.

4.5 Service Directors

Service Directors (in liaison with the Medical Director and Director of Nursing, Therapies and Quality) have responsibility to ensure that the most appropriate colleagues are identified to meet with the patient and/or their families, carers or their "relevant person." For the purpose of this policy they are known as the nominated lead. In determining the most appropriate person to be the nominated lead consideration of seniority, relationship to the person using the service and experience and expertise in

the type of incident that has occurred in order to ensure that the nominated lead is credible to service users, families and carers. The nominated lead should also have received training in communication of patient safety incidents.

4.6 All Colleagues

All colleagues will be expected to adhere to this policy. Colleagues will also be aware of the relevant requirements regarding the duty of candour as set out in their relevant professional regulatory body's code of conduct. All colleagues have a responsibility for ensuring that patient safety incidents are acknowledged and reported via the Datix incident reporting system as soon as they are identified. In the event where the patient; their family and/or carers inform us that something untoward has happened, it must be taken seriously from the outset. Any concerns should be treated with compassion and understanding by all colleagues.

It is not always appropriate for junior members of staff to be involved with duty of candour discussions, particularly if they are distressed. However, when a junior member of staff who has been involved in a patient safety incident asks to be involved in the discussion, it is important they are accompanied and supported by a senior team member.

A junior member of staff should not routinely communicate patient safety information alone or to be delegated the responsibility to lead a duty of candour discussion unless the following have been considered:

- The incident resulted in low harm;
- They have expressed a wish to be involved in the discussion with the patient, their family and carers;
- The senior healthcare professional responsible for the care is present for support;
- The patient, their family and carers agree.

4.7 Managers

All managers are responsible for reviewing patient safety incidents reported via the Datix incident reporting system. In line with the "Incidents Policy including Serious Incidents" they must authorise the record and escalate the incident immediately if **moderate**, **severe**, **prolonged psychological harm**, or **death** is reported or a potential outcome (having first determined if the incident has been correctly recorded and the outcome in terms of harm to the patient is graded accurately).

When moderate or serious harm and/or death is reported, only members of the Patient Safety Team can finally approve the incident on the Datix incident reporting system. They have a personal duty to ensure that all actions as described in this policy are undertaken **without delay** in line with duty of candour principles.

4.8 Supportive Roles

The Associate Director of Patient Safety and Learning and the Associate Director of Quality Assurance and Compliance are the Trust leads for duty of candour. Their key duties are:

- Provide support and guidance to colleagues on duty of candour process.

- Ensure duty of candour process is followed.
- Identify any staff support requirements.
- Ensure patients, their families and/or their carers have the opportunity to be involved in the investigation.
- Ensure the Datix incident reporting system and the Patient Safety Team incident data base is updated with full details including assurance that the duty of candour process has been followed including feedback to patients, their families and /or their carers.
- Ensure the incident is investigated appropriately.
- Ensure the incident is reported to the Chief Executive, Director of Nursing, Therapies and Quality, Chief Operating Officer, relevant Heads of Service and the appropriate Quality Committee and relevant Groups.
- Ensure colleagues involved in the incident receive feedback and are provided with the opportunity to give an account of their personal experience of being involved in the investigation process.
- Ensure assurance of learning from incidents has been actioned.

5. POLICY DETAIL

5.1 In the event of any incident that compromises patient safety; irrelevant of the level of harm, saying sorry is the right thing to do. ***Saying sorry is not admitting fault neither is it an admission of liability.***

5.2 As soon as you are able, a verbal apology should be made to the patient and/or their "relevant person." The following link provides guidance as directed by NHS Resolution on how to "say sorry" https://resolution.nhs.uk/resources/saying-sorry/

5.3 The verbal apology must be documented in the patient's clinical records. State who you have apologised to, the time and date that the apology was made, by what means you said sorry, and what you are apologising for.

5.4 Provide a true account of what happened and explain whatever you know at that point.

5.5 Explain to the patient and/or their "relevant person" what further enquires or investigations you believe to be appropriate at that juncture.

5.6 Patient safety incidents that have been confirmed by the Incident Handler to have a severity rating of "no" or "low harm" do not require a formal investigation in the form of a Root Cause Analysis (RCA). Learning from such incidents can be shared at a local level in the relevant governance forums. However, if it is established that the level of learning would benefit the entirety of the Trust, an RCA is advisable. The Patient Safety Team should be notified that the RCA is underway and sent to them on completion to GHC Incident Reporting Mailbox: GHCIncidentReporting@ghc.nhs.uk

5.7 ***Notifiable safety incidents*** are incidents of ***"moderate" harm and above*** in accordance with the definitions as set out by the National Reporting and Learning System (NRLS) (Department of Health, 2014). The Trust's Datix incident reporting system is consistent with the NRLS levels of harm.

5.8 Notifiable safety incidents are reported to the NRLS, the CQC, the national Strategic

Executive Information System (STEIS) and the Gloucestershire Clinical Commissioning Group (GCCG).

5.9 The notification happens once it has been established that a patient has come to avoidable harm whilst under the care of the Trust. This is decided at a multi-professional incident review meeting which is led by the Patient Safety Team.

5.10 Notifications also include apparent suicides whilst the patient was open to NHS mental health services and more recently, Hospital Onset Probable Hospital Acquired (HOPHA) and Hospital Onset Definite Hospital Acquired (HODHA) cases of COVID-19.

5.11 The CQC and the Trust use the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20 to comply with duty of candour. A synopsis is provided below. For comprehensive guidance please follow this link: https://www.cqc.org.uk/sites/default/files/20150324_guidance_providers_meeting_regulations_01.pdf

5.12 Once it has been established that an incident meets the notifiable safety incident threshold, the patient and/or their "relevant person" needs to be informed as soon as is practicable. ***This must be given in person by a representative of the registered person.***

5.13 The registered person for the Trust is the Chief Executive Officer (CEO). The representative is the person best placed to inform the patient and/or their "relevant person" that a notifiable safety incident has been declared. This is decision is made at the multi-professional incident review meeting, if not before.

5.14 The patient and/or their "relevant person" must be provided with an account to the best of the informant's knowledge, all of the facts that are known about the incident at the point of the notification.

5.15 The patient and/or their "relevant person" must be advised regarding what further enquiries into the incident are deemed to be appropriate.

5.16 A verbal apology must be made to the patient and/or their "relevant person."

5.17 The verbal apology must be documented in a written record which is kept securely by the registered person.

5.18 The patient and/ or their "relevant person" must be provided with reasonable support in relation to the incident, including at the time of receiving the notification. The registered person appoints either a Family Liaison Officer (FLO) or a nominated health care professional who can support the patient and/or their "relevant person" with compassion and objectivity.

5.19 Once the verbal apology has been made, this needs to be followed up in writing in the initial duty of candour letter. The written apology needs to open, honest and specific. The letter needs to include the aforementioned points raised in **5.14; 5.15** and provide

the contact details of the nominated FLO/healthcare professional who will be supporting the patient and/or "relevant person." If there have been any further updates regarding the progress of the investigation, these also need to be included.

5.20 Owing to the nature of the incident, details of statutory and non-statutory organisations may be included in the initial duty of candour letter to provide an additional layer of support to the patient/and or "relevant person." This is particularly relevant in cases of suspected suicide where details of agencies such as Survivors of Bereavement by Suicide (SOBS) and Winston's Wish are relayed.

5.21 There are occasions where the "relevant person" cannot be contacted, or declines to engage with the representative of the registered person. In these circumstances all attempts to contact or speak to the "relevant person" must be documented in a written record which is kept securely by the registered provider.

5.22 Once the notifiable safety incident investigation is complete following 60 working days, the patient and/or their "relevant person" should be given a copy of the final report if they wish to receive it. The timeframe for this is 10 working days after the final report has been submitted to the GCCG. It is best practice for the findings to be discussed with the patient and/or their "relevant person" by the Investigating Officer and the nominated FLO/healthcare professional on a face to face basis. The minutes of the meeting should be contemporaneously recorded and kept securely by the registered provider.

5.23 If the patient/"relevant person" does not want a copy of the final report, or meet with the Investigating Officer and the nominated FLO/health care professional this should be documented in the same manner as set out in this guidance.

Supporting Colleagues in Notifiable Safety Incidents

5.24 All colleagues involved in notifiable safety incidents can be understandably upset and distressed for a multitude of reasons. Although the Trust supports a non-blame culture, colleagues may doubt their professional practice and question whether there were adequate systems and processes in place to reduce the risk of the incident occurring.

5.25 In line with the duty of candour principles, the Trust welcomes the views of all those who have provided care for the patient in these, or any circumstances as an opportunity to learn and continually improve patient safety and experience.

5.26 It is advised that any colleague who wishes to raise a concern regarding patient safety and/or care provision speaks to their immediate manager in the first instance. If it is not appropriate to do so because there is a conflict of interests, the Freedom to Speak Guardian is available to discuss any concerns. The Trust also operates "Paul's Open Door" which provides an informal way of contacting our Chief Executive Officer. This service can be accessed via the Trust's intranet site "Indigo."

"Working Well" the Trust's Occupational Health Department can also assist colleagues with psychological support following notifiable safety incidents.

Putting Patients and their Families at the centre of Notifiable Safety Incidents

5.27 There is an array of evidence that clearly demonstrates that patients, their families and/or their carers have felt excluded from notifiable safety incident investigations.

5.28 The Mid Staffordshire NHS Foundation Trust Public Inquiry chaired by Sir Robert Francis in 2013 changed the face of patient involvement not only in the NHS, but for other statutory and non-statutory organisations.

5.29 In 2015, following the preventable death of Connor Sparrowhawk in July 2013, NHS England commissioned Mazars to investigate all patient deaths at Southern Health NHS Foundation Trust from April 2011 to March 2015. For that period, 10,306 patients had died; 1,454 were unexpected deaths, 272 were deemed to be critical incidents and 195 were declared as notifiable safety incidents. Of the 195 notifiable safety incidents, only one third had involved the patient's family.

5.30 Following the publication of the Mazars report, the Health Secretary Norman Lamb, asked the CQC to undertake a wider review into the investigation of deaths in a sample of NHS Trusts in various parts of the country. The sample included acute, mental health and community NHS Trusts. Gloucestershire Care Services NHS Trust was identified as one of the 12 Trusts. During their review, the CQC assessed whether opportunities for prevention of death had been missed including a late diagnosis of physical health problems. In 2016, the CQC published their findings in their report entitled ***"Learning, candour and accountability. A review of the way NHS trusts review and investigate the deaths of patients in England."***
https://www.cqc.org.uk/sites/default/files/20161213-learning-candour-accountability-full-report.pdf

5.31 More recently in 2018, the Behavioural Insights Team from NHS Resolution published their study in relation to what motivates patients to make a claim in the event of clinical negligence. Of the 728 patients who participated in the study reported the following:

- Almost two thirds (63%) felt that no explanation of the incident was given to them. The majority of those that did receive an explanation waited ten or more days to receive it.
- Less than one third of patients (31%) felt that they received an apology. A minority of those who did receive an apology rated that apology highly.
- The majority of patients (71%) did not think that their healthcare provider investigated the incident in the first instance.
- Where healthcare providers had investigated the incident, only 49% were invited to a meeting to discuss the findings.
- Only 6% felt that actions were taken that would reduce the risk of the same incident happening again.

5.32 The Trust makes every effort to involve patients, their families and/or carers in notifiable safety incident investigations. The ultimate aim of their involvement is to achieve a learning organisation where they become central to co-production and co-design of services.

5.33 Particular Patient Circumstances

Someone may act on the behalf of the person who was harmed if:

- The patient has died
- Is under 16 years of age and not competent to make decisions about their care or the consequences of the notifiable safety incident
- Is over the age of 16 years and lacking in capacity.

This is in accordance with the Mental Capacity Act 2005. Please follow the link for comprehensive guidance. https://www.nhs.uk/conditions/social-care-and-support-guide/making-decisions-for-someone-else/mental-capacity-act/

5.34 When a Patient has Died

When an incident has resulted in a patient's it is crucial that communication is sensitive, empathic and open. It is important to consider the emotional state of bereaved relatives and carers and to involve them in deciding when it is appropriate to discuss what has happened. The service user's family and/or carers will likely require information on the processes that will be followed to identify the cause(s) of death. They may also need emotional support. Establishing open channels of communication may allow the family and/or carers to indicate if they need bereavement counselling or assistance at any stage.

Duty of candour discussions and any investigation occur before the Coroner's inquest. In certain circumstances it may be appropriate to wait for the Coroner's inquest before holding the duty of candour discussion with the patient's family and/or carers. In any event an apology and sincere condolences must be issued as soon as possible after the patient's death, together with an explanation that the Coroner's process has been initiated and a realistic timeframe of when the family and/or carers will be provided with more information and how this relates to the Coronial process.

Where a death of a patient is investigated as a notifiable safety incident, a copy of the final report will be shared with the Coroner in order to assist them with their inquiry.

5.35 Children

The legal age of maturity for giving consent to treatment is 16. It is the age at which a young person acquires the full rights to make decisions about their own treatment and their right to confidentiality becomes vested in them rather than their parents or guardians. However, it is still considered good practice to encourage competent children to involve their families in decision making.

The courts have stated that younger children who understand fully what is involved in the proposed procedure can also give consent. This is sometimes known as Gillick competence or the Fraser guidelines. Where a child is judged to have the cognitive ability and the emotional maturity to understand the information provided, they should be involved directly in the duty of candour process after notifiable safety incident.

The opportunity for parents to be involved should still be provided and would be seen as good practice unless the child expresses a wish for them not to be present.

Where children are deemed not to have sufficient maturity or ability to understand, consideration needs to be given to whether information is provided to the parents alone or in the presence of the child. In these instances, the parents' views on the issue

should be sought.

More information can be found on the Department of Health and Social Care's website Department of Health and Social Care - GOV.UK (www.gov.uk)

5.36 Patients with Cognitive Impairment

A patient with a cognitive impairment should, where possible, be involved directly in communications about what has happened. An advocate with appropriate skills should be available to the patient to assist in the communication process. Some individuals have conditions that limit their ability to understand what is happening to them or to understand information that they receive, in these instances the Trust must take all reasonable steps to support the individual to understand.

They may have authorised a person to act on their behalf by a lasting power of attorney. In these cases, steps must be taken to ensure this extends to decision making and to the medical care and treatment of the service user. The duty of candour discussion would be held with the holder of the power of attorney. Where there is no such person the clinicians may act in the service user's best interests in deciding who the appropriate person is to discuss the incident information with, regarding the welfare of the patient as a whole and not simply their medical interests.

5.37 Patients with Learning Disabilities

Where a patient has difficulties in expressing their opinion, an assessment should be made about whether they are also cognitively impaired (see above). If the patient is not cognitively impaired they should be supported in the duty of candour process by alternative communication methods (i.e. given the opportunity to write questions down; given easy read information on what's happened). An advocate, agreed in consultation with the patient, should be appointed. Appropriate advocates may include carers, family or friends of the service user. The advocate should assist the patient during the duty of candour process, focusing on ensuring that the patient's views are considered and discussed.

5.38 Patients with Language or Cultural Considerations

The need for translation and advocacy services, and consideration of special cultural needs (such as for patients from cultures that make it difficult for a woman to talk to a male about intimate issues), must be taken into account when planning to discuss notifiable safety incident information. It would be worthwhile to obtain advice from an advocate or translator before the meeting on the most sensitive way to discuss the information. Avoid using 'unofficial translators' and/or the patient's family or friends as they may distort information by editing what is communicated. Refer to the ***Translation and Interpretation Policy.***

5.39 Patients with Communication Needs

A number of patients will have particular communication difficulties, such as hearing impairment. Plans for the meeting should fully consider these needs.

Knowing how to enable or enhance communications with a patient is essential to facilitating an effective duty of candour process, focusing on the needs of individuals

and their families. The Head of Profession for Speech & Language Therapy can be approached for advice regarding appropriate communication with people who have complex communication difficulties.

6. DEFINITIONS

Act in an open and transparent way: Clear, honest and effective communication with patients, their families and carers throughout their care and treatment, including when things go wrong, in line with the definitions below:

Openness: Enabling concerns and complaints to be raised freely without fear and questions asked to be answered.

Transparency: Allowing information about the truth about performance and outcomes to be shared with staff, people who use the service, the public and regulators.

Candour: Any person who uses the service harmed by the provision of a service provider is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it.

Apology: An "apology" is an expression of sorrow or regret in respect of a notifiable safety incident; it is not an admission of guilt.

Appropriate written records: Records are complete, legible, accurate and up to date. Every effort must be made to ensure records are updated without delays.

Cancelling treatment: Where planned treatment is not carried out as a direct result of the notifiable safety incident.

Notifiable safety incident: Any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in reasonable opinion of a health care professional, could result in, or appears to have resulted in:

Moderate harm: "Moderate harm" means harm that has required a moderate increase in treatment, and significant, but not permanent, harm, for example a "moderate increase in treatment" means an unplanned return to surgery, and unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling treatment, or transfer to another treatment area (such as intensive care).

Prolonged pain: "Prolonged pain" means pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

Prolonged psychological harm: "Prolonged psychological harm" means psychological harm which a service user has experienced, or is likely to experience for a continuous period of at least 28 days.

Severe harm: "Severe harm" means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.

Relevant person: This is the person who is receiving services or someone acting lawfully on their behalf in the following circumstances: on their death, or where they are under 16 and not competent to make a decision in relation to their care or treatment, or are 16 or over and lack the mental capacity in relation to the matter in accordance with the Mental Capacity Act 2005.

Root Cause Analysis (RCA): A systematic process whereby the factors that contributed to the incident are identified. As an investigation technique for patient safety incidents, it looks beyond individuals concerned and seeks to understand the underlying causes and environmental context in which an incident happened.

Written Notification: A written notification is one given or sent to the relevant person in written form 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).

7. PROCESS FOR MONITORING COMPLIANCE

There are four levels of regulatory compliance in relation to duty of candour:

7.1 Individual

All registered healthcare professionals must act in line with their regulatory professional body's code of conduct/standards. "The Code" directed by the Nursing and Midwifery Council (NMC) under the domain of "Preserve Safety" states:

"Be open and candid with all service users about all aspects of care and treatment, including when any mistakes or harm have taken place

To achieve this, you must:

- Act immediately to put right the situation if someone has suffered actual harm for any reason or an incident has happened which had the potential for harm.

- Explain fully and promptly what has happened, including the likely effects, and apologise to the person affected and, where appropriate, their advocate, family or carers.

- Document all these events formally and take further action (escalate) if appropriate so they can be dealt with quickly.

Datix Incident Handlers have a responsibility to complete the **"Openness and Transparency"** field on the GHC DatixWeb Incident Admin and Specialist Reviewer Form (DIF3). They are also asked to "confirm" the "reported" result and level of harm from the incident to the patient. In the event that a patient has come to "moderate", "severe" or "catastrophic" harm, the Patient Safety Team will also be notified of this result and the investigation process will commence.

The Datix Incident Handler requires assurance from their team member that a verbal apology has been made to the patient, and that this has been contemporaneously documented in the patient's clinical records.

It is best practice for patient's to also receive a verbal apology where there has been a "near miss" or a severity rating of "low harm." This must also be documented in the patient's clinical records. It is unlikely that incidents with this severity rating require formal investigation in the form of a Root Cause Analysis (RCA). However, opportunities for local and organisational learning should be encouraged.

7.2 Team

The Patient Safety Team monitor all incidents of "moderate" harm and above via the GHC Incident Reporting Mailbox. Once it has been established that a patient has come to "moderate", "severe" or "catastrophic" harm, a member of the team will request a concise RCA from the service area where the incident occurred.

The recommended timeframe for this investigation is five working days. On receipt of the concise RCA, the Patient Safety Team will decide whether the incident needs to be discussed at an "Incident Review Meeting."

The "Incident Review Meeting" provides the forum to discuss whether the incident meets the threshold as a "notifiable safety incident" and if duty of candour applies.

However, the first stages of the duty of candour process should have been initiated at that point in that a face to face verbal apology should have been made to the patient and /or their "relevant person" and that this has been documented in the patient's clinical records.

7.3 Organisation

The Duty of Candour Assurance Lead provides the Trust with assurance that there have been no breeches in the application of duty of candour. This is achieved through a retrospective, quarterly review of all patient safety incidents that were "reported" as moderate harm and above.

The Regulatory Compliance Group (RCG) provides the next stage of the governance process. The RCG are provided with a verbal update on duty of candour on a monthly basis, and a written report every quarter. Following recommendations and approval by the RCG, the paper progresses to the Quality Assurance Group (QAG).

In the event that there are cases of concern regarding the application of duty of candour, these will be presented to the Improving Care Group (ICG) for review. If the ICG is in agreement that an incident meets the criteria for duty of candour, this will be escalated to the Patient Safety Team and will be declared as a notifiable safety incident.

7.4 The CQC

Where the CQC has reason to believe that duty of candour is not being applied, they can use their powers of enforcement to prosecute breaches of Regulation 20.

Regulation 20 also allows the CQC to enforce criminal action.

In September 2020, University Hospitals Plymouth Trust was the first NHS Trust to be

prosecuted under duty of candour laws.

8. TRAINING

8.1 Statutory training requirements for duty of candour are provided at clinical induction for colleagues who are new to the Trust.

8.2 Bespoke duty of candour training sessions are available to those colleagues who form part of the Care Certificate and Preceptorship Programme.

8.3 For existing staff, the requirements of duty of candour will be provided as part of Investigations/Root Cause Analysis Training.

9. REFERENCES

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10. ASSOCIATED DOCUMENTS

- Incidents Policy including Serious Incidents (Clinical Governance Policy CGP001)
- Learning from Deaths Policy (CGP005)
- Coroners Enquiries and Inquests Policy (Clinical Governance Policy CGP007)
- Handling and Resolving Complaints and Concerns Policy and Procedure
- Datix – Operational Policy (CGP002)
- Translation and Interpretation Policy
- Speaking Up at Work Policy
- Disciplinary Policy and Procedure (G009)

Appendix 1

NHS Resolution

Saying sorry

Saying sorry meaningfully when things go wrong is vital for everyone involved in an incident, including the patient, their family, carers, and the staff that care for them.

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

Why?

Not only is it a moral and right thing to do - it is also a statutory, regulatory, and professional requirement. It can also support learning and improve patient safety.

When?

As soon as possible after you become aware something has gone wrong you should seek out the patient and or their family and say sorry and acknowledge what has happened and tell them that you will find out more. Reassure them that you will keep them informed.

Who?

Everyone can say sorry, but you may need to be supported to do so. You may need the backing of more senior people and staff may need training but it should not stop you from simply saying sorry. As part of an initial apology it is best practice to provide the patient and their family with a key contact wherever possible.

What if there is a formal complaint or claim?

The Compensation Act 2006 states; 'An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty'. (source: Compensation Act 2006 – Chapter 29 page 3)

In fact, delayed or poor communication makes it more likely that the patient will seek information in a different way such as complaining or taking legal action. The existence of a formal complaint or claim should never prevent or delay you saying sorry.

How?

The way you say sorry is just as important as saying it. An apology should demonstrate sincere regret that something has gone wrong and this includes recognised complications referred to in the consent process. It should be confidential and tailored to the individual patient's needs.

Where possible you should say sorry in person and involve the right members of the healthcare team. It should be heartfelt, sincere, explain what you know so far and what you will do to find out more.

It is the starting point of a longer conversation; as over time this will lead to sharing information about what went wrong, what you will do differently in the future. It is vital to avoid acronyms and jargon in all communications.

You may also need to say sorry in writing where significant harm has been caused or in response to a written complaint. An example of this could be:

"I wish to assure you that I am deeply sorry for the poor care you have been given and that we are all truly committed to learning from what happened. I apologise unreservedly for the distress this has caused you and your family"

What about the Duty of Candour?

The statutory Duty of Candour requires all NHS staff to act in an open and transparent way. Regulations governing the duty set out the specific steps healthcare professionals must follow if there has been an unintended or unexpected event which has caused moderate or severe harm to the patient.

These steps include informing people about the incident, providing reasonable support, truthful information and an apology. Saying sorry forms an integral part of this process. Process should never stand in the way of providing a full explanation when something goes wrong.

Don't say	Do say
x I'm sorry you feel like that	✓ I'm sorry X happened
x We're sorry if you're offended	✓ We're truly sorry for the distress caused
x I'm sorry you took it that way	✓ I'm sorry, we have learned that...
x We're sorry, but...	

"We have never, and will never, refuse cover on a claim because an apology has been given."

Helen Vernon, Chief Executive, NHS Resolution

For more information

Nursing and Midwifery Council & General Medical Council joint guidance on openness and honesty when things go wrong
www.gmc-uk.org/guidance/ethical_guidance/27233.asp

Reports and consultations on complaint handling (Parliamentary and Health Service Ombudsman)
www.ombudsman.org.uk

AvMA (Action against Medical Accidents) Duty of Candour leaflet www.avma.org.uk/policy-campaigns/duty-of-candour/duty-of-candour-leaflet

Care Quality Commission - Regulation 20: Duty of Candour www.cqc.org.uk/content/regulation-20-duty-candour

The Patients Association
https://www.patients-association.org.uk

The NHS Constitution

Patients: "you have the right to an open and transparent relationship with the organisation providing your care. You must be told about any safety incident relating to your care which in the opinion of a healthcare professional, has caused or could still cause significant harm or death. You must be given the facts, an apology, and any reasonable support you need".

Staff: "you should aim to be open with patients… if anything goes wrong; welcoming and listening to feedback and addressing concerns promptly and in the spirit of cooperation."

If you want to get in touch
safetyandlearningenquiries@resolution.nhs.uk

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www.resolution.nhs.uk

Appendix 2 – Example of an Initial Duty of Candour Letter

Edward Jenner Court
Gloucester Business Park
1010 Pioneer Ave, Brockworth,
Gloucester GL3 4AW
Tel: *[Telephone Number]*

If you call or telephone please ask for: [*Name]*
E-mail : [*Email Address]*

Private & Confidential
[Title and Name of the recipient]
[Address Line 1]
[Town / Locality]
[County]
[Postcode]

[Date]

Dear [Name of the recipient]

I am very sorry to be writing to you in these circumstances having recently been told of the incident on [*Name] Ward* at [*Name]* Hospital on [*Date]*, where your wife [*Name]* was found on the floor. I would like to offer my sincere apology that she fell whilst in receipt of care from the Trust, and that this fall resulted in a fracture of her left hip.

I understand that you were promptly informed of the incident by the staff on the Ward and [*Name]* was transferred to Gloucestershire Hospitals NHS Foundation Trust where she received a surgical repair to her hip. I was pleased to be told that the operation went well and that [*Name]* has since returned to [*Name]* Ward to continue her recovery, assisted by our physiotherapists and ward team.

When a person who is receiving inpatient care from the Trust experiences an injury of this sort, we undertake an investigation of the care with the aim of developing and improving practice wherever possible. This review involves a number of stages including an immediate meeting of involved clinicians and managers and subsequently a formal review of events with clinicians.

Meeting with carers or relatives assists us to take into account their perspective and experiences in the expectation that the combination of relative and clinical perspective will provide a more complete view. I have appointed **[*Name]*** as the Investigating officer regarding the incident that happened to your wife. If you would like to speak with [*Name]* directly please do let [*Name]*, my Patient Safety Manager know, especially if you have questions that you would like the investigation to address or information you would like to provide. [*Name's*] contact details are at the top of this letter.

Once again, please accept my sincere apology, and if there is anything I can do to help please let me know.

Kind regards.

Yours sincerely

[Name and Title]
On behalf of [Name] Chief Executive

Appendix 3 - Example of a Final Duty of Candour Letter

Edward Jenner Court
Gloucester Business Park
1010 Pioneer Ave, Brockworth,
Gloucester GL3 4AW
Tel: *[Telephone Number]*

If you call or telephone please ask for: [*Name]*
E-mail : [*Email Address]*

Private & Confidential
[Title and Name of the recipient]
[Address Line 1]
[Town / Locality]
[County]
[Postcode]

[Date]

Dear [Name of the recipient]

Further to my letter of *[Date]* I am writing to update you with regard to the outcome of the recent Serious Incident Requiring Investigation conducted by the Trust following your wife's fall whilst she was an inpatient on *[Name]* Ward at *[Name]* Hospital on *[Date]*.

Firstly, I would like to say how sorry we are that this incident occurred in our hospital and there were such serious consequences for *[Name]*. I understand that the Ward Manager from *[Name]* Ward contacted you on the morning that the incident occurred to explain what had happened and apologise for the incident during our care. I am also aware that *[Name]*, the Investigating Officer, spoke to you shortly after the incident to explain how the investigation would progress and identify any issues from your perspective, relevant to the investigation.

This letter summarises the key findings from the investigation:

1. *[Name]* was found on her bedroom floor at 2.45am by nursing staff on the night shift who were completing regular patient checks during the night. The cause of *[Name's]* fall remains unknown because it was unwitnessed. It is with regret that *[Name]* sustained a fractured left neck of femur (broken hip). It is thought she slipped off or accidentally fell in her bedroom, but the exact circumstances of the fall could not be identified. *[Name]* could not recall the cause of the incident and there was no night time alert or surveillance system available to monitor her movement.

2. Following a patient fall at *[Name]* Hospital there is a protocol called "The Service User Falls Pathway" in place which identifies what should happen and this was followed by the staff on duty. Vital checks and clinical observations were immediately carried out and the Duty Doctor was informed, but before they arrived it was noted that *[Name]* could not move her left leg. The nurse in charge immediately suspected a possible fracture or dislocation and an emergency ambulance was called. *[Name]* remained alert and responsive while waiting for the paramedics. Ward staff continued to undertake physical and neurological observations

until they arrived. *[Name]* was immediately transported by emergency ambulance to Gloucester Royal Hospital (GRH) and was accompanied by a member of nursing staff from *[Name]* Ward. On arrival to the Emergency Department at GRH, your wife was re-examined and an X-ray confirmed the provisional diagnosis of a left fractured neck of femur.

3. A number of observations made during the investigation and the identification of "lessons learned" have led to developments and recommendations to improve services as a result of your wife's incident.

a. During the investigation, you kindly pointed out to *[Name]* that you did not know what *[Name's]* bedroom looked like owing to the COVID-19 visiting restrictions. As a result, a "virtual video tour" of the wards, bedrooms, bathrooms and communal areas at *[Name]* Hospital is currently being filmed to provide patients, their families and carers the opportunity to familiarise themselves with the environment and facilities.

b. It was acknowledged that it is difficult to monitor patients in their bedrooms, especially at night. An innovative new digital system is being considered for a trial on *[Name]* Ward subject to funding. It will assist in the analysis of falls that do occur, and assist with their prediction and prevention through the use of discrete remote monitoring. It has already been tested successfully in other parts of the NHS with proven results in reducing falls.

c. On occasions it was noted that *[Name's]* clinical records did not identify clear and consistent information about her mobility and risk of falls. This did not appear to have a negative impact on the incident. A number of measures have now been put in place to improve record keeping, including a new daily record sheet, monthly audits and additional training for ward staff. This will be led by the Ward Manager.

d. It was also noted that it was of great benefit to *[Name]* that she was able to return to *[Name]* Ward following her surgery at GRH to continue her recovery and rehabilitation. We want you to be assured that the *[Name]* Ward Team have liaised with the staff at GRH to ensure that your wife's physical rehabilitation is properly provided.

I hope that the information provided in this letter helps you to understand the events surrounding *[Name's]* fall on *[Date]*. As a Trust, we take incidents such as these extremely seriously. It is of paramount importance that we continually learn from incidents in order to review services and improve patient care. We would also like to take this opportunity to thank you so much for helping us with our investigation and seeing things from your perspective.

I understand that *[Name]* is planning to meet you on *[Date]* here at Edward Jenner Court so that she can give you a final copy of the investigation report and answer any further questions that you may have.

Yours sincerely

[Name and Title]
On behalf of [Name] Chief Executive