

# CLINICAL GOVERNANCE POLICY

## Duty of Candour

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Policy Number	CGP004
Version:	V3.1
Purpose:	To ensure that the infrastructure is in place to support all colleagues to fulfil professional and statutory Regulation 20 Duty of Candour requirements with patients, families and carers following an incident, complaint, or claim.
Consultation:	Operational Colleagues, Patient Safety Team, Patient Safety Partners, Quality and Regulatory Compliance Group, Legal Team, Associate Director of Patient Safety, Quality and Clinical Compliance, Senior Quality Nurse ICB
Approved by:	Clinical Policy Group 16/04/2024 / Quality and Regulatory Compliance Group 23/01/2024
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Author:	Gemma Evans - Duty of Candour Lead
Date issued:	29/04/2024
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Audience:	All Trust Colleagues
Dissemination:	The policy will be published on the GHC intranet, and its update will be listed on the Clinical Policy update bulletin.
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 Issued	Reason for Change
V1	Oct 2019	New Policy
V2	20/10/2021	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

V3	29/04/2024	To incorporate the updated Care Quality Commission (CQC) guidance in 2022. To align with the updated Incidents Policy including Serious Incidents (Clinical Governance Policy CGP001) and to reflect the new Patient Safety Incident Response Framework (PSIRF) and Learn from Patient Safety Events (LFPSE) service which replaces the National Reporting and Learning System (NRLS) and Strategic Executive Information System
V3.1	26/11/2024	Minor update: 'Datix Handler' changed to 'Incident Handler' for accuracy. Change in focus: first line support from Patient Safety team with further support as required from DoC Lead, to reflect operational change in process.

## SUMMARY

This policy is to support all colleagues to be open and honest with patients and their families and carers following a patient safety incident, complaint, or claim. The policy clarifies the duty of candour responsibilities including professional, statutory and overarching principles.

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## ABBREVIATIONS

Abbreviation	Full Description
GHC	Gloucestershire Health and Care NHS Foundation Trust
DoC	Duty of Candour
CQC	Care Quality Commission
LFPSE	Learn From Patient Safety Events
PSIRF	Patient Safety Incident Response Framework

## 1. INTRODUCTION

1.1 Gloucestershire Health and Care NHS Foundation Trust (hereafter referred to as ‘the Trust’) is committed to delivering high quality services with honesty, openness, transparency, accountability, and integrity. All staff are encouraged to actively contribute to an open and honest culture to support duty of candour, improvements in patient safety and the quality of the service user experience. The Trust considers ‘being open’ as fundamental to relationships between patients, the public, staff, and other healthcare organisations.

***In essence, the duty of candour is a requirement to act in an open, honest and transparent way, at all times and in all cases, with patients receiving care or treatment, and their families and carers.***

## 2. BACKGROUND

2.1 The tragic case of Robbie Powell and the perseverance of his parents through the UK and European Courts exposed the absence of the legal duty of candour in 1990. Robbie Powell was aged 10 when he died of Addison’s disease due to multiple failures and missed opportunities in his care (in what was a preventable death), followed by cover-ups by those involved.

2.2 In 2013, the Francis Inquiry found serious failings in openness and transparency at Mid Staffordshire NHS Foundation Trust and recommended that a statutory duty of candour be introduced for all health and care providers, in addition to the existing professional duty of candour and the requirement for candour in the NHS standard contract. This statutory duty of candour was brought into law in 2014 for NHS Trusts and is now seen as a crucial, underpinning aspect of a safe, open, and transparent culture.

## 3. PURPOSE

3.1 The purpose of this policy is to support all colleagues to be open and honest with patients and their families and carers following a patient safety incident, complaint, or claim. This policy clarifies the duty of candour responsibilities and the requirements that must be fulfilled.

## 4. SCOPE

4.1 The policy applies to all colleagues working for Gloucestershire Health and Care NHS

Foundation Trust. This policy is relevant to all care and treatment provided by the Trust and applies to all patient safety incidents. There are no limitations regarding its circulation.

## 5. DUTIES – ROLES AND RESPONSIBILITIES

### 5.1 General Roles, Responsibilities and Accountability

**Gloucestershire Health and Care NHS Foundation Trust (GHC)** aims to take all reasonable steps to ensure the safety and independence of its patients and service users to make their own decisions about their care and treatment.

In addition, **GHC** will ensure that:

- All employees have access to up-to-date evidence-based policy documents.
- Appropriate training and updates are provided.
- Access to appropriate equipment that complies with safety and maintenance requirements is provided.

**All Staff Working for GHC** will ensure that they:

- Promote a culture of openness, honesty, transparency, and learning.

**Managers and Heads of Service** will ensure that:

- All staff are aware of and have access to policy documents.
- All staff access training and development as appropriate to individual employee needs.
- All staff participate in the appraisal process, including the review of competencies.

**Employees (including bank, agency, and locum staff)** must ensure that they:

- Practice within their level of competency and within the scope of their professional bodies where appropriate.
- Read and adhere to GHC policy
- Identify any areas for skill update or training required.
- Participate in the appraisal process.
- Ensure that all care and consent comply with the Mental Capacity Act (2005) – see section on [MCA Compliance below](#).

### 5.2 Roles, Responsibilities and Accountability Specific to this Policy

**All Staff who Identify a Patient Safety Incident will:**

- Report the incident promptly on Datix as per the Incident Reporting and Management Policy and Procedure (CGP001)
- Complete the Datix duty of candour section (if appropriate)
- Ensure the overarching and professional duty of candour requirements have been met, particularly a meaningful apology using the word ‘sorry’
- Document details of any communication with the patient and their family/carer related to the incident in the clinical or Datix records.

Individual health and care professionals must comply with the Professional Duty of Candour standards set out by their professional governing body (see references).

**The Incident Handler will:**

- Review the incident and Datix record and complete the 'Overall result and severity' level of harm
- Review and complete the Datix duty of candour section and identify if the incident meets the Regulation 20 Duty of Candour threshold
- Ensure the overarching and professional duty of candour requirements have been met
- If required, ensure all Regulation 20 Duty of Candour requirements are met including both the verbal and written notifications
- Document details of any communication with the patient and their family/carer related to the incident in the clinical or Datix records
- Seek support from the Patient Safety Team regarding duty of candour requirements as needed.

**The Patient Safety Team (supported by the DoC Lead) will:**

- Identify notifiable safety incidents from ongoing Datix incident management, incident tracker meetings and incident review processes
- Identify and inform the named person responsible (usually the Incident Handler) for completing Regulation 20 Duty of Candour requirements for notifiable safety incidents
- Support the person responsible / Incident Handler to fulfil the duty of candour responsibilities
- Escalate any concerns where the duty of candour process has not been adhered to.

**The Duty of Candour Lead will:**

- Ensure relevant up to date duty of candour resources and supporting information is accessible via the Trust intranet
- Ensure ongoing staff duty of candour awareness and training
- Offer training and support to teams following specific or complex incidents, or through identified themes or trends in reported incidents
- Review compliance, provide assurance and raise any concerns to the Associate Director of Patient Safety, Quality and Clinical Compliance and Head of Patient Safety.

**The Directors, Deputy Service Directors, Heads of Service, Managers, Clinical and Professional Leads and Matrons will:**

- Ensure all staff are supported to fulfil duty of candour requirements
- Promote the Duty of Candour Policy and duty of candour compliance as part of quality and governance, staff training and updates.

**The Associate Director of Patient Safety, Quality and Clinical Compliance will:**

- Ensure oversight of the Trust duty of candour process
- Report compliance and provide assurance to the Quality Assurance Group (QAG).

**The Chief Executive and Trust Board will:**

- Ensure the Trust's commitment to the duty of candour principles and standards and ensure organisational systems are in place for the implementation of the duty of candour

- Retain overall accountability for compliance with the statutory Regulation 20 Duty of Candour.

## 6. MENTAL CAPACITY ACT COMPLIANCE

6.1 Where parts of this document relate to decisions about providing any form of care treatment or accommodation, staff using the document must do the following: -

- Establish if the person able to consent to the care, treatment or accommodation that is proposed? (Consider the 5 principles of the Mental Capacity Act 2005 as outlined in section 1 of the Act. In particular principles 1,2 and 3) [Mental Capacity Act 2005 \(legislation.gov.uk\)](https://legislation.gov.uk).
- Where there are concerns that the person may not have mental capacity to make a specific decision, complete and record a formal mental capacity assessment.
- Where it has been evidenced that a person lacks the mental capacity to make a specific decision, complete and record a formal best interest decision making process using the best interest checklist as outlined in section 4 of the Mental Capacity Act 2005 [Mental Capacity Act 2005 \(legislation.gov.uk\)](https://legislation.gov.uk).
- Establish if there is an attorney under a relevant and registered Lasting Power of Attorney or a deputy appointed by the Court of Protection to make specific decisions on behalf of the person (N.B. they will be the decision maker where a relevant best interest decision is required. The validity of an LPA or a court order can be checked with the Office of the Public Guardian) [Office of the Public Guardian - GOV.UK \(www.gov.uk\)](https://www.gov.uk).
- If a person lacks mental capacity, it is important to establish if there is a valid and applicable Advance Decision before medical treatment is given. The Advance Decision is legally binding if it complies with the MCA, is valid and applies to the specific situation. If these principles are met it takes precedence over decisions made in the persons best interests by other people. To be legally binding the person must have been over 18 when it was signed and had capacity to make, understand and communicate the decision. It must specifically state which medical treatments, and in which circumstances the person refuses and only these must be considered. If a patient is detained under the Mental Health Act 1983 treatment can be given for a psychiatric disorder.
- Where the decision relates to a child or young person under the age of 16, the MCA does not apply. In these cases, the competence of the child or young person must be considered under Gillick competence. If the child or young person is deemed not to have the competence to make the decision then those who hold Parental Responsibility will make the decision, assuming it falls within the Zone of Parental control. Where the decision relates to treatment which is life sustaining, or which will prevent significant long-term damage to a child or young person under 18 their refusal to consent can be overridden even if they have capacity or competence to consent.

## 7. SAYING SORRY

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

7.2 Saying Sorry is:

- **Always** the right thing to do
- Not an admission of liability

- A way to acknowledge something could have gone better
- The first step to learning from what happened and preventing it recurring.

**7.3** How we say sorry is just as important as the use of the word. A genuine and meaningful apology should be given in person with the use of the word 'sorry' (see Helpful Phrases resource).

**7.4** To ensure that our patients, and their families and carers, from all backgrounds and minority ethnic communities and people with disabilities receive the same quality of duty of candour communication, staff must consider the use of advocates, accessible formats, interpreters, and translators where appropriate. Staff should refer to the Translation and Interpretation Clinical Policy (CLP246).

**7.5** NHS Resolution are clear that an apology is not an admission of liability. *"We have never, and will never, refuse cover on a claim because an apology has been given."* Helen Vernon, Chief Executive, NHS Resolution. (*NHS Resolution: Saying sorry (2023)*).

## **8. PROFESSIONAL DUTY OF CANDOUR**

**8.1** The professional duty applies to individual health and care professionals. It is overseen by the regulators of specific healthcare professions: General Medical Council (GMC), Nursing and Midwifery Council (NMC), General Dental Council (GDC), General Pharmaceutical Council (GPhC) and Health and Care Professions Council (HCPC).

**8.2** A joint statement from the Chief Executives of statutory regulators of healthcare professionals was published in 2014 clarifying the requirements:

**8.3** Every healthcare professional must be open and honest with patients when something goes wrong with their treatment or care which causes, or has the potential to cause, harm or distress.

**8.4** Healthcare Professionals must:

- Tell the patient\* when something has gone wrong
- Apologise to the patient\*
- Offer an appropriate remedy or support to put matters right (if possible)
- Explain fully to the patient\* the short and long-term effects of what has happened.

*\*(or, where appropriate, the patient's advocate, carer, or family).*

**8.5** Healthcare Professionals must also:

- Be open and honest with their colleagues, employers, and relevant organisations
- Take part in reviews and investigations when requested
- Be open and honest with their regulators, raising concerns where appropriate
- Support and encourage each other to be open and honest and not stop someone from raising concerns.

**8.6** Staff should also refer to the Incident Reporting and Management, Speaking up at Work, Safeguarding Adults, Safeguarding Children and Handling and Resolving Complaints Policies (see Associated Documents list).

## 9. STATUTORY REGULATION 20 DUTY OF CANDOUR

9.1 Regulation 20 Duty of Candour (DoC) applies to every health and social care provider organisation and is regulated by the CQC under Regulation 20 of the Health and Social Care Act 2008.

9.2 Regulation 20 DoC involves specific verbal and written requirements for certain incidents defined as **'notifiable safety incidents.'** If something qualifies as a notifiable safety incident, carrying out the professional duty alone will not be enough to meet the requirements of the statutory duty. The specific requirements are detailed below.

9.3 If staff are unsure whether an incident meets the Regulation 20 Duty of Candour threshold this should be discussed with their Line Manager in the first instance. If further support is required, this should be escalated to the Patient Safety Team who will seek further support from the DoC Lead as required.

9.4 **'Notifiable Safety Incidents'** This is a specific term defined in the duty of candour regulation. It should not be confused with other types of safety incidents or notifications.

9.5 A notifiable safety incident must meet **all** 3 of the following criteria:

**(1) It must have been unintended or unexpected**

**(2) It must have occurred during the provision of GHC care or treatment**

**(3) In the reasonable opinion of a healthcare professional, already has, or might, result in death, or severe or moderate harm to the person receiving care.**

If any of these criteria are not met, it is not a notifiable safety incident.

9.6 The presence or absence of fault on the part of a provider has no impact on whether or not something is defined as a notifiable safety incident.

9.7 Even if something does not qualify as a notifiable safety incident, there is always the professional duty of candour and an overarching duty to be open and transparent with people using services.

9.8 **The specific requirements of Regulation 20 Duty of Candour must be started as 'soon as reasonably practicable'.**

9.9 **The Duty of Candour is a process rather than a 'one-off event'.**

9.10 **Unintended or Unexpected:**

Unintended or unexpected is in relation to the care and treatment, not to the outcome of the incident. If the treatment or care provided went as intended, and as expected, an incident may not qualify as a Notifiable Safety Incident, even if harm occurred.

Please see the 'DoC Simplified Reasoning Tool – unintended or unexpected' and 'GHC DoC Examples' resources ([Appendices](#)).

9.11 **Levels of Harm:**



The grading of level of harm should be based on an assessment of the information available at the point of recording and can be amended if further information becomes available:

***Moderate Harm:***

Requires a moderate increase in treatment and significant, but not permanent, harm.

***Moderate Increase in Treatment:***

An unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care).

***Prolonged Pain:***

Pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

***Prolonged Psychological Harm:***

Psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

***Severe Harm:***

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.

***Death:***

Directly due to the incident, rather than the natural course of the person's illness or underlying condition.

**9.12 Please note:** the LFPSE definitions of harm are defined separately (see below section and reference: NHS England (2023): Policy guidance on recording patient safety events and levels of harm. Definitions – harm grading).

**9.13 The Verbal Notification must:**

- Tell the relevant person (or acknowledge) that a notifiable safety incident has taken place.
- Include an apology.
- Provide a true account of what happened, explaining whatever you know at that point.
- Explain to the relevant person what further enquiries or investigations you believe to be appropriate.
- Provide reasonable support to the relevant person in relation to the incident, including when giving the notification.
- Be recorded in a written record (patient's clinical records and Datix).

**9.14 The Written Notification must:**

- Provide a true account of what happened, explaining whatever you know at that point.
- Explain to the relevant person what further enquiries or investigations you believe to be

appropriate.

- Include the results of any further enquiries.
- Include an apology.
- Be uploaded to the Datix record.

A secure written record of all meetings and communications with the relevant person must be kept in the patient's clinical records and/or Datix.

### **9.15 As Soon as Reasonably Practicable:**

- Duty of candour should be carried out as soon as possible to ensure good, timely communication and openness. However, it is important to manage each case individually, taking the current clinical, patient and family situation into consideration.
- As a Trust the agreed standard is for the verbal notification requirement to be completed within 10 working days of the incident being identified and/or reported.
- The written notification requirement is to be completed within 30 working days of the verbal notification. However, in some circumstances it may be appropriate to carry out the duty of candour much more promptly.
- A delayed duty of candour conversation may be required to enable a patient to recover physically and/or psychologically following the incident and to allow time for the person to be able to engage meaningfully with the conversation.
- In some cases, the Trust is informed of an incident by another health care provider, organisation or family member and there will therefore be a delay between the incident and the duty of candour conversation and letter.
- An initial delay in starting the duty of candour process is not a valid reason for not fulfilling the requirements.
- Where there is a delay in the duty of candour process the reasons for the delay should be documented in the Datix and/or clinical record.

### **9.16 Relevant Person:**

The duty of candour applies to the 'relevant person'. This is either the person who was harmed or someone acting lawfully on their behalf.

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

- The person has died
- Is under 16 and not competent to make decisions about their care or the consequences of the incident
- Is over 16 and lacking mental capacity.

(In accordance with the Mental Capacity Act 2005).

### **9.17 Further Enquiries or Investigations:**

Further enquiries into a patient safety incident should be undertaken in line with the Incident

Reporting and Management Policy and Procedure (CGP001) and PSIRF processes supported by the Patient Safety Team.

The focus of incident reviews should be on learning and prevention of recurrence, with the engagement and involvement of patients, families, and staff (where possible). Where possible and appropriate, the findings of the review and any learning identified should be shared with the patient and their family/carer.

#### **9.18 Reasonable Support:**

This will vary with each incident and could include (but is not limited to):

- Environmental adjustments
- The support of an interpreter or advocate
- Information in accessible formats
- Signposting to mental health services
- Independent help and advice such as AvMA (Action against Medical Accidents), bereavement care, post suicide support.

If the relevant person consents, family members and carers should be involved, and reasonable steps taken to ensure communication is as accessible and supportive as possible.

#### **9.19 When the Incident has Resulted in a Patient Death:**

The Patient Safety Team (PST) will follow the Patient Safety Incident Response Framework (PSIRF) review process and offer direct support to the team involved. Following a patient safety 'After Action Review' (or 'Huddle') the PST Lead Reviewer will send a condolence letter to the family on behalf of the Director of Nursing, Therapies and Quality if duty of candour applies. Further duty of candour requirements will be fulfilled through ongoing communication with the family by the Family Liaison Practitioner (FLP) (if allocated), and the PST as part of the PSIRF process.

Duty of candour processes can start prior to receiving a cause of death from the coroner.

#### **9.20 When the Level of Harm is Amended:**

If it is identified at a later stage that the level of harm has increased e.g., patient's physical condition has deteriorated and/or psychological harm becomes evident, the appropriate duty of candour should be commenced, or continued, from that point and documented accordingly.

If Regulation 20 Duty of Candour is in progress and the incident level of harm is subsequently downgraded following review, communication with the patient and/or family should be continued as appropriate, but further written requirements may not have to be fulfilled. Each case should be reviewed individually.

#### **9.21 Multiple Providers Contributed to the Harm:**

If multiple providers contributed to the harm, they should work together during the incident review. Each provider must fulfil its own responsibilities under the duty of candour.

## **9.22 Incidents not Identified at the Time of the Event:**

Occasionally incidents are identified some time after the event, most commonly through the complaint, legal or coronial inquest processes. In these cases, a review will be undertaken by the Trust and a response provided to the relevant person which should meet the duty of candour requirements. A point of contact for ongoing communication between the relevant person and the Trust should be established from the Patient Carer Experience, Patient Safety or Legal team.

## **9.23 Best Interest Decisions:**

Very occasionally, a best interest decision may be made to not fulfil Regulation 20 Duty of Candour requirements, in part or full. This will most likely be within the mental health setting where revisiting the incident may cause additional patient distress or psychological harm. All factors should be considered such as identifying a member of staff trusted by the person, timing and setting of the conversation, and whether the conversation may be appropriate, but the letter withheld.

These cases should be discussed with the Patient Safety Team with further support from the DoC Lead as required, and the reasons for any best interest decisions clearly documented in the Datix record.

The incident must still be reported and reviewed for any learning to try and prevent harm occurring to others.

## **9.24 When Duty of Candour is not Required:**

If the relevant person cannot be, or refuses to be contacted, it may not be possible to carry out the duty of candour. However, every reasonable attempt to contact the relevant person through different means of communication should be made and all attempts documented.

If the relevant person has died or does not have capacity to understand the implications of the incident, and there is nobody who can lawfully act on their behalf, this should be documented in the Datix record.

The incident must still be reported and reviewed for any learning to try and prevent harm occurring to others.

## **10. SPECIFIC INCIDENT CATEGORIES**

**10.1** Staff should refer to the Trust intranet resources for specific incident types to support Regulation 20 Duty of Candour reasoning. These currently include:

- Simplified Reasoning Tool: 'unintended and unexpected'
- GHC DoC Examples
- Patient Fall Requiring Transfer to an Acute Hospital - DoC Guidance
- Termination of Pregnancy Procedure - DoC Guidance
- Letter Templates: pressure ulcers, falls, termination of pregnancy.

See [Appendix 1](#)

## **11. PSIRF AND REGULATION 20 DUTY OF CANDOUR:**

### 11.1 Grading / Level of Harm:

- Regulation 20 Duty of Candour is based on harm levels.
- PSIRF is based on system-based approaches for learning, not harm level.

**Therefore, separate checks are required to determine the Duty of Candour response and PSIRF response.**

### 11.2 Compatibilities:

- Regulation 20 Duty of Candour states that the 'relevant person' is 'notified', and verbal and written notification requirements are met.
- PSIRF requires compassionate engagement of 'those affected' including staff, patients, and families in the broadest sense.

### 11.3 CQC Guidance / Quality Statement:

- Regulation 20 Duty of Candour states: 'what further enquiries are believed to be appropriate'
- Safe / Learning culture states: 'We have a proactive and positive culture of safety based on openness and honesty, in which concerns about safety are listened to, safety events are investigated and reported thoroughly, and lessons are learned to continually identify and embed good practices.'

## 12. LFPSE AND REGULATION 20 DUTY OF CANDOUR:

**12.1** The LFPSE definitions of harm are clearly defined. These can be found in the reference: NHS England (2023): Policy guidance on recording patient safety events and levels of harm. Definitions – harm grading.

**12.2** LFPSE requires that a harm level is recorded for both physical and psychological harm by the Incident Reporter. An 'overall severity' level is then graded by the Incident Handler.

**12.3** If any of the harm levels; 'physical', 'psychological' or 'overall severity' are recorded as moderate or severe harm, or fatal then Regulation 20 Duty of Candour must be considered.

## 13. STAFF SUPPORT

**13.1** It is important that staff involved in the incident are supported. Staff are encouraged to seek support through their line manager, clinical lead, the Wellbeing Line or Working Well service.

Managers should identify staff who may need additional support and consider debrief sessions, peer support and referral to Working Well.

The Patient Safety Team should be contacted for any support required in regard to DoC. Further support should be provided by the DoC Lead as required.

## 14. PROCESS FOR MONITORING COMPLIANCE

Are the systems or processes in this document monitored in line with national, regional, trust or local requirements?	YES
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Monitoring Requirements and Methodology	Frequency	Further Actions
From November 2024 the Audit team will complete a bi-annual DoC audit of patient safety incidents where the physical, psychological, or overall severity was graded as moderate or severe harm, or fatal.	Annually	Will be submitted to the QRCG, and updates will go to QAG
The Audit team and Duty of Candour Lead will provide bi-annual updates to the Quality and Regulatory Compliance Group (QRCG). Current incidents, good practice, learning and areas for improvement will be highlighted and the updates submitted to QAG as part of the QRCG work.	Monthly	Will be submitted to the QRCG, and updates will go to QAG
There are four levels of regulatory compliance in relation to duty of candour: <ul style="list-style-type: none"> <li>• <b>Individual</b> – monitored through Datix</li> <li>• <b>Team</b> – monitored by the PST through Datix Incidents</li> <li>• <b>Organisation</b> – Bi-annual audit of DoC by Clinical Audit Manager and DoC Lead</li> <li>• <b>CQC</b> – specific notifiable safety incident reviews and inspection criteria ‘well led’ and ‘open and safe culture’.</li> </ul>	Ongoing	Any concerns regarding duty of candour compliance will be escalated to the Head of Patient Safety and/or Associate Director of Patient Safety, Quality Assurance and Clinical Compliance.

## 15. DUTY OF CANDOUR ENFORCEMENT

### 15.1 Professional Duty of Candour:

The Trust Human Resources Policy Manual (2024) policies provide a framework for maintaining satisfactory standards of conduct and associated processes (see [Associated Documents](#) below).

Each regulatory body has clearly defined professional standards which include duty of candour. If a concern is raised about a registrant’s fitness to practice this will be investigated and managed by the appropriate regulator.

### 15.2 Statutory Regulation 20 Duty of Candour:

The ultimate responsibility for ensuring the duty of candour is carried out rests with the registered person and the Trust. Where the CQC believe this is not happening, they can use their powers of enforcement and can prosecute breaches of the regulation. The CQC will investigate specific notifiable safety incidents where there are concerns.

Duty of candour will be monitored as part of the CQC inspections under:

- Being well-led
- Having an open and safe culture
- Meeting the regulatory requirements of the duty of candour.

## 16. TRAINING

**16.1** Duty of candour training is part of the clinical induction for all colleagues who are new to the Trust and is included in the Preceptorship programme.

**16.2** The Patient Safety Team and / or Duty of Candour Lead is available to provide training sessions for all colleagues and teams. This may be by direct request, following specific or

complex incidents, or through identified themes or trends in reported incidents.

- 16.3** Additional related training may be appropriate and is accessible via Care to Learn such as (but not limited to) 'Challenging Conversations Workshop', 'Record Keeping for Clinical Staff', 'Mental Capacity Act Level 1 eLearning' 'Information Governance', Datix and Patient Safety modules.

## **17. REFERENCES**

*Action against Medical Accidents (AvMA): Robbie's Law:* [AvMA - Robbie's Law](#)

*Care Quality Commission (2022): Regulation 20: Duty of Candour:* [Regulation 20: Duty of candour - Care Quality Commission \(cqc.org.uk\)](#)

*House of Commons Library: The Francis Report (report of the Mid-Staffordshire NHS Foundation trust public enquiry) and the Government's response (2013):* [The Francis Report \(Report of the Mid-Staffordshire NHS Foundation Trust public inquiry\) and the Government's response - House of Commons Library \(parliament.uk\)](#)

*Mental Capacity Act 2005:* [Mental Capacity Act 2005 \(legislation.gov.uk\)](#)

*NHS England: Patient Safety Incident Response Framework (PSIRF) / Engaging and involving patients, families and staff following a patient safety incident:* [NHS England » Patient Safety Incident Response Framework](#)

*NHS England (2023): Policy guidance on recording patient safety events and levels of harm. Definitions – harm grading:* [NHS England » Policy guidance on recording patient safety events and levels of harm](#)

*NHS Resolution (2018): Behavioural insights into patient motivation to make a claim for clinical negligence:* [Behavioural insights into patient motivation to make a claim for clinical negligence - NHS Resolution](#)

*NHS Resolution: Saying sorry (2023):* [Read saying sorry \(duty of candour\) - NHS Resolution](#)

### **Professional Regulatory Body Guidance:**

*General Medical Council (GMC):* [The professional duty of candour - professional standards - GMC \(gmc-uk.org\)](#)

*Nursing and Midwifery Council (NMC):* [The professional duty of candour - The Nursing and Midwifery Council \(nmc.org.uk\)](#)

*General Dental Council (GDC):* [The professional duty of candour \(gdc-uk.org\)](#)

*General Pharmaceutical Council (GPhC):* [The professional duty of candour - joint health regulators statement | General Pharmaceutical Council \(pharmacyregulation.org\)](#)

*Health and Care Professions Council (HCPC):* [The duty of candour | \(hcpc-uk.org\)](#)

## 18. ASSOCIATED DOCUMENTS

- Incident Reporting and Management Policy and Procedure (CGP001)
- Learning from Deaths Policy (CGP005)
- Coroners Enquiries and Inquests Policy (Clinical Governance Policy CGP007)
- Handling and Resolving Complaints and Concerns Policy and Procedure (CGP010)
- Health Records and Clinical Record Keeping Policy (CLP005)
- Consent to Examination or Treatment Policy (CLP213)
- Safeguarding Adults Policy (CLP101)
- Safeguarding Children Policy (CLP071)
- Overarching Supervision Policy: Clinical and Non-Clinical Supervision (CLP116)
- Human Resources Policy Manual 2024: Disciplinary Policy, Improving Performance, Professional Registration, reporting unfitness to practice
- Translation and Interpretation Clinical Policy (CLP246)
- Speaking Up at Work Policy
- Risk Management Policy (COR08).

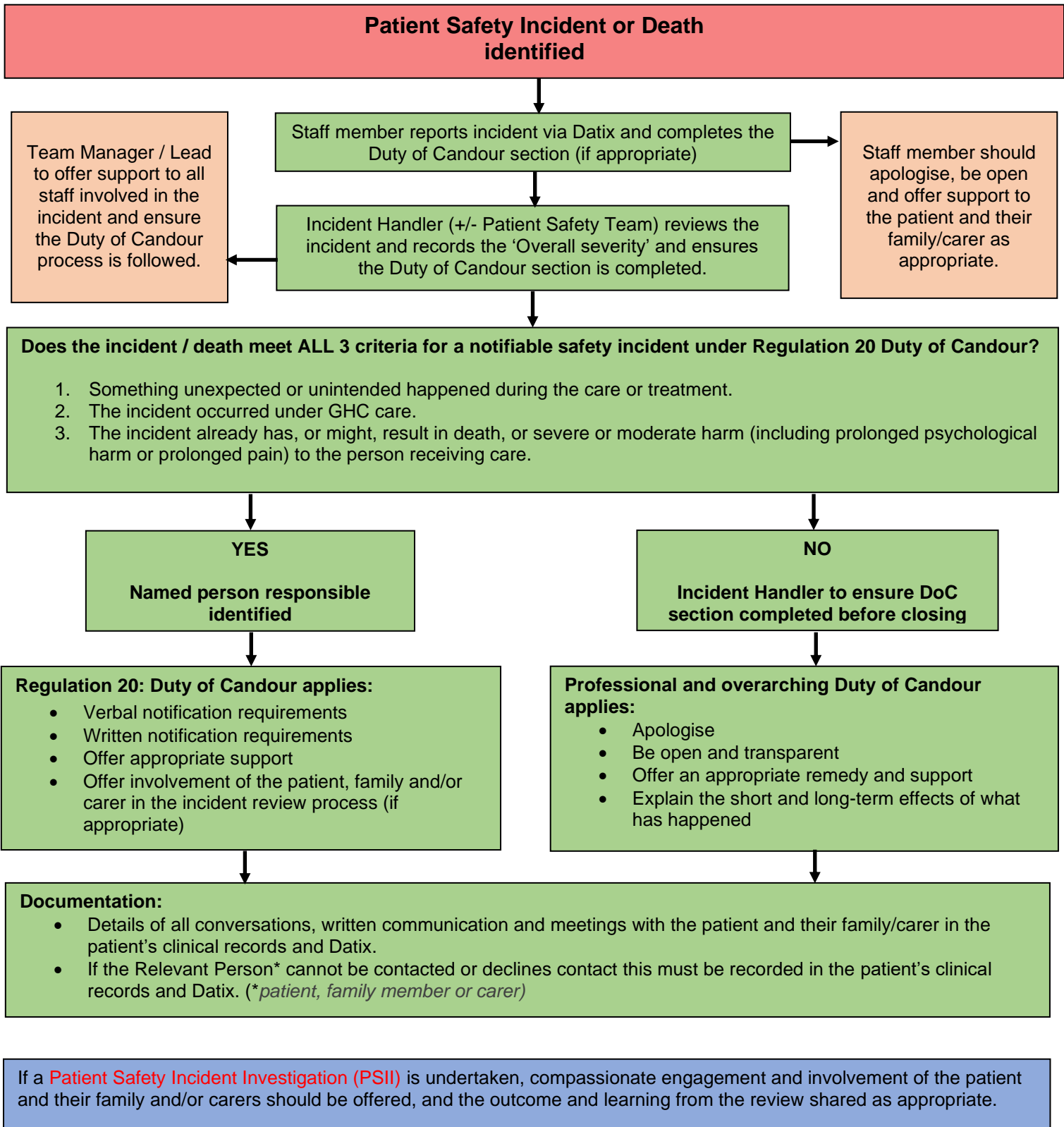


## Appendix 1 – Resources available on the Trust Duty of Candour Intranet Page

### [Duty of Candour - Interact \(ghc.nhs.uk\)](https://ghc.nhs.uk)

- Duty of Candour on a page
- Helpful Phrases
- Simplified reasoning tool: 'unintended and unexpected'
- GHC DoC Examples
- Patient Fall Requiring Transfer to an Acute Hospital - DoC Guidance
- Termination of Pregnancy Procedure - DoC Guidance
- Letter Templates: pressure ulcers, falls, termination of pregnancy
- Good examples of Duty of Candour letters
- LFPSE Harm Grading poster

## Appendix 2 - Duty of Candour Process Chart



**Staff should contact the Patient Safety Team for advice and guidance as required.**