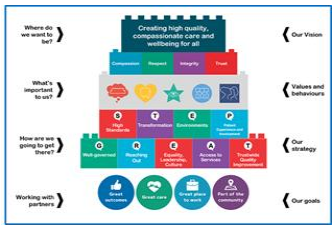

Leicestershire Partnership NHS Trust

A Culture of Candour Policy (Incorporating 'Being Open' and 'Duty of Candour')

This policy sets out the Trust application of statutory duty of candour and our culture of 'being open' and communicating with our patients and/or their family following a Patient Safety Incident or Near Miss and care has not gone as planned, or, where we consider there is learning.

Key words: Communication, Candour, openness, incidents, acknowledging, apologising, sorry, explaining, Transparency.

Version: 11 (complete review in line with Patient Safety Incident Response Framework)

Approved by: Safety Forum

Ratified By: Incident Oversight Group

Date this version was ratified: May 2025

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Review date: 1st January 2028

Expiry date: 30th June 2028

Type of Policy: clinical and non-clinical

Contents

Policy On A Page

SUMMARY & AIM

This policy describes the Trusts commitment to openness (being open), and transparency always when a patient safety incident has occurred, and something appears to have gone wrong as part of healthcare and describes the requirements under the Health & Social Care Act (2008) Regulation 20: Duty of Candour Duty for incidents that meet the notifiable threshold. A Culture of Candour can make an important contribution in creating a culture of openness, transparency and honesty which always places the safety and needs of the patient and family above the reputation of the organisation.

It is has recognised there is a need of a culture of openness and honesty, and the enactment a duty of candour, which is wholeheartedly adopted by organisations and individuals. This will enable our patients to be reassured that when things go wrong, we will learn, and we will improve. (Dalton Review 2014).

TARGET AUDIENCE: Who is involved with this policy?

All staff who are involved in all types of NHS care delivered to our patients here at LPT, with additional responsibilities for staff who have leadership/managerial responsibility who have a responsibility to apologise, say sorry and be open, transparent when care has not gone as planned or where an incident has occurred and there is opportunity for learning. All staff who have a responsibility to enact the statutory function of duty of candour for notifiable incidents.

TRAINING - What training is there for this policy?

There is a e-learning session available on Ulearn related to the fundamentals of 'Duty of Candour'

KEY REQUIREMENTS -What do I need to follow?

To understand the basic principles of the application of statutory duty of candour and our culture of 'being open' and communicating with our patients and/or their family following a Patient Safety Incident or Near Miss and care has not gone as planned, or, where we consider there is learning.

Duty of Candour is a process rather than a one-off event.

'Being open and honest' relies on staff and the rigorous reporting of patient safety incidents. The Trust supports a positive reporting culture and 'being open and honest' with patients in the most compassionate way when an incident occurs.

'Being open' is aligned with compassionate engagement principle of PSIRF and refers to the processes for communicating adverse events with patients, families, and carers. It is the opportunity to say sorry at the onset.

'Duty of candour' refers to the 'volunteering of all relevant information to persons who have or may have been harmed by the provision of services, whether the information has been requested and whether a complaint or a report about that provision has been made'.

The principles of 'being open' and the 'duty of candour' provide a structure and process for communicating with people in the right way when a patient safety incident (PSI) has occurred. The CQC also set out expected standards required by healthcare providers in Regulation 20 'Duty of Candour' (Health and Social Care Act 2008 (Regulated Activities) Regulations, 2014).

Duty of Candour - Frequently asked questions (as described by CQC in March 2025) can be found in Supporting Guidance C.

1.0 Quick look summary

Please note that this is designed to act as a quick reference guide only and is not intended to replace the need to read the full policy.

It was recognised that there needed to be a 'culture of openness and honesty, stimulated by a duty of candour, which is wholeheartedly adopted by organisations and individuals. This will enable our patients to be reassured that when things go wrong, we will learn, and we will improve'. (Dalton Review 2014)

This policy describes the Trusts commitment to openness (being open), and transparency always when a patient safety incident has occurred, and something appears to have gone wrong as part of healthcare and describes the requirements under the Health & Social Care Act (2008) Regulation 20: Duty of Candour Duty. A Culture of Candour can make an important contribution to creating a culture of openness, transparency and honesty which always places the safety and the needs of the patient and family above the reputation of the organisation.

NHS England (NHE) describe a '**Patient Safety Incident** – Something unexpected or unintended has happened, or failed to happen, that could have or did lead to patient harm for one or more person(s) receiving healthcare.

What does this mean? – This event type encompasses all patient safety incidents, including "near misses". Select this option if you know that something did not go as intended or expected – whether an act or an omission – and as a direct result the incident could have or did harm one or more patients'.
https://www.england.nhs.uk/long-read/policy-guidance-on-recording-patient-safety-events-and-levels-of-harm/

The commitment to candour must be about values and it must be rooted in genuine engagement of staff building on their own professional duties and their personnel commitments to their patients.

Summary of the 'Stages of the Duty of Candour Process' that underpins the culture of applying all stages of the culture of candour, including the statutory stages of duty candour here at LPT can be found on page 17.

There are 2 aspects to the statutory duty of candour:

1. Initial duty of candour

Undertaken as soon as reasonably practicable after a PSI is recognised to meet the 'notifiable' threshold as described by the CQC (**statutory – see supporting guidance B**) or where the trust considers the incident to be serious enough that it requires as higher level of investigation in relation to PSIRF local priorities (not notifiable). This should consist of a verbal/ and/or face to face apology with the conversation and next steps described in a formal letter, using the template set out in **Supporting Guidance E** accompanied by the AVMA 'The Duty of Candour' leaflet.

2. Final duty of candour

Undertaken once an investigation/review has completed, the findings shared and agreed with the patient/family and is followed by a formal letter outlining the findings and proposed actions and a further apology.

1.1 Version control and summary of changes

Version number	Date	Comments (description change and amendments)
Version 5	October – November 2019	Policy completely reviewed & updated to reflect current National NHS & LPT processes; future strategy and direction of services and serious incident/patient safety management. Provide appendices that include staff guides.
Version 6	November/ December 2020	Post 'Duty of Candour' 360 Assurance Review - Updated to reflect feedback. Title altered to reflect the national direction of patient safety incident investigations 'Culture of Candour'. Flow chart realigned. Feedback from staff (DMH) to include an example of final sharing letter
Version 10	Oct 2021	Post CQC inspection to review and make actions clearer and responsibility for Directorates. CPST.
Version 10a	Jan 2022	Reviewed by Kerry O'Reardon – Risk and Assurance Lead (any amendments undescribed)
Version 11	Nov 2024 – April 2025	Complete review as part of transfer to Patient Safety Incident Response Framework (PSIRF) and general review of information published from government in relation to statutory review & info published from NHS Resolution, NHSE, CQC via Patient Safety Hub. S Arnold – Lead Nurse CPST

For Further Information Contact:

Head of Patient Safety / CPST

Room 170, Pen Lloyd Building, County Hall, Leicester, LE3 8TH

1.2 Key individuals involved in developing and consulting on the document.

Name	Designation/Role
Susan Arnold (Reviewer)	CPST Lead Nurse
Jo Nicholls	Patient Safety Manager (role at time of Initial version of policy)
Tracy Ward	Head of Patient Safety (all versions since 2019)
360 Assurance 2021 (pre & post Audit)	
Current policy (2024)	Group/Designation
Group Membership (2024/2025)	Incident Oversight Group
Group Membership (2024/25)	Safety/Quality Forum
Policy Expert Group	

1.3 Governance

Level 2 or 3 approving delivery group – Incident Oversight Group

Level 1 Committee to ratify policy – Safety Forum

1.4 Equality Statement

Leicestershire Partnership NHS Trust (LPT) aims to design and implement policy documents that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. It takes into account the provisions of the Equality Act 2010 and promotes equal opportunities for all. This document has been assessed to ensure that no one receives less favourable treatment on the protected characteristics of their age, disability, sex (gender), gender reassignment, sexual orientation, marriage and civil partnership, race, religion or belief, pregnancy, and maternity.

If you would like a copy of this document in any other format, please contact lpt.corporateaffairs@nhs.net

1.5 Due Regard

LPT will ensure that due regard for equality is taken and as such will undertake an analysis of equality (assessment of impact) on existing and new policies in line with the Equality Act 2010. This process will help to ensure that:

- Strategies, policies and procedures and services are free from discrimination.
- LPT complies with current equality legislation.
- Due regard is given to equality in decision making and subsequent processes.
- Opportunities for promoting equality are identified.

Please refer to due regard assessment (**Supporting Guidance 4**) of this policy

1.6 Definitions that apply to this policy.

Due Regard: Having due regard for advancing equality involves:

- Removing or minimising disadvantages suffered by people due to their protected characteristics.
- Taking steps to meet the needs of people from protected groups where these are different from the needs of other people. Encouraging people from protected groups to participate in public life or in other activities where their participation is disproportionately low.

CPST	Corporate Patient Safety Team
Duty of Candour (DoC)	DUTY OF CANDOUR is a statutory (legal) duty to be open and honest with patients (or 'service users'), or their families, when something goes wrong that appears to have caused or could lead to significant harm in the future. It applies to all health and social care organisations registered with the regulator, Care Quality Commission (CQC) in England. It is currently described in CQC Regulation 20.
Being Open	Discussing and communicating openly, promptly, fully, effectively, and compassionate with those involved in incidents, complaints, or claims. It is about being open and transparent with service users about their care and treatment, including when it goes wrong.
Transparency	Allowing information about the truth about performance and outcomes to be shared with staff, patients, the public and regulators
Apology	An 'apology' is an expression of sorrow or regret in respect of a notifiable safety incident. It is not an admission of guilt. Saying 'Sorry' is always best practice
Severe Harm	Permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage related directly to the incident (and not a natural cause of the patient/service user's illness or underlying condition)
Moderate Harm	A moderate increase in treatment (i.e., "*a 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)"); and* *(b) significant, but not permanent, harm, or* *(c) prolonged psychological harm/prolonged pain persisting for over 28 days*
Relevant Person	This may be the patient, or the person acting lawfully on their behalf in the following circumstances: on the death of the patient, or where the patient is under 16 and not competent to make a decision in relation to their care or treatment, or where the patient is 16 or over and lacks the mental capacity in relation to the matter in accordance with the Mental Capacity Act 2005.

Stakeholders	Staff, Patients/ /Families/carers.
Patients, Service Users	Term used interchangeable in the policy related a person who is in receipt of care from the Trust
Patient Safety Incident Response Framework (PSIRF)	Adopted by NHSE August 2022. The Patient Safety Incident Response Framework (PSIRF) sets out the NHS's approach to developing and maintaining effective systems and processes for responding to patient safety incidents for the purpose of learning and improving patient safety.
Ulysses	The incident reporting database system used here at LPT to record and update incidents and store associated information.

2.0 Purpose and Introduction/Why we need this policy and Background

'Openness and transparency are not just regulatory requirements—they are the foundations of a culture that puts patients first'.

(Patient Safety Management Network (PSMN) March 2025) Patient Safety Management Network: Strengthening understanding of Duty of Candour through collaboration - Methodology and guidance: How to do an investigation - Patient Safety Learning - the hub

As part of LPT's requirements under the statutory duty of candour policy, where a patient suffers moderate harm or greater, or the incident is 'notifiable' as described by the Care Quality Commission (CQC) **also see supporting guidance B**, we have an obligation to provide a verbal apology and to follow this up with a written apology – providing details of any potential learning review/investigation that may be ongoing.

The Culture of Candour policy has been refreshed to reflect the Patient Safety Incident Response Framework (PSIRF), national review and the national safety steer focusing on how compassionate engagement and Duty of Candour work hand in hand to support patients and their families following a Patient Safety Incident (PSI).PSIRF provides a greater emphasis on good quality and meaningful engagement with patients and staff.

At LPT our staff work hard to deliver safe and high-quality care, however, sometimes, things do go wrong, and incidents will occur. When this happens it's important that the trust responds quickly and positively to ensure the wellbeing of patients, staff, and the public.

The principles of 'being open' and the 'duty of candour' provide a structure and process for communicating with people in the right way when a PSI has occurred. The CQC also set out expected standards required by healthcare providers in

Regulation 20 ‘Duty of Candour’ (Health and Social Care Act 2008 (Regulated Activities) Regulations, 2014) and describe their definition of a ‘notifiable patient safety incident’. (See **Supporting Guidance B**)

Following the occurrence of a ‘notifiable patient safety incident’ of moderate harm, severe harm, or death, we are required to fulfil responsibilities under CQC Regulation 20 of the Health and Social Care Act 2008. Duty of Candour is a direct response to Recommendation 181 that arose from the Mid Staffordshire NHS Foundation Trust Public Inquiry (2013). This high-profile failure in NHS healthcare led to important questions about ways in which harm during healthcare can be prevented and about how, when this does not happen (for whatever reason), it can be acknowledged and act as a source of learning and improvement.

Incidents considered as ‘No Harm’ or ‘Low’ in general, do not have to be managed under ‘statutory Duty of Candour’ using this policy. However, there should be a culture of sharing with patients/families when incidents have happened using ‘being open’ principles following these incidents and is the ‘right thing to do’. An example would be where the incident could have resulted in severe harm or death but through luck did not (near miss). As such, the duty of candour is a crucial, underpinning aspect of an open and transparent culture which supports staff to be candid. The duty permits a level of scrutiny to be applied, which gives an opportunity to consider each situation objectively, look at what could have been done better and implement any necessary changes to advance patient safety.

Current Thinking and Application of Candour Principles

A fundamental element of high-quality care is honesty. Patients and their family/loved ones, place a large amount of trust in health care providers. They must feel confident that should anything untoward occur, they will be entitled to an open and honest response. This means that staff have a responsibility to contact the patient and where appropriate, their family and carers, to make them aware of the incident, offer an apology, support, and information for next steps. This overarching policy will guide staff to appropriately fulfil this duty.

In December 2023, the government announced a review of the legislation around ‘Duty of Candour’ in response to the ‘Hillsborough Disaster Report’. This is ongoing at the time of this policy review, however, the initial themes from the public consultation were published in November 2024 and are described as:

- Culture (of the health and care system)
- Inconsistency (in understanding and applying the duty)
- Training (the lack of it, the need for further training)

Further information can be found at Findings of the call for evidence on the statutory duty of candour - GOV.UK

This policy supports the trust to co-create a great experience for all patients, carers, and families from its diverse population by supporting patients and their families/carers to cope better with the after-effects of a patient safety incident by:

- **Being open, respectful, and compassionate in a timely way following an incident.** This is known to help those affected feel supported and reduce additional harm such as lack of trust or feelings that duty of care has been removed (PSIRF 2022)
- **Engaging with those affected by a patient safety incident.** This improves our understanding of what happened, and potentially how to prevent a similar incident in future. Everyone will experience the same incident in different way, no one truth should be prioritised over others.
- **Listening.** The opportunity to be listened to is also part of restoring trust and repairing relationships between organisations and staff, patients, and families.
- **Saying sorry when things have gone wrong.** Getting an apology right, sets the tone for everything that follows.

This policy supports the trust to co-create a great experience for our staff by:

- **Providing guidance and support for staff** on what to do when things go wrong during care and treatment or, are considered to have gone wrong the Trust is providing.
- **Promoting an open and honest culture** so staff feel safe to talk about and learn from patient safety incidents.
- **Supporting staff to cope better with the after-effects of a patient safety incident** by being open and compassionate in a timely way following an incident.

This policy supports the trust to be a great partner by:

- Setting out how our staff will adhere to professional codes and statutory duties of candour expected by our professional bodies/regulators.
- Setting out expectations that we will work with partners such as Police, Local Authority, bereavement services, other agencies as well as via independent advocacy services to support and signpost patients and families following an incident.
- To promote a 'culture of candour' across our services.

Being Open – 'candour'

This is aligned with compassionate engagement principle of PSIRF and refers to the processes for communicating PSI with patients, families, and carers in the first instance.

It also applies for those incidents that do not meet CQC 'notifiable incident' threshold. It is the opportunity to say sorry at the onset and to recognition those affected by a PSI.

All Staff have a professional responsibility to be open and honest with patients when things in care appear to have not gone as planned. Evidence suggests that openness and early apology is welcomed by patients/families who are more likely

to forgive errors when they are discussed fully in a timely and thoughtful manner and that being open, and candid can decrease the trauma felt following an incident.

To assist you, there is a guide: 'The 10 key principles of 'Being Open'' are set out in **Supporting Guidance A.**

Duty of Candour (DoC)

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

The CQC regulation Duty of candour is a general duty to be open and transparent with people receiving care. It applies to every health and social care provider that CQC regulates and is described in Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.
It also refers to the 'volunteering of all relevant information to persons who have or may have been harmed by the provision of services, whether the information has been requested and whether a complaint or a report about that provision has been made.'

Regulation 20 defines 'notifiable safety incidents' and specifies how registered persons must apply DoC if these incidents occur (see **Supporting Guidance B**).
The DoC regulations require the conversation to be 'as soon as reasonably practicable'.

'As soon as reasonably practicable'

The initial duty of candour should be carried out as soon as possible to ensure good communication and openness; however, it is important to treat each case individually, taking the current clinical situation into consideration.
For example – a duty of candour conversation may require a delay to enable a patient to recover from a serious procedure/illness to be able to fully comprehend and recall the apology or when family members are ready to have the conversation following the death of a loved one.

Equally, if an incident is only identified after the fact (e.g., following a notification from another health provider) then there will be a delay between the PSI and the apology. If there is a delay between the two events, it is important to document the reasons for this within the Ulysses incident record.

Basic 'culture of candour response' required by staff lead undertaking initial duty of candour:

- As part of engagement describe the investigation/review process, considering patient/family concerns and provide a **formal written** apology using ensuring the word 'sorry' is used and that it is expressed in a meaningful way. (for an example of letter template see **Supporting Guidance E**).
- Ensure good records are kept of this action and uploaded to Ulysses.

Basic 'culture of candour response' required by staff lead undertaking final duty if candour:

(Usually clinical director of operations/head of nursing) following the completion of the investigation/review and that the patient/family are happy with the contents of the report:

- Share the findings of the investigation and a **further written** apology specific to the findings and proposed actions following the investigation/review.
- Ensure good records are kept of this action and uploaded to Ulysses.

'Saying Sorry'

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

An 'apology' is an expression of sorrow or regret in respect of a notifiable safety incident. It is not an admission of guilt. NHS Resolution is the organisation that manages clinical negligence claims against the NHS. Their 'Saying Sorry' leaflet confirms that apologising will not affect indemnity cover.
'Saying Sorry' is:

- Always the right thing to do.
- Not an admission of liability.
- Acknowledges that something could have gone better.
- The first step to learning from what happened and preventing it recurring.

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

3.0 Policy Requirements

Key Message

Duty of Candour is a process rather than a one-off event.

Definition

Candour is about being open, honest, and transparent with patients and/ or their family in a compassionate and respectful way if something goes wrong with their treatment or care that causes or has the potential to cause harm and/or distress.

A statutory duty of candour was brought into law in 2014 for NHS Trusts and 2015 for all other providers and is now seen as a crucial, underpinning aspect of a safe, open, and transparent culture. It is so fundamentally linked to concepts of openness and

transparency that often the policies and procedures related to it have come to be known by staff by other names, for example, “Being Open”, “Saying Sorry”, and “Just Culture” and most recently the introduction of PSIRF the principle focus of compassionate engagement with patients/families has further placed the importance of openness and transparency.

Overseen by the Care Quality Commission (CQC), it compliments and strengthens the existing professional and contractual duty of candour requirements set out below, but in addition is enforceable by law.

3.1 Statutory responsibility

Since 2015, where it was introduced in response to the Francis Inquiry at the Mid-Staffordshire NHS Foundation Trust, the Care Quality Commission (CQC) has made Duty of Candour a statutory responsibility. The formal part of the Duty of Candour is: Fundamental Standard Regulation 20: Duty of Candour (Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulation 2015).

The Duty of Candour Regulation 20: Duty of candour - Care Quality Commission process applies to any unintended OR unexpected notifiable safety incident that could have or did lead to harm for anyone to who we provide care and treatment to.

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 a regulated activity (something that relates to the care and treatment that the Trust provides)

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 three criteria are not met, it is not a notifiable safety incident (but remember that the overarching duty of candour, to be open and transparent, always applies).

https://www.cqc.org.uk/guidance-providers/all-services/regulation-20-duty-candour

- also see **supporting guidance B**.

Harm Levels as described by NHSE.

These have been upgraded as part of the PSIRF and the use of LFPSE to provide context and guidance on selection of appropriate categories when recording patient safety incidents. It focuses on which ‘Event Type’ is appropriate for different circumstances, and how to select the most appropriate options for the ‘Levels of Harm’ categorisation required within Patient Safety Incidents. These are described by NHSE (2023 – updated 2024) as follows:

https://www.england.nhs.uk/long-read/policy-guidance-on-recording-patient-safety-events-and-levels-of-harm/

Previous harm grades	New physical harm grades	New psychological harm grades
No Harm	No physical harm	No psychological harm
Low harm	Low physical harm	Low psychological harm
Moderate harm	Moderate physical harm	Moderate psychological harm
Severe harm	Severe physical harm	Severe psychological harm
Death	Fatal	n/a

3.2 Contractual responsibility

Duty of Candour is a contractual obligation that requires NHS provider organisations to implement and measure the principles of being open. The Duty of Candour, whether contractual, statutory, or professional, rests on the same fundamental principle: being open, honest, and transparent with patients in your care. Leicestershire Partnership NHS Trust (LPT) fully supports this as a prerequisite to improving patient safety and the quality-of-service, user, and carer experience.

3.3 Professional responsibility

All Healthcare Professionals have a professional responsibility to uphold the Duty of Candour and be honest with patients and involve them and their family when things go wrong. This is described by the Nursing and Midwifery Council (NMC) and General Medical Council (GMC) as the Professional Duty of Candour, and forms part of a joint statement from eight regulators of healthcare professionals in the UK.

https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/openness-and-honesty-when-things-go-wrong-the-professional-duty-of-candour-1224.pdf (2015 - last updated on 13 December 2024).

3.4. Information to be shared with patient/families. Key message

Communication should be timely, informing the patient and, or their carer what has happened as soon as is practicable and upon completion of investigation/review.

1. Initial Discussion then followed up in writing for initial duty of candour.
An account of all relevant facts known about the PSI at the time should be given, in person or by telephone, by one or more appropriate representatives of the trust. This should:

- Include as much or as little relevant information as the patient/family want to hear.
- Be jargon-free and explain any complicated terms in line with the accessible information standards.
- Include an explanation of any further planned enquiries and investigations/reviews.
- Be given in a way that patient or family can understand, for example, staff should consider if appropriate interpreters, advocates, communication aids and so on, should be present, however, should be conscious of any potential breaches of confidentiality in doing so and ensure that patient/family is accepting of this.
- Be followed up in writing.

2. Final Discussion then followed up in writing for final duty of candour.

This will take place once report has been shared or offered for their review and the patient/family agree contents.
A verbal final summary account of all relevant facts and findings of any investigation/review should be given, in person or by telephone, by one or more appropriate representatives of the trust. This should:

- Include as much or as little relevant information as the patient/family want to hear.
- Be jargon-free and explain any complicated terms in line with the accessible information standards.
- Include an explanation of any safety improvements/actions planned.
- Be given in a way that patient or family can understand, for example, staff should consider if appropriate interpreters, advocates, communication aids and so on, should be present, however, should be conscious of any potential breaches of confidentiality in doing so and ensure that patient/family is accepting of this.
- Be followed up in writing.

3. Being Open for incidents that are not considered to be 'notifiable' by definition.

We are not obligated to put in writing to our patients/families incidents that are not described as 'notifiable incidents' under Regulation 20 and we are 'being open' and transparent. It is, however, as part of compassionate engagement it is good practice to do so, and we should promote this and recognise those involved in an incident and the impact on them.

Summary of Stages of the Duty of Candour Process

Summary of stages of Duty of Candour Process		
Applies to all notifiable incidents where moderate, severe or death is considered at the time be the level of harm to the patient		
Requirement under Duty of Candour	**Timeframe**	**Responsible Person(s)**
Step 1 - Initial verbal notification of incident to patient/family must:	As soon as reasonably	Senior clinician responsible & is relevant for the team or episode of care when incident

• Talk (face-to-face, where possible) unless the patient/family declines notification or cannot be contacted in person. • Apologise - Say sorry. • Step-by-step explanation of the known facts at the time • Include offer of support • Keep written documentation of any meetings. If meetings are offered but declined this must be recorded. • Record what you shared in patient record. • Complete relevant documentation & upload to Ulysses by clinical governance team (CGT)/CPST. • Team debrief/ensure staff are aware of conversation & content.	practicable after the incident has been identified & reported. Try, where possible, within 10 working days of the incident. -***NB*** - this is not monitored, however, should be considered from a transparency & compassionate view.	occurred (Team leader esp. in case of pressure ulcer incidents / non-clinical staff). The Head of Nursing/ Service should be made aware & if appropriate, involved. ***NB –*** Initial apology may well also have been done by staff who identified & managed the incident this does not negate this step.
Step 2 - Written notification to the Patient/family must: • Always start with an apology & outline the facts discussed verbally. • Include contact details of a member of staff for further information/ investigator if known. • Include importance of their involvement if they wish to be. • Share that the outcome of investigation/review & draft report will be shared for their review (unless they have indicated otherwise – must be documented in patient's record). • Record made in patient's record. • Relevant documentation completed & uploaded onto incident on Ulysses by CGT/CPST.	As soon as reasonably practicable. Try, where possible, within 10 working days of incident recognition. -***NB*** - this is not monitored, however, should be considered from a transparency & compassionate view. All letters must be personalised to individual needs of person receiving letter & use simple language.	Senior clinician responsible & is relevant for the team or episode of care when incident occurred (Team leader esp. in case of pressure ulcer incidents / non-clinical staff). Head of Nursing / Service (or nominated deputy) should be made aware & if appropriate, involved & may wish to review letter. Copy of signed letter to be uploaded onto incident on Ulysses by CGT/CPST & relevant documentation completed as required.

Step 3 - After the investigation/ review completed & patient/family happy with report contents. • Share investigation/review findings (including action plans) in a letter &/or report, as requested, with an accompanying letter, using simple language, avoiding jargon & a further apology.	Try, where possible, to achieve this within 10 working days of closure of investigation/review or report being signed off by Exec. ***-NB -*** this is not monitored, however, should be considered from a transparency & compassionate view. All letters must be personalised to individual needs of person receiving letter.	Senior clinician for episode of care when incident occurred (Team leader esp. in case of Pressure ulcer incidents / non-clinical staff) to draft letter & send to Clinical Director (CD). CD to review/sign final letter & ensure it is sent to patient /family. A copy sent back to CGT & CGT/CPST to upload copy of signed letter to incident on Ulysses & relevant documentation completed.

4.0 Duties within the Organisation

Key Message

'Being open and honest' relies on staff and the rigorous reporting of patient safety incidents. The Trust supports a positive reporting culture and 'being open and honest' with patients in the most compassionate way when an incident occurs.

4.1 Chief Executive

The Chief Executive is responsible for ensuring that there are effective arrangements for Being Open and Duty of Candour within LPT.

4.2 Executive Director of Nursing/Allied Health Professionals & Quality

To promote the Being Open/Duty of Candour culture and ensure overall implementation of this document supported, where appropriate, by the Medical Director. To ensure that the CPSThas effective systems in place for monitoring assurance purposes.

4.3 Medical Director

Has Caldicott Guardian responsibilities and will support Consultant colleagues with the principles and execution of 'Being Open' and compliance with the 'Duty of Candour'.

4.4 Clinical Directors & Heads of Nursing – individual directorates

Clinical Directors / Heads of Nursing are responsible for ensuring that the policy principles are applied consistently across their Directorate. To ensure that patients and /or, their families have been informed when it is considered that there may have been harm caused and any communication is compassionate. There is also a responsibility to support open communication between staff, patients, families, and carers. Both are responsible for leading Duty of Candour in their directorates.

4.5 Local Clinical Quality Governance Leads and their team (CGT)

The Clinical Quality Governance Leads and their team, along with heads of service/service managers support the CPST/Patient Experience Team in recognition of an incident meeting the threshold for both being open and duty of candour, ensure that appropriate discussions with patient/family/carers have taken or will take place and are recorded appropriately on Ulysses utilising documents available.
Through the clinical areas they will promote and support the 'Culture of Candour' and compassionate engagement to all staff groups and ensure that they access relevant training.

Additional responsibilities:

- Monitoring completion of the 'Duty of Candour' and 'Being Open' process using the relevant section of the Trust incident reporting system Ulysses and documentation available to them.
- Oversee the timely review of incidents in their Directorate to ensure that all incidents that meet the requirement for duty of candour are identified in a timely way.
- Escalation to their Clinical Director and/or Head of Nursing of any instance where the Duty of Candour process has not been adhered to.
- Ensure there is recorded governance oversight of this compliance.

4.6 Heads of Service/Service Managers/Deputy Heads of Nursing/Matrons

They must be cited of all incidents that result in moderate, severe harm or death, and that patients/families/carers have been informed; 'being open'. They may also be the persons who enact the initial duty of candour.

4.7 Head of Patient Experience/CPST

The Head of Patient Experience and CPST will undertake assurance in respect of becoming aware of a complaint that meets the criteria for potential incident review.

A designated member of the CPST, with the support of the Trust's Legal Facilitator, will be the lead point of communication with HM Coroner and other interested external stakeholders (e.g., commissioners, Police) where required.

4.8 Lead Clinician Responsible for Care of Patient

The lead clinician responsible for the care of the patient involved in any event may be involved in 'Being Open/Duty of Candour' practice or will participate fully with the lead responsible for communicating with the person involved in the event.

4.9 All Staff

All staff, including temporary staff, have a responsibility to participate with the requirements of this policy and the need to report, inform and discuss patient safety incidents with the patients, families/carers, in line with this policy. In addition, all staff are required to inform their manager immediately if they consider a PSI and duty of candour may have occurred.

4.10 Registered healthcare professionals have a 'professional Duty of Candour'

Described above in section 3.3.

4.11 The Person Responsible for the initial conversation of 'Being Open.'

For the initial notification that a PSI has occurred; this will be undertaken by the most appropriate person; usually a manager; it could also be a member of staff who already has an established relationship with the affected patient, their family and/or carers. This will be agreed locally, likely to be a member of staff that works in a role that directly involves them or their team with the patient. It is the responsibility of this person to complete the information on both the available documentation and where possible Ulysses.

4.12 Ward/Team Managers/Matron

Following a PSI, the Ward/Team Manager/Matron has the responsibility to check that the incident has been initially reviewed, and for appropriate cases that the patient/family and relevant others have been informed. A record of this conversation must be recorded within the Ulysses incident record by the reviewing manager. If it has been identified that the patient/family have not been informed, the Ward/Team Manager/Matron will take appropriate steps to ensure the appropriate communication takes place as soon as possible.

4.13 Patient Safety Incident Investigators, Local Learning Response Leads and Patient and Family Liaison Officer (PFLO)

It is not the role of the Patient Safety Incident Investigators/PFLO to undertake Duty of Candour or being open. Their role is support and engage patients and/or families/carers with the investigation/review and supportive communication process. However, the following does apply:

- They should seek assurance that 'Being Open/Duty of Candour' communication has taken place with the patient/family as an early priority.
- Always contact patient/family where possible if a person has the capacity to make 'particular decisions when it needs to be made' unless you have evidence they do not (according to the statutory principles of the Mental Capacity Act 2005). Or in cases where it is known they do not, invite the relevant person to contribute to the investigation/review and reflect their contribution in the final report. Patients/family members, who are proven to lack capacity, should always, where possible, be present during discussion/any decision making.

- Refer to the Being Open/Duty of Candour discussions recorded in the health records/incident record and included in the initial service managers review (ISMR).
- Notify their local CGT and CPST where there are concerns identified related to the 'Being Open/Duty of Candour' process.
- Ensure that an accurate record kept of all contact/discussion utilising documentation available and where possible included on Ulysses.

Documenting all communication – all staff engaged or supporting the communication with patients/families.

A clear and contemporaneous record must be maintained of all communication. It is important throughout the being open process that records of discussions with the patient and, or their family as well as the PSI are maintained.

The initial apology and explanation given should be documented, where possible, in the Ulysses incident form, and in-depth detail recorded in the appropriate available documentation and in the patient's record.

The Ulysses incident will be the main record repository for duty of candour processes, with copies of letters and written documents including any notes made being scanned and uploaded into the system.

Once the patient/family has been informed in person about the notifiable incident or PSI, the trust must provide a written record of the discussion, and copies of all correspondence must be kept by the trust, along with any enquiries or investigations/reviews undertaken, and the outcomes. A record of such communications should also be included in the patient record, Ulysses, and complaints file/Ulysses module as applicable.

All 'being open' communication such as an incident outside the duty of candour and the remit of the above policies will be recorded in the Ulysses incident and patient's health record.

Staff should make every reasonable effort to contact the relevant people through various communication means. All attempts to contact the relevant people should be documented. If the patient/family declines to contact/engage with the trust, their wishes should be respected and a record of this kept.

Good documentation is crucial. All discussions around the time of an PSI should be recorded in the patient records. Any subsequent meetings, beyond duty of candour requirements, should have notes taken and shared with patient/family by letter.

The outcomes or results of any enquiries and investigations/reviews should also be provided in writing to patient/family, should they wish to receive them. Any

correspondence from patient/family relating to the PSI should be responded to in an appropriate, compassionate, and timely manner and a copy of the record of communications kept on Ulysses.

Special Consideration and Additional Information

Patient involved is subject to Police investigation.

Delay to being open/duty of candour and explanation of next steps in relation to PSI maybe delayed due to the Police instructing the trust not to make contact, not to process with any formal PSI review due to criminal investigation. This must be clearly recorded in the Ulysses record and communicated to the treating team/directorate. This contact/communication with be led by CPST in the first instance and is not seen as a breach of duty of candour requirements.

If a patient death has occurred within another organisation (e.g., secondary care)

Whoever first identifies or identifies or is made aware that a PSI has occurred must also incident report this and support the trusts response and identify next steps for contact with the family/carers. A review of the care provided by LPT prior to the patient's death may still be appropriate and therefore Duty of Candour still applies.

If there has been a significant delay in notification (e.g., notification has come via the Coroner's Court or GP several months later) a Ulysses incident should still be raised. However, in these circumstances the candour process may require additional consideration in order that the carers/families/carers are informed of the suspected incident carefully to avoid unexpected shock or distress.

Data/confidentiality breaches

Where there is a confirmed breach of confidential personal data, it is best practice that the organisation legally responsible for the data, should notify the relevant person(s) of this breach. This best practice guidance is supported further by the General Data Protection Regulation (GDPR). This regulation makes it a legal requirement to inform data subjects (relevant persons) of a breach of their data rights when the risk to the data subject is considered 'high'.

Risk exists when the data breach could lead to physical, material, or non-material damage to the data subject. Any breach of sensitive personal data as defined by the Data Protection Act 1998 or of the special categories of personal data as defined by the General Data Protection Regulation should be considered likely to cause damage.
Notification to the data subject should include a full explanation of the cause of the breach with the remedial action being undertaken and an apology.
The Data Privacy Team will provide specialist advice to services on request.

Criminal or intentional unsafe act

PSI's 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,

the Director of Nursing. AHP & Quality should be notified immediately.

Additional considerations/Special Circumstances when applying being open/duty of candour.

There are instances where the approach to 'Being Open/Duty of Candour' may need to be modified according to the patient/family and their circumstances, particularly regarding mental capacity:

Children & Young People

The legal age of maturity and acquisition of the full rights to make decisions regarding treatment and for giving of consent is 16 years of age.
By virtue of section 8 of the Family Law Reform Act 1969, people aged 16 or 17 are presumed to be capable of consenting to their own medical treatment, and any ancillary procedures involved in that treatment, such as an anaesthetic.
The individual's right to confidentiality becomes vested in them rather than parents/guardians. However, it is still considered good practice to encourage competent children to involve their families in any decision-making. Previous legal rulings have determined that children under 16, who fully understand what is involved in any planned treatment/care or a decision process, can also give consent (also known as Gillick competence based on Fraser Guidelines as detailed in Gillick v West Norfolk & Wisbeck Area Health Authority [1986] AC 112 House of Lords.). Where a child is involved in a PSI and is judged to have the cognitive ability and emotional maturity to understand the information provided, she/he should be directly involved the 'Being Open/Duty of Candour' process. The parents should still be involved unless the child expresses a wish for them not to be present.

Where a child is deemed not to have sufficient maturity or the ability to understand, consideration needs to be given to whether information is provided to the parents alone or in the presence of the child and the views of the parents should be sought first. In addition, you must assume a 16–18yr old is competent until proven otherwise.

To establish whether a young person aged 16 or 17 has the requisite capacity to consent to the proposed intervention, the same criteria as for adults should be used. If a young person lacks capacity to consent because of an impairment of, or a disturbance in the functioning of, the mind or brain then the Mental Capacity Act 2005 will apply in the same way as it does to those who are 18 and over.

Looked after children have social worker allocated; discussion around those under 16yrs of age will require local and inclusive discussion about the approach to enacting statutory duty of candour and being open on an individual case by case basis, led by the treating team.

Patients under the care of a mental health services

The usual process around Being Open/Duty of Candour should be followed unless the service user also has a cognitive impairment (see below). The only circumstance where it is appropriate to withhold patient safety incident information from a service user under

the care of a mental health team is when it would cause adverse psychological harm to disclose the information. This decision should be made by their responsible medical clinician and supported by a second opinion. Apart from exceptional circumstances, it is rarely appropriate to discuss PSI information with a family/carer without permission of the patient just because they have mental health illness. To do so is an infringement of the patient's confidentiality and human rights.

Patients with cognitive impairment at time of the PSI

Where an individual has a condition which limit their ability to understand what is happening to them, they may have an authorised person able to act on their behalf under a lasting/enduring Power of Attorney (LPOA). After confirming this LPOA extends to decision making and medical care/treatment of the patient the Being Open/Duty of Candour discussion would be held with the holder of the LPOA. Where LPOA has not been appointed, the clinicians may act in the service user's best interest in deciding who the appropriate person is to discuss incident information with, regarding the welfare of the service user as a whole and not simply their medical interests. However, the patient with a cognitive impairment should, where possible, be involved directly in communications about what has happened. An advocate with appropriate skills should be considered and made available to the patient to assist in the communication process.

Patients/Service users with reduced intellectual ability and difficulty with everyday activities (learning disabilities)

Where a patient has difficulties in expressing their opinion verbally, an assessment should be made about whether they are also cognitively impaired (see above). If not cognitively impaired they should be supported in the 'Being Open/Duty of Candour' process by alternative communication methods (i.e., communication support following personalised communication guidelines).

On agreement and consultation with the patient, family/carer, an advocate should be appointed; appropriate advocates may include carers, family, or friends of the service user. The advocate should assist the patient during the 'Being Open/Duty of Candour process', focusing on ensuring that their views are considered and discussed.

Statutory Requirements of the Trust of duty of candour under Regulation 20. (also see Supporting Guidance B & C)

Identification of a statutory Breach

Should the Directorate or CPST consider a statutory breach has occurred this must be escalated to Executive Management Board and if confirmed a statutory notification will be made

What are the consequences of breaching the duty? CQC perspectives

If we notify, or when CQC identifies a breach of Regulation 20, it will assess the impact and decide whether it needs to take regulatory action.

Overall whilst individual healthcare professionals will not be personally liable in terms of any criminal sanctions; where CQC identifies a breach, it is open to prosecute the organisation should they feel that the breach is serious enough. Consequently, it is entirely possible for an organisation to be prosecuted for failing to meet the statutory requirements of Regulation 20.

It was the case that where an organisation failed to meet the requirements of a Regulation, a warning notice was issued with a timescale for compliance. If that organisation then failed to comply, CQC may decide to bring a prosecution. If the organisation did comply, then no prosecution could be brought. This has now changed with the implementation of Regulation 20 so if an organisation is not meeting its obligations in terms of its statutory duty of candour, it is open to the CQC to immediately prosecute.

6.0 Consent

Clinical staff must ensure that consent has been sought and obtained before any care, intervention or treatment described in this policy is delivered. Consent can be given orally and/ or in writing. Someone could also give non-verbal consent if they understand the treatment or care about to take place. Consent must be voluntary and informed, and the person consenting must have the capacity to make the decision.

If the patient's capacity to consent is in doubt, clinical staff must ensure that a mental capacity assessment is completed and recorded. Someone with an impairment of or a disturbance in the functioning of the mind or brain is thought to lack the mental capacity to give informed consent if they cannot do one of the following:

- Understand information about the decision.
- Remember that information.
- Use the information to make the decision.
- Communicate the decision.

6.0 Monitoring Compliance and Effectiveness

Page/Section	Minimum Requirements to monitor	Method for Monitoring	Responsible Individual /Group	Where results and any Associate Action Plan will be reported to, implemented and monitored.
All	a) how communication between healthcare organisations, healthcare teams, staff, patients, their	Compliance with Duty of Candour is monitored monthly by the incident oversight group,	Incident Oversight Group (IOG)	Monthly

Page/Section	Minimum Requirements to monitor	Method for Monitoring	Responsible Individual /Group	Where results and any Associate Action Plan will be reported to, implemented and monitored.
	relatives and carers is undertaken. b) how staff acknowledge, apologise, and explain when PSI has occurred.	monthly compliance status shared with Quality Forum and Trust Board via patient Safety Report A yearly audit of the quality of this will be in a peer review style	Incident Oversight Group (IOG)	Annual (in September)

7.0 References and Bibliography

Tees, Esk and Wear Valleys NHS Foundation Trust 'Duty of Candour Policy' (2023)

https://www.tewv.nhs.uk/wp-content/uploads/2021/10/Duty-of-Candour-Policy.pdf

Rotherham, Doncaster, and South Humber NHS Foundation Trust 'Being Open Policy' (2023) https://www.rdash.nhs.uk/policies/being-open-policy/#11

CQC Regulation 20: Duty of candour https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour

CQC - Duty of candour: notifiable safety incidents

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

NHS England (NHSE) Policy guidance on recording patient safety events and levels of harm https://www.england.nhs.uk/long-read/policy-guidance-on-recording-patient-safety-events-and-levels-of-harm/

AvMA	Action against Medical Accidents	http://www.avma.org.uk/
Cruse	Bereavement Care	www.crusebereavementcare.org.uk
GMC	General Medical Council	http://www.gmc-uk.org/
HCPC	Health and Care Professions Council	http://www.hcpc-uk.co.uk/
MDU	Medical Defence Union	http://www.the-mdu.com/

MPS	Medical Protection Society http://www.medicalprotection.org/uk	
NMC	Nursing and Midwifery Council	http://www.nmc-uk.org/
RCN	Royal College of Nursing	www.rcn.org.uk
RCGP	Royal College of General Practitioners	http://www.rcgp.org.uk
RCP	Royal College of Physicians	www.rcplondon.ac.uk
NHS Resolution		https://resolution.nhs.uk/
Care Quality Commission		https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour

Francis Enquiry: Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry: Executive Summary. Francis, R. (2013). https://www.gov.uk/government/publications/report-of-the-mid-staffordshire-_nhs-foundation-trust-public-inquiry

The Report of the Morecambe Bay Investigation Dr Bill Kirkup CBE March (2015) https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/408480/47487_MBI_Accessible_v0.1.pdf

Guidance on the professional duty of candour: Joint guidance with the General Medical Council on the duty of candour. https://www.nmc.org.uk/standards/guidance/the-professional-duty-of-candour/

Patient Safety Incident Response Framework (2022)

https://www.england.nhs.uk/patient-safety/incident-response-framework/

Learning from deaths: Guidance for NHS trusts on working with bereaved families and carers (2018)

8.0 Fraud, Bribery and Corruption consideration

The Trust has a zero-tolerance approach to fraud, bribery, and corruption in all areas of our work and it is important that this is reflected through all policies and procedures to mitigate these risks.

Fraud relates to a dishonest representation, failure to disclose information or abuse of position in order to make a gain or cause a loss. Bribery involves the giving or

receiving of gifts or money in return for improper performance. Corruption relates to dishonest or fraudulent conduct by those in power.

Any procedure incurring costs or fees or involving the procurement or provision of goods or service, may be susceptible to fraud, bribery, or corruption so provision should be made within the policy to safeguard against these.

If there is a potential that the policy being written, amended or updated controls a procedure for which there is a potential of fraud, bribery, or corruption to occur you should contact the Trusts Local Counter Fraud Specialist (LCFS) for assistance.

Supporting Guidance, A – 10 Principles of 'Being Open'

1. Acknowledgement

All patient safety incidents should be acknowledged and reported as soon as they are identified. Notify and apologies to the patient or relevant person, verbally or face to face where possible unless the person or family in case of deceased patient, cannot be contacted or declines notification. In cases where the patient, their family and carers inform healthcare staff when something untoward has happened, it must be taken seriously from the outset. Any concerns should be treated with compassion and understanding by all healthcare professionals.

2. Truthfulness, timeliness, and clarity of communication

Information about a patient safety incident must be given to patients, their families, and carers in a truthful and open manner by an appropriately nominated, person. Patients should be provided with a step-by-step explanation of what happened, that considers their individual needs and is delivered openly.

Communication should also be timely; patients, their families and 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 professionals should explain that new information may emerge as an incident investigation is undertaken, and that patients, their families and carers will be kept up to date with the progress of an investigation. Patients, their families, and 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 the use of medical jargon, which they may not understand, should be acknowledged.

3. Apology

Patients, their families, and carers should receive a meaningful apology, one that is a sincere with expression of sorrow or regret for the harm that has resulted from a patient safety incident. This should be in the form of an appropriately worded and agreed manner of apology as early as possible. Where the death or injury of a person has occurred, an apology does not constitute an admission of liability or unsatisfactory professional performance.

A decision should be made as to who is the most appropriate member of staff to give both verbal and written apologies to patients, their families, and carers. The decision should consider seniority, relationship to the patient, and experience and expertise in the type of patient safety incident that has occurred. Verbal apologies are essential because they allow face-to-face contact between the patient, their family and carers and the healthcare team. This should be given as soon as staff are aware an incident has occurred. A written apology, which clearly states the healthcare

organisation is sorry for the suffering and distress resulting from the incident, must also be given. It is important not to delay giving a meaningful apology for any reason and may include setting up a more formal multidisciplinary 'being open' discussion with the patient, their family and carers if required; due to fear and apprehension; or lack of staff availability. Delays are likely to increase the patient's, their families and their carers' sense of anxiety, anger, or frustration.

4. Recognising patients, families, and carers expectations

Patients, their families, and carers can reasonably expect to be fully informed of the issues surrounding a patient safety incident, and its consequences, in a face-to-face meeting with representatives from the healthcare organisation. They should be treated sympathetically, with respect and consideration. They should also be provided with support if they require it, in a manner appropriate to their needs.

When communicating with relatives and when appropriate, the issue of consent should also be considered and any discussion in relation to the patient wishes should be clearly documented.

5. Professional support

All staff, whether directly employed or independent contractors, should report patient safety incidents and staff should feel supported throughout the incident. They should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk, or any threat to their registration.

The Just Culture Guide (NHS Improvement, 2018) 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.

6. Risk Management and systems improvement

The trust investigation process, if undertaken, will be used to identify system failures/weaknesses and human error of a patient safety incident.

7. Multidisciplinary responsibilities

Most healthcare provision is through multidisciplinary teams. This should be reflected in the way that patients, their families, and other relevant people are communicated with when things go wrong. This will ensure that the being open process is consistent with the philosophy that incidents usually result from systems failures and rarely from the actions of an individual.

8. Clinical governance

Being open requires the support of patient safety and quality improvement processes through clinical governance frameworks in which patient safety incidents are reviewed, investigated, and analysed to find out what can be done to prevent their recurrence. These findings should be disseminated to healthcare professionals so that they can learn from patient safety incidents.

Within the trust, monitoring and reporting is carried out through the Ulysses system.

9. Confidentiality

Being open should give full consideration of, and respect for, the patient's, their families and other relevant people's and staff privacy and confidentiality. Details of a patient safety incident should always be considered confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient, in line with the CQC's guidance for outcome 20. Where this is not practical, or an individual refuses to consent to the disclosure, it may still be lawful if justified in the public interest, or where those investigating the incident have statutory powers for obtaining information.

Communications with parties outside the clinical team should also be on a strict need to know basis and, where practicable, records should be anonymous. In addition, 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.

10. Continuity of care

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

Please note, the being open approach may need to be modified according to the individual patient or personal circumstances, for example (but not restricted to):

- When a patient dies
- When there is no identified 'relevant person'
- Patients in the community
- Patients who have a cognitive impairment and may lack capacity.
- Patients with a different language or cultural considerations
- Patients with different communication needs
- Children and young people

- When there is a corresponding criminal enquiry (see section 5.7 special considerations)

Supporting Guidance B – Duty of Candour: Notifiable Safety Incidents (as described by CQC 2022)

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

‘ ‘Notifiable safety incident’ is a specific term defined in the duty of candour regulation. It should not be confused with other types of safety incidents or notifications.

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 an activity we regulate.
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. This element varies slightly depending on the type of provider.

If any of these three criteria are not met, it is **not a notifiable safety incident** (but remember that the overarching duty of candour, to be open and transparent, always applies).

You should interpret "unexpected or unintended " in relation to an incident which arises in the course of the regulated activity, not to the outcome of the incident. By "regulated activity" we mean the care or treatment provided. By "outcome" we mean the harm that occurred or could have occurred. So, 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.

This does not mean that known complications or side effects of treatment are always disqualified from being Notifiable Safety Incidents. In every case, the healthcare professionals involved must use their judgement to assess whether anything occurred during the provision of the care or treatment that was unexpected or unintended.

The definitions of harm vary slightly between health service bodies and all other providers. This is because when the regulation was written, harm thresholds were aligned with existing notification systems to reduce the burden on providers.

It is possible for an incident to trigger the harm threshold for NHS trusts, but not for other service types, or vice versa.

It is helpful to remember that the statutory duty relates to the provision of regulated activities, and so you should follow the notifiable safety incident definition relating to the type of organisation or provider you are working within.

Health Service Body

Section 9 of the National Health Service Act 2006 defines a 'health service body'. For the purposes of the duty of candour, a health service body means either an:

- NHS trust
- NHS Foundation trust.

Paragraph 8 of Regulation 20 defines the harm thresholds for Health Service Bodies:

In the reasonable opinion of a healthcare professional, the incident could result in or appears to have:

- resulted in the death of the person - directly due to the incident, rather than the natural course of the person's illness or underlying condition.
- led to the person experiencing severe harm, moderate harm, or prolonged psychological harm.

These definitions of harm are linked to the National Reporting and Learning System (NRLS) definitions.

– NB - NRLS has been replaced by Learning from Patient Safety Events (LFPSE) as part of the response to PSIRF.

Definitions of harm

These definitions are common to all types of service.

Moderate harm: Harm that requires a moderate increase in treatment and significant, but not permanent, harm.

Severe harm: 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.

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.

Identifying a notifiable safety incident

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. Saying sorry is not admitting fault.

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

Supporting Guidance C - Duty of Candour: Frequently Asked Questions

These FAQs should be read in conjunction with the published Care Quality Commission (CQC) guidance Regulation 20: Duty of candour - Care Quality Commission and are accurate as of March 2025. Any updates to the CQC guidance beyond this date will not necessarily be reflected in these FAQs and the CQC guidance should be the primary source of guidance.

The Professional Duty of Candour

1. What is the Professional Duty of Candour?

The Professional Duty of Candour applies to individual healthcare professionals, requiring them to be honest with patients when something goes wrong with their care. This includes taking responsibility, apologising, explaining what happened and working to prevent future occurrences. It is enforced by professional regulatory bodies such as the General Medical Council (GMC) and the Nursing and Midwifery Council (NMC).

The Statutory Duty of Candour – an outline

2. What is the Statutory Duty of Candour?

The Statutory Duty of Candour applies to every health and social care provider that the Care Quality Commission (CQC) regulates. It is a legal obligation that requires registered providers and registered managers (known as 'registered persons') to act in an open and transparent way with people receiving care or treatment from them.

3. Who does the Statutory Duty of Candour apply to?

The Statutory Duty of Candour applies to all health and social care providers regulated by CQC. This includes NHS and private healthcare organisations, care homes and other regulated services.

4. When must the Statutory Duty of Candour be applied?

There are two parts of the Statutory Duty of Candour:

- The overarching duty to be open and transparent with people receiving care. This part **applies at all times, in all cases.**
- **Notifiable Safety Incidents (NSI).** Where an NSI has occurred, the regulation specifies exactly how the Duty of Candour must be applied.

The Statutory Duty of Candour – What is a Notifiable Safety Incident (NSI)?

5. What is an NSI?

A NSI is a specific term defined in the regulations and it should not be confused with other types of safety incidents or notifications. An NSI must meet all of three of the following criteria:

1. It must have been unexpected or unintended.
2. It must have occurred during the provision of an activity regulated by CQC.
3. In the reasonable opinion of a healthcare professional, it already has, or might, result in death, or severe or moderate harm to the person receiving care. The levels of harm are defined differently depending on the type of provider, as set out in Table 1 below, but mean it is possible to trigger the harm threshold for NHS trust, but not for other service types, or vice versa.

Table 1

NHS Trusts and NHS Foundation Trusts	All other regulated providers
In the reasonable opinion of a healthcare professional, the incident could result in or appears to have: • Resulted in the death of the person – directly due to the incident, rather than the natural course of the person's illness or underlying condition. • Led to the person experiencing severe harm, moderate harm or prolonged psychological harm. These definitions are aligned in the regulation to the National Reporting and Learning System (NRLS) definitions. The new Learn from Patient Safety Events (LfPSE) has changed these definitions. A joint statement on how to align the LfPSE definitions with the Duty of Candour requirements has been published and is available on NHS Futures (login required).	In the reasonable opinion of a healthcare professional, the incident appears to have resulted in, or requires treatment to prevent: • The death of a person – directly due to the incident, rather than the natural course of the person's illness or underlying condition. • The person experiencing a sensory, motor or intellectual impairment that has lasted, or is likely to last, for a continuous period of at least 28 days, • Changes to the structure of the person's body. • The person experiencing prolonged pain or prolonged psychological harm, or • A shorter life expectancy for the person using the service.

6. What does the first criterion about unintended or unexpected mean? What does it mean in relation to known complications?

The CQC guidance states:

‘You should interpret "unexpected or unintended " in relation to an incident which arises in the course of the regulated activity, not to the outcome of the incident. By "regulated activity" we mean the care or treatment provided. By "outcome" we mean the harm that occurred or could have occurred. So, 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.

This does not mean that known complications or side effects of treatment are always disqualified from being Notifiable Safety Incidents. In every case, the healthcare professionals involved must use their judgement to assess whether anything occurred during the provision of the care or treatment that was unexpected or unintended’.

Additionally, CQC guidance states that an NSI can still occur even if a patient consented to the procedure.

Take these hypothetical scenarios, which illustrate the potential difference:

- Case A – A patient undergoes hip replacement surgery. A recognised complication is a venous thrombo-embolism (VTE) (blood clot). The consent process was followed, and the risk was clearly explained. The patient received all appropriate chemical and mechanical prophylaxis, and the surgery went as intended. However, the patient suffered a stroke.
- Case B – The circumstances are the same as Case A, however, this patient did not receive prescribed chemical prophylaxis.

In Case A, although harm occurred, it occurred in relation to the outcome; that is, nothing unintended or unexpected happened in the care and treatment provided that contributed to that harm. In Case B, the same harm occurred but something unintended or unexpected happened in the care and treatment (prescribed prophylaxis was not given) that contributed to the harm.

The provider would be required to act in an open and transparent way in both cases (the first part of the Statutory Duty of Candour), but Case B is also a Notifiable Safety Incident and therefore specific actions must be taken.

7. What does the second criterion about a regulated activity mean?

Providers must register with CQC if they provide one or more of the Regulated Activities set out in Schedule 1 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. A description of each of the Regulated Activities is available in CQC’s Scope of Registration Guidance.

8. Is a patient receiving a regulated activity as soon as they call 999?

Once the 999 call is transferred to the ambulance service then yes, this is captured under the Regulated Activity for Transport Services, Triage, and Medical Advice Provided Remotely.

9. Under criterion 3, what is considered 'reasonable' in determining harm levels?

The 'reasonableness' is about whether, given the same information, another healthcare professional would come to the same conclusion.

10. Should ambulance services contact receiving hospitals to confirm the level of harm?

It would not be reasonable to expect a service to routinely commission advice from an external healthcare provider in order to answer this question in every case (although there may some incidents where this is done). It is possible that a receiving provider may be of the opinion that something in the ambulance service's care and treatment contributed to harm, in which case they should follow the CQC Guidance: NSI occurred in a different provider:

"If you discover a notifiable safety incident that occurred in a different provider, you should inform the previous provider.

You must also be open and transparent with the person receiving care about whatever you have discovered. But you do not need to carry out the specific procedures relating to notifiable safety incidents.

The provider where the incident happened must carry out the notifiable safety incidents procedures."

11. Are incidents that trigger professional Duty of Candour always NSIs?

No. An incident must meet all three NSI criteria to qualify. Some incidents may require professional openness without meeting NSI thresholds.

The Statutory Duty of Candour – What to do if an NSI occurs?

12. What actions are required if an NSI has occurred?

If a NSI has occurred, the provider must, as soon as reasonably practicable:

- Tell the relevant person (the service user who was harmed or someone acting lawfully on their behalf), in person, that an NSI has occurred.
- Apologise for what happened.
- Provide a true account of what happened, explaining what you know at that point.
- Explain to the relevant person what further enquiries or investigations you believe to be appropriate.
- Follow up by providing this information, and the apology, in writing, and provide an update on any enquiries.
- Keep a secure written record of all meetings and communications with the relevant person.

Duty of Candour is complete once all the above steps have been followed. Any new information that comes to light at a later date may require further communication with the relevant person. If the relevant person cannot, or refuses to, be contacted, then you may not be able to carry out the actions outlined above, but you must keep a written record of all attempts to make contact.

Throughout this process you must give reasonable support to the relevant person, both in relation to the incident itself and when communicating with them about the incident. This will vary with every situation but could include, for example:

- Environmental adjustments for someone who has a physical disability.
- An interpreter for someone who does not speak English well.
- Information in accessible formats.
- Signposting to mental health services.
- The support of an advocate.
- Drawing their attention to other sources of independent help and advice.

13. What does ‘as soon as reasonably practicable’ mean? Why are there no defined timescales?

Providers are expected to act promptly as soon as an NSI has been discovered. No defined timescales are given as each NSI, and the circumstances of the relevant person who has been affected, will be different. For example, the relevant person may not be contactable for a period of time.

14. Does the apology for a NSI have to be given face-to-face?

The legislation states that the apology must be given in person and the CQC guidance interprets this as face-to-face; so that should be the case where possible, if it best meets the needs of the service user. However, if face-to-face is not possible or not in the best interest of the service user, it may be given in person another way, such as by telephone or virtually. The key principle is ensuring openness and transparency.

15. Is an apology an admission of liability?

No, an apology under the Duty of Candour is not an admission of legal liability. In many cases it is the lack of a timely apology that pushes people to take legal action. NHS Resolution's 'Saying Sorry' leaflet confirms that apologising will not affect indemnity cover.

16. Can NHS Resolution's 'Being Open' be used instead of Duty of Candour to simplify compliance?

No. The statutory Duty of Candour has two parts:

1. A general duty to be open, and transparent at all times.
2. A specific process that must be followed if an NSI occurs.

Being Open aligns with part one but does not replace statutory obligations in relation to NSI.

The Statutory Duty of Candour – Illustrative examples

17. Whose responsibility is it to enact Duty of Candour when ambulances are delayed because of waits in other providers, and there is no learning for the ambulance services to share?

Duty of Candour is primarily about being open and transparent with service users, which may involve an element of sharing learning, but that is not the primary driver and therefore 'not having any learning' does not mean that the duty is not triggered. The specifics of the regulation still need to be carried out if it is an NSI. In this scenario, the requirement to tell the relevant person about the appropriate enquiries or investigations might, for example, include work being done across the system to reduce waits.

18. How does Duty of Candour apply to delays in diagnosis or treatment?

In terms of the unexpected or unintended criterion, there is the need to consider whether the delay contributed to the harm experienced. If the delay did not affect the patient outcome, then it is unlikely to meet this criterion.

19. Should a follow-up letter be sent if a porter apologises for accidentally injuring a patient by catching their arm?

A letter is only required if the incident is a NSI. It seems unlikely that the harm levels would be met in this scenario, but if they are (and the other criterion are also met)

then it would be a NSI and all actions, including following up the face-to-face notification with a written letter, must be carried out.

20. Who is responsible for informing a patient's family if an incorrect ambulance referral results in death?

In this scenario, the receiving provider should inform the referring provider that they believe an NSI has occurred (see question 10). The referring provider can assess whether the incident is an NSI, and it is they who should carry out the specifics of the regulation as required.

The Statutory Duty of Candour – the role of CQC

21. How is the Statutory Duty of Candour enforced?

The ultimate responsibility for ensuring the Statutory Duty of Candour is carried out rests with the registered provider or manager. Where CQC believe that it is not happening, they can use powers of enforcement, including action plan requests, warning notices, imposition of conditions and criminal prosecution. Any decisions will follow CQC's Enforcement Policy and Decision Tree.

Regulatory bodies such as the CQC in England, Healthcare Improvement Scotland, Healthcare Inspectorate Wales, and the Regulation and Quality Improvement Authority (RQIA) in Northern Ireland monitor compliance.

The Statutory Duty of Candour – interactions with the Patient Safety Incident Response Framework (PSIRF)

22. If an incident is not an NSI, should the patient still be involved in the investigation? Yes. PSIRF promotes compassionate engagement. Patients should be given an informed choice about their level of involvement in a learning response, as set out in the 'Engaging and involving patients, families and staff following a patient safety incident' guidance.

23. How does Duty of Candour, PSIRF and compassionate engagement align?

- Duty of Candour ensures openness and transparency, requiring healthcare providers to inform, apologise, and support patients and families after an NSI.
- PSIRF shifts focus from blame to learning and improvement, ensuring proportionate responses to patient safety incidents rather than automatic investigations.

- Compassionate engagement is central to both, ensuring empathetic, meaningful involvement of patients, families, and staff in the response process.

Together, these principles promote trust, learning and system-wide safety improvements**.**

The Statutory Duty of Candour – other issues

24. What has happened with the review into the Duty of Candour? Were the consultation figures low?

A review into the statutory Duty of Candour was announced in the Government's response to the Hillsborough disaster report in December 2023. A call for evidence closed in May 2024, with the findings of the call for evidence published in November 2024. The published findings state there were 261 responses, which is a small response rate given its wide applicability. A final response to the review has not yet been published by the Department of Health and Social Care (DHSC).

25. Why is there little focus in the guidance on applying statutory Duty of Candour in mental health services?

The statutory duty applies to any provider registered by CQC. While there is a mental health example in CQC's guidance it is about a medication error that has occurred in a mental health setting. Once the situation regarding the DHSC review of the duty is clearer, CQC will look to strengthen the guidance and provide further examples for this sector.

26. Should there be a Duty of Candour towards staff?

Any legislative changes to create a statutory Duty of Candour for staff would require action from the DHSC. However, CQC's assessment framework emphasises:

- A culture where staff can raise concerns without fear.
- Workforce wellbeing, ensuring staff feel supported and valued.

Supporting Guidance D – examples of applying duty of candour

Mental Health Examples - In-Patient Self-Harm

NICE guidance defines self-harm as:

'[…] any act of non-fatal self-poisoning or self-injury carried out by a person, irrespective of their motivation. This commonly involves self-poisoning with medication or self-injury by cutting. Self-harm is not used to refer to harm arising from overeating, body piercing, body tattooing, excessive consumption of alcohol or recreational drugs, starvation arising from anorexia nervosa or accidental harm to oneself.'

Patients who present self-harming behaviours must have a robust risk assessment, safety care plan and developed in collaboration with the patient. However, it is recognised that self-harm is complex and even with these being in place, self-harm behaviour may still occur.

If a patient who has self-harmed has done so because of an omission, an error or deviation from a risk management plan, these events will trigger the Duty of Candour process. However, where a patient has self-harmed and this was not as a direct result of any potential failures by staff in the delivery of care, such events are not liable to the Duty of Candour. Being open will still apply around sharing information about a PSI and any action.

Therefore:

A patient detained under the Mental Health Act, known to be at risk of self-harm, had to be transferred by ambulance to neighbouring acute hospital for surgery to close self-inflicted wounds. A review of observation records found gaps and it could not be evidenced that the patient had received the agreed levels of observation to control known risks. **The Duty of Candour applies**.

Died by Suicide

A patient on a mental health inpatient ward or in the community has apparently died by suicide.
This is an example where the incident resulted in death. **The Duty of Candour applies**.

Restraint Injury

A patient's arm was broken during a restraint which resulted in surgery and/or wearing a cast for several weeks. This is an example where an incident resulted in moderate/severe harm. **The Duty of Candour applies**.

Patient Assault

There is an altercation between two patients which results in one patient suffering severe bruising and injuries which require requires surgery or significant treatment in Emergency Department. This is an example where an incident resulted in moderate harm. **The Duty of Candour applies** (relating to the victim).

Suspected death by Suicide in Community Forensic Services

A person was arrested and detained at a local Police Station on suspicion of carrying out an offence. When the person came into police custody, he reported no concerns to the custody staff but was upset at the allegations made against him. Because of this, the Community Liaison and Diversion Team were asked to offer the detainee an assessment of his mental health and wellbeing, which they did. The detainee declined this, and the offer of an opt-in letter and crisis contact information, stating that he was ok. He was subsequently released under investigation by the police and no further contact received from anyone until the team were notified about his death by the police. **The Duty of Candour does not apply.**

General Health Community Examples

Pressure Ulcers

A patient who is on the case load of a community nursing team is being cared for at home. The patient was very frail, had poor mobility and often spent a significant time in bed. The patient had been assessed and an appropriate care plan was in place which was implemented; however, they developed a category 4 acquired pressure ulcer. **The Duty of Candour applies**.

Fall from a Hoist

A patient in the community falls from a hoist whilst being cared for by Trust staff and fractures their femur requiring admission to an acute trust and surgery. This would be classified as moderate/ severe harm requiring an unplanned increase in treatment and prolonged pain. **The Duty of Candour applies**.

Medication Error

A patient in the community was assessed as needing full staff support in the management of their insulin. A nurse visits to give their morning dose and finds the patient unconscious, calls 999 and they get admitted to an acute trust. It was later identified that the nurse who administered the evening medication had misread the medicine chart and had given the patient too much insulin. The patient fully recovered and returned home. This is an example of moderate harm resulting in an unplanned admission. **The Duty of Candour applies**.

This is an example of where the policy may not be followed immediately as the patient may not have been unconscious because they had been harmed. This policy would be followed when the medication error became apparent.

General Health and Mental Health Examples - In-Patient Fall (1)

A confused elderly patient who, *should have been supervised* but wasn't; falls and sustains a fracture that requires surgery and/or extra time in hospital. This would be classified as moderate/ severe harm requiring an unplanned increase in treatment and prolonged pain. In this case it is clear at the outset that care was not delivered as planned. **The Duty of Candour applies**.

In-Patient Fall (2)

A confused elderly patient on a ward has fallen and sustains a fracture that requires surgery and/or extra time in hospital. This would be classified as moderate/ severe harm requiring an unplanned increase in treatment and prolonged pain. Although in this case it is not known at the time of the fall whether there were any problems in the care delivered, this policy should be followed as to wait for the outcome of an investigation which may identify issues in the care is too late to apologise for the harm and suffering caused. **The Duty of Candour applies**.

Sudden death of an in-patient

A patient dies suddenly on an in-patient ward and the cause is not known, but it could be natural causes (e.g., a stroke). At this stage it is not known whether any problems in care may have contributed to the death; however, this policy should be followed as to wait for the outcome of an investigation which may identify issues in the care is too late to apologise to the family for their loss. **The Duty of Candour applies**. Until the outcome of the investigation and if there is no 'incident' being open would then apply

Offender Health Examples - Violence against a prisoner

If the only contact a patient had had with healthcare was due to a minor healthcare problem, e.g., verruca on his foot being removed and he was then stabbed to death by another prisoner who had not had any contact with healthcare then the **Duty of Candour does not apply.**

Mental health contact

A patient had been referred to the mental health team due to being high risk of attempting to end his/her life on admission but had not been seen within the first two weeks by anyone from the mental health team, had not been put on an assessment, care in custody and teamwork process in prison (ACCT) and then died by suicide. **The Duty of Candour applies**.

Community Forensic Examples - Suspected death by suicide in Community Forensic Services

A person was arrested and detained at a local Police Station on suspicion of carrying out an offence. When the person came into police custody, he reported no concerns to the custody staff but was upset at the allegations made against him. Because of

this, the Community Liaison and Diversion Team were asked to offer the detainee an assessment of his mental health and wellbeing, which they did. The detainee declined this and also the offer of an opt-in letter and crisis contact information, stating that he was ok. He was subsequently released under investigation by the police and no further contact received from anyone until the team were notified about his death by the police. **The Duty of Candour does not apply.**

Information Governance Breach

Member of staff went to their car in the morning and found that their laptop, camera, and all cables had been stolen from their work bag that had been left in the boot of the car. The laptop was encrypted and there was no patient or staff identifiable information stored directly on the laptop as it was all on the shared drive. There was no paperwork with patient identifiable information in the bag that could have been stolen. However, the camera contained photos of pressure ulcers and skin damage on patients with their patient record labels attached which included patient identifiable information.
The Duty of Candour applies.

Supporting Guidance E – Example of basic information for 'Initial Duty Candour' Letter contents *(must include current LPT logo & letter template)*

All comments are included to support staff – please remove before sharing.

Address of Directorate

Tel: 0116 xxx ext. xxx/ Mobile Contact nos:

Email (of sender):

Ref: (Ulysses No)

Date:

Private & Confidential

Name

Address

Dear xxx

Regarding: Name, Date of Birth, Hospital number,

Thank you for taking the time to talk to me (or other)I am writing further to our conversation on date. Please let me offer again my sincere apologies/condolences for what has happened, and I am sorry for the distress this has caused.

During our conversation (or other) I/we explained that we believed errors or omissions may have occurred during your/name's care whilst in our care In our/your conversation described that the following had occurred: xxxxxx

We take incidents very seriously and will being undertaking a review to identify any learning and to explore what has happened, we will provide you with an explanation of why it happened and identify any changes that should be considered to prevent future similar events and to share our findings with you. We will be open and honest with you during this process and have a statutory duty of candour to you.

The timescale for the review and how you can be included will be discussed with you by the person who will be undertaking the review. As part of the review, it is important that we hear your experience of what happened.

The named person for any correspondence related the review is:

- Name:
- Job title:
- Contact telephone:
- Email:

If you do not wish to be involved in the review or for us to contact you about the findings of the review, or, if you would prefer us to contact a relative or carer on your behalf, please let us know.

I have enclosed a copy of the charity AvMA's leaflet on Duty of Candour. This describes what you can expect from the Trust in relation to us being open and honest with you. It also provides you with details of an organisation who you can contact for support should you wish to. You might also like to talk to your GP about what has happened.

Support is also available through:

If there is anything in this letter that we have not explained clearly enough, or there is anything else I can help with, please contact me. My contact details are at the top of this letter. Please allow me to again express my apologies for what has happened.

Yours sincerely

Name

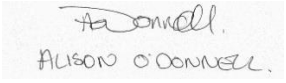
Job Title

Action against medical accidents (AVMA) leaflet Link

https://www.avma.org.uk/wp-content/uploads/Duty-of-candour.pdf (Do not include this link)

Appendix 1 Training Needs Analysis

Training required to meet the policy requirements must be approved prior to policy approval and publication. Learning and Development manage the approval of training. Send this form to lpt.tel@nhs.net for approval.

Training topic/title:	Duty of Candour		
Type of training: (see Mandatory and Role Essential Training policy for descriptions)	☐ Not required ☐ Mandatory (must be on mandatory training register) X Role Essential (must be on the role essential training register) ☐ Desirable or Developmental		
Directorate to which the training is applicable:	X Directorate of Mental Health X Community Health Services ☐ Enabling Services ☐ Estates and Facilities X Families, Young People, Children, Learning Disability and Autism ☐ Hosted Services		
Staff groups who require the training: (consider bank /agency/volunteers/medical)	All registered clinical staff		
Governance group who has approved this training:	Safety Forum	Date approved:	2025
Named lead or team who is responsible for this training:	Patient Safety Team		
Delivery mode of training: elearning/virtual/classroom/ informal/adhoc	elearning		
Has a training plan been agreed?	yes		
Where will completion of this training be recorded?	X uLearn ☐ Other (please specify)		
How will compliance with this training to be audited?	X Manager ulearn report ☐ Local manager personal records X StatMand (Flash) topic compliance report ☐ Other please specify		
Signed by Learning and Development Approval name and date		Date: 3.7.25	

Appendix 2 The NHS Constitution

- The NHS will provide a universal service for all based on clinical need, not ability to pay.
- The NHS will provide a comprehensive range of services.

Shape its services around the needs and preferences of individual patients, their families, and their carers Answer Yes to ALL

Respond to different needs of different sectors of the population

Work continuously to improve quality services and to minimise errors.

Support and value its staff.

Work together with others to ensure a seamless service for patients.

Help keep people healthy and work to reduce health inequalities.

Respect the confidentiality of individual patients and provide open access to information about services, treatment, and performance.

Appendix 3 Due Regard Screening Template

Section 1	
Name of activity/proposal	A Culture of Candour Policy (Incorporating 'Being Open' and 'Duty of Candour'
Date Screening commenced	01/12/2024
Directorate / Service carrying out the assessment	Enabling/ Corporate Patient Safety Team (CPST)
Name and role of person undertaking this Due Regard (Equality Analysis)	Sue Arnold – Lead Nurse CPST
Give an overview of the aims, objectives, and purpose of the proposal:	
AIMS: The aim of the policy is to uphold and ensure communication is open, honest and occurs as soon as possible following an incident. It encompasses communication between healthcare organisations, healthcare teams and patients, ,, families and/or their carers.	
OBJECTIVES: This document describes how the Trust implements this policy and enacts its statutory duty of candour requirements under Regulation 20 of the Health & Social Care Act and compassionately engages with patients and their families following a patient safety incident, during an investigation/review and the sharing of the learning/findings.	

Section 2	
Protected Characteristic	If the proposal/s have a positive or negative impact please give brief details
Age	No negative impacts identified.
Disability	No negative impacts identified.
Gender reassignment	No negative impacts identified.
Marriage & Civil Partnership	No negative impacts identified.
Pregnancy & Maternity	No negative impacts identified.
Race	No negative impacts identified.
Religion and Belief	No negative impacts identified.
Sex	No negative impacts identified.
Sexual Orientation	No negative impacts identified.
Other equality groups?	No negative impacts identified.

Section 3	
Does this activity propose major changes in terms of scale or significance for LPT? For example, is there a clear indication that, although the proposal is minor it is likely to have a major affect for people from an equality group/s? Please tick appropriate box below.	
Yes	No √
High risk: Complete a full EIA starting click here to proceed to Part B	Low risk: Go to Section 4.

Section 4			
If this proposal is low risk please give evidence or justification for how you reached this decision:			
Signed by reviewer/assessor	S Arnold	Date	01/12/2024
Head of Service Signed	T Ward	Date	01/03/2025

Appendix 4 Data Privacy Impact Assessment Screening

Data Privacy impact assessment (DPIAs) are a tool which can help organisations identify the most effective way to comply with their data protection obligations and meet Individual's expectations of privacy.
The following screening questions will help the Trust determine if there are any privacy issues associated with the implementation of the Policy. Answering 'yes' to any of these questions is an indication that a DPIA may be a useful exercise. An explanation for the answers will assist with the determination as to whether a full DPIA is required which will require senior management support, at this stage the Head of Data Privacy must be involved.

Name of Document:	**A Culture of Candour Policy (Incorporating 'Being Open' and 'Duty of Candour'**	
Completed by:	**Sue Arnold**	
Job title	**Lead Nurse CPST**	**Date 01/12/2024**

Screening Questions	**Yes / No**	**Explanatory Note**
1. Will the process described in the document involve the collection of new information about individuals? This is information in excess of what is required to carry out the process described within the document.	No	
2. Will the process described in the document compel individuals to provide information about them? This is information in excess of what is required to carry out the process described within the document.	No	
3. Will information about individuals be disclosed to organisations or people who have not previously had routine access to the information as part of the process described in this document?	No	
4. Are you using information about individuals for a purpose it is not currently used for, or in a way it is not currently used?	No	
5. Does the process outlined in this document involve the use of new technology which might be perceived as being privacy intrusive? For example, the use of biometrics.	No	
6. Will the process outlined in this document result in decisions being made or action taken against individuals in ways which can have a significant impact on them?	No	
7. As part of the process outlined in this document, is the information about individuals of a kind particularly likely to raise privacy concerns or expectations? For examples, health records, criminal records or other information that people would consider to be particularly private.	No	
8. Will the process require you to contact individuals in ways which they may find intrusive?	No	

If the answer to any of these questions is 'Yes' please contact the Data Privacy Team via Lpt-dataprivacy@leicspart.secure.nhs.uk In this case, ratification of a procedural document will not take place until review by the Head of Data Privacy.

Data Privacy approval name:	**N/A**
Date of approval	

Acknowledgement: This is based on the work of Princess Alexandra Hospital NHS Trust