Status Active PolicyStat ID 15266619

Harrogate and District NHS Foundation Trust

Origination	01 Mar, 2010
Last Approved	04 Mar, 2024
Effective	04 Mar, 2024
Last Revised	04 Mar, 2024
Next Review	04 Mar, 2027
Owner	MELANIE JACKSON: Clinical Effectiveness Co-Ordinator
Area	CS Corporate Affairs and Quality
Document Types	Policy

Duty of Candour and Being Open Policy

Version	Date	Purpose of Issue/Description of Change	Review Date
3	March 2010	Incorporating new NPSA Being Open Framework	March 2012
4	July 2011	Revision against 2010/11 NHSLA Standards	July 2013
5	June 2012	Review against NHSLA standards 2012/2013	June 2014
6	January 2016	Revision against Statutory Duty of Candour (Health and Social Care Act 2008 (regulated activities) Regulations 2014	January 2018
6.1	March 2017	Minor amendments following review of Incidents Policy and internal audit into duty of candour	January 2018
7	January 2018	Minor amendments as part of scheduled review	January 2020
8	April 2020	Minor amendments as part of scheduled review	January 2020
8.1	July 2020	Minor amendments as part of scheduled review	January 2020
9.0	March 2023	Minor amendments as part of scheduled review	January 2020

		Amendments to governance arrangements **Amendments as part of scheduled review**	**April 2022** **April 2022** **March 2025**
Status		**Open**	
FOI Classification		**Our policies and procedures**	
Document Type		**Policy**	
Key Words		**Being Open, Apology, Patient Safety Incident, Event, Candour, Duty of Candour**	
Executive Lead		**Director of Nursing, Midwifery and AHPs**	
Policy Lead		**Deputy Head of Quality and Safety**	
Author (if different from above)			
Governance Group (that will oversee effectiveness of implementation)		**Quality Governance and Management Group (QGMG)**	
Approval Body		**Senior Management Team**	**Date/s April 2023**
Review Date (Usually 3 years from approval date)		**March 2025**	

PURPOSE

Every day people are treated safely in the NHS and HDFT strives to deliver the best possible care to the patients we serve. However, occasionally, sometimes, despite our best efforts, things can, and do not go as expected, and a patient is harmed (this is known as a patient safety event).

Harrogate and District NHS Foundation Trust (HDFT) is committed to promoting an open and honest culture and staff are encouraged to report patient safety events that have occurred. This policy offers guidance on the statutory duty of candour and will assist staff to effectively communicate openly and honestly with patients and/or their next of kin following a patient safety event or notifiable safety incident.

This policy aims to provide assurance of the Trust's commitment to improving patient safety and continuous quality improvement and aims to complement other existing trust polices, and practices that are in place with a key focus on the promotion of a restorative just culture.

1. BACKGROUND/CONTEXT

Until 2014 there was no legal duty on care providers to share information with the people who had

been harmed, or their families. The tragic case of Robbie Powell and the perseverance of his parents through the UK courts and then the European Court of Human Rights exposed the absence of this legal duty.

In 2013, the Francis Inquiry also found serious failings in openness and transparency at Mid Staffordshire NHS Foundation Trust: "The way in which the Trust handled the matter can be viewed as an object lesson in how the tragedy of an avoidable death can be exacerbated by inappropriate handling of the case. It demonstrates the sad fact that, for all the fine words printed and spoken about candour, and willingness to remedy wrongs, there lurks within the system an institutional instinct which, under pressure, will prefer concealment, formulaic responses and avoidance of public criticism." (Francis Inquiry into the failings at Mid-Staffordshire NHS Foundation Trust, 2013) The Francis Inquiry recommended that a statutory duty of candour be introduced for all health and care providers, in addition to the existing professional duty of candour and the requirement for candour in the NHS standard contract.

This statutory duty of candour was brought into law in 2014 for NHS Trusts and 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".

Overseen by the Care Quality Commission (CQC), it compliments and strengthens the existing professional and contractual duty of candour requirements, overseen by bodies such as the General Medical Council (GMC), Nursing and Midwifery Council (NMC) and the General Dental council (GDC), but in addition is enforceable by law.

Duty of Candour (CQC Regulation 20) requires registered providers and registered persons to act in an open and transparent way with people receiving care or treatment from them (CQC, 2014). 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.

The regulation also defines what is a 'notifiable safety incident' and specifies how registered persons must apply the duty of candour in these circumstances. Refer to appendix one for the Duty of Candour regulation in full (cqc.org.uk)

A crucial part of the duty of candour is the apology. Apologising is not an admission of liability.

"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."

The initial Duty of Candour discussion with the patient and/or their carers should occur as soon as is practicably possible after recognition of the event, ***or at the latest within 10 days of the incident.***

This policy is relevant and applies to all permanent (clinical and non-clinical) staff, locum, agency, bank, voluntary staff and students working within the Trust and applies to:

Patient safety events that have caused physical and / or psychological:

- moderate harm
- severe harm
- death
- potential to cause significant harm in the future

For incidents where no or low harm has occurred, staff should offer an apology and explanation of what has happened at the time the incident occurs in line with their professional duty of candour.

2. DEFINITIONS

- **Relevant person -** This is usually the person who has been affected by the patient safety incident or the person acting lawfully on their behalf.
- **Apology -** An expression of sorrow or regret in respect of a notifiable patient safety incident.
- **Notifiable patient safety incident** (specific term in the duty of candour regulation). A notifiable safety incident must meet **all three** of the following criteria:
    1. It must have been unintended or unexpected which could have or did lead to harm for one or more patients receiving NHS funded care.
    2. It must have occurred during the provision of an activity CQC regulates.
    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.

A notifiable patient safety incident is also applicable if discovered when undertaking mortality reviews, or other retrospective audits. These could have happened some time ago, or relate to care delivered by another provider. The provider who discovers the incident should work with others who are responsible for the incident that occurred in notifying the relevant person of the incident.

Definitions of harm:

See Appendix B

3. POLICY EFFECT

This policy provides guidance on the statutory duty of candour to assist staff to effectively communicate with patients and/or their next of kin involved in patient safety incidents to ensure that staff feel empowered and supported to be open with patients and/or their family when moderate harm and above has occurred within the Trust.

The Trust encourages staff to report any patient safety events that have occurred or were prevented, i.e. 'near misses', as well as patient safety incidents that have caused moderate harm, prolonged psychological, severe harm or death.

For details of the process to be followed see Appendix A

4. ROLES AND RESPONSIBILITIES

Board of Directors

Members of the Board are responsible for ensuring the Being Open and Duty of Candour Policy and principles are embedded in the organisation and being open is at the core of the organisation's values and culture.

Chief Executive

The Chief Executive has overall accountability for ensuring that systems are in place to enable the implementation of the Being Open and Duty of Candour Policy. The Chief Executive will, on behalf of the Board, make a public statement endorsing the principles of Being Open and Duty of Candour and reinforcing the Trust's full support of an open, honest and fair culture.

Executive Medical Director & Executive Director of Nursing, Midwifery & AHPs

These are responsible for promoting the policy and act as nominated officers in the Being Open/ Candour communication. The Executive Director of Nursing, Midwifery & AHPs is the Board lead for Being Open/Duty of Candour.

Quality Governance and Management Group (QGMG)

The Group is responsible for the oversight of compliance to the policy will receive a monthly report from each Directorate on their compliance in meeting the statutory 10 days requirement.

Clinical Directors, Operational Directors, General Managers, Service Managers and Quality Assurance Leads

The Clinical Directors, Operational Directors, General Managers, Service Managers, and Quality Assurance Leads supported by Consultant of Care, Senior Nurses and other clinical colleagues are responsible for the implementation of the Being Open and Duty of Candour Policy when patients are harmed within their directorates. They will also promote the policy and ensure that all staff are familiar with the policy.

All Staff

Have a responsibility to acknowledge and report any patient safety event and then to take appropriate advice from that point. Staff have a responsibility to act within their professional codes of conduct and to promote a culture within the Trust of openness, honesty and sound communication with patients, their family and carers.

5. EQUALITY ANALYSIS

This policy was developed following wide consultation. It has undergone Stage 1 Equality Impact Assessment screening. It does not require a full Stage 2 Equality Impact Assessment.

Information about Equality, Diversity and Inclusion and EIA forms and resources are available on the intranet.

If you need this information in a different format or another language, please contact the Quality Team on 01423 554449.

6. CONSULTATION, REVIEW AND COMMUNICATION

Annex 1 identifies the Departments and individuals consulted on this Procedure.

The Procedure will be was endorsed by the Clinical Effectiveness Forum and approved by the Executive medical Director.

This Procedure will be made available electronically on the Trust Intranet. Further information will be communicated by the Compliance Team to the members of the Directorate Governance meetings.

7. STANDARDS/KEY PERFORMANCE INDICATORS

CQC Regulation 20 (in force from 27 November 2014)

1. Registered persons must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.
2. As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a registered person must:
    a. notify the relevant person that the incident has occurred in accordance with paragraph (3), and
    b. provide reasonable support to the relevant person in relation to the incident, including when giving such notification.
3. The notification to be given under paragraph (2.a) must:
    a. be given in person by one or more representatives of the registered person
    b. provide an account, which to the best of the registered person's knowledge is true, of all the facts the registered person knows about the incident as at the date of the notification,
    c. advise the relevant person what further enquiries into the incident the registered person believes are appropriate,

d. include an apology, and

e. be recorded in a written record which is kept securely by the registered person.

4. The notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person containing:
    a. the information provided under paragraph (3)(b),
    b. details of any enquiries to be undertaken in accordance with paragraph (3)(c),
    c. the results of any further enquiries into the incident
    d. an apology.
5. If the relevant person cannot be contacted in person or declines to speak to the representative of the registered person:
    a. paragraphs (2) to (4) are ***not to*** apply, and
    b. a written record is to be kept of attempts to contact or to speak to the relevant person
6. The registered provider must keep a copy of all correspondence with the relevant person under paragraph (4).

NPSA Being Open Alert (November 2009)

1. Local policy: Review and strengthen local policies to ensure they are aligned with the Being open framework and embedded with your risk management and clinical governance processes
2. Leadership: Make a board-level public commitment to implementing the principles of Being open.
3. Responsibilities: Nominate executive and non-executive leads responsible for leading your local policy. These can be leads with existing responsibilities for clinical governance.
4. Training and support: Identify senior clinical counsellors who will mentor and support fellow clinicians. Develop and implement a strategy for training these staff and provide ongoing support.
5. Visibility: Raise awareness and understanding of the Being open principles and your local policy among staff, patients and the public, making information visible to all
6. Supporting patients: Ensure Patient Experience Team (PET), and other staff have the information, skills and processes in place to support patients through the Being open process.

8. MONITORING COMPLIANCE AND EFFECTIVENESS

Policy element to be monitored	Standards and Performance indicators	Process for monitoring	Individual or group responsible for monitoring	Frequency or monitoring	Responsible individual or group for development of action	Responsible group for review of assurance reports and

					plan	**oversight of action plan**
Process for fulfilling being open when Duty of Candour is triggered	CQC Regulation 20	DATIX Dashboard	Directorate Management Team via Quality Huddles	Weekly	Directorate Management Team	QGMG

9. REFERENCES/ASSOCIATED DOCUMENTATION

CQC (2022) 'Regulation 20: Duty of candour'. Available at : https://www.cqc.org.uk/sites/default/files/2022-07/20220722-duty-of-candour-pdf-version-FINAL_0.pdf (Accessed 27 September 2022).

CQC (2022) 'About the Mental Capacity Act'. Available at: About the Mental Capacity Act - Care Quality Commission (cqc.org.uk) (Accessed 29 September 2022).

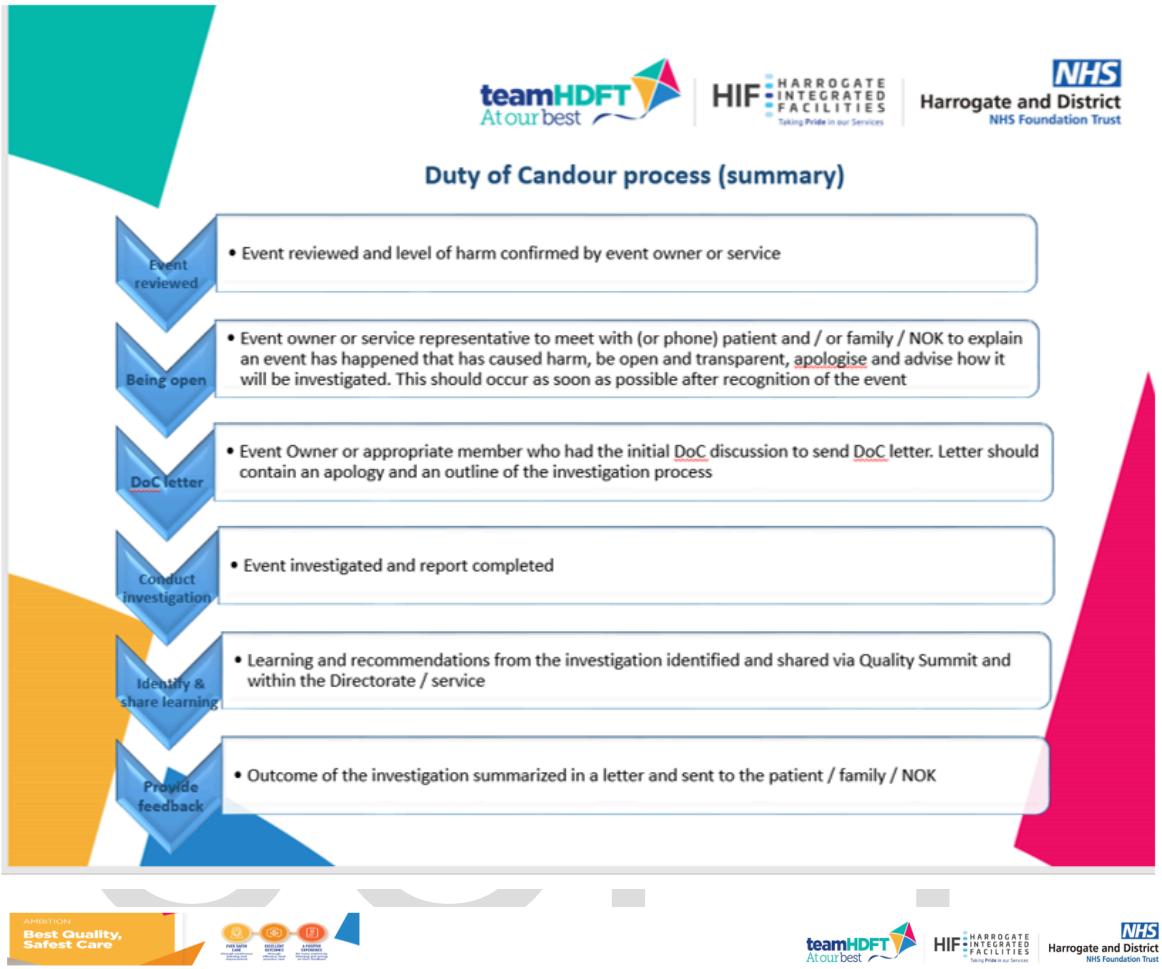
Gov.UK (2018). 'Data protection'. Available at Data Protection Act 2018 (legislation.gov.uk) (Accessed 29 September 2022).

NHS Resolution (2017). 'Saying sorry'. Available at: NHS-Resolution-Saying-Sorry-2017.pdf (Accessed 23 September 2022).

NHS England (2022). 'Patient Safety Incident Response Framework v1'. Available at: B1465-1.-PSIRF-v1-FINAL.pdf (england.nhs.uk) (Accessed 23 September 2022).

Healthcare Safety Investigation Branch (2022). 'HSIB works with NHS England on Patient Safety Incident Response Framework'. Available at: HSIB works with NHS England on PSIRF | HSIB (Accessed 29 September 2022)

Appendix A – Pathway: Duty of Candour



Appendix B – Level of Harm

Harm Level	Physical Harm Sustained by the Patient	Psychological Harm Sustained by the Patient	Actual Impact – Harm Caused by UHMBT
	The actual physical harm sustained to the patient regardless of how HDFT contributed to this.	The actual psychological harm sustained to the patient regardless of how HDFT contributed to this.	The overall harm caused by HDFT due to a lapse or omission in care. If your review has identified lapses in care, the harm caused by HDFT should reflect the highest level of physical or psychological harm.
No Harm	The patient has sustained no physical harm as a result of this event.	Distress is inherent in being involved in any patient safety incident, but please select this option if there is no specific psychological	No harm caused by an act or omission in care by HDFT.

		harm over and above this	
Low Harm	Low physical harm is when all of the following apply: • did not or is unlikely to need further healthcare beyond a single GP, community healthcare professional, emergency department or clinic visit • did not or is unlikely to need further treatment beyond simple dressing changes or short courses of oral medication ? did not or is unlikely to affect that patient's independence • did not or is unlikely to affect the success of treatment for existing health conditions	Low psychological harm is when at least one of the following apply: • distress that did not or is unlikely to need extra treatment beyond a single GP, community healthcare professional, emergency department or clinic visit • distress that did not or is unlikely to affect the patient's normal activities for more than a few days • distress that did not or is unlikely to result in a new mental health diagnosis or a significant deterioration in an existing mental health condition	Minimal harm caused by a gap in care whilst the patient was under the care of HDFT that requires extra observation or minor treatment.
Moderate Harm	Moderate harm is when at least one of the following apply: • has needed or is likely to need healthcare beyond a single GP, community healthcare professional,	Moderate psychological harm is when at least one of the following apply: • distress that did or is likely to need a course of treatment or therapy sessions that extends for less	Short term harm caused by a gap in care whilst the patient was under the care of HDFT that requires further treatment or procedure.

	emergency department or clinic visit, and beyond simple dressing changes or short courses of medication, but less than 2 weeks additional inpatient care and/or less than 6 months of further treatment, and did not need immediate life-saving intervention • has limited or is likely to limit the patient\s independence, but for less than 6 months • has affected or is likely to affect the success of treatment, but without meeting the criteria for reduced life expectancy or accelerated disability described under severe harm	than six months • distress that did or is likely to affect the patient's normal activities for more than a few days but is unlikely to affect the patient's ability to live independently for more than six months • distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, but where recovery is expected within six months	
Severe Harm	Severe harm is when at least one of the following apply: • needed immediate live-saving clinical intervention ? is likely to have reduced the	Severe psychological harm is when at least one of the following apply: • distress that did or is likely to need a course of treatment or therapy sessions that	Permanent or long term harm caused by a gap in care whilst the patient was under the care of HDFT

	patient's life expectancy • has, or is likely to have, reduced the chances of preventing or delaying disability from their existing healthcare conditions • needed or likely to need additional inpatient care of more than 2 weeks and/or more than 6 months of further treatment • has limited or is likely to limit the patient's independence for 6 months or more	continues for more than six months • distress that did or is likely to affect the patient's normal activities or ability to live independently for more than six months • distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, and recovery is not expected within six months	
Death	You should select this option if the patient has died and there is at least a slight possibility the incident that you are recording may have contributed to the death, including stillbirth or pregnancy loss. You will have the option later to estimate to what extent a patient safety incident contributed to this fatal outcome.		Death caused by gap in care whilst the patient was under the care of HDFT
Near Miss (Potential for Low Harm)			Any patient safety event that had the potential to cause harm **but was prevented**, resulting in no harm to people receiving NHS-funded care but could have caused low

			harm if the incident occurred.
Near Miss (Potential for Moderate or Above Harm)			Any patient safety event that had the potential to cause harm **but was prevented**, resulting in no harm to people receiving NHS-funded care but could have resulted in moderate or above harm if the incident occurred.

Annex 1: Consultation Summary

Those listed opposite have been consulted and any comments/actions incorporated as appropriate. The author must ensure that relevant individuals/groups have been involved in consultation as required prior to this document being submitted for approval.	**List Groups and/or Individuals Consulted**
	Executive Medical Director
	Executive Director of Nursing, Midwifery & AHPs
	Associate Directorate of Quality & Corporate Affairs
	Quality Team
	Patient Safety Forum
	Quality Governance and Management Group
	Quality Committee
	Quality Assurance Leads
	Directorate Management teams

Executive Lead	Emma Nunez, Director of Nursing, Midwifery and AHPs
Governance Group (that *will oversee effectiveness of implementation*	**Quality Governance and Management Group (QGMG)**

Approval Signatures

Step Description	Approver	Date
Policy Governance Team Review	Karen Cleminson: Administrative Assistant	04 Mar, 2024
Policy Governance Team Review	PGT Policy Governance Team [KK]	04 Mar, 2024
	MELANIE JACKSON: Clinical Effectiveness Co-Ordinator	01 Mar, 2024