NHS
Yorkshire
Ambulance Service
NHS Trust

Being Open (Duty of Candour) Policy

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Staff Summary

Robert Francis QC's report of the Mid Staffordshire Foundation Trust Public Inquiry included 12 recommendations relating to openness, transparency and candour.
In 2008, Regulation 20 of the Health and Social Care Act stated that: "Registered persons must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity."
The Care Quality Commission (CQC) oversee the statutory requirements for duty of candour through Regulation 20.
The purpose of this Policy is to ensure that YAS has a clear system in place to identify when the Trust needs to be open about incidents where harm or potential for harm has occurred (including near misses).
'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.
As soon as is 'reasonably practicable' after becoming aware of the incident the 'registered person' or delegated responsible person must notify the 'relevant person'.
The CQC does have the power to bring a criminal prosecution against the organisation if it identifies that the Duty of Candour is breached. A prosecution can cause significant reputational damage for Trusts and attract further scrutiny from the CQC.
Lessons learned and action plans following the patient safety incident will be monitored via the processes outlined in the Incident and Serious Incident Management Policy. Learning arising from the Duty of Candour process will be recorded on the Datix record and reported to the Trust Learning Group (TLG) when appropriate. The Significant Events Report sent to Trust Board and Quality Committee will include information on application of the Duty of Candour process.
All staff will be made aware of the Trust's Being Open and Duty of Candour Policy through corporate induction and basic training. This will be part of the Trust's efforts to build a culture of openness, honesty, truthfulness and transparency. Those who actively take part in 'being open' meetings with family will also receive additional training and guidance on how to do this, particularly where there is bad news being delivered.
The Duty of Candour process, whilst owned by the Quality & Safety Team will be worked collaboratively where appropriate to satisfy 'being open' principles with families and carers as part of other internal processes such as the mortality review, complaint handling and investigations undertaken by HM Coroner.

1.0 Introduction

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

1.2 From 2013-14 the NHS Standard Contract (NHS Commissioning Board, 2013) includes a contractual duty of candour. These requirements are covered within this policy.

In 2008, Regulation 20 of the Health and Social Care Act stated that: "Registered persons must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity."

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

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

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

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

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

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

1.9 Duty of candour is strongly aligned to "The Seven Principles of Public life" which were set out by Lord Nolan in his report to the Committee on Standards in Public life in

1995. They outline the ethical standards for those people working in the public sector and are expected to be adhered to.

The seven principles are:

- **Selflessness**
- **Integrity**
- **Objectivity**
- **Accountability**
- **Openness**
- **Honesty**
- **Leadership**

2.0 Purpose/Scope

2.1 The purpose of this Policy is to ensure that YAS has a clear system in place to identify when the Trust needs to be open about incidents where harm or potential for harm has occurred (including near misses). Discussing patient safety incidents promptly, fully and compassionately can help patients and professionals to cope better with the after-effects. Openness and honesty can help to prevent such events becoming formal complaints and litigation claims.

2.2 This Policy applies to all patient safety incidents that occur during care and associated activities carried out by Yorkshire Ambulance Service NHS Trust that result in harm, or possible future harm and where a notifiable safety incident has occurred and has been identified using the flow chart for decision making at Appendix E, taken from the following guidance: The duty of candour: guidance for providers (cqc.org.uk)

3.0 Process

Principles for Duty of Candour

3.1 There are two elements to the Duty of Candour principles in order to satisfy both the professional duty and the statutory duty.

Both the statutory duty of candour and professional duty of candour have similar aims – to make sure that those providing care are open and transparent with the people using their services, whether or not something has gone wrong.

Under the statutory duty of candour, the Trust is required to comply with obligations regarding candour if a notifiable safety incident occurs or is suspected to have occurred.

A notifiable safety incident can be defined as:

‘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’

3.2 Providers are required to maintain a ‘registered person’ or persons responsible for carrying out or delegating responsibility for carrying out the duty.

As soon as is ‘reasonably practicable’ after becoming aware of the incident the ‘registered person’ or delegated responsible person must notify the ‘relevant person’.

Notification must include the following items:

1. Tell the relevant person, face-to-face, that a notifiable safety incident has taken place.
2. Apologise.
3. Provide a true account of what happened, explaining whatever you know at that point.
4. Explain to the relevant person what further enquiries or investigations you believe to be appropriate.
5. Follow up by providing this information, and the apology, in writing, and providing an update on any enquiries.
6. Keep a secure written record of all meetings and communications with the relevant person.

3.3 The CQC does have the power to bring a criminal prosecution against the organisation if it identifies that the Duty of Candour is breached. A prosecution can cause significant reputational damage for Trusts and attract further scrutiny from the CQC.

3.4 The statutory duty imposes similar implications on the organisation however does not hold the timescales that are enforced through the contract. It also requires that organisations offer reasonable support to those involved in the incident in contrast to the contractual duty which requires all necessary support will be given. Both the professional and the statutory duties fundamentally require Yorkshire Ambulance Service NHS Trust to act in an open, honest and transparent manner with patients and others involved in a notifiable safety incident.

3.5 Families and carers have a right to be involved in investigations if they wish to do so. The Trust will accommodate this and ensure that all relevant questions of the family are built into the investigation and that they have input into it.

3.5b Throughout the process the Trust must give ‘reasonable support’ to the relevant person, both in relation to the incident itself and when communicating with them about the incident. ‘Reasonable support’ 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 such as AvMA (Action against Medical Accidents) or Cruse Bereavement Care.

Practical guidance

3.7 The Trust has a detailed Standard Operating Procedure which outlines the step-by-step process for application of the Duty of Candour to notifiable safety incidents. This can be found at Appendix C. The process is managed by the Quality & Safety Team with the Head of Investigations & Learning being the Trust’s ‘Responsible Person’. No correspondence should be issued under the being open principles unless it has been coordinated and approved by the Head of Investigations & Learning (or appropriate deputy).

3.8 Patient safety incidents are identified and graded through the Trust Incident and Serious Incident Management Policy.

3.9 The Quality & Safety Team (or Integrated Urgent Care (IUC) Governance Team for cases involving their service line) will keep full records of all correspondence, written and verbal, with the patient and/or others involved in the incident. These will be recorded on the Datix record for each case. A Duty of Candour log is also utilised to track progress of cases with full information being available on the Datix record. This will include an archive of all closed cases.

3.10 Lessons learned and action plans following the patient safety incident will be monitored via the processes outlined in the Incident and Serious Incident Management Policy. Learning arising from the Duty of Candour process will be recorded on the Datix record and reported to the Trust Learning Group (TLG) when appropriate.

Principles of Communication

- Patients and/or their carers/families/appointed advocate or representatives will be given a single point of contact for any questions or requests they may have throughout the process.

- Patients and/or their carers/families/appointed advocate or representatives will be offered a sincere apology as soon as possible following identification of the incident, using principles highlighted in the NHS Resolution ‘saying sorry’ guide 2017 (appendix D).

- Patients and/or their carers/families/appointed advocate or representatives will receive clear, unambiguous information which is free from medical jargon.

- Communication, including written communications will be tailored to the specific requirements and preferences of the individual and conform to Plain English standards as a minimum.

- Where an individual requires additional support, such as a translator, interpreter independent advocate or use of alternative methods of communication such as audio-recording or Braille, all reasonable measures will be taken to accommodate these requirements.

- All communications and records will be carried out and handled with full regard for patient confidentiality. Information will only be disclosed to third parties with the appropriate patient/next-of-kin consent.

3.11 The Quality & Safety Team will work alongside colleagues from other Directorates particularly within the Clinical Team and Legal Services Department to ensure all families are supported when there is a death in YAS’ care. This may be identified via the Mortality Review process or via a request from HM Coroner. The same level of involvement and support to relatives must be offered. Details of how this will be applied in practice will be covered within associated policies on the above processes.

3.12 Where there is a complaint that identifies that moderate or above harm has been caused to a patient, the Duty of Candour will be delivered via the Patient Relations Team as part of the complaint handling processes.

4.0 Training expectations for staff

4.1 All staff will be made aware of the Trust’s Being Open (Duty of Candour) Policy through corporate induction and basic training. This will be part of the Trust’s efforts to build a culture of openness, honesty, truthfulness, and transparency. Information on

this policy and process will also be covered as part of the 1-day Serious Incident Investigation & Root Cause Analysis training day.

4.2. Staff within the Quality, Governance & Performance Assurance directorate will receive guidance and support relating to their roles to ensure that they are able to carry out their duties effectively. The Deputy Director of Quality will ensure that this guidance and support is in place, including arranging provision for colleagues to attend bespoke Family Liaison training where available.

4.3 Senior managers responsible for taking part in 'being open' meetings will receive guidance and support on carrying out these responsibilities. This will be provided by (or on behalf of) the Head of Investigations & Learning.

4.4 All Trust staff will be offered the opportunity to complete levels 1 and 2 of the NHS England 'Patient Safety Syllabus', with colleagues in the Quality, Governance and Performance Assurance directorate offered support to complete further enhanced study as and when it becomes available.

5.0 Implementation Plan

5.1. The following stakeholders have been consulted in the development, consultation, and review of this policy:

Clinical Quality Development Forum (CQDF)	Clinical Governance Group (CGG)	Legal Services Manager
Patient Relations Manager	Information Governance Manager	Safety Governance Manager
Duty of Candour Co-Ordinator	Interim Associate Director of Quality and Safety	

5.2. The policy has been reviewed by members of the Clinical Governance Group and has been recommended to the Trust Management Group for approval.

5.3 The latest approved version of this Policy will be posted on the Trust Intranet site for all members of staff to view. New members of staff will be signposted to how to find and access this guidance during Trust Induction.

5.4. Archived documents will be stored electronically within the Document Library archive. A copy of previous versions of the policy will be additionally held by the policy author.

6.0 Monitoring compliance with this Policy

6.1 The YAS Being Open Log will maintain an up-to-date record of all current and archived cases of moderate harm, severe harm or death. Full details can be accessed via the Datix records.

6.2 Reports will be produced to inform the Quality Committee & Trust Board on the application of the Duty of Candour process as well as information being published within the Quality Account and Annual Report. Commissioners will receive updates on a case-by-case basis and through contract reports on the Duty of Candour.

6.3 An audit will be undertaken by the Head of Investigations & Learning monthly, quarterly, bi-annually and annually to ensure that all patient safety incidents with moderate or above recorded harm have been subject to the being open process.

7.0 References

- Being Open – Communicating patient safety incidents with patients, their families and carers, National Patient Safety Agency, London, 2009.
- Report of the Mid-Staffordshire NHS Foundation Trust Public Enquiry, Robert Francis QC, February 2013, HHC 947, London: The Stationary Office.
- Technical Guidance to NHS Contract 2013-14, Annex 4, available at: http://www.england.nhs.uk/wp-content/uploads/2013/02/contract-tech-guide.pdf
- Health and Social Care Act 2008 (Duty of Candour) Regulations 2014
- CQC 2015. Regulation 20: Duty of candour. Information for providers: NHS Bodies, adult social care, primary medical and dental care and independent healthcare. Regulation 20: Duty of candour | Care Quality Commission (cqc.org.uk)
- CQC 2021. The duty of candour guidance for providers. The duty of candour: guidance for providers (cqc.org.uk)
- Learning from Deaths guidance, National Quality Board (2019)
- Learning from Deaths guidance for NHS Trusts on Working with Bereaved Families and Carers, NHS England (2018)
- Public Health England – Duty of Candour Guidance (Updated October 2020) Duty of candour - GOV.UK (www.gov.uk)

- NHS England & Improvement – Patient Safety Incident Response Framework (PSIRF) NHS England » Patient Safety Incident Response Framework

- NHS England – Patient Safety Syllabus (2021) NHS Patient Safety Syllabus training - elearning for healthcare (e-lfh.org.uk)

- NHS Resolution – Saying Sorry (2017) NHS-Resolution-Saying-Sorry.pdf

- NOLAN The seven principles of public life, the Committee on standards in public life (1995) The Seven Principles of Public Life - GOV.UK (www.gov.uk)

8.0 Appendices

8.1 The following appendices are included within the policy:

Appendix A – Definitions

Appendix B – Roles & Responsibilities

Appendix C – Being Open (Duty of Candour) Standard Operating Procedure

Appendix D – NHS Resolution 'Saying Sorry' 2017

Appendix E – Care Quality Commission – The duty of candour: Guidance for providers (Identifying a notifiable safety incident)

Appendix A - Definitions

Apology

Expression of sorrow or regret in respect of a notifiable safety incident.

Notifiable Safety Incident

‘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.

The definitions of harm vary 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.

No harm

Incident prevented – any patient safety incident that had the potential to cause harm but was prevented, and no harm was caused to patients receiving NHS-funded care.

Incident not prevented – any patient safety incident that occurred but no harm was caused to patients receiving NHS-funded care.

Low Harm

Any patient safety incident that required extra observation or minor treatment and caused minimal harm to one or more patients receiving NHS-funded care.

Minor treatment is defined as first aid, additional therapy, or additional medication. It does not include any extra stay in hospital or any extra time as an outpatient, or continued treatment over and above the treatment already planned; nor does it include a return to surgery or readmission.

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).

Death

Any patient safety incident that directly resulted in the death of one or more patients receiving NHS-funded care.

The death must be related to the incident rather than to the natural course of the patient's illness or underlying condition.

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.

Relevant Person

The service user or in the following circumstances, a person lawfully acting on their behalf –

a) on the death of the service user, where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or

b) where the service user is 16 or over and lacks capacity (as determined in accordance with the Mental Capacity Act 2005 in relation to the matter.

Registered Person

The ‘registered person’ is responsible for carrying out, or delegating the responsibility for carrying out, the duty and must liaise with the ‘relevant person’.

The ‘registered person’ is the registered manager or the registered provider.

At Yorkshire Ambulance Service NHS Trust – This is the Chief Executive Officer (CEO)

Responsible Person

The ‘responsible person’ is the person best placed within the Trust to carry out the duty on behalf of the ‘registered person’

At Yorkshire Ambulance Service NHS Trust – This is the Head of Investigations and Learning (HOIL) or nominated Patient Safety Specialist (PSS).

‘Face to Face’

In order to meet the requirements under regulation 20, Trust representatives will be guided by patients and/or their carers/families/appointed advocate or representatives in discussion regarding how they wish to engage which may include (but not be limited too) telephone, written letter, face to face meeting, digital communications such as video conferencing/instant messaging services/recorded digital media.

Appendix B - Roles & Responsibilities

The Trust Board is responsible for:

- Establishing a culture of openness and candour and making a public commitment to the principles of Being Open.

The Quality Committee is responsible for:

- Gaining assurance that the Policy on Being Open & Duty of Candour is being delivered effectively in practice.

The Incident Review Group is responsible for:

- Maintaining an overview of all Being Open cases and agreeing the decisions and proposed course of action.

- Supporting those involved in Being Open cases with clinical expertise and/or best practice on management of meetings.

- Highlighting cases not automatically within the Being Open system (i.e. those graded as Yellow or Green through the Trust Risk Management Procedures) which should be considered for Being Open.

- Closing Being Open cases at the appropriate stage of the process i.e. when contact has been made, findings shared and no further action required or when contact has not been established despite reasonable attempts being made by YAS.

All Staff

- Be aware and act upon guidance as outlined in this policy
- Identify potential incidents and report though agreed processes
- Provide statements if required and participate in some feedback to patients where appropriate.
- At all times, act in an honest and transparent way.

Executive Director of Quality, Governance & Performance Assurance is responsible for:

- Being the ultimate lead within the Trust for Duty of Candour.

- Ensuring that the Being Open (Duty of Candour) Policy is fully integrated with other policies, specifically clinical governance risk management and complaints/concerns policies.

- Through attendance at the Incident Review Group, reviewing the notifiable safety incidents and confirming that agreed actions and next steps in line with this policy.

- Being accountable for decisions made in relation to the Duty of Candour process.

Executive Medical Director is responsible for:

- Chairing the Incident Review Group, reviewing notifiable safety incidents and confirming that agreed actions and next steps for current patient safety incidents are in line with this policy.

- Where required, nominating an appropriate individual to represent the Clinical Directorate at meetings with relevant persons.

Head of Investigations & Learning is responsible for:

- Acting as the 'Responsible Person' and Trust lead for Being Open for the management and application of the policy and representing the Trust with correspondence with relevant persons.

- Receiving notification of all new notifiable safety incidents resulting in moderate harm, severe harm or death and identifying how YAS will discharge its responsibility under this policy.

- Ensuring that each case has a nominated individual to act as a single point of contact and that communications are carried out by appropriately qualified and trained individuals.

- Ensuring that learning from Being Open cases is identified, triangulated with other sources of information and used to reduce future patient harm and inform the future development of this policy.

- Ensuring that staff involved in the Being Open process have the necessary skills and training to carry out their roles.

- Ensuring that there is an awareness by all Trust staff of the Duty of Candour and what this means in practice for working with honesty, openness and truthfulness.

- Presenting the Duty of Candour updates to the Trust Learning Group (TLG) and highlighting any cases that require discussion and action.

- Escalating any concerns relating to the Duty of Candour application to the Executive Director of Quality, Governance & Performance Assurance.

- Reporting to the commissioners under the standard contract updates on the Duty of Candour including any exceptions to the application of this process.

Quality and Risk Coordinator is responsible for:

- Maintaining the Duty of Candour log and the Datix records for each notifiable safety incident in relation to Duty of Candour application.

- Maintaining an archive of closed Being Open cases.

- Ensuring that full records are kept, and are accessible to appropriate parties, of Being Open cases.

- Acting as the single point of contact for the relevant persons throughout the Duty of Candour process where identified as appropriate.

Appendix C – Being Open (Duty of Candour) Standard Operating Procedure

NHS
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YAS Quality, Governance & Performance Assurance Standard Operating Procedure
Managing Duty of Candour

Responsible Manager: Simon Davies (Head of Investigations & Learning)
Responsible Lead: Clare Ashby (Executive Director of Quality, Governance & Performance Assurance) (interim)
Version: 3.1
Issue Date: June 2019
Review Date: November 2021

Aim

The aim of this document is to provide guidance to the members of the Quality, Governance & Performance Assurance team on the process for managing the Duty of Candour process.

1. Identification & Recording of Duty of Candour cases

Moderate & above harms

- All incidents with moderate or above patient harm are alerted to the Safety Governance Manager and coordination team. A review will be undertaken upon alert of the incident to assess whether the severity is accurate. This will be done by reviewing the information available and assessing the patient outcome. Where appropriate incident severity will be downgraded, and rationale recorded on the Datix record.

- Where it is determined that the level of harm is accurate discussions will take place with the Executive Director of Quality, Governance & Performance Assurance and other appropriate colleagues to assess whether the incident meets the criteria for reporting as a Serious Incident and whether it meets the Duty of Candour criteria.

- Where a decision is made that Duty of Candour criteria has been met the Head of Investigations & Learning and Quality & Risk Coordinator will be notified to initiate the Duty of Candour process.

- Where further discussion is required or in instances where incidents with moderate or above harm are reported within 2 working days of Incident Review Group, the Safety Governance Manager will present these to the Incident Review Group (IRG).

- Discussion will be held at IRG to determine whether the level of harm is accurate. This is based on assessment of whether YAS contributed to this level of harm.

- If level of harm is determined to be less than moderate the incident should be downgraded on Datix with notes to explain the rationale for downgrade. This will be done by the Safety Governance Manager or nominated deputy. In these cases, downgrading the level of harm from moderate or above will mean they will no longer meet Duty of Candour criteria.

- If the level of harm is determined to be accurate at moderate or above these cases will be added to the Duty of Candour log and documented within the Datix record by the Head of Investigations & Learning.

- On occasion where the criteria for Duty of Candour are not met following discussion at IRG (refer to the national Duty of Candour guidance for examples of when this might be relevant) these cases would not be added to the log but rationale for decision to be documented on the Datix record by the Head of Investigations & Learning.

Other cases

- On occasion IRG or Trust Learning Group (TLG) will request Duty of Candour to commence on cases unrelated to the degree of harm due to the nature of the case. This will follow the above process for recording on the Duty of Candour log and documented on the Datix record by the Head of Investigations & Learning.

- If other persons across the Trust identify cases for Duty of Candour consideration these will be flagged to the Head of Investigations & Learning and/or be taken through the above outlined process of discussion and decision making at IRG.

Audit & Monitoring

- On occasion there may be incidents that get upgraded to moderate or above level of patient harm outside of the IRG process following further information gathering.

- A monthly check will be conducted by the Head of Investigations & Learning & the Quality & Risk Coordinator to identify any cases that have not undertaken the IRG review process. These will be flagged to the Safety Governance Manager for review of the degree of harm.

- Where it is determined that the level of harm is accurate this case will be flagged to the Head of Investigations & Learning to commence the Duty of Candour process.

- Where it is determined that the level of harm is not accurate the Safety Governance Manager will downgrade the level of harm and record on Datix as outlined above.

2. Contact Details

Agreed Lead for Duty of Candour Process

- If identification of the incident was highlighted via a complaint from the patient/relative the Patient Relations Manager will lead the Duty of Candour process having already developed a relationship and contact with the patient / NOK. This communication will follow the 4Cs policy and practice.

- Where the case was highlighted via a service-to-service complaint or any other route the Head of Investigations & Learning will lead the Duty of Candour process.

- If the incident is an Integrated Urgent Care (IUC) incident the IUC Head of Nursing & Quality Assurance will lead on the Duty of Candour process in regular liaison with the central Quality Team.

- If the investigation is joint with another organisation, whoever is deemed the lead for that investigation should lead the Duty of Candour process. This needs to be explicitly stated and agreed at the start of the investigation. If another Trust is leading on the Duty of Candour process YAS will feed into their investigation and offer attendance at meetings or contact independent to the other Trust if requested by the family. Enquiry relating to this will be led by the lead organisation and regular updates will be provided to YAS throughout the duration of this contact.

- If the action of the other Trust is unclear YAS will initiate direct contact with the patient or family.

Obtaining Patient Contact Details

- If the patient is able to participate in the Duty of Candour process, the Quality & Risk Coordinator will obtain contact details for the patient.

- The Electronic Patient Record (ePR) would be obtained and reviewed to identify the correct contact details for the patient. If the ePR does not contain appropriate information (primarily phone number and/or address) and we cannot obtain this internally either via IUC or Patient Relations, this information will be sought from the GP Practice, HM Coroner or the receiving hospital.

- Contact details will be recorded on the Datix record by the Quality & Risk Coordinator.

- In any case where contact details are unobtainable after exhausting all routes, detailed documentation will be added to the Trust incident record noting attempts made and routes used.

Next of Kin Details

- If the patient is unable to participate, next of kin (NOK) details will be sought.
- As outlined above, these will be obtained from the ePR where recorded accurately and sufficiently. If the ePR does not include full relevant information and we cannot obtain this internally information will be sought externally.
- When the Trust declares a Serious Incident in which the patient has deceased the Legal Services Department informs HM Coroner. As part of this process, they will also request NOK details to be returned to YAS. If the case has not been referred to HM Coroner (i.e. when not reported as an SI) or if NOK details are not made available, attempts will be made to obtain the NOK details via the GP Practice and/or the receiving hospital.

If all of the above attempts have been unsuccessful the case will be closed on the basis of reasonable attempts having been made to obtain the contact details. All of the above attempts should be fully documented on the Datix record by the Quality & Risk Coordinator and presented to IRG for final decision to close the case on the basis of lack of contact details. Contact details should aim to be obtained within 5 working days of the being open process being initiated.

3. Making Contact

- Preferred initial contact will be initiated by the Head of Investigations & Learning to the patient or NOK within 5 working days of the contact details being established. This should be done via letter (produced by the Head of Investigations) and should be sent recorded delivery. A letter template can be found in the Duty of Candour folder on the Trust file share system.
- If the case is a SI then the initial letter should also include the 'Patient Information Leaflet' however this is not necessary for NON SI Duty of Candour cases.
- If this cannot be done or if it is deemed more appropriate based on individual circumstances, a phone call should be made by the Head of Investigations & Learning. 3 attempts of a phone call will be made over a period of 5 working days. No voice messages will be left in line with information governance guidelines. A follow up letter after telephone call is required.
- Within the letter the patient or NOK will be invited to participate in the investigation if they wish to do so. As an alternative if they do not wish to participate, they will be offered to receive the findings at the conclusion of the investigation. They will also have the choice not to be involved if they so wish. Contact details of the Quality & Risk Coordinator will be provided.

4. Participation

- The letter will advise the patient or NOK to contact the Quality & Risk Coordinator if they wish to participate in the investigation or receive feedback following investigation or if they do not wish to be involved.
- The letter will state that unless we receive specific instruction that the patient or NOK do not want to take part or be made aware of the findings from the investigation, a subsequent letter will be sent upon completion of the investigation to arrange a meeting to share the findings.

5. Investigation

- The investigation into the incident will now be underway. Please refer to the investigation's guidance within the Quality & Risk Team for details of investigation process. Timescales outlined above to the patient or NOK are in line with the appropriate investigation timescales.
- If deemed appropriate by the Lead Investigator or if the patient or NOK request certain aspects to be covered as part of the investigation this will be built into the investigation and where appropriate further information may be sought from the patient or NOK if involved in the incident by the Lead Investigator.

6. Regular Follow up and Review (PSIRF Pre-Action)

- In line with expectations from 2022, monthly updates should be provided to the family/relative/patient, offering realistic timescale regarding completion. If any pertinent details are known at this point, these should be briefly relayed within the contact, with a genuine apology and condolences where appropriate.
- This can be done by either the coordinator for DOC, or the investigator themselves with support from the wider team.
- During any period where the Trust is unable to meet 60-day deadlines such as national pandemic or disruption which affects BAU, it should be clearly identified to family/relatives/patients that the Trust is working under extreme pressure and doing everything possible to maintain usual levels of service and minimise disruption.
- Family/Relatives/Patients should be offered the opportunity to add any new information or questions into the investigation at this point.

7. Feedback

- Following conclusion of the investigation feedback will be provided to the patient or NOK.

- If the incident has been declared an SI, contact will be made by the Head of Investigations & Learning to the patient or NOK to arrange a meeting if one not already scheduled. Contact should be made within 5 working days of the investigation concluding. This contact will be made via letter in the first instance and email or telephone where patients and NOK have outlined this is their preferred method of contact with YAS. When contacting via telephone this will be in line with the above outlined process; if contact is not made within 3 attempts, a letter will be sent if address details are available. If no communication is received within 4 weeks of a letter being sent the case will be closed.

- The meeting will be offered within 4 working weeks of the investigation concluding however this is dependent on patient or NOK availability. If the patient or NOK does not wish to meet a telephone discussion can be offered or written findings from the investigation can be posted or emailed password protected. This will be in the format of an investigation report.

- If a meeting is held to feedback the findings to the patient or NOK this will be led by the Head of Investigations & Learning (or appropriate deputy) and an appropriate senior manager from the service involved in the incident (or the Lead Investigator). In the first instance the meeting should be offered at one of the Trust's 3 administration offices in Wakefield, York or Rotherham. Alternatively, a local GP Practice may be sought. Travel expenses of the patient or NOK can be covered and if the meeting place is not suitable for the patient or NOK an alternative arrangement can be agreed.

- Meeting in private locations such as patient's homes will be considered on a case-by-case basis and lone working requirements must be utilised as part of this alternative arrangement to ensure safety of those attending from the Trust.

- **As a minimum requirement, 2 colleagues should be present where meetings are arranged in a private location.**

- Where Patient Relations are leading the Duty of Candour process (when the event initiated as a complaint) a meeting will also be offered and details of this is outlined within the 4Cs policy.

- A recording of the meeting will be taken using the Dictaphone held by the Quality and Risk Coordinator (with agreement from the participant) and a copy of the recording will be shared with them following the meeting should they wish to receive this. If sending a copy, a confidentiality agreement should be signed at the meeting. If they do not want the meeting to be recorded, notes should be taken that summarise the key discussion points and any actions. A follow up letter should be sent after the meeting. The investigation report should be shared with the participants, and this can be before or after the meeting depending on what is agreed.

8. Closure & Learning

- Following the feedback meeting the case is then taken to IRG for closure and all records updated on Datix.
- If the response was shared in writing, or if no response was received from the patient following the Investigation Finished letter, the case can be closed 4 weeks later if no further correspondence is received.
- All cases for closure must be agreed at IRG,
- Any learning relating to the Duty of Candour process is recorded on Datix and appropriate action taken for improvement and reported to IRG if identified. This could be highlighted within the meeting with the patient or NOK or via internal process
- Should a family respond to the Trust following closure of the case, the case should immediately be reopened, and requests should be complied with in a timely manner.

Appendix D – NHS Resolution ‘Saying Sorry’ Published 2017

Saying sorry

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

Advise / Resolve / Learn

Saying sorry is:
<u>always</u> the right thing to do
<u>not an admission</u> of liability
<u>acknowledges</u> that something could have gone better
the first step to <u>learning</u> from what happened and <u>preventing</u> it recurring

Why?

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

When?

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

Who?

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

What if there is a formal complaint or claim?

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

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

How?

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

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

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

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

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

What about the Duty of Candour?

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

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

Don't say

- x I'm sorry you feel like that
- x We're sorry if you're offended
- x I'm sorry you took it that way
- x We're sorry, but...

Do say

- ✓ I'm sorry X happened
- ✓ We're truly sorry for the distress caused
- ✓ I'm sorry, we have learned that...

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

Helen Vernon, Chief Executive, NHS Resolution

For more information

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

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

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

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

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

The NHS Constitution

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

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

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

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Appendix E – CQC Duty of Candour Guidance for Providers, Identifying a notifiable safety incident.