South East Coast Ambulance Service NHS
NHS Foundation Trust

Being Open and Duty of Candour Procedure

Contents

1 Scope

1.1. Every healthcare professional must be open and honest with patients and families or next of kin if appropriate. Every NHS Trust, since November 2014, has a statutory responsibility in relation to Duty of Candour.

1.2. Candour is defined by Robert Francis as: “The volunteering of all relevant information to persons who have or may have been harmed by the provision of services, whether or not the information has been requested and whether or not a complaint or a report about that provision has been made”.

1.3. The Being Open principles and ethical duty of openness apply to all incidents and any failure in care or treatment. The Duty of Candour applies to incidents whereby moderate harm, significant harm or death has occurred.

1.4. It is a matter of judgment that needs to be exercised on a case by case basis to determine whether an incident that meets the Duty of Candour criteria has occurred. What may not appear to be such an incident at the outset may look very different once more information comes to light, and may therefore lead to an incident becoming notifiable under the Duty of Candour.

1.5. **Purpose of this Procedure:**

1.5.1. This Procedure informs staff of the Duty of Candour requirements and ensures they communicate effectively within a structured manner with patients or their families when patients sustain moderate harm, severe harm or who die following a notifiable patient safety incident.

1.5.2. The associated Duty of Candour Policy sets out the background upon which the Duty of Candour was introduced (Regulation 20), the contractual requirements as determined by the NHS Standard Contract (Service Condition 35) and the underlying principles associated with the “Being Open” Guidance introduced by the NPSA in 2009.

2 Procedure

2.1. The requirements of the Duty of Candour are as follows:

2.2. Within 10 working days from the date of the incident, or as soon as is reasonably practicable once the Trust is made aware of a patient safety incident, the healthcare professional must:

(a) notify the ‘relevant person’ (this is usually the patient but may in some circumstances be the relative, carer or advocate) that the incident has occurred and;

(b) provide reasonable support to the relevant person in relation to the incident.

2.3. The notification must:

(a) be given in person (either face-to-face, or by telephone) by one or more members of staff (in the instance when it may not be possible to notify the relevant person in person refer to section 3.1.1. of this procedure). This should be done within 10 working days of becoming aware of the incident, or as soon as reasonably practicable;

(b) provide an account of all the facts known about the incident to date;

(c) advise the relevant person what further enquiries into the incident will be undertaken;

(d) include an apology and/or a sincere expression of regret, and;

(e) be recorded in writing in the notes. This notification must be followed up in writing to the relevant person.

2.4. The Trust requires that this is done within 10 working from the date of the incident, or as soon as is reasonably practicable once the Trust is made aware of the incident.

2.5. The member of staff should be clear in the first meeting that the facts may not yet have been established, tell the relevant person only what is known and believed to be true, and answer any questions honestly and as fully as they can.

2.6. The aim of the Duty is to ensure that patients are told when harm occurs as a result of the care they receive. Where the degree of harm is not yet clear but may fall into the moderate or above categories, then the relevant person must be notified

2.7. **Overview of the Duty of Candour Requirements**

2.7.1. The Trust and its staff must act in an open and transparent way in relation to care and treatment provided to its patients and service users.

2.7.2. Staff must notify the relevant person, in person (either face-to-face, or by telephone), as soon as is reasonably practicable after becoming aware (within ten working days or as shift patterns allow) that a notifiable safety incident has occurred, and provide support to them in relation to the incident, including when giving the notification.

2.7.3. The Trust must provide an account of the incident which, to the best of the Trust's knowledge, is true of all facts as known about the incident as at the date of notification.

2.7.4. The Trust must advise the relevant person what further enquiries the Trust believes are appropriate.

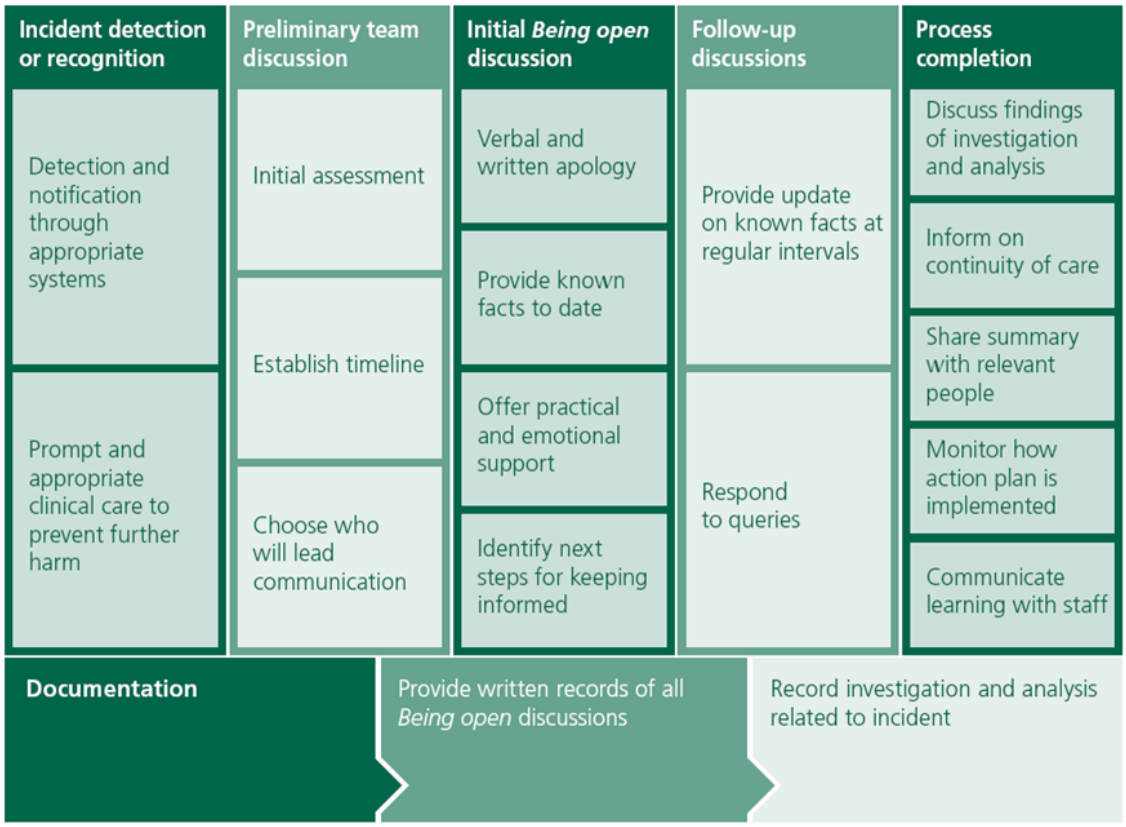
2.7.5. The Trust must offer an apology.

2.7.6. The Trust must give consent the relevant person a written notification, which confirms all of the above, together with the results of any further enquiries.

2.7.7. Any investigation reports must be shared with the patient, family or carer within ten days of being signed off as complete.

2.7.8. The Trust must keep securely a written record of all and every communication with the relevant person which must be uploaded onto the Datix incident record

Figure 1. Overview of the Duty of Candour Process:



3 Notifications

Notifications required following detection of a notifiable patient safety incident:

3.1. The patient or their family must be informed within 10 working from the date of the incident, or as soon as is reasonably practicable once the Trust is made aware of the incident. This should be done by the most senior healthcare professional within the clinical team or ideally by someone who is known to, and trusted by, the patient and/or family.

3.1.1. If the patient and/or family cannot be contacted in person (either face-to-face, or by telephone), or declines to speak to the Trust, the verbal and written notifications outlined in 2.3. of this procedure do not apply. However,

a written record must be kept of all attempts to contact or speak to the relevant person.

3.1.2. The person selected to notify the patient and/or family should have a good grasp of the facts of the incident, be senior enough to have sufficient training, experience and expertise and be credible to the patient and/or family; have excellent interpersonal skills and be able to communicate sympathetically and effectively; be willing and skilled in offering an apology, reassurance and feedback; be able to maintain a relationship with the patient or family throughout the forthcoming investigation; be able to provide continued support and information; be culturally and socially aware, and be informed about the specific needs of the patient and/or family.

3.1.3. **Apology**: a key element of the Duty is that a sincere expression of sorrow or regret must initially be provided verbally and then in writing to the relevant person for any suspected or actual harm caused. The apology is not related to the cause of the harm.

3.1.3.1. The wording must make it clear the Trust and relevant staff are very sorry for the suffering and distress caused. An apology is not an admission of liability. It will not compromise the Trust's ability to deal with any subsequent complaint or claim and no member of staff will be admonished for saying sorry to a patient or their family in such circumstances as it is the right thing to do

3.2. **The initial notification**: must be in person (either face to face, or by telephone) and should be held as soon after the incident as possible. Consider the patient's and/or their family's home and social circumstances. Ideally offer them a choice of times and confirm the chosen date in writing. Do not cancel the meeting unless absolutely necessary.

3.2.1. It is important that the patient and/or family are given the opportunity to ask questions and have any matters they raise investigated. It is often appropriate for them to be interviewed by the Investigating Officer as part of the Root Cause Analysis.

3.2.2. The manner of feedback to the patient and/or family and timescales should also be discussed and agreed at this meeting. The patient and/or family's wishes must be taken into account. Be aware that the patient and/or family have the right to change their mind as the investigation proceeds about being involved or not being involved.

3.2.3. Consent should be gained from the patient to share the information concerning the incident.

3.2.4. During the **initial notification**, the staff member leading it **must** also:

a) acknowledge the incident and apologise for the pain, distress and suffering caused
b) Include in the account all the facts known at that point in time. Be cautious where the facts are not yet known. It can be more damaging

to speculate inaccurately and prematurely than to investigate and find facts and then to provide the extra information;

c) explain the investigation process and assure the patient and/or their family that more information will be shared if and when more information becomes available during the investigation;
d) if appropriate, ask the patient and/or family why they thought it went wrong and an error occurred;
e) **always** provide an opportunity for the patient and/or family to ask any questions;
f) agree what further enquiries into the incident are appropriate;
g) inform the patient and/or family what steps are being / will be taken to prevent the incident recurring;
h) provide an explanation as to what will happen next in terms of the short and/or long term treatment plan;
i) not attribute blame, nor provide conflicting information, nor deny responsibility for what happened;
j) suggest any sources of additional support and counselling and provide written information if appropriate;
k) **always** check the patient and or family have understood what they have been told taking into account cultural or generational factors that may influence the discussion;
l) provide the name of a member of staff and their contact details who they can speak to again;
m) agree with the patient and/or family any future meetings if appropriate;
n) be recorded in a written record which is kept securely by the team manager.

3.2.5. The following will help to set the right environment for the meeting:

3.2.5.1. Consider carefully where the patient and/or family would feel most comfortable. If not held at the patient's or family's home the meeting should be held in a quiet room where staff will not be interrupted or distracted by work;

3.2.5.2. the meeting should not be hosted near to the place where the incident occurred if this may be difficult for the patient and/or their family;

3.2.5.3. everyone present should be introduced and their role explained to the patient and/or family who should be asked if they are happy with those present;

3.2.5.4. the patient and/or their family should always be spoken to in a sensitive and caring manner. Do not use jargon or acronyms; use clear, straightforward language;

3.2.5.5. the needs of the patient should be considered: for example, linguistic, cultural or learning disabilities, including for example, using the patient's preferred name.

3.2.5.6. Be aware that patients and their families may be anxious, angry and frustrated even when the Duty of Candour discussion is conducted appropriately.

3.2.6. The **investigating officer** is responsible for keeping the patient and/or family up to date with how the investigation is progressing, maintaining a dialogue by addressing new concerns, sharing new information as and when it becomes available and providing information on counselling as appropriate.

3.2.6.1. Depending upon the severity of harm caused, the person taking the lead should be supported by at least one other member of staff, such as a member of the healthcare team treating the patient or a member of the Quality and Governance team, or in some circumstances the Nursing or Medical Director.

3.2.6.2. Some incidents that result in moderate harm, severe harm or death will result from errors made by staff whilst caring for the patient. In cases where the healthcare professional who has made the error wishes to attend the discussion and apologise personally, they should feel adequately supported by their colleagues throughout the meeting. Where the patient or their family express a preference for the clinician not to be present, it is advised that a personal written apology is given to the patient or their family during this initial discussion.

3.2.6.3. It is unacceptable for junior healthcare staff (including Band 6), to communicate patient safety information alone or to be delegated the responsibility to lead a Duty of Candour discussion except when all of the following criteria have been considered:

- they have expressed a wish to be involved in the discussion;
- the senior healthcare professional responsible for the care is present for support;
- the patient and/or family agree

3.2.7. **Recording** the initial notification and any subsequent meetings **in writing**:

3.2.7.1. The senior member of staff leading the Duty of Candour discussion is responsible for maintaining complete records, a copy of which should be uploaded onto Datix.

3.2.7.2. The written records of the Duty of Candour discussion(s) should include:

a) the time, place, date, as well as the name and relationships of all attendees;
b) the plan for providing further information to, and involvement of, the patient and/or family;
c) offers of assistance and the patient's and/or family's response;
d) the questions raised by the patient and/or family or their representatives and the answers given;
e) plans for follow-up, as discussed;
f) progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient and/or their family;
g) copies of letters sent to patients, family and the GP for patient safety incidents not occurring within primary care;

h) copies of any written reflections taken in relation to the patient safety incident; a copy of the incident report. [Be aware that families are often distressed by the terms P1, P2 etc. which are often used in incident forms so where this occurs, a covering explanation should always be included].

3.2.8. **The written notification:**

3.2.8.1. The initial notification (whether face to face meeting or by telephone) must be followed up by a letter from either the appropriate healthcare professional or the team manager and include an apology. It is the responsibility of the Service Manager to ensure this occurs although this task may be delegated to a member of staff who has a good relationship with the patient or family. The letter should include what form the investigation will take, the timescale for completion, how the patient and/or family wish to be involved in the investigation, and any matters which the patient or their family requested be addressed during the investigation.

3.2.8.2. All communication should be clear, sympathetic and effective throughout all stages of the Duty of Candour process. Appropriate language should be used and jargon and abbreviations should be avoided. In the event a should die, a letter of condolence should be sent to the family. It should be discussed and agreed by the clinical team who is the most appropriate person to sign and send this letter. If a decision is taken not to do so, a written record should be maintained of the reasons why.

3.2.8.3. Relevant staff may continue to meet with the patient and family to support continuity of communication and relationship building. However, records of any meetings must be maintained and a copy uploaded onto Datix.

3.2.9. A **written record** must be maintained by the investigating officer of the progress with the investigation and contacts with the service user and family.

3.2.9.1. If the patient and/or family is already aware of the incident (e.g. they brought the matter to the Trust's attention via the Complaints and PALS team) then the investigating officer should work with the Complaints team to ensure the patient or family are invited to meet with them (the investigating officer) on a mutually convenient date and time.

3.2.9.2. Where a Serious Incident (SI) investigation is already underway and a complaint about the same aspect of service or care deliver is received, the situation must be discussed with the complainant to ascertain, with approval, whether it is appropriate for the questions to be added to the investigation. The complaint would either then:

a) remain open if there are outstanding issues related solely to the complaint and not encompassed within the SI investigation; or
b) be closed if all matters are covered in the SI investigation. The complainant would receive a copy of the full SI investigation report.

3.2.9.3. Should a complaint highlight that a Serious Incident (SI) has occurred but has not been identified as such through the Trust reporting systems, the Serious Incident (SI) process would be triggered. All relevant concerns from the complaint would be added to the Terms of Reference for the investigation. At this point the options for the status of the complaint would be as per reference 3.2.9.2. a) and b), as above.

3.2.10. **Treat each case on its own merits**: each patient safety event is different and for this reason the roles and responsibilities outlined in this section are meant as a guide. Patients, staff and relevant others will respond differently to a patient safety event and for this reason roles and responsibilities will often be identified and agreed on a case-by-case basis

3.2.11. **Provision of known facts to date**

3.2.11.1. The known facts are those agreed by the multidisciplinary team. Where there is disagreement, communication about these events should be deferred until after the investigation has been completed. It is very important that staff do not speculate as to what happened but await the outcome of the investigation. The patient and/or their family should be informed that an incident investigation is being carried out and more information will become available as it progresses. Where an incident result in the death of a patient with mental health problems and suicide is suspected, the family will often have very valuable information about the patient's mood and behaviour before the incident and it is vital their knowledge and input into this process is sought.

3.2.12. **Root Cause Analysis (RCA) Investigation**

3.2.12.1. When an investigation is required, it will be undertaken in line with the Trust's incidents policy(ies).

3.2.12.2. When drafting the terms of reference for the investigation, the patient's and/or family's understanding of what happened must be taken into consideration. It must be demonstrated that any aspects the patient or family asked to be investigated are being heard, taken seriously and addressed. Sometimes the family may be the only people involved with the patient from the start to the end and often have other insights into what happened, when and why.

3.2.12.3. It is important that the investigating officer maintains a dialogue by addressing any new concerns, sharing new information as and when it becomes available and providing patients and/or their families with the information and findings from the investigation. They may also need to signpost the patient or family to the various counselling or support services available.

3.2.12.4. Meetings should be held when there is important information to report and these should always be followed up in writing with the investigating officer reiterating key points discussed and confirming in writing any information provided or any timescales/deadlines agreed.

3.2.12.5. At the conclusion of the investigation, the investigating officer should offer to meet with the patient and/or family to provide feedback on the findings of the investigation and to share a copy of the report. If the patient or family decline the offer of a meeting, the report should be sent to them under cover of a separate letter.

3.2.12.6. Any recommendations identified in the report's action must be assigned to named individuals with a clear timeframe for completion.

3.2.13. **Addressing the support needs of the patient and/or family members**

3.2.13.1. Throughout the incident notification process and subsequent investigation, the clinical team and any staff who are keeping in contact with the patient and/or family should offer both practical and emotional support.

3.2.13.2. Patients should be reassured that they will continue to be treated with respect and compassion and according to their clinical needs even in circumstances where there is a dispute between them and the healthcare team. If a patient expresses a preference for their healthcare needs to be taken over by another team, the appropriate arrangements should be made for them to receive treatment elsewhere.

3.2.14. **Completing the Duty of Candour process**

3.2.14.1. The offer of an investigation feedback meeting to the patient and/or family must be made within 10 working days (or as working shift patterns allow) of the investigation being signed off by the Trust, as soon as reasonably practicable. This should include the full written RCA report and action plans. The feedback meeting is an opportunity to have a frank and open discussion of the findings and the lessons learnt. Following this meeting a letter should be sent to the patient and/or family, including a final apology.

3.2.14.2. The following information should also be provided at the meeting:

- where shortcomings in the delivery of care that led to the patient safety incident are identified we should repeat the apology for any resulting distress that has been caused;
- an outline of the chronology of care and a summary of the factors that contributed to the incident (included within the RCA);
- an outline of the findings and lessons learnt (included within the RCA);
- information on what has been and will be done to avoid recurrence of the incident and how these improvements will be monitored.

3.2.14.3. Where the patient or family decline the offer of a final feedback meeting, the investigation report should be sent to them under cover of a separate letter. It should be noted that some families may ask not to see the final report, which is, of course, their decision. Recording of this decision should be made within Datix as other Duty of Candour information is.

3.2.15. **Occasions when information may be withheld:**

3.2.15.1. It is expected that in most cases there will be a complete disclosure and discussion of the findings of the investigation and analysis. In very rare cases information may be withheld or restricted. In such cases initial advice must be sought from the Head of Legal Services and the patient and/or family will be informed of the reasons for the restrictions. Examples where information may be excluded:

- the information might adversely affect the health of the patient;
- investigations are subject to specific legal requirements;
- performance action or measures are being taken with a named member of staff;
- there is a danger of adverse repercussions for Trust staff;
- When a competent patient withholds consent to share information with their family and subsequently dies, a redacted RCA report should be shared with the family.

3.2.16. **Confidentiality and Effective Information Sharing**

3.2.16.1. Trust staff have a common law duty of confidentiality to patients and are expected to handle the personal confidential information of patients in accordance with the Data Protection Act (1998) and the Caldicott Principles. Please refer to the Trust's Information Sharing Policy for further information.

3.2.16.2. Caldicott and Data Protection Principles are not an obstacle to sharing information. The statute and relevant Trust policies provide the framework for staff to share information effectively to ensure patients receive the most appropriate and safest treatment and care from the Trust's clinical services. It is of crucial importance that staff understand patients' wishes in relation to sharing information with families/carers and must respect their wishes. At times when patients refuse to share information with their carers and family members despite a good history of relationship, staff are expected to outline the advantages of sharing information effectively.

3.2.16.3. When a competent patient withholds consent to share information with their family and subsequently dies, a redacted RCA should be shared with the family. This matter should be considered at the 48-hour panel and the decision of the meeting minuted by the Panel Chairperson.

3.2.16.4. Please refer to Subject Access Requests and Disclosure of Personal Data Procedure when a patient dies and the family request access to the patient's clinical records.

3.2.17. **Investigation Findings which require further action**

3.2.17.1. Individual members of staff who are professionally registered are separately subject to the professional Duty of Candour, which is overseen by the professional regulatory bodies such as Health and Care Professions Council (HCPC) and Nursing & Midwifery Council (NMC). Where the investigation identifies possible breaches of the professional duty of staff, the investigating officer must discuss this with their relevant manager and HR Team to ensure all appropriate actions are taken.

3.2.17.2. Wherever appropriate, it may be helpful to send a brief communication to the patient's GP, describing what happened. It should contain summary details of:

- the nature of the safety incident and the ongoing care and treatment;
- the current condition of the patient;
- key investigations that have been carried out to establish the patient's clinical condition;
- recent results, and prognosis.

3.2.17.3. Consideration should be given to contacting the referring GP at an early stage for incidents that have not occurred within primary care but have implications for continuity of care. By informing them they have an opportunity to offer their support to the patient and/or their family.

3.2.17.4. Where a Serious Incident (SI) report has been written in relation to a patient whose death is being investigated by HM Coroner and the SI report is relevant to the circumstances surrounding the death, the Trust's Legal Services department should send a copy of the report to the investigating Coroner.

3.2.18. **Special considerations for consent**

3.2.18.1. For more detailed guidance relating to special considerations of consent including (but not limited to) children, patients with mental health issues, patients lacking mental capacity, difficulty in expression, languages other than English, or cultural considerations, please see the policy: Consent for Treatment Policy.

3.2.19. **Patients who do not agree with the information provided**

3.2.19.1. Sometimes, despite the best efforts of healthcare staff or others, the relationship between the patient, their family and carers and the healthcare professional breaks down. They may not accept the information provided or may not wish to participate in the Duty of Candour process. In this case, the following strategies may assist:

a) attempt to resolve the issue as soon as it emerges;
b) where the patient agrees, ensure their family and carers are involved in discussions from the beginning;
c) ensure the patient has access to support services;

d) where the senior health professional is aware of the relationship difficulties, provide mechanisms for communicating information, such as the patient expressing their concerns to other members of the clinical team;
e) offer the patient, their family and carers another contact person with whom they may feel more comfortable. This could be another member of the team or the individual with overall responsibility for clinical risk management;
f) use a mutually acceptable mediator to help identify the issues between the healthcare organisation and the patient/service user, and to look for a mutually agreeable solution;
g) ensure the patient, their family and carers are fully aware of the Trust's formal complaints procedure;
h) write a comprehensive list of the points that the patient, their family and carers disagree with and reassure them you will follow up these issues and ensure they are addressed.

4 Definitions

4.1. **Notifiable Safety Incident** means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in: (a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or (b) severe harm, moderate harm or prolonged psychological harm to the service user.

4.2. The term **Moderate Harm** means a) harm that requires a moderate increase in treatment, and b) significant but not permanent harm.

4.2.1. "Moderate increase in treatment" means 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).

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

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

4.5. The term **Prolonged Pain** means pain which a service user has experienced, or is likely to experience, for a continuous period for at least 28 days.

4.6. The term **Relevant Person** means the service user or a person lawfully acting on their behalf (see definitions for full description).

4.6.1. Regulation 20 uses the terms "service user" and "relevant person". However, for ease of reference, the term 'patient' and 'family' are being used throughout this document. 'Patient' refers to all people who make use of any of the health or social care services provided by the Trust. 'Family' refers to anyone who represents the patient with their consent. Identify key phrases or words and explain their meaning to aid understanding and avoid misinterpretation.

5 Responsibilities

5.1. The **Chief Executive Officer (CEO)** is ultimately accountable for the implementation of this Policy.

5.2. The **Trust Board** have the responsibility to obtain assurance that the processes described work effectively and support the board level public commitment to implementing the being open principles and Duty of Candour requirements.

5.3. The **Director of Nursing and Quality** has delegated responsibility to ensure compliance with the 'Being Open' and 'Duty of Candour' process. The Director of Nursing and Quality will report to the Trust Board and the Chief Executive Officer on matters relating to this Policy.

5.4. The **Senior Management Teams** within the Trust are responsible for ensuring compliance with this policy and the associated processes within their areas / stations / departments.

5.5. **All staff** employed by the Trust are required to follow the principles outlined in this policy and demonstrate the principles of 'Being Open' and adhere to the statutory requirements of 'Duty of Candour' in their interaction with patients.

6 Audit and Review

6.1. The Head of Compliance (or equivalent role) will review this policy every three years or sooner if new legislation, codes of practice or national standards are introduced.

6.2. The effectiveness this policy will be assessed annually by the Head of Compliance (or equivalent role). Where non-compliance is identified as a result of the monitoring processes described in section 8.1 the policy and its associated documentation will be reviewed to ensure its aims and objectives are capable of being met.

7. References

7.1. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

7.2. Patient Briefing, Being Open – 'saying sorry when things go wrong,' NPSA. 19th November 2009

7.3. Seven steps to patient safety, NPSA, August 2004

7.4. The Mid Staffordshire NHS Foundation Trust Public Inquiry, Chair by Robert Francis QC, 2012

7.5. http://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour

7.6. CQC Learning, Candour and Accountability Review 2016

7.7. NHSE National Guidance on Learning from Deaths 2017


South East Coast Ambulance Service NHS
NHS Foundation Trust
Step by Step Guide to Duty of Candour
Actions for station level /department
Actions for investigating managers
As soon as incident is known...
Within 10 working days of incident:
Within 60 days of incident:
Within 10 working days of closure of investigation:
Manage immediate issue and make safe
Notify patient in person with compassion, understanding and regret for incident that has occurred
Offer support
Investigating Manager conducts Investigation using Root Cause Analysis (RCA)
Offer the patient a copy of the investigation report
Offer and provide immediate support and assistance to patient and any staff affected by the incident
Notification must:
Be truthful and open
Include the sharing of a copy of the Trust's Duty of Candour process
Offer interim updates to patient and/or family during the course of the investigation
Provide appropriate support to patient and staff
Obtain approval of the relevant Director before the patient report is shared with the patient or family
Record incident on Datix (IWR-1)
Be conducted by the department involved and include the treating crew member/clinician
Maintain full written records of any form of contact or meeting with the relevant person in relation to the incident and upload these to Datix
Send a copy of the approved investigation report with a covering letter (templates available)
Discuss next steps with line manager and/or professional standards team to define Duty of Candour roles and identify Investigating Manager
Provide all the facts currently known about the incident
Include a sincere apology for the harm caused
Record any refusal by the patient or family of a meeting or other contact or information in relation to the incident using Datix
Share lessons learned to help improve systems of care and service delivery
Be supplemented by a written notification (templates available)
Be recorded in writing for audit purposes
Duty of Candour became a statutory requirement for all CQC registered Trusts from 27 November 2014
For more information refer to this Trust's 'Being Open and Duty of Candour Policy'

Appendix B: Datix Duty of Candour Screenshots

When a notifiable **patient safety** incident is reported, or a complaint is received, the Datix electronic incident reporting system has a new Duty of Candour menu. The upgraded system contains a link to the National Learning and Reporting System (NRLS) detailing the definitions of the categories of harm, and an activated drop down menu of 9 questions relating to the Duty of Candour process.

The incident cannot be finally approved and closed until this additional information has been added and documented, and the completed investigation report uploaded to the system. (AMBER report for moderate harm that does not trigger criteria for notification of SI, Root Cause Analysis investigation report for SI- see Appendix C).

The Datix grading of harm and DoC summary of compliance 9 question menu is demonstrated in the screenshots- Figure 2-3. The incident cannot be finalised or closed until this process is completed and the documentation uploaded.

Figure 2:

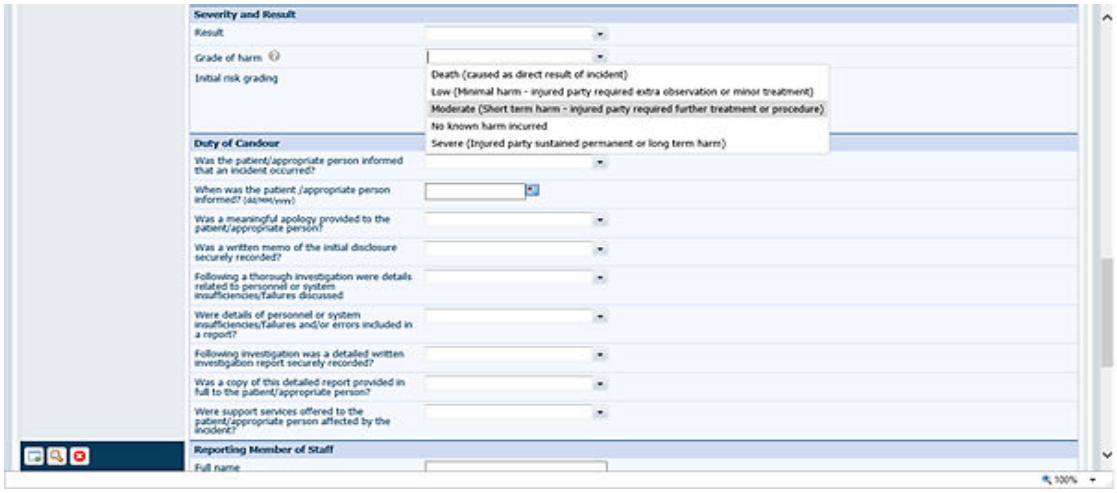


Figure 3:

South East Coast Ambulance Service NHS
NHS Foundation Trust

Internal Concise Investigation Report (Moderate Harm Incident)

Datix Reference Number	WEB (Also copy into report footer)
Date of Incident / Event	
Location of Incident	
Incident Category and Severity	
Complaint Reference Number (Information contained within report?)	
Duty of Candour - Verbal apology / discussion (Please state if patient/family declined follow-up following investigation)	Date: Documented in Notes:
Duty of Candour Letter Sent	Date Sent: Uploaded on Datix:
Investigator(s) (By job title(s))	
Date of Report	
Report Version Number	

Risk Score

Severity (1 – 5)	**Likelihood of reoccurrence (1 – 5)**	**Overall risk score (e.g. severity 2 x Likelihood 5 = 10)**

1. Methods of enquiry and support for staff (State yes for relevant option and provide explanation / detail):	
Review of clinical records	
Review of clinical guidelines /best practice	
Face to face discussion with all staff involved	
Staff statements/ written accounts	
Patient/family account of events and perspective obtained through discussion with them	
Tabular Timeline (see appendix 1)	
Group Discussion (After Action Review)	
Staff Support for investigation	
Staff feedback from incident and findings	

2. What was the incident / event? (Please provide a sentence to state what happened, to who and harm caused)?

3. What was expected to happen / expected process? (What is the normal process / planned care for patient? Please include information on the correct process/procedure in place, NICE Guidance, best practice, trust policy)

4. Describe the complete event (what actually happened?) (Description of actual events in a format patient/family can understand – Use chronology in Appendix 1 for the list of dates/times of events that occurred)

5. Analysis / Key Findings – Lessons Learnt (What are the key findings? Why was there deviation from expected plan of events detailed in section 2 above and the actual event?)

6. Identify the root cause(s)

7. Recommendations from key findings / analysis (What can be done or changed to prevent recurrence?)
Bullet Points Below: •

8. Action plan

#	Recommendation	Action	Source of assurance action embedded in practice	Lead	Deadline	Date Completed
1						
2						
3						
4						
5						

9. Closure checklist (Governance Team Completion)

Has the patient or relative been sent a copy of the investigation and offered meeting (Duty of Candour Closure)? Please add here if they declined involvement.	
Has the report been submitted and closed by review group?	
Have the actions been uploaded onto Datix and assigned to the Clinical Unit and individual lead?	
Have the key learning points been shared with team involved?	
How has learning been shared across organisation if relevant to other departments?	
Report and all associated documents uploaded onto Datix	

Appendix A: Chronology / Timeline

Date / Time	Event	Comments (Key findings of contributory factors such as service delivery or care delivery problems. Identify good practice where relevant)

Appendix D: Example of Duty of Candour Letter (First meeting/SI patient death)

These are examples only and are designed to be adapted and personalised to suit individual circumstances.

South East Coast Ambulance Service NHS
NHS Foundation Trust

Trust address

Patient/NoK/Carers Address

Dear ……..,

I am writing to express my sincere regret that (you/your relative XXXXX) has been involved in an incident whereby ……(describe event here).

Or/ I am sorry to be writing to you out of the blue at this incredibly sad and difficult time.

I am one of the Investigating Officers representing South East Coast Ambulance NHS Foundation Trust and I am leading a review of xxxxx care.

The Serious Incident (SI) review was instigated following concerns raised by the Quality and Patient Safety team regarding aspects of ……. care. The aim of the review is to understand the clinical decisions made and identify any learning or changes in future practice required.

It is the policy of the Trust to be open and to share the findings of any investigation with patients and/or their next of kin – if that is their wish. As part of this, I would very much value the opportunity to meet with you in person to hear your experience of events and any concerns or questions you had about xxxxxxx care. If you would be willing to meet, please do contact me and we can arrange a time and place to meet that would be convenient for you. I understand that, for various reasons, it may not be possible for us to arrange a suitable venue so I would be very happy to meet with you in your home if this would be your preference.

If I do not hear from you, I will contact you again once the investigation is complete to see if you would like to receive a copy of the report and/or meet to discuss the findings.

I apologise again for intruding on your grief at this very sad time.

Yours sincerely,

Appendix E: Example of Duty of Candour Letter (First meeting Moderate/Serious harm)

South East Coast Ambulance Service NHS
NHS Foundation Trust

Trust address

Patient/NoK/Carers Address

Dear ……..,

I am writing to express my sincere regret that (you/your relative XXXXX) has been involved in an incident whereby ……(describe event here).

I would like to introduce myself as one of the Investigating Officers representing South East Coast Ambulance NHS Foundation Trust and I am leading a review of xxxxx care.

The Serious Incident (SI) review was instigated following concerns raised by the Quality and Patient Safety team regarding aspects of …… care. The aim of the review is to understand the clinical decisions made and identify any learning or changes in future practice required.

It is the policy of the Trust to be open and to share the findings of any investigation with patients and/or their next of kin – if that is their wish. As part of this, I would very much value the opportunity to meet with you in person to hear your experience of events and any concerns or questions you had about xxxxxxx care. If you would be willing to meet, please do contact me and we can arrange a time and place to meet that would be convenient for you. I understand that, for various reasons, it may not be possible for us to arrange a suitable venue so I would be very happy to meet with you in your home if this would be your preference.

If I do not hear from you, I will contact you again once the investigation is complete to see if you would like to receive a copy of the report and/or meet to discuss the findings.

Yours sincerely,