

Being Open and Duty of Candour Policy

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This document remains valid whilst under review

TARGET AUDIENCE (including temporary staff)	
People who need to know this document in detail	All clinical staff and all operational managers.
People who need to have a broad understanding of this document	All staff who provide a direct service to patients.
People who need to know that this document exists	All staff

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Reviewed by:

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Date of next review: November 2022

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VERSION CONTROL

Record of Changes		
Date	Version	Changes / Comments
31.03.15	1.0	Updated to reflect new statutory guidance on Duty of Candour
September 2018	2.1	Updated to reflect changes in structure of Trust and policies template.
November 2020	7.0	Policy update and review.

1. INTRODUCTION

1.1 Purpose

Sussex Community NHS Foundation Trust (SCFT) has a genuine commitment to greater openness and candour; to developing a culture dedicated to learning and improvement, which constantly strives to reduce avoidable harm.

There is a requirement under the NHS Standard Contract, issued by NHS England, to inform patients and/or their families about patient safety incidents that affect them; provide an apology and keep them informed about investigations. It is also a professional responsibility for all healthcare professionals to be honest with patients when things go wrong. This is incorporated into professional codes of conduct by the registering bodies; General Medical Council (GMC), Nursing and Midwifery Council (NMC), Health Care Professions Council (HCPC).

The publication of the Francis Inquiry report in February 2013 instigated many changes to health and social care providers, including the drive to improve transparency and openness within the NHS and to provide assurance to our patients that we are doing everything we can to keep them safe. This resulted in a legal Duty of Candour coming into force in November 2014 for NHS trusts. The Care Quality Commission (CQC) is the independent regulator of health and adult social care organisations in England and is responsible for monitoring compliance with the legal duty of candour with conveyed powers to prosecute breaches of the duty.

SCFT is committed to improving patient safety and communication with patients and/or family members/carers when a patient is involved in an incident, which includes moderate harm, (non-permanent harm) severe harm, or death. SCFT will ensure that patients, their carers, or family where appropriate, are kept informed of the investigation and any outcomes, with the opportunity to ask questions.

Open and effective communication with patients begins at the start of their care and should continue throughout their time within the healthcare system. This should be no different when a patient safety incident occurs; when a patient makes a complaint; or in the case of a lawsuit, claim, or litigation.

The Trust aims to promote a culture of openness, which it sees as a prerequisite to improving patient safety and the quality of patient's experience. Effective and compassionate transparency and implementation of the regulated Duty of Candour relies initially on our staff and the rigorous reporting of patient safety incidents.

The Trust aims to promote a just culture of fairness, openness and learning to enable staff to feel confident to speak up when things go wrong, rather than fearing blame. Supporting staff to be open about mistakes allows valuable lessons to be learnt so the same errors can be prevented from being repeated.

1.2 Scope

This policy only relates to those incidents, complaints, inquests and claims where a patient (or more than one patient) has been harmed, or has the potential to be harmed, as a direct result of when things have gone wrong.

This policy is only applicable for incidents, complaints and claims in which SCFT patients and staff are directly involved. The Trust encourages all groups of independent contractors to adopt this policy, or to develop similar procedures based on NHS Improvement Patient Safety (formally the National Patient Safety Agency) guidance.

SCFT encourages staff to report **all** patient safety incidents, including those where there was no harm, or near misses, via the Trust's electronic reporting system, using the principles set out in the Incident Management and Reporting Policy.

Any staff who are concerned about the non-reporting or concealment of incidents, or about on-going practices which present a serious risk to patient safety, are encouraged to raise their concerns under the Freedom to Speak Up: Raising Concerns (Whistleblowing) Policy and Procedure which can be found on SCFT's Intranet, the Pulse.

1.3 Definitions

Below is a list of key terms that appear within this document and their meaning.

Apology	An apology is a sincere expression of regret, or sorrow when something goes wrong. An apology is not an admission of guilt or liability.
Being Open	Communicating with patients, their families and carers, staff and visitors in a manner that is clear, honest and effective, including, but not limited to, when things go wrong.
Candour	Candour is the quality of being open and honest. Patients, or someone lawfully acting on their behalf, should as a matter of course, be properly informed about all of the elements of their treatment and care and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it.
Care Quality Commission (CQC)	The independent regulator of health and social care in England.
Duty Of Candour	A legal duty to follow a specific process laid down in regulation 20 of The Health and Social Care Act 2008, when a patient safety incident results in moderate harm, severe harm, or death in line with section 2 – Application of Being Open and Duty of Candour. A professional duty imposed by health care professionals registering bodies. A contractual duty in the NHS Standard Contract.
Moderate Harm	'Moderate harm' means harm that requires a moderate increase in treatment, and significant, but not permanent, harm, for example a "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).
NHS Resolution	NHS Resolution is an arm's-length body of the Department of Health and Social Care. They provide expertise to the NHS on resolving concerns and legal disputes fairly, sharing learning for improvement and preserving resources for patient care.
National Reporting and Learning System (NRLS)	The national database of patient safety incident reports. All information submitted is analysed to identify hazards, risks and opportunities to continuously improve the safety of patient care.
Openness	Ensuring concerns and complaints can be raised freely, without fear and that questions asked, will be answered honestly.

Patient Safety Incident	Patient safety incidents are any unintended or unexpected incident, which could have, or did, lead to harm for one or more patients receiving healthcare. Reporting them supports the NHS to learn from mistakes and to take action to keep patients safe. <i>NHS Improvement, 2017.</i>
Prolonged Pain	‘Prolonged pain’ means pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.
Prolonged Psychological Harm	Prolonged psychological harm means psychological harm that a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.
Root Cause Analysis	A systematic review technique that looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which the incident happened.
Serious Incident	<p>A Serious Incident is an incident where one or more patients, staff members, visitors or members of the public experience serious or permanent harm, alleged abuse or a service provision is threatened.</p> <p>There are a variety of terms used which provide similar definitions of a Serious Incident, including:</p> <ul style="list-style-type: none"> • Serious Clinical Event; • Major Clinical Incident or event, and; • Major, serious, adverse or untoward, event or incident. <p>SCFT uses the term Serious Incident to cover all of these terms and defines it as an incident that occurred in relation to NHS funded care resulting in one of the following:</p> <ul style="list-style-type: none"> • Unexpected or avoidable death; • Serious harm; • Major surgical / medical intervention; • Permanent physical harm or prolonged pain; • Psychological harm; • Any scenario which prevents SCFT's ability to deliver healthcare services; • Allegations of abuse; • Adverse media coverage; • Information Governance Incidents requiring reporting to the Information Commissioners Office, and; • Any Never Event. <p><i>(taken from SCFT's Incident Management and Reporting Policy)</i></p>
Severe Harm	‘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.
Transparency	Allowing truthful information about performance and outcomes to be shared with staff, people who use the service, the public and regulators.

2. APPLICATION of BEING OPEN & DUTY of CANDOUR

Incident Level	NRLS Definition of Harm Level	Which Process Applies
No Harm	<p>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.</p> <p>Incident not prevented - any patient safety incident that occurred, but no harm was caused to patients receiving NHS-funded care.</p>	<p>The SCFT policy does not require prevented patient safety incidents or 'No Harm' incidents to be disclosed to patients/relatives. The decision of whether to communicate these to patients depends on local circumstances and advice should be sought from the senior health care professional concerned.</p>
Low Harm	<p>Any patient safety incident that required extra observation, or minor treatment or which caused minimal harm to one or more patients receiving NHS-funded care.</p> <p>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.</p>	<p>Low harm incidents should be communicated to patients/relatives under the 'Being Open' process.</p>
Moderate Harm	<p>Any patient safety incident that resulted in a moderate increase in treatments and which caused significant, but not permanent harm, and or prolonged psychological harm, to one or more patients receiving NHS-funded care.</p> <p>Moderate increase in treatment is defined as a return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment or transfer to another area, such as intensive care as a result of the incident. Prolonged psychological harm, which means psychological harm a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.</p>	<ul style="list-style-type: none"> • Being Open principles; and • Duty of Candour process.

<p>Severe Harm</p>	<p>Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-Funded care. Permanent harm directly related to the incident and not related to the natural course of the patient's illness or underlying condition is defined as permanent lessening of bodily functions, sensory, motor, physiological or intellectual including removal of the wrong limb or organ, or brain damage.</p>	<ul style="list-style-type: none"> • Being Open principles; • Duty of Candour process; and • Serious Incident requiring investigation process, (Root Cause Analysis).
<p>Death</p>	<p>Any patient safety incident that directly resulted in the death of one or more persons 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.</p>	<ul style="list-style-type: none"> • Being Open principles; • Duty of Candour process; and • Serious Incident Requiring Investigation Process.

2.1 Understanding the Being Open principles

Being Open recognises that everyone has the right to be treated with respect and to receive fair and dignified treatment. *Being Open* enables the Trust to fulfil its duties to promote human rights in a practical, day-to-day level. It particularly enables the Trust to promote the right to a fair trial and the right to freedom of expression.

Patients are more likely to forgive errors if they are discussed fully and in a timely and thoughtful manner. By *Being Open*, staff can lessen the trauma felt by patients following a patient safety incident.

Being Open involves:

- Acknowledging, apologising and explaining when things go wrong;
- Conducting a thorough investigation into the incident and reassuring patients, their families and carers that lessons identified will help prevent the incident recurring; and
- Providing support for those involved to cope with the physical and psychological consequences of what happened.

In addition to the application of the Being Open process, our legal Duty of Candour requires a formal process, which is explained in the section 2.3.

2.1.1 The benefits for patients

Our patients receive a sincere apology and explanation when things go wrong and this will support:

- Feeling their concerns and distress have been acknowledged;
- Reassurance that SCFT will identify lessons to prevent harm happening to anyone else;
- Reducing the suffering felt when things go wrong;
- Improving respect and trust for the organisation; and
- Reassurance that treatment will continue according to clinical needs.

2.1.2 The benefits for SCFT and our staff

Being Open not only benefits patients, their families and carers, but also healthcare staff and healthcare organisations.

For healthcare organisations and teams, the benefits are:

- An enhanced reputation of respect and trust for the organisation/service/team;
- A reinforced culture of openness;
- Improving the patient experience and satisfaction;
- A reputation for supporting staff when things go wrong;
- Embodying the NHS Constitution for England pledge to patients around *Being Open*;
- The opportunity to learn when things go wrong; and
- The potential to reduce the costs of litigation.

For our staff, the benefits are:

- Confidence in how to communicate effectively when things go wrong;

- Feeling supported when apologising or explaining to patients, their families and carers;
- Satisfaction that communication with patients and/or their carers following a patient safety incident has been handled in the most appropriate way;
- Improving the understanding of incidents from the perspective of the patient and/or their carers;
- The knowledge that lessons identified from incidents will help prevent them happening again;
- Having a good professional reputation for handling a difficult situation well and earning respect among peers and colleagues; and

2.1.3 Confidentiality

Patient confidentiality is still a requirement in the event of a patient's death, or they no longer have the capacity to make decisions on their care. Careful consideration must be taken when releasing information to family members if the information is relating to any of the following topics: trans identity, sexual preferences, other protected characteristics that may not be known, or when information has been shared with SCFT in confidence. In these events, a data protection impact assessment should be completed on a case by case basis as appropriate. If in any doubt, please seek guidance from the IG Team.

2.2 SCFT policy follows the NRLS 10 principles of Being Open;

1. Acknowledgement

All patient safety incidents should be acknowledged and reported on Datix as soon as they are identified.

2. Truthfulness, timeliness and clarity of communication

An appropriately nominated person must give information about a patient safety incident to patients, their families and/or their carers in a truthful and open manner.

3. Apology

Patients, their families and/or their carers should receive a sincere expression of sorrow or regret for the harm that has resulted from a patient safety incident, i.e. a meaningful apology. Saying sorry to patients, their families and/or their carers is not an admission of liability.

4. Recognising patient and carer expectations

Patients, their families and/or their carers can reasonably expect to be fully informed of the issues surrounding a patient safety incident and its consequences, in a face-to-face meeting with representatives from the Trust.

5. Risk management and systems improvement

Root Cause Analysis or similar incident investigation techniques will be used to uncover the underlying causes of all relevant patient safety incidents. All investigations should focus on improving systems of care, which will then be reviewed for their effectiveness.

6. Professional support

SCFT will create an environment in which all staff, whether directly employed or independent contractors, are encouraged to report patient safety incidents. SCFT will ensure staff are supported throughout any incident investigation, as we recognise that they may have been affected. We will not unfairly expose staff to punitive disciplinary action.

7. Multidisciplinary responsibility

SCFT's Being Open policy will apply to all staff who have key roles in a patient's care.

8. Clinical governance

Being Open requires the support of the organisation's patient safety and quality improvement processes through clinical governance frameworks, in which patient

safety incidents are investigated and analysed to find out what can be done to prevent their recurrence.

9. Confidentiality

SCFT's Being Open policy should give full consideration of, and respect for, the privacy and confidentiality of patients, their family and/or carers and staff, in line with the CQC's five key questions (are services safe, effective, caring, responsive and well led?).

10. Continuity of care

Patients are entitled to expect that they will continue to receive treatment and to be treated with dignity, respect and compassion. If a patient's healthcare needs are to be taken over by another team, appropriate arrangements should be made for the transition of care to the new team.

2.3 Applying the statutory Duty of Candour

<p>Step 1</p>	<p>Incident is identified (Moderate or Severe Harm) An incident may be identified by a patient, a carer, a Trust staff member or an independent contractor. Support must be given to the patient and staff affected.</p> <p>Following an incident, the patient should continue to receive treatment and should continue to be treated with respect and compassion by Trust staff. Should the patient wish to receive treatment from another healthcare team, arrangements should be made to facilitate this wish, if possible. Patients/relatives/carers should be reassured that the incident and its investigation will not affect any continuing treatment provided.</p>
<p>Step 2</p>	<p>Record incident on Datix and inform your line manager An on-line incident reporting form must be completed and the line manager must be notified in accordance with the Trust's Incident Reporting Policy and Procedure.</p>
<p>Step 3</p>	<p>Discussion with Senior Staff A member of staff from the team directly involved in the incident should discuss the incident with their Senior Manager and, the incident should be reported to the relevant Director if appropriate. The team must agree on who will hold the initial disclosure discussion with the patient and / or their family and when this will take place. This will usually be a member of staff at band 7 or above.</p>
<p>Step 4</p>	<p>Initial Notification and Verbal apology A member of the service/ clinical team involved directly with the patient's care should confirm to the patient/relative/carer that an incident has occurred and that this will be investigated. The initial discussion with the patient and/or their carers should occur as soon as possible after recognition of the patient safety incident and must be within 10 working days of knowledge of the incident occurrence (see section 2.4 for guidance on holding the discussion).</p> <p>A meaningful verbal apology must be made during the conversation along with sharing any established facts known at that point in time. Assurance should be provided that an investigation will be</p>

	undertaken. Following the conversation, this must be confirmed in writing. (Please use the notification letter template as a guide, appendix A). A copy of the notification letter must be attached to the Datix Incident Report.
Step 5	<p>Investigation</p> <p>Senior staff or a Patient Safety Lead will carry out an Root Cause Analysis (RCA) investigation. In the event of a serious incident (as defined by NHS England guidelines), the Serious Incident and RCA Review Group (SIRCARG) will review the investigation findings. Where the outcome of the investigation is shared through the 'Investigation Findings and Apology letter' (appendix B) this must be reviewed and approved by the Area Head of Nursing and Governance and Patient Safety Manager.</p> <p>If a complaint has also been received in relation to the incident, the 'Investigation Findings and Apology letter' will be reviewed and signed by the Trust's Chief Executive.</p>
Step 6	<p>Outcome and Written Apology</p> <p>After completion of the incidents RCA investigation, feedback should take the form most acceptable to the patient. The manager or clinician or Patient Safety Lead taking responsibility for the Duty of Candour process, must contact the patient (or next of kin) within 10 working days of completion of the investigation to offer to discuss the outcome of the investigation, including any learning.</p> <p>The investigation summary and 'Investigation Findings and Apology letter' should then be offered to the patient/relative/carer and a copy attached to the Datix Incident Report. The Duty of Candour fields in the Datix Incident report must be completed.</p>
Step 7	<p>Feedback</p> <p>The patient/relative/carer should be given the opportunity to respond to the findings with any feedback documented and responded to, as required.</p>
Step 8	<p>Action Plans</p> <p>Copies of action plans should be sent to the SCFT Patient Safety Manager.</p>
Step 9	<p>Communication of Learning</p> <p>Effective communication with staff is a vital step to ensuring that recommended actions are fully implemented and monitored, and to increase awareness of patient safety and the value of Being Open</p> <p>Team meetings, newsletters and the Trust website are all available to help communicate with staff.</p>

2.4 Factors to consider - Holding a Candid Being Open Discussion and meetings

2.4.1 Notification Discussion

The purpose of a notification discussion is to inform a patient/family/carer that an incident has occurred and to offer an apology and sympathetic support. Verbal communication should always occur before a letter is sent. It is useful to identify an appropriate senior staff member to be a single SCFT point of contact.

A summary of the discussion and support needed should be made and followed up in writing, using the template provided in appendix A.

The patient/family should be offered an opportunity to discuss and contribute to the investigation and have their questions addressed during the process. The approach should be agreed with the patient/family. The patient/family may request meetings at any stage during the investigation. Patient/family concerns and preferences should be considered in the investigation and documented in the investigation records and/or Datix report

2.4.2 Practical factors to consider before arranging a Being Open /Duty of Candour meeting

These include:

- The clinical condition of the patient.
- Some patients may require more than one meeting to ensure that all the information has been communicated to and understood by them.
- The availability of key staff involved in the incident.
- The requirement for truthfulness, timeliness and clarity of communication.
- The availability of the patient's family and/or carers.
- The availability of additional support, for example an interpreter or an independent advocate, if required.
- Patient preference (in terms of when and where the meeting takes place and who leads the discussion).
- The patient/relative/carer may express a preference regarding which staff should attend the meeting and this must be respected.
- The privacy and comfort of the patient.
- Arranging the meeting in a sensitive location.
- Saying sorry to a patient/relative/carer is not an admission of liability.

2.4.3 Identify support needed by Patient/Relative/Carer/Staff

Patients/relatives/carers may need support from the PALS and Complaints team, an independent patient advocate, or interpreter at any stage throughout the process. How to access these should be reiterated at regular intervals throughout the procedure. Staff should facilitate this process. If a patient is incapacitated because of the incident and does not have relatives/carers to assist them, an independent representative may be assigned.

Staff members involved in the incident may also be affected and should be fully supported by their line manager. The HR team, Occupational Health and Staff Counselling are additional sources of support, if required. See appendix C for a list of contacts.

2.4.4 Face to Face Meeting with Patient/Relative/Carer and appropriate members of the Trust staff.

A meeting should be offered and set up at the earliest convenience to discuss the incident and the issues involved. The patient/relative/carer may express a preference for which staff should attend the meeting.

Trust staff should introduce themselves and explain their role.

An official, independent interpreter should attend if required. If the patient/relative/carer requires any support to deal with the consequences of the incident, information on where this support can be obtained should be provided.

Information may also be provided on the Trust's PALS and Complaints Procedure.

Patients/relatives/carers should be advised who their information will be shared with and may raise objections to this. When information has to be shared to meet legal requirements, or disclosure is justified in the public interest, information may be shared without the patient's consent. Staff should raise any concerns with their line manager and escalate to the Information Governance Lead when necessary.

Trust staff should consider that the patient/relative/carer might express anger or anxiety during the meeting and respond appropriately and professionally. In the event that the patient/relative/carer decline a meeting, this should be respected and recorded.

The following guidelines should assist in making the communication effective:

- The discussion should occur at the earliest practical opportunity, once there is information to report.
- Consideration should be given to the timing of the meeting/discussion, based on both the patient's health and personal circumstances.
- Feedback should be given on progress to date and information provided on the investigation process.
- There should be no speculation or attribution of blame. Similarly, the healthcare professional communicating the incident must not criticise or comment on matters outside their own experience.
- The patient and/or their carers should be offered an opportunity to discuss the situation with another relevant professional where appropriate.
- A written record of the discussion should be kept and shared with the patient and/or their carers.
- All queries should be responded to appropriately.
- If completing the process at this point, the patient and/or their carers should be asked if they are satisfied with the investigation and a note of this made in the patient's records (see section 2.7).
- The patient should be provided with contact details so that if further issues arise later there is a route back to the relevant healthcare professionals, or an agreed substitute.

2.5 Incident Investigation

An investigation into the cause of the incident must be conducted in accordance with the Trust's policies and procedure for Serious Incidents (SI's) or Complaints. This reflects that incidents usually result from system failures, rather than individual actions, and ensures that all possible contributory factors are identified and taken into account. The investigation should include the use of the Root Cause Analysis approach.

The manager or clinician must contact the patient (or next of kin) within 10 working days on completion of the investigation to offer to go through the outcome of the investigation, including any lessons identified. A copy of the investigation summary should be provided to the patient or next of kin (please use Outcome letter template as a guide – appendix B).

Patients/relatives/carers should be given regular updates on the progress of the investigation either verbally/written/or by further meetings, adhering to the principles in previous stages of this procedure. Before information is provided to the patient/relatives/carers, this should be confirmed by an appropriate senior member of staff involved in the investigation.

For Serious Harm or Moderate Harm incidents, the Serious Incident and RCA Review Group (SIRCARG) or Associate Director of Quality and Safety must approve investigation reports, before they are shared with patients/relatives/carers.

2.6 Documentation

The communication of patient safety incidents must be recorded. Duty of Candour notifications and meetings must be recorded on Datix records with the time, place, and date, as well as the name and relationships of all attendees, together with the outcome. Required documentation includes:

- incident reports;
- records of the investigation and analysis process; and
- copies of all correspondence to the patient, or next of kin.

There should also be documentation of discussion meetings regarding the incident, including:

- the time, place, and date, as well as the name and relationships of all attendees;
- the plan for providing further information to the patient and/or their carers;
- offers of assistance to the patients/family or carer;
- questions raised by the family and/or carers or their representatives with the answers given;
- plans for follow-up;
- progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient and/or their carers;
- copies of letters sent to patients, carers and the GP for patient safety incidents not occurring within primary care;
- copies of any statements taken in relation to the patient safety incident; and
- a copy of the incident report.

2.7 Outcome, Feedback and Written Apology post investigation

2.7.1 Feedback on the outcome of the investigation

After completion of the incident investigation, feedback should take the form most acceptable to the patient, but in all cases put in writing (see appendix B for letter template). The manager or clinician must contact the patient/family or carer within 10 working days on completion of the investigation to offer to go through the outcome of the investigation, including any lessons identified. A copy of the investigation summary will be offered to the patient or next of kin.

The feedback must include:

- The chronology of clinical and other relevant facts.
- Details of the patient's and/or their carer's concerns and complaints.
- A repeated meaningful apology for the harm suffered and any shortcomings in the delivery of care that led to the patient safety incident.
- A summary of the factors that contributed to the incident.
- Information on what has been, and will be, done to avoid recurrence of the incident and how these improvements will be monitored.
- It is expected that in most cases there will be a complete discussion of the findings of the investigation and analysis.
- In some cases, information may be withheld or restricted, e.g. where communicating information will adversely affect the health of the patient; where investigations are pending coronial processes or where specific legal requirements preclude disclosure for specific purposes. In these cases, the patient will be informed of the reasons for the restrictions.
- The patient/relative/carer should be given the opportunity to respond to the outcome of the investigation, with any responses documented.

2.7.2 Patients / Relatives/ Carers not satisfied with the outcome

Should this occur, a mutually acceptable mediator should be arranged, to help identify areas of disagreement. Each point of disagreement should be addressed and a response provided in writing. The patient/relative/carer should also be informed how to make a formal complaint, in accordance with the Trust's Complaints Procedure.

2.8 Special Circumstances/Exceptions

The approach to Duty of Candour may need to be modified according to the patient's personal circumstances and the issues documented below should be taken into consideration.

2.8.1 When the incident occurs in another organisation

In the event a patient safety incident has occurred in another organisation, e.g. when a patient is transferred into SCFT from another healthcare provider, the individual who first identifies an earlier patient safety incident must notify the Patient Safety Manager who will make arrangements to establish whether:

- the patient safety incident has already been recognised;
- the process of Being Open has commenced; and
- an incident investigation is underway.

2.8.2 Delayed discovery of an incident

On occasions, incidents come to light as the result of a specific review or audit. Where this happens, it is important to look at the resulting investigation and the time that has elapsed since the initial incident. It is important to consider the impact the information may have on the patient's family and/or carer and consider whether the policy still applies. The Medical Director must make this decision.

2.9 Identifying Lessons and Communicating these

2.9.1 Identifying lessons

It is essential that any RCA investigation identifies lessons to minimise the possibility of recurrence of the events that led to harm.

Action plans should be drafted to manage these and the progress of these should be reported through the clinical governance structures.

Lessons identified will be communicated during the discussion with patients/families/carers affected by the incident.

2.9.2 Communication of changes to staff

Effective communication with staff is a vital step in ensuring that recommended changes are fully implemented and monitored. It also increases awareness of patient safety and the value of Being Open. Team meetings, patient stories to the board, newsletters and the Trust website are all available to help communicate with staff.

3. RESPONSIBILITIES

Chief Executive

The Chief Executive is ultimately responsible for ensuring the safety of patients, visitors and staff within the organisation. It is therefore the Chief Executive's responsibility to ensure that there are robust systems in place by which the principles of "*Being Open*" are implemented within the organisation. The Chief Executive is responsible for ensuring that this policy is implemented within all areas of the organisation through responsible Executive Directors, Area Directors, Deputy Area Directors, General Managers and Clinical Service Managers.

All Managers

All Managers are responsible for ensuring all staff are encouraged to report incidents; that all patients, their families, visitors, carers and others are communicated with in a timely manner, with openness and honesty; and that all communication is documented.

All Staff

All staff involved in an incident resulting in long term injury or death need to understand the Being Open policy and follow the accompanying Being Open Process (available on the Pulse). A senior manager or senior responsible person will support any junior staff involved in the Being Open process.

All staff are required to complete in full and as directed any templates or proformas as instructed, for use as part of this policy.

4. ASSOCIATED DOCUMENTS AND REFERENCES

Elements of the Being Open policy are related to other government directives, initiatives and recommendations, including:

- National Health Service (NHS) Constitution for England, which includes a pledge to patients in relation to complaints and redress
<https://www.gov.uk/government/publications/the-nhs-constitution-for-england> accessed 12.11.2020;
- Listening, Responding, Improving - A guide to better customer care. Six principles of good complaint handling
http://webarchive.nationalarchives.gov.uk/+http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_095408 accessed 12.11.2020;
- Health and Social Care Act 2008 that states, 'service providers encourage and support a culture of openness'

- <https://www.legislation.gov.uk/ukdsi/2009/9780111487006/contents> accessed 12.11.2020;
- The Duty of Candour Regulation 20 provisions <https://www.legislation.gov.uk/uksi/2014/2936/regulation/20/made> accessed 12.11.2020
 - NHS Resolution ‘Saying Sorry’ which encourages healthcare professionals to apologise and provide explanations to patients harmed as a result of healthcare treatment <https://resolution.nhs.uk/wp-content/uploads/2017/07/NHS-Resolution-Saying-Sorry-Final.pdf> accessed 12.11.2020;
 - Recommendations in the 5th Shipman Inquiry Report about appropriate documentation of patient deaths <http://webarchive.nationalarchives.gov.uk/20090808160144/http://www.the-shipman-inquiry.org.uk/fifthreport.asp> accessed 12.11.2020;
 - Recommendations in the Francis report into the failures of care at Mid Staffordshire NHS Foundation Trust <http://webarchive.nationalarchives.gov.uk/20150407084003/http://www.midstaffpublicinquiry.com/> accessed 12.11.2020;
 - Clywd and Hart *Review of the NHS Hospitals Complaints Process – Putting Patients Back in the Picture* https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/255615/NHS_complaints_accessible.pdf accessed 12.11.2020;
 - Transforming Care: A national response to Winterbourne View Hospital, Department of Health (2012) https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/213215/final-report.pdf accessed 12.11.2020;
 - A Promise to Learn - a commitment to act: Improving the safety of patients in England, (2013) <https://www.gov.uk/government/publications/berwick-review-into-patient-safety> accessed 12.11.2020;
 - Hard Truths: The Journey to Putting Patients First (2014) https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/270368/34658_Cm_8777_Vol_1_accessible.pdf accessed 12.11.2020;

Further references:

- Patient Safety Alert NPSA/2009/PSA003 NPSA, London, November 2009
- Patient Safety Alert NPSA/2009/PSA003 Being Open – Supporting Information NPSA, London, November 2009
- Safer Practice Notice 10, ‘Being Open When Patients Are Harmed’ NPSA/2005/10 NPSA; London; 2005
- What is a patient safety incident? <https://www.england.nhs.uk/patient-safety/report-patient-safety-incident/>
- Confidentiality Code of Practice, Department of Health, 2013. <https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice> accessed 12.11.2020
- CQC regulation 20 guidance http://www.cqc.org.uk/sites/default/files/20150327_duty_of_candour_guidance_final.pdf accessed 12.11.2020

5. MONITORING COMPLIANCE

Compliance against this policy will be overseen by the Trust-wide Governance Group. Additionally, all Root Cause Analysis investigations into Serious Incidents are checked to

ensure they have followed *Being Open* via the Trust's Serious Incident and RCA Review Group, with further scrutiny via the Clinical Commissioning Group's Scrutiny Panel.

6. DISSEMINATION AND IMPLEMENTATION

This policy is available on the intranet, and publicised through the Trust internal electronic newsletter.

7. CONSULTATION, APPROVAL, RATIFICATION & REVIEW

This policy has been reviewed by:

- Members of the Patient Experience Group;
- The Associate Director of Quality and Safety ;
- The Patient Safety Manager; and
- The Information Governance Lead.

The policy will be approved by the Patient Experience Group and ratified by the Trust-Wide Governance Group.

Appendix A – Initial Disclosure Letter Template



Private & Confidential
(Name and address)

(SERVICE ADDRESS)

Phone:ADD

Incident No: ADD

Date ADD

sc-tr.serviceexperience@nhs.net
www.sussexcommunity.nhs.uk

Dear XXXX

Thank you for taking the time to talk with me/my colleague regarding XXXX (e.g. your father's fall on 16 April and subsequent fractured hip).

The members of the team involved in the care of your XXXX and I would like to express our sincere apologies that this event occurred whilst XXXX was in our care.

Or in the event of a death

On behalf of the Trust, and the members of the team involved in the care of your XXXX, please accept our sincere condolences at this sad time.

At Sussex Community NHS Foundation Trust, we aim to provide a quality service to patient/service users and families and want to assure you that we will be conducting a thorough investigation. We want to understand how the incident happened so that we can use this learning to improve quality and safety across our services. Our aim is to prevent this happening to anyone else.

As a Trust, we are committed to being open and ensuring that our findings are shared with those involved. Therefore, we will endeavour to keep you informed of the progress of our investigation. We would welcome the opportunity to meet with you to discuss the investigation process and findings personally and answer any questions you may have.

We will do everything we can to support you and your family during this process.

IF THE INCIDENT INVOLVES A LOSS OF RELATIVE ADD - Please be assured that it is not our intention to intrude upon you, or your family at this difficult time, however, we would like to keep you informed.

In the meantime, if you have any questions, or queries about this letter please do not hesitate to contact me on XXXXX XXXXXX (or named investigator or Patient Safety Lead on XXXX XXXXXX)

If you would like this information in an alternative format, or language, please contact sc-tr.equality@nhs.net, or me so we can arrange.

Yours sincerely

Name

Role

Sussex Community NHS Foundation Trust

Appendix B – Investigation Findings and Apology Letter



Private & Confidential
(Name and address)

(SERVICE ADDRESS)

Phone: ADD

Incident No: ADD

Date ADD

sc-tr.serviceexperience@nhs.net
www.sussexcommunity.nhs.uk

Dear NAME OF PATIENT/RELATIVE

Further to our previous communications, please find below a summary of our investigation into the incident, which happened on (date).

Description:

Immediate Action Taken:

Investigation Findings:

Lessons Learned:

How these lessons will be shared across the organisation:

I hope the investigation and the findings help to assure you that we have taken appropriate steps to understand why this incident happened and to identify any lessons that may need to be learned to help prevent a similar happening again.

Once again, I would like to offer my sincere apologies for what happened on behalf of Sussex Community NHS Foundation Trust.

If you have any queries about this letter please do not hesitate to contact me.

Yours sincerely

Name
Role
Sussex Community NHS Foundation Trust

Appendix C – Support for Patients/Families/Carers

SCT PALS – Patient Advice and Liaison Service – 01273 242292 or sc-tr.serviceexperience@nhs.net

Find out more about local services at Patient UK - www.patient.co.uk.

National Organisations

Independent Health Complaints Advocacy

The Independent Health Complaints Advocacy is a free, independent advocacy service that can help you make a complaint about any aspect of your NHS care or treatment. This includes treatment in a private hospital, or care home that is funded by the NHS.

<https://www.theadvocacypeople.org.uk/nhs-complaints-advocacy>

Healthwatch West Sussex

Healthwatch West Sussex runs the West Sussex Independent Health Complaints Advocacy Service

<https://www.healthwatchwestsussex.co.uk/help-making-complaint>

The Child Bereavement Trust

National UK charity providing specialised training and support for professionals to help them respond to the needs of bereaved families, together with resources and information for bereaved children and families as well as the doctors, nurses, midwives, teachers, police, emergency services and voluntary sector support services.

Address: Clare Charity Centre, Wycombe Road, Saunderton, Buckinghamshire HP14 4BF
Tel: 01494 568 900

Email: support@childbereavementuk.org

www.childbereavement.org.uk

Action against Medical Accidents (AvMA)

AvMA is a national charity that provides free specialist advice and support with complaints where harm is believed to have been caused or there are patient safety implications. The website is www.avma.org.uk and the helpline number is 0845 123 23 52

Cruse Bereavement Care

The Cruse Bereavement Care Freephone National Helpline is staffed by trained bereavement volunteers, who offer emotional support to anyone affected by bereavement.

Our volunteers are here to help you talk things through. They can also help you find your local Cruse service, or signpost you to other services and useful sources of information.

The helpline is open Monday-Friday 9.30am-5pm (excluding bank holidays), with extended hours on Tuesday, Wednesday and Thursday evenings, when we're open until 8pm.

The number is **0808 808 1677**

<https://www.cruse.org.uk/>

Supportline

SupportLine provides a confidential telephone helpline offering emotional support to any individual on any issue. The Helpline is primarily a preventative service and aims to support people before they reach the point of crisis. It is particularly aimed at those who are socially isolated, vulnerable, at risk groups and victims of any form of abuse. SupportLine is a member of the Helplines Association. SupportLine also provides support by email and post.

Helpline: 01708 765200 (*hours vary so ring for details*)

Admin: 01708 765222

info@supportline.org.uk

SupportLine, PO Box 2860, Romford, Essex RM7 1JA

www.supportline.org.uk

British Association for Counselling and Psychotherapy

The 'Seeking a Therapist' section of the website gives lists of qualified counsellors and psychotherapists available in your area. This service is also available over the phone.

Email: bacp@bacp.co.uk

Telephone: 01455 883300

Twitter: [@BACP](https://twitter.com/BACP)

Mail: BACP, 15 St John's Business Park, Lutterworth, Leicestershire LE17 4HB, United Kingdom

www.bacp.co.uk

Jewish Bereavement Counselling Service

The Jewish Bereavement Counselling Service (JBACS) is a service dedicated to bereavement counselling. JBACS is committed to ensuring that professional, skilled and confidential bereavement counselling is available to everyone in the Jewish Community. tel 0208 951 3881

email enquiries@jbacs.org.uk

<http://jbacs.org.uk/>

Samaritans

24-hour confidential emotional support for anyone in a crisis.

Helpline: [116 123 \(UK\)](tel:116123)

jo@samaritans.org (UK)

Freepost RSRB-KKBY-CYJK, PO Box 9090, STIRLING, FK8 2SA

www.samaritans.org

Support for Carers

Information, support and practical help for all Carers.

www.carers.org

Age UK

Free national information service for senior citizens, their carers and relatives.

Age UK Advice Line

0800 055 6112

Free to call 8am-7pm 365 days/year.

www.ageuk.org.uk

Alzheimer's Society

National Dementia Helpline: 0300 222 1122

43-44 Crutched Friars, London, EC3N 2AE

0330 333 0804

www.alzheimers.org.uk

Help for young people

The youth branch of Cruse, set up to help young people after the death of someone close.

<http://hopeagain.org.uk/>

Private email: hopeagain@cruse.org.uk

FREE phone helpline: [0808 808 1677](tel:08088081677) Monday-Friday, 9:30am - 5:00pm.

Winston's Wish

Charity that offers support to children and young people who have experienced bereavement.

Email: info@winstonswish.org

Helpline: 08088 020021

www.winstonswish.org.uk

ChildLine

Free, 24-hour helpline for children and young people who need to talk about any problem they may have.

Helpline: 0800 1111

www.ChildLine.org.uk

Childhood Bereavement Network

The Childhood Bereavement Network (CBN) is a hub for those working with bereaved children, young people and their families across the UK.

www.childhoodbereavementnetwork.org.uk

Appendix D

Illustrative examples of incidents that trigger the threshold for the Duty of Candour Regulation

These examples have been developed by the CQC with stakeholders to illustrate examples of notifiable safety incidents that trigger the threshold for the duty of candour regulation. The examples presented are illustrative only and not an exhaustive list.

Example	Interpretation
A patient arrived for planned surgery but had not been given the correct advice to discontinue their Warfarin treatment. The surgery had to be postponed.	This would be an example where an incident appeared to have resulted in moderate harm
A confused elderly patient was supposed to have 1:1 supervision on a medical ward. The patient was left unsupervised for a period of time whilst the shift change was occurring, and the patient fell out of bed, sustaining a severe head injury from which they later died.	This would be an example where an incident resulted in death.
A patient who is normally very shy sustains an extravasation injury (soft tissue burn) from an intravenous line. This causes irreversible and extensive scarring on her arm and as a result she becomes severely socially anxious for which she needs a prolonged period of therapy.	This would be an example of an incident leading to prolonged psychological harm.

Taken from: Regulation 20: Duty of Candour CQC, March 2015

https://www.cqc.org.uk/sites/default/files/20150327_duty_of_candour_guidance_final.pdf accessed 25.9.18

Equality and Human Rights Analysis (EHRA)

Title(s): Being Open and Duty of Candour Policy
<p>Aims: There is a requirement under the NHS Standard Contract, issued by NHS England, to ensure that patients and/or their families are told about patient safety incidents that affect them; receive an appropriate apology and are kept informed about investigations.</p> <p>This policy only relates to those incidents, complaints and claims where a patient (or more than one patient) under the care of SCFT has been harmed, or has the potential to be harmed, as a direct result of when things have gone wrong.</p>

Evidence

Please summarise any evidence about how the work may impact people either positively or negatively specifically linked to their [characteristics](#).

- E.g. performance or survey data; focus groups; PALS; incident reviews; NICE guidance; research; good practice; demographic data
- Mark an 'X' in the columns for as many characteristics as are relevant

	Mark 'X' relevant characteristics								
	Age	Disability and Carers	Race	Religion or Belief	Sex	Pregnancy or Maternity	Gender Reassignment	Sexual Orientation	Other (e.g. Armed Forces)
Positive impacts:									
<p>Negative impacts: The policy applies to all people with, or without a protected characteristic. However, it is recognised some personal life decisions, e.g. gender identification, religion, etc. may not have been openly communicated to a patient's family or representatives. This has been covered in section 2.1.3 under confidentiality.</p>									

Equality Analysis

Please evaluate how the work may impact people with protected characteristics to meet the three **aims (A-C)** below, referencing any evidence identified above. If an aim is not relevant to your work, please explain why.

Aim A. Eliminate discrimination – Please evidence if the work could unlawfully discriminate:

Include who is discriminated (e.g. disabled adults) and how. Include detailed reasons if it is lawful

N/A

Aim B. Advance equality of opportunity – Please evidence if the work:

- Minimises disadvantage – Does the work address any poorer outcomes for particular protected groups?
- Meets different needs – Does the work meet different protected groups’ social, cultural or other needs?
- Encourages participation – Does the work target under-represented groups to increase involvement?

N/A

Aim C. Foster good relations – Please evidence if the work:

- Tackles prejudice – Does the work increase contact between groups to reduce negative attitudes?
- Promotes understanding – Does the work educate people about groups to change negative attitudes?

N/A

Human Rights Analysis

Mark ‘X’ against the relevant rights which are safeguarded (+) or breached

(-) by the work:

Article 2. Right to life (e.g. The Deteriorating Patient policy, DNACPR or Clinical competencies)

Article 3. Prohibition of torture, inhuman or degrading treatment (e.g. Consent or Safeguarding)

Article 5. Right to liberty and security (e.g. Deprivation of Liberty or Restrictive Interventions)

Article 8. Right to respect for private and family life, home and correspondence (e.g. Confidentiality, health records, carer involvement, correspondence or staff leave)

+	-
X	
X	
X	
X	

Mark 'X' against the relevant rights which are safeguarded (+) or breached

(-) by the work:

+	-
X	
X	
	X

Article 9. Freedom of thought, conscience and religion (e.g. End of Life Care or Prescribing)

Article 10. Freedom of expression (e.g. Patient information or Raising Concerns policy)

Article 12. Right to marry and found a family (e.g. Pregnancy testing procedure)

Monitoring

Please describe how any impacts will be monitored: (e.g. annual policy review, audit, performance metric)

On a case by case basis, as appropriate.

Outcome

Choose the final outcome(s) **a-d** of the analysis with an 'X' and explain the reasons in the space below:

- (a) [Continue the work](#)
- (b) [Change the work](#)
- (c) [Justify and continue the work](#)
- (d) [Stop the work](#)

Detailed reasons (copy this statement into your main paperwork and any committee papers – this is what you want the decision-makers to see):

Please score any risks to equality or human rights below and update your risk register:

Consequence score:	3	x	Likelihood score:	1	=	<u>Equality and Human Rights Risk Score:</u>	3
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Assurance Statement: I have reviewed the evidence with rigour and an open-mind and am satisfied there has been [due regard](#) to the need to eliminate discrimination, advance equality of opportunity and foster good relations, and there is compliance with [Section 149 of the Equality Act 2010](#).

Analysis Lead(s) names: Debbie Johnson	Date: November 2020
Ratifying committee / body: TWGG	Date: 05/01/2021
Reviewer (office use):	Decision: Date:

Improvement Plan

<u>Description of actions</u>	Date	Person	How will this be delivered?
<i>Add more rows if necessary</i>			

Send this form along with your main paperwork for consultation to sc-tr.equality@nhs.net

RATIFICATION CHECKLIST
Trust-Wide Governance Group
05/01/2021

Agenda Item: 21
 Policy Title: **Being Open & Duty of Candour Policy**
 Policy Author: Patient Safety Manager
 Presented By: Patient Safety Manager
 Purpose: **Ratification**

Checklist for Ratification			
1.	Reason for Review:		
	Review date due or expired: November 2020.		
2.	Summary		
	<p>Please give a brief overview of the following:</p> <ul style="list-style-type: none"> <i>Purpose and scope of document</i> <p>There is a requirement under the NHS Standard Contract, issued by NHS England, to ensure that patients and/or their families are told about patient safety incidents that affect them; receive an appropriate apology and are kept informed about investigations. This requirement is also enacted in the Duty of Candour regulation 20 of The Health and Social Care Act 2008.</p> <p>This policy only relates to those incidents, complaints and claims where a patient (or more than one patient) under the care of SCFT has been harmed, or has the potential to be harmed, as a direct result of when things have gone wrong.</p> <ul style="list-style-type: none"> <i>Any specific exclusions contained within the document (i.e. does not apply to certain staff / areas within the Trust)</i> <p>None.</p> <ul style="list-style-type: none"> <i>Please summarise any significant changes from previous versions e.g. in response to new legislation or national guidance</i> <p>The policy has been updated to take into account changes within the Trust and regarding templates. However, there have been are no substantive changes.</p>		
3.	Format		
	Has the standard SCFT template been used?	Yes	Comments:
4.	Consultation		
	Name	Group Member	Response Y/N
	Patient Safety Manager		Y
	Quality Development Manager		Y
	Safety and Risk Manager		
	Medical Director		
	Information Governance Manager		
	Patient Safety Leads		
	Freedom to Speak Up Guardian		Y
5.	Dissemination/Implementation Process		
	The policy will be disseminated via the Trust's intranet and regular internal communications email.		

6. Cost/Resource Implications		
Does this policy/procedures have any cost and/or resource implications?		N
If Yes:		
Please provide details of the cost/resource implications: <i>e.g. training, equipment, additional staff</i>		
Has this been agreed by the accountable Director?		Y/N
Name	Job Title	Date
7. Approval		
Please state the name of the Group that has approved this document?		Name: Patient Experience Group
Date of Group Approval:		Date: 17/11/2020
8. Equality Analysis		
Has the Equality Impact Assessment been completed?	Yes	Comments
9. Review		
Please state the timescale for review:		Bi-annually

DECISION OUTCOME AND RECOMMENDATIONS

<i>For completion by the Chair of the Group or Committee considering ratification.</i>		
Is the Committee / Group satisfied and assured that due process has been followed in order to produce or review the Policy?	Yes	Comments:
Is the Committee / Group satisfied and assured with the consultation on the Policy?	Yes	Comments:
Does anybody (Group or individual) else need to be consulted prior to ratification?	No	Please state who:
Other Comments		
Outcome:		

Was the Policy Ratified?	Yes
Other comments: Including strengths and good practice.	
Additional actions required for ratification: Must be SMART	
Chair: Sara Lightowers, Medical Director Date: 05/01/2021	