Somerset Partnership NHS
NHS Foundation Trust

BEING OPEN AND DUTY OF CANDOUR POLICY

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DOCUMENT CONTROL

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1. INTRODUCTION

1.1 Somerset Partnership NHS Foundation Trust is committed to providing high quality health care. It has robust systems in place to ensure patient safety is at the heart of all it does. However, on rare occasions we recognise that mistakes can happen.

1.2 The Trust has a duty to limit the potential impact of clinical and non-clinical risks and put in place robust and transparent systems to make sure all incidents which might cause actual or potential harm to patients, visitors and staff are identified, investigated and lessons learnt from them.

1.3 The effects of a patient being harmed can have devastating emotional and physical consequences for patients, their families and carers. It can also be distressing for the staff involved. Openness and honesty is essential to improving the safety of patients, staff and visitors as well as the quality of the care offered by the Trust. Being open and honest when things go wrong ensures the Trust gets to the root cause of the event and promotes organisational learning.

1.4 *Being Open* is fundamental in relationships with and between patients, the public, staff and healthcare organisations.

1.5 The *Duty of Candour* (introduced from 1 April 2013) is a contractual requirement to ensure the *Being Open* process is followed when a patient safety incident results in moderate harm, severe harm or death.

1.6 The Trust endorses the principles of *Being Open* and the *Duty of Candour* by committing to:

- acknowledging, apologising and explaining when things go wrong;
- conducting a thorough investigation into the patient safety event, informing and involving patients and families at an early stage and reassuring patients, their families and carers that lessons learned will help prevent the patient safety event recurring;
- providing support for those involved (both patients and staff) to cope with the physical and psychological consequences of a patient safety event.

2. PURPOSE AND SCOPE

2.1 This policy addresses the information and methods of sharing information with patients, relatives and their carers, staff and other healthcare organisations when incidents happen. The extent to which it is used will be determined on the grading of the severity of the event. The same principles and process are applied if a member of staff or visitor suffers harm as a result of an incident.

2.2 It is aimed at any Trust member of staff responsible for making sure we maintain openness between staff, patients and/or their carers following an incident, complaint or claim. It describes the processes of *Being Open* with patients and the *Duty of Candour* to inform and involve patients and gives advice on communicating with patients and/or their carers following harm.

2.3 The Trust's incident reporting mechanism, Datix and investigation processes adopted by the Trust encourage all staff to report all patient safety incidents, including those where there was no harm or it was a 'near miss'.

2.4 This policy relates to those incidents that cause moderate harm, severe harm or death (see paragraph 4.8), incidents that are no harm/near miss are not specifically within the scope of this policy but we will always seek to be open about any incidents and near misses

2.5 For incidents and complaints the process outlined in this policy will be adopted as and when an issue is identified. If an issue reaches the stage of a claim; the documentation which will have been prepared in relation to the *Being Open* and *Duty of Candour* process will be disclosed in accordance with the due legal process.

2.6 The principles of *Being Open* and *Duty of Candour* also apply to open communication between healthcare organisations, healthcare teams, staff and patient's carers/relatives.

3. DUTIES AND RESPONSIBLITIES

3.1 The **Chief Executive** is responsible for making sure the infrastructure is in place to support openness between Trust staff and patients and/or their carers, staff and visitors. In conjunction with the Trust Board, the Chief Executive is responsible for actively championing the *Being Open* and *Duty of Candour* culture and process by promoting an open, honest and fair culture which fosters peer support.

3.2 The **Executive Directors** are responsible for promoting an open, honest and fair culture within the organisation.

3.3 The **Director of Governance and Corporate Development** is the Lead Director who has devolved responsibility and will oversee the monitoring and implementation of this policy in order to ensure it is applied throughout the Trust.

3.4 **Heads of Division, Service Managers and Heads of Service** are responsible for promoting an open, honest and fair culture within the Trust. They are responsible for making sure local management arrangements are suitable and sufficient to allow for all aspects of this policy to be implemented.

3.5 The **Head of Risk** is responsible for risk management and the Datix reporting system and providing advice and support to both Staff and Managers involved in the Trust's Serious Incidents Requiring Investigation (SIRI) process.

3.6 **Head of Corporate Business** is the Document Author who will ensure the process adopted by the Trust complies with local and national guidance. In addition, the Head of Corporate Business is responsible for the management of the handling of all clinical and non-clinical personal injury claims made against the Trust, in accordance with both statutory and mandatory requirements.

3.7 The **Patient Experience Manager** is responsible for promoting an open, honest and fair culture within the Trust when dealing with complaints and reporting any incidents (which become apparent during the course of a

complaint) to the Risk Team.

3.8 The **Patient Advice and Liaison** (PALS) service is responsible for promoting an open, honest and fair culture within the Trust when dealing with enquiries and concerns and reporting any incidents (which become apparent during the course of an enquiry) to the Risk Team.

3.9 There is a responsibility for **Medical Staff** to be open and honest in their dealings with patients. Draft guidance has been published by the GMC http://www.gmc-uk.org/Openness_and_honesty___Draft_guidance.pdf_58423740.pdf .All medical staff are expected to uphold the 'Duty of Candour' under Good Medical Practice regulations.

3.10 All **registered nurses** have a professional duty of candour which consists of two core responsibilities. It is the registered nurse's duty to be open and honest with patients in their care, or those close to them, if something goes wrong. It is the registered nurse's duty to be open and honest with their organisation, and to encourage a learning culture by reporting adverse incidents that lead to harm, as well as near misses

3.11 **All staff** working within the Trust will be expected to adhere to this policy and promote an open, honest and fair culture within the organisation. All staff have a responsibility to ensure incidents or complaints are acknowledged and reported as soon as they are identified. Any issues or concerns raised with staff by patients and/or carers should be taken seriously from the outset and responded to appropriately. Any concerns should be treated with compassion and understanding by all staff.

3.12 The **Serious Incident Requiring Investigation (SIRI) Review Group** is responsible for the reviewing of SIRIs and includes representation from Executive Directors; a range of Trust staff and a representative of Somerset Clinical Commissioning Group.

4. EXPLANATIONS OF TERMS USED

4.1 **Being Open** is the process by which the patient, their family and carers are informed about a patient safety incident/complaint/claim involving them.

4.2 **Candour**: "Any patient harmed by the provision of healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked." (Francis 2013).

4.3 **Claim** – defined by the Clinical Negligence Scheme for Trust (CNST) as: "any demand, however made, but usually by the patient's legal adviser, for monetary compensation in respect of an adverse clinical incident leading to a personal injury".

4.4 **Complaint** is any expression of dissatisfaction with care provision, or a perceived grievance or injustice.

4.5 **Event** is any occurrence that results in a patient safety incident, complaint or claim.

4.6 **DATIX** is the on-line electronic system for reporting and recording all Incidents, PALS and Complaints and Risks Trust wide (individual patient

related clinical risk should always be recorded within the patient's clinical record.

4.7 **Duty of Candour** is the legal obligation to disclose errors which may not be immediately obvious to the patient. Exercising candour narrows the gap between what the healthcare professional and the patient know about an incident.

4.8 The National Patient safety (NPSA) definitions of levels of **harm** are:-

- **No harm**: Impact prevented – any patient safety incident which had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care. Impact not prevented – any patient safety incident that ran to completion but no harm occurred to people receiving NHS-funded care.
- **Low Harm**: Any patient safety incident that required extra observation or minor treatment and caused minimal harm, to one or more persons receiving NHS-funded care.
- **Moderate Harm**: Any patient safety incident that resulted in a moderate increase in treatment (e.g. increase in length of hospital stay by 4-15 days) and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.
- **Severe Harm**: Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care.
- **Death**: Any patient safety incident that directly resulted in the death of one or more persons receiving NHS-funded care.

4.9 **Never Events** are serious, largely preventable patient safety incidents which should not occur if the available preventative measures have been taken.

4.10 The **National Reporting and Learning System** (NRLS) is the electronic system by which all NHS Trusts inform the NHS Commissioning Board Special Health Authority patient safety incidents. Where a patient safety incident is discovered through a complaint, concern or claim that has not previously been reported, case by case consideration should be given as to whether the incident is reflected on the NRLS retrospectively. It may be considered that the delay in reporting be reported as an incident itself.

4.11 A **Notifiable Safety Incident** is any unintended or unexpected incident which could have or did lead to harm for one or more patients.

4.12 A **Serious Incident Requiring Investigation** (SIRI) is any incident occurring in relation to care that is reportable to NHS England.

4.13 **StEIS** is the Strategic Executive Information system. It is a national database of serious incidents that is monitored locally, regionally and nationally.

5. BASIC PRINCIPLES

5.1 This policy reflects the 'Ten Principles of *Being Open* as identified in *Being Open: communicating patient safety incidents with patients and their carers* (NPSA, 2005), described in further detail in Appendix A, and the revised *Being Open Framework* issued in November 2009. It also reflects the requirements of the NHS Standard Contract.

5.2 Appendix B details the requirements, responsibilities and timescales applicable to the *Duty of Candour*.

Acknowledgement

5.3 All events should be reported as soon as they are identified. Where the concerns are raised by the patient, their family or carers, the concern should be taken seriously from the outset and treated with compassion and understanding by all healthcare professionals. An example initial contact letter is set out at Appendix F.

Notifiable safety incidents

5.4 These should be acknowledged and documented in the clinical notes as soon as an incident is identified and entered on to the DATIX system. The communication with the patient should be initially verbal, with the offer of a written notification. This should be within 10 days of the incident being reported. This will also be documented within the investigation (RCA – root cause analysis) report. In the event that the incident is notifiable under the provisions of the Duty of Candour, the reporting requirements set out in Appendices B and C will apply.

5.5 The judgement as to whether an incident is notifiable is down to the opinion of the healthcare professional. Any decision made regarding notification by the healthcare professional must be clearly documented in the clinical notes, demonstrating clear rationale for decisions made. Please see the guidance and scenarios set out in Appendix C.

Complaints

5.6 These should be acknowledged within 3 working days of receipt.

Claims

5.7 These should be acknowledged within 14 calendar days of receipt.

Apology

5.8 A sincere, meaningful apology for the event should be offered as early as possible where it is clear that there has been an error or harm has been caused. An apology does not signify an admission of guilt or blame. Verbal apologies allow face-to-face contact between the patient and the healthcare team and should be given as soon as staff are aware that an incident has happened. This should be documented in the medical case notes by the clinician holding the 'Being Open' discussion and within any response to a complaint if one is raised.

5.9 Where the event results in a claim, it will remain the decision of the case manager to assess whether the apology or further explanation is subject to privilege and therefore not disclosable. The reason for not apologising or explaining should be documented in the claims case file.

5.10 In litigation cases the NHS Litigation Authority will prepare letters of apology (where the following process has not already been completed as a result of an incident or complaint giving rise to the claim).

5.11 It is important not to delay the apology for any reason, including the setting up of a more formal 'Being Open' or 'Duty of Candour' meeting, but the meeting

must happen only once there is reasonable assurance that the facts are known and understood.

Truthfulness, timeliness, clarity of communication and explanation

5.12 Patients and their carers can reasonably expect to be informed of if the issues surrounding the event, and its consequences in a face-to-face meeting. They should be treated sympathetically, with respect and consideration. The information about the event must be relayed in an honest and candid open manner, by the appropriate person, as soon as is practicable. It should be based only on the facts known at the time, and provide the patient with a step-by-step explanation of what happened.

5.13 Information should be unambiguous and free from jargon. Care should be taken that patients do not receive conflicting information from different members of the team. Any discussion with the patient, their family or carers should be documented in the medical records at the time of discussion. The patient, family or carer should be informed that there will be an investigation and they should be offered the opportunity to review the final report should they wish.

5.14 Any medical terminology should be clearly explained. Where appropriate, the patient should be offered the opportunity to contribute to the investigation. For patient safety incidents, this will be demonstrated within the investigation report.

5.15 This should be incorporated into any complaint response and/or the sharing of a SIRI investigation report with the patient and their family/ carers.

6. TRAINING REQUIREMENTS

6.1 New staff will receive Induction training, which includes Trust policies. Existing staff will receive training appropriate to their level of responsibility as directed by their Service Manager.

6.2 Senior Managers and medical staff identified by Directors will receive training in Root Cause Analysis to assist in the investigation process.

6.3 In addition to the framework within the *Being Open* guidance there are a number of supporting tools and there is an e-learning tool. There is more information on these supporting tools on www.nrls.npsa.nhs.uk/beingopen and this information will be added to the Trust Intranet.

6.4 Service and Team managers will receive training in managing difficult conversations and the requirements of the Duty of Candour to support them in handling sensitive conversations with patients, carers and families.

7. EQUALITY IMPACT ASSESSMENT

7.1 All relevant persons are required to comply with this document and must demonstrate sensitivity and competence in relation to the nine protected characteristics as defined by the Equality Act 2010. In addition, the Trust has identified Learning Disabilities as an additional tenth protected characteristic. If you, or any other groups, believe you are disadvantaged by anything contained in this document please contact the Equality and Diversity Lead who will then actively respond to the enquiry.

8. MONITORING COMPLIANCE AND EFFECTIVENESS

8.1 Monitoring arrangements for compliance and effectiveness

The monitoring will be performed each quarter by the **Serious Incident Requiring Investigation (SIRI) Review Group**.

The Group is accountable to and will provide the **Clinical Governance Group** with a quarterly report and will include the results of the monitoring highlighting good practice, areas of concern, risk issues, action plans and lessons learnt. This Group will be responsible for ensuring action plans are completed and improvements, where necessary, are implemented.

The **SIRI Review Group** will monitor the quality of SIRI Root Cause Analysis reports each meeting (monthly), along with actions identified from these reviews and outcomes of meetings with patients and carers. The SIRI Review Group will monitor recorded activity on DATIX in respect of Serious Incidents. As a minimum the report will include assurance that all communication in respect of acknowledgements, apologies and explanations have been conducted and recorded in a timely manner.

The SIRI Review Group is accountable to and will provide the **Clinical Governance Group** with a monthly report using the Governance Group Reporting template and will include the results of the monitoring highlighting good practice, areas of concern, risk issues, action plans and lessons learnt. This Group will be responsible for ensuring action plans are completed and improvements, where necessary, are implemented.

Lessons learnt from SIRIs will be discussed in the Serious Incidents Requiring Investigation Review Group and added to the Lessons Learnt register, following each meeting the register will be accessible to all staff on the Trust Intranet and hyperlinked into 'WhatsOn@Sompar' newsletter to raise awareness.

The Head of Risk will provide the Trust Board with a report to ensure the Board is aware and monitor SIRI activity.

9. COUNTER FRAUD

9.1 The Trust is committed to the NHS Protect Counter Fraud Policy – to reduce fraud in the NHS to a minimum, keep it at that level and put funds stolen by fraud back into patient care. Therefore, consideration has been given to the inclusion of guidance with regard to the potential for fraud and corruption to occur and what action should be taken in such circumstances during the development of this procedural document.

10. RELEVANT CARE QUALITY COMMISSION (CQC) REGISTRATION STANDARDS

10.1 Under the **Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3), the fundamental standards** which inform this procedural document, are set out in the following regulations:

Regulation 9:	Person-centred care
Regulation 10:	Dignity and respect
Regulation 11:	Need for consent
Regulation 12:	Safe care and treatment
Regulation 13:	Safeguarding service users from abuse and improper treatment
Regulation 14:	Meeting nutritional and hydration needs
Regulation 15:	Premises and equipment
Regulation 16:	Receiving and acting on complaints
Regulation 17:	Good governance
Regulation 18:	Staffing
Regulation 19:	Fit and proper persons employed
Regulation 20:	Duty of candour
Regulation 20A:	Requirement as to display of performance assessments.

10.2 Under the **CQC (Registration) Regulations 2009 (Part 4)** the requirements which inform this procedural document are set out in the following regulations:

Regulation 12:	Statement of purpose
Regulation 16:	Notification of death of service user
Regulation 17:	Notification of death or unauthorised absence of a service user who is detained or liable to be detained under the Mental Health Act 1983
Regulation 18:	Notification of other incidents

10.3 Detailed guidance on meeting the requirements can be found at http://www.cqc.org.uk/sites/default/files/20150311%20Guidance%20for%20providers%20on%20meeting%20the%20regulations%20FINAL%20FOR%20PUBLISHING.pdf

Relevant National Requirements

National Patient Safety Agency

NHSLA Risk Management Standards for NHS Trusts providing Acute, Community or Mental Health & Learning Disabilities Services and Non-NHS Providers of NHS Care, 2012-2013

11. REFERENCES, ACKNOWLEDGEMENTS AND ASSOCIATED DOCUMENTS

11.1 References

National Health Service Litigation Authority (NHSLA) – Apologies and Explanations Letter to Chief Executives and finance directors (2009)

NPSA/2009/PSA003 Being Open – Communicating with patients, their families and carers following a patient safety incident.

National Quality Board: Review of early warning systems in the NHS (February 2010)

National Patient Safety Agency (2005) *Being Open: Communicating patient*

safety incidents with patients and carers [Online] National Patient Safety Agency
Available from: http://www.nhsa.nhs.uk [Accessed 01 October 2007]

National Patient Safety Agency (April 2004) *Seven Steps to Patient Safety: An overview guide for NHS Staff* [Online] National Patient Safety Agency
Available from: http://www.npsa.nhs.uk/sevensteps [Accessed 01 October 2007]

Good Medical Practice General Medical Council (2001)

NHS Constitution (2012)
www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_113613

"Involving and Communicating with Patients and the Public" National Patient Safety Agency, 2005

The 5th Shipman Inquiry Report

"Striking the Balance" The NHS Litigation Authority

"Making Amends" Chief Medical Officer

NMC The Code: Standards of conduct, performance and ethics for nurses and midwives (2008).

Guidance for NHS bodies on the fit and proper person requirement for directors and the duty of candour (Consultation) Care Quality Commission July 2014

NHS Standard Contract: NHS Commissioning Board

Worcestershire Health and Social Care NHS Trust 'Being Open and Duty of Candour Policy'

11.2 **Cross reference to other Trust procedural documents**

Changing Your Healthcare Professional Policy

Claims Handling Policy

Complaints, Concerns and Compliments Policy

Consent and Capacity to Consent to Treatment Policy

External Recommendations and Best Practice Guidance Procedure

Privacy, Dignity and Respect Policy

Professional Interpreting and Translation Services Policy

Risk Management Policy and Procedure

Risk Management Strategy

Serious Incidents Requiring Investigation (SIRI) Policy

Single Equality Strategy and Action Plan 2010-2013

Untoward Event Reporting Policy

Whistle blowing Policy

All current policies and procedures are accessible in the policy section of the public website (on the home page, click on 'Policies and Procedures'). Trust Guidance is accessible to staff on the Trust Intranet.

12. APPENDICES

12.1 For the avoidance of any doubt the appendices in this policy are to constitute part of the body of this policy and shall be treated as such.

Appendix A	**The Ten Principles of Being Open**
Appendix B	**Duty of Candour Requirements**
Appendix C	**The Being Open and Duty of Candour Process**
Appendix D	**72 Hour Review reporting for Duty of Candour**
Appendix E	**Special Circumstances**
Appendix F	**Example Letter**

APPENDIX A

THE TEN PRINCIPLES OF *BEING OPEN*

(Adapted from Being Open: Saying sorry when things go wrong (NPSA 2009))

"Being open" is a process rather than a one-off event. With this in mind, the following principles have been drawn up to support the policy.

1. Acknowledgement

All patient safety incidents should be acknowledged and reported as soon as they are identified. In cases where the patient, their family and carers inform healthcare staff when something untoward has happened, it must be taken seriously from the outset. Any concerns should be treated with compassion and understanding by all Trust staff.

2. Truthfulness, timeliness and clarity of communication

Information about a patient safety incident must be given to patients, their families and carers in a truthful and open manner by an appropriately nominated person. Patients should be provided with a step-by-step explanation of what happened, that considers their individual needs and is delivered openly. Communication should also be timely; patients, their families and carers should be provided with information about what happened as soon as practicable. It is also essential any information given is based solely on the facts known at the time. Trust staff should explain new information may emerge as an incident investigation is undertaken, and patients, their families and carers will be kept up-to-date with the progress of an investigation. Patients, their families and carers should receive clear, unambiguous information and be given a single point of contact for any questions or requests they may have. They should not receive conflicting information from different members of staff, and the use of medical jargon, which they may not understand, should be avoided.

3. Apology/Expressing Regret

Patients, their families and carers should receive a meaningful apology – one that is a sincere expression of sorrow or regret for the harm that has resulted from a patient safety incident. This should be in the form of an appropriately worded and agreed manner of apology as early as possible and it should be ensured any apology does not constitute an acceptance of liability. Based on local circumstances, the Trust should decide on the most appropriate member of staff to give both verbal and written apologies to patients, their families and carers. The decision should consider seniority, relationship to the patient, and experience and expertise in the type of patient safety incident that has occurred. Verbal apologies are essential because they allow face-to-face contact between the patient, their family and carers and the healthcare team. This should be given as soon as staff are aware an incident has occurred. A written apology, which clearly states the Trust is sorry for the suffering and distress resulting from the incident, must also be given. It is important not to delay giving a meaningful apology for any reason, including: setting up a more formal multidisciplinary *Being Open* discussion with the patient, their family and carers; fear and apprehension; or lack of staff availability. Delays are likely to increase the patient's, their families and their carers' sense of anxiety, anger or frustration.

4. Recognising patient and carer expectations

Patients, their families and carers can reasonably expect to be fully informed of the issues surrounding a patient safety incident, and its consequences, in a face-to-face meeting with representatives from the healthcare organisation. They should be treated sympathetically, with respect and consideration.

Patients, their families and carers should also be provided with support in a manner appropriate to their needs. This involves consideration of special circumstances that can include a patient requiring additional support, such as an independent patient advocate or a translator. Where appropriate, information on PALS and other relevant support groups e.g. Cruse Bereavement Care and Action against Medical Accidents (AvMA) should be given to the patient as soon as it is possible.

5. Professional support

The Trust will create an environment in which all staff, whether directly employed or independent contractors, are encouraged to report patient safety incidents. Staff should feel supported throughout the incident investigation process because they too may have been traumatised by being involved. They should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration. The NCAS can be contacted for advice on handling the concern and whether an assessment of the individual's practice would be helpful.

Where there is reason for the Trust to believe a member of staff has committed a punitive or criminal act, it will take steps to preserve its position, and advise the member(s) of staff at an early stage to enable them to obtain separate legal advice and/or representation. The Trust will also encourage staff to seek support from relevant professional bodies such as the GMC, royal colleges, the MDU, the MPS and the Nursing and Midwifery Council.

6. Risk management and systems improvement

Root Cause Analysis, Significant Event Audit (SEA) or similar techniques should be used to uncover the underlying causes of a patient safety incident. These investigations should focus on improving systems of care, which will then be reviewed for their effectiveness. The Trust's *Being Open and Saying Sorry When Things Go Wrong* policy will be integrated into local incident reporting and risk management policies and processes. *Being Open* is one part of an integrated approach to improving patient safety following a patient safety incident. It will be embedded in an overarching approach to risk management that includes local and national incident reporting, analysis of incidents using Root Cause Analysis or Significant Event Audit, decision-making about staff accountability using the Incident Decision Tree and the Trust approach that follows *Seven steps to patient safety*

7. Multidisciplinary responsibility

The Trust's *Being Open and Duty of Candour policy* on openness applies to all staff who have key roles in the patient's care. Most Trust provision is through multidisciplinary teams. This is reflected in the way patients, their families and carers are communicated with when things go wrong. This will ensure that the *Being Open* process is consistent with the philosophy that incidents usually result from systems failures and rarely from the actions of an individual. To

ensure multidisciplinary involvement in the *Being Open* process, it is important to identify clinical, nursing and managerial opinion leaders who will support it. Both senior managers and senior clinicians who are local opinion leaders must participate in incident investigation and clinical risk management.

8. Clinical governance

Being Open requires the support of patient safety and quality improvement processes through clinical governance frameworks in which patient safety incidents are investigated and analysed to find out what can be done to prevent their recurrence. These findings will be disseminated to members of staff so they can learn from patient safety incidents. It also involves a system of accountability through the Trust Chief Executive to the Trust Board who will ensure changes are implemented and their effectiveness reviewed. Continuous learning programmes and audits will be developed that allow the Trust to learn from the patient's experience of *Being Open*, and monitor the implementation and effects of changes in practice following a patient safety incident.

9. Confidentiality

The Trust's *Being Open and Duty of Candour policy* gives full consideration of, and respect for, the patient's, their families and carers' and staff privacy and confidentiality in line with the CQC's guidance for Outcome 19. Details of a patient safety incident will at all times be considered confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient, in line with the CQC's guidance for Outcome 20. Where this is not practical, or an individual refuses to consent to the disclosure, it may still be lawful if justified in the public interest, or where those investigating the incident have statutory powers for obtaining information. Communications with parties outside of the clinical team should also be on a strictly need to know basis and, where practicable, records should be anonymous. In addition, it is good practice to inform the patient, their family and carers about who will be involved in the investigation before it takes place, and give them the opportunity to raise any objections.

10. Continuity of care

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

APPENDIX B

DUTY OF CANDOUR REQUIREMENTS

	Requirement under Duty of Candour	Responsible person/ department	Timeframe
1	Patient and/or their family/carer must be informed that a suspected or actual incident has occurred (moderate harm, severe harm or death) Head of Division and Risk Team should be made aware/involved.	Matron/ward manager/service manager and Clinician* responsible for episode of care during, or as a result of which, the incident occurred.	Maximum ten working days from incident being reported on Datix
2	Initial notification of incident must be verbal (face-to-face, where possible) unless patient or their family/carer decline notification or cannot be contacted in person. Sincere expression of apology must be provided verbally. This must be recorded.	Matron/ward manager/service manager and Clinician responsible for episode of care during, or as a result of which, the incident occurred.	Maximum ten working days from incident being reported on Datix
3	Offer of written notification. Including sincere apology must be provided in writing. Whether declined or accepted, this must be recorded.	As Above	Maximum ten working days from incident being reported on Datix
4	Step-by-step explanation of the facts (in plain English) must be offered. This may just be an initial view, pending investigation.	As Above	As soon as practicable.
5	Maintain full written documentation of any meetings. If meetings are offered but declined this must be recorded.	As above. All follow -up letters to patients/ relatives will be approved for release by the Medical Director	No timeframe prescribed.
6	Emerging information (whether during investigation or after investigation) must be offered.	As Above	As soon as practicable.
7	Share incident investigation report (including action plans)		Within ten working days of report being signed off as complete and incident closed.
8	Provide copies of any information shared with the patient to the commissioner, upon request.	Risk Management team to coordinate	As required.

APPENDIX C

THE *BEING OPEN* AND *DUTY OF CANDOUR* PROCESS

1. Overview of the *Being Open* and Duty of Candour process

<table>
<tr><th>Incident detection or recognition</th><th>Preliminary team discussion</th><th>Initial Being open discussion</th><th>Follow-up discussions</th><th>Process completion</th></tr>
<tr><td rowspan="2">Detection and notification through appropriate systems</td><td rowspan="2">Initial assessment including if it meets the Duty of Candour criteria (72 hour review)</td><td>Verbal and written apology (within 10 days)</td><td rowspan="2">Provide update on known facts at regular intervals</td><td>Discuss findings of investigation and analysis</td></tr>
<tr><td>Provide known facts to date</td><td>Inform on continuity of care</td></tr>
<tr><td rowspan="3">Prompt and appropriate clinical care to prevent further harm</td><td rowspan="2">Establish timeline</td><td>Offer practical and emotional support</td><td rowspan="3">Respond to queries</td><td>Share summary with relevant people</td></tr>
<tr><td rowspan="2">Choose who will lead communication</td><td>Identify next steps for keeping informed</td><td>Monitor how action plan is implemented.</td></tr>
<tr><td colspan="3">Documentation: Provide written records of all discussions and written summary to patient/carer</td><td>Record investigation and analysis related to the incident. Send final response to patient/carer with apology as appropriate</td></tr>
</table>

2. Detecting and recognising an incident

The *Being Open* and *Duty of Candour* process begins with the recognition and acknowledgement that a patient has suffered moderate harm, major harm or has died as a result of a patient safety incident. In all cases relating to incidents, the Trust's Untoward Events Reporting Policy and the Serious Incidents Requiring Investigation (SIRI) policy must be followed.

As soon as a patient safety incident is identified the actions required are:

- first priority: prompt and appropriate clinical care with prevention of further harm. If additional treatment is required, it should happen as soon as reasonably practicable after a discussion with the patient (or carer if the patient is unable to participate in discussion) and with appropriate consent;
- incidents must be reported through the Datix incident reporting system in accordance with Trust' Untoward Events Reporting Policy.

In addition to the Trust's incident notification systems, the following should be considered (if appropriate):

- Contacting the referring GP, for incidents which have not occurred within primary care but have implications for continuity of care, as they can offer their support to the patient, family and carers.

- All cases of untimely, unexpected or unexplained death, and suspected unnatural deaths, need to be reported to HM Coroner. A Coroner may request the case is not discussed with other parties until the facts have been considered. In this situation it should be made clear to the family a full discussion of the circumstances and any concerns will be arranged at a date to suit both parties after the Coroner's assessment is finished.
- The Trust will ensure it complies with national notification requirements, such as the Serious Incident Management process and reporting to external agencies (as described within the Serious Incidents Requiring Investigation Policy), such as the Police and NHS Somerset.
- In such circumstances when the incident may have caused significant harm, the Serious Incidents Requiring Investigation Policy will be followed and the appropriate Root Cause Analysis Investigation will take place (as described within the SIRI Policy). This will commence with a 72 hour review.

3. Implementing the *Duty of Candour* requirements

Where an incident is reported, consideration should be given as to whether it meets the requirements for the Duty of Candour as set out in Appendix B. If the incident is identified as moderate, severe or death the reporter must inform their manager as soon as possible of the incident. An initial investigation will be carried out to validate the harm caused prior to informing the patient of their relatives/next of kin. The record of this decision and actions taken will be included in the report of the 72 hour review (see Appendix D).

Sir David Dalton and Professor Norman Williams at paragraph 52 of their review of the threshold for the duty of candour 'Building a Culture of Candour' (2013) comment:

"We do, however, understand that recognition of a patient safety incident that leads to harm is not necessarily straightforward. Indeed, the majority of harm that occurs is not a simple case of one error leading to obvious identifiable harm. Most harm is a consequence of multiple instances of sub-optimal care that are not necessarily obvious to those involved in the delivery of care. It is therefore vital that the enforcement of the duty of candour is, as we have said, proportionate, and is sensitive to the realities of healthcare."

Essentially therefore, in the regulations the judgement as to whether an incident is notifiable is down to the opinion of the healthcare professional. Any decision made regarding notification by the healthcare professional must be clearly documented in the clinical notes, demonstrating clear rationale for decisions made.

Example Scenario – A Fall

There will be many cases where a patient reports harm that may or may not have occurred because of an error or mistake in the treatment they received. A dementia patient may fall on the ward for example sustaining injuries that require a moderate increase in treatment. As the patient did not sustain a fracture, this would not be classed as a Serious Incident. Everything may have been done appropriately to care for that individual and the fall may simply be an accident. However, the incident is almost certainly going to be something that you would want to discuss with the 'relevant person' be that the patient or a relative.

It is possible that a review of the incident reveals that more could have been done to prevent the fall - in which case the incident becomes a notifiable patient safety incident and the statutory Duty of Candour applies.

Grade 3 and 4 pressure ulcers constitute a large proportion of incidents in the Trust that would be classed as moderate and severe harm incidents, using the NPSA definitions. Consideration needs to be given to these as to whether they would also be notifiable incidents. There are a variety of scenarios that may occur including whether the pressure ulcer is subsequently not confirmed (in which case no action need be taken) or is identified as being pre-existing before reaching our services (in which case the patient should be advised that it has been referred to the CCG).

Example Scenario – Pressure Ulcer

A team are caring for a patient who develops a Grade 3 pressure ulcer. This, in line with Trust policy, is reported as a Serious Incident on StEIS. As a grade 3 or 4 pressure ulcer may require a moderate increase in treatment and significant harm will be experienced by the patient, this incident will almost certainly invoke the Duty of Candour. A notification meeting therefore takes place with the relevant person explaining that a pressure ulcer has been identified and it is being investigated but it is not clear at this stage how the pressure ulcer has developed.

Subsequently the Root Cause Analysis investigation reveals that everything was put in place by the clinical team to help prevent the pressure ulcer – healthcare staff had evaluated the patient's clinical condition and pressure ulcer risk factors. The team had planned and implemented interventions and had regularly evaluated the impact of the interventions. All care and treatment had been appropriately recorded in the patient's notes.

The incident was therefore unintended and unavoidable. The relevant person should still be informed of the outcome of the investigation and should receive a full explanation of the facts.

The following actions are the responsibility of the manager and the clinician responsible for the episode of care during, or as a result of which, the incident happened. It is not appropriate for others to give information to the patient. The Risk Team should be made aware:

- Moderate, severe or death incidents must be reported to patient/carer with consent within a maximum of 10 working days from the incident being reported on Datix.
- The initial notification of the incident must be verbal (face-to-face, where possible) unless the patient or their family/carer decline notification or cannot be contacted in person. A sincere expression of apology must be provided verbally. This must be recorded. At that time, an initial apology and explanation must be given.
- Patient and/or carer must be offered written notification (including a sincere apology) of the incident. Offer must be recorded whatever the outcome.
- A step-by-step explanation of the facts (in plain English) must be offered as soon as practicable. This may just be an initial view pending investigation.
- Full written documentation of any letters, discussions and meetings must be maintained. It does not need to be a verbatim record of the discussions. The response of the patient/carers should also be recorded. If meetings are offered but declined this must be recorded. All follow-up letters to patients/relatives must be approved for release by the Medical Director.
- Any emerging information (whether during the investigation or after the investigation) must be offered.
- Within 10 working days of the report of the investigation being signed off as complete by the SIRI Group it should (together with action plans) be signed off by the Medical Director and shared with the patient/relatives.

It is important patients and/or their relatives receive a meaningful apology. An apology does not constitute an admission of liability. Patients and the relatives increasingly ask for detailed explanations of what led to adverse outcomes and they frequently say that they derive some consolation from knowing that lessons have been learned for the future. Explanations should not contain admissions of liability.

Where an issue reaches a claim the NHS Litigation Authority will agree the terms of formal admissions (if appropriate) within or before litigation. This policy relates to the earlier, more informal apologies and explanations desired by patients and their families.

Where an incident or error has come to light through a complaint, the Complaints, Concerns and Compliments Policy which encourages *Being Open* will be implemented. Meetings with patients and their carers are recorded and full explanations given both verbally and in writing.

Where an incident or error has come to light through a legal claim the requirements of the Claims Handling Policy will be followed by the Claims and Litigation Manager.

In all cases the Incident Reporting Policy & Procedures should be implemented including when there has been a delay in identifying an incident.

No harm, near misses and prevented incidents should not routinely be communicated to patients as discussing no harm incidents with them can result in additional stress and loss of confidence in the standard of care. There may, however, be circumstances which warrant the patient being informed e.g. over exposure of radiation.

4. Meetings with the patient their relatives and/or their carer

The following factors should be taken into account when organising a meeting with a patient and/or their carer.

Timing?

- within 10 days of the incident, bearing in mind the clinical and emotional condition of the patient;
- the patient should be asked if they are happy with the timing and if possible offer a choice of times and confirm the arrangements in writing;
- do not cancel the meeting unless absolutely necessary.

Who should attend?

- the patient's Consultant at the time of the incident, or a senior person responsible for the patient's care at the time of the incident, in the absence of the Consultant;
- if it becomes apparent that the patient would prefer to speak to a different healthcare professional, the patient's wishes should be respected. A substitute with the appropriate seniority and skills and with whom the patient is satisfied should be provided;
- care should be taken to make sure that those members of staff attending can continue to do so as continuity is very important in building relationships;
- the person taking the lead should be supported by at least one other member of staff;
- the patient should also be asked who they would like to be present;
- consider the diverse needs of all patients, for example linguistic or cultural needs or reasonable adjustments for people with disabilities; some people may like an interpreter or advocate present;
- the communication skills of each of the team members should be considered as they need to be able to communicate clearly, sympathetically and effectively;
- when the most senior person is unknown to the patient, a healthcare professional, such as their named nurse, should be present to provide support and to promote an environment of trust;
- junior staff or those in training should not lead the *Being Open* process. Where a junior healthcare professional who has been involved in a patient safety incident asks to be involved in the "Being open" discussion, it is essential they are accompanied and supported by a

senior, suitably skilled team member;

- a pre-meeting of healthcare professionals should be held so that everyone knows the facts and understands the aims of the meeting.

Where?

- A quiet room should be used where you will not be distracted by work or interrupted;
- consider holding the meeting in the patient's home if this would be more helpful and acceptable for the patient;
- do not host the meeting near to the place where the incident happened if this may be difficult for the patient and/or their carers.

Discussion and communication

- Speak to the patient and/or their carers as you would want someone in the same situation to communicate with you or a member of your own family;
- do not use jargon or acronyms: use clear straightforward language;
- introduce everyone present at the meeting and confirm that they are happy with those present;
- acknowledge what happened and apologise on behalf of the team and the organisation. Expressing regret is not an admission of liability;
- explain what led to the adverse outcome (which should not contain an admission of liability);
- information on likely short and long-term effects of the incident (if known) should be shared with an explanation of what happens next;
- stick to the facts that are known at the time and assure them that if more information becomes available, it will be shared with them;
- do not speculate, attribute blame or provide conflicting information;
- do not comment outside your own experience;
- check they have understood what you have told them and offer to answer any questions;
- offer practical and emotional support. This may involve giving information on third parties such as charities, voluntary organisations or support/help lines to the patient/carer, as well as offering more direct assistance. Information about the patient and the incident should not normally be disclosed to third parties without the patient's consent;
- give the contact details of one member of staff who will act as a contact point for them, to provide both practical and emotional support;
- if a patient expresses a preference for their healthcare needs to be taken over by another team, they should be referred for treatment elsewhere;
- give written and verbal information on the complaints procedure and offer assistance if they wish to make a complaint.

Documentation

- Make sure a record of the meeting, including where, when, those present and the discussion is taken;
- the record does not have to be verbatim but the responses of the patient and carers should be recorded;
- if requested, clarify the information given (in writing), reiterate key points and record action points
- assign responsibilities and deadlines for the action points;
- make sure that the patient's clinical record contain a complete, accurate record of the discussion(s) including the date and time of each entry, what the patient and/or carers have been told and a summary of the agreed actions points;
- send a copy of the documentation to the incident investigating officer; Advise the patient's GP of the adverse event as it may have an effect on continuing care;
- maintain a dialogue by addressing any new concerns and sharing new information when it becomes available;
- ask the patient/carers if they wish to receive a written copy.

Follow-up

The preliminary follow-up discussion with the patient and/or their carers is an important step in the process. The following guidelines should assist in making the communication effective:

- follow-up should happen as soon as practicable at a time and place based on the patient's health and personal circumstances;
- feedback on progress in the investigation process;
- there should be no speculation or attribution of blame. The healthcare professional should not comment outside their own experience;
- give the patient/carer opportunity to discuss the situation with other relevant professionals where appropriate;
- make sure that a record of the meeting, including where, when, those present and the discussion is taken;
- if completing the process at this point the patient/carer should be asked if they are satisfied with the outcome which should be noted;
- the contact information should be reiterated.

Completion of the process

After completion of the incident investigation, the patient/carer must be provided with the written report of the investigation and action plan (unless the offer has been refused and recorded as such). This can be done following sign off by the SIRI Group. The report should include the following information:

- a summary of the factors that contributed to the incident; Information on what has been and will be done to reduce the risk of a similar incident in the future; Information about how these improvements will be

monitored;

- a repeated apology for the harm suffered and any shortcomings in the delivery of care that led to the patient safety incident;
- 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, for example, 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 and/or their carers will be informed of the reasons for the restrictions.

Continuity of care

When a patient has been harmed during the course of treatment and requires further therapeutic management or rehabilitation, they should be informed of the ongoing clinical management plan. This may be included in discharge documentation addressed to designated individuals such as the referring GP, attending district nursing service or healthcare organisation if the patient is being transferred.

Patients and/or their carers should be reassured that they will continue to be treated according to their clinical needs even in circumstances where there is a dispute between them and the healthcare team. They should also be informed that they have the right to continue their treatment elsewhere if they have lost confidence in the healthcare team involved in the patient safety incident.

External communications
Wherever possible, it is advisable to send a brief communication to the patient's GP, before discharge, describing what happened.

When the patient leaves the care of the Trust, a discharge letter should also be forwarded to the GP or appropriate community care service (a copy being sent with the patient should they be transferred) with a brief summary of:

- the nature of the patient safety incident and the continuing care and treatment requirements;
- the current condition of the patient, key investigations with results and prognosis.

Communication of lessons learned (internally and externally)
Lessons learned from incidents, complaints and claims and the "Being open" and Duty of Candour process will be shared:

Internally
Lessons learned should be shared in accordance with Trust policy and procedures including at a local level through ward/department team meetings and Trustwide through the governance arrangements.

Externally

The incident reports of patient safety incidents are fed through the National Reporting Learning Service to the NHS England and the Care Quality Commission.

The NPSA will publish patient safety alerts, safer practice notices and patient safety information notices through the Safety Alert Broadcast System to highlight common factors that cause patient safety incidents, and to publicise its advice and solutions to the service. The primary aim will be to help reduce the risk of such incidents recurring.

(For Moderate, Severe Harm or incidents where patient has died) **APPENDIX D**

		Yes / No If no, state reason	Notes	Documented in health record?	Achieved within 10 working days Yes/No
1	Has the patient been informed face to face of this incident?				
2	Has the family been informed face to face of this incident? (*with patient's consent or if patient does not have capacity*) If so, state initial and relationship				
3	Has the patient or family been provided with an appropriate apology?				
4	Have they been offered written confirmation of the initial discussion regarding this incident?				
4a	If yes, did they accept the offer of written confirmation of the initial discussion?				
5	Has the patient / family been asked whether they wanted any specific question(s) answered as part of the investigation? List any specific questions in *notes*				
6	Have they been offered a copy of the incident investigation outcome (following approval)?				
6a	If yes to above; was this within 10 working days of completion of investigation outcome/approval?				
6b	If yes, has the patient / family been offered a face to face meeting to discuss the outcome of the investigation?				
6c	Did they accept the offer of a face to face meeting?				
6d	Date of meeting / with whom				

APPENDIX E

SPECIAL CIRCUMSTANCES

The approach to *Being Open* and the *Duty of Candour* may need to be modified according to the patient's personal category and patient circumstances.

Children

The legal age of maturity for giving consent to treatment is 16. It is the age at which a young person acquires the full rights to make decisions about their own treatment and their right to confidentiality becomes vested in them rather than their parents or guardians. However, it is still considered good practice to encourage competent children to involve their families in decision- making.

The courts have stated that younger children who understand fully what is involved in the proposed procedure can also give consent. This is sometimes known as Gillick competence or the Fraser guidelines. Where a child is judged to have the cognitive ability and the emotional maturity to understand the information provided, he/she should be involved directly in the "Being open" process after a patient safety incident. The opportunity for parents to be involved should still be provided unless the child expresses a wish for them not to be present.

Where children are deemed not to have sufficient maturity or ability to understand, consideration needs to be given to whether information is provided to the parents alone or in the presence of the child. In these instances the parents' views on the issue should be sought. More information can be found in the Consent and Capacity to Consent to Treatment policy.

Patients with mental health problems

Being Open for patients with mental health issues should follow normal procedures, unless the patient also has cognitive impairment (see below). The only circumstances in which it is appropriate to withhold patient safety incident information from a mentally ill patient is when advised to do so by a consultant psychiatrist who feels it would cause adverse psychological harm to the patient. However, such circumstances are rare and a second opinion (by another consultant psychiatrist) would be needed to justify withholding information from the patient. Apart from in exceptional circumstances, it is never appropriate to discuss patient safety incident information with a carer or relative without the express permission of the patient. To do so is an infringement of the patient's human rights.

Patients with cognitive impairment

Some individuals have conditions that limit their ability to understand what is happening to them. They may have authorised a person to act on their behalf by an lasting enduring power of attorney. In these cases steps must be taken to ensure this extends to decision-making and to the medical care and treatment of the patient. The "Being open" discussion would be held with the holder of the power of attorney. Where there is no such person the clinicians may act in the patient's best interest in deciding who the appropriate person is to discuss incident information with, regarding the welfare of the patient as a whole and not simply their medical interests. However, the patient with a cognitive impairment should, where possible, be involved directly in

communications about what has happened. An advocate with appropriate skills should be available to the patient to assist in the communication process.

Patients with learning disabilities
Where a patient has difficulties in expressing their opinion verbally, an assessment should be made about whether they are also cognitively impaired (see above). If not cognitively impaired they should be supported in the "Being open" process by alternative communication methods (i.e., given the opportunity to write questions down). An advocate, agreed on in consultation with the patient, should be appointed. Appropriate advocates may include carers, family or friends of the patient. The advocate should assist the patient during the "Being open" process, focusing on ensuring that the patient's views are considered and discussed.

Patients who do not agree with the information provided
Sometimes, despite the best efforts of healthcare staff or others, the relationship between the patient and/or their carers and the healthcare professional breaks down. They may not accept the information provided or may not wish to participate in the *Being Open* process. In this case the following strategies may assist:

- deal with the issue as soon as it emerges;
- where the patient agrees, make sure their carers are involved in discussions from the beginning;
- where the senior health professional is not aware of the relationship difficulties, provide mechanisms for communicating information, such as the patient expressing their concerns to other members of the clinical team and/or offer the patient and/or their carers another contact person;
- appoint a mediator to help identify the issues between the healthcare organisation and the patient, and to look for a mutually agreeable solution.

APPENDIX F

EXAMPLE LETTER

Guidance letter template for initial communication letter in accordance with requirements of Duty of Candour.

NB This is provided purely for guidance. All letters must be personalised and tailored to the individual needs of the person receiving the letter.

Dear Mr/Mrs/Ms xxxxxxxxxxx

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

As a Trust we are committed to being open with patients and carers when events such as these occur so that we gain a shared understanding of what happened, and what we can do to prevent such an incident occurring again in the future.

An investigation is already underway to try and establish the cause of the incident. If you would like to meet with a member of staff to discuss this, please let me know within the next two weeks, and we will arrange a mutually convenient time and place to meet.

If you would like support in attending this meeting or discussing your concerns, please contact out Patient Advice and Liaison Service (PALS) on 01278 432022 or at PALS@sompar.nhs.uk.

Staff member XXXXX is acting as your lead contact for the duration of the investigation. They can be contacted by email on xxxxxxxxxxxxxxx or on telephone number xxxxx xxxxxxx.

Yours sincerely