NHS
South Central
Ambulance Service
NHS Foundation Trust

BEING OPEN AND DUTY OF CANDOUR POLICY

South Central Ambulance Service NHS Foundation Trust
Unit 7 & 8, Talisman Business Centre, Talisman Road,
Bicester, Oxfordshire, OX26 6HR

Document Information

Author: Jane Campbell - Director for Quality and Patient Care.

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- CQC Regulation 20 added
- Policy placed into new format
- Following sections added
- Exec Summary
- 9.0: Training
- 10.0: External Regulation
- 12.0: Monitoring of the policy
- 13.0: Policy Review
- 14.0: Dissemination and Implementation Arrangements
- 15.0 Audit
- 16.0: References
- 17.0: Supporting Documents
- Appendix C: CQC Full Regulation Details
- Appendix D: Duty of Candour Sample Letters

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EXECUTIVE SUMMARY

The effects on patients, relatives, carers, and staff when things go wrong, can be devastating. 'Duty of Candour' outlines the principles that healthcare staff should use when communicating with patients, their families, next of kin and carers following a patient safety incident, complaint or claim where a patient was harmed, or where there is a risk or possibility that the event could lead to or result in harm to a patient. It underpins a culture of openness, honesty and transparency and is a duty on the organisation as well as individual practitioners working within the organisation.

1. INTRODUCTION

Candour is the quality of being open and honest. Patients should be well informed about all elementsof their care and treatment, and All staff have a responsibility to be open and honest to those in their care.

All organisations should have and sustain a culture which supports staff to be candid. It cannot be an 'add on' or a matter of compliance, it will only be effective as part of a wider commitment to safety, learning and improvement. This will require a considerable commitment to supporting staff through induction, training, and processes of review to create a culture of learning and improvement and avoiding temptations of defensiveness and blame.

The obligations and challenges of candour serve to remind us that for all its technological advances, healthcare is a deeply 'human' business. Systems and processes are necessary supports to good, compassionate care, but they can never serve as a substitute. Making a reality of candour is a matter of 'hearts and minds'. The commitment to being candid must be about values rooted in genuine engagement of staff to 'do the right thing'

In September 2005 the National Patient Safety Agency (NPSA) issued a Safer Practice Notice advising all NHS organisations to implement a "Being Open Policy". In November 2009 a Patient Safety Alert was issued by the NPSA to ensure that providers of NHS funded care implemented the principles of Being Open. Compliance with the requirements is subject to assessment by the NHS Litigation Authority*. The NHS Standard Contract 2014/15 specifically requires NHS provider organisations to implement and measure the principles of Being open under a contractual Duty of Candour. In addition, the Francis Report (2013) makes recommendations regarding Openness, Transparency and Candour.

This policy describes how South Central Ambulance Service NHS Foundation Trust (referred to as SCAS) will demonstrate its openness with patients and relatives when mistakes are made.

*The NHS Litigation Authority has now changed to NHS Resolution. For the purpose of this document the term NHS Litigation Authority will remain in use.

Being open is a set of principles that healthcare staff should use when communicating with patients, their families and carers following an incident in which the patient was harmed (severe or moderate harm). The specific delivery of "Being open" communications will vary according to the severity grading, clinical

outcome, and family arrangements of each specific event. The Duty of Candour applies to those patient safety incidents which resultin moderate harm, severe harm, or death.

The Trust aims to promote a culture of openness, which it sees as a prerequisite to improving patient safety and the quality of a patient's experience.

This policy is to be implemented following all patient safety incidents where moderate, severe harm or death has occurred contractually and ethically.

Being open relies initially on its staff and the rigorous reporting of Patient safety incidents. The Trust endorses the Francis Report Recommendation 173.

"***Every healthcare organisation and everyone working for them must be honest, open and truthful in all their dealings with patients and the public, and organisational and personal interests must never be allowed to outweigh the duty to be open, honest and truthful." Therefore, staff who are concerned about the non-reporting or concealment of incidents, or about ongoing practices which present a serious risk to patient safety, are encouraged to raise their concerns under the Trust's Whistleblowing Policy.*** N.B. The Whistleblowing policy has now been replaced by the Freedom to Speak Up Policy

2. SCOPE

This document outlines the Trust's policy on openness and how SCAS meets its obligations to patients, relatives, and the public by Being open and honest about any harm events that are made whilst trust staff care for, see, and treat and transport patients.

This document is aimed at all staff working within the Trust and sets out the infrastructure which is in place to support openness between healthcare professionals and patients, their families, and carers, following a patient safety incident.

3. OBJECTIVES AND PURPOSE

The objectives of this policy are to evidence that a robust risk management system is in place which reflects the following:

3.1 A patient has a right to expect openness from their healthcare providers.

3.2 The Trust will learn from mistakes with full transparency and openness.

3.3 A proactive approach to patient safety with the onus on risk management systems and processes identifying incidents which require review and learning.

3.4 Working in partnership with all stakeholders

3.5 Staff do not intend to cause harm but unfortunately incidents do occur. When mistakes happen, patients/relatives/carers/others should receive an apology and explanation as soon as possible. Apologising is not an admission of liability and staff should feel able to apologise at the earliest opportunity.

3.6 Senior managers undertaking Serious Incident requiring investigation must follow

the SCAS Serious Incident policy. They must ensure that appropriate support is offered to the patient/families/carers/others. A single point of contact will be identified with the patient/carer/relative to maintain communication and feedback of information about the incident.

3.7 Line managers should understand that an individual or team might require support during the investigation and, after discussion, should guide them to the appropriate support mechanism.Support for staff should be offered from the line manager and Occupational Health Services or the HR Directorate. This will include contact details of both external and internal support.

3.8 SCAS aims to comply with the requirements of the NHS Litigation Authority (NHSLA) Risk Management Standards for Ambulance Services.

4. RESPONSIBILITIES

4.1 Trust Board

The Trust Board have responsibility to obtain assurance that the processes work effectively to support the board level public commitment to implementing the Being open principles and Dutyof Candour.

4.2 Chief Executive

Chief Executive is ultimately responsible for the process of managing and responding to the *Being open* process and for the delegation of this role when required.

4.3 Executive Directors

The Executive Management Team is responsible for compliance with the *Being open* process.They are accountable to the Trust Board and the Chief Executive for the implementation of an effective Duty of Candour process.

4.4 Senior Management Team

The Senior Leadership Team is responsible for monitoring compliance with the Being open and Duty of Candour policy and implementing the associated process.

4.5 Patient Safety Group (PSG)

PSG will have overall responsibility for monitoring the *Being open* and Duty of Candour process. The group links with the Quality and Safety Committee and reports to the other relevant risk management committees and groups. The group is responsible for ensuring continuous development of the Being open and Duty of Candour policy in accordance with national guidance The Patient Safety Incident Group (PSIG) (formally known as the SIRI review group) will also ensure this policy is adhered to The group will communicate up to board level via the Quality and Safety Committee . The group in conjunction with the PSIG facilitates organisational learning and improvement as a result of effective Being open processes by making sure that any lessons learned are disseminated through the Trust.

4.5 The Assistant Director of Quality

The Assistant Director of Quality is responsible for monitoring compliance with and reporting on the effectiveness of the management of ‘Being Open’ to the PSG. A quarterly report will be produced for the group and data will be collated for submission to the commissioners.

4.6 Trust Managers

It is the responsibility of all Trust managers to support staff so that they comply with this policy

4.7 All Staff

All staff working within or on behalf of SCAS are expected to follow this policy and demonstrate the principles of Being open and Duty of Candour when a patient safety incident occurs.

5. DEFINITIONS

5.1 Patient Safety Incident

Any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare' (Seven Steps to Patient Safety, NPSA 2003).

This can be identified in the course of an incident report, complaint, and/or enquiry to Patient Experience Department or a legal claim.

5.2 Serious Incident

Serious incidents are events in health care where the potential for learning is so great, or theconsequences to patients, families and carers staff or organisations are so significant that they warrant using additional resources to mount a comprehensive response. (Serious Incident Framework, NHS England 2015 and the NHS Patient Safety Strategy, July 2019).

5.3 Openness

Enabling concerns and complaints to be raised and disclosed freely without fear, and for questions to be answered.

5.4 Transparency

Allowing information about the truth regarding performance and outcomes to be shared with staff, patients, the public and regulators.

5.5 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)

5.6 Moderate harm

Any incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons receiving NHS funded care.

5.7 Severe harm

Any incident that appears to have resulted in permanent harm to one or more persons receiving NHS funded care– related directly to the incident and not to the natural course of the patient's illness or underlying condition.

5.8 Catastrophic or Death

Any incident that directly resulted in the death of one or more persons receiving NHS funded care. Death must be related to the incident rather than the underlying condition or illness.

6. CLINICAL SUPPORT AND ADVICE

6.1 Immediate clinical support and advice for staff involved in a patient safety incident is provided according to how serious the patient safety incident is classified. The incident is graded using the Trust's DATIX system with support from operational managers and the Patient Care Directorate as described below:

- The initial level of support is provided by local managers (working at station level)for staff involved in a patient safety incident who will give advice so that they are able to manage the incident in real time, as soon as possible after the incident has happened. This includes advising on the Being Open/Duty of Candour process and general guidance about how to communicate with patients, relatives and carers. The second level of support is provided by Head of Operations 111/NEPTS managers andmay include Education managers. Further escalation may be required depending on the severity of the incident. Where support is needed from the Trust's senior operational managers then the Operations Directors/NEPTS manager/EOC Assistant Director/111 Assistant Director may be required.

- A further level of support can be provided by the Assistant Medical Directors in conjunction with the Medical Director. Out of hours the Duty Director and Silver and Gold on call can assist.

6.2 Patients, their families, carer, or representative may need considerable practical and emotional help and support after experiencing an incident. The most appropriate type of support will vary, and it is therefore important to discuss with the patient, their family, carer or representative their individual needs. Support may be provided by patient's family, social workers, religious representatives, advocacy services or the Advice and Complaints Service. Where the patient needs more detailed long-term emotional support, advice should be provided on how to gain access to appropriate counselling and support services.

7. BEING OPEN AND DUTY OF CANDOUR PROCEDURE

7.1 The patient or their family/carer must be informed that a suspected patient safety incident has occurred within at most **10 working days** of the incident being reported to the local systems, and sooner where possible.

7.2 SCAS will review all DATIX incidents resulting in moderate or severe harm as reported to the NRLS with a view to ascertain where duty of candour is required

7.3 The Clinical Governance team will liaise with operational managers to inform them that a duty of candour applies to particular incidents where moderate or severe harm is suspected

7.4 The initial notification must be verbal and face to face, where possible, and will be followed by a letter from the appropriate manager.

7.5 An apology must be provided – an apology for any suspected harm caused must be provided verbally and in writing.

7.6 The nominated operational manager will normally be the Head of Operations as the most senior person responsible for the patient's care and/or someone with the experience and expertise in the type of incident that has occurred. This person

will be supported by at least one other member of staff within the department or Patient Care Directorate. If the incident is serious and a confirmed harm of moderateor above.

7.7 If the patient or family are aware of the incident then the immediate actions as stated above should be followed by a letter.

7.8 The letter should be sent to the patient and/or relatives and others inviting them to meet with the nominated staff, offering them a choice of venues and times and advising of the independent advocacy service available to support and assist them (in accordance with the Trusts Patient Experience Policy and Serious Incident Policy.)

7.9 The patient and/or the relatives and others should be given the opportunity to choose:

- Whom they would prefer to meet with;
- Where and when the meeting will be held;
- Whether they would like to bring a friend to the meeting;
- The date, time and venue should be confirmed in writing including email.

7.8 The meeting is held as soon as possible after the incident, considering the patient's and/or the relative's and others' wishes.

7.9 Any meeting should be held in deference to the patient/relative/advocate's wishes. The same applies as to any venue; it is usually for the patient/relative to decide and for the trust to accommodate.

7.10 The local management team will be kept up to date on progress with the investigation and contacts with the patient and family.

7.11 Procedure for the Nominated Investigations Manager

7.11.1 At the meeting with the patient and/or relatives and others, the nominated staff from the investigating team should follow the procedure below.

7.11.2 Apologise for what happened.

7.11.3 If known, explain what went wrong and where possible, why it went wrong.

7.11.4 Give the patient and/or relatives an opportunity to ask as to why they thought it went wrong and an error occurred. This may include relevant personal circumstances should staff agree these can be shared.

7.11.5 Inform the patient and/or relative(s) and others what steps arebeing/will be taken to prevent the incident recurring.

7.11.6 Provide opportunity for the patient and/or relatives and others to ask any questions.

7.11.7 Agree with the patient and/or relatives and others any future meetings as appropriate.

7.11.8 An auditable record of contacts will be maintained with the Root Cause Analysis

7.12 Communication with the Relevant Person or those acting on their behalf. Information

should only be disclosed to family members or carers where the relevant person has given their expressed or implied consent.

The Trust (responsible person) must make every reasonable attempt to contact the relevant person through all available communication channels. All attempts made to establish contact must be recorded on Datix.

If the relevant person cannot be contacted or does not wish to communicate with the Trust, their wishes must be respected and a record of this must be kept. However, a written record is to be kept of attempts made to contact the relevant person and /or the discussions that took place up to and including refusal to be contacted.

If the relevant person has died and there is nobody who can lawfully act on their behalf, a record of this should be kept on Datix.

7.13 Patients with limited understanding Some service users have conditions that may limit their ability to understand what is happening to them. They may have authorised a person to act on their behalf by an enduring Power of Attorney. In these cases, steps must be taken to ensure that this extends to decision making and to the medical care and treatment of the patient. The Being Open discussion would be conducted 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, patients with 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.

7.14 Patients with different language or cultural considerations the need for translation and advocacy services, and consideration of special cultural needs (such as for patients from cultures that make it difficult for a woman to talk to a male about intimate issues), must be taken into account when planning to discuss patient incident information. It is useful to obtain advice from an advocate or translator before the meeting on the most sensitive way to discuss the information. Avoid using "unofficial translators" and/or the patient's family or friends as they may distort the information by editing what is communicated.

7.15 Patients with different communication needs a number of patients will have particular communication difficulties, such as a hearing impairment. Plans for the meeting should fully consider these needs. Knowing how to enable or enhance communications with a patient is essential to facilitating an effective Being Open process. This involves focusing on the needs of the patient, their family, and carers, and being personally thoughtful and respectful.

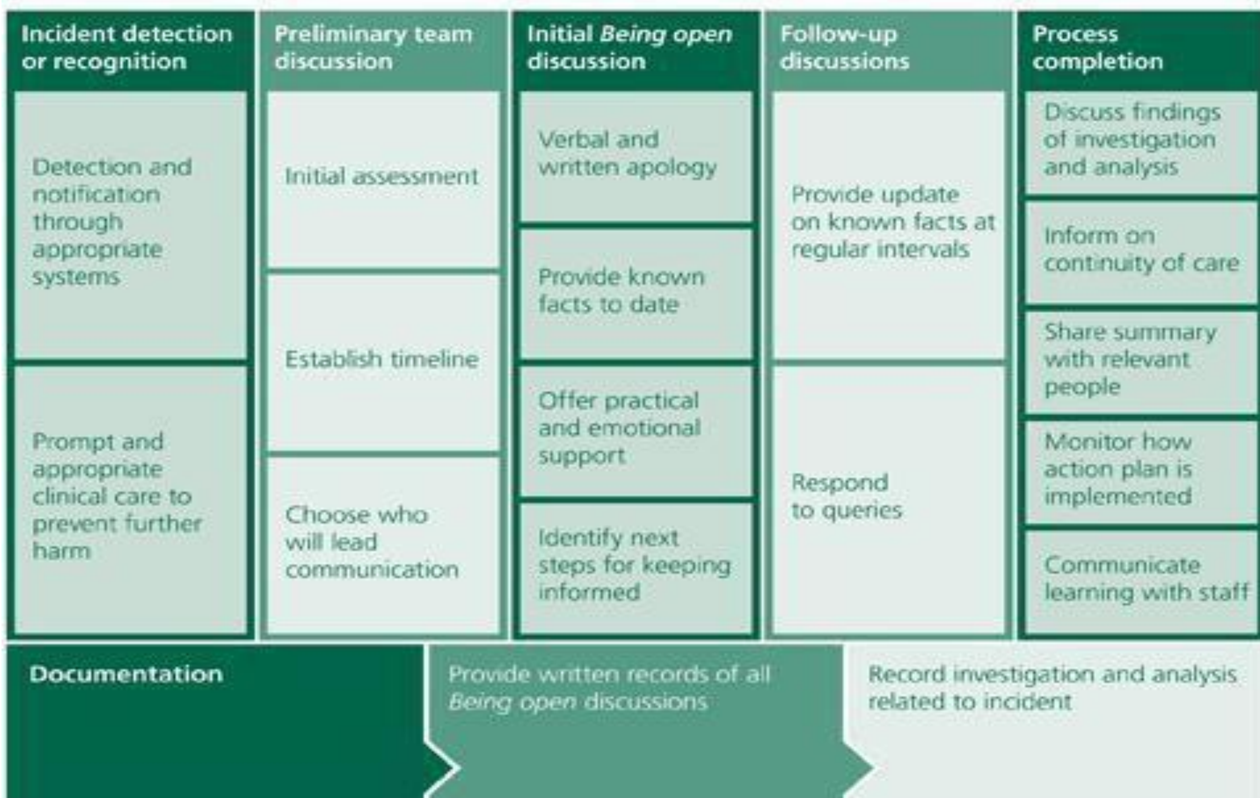
7.16 Some patients who do not agree with the information provided Sometimes, despite the best efforts of healthcare staff or others, the relationship between the patient, their family and carers and the healthcare professional breaks down. They may not accept the information provided or may not wish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

- Deal with the issue as soon as it emerges.
- Information on how to make a formal complaint and/or any other available means of giving positive or negative feedback to healthcare staff involved in their care.
- Where the patient agrees, ensure their family and carers are involved in

discussions from the beginning.

- Ensure the patient has access to support service.
- Use a mutually acceptable mediator to help identify the issues between the healthcare organisation and the patient, and to look for a mutually agreeable solution.
- Write a comprehensive list of the points that the patient, their family, and carers disagree with and reassure them you will follow up these issues.

7.17 A summary of the various stages of the Being Open process



This picture is taken from NPSA. (2009). Being Open. p.3

Stage 1: Patient safety incident detection or recognition - This covers how patient safety incidents are identified; the prompt and appropriate clinical care and prevention of further harm; and who to notify about the patient safety event.

Stage 2: Preliminary team discussions - This covers the preliminary team discussion to establish the basic clinical and other facts; undertaking the initial assessment to determine the level of response required; the timing of the discussion with the patient, their family, and carers; and choosing who will be the lead in communicating with the patient, their family, and carers

Stage 3: The initial Being open discussion - This covers the content of the discussion and what should not occur: speculation, attribution of blame, denial of responsibility and provision of conflicting information from different individuals.

Stage 4: Follow-up discussions - This covers the subsequent discussions with the

patient,their family, and carers.

8. DOCUMENTATION

The requirements for documenting all communication are set out below:

- the record of an open and honest apology.
- sharing any facts that are known and agreed with the patient/carers.
- an invitation to the patient/carers to participate in the investigationand to agree how they will be kept informed of the progress and results of that investigation.
- an explanation of any likely short and long-term effects of the incident.
- a clear response to questions the patient/carer may have.
- an offer of appropriate practical and emotional support to the patient/carer.

9. TRAINING AND GUIDANCE

Staff are supported by the Governance Lads, Freedom to Speak Up Guardian, Legal Services Manager and Patient Safety Managers to respond to required actions from the time an incident occurs to the end of the investigation.

10. EXTERNAL REGULATION

Duty of candour remains part of the regulated activity (Regulation 20) under the Health and Social Care Act 2008 which encompasses the Care Quality Commission (CQC) (Registration) Regulations 2009 (the full regulation can be found in Appendix C). The CQC states, “The duty of candour requires registered providers and registered managers (known as ‘registered persons’) to act in an open and transparent way with people receiving care or treatment from them. The regulation also defines ‘notifiable safety incidents’ and specifies how registered persons must apply the duty of candour if these incidents occur”.

There are two types of duty of candour, statutory and professional.

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

This guidance is about the statutory duty of candour. The CQC states “We regulate the statutory duty, while the professional duty is overseen by regulators of specific healthcare professions such as the Health and Care Professionals Council (HCPC), General Medical Council (GMC), Nursing and Midwifery Council (NMC) and the General Dental Council (GDC).”

The statutory duty also includes specific requirements for certain situations known as ‘notifiable safety incidents’. If something qualifies as a notifiable safety incident, carrying out the professional duty alone will not be enough to meet the requirements of the statutory duty.

Further information can be sought by reviewing the CQC website or by clicking here.

11. THE PRINCIPLES OF BEING OPEN

Being open involves apologising when something has gone wrong, being open about what has happened, how and why it may have happened, and keeping the patient and their family informed as part of any subsequent review.

11.1 Principle of Acknowledgement

All patient safety events should be acknowledged and reported as soon as they are identified. In cases where the patient, their family and carers inform healthcare staff that something has happened, their concerns must be taken seriously and should be treated with compassion and understanding by all staff. The Trust recognises that denial of a person's concerns or defensiveness will make future open and honest communication more difficult.

11.2 Principles of Truthfulness, Timeliness and Clarity of Communication

Information about a patient safety incident must be given in a truthful and open manner by an appropriately nominated person. Communication from Operational/Clinical staff must only be from Clinical Operations Manager grade staff or above. Communication should also be timely, informing the patient, their family and carers what has happened as soon as is practicable, based solely on the facts known at that time. It will be explained that new information may emerge as the event investigation takes place and that they will be kept up to date. Patients, their families and carers and appointed advocates should receive clear, unambiguous information and be given a single point of contact for any questions or requests they may have.

11.3 Principle of Apology

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 event or that the experience was poor. This should be in the form of an appropriately worded agreed manner of apology, as early as possible. Both verbal and written apologies should be given. **Saying sorry is not an admission of liability and it is the right thing to do.** Verbal apologies are essential because they allow face to face contact, where this is possible or requested. A written apology, which clearly states the organisation is sorry for the suffering and distress resulting from the patient safety event, will also be given.

11.4 Principle of Risk Management and Systems Improvement

Root Cause Analysis (RCA) or similar techniques should be used to uncover the underlying causes of patient safety events. Investigations at any identified level will however focus on improving systems of care, which will be reviewed for their effectiveness. Being open is integrated into patient safety incident reporting and risk management policies and processes.

11.5 Principles of Clinical Governance

Being open involves the support of patient safety and quality improvement through the Trust's clinical governance framework, in which patient safety incidents are

investigated and analysed, to identify what can be done to prevent their recurrence. It is a system of accountability through the chief executive to the board to ensure that these changes are implemented, and their effectiveness reviewed. Findings are disseminated to staff so they can learn from patient safety incidents. Audits are an integral process, to monitor the implementation and effects of changes in practice following a patient safety incident.

11.6 Principle of Confidentiality

Details of a patient safety incidents should 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. The Trust will anonymise any incident it publishes but still seek the agreement of those involved.

Where it is not practical or an individual refuses consent to disclosure, disclosure may still be lawful if justified in the public interest or where those investigating the patient safety event have statutory powers for obtaining information. Communications with parties outside of the incident lead and those involved in the investigation will be on a strictly need to know basis and, where practical, records are secure and anonymised where released. Where possible, it is good practice to inform the patient, their family and carers about who will be involved in the investigations before it takes place and give them the opportunity to raise any objections.

11.7 Principle of Continuity of Care

The Trust acknowledges that patients are entitled to expect they will continue to receive all usual treatment and continue to be treated with respect and compassion.

12. MONITORING OF THIS POLICY

Compliance with this policy will be monitored through the use of feedback from patients/relatives and via the review of closed investigation files. The Patient Safety Incident Review Group and Patient Safety Group will review closure of cases.

Contractual duty of candour is monitored via commissioners through contract review.

Any identified areas of non-adherence or gaps in assurance arising from the monitoring of this policy will result in recommendations and proposals for change to address areas of non-compliance and/or embed learning.

Responsibilities of staff will be monitored through attendance at meetings, management of systems, development of reports and theappraisal process.

13. POLICY REVIEW

This policy will be reviewed every **two years** or at any time before this date that a significant change is identified either by regulation or otherwise.

14. DISSEMINATION AND IMPLEMENTATION ARRANGEMENTS

The Being Open and Duty of Candour Policy will be placed on the Trust intranet. Senior managers and team leaders have a responsibility to ensure that all staff are made aware of it. Staff requiring clarification or support with implementing this policy should contact their line manager.

15. AUDIT

The Patient Safety Group will receive specific audits will be identified and undertaken as required in order to identify compliance with the requirements of this policy and to evaluate the effectiveness of the policy.

16. REFERENCES

National Patient Safety Agency - Safer Practice Notice - 2005
National Patient Safety Agency - Patient Safety Alert - 2009
NHS Standard Contract - 2014/2015
NHS Litigation Authority
Francis Report Mid Staffordshire NHS Foundation Trust Public Inquiry - 2013
National Patient Safety Agency – Seven Steps to Patient Safety – 2003
NHS England – Serious Incident Framework - 2015
NHS England – Patient Safety Strategy - 2019
Health and Social Care Act 2008
Care Quality Commission (Registration) Regulations 2009
CQC Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20, The regulation in full.

17. SUPPORTING DOCUMENTS

This policy should be read in conjunction with the following documents.

Freedom to Speak Up Policy/Procedure
Patient Experience Policy
Serious Incident Requiring Investigation Policy
Adverse Incident Reporting Policy
NHSLA Risk Management Standards for Ambulance Services 2012/13

APPENDIX A: Equality Impact Assessment Form Section One – Screening

A full Equality Impact Assessment has been carried out on this policy and is available on request to the public and internally via our Staff Intranet.

APPENDIX B: CQC Health and Social Care Act 2008

(Regulated Activities) Regulations 2014: Regulation 20, The regulation in full

1. Registered persons must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.

2. As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a registered person must—
   a. notify the relevant person that the incident has occurred in accordance with paragraph (3), and
   b. provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

3. The notification to be given under paragraph (2)(a) must—
   a. be given in person by one or more representatives of the registered person,
   b. provide an account, which to the best of the registered person's knowledge is true, of all the facts the registered person knows about the incident as at the date of the notification,
   c. advise the relevant person what further enquiries into the incident the registered person believes are appropriate,
   d. include an apology, and
   e. be recorded in a written record which is kept securely by the registered person.

4. The notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person containing—
   a. the information provided under paragraph (3)(b),
   b. details of any enquiries to be undertaken in accordance with paragraph (3)(c),
   c. the results of any further enquiries into the incident, and
   d. an apology.

5. But if the relevant person cannot be contacted in person or declines to speak to the representative of the registered person —
   a. paragraphs (2) to (4) are not to apply, and
   b. a written record is to be kept of attempts to contact or to speak to the relevant person.

6. The registered provider must keep a copy of all correspondence with the relevant person under paragraph (4).

7. In this regulation—
   "apology" means an expression of sorrow or regret in respect of a notifiable safety incident; "moderate harm" means—
   a. harm that requires a moderate increase in treatment, and
   b. significant, but not permanent, harm;
      "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);
"notifiable safety incident" has the meaning given in paragraphs (8) and (9);
"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" means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;
"relevant person" means the service user or, in the following circumstances, a person lawfully acting on their behalf—

c. on the death of the service user,
d. where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or
e. where the service user is 16 or over and lacks capacity in relation to the matter;
"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.

8. In relation to a health service body, "notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in—
   a. the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or
   b. severe harm, moderate harm or prolonged psychological harm to the service user.
9. In relation to any other registered person, "notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional—
   a. appears to have resulted in—
      i. the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition,
      ii. an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of at least 28 days,
      iii. changes to the structure of the service user's body,
      iv. the service user experiencing prolonged pain or prolonged psychological harm, or
      v. the shortening of the life expectancy of the service user; or
   b. requires treatment by a health care professional in order to prevent—
      i. the death of the service user, or
      ii. any injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a).

APPENDIX C: DUTY OF CANDOUR SAMPLE LETTERS

Appendix D: Duty of Candour Sample Letters

Please Note: This template should be used for guidance ONLY!

Letter to be sent to the patient affected by the incident
(*remove priory to sending*)

Dear (name of patient)

You recently received care from South Central Ambulance Service NHS Foundation Trust and as ***(Name and Designation)*** explained to you ***(brief description of the incident and what has previously been discussed)***

I would like to take this opportunity to express my sincere apologies that this event has occurred while you were under our care and to assure you that the Trust aims to provide a quality service to all our patients. We are therefore, undertaking a full investigation into the incident in an effort to understand exactly what happened and to find out whether there is something that we could do differently in future to prevent this happening to anyone else.

We would like the opportunity to discuss and share our findings with you and therefore, I would like to invite you to come to a meeting, or have a telephone call if you are unable to attend a face to face meeting, once the investigation has been completed, which can be arranged at a mutually convenient time. Alternatively, it may be that you do not feel a meeting would be of any help, either now or in the future, we just wanted to give you the opportunity should you wish to do so.

The investigation process can take up to 60 working days to complete. At this stage ***(I/ Staff member contact details on top of page)*** will be acting as your lead contact for the duration of this process.

Yours sincerely

Please Note: This template should be used for guidance ONLY!

Letter to be sent to relatives where patient does not have capacity (*remove priory to sending*)

Dear (name)

Your *[Mother/Father/Son etc)* recently received care from South Central Ambulance Service NHS Foundation Trust and as ***(Name and Designation)*** explained to you *(brief description of the incident and what has previously been discussed)* whilst your *[Mother/Father/Son etc]* was in our care.

I would like to take this opportunity to express my sincere apologies that this event has occurred while *(name of patient)* were under our care and to assure you that the Trust aims to provide a quality service to all our patients. We are therefore, undertaking a full investigation into the incident in an effort to understand exactly what happened and to find out whether there is something that we could do differently in future to prevent this happening to anyone else.

We would like the opportunity to discuss and share our findings with you and therefore, I would like to invite you to come to a meeting, or have a telephone call if you are unable to attend a face to face meeting, once the investigation has been completed, which can be arranged at a mutually convenient time. Alternatively, it may be that you do not feel a meeting would be of any help, either now or in the future, we just wanted to give you the opportunity should you wish to do so.

The investigation process can take up to 60 working days to complete. At this stage *(I/ Staff member contact details on top of page)* will be acting as your lead contact for the duration of this process.

Yours sincerely

Please Note: This template should be used for guidance ONLY!

<u>Letter to be sent to relatives where the patient has died</u>
<u>(Remove prior to sending)</u>

Dear (name)

I am writing to offer you my sincere condolences on the recent death of your *[Mother/Father/Son] [name of patient].*

Your *[Mother/Father/Son etc)* recently received care from South Central Ambulance Service NHS Foundation Trust and as ***(Name and Designation)*** explained to you *(brief description of the incident and what has previously been discussed)* whilst your *[Mother/Father/Son etc]* was in our care.

I would like to take this opportunity to express my sincere apologies that this event has occurred while *[name of patient)* were under our care and to assure you that the Trust aims to provide a quality service to all our patients. We are therefore, undertaking a full investigation into the incident in an effort to understand exactly what happened and to find out whether there is something that we could do differently in future to prevent this happening to anyone else.

We would like the opportunity to discuss and share our findings with you and therefore, I would like to invite you to come to a meeting, or have a telephone call if you are unable to attend a face to face meeting, once the investigation has been completed, which can be arranged at a mutually convenient time. Alternatively, it may be that you do not feel a meeting would be of any help, either now or in the future, we just wanted to give you the opportunity should you wish to do so.

The investigation process can take up to 60 working days to complete. At this stage *(I/ Staff member contact details on top of page)* will be acting as your lead contact for the duration of this process.

Yours sincerely