



Duty of Candour Policy

Document Reference	POL019
Document Status	Approved
Version:	V4.0

DOCUMENT CHANGE HISTORY		
Initiated by	Date	Author (s)
SI Panel	January 2015	Emma de Carteret, Interim Head of Quality Governance
Version	Date	Comments (i.e. viewed, or reviewed, amended approved by person or committee)
V1.1	January 2016	Amendments recommended by commissioners
V2.0	March 2016	Approved by Executive Leadership Board
V2.1	September 2017	Review for extension by Safety and Risk Lead
V3.0	November 2017	Approved by Executive Leadership Board

Duty of Candour Policy

Document Reference	NHS England Serious Incidents Framework (2015) Directorate: Clinical Quality and Improvement
Recommended at Date	
Approved at Date	ELB 7 March 2019
Review date of approved document	March 2021
Equality Analysis	January 2015
Linked procedural documents	Quality and Safety Strategy Claims Policy Complaints Policy Investigation Guidance Management of Incidents Policy Whistle-blowing Policy Risk Management Strategy Serious Incident Policy Safeguarding Policy NHS England Serious Incident Framework (2015)
Dissemination requirements	All managers and staff via email and intranet
Part of Trust's publication scheme	Yes

The East of England Ambulance Service NHS Trust has made every effort to ensure this policy does not have the effect of unlawful discrimination on the grounds of the protected characteristics of: age, disability, gender reassignment, race, religion/belief, gender, sexual orientation, marriage/civil partnership, pregnancy/maternity. The Trust will not tolerate unfair discrimination on the basis of spent criminal convictions, Trade Union membership or non-membership. In addition, the Trust will have due regard to advancing equality of opportunity between people from different groups and foster good relations between people from different groups. This policy applies to all individuals working at all levels and grades for the Trust, including senior managers, officers, directors, non-executive directors, employees (whether permanent, fixed-term or temporary), consultants, governors, contractors, trainees, seconded staff, homeworkers, casual workers and agency staff, volunteers, interns, agents, sponsors, or any other person associated with the Trust.

All Trust policies can be provided in alternative formats.



Contents

1.0	Introduction	4
2.0	Purpose	4
3.0	Duties	4
3.1	Trust Board	4
3.2	Chief Executive Officer	5
3.3	Director of Nursing and Clinical Quality	5
3.4	Safety and Risk Lead	5
3.5	Patient Safety Team	5
3.6	Senior Locality Managers, Heads of Department and equivalent	5
3.7	Investigation Officer	5
3.8	All Staff	6
3.9	Clinical Quality and Safety Group	6
3.10	Quality Governance Committee	6
4.0	Identifying the Need for Duty of Candour	6
5.0	Duty of Candour Process	7
5.1	Who to be Informed	9
5.2	Making Initial Contact	10
5.3	Initial Duty of Candour Meeting	11
5.4	Follow up Letter	12
5.5	Subsequent Discussions and Sharing Findings	12
6.0	Support	12
7.0	Documentation of Duty of Candour	12
8.0	Working Across Organisations	13
9.0	Erroneous Identification	13
10.0	General Principles of Openness and Honesty	13
11.0	Equality Impact Assessment	14
12.0	Process for Monitoring Compliance and Effectiveness	14
13.0	Standards / Key Performance Indicators	14
14.0	References	15
15.0	Associated Documents	15
Appendix – Equality Analysis		16



1 Introduction

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 came into force on 27 November 2014. These brought into force new statutory provisions regarding Duty of Candour (Regulation 20).

The regulations make it a statutory requirement that health service providers act in an open and honest way to patients and their families or carers in relation to care and treatment provided, on occasions when avoidable harm has been caused. This formalises the previously unregulated principles of Being Open, set out by the National Patient Safety Agency.

The Trust's Duty of Candour Policy builds upon the incident and risk management documents to provide a framework within which patient safety events can be communicated between healthcare organisations, healthcare teams, patients, their families and carers, as per the Duty of Candour provisions set out in the Health and Social Care Act.

Being open about what happened and discussing patient safety events promptly, fully and compassionately with patients and/or their carers can:

- Help patients and/or relatives cope better with the after-effects;
- Undertake a thorough investigation into the patient safety event and provide assurance that lessons learned will help prevent to ensure a similar type of incident does not recur;
- Provide an environment where patients and/or their carers, healthcare professionals and managers feel supported when things go wrong;

2 Purpose

The purpose of this policy is to ensure that patients, their families, carers and staff feel supported when patient safety events occur or something goes wrong.

This policy also aims to improve the quality and consistency of communication with patients, their families and carers when patient safety events occur, so that they receive promptly the information they need to enable them to understand what happened; that a meaningful apology is offered; and they are informed of the action the Trust will take to try and ensure that a similar type of patient safety event does not recur. It also aims to provide clear information to staff on what they do when they are involved and the support available to them to cope with the consequences of what happened and to communicate with patients, their families and carers effectively.

3 Duties

3.1 Trust Board

The Trust Board will be assured that the processes in place with regard to Duty of Candour work effectively and is committed to promoting a culture of openness within the Trust.

3.2 The Chief Executive

The Chief Executive has overall responsibility for integrated governance, including risk management and clinical governance within the Trust which includes the process, management and response to the Duty of Candour process. The Chief Executive delegates the responsibility for patient safety to the Director of Clinical Quality.

3.3 The Director of Clinical Quality and Improvement

The Director of Clinical Quality and Improvement is responsible for ensuring an integrated governance system is in place which incorporates all aspects of effective risk management and will ensure that:

- Complaints, incidents and Serious Incidents are dealt with in line with the Trust's policies and that risks identified and lessons learned are communicated throughout the Trust.
- The Trust's response to high and medium risk patient safety events are monitored ensuring that the principles of Duty of Candour are observed

3.4 Safety and Risk Lead

The Safety and Risk Lead is responsible for overseeing the incident and Serious Incident process and for ensuring that Duty of Candour is implemented in a timely manner, and documented accordingly. The Lead will provide support and guidance to those managers discharging Duty of Candour on behalf of the Trust.

3.5 Patient Safety Team

The Patient Safety Team are responsible for monitoring Serious Incidents and potential Serious Incidents and will liaise with local management teams to ensure that the need for Duty of Candour is recognised and completed as per the policy.

3.6 General Managers, Heads of Department and equivalent

All managers working within the Trust are expected to follow the Duty of Candour Policy and have a responsibility for ensuring that all patient safety events are acknowledged and reported as soon as they are identified in line with the Trust's Management of Incidents Policy. They should be aware that an individual member (or members) of staff might require support during the investigation and provide the appropriate help and guidance for them which may in some cases come from external agencies.

Senior Managers are responsible for planning and discharging Duty of Candour as per this policy in relation to incidents occurring in their locality/area of work.

3.7 Investigating Officers

Investigating Officers are responsible for ensuring that Duty of Candour is discharged in line with the policy to the correct individual for the incidents they investigate. They should provide support to the General Manager or equivalent in Duty of Candour meetings and ensure that written notification is completed and Duty of Candour is fully recorded on the incident record on Datix.

Following completion of a Duty of Candour discussion, the Investigating Officer is responsible for ensuring that the patient/family's concerns and issues are addressed as part of the investigation.

3.8 All Staff

All members of staff should make themselves familiar with this policy and the advice contained therein. They should follow the guidance to achieve openness with healthcare partners, other healthcare organisations, patients, their relatives and /or their carers.

When a mistake is made or in instances where harm has been caused by the care, treatment or service provided, staff with the patient should provide an immediate apology and explain the issue will be raised with managers for investigation.

All members of staff must reported any adverse incidents via the reporting system (Datix) and in instances where Duty of Candour is required on behalf of the Trust, this should be escalated to the Manager on duty at the time of the incident.

3.9 Clinical Quality and Safety Group (CQSG)

The CQSG is directly accountable to the Executive Leadership Board and has decision-making powers devolved from the Board. Its purpose is to promote the delivery of safe, effective patient care outcomes and ensure patient and carers' views are actively sought, considered and acted upon and to ensure that appropriate mechanisms are in place to deliver high quality care.

The CQSG will receive reports from the Patient Safety Team on Duty of Candour to monitor compliance and identify any areas of concern, taking action where appropriate.

3.10 Quality Governance Committee

The Committee is directly accountable to the Board and seeks to provide assurance relating to systems and procedures relating to patient safety.

The Committee will receive reports relating to the Duty of Candour process and issues highlighted in order to provide assurance to the Board, or to raise concerns.

4 Identifying the Need for Duty of Candour

Effective communication between staff who recognise an incident and their management team is vital in order to ensure that the Duty of Candour process is implemented from the outset.

As soon as a patient safety event is identified where harm has occurred, the top priority is to ensure appropriate clinical care is given and action taken to prevent further harm. Whenever practicable, appropriate discussion and patient consent should be gained prior to providing any additional treatment that is required.

Duty of Candour Policy

The following table outlines the parameters for implementing Duty of Candour:

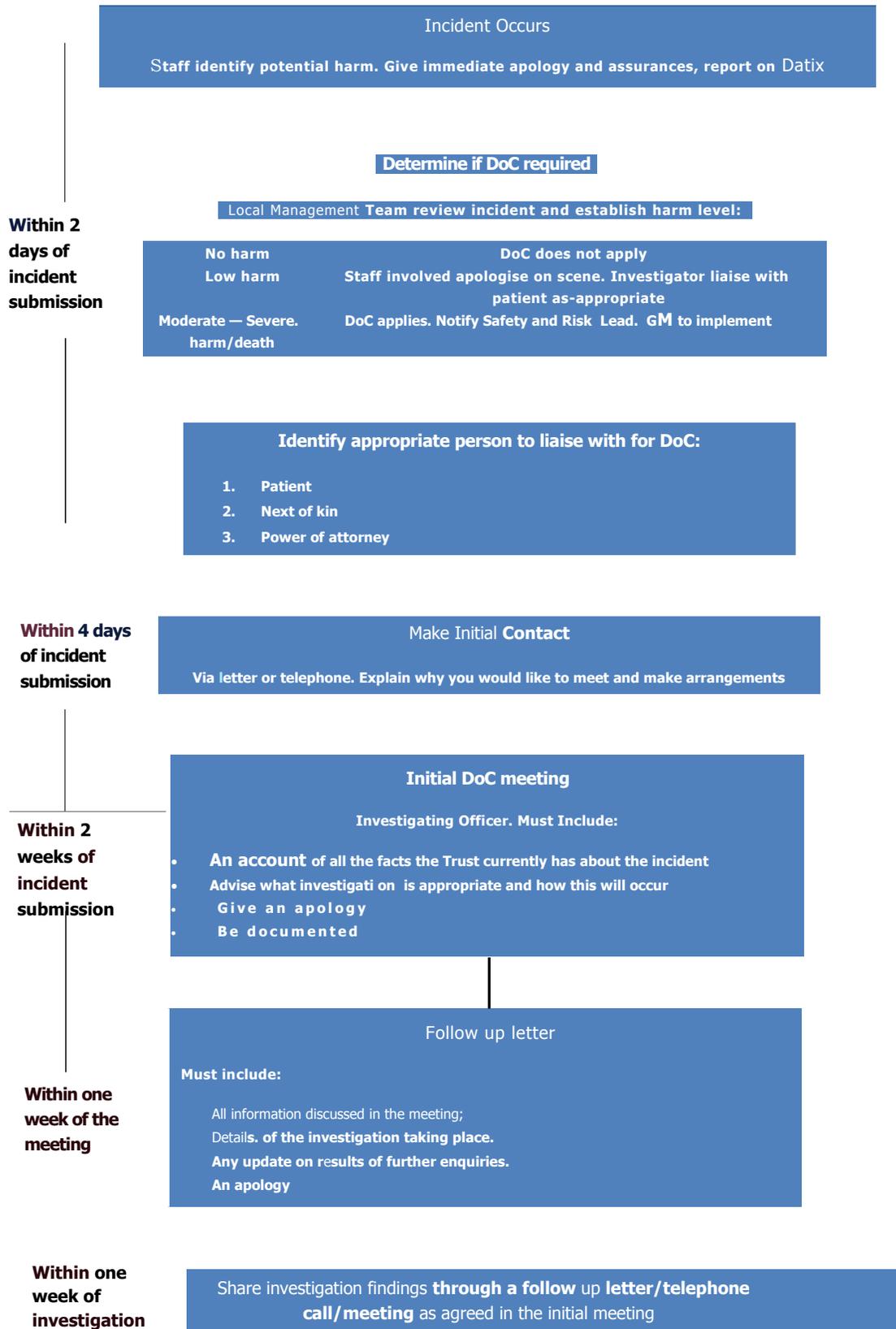
Incident	Action
No harm (including prevented patient safety incident)	Patients are not usually contacted or involved in investigations and these types of incidents are outside the scope of Duty of Candour. Individual investigators are able to decide whether 'no harm' events are discussed with patients and/or their carers, depending on circumstances.
Low harm	Unless there are specific indications or the patient requests it, the communication, investigation and analysis, and the implementation of changes will occur at local service delivery level with the participation of those directly involved in the incident. Communication should take the form of an open discussion between the staff providing the patient's care and the patient and/or their carers, depending on the circumstances. It is important to note that whilst not essential under legislation, the Trust considers it best practice to inform patients/their relatives of any harm caused
Moderate harm, severe harm or death	A higher level of response is required in these circumstances. The Safety and Risk Lead should be notified immediately and be available to provide support and advice during the process as required. The organisation's Duty of Candour Policy must be implemented.

5 Duty of Candour Process

The following flowchart demonstrates the process for identifying the need to implement Duty of Candour, relevant timescales and responsibilities:



Duty of Candour Policy



5.1 Who to be informed

Wherever possible, Duty of Candour discussions must be held with the patient directly. However, this is not always possible and reasons for this could be the death of a patient, their circumstances, their age, or of the patient wishes someone else to represent them.

In instances where discussions are held with the patient, no consent is required but the Manager must ensure they are speaking with the patient themselves. In all other instances, suitable consent must be gained prior to discussions commencing and should be requested in the initial contact.

Where consent is required, it is important to establish at an early stage the extent to which information concerning the patient safety event and/or the patient's healthcare can be shared with:

- Relatives and/or the patient's carers
- Agencies/organisations that can provide for the patient's/relatives'/carers' emotional/physical needs
- Other healthcare professionals.

This has to be done on the basis of respecting patient confidentiality and informed consent.

In addition the following further wishes need to be embraced:

- Any special restrictions on openness required by the patient/relatives/representatives that the healthcare team are required to respect
- Whether the patient/relatives/representatives wish to know every aspect of what went wrong
- Whether the patient/relatives/representatives wish to participate or have representation in the Duty of Candour discussions.

The decision maker for the patient will be dependent upon the status of the patient.

Patient Death

When the incident has resulted in a patient's death then the basis of consent and wishes lies with the patient's executors or bereaved relatives (as appropriate) and the Duty of Candour discussion will be conducted with them.

Children

The legal age for consent is 18. In broad terms patients between 16 and 18 years are able to agree to treatment (if they have capacity) but presently they cannot refuse treatment without support from a parent/guardian. Patients under 18 should be encouraged to involve their parents/guardians in any decision making.

In some circumstances younger children who understand fully what is involved can also give consent (Gillick competence). Where this is the case then the patient should be directly involved in the Duty of Candour process. The opportunity for the child's parents/guardians to be involved should also be provided unless the child expresses a wish for them not to be present and they have competence to reach such a conclusion.

In all cases it needs to be very carefully considered whether the information should just be provided to the guardians/parents alone or in the presence of the child. This will need to take

account of the guardians/parents' wishes. In these situations operational staff or managers would be wise to seek guidance from the Trust support systems when dealing with children. Support can be sought from the Clinical Advice Line or the Patient Safety Team

Patients with cognitive impairment

Patients with cognitive impairment, should, wherever 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.

Where this is not possible and the patient has authorised a person to act on their behalf by an enduring power of attorney, it needs to be established that this extends to decision making and the medical care and treatment of the patient. In this case the Duty of Candour discussion would be held with the holder of the Power of Attorney.

Patients with mental health issues

It is only appropriate to withhold patient safety incident information from mentally ill patients if it would be detrimental to the psychological wellbeing of the patient. This decision would need to be based upon advice received from the patient's psychiatrist. However such circumstances are rare and a second opinion may be needed by an independent consultant psychiatrist to justify withholding information from the patient.

While it is not appropriate to discuss patient safety incident information with a carer or relative without the express permission of the patient, there are situations when this absolute provision may be appropriately waived, where the patient lacks capacity so permitting those responsible to act in the patient's best interests which might involve carers or relatives.

Patients where is a barrier to effective communication

In other circumstances where there is, for example, sensory loss or there is another language barrier, the patient needs to be supported in making their wishes and informed consent clear to the healthcare/Duty of Candour team. This may require advocacy services that take account of cultural sensitivities and the communication difficulties of the patient. Where necessary, independent translator services may also be required.

5.2 Making Initial Contact

The prerequisite for any meeting to be held is for the patient (or executor/next of kin if the patient has died) to want to be given an explanation or further information about the incident including the Trust's plans to investigate the incident.

Wherever possible, discussions should be held in person and as such, an initial telephone call to briefly explain the need to meet and make arrangements is deemed as best practice. If however there is uncertainty as to the most appropriate person to communicate with, or telephone contact details are not available, an initial letter should be sent asking the person to make contact so that Duty of Candour can be discharged.

5.3 Initial Duty of Candour Meeting

The individual delivering the Duty of Candour message to the patient or their representative should be a senior member of staff, ideally responsible for the area in which the incident occurred. They should have a good grasp of the facts relevant to the incident and be aware of any interim findings so far in the investigation. Wherever possible, the Senior Manager should be supported by the Investigating Manager during this meeting to ensure the views of the patient and their representative are considered during the subsequent investigation.

The meeting must include:

- Introductions of all present and an explanation of why the meeting was requested
- A detailed and honest account of all the facts that the Trust currently has about the incident, and what action has been taken so far
- An apology
- An explanation of the level of investigation that is being conducted, how this will occur and the anticipated timescales
- A discussion to determine any questions or concerns that the patient or representative specifically wish to be investigated
- Gathering of facts from the patient or their representative as appropriate
- Confirmation that a written summary of the meeting will be provided in a letter

The content of the meeting must be documented in written notes and attached to the incident on Datix.

The facts relating to the incident need to be presented to the patients/relatives/representatives (as appropriate) and/or the patient's carers. This should avoid:

- Speculation
- Acknowledgment of blame
- Denial of responsibility
- Provision of conflicting information

Any areas where there is disagreement need to be deferred to a subsequent meeting after the investigation has completed. Where the incident investigation is still in progress then the patient/relatives/representatives and/or the patient's carers will be informed that more information will become available and new facts may emerge as the investigation progresses.

The meeting should also provide an overview of the incident reporting and investigation process, how to contact PALS and the complaints procedure.

Where there are legal restrictions on the disclosure of information, then these restrictions need to be made clear to all meeting attendees.

An explanation of 'what happens next' needs to be given.

The patient/relatives/representatives and/or the patient's carers should again be reminded of sources of emotional support or help that is available to them.

5.4 Follow up letter

Following completion of the initial Duty of Candour meeting, a summary of the discussion should be presented to the patient or their representative in a letter format. This should be sent within a week of the meeting occurring and a copy should be stored on the relevant incident on Datix. For a template letter, liaise with the Safety and Risk team.

5.5 Subsequent discussions and sharing findings

Similar considerations to the initial meeting need to be taken for any preliminary follow-up and subsequent meetings or correspondence. Feedback needs to be given on progress-to-date and information provided on the investigation process. Again there should be no speculation or attribution of blame.

All queries need to be responded to appropriately.

The full findings of the investigation should be shared with the patient or their representative, with a copy of the full, approved report provided to them if they wish to receive a copy. This should include the actions to be taken as a result of the investigation, and the timeframes for completion. If the patient or their relative wishes to receive assurance in relation to completion of the actions, this should be offered in the form of a follow up letter.

If this is to be the last discussion, the patient/relative/representative and/or the patient's carers need to be asked if they are satisfied with the investigation and a note made in the records.

Contact details should be provided to the patient/relatives/representatives and/or the patient's carers so that if further issues arise these can be linked back to the relevant case.

6 Support

The Trust recognises the importance of appropriate support to patients and their relatives during difficult times. The Senior Manager or staff member involved is responsible for discussing support needs with the individual and consider whether it would be appropriate to offer further support, i.e. through their GP, registered charities and other relevant organisations. If this is indicated, the Senior Manager should liaise with the Patient Safety Team for appropriate signposting to the relevant service.

It is also acknowledged that staff involved in an incident involving requiring Duty of Candour implementation may require additional support. This should be accessed initially through their line manager, but other options include Occupational Health, the Union, the Employee Assistance Programme, or in the case of complaints and PALS issues, the Complaints Manager.

7 Documentation of Duty of Candour

The Trust requires all communication relating to an incident, complaint, PALS enquiry or a claim to be documented, in order to establish a clear audit trail and keep a record of the reasoning behind steps taken.

Records of all meetings, telephone calls and letters sent must be kept, and attached to the relevant incident on the Trust's Datix system.

A copy of the notes of any meetings with patients, their family and/or carers should also be provided to all of the individuals present, for their own records.

The Duty of Candour record for each meeting should contain the following information:

- The time, place, date as well as the name and relationships of all attendees;
- The plan for providing further information to the patient and/or their carers;
- Offers of assistance and the patient's and/or their carer's response;
- Questions raised by the patient, family and/or carers or their representatives, and the answers given;
- Plans for follow-up as discussed;
- Progress notes and accurate summary of all points explained to the patient and/or their carers;
- Copies of letters sent to patients, carers and the GP;
- Copies of any statements taken.

8 Working Across Organisations

The Trust will share cross-border risks with other NHS and local authority partners and will work collaboratively in any investigation and subsequent implementation of control measures. There will be open communication with healthcare organisations, healthcare teams, staff and patients and/or their carers to facilitate robust investigations and learning. This communication process will be led by the Investigating Officer if communication is required as part of the investigation process. During this process, coordination between organisations will occur to determine who will lead Duty of Candour discussions with the patient/family/carer. All decisions must be clearly documented on the Datix system.

9 Erroneous Identification

It is possible that the identification of an incident believed to have affected patient safety and to have caused harm, made in good faith, is found upon investigation to be erroneous. In such circumstances the principles of truthful, timely and open communication continue to apply, with full and consistent explanations being provided to the staff involved, patient and/or carer and any relevant organisations. Similarly, the identification and dissemination of any learning points continues to be an important part of the Duty of Candour Policy.

10 General Principles of openness and honesty

In order to ensure that the Trust complies with the general principles of openness, honesty and transparency, the Trust commits to the following:

- Publication of summaries of serious complaints via the public website and staff intranet (subject to patient/family approval)

Duty of Candour Policy

- Publication of Discovery Interviews with patients via the public website and staff intranet (subject to patient/family approval)
- Sharing of key issues and learning from Serious Incidents, patient safety issues and complaints with the National Ambulance groups to maximise service improvements wherever possible (subject to patient/family approval)
- Publication of trends and themes across the organisation to enable staff to assist in safety improvements

The Trust commits, via the Patient Safety Strategy, to identify the best way in which to share lessons and learning from Serious Incidents and Parliamentary and Health Service Ombudsman reviews.

11 Equality Impact Assessment

The East of England Ambulance Service NHS Trust has made every effort to ensure this policy does not have the effect of discriminating, directly or indirectly, against employees, patients, contractors, or visitors on the grounds of race, colour, age, nationality, ethnic (or national) origin, gender, sexual orientation, marital status, religious belief or disability. This policy will apply equally to full and part time employees. All East of England Ambulance Service NHS Trust policies can be provided in large print or Braille formats if requested, and language line interpreter services are available to individuals who require them.

12 Process for Monitoring Compliance and Effectiveness

The Executive Management Board have devolved responsibility for monitoring the Duty of Candour process to the Clinical Quality and Safety Group (CQSG). Regular reports monitoring compliance with Duty of Candour will be prepared by the Patient Safety Team for submission to the CQSG. Assurance papers will also be provided to the Patient Safety and Care Standards Committee for Board assurance purposes.

Compliance with this policy will be measured through set standards and Key performance Indicators (section 13 below).

13 Standards/Key Performance Indicators

- Number of incidents and complaints with moderate or severe harm levels, or death.
- Of these:
 - Initial contact made within four days (100%)
 - Initial meeting conducted within two weeks (100%)
 - Follow up letter completed (100%)
 - Letter includes all criteria (100%)

14 **References**

Care Quality Commission (2014). *A fresh start for the regulation of ambulance services. Working together to change how we regulate ambulance services*

Department of Health. (2004). *Memorandum of understanding: Investigating patient safety incidents involving unexpected death or serious untoward harm: A protocol for liaison and effective communications between the National Health Service, Association of Chief Police Officers and Health and Safety Executive.* London: Department of Health. Available at: www.dh.gov.uk and www.acpo.police.uk

Francis, R (2010). The Mid Staffordshire NHS Foundation Trust Independent Inquiry (online).

National Patient Safety Agency (NPSA). (2005). *Building a Memory: Preventing Harm, Reducing Risks and Protecting Patient Safety.* London: NPSA. Available at: www.npsa.nhs.uk

NHS Commissioning Board (2013). *Serious Incident Framework March 2013*

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

15 **Associated Documents**

- Management of Incidents policy
- Serious Incident Policy
- Complaints Policy
- Investigations Guidance
- Safeguarding Children, Young People and Vulnerable Adult policy
- Information Governance Policy
- Release of Information Policy

Appendix: Equality Analysis

<p>1. Name of policy/procedures/guidelines being assessed:</p>	<p>Title: Duty of Candour Policy</p>
<p>1. Is this a new or existing document?</p>	<p>New Existing</p> <p>Version being assessed (if existing): V4.0</p> <p>Last review date of document: January 2015</p>
<p>2. What is the Purpose of the document? (copy the purpose from the relevant document)</p>	<p>(a) What is it trying to achieve and why?</p> <p>Outline the approach to openness, honesty and transparency to patients and their families when harm may have been caused during contact with the ambulance service.</p> <p>(b) Who is intended to benefit and how?</p> <p>All Trust staff and external stakeholders wishing to know the duty of candour policy content. Application of the policy itself will benefit all patients and families who have been subject to avoidable harm</p>



4. Tick the boxes below to assess the potential for differential impact (negative or positive) on any of the protected characteristics?

Tick Box for Positive Impact

- Age
- Disability
- Gender Reassignment
- Marriage and Civil Partnership
- Pregnancy and Maternity
- Race
- Religion or Belief (including lack of belief)
- Sex
- Sexual Orientation

Cross Box for Negative Impact

- Age
- Disability
- Gender Reassignment
- Marriage and Civil Partnership
- Pregnancy and Maternity
- Race
- Religion or Belief (including lack of belief)
- Sex
- Sexual Orientation

5. Is there the possibility of discriminating unlawfully, directly or indirectly, against people from any protected characteristic?

Types of Discrimination:

- Direct
- Indirect
- Associative
- Perceptive
- Harassment
- Third Party Harassment
- Victimisation
- Institutional

Yes

No

If yes, please state the reason:

6. Could there be an effect on relations between certain groups?

Yes

No

If yes, please state the reason:

Duty of Candour Policy

7. Does the policy explicitly involve, or focus on a particular equalities group, i.e. because they have particular needs?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> If yes, please state reason:
7. Does the policy explicitly involve, or focus on a particular equalities group, i.e. because they have particular needs?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> If yes, please state reason:

8. PLEASE INDICATE BELOW ANY AMENDMENTS OR CHANGES TO THE POLICY/PROCEDURE:

Minor amendments made to the language within the policy, to bring up to date with current terminology

If the answers are 'no' to questions 5, 6, 7 then there is no need to proceed to a Full Equality Analysis. Summary Form should be completed and submitted to the relevant committee(s).

If 'yes' then a Full Equality Analysis of the document will be required. *(link to be added)*



