



London Ambulance Service **NHS**
NHS Trust

Being Open and Duty of Candour Policy & Procedure

DOCUMENT PROFILE and CONTROL.

Purpose of the document: To ensure that the Trust meets its obligations to patients, relatives and the public in *Being Open* and complying with the statutory Duty of Candour.

Sponsor Department: Corporate Services

Author/Reviewer: Head of Legal Services/Head of Governance and Assurance To be reviewed by August 2015.

Document Status: Final

Amendment History			
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21/05/2015	6.0	Head of Legal Services/Head of Governance and Assurance	Revised throughout due to new legislation
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19/03/2013	5.1	Director of Corporate Services	Update following EMT
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01/03/2013	4.3	AD Corporate Services	Update to include Contractual duties and Francis recommendations.
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25/06/2010	2.3	Head of Governance and Compliance/ Governance & Compliance Manager	Revised throughout
8/06/2010	2.1	Governance lead	Updated process and monitoring requirements
06/10/2008	1.2	Head of Patient Experience	Reformatted. Minor amendments.

***Version Control Note:** All documents in development are indicated by minor versions i.e. 0.1; 0.2 etc. The first version of a document to be approved for release is given major version 1.0.

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Upon review the first version of a revised document is given the designation 1.1, the second 1.2 etc. until the revised version is approved, whereupon it becomes version 2.0. The system continues in numerical order each time a document is reviewed and approved.

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HR003	Whistleblowing Procedure	
TP004	Complaints and Feedback Policy	
TP013	Claims Handling Policy and Procedure	
TP054	The Investigation and Learning from Incidents PALS Complaints and Claims Policy	

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TP006	Serious Incident Policy	
HS011	Incident Reporting Procedure	
HR039	Management of Safeguarding Allegations Against Staff	
TP018	Safeguarding Children and Young People Policy	
TP019	Safeguarding Adults at Risk Policy	
External	The NHS Constitution	March 2012
External	The NHS Mandate	
External	Technical Contract Guidance 2014/15	Feb 2013
External	The Mid Staffordshire NHS Foundation Trust Public Inquiry Volume 3; Chapter 22. Robert Francis QC	Feb 2013
External	The Health and Social Care Act 2008 (Regulated Activity) Regulations 2014, as amended	
External	CQC Guidance: Regulation 20: Duty of Candour – Information for all providers: NHS bodies, adult social care, primary medical and dental and independent healthcare	March 2015
External	NRLS definitions of harm (https://www.eforms.nrls.nhs.uk/staffreport/help/ALL/Dataset_Question_References/Patient_details/Individual_patient/Impact_on_patient/PD09.htm)	Accessed April 2015

Document Status: This is a controlled record as are the document(s) to which it relates. Whilst all or any part of it may be printed, the electronic version maintained in P&P-File remains the controlled master copy. Any printed copies are not controlled or substantive.

1. Introduction

On 27 November 2014 the statutory Duty of Candour came into force for the NHS in accordance with Regulation 20 of The Health and Social Care Act 2008 (Regulated Activity) Regulations 2014 (the Regulations).

This policy describes how the London Ambulance Service NHS Trust (LAS) will demonstrate its openness with patients and relatives when mistakes are made to ensure that the principles of Being Open and the requirements of the Duty of Candour are applied, as appropriate.

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. 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 (HR003).

This Policy reflects the operational re-structure that is coming into place in Quarter 1/2 2015/16. Until then, the process adopted will be that as set out in Appendix 5.

2. Scope

This document outlines LAS' policy on how it meet its obligations to patients, relatives and the public by being open and complying with the requirements of the Duty of Candour.

This document is aimed at all staff working for LAS and sets out the commitment by LAS to embedding a transparent and open culture. This document outlines the infrastructure in place to support openness as well as compliance with the Duty of Candour following a notifiable safety incident.

3. Objectives

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, as appropriate, should receive an apology and explanation as soon as possible. Saying sorry is not an admission of liability and staff should feel able to apologise at the earliest opportunity.
- 3.6 The LAS Serious Incident policy (TP006) and Incident Reporting Procedure (HS011) must be followed to ensure that appropriate support is offered to the patient/families/carers/others, as appropriate, where a patient safety incident has occurred.
- 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 Staff Counselling and Occupational Health Services Manager or the Workforce Directorate. This will include contact details of both external and internal support.

4. Responsibilities

4.1 Trust Board

The Trust Board has a responsibility to obtain assurance that the processes work effectively to support the board level public commitment to being open and complying with the requirements of the Duty of Candour.

4.2 Chief Executive

The Chief Executive is ultimately responsible for the process of managing and responding to the being open and Duty of Candour 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 and Duty of Candour process and is accountable to the Trust Board and the Chief Executive for the effective implementation of such process.

4.4. The Clinical Safety, Development and Effectiveness Committee*

The Clinical Safety, Development and Effectiveness Committee (CSDEC) has overall responsibility for monitoring the being open and Duty of Candour process CSDEC is responsible for ensuring continuous development of this policy in accordance with national guidance. CSDEC will communicate up to board level, and to the local management levels and facilitates organisational learning and improvement by making sure that any lessons learned are disseminated throughout the Trust.

*Quarter1/2 of 2015/16 will see a review of the LAS committee structure, with the likely committee to be tasked with monitoring this Policy to be a newly

created Clinical Safety and Standards committee. As such, this Policy will be reviewed and updated to reflect any changes at the earliest opportunity.

4.5 Director of Nursing and Quality/Head of Safeguarding

The Director of Nursing and Quality and/or Head of Safeguarding will liaise with the Duty of Candour Champion when a notifiable safety incident is identified in accordance with the procedures set out in the Policy and Procedure on the Management of Safeguarding Allegations Against Staff (HR039) or the Trust's Safeguarding policies (TP018 and TP019). Where appropriate, the matter will be referred to the Serious Incident Group.

4.6 The Head of Governance and Assurance

The Head of Governance and Assurance is responsible for monitoring compliance with and reporting quarterly on the effectiveness of the management of this policy to CSDEC and collating the required data for submission to the commissioners.

4.7 The Governance and Assurance department

The Governance and Assurance department will coordinate implementation of the Duty of Candour in the management of serious incidents and will provide support to those staff involved in carrying out this policy.

4.8 The Legal Services Department

Where an inquest has been opened the Legal Services Department will liaise with the Governance and Assurance Department/the relevant Duty of Candour Champion to coordinate implementation of the Duty of Candour in the management of inquests to ensure that legal support is provided to those staff who may be called to give evidence at the inquest.

4.9 The Health Safety and Risk department

The Health, Safety and Risk department will liaise with the Governance and Assurance Department/the relevant Duty of Candour Champion to coordinate implementation of the Duty of Candour.

4.10 Patient Experience Department (PED)

The Patient Experience Department will liaise with the Governance and Assurance Department/the relevant Duty of Candour Champion to coordinate implementation of the Duty of Candour for all complaints where a notifiable safety incident is identified.

Complaints and enquiries by Healthcare Professionals can come in by a number of routes – compliance will be managed under s.8 of the Complaints Regulations by PED, serious incident enquires by the Medical Directorate.

4.11 The Duty of Candour Champions

An appropriately trained and resourced member of Trust staff who will be the point of contact throughout an investigation between the Relevant Person and the Trust. Unless otherwise directed by the Governance and Assurance

Department, The Duty of Candour Champion will act as the Family and Patient Liaison Officer and ensure completion of the Duty of Candour Checklist and collation of the relevant evidence.

The Duty of Candour Champion will ordinarily be the relevant **Quality Governance and Assurance Manager, Clinical Hub Manager, NHS 111 Clinical Governance Manager or the Patient Transport Service Practice Learning Manager**. Pre-operational restructure this role will be undertaken by the Nominated Manager.

4.12 Nominated Manager

The Nominated Manager will act as the Duty of Candour Champion pre operational restructure. This role will ordinarily be undertaken by the relevant Ambulance Operations Manager (AOM), alternatively if there is no available AOM, then a Duty Station Officer or other manager nominated by the relevant Assistant Director of Operations.

Where the Nominated Manager is not a healthcare professional they will obtain the view of a healthcare professional not directly involved in the incident in order to assess whether it is a notifiable safety incident. They will also ensure that this assessment is recorded on the Duty of Candour Checklist (Appendix 6).

5. Definitions

Definitions of the terms used within this document are consistent with those in the Trust's Incident Reporting Policy (HS011) and Serious Incident Policy (TP006).

Apology, a meaningful and sincere expression of sorrow or regret for any suspected harm caused. The NHS Litigation Authority has provided guidance on making an apology which sets out that saying sorry is not an admission of liability.

Being Open – open communication of patient safety incidents that result in harm or the death of a patient while receiving healthcare. The principles of Being Open are set out in Appendix 1.

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

Duty of Candour – both a contractual and statutory duty enforceable by the Care Quality Commission that requires NHS provider organisations to be open and transparent with the relevant person when a notifiable patient safety incident occurs in relation to the care provided.

Moderate Harm- harm requiring a moderate increase in treatment (i.e. an unplanned return to surgery/readmission, a prolonged episode of care, extra

time as an inpatient or outpatient, cancelling of treatment or transfer to another treatment area such as ITU) and is significant but not permanent.

Notifiable safety incident – any unintended or unexpected incident that occurred in respect of a service user that, in the reasonable opinion of a healthcare professional, could or appears to have resulted in the death of the service user (where the death relates directly to the patient incident rather than any underlying condition) or severe, moderate or prolonged psychological harm. This may be identified in the reporting of an incident, or the course of a complaint, enquiry or claim.

Prolonged psychological harm – psychological harm that a service user has experienced, or is likely to experience, for a continuous period of 28 days or more.

Relevant person – the service user or, in the following circumstances a person acting lawfully on their behalf:

- (a) On the death of the service user
- (b) Where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or
- (c) Where the service user is 16 or over and lacks capacity in relation to the matter.

Serious Incident - an incident that has occurred during NHS funded healthcare which resulted in one or more of the following:

- Unexpected or avoidable death of one or more patients, staff, visitors or any person that is affected by the Trust's undertaking;
- Serious harm to one or more patients, staff, visitors or members of the public or where the outcome requires life-saving intervention, major surgical/medical intervention, permanent harm or will shorten life expectancy or result in prolonged pain or psychological harm (including incidents graded under the NPSA definition of severe harm);
- A scenario that prevents, or threatens to prevent, a provider organization's ability to continue to deliver healthcare services, for example, actual or potential loss of personal/ organisational information, damage to property, reputation or the environment, IT failure;
- Allegations of abuse;
- Adverse media coverage or public concern about healthcare or the organisation;
- A never event – a serious, largely preventable patient safety incident that should never occur if the available preventative measures are in place. (As listed in Appendix 4 of the Serious Incident Policy TP006).

Severe Harm – a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions that is directly related to the incident and not related to the natural course of the service user's illness or underlying condition.

Transparency – allowing information about the truth about performance and outcomes to be shared with staff, patients, the public and regulators.

6. Implementing *Being Open* or the Duty of Candour

6.1 The following table sets out whether the Being open principles or the Duty of Candour requirements should be applied to a patient safety incident.

Level of harm to patient	Process to follow
No Harm	Ordinarily patients are not notified of a no harm incident. However, the investigating manager will need to exercise discretion as to whether such events are discussed with the patient dependent upon the circumstances.
Low Harm	Principles of Being Open and the Being Open Procedure
Moderate, severe, prolonged psychological harm or death*	Duty of Candour Procedure

**the harm or death is as a result of a patient safety incident which occurred during the provision of the Trust carrying out a 'regulated activity' i.e. in the course of the patient using the Trust's services.*

7. Being open

7.1 Being open relies initially on the Trust's 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."

7.2 An overview of the Being Open Process can be found at Appendix 1 and the principles of Being Open at Appendix 2.

8. Duty of Candour Procedure

8.1 In accordance with Regulation 20 of the Regulations the Trust must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users when carrying out its services.

8.2 There are specific requirements that must be met when a notifiable safety incident occurs. Appendix 4 sets out a flowchart of the LAS process as detailed below. This reflects the operational re-structure that is coming into place in Spring/Summer 2015. Until then, the process adopted will be that as set out in Appendix 5.

8.3 As soon as reasonably practicable, and at most within **10 working days** of a notifiable safety incident being identified, LAS must inform the Relevant Person that a suspected or actual notifiable safety incident has occurred (the initial notification).

8.4 *The Initial Notification*

8.4.1 As soon as reasonably practicable, and at most within **10 working days** of a notifiable safety incident being identified, LAS must inform the Relevant Person that a suspected or actual notifiable safety incident has occurred (the initial notification) **in person** (see 8.4.4 and 8.4.5 below).

8.4.2 As set out in Appendix 4 ordinarily, the person within LAS responsible for ensuring the initial notification is made is the Duty of Candour Champion. In accordance with Appendix 5, the Nominated Operational Manager will be responsible for ensuring the initial notification is provided pre-operational re-structure due Quarter 1/2 2015/16.

8.4.3 The Duty of Candour Champion is responsible upon notification of a potential notifiable safety incident for ensuring that Datix is checked to ascertain whether LAS is already aware of the incident (e.g. by way of complaint/request from Coroner etc.) and, if so, to liaise with the relevant LAS department to ensure that a joined up approach to contacting the Relevant Person is adopted. The Duty of Candour Checklist at Appendix 6 highlights the preparation to be undertaken prior to the initial notification being made.

8.4.4 Best practice is to contact the Relevant Person by telephone to arrange the initial-notification meeting. If a contact phone number/identity of the Relevant Person is uncertain then the initial approach should be made in writing asking the recipient to contact the Duty of Candour Champion.

8.4.5 Regulation 20 provides that the initial notification must be given in person. LAS recognises that given its patient population, it may not always be possible to achieve this but nevertheless, requires reasonable attempts to be made and, if the 'in-person' element of the notification

does not prove possible, then the reasons are to be documented on the Duty of Candour Checklist (Appendix 6). Examples of when it may not always prove possible to provide an 'in-person' initial notification, may include: the location of the Relevant Person or the meeting being declined by the Relevant Person.

- 8.4.6 The initial notification must be given in person (see paragraphs 8.4.4 and 8.4.5) to the Relevant Person and:
- provide a full account of the facts as known
 - set out what further enquiries LAS believes to be appropriate,
 - provide an Apology, and
 - provide reasonable support to them in relation to the incident.

consideration must be given to what support should be offered to the Relevant Person when providing the initial notification.

8.5 *The responsibilities of the Duty of Candour Champion*

- 8.5.1 The Duty of Candour Champion will:
- upon notification of a potential notifiable safety incident will start the Duty of Candour Checklist (Appendix 6) and ensure that this updated and upon completion sent to the Head of Governance and Assurance.
 - Make reasonable efforts to identify and inform the Relevant Person of the notifiable safety incident. However, if after making reasonable attempts to contact the Relevant Person the Duty of Candour Champion concludes that they are un-contactable or they have confirmed that they do not want to liaise with LAS then this must be documented on the Duty of Candour Checklist (Appendix 6).
 - make the initial notification in person
 - follow up the initial notification in writing
 - ensuring that they identify the needs of the Relevant Person in order to that no-one will be disadvantaged in any way
 - be responsible for keeping the Relevant Person up-to-date with the progress of the investigation
 - ensure that factual feedback is given to the Relevant Person at the earliest opportunity. No communication errors should arise by giving unsubstantiated facts as this can create anxiety, and
 - will keep the local management team up to date on progress with the investigation and contact with the Relevant Person

8.6 Where the notifiable safety incident is being considered as a potential serious incident or is declared and investigated as a serious incident then the Duty of Candour Champion will be supported by the Governance and Assurance Department.

8.7 Where the notifiable safety incident is being handled as a complaint then the Duty of Candour Champion will be supported by the Head of Patient Experience.

8.8 Where a notifiable safety incident is identified in accordance with the procedures set out in Policy and Procedure on the Management of Safeguarding Allegations Against Staff (HR039) or the Safeguarding policies (TP018 and TP019) the Director of Nursing and Quality will liaise with the relevant Duty of Candour Champion to ensure that the relevant requirements are met. In each case consideration will ensure that consideration is given as to whether notifying the Relevant Person may prejudice the safeguarding process. It may be appropriate for the Director of Nursing and Quality to contact social services/the Police to ascertain their views before reaching a decision. Where appropriate, the matter will be referred to the Serious Incident Group.

9. Failure to comply – the implications

9.1 The Trust aims to promote a culture of openness and recognises that staff do not intend to cause harm but unfortunately incidents do occur. When mistakes happen, service users, or their representative if appropriate, should receive an apology and explanation as soon as possible. The failure to do so can negatively affect the service user or their representative and can limit the extent to which LAS can learn from the incident.

9.2 Alongside the implications for the service user, a failure to provide the four elements of the initial notification to the Relevant Person is a breach of 20(2)a and 20(3) of the Regulations which can result in a criminal prosecution being brought by the CQC.

9.3 In addition, a failure to comply with the Duty of Candour can see the Commissioner fine the Trust the cost of the episode of care, or if unknown, up to £10,000.

10. Learning and reporting

10.1 All learning from the incidents will be cascaded to the whole organisation, via CSDEC, Area Quality Governance Committees, and Trust communications systems including the website. E.g. anonymised case studies.

10.2 CSDEC will ensure that where appropriate details are shared with any other healthcare organisation or relevant stakeholder.

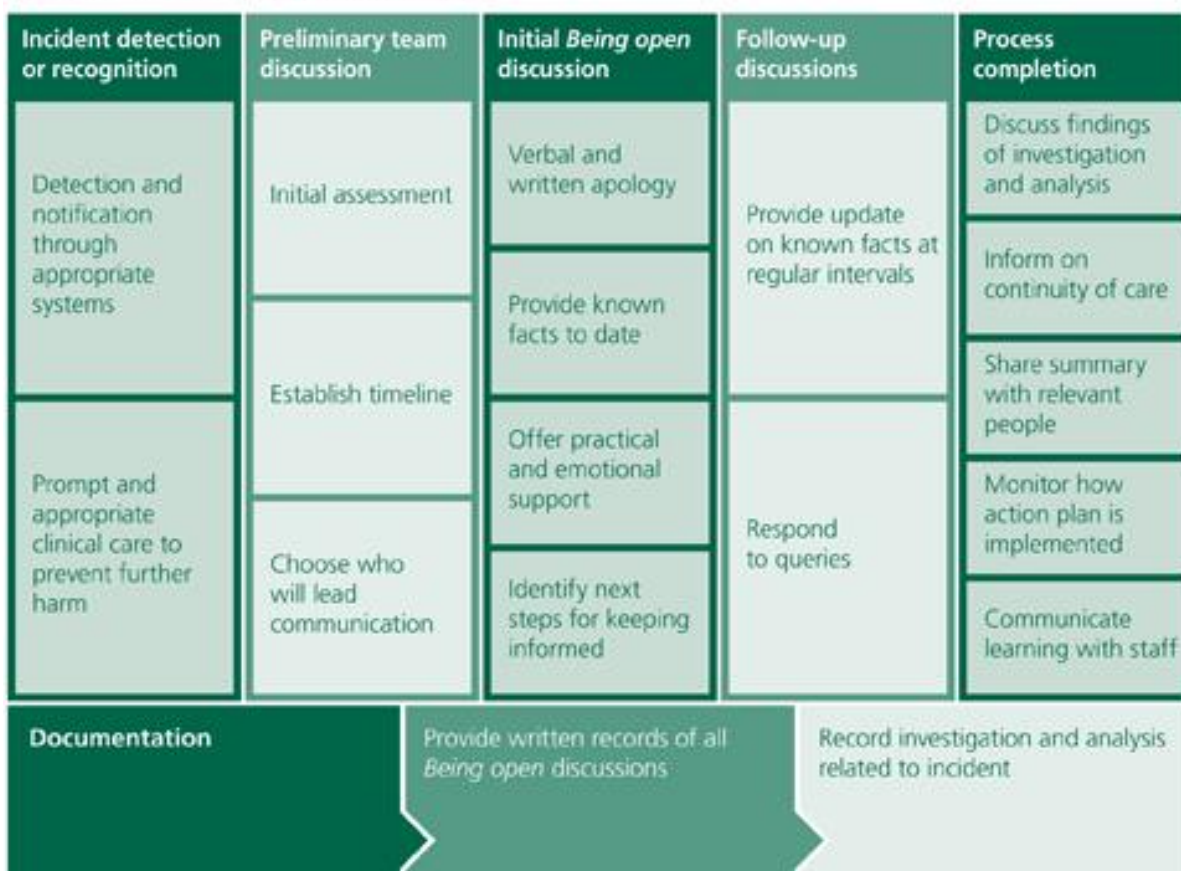
10.3 The Head of Governance and Assurance is responsible for monitoring compliance with and reporting quarterly on the effectiveness of the management of this policy to CSDEC and collating the required data for submission to the commissioners.

11. Erroneous Identification

It is possible that the identification of an incident believed to have affected patient safety and may 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 patient and/or carer, staff involved, and any relevant organisations. Similarly, the identification and dissemination of any learning points continues to be an important part of the Duty of Candour.

IMPLEMENTATION PLAN				
Intended Audience	All LAS Staff			
Dissemination	Available to all staff on the Pulse and to the public on the LAS website.			
Communications	Revised Policy and Procedure to be announced in the RIB and a link provided to the document. Consideration to be given to appropriate mechanisms for raising awareness amongst staff.			
Training	The Trust provides training on Incident Investigation and Root Cause Analysis with support from the Governance & Assurance team. The Trust will provide a Duty of Candour Champion training package for the relevant members of staff.			
Monitoring:				
Aspect to be monitored	Frequency of monitoring AND Tool used	Individual/ team responsible for carrying out monitoring AND Committee/ group where results are reported	Committee/ group responsible for monitoring outcomes/ recommendations	How learning will take place
Initial notification is made to the Relevant Person within a maximum of 10 days (100%) Follow up letter is to be sent out within a further	Quarterly via submissions from Duty of Candour champions	Head of Governance and Assurance, reporting to commissioners, SMT and EMT where appropriate.	Commissioners, SMT and EMT where appropriate	Comparison of performance against expected practice

<p>10 days (100%)</p> <p>Meeting in person is to take place as soon as reasonably practicable (100%)</p> <p>Report is shared with the Relevant Person once completed (100%)</p>				
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Overview of the *Being open* process

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.

Stage 5: Process completion - This covers repeating the apology; providing feedback on the findings of the investigation into the patient safety incident; what the organisation will be doing to prevent recurrence. The investigation report has to be shared with the patient or family within 10 working days of approval and sign off by the Trust.

It should include provision of an ongoing clinical management plan (if appropriate) and communicating with relevant community care providers and commissioners what has happened. This will also include monitoring how the recommendations have been implemented and communicating with staff the recommendations to spread the learning.

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.

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.

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 Ambulance Operation 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.

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.

Principle of 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 organisation and/or in accordance with the local resolution process where a complaint is at issue. They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times. Patients, their families and carers should also be provided with support in a manner to meet their needs. This may involve an independent advocate or an interpreter. Information about the Patient Experiences Department and Independent Complaints Advocacy Service is routinely offered accordingly; See also

[http://www.londonambulance.nhs.uk/talking_with_us/enquiries, feedback and compla.aspx](http://www.londonambulance.nhs.uk/talking_with_us/enquiries,_feedback_and_compla.aspx)

Information enabling to other relevant support groups will be given as soon as possible and as appropriate.

Principle of Professional Support

The Trust has set out to create an environment in which all staff are encouraged to report patient safety events. Staff should feel supported throughout the patient safety event investigation process; they too may have been traumatised by the event. Resources available are referred to within the respective Trust policies, (HS011, TP004), to ensure a robust and consistent approach to patient safety event investigation. Where there are concerns about the practice of individual staff the relevant professional body and/or Human Resources department can be contacted for advice. Where there is reason to believe a member of staff has committed a punitive or criminal act, the Trust 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. Staff should be encouraged to seek support from relevant professional bodies. Where appropriate, a referral will also be made to the Independent Safeguarding Authority.

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.

Principles of Multi-Disciplinary Responsibility

Being open document applies to all staff who have key roles in patient care. Emergency care provision is often a component of the totality of total healthcare and can involve multi-disciplinary teams. This is reflected in the way that patients, their families and carers are communicated with when things go wrong. This ensures that the *Being open* process is consistent with the philosophy that patient safety incidents usually result from system failures and rarely from actions of an individual. To ensure multi-disciplinary involvement in the *Being open* process, especially if working with NHS trusts in other sectors (e.g. acute care or mental health) it is important to identify clinical and managerial leaders who will support this across the health and care agencies that may be involved. Both senior managers and senior clinicians will be asked to participate in the patient safety incident investigation and clinical risk management as set out in the respective Trust policies and practice guidance.

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.

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 practicable 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 practicable, 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.

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.

Appendix 3 – Practical application of the Duty of Candour

Incident	Definition	Duty of Candour?	Action	Examples*
No harm (including prevented harm)	An incident occurred where there was no harm/ the potential for harm but none materialised.	No	Ordinarily, patients are not contacted where there has been a 'no harm' or 'prevented harm' incident.	<ul style="list-style-type: none"> ▪ When intubating, the cuff on the endotracheal tube fails to inflate, recognised by the use end tidal Co2. A new tube is immediately used. The patient is intubated, stabilized, conveyed to hospital and makes a complete recovery.
Low harm	<p>NRLS define this as:</p> <p>“Any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons”.</p>	No	Low harm incidents should be dealt at a local level, applying the principles of being open to include a discussion with the patient by those providing the care.	<ul style="list-style-type: none"> ▪ In an assisted transfer to the ambulance a patient stumbles and hits their leg on the end of the trolley bed sustaining a bruise. ▪ A patient is given a recently out of date drug which makes the patient nauseous, and an anti-emetic is given. The patient is conveyed to hospital and makes a complete recovery. ▪ On arrival a crew decide to administer oxygen, and are then told the patient has had a laryngectomy. There are no laryngectomy masks on the vehicle so the crew have to attempt to oxygenate the patient using a face mask over the stoma. On arrival in A&E the patient's oxygen saturation levels have dropped from 92% to 85%. – NRLS website

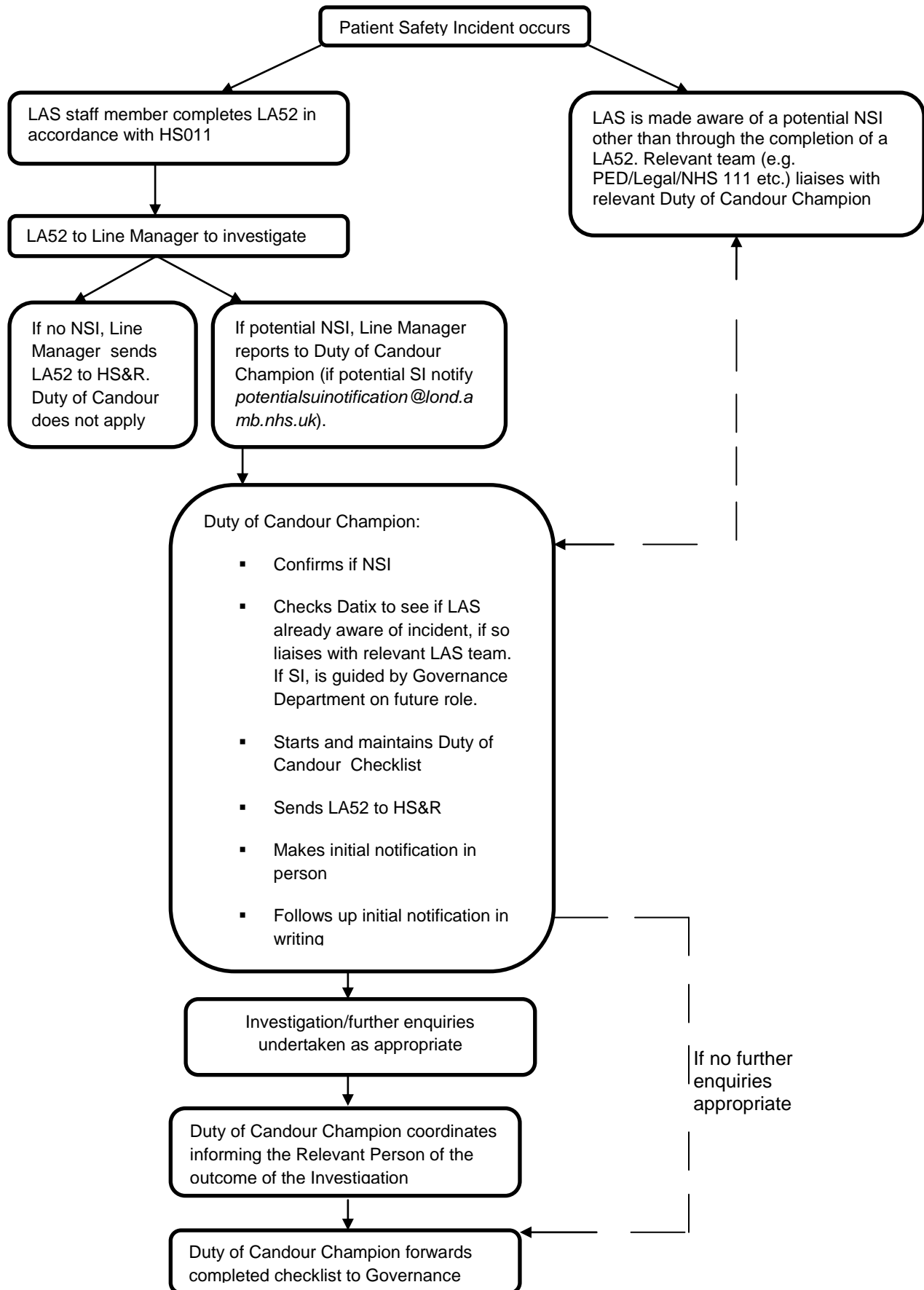
Incident	Definition	Duty of Candour?	Action	Examples*
Moderate harm	<p>In accordance with Regulation 20 this is defined as:</p> <p>“harm requiring a moderate increase in treatment (i.e. an unplanned return to surgery/readmission, a prolonged episode of care, extra time as an inpatient or outpatient, cancelling of treatment or transfer to another treatment area such as ITU) and is significant but not permanent”.</p>	Yes	Follow process described in TP/034 Appendix 4 or 5	<ul style="list-style-type: none"> ▪ Incorrect route of administration during drug therapy which means that the patient has to stay in hospital overnight and requires additional treatment. ▪ A patient is found collapsed in the street, there is a delayed diagnosis of his clinical condition including a suspected fractured femur, as a result an appropriate transfer was not conducted exacerbating the fracture which saw the patient undergo a prolonged inpatient stay. ▪ A crew are conveying a patient from the ambulance to A&E on a trolley bed. The patient is left unattended for a short period and the trolley bed tips over. The patient suffers short-term loss of consciousness and needs to be admitted to hospital for observation. There is no longer-term head injury. – NRLS website

Incident	Definition	Duty of Candour?	Action	Examples*
Severe harm	<p>In accordance with Regulation 20 this is defined as:</p> <p>“a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions that is directly related to the incident and not related to the natural course of the service user’s illness or underlying condition”.</p>	Yes	Follow process described in TP/034 Appendix 4 or 5	<ul style="list-style-type: none"> ▪ A patient in whom inappropriate administration of an intravenous drug leads to tissue necrosis, causing permanent tissue scarring and reduced joint mobility ▪ A patient who has fallen from scaffolding. On arrival the patient is conscious but lying awkwardly, with a leg that is clearly fractured and twisted. Before carrying out a full assessment or immobilising the cervical spine, the crew reposition the patient to straighten the leg. After repositioning, the patient is unable to move any of their limbs, and later investigations identify that they have a cervical fracture and spinal cord damage. The spinal cord was, however, immobilised immediately after repositioning. The patient is left with long-term paralysis from the neck down. – NRLS website

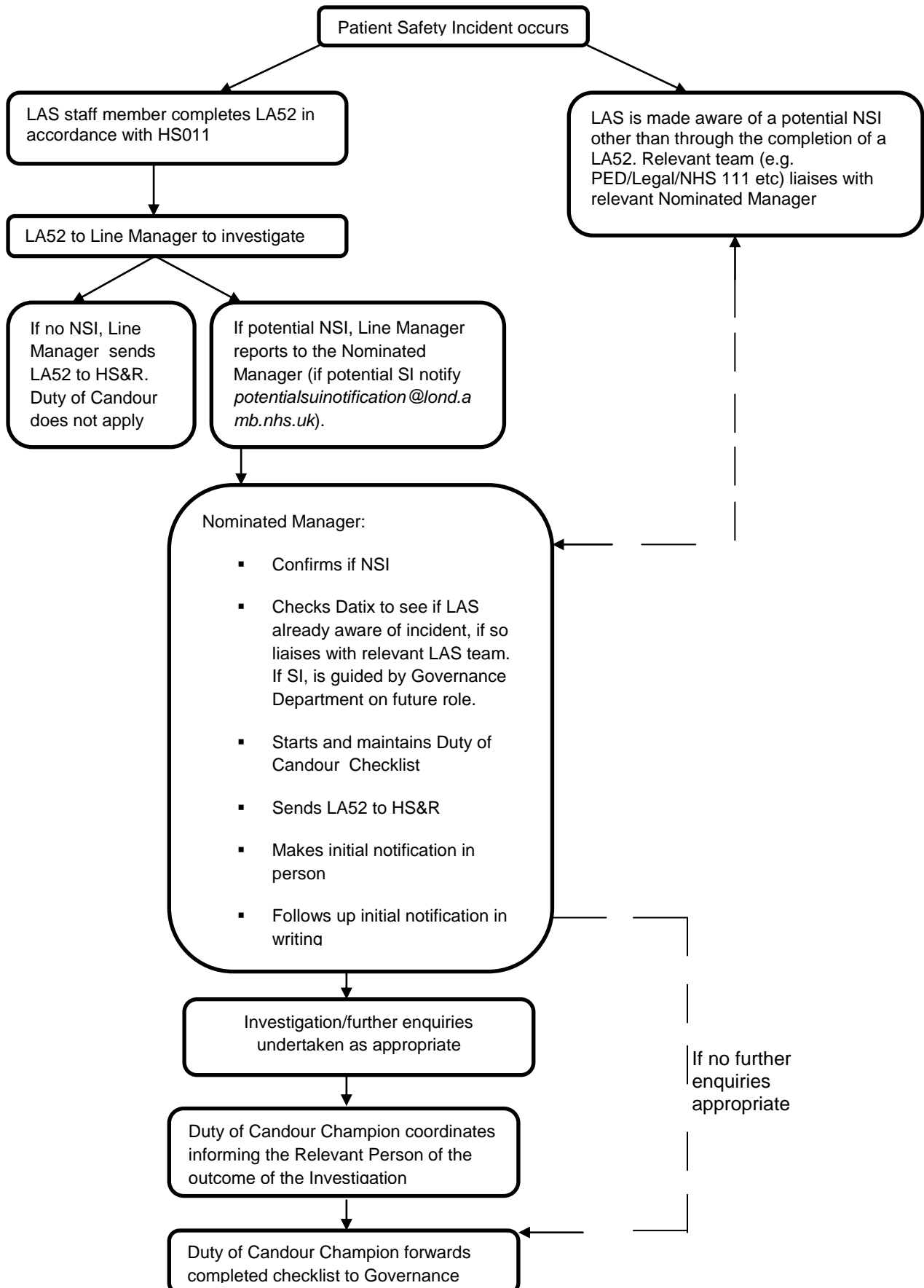
Incident	Definition	Duty of Candour?	Action	Examples*
Death	<p>In accordance with Regulation 20 this is defined as:</p> <p>“where the death relates directly to the patient incident rather than any underlying condition”.</p>	Yes	Follow process described in TP/034 Appendix 4 or 5	<ul style="list-style-type: none"> ▪ On arrival to the patient he advises the crew of his severe allergy to a drug. The drug mentioned by the patient is administered and the patient dies as a result of the allergic reaction.
Prolonged psychological harm	<p>Under the duty of Candour this is defined as:</p> <p>“psychological harm that a service user has experienced, or is likely to experience, for a continuous period of 28 days or more”.</p>	Yes	Follow process described in TP/034 Appendix 4 or 5	<ul style="list-style-type: none"> ▪ A complaint is received by PED which sets out how the elderly patient continues to have panic attacks and flashbacks of an incident 2 months after waiting 4 hours for an ambulance to attend following a fall.

* These examples are for illustrative purposes only. If you are not sure about whether the Duty of Candour applies you should contact your relevant Duty of Candour Champion

Appendix 4 - LAS Process for dealing with Duty of Candour – post re-structure



Appendix 5 - LAS Process for dealing with Duty of Candour – pre re-structure



Duty of Candour – Checklist

Completed by LAS Duty of Candour Champion: **Checklist started:**

As soon as a notifiable safety incident (NSI) is identified the following checklist is to be populated by the Duty of Candour Champion who is responsible for ensuring each step is completed in the requisite timeframe.

Patient’s Name:

Relevant person:

The Relevant Person will be the patient, unless the patient lacks capacity, is under 16 and not competent to make a decision about their care or treatment, or is deceased - in which case the Relevant Person will be the a person acting lawfully on their behalf.

Relevant person’s contact details:

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Being Open and the Duty of Candour Policy (TP034) requirement	Action required	Timeframe for compliance	Evidence of completion (including date) <i>please complete</i>
Potential NSI referred to Duty of Candour Champion for consideration as to whether there has been moderate/severe/prolonged psychological harm or death in accordance with Regulation 20 definitions (as set out within TP034)	Record assessment of harm and whether Duty of Candour applies. If so, follow procedure as set out in TP034 and populate rest of checklist.	As soon as made aware of incident (within 24 hours)	

Being Open and the Duty of Candour Policy (TP034) requirement	Action required	Timeframe for compliance	Evidence of completion (including date)
Is this the first time LAS is aware of the NSI/is the matter being referred to Serious Incident Group (SIG)?	Check Datix – if LAS already aware/being considered by SIG discuss next steps with relevant department/Governance.	As soon as made aware of incident (within 24 hours)	
Prepare for initial notification to Relevant Person	<ul style="list-style-type: none"> (i) Identify Relevant Person (ii) Obtain contact details for Relevant Person (iii) Consider support available for Relevant Person (iv) Make contact with Relevant Person and offer meeting to give initial notification' in person (v) Consider what if any further enquiries/investigation required <p><i>if 'in person notification' declined, record on checklist and proceed to next step by phone</i></p> <p><i>If unable to contact – record date, time method and number of attempts made–reasonable attempts should be made.</i></p>	As soon as reasonably practicable (maximum 10 working days of LAS being aware of NSI)	
Make initial notification in person	<ul style="list-style-type: none"> (i) Provide a full account of facts as currently known (ii) Set out further enquiries LAS believes to be Appropriate (if any) (iii) Provide an apology (iv) Provide reasonable support to the Relevant Person 	As soon as reasonably practicable (maximum 10 working days of LAS being	

Being Open and the Duty of Candour Policy (TP034) requirement	Action required	Timeframe for compliance	Evidence of completion (including date)
Follow up initial notification in writing	Set out the information provided in the initial notification in writing to the Relevant Person	Within 10 days of initial notification	
Maintain log of any additional contact with Relevant Person	Append to this checklist details of any subsequent telephone calls/emails/meeting minutes	Log to be kept in a timely fashion	
Co-ordinate informing the Relevant Person of the outcome of the investigation	<p>Subject to the incident having been investigated as a Serious Incident, the Duty of Candour Champion will contact the Relevant Person with the outcome of the LAS investigation.</p> <p><i>If the matter has been investigated as a Serious Incident, the Duty of Candour Champion shall liaise with Governance.</i></p>	Within 10 days of the final investigation report having been completed.	
Provide a completed copy of this checklist to the Governance Department	Provide a completed copy of this checklist to the Governance Department	Within 10 days of the final investigation report having been shared with the Relevant Person.	

Checklist completed date:

Sent to Governance date: