

**TRUST-WIDE
 CLINICAL SERVICE BASED POLICY DOCUMENT**

DUTY OF CANDOUR

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 DOCUMENT**

2023 – Version 6

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DUTY OF CANDOUR (incorporating Engagement with those affected by a patient safety incident)

Further information about this document:

Document name	SA13 Duty of Candour policy (incorporating engagement with those affected by a patient safety incident)
Document summary	This policy applies to all clinical staff including permanent and temporary staff employed by the Trust. The policy also applies to students, bank and locum staff, contracted staff and volunteers. Every healthcare professional in the Trust must be open and honest with patients when care or treatment does not go as planned and which causes, or has the potential to cause, harm or distress. Engagement with those affected by a patient safety incident will be managed compassionately and on an individualised basis.
Author(s) Contact(s) for further information about this document	Claire Brockbank, Head of Integrated Governance – Safety Telephone: 07435 412560 Email: claire.brockbank2@merseycare.nhs.uk
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To be read in conjunction with	SA02 Risk Management Strategy SA05 Management and Investigation of Claims SA45 Learning from Deaths SD02 Death of a Service User SA03 Reporting, Management, Review and Learning from Incidents SA06 Management of Complaints & Concerns SA53 PSIRF Policy SD17 Safeguarding Adults from Abuse

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Version 6	Reconciliation as per step one	February 2024

SUPPORTING STATEMENTS

this document should be read in conjunction with the following statements:

SAFEGUARDING IS EVERYBODY'S BUSINESS

All Mersey Care NHS Foundation Trust employees have a statutory duty to safeguard and promote the welfare of children and adults, including:

- being alert to the possibility of child / adult abuse and neglect through their observation of abuse, or by professional judgement made as a result of information gathered about the child / adult;
- knowing how to deal with a disclosure or allegation of child /adult abuse;
- undertaking training as appropriate for their role and keeping themselves updated;
- being aware of and following the local policies and procedures they need to follow if they have a child / adult concern;
- ensuring appropriate advice and support is accessed – contact the Safeguarding Duty Hub on Tel: 0151 351 8484;
- participating in multi-agency working to safeguard the child or adult (if appropriate to your role);
- ensuring contemporaneous records are kept at all times and record keeping is in strict adherence to Mersey Care NHS Foundation Trust policy and procedures and professional guidelines. Roles, responsibilities and accountabilities, will differ depending on the post you hold within the organisation;
- ensuring that all staff and their managers discuss and record any safeguarding issues that arise at each supervision session

EQUALITY AND HUMAN RIGHTS

Mersey Care NHS Foundation Trust recognises that some sections of society experience prejudice and discrimination. The Equality Act 2010 specifically recognises the *protected characteristics* of age, disability, sex, race, religion and belief (or lack thereof), sexual orientation, gender reassignment, pregnancy and maternity and marital and civil partnership status. The Equality Act also requires regard to socio-economic factors.

The trust is committed to promoting and advancing equality and removing and reducing discrimination and harassment and fostering good relations between people that hold a protected characteristic and those that do not both in the provision of services and in our role as a major employer. The trust believes that all people have the right to be treated with dignity and respect and is committed to the elimination of unfair and unlawful discriminatory practices.

Mersey Care NHS Foundation Trust also is aware of its legal duties under the Human Rights Act 1998. Section 6 of the Human Rights Act requires all public authorities to uphold and promote Human Rights in everything they do. It is unlawful for a public authority to perform any act which contravenes the Human Rights Act.

Mersey Care NHS Foundation Trust is committed to carrying out its functions and service delivery in line with a Human Rights based approach and the FREDAs principles of **F**airness, **R**espect, **E**quality **D**ignity, and **A**utonomy

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1. PURPOSE AND RATIONALE

- 1.1 Mersey Care (The Trust) has established processes to operate the Patient Safety Incident Response Framework (PSIRF) and it's underpinning principles including compassionate engagement and involvement of those affected by patient safety incidents.
- 1.2 The Trust accepts the NHS England (2022) PSIRF supporting guidance on engaging and involving those affected by a patient safety incident as best practice. The guidance sets out the principles on engaging to minimise harm to those affected by a patient safety incident and involving those affected with the aim of learning and improving to reduce future risk and associated harm (see Appendix 1).
- 1.3 The purpose of this policy is to set out how engagement with those affected will be managed within the Trust and also how the Trust will meet it's statutory requirements in respect of the Duty of Candour regulation (2014) as updated in 2022. With the implementation of PSIRF there is a promotion of systematic, compassionate, and proportionate responses to patient safety incidents. These should be anchored in the engagement principles and our restorative just and learning culture which are based on openness, inclusivity, fair accountability, learning and continuous improvement.
- 1.4 For the purposes of the policy, the term engagement describes everything an organisation does to communicate with and involve people affected by a patient safety incident in a learning response. This may include the Duty of Candour disclosure or discussion, as well as actively engaging patients, families, and healthcare staff to seek their input to the response and develop a shared understanding of what happened that can prompt improvement work for the mitigation, prevention or recurrence of incidents.
- 1.5 Compassionate engagement describes an approach that prioritises and respects the needs of people who have been affected by a patient safety incident. Involvement is part of wider engagement activity but specifically describes the process that enables patients, families, and healthcare staff to contribute to a learning response. The Trust recognises that meaningful learning and improvement following a patient safety incident can only be achieved if supportive systems and processes are in place.
- 1.6 The commitment to the engagement principles and our fulfilling the statutory Duty of Candour requirement also contributes to the overall Trust aim of creating and operating at all times within a Restorative Just and Learning culture to improve the safety of all our people. We recognise in every human system that mistakes will happen. In Mersey Care, we know we operate in one of the most complex environments and how we respond to those mistakes is critical to our aspiration to deliver perfect care in a just culture. Creating a Restorative Just and Learning Culture is a commitment to our workforce and to our patients that our organisation will take every opportunity to learn and improve. The Trust aims to create a compelling place to work, where we attract, retain and develop people to be the best they can be and deliver the best care.

2. OUTCOME FOCUSED AIMS AND OBJECTIVES

- 2.1 The Trust accepts that those affected by an incident may have a range of needs (including clinical needs) which may need to be met as a result of a patient safety incident and will aim to meet those where possible. This is part of our duty to care. This will help alleviate any harm that has occurred and prevent that harm being compounded. Whilst we may not be able to change that fact that an incident has taken place, we will compassionately engage with those affected, listen to and answer their questions and try to meet their needs.

- 2.2 Engaging those affected by a patient safety incident is in keeping with our aim of a restorative just and learning culture – this encourages a culture of safety that supports organisational and personal learning. Engagement with a meaningful apology and exploration of a shared understanding of a patient safety incident can support learning that can lead to explanation of what happened to patients/service users, their family or carers and can demonstrate a transparency and openness with patients and those significant to them.
- 2.3 Staff also have a duty to be open and honest with the organisation by reporting patient safety incidents, this includes near misses as well as those that lead to harm. The Trust’s processes for this and commitment to a just and learning safety culture can be found in the Trust policies concerning PSIRF (SA53) and incident reporting, management and review (SA03).
- 2.4 Transparency and openness following a patient safety incident is integral to the Duty of Candour. Registered healthcare professionals have a professional Duty of Candour as laid out in their codes of practice according to their statutory professional regulators.
- Good Medical Practice (General Medical Council; GMC, 2013).
 - The Code: Professional Standards of Practice and Behaviour for Nurses and Midwifery (Nursing and Midwifery Council; NMC, 2015).
 - Standards for pharmacy professionals (General Pharmaceutical Council, 2017)
 - Standards for the Dental Team (General Dental Council, 2016).
 - Standards of conduct, performance and ethics (Health and Care Professions Council, 2016).

The professional Duty of Candour means that registered healthcare personnels must be open and honest with patients when things go wrong during treatment that has caused or has the potential to cause harm or distress.

- 2.5 A statutory Duty of Candour also applies since coming into force in 2014 (Care Quality Commission (CQC) Regulation 20: Duty of Candour). This organisational duty requires healthcare providers to act in an open and transparent way. It includes all aspects of the professional Duty of Candour and, in addition, the actions which providers must undertake when the threshold of a ‘notifiable safety incident’ is reached. (see section 4.1 for full definition). These are as follows:
- a) Carry out a thorough review into the causes of the incident and share relevant details and findings with the patient and/or relevant other.
 - b) Provide an apology in writing, following the verbal apology in person.
 - c) Provide reasonable support to the patient in relation to the incident.
 - d) Establish a formal and defined process of harm disclosure as part of the provider’s governance processes.
- 2.6 Whilst the statutory duty lays with the healthcare provider, the Trust relies upon individual clinicians to carry out the duty on behalf of the organisation. Regulation 20 makes clear that cooperation between a healthcare organisation and its staff is vital. The Trust will provide training and support for its staff to be open and honest with those affected by a patient safety incident in order to discharge this duty.

- 2.7** The Trust is fully committed to compliance with statutory duty of candour. Non-compliance with Regulation 20: Duty of candour is a criminal offence and the CQC can move directly to prosecution without serving a Warning Notice. The CQC may take other regulatory action where non-compliance is evidenced. The details of current Regulation 20: Duty of Candour Guidance – (2022) can be found in Appendix 2.
- 2.8** The Trust will fulfil its obligations for disclosure under the terms of the statutory Regulation 20: Duty of Candour to ensure that staff are open and honest following any notifiable patient safety incident, this is incorporated into the NHS Standard Contract and as noted in 2.4 above is an expected part of the conduct of registered healthcare professionals.
- 2.9** The Trust is committed to ensuring that the care and treatment provided to service users and patients is of a high standard and will not suffer as a result of raising a concern or complaint. The Trust has a duty to be open and honest when dealing with complainants and their care and treatment will not be affected as a result of raising a concern or complaint. The CQC's Regulation 16: Receiving and Acting on Complaints states that 'providers must act in accordance with Regulation 20: Duty of Candour in respect of complaints about care and treatment that have resulted in a patient safety incident'. The NHS Constitution (2013) commits the NHS to treat all complainants with courtesy, giving an apology and ensuring that appropriate explanation is given.
- 2.10** The aims and objectives of this policy are:
- a) To ensure that the Regulation 20: Duty of Candour within the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and any subsequent amendment is consistently adhered to in all Divisions across the Trust.
 - b) To clearly set out the legal requirements to ensure all clinical staff working within the Trust are fully informed what their responsibilities are to meet Regulation 20: Duty of Candour and comply with Regulation 16: Receiving and acting on complaints in respect of handling complaints and concerns about patient safety.
 - c) To explain how to apply Duty of Candour when a notifiable safety incident has occurred with specific actions to be followed.
 - d) To provide guidance on how to engage with those affected by a patient safety incident, being truthful, open and honest about the incident with an apology.
 - e) To ensure all staff are aware of the importance of highlighting significant incidents to continue to embed safety within the Trust's restorative just and learning culture and allow for Duty of Candour and engagement to take place for the Trust to improve and reduce the risk of recurrence of incidents that have potential for or have caused harm.
 - f) To ensure that the principles outlined in this policy are integrated with other patient safety processes and policies, for example incident reporting and review approaches under Patient Safety Incident Response Framework (PSIRF).
 - g) To set out arrangements for the management and operation of engagement processes across the Trust to ensure that Divisions can meet the engagement needs of patients, service users and their families/carers. This will include meeting the national patient safety incident response standards relating to engagement (NHS England 2022) and the conduct of Duty of Candour as set out above.

- h) To monitor compliance with meeting Duty of Candour and the operation of engagement processes through various methods.

The potential implications of not implementing the Duty of Candour requirements

- 2.11 As the Duty of Candour is a statutory requirement, non-compliance is a criminal offence. Commissioners can withhold the cost of the episode of care or implement a fine of £10,000 if the cost is not known. In addition, they can do any/all of the following:
 - a) Inform the CQC.
 - b) Require that the Chief Executive send an apology and an explanation of the breach to the patient and the relatives.
 - c) Publish details of the breach on the Trust web-site.

- 2.12 The CQC in their guidance relating to the Duty of Candour explain the approach they will be taking to assess whether a provider is complying with the new regulation. The CQC's key lines of enquiry will be:
 - a) Is the culture centred on the needs and experience of people who use services?
 - b) Does the culture encourage openness and honesty at all levels within the organisation, including with people who use services, in response to incidents?
 - c) How are lessons learned and themes identified, and is action taken as a result when things go wrong?

3. SCOPE

- 3.1 This policy specifically applies to engagement with those affected by a patient safety incident. All patient safety and other incidents should be reported onto the Radar system, this should not be confused with the specific term of 'notifiable safety incident' referred to in the statutory Duty of Candour regulation. The CQC regulation explains that this means any unexpected or unintended event in delivery of our care and treatment which has or may result in moderate or greater levels of harm. Brief definitions of important terms, harm levels and the level of engagement to be undertaken are noted within Section 4. Appendix 3 gives fuller definitions to allow for decision making.

- 3.2 Other incidents that may occur are not covered by this Policy, such as loss or damage of property occurring to members of staff, public or others may still require an open and honest response in line with the Trust's restorative just and learning culture. There may be exceptions to implementing the Duty of Candour, such as where it may cause unacceptable additional distress/mental health issues to the individual. Decision making regarding such exceptions should be escalated to the Patient Safety team with urgency so that this can be considered by the membership of the Trust Patient Safety Panel and a collaborative decision arrived at, following which a sound rationale for why Duty of Candour is not to be applied can be clearly recorded.

- 3.3 This policy deals with the information and methods of sharing of information with the relevant person. Patients and those close to them will vary in how much information they want, and when they want it. Some people will want as much detail as possible, including details of rare risks, to those who ask health professionals to make decisions for them. There will always be an element of professional judgement in determining what information should be given.

- 3.4 However, the presumption must be that the relevant person wishes to be well informed about the risks and benefits of the various options. Where the relevant person makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented.
- 3.5 On occasion, an incident that happened some time ago may be discovered and a delay in discovering an incident does not mean that the Duty of Candour does not apply. Such incidents must be reported in the usual way on incident management system. The processes however may require additional consideration in order that the patient is informed of the incident with care to avoid unexpected shock or distress.
- 3.6 For patient safety incidents that are discovered which relate to care delivered by another provider, the Trust will report this to the provider and ICB colleagues under its commitment to cross-system working under PSIRF. The other provider will then be responsible for implementing the Duty of Candour.

4. DEFINITIONS

- 4.1 **Notifiable Safety Incident** for trusts such as Mersey Care – any unintended or unexpected incident that occurred in respect of a patient's care that, in the reasonable opinion of a healthcare professional, appears to have resulted in, requires treatment to prevent or might result in :
- a) The patient's death.
 - b) Severe physical or psychological harm.
 - c) Moderate physical or psychological harm
- 4.2 This definition (and the whole Duty of Candour) refers to harm directly caused by the incident, and not by the natural course of the patient's illness or underlying condition. More information on the details of the statutory Duty of Candour can be found in Appendix 2.
- 4.3 The levels of harm noted in this section are taken from the current CQC guidance. Please see Appendix 3 for how these align to the latest guidance on harm definitions from NHS England.
- 4.4 Identifying something as a notifiable safety incident does not automatically imply error, negligence or poor quality care. It simply indicates that an unexpected and undesirable clinical outcome resulted from some aspect of the patient's care or treatment, rather than their underlying condition.

Summary Harm levels and engagement actions to be taken

- 4.4 Further details on definitions of harm can be found at Appendix 3

Harm assessment	Impact on patient	Engagement process
No harm	No physical or psychological harm	Openness and transparency
Low harm	Minimal physical or psychological harm	Openness and transparency
Moderate harm	Requires significant intervention but physical or psychological harm is not likely to extend for greater than six months	Duty of Candour
Severe harm	Permanent injury likely to limit a patient's independence or psychological harm causing distress likely to last greater than six months or cause a significant deterioration in a pre-existing mental health condition	Duty of Candour
Death	Death where a patient safety incident contributed to the death	Duty of Candour

- 4.5 Severe harm** – 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 to the natural course of the patient's illness or underlying condition.
- 4.6 Moderate harm** – harm that requires a moderate increase in treatment and significant, but not permanent, harm.
- 4.7 Low harm** – any incident that required extra observation or minor treatment and caused minimal harm to the patient.
- 4.8 No harm** means:
- a) Any incident that had the potential to cause harm but was prevented and therefore no harm occurred to the patient (near miss). Near misses are not notifiable incidents – the intention of the term 'might result in' harm noted in 4.1 above refers to where harm is not apparent at the time of the incident but which might appear later.
 - b) Any incident that was not prevented but resulted in no harm to the patient.
- 4.9 Prolonged psychological harm** – psychological harm which a patient has experienced or is likely to experience, for a continuous period of at least 28 days.
- 4.10 Apology** – an expression of sorrow or regret in relation to an unexpected incident that resulted in patient harm. Apology does not imply acceptance of responsibility for the incident and the resulting harm. In some cases, however, where harm is linked to an error in the care of the patient, then an apology should also include an acknowledgement and acceptance of responsibility.

- 4.11 Prolonged pain** – pain which a patient has experienced, or is likely to experience, for a continuous period of at least 28 days.
- 4.12 Written notification** – one given or sent to the relevant person in written form containing the information provided in any initial notification made in person, details of any inquiries to be undertaken, advise of any appropriate enquiries to be undertaken, the results of any further enquiries, and an apology.
- 4.13 Openness** – enabling concerns and complaints to be raised freely without fear and questions asked to be answered.
- 4.14 Transparency** – allowing information about the truth about performance and outcomes to be shared with staff, patients, the public and regulators.
- 4.15 Candour** – any patient harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it.
- 4.16 Relevant person** – this is either the person who was harmed, or in the specific circumstances noted below, a person lawfully acting on their behalf:
- a) On the death of the service user (also means patient in Mersey Care).
 - b) Where the service user is under 16 and not competent to make a decision in relation to their care or treatment;
 - c) Where the service user is 16 or over and lacks capacity (as determined in accordance with the Mental Capacity Act 2005) in relation to the matter.

5. DUTIES

- 5.1** All clinical staff have a responsibility to adhere to this policy, and the Trust promotes an open and just safety culture with honesty at all levels in order to uphold the principles of engagement and fulfill the Statutory Duty of Candour requirement.
- 5.2** The Trust expects all those who take a lead in engagement with those affected by a patient safety incident to display the following behaviours as set out in the national patient safety incident response standards (NHS England, 2022):
- a) to communicate and engage with patients, families, staff and external agencies in a positive and compassionate way.
 - b) to listen and hear the distress of others in a measured and supportive way.
 - c) maintain clear records of information gathered and contact with those affected.
 - d) identify key risks and issues that may affect involvement of patients/families/staff.
 - e) recognise when those affected by patient safety incidents required onward signposting or referral to support services.
- 5.3 Trust Board** - The Chief Executive Officer, Chief Medical Officer, Chief Nurse, Director of Patient Safety and Executive Directors must ensure that mechanisms are in place to enable all clinical staff to adhere to this policy and they have oversight of these arrangements. This includes:

- a) ensuring that engagement and involvement of those affected by a patient safety incident is a genuine priority.
 - b) ensuring that the Trust meets its statutory requirement to fulfil Duty of Candour.
- 5.4 **Chief Medical Officer** - The Chief Medical Officer is the Executive Director that holds overall responsibility for this policy. This includes:
- a) development, implementation and review of this policy,
 - b) ensuring the processes are in place so that meaningful information about reporting and management of engagement as well as Duty of Candour is presented to and reviewed by the Trust Board via the Trust Quality Committee.
 - c) joint responsibility or delegated responsibility to a nominated deputy for defining and verifying an incident as requiring Duty of Candour.
 - d) Ensuring that PSIRF processes such as Patient Safety panels incorporate consideration of Duty of Candour compliance.
- 5.5 **Director of Patient Safety** - The Director of Patient Safety is responsible for:
- a) Ensuring that the Chief Medical Officer is kept fully informed about compliance with Duty of Candour and for reporting compliance to the Quality Assurance Committee.
 - b) Monitoring and ensuring compliance with Duty of Candour and management of engagement processes across all Divisions as Chair of Strategic Patient Safety & Improvement Group (SPSIG).
 - c) Ensuring reporting is carried out in line with the Care Quality Commission (CQC) regulatory framework.
 - d) Professional leadership and independent clinical overview for the Trust Board regarding Duty of Candour.
- 5.6 **Deputy Director of Patient Safety** - will ensure that policies and processes are in place to enable the Trust and its staff to enact the requirements of CQC Regulation 20: Duty of Candour. This will include:
- a) To ensure processes are in place for the central monitoring and reporting on the level of compliance with the Duty of Candour process following notifiable safety incidents.
 - b) To ensure that effective processes are in place to support engagement and involvement of those affected by patient safety incidents including management of Duty of Candour for any notifiable patient safety incidents. This will include the provision of expert advice, audit, training and education.
- 5.7 **Director of Patient Safety/Deputy Directors and Senior Managers** - all Trust Directors and Deputies, Associate/Assistant Directors, Heads of Service and Senior Managers have responsibility for the management of incidents within their areas of their remit and control. This must include systems and standard operating procedures to ensure that the engagement principles as outlined in Appendix 1 and Duty of Candour responsibilities are fully discharged within their services.
- 5.8 **Associate Directors of Nursing** – As part of their role Associate Directors of Nursing are designated Patient Safety Leads for their Division and are responsible for:

- 5.8.1 Developing and adapting Standard Operating Procedures (SOP's) to support Divisional compliance with the NHS England engagement principles (Appendix 1) and Duty of Candour requirements.
 - 5.8.2 Monitoring compliance with required timescales and escalating concerns of non-compliance with regards to Duty of Candour.
 - 5.8.3 Ensuring that systems are in place to monitor engagement actions including Duty of Candour fulfilment via the Divisional governance processes.
 - 5.8.4 Developing mechanisms to ensure the allocation of Family Support Leads as required for Patient Safety Learning Response reviews undertaken on the Divisions behalf.
 - 5.8.5 Encouraging a positive, open reporting culture and sharing learning within and between teams.
 - 5.8.6 Signposting staff to support mechanisms for staff involved in incidents.
 - 5.8.7 Ensuring each Division undertakes audit relating to Duty of Candour including auditing the quality of Duty of Candour correspondence and compliance with the legal requirements of the Regulation 20.
 - 5.8.8 Sharing audit and other findings at an appropriate Divisional forum and to the SPSIG to drive improvement and learning.
- 5.9 Divisional Risk and Governance Leads/Operations Managers - responsible for:**
- 5.9.1 Ensuring that relevant staff members are aware of and operate within the Duty of Candour Policy and associated local SOP's and other procedures are followed within their services.
 - 5.9.2 Ensuring that they monitor adherence to the Policy within their services.
 - 5.9.3 Ensuring that any appropriate training associated with Engagement, Duty of Candour and the Duty of Candour Champion role is undertaken by relevant staff within their service.
 - 5.9.4 Ensuring that Duty of Candour is implemented in accordance with Regulation 20.
 - 5.9.5 Advising, where needed, on who will provide the initial notification to the patient/service user or their relevant other. (In most circumstances this will be the senior clinician responsible for the patient's care).
 - 5.9.6 Supporting service lines/places to ensure an appropriate person is identified to be the contact person with the person affected or relevant other during any engagement process.
 - 5.9.7 Ensuring that all conversations with the person affected or relevant other are documented.
 - 5.9.8 Ensuring that the Duty of Candour fields are completed on the incident event report form within Radar.

5.9.9 Ensuring that staff and patients involved in incidents are provided with the support they require.

5.9.10 Disseminating Duty of Candour compliance audit information to drive improvement.

5.10 Family Support Lead (FSL) - some patient safety incidents may meet the requirement to have a Patient Safety Learning Response Review (PSLR) undertaken as part of the Trust's PSIRF response, as well as trigger the statutory Duty of Candour. In such cases a FSL will be appointed from within the relevant Division, see Appendix 4 for further details of the FSL role. Those undertaking this role should:

- a) Undertake necessary training and education to allow them to be able to meaningfully engage and support a patient/family during the course of a PSLR.
- b) Be prepared to be a point of contact for a patient or their family who wish to be supported during the course of a PSLR, acting as a conduit to ensure that the patient or their family are engaged within the review process and have had an opportunity to contribute to key lines of enquiry. This includes assessing for and ensuring that any inclusivity needs are attended to. (Sections 6.8 to 6.18 below, Appendix 4,)
- c) Work closely with the Learning Response Lead and Patient Safety Reviewer allocated to any PSLR to ensure that a patient or their family can be kept up to date throughout the course of a review using the four stage approach detailed in Appendix 4.

5.10 Ward/Department Managers - must ensure that they and their clinical staff:

5.10.1 Know how and why to report incidents, including the grading of the level of harm.

5.10.2 Recognise an incident that triggers the statutory Duty of Candour (a notifiable safety incident).

5.10.3 Know how to escalate such an incident so that the Duty of Candour process starts within the required 10 days of recognition of a notifiable safety incident.

5.10.4 Ensure that any of their staff involved in an incident are offered appropriate support including from the Duty of Candour Champion.

5.11 Duty of Candour Champion – this role within the clinical Divisions is to empower others to act. Duty of Candour champions should:

- a) Ensure that the member of staff, as the person with first-hand knowledge of an incident with potential to require Duty of Candour disclosure, deals with this effectively and is supported with the process.
- b) Acts as an Ambassador, to support Governance Leads within the Division, to increase awareness of Duty of Candour and requirement for disclosure and processes involved. See Appendix 5 for further details of the Duty of Candour Champion Role.

5.11 Staff involved in responding to Complaints and/or Claims - all staff involved in reviewing and responding to complaints and/or claims must do so in a way that fulfils the requirements of the professional and statutory Duty of Candour. Please refer to the [Complaints Policy SA06](#) in conjunction with this policy.

6. PROCESS

- 6.1 Patient Safety incidents are considered for harm caused as part of the mechanisms established in response to the Trust PSIRF Plan and Policy. How review of any patient safety incident is to take place will be determined according to the PSIRF Plan and Policy and engagement will vary according to harm, the circumstances of the incident and any statutory Duty of Candour requirement.
- 6.2 Section 4.4 above gives a simple guide to the expected actions that should be taken for engagement on a patient safety incident once the level of harm has been established and an assessment of whether an incident meets the definition of a 'notifiable safety incident' for Duty of Candour purposes.
- 6.3 Regardless of whether an incident meets a National and Local priority for review under PSIRF, where a patient safety incident involves or might have involved unintended or unexpected moderate or greater harm to the patient in the course of regulated care activity, this meets the criteria of a 'notifiable safety incident'. Such incidents are specified in Regulation 20: Duty of Candour as requiring Duty of Candour to be fulfilled.
- 6.4 When a patient safety incident with potential to be a notifiable safety incident has occurred, healthcare professionals (and the Trust) must comply with the statutory Duty of Candour. They must:
- a) Acknowledge that an incident has occurred, reporting it appropriately to a senior member of staff in the department in which it occurred and on RADAR.
 - b) As soon as possible after detection of the incident, the senior member of staff should inform both Divisional governance leads and the service line senior leadership team (SLT including Assistant Directors of Nursing) that a potential notifiable safety incident has occurred.
 - c) The governance lead and SLT will offer an objective view of whether Duty of Candour requirement will apply to the incident concerned. This will be confirmed by the Divisional Patient Safety panel. There should be no unnecessary delays to this process.
 - d) Following confirmation, that duty of candour applies, the senior professional from the team will inform the patient, family or carer (the relevant person) of the incident with a factual explanation of all known facts. Within Mersey Care this disclosure should preferably be carried out by the patient's consultant or a senior member of the nursing/AHP team looking after the patient (see 6.5 below).
 - e) Communication should be verbal, preferably face to face or by telephone.
 - f) Offer a sincere and heartfelt apology, NB: an apology is not an admission of liability.
 - g) Explain the possible consequences to the patient if not already evident, and any immediate or possible future help implications.

- h) Offer an appropriate remedy (if possible) and/or support to the patient, family or carer.
 - i) Explain any immediate steps that will be taken to minimise or prevent the same incident recurring and that a more detailed review will take place.
 - j) Let them know that a member of staff will follow up this initial discussion with more information after further review.
 - k) Document this initial disclosure discussion in the patient's notes, record on RADAR and follow it up with a letter to the patient, family or carer detailing what was discussed using a personalised copy of the template letter in Appendix 6.
- 6.5 For incidents that do not require a PSLR, the Clinical Team Leader will arrange follow up discussion or disclosure with the patient, family or carer. This would usually be in the form of a follow-up letter. This should include a repeat of the apology and outline the measures taken by the Trust to prevent recurrence of similar incidents. This may include sharing a summary of improvement works/plans where appropriate. For further guidance on engagement with patients or their families, please see Appendix 4.
- 6.5 Where a PSLR is required, a Family Support Lead will be appointed by the Division concerned to maintain open lines of communication as noted in 5.9 above. For a PSLR, the Family Support Lead should work closely with the Learning Response Lead and Patient Safety Reviewer, to communicate with the person affected or relevant other introducing themselves as the Family Support Lead and explaining the process to be followed. Specific details on engagement throughout the PSLR process is included in Appendix 4.
- 6.6 Where the relevant person requests or consents, the Trust will take reasonable steps to involve family members and carers in any discussions. This is to make sure that engagement is carried out in a way that is as accessible and supportive as possible.
- 6.7 Throughout the process of fulfillment of Duty of Candour or any other engagement required as part of the response to a patient safety incident, there must be 'reasonable support' given to the relevant person, both in relation to the incident itself and when communicating with them about the incident. 'Reasonable support' will vary with every situation, but could include, for example:
- environmental adjustments for someone who has a physical disability
 - the provision of an interpreter as required
 - information in accessible formats
 - signposting to mental health services
 - the support of an advocacy services or drawing their attention to other sources of independent help and advice such as AvMA (Action against Medical Accidents) or Cruse Bereavement Care.

Duty of Candour and engagement in special circumstances

- 6.8 As noted in 6.8 above the duty of candour or engagement approach may need to be modified according to the patient's personal circumstances, and there are some specific situations that may require and adapted approach or have additional needs associated. The following is offered as guidance on the process to be followed in specific circumstances. Refer to Appendix 4 for help on engagement with patients and their families or carers.

- 6.9 When a patient dies - When a patient safety incident has resulted in a patient's death it is crucial that communication is sensitive, empathic and open. It is important to consider the emotional state of bereaved relatives or carers and to involve them in deciding when it is appropriate to discuss what has happened. The patient's family and/or carers will probably need information on the processes that will be followed to identify the cause(s) of death. They will also need emotional support. Establishing open channels of communication may also allow the family and/or carers to indicate if they need bereavement counselling or assistance at any stage.
- 6.10 Coroner's inquests - Where a case is referred to a medical examiner or HM Coroner's inquest processes are commenced any duty of candour apology should be followed by an explanation of the process involved. Advice and information can be sought from the Trust's Legal Services Department and Divisional Risk and Governance leads may be able to support in these circumstances. The Trust will continue with review of any patient safety incident except where any police investigation prohibits it. This should also be explained to the patient's family and/or carers and a realistic timeframe for review given to prevent further distress from apparent delays.
- 6.11 Competent children - The legal age of maturity for giving consent to treatment is 16. It is the age at which a young person acquires the full rights to make decisions about their own treatment and their right to confidentiality becomes vested in them rather than their parents or guardians. It is still considered good practice to encourage competent children to involve their families in decision-making. The courts have stated that younger children who understand fully what is involved in the proposed procedure can also give consent. This is sometimes known as Gillick competence or the Fraser guidelines. Where a child is judged to have the cognitive ability and the emotional maturity to understand the information provided, he/she should be involved directly in the process after a patient safety incident. The opportunity for parents/guardians to be involved should still be provided unless the child expresses a wish for them not to be present.
- 6.12 Children lacking competence -Where children are deemed not to have sufficient maturity or ability to understand, consideration needs to be given to whether information is provided to the parents/guardians alone or in the presence of the child. In these instances, the parents'/guardians' views on the issue should be sought. More information can be found in the Trust's Consent Policy or on the Department of Health's website.
- 6.13 Patients/Carers with mental health issues - The process for patients (or carers) with mental health issues should follow normal procedures unless the patient also has cognitive impairment (see below).
- 6.14 If, however, the consultant psychiatrist believes that the process would cause adverse psychological harm to the patient then this should be escalated for discussion at the next Trust Patient Safety panel as in Section 3.3 above. Apart from in exceptional circumstances, it is never appropriate to discuss patient safety incident information with a carer or relative without the express permission of the patient. To do so is an infringement of the patient's human rights.
- 6.15 Patients/Carers with cognitive impairment - Some individuals have conditions that limit their ability to understand what is happening to them. They may have authorised a person to act on their behalf by an enduring power of attorney. In these cases, steps must be taken to ensure this extends to decision-making and to the medical care and treatment of the patient.

- 6.16 The discussion would be held with the holder of the power of attorney. Where there is no such person the clinicians may act in the patient's best interest in deciding who the appropriate person is to discuss incident information with, regarding the welfare of the patient as a whole and not simply their medical interests. However, the patient with a cognitive impairment should, where possible, be involved directly in communications about what has happened. An advocate with appropriate skills should be available to the patient to assist in the communication process.
- 6.17 Patients/Carers with learning disabilities - Where a patient (or carer) has difficulties in expressing their opinion verbally, an assessment should be made about whether they are also cognitively impaired (see above). If the patient is not cognitively impaired, they should be supported in the process by alternative communication methods (i.e., given the opportunity to write questions down). An advocate, agreed on in consultation with the patient, should be appointed. Appropriate advocates may include carers, family or friends of the patient. The advocate should assist the patient during the process, focusing on ensuring that the patient's views are considered and discussed. Advice can be sought from the Trust's Liaison Nurses for Learning Disability.
- 6.18 Patients/Carers with a different language or cultural considerations -The need for translation and advocacy services, and consideration of special cultural needs (such as for patients/carers 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 safety incident information. It would be worthwhile 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 information by editing what is communicated. Translators can be booked via the General Office. Advice on cultural issues can be sought from the Trust's Human Rights, Equality and Inclusion Lead.
- 6.19 Patients/Carers with different communication needs - A number of patients (or carers) 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 discussion, focusing on the needs of individuals and their families and being personally thoughtful and respectful.
- 6.20 Supporting staff - Staff involved in an incident, complaint or claim will be given all necessary support for as long as it is needed. This may be managed within their own team or service areas or, exceptionally, with an independent senior colleague who is able to offer such support as needed. All correspondence and verbal communications should be in plain language, avoiding technical terminology, where possible to avoid misunderstanding or confusion.
- 6.21 Staff members involved in a patient safety incident that progresses to PSLR will be offered a copy of the PSLR information booklet on what to expect from involvement in the process which details the steps in 6.5 above but from a staff perspective.
- 6.22 **Low harm incidents** - do not require a statutory disclosure but in the interest of transparency and openness must be addressed. Notify the patient about the incident as soon as possible with a factual explanation of all facts known at the time of the notification and provide an open conversation by:
- Providing an apology.
 - Explaining fully the short and long-term effects of the incident.

- Offering an appropriate remedy or support to put matters right (if possible).
- Explaining steps that will be taken to prevent recurrence of incidents (as relevant).
- Recording details of the discussion in the patient's clinical record.
- Disclosing the process can conclude here for low harm incidents.

6.23 **Documentation of Duty of Candour and other engagement following a patient safety incident** - There must be a record maintained of details of engagement with patient and their families or carers. For Duty of Candour purposes, the Duty of Candour form for the incident on Radar must be completed. This will allow all incident-related information to be comprehensively held in one place and facilitates reporting and monitoring. Ideally, other engagement conversations should also be recorded on the incident report form held on Radar.

6.24 Where personal notes regarding engagement with a patient, family or carer are made they should include the following -

- a) The time, place, date, as well as the name and relationships of all attendees at the conversation.
- b) The plan for providing further information to the patient and/or their carers.
- c) Offers of assistance and the patient's and/or carer's response.
- d) Questions raised by the family and/or carers or their representative and any answers given.
- e) Plans for follow-up as discussed.

6.24 This can all be transcribed on to the Radar incident report. Any additional documentation for any correspondence (most usually around a PSLR review) must be stored in accordance with Trust's Data Protection and Confidentiality Policies in a password protected shared file for the incident on the Patient Safety team shared drive.

7. CONSULTATION

7.1 Consultation in devising this policy has been in conjunction with the following groups of staff with representation across the different divisions of the Trust:

- Divisional Associate Directors of Nursing and their Deputies
- Divisional Risk and Governance Leads
- Director of Patient Safety
- Deputy Director of Patient Safety,
- Assistant Director of Governance and Compliance for Patient Safety
- Head of Integrated Governance and Patient Safety
- Head of Risk
- Mortality and Incident Clinical Manager.

8. TRAINING AND SUPPORT

8.1 The day-to-day responsibility for the ensuring compliance with this policy and the implementation, training and support lies with the Divisional Associate Directors of Nursing who may delegate this to the Risk and Governance Leads within each Division.

8.2 Training and support initiatives relevant to this policy within the Trust include the following which may be delivered as formal training, elearning and planned and ad-hoc 'clinic' support sessions by the Patient Safety team:

- a) Duty of Candour/Being Open training.
- b) Restorative Just Culture training modules.
- c) Incident Management training.
- d) Dealing with concerns and complaints.

9. MONITORING

- 9.1** The Trust will monitor compliance with this policy through the patient safety reporting process; references in learning response reviews, complaints reports, mortality reviews and by incorporating information on its implementation into the annual Safety report containing integrated claims, complaints and incidents information which is shared with the Board of Directors and in the bi-monthly reports presented to the Quality Committee.
- 9.2** Each Patient Safety Learning Response review report will be expected to clarify how engagement and Duty of Candour has been facilitated in each case, how the Duty of Candour process has been followed, where needed and this information will be monitored by the Divisional Safety Huddle meetings (see Appendix 7 Duty of Candour Process Flow-Chart).
- 9.3** A quarterly audit of Duty of Candour compliance within each Division will be undertaken by the Divisions across the Trust. The monitoring process and information collated in this audit is outlined within the Duty of Candour audit questions (Appendix 8 Duty of Candour Audit). It is the responsibility of Governance Leads within each Division to ensure this audit is completed and they may have local arrangements to be supported by the Duty of Candour Champions in this. Audit findings should be saved to the Audit Management and Tracking (AMaT), digital audit system. This will then be reviewed by the central Patient Safety team and reported on to Director and Deputy Director of Patient Safety to Trust Board. Quality improvement work, where necessary, will be informed by the outcomes of this audit and other measures of conformance with the statutory regulation as outlined in 9.1.

10. REFERENCES

- 10.1** **NHS England (2022)** PSIRF Supporting Guidance - Engaging and involving patients, families and staff following a patient safety incident.
- 10.2** **NHS England (2023)** Policy Guidance on recording patient safety events and levels of harm.
- 10.3** **Care Quality Commission (2022)** Regulation 20: Duty of Candour.

11. EQUALITY IMPACT ANALYSIS

Title	SA13 Duty of Candour including Being Open Policy		
What is being considered?	Policy		
Who will be affected?	Patients [<input checked="" type="checkbox"/>]	Staff [<input checked="" type="checkbox"/>]	Public [<input type="checkbox"/>] Partner agencies [<input type="checkbox"/>]
What engagement is taking place or has already been undertaken? <i>Mark any of the engagement methods in the Public, Partners and Staff you are employing</i>	<p style="text-align: center;">Public</p> <p>Interviews Focus groups Public event Carer forum Questionnaires Publications and promotional materials On line forum Local media Other (please state)</p>	<p style="text-align: center;">Partners</p> <p>CCG / CSU Multi agency event Joint working group Multi agency network Regional E&D forum GP practices Local / County Council Other NHS Trust Health Watch Voluntary organisations</p>	<p style="text-align: center;">Staff</p> <p>Staff event / workshop Board meeting <input checked="" type="checkbox"/> Executive Committee Staff side Staff Networks Head of EDI <input checked="" type="checkbox"/> Governance <input checked="" type="checkbox"/> Annual General Meeting Communication methods <input checked="" type="checkbox"/> Learning & Development</p>
What evidence has been analysed? <i>Please highlight or mark what evidence or research you have considered?</i>	<p>Evidence / Research :</p> <p>ONS census 2011 or later Other sources of regional / local demographics Previous strategy https://yourspace.merseycare.nhs.uk/duty-candour Department of Health report / National guides / NICE <input checked="" type="checkbox"/> https://www.cqc.org.uk/sites/default/files/20210421%20The%20duty%20of%20candour%20-%20guidance%20for%20providers.pdf Joint Strategic Needs Assessments (JSNA) Equality Action plans WRES / WDES NHS People Plan https://www.england.nhs.uk/patient-safety/incident-response-framework/faqs/ Local / regional mapping Risk Assessments NHS Constitution (2021) Research Socio-economic and health inequality reports Legislation update</p>		

<p>What is the result of the analysis? Will there be an impact against the protected groups below?</p> <ul style="list-style-type: none"> • Age • Disability • Gender Reassignment • Marriage and Civil Partnership • Pregnancy and Maternity • Race • Religion and Belief • Sex (Gender) • Sexual Orientation • Human Rights articles ✓ 	<p>This policy applies to all staff including permanent and temporary staff employed by the Trust. It also applies to students, bank and locum staff, contracted staff and volunteers. Every healthcare professional in the Trust must be open and honest with patients when something goes wrong with their treatment or care which causes, or has the potential to cause, harm or distress.</p> <p>This policy provides clear guidance to all staff as to their responsibilities to follow the guidance being presented according to the most recent legislation and national guidance. There would be no anticipated adverse or differential impacts towards the protected characteristics or Human Rights Articles. The Restorative Just Learning Culture within the Trust promotes all staff being valued and supported: https://yourspace.mersecare.nhs.uk/restorative-just-culture</p> <p>Human Rights Act (1998) Article 6 Right to a fair Trial – Positive impact The policy upholds the absolute rights for individuals, their families and dependants to understand the processes and decisions undertaken by Mersey Care in its service delivery, decision-making and related functions, in order to adhere to the statutory obligations under the duty of candour.</p> <p>The Equality Act (2010) and Human Rights Act (1998) set out legislative responsibilities for employers to ensure staff within protective groups are provided with the appropriate support to enable them to access, review and follow this policy. Equality Act 2010 https://www.gov.uk/guidance/equality-act-2010-guidance Human Rights Act 1998 https://www.legislation.gov.uk/ukpga/1998/42/contents</p>		
<p>Do further steps in the following areas need to be taken to mitigate or safeguard these impacts - <i>Involvement & Consultation, Data collection & Evidence, Assessment & Analysis, Procurement & Partnerships, Education and Workforce</i>? If so complete the action plan below:</p>			
<p>Outcome</p>	<p>Actions required</p>	<p>Time scale</p>	<p>Responsible officer</p>
<p>Employees understand their rights and responsibilities under this policy</p>	<p>Translation options are made available where English is not the first language of the employee and BSL interpretation is made available to Deaf/ Hearing Impaired employees. Easy Read format or PA support is provided where employees have a learning disability or support around mental capacity.</p>	<p>On-going</p>	<p>Line Manager EDI representatives Human Resources</p>

How will we monitor this and to whom will we report outcomes?	The policy will be monitored by Governance Leads within each Division, Deputy Director of Patient Safety, Head of Integrated Governance and Patient Safety, Service Leads and Duty of Candour Champions. Duty of Candour compliance will be monitored as per the policy and any concerns escalated to the appropriate Governance Lead and Patient Safety Team. Duty of Candour compliance will be reported to the Quality Committee.		
Author Claire Brockbank	Title Head of Governance and Safety, Governance	Date xxxx	
EIA assessed by <i>Joe O'Grady</i>	Title Head of Equality Diversity & Inclusion	Date xxxxx	

The Equality Act (2010) has brought a Public Sector Equality Duty to all Public Authorities. This Equality Analysis provides assurance of the steps that Mersey Care NHS Foundation Trust is taking in meeting its statutory obligation to pay due regard to:

- Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Act.
- Advance equality of opportunity between people who share a protected characteristic and those who do not.
- Foster good relations between people who share a protected characteristic and those who do not.

This equality analysis also provides evidence of discharging Public Sector statutory obligations under the Human Rights Act (1998).

For further information or guidance please contact the Equality & Diversity Team

Appendix 1 Engagement Principles

These principles outlined in the NHS England Guidance (2022) form the basis of Mersey Care's system and processes for engaging and involving those affected by a patient safety incident. The Trust provides a broad range of services and incidents that can occur and the different needs of those affected means these principles should be applied in a flexible way when engaging with someone involved or affected by a patient safety incident. These principles are aligned with the obligations of Duty of Candour that the Trust will uphold.

1. Apologies are meaningful - Apologies need to demonstrate understanding of the potential impact of the incident on those involved, and a commitment to address their questions and concerns. Ideally, an apology communicates a sense of accountability for the harm experienced, but not responsibility for it ahead of investigation. Getting an apology right is important – it sets the tone for everything that follows. Apologising is also a crucial part of the Duty of Candour.

2. Approach is individualised - Engagement and involvement should be flexible and adapt to individual and changing needs. These needs could be practical, physical, or emotional. Engagement leads should recognise that every response might need to be different, based on an understanding of the different needs and circumstances of those affected by an incident.

3. Timing is sensitive - Some people can feel they are being engaged and involved too slowly or too quickly, or at insensitive times. Engagement leads need to talk to those affected about the timing and structure of engagement and involvement, and any key dates to avoid (eg birthdays, funeral dates, anniversaries), particularly where someone has lost a loved one.

4. Those affected are treated with respect and compassion - Everyone involved in a learning response should be treated respectfully. There should be a duty of care to everyone involved in the patient safety incident and subsequent response, and opportunities provided for open communication and support through the process. Overlooking the relational elements of a learning response can lead to a breakdown of trust between those involved (including patients, families, and healthcare staff) and the organisation.

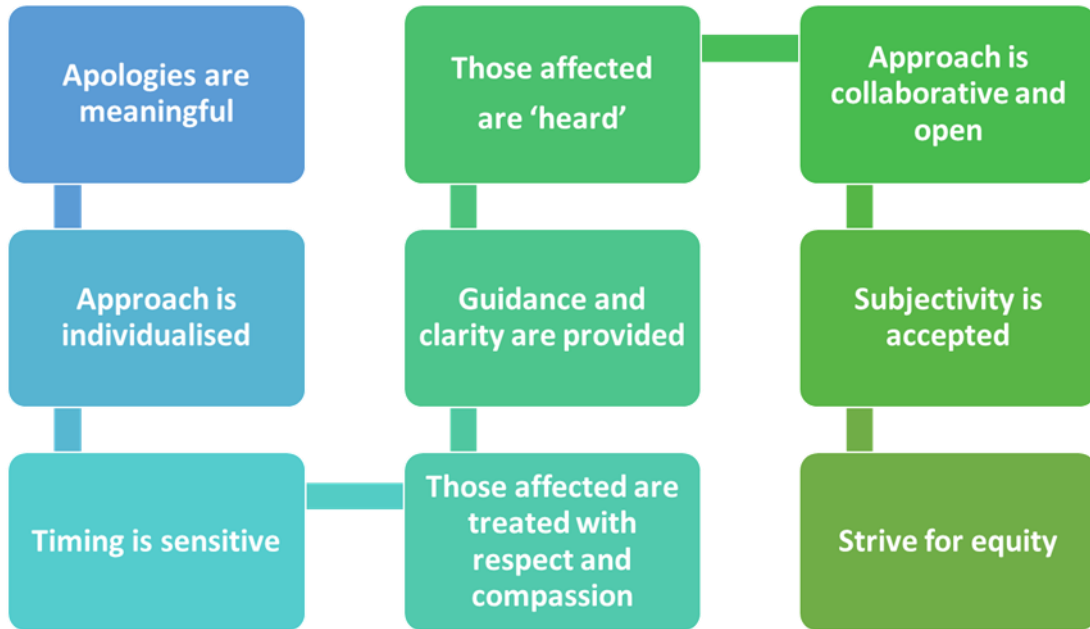
5. Guidance and clarity are provided - Patients, families, and healthcare staff can find the processes that follow a patient safety incident confusing. Those outside the health service, and even some within it, may not know what a patient safety incident is, why the incident they were involved in is being investigated or what the learning response entails. Patients, families, and healthcare staff can feel powerless and ill-equipped for the processes following a patient safety incident. Therefore, all communications and materials need to clearly describe the process and its purpose, and not assume any prior understanding.

6. Those affected are 'heard' - Everyone affected by a patient safety incident should have the opportunity to be listened to and share their experience. They will all have their individual perspective on what happened and each one is valid in building a comprehensive picture to support learning. Importantly, the opportunity to be listened to is also part of restoring trust and repairing relationships between organisations and staff, patients, and families.

7. Approach is collaborative and open - An investigation process that is collaborative and open with information, and provides answers, can reduce the chance litigation will be used as a route for being heard. The decision to litigate is a difficult one. Organisations must not assume that litigation is always about establishing blame – some feel it is the only way to get answers to their questions.

8. Subjectivity is accepted - Everyone will experience the same incident in different ways. No one truth should be prioritised over others. Engagement leads should ensure that patients, families, and healthcare staff are all viewed as credible sources of information in response to a patient safety incident.

9. Strive for equity - Organisations may differ from patients, families, and healthcare staff in what they consider is the appropriate response to a patient safety incident. The opportunity for learning should be weighed against the needs of those affected by the incident. Engagement leads need to understand and seek information on the impact of how they choose response types on those affected by incidents and be aware of the risk of introducing inequity into the process of safety responses.



Appendix 2 Statutory Duty of Candour summary

The current Regulation in full can be accessed at the following link

[Regulation 20: Duty of candour - Care Quality Commission \(cqc.org.uk\)](https://www.cqc.org.uk/about-us/regulation-20-duty-of-candour)

Until 2014, there was no legal duty on trusts such as Mersey Care to share information with people who had been harmed, or their families. Following individual cases such as that of Robbie Brown and the inquiry findings of Sir Robert Francis into the Mid Staffordshire Trust in 2013 amongst others, a statutory Duty of Candour was introduced on 27 November 2014. This supplemented an existing professional duty of candour and a need for candour in the NHS standard contract. In Mersey Care, Duty of Candour underpins our restorative just and learning culture and is an integral part of operating within a safe, open and transparent culture. Duty of Candour must be applied to notifiable safety incidents.

Notifiable safety incidents

This is a specific term within the regulation and should not be confused with other types of safety incidents or notifications. A notifiable safety incident must meet all 3 of the following criteria:

1. It must have been unintended or unexpected.
2. It must have occurred during the provision of an activity the CQC regulate.
3. In the reasonable opinion of a healthcare professional, could result in or appears to have:
 - Resulted in the death of the person – directly due to the incident, rather than the natural course of the person's illness or underlying condition
 - Led to the person experiencing severe harm, moderate harm or prolonged psychological harm

If any of these criteria are not met, then there is no 'notifiable safety incident' but we must still be open and transparent in our engagement with the person affected.

Further clarification is given around terms used within the regulation. 'Unexpected or unintended' should be interpreted in relation to an incident that arises in the course of Mersey Care activity not to the outcome of the incident. 'Outcome' means harm that occurred or could have occurred. If treatment and care provided went as intended, and as expected, an incident may not be a notifiable safety incident, even if harm occurred.

This does not mean that known complications or side effects are always disqualified from being notifiable patient safety incidents. In every case, the healthcare professionals involved must use their judgement to assess whether anything occurred during the provision of the care or treatment that was unexpected or intended.

The presence or absence of fault on the part of Mersey Care or its employees has no impact on whether or not something is defined as a notifiable safety incident. NHS Resolution have been clear that saying sorry is not an admission of fault and we should be open and transparent with those using our services. Saying sorry is:

- Always the right thing to do
- Not an admission of liability
- Acknowledges that something could have gone better
- The first step to learning from what happened and preventing it from recurring.

Even if a patient/service user has given consent for a procedure to be carried out there may still be a notifiable safety incident. This depends on the level of harm and whether something unexpected or unintended happened during care and treatment regardless of consent given.

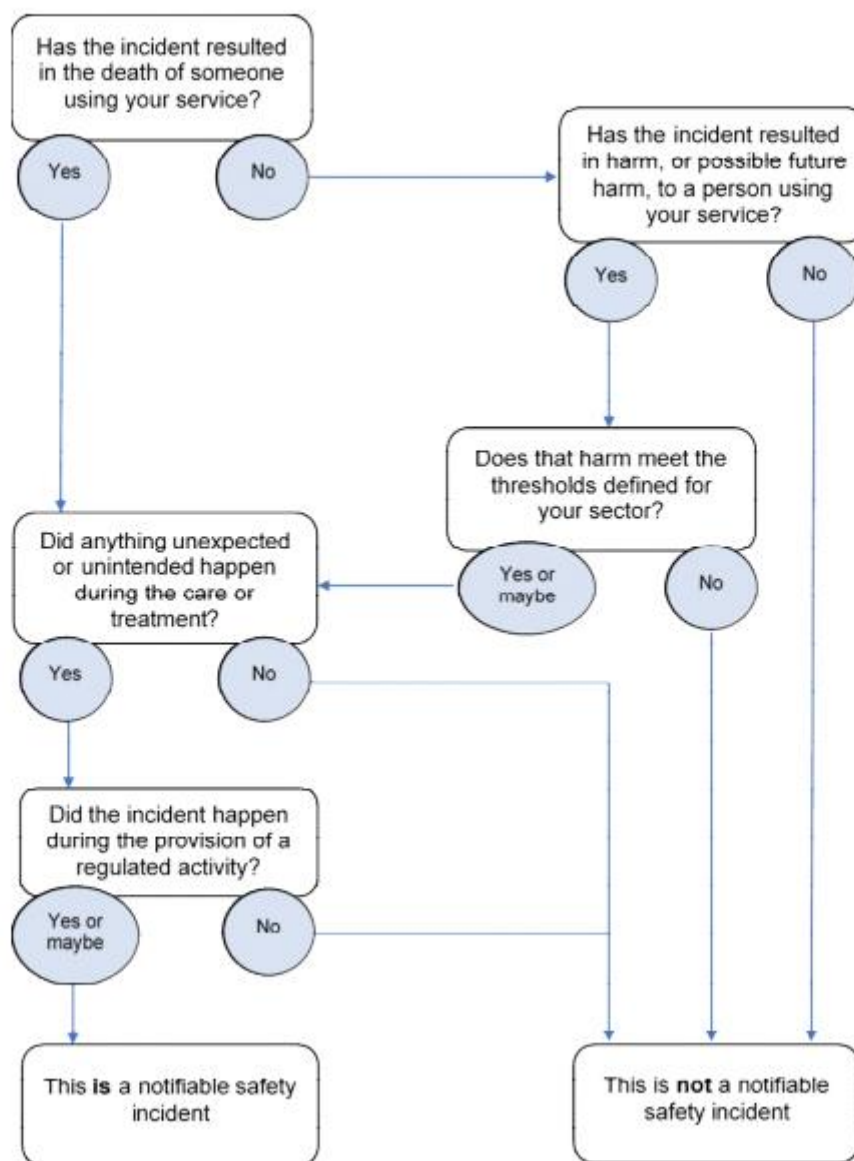
Levels of harm

These are defined in detail in Appendix 3. The regulation describes prolonged pain and prolonged psychological harm as a part of the criteria for deciding upon level of harm overall. In the regulation where such harm has been experienced, it is considered to be prolonged where it has or is likely to be experienced for a continuous period of at least 28 days.

The application of duty of candour is included within the process described in this policy (Section 6 above) and in the guidance on engagement included in Appendix 4.

The Care Quality Commission decision making tool has been included below and a diagrammatic representation of the Mersey Care process for this is set out in Appendix 7.

Regulation 20: duty of candour



Appendix 3 - Definitions of Harm

NHS England issued new guidance on harm levels in 2023. Below is a listing of harm levels along with some other useful definitions to support decision-making in patient safety incidents and to guide engagement and allow fulfillment of Duty of Candour.

The degree of harm recorded should relate to the actual impact on the patient/service user and should be applied based on the best information about that impact at the time of recording. Harm recording can be reviewed and updated as more information becomes available.

Patient Safety Incident	Something unexpected or unintended has happened, or failed to happen, that could have or did lead to patient harm. This includes acts or omissions and 'near misses'.
Notifiable patient safety incident	Any patient safety incident which meets all 3 of the following circumstances: <ul style="list-style-type: none"> • unintended or unexpected incident • occurred in during the provision of a CQC regulated activity (care and treatment) • in the reasonable opinion of a healthcare professional, already has, or might result in <ul style="list-style-type: none"> - the death of the person – directly due to the incident rather than the natural course of the person's illness or underlying condition -the person experiencing severe harm, or prolonged psychological harm
No Harm	Any patient safety incident which has resulted in: <ul style="list-style-type: none"> • No physical harm • Where we are not aware of any psychological harm that meets the description of low psychological harm or worse (Pain should be considered under physical harm)
Low Harm	
Low physical harm	Any patient safety incident when all of the following apply: <ul style="list-style-type: none"> • minimal harm occurred – patient(s) require extra observation or minor treatment • did not or is unlikely to need further healthcare beyond a single GP, community healthcare professional, emergency department or clinic visit • did not or is unlikely to need further treatment beyond dressing changes or short courses of oral medication • did not or is unlikely to affect the patient's independence • did not or is unlikely to affect the success of treatment for existing health conditions
Low psychological harm	Any patient safety incident when at least one of the following apply: <ul style="list-style-type: none"> • distress that did not or is unlikely to need extra treatment beyond a single GP, community healthcare professional, emergency department or clinic visit • distress that did not or is unlikely to affect the patient's normal activities for more than a few days • distress that did not or is unlikely to result in a new mental health diagnosis or a significant deterioration in an existing mental health condition

Moderate harm	
Moderate physical harm	Any patient safety incident when at least one of the following apply: <ul style="list-style-type: none"> • had needed or is likely to need healthcare beyond a single GP, community healthcare professional, emergency department or clinic visit, and beyond dressing changes or short courses of medication, but less than 2 weeks additional inpatient care and/or less than 6 months of further treatment and did not need immediate life-saving intervention. • Has limited or is likely to limit the patient's independence, but for less than 6 months • Has affected or is likely to affect the success of treatment, but without meeting the criteria for reduced life expectancy or accelerated disability described under severe harm
Moderate psychological harm	Any patient safety incident when at least one of the these apply: <ul style="list-style-type: none"> • distress that did or is likely to need a course of treatment that extends for less than 6 months • distress that did or is likely to affect the patient's normal activities for more than a few days but is unlikely to affect the patient's ability to live independently for more than 6 months • distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, but where recovery is expected within 6 months
Severe harm	
Severe physical harm	Any patient safety incident when at least one of the following apply: <ul style="list-style-type: none"> • permanent harm/permanent alteration of the physiology • needed immediate life-saving clinical intervention • is likely to have reduced the patient's life expectancy • needed or is likely to need additional inpatient care of more than 2 weeks and/or more than 6 months of further treatment • has, or is likely to have, exacerbated or hastened permanent or long term (greater than 6 months) disability, of their existing health conditions • has limited or is likely to limit the patient's independence for 6 months or more
Severe psychological harm	Any patient safety incident when at least one of the following apply: <ul style="list-style-type: none"> • distress that did or is likely to need a course of treatment that continues for more than 6 months • distress that did or is likely to affect the patient's normal activities or ability to live independently for more than 6 months • distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, and recovery is not expected within 6 months

APPENDIX 4. ENGAGEMENT AND INVOLVEMENT PROCESS WITHIN MERSEY CARE INCORPORATING THE EXPECTED ROLE OF THE FAMILY SUPPORT LEAD (FSL)

This guidance is intended to further detail a way in which engagement and involvement can be managed effectively and those affected by a patient safety incident are treated with compassion and understanding. This will support the engagement and Duty of Candour process as outlined in the main policy (Section 6).

Family Support Lead (FSL)

The role of Family Support Lead (FSL) has developed significantly since the introduction of a Statutory Duty of Candour which was brought into legislation in response to recommendations from the 2013 Francis, Keogh and Berwick Reports. These reports all highlighted the importance of transparency and openness that underpin the previous Being Open principles (2009) and the new engagement principles for NHS providers (see Appendix 1). The role of the FSL has been further developed to provide clarity as to how this role addresses this change in legislation.

The role of FSL may also be utilised in any situation where, as part of a service user receiving care, there is a need for a support and a point of contact. For example, this may be appropriate as a single point of contact after a death by natural causes with family and carers to provide on-going contact and support. Most usually within Mersey Care, a FSL will be appointed where a patient safety incident has occurred which requires review by a Patient Safety Learning Response Review (PSLR, known nationally as a Patient Safety Incident Investigation or PSII).

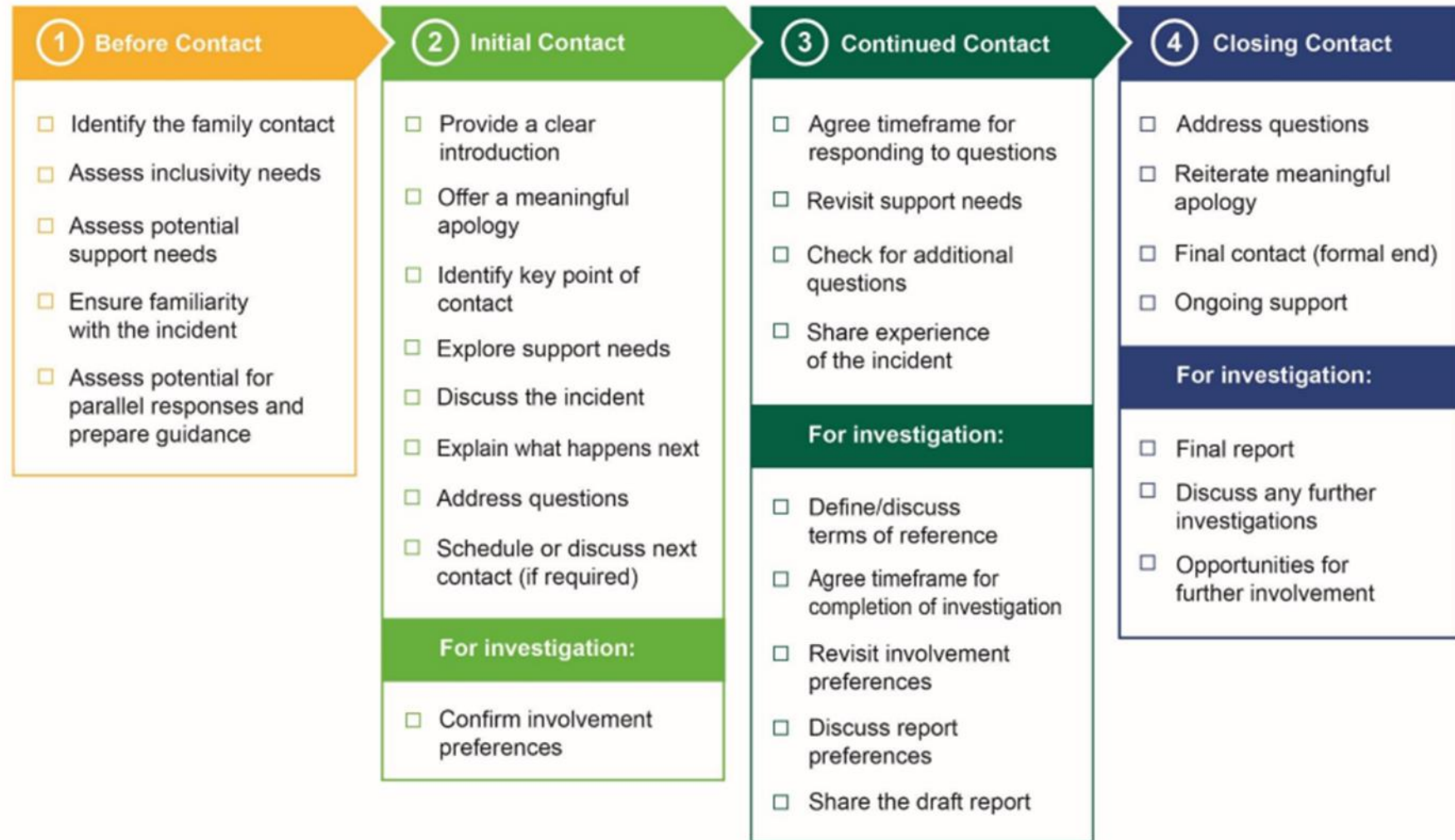
Some NHS organisations use the term Family Liaison Officer (FLO), however, this has caused some confusion to families and carers. Expectations and comparison to the formal police FLO role have been identified, therefore within Mersey Care, the role is known as the Family Support Lead (FSL). We use the term 'families' in the broadest sense; it covers people closest to the person who has suffered harm or sadly died, including 'significant others' i.e., friends, partners, carers, and important others.

The NHS England guidance on engagement with those affected by a patient safety incident refers to Engagement Leads. Within Mersey Care any appropriate member of staff may lead on engaging and involving those affected by a patient safety incident for purposes of completion initial or further disclosure for fulfillment of a Duty of Candour requirement. Where engagement and involvement is needed for a PSLR this will be carried out by a FSL who will have had additional training to undertake this role.

The remainder of this Appendix will be based on the NHS England guidance that has been accepted within the attached policy as current best practice. Most importantly, engagement and the level of involvement must be in keeping with the wishes of those affected as far as possible and any approach must be adapted to the circumstances of the particular incident and the individuals affected. Consideration should be given to how the steps for engagement as outlined on the next page are followed such as being aware of timings, such as avoiding the anniversary of a death and the complexity of what is being asked of those being engaged and involved.

All engagement with patients, families and carers will follow the four steps as outlined by NHS England, details are given below of how this should operate within Mersey Care. For additional clarity, this guidance has been separated into general details for all who may be involved in engagement, with that relevant specifically to FSL's within the blue boxes.

Four Steps of Engagement



1. BEFORE CONTACT

Identify the family contact

Identify who is the main family point of contact before beginning any engagement – in most cases this will be the patient themselves. If the patient is unable to participate or has died, then there may be indication within the healthcare records of who they would like to represent them, but this should be done with regard to confidentiality and any instructions about this that the patient has made during their life. Note also that it is possible that this contact might change if family or carer circumstances change.

Assess inclusivity needs

Although initial contact needs to be prompt, care and consideration should be given in its planning. The staff member making contact should ask themselves the following:

- What is known about the people affected by and the circumstances of the incident?
- Do those affected or their agreed representative have any specific communication needs?
- What, if any, engagement has happened so far and have any specific needs been identified?

The nine protected characteristics of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation need to be considered and appropriate adjustments made if required, for example use of language services. Wider health inequality variables such as pre-existing mental health conditions that can affect care that people receive should also be considered.

Assess potential support needs

Some patient safety incidents may leave people suddenly bereaved or with complex trauma, Those affected may not be ready to participate in engagement activities for a variety of reasons which may be emotional, psychological or physical. Here those who are to make initial contact should plan carefully so that support needs can be identified and met at the earliest opportunity.

For colleagues who may have been involved in previous patient safety incidents, or supported /witnessed others involvement in the past, there may be heightened anxiety. Colleagues may therefore need additional support and input to allow for their meaningful involvement.

Ensure familiarity with the incident

As well as having a grasp of the facts of the incident, it is critical to know who you are talking about (their name) and who you are talking to – this may be the patient, next of kin or another staff member.

Assess potential for parallel responses and prepare guidance

The incident may prompt a parallel response such as a HM Coroner inquest or police investigation, which may affect the timeframe of the Trust response. If you know of this you should prepare to inform those affected of this and have information to hand to share if needed.

2. INITIAL CONTACT

First impressions count and initial conversations with anyone affected by a patient safety incident set the tone for future interactions: establishing trust and respect at the outset is key.

You should give careful consideration to the timing of any initial contact – for example this may not be appropriate if someone is still receiving medical treatment or, for a staff member if they are at the end of their shift. You will also need to consider and recognise at the initial contact if the person affected is not ready to engage – because they are distressed, grieving or for any other compounding reasons.

Wherever possible initial contact should be in person and colleagues should not find out about involvement in a patient safety incident by email or third party.

Provide a clear introduction

Introduce yourself clearly by providing

- your full name (repeat if needed)
- your role title and work location within the Trust
- what your role with them entails and how engagement following a patient safety incident usually proceeds (the 4 steps diagram can be useful to refer to if needed)

Offer a meaningful apology

Patients, families and carers should be offered an meaningful apology – one that sincerely expresses sorrow or regret for the harm that resulted from the incident. Face-to-face verbal apologies are always preferable and as soon after the incident has occurred as possible. A written apology should also be given clearly stating that the Trust is sorry for any resulting suffering or distress. Template letters are attached to this policy but they must always be personalized to the individual and the circumstances concerned.

Do not delay giving a meaningful apology for any reason as this is likely to increase the patient or family's anxiety, anger and frustration.

Remember that apologising is the right thing to do; it is not an admission of liability and our patients have a right to expect openness in their health care. NHS Resolution who support the legal work within the NHS have helpful guidance on saying sorry [Read saying sorry \(duty of candour\) - NHS Resolution](#)

Registered practitioners must uphold both professional and statutory duty of candour. Your professional body will also have guidance on this to support you.

Identify key point of contact

You should make sure that those affected know who their point of contact is within the Trust. Remember, the initial point of contact may not be the same colleague who maintains subsequent contact.

Explore support needs

Everyone has their own response to incidents, some individuals will be more aware of their support needs than others. Remember not everyone will need support but also that needs may change over time. You will need to assess if someone needs support and to respond appropriately. Needs may stem from the being involved in the response to the patient safety incident and/or be pre-existing.

You should consider the following:

- Does this person need support? Individuals may not be aware they need support, even if the incident was particularly traumatic. You may wish to tell someone about the support options available, and then given them time and space to decide if they need such support.
- If so, what type of support? Support needs can manifest in many ways – they can be emotional, practical or psychological. You should sensitively try and prompt people to think about the different types of support they may need.
- What support resources can you share? We have a broad range of services within Mersey Care and based on conversations with those affected you should offer resources or discuss what other organisations can offer but leave the individuals to decide which would be most appropriate for them.
- Sources of independent advice should be shared at the earliest opportunity.

Discuss the incident

Explain the patient safety incident clearly and in language appropriate to the person. Base your description only on what is known at the time and do not make any predictions to the cause of an incident or what an outcome might be.

Explain what happens next

Describe any immediate actions that have already been taken in response to the incident and discuss how the Trust intends to respond according to our Trust PSIRF plan and policy. This should include:

- What form the response will take
- What improvement work is underway
- Whether further review is needed to explore possible learning

You may need to reiterate that the trust operates a restorative just and learning culture and that review under PSIRF are to explore systemic learning for improvement. For PSLRs a Family Support Lead (FSL) will make contact with the family for ongoing support and engagement.

Address questions

You should make time to answer any questions or concerns and address the identified needs of those affected, ensuring everyone has equal opportunity to engage with the process. If you cannot answer certain questions, be honest about this and say you will come back to them with an answer once you've gathered more information, or direct people to a source of information that could give them an answer. This may be necessary where the question being asked lies outside the scope of the learning response.

Schedule or discuss next contact (if required)

At the end of the initial contact, you need to agree when the next contact will be, how contact will be made and who will make it. For non-complex incidents the next contact may be when a review has been completed if this will be of short duration. Any contact that is promised, however, must be delivered. Effective ongoing communication will involve agreeing the frequency of future contact and the preferred method of contact. For a PSLR, this may mean that future contact will be managed by a FSL. Patients, family members and healthcare staff may not welcome and even be daunted by unstructured contact (that is, without prior discussion of how and when). People will have different communication requirements. A family or staff member in distress may need more regular contact and more detailed guidance to aid understanding and retention of information. You should also agree on what the best form of communication is. Individuals should also be asked if there are any specific dates and which they should not be contacted as there may be significant dates on which they will not want to talk about what happened. Additionally consider your own needs and whether you have planned leave or other work commitments that might disrupt regular communication.

FSL/PSLR specific

Ensure contact is planned

Preparing for the Initial Meeting

- FSL should be allocated within the Division as the most suitable member of staff to support a particular individual or family.
- The majority of meetings may take place at the family's home address although ensure a flexible approach to venues, taking into consideration the option of virtual meetings if requested by the family. Consider the family's commitments such as work and childcare; the FSL should be flexible.
- Due consideration should be given to any potential situational, relational, and environmental risks that may be encountered during the visit.
- This initial visit should preferably be completed with an identified member of the Review team, usually the Lead reviewer.

(continued)

For initial contact ensure that:

- The FSL and Reviewer familiarise themselves with the incident and care provided prior to the harm occurring.
- The FSL and Reviewer have had sight of the completed rapid review report to support this information.
- Although it is not the responsibility of the FSL to write a letter to the individual regarding Duty of Candour it is important that the FSL makes themselves aware that this letter has been sent (if not escalate to divisional SLT).
- Know the name of the person affected and who you are planning to meet. Try to ascertain if the Service User/family will have someone with them to provide support.
- Know the address and allow enough travel time.
- FSL should ensure sufficient time is assigned for this meeting, it is recommended that at least two hours is protected for this.
- The FSL should be familiar with local support services and take this information with them to the meeting including the Trust engagement booklet.

The FSL should be prepared to undertake the following:

- Share the patient/family booklet if this is wanted, ask about how information on the review process is to be shared.
- Explain the review process including any likely delays. Timeframes should be discussed and, where possible, mutually agreed.
- Explain anything that has already been done and why it was necessary to begin before involving those affected.
- Ask (check) if there are any questions about the process

Confirm involvement preferences

- An individual should be helped to make an informed decision about whether to be involved in an investigation by being given appropriate information about how the investigation will run, and how they could be involved and supported throughout the process.
- Be mindful that the family member with whom you make initial contact may not be the only family member who has useful information about the incident. You may need to engage with several family members, but where possible try and arrange for contact to be through one individual, to minimise the number of contacts. Of course, some families will want to nominate one member as the person the learning response team speaks to on behalf of the whole family; this should be discussed and documented in each case.
- In early discussions, personalise your approach by finding out how family members like to be referred to; this can include preferred names and their correct pronunciation.

3. CONTINUED CONTACT

Maintaining contact is particularly important when it has not been possible to address all initial concerns or questions from those affected and when an investigation is underway. Although you may not always have something to update people about, you must reliably maintain contact where doing so has been agreed. If communication cannot be maintained as agreed for any reason, you should let people know as soon as possible and arrange another mutually convenient time to contact them. It is also important to be transparent about how much progress has been made since the last communication. By maintaining contact and being open, you will continue to build trust with the family and healthcare staff affected.

The timings of updates will be based on the specific circumstances of each incident and what has been agreed with the family and staff involved. The degree of physical and emotional distress they are under must always be considered, so that the timing and content of communications and activities can be managed accordingly.

Agree timeframe for responding to questions

If further information gathering is required to address questions and concerns raised, you should agree with those affected when you will respond. The time needed will depend on the nature of the incident and the questions asked.

Revisit support needs

Support needs can change over time. You should raise and discuss potential support needs throughout continued contact. Refer to the considerations in the 'Explore support needs' section above. Adapt signposting advice as necessary.

Check for additional questions

Families and staff may lack the confidence to ask questions, particularly during the initial contact phase. You should check if they have any additional questions through continued contact. If questions lie outside the scope of understanding what happened and learning and improvement (eg. are to do with culpability), you should support families to find people or organisations that could provide answers.

Share experience of the incident

Everyone will have their own lived experience of the care leading up to a patient safety incident and what caused the incident. It is always important, with agreement, to understand the experience of those affected. For investigations, it is important to consider all subjective experiences. In some circumstances understanding these experiences of the incident may be important for addressing questions or concerns raised and/or contributing to another type of learning response. Establish what media or method the person sharing their experience finds most comfortable. Where available resources allow and the method complies with trust policy, it should be facilitated. For example, could you have this conversation on a video call or face-to-face to make it easier to respond to people as they share their experience? Could you visit them at home? (Home visits should not be carried out alone) Could you offer people the opportunity to have someone with them while you have this conversation? They might welcome the opportunity for support. Consider the environment in which families and staff share their experience. The conversation should take place in a quiet, relaxed setting and for staff, if possible, away from their usual place of work and not where the patient safety incident occurred. Further information on sharing experience of a patient safety incident for both staff and families can be found in the Interview guide [NHS England » Guidance on planning and conducting interviews as part of a patient safety incident learning response](#). Sharing experiences can be difficult, emotional, and daunting. If people feel comfortable, they are more likely to share everything they remember about the incident and the events that surrounded it. You need to help them feel more comfortable by being transparent about how information will be recorded and used. You should give people the time and space to share their experience with you in full. If you only have a set amount of time, be honest about this and offer to arrange a second conversation. Thank people for sharing their experience and recognise both how difficult this may have been to do and how invaluable a contribution they have made. Shortly after (eg. 24 to 48 hours), check with the patient, family member or staff member who has provided an account of their experiences if they need any extra support. You could offer the support resources identified in response to the initial contact if these have not already been taken up.

FSL/PSLR specific

- People will want different levels of involvement in a PSLR. Although their preferences might change as the review progresses, discussions at the initial contact will set clear expectations about how and when those affected would like to be involved.
- As the review progresses, you will need to enact the ways of working that enable involvement in the review process by those who want to be, and remain flexible in your continued contact in case people change their mind about being involved.
- Continued contact means being open and clear about how the review is progressing. You need to recognise that it can be difficult for people to engage meaningfully with a system or process that they are unfamiliar with. Your continued contact with people provides them with both the opportunity and support to access those parts of the review process they want to be involved in, as well as updating them on the review's progress.
- For people who want to be involved in the review, your continued contact with them will be very similar to your initial conversations: you will provide information, discuss experiences, answer their questions, and pay attention to support needs. For people who do not want to be as involved, or involved at all, in your continued contact you may only need to give simple updates or basic information.

Define/discuss terms of reference

- The Division will draft the terms of reference (ToRs) or key lines of enquiry (KLOEs) for the review process, supported by the Trust Patient Safety panel. You should share (checking first how it should be received) and discuss this with those involved and adjust where appropriate. You need to explain the importance of the ToR to those affected – that is, they guide what the review will look at, and the questions that need to be answered during the review.
- When sharing the draft ToR, you should:
 - Explain how the draft ToR were developed.
 - Ask people if they have any questions not covered by the ToR. If they do, be open about whether you think you will be able to answer them within the terms of the review or not
 - Adjust TORs where appropriate
- If the scope of the review will not provide answers to their questions, support people to access different sources of information and types of review.

Agree timeframe for completion of review

- Timeframes for completion of a review are flexible and will depend on the nature of the incident and family and staff involvement.
- Provided the family and staff affected are willing and able to be involved in the decision about the timeframe, this should be set in consultation with them as part of agreeing the ToR for the PSLR. A response must start as soon as possible after an incident is identified, and usually completed within one to three months.
- In exceptional circumstances a longer timeframe may be needed. Where a timeframe needs to be extended, this should also be explained to those affected.

(Continued)

- The time needed to conduct a thorough review must be balanced against the impact of long timescales on those affected by the patient safety incident, and the risk that action may not be taken to improve safety. Where external bodies cannot provide information within four months, a local PSLR should be finalised using the information available; it may be revisited later, should new information indicate the need for further review activity.

Revisit involvement preferences

- People may change their wishes on level of involvement as the review progresses. You should check that people are still happy with the preferences they expressed in the initial contact.
- For people who initially did not want to be involved in the review, use your discretion when deciding how to revisit their preferences. If you think they may have been unsure initially, you could send a brief email or a short letter to check that this is still their view.
- For people who are involved in the review, you can revisit this during one of your regular communications. Depending on the progress of the review, you should discuss individual preferences for involvement in:
 - TORs
 - information gathering
 - draft report
 - final report
- Make it clear what the deadline is likely to be for contributions to each of these key parts of the review. (The Lead reviewer should be able to share their review planner with you). This sets clear expectations and equal opportunity for everyone involved.

Discuss report preferences

As PSLR's remain within the Trust, the reports can include the name of the patient. Personalisation preferences should be discussed with the family and adopted in the draft before it is shared. It is important to remember that family members may have different preferences; these should be resolved on a case by case basis.

Share the draft report

- The PSLR report must be shared in draft form before it is finalised, and those affected given a realistic opportunity to influence the content before it is finalised.
- You will have a good idea of what the report will contain and of the safety actions that are to be suggested by the Lead reviewer. Involving those affected at this stage may feel daunting but they should have the chance to check for inaccuracies and to ask questions about the draft.
- Ask if and how families and staff would like to receive the draft report and in what format. Be clear if you are unable to send the report in certain ways before it is finalised.
- Be clear about what people can comment on: the boundaries, as well as what you might and might not be able to change, are best conveyed in a verbal discussion. This will set clear expectations. You could highlight those areas they should look particularly close at or include some prompts to focus their comments – the Lead reviewer can work with you on this.
- Could you have a conversation with those affected before sending them the draft report, and then arrange a time to discuss it? People will need time to read the draft report, and possibly support to access or discuss it.
- Explain how you will use their comments. If you cannot change something, be honest and explain why not. People might not be aware of the organisational processes involved at this stage.

(Continued)

- Be clear about how you will develop the final report from this draft, and any changes that will be made.
- Be aware that it is possible that a draft report will end up in the public domain. See further information on media involvement below.

4. CLOSING CONTACT

The end of engagement is a point of closure for everyone involved. This can be an emotional process for people, regardless of their level of engagement and involvement during the review process.

By this stage you should be more aware of individuals' needs and preferences, which should enable you to close contact with them respectfully, sensitively, and empathetically. **This is important to minimise the likelihood of compounding any harm caused by the incident.**

At this point you may move on to another review or return to your own full-time clinical or operational work. For patients, families and healthcare staff, the end of any engagement or review may be the start of a new normal. Some may have no choice but to learn to live with the impact of the incident on them, whether that is physically, emotionally, or psychologically. Patients and families may have to navigate additional healthcare services, or process life-changing injuries or bereavement. Healthcare staff may have to process feelings of guilt or moral injury and may question their professional ability. They may be nervous about what people think of them, or about another incident happening while they are on shift.

The engagement or review may have provided structure for people during a difficult time. It is important that closing contact is as positive an experience as it can be, and the potential impact of the end of the contact on everyone involved is recognised. A complaint or claim may still be ongoing. Closing contact should be well timed and considerate and, as with all contact, known significant dates for the family and staff affected should be avoided; not doing so could mean the message is not received as intended.

Address questions

At this stage you should have the information to answer all questions or concerns raised by those affected and that are within scope, and you should share this information with them in an accessible manner – eg. a letter or through a discussion. For questions that are not within scope, you should support families to find people or organisations who could provide answers or explain why that may not be possible.

Reiterate meaningful apology

Reiterate the meaningful apology you gave at the beginning of the engagement process – a sincere expression of sorrow or regret for the effect the patient safety incident had on them, and that the trust is committed to learning and improving (even if a learning response method was not used in response to this incident). Now armed with a greater understanding of the impact of the patient safety incident, you may want to expand your original apology. If a PSLR has been undertaken, you may want to outline how the trust might respond to its findings, if you know.

Final contact (formal end)

Formally close the engagement/involvement process so that all parties are aware it has been closed. People will have had different levels of engagement and how you formally close may be dependent on this.

For people with whom you have had regular contact, you can close communication at the last regular contact. You should thank them for their contributions. Where you have had minimal contact with those affected, make them aware that the investigation has officially finished, perhaps by sending an email or letter.

Ongoing support

At the conclusion of engagement or a review, review the support you have signposted individuals to and consider they may need any extra support. You should be flexible in meeting people's different needs.

FSL/PSLR specific Closing contact

Final Report

Receipt of the final report will mark the end of the investigation process for everyone involved.

- Ask those affected if they want to see the final report, and if they do, what the easiest format is for them to receive it in. Make it clear when they can expect to receive a copy of the final report so that it does not arrive as a surprise.
- Ask people if they would like to discuss the final report. You should be prepared to discuss the report's content and answer any questions from people affected. Consider offering to discuss the report on a video call or face-to face so that you can give immediate answers to their questions/comments, and whether they would like someone with them.
- Explain how the trust will use the report. Tell people about how the trust will respond to the investigation report.

Discuss any further investigations

- Although the final report will mark the end of the trust-level review process, other review processes may be ongoing or follow the trust's review (such as HM Coroner inquest). Although you may not be involved in these, you should inform people affected about any processes you know about that will occur from this point.
- Using your previous experience and any information you have, tell people what you know about these other review processes, and if you can direct them to others who will be able to give them more detail. The Trust Legal team can support you with information regarding the coronial process.
- When the final report has been published or shared with the patient and family, acknowledge with the family the end of your 'relationship'.

Opportunities for further involvement

- Patients, family, and staff members can give valuable insight into how a trust could improve processes to reduce the likelihood of incidents happening again. If you think someone with whom you have engaged could support the trust with specific ideas for change or improvement, and may be interested in doing so, you could offer them an opportunity for further involvement. You could discuss this with the Patient Safety or Patient Participation and Engagement teams.
- Those who agree to support the trust should still have a plan for their continued access to their own support. You should make sure any trust colleagues they work with have a clear plan for their involvement, including how and when it will end. It is known that a lack of formal closure can leave people feeling used or compound the harm they experienced because of the incident.

Additional considerations

Assessing risks throughout engagement

Engagement leads including FSLs must ensure the personal safety of the patients, families, and staff with whom they engage.

Risk assessment will be familiar to colleagues throughout the trust as a dynamic process and this is equally true throughout the engagement and review process. Risk should be considered in relation to:

- people (eg. adverse behaviour of the people present)
- activity (eg. risks associated with an action)
- location/environment (eg. allergies, safeguarding concerns).

Details of any known or perceived risk should be recorded before contacting those affected and then be regularly reviewed. Any control measures that can be put in place (eg. working in pairs if visiting someone at their home or another location external to the healthcare setting) and any action taken should be recorded.

Keeping good records

Every communication should be documented, even when attempts to make contact are unsuccessful, and what was discussed recorded. This ensures an accurate audit trail, demonstrates the efforts made and allows a thorough handover if ever required. Where [possible] details should be recorded on the Radar incident. This can then be referred to whenever it is needed to confirm the conversations that have taken place, which can be helpful to people who may be finding it hard to retain information due to their individual circumstances.

Records should contain:

- date and time of all contacts, including any meetings
- method of contact (eg. telephone, email)
- who was present during the contact
- purpose of contact and any information exchanged
- details of who initiated the contact
- details of non-family members or support present at any meeting
- all unsuccessful attempts to contact those affected or their representatives
- all contacts with those affected that were refused or declined, and any reasons given.

Addressing communication barriers

Those engaging with those affected by a patient safety incident should identify any barriers to effective communication as soon as possible and make any reasonable adjustments required. They also need to recognise that they may need to make subtle changes to their communication or approach to respect an individual's culture and lifestyle.

Using language services

Those engaging with those affected by a patient safety incident should be aware of the trust's process for booking language services (MCT01 Accessible information standard) .

Use of 'unofficial translators' - whether family members or friends, or technology such as Google translate, should be avoided as they may distort information by editing what is communicated.

When requesting an interpreter, as much notice as possible should be given and ensure the exact dialect required is understood. The proposed interpreter should be spoken with before a family contact – to provide some background on the patient safety incident as well as to assess the interpreter's suitability.

This ensures the interpreter is aware of the nature of what they will be interpreting and will be emotionally preparedness for the conversations that may follow.

It should never be assumed that a person's ability to speak a language means they can read that language – the preferred language for written documentation should be confirmed.

Where lengthy text needs to be translated, or the language is not a common one, extra time may be needed for this. Proof reading should always be requested as it is uncertain that you will be able to read and ensure the accuracy of translated material.

If communication breaks down

Sometimes, despite the best efforts, relationships break down. Families and staff affected may not accept or agree with the information they are given or may not wish to participate in any further engagement or review process. When this happens what the engagement lead or FSL should do will depend on the stage the process has reached when those affected change their minds about being engaged or involved in the review. The following strategies may help:

- Offer the family or staff member another contact person with whom they may feel more comfortable. This could be another member of the team or the person with overall responsibility for clinical risk management.
- Use a mutually acceptable mediator to help identify the issues between the healthcare organisation and the patient, and a mutually agreeable solution.
- Ensure family and staff members are fully aware of the formal complaint procedures.
- Write a comprehensive list of the points of disagreement and follow-up the issues.

Media involvement

Some cases may attract local or national media attention due to the individual circumstances or place where the incident occurred. Some families may approach the media as they wish to share their story or to campaign. The trust communications team should be notified of any cases the media is covering or interested in. Families may also post on social media, and it is important that staff do not engage with families via this method. Staff should be aware of and follow the trust standard in relation to the use of social media ((SS01). They must not reveal confidential information about any investigation or family, including any information that could be used to reveal the identity of another person.

Support for the Family Support Lead

It is acknowledged that the FSL role can impact emotionally on the wellbeing of staff. It is important that the Divisional Patient Safety panel recommend this role to an experienced member of the team who is competent and confident to take on the responsibilities involved. The leadership and governance team will provide supportive supervision to all staff who undertake the FSL role. The Patient Safety will also encourage peer support and development by networking opportunities between FSL's. (see the Patient Safety Team YourSpace page for details).

APPENDIX 5. DUTY OF CANDOUR CHAMPION ROLE DESCRIPTION

The Duty of Candour Champions will support being open and Duty of Candour practices across Mersey Care NHS Foundation Trust. The role of the Duty of Candour Champion is to act as a resource and role model and to be a link across the Trust for all disciplines. The Champions will provide support and advice in their practice area and act under the supervision and support of the Divisional Risk and Governance Lead(s). The Champion is responsible for delivering accurate updates in Duty of Candour to peers and colleagues as well as providing advice and support to colleagues and students.

Roles and Responsibilities

The Duty of Candour Champion will:

- a) Act as a link between their own practice area and the Governance Lead(s).
- b) Attend monthly champion meetings to receive support, education and feedback on practice issues with Duty of Candour.
- c) Increase awareness of Duty of Candour application and practice issues in their team/service and motivate staff to improve practice.
- d) Support the Divisional Risk and Governance Lead(s) to develop, review and implement local standard operating procedures in line with Trust policy.
- e) Act as a champion within their own practice area supporting staff in implementing local standard operating procedures within their service/team and being a local point of contact for queries. Act as point of reference for further expert advice.
- f) Promote good practice and provide advice and support to colleagues within the workplace, acting as an advocate for patients, families and carers.
- g) Support clinical audit for Duty of Candour within their team/service.
- h) Maintain up to date knowledge of the specialty subject and promote evidence-based practice.
- i) Attend, contribute to, and deliver identified training and awareness raising sessions.
- j) Disseminate pertinent information within the workplace in an appropriate and timely manner.
- k) Maintain and monitor standards of care delivery in the workplace, providing feedback to individuals and Divisional Governance Lead(s).

Skills Required:

- a) Nursing Associate or Registered Nurse
- b) Knowledge and understanding of audit
- c) Communication skills including:
 - i. Presentation skills
 - ii. High visibility within the clinical area/department
 - iii. Approachability
 - iv. Personal and people development skills including team working
 - v. Time and resource management
 - vi. Culture and diversity – are focused and non-judgmental, and shows respect for people's views, therefore, not undermining those participating in training sessions in any way
 - vii. Desire and willingness to ensure evidence-based practice occurs through practical application

Champions will receive:

- a) Training via the Patient Safety Team and Risk and Governance Lead(s) to support development in the role and maintain their competence.
- b) Materials and resources to support training and awareness raising within their team/service
- c) Allocated protected time to attend meetings and education sessions.
- d) Allocated protected time to deliver role in practice to include, teaching, awareness raising and audit.
- e) Evidence to support continuous professional development and revalidation

APPENDIX 6. LETTER TEMPLATES FOR COMMUNICATION

Guidance letter template for initial communication letter. This letter has been designed to be used for any incident requiring Duty of Candour but which does not require a PSLR. The template is provided purely for guidance. All letters must be personalised and tailored to the individual needs of the person receiving the letter.

Our Ref: [ID]
Date:
Name
Name Address 1
Address 2
Address

Consider reasonable adjustments

Dear

I am writing to confirm and follow up on the details of our earlier conversation **today /on (insert date)**. Thank you for speaking to me, I appreciate this must be a very difficult time for you **(and your family)**. I am writing to express my sincere apologies that **(insert detail of incident that has occurred)** happened whilst you/your **(insert relationship, name)** were/was receiving care from the Trust. **(Please personalise as appropriate, for example if related to a bereavement, offer condolences)**

At Mersey Care, we seek to reduce the chance of such events happening by understanding what has led to **(insert detail of incident)**, to improve our care and treatment and the processes involved.

Mersey Care will be undertaking a review into your/**(insert relationship/first name of patient)** care and treatment leading up to **(insert date)** to understand what has happened and to identify learning and how we can make changes to improve in the future. Once this review has been completed, we will contact you again to share the findings, if you **(or your family)** would like this and to discuss any further concerns.

Once again, I would like to offer my sincere apologies at this moment in time and please do not hesitate to contact me with any concerns you may have.

Yours sincerely

Name, Designation, Department, Contact Details

Guidance letter template for initial communication letter. This letter has been designed to be used for any incident requiring Duty of Candour which is progressed to a PSLR. The template is provided purely for guidance. All letters must be personalised and tailored to the individual needs of the person receiving the letter.

Our Ref: [ID]
Date:
Name
Name Address 1
Address 2
Address

Consider reasonable adjustments

Dear

Re: Duty of Candour

I am writing to confirm and follow up on the details of our earlier conversation **today /on (insert date)**. Thank you for speaking to me, I appreciate this must be a very difficult time for you **(and your family)**. I am writing to express my sincere apologies that **(insert detail of incident that has occurred)** happened whilst you/your **(insert relationship, name)** were/was receiving care from the Trust. **(Please personalise as appropriate, for example if related to a bereavement, offer condolences)**

At Mersey Care, we actively seek to learn from such events and reduce the chance of them happening again by understanding what has led to **(insert detail of incident)**. We are committed to working **(with patients and their families)** to improve the quality of care delivered and the processes involved.

Mersey Care will now commence a review into your/**(insert relationship/first name of patient)** care and treatment leading up to **(insert date)**. This will enable us to understand what has happened to identify any possible learning and how we can make changes to improve in the future. As part of the review, the Trust will be in contact to ensure you are listened to and you can contribute to this review with any questions or lines of enquiry that you **(or your family, with your agreement)** have, this will ensure we gain a shared understanding of what happened. The Trust commits to share the findings from the review and will ensure that you are included at all key stages. We will feed back to you **(and your family)** during and upon the review completion if this is your choice.

A Family Support Lead has been appointed and will be in contact with you shortly, this is a member of our staff who will help support you throughout the learning review process. During the review we will be guided by you as to how and when you would like us to keep in touch. You are welcome to involve a relative, friend or advocate in this process to provide support to you as required.

Please do not hesitate to contact me using the details at the top of this letter to discuss any matters and once again I would like to offer my sincere apologies at this time.

Yours sincerely

Name, Designation, Department, Contact details

Infection Prevention and Control Duty of Candour Letter Template

Our Ref: [ID]

Date:

Name Address 1

Address 2

Address 3

Dear {Title and Name}

I am writing to say sorry that (you/your relative xxx) has developed an infection {add name of infection here} during (your/their) hospital stay. At Mersey Care NHS Foundation Trust we are committed to being open with patients and relatives/carers when events such as these occur so that we gain a shared understanding of what happened and identify if there is anything that can be done to prevent such an incident occurring again in the future. Although some infections cannot be prevented, we aim to protect patients from infection whenever possible and learn at every opportunity in line with the Trust's "Just" patient safety culture. Being open and honest is important within the culture of the organisation.

I am writing to you to let you know that the infection is being reviewed in order to help find out whether there was anything that could have been done to prevent it. By undertaking a review of infections in this way we aim to identify ways in which we can further reduce the risk of infections to patients.

A review is already underway. We will let you know the outcome of this once it has concluded. If you would like to discuss anything related to this infection or your illness, your point of contact is {Name and Title} and they can be contacted on {Telephone contact details}

Yours sincerely

Name, Designation, Department

Letter template for sharing Incident Learning Review findings

Our Ref: [ID]

Date:

Name Address 1

Address 2

Address 3

Dear

Re: [Insert as appropriate]

I am writing to inform you of the outcome of our review following [description] which resulted in [result].

The review found that [Action taken (review)].

From this the Trust is taking the following [outcome of review]. Lessons learnt from this include [lessons learned].

If you would like to meet to discuss the outcome of the review then please do not hesitate to contact me using the contact details below.

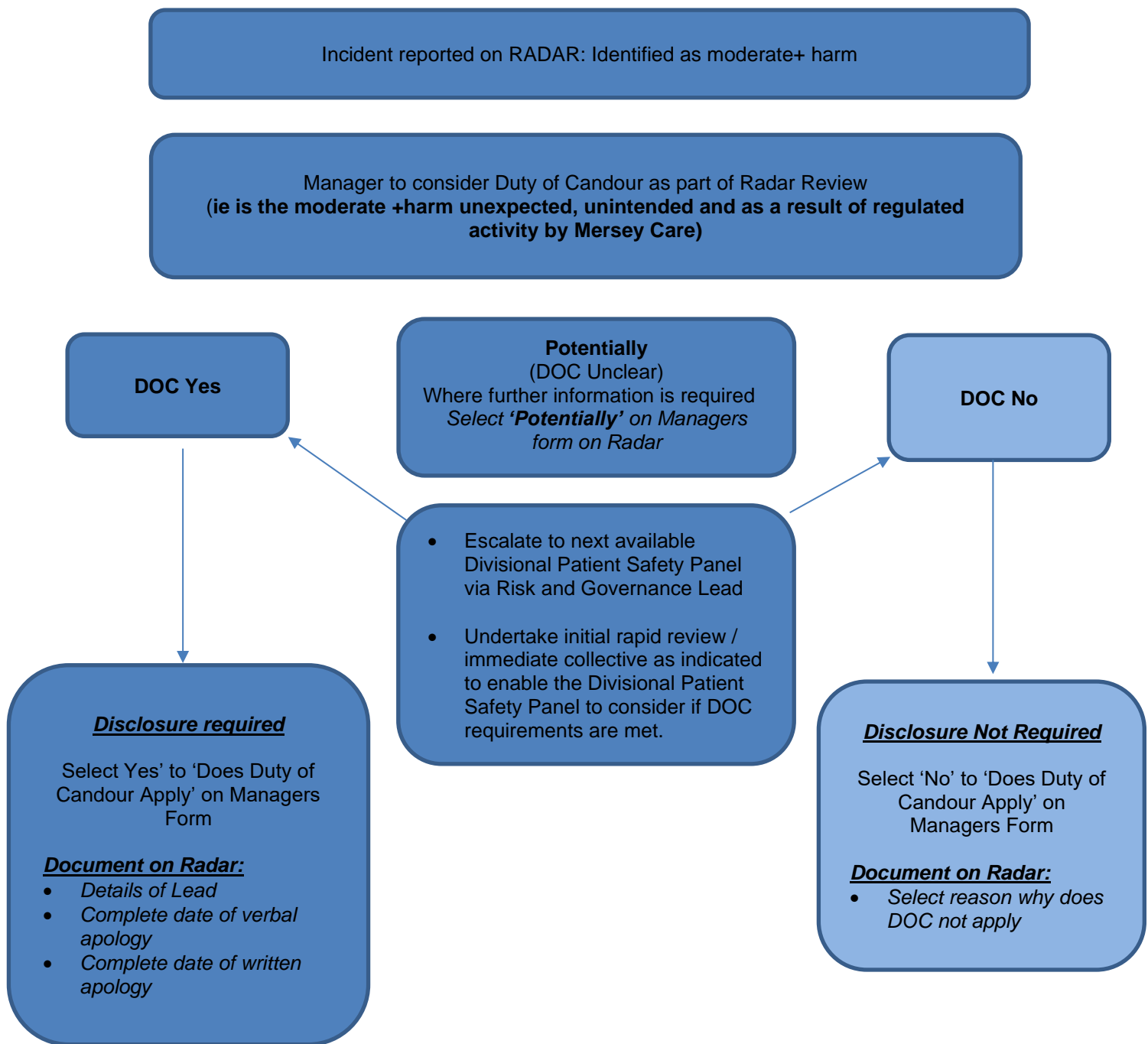
I would like to once again express my sincere apologies to you.

Yours sincerely

Name, Designation, Department

Enclosure: Copy Learning Review outcome report

APPENDIX 7 TRUST WIDE DUTY OF CANDOUR PROCESS



APPENDIX 8. DUTY OF CANDOUR QUARTERLY AUDIT

Details of the Duty of Candour Regulation can be found at Appendix 2

- Verbal disclosure for initial Duty of Candour fulfilment to be completed within 10 days of confirmation of a notifiable safety incident
- Written follow up confirmation of initial disclosure within 15 days of confirmation of a notifiable safety incident
- Written confirmation of final disclosure (sharing of learning) within 10 days of completion of any patient safety learning response (local review/patient safety review/PSLR)

Patient Safety Team to produce a report detailing 5% moderate harm and above incidents (or a minimum of ten incidents per division) and upload to AMaT. Generate reports and pass back to divisions to complete

Does DOC Apply?

1. Has Duty of Candour been applied to this incident? *Yes/No/Box for comments*
2. If yes – go to initial contact questions
3. If no – is there evidence that the incident does not meet the criteria for statutory Duty of Candour? *Yes/No/Box for comments*
4. Has the rationale for not applying duty of candour been applied correctly?
Yes/No/Box for comments

If the family have declined to participate in the duty of candour process at any point, please select “no” for the below questions and document this in the comments box.

Initial Contact

1. Is there evidence in the clinical records that an initial contact has been made notifying the relevant person of a safety incident? *Yes/No/Box for comments*
2. Is there evidence in the clinical records that a verbal apology was given as part of the initial contact? *Yes/No/Box for comments*
Is there evidence that attempts were made to give a verbal apology within 10 days of the confirmation of a notifiable safety incident? *Yes/No/Box for comments*
3. Is there evidence in the clinical record that an explanation was provided as part of the initial contact and that a further review would be undertaken? *Yes/No/Box for comments*
4. Is there evidence of an initial DOC letter in RADAR? *Yes/No/Box for comments*
5. *If a verbal apology has been provided, is there evidence that a written apology (initial DOC letter) was sent within 15 days of the confirmation of a notifiable safety incident? Yes/No/Box for comments*

Follow up

1. Is there evidence of a follow up DOC letter in RADAR? *Yes/No/Box for comments*
2. Is there evidence that the review was shared with the family?
Yes/No/The family did not wish to see the report/Box for comments
3. Have the progress notes in RADAR been updated at each stage?
Yes/No/Box for comments

4. If applicable were reasonable adjustments in place throughout the Duty of Candour process? For example:
- environmental adjustments for someone who has a physical disability
 - an interpreter for someone who does not speak English well
 - information in accessible formats
 - signposting to mental health services
 - the support of an advocate
 - drawing their attention to other sources of independent help and advice such as AvMA (Action against Medical Accidents) or Cruse Bereavement Care