Lincolnshire Partnership NHS
NHS Foundation Trust

DUTY OF CANDOUR (including principles of Being Open) POLICY

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Executive Summary

Every healthcare professional must be open and honest with patients. Every NHS Trust, since November 2014, has a statutory Duty of Candour.

Candour is defined by Sir Robert Francis as: 'The volunteering of all relevant information to persons who have or may have been harmed by the provision of services, whether or not the information has been requested and whether or not a complaint or a report about that provision has been made'.

The Being Open principles and ethical duty of openness apply to all incidents and any failure in care or treatment. The Duty of Candour applies to incidents whereby moderate harm, severe harm or death has occurred.

It is a matter of judgment that needs to be exercised on a case by case basis to determine whether an incident that meets the Duty of Candour criteria has occurred. What may not appear to be such an incident at the outset may look very different once more information comes to light, and may therefore lead to an incident becoming notifiable under the Duty of Candour.

The requirements of the Duty of Candour are as follows:

As soon as reasonably practicable after becoming aware that a safety incident has occurred that falls into the moderate harm or more serious categories the healthcare professional must:

(a) notify the 'relevant person' (this is usually the patient but may in some circumstances be the relative, carer or advocate) that the incident has occurred and;

(b) provide reasonable support to the relevant person in relation to the incident.

The notification must:

(a) be given in person by one or more members of staff;

(b) provide an account of all the facts known about the incident to date;

(c) advise the relevant person what further enquiries into the incident will be undertaken;

(d) include an apology and/or a sincere expression of regret, and;

(e) be recorded in writing in the notes.

This notification must be followed up in writing to the relevant person.

The member of staff should be clear in the first meeting that the facts may not yet have been established, tell the relevant person only what is known and believe to be true, and answer any questions honestly and as fully as they can.

The aim of the Duty is to ensure that patients are told when harm occurs as a result of the care they receive. Where the degree of harm is not yet clear but may fall into the moderate or above categories, then the relevant person must be notified.

1. Introduction

Regulation 20 of The Health and Social Care Act 2008 (Regulated Activity) Regulations 2014, introducing the statutory Duty of Candour for the NHS, came into force on 27th November 2014. The introduction of Regulation 20 is a direct response to recommendation 181 of the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust, which recommended that a statutory Duty of Candour be imposed on healthcare providers. The regulations can be found here http://www.legislation.gov.uk/uksi/2014/2936/regulation/20/made

Subsequently the CQC issued a guidance document addressing the Duty of Candour: http://www.cqc.org.uk/sites/default/files/20141120_doc_fppf_final_nhs_provider_guidance_v1-0.pdf

The intention of this regulation is to ensure that providers are open and transparent with people in relation to care and treatment, and specifically when things go wrong with care and treatment, and that they provide people with reasonable support, truthful information and an apology.

Lincolnshire Partnership NHS Foundation Trust (the Trust) wants to make this duty a reality for people who come into contact with our services. We want to ensure there is clear, strong organisational support for staff to follow their ethical responsibility in being open and honest with patients. This policy is a reinforcement of our development of a wider culture of safety, learning and improvement.

Clinicians already have had an ethical duty of candour under their professional registration to tell patients about errors and mistakes. This policy builds on individual professional duty and places an obligation on the organisation - not just individual healthcare professionals - to be open with patients when harm has been caused.

It is broadly acknowledged that healthcare treatment is not risk free. Patients, families and carers usually understand this, and want to know not only that every effort has been made to put things right, but every effort is made to prevent similar incidents happening again to somebody else**.** A critical test for patients' trust in our organisation is how we respond when things go wrong. Openness is comparatively easy when all is well, but can be far more challenging in cases of actual or possible harm.

The impact and consequences of mistakes or errors can affect everyone involved and can be devastating for individual staff or teams; this policy aims to ensure there is unequivocal, sustained support for staff in reporting incidents and in being open.

Our approach to candour underpins a commitment to providing high quality of care, understanding and sharing the truths about harm at an organisational as well as an individual level, and learning from them. It is about our organisational values being rooted in genuine engagement of staff, our clinical leadership building on professional accountability, and on every member of staff's personal commitment to the safety of patients.

The processes contained within this policy reflect those set out in Regulation 20 and in the associated CQC guidance.

2. Definitions

The 'Duty of Candour' requirements reinforce the 'being open' principles by placing more emphasis on organisational responsibility. While the Duty applies to organisations, not individuals, it is clear that individual NHS staff must cooperate with it to ensure the Duty is met.

2.1 Duty of Candour

Candour is defined in The Francis report:

"The volunteering of all relevant information to persons who have or may have been harmed by the provision of services, whether or not the information has been requested and whether or not a complaint or a report about that provision has been made."

Unlike the existing professional and ethical duty which applies to all circumstances where a patient is harmed when something goes wrong, the statutory Duty of Candour only applies to incidents where a patient suffered (or could have suffered) unintended harm resulting in moderate or severe harm or death or prolonged psychological harm (Table 1 – page 10 provides harm definitions).

The requirements of the Duty of Candour as set out by the regulations are as follows.

As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a health service body must:

(a) notify the relevant person that the incident has occurred;

(b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

The notification to be given must:

(a) be given in person by one or more representatives of the health service body;

(b) provide an account, which to the best of the health service body's knowledge is true, of all the facts the health service body knows about the incident as at the date of the notification;

(c) advise the relevant person what further enquiries into the incident the health service body believes are appropriate;

(d) include an apology, and

(e) be recorded in a written record which is kept securely by the health service body.

This notification must be followed up in writing.

Incidents that result in no harm or low harm are not covered by the Duty of Candour. Patients should still be informed of such events in line with being open, but the emphasis for the Duty of Candour is on incidents that result in moderate harm, severe harm or death.

2.2 Being Open

Being open was described by the National Patient Safety Agency in 2009 as 'discussing patient safety incidents promptly, fully and compassionately' adding that this 'can help patient and professionals to cope better with the after effects'. The Being Open principles are contained in Appendix 1.

2.3 Patient Safety Incident

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

2.4 Serious Incident

Serious incidents requiring investigation are defined by the NPSA's 2010 National Framework for Reporting and Learning from Serious Incidents Requiring Investigation. This definition was subsequently endorsed by NHS England's Serious Incident Framework (2015).

A serious incident is an incident that occurred during NHS funded healthcare which resulted in one or more of the following;

- Unexpected or avoidable death or severe harm of one or more patients, staff or members of the public;
- A never event - all never events are defined as serious incidents although not all never events necessarily result in severe harm or death;
- A scenario that prevents, or threatens to prevent, an organisation's ability to continue to deliver healthcare services, including data loss, property damage or incidents in population programmes like screening and immunisation where harm potentially may extend to a large population;
- Allegations, or incidents, of physical abuse and sexual assault or abuse;
- Loss of confidence in the service, adverse media coverage or public concern about healthcare or an organisation.

Further guidance in relation to Serious Incidents is available in the Trust's Incident Reporting Policy. It is important to note that a Serious Incident is not necessarily the same as a Duty of Candour notifiable incident, although there will be some cases where a serious incident is also a notifiable incident.

2.5 Notifiable Incident

This describes an incident that needs to be notified to the patient and/or their carer/family under the Duty of Candour. A notifiable incident and a serious incident are not necessarily one and the same.

Notifiable Safety Incident

The regulations state that a "notifiable safety incident" means "any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in—

(a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or

(b) severe harm, moderate harm or prolonged psychological harm to the service user;

"prolonged psychological harm" means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days."

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

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

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

Example Scenario – A Fall

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

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

It is a matter of judgment from a healthcare professional that needs to be exercised on a case by case basis to determine whether a notifiable incident has occurred. What may or may not appear to be an incident at the outset may look very different once more information comes to light, and may therefore mean an incident becomes notifiable under the Duty of Candour.

It should be remembered that the whole point of the Duty is to ensure that patients are told when harm occurs as a result of the care they receive. Where the degree of harm is not yet clear but may fall into the moderate or above categories, then the relevant person must be informed. It also may not be clear whether the incident or harm was as a result of the care the patient received. If, after using professional judgement, there is uncertainty about whether the incident is notifiable then the patient should be fully informed of the facts, and should be kept informed until the conclusion of the episode.

Any decisions made, and the outcome of the decisions, must be recorded in the notes.

2.6 Relevant Person

The regulations use the term of the "relevant person" when describing the person who will be informed of an incident in the Duty of Candour process. This may be the service user or patient, or the person acting on their behalf. The term "relevant person" is therefore used throughout this Trust policy.

Relevant Person

The regulations state that the "relevant person" means the service user or, in the following circumstances, a person lawfully acting on their behalf:

(a) on the death of the service user,

(b) where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or

(c) where the service user is 16 or over and lacks capacity (as determined in accordance with Sections 2 and 3 of the 2005 Act) in relation to the matter.

2.7 Level of Harm

Level of Harm

The regulations state that the Duty of Candour applies to incidents as follows:

a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or

(b) severe harm, moderate harm or prolonged psychological harm to the service user; "prolonged psychological harm" means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

Moderate harm" means—

(a) harm that requires a moderate increase in treatment, and

(b) significant, but not permanent, harm;

"moderate increase in treatment" means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care);

Grade 3 and 4 pressure ulcers constitute incidents in the Trust that would be classed as moderate and severe harm incidents, using the NPSA definitions. Consideration needs to be given to these as to whether they would also be notifiable incidents.

Example Scenario – Pressure Ulcer

A multi-disciplinary team are caring for a patient who develops a Grade 3 pressure ulcer. This, in line with Trust policy, is reported as a Serious Incident on Datix. As a grade 3 or 4 pressure ulcer may require a moderate increase in treatment and significant harm will be experienced by the patient, this incident will almost certainly invoke the Duty of Candour. A notification meeting therefore takes place with the relevant person.

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

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

3. Scope

This policy applies to all 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 something goes wrong with their treatment or care which causes, or has the potential to cause, harm or distress.

The Being Open principles (Appendix 1) and ethical duty of openness applies to all incidents and any failure in care or treatment. The Duty of Candour applies to incidents whereby moderate harm, significant harm or death has occurred.

There will be exceptions to implementing the Duty of Candour; there must be very sound reasons, which must be clearly recorded, for not having the Duty of Candour principles applied.

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. 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.

<u>The potential implications of not implementing the Duty of Candour requirements</u>

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:

- Inform the CQC
- Require that the Chief Executive send an apology and an explanation of the breach to the patient/relatives
- Publish details of the breach on the Trust web-site.

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:

1. Are lessons learned and improvements made when things go wrong?
2. Are people who use services told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result?
3. How does the leadership and culture reflect the vision and values, encourage openness and transparency and promote good quality care?
4. Does the culture encourage candour, openness and honesty?

<u>Incidents that are later uncovered or that have occurred within the care of another provider</u>

On occasion, an incident that happened some time ago may be discovered. The incident should be reported in the usual way on Datix, and agreement reached by the senior clinician and the Quality & Safety Team Leader as to the most appropriate action to take. A delay in discovering an incident does not mean the Duty of Candour does not apply. 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.

Incidents that are discovered that relate to care delivered by another provider will be reported to a senior manager in that organisation, and to the commissioning body. That organisation is then responsible for implementing the Duty of Candour. The Trust will work in partnership with other providers to ensure the Duty of Candour applies as an economy wide, patient-centred policy.

4. Aim

Conversations between patients, families and staff about risk and the potential for harm are essential for fostering a culture of candour, both as a means of preparing patients should something happen, and in encouraging clinicians and healthcare staff to do the right thing when errors occur.

The principle of this policy is to reinforce a 'conversation of equals' between people who use our services and staff who provide the services. Having a candid conversation when something goes wrong might not be so difficult if it is part of an on-going clinical relationship, in which issues of risk and consent are clearly discussed with the patient from the outset.
This policy underpins the Trust's values and aims to ensure:

- The patient's right to openness from the Trust is clearly understood by all staff;
- That this right is integrated into the everyday business of the Trust;
- The Trust learns from mistakes with full transparency and openness;
- Patients and their families and carers can trust us to share information with them in an open and collaborative way;
- The Trust works in partnership with others to protect patients;
- Trust staff ensure appropriate support is offered to the patient/families/carers/ and colleagues and;
- That line managers understand an individual or team may well require support during and after an incident. Support for employees is available from the Employee Counselling and Occupational Health Service and the Human Resources Department in the Trust.

The following paragraph is taken from the Dalton and Williams review of the thresholds for the Duty of Candour:

"The obligations and challenges of candour serve to remind us that for all its technological advances, healthcare is a deeply human business. Systems and processes are necessary supports to good, compassionate care, but they can never serve as its substitute. It follows from this that making a reality of candour is a matter of hearts and minds more than it is a matter of systems and processes, important as they can be. A compliance-focused approach will fail. If organisations do not start from the simple recognition that candour is the right thing to do, systems and processes can only serve to structure a regulatory conversation about compliance. The commitment to candour has to be about values and it has to be rooted in genuine engagement of staff, building on their own professional duties and their personal commitment to their patients".

5. Responsibilities

5.1 Trust Board

The Board fully endorses the principles of being open and actively promotes an open, honest and fair culture. The Trust Board will seek assurances that the principles and processes set out in this policy work effectively to support the commitment to implementing the Duty of Candour.

Employees involved in patient safety incidents in which a patient has been harmed can be traumatised by the event. The Board ensures that systems are in place to provide support to employees in these circumstances.

5.2 Chief Executive

The Chief Executive is ultimately responsible for the process of managing and responding to the being open/Duty of Candour process and for the delegation of this role as required.

5.3 Executive Directors

The Executive Directors are responsible for actively supporting the Chief Executive with being open and the Duty of Candour principles and process.

5.4 The Patient Safety and Experience Committee

The Patient Safety and Experience Committee will monitor Route Cause Analysis reports to determine whether the principles of being open and the Duty of Candour have been followed appropriately in each case.

5.5 Professional Bodies and Trade Union organisations

The above bodies accept the responsibility of working with the Trust on issues with the shared intention of investigating and learning from incidents. Trade Unions can play a vital role in representing employees in individual matters and supporting them through difficult and stressful situations.

5.6 The Director of Nursing and Quality

The Director of Nursing and Quality is responsible for ensuring the effective implementation of the Being Open and the Duty of Candour is reported to the Quality Committee and Trust Board.

5.7 Line Managers' Responsibility

It is the responsibility of all Trust managers to support employees to comply with this policy and to ensure members of their teams are aware of this duty.

5.8 Employee Responsibility

All employees must comply with their relevant professional code. A joint statement on candour has been issued by the following professional healthcare regulators:

- General Chiropractic Council
- General Dental Council
- General Medical Council
- General Optical Council
- General Osteopathic Council
- General Pharmaceutical Council
- Nursing and Midwifery Council
- Pharmaceutical Services of Northern Ireland

All employees must understand their duty for being open and must demonstrate the principles of being open in their work.

All employees who become aware of an incident or near miss having occurred must follow the Trust Incident Reporting Policy and apply the principles of being open and the Duty of Candour throughout these processes.

All employees dealing with patients or relatives should abide by the Trust's complaints process and advise who patients or carers should write to if they wish to formalise a complaint.

Employees who are concerned about the non-reporting or concealment of incidents, or about on-going practices which present a serious risk to patient safety, must raise their concerns either through established governance routes or through the Trust's Whistle Blowing Policy.

5.9 Investigating Officer

An Investigating Officer must have received training in undertaking Root Cause Analysis (RCA) and be able to demonstrate competence with this skill. The Investigating Officer could be the point of contact throughout an investigation between the patient, the family and the Trust if it is agreed that this is most appropriate approach. This communication role can be undertaken by another person such as the lead clinician or senior manager if this is more appropriate, but whoever the contact is must be recorded in the clinical notes and the RCA documentation.

5.10 Senior Clinician

The most senior clinician involved in the incident will determine whether the incident is notifiable. Advice can be obtained from senior managers, the Head of Quality and Safety, Associate Director of Nursing and Quality or the Director of Nursing and Quality.

5.11 Notifying the Relevant Person

In making a decision about who is most appropriate member of staff to lead on the notification discussion and apology, the member of staff's seniority, relationship to the person using the service, and experience should all be considered. Issues of consent and confidentiality and will determine who will lead on the discussions with the relevant person.

Children and Young People

Young people are owed the same duties of care and confidentiality as adults. Confidentiality may only be broken when the health, safety or welfare of the young person, or others, would otherwise be at grave risk.

Where a child or young person is judged to have the mental capacity and the emotional maturity to understand the information provided (refer to the Fraser guidelines), then he/she should be involved directly in the Duty of Candour process following a notifiable patient safety incident.

Where children are deemed not to have sufficient maturity or ability to understand, consideration needs to be given to whether information is provided to the parents alone or in the presence of the child. In these instances the parents' or legal guardian's views on the issue should be sought.

6. Training

All new employees of the Trust are made aware of the 'Being Open' process and Duty of Candour as part of the Trust Induction Programme.

All Investigating Officers receive RCA training before undertaking an investigation. The Duty of Candour processes form part of this training.

Awareness of the being open principles will be promoted to all staff through existing Quality Governance structures.

A Quick Reference Guide to the Being Open principles and the Duty of Candour is contained in appendix 2 and 3.

7. Support and Advice for Staff

It is very rare for staff in healthcare to go to work with the intention of causing harm or failing to do the right thing. While we do all we can to minimise risks, it will never be possible to eliminate them fully. It should be acknowledged from the outset that many 'human factors' can increase the risk of incidents occurring such as:

- Workload
- Distractions
- Physical environment
- Physical demands
- Device/product design.

and that it is uncommon for any single action or 'failure' to be wholly responsible. The focus following an incident should always be on learning and prevention rather than individual blame.

Involvement in an incident and particularly a serious incident can have profound consequences on staff members who may experience a range of reactions. The high personal and professional standards of most clinicians and other staff may make them particularly vulnerable to these experiences. Different individuals will have differing responses to the same incident and support should always therefore be tailored to the individual. The Staff Wellbeing Service is able to advise on resources available in the Trust, but the support of close team members and managers is invaluable for the staff involved, and for taking forward learning from the event.

- The initial level of support is provided by line managers for employees involved in a patient safety incident.

- The second level of support is provided by appropriate Senior Managers and may include guidance from professional leads. Further escalation may be required depending on the severity of the incident.

- A further level of support is provided by the Executive Directors who participate in the 24 hour on call rotas.

Learning from serious events in the Trust has taught us that that practitioners or teams who work in isolated services or have lone working practices may be more likely to need support. These staff also need to be able to assure their Line Managers and the Trust that they are acting in an open and candid manner with patients.

8. Being Open and Duty of Candour Processes

Most clinicians will find themselves in the difficult position of having to discuss harm or potential harm with a patient at some time in their career. The following guidance provides a framework for staff to work to. It is recognised however that many scenarios do not always follow predetermined processes, and staff must use their own professional judgement in deciding, for example, when is the right time to talk to patients and families/carers. There is no substitute for clinical and professional expertise and compassionate care.

A summary of the stages involved in this process is provided in Appendix 2 together with a flow chart in Appendix 3.

Stage One

Incident Identification and Reporting

Firstly any actions that can be taken immediately to reduce the risk of harm to the patient must be implemented.

The initial facts of the incident should be established and an assessment of the level of harm that has happened to the patient as a result of the incident (see table below) should be undertaken.

Incident	Action
No harm *(including prevented patient safety incidents)*	○ Patients are not usually contacted or involved in investigations and these types of incidents are **outside** the scope of the *Duty of Candour*. Openness is remains best practice, but there is no requirement to follow the Duty of Candour processes.
Low harm	○ Unless there are specific indications or the patient requests it, the communication, investigation and analysis, and the implementation of changes will occur at local service delivery level with the participation of those directly involved in the incident. ○ Communication should take the form of an open discussion between the staff providing the patient's care and the patient and/or their carers. ○ Reporting to the operational managers will occur through standard incident reporting and will be analysed centrally to detect high frequency events. ○ Review will occur through aggregated trend data and local investigation. Where the trend data indicates a pattern of related events, further investigation and analysis may be needed. Openness remains best practice, but there is no requirement to follow the Duty of Candour processes for incidents that result in this level of harm. .
Moderate harm **Severe harm or death**	○ The *Duty of Candour* policy is implemented. ○ It may be necessary to inform the relevant Senior Operational Manager. For Never Events senior manager must be informed immediately and for the most serious incidents, the Quality & Safety Team will also need to be contacted as quickly as possible to ensure everyone who needs to know is informed. The Trust operates within openness principles with our commissioners and regulators, and we will inform these organisations of the incident and the management plans as soon as possible.

All incidents must be reported onto Datix.

Stage Two

Being Open

There are a set of principles for being open (Appendix 1) that staff should refer to when communicating with the relevant person following an incident in which the patient/service user was harmed.

Mental Capacity

Where the patient or service user is assessed as not having the capacity to make a decision in relation to their care or treatment, or where the patient/service user is under 16 and deemed not to have the necessary competency, then the most appropriate relevant person should be notified of the incident.

Confidentiality

Details of a patient's care and treatment should at all times be considered confidential. Where the Duty of Candour would include providing confidential information to family or carers, then the consent of the individual concerned should be sought prior to disclosing information. This consent or denial of consent to share should be recorded in the clinical notes and subsequent RCA documentation.

Communication with parties outside of the clinical team should be on a strictly need-to-know basis and, where practicable, records should be anonymised.

Further advice is available in the Trust's Records Lifecycle Management and Information Governance Policy.

The relevant person cannot be contacted or declines to have further information

If, after discussion, the patient says they do not want more information, then the possible consequences must be explained to them. It should be made clear that they can change their mind and have more information at any time.

All Duty of Candour conversations must be recorded in the notes including instances when the patient has declined the offer of further information.

Where a relevant person cannot be contacted, a clear written record must be kept of the attempts made to contact or speak to the relevant person. This should evidence that every reasonable effort was made to contact the person by stating how many attempts were made, who by and when.

Stage Three

The initial 'being open' communications will vary according to the individual needs of the relevant person, the severity grading of the incident, clinical outcome and family circumstances for each specific event. The most senior clinician on the clinical shift should coordinate this initial communication, ensuring that the relevant person receives clear, unambiguous explanation of the event and the next steps to be taken. It is also vital that staff involved in the incident receive appropriate support from the outset.

The following is intended as broad advice as it is recognised that the vast majority of clinical staff have extensive, highly tuned communication skills.

Apology

Where a patient safety incident has caused harm, an apology must be offered to the relevant person – a sincere expression of sorrow or regret for any possible harm and distress caused.

Guidance from the NHS Litigation Authority (2009) states:

"It is both natural and desirable for clinicians who have provided treatment which produces an adverse result, for whatever reason, to sympathise with the patient or the patient's relatives; to express sorrow or regret at the outcome; and to apologise for shortcomings in treatment. It is most important to patients that they or their relatives receive a meaningful apology. We encourage this, and stress that apologies do not constitute an admission of liability. In addition, it is not our policy to dispute any payment, under any scheme, solely on the grounds of such an apology."

Clarity of Communication

The individual communication needs of the relevant person, for example, linguistic or cultural needs, learning disabilities, or sensory impairments must be considered and taken into full account before any discussion takes place. This involves consideration of circumstances that can include a patient requiring additional support, such as an independent patient advisor or a translator.

The relevant person should be fully informed of the issues surrounding the patient safety incident and its consequences in a face to face meeting.

The facts that are known should be explained. When talking to the relevant person about the incident staff must use clear, straightforward language and be honest with responses to any questions that are raised.

The relevant person should be informed that an incident analysis will be carried out and more information will become available as this progresses.

It should be made clear to the relevant person that new facts may emerge as the incident analysis proceeds.

The relevant person's understanding of what happened should be established from the outset, as well as any questions they may have.

There should be consideration and formal noting of the relevant person's views and concerns, and demonstration that these have been heard and taken seriously.

An explanation should be given about what will happen next in terms of the long term treatment plan for the patient as well as the incident analysis findings.

Information on likely short and long-term effects of the incident (if known) should be shared.

An offer of practical and emotional support should be made to the relevant person.

Patients, family and/or carers might be anxious, angry and frustrated, even when the discussion is conducted appropriately. It is essential that staff are not drawn into speculation, attribution of blame, denial of responsibility or the provision of conflicting information.

Stage Four

The Investigation

For Serious Incidents, the Investigating Officer (IO) will undertake the RCA as set out in the Trust's Reporting and Management of Risk Policy. The IO will meet with the employee(s) directly involved in the incident to establish the facts.

Where an incident is notifiable but does not meet the criteria for a Serious Incident, it is classed as a 'significant event and an RCA must be undertaken.

The actions above should be followed by a letter to the patient/relatives with an offer of a meeting, if this is appropriate. This should be written by the most appropriate person. This may be before the conclusion of the investigation. An example template letter is provided in Appendix 4.

The letter should advise the patient of the independent advocacy service available to support and assist them.

The IO will keep the relevant Divisional Lead, Quality and Safety Team Leader and the person who is overseeing the Duty of Candour process up to date on progress with the investigation.

Stage Five

Communication with the Relevant Person – the Notification Meeting

A meeting with the relevant person should be arranged as soon as possible after the incident has happened to notify them of the incident. If they are unable or do not wish to meet face to face then the following process should be followed via telephone. This meeting should always take place within 10 working days of the incident being discovered.

It may be appropriate for more than one member of staff to meet with the relevant person for support or for additional information.

At the meeting the nominated member of staff should follow the procedure below.

- If known, explain what went wrong and where possible, why it went wrong;
- Inform the patient and/or relative(s) and others what steps are being/will be taken to prevent the incident recurring;
- Offer an apology:
- Provide opportunity for the patient and/or relatives and others to ask any questions;
- Agree with the patient and/or relatives and others any future meetings as appropriate;
- Suggest any sources of additional support and counselling and provide written information if appropriate.
- Inform the relevant person that they will receive a written summary of the incident and that they will be, if they wish, be informed of progress with the investigation. The relevant person will also receive a copy of the final investigation report.

Wherever possible a named contact should be provided who the relevant person can speak to regarding the incident. This can be a manager in the clinical team or another member of staff who has the skills and knowledge to undertaken this role. It is vitally important that whoever is named as the contact is made aware of this, agrees to the role and is furnished with all of the information they may need to ensure clear and honest communication takes place.

The senior manager/clinician for the service should be informed of the outcome of any meeting.

The communication and outcome of the notification must be clearly recorded in the clinical notes by the person who has informed the patient/family.

A letter should then be written to the relevant person setting out what was explained at the notification meeting/phone call. The letter should be drafted immediately after the notification meeting and forwarded to the Quality and Safety Team Leader for approval prior to sending out. The letter must contain all the information that was provided at the initial notification meeting/phonecall.

The regulations state that the notification given must be followed by a written notification given or sent to the relevant person containing—

(a) the information provided,

(b) details of any enquiries to be undertaken,

(c) the results of any further enquiries into the incident, and

(d) an apology.

Any Duty of Candour letters arising out of the notification meeting must be signed off by the most appropriate senior manager/clinician; this would usually be the Band 7 ward manager or team coordinator. A copy of the letter must be scanned into the correspondence section of the clinical records and a copy sent to the Quality and Safety Team.

If, for whatever reason, the patient cannot be contacted in person or declines to speak to anyone from the Trust in relation to the incident, then the above processes do not apply but a written record must be kept of the attempts made to contact or to speak to the relevant person.

Stage Six

Investigation Closure and Learning

The full RCA report is signed off by a nominated Executive Director (level 1) or Trust Board meeting (level 2). This will include details of how the Duty of Candour has been implemented.

Once the incident is signed off for closure, a letter should be sent to the relevant person together with the anonymised investigation report and action plan. The supporting letter should provide information in the event that the individual wishes to pursue legal action against the Trust. This letter will be signed off by the Chief Executive or their nominated deputy.

If the RCA is not available within the usual time frame for closure, a letter should be sent to the relevant person to provide an explanation as to when they can expect to be provided with additional details. This letter should clarify the information previously provided; reiterate

key points, and record action points and future deadlines. This letter should also provide information in the event that the individual wishes to pursue legal action against the Trust.

All learning from the incidents must be cascaded via the Operations Governance and Quality Meeting, Patient Safety and Experience Committee, Quality Committee and Learning Lessons Bulletin. This information will be relayed to Trust Board through the Director of Nursing and Quality.

The outcome of reports must also be shared with any other healthcare organisation or relevant stakeholder as appropriate to optimise learning from the incident.

9. Documentation

All correspondence should be held in accordance with Trust's Records Lifecycle Management and Information Governance Policy.

With specific relation to the Being Open/Duty of Candour the clinical records must:

- Record the sharing of any facts that are known and agreed with the relevant person;
- Record how it has been agreed that the relevant person will be kept informed of the progress and results of that investigation;
- Record, where appropriate, a full apology to the patient and their family/carers;
- Record any explanation given of the likely short and long-term effects of the incident;
- Contain copies of any letters sent to the relevant person;
- Record an offer of appropriate practical and emotional support.

10. Performance/Disciplinary Issues

Where concerns are identified about the performance of staff, the Trust's Human Resources policies will be invoked.

This will particularly be the case in matters where safeguarding issues are identified. The appropriate professional body (GMC/NMC etc.) may also need to be notified.

11. Monitoring the Policy

Monitoring implementation will be undertaken by the Quality and Safety Team with compliance reported to each Board meeting. The outcome of this will be reported to the Quality Committee and Trust Board. The Policy will be reviewed bi-annually and sooner of necessary.

12. Associated Documents/References

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 No. 2936 PART 3SECTION 2 Regulation 20 http://www.legislation.gov.uk/uksi/2014/2936/regulation/20/made
The Francis Enquiry http://www.midstaffspublicinquiry.com/
A promise to learn – a commitment to act: Improving the Safety of Patients in England, Berwick and the National Advisory Group on the Safety of Patients in England, 2013, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf.
Building a culture of candour - A review of the threshold for the duty of candour and of the incentives for care organisations to be candid http://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf
Human Factors in Healthcare – National Quality Board 2013 http://www.patientsafetyfirst.nhs.uk/ashx/Asset.ashx?path=/Intervention-support/Human+Factors+How-to+Guide+v1.2.pdf
NPSA – Being Open resources: http://www.nrls.npsa.nhs.uk/resources/?entryid45=65077
Mental Capacity Act 2005 – Code of Practice http://www.justice.gov.uk/protecting-the-vulnerable/mental-capacity-act
Fraser Guidelines http://www.fpa.org.uk/factsheets/under-16s-consent-confidentiality
General Medical Council, Good medical Practice, 2006 www.gmc-uk.org/guidance/good_medical_practice/index.asp
National Patient Safety Agency, Seven Steps to Patient Safety, April 2004 http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/
NHS Litigation Authority, Litigation Circular No. 02/02 Apologies and Explanations, 11 February 2002 www.nhsla.com
NHS Litigation Authority – Saying Sorry: 2013 - http://www.nhsla.com/Claims/Documents/Saying%20Sorry%20-%20Leaflet.pdf
CQC Provider Guidance http://www.cqc.org.uk/sites/default/files/20141120_doc_fppf_final_nhs_provider_guidance_v1-0.pdf

APPENDIX 1

The 10 Principles of Being Open - *Being open* involves apologising when something has gone wrong, being open about what has happened, how and why it may have happened, and keeping the patient and their family informed as part of any subsequent review.

1. Principle of Acknowledgement

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

2. Principles of Truthfulness, Timeliness and Clarity of Communication

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

3. Principle of an Apology

Patients, their families and carers should receive a meaningful apology - one that is a sincere expression of sorrow or regret for the harm that has resulted from a patient safety event or that the experience was poor. Both verbal and written apologies should be offered. **Saying sorry is not an admission of liability and it is the right thing to do.** Verbal apologies are essential because they allow face to face contact, where this is possible or requested. A written apology, which clearly states the organisation is sorry for the suffering and distress resulting from the patient safety event, should also be given.

4. Principle of Recognising Patient and Carer Expectations

Patients, their families and carers can reasonably expect to be fully informed of the issues surrounding a patient safety incident, and its consequences, in a face to face meeting with representatives from the organisation and/or in accordance with the local resolution process where a complaint is at issue. They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times. Patients, their families and carers should also be provided with support in a manner to meet their needs. This may involve an independent advocate or an interpreter. Information enabling to other relevant support groups will be given as soon as possible and as appropriate.

5. Principle of Professional Support

The Trust has set out to create an environment in which all employees are encouraged to report patient safety events. Employees should feel supported throughout the patient safety event investigation process; they too may have been traumatised by the event. Resources available are referred to within the respective Trust policies, to ensure a robust and

consistent approach to patient safety event investigation. Where there are concerns about the practice of individual employee the Trust's Human Resources department must be contacted for advice. Where there is reason to believe an employee has committed a punitive or criminal act, the Trust will take steps to preserve its position and advise the employee at an early stage to enable them to obtain separate legal advice and/or representation. Employees should be encouraged to seek support from relevant professional bodies. Where appropriate, a referral will also be made to the Independent Safeguarding Authority.

6. Principle of Risk Management and Systems Improvement

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

7. Principles of Multi-Disciplinary Responsibility

Being open applies to all employees who have key roles in patient care. This ensures that the *Being open* process is consistent with the philosophy that patient safety incidents usually result from system failures and rarely from actions of an individual. To ensure multi-disciplinary involvement in the *Being open* process, it is important to identify clinical and managerial leaders who will support this across the health and care agencies that may be involved. Both senior managers and senior clinicians will be asked to participate in the patient safety incident investigation and clinical risk management as set out in the respective Trust policies and practice guidance.

8. **Principles of Clinical Governance**

Being open involves the support of patient safety and quality improvement through the Trust's clinical governance framework, in which patient safety incidents are investigated and analysed, to identify what can be done to prevent their recurrence. It is a system of accountability to ensure that these changes are implemented and their effectiveness reviewed. Findings are disseminated to employees so they can learn from patient safety incidents. Audits are an integral process, to monitor the implementation and effects of changes in practice following a patient safety incident.

9. **Principle of Confidentiality**

Details of a patient safety incidents should at all times be considered confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient. The Trust will anonymise any incident it publishes but still seek the agreement of those involved.

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

Consent and duty to inform for incidents involving patients in Offender Health will be dealt with in accordance with the normal prison protocol.

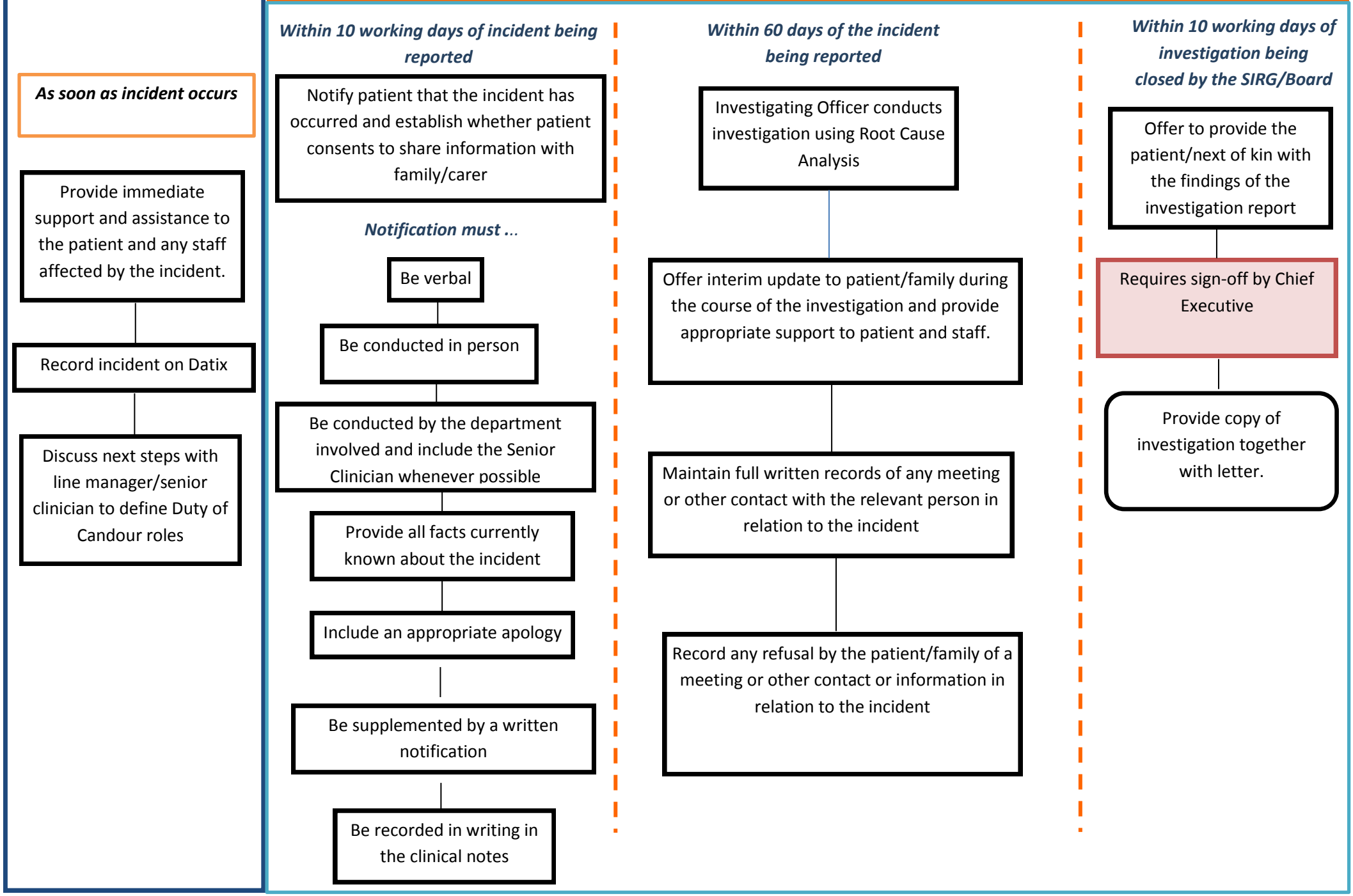
10. Principle of Continuity of Care

Patients will continue to receive all usual treatment and continue to be treated with respect and compassion.

APPENDIX 2

Brief Summary of the Stages in the Duty of Candour Process

Requirement under Duty of Candour	**Responsible Person/Department**	**Timeframe**
For incidents where moderate harm, serious harm or death has occurred, the relevant person must be informed.	Senior clinician for episode of care during which the incident occurred. The Clinical/Operational Manager should be made aware and if appropriate, involved.	As soon as possible after the incident has been detected and reported but always within 10 working days of the incident
Initial notification of incident must be verbal (face-to-face, where possible) unless the relevant person declines notification or cannot be contacted in person. Sincere expression of regret or sorrow must be provided verbally. This must be recorded in the notes.	Senior clinician for episode of care during which the incident occurred. The Clinical/Operational Manager should be made aware and if appropriate, involved.	As above.
Step-by-step explanation of the known facts must be offered to the relevant person.	As above	As above
Written notification to the relevant person. The written notification should outline the facts discussed at the notification meeting and include a sincere expression of regret or sorrow.	As above. All letters must be approved by the operational manager (usually ward manager or team coordinator) or their nominated deputy.	As above (template letter available for guidance – all letters must be personalised and tailored to the individual needs of the person receiving the letter).
Maintain full written documentation of any meetings. If meetings are offered but declined this must be recorded	As above. All follow-up letters to patients/ relatives to be approved for release by the operational manager (usually ward manager or team coordinator) or their nominated deputy.	
Share incident investigation report (including action plans) with an accompanying letter.	Investigating Officer or other nominated person.	As soon as reasonably practicable but always within 25 working days of report being signed off as complete and incident closed by the SIRG.


As soon as incident occurs
Provide immediate support and assistance to the patient and any staff affected by the incident.
Record incident on Datix
Discuss next steps with line manager/senior clinician to define Duty of Candour roles
Within 10 working days of incident being reported
Notify patient that the incident has occurred and establish whether patient consents to share information with family/carer
Notification must ...
Be verbal
Be conducted in person
Be conducted by the department involved and include the Senior Clinician whenever possible
Provide all facts currently known about the incident
Include an appropriate apology
Be supplemented by a written notification
Be recorded in writing in the clinical notes
Within 60 days of the incident being reported
Investigating Officer conducts investigation using Root Cause Analysis
Offer interim update to patient/family during the course of the investigation and provide appropriate support to patient and staff.
Maintain full written records of any meeting or other contact with the relevant person in relation to the incident
Record any refusal by the patient/family of a meeting or other contact or information in relation to the incident
Within 10 working days of investigation being closed by the SIRG/Board
Offer to provide the patient/next of kin with the findings of the investigation report
Requires sign-off by Chief Executive
Provide copy of investigation together with letter.

APPENDIX 4

Guidance letter template for initial communication letter in accordance with requirements of Duty of Candour for an incident graded as MODERATE

Making a difference

Lincolnshire Partnership NHS
NHS Foundation Trust

Our ref :
NHS Number :

Date

Team or Directorate
Address 1
Address 2
Address 3
Town/City
Postcode

Name
Address 1
Address 2
Address 3
Town/City
Postcode

Tel :
Fax :
Email :

Dear

Further to our conversation on …… I am writing to express my sincere regret that you/your relative (name) have/has been involved in an incident whereby (describe event).

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

If you would like to meet with a member of staff to discuss further any thoughts or concerns you have please let me know within the next two weeks and we will arrange a mutually convenient place and time to meet.

Yours sincerely

Name
Designation

Guidance letter template for an incident graded as <u>SEVERE or DEATH</u>

Making a difference

Lincolnshire Partnership NHS
NHS Foundation Trust

Our ref :
NHS Number :

Date

Team or Directorate
Address 1
Address 2
Address 3
Town/City
Postcode

Name
Address 1
Address 2
Address 3
Town/City
Postcode

Tel :
Fax :
Email :

Dear

Further to our conversation on …… I am writing to express my sincere regret that you/your relative (name) have/has been involved in an incident whereby (describe event).

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

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

(staff member name) will act as your lead contact for the duration of the investigation and they can be contacted by email on …… or via telephone on…… You will also be contacted by the assigned investigator for you to be involved in the investigation should you wish.

Yours sincerely

Name
<u>Designation</u>