Being Open and Duty of Candour Policy and Procedure	
Author (s)	Philip Boynes – Quality Lead for Specialist Services, Health and Justice (Leeds Community Healthcare NHS Trust) Simon Boycott – Head of Development and Governance
Corporate Lead	
Document Version	1.0
Document Status	FINAL
Date approved by Quality, Performance & Finance Committee	8th July 2019
Date issued	9th July 2019
Review date	July 2020

Executive summary

This policy provides a best practice framework for the Leeds General Practice Confederation (the Confederation) to create an environment where patients, their representatives, healthcare professionals and managers feel supported in being open with all patients and services users regarding their care and treatment, particularly when things go wrong and they have the confidence to act appropriately.

This policy provides guidance for all staff employed by The Leeds General Practice Confederation including locum and agency staff on what is expected from them to ensure that the Confederation is meeting the requirements as set out in Regulation 20: Duty of Candour from the fundamental standards of care. (The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

The policy ensures that communication between the Confederation, healthcare organisations, healthcare teams, patients, and their relatives or carers is both honest and timely.

Changes made to this version:

Section	Detail of each change made

Contents

1 Introduction

The Leeds General Practice Confederation (the Confederation) seeks to promote a culture of openness, which is a pre requisite for improving patient safety and the quality of healthcare. This is in line with the Duty of Candour regulations, which place a requirement on registered providers of health and adult social care and to be open with patients when things go wrong, ensuring that honesty and transparency are the norm. This is a key recommendation from the Mid Staffordshire NHS Foundation Trust Public Inquiry (the Francis Inquiry) Francis Inquiry which became a statutory requirement for all Care Quality Commission (CQC) registered Trusts, from November 2014.

The principles of Being Open will apply to all patient safety incidents with the statutory Duty of Candour requirement being triggered where a patient suffers a notifiable safety incident resulting in moderate harm, major harm or death (see definition section 3) as a result of a regulated healthcare activity. The patient or their representative must be informed of the fact, an apology be given and an appropriate remedy and support is offered, whether or not a complaint has been made or a question asked about it.

Adherence to this policy and procedure will ensure that communication between the Confederation, healthcare teams, patients, and their representatives is both honest and timely. It will also ensure that all staff fulfil their responsibility under the duty of candour.

2 Scope

The scope of this document is organisation wide, and applies to all permanent, locum, agency, bank and voluntary staff working for The Leeds General Practice Confederation.
In line with national guidance the specific Duty of Candour process applies to patient safety incidents and complaints that occur during the provision of a regulated healthcare activity which has resulted in, or are suspected to have resulted in, moderate harm, severe harm or death. The deterioration in a patient condition that is part of the natural disease process would not trigger the duty of candour regulations.
No harm, including prevented near miss patient safety incidents, are outside the scope of the Duty of Candour statutory regulations but are part of the Being Open principles

3 Aims and Objectives

This policy/procedure sets out the appropriate processes for communicating with a patient or their representative following a notifiable patient safety incident and should be followed in conjunction with the Confederation Incident and Serious Incident Management Policy (including near misses). This encourages staff to report all patient safety incidents, including those where there was no harm or it was a prevented patient safety incident (near miss).

Adherence to the Being Open and Duty of Candour Policy and Procedure will help patients /representatives feel confident in the Confederation’s communication and provision of information and help healthcare professionals feel supported.

4 Definitions

Openness: enabling concerns and complaints to be raised freely without fear and questions asked to be answered.

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

A duty of candour : '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.

Notifiable safety incident: 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 healthcare professional, could result in, or appears to have resulted in: **The death of a service user**, **severe harm, moderate harm** or **prolonged psychological harm** (continuous period of at least 28 days) to the service user.

Near Miss: Is any event or circumstance that was prevented or narrowly avoided injury or harm, which could have had a detrimental impact.

No harm: The incident had potential to cause harm, but no harm was caused to the patient.

Minimal harm: Any patient safety incident that occurred where the patient required extra observation or minor treatment.

Moderate harm: Any patient safety incident that required a moderate increase in treatment **and** caused significant but not permanent harm.

Major harm: Any patient safety incident that appears to have resulted in permanent harm – related directly to the incident and not to the natural course of the patient's illness or underlying condition.

Death: Death must be related to the incident rather than the underlying condition or illness.

Unavoidable harm: "Unavoidable" means that the person receiving care experiences harm even though the provider of the care had evaluated the person's clinical condition and risk factors; planned and implemented interventions that are consistent with the persons needs and goals; and recognised standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate; or the individual person refused to adhere to prevention strategies in spite of education of the consequences of non-adherence.

Avoidable harm: Means harm that could have been prevented if the provider of care had evaluated the person's clinical condition and risk factors; or following the planned interventions that are consistent with the persons needs and goals; or followed recognised standards of practice

5 Responsibilities

The Trust's Chief Executive
The Trust's Chief Executive has overall responsibility for patient safety and must ensure that mechanisms are in place so that all staff are aware of this policy.

Medical Director
The Executive Director of Nursing has delegated authority from the Chief Executive to ensure there is a suitable process for the management of patient safety incidents and it is functioning in accordance with this Policy.

General Manager/Clinical Lead for each business unit. (BU)
Following a patient safety incident that triggers a serious incident (SI) it shall be the responsibility of the operational manager/clinical lead or nominated other to ensure that an appropriately experienced person is chosen to lead the incident investigation.

Complaints Manager
The complaints manager is responsible for promoting an open, honest and fair culture within the organisation when dealing with complaints and reporting any incidents (which become apparent during the course of a complaint) to the Incident and Assurance Manager.

Service Manager / Clinical Pathway Lead / Member of Portfolio leadership Team
Following a patient safety incident that does not trigger a serious incident it shall be the responsibility of the service manager/ clinical pathway lead etc. to ensure that an appropriately experienced person is chosen to lead on the investigation and agree who will lead on the initial being open conversations with patients. They will be responsible for ensuring that the duty of candour process is followed; that meetings happen preferably within 10 days of the incident being known. They will ensure that the process is responsive and accessible to patients /representative's needs. They will provide information on support available for staff. (This is available on the Confederation Intranet)

Senior Healthcare Professional /Team manager
The senior healthcare professional / team manager will be responsible for ensuring that all staff are aware of their responsibilities for the reporting of patient safety incidents and that learning from incidents is applied in practice. They should ensure that where a member of staff has been involved in a safety incident that they are provided with adequate support.

All Staff
All staff employed by The Leeds General Practice Confederation and those not directly employed such as; bank/agency staff, trainees on rotation and self-employed GP's must work in concordance with all Leeds Community Healthcare policies and procedures including Leeds Safeguarding multi-agency policies and procedures and local guidelines in relation to any safeguarding concerns they have for service users and the public with who they are in contact.

Staff are required to report suspected notifiable safety incidents or poor practice to their

line manager and via Datix® (also see Whistleblowing Policy)
Staff must be aware of their level of responsibility, in relation to ensuring that all communication with patients/representatives is open and honest. This is particularly important following an incident, compliant or claim. Staff must read this policy and understand their individual responsibilities.

6 Key Elements of Being Open

Effective communication with patients begins at the start of their care and should continue throughout their care. This should be no different when a patient safety incident occurs. Openness about what happened and discussing the incident promptly, fully and compassionately can help patients cope better with their experience. Patient safety incidents can incur extra costs through litigation and further treatment; openness and honesty can help prevent such events becoming formal complaints and litigation claims. Openness when things go wrong is fundamental to the partnership between patients and those who provide their care.

Being Open addresses these through ensuring that staff are clear about their duty to be honest, open and truthful in all their dealings with patients and the public and not allow organisational and personal interests to outweigh this duty.

For patients, Being Open is important because:

- it is the right thing to do
- acknowledgement is given to the distress the patient safety incident caused
- patients are more likely to understand what has happened if they are discussed fully, in a timely and thoughtful manner
- it can decrease the trauma felt by patients following a patient safety incident

For the Confederation, *Being Open* involves:

- acknowledging, apologising and explaining when things go wrong
- conducting a thorough investigation into the incident and reassuring patients/representatives that lessons learned will be embedded into practice which will help reduce the risk of reoccurrence
- providing support to patients to cope with the physical and psychological consequences of what happened

For healthcare staff, *Being Open* has several benefits, including:

- satisfaction that communication with patients / representatives following a patient safety incident is effective and appropriate
- improving the understanding of incidents from the perspective of the patient/representative
- the knowledge that lessons learned from incidents will help reduce the risk of them happening again
- having a good professional reputation for handling a difficult situation well and earning respect among peers and colleagues

See Appendix A ‘Ten Principles of Being Open’

7 Incident Detection or Recognition

The being open process begins with the recognition that a patient has suffered unintended harm. If the harm is **Moderate or above or they have died**, then this would trigger the duty of candour process. See definitions section 4 and process flowchart on the Confederation intranet.

A patient safety incident may be identified by:

- a member of staff (including agency staff etc) at the time of the incident;
- a member of staff retrospectively when an unexpected outcome is detected;
- a patient and/representatives who expresses concern or dissatisfaction with the patient's healthcare either at the time of the incident or retrospectively;
- incident detection systems such as incident reporting or medical records review;
- other sources such as detection by other patients, visitors or non-clinical staff.

As soon as a patient safety incident is identified, the priority is prompt and appropriate clinical care and prevention of further harm. Where additional treatment is required, this should occur whenever reasonably practicable after a discussion with the patient and with appropriate consent. The Incident and Serious Incident Management Policy must be implemented. This would include:

- acknowledgement of incident and a verbal apology given to the patient
- incident form completed via Datix®
- identify if Root Cause Analysis investigation is required
- identify if incident fulfils the criteria for reporting as a Serious Incident (SI)Root Cause Analysis being undertaken.

Patient safety incidents occurring elsewhere, including other healthcare organisations

A patient safety incident, that would trigger the duty of candour, may have occurred in another organisation, not the Confederation. The individual who first identifies the possibility of an earlier patient safety incident should escalate the incident, as per the the Confederation Incident and Serious Incident Management Policy. The clinical Governance Manager/Incident Assurance Manager will then contact their equivalent at the organisation where the incident occurred and establish whether:

- the patient safety incident has already been recognised;
- the process of Being Open has commenced;
- incident investigation and analysis is underway.

The duty of candour process and the investigation and analysis of a patient safety incident should normally occur in the healthcare organisation where the incident took place. The clinical Governance Manager/Incident Assurance Manager if agreed with the other organisation would be kept notified of the proceedings by the investigating organisation. The duty of candour process would be updated on Datix®.

Multi-Organisational Care

There are occasions in which patients are receiving care from more than one organisation at the time the incident occurs. It is crucial that an agreement is reached, between all organisations involved in providing care on who will lead the investigation and being open process. The Clinical Governance Manger/Incident Assurance manager will agree this.

Incident occurring in GP practices
Where it is identified that the incident occurred in a GP practice the member of staff identifying the incident must report this via the incident reporting process. The service clinical lead/service manager would make contact with the GP practice to establish whether:

- the patient safety incident has already been recognised;
- the process of Being Open has commenced;
- if incident investigation and analysis is underway.

Criminal or intentional unsafe act
Patient safety incidents are almost always unintentional. However, if at any stage following an incident it is determined that harm may have been the result of a criminal or intentional unsafe act, an executive director should be notified immediately.

8 Notification

Management

The clinician who discovers the incident should report it through their line manager and record the incident on Datix®. When an incident leads to major harm, or where a criminal act is suspected, reporting processes should be followed as outlined in the Incident and Serious Incident Management Policy.

General practitioner

It would be good practice to notify the patient's GP at an early time for incidents that have not occurred within primary care, but have implications for continuity of care'.

The Coroner

All cases of untimely, unexpected or unexplained death, or suspected unnatural deaths, need to be reported to the Coroner, this will be performed through the Incident and Serious Incident Management reporting process. Refer to incident policy.

A Coroner may request the case is not discussed with other parties until the facts have been considered. However this should not preclude a verbal and written apology or expression of regret where appropriate. In this situation it should be made clear to the family that a full discussion of the circumstances and any residual concerns will be arranged at a date to suit both parties, after the Coroner's assessment is finished. Or when coroner gives agreement.

Appendix C gives contact details for various support groups for families if needed.

Relevant statutory/other bodies

The Incident and Serious Incident Management Policy details which external agencies should be informed of a patient safety incident and when this should occur. The Confederation Compliance Manager is responsible for notifying relevant agencies such as the NHS Resolution and Medical Defence Organisations.

9 Initiating the Duty of Candour Process (Appendix B Special Circumstances)

Preliminary team discussion

The multidisciplinary team, where relevant, service clinical lead/service manager and most senior health professional involved in the patient safety incident, should meet/discuss as soon as possible after the event to:

- undertake a fact finding exercise including establishing the clinical facts. Complete 3 day fact find attached to Datix®;
- determine if the incident has been graded appropriately or if incident occurred due to delivery of care by another organisation and amend if required; See Duty of Candour Decision Making Process on the Confederation Intranet.
- assess the incident to determine the level of immediate response and if appropriate action has been taken;
- identify who will be responsible for discussion with the patient /representative and timeliness as may not always be appropriate to contact immediately.
- consider the appropriateness of engaging patient support at this early stage. This includes the use of a facilitator, a patient advocate or a healthcare professional who will be responsible for identifying the patient's needs and communicating them back to the healthcare team;
- establish whether an interpreter is required;
- identify immediate support needs for the healthcare staff involved;
- ensure there is a consistent approach by all team members around discussions with the patient /representative and healthcare professionals involved.

In addition to this, it will be an advantage to provide facilities for formal and informal debriefing of the clinical team involved in the patient safety incident, where appropriate, as part of the support system and separate from the requirement to provide statements for the investigation. Staff may also benefit from individual feedback about the final outcome of the patient safety incident investigation.

Managers should also provide information on the support systems currently available for professionals distressed by patient safety incidents. These include counselling services offered by their professional bodies and staff counselling service, stress management courses and mentoring for staff that have the responsibility for leading *Being Open* discussions/process.

Initial assessment to determine level of response

All incidents should be initially assessed using the definitions of the degree of harm on the Datix® incident form.

Grading of patient safety incidents to determine level of Open and Honest Care response and if this falls within the statutory Duty of Candour requirements

Incident	Level of response
No harm (including prevented near miss patient safety incidents)	Patients are not usually contacted or involved in investigations. Being open principles apply to no harm and prevented incidents but the Duty of candour regulations to not apply.
Low harm - short term injury resolved in about 1month	Unless there are specific indications or the patient requests it, the communication, investigation, 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/representative, **(if requested)** which should be recorded in the patient's records. Reporting to the incident management team will occur through standard incident reporting mechanisms, and 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. Being open principles apply to low harm incidents but the Duty of candour regulations to not apply.
Moderate harm – a moderate increase in treatment and significant but not permanent harm which includes, psychological harm for greater than 28 days	A high level of response is required in these circumstances. Being open discussions will normally take the form of an open discussion between a manager/clinical pathway lead etc. of the service, member of staff providing the patient's care and the patient, family member. • Apply the principles of Being Open. • Summary of Being Open communications should be documented on the incident system. **The Duty of Candour Policy and Procedure is implemented.**
Major harm or death – Long term or permanent harm, such as brain damage or disability.	A higher level of response is required in these circumstances. The lead director, or their deputy, should be notified immediately and be available to provide support and advice during the *Being Open* process if required. **The Duty of Candour Policy and Procedure is implemented.**

10 Choosing the individual to communicate with patients/representatives. The healthcare professional who informs the patient/representative about a patient safety incident

The patient may have already been informed of the suspected safety incident and received an initial verbal apology from the clinician providing their care at the time the incident was identified. Formal notification from the service needs to be verbal and ideally face to face. This should be made by one or more representatives from the service. (*Where partner organisations are involved there needs to be joint agreements which organisation will take the lead on the being open discussions*). This may be the clinical lead/service/team manager but including a clinician if possible. The NHS contract recommends that where possible this is the clinician responsible for the episode of care which resulted in the patient safety incident – the service manager should consider this on a case by case basis in consultation with the clinician and wishes of the patient/patient representative.

The person leading on the *Being Open* discussions (which is part of the duty of candour process for moderate harm incidents and above) should:

- where possible be known to, and trusted by, the patient /representatives.
- have a good understanding/knowledge of the facts relevant to the incident;
- be senior enough, or have sufficient experience and expertise in relation to the type of patient safety incident to be credible to patients/representative and colleagues;
- have excellent interpersonal skills, including being able to communicate with patients/representatives in a way they can understand and avoiding excessive use of medical jargon;
- where medical jargon is referenced, explanation should be included;
- be willing and able to offer an apology, reassurance and feedback to patients /representatives in a truthful, timely and clear manner;
- be able to maintain a medium to long term relationship with the patient /representatives, where possible, and to provide continued support and information;
- be culturally aware and informed about the specific needs of the patient /representatives. See appendix B for further guidance.

Use of a substitute healthcare professional for the Being Open discussion

In exceptional circumstances, if the healthcare professional or senior manager who usually leads the Being Open discussion cannot attend, they may delegate to an appropriately experienced substitute. The qualifications, training, scope of responsibility and experience of this person should be clearly identified. This is essential for effective communication with the patient /representative without jeopardising the rights of the healthcare professional, or their relationship with the patient.

Consultation with the patient regarding the healthcare professional leading the Being Open discussion

If, for any reason it becomes clear during the initial discussion that the patient would prefer to speak to a different healthcare professional, the patient’s wishes should be respected. A substitute, with whom the patient is satisfied, should be provided.

Patient safety incidents related to the environment of care

In such cases a senior manager of the relevant service will be responsible for communicating with the patient /representative. A senior member of the multidisciplinary team should be present to assist at the initial *Being Open* discussion. The healthcare professional responsible for treating the injury should also be present, to assist in providing information on what will happen next and the likely effects of the harm.

Involving healthcare staff who made mistakes

Some patient safety incidents that result in moderate harm, severe harm or death will result from errors made by healthcare staff whilst caring for the patient. In these circumstances the member(s) of staff involved may or may not wish to participate in the *Being Open* discussion with the patient /representatives. Every case where an error has occurred needs to be considered individually, balancing the needs of the patient /representative with those of the healthcare professional concerned. In cases where the healthcare professional who has made an error wishes to attend the discussion to apologise personally, they should feel supported by their managers throughout the meeting. In cases where the patient/representative expresses a preference for the healthcare professional not to be present, it is advised that a personal written apology is handed to the patient /representative during the first *Being Open* discussion.

For further supporting information see Appendix A “Ten Principles of Being Open”

11 Timing

The initial being open discussion with the patient /representative should occur as soon as reasonably practicable after recognition of the patient safety incident. Factors to consider when timing this and follow up discussion include:

- clinical condition of the patient. Some patients may require more than one meeting to ensure that all the information has been communicated to and understood by them;
- availability of key staff involved in the incident and in the duty of candour process;
- availability of the patient’s /representative;
- availability of support staff, for example a translator or independent advocate, if required;
- patient preference (in terms of when and where the meeting takes place and who leads the discussion);
- privacy and comfort of the patient;
- arranging the meeting in a sensitive location.

12 Communications with the patient/representative

Where the patient/representative cannot be contacted or they decline to speak with the service, then the service will **not** be required to:

- notify the patient/representative of the incident
- provide an apology
- provide support
- provide a report of the incident findings.

The service must keep records of all attempts to contact or speak with the patient. These should be recorded in Datix® and the patient’s health record.

Content of the initial *Being Open* discussion with the patient or their representatives.

Ideally this conversation should be face to face. However with the patient's /representatives agreement this conversation can take place over the phone. If the patient is unable to participate, or has died, then their representatives may be provided with information in order to make decisions, but this should be done with regard to confidentiality and any patient instructions. Carers and people close to the patient can be referred to the Coroner for more information. The patient/representative should also be given a leaflet on the *Being Open* / Duty of candour process so that they know what to expect.

- The patient/ representative should be advised of the identity and role of all people attending the Being Open discussion before it takes place. This allows them the opportunity to state their own preferences about which staff should be present. If the patient does not wish to attend a meeting but prefers to communicate by phone they should be informed of the lead investigators name and role.
- There should be an expression of genuine sympathy, regret and an apology for the harm that has occurred.
- The known facts are shared with the patient. Where these are disputed, communication about these events should be deferred until after the investigation has been completed.
- It should be made clear to the patient /representative that new facts may emerge as the incident investigation progresses.
- The patient's/representatives understanding of what happened should be taken into consideration, as well as any questions they may have.
- There should be consideration and formal noting of the patient's/representatives views and concerns, and demonstration that these are being heard and taken seriously.
- Appropriate language and terminology should be used when speaking to patients /representatives. For example, using the terms 'patient safety incident' or 'adverse event' may be meaningless, or insulting, to a patient /representative. If a patient's/representatives first language is not English, or they have other additional communication requirements, these needs should be addressed, as well as providing information in both verbal and in written formats.
- An explanation should be given about what will happen next in terms of the long term treatment plan.
- They will have the opportunity to be informed of the incident analysis and findings.
- Information on likely short and long term effects of the incident (if known) should be shared. The latter may have to be delayed to a subsequent meeting when further information may be known. Some patients may not wish to know every detail of an incident. They should be reassured that if they change their minds, this information will be made available to them.
- An offer of practical and emotional support should be made to the patient /representative. This may involve giving information on third parties such as charities and voluntary organisations to the patient/representative, as well as offering more direct assistance. Information about the patient and the incident should not normally be disclosed to third parties without the patient's consent.

The patient may not wish third parties to know every detail of the incident. See Appendix C for a list of support groups.

- The patient/representative should be given the contact details of one member of staff who will act as a contact point for them. Their role will be to provide both practical and emotional support in a timely manner.
- It should be explained to the patient that they are entitled to continue to receive all usual treatment and continue to be treated with respect and compassion. If a patient expresses a preference for their healthcare needs to be taken over by another team, the appropriate arrangements should be made for them to receive treatment with another clinician.
- Patients/representatives should be given information on the complaints procedure, and offered assistance if they wish to make a complaint.
- It should be recognised that patients/representatives may be anxious, angry and frustrated at any stage of the being open process.

It is essential that the following does not occur:

- speculation
- attribution of blame
- denial of responsibility
- provision of conflicting information from different individuals.

The initial *Being Open* discussion is the first part of an ongoing communication process. There should be repeated opportunities for the patient /representative to obtain information about the incident and many of the points raised here should be expanded on in subsequent meetings/conversations. The Reportable Patient Safety Incident Initial Discussion Pro-forma can be used to record the initial discussion (Appendix D).

Certain patient groups or circumstances will require a different approach. See Appendix B for guidance.

Following the initial meeting / conversation an acknowledgment letter must be sent to the patient unless they have explicitly asked for no written communication.

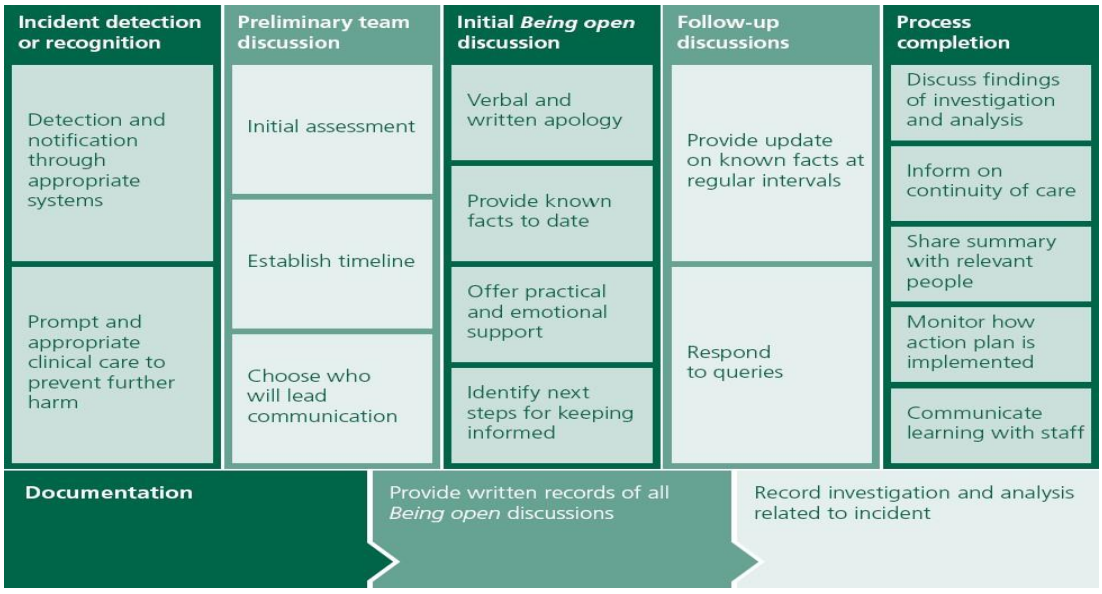
13 Follow-up/closure Meeting (if requested)

The follow-up/closure meeting with the patient /representatives is an important step in the Duty of candour process. The following guidelines should assist in making the communication effective:
this meeting should occur within 10 working days of the incident investigation being completed and finally approved on Datix®. Where this is an SI within 10 working days of the report being submitted to the commissioners.

- the patient/representative will be provided with a summary of the findings report into the incident if this is the final meeting. See final apology letter and summary of investigation findings on the Confederation Intranet.
- there should be no speculation or attribution of blame. Similarly, the healthcare professional communicating with the patient/representative must not criticise or comment on matters outside their own experience;
- the patient /representative should be offered an opportunity to discuss the situation with another relevant professional where appropriate;

- details of the patient's representatives concerns/queries and complaints should be covered;
- If this is not the final meeting a written record of the discussion should be kept and shared with the patient and/or their carers;
- a repeated apology for the harm suffered and any shortcomings in the delivery of care that led to the patient safety incident must be given.
- information on what has been and will be done to avoid recurrence of the incident, and how these improvements will be shared and monitored should be given.
- The patient/representatives should be asked if they are satisfied with the investigation and a note of this made in the patient's records; under Quick note and progress notes on Datix®. If they are unhappy with the outcome of the investigation they should be given the details of the complaints team.
- the patient should be provided with contact details, so that if further issues arise later there is a conduit back to the relevant healthcare professionals or an agreed substitute.
- It is expected that in most cases there will be a complete discussion of the findings of the investigation and analysis. In some cases information may be withheld or restricted, for example, where communicating information will adversely affect the health of the patient; where investigations are pending coronial processes; or where specific legal requirements preclude disclosure for specific purposes. If you consider that information needs to be withheld then you **must** get guidance from Information Governance or/ legal advice before restricting and / or withholding information.

Overview of Duty of Candour Process



14 Documentation

General

The communication of patient safety incidents must be recorded. Required documentation includes:

- a copy of relevant medical information, which should be filed in the patient's medical records;
- incident reports;
- records of the investigation and analysis process.

The incident report and record of the investigation and analysis process will be recorded on Datix®.

The initial incident will be reported using the procedures detailed within the Incident and Serious Incident Management Policy and will be recorded on Datix® and reported to NHS England through the National Reporting and Learning System (NRLS).

Written records of discussion held under the Duty of candour process

There should be documentation of:

- the time, place, date, as well as the name and relationships of all attendees;
- the plan for providing further information to the patient/representatives;
- offers of assistance and the patient/representatives
- questions raised by the patient/representatives and the answers given.
- plans for follow-up as discussed;
- progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient and/or their carers;
- copies of letters sent to patients, representatives and the GP for patient safety incidents not occurring within primary care;
- copies of any statements taken in relation to the patient safety incident;
- a copy of the incident report.
- any action plans developed following any learning identified

A summary of the discussions held should be shared with the patient. All documentation should be stored in line with the Confederation Records Management Policy including Health Care Records Keeping Guidance.

All incidents that trigger the formal Duty of Candour process will have this documented within the Datix® incident record to enable monitoring of compliance with the statutory requirements.

15 Continuity of care & the provision of additional support

When a patient has been harmed during the course of treatment and requires further therapeutic management or rehabilitation, they should be informed, in an accessible way, of the ongoing clinical management plan. This may be encompassed in discharge planning policies addressed to designated individuals, such as the referring GP when the patient safety incident has not occurred within the Confederation.

Patients/representative should be reassured that they will continue to be treated according to their clinical needs, even in circumstances where there is a dispute between them and the healthcare team. They should also be informed that they have the right to continue their treatment with another the Confederation team, where this is appropriate, if they have lost confidence in the healthcare team involved in the patient safety incident.

16 Staff Support

Systems are in place to assist staff during the investigation of a potential incident, complaint and claim and all members of staff must be informed about the support and counselling service available from the Occupational Health Department. Any member of staff involved in the investigation of a claim will be kept informed of the progress of an investigation. Staff should be provided with support which could include:

- **Immediate support –** Via line managers and counselling service
- **Ongoing support –** Counselling service and Occupational Health
- **Advice –** from staff side, human resources and professional bodies

It is not the intention of the investigation process to assess whether disciplinary action against an individual member of staff should be considered. However, if, as a result of the investigation, there is evidence of a breach of the law, professional misconduct, or repetitive incidents, further action may be taken. In these circumstances, the appropriate senior manager will decide whether the disciplinary procedure should be invoked. Further advice is contained in the the Confederation Disciplinary Policy and Procedure.

17 Monitoring of Improvement Plans

Any recommendations for systems improvements and changes implemented will be detailed in an action plan, which will be linked to the incident on Datix®. See “Incident and Serious Incident Management Policy” for monitoring. The learning and action plan will have been shared with the patient/patient representative and recorded on Datix®.

Communication of changes to staff

Effective communication with staff is a vital step in ensuring that recommended changes are fully implemented and monitored. It will also facilitate the move towards increased awareness of patient safety issues and the value of *Being Open*. Team meetings; newsletters and the Trust web site are all available to help communicate with staff.

Communication of lessons learned throughout the health service

NHS England will publish patient safety alerts, safer practice notices and patient safety information notices through the Central Alert System to highlight common factors that cause patient safety incidents, and to publicise its advice and solutions to the service. The primary aim will be to help reduce the risk of such incidents recurring.

18 Training Needs

All new staff will receive duty of candour briefing at Trust induction.
Additional e-learning training is available via staff ESR e-learning account.
Search “being open”

19 Risk Assessments

Any risks need to be managed and mitigated in line with the associated documents which support this policy and are listed towards the end of this document (page 19).

20 Mental Capacity Act (MCA 2005 Code of Practice)

This Act applies to all persons over the age of 16 who are judged to lack capacity to consent or withhold consent to acts which are considered by health and social care professionals to be in the best interests of their welfare and health.

The Mental Capacity Act 2005 imposes a legal requirement on health and social care professionals to 'have regard to' relevant guidance within the Code of Practice when acting or making decisions on behalf of someone who lacks capacity to make the decision for themselves. Furthermore, they should be able to explain how they had regard to the Code when acting or making decisions.
See appendix B for further information.

For further information see the Leeds Community Healthcare (the Confederation) Intranet.

21 Deprivation of Liberty (DoLs)

In March 2014 it was ruled that a person without capacity is deprived of their liberty if they are both subject to continuous supervision and control and unable to leave.

Any deprivation of liberty of a person who lacks capacity has to be carried out in accordance with law. If a the Confederation staff member is aware of anyone they believe is or is likely to be deprived of their liberty, they must act in accordance with the MCA policy and DoL's guidance or they must discuss their concerns with a member of the Adult Safeguarding Team.

For further information on the MCA 2005 or on Deprivation of Liberty see the the Confederation Intranet or speak to the Named Nurse MCA/DoLs, Dementia or one of the MCA Champions.

22 Safeguarding

This policy describes the roles and responsibilities for the Trust in relation to the safeguarding of children and young people. All provider organisations commissioned by NHS Leeds Clinical Commissioning Groups (CCG's) have a responsibility to ensure they meet the agreed standards for Section 11 of the Children Act 2004, and statutory guidance outlined in Working Together to Safeguard Children 2013.

They are expected to follow the multi-agency procedures, comply with this policy and assist in taking the necessary action to safeguard children experiencing or at risk of abuse.
The CCG's have a duty to take reasonable care to ensure the quality of the services commissioned. It is an expectation that all provider organisations, including Leeds Community Healthcare, demonstrate robust safeguarding systems and safe practice within agreed local multi-agency procedures.

The Children Acts of 1989 and 2004 and the statutory guidance Working Together to Safeguard Children (2013) set out the safeguarding principles for and promoting the welfare of children and young people.

Working Together to Safeguard Children (2013, page 7) defines safeguarding children and young people as:

- Protecting from maltreatment
- Preventing impairment of health and development
- Ensuring that children and young people are growing up in circumstances consistent with the provision of safe and effective care; and
- Taking action to enable all children to have the best outcomes

The Children Act 2004 emphasises that we all share a responsibility to safeguard children and young people.

For further information see the the Confederation Intranet.

23 Monitoring Compliance and Effectiveness

Minimum requirement to be monitored / audited	Process for monitoring / audit	Lead for the monitoring/audit process	Frequency of monitoring / auditing	Lead for reviewing results	Lead for developing / reviewing action plan	Lead for monitoring action plan
For all moderate harm incidents and above recording if duty of candour applies and if initial apology given	Datix® reports	QPF Committee	Monthly	QPF Committee	Service Managers	QPF Committee
Where an initial apology has not been given that a documented reason is recorded.	Datix® reports	QPF Committee	Monthly	QPF Committee	Service Managers	QPF Committee
The final apology letter and summary report have been passed to the patient / representative within 10 days of investigation being signed off	Datix® reports	QPF Committee	Monthly	QPF Committee	Service Managers	QPF Committee

24 Approval and Ratification process

The policy has been approved by the Clinical and Corporate Policy Group and ratified by the Quality Committee on behalf of the Board.

25 Dissemination and Implementation

Dissemination of this policy will be via the Clinical and Corporate Policy Group to services and made available to staff via the intranet.
Implementation will require:

- Operational Directors/ Heads of Service/General Managers to ensure staff have access to this policy and understand their responsibilities for implementing it into practice
- The Quality and Professional Development and workforce Department will provide appropriate support and advice to staff on the implementation of this policy
- This policy will be discussed at induction sessions.

26 Review arrangements

This policy will be reviewed in three years following ratification by the author or sooner if there is a local or national requirement.

27 Associated documents

Incident and Serious Incident Policy
Consent to Examination or Treatment Policy
Disciplinary Policy and Procedure
Whistle-blowing Policy
Managing Concerns with Performance Policy
Records Management Policy
Risk Management Policy
Patient Experience Policy

These policies are available on the Confederation Website

28 References

Care Quality Commission (2015) Regulation 20: Duty of candour Information for all providers: NHS bodies, adult social care, primary medical and dental care, and independent healthcare http://www.cqc.org.uk/sites/default/files/20150327_duty_of_candour_guidance_final.pdf

Mid Staffordshire NHS Foundation Trust Public Inquiry (2013) Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, Chaired by Sir Robert Francis QC https://www.gov.uk/government/publications/report-of-the-mid-staffordshire-nhs-foundation-trust-public-inquiry

National Patient Safety Agency (2009). *Being Open.* Available at www.npsa.nhs.uk http://www.nrls.npsa.nhs.uk/beingopen/?entryid45=83726

National Patient Safety Agency (2004). *Seven Steps to Patient Safety. The Full Reference Guide.* Available at www.npsa.nhs.uk/sevensteps
http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/

National Health Service Litigation Authority (2002). Litigation Circular No: 02/02. *Apologies and Explanations.* Issued 11 February 2002.
http://www.nhsla.com/Claims/Documents/Saying sorry.doc

National Patient Safety Agency (2005) Patient Briefing, Being Open – 'saying sorry when things go wrong
http://www.npsa.nhs.uk/EasysiteWeb/getresource.axd?AssetID=1027&type=Full...

Lincolnshire Community health Services NHS Trust. Policy "Open and Honest care (incorporating Duty of candour)" September 2017
https://www.lincolnshirecommunityhealthservices.nhs.uk/application/files/7515/1782/7875/P_CIG_16_Open_and_Honest_Care.pdf

Southern Health NHS Foundation Trust. "The Being Open Policy (incorporating the legal Duty of Candour) Version: 4 November 2017
http://www.southernhealth.nhs.uk/about/policies/?entryid41=69172&q=0~candour~

NHS Service Contract Service Conditions 2017/2019
https://www.england.nhs.uk/nhs-standard-contract/17-19-updated/.

National Reporting and Learning Service, National Patient Safety Agency
November 2009 Saying sorry when things go wrong, Being Open, Communicating patient safety incidents with patients, their families and carers
http://www.nrls.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=65172

2014 No. 000 NATIONAL HEALTH SERVICE, ENGLAND SOCIAL CARE, ENGLAND PUBLIC HEALTH, ENGLAND.
The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
https://www.legislation.gov.uk/uksi/2014/2936/contents/made

NPSA 2005 Being Open; Communicating Patient Safety Incidents with patients and their carers. (The 10 Principles) Click here

Appendix A

Ten Principles of Being Open

Being Open is a process rather than a one-off event. With this in mind, the following principles apply to support the policy.

I. **Principle of acknowledgement**

All patient safety incidents should be acknowledged and reported as soon as they are identified. In cases where the patient and/or their carers inform healthcare staff when something untoward has happened, it must be taken seriously from the outset. Any concerns should be treated with compassion and understanding by all healthcare staff. Denial of a patient's concerns will make future open and honest communication more difficult.

II. **Principle of truthfulness, timeliness and clarity of communication**

Information about a patient safety incident must be given to patients /representatives in a truthful and open manner by an appropriately nominated person. Patients/representatives want a step-by-step explanation of what happened, that considers their individual needs and is delivered openly.

Communication should also be timely; patients and/or their carers should be provided with information about what happened as soon as practicable. It is also essential that any information given is based solely on the facts known at the time. Healthcare staff should explain that new information may emerge as an incident investigation is undertaken, and patients and/or their carers should be kept up-to-date with the progress of an investigation.

Patients and/or their carers should receive clear, unambiguous information and be given a single point of contact for any questions or requests they may have. They should not receive conflicting information from different members of staff. Medical jargon, which they may not understand, should be avoided.

III. **Principle of apology**

Patients and/or their carers should receive a sincere expression of sorrow or regret for the unintended harm that has resulted from a patient safety incident. This should be in the form of an appropriately worded apology, as early as possible.

Both verbal and written apologies should be given. The decision on which staff member should give the apology should consider seniority, relationship to the patient, and experience and expertise in the type of patient safety incident that has occurred.

Verbal apologies are essential because they allow face-to-face contact between the patient and/or their carers and the healthcare team. This should be given as soon as staff are aware an incident has occurred. It is important not to delay for any reason; including setting up a more formal multidisciplinary *Being Open* discussion with the patient and/or their carers, fear and apprehension, or lack of staff availability. Delays are likely to increase the patient's and/or their carer's sense of anxiety, anger or frustration. A written apology, which clearly states the healthcare organisation is sorry for the suffering and distress resulting from the incident, must also be given. An apology is not an admission of liability.

IV. **Principle of recognising patient and carer expectations**

Patients and/or their 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. They should be treated sympathetically, with respect and consideration. Confidentiality must be

maintained at all times. Patients and/or their carers should also be provided with support in a manner appropriate to their needs. This involves consideration of special circumstances that can include a patient requiring additional support, such as an independent patient advocate or a translator.

When appropriate, information on accessing the Patient Advisory and Liaison Service (PALS) and other relevant support groups like Cruse Bereavement Care and Action against Medical Accidents (AvMA) should be given to the patient as soon as it is possible.

V. Principle of professional support

The Trust supports an environment in which all staff are encouraged to report patient safety incidents. Managers should ensure that staff feel supported throughout the incident investigation process, as they too may have been traumatised by being involved. They should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration.

To ensure a robust and consistent approach to incident investigation, the NPSA's Incident Decision Tree (IDT) has been developed as an aid to improve the consistency of decision making about whether human error or systems failures contributed to an incident. It is designed for use by anyone who has the authority to exclude a member of staff from work following a patient safety incident, (including medical and nursing directors, chief executives and human resources staff). More details can be found in Seven Steps to Patient Safety and on the NPSA website: www.npsa.nhs.uk

Where there is reason for the Trust to believe a member of staff has committed a punitive or criminal act, the Trust will take steps to preserve its position, and advise the member(s) of staff at an early stage to enable them to obtain separate legal advice and/or representation. Staff will also be encouraged to seek support from relevant professional bodies such as the General Medical Council, Nursing and Midwifery Council. Health Professions Council, Royal Colleges, the Medical Protection Society, the Medical Defence Union, etc.

VI. Principle of risk management and systems improvement

Root cause analysis (RCA) should be used to uncover the underlying causes of a patient safety incident. Investigations should focus on improving systems of care, which will then be reviewed for their effectiveness.

VII. Principle of multidisciplinary responsibility

This principle applies to all staff who have key roles in the patient's care. Most healthcare provision involves multidisciplinary teams and communication with patients and/or their carers following an incident that led to unintended harm, should reflect this. This will ensure that the *Being Open* process is consistent with the philosophy that incidents usually result from systems failures and rarely from the actions of an individual.

VIII. Principle of clinical governance

Being Open has the support of patient safety, risk management and quality improvement processes through the clinical governance framework, in which patient safety incidents are investigated and analysed, to find out what can be done to prevent their recurrence. It also involves a system of accountability through the Chief Executive to the Board to ensure these changes are implemented and their effectiveness reviewed. The findings are disseminated to staff so that they can learn from patient safety incidents.

IX. Principle of confidentiality

Full respect should be given to the patient's and/or their carer's and staff's privacy and confidentiality. Details of a patient safety incident 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. Where this is not practicable or an individual refuses to consent to the disclosure, disclosure may still be lawful if justified in the public interest, or where those investigating the incident have statutory powers for obtaining information. Communications with parties outside of the clinical team should also be on a strictly need-to-know basis and, where practicable, records should be anonymous. In addition, it is good practice to inform the patient and/or their carers about who will be involved in the investigation before it takes place and give them the opportunity to raise any objections.

X. Principle of continuity of care

Patients are entitled to expect they will continue to receive all usual treatments and continue to be treated with respect and compassion. If a patient expresses a preference for their healthcare needs to be taken over by another team, the appropriate arrangements should be made for them to receive treatment elsewhere.

Appendix B

SPECIAL CIRCUMSTANCES

The approach to *Being Open* may need to be modified according to the patient's personal circumstances.

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.

Usually, the *Being Open* discussion and any investigation occur before the Coroner's inquest, if applicable. However, in certain circumstances the healthcare organisation may consider it appropriate to wait for the Coroner's inquest before holding the *Being Open* discussion with the patient's family and/or carers. The Coroner's report on post-mortem findings is a key source of information that will help to complete the picture of events leading up to the patient's death. In any event, an apology should be issued as soon as possible after the patient's death, together with an explanation that the Coroner's process has been initiated and a realistic timeframe of when the family and/or carers will be provided with more information.

Children

The legal age (with capacity) 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. However, 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 *Being Open* process after a patient safety incident. The opportunity for parents to be involved should still be provided unless the child expresses a wish for them not to be present.

Where children are deemed not to have sufficient maturity or ability to understand, consideration needs to be given as to whether information is provided to the parents alone or in the presence of the child. In these instances the parents' views on the issue should be sought. More information can be found on the Department of Health's website: www.dh.gov.uk

Patients with mental health issues

Being Open for patients with mental health issues should follow normal procedures, unless the patient also has cognitive impairment (see below). The only circumstances in which it

is appropriate to withhold patient safety incident information from a mentally ill patient, is when advised to do so by a consultant psychiatrist who feels it would cause adverse psychological harm to the patient. However, such circumstances are rare and a second opinion (by another consultant psychiatrist) would be needed to justify withholding information from the patient. 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.

Patients 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. The *Being Open* 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.

Patients with learning disabilities

Where a patient 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 *Being Open* 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 *Being Open* process, focusing on ensuring that the patient's views are considered and discussed.

Patients who do not agree with the information provided

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

- deal with the issue as soon as it emerges;
- where the patient agrees, ensure their carers are involved in discussions from the beginning;
- ensure the patient has access to support services;
- where the senior health professional is not aware of the relationship difficulties; provide mechanisms for communicating information, such as the patient expressing their concerns to other members of the clinical team and/or offer the patient and/or their carers another contact person with whom they may feel more comfortable. This could be another member of the team or the individual 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 to look for a mutually agreeable solution;

- ensure the patient and/or their carers are fully aware of the formal complaints procedures;
- write a comprehensive list of the points that the patient and/or their carer wish to raise and these will be addressed and fedback.

Patients with a different language or cultural considerations

The need for translation and advocacy services, and consideration of special cultural needs (such as for patients from cultures where it is 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.

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

Patients in Police Custody Suits and the Prison Service
Communication with these patients would be led by the relevant police/prison liaison officer.

Appendix C

SUPPORT GROUPS

Support for patients

Leeds Bereavement Forum
http://www.lbforum.org.uk/module_directory/

Leeds Palliative Care
http://www.leedspalliativecare.co.uk/patients-and-carer-information/bereavement/

Survivor Led Crisis Service
http://www.lslcs.org.uk/how-can-we-help including Connect helpline 0808 800 1212

Carers Leeds
http://www.carersleeds.org.uk/

And nationally:
http://www.nhs.uk/Livewell/bereavement/Pages/bereavement.aspx

Helplines Partnership
https://helplines.org/helplines/ has carers and bereavement info

Cruse Bereavement Care
http://www.cruse.org.uk/Leeds-area

Appendix D

Duty of Candour
Initial being open conversation with patients

Datix Number: _____
Date, Time and Location of Conversation: _____

Summary of Incident
_____
_____

Who is present at this meeting
_____
_____
_

Name of Patient:	DOB
Who was informed: Patient/Patient representative (please circle as appropriate) (If discussing with patient representative please ensure you have obtained consent from patient if they have capacity?)	NHS Number
If patient representative please add name/address/contact details:	
Describe a summary of what has been said to the patient or representative ensuring an appropriate apology is offered:	
Offers of assistance and the patient's/service user's and/or carer's response	
Questions raised by the family and/or carers or their representatives and the answers given.	
Does the patient/representative wish to have written notification that the incident has occurred? (Please ensure that a copy of the written notification is attached to the Datix if requested)	
Does the patient/representative wish to be informed as the investigation continues of the findings?	
If the answer is yes Plans for follow-up as discussed.	
Does the patient want a written copy of the investigation once complete?	

Print name _____

Policy Consultation Process

Title of Document	Being Open and Duty of Candour Policy and Procedure.
Author (s)	
New / Revised Document	
Lists of persons involved in developing the policy	
List of persons involved in the consultation process	