NLG(18)065

DATE OF MEETING	**27 February 2018**
REPORT FOR	**Trust Board of Directors – Public**
REPORT FROM	**Wendy Booth, Director of Governance & Assurance and Trust Secretary**
CONTACT OFFICER	**Kelly Burcham, Head of Risk**
SUBJECT	**Being Open & Duty of Candour Policy (communicating with patient and / or their relatives / carers following a patient safety incident)**
BACKGROUND DOCUMENT (IF ANY)	**Francis Inquiry** **NGO Case Review**
PURPOSE OF THE PAPER:	**For Approval**
EXECUTIVE SUMMARY **(PLEASE INCLUDE A BRIEF SUMMARY OF THE PAPER, KEY POINTS & ANY RISK ISSUES AND MITIGATING ACTIONS WHERE APPROPRIATE)**	**The paper provides the revised Being Open & Duty of Candour Policy following annual review** **Amendments to the policy are highlighted and include reference to the Freedom to Speak Up Guardian and Associate Guardians as another source of support for staff involved in or who report a patient safety or other incident**
HAVE STAFF SIDE BEEN CONSULTED ON THE PROPOSALS?	**N/A**
HAVE THE RELEVANT SERVICE USERS/CARERS BEEN CONSULTED ON THE PROPOSALS?	**N/A**
ARE THERE ANY FINANCIAL CONSEQUENCES ARISING FROM THE RECOMMENDATIONS?	**NO**
IF YES, HAVE THESE BEEN AGREED WITH THE RELEVANT BUDGET HOLDER AND DIRECTOR OF FINANCE, AND HAVE ANY FUNDING ISSUES BEEN RESOLVED?	**N/A**
ARE THERE ANY LEGAL IMPLICATIONS ARISING FROM THIS PAPER THAT THE BOARD NEED TO BE MADE AWARE OF?	**NO**
WHERE RELEVANT, HAS PROPER CONSIDERATION BEEN GIVEN TO THE NHS CONSTITUTION IN ANY DECISIONS OR ACTIONS PROPOSED?	**N/A**
WHERE RELEVANT, HAS PROPER CONSIDERATION BEEN GIVEN TO SUSTAINABILITY IMPLICATIONS (QUALITY & FINANCIAL) & CLIMATE CHANGE?	**N/A**
THE PROPOPSALS OR ARRANGEMNTS OUTLINED IN THIS PAPER SUPPORT THE ACHIEVEMENT OF THE TRUST OBJECTIVE(S)	**YES**
THE PROPOSAL OR ARRANGEMENTS OUTLINED IN THIS PAPER ENSRE COMPLIANCE WITH THE REGULATORY OR GOVERNANCE REQUIREMENTS LISTED	**Ensures top level commitment to being open and the duty of candour**

THE PROPOSALS OR ARRAGEMENTS OUTLINED IN THIS PAPER TAKE ACCOUNT OF REQUIREMENTS IN RESPECT OF EQUALITY & DIVERSITY	**YES**
ACTION REQUIRED BY THE BOARD	**The Board is asked to approve the revisions to the policy**

Northern Lincolnshire and Goole NHS Foundation Trust

Directorate of Governance and Assurance

BEING OPEN AND DUTY OF CANDOUR POLICY (COMMUNICATING WITH PATIENTS AND / OR THEIR RELATIVES / CARERS FOLLOWING A PATIENT SAFETY INCIDENT)

Reference:	DCP043
Version:	
This version issued:	
Result of last review:	
Date approved by owner (if applicable):	
Date approved:	
Approving body:	Trust Board
Date for review:	
Owner:	Wendy Booth, Director of Governance & Assurance
Document type:	Policy
Number of pages:	22 (including front sheet)
Author / Contact:	Wendy Booth, Director of Governance & Assurance

Northern Lincolnshire and Goole NHS Foundation Trust actively seeks to promote equality of opportunity. The Trust seeks to ensure that no employee, service user, or member of the public is unlawfully discriminated against for any reason, including the "protected characteristics" as defined in the Equality Act 2010. These principles will be expected to be upheld by all who act on behalf of the Trust, with respect to all aspects of Equality.

Contents

1.0 Introduction & Purpose

1.1 Each day more than a million people are treated safely in the NHS. Occasionally, however, something goes wrong and a patient is harmed (this is often referred to as an adverse incident or a patient safety incident). Healthcare staff may feel cautious about apologising for things that go wrong as they worry that they might say the wrong things, make the situation worse and/or may be blamed for the mistake. This policy has been designed to assist staff within the Trust to be more open with patients and/or their carers following such incidents and provides some useful guidance on the points to consider.

1.2 'Being open' simply means apologising and explaining what happened to patients and/or their carers who have been involved in a patient safety incident and which may or may not result in a complaint or claim. Communicating openly and effectively with patients and/or their carers is a vital part of the process of dealing with errors or problems in their treatment and can also decrease the trauma felt[1]. Research has shown that patients will forgive medical errors when they are disclosed promptly, fully and compassionately[2] and such an approach can even reduce the likelihood of a subsequent complaint or claim.

1.3 Openness also has benefits for healthcare staff. These include satisfaction that communication with patients and/or their carers has been handled in the most appropriate way; developing a good professional reputation for handling a difficult situation properly; and improving their understanding of incidents from the perspective of the patient and/or their carers. Openness is also beneficial for the reputation of the healthcare organisation.

1.4 This policy is based on the NPSA's Being Open Policy, the principles of which are fully supported by a wide range of royal colleges and professional organisations and, is consistent with the Department of Health's 2003 'Making Amends' consultation document, which states, "The individual who has suffered harm as a result of the healthcare they have received must get an apology". This should be regardless of whether the patient goes on to complain or claim.

1.5 A duty of candour (to be open with patients about harm caused) is now also included as a statutory obligation in the NHS Standard Contract. This arises from the report and recommendations of Robert Francis QC into the failings at Mid Staffordshire. The contract requires NHS Trusts to ensure that 'patients/their families are told about patient safety incidents that affect them, receive appropriate apologies, are kept informed of investigations and are supported to deal with the consequences'. The duty applies to patient safety incidents that occur during care provided under the NHS Standard Contract and that result in moderate, severe harm or death. The NHS definitions of harm are:

- **Moderate Harm:** Any patient safety incident that requires a moderate increase in treatment (unplanned return to surgery, an unplanned readmission, 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) and which caused significant but not permanent harm. Prolonged psychological harm (means psychological harm which a service

[1] C. Vincent. 'Caring for patients harmed by treatment' Qua; Health Care. 1995;4:144-150
[2] Crane M. 'What to say if you've made a mistake' Medical Economics. 2001;78(16):26-8, 33-6

user has experiences , or is likely to experience, for a continuous period of at least 28 days)

- **Severe Harm:** Any patient safety incident that appears to have resulted in permanent harm (permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of wrong limb or organ or brain damage)

- **Death:** Any patient safety incident that directly resulted in the death (related to the incident rather than to the natural course of the patient's illness or underlying condition) of one or more persons

1.6 The Francis Inquiry report also outlined that the provision of information in compliance with this requirement should not of itself be evidence or an admission of any civil or criminal liability, but non-compliance with the statutory duty should entitle the patient to a remedy."

1.7 The recommendations from the Francis Inquiry report are attached at **Appendix A**.

1.8 The approach outlined within this policy is integral to the Trust's commitment to improving patient safety and continuous quality improvement and aims to complement existing arrangements and practices. Further, it is consistent with the Trust's 'fair blame' approach following incidents which focuses on 'what went wrong, not who went wrong' and importantly the actions required to prevent recurrence and ensure appropriate follow-up of the affected patient(s).

1.9 This document should be read in conjunction with the following existing Trust documents:

- Risk Management Strategy
- Incident Reporting Policy/Procedure
- Policy for Dealing with Serious Incidents (Clinical & Non-Clinical)
- Root Cause Analysis Toolkits
- Policy & Procedure for the Management of Complaints
- Claims Handling Policy & Procedure

1.10 The Trust is committed to being open with patients (and this is integral to the processes in place for managing incidents, complaints and claims), and a charter to this effect and agreed by the Board is in place (see **Appendix B**).

2.0 Area

2.1 This policy applies to all staff employed by and contracted to the Trust.

2.2 This policy applies to **patient safety incidents** involving **moderate, severe harm or death**, and which require a more formal response and is intended to ensure that all communication with patients and/or relatives and between staff/healthcare teams and, where relevant, other healthcare organisations, when things have gone wrong is

open, honest and occurs as soon as possible following an incident, complaint or claim.

2.3 The Trust encourages staff to report patient safety incidents that were prevented (i.e. 'near misses'), no harm and low harm incidents as well as patient safety incidents that have caused moderate harm, severe harm or death. It is **not**, however, a requirement of this policy that prevented patient safety incidents and no harm incidents are discussed with patients. For minor or low incidents, it is anticipated that being open principles will still be applied and an apology and/or explanation will be provided at the time the incident or issue occurs.

2.4 It should be stressed that this policy is not intended to cover all eventualities and not all of the stages of the processes which follow will be applicable or necessary in respect of all of the incidents which are covered by this policy. The text that follows is intended as a guide to assist staff to effectively communicate with patients and/or their relatives/carers involved in patient safety incidents and to ensure that staff feel supported and empowered to do so.

3.0 Duties & Responsibilities

3.1 The **Director of Governance and Assurance** is responsible for ensuring that a 'Being Open' Policy (which outlines the Trust's commitment and approach to the Duty of Candour) is in place.

3.2 The **Head of Risk** is responsible for the development and implementation of this policy and for ensuring that suitable training programmes are in place.

3.3 **Clinical Directors / Clinical Leads / General Managers/Line Managers** are responsible for ensuring the implementation of this policy within their areas and for ensuring that staff are open with patients and/or their relatives/carers following patient safety incidents and as part of the processes in place for responding to complaints – including those which have the potential to become a claim.

3.4 **Staff** involved in the incidents, investigation or follow-up of incidents/serious incidents, complaints and claims including being open with patients and/other relatives/carers following patient safety incidents are responsible for ensuring that these discussions are managed in accordance with the principles and processes outlined within this policy.

3.5 The **Quality and Safety Committee**, on behalf of the Trust Board, is responsible for monitoring compliance with this policy.

3.6 The **Trust Board** is responsible for the ratification of this policy and for providing top level commitment to being open and the duty of candour.

3.7 The existing **Non-Executive Director (NED) Lead for Governance** will also be the NED lead for the Trust's 'Being Open' Policy.

3.8 **The Medical Director / Chief Nurse / Clinical Directors & Clinical Leads** are responsible for mentoring and supporting their colleagues in being open and throughout the being open process (following incidents/serious incidents/complaints and claims). An outline of the role is provided at **Appendix C**.

4.0 The Ten Principles of Being Open

Being open is a process rather than a one-off event, with this in mind the following principles have been drawn up to underpin this policy.

4.1 **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 relatives/carers inform healthcare staff when something untoward has happened, it must be taken seriously from the outset. Any concerns or complaints should be treated with compassion and understanding by all healthcare staff. Denial of a patient's concerns or complaints will make future open and honest communication more difficult.

4.2 **Principle of Truthfulness, Timeliness and Clarity of Communication** – information about a patient safety incident must be given to patients and/or their relatives/carers in a truthful and open manner by an appropriately nominated person. Patients want a step-by-step explanation of what happened, that considers their individual needs and is delivered openly.

4.2.1 Communication should always be timely – and this may often be at the time the incident occurs – although this will clearly depend on the circumstances and the condition of the patient. Patients and/or their carers/relatives should be provided with information about what happened as soon as practicable (and certainly no later than 10 working days from the date the incident was reported). 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 relatives/carers should be kept up to date with the process of an investigation. This must be done within ten working days of the incident being reported to local systems.

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

4.3 **Principle of Apology** – patients and/or their relatives/carers should receive a sincere expression of sorrow or regret for the harm that has resulted from a patient safety incident. This should be in the form of an appropriately worded and agreed manner of apology as early as possible.

4.3.1 Both verbal and written apologies should be given. A decision will be required as to the most appropriate member of staff to issue these apologies. The decision should consider seniority, relationship with the patient and experience, the circumstances of the incident and expertise with the type of patient safety incident that has occurred.

4.3.2 Verbal apologies are essential because they allow face to face contact between the patient and/or their relatives/carers and the healthcare team. This should be given as soon as staff are aware an incident has occurred.

4.3.3 A subsequent, written apology, which clearly states that the healthcare organisation is sorry for the suffering and distress resulting from the incident, must also be given. This would typically be provided as part of the formal response outlining the outcome of the Trust's investigation of the incident or in the response to a formal complaint or on settlement of a claim.

4.4 **Principle of Recognising Patient's and/or Carer/relatives Expectations** – patients and/or their relatives/carers can reasonably be expected 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 healthcare organisation. They should be treated sympathetically and with respect and consideration. Confidentiality should be maintained at all times. Patients and/or their carers should also be provided with support in a manner appropriate to their needs. This will involve consideration of special circumstances that can include a patient requiring additional support, such as an independent patient advocate or a translator.

4.5 **Principle of Professional Support** – the Trust is committed to creating an environment in which all staff, whether directly employed or independent contractors, are encouraged to report patient safety incidents. Within NLG, a 'fair blame' culture exists and the approach adopted when adverse incidents occur is 'what went wrong not who went wrong'.

4.6 **Principle of Risk Management and Systems Improvement** – root cause analysis or similar technique should be used to uncover the underlying causes of patient safety incidents. The Trust has in place Root Cause Analysis Toolkits which are available on the Risk Management website. Further details on incident investigation and root cause analysis are also outlined in the Trust's Incident Reporting Policy.

4.7 **Principles of Multi–Disciplinary Responsibility** – this policy applies to all staff who have key roles in the patient's care. Most healthcare provision involves multi-disciplinary teams and communication with patients and/or their relatives/carers following an incident that led to harm should reflect this.

4.8 **Principles of Clinical Governance** – the approach to being open should be an integral part of the approach to governance within Directorates/Groups.

4.9 **Principle of Confidentiality** – the application of this policy should give full consideration to and respect for the patients and/or their relatives/carers and staff privacy and confidentiality. Details of a patient safety incident should at all times be considered confidential.

4.10 **Principle of Continuity of Care** – patients are entitled to expect that they will 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 clinician or team, the appropriate arrangements should be made to facilitate this.

5.0 Being Open – The Process

5.1 Apologising and explaining when patients have been harmed can be very difficult. Patients and/or their relatives/carers should receive an apology as soon as possible and no later than 10 days after a patient safety incident identified as moderate, severe or death has occurred and staff should feel able to apologise on the spot. Saying sorry is **not** an admission of liability and it is the right thing to do. Patients have a right to expect openness in their healthcare. The initial notification of the incident must be verbal (face-to-face where possible) unless the patient or their family/carer decline notification or cannot be contacted in person. A sincere expression of apology must be provided verbally, this must be recorded at the time an initial apology and explanation must be given. The Patient and/or carer must be offered written notification (including a sincere apology) of the incident. [Template

letters have been developed to assist (please see **Appendix C)**. These letters can be adapted to the circumstances of the incident. The offer must be recorded whatever the outcome].

5.2 The Trust is committed to being open with patients and/or their relatives/carers when things go wrong and will encourage and reinforce this requirement as part of relevant awareness/training sessions for staff. The Trust will also encourage patients to ask questions and raise concerns with staff through awareness campaigns (e.g. 'please ask', clean your hands' etc.) and information leaflets (e.g. risk management strategy leaflet for patients and visitors, PALS leaflets, Complaints leaflet – 'How to give us your feedback (IFP-779), and the 'Being Open – Patient Safety' leaflet (IFP-598).

5.3 **Quick Reference Guide to Being Open** – The following provides a quick reference guide to being open in respect of incidents involving actual harm and the process which may be followed. As indicated above, not all of the stages of the processes which follow will be applicable or necessary in respect of all incidents and a judgement will be required, as part of the investigation of the incident or management of the complaint, and will be dependent on the circumstances and seriousness of the incident. The Senior Clinician(s) within your area will be able to provide you with advice and support throughout the being open process. Alternatively, please contact a member of the Risk & Governance Team.

5.3.1 Stage 1 – Preliminary Meeting with the Patient and/or their Relatives/Carer (within 10 days of the identified patient safety incident)

- **Who Should Attend?**
  - A lead staff member who is normally the most senior person responsible for the patient's care and/or someone with experience and expertise in the type of incident that has occurred. **N.B.** Staff should not attend being open discussions alone
  - Ensure that those members of staff who do attend the meetings can continue to do so; continuity is very important in building relationships
  - The person taking the lead should be supported by at least one other member of staff, such as the Trust Risk Manager, Director/Group governance lead, nursing or medical director, or member of the healthcare team treating the patient
  - Ask the patient and/or their carers who they would like to be present
  - Consider each team member's communication skills; they need to be able to communicate clearly, sympathetically and effectively
  - Hold a pre-meeting amongst healthcare professionals so that everyone knows the facts and understands the aims of the meeting
- **When should it be held?**
  - As soon after the incident as possible (must be held within 10 days of the incident)

- Consider the patient's and/or their relatives/carer's home and social circumstances
- Check that they are happy with the timing
- Offer them a choice of times and confirm the chosen date in writing
- Do not cancel the meeting unless absolutely necessary

- **Where should it be held?**
  - Use a quiet room where you will not be distracted by work or interrupted
  - Do not host the meeting near the place where the incident occurred as this may be difficult for the patient and/or their relatives/carers

5.3.2 Stage 2 – Discussion:

- **How should you approach the patient and/or their relatives/carers?**
  - Speak to the patient and/or their carers as you would want someone in the same situation to communicate with a member of your own family
  - Do not use jargon or acronyms: use clear, straightforward language
  - Consider the needs of patients with special circumstances, for example, linguistic or cultural needs, and those with learning difficulties

- **What should be discussed?**
  - Introduce and explain the role of everyone present to the patient and/or their relatives/carer and ask them if they are happy with those present
  - Acknowledge what happened and apologise on behalf of the team and the organisation. Apologising and expressing regret is not an admission of liability
  - Agree what will be discussed
  - Stick to the facts that are known at the time and assure them that if more information becomes available, it will be shared with them
  - Do not speculate or attribute blame
  - Suggest sources of support and counselling
  - Check they have understood what you have told them and offer to answer any questions
  - Provide a named contact who they can speak to again
  - Agree next steps in terms of investigation, care of the patient, process for feeding back

– As per the note below, full written documentation of meetings must be maintained

5.3.3 Stage 3 – Follow-Up

- Clarify in writing the information and apologies given, reiterate key points, record action points and assign responsibilities and deadlines [Template letters have been developed to assist, see **Appendix C**. These letters can be adapted to the circumstances of the incident.]

- The patient's notes should contain a complete, accurate record of the discussion(s) and apologies given including the date and time of each entry, what the patient and/or their relatives/carers have been told, and a summary of agreed action points

- Maintain a dialogue by addressing any new concerns, share new information once available and provide information on support and counselling, as appropriate

Notes:

1. It is essential that written records are maintained of any discussion with and apology given to patients and/or their carers following patient safety incidents – either at the time the incident occurs whilst the patient may be still on the ward/in the clinic etc. or at any time subsequent to the incident. This will include appropriate entries in the patient's notes and as part of the incident investigation, complaint or claim file. In respect of the latter, incident, complaint and claim information is held electronically on DATIX, therefore, all written communications should be saved to the relevant entry.

2. It is important that patients and/or their relatives receive a meaningful apology. An apology does not constitute an admission of liability. Patients and the relatives increasingly ask for detailed explanations of what led to adverse outcomes and they frequently say that they derive some consolation from knowing that lessons have been learned for the future. Explanations should not contain admissions of liability.

Documentation of being open discussions should include (as appropriate):

- the time, date and place, as well as the names and job titles of attendees

- the plan for providing further information to the patient and/or their carers or other nominated representative or the GP in relation to the incident

- apologies given

- offers of assistance and the response of the patient and/or carer

- questions raised and answers given

- plans for any follow-up meetings

- progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient and/or carer

- any investigation reports will have to be shared with the patient/relative/carer within ten days of being signed off as complete (including assurance by the relevant CCG).

6.0 Supporting Staff Following a Patient Safety Incident

When a patient safety incident occurs, healthcare professionals involved in the patient's clinical care may also require emotional support and advice. Both clinicians who have been directly involved in the incident and those with the responsibility for the being open discussion should be given access to assistance, support and any information they need to fulfill this role. To support healthcare staff involved in patient safety incidents, the following arrangements are in place within NLG:

- The Trust has in place a 'fair blame' culture that discourages the attribution of blame and, following adverse incidents, focuses on 'what went wrong, not who went wrong'

- Clinical Directors and Clinical Leads whose role is to mentor and support colleagues in being open and throughout the being open process. Alternatively, please contact a member of the Risk & Governance Team

- Arrangements are in place within Directorates for de-briefing of the clinical team involved in patient safety incidents, where appropriate, as part of the support system and separate from the requirement to provide statements for the investigation. Mechanisms are also in place to ensure that staff involved in adverse incidents receive feedback following the incident investigation and this includes the staff member(s) who initially 'spoke up' and raised the issue/concern or reported the incident

- Counselling and support services are available via Occupational Health and 'Confidential Care' – a confidential and anonymous support helpline – 0800 085 1376 24.

- Support to staff can also be accessed via the Freedom to Speak up Guardian & Associates – contact details are available on the Intranet / Hub.

7.0 Monitoring Compliance and Effectiveness

7.1 Compliance with this policy will be monitored by the Quality and Safety Committee. Receipt of information on incident follow-up will involve review by the Quality and Safety Committee of the mechanisms for being open/providing feedback and support to patients and/or their relatives/carers following patient safety incidents. The 'SI Management Checklist', which is submitted with all SI Investigation reports, reinforces requirements in respect of 'being open' and asks for confirmation of actions taken in this regard. Datix is used to record duty of candour and a KPI is in place and included within the Integrated Performance Dashboard to monitor compliance at group level.

7.2 The contractual requirement in respect of the Duty of Candour appears in Condition 35 of the NHS Standard Contract and providers are required to notify commissioners if they receive a complaint that there has been a failure to disclose a relevant patient safety incident. Where a provider is found to have failed to be open the commissioners will implement the consequences set out in the contract section 35.3 and 35.4, these are:

- notify the CQC of that failure; (please see specific CQC Requirements at section 7.3 below); and/or
- a direct written apology and explanation for the breach to the individual affected from the providers Chief Executive and copied to the relevant commissioner
- publish details of that failure prominently on the providers website

7.3 Regulation 20 of the CQC fundamental standards of care specifies that:

- 20(1) A health service body must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity
- 20(2) As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a health service body must: 20(2)(a) notify the relevant person that the incident has occurred; 20(2)(b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification
- 20(3) The notification to be given under paragraph (2)(a) must – 20(3)(a) be given in person by one or more representatives of the health service body; 20(3)(b) to 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; 20(3)(c) advise the relevant person what further enquiries into the incident the health service body believes are appropriate; 20(3)(d) include and apology, and 20(3)(e) be recorded in a written record which is kept securely by the health service body
- 20(4) The notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person containing – (a) the information provided under paragraph (3)(b), (b) details of any enquiries to be undertaken in accordance with paragraph (3)(c), (c) the results of any further enquiries into the incident, and (d) an apology
- 20(5) But if the relevant person cannot be contacted in person or declines to speak to the representative of the health service body – (a) paragraphs (2) to (4) are not to apply, and (b) a written record is to be kept of attempts to contact or to speak to the relevant person

7.4 **Policy Review & Revision** – This policy will be reviewed every 3 years or sooner should the need arise.

8.0 Further Reading / Associated Documents

This document should be read in conjunction with the following policies:

- Risk Management Strategy
- Incident Reporting Policy
- Policy on the Management of Serious Incidents (Clinical & Non-Clinical)

- Root Cause Analysis Toolkits
- Policy & Procedure for the Management of Complaints
- Claims Handling Policy & Procedure
- Information Leaflet for Patients and/or Carers: 'Being Open – Patient Safety'(IFP-598)
- Information Leaflet for Staff: 'Quick Reference Guidance to Being Open'

9.0 References

9.1 NHS Litigation Authority. (2009). Circular: Apologies and Explanations. London: NHS Litigation Authority.

9.2 National Patient Safety Agency. (2004). Seven Steps to Patient Safety. London: National Patient Safety Agency.

9.3 National Patient Safety Agency. (2005). Being Open – Communicating Patient Safety Incidents with patients and their carers. London: National Patient Safety Agency.

9.4 National Patient Safety Agency. (2005). Patient Briefing – Saying Sorry When Things Go Wrong. London: National Patient Safety Agency.

9.5 Department of Health (DOH). (2003). Making Amends. London: DOH.

9.6 National Patient Safety Agency. (2009). Being Open – Communicating Patient Safety Incidents with patients and their carers (revised guidance). London: National Patient Safety Agency.

9.7 Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry 2013.

9.8 2017-18 NHS Standard Contract, Technical Guidance.

9.9 CQC Guidance to providers on meeting the fundamental standards and on CQCs enforcement powers. March 2015.

9.10 GMC Joint statement from Chief Executives of statutory regulators of healthcare professionals "Openness and honesty – the professional duty of candour". October 2014.

10.0 Definitions

10.1 **Apology** – a sincere apology of regret for harm sustained.

10.2 **Being Open** – open communication of patient safety incidents that resulted in moderate harm, severe harm or death of a patient whilst receiving healthcare.

10.3 **Harm** – injury (physical or psychological), disease suffering, disability or death. The NHS definitions of harm are:

- **Moderate Harm:** Any patient safety incident that requires a moderate increase in treatment (unplanned return to surgery, an unplanned readmission, 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) and which caused significant but not permanent harm. Prolonged psychological harm (means psychological harm which a service user has experiences, or is likely to experience, for a continuous period of at least 28 days)

- **Severe Harm:** Any patient safety incident that appears to have resulted in permanent harm (permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of wrong limb or organ or brain damage)

- **Death:** Any patient safety incident that directly resulted in the death (related to the incident rather than to the natural course of the patient's illness or underlying condition) of one or more persons

10.4 **Injury** – damage to tissues caused by an agent or circumstance.

10.5 **Patient Safety Incident** – any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS funded healthcare.

10.6 **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.

10.7 **Root Cause Analysis (RCA)** – a systematic process whereby the factors that contributed to an incident are identified. As an investigation technique for patient safety incidents, it looks beyond the individual concerned and seeks to understand causes and environmental context in which an incident happened.

11.0 Consultation

11.1 Quality and Safety Committee.

11.2 Trust Board.

12.0 Approval and Ratification Process

The Trust Board is responsible for the approval of this policy and for approving any revisions.

13.0 Dissemination

This policy will be disseminated to Directorates including governance and clinical staff. Amendments to the policy will be communicated to the above as and when they occur, via email communication and via publication in the Trust's 'Weekly Bulletin'. The policy will be made available via the Intranet to ensure ease of access and to ensure that changes made are quickly communicated.

14.0 Implementation

Training:

- Awareness and training in respect of the principles outlined in this policy will be provided as part of investigation and root cause analysis training and as part of complaints/claims awareness sessions

- Advice and training on the investigation and management of incidents, complaints and claims including the requirement for openness and communication with patients and/or relatives is in place within the Trust – please refer to the Learning Directory, which is available on the Trust's Intranet site. Root Cause Analysis Toolkits are also in place (both generic and in relation to specific incidents e.g. MRSA Bacteraemias, C.difficile, Falls, Pressure Ulcers, Medication Incidents etc) for assisting staff in the investigation of incidents

15.0 Equality Act (2010)

15.1 In accordance with the Equality Act (2010), the Trust will make reasonable adjustments to the workplace so that an employee with a disability, as covered under the Act, should not be at any substantial disadvantage. The Trust will endeavour to develop an environment within which individuals feel able to disclose any disability or condition which may have a long term and substantial effect on their ability to carry out their normal day to day activities.

15.2 The Trust will wherever practical make adjustments as deemed reasonable in light of an employee's specific circumstances and the Trust's available resources paying particular attention to the Disability Discrimination requirements and the Equality Act (2010).

The electronic master copy of this document is held by Document Control, Directorate of Governance and Assurance, NL&G NHS Foundation Trust.

Appendix A

Francis Inquiry Recommendations – Duty of Candour

Recommendation 181

A statutory obligation should be imposed to observe a duty of candour:

- On healthcare providers who believe or suspect that treatment or care provided by it to a patient has caused death or serious injury to a patient to inform that patient or other duly authorised person as soon as is practicable of that fact and thereafter to provide such information and explanation as the patient reasonably may request;

- On registered medical practitioners and registered nurses and other registered professionals who believe or suspect that treatment or care provided to a patient by or on behalf of any healthcare provider by which they are employed has caused death or serious injury to the patient to report their belief or suspicion to their employer as soon as is reasonably practicable.

The provision of information in compliance with this requirement should not of itself be evidence or an admission of any civil or criminal liability, but non-compliance with the statutory duty should entitle the patient to a remedy."

Recommendation 183

It should be made a criminal offence for any registered medical practitioner, or nurse, or allied health professional or director of an authorised or registered healthcare organisation:

- Knowingly to obstruct another in the performance of these statutory duties;

- To provide information to a patient or nearest relative intending to mislead them about such an incident;

- Dishonestly to make an untruthful statement to a commissioner or regulator knowing or believing that they are likely to rely on the statement in the performance of their duties."

Recommendation 28

Zero tolerance: A service incapable of meeting fundamental standards should not be permitted to continue. Breach should result in regulatory consequences attributable to an organisation in the case of a system failure and to individual accountability where individual professionals are responsible. Where serious harm or death has resulted to a patient as a result of a breach of the fundamental standards, criminal liability should follow and failure to disclose breaches of these standards to the affected patient (or concerned relative) and a regulator should also attract regulatory consequences. Breaches not resulting in actual harm but which have exposed patients to a continuing risk of harm to which they would not otherwise have been exposed should also be regarded as unacceptable."

Appendix B

PATIENTS' CHARTER: 'BEING OPEN' WITH OUR PATIENTS

(DUTY OF CANDOUR)

Staff work hard to deliver the highest standards of healthcare to all patients within Northern Lincolnshire & Goole NHS Foundation Trust.

We provide safe and effective care to many thousands of people every year but sometimes, despite our best efforts, things can and do go wrong.

If a patient is harmed as a result of a mistake or error in their care, in line with our culture within our services that is honest and open at all levels, that we believe that they, their family or those who care for them, should be told in a timely manner and receive a written and truthful account of the incident and an explanation about any enquiries and investigations, be kept fully informed as to what has happened, have their questions answered and know what is being done in response and should receive an apology in writing. This is something that we call 'Being Open' and to fulfil 'Duty of Candour' requirement to ensure that patients/families are informed of medical errors causing moderate, severe harm or death and are provided with support, we make a commitment to our patients to:

- apologise for the harm caused
- explain, openly and honestly, what has gone wrong
- describe what we are doing in response to the mistake
- offer support and counselling services that might be able to help
- provide the name of a person to speak to
- give updates on the results of any investigation

Trust Board

Northern Lincolnshire & Goole NHS Foundation Trust

Appendix C

Northern Lincolnshire and Goole NHS Foundation Trust

Hospital Title
Address Line 1
Address Line 2
Address Line 3
Postcode

Tel: xxxxx xxxxxx

TEMPLATE LETTER 1: ON ESCALATION OF AN SI

[INSERT DATE]

[INSERT NAME & ADDRESS OF PATIENT / RELATIVE]

Dear **[INSERT NAME OF PATIENT / RELATIVE]**

I write further to the incident which occurred on **[INSERT DATE]** and which was discussed with you by **[INSERT NAME]** on **[INSERT DATE].**

[INSERT HERE A BRIEF SUMMARY OF THE INCIDENT AND THE DISCUSSION WITH THE PATIENT / RELATIVE ON THE ABOVE DATE].

Please be assured that this incident will be investigated in accordance with the Trust's Policy on Dealing with Serious Incidents. The investigation will take approximately 12 weeks to complete and should therefore be completed by **[INSERT DATE].** If for any reason, there is likely to be a delay in completing this investigation, we will notify you.

On conclusion of the investigation we will contact you again to provide a copy of the investigation report and to arrange to meet with you to go through the report and answer any additional questions or concerns which you may have and to confirm the actions that we have taken or propose to take as a result of the investigation.

Should you wish to discuss matters further in the meantime, please do not hesitate to contact **[INSERT NAME OF AGREED FAMILY LIAISON]** on **[INSERT TELEPHONE NUMBER]** or via email **[INSERT EMAIL ADDRESS].**

Finally, please accept my sincere and unreserved apologies for the distress caused by this incident.

Yours sincerely,

[INSERT CHIEF EXECUTIVE / DIRECTOR / CLINICAL DIRECTOR]

Northern Lincolnshire and Goole NHS Foundation Trust

TEMPLATE LETTER 2: ON COMPLETION OF SI INVESTIGATION

Hospital Title
Address Line 1
Address Line 2
Address Line 3
Postcode

Tel: xxxxx xxxxxx

[INSERT DATE]

[INSERT NAME & ADDRESS OF PATIENT / RELATIVE]

Dear **[INSERT NAME OF PATIENT / RELATIVE]**

Dear

I write further to my letter of **[INSERT DATE]** in respect of the incident which occurred on **[INSERT DATE].**

The Trust's investigation has now been concluded and I enclose a copy of the investigation report as promised. As I am sure you will appreciate, reports such as this are written for a specific purpose and so can appear very clinical and on that basis can be upsetting and I would apologise for this.

As indicated in my earlier correspondence to you, we would like to make arrangements to meet with you to go through the report in order to answer any additional questions or concerns which you may have and importantly to confirm the lessons learnt and actions we have taken or intend to take as a result of this incident and in order to minimise the risk of further such incidents.

I understand that meeting arrangements have already been discussed and agreed with you **OR*** If you would like to take up this offer of a meeting, please contact **[INSERT NAME OF AGREED FAMILY LIAISON]** on **[INSERT TELEPHONE NUMBER]** or via email **[INSERT EMAIL ADDRESS].**

[*DELETE AS APPROPRIATE]

Finally and once again, please accept my sincere and unreserved apologies on behalf of the Trust for the distress caused by this incident. I would like to assure you that the Trust takes seriously incidents such as this and steps are being taken to ensure that lessons are learnt not only in the area concerned but across the Trust as a whole.

Yours sincerely

[INSERT CHIEF EXECUTIVE / DIRECTOR / CLINICAL DIRECTOR]

ENC

Northern Lincolnshire and Goole NHS Foundation Trust

TEMPLATE LETTER 1: ON ESCALATION OF AN INCIDENT THAT TRIGGERS THE DUTY OF CANDOUR REQUIREMENT (SEE SEPARATE TEMPLATE LETTERS FOR SIs)

Hospital Title
Address Line 1
Address Line 2
Address Line 3
Postcode

Tel: xxxxx xxxxxx

[INSERT DATE]

[INSERT NAME & ADDRESS OF PATIENT / RELATIVE]

Dear **[INSERT NAME OF PATIENT / RELATIVE]**

I write further to the incident which occurred on **[INSERT DATE]** and which was discussed with you by **[INSERT NAME]** on **[INSERT DATE].**

[INSERT HERE A BRIEF SUMMARY OF THE INCIDENT AND THE DISCUSSION WITH THE PATIENT / RELATIVE ON THE ABOVE DATE].

Please be assured that this incident will be investigated in accordance with the Trust's Incident Reporting Policy. The investigation will take approximately **[X - INSERT]** weeks to complete and should therefore be completed by **[INSERT DATE].** If for any reason, there is likely to be a delay in completing this investigation, we will notify you.

On conclusion of the investigation we will contact you again to arrange to meet with you to discuss the investigation findings and answer any additional questions or concerns which you may have and to confirm the actions that we have taken or propose to take as a result of the investigation.

Should you wish to discuss matters further in the meantime, please do not hesitate to contact **[INSERT NAME OF AGREED FAMILY LIAISON]** on **[INSERT TELEPHONE NUMBER]** or via email **[INSERT EMAIL ADDRESS].**

Finally, please accept my sincere and unreserved apologies for the distress caused by this incident.

Yours sincerely,

[INSERT CHIEF EXECUTIVE / DIRECTOR / CLINICAL DIRECTOR]

Northern Lincolnshire and Goole NHS Foundation Trust

TEMPLATE LETTER 2: ON COMPLETION OF THE INVESTIGATION OF AN INCIDENT THAT TRIGGERS THE DUTY OF CANDOUR REQUIREMENT (SEE SEPARATE TEMPLATE LETTERS FOR SIs)

Hospital Title
Address Line 1
Address Line 2
Address Line 3
Postcode

Tel: xxxxx xxxxxx

[INSERT DATE]

[INSERT NAME & ADDRESS OF PATIENT / RELATIVE]

Dear **[INSERT NAME OF PATIENT / RELATIVE]**

I write further to my letter of **[INSERT DATE]** in respect of the incident which occurred on **[INSERT DATE].**

The Trust's investigation has now been concluded. As indicated in my earlier correspondence to you, we would like to make arrangements to meet with you to discuss the investigation findings and to answer any additional questions or concerns which you may have and importantly to confirm the lessons learnt and actions we have taken or intend to take as a result of this incident in order to minimise the risk of further such incidents.

I understand that meeting arrangements have already been discussed and agreed with you **OR*** If you would like to take up this offer of a meeting, please contact **[INSERT NAME OF AGREED FAMILY LIAISON]** on **[INSERT TELEPHONE NUMBER]** or via email **[INSERT EMAIL ADDRESS].**

[*DELETE AS APPROPRIATE]

Finally and once again, please accept my sincere and unreserved apologies on behalf of the Trust for distress caused by this incident. I would like to assure you that the Trust takes seriously incidents such as this and steps are being taken to ensure that lessons are learnt not only in the area concerned but across the Trust as a whole.

Yours sincerely

[INSERT CHIEF EXECUTIVE / DIRECTOR / CLINICAL DIRECTOR]

Appendix D

ROLE AND RESPONSIBILITIES OF THE CLINICAL DIRECTORS / CLINICAL LEADS

Senior clinicians will mentor and support healthcare colleagues in the 'being open' process and with the implementation of the Trust's 'Being Open' Policy.

Senior Clinicians will:

- Practice and promote the principles of 'being open'
- Support fellow healthcare professionals with being open by:
  - mentoring colleagues during their first being open discussion
  - advising on the being open process
  - being accessible to colleagues prior to initial and subsequent being open discussions
  - facilitating the initial team meeting to discuss the incident when appropriate
  - signposting the support services within the organisation for colleagues involves in being open discussions
  - facilitating de-briefing meetings following being open discussions
- Support fellow healthcare professionals in dealing with patient safety incidents within the organisation by:
  - signposting the support services within the organisation for colleagues involved in patient safety incident discussions
  - advising on the reporting system for patient safety incidents