BEING OPEN AND DUTY OF CANDOUR POLICY

MARCH 2015

This policy supersedes all previous policies for Being Open
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Approved by (Group): N/A

Approved by (Committee): Quality Committee

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<table>
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</tr>
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<tbody>
<tr>
<td>August 2008</td>
<td>1</td>
<td>New Policy</td>
</tr>
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</table>

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Further copies of this document can be found on the Foundation Trust intranet.
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1. **Trust values**

Camden and Islington NHS Foundation Trust developed its set of six values with more than 500 service users and members of staff.

Our values are important to us. They are our promise to service users as well as to each other that we will behave in a certain way, no matter what our job title is or how under pressure we feel.

Our commitment to our values makes us who we are. It gives our service users confidence that they will be treated in the most compassionate way possible as they go through their journey to recovery. It also gives us pride in the knowledge we are providing the best care.

Our values show that we are welcoming, respectful and kind. Professional in our approach. Positive in our outlook. Working as a team, we are your partner in care and improvement.

These values are part of a wider campaign, Changing Lives which is helping to drive up the standards of care across the Trust.

In simple terms our values assure our service users that:

- They will receive a warm welcome throughout the journey to recovery;
- They, their dignity and their privacy will always be respected;
- Their care will be founded on compassion and kindness;
- They will receive high quality, safe care from a highly trained team of professionals;
- We work together as a team to ensure they feel involved and offer solutions and choices – ‘no decision about you, without you’;
- We are positive so they can feel hopeful and begin their journey of recovery knowing we will do our very best.

2. **Policy and governance**

A policy is an organisational statement of rules and standards which govern performance and actions required to be followed by those in employment by the Trust. A policy provides a framework for the Trust to work within and should specify actions which are required. A policy may include detailed procedures which supply standardized methods of performing clinical or
non-clinical tasks by providing a series of actions to be conducted in a certain order to achieve a safe and effective outcome in a consistent method by all concerned. Policies should take account of existing good quality evidence. The Whittington Health Library provides a library service to the Foundation Trust and can assist with literature searches and finding evidence to inform policy and practice. For more information please contact:

Richard Peacock
Librarian
Whittington Health Library
020 7288 3607
richardpeacock@nhs.net

Good governance lies at the heart of all successful organisations. Good governance helps protect the Trust, its staff and service users from poor decisions and exposure to risks. All Trust policies must be compliant with the relevant statutory legislation, e.g.: the Mental Health Act 1983 (which was amended in 2007) and national expectations, e.g.: the NHS Litigation Authority Risk Management Standards 2012-13.

A policy which has not been scrutinized and approved by the appropriate Trust committee but is being used by staff could lead to poor practice being delivered which could potentially harm service users and have consequences for staff. It is therefore essential that in either developing or revising a policy, managers ensure that the proper governance procedures have been followed. By following the correct governance procedures, we all help to reduce risk and assure safe and effective care is delivered to service users.

3. Policy statement
Camden and Islington NHS Foundation Trust provides safe and quality care to thousands of service users every year but sometimes, despite our best efforts, things go wrong. The Trust Board on behalf of the organisation declares its commitment to openness and transparency. When things go wrong, the Trust will be open about what happened and discussing patient safety incidents promptly, fully and compassionately with service users, their families and carers.

In September 2005, the National Patient Safety Agency (NPSA) issued a Safer Practice Notice advising all NHS organisations to implement a Being Open Policy. In November
2009 a Patient Safety Alert was issued by the NPSA to ensure that providers of NHS funded care implemented the principles of Being Open.

Being Open involves:

- Acknowledging, apologising and explaining when things go wrong.
- Conducting a thorough investigation into the patient safety incident and reassuring service users, their families and carers that lessons learned will help prevent the patient safety incident recurring.
- Providing support for those involved to cope with the physical and psychological consequences of a patient safety incident.

In April 2013, NHS organisations became subject to a contractual duty of candour under the NHS Standard Contract. Contractual requirements are clearly set out in Standard Condition 35 of the contract.

In November 2014, a new law came into force. Regulation 20: Duty of Candour was introduced. The aim of this regulation is to ensure that health service bodies\(^1\) are open and transparent with the relevant person\(^2\) when certain incidents occur in relation to the care and treatment provided to service users. It was introduced as a direct response to recommendation 181 of the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust\(^3\), which recommended that a statutory duty of candour be imposed on healthcare providers. The emphasis is on **notifiable safety incidents**\(^4\) and this policy will focus on such incidents and not all patient safety incidents.

The duty of candour is a legal duty on hospital, community and mental health trusts. **It is enforceable by the CQC.** It requires immediate reporting of notifiable safety incidents through Datix, and as soon as reasonably practicable, and in any event, within 10 working days of identifying and reporting the incident, notify the relevant person that the incident has occurred or is suspected to have occurred.

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1. Health service bodies are defined in the regulations as NHS Trusts, NHS Foundation trusts and special health authorities
2. The person using the services or person/s acting lawfully on their behalf – See definitions
4. See definition
<table>
<thead>
<tr>
<th>Trust Values</th>
<th>Yes/No</th>
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<tr>
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</tr>
<tr>
<td>professionals</td>
<td></td>
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</tr>
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</table>

4. Executive summary

4.1 Executive Statement

Camden and Islington NHS Foundation Trust is committed to the provision of high quality health care in all aspects of its services to service users, visitors, the local community and staff. Promoting a culture of openness and transparency is a prerequisite to improving patient safety and the quality of healthcare systems. The Trust Board therefore supports this policy and a culture of openness and transparency.

4.2 The purpose of this policy is:

- To strengthen and embed a culture of openness and transparency across the Trust
- To embed learning from incidents, complaints and claims arising from notifiable safety incidents to improve services for service users.
- To facilitate compliance with regulation 20 requirements (section 7.2) and in the process improve the quality and consistency of communication with service users, their families and carers when notifiable safety incidents occur.
- To ensure that service users, their families and carers, and staff all feel supported when notifiable safety incidents occur.
4.3 Scope

This policy is aimed at all staff working within the Trust and sets out the infrastructure which is in place to support openness and transparency between healthcare professionals and service users, their families and carers, following a notifiable safety incident.

All staff must note the limitations and exemptions that apply.

- **A notifiable safety incident** comprises of incidents that could result in, or appear to have resulted in, the death of a service user or severe harm, moderate harm, or prolonged psychological harm. The trust is not required under the regulation to inform a service user when a ‘near miss’ or an incident that resulted in no harm has occurred.

- **Relevant person** (Service User) – in circumstances where the service user involved in an incident is under 16 years or over 16 years of age and not competent or lack capacity to make a decision regarding their care and treatment, or upon their death, a person acting lawfully on their behalf shall be treated as the relevant person.

- **Family members and carers** – Information should only be disclosed to them where the service user has given their expressed or implied consent; and in accordance with the Information Governance Policy and Data Protection Policy.

All staff must bear in mind that although this policy is restricted to notifiable safety incident, all incidents including ‘near miss’ must be reported in accordance with the Incident Reporting Policy; take immediate steps to contain the incident to minimise harm, inform your manager, withdraw and retain for examination any evidence including equipments and report via Datix as soon as practicable but within 24hrs.

5. **Duties and responsibilities**

5.1 **Trust Board** – It is the responsibility of the Trust Board to ensure that the contractual requirement of the duty of candour is adhered to and that the policy is implemented across the trust and has assurance processes on place to this effect.
5.2 **The Chief Executive** has a duty of candour and is ultimately responsible for the procedures and processes in place to implement the policy and is accountable to the board. This responsibility is delegated to the Director of Nursing and People.

5.3 **Executive Directors** are responsible for promoting an open, honest and fair culture within the organisation.

5.4 **Quality Committee** – This committee has the overarching responsibility for monitoring implementation and to provide assurance to the Board.

5.5 **The Director of Nursing and People is the identified lead for being open and the duty of candour.** She is responsible for the implementation of the procedures and processes in place and to ensure compliance with the requirements of the duty of candour. She is also responsible to ensure that the assurance processes are effective.

5.6 **Associate Divisional Directors and Associate Clinical Directors** must ensure that communication and management systems are in place to enable senior managers to implement the policy in their service areas.

5.7 **The Associate Director, Governance and Quality Assurance** through the Clinical and Corporate Policy Manager, is responsible for dissemination of the policy, identifying resource implications relating to compliance, ensuring that monitoring systems in place are fit for purpose and to facilitate the review process for policies.

5.8 **Managers** are to support their staff in implementing the policy in their service areas and ensuring that services provided to service users are as safe as possible in accordance with this policy. Managers must also be familiar with the incident reporting policy and serious incident policy.

5.9 **Risk and Patient Safety Manager** is responsible for coordinating the overall management, investigation and learning from notifiable safety incidents.
5.10 All Trust staff are responsible for ensuring that they are familiar with the policy and adhere to its content. Staff must make it their responsibility to find out about the systems in place in their work area to comply with the duty of candour.

6. Definitions

6.1 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 health care professional, could result in, or appears to have resulted in:

- The death of a service user, where the death relates directly to the incident rather than to the natural course of the service user’s illness or underlying condition, or
- Severe harm or
- Moderate harm or
- Prolonged psychological harm to the service user.

6.2 Relevant Person – This refers to the Service User or to a person lawfully acting on their behalf in the following circumstances:

- On the death of the service user
- Where the service user is under 16 and not competent or over 16 and lacks capacity (as determined in accordance with sections 2&3 of the 2005 Act) to make a decision in relation to their care and treatment

6.3 Severe harm - a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage that is related directly to the incident and not related to the natural course of the service user’s illness or underlying condition.

6.4 Moderate harm – harm that requires moderate increase in treatment (an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area; such as intensive care) AND significant but not permanent harm.
6.5 **Prolonged psychological harm** - psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days

6.6 **Apology** – an expression of sorrow or regret in respect of a notifiable safety incident. Saying sorry is not an admission of liability; it is the right thing to do.

7. **Being Open and Duty of Candour principles and requirements**

7.1 **Principles of Being Open**

7.1.1 This policy reflects the ‘Ten Principles of “Being Open” as identified in the National Patient Safety Agency’s document “Being open”: communicating patient safety incidents with patients and their carers’ (NPSA, 2005) which are described in Appendix 2

7.2 **Duty of candour Requirements**

7.2.1 To meet the statutory duty of candour requirements (Regulation 20) the Trust has to:

- Make sure it acts in an open and transparent way with relevant persons in relation to care and treatment provided to people who use services in carrying on of a regulated activity.

- Tell the relevant person in person as soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred, and provide support to them in relation to the incident, including when giving the notification.

- Provide an account of the incident which, to the best of the Trust’s knowledge, is true of all the facts the Trust knows about the incident as at the date of the notification.

- Advise the relevant person what further enquiries the Trust believes are appropriate.

- Offer an apology.

- Follow this up by giving the same information in writing, and providing an update on the enquiries.

- Keep a written record of all communication with the relevant person.
8. Being Open and Duty of Candour Procedures

8.1 Incident detection and recognition

The being open and duty of candour process starts with the recognition and acknowledgement that a service user has suffered death, severe harm, moderate harm or prolonged psychological harm as a result of a patient safety incident. In all cases relating to incidents, the Trust’s Incident Reporting Policy and Serious Incident Policy must be referred to for guidance on immediate actions to be taken following an incident, reporting, determining the severity of the incident, and further actions once the severity of the incident has been established.

The table below will assist in determining a notifiable safety incident.

<table>
<thead>
<tr>
<th>Patient Safety Incident Severity level</th>
<th>Notifiable Safety Incident?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Near Miss / No harm</td>
<td>No</td>
</tr>
<tr>
<td>Low Harm / Minor harm</td>
<td>No – Unless there are specific indications or the service user make a request.</td>
</tr>
<tr>
<td>Moderate harm</td>
<td>Yes</td>
</tr>
<tr>
<td>Severe Harm</td>
<td>Yes</td>
</tr>
<tr>
<td>Prolonged Psychological harm</td>
<td>Yes</td>
</tr>
</tbody>
</table>

It is possible that the Trust may discover a notifiable safety incident that happened some time ago. The duty to notify the relevant person starts at the time the incident was identified and established as a notifiable incident. The timeframe of within 10 working days applies.

An incident that relates to care that was delivered by another provider could also be identified. The provider that discovers the incident should work with others who are responsible for notifying the relevant person.
8.2 Procedure for implementing the duty of candour requirements

Once it has been established that the incident is a notifiable safety incident, the following sections under section 8.2 should be adhered to.

8.2.1 Preliminary Review and Preparation for notification in person

In accordance with the Serious Incident Policy, the Risk and Patient Safety Manager will commission a preliminary review a preliminary review report from the team most closely associated with the incident within one working day of the incident being reported to them. The preliminary report should be completed within 72 hours. The Risk and Patient Safety Manager will gather any further information to support a recommendation to the Chief Executive and the Director of Nursing and People as to the level of further action to be taken following the notifiable incident.

The relevant person has to be notified of the incident in the first instance in person. This must happen as soon as the preliminary report is prepared and no later than 4 working days from the time the incident was identified and reported.

The following actions should be completed prior to contacting the relevant person.

- The level of immediate response to the relevant person.
- Appointment of a Responsible Person to make the initial contact and to act as liaison on behalf of the Trust.
- Decide on what form the notification in person will take; phone call, arrange a meeting etc. realising that a written notification has to be given within 10 working days of the incident being identified and reported.
- Prepare the immediate response. This should include:

  1. A full account of the incident which to the best of the organisation’s knowledge is true of all the facts the organisation knows of the incident, as at the date the first contact with the relevant person is made. Apply a step by step approach of the relevant facts.
2. Information on what further enquiries into the incident would be undertaken that the organisation believes is appropriate. Also an explanation of the next steps which includes writing to the relevant person within 10 days of the incident being identified.

3. Statement of apology

4. Arrangement for recording and storage of all information shared with the relevant person and their responses. Copies to be sent to the Risk and Patient Safety Manager.

- In situations where the degree of harm is not yet clear but likely to fall under notifiable safety incident, the above actions should be taken.
- Consider the appropriateness of engaging patient support at this early stage. This includes the use of a facilitator, a patient advocate or a care professional who will be responsible for identifying the relevant person’s needs and communicating them back to the care team.
- Identify immediate support needs for staff involved.
- Ensure there is a consistent approach by all team members around discussions with the relevant person or their representatives.

The Serious Incident Policy should be referred to for guidance on how to support all those involved in an incident including staff in terms of debriefing, and the support mechanisms available to the Trust

8.2.2 Choosing the Responsible Person

The responsible person shall be nominated by the Associate Divisional Director of the relevant Division. This could either be the service user's consultant, primary nurse / care coordinator, or any other care professional who has a designated caseload of patients.

They should:
- Be known to, and trusted by, the service user and/or their lawful representative.
- Have a good grasp of the facts relevant to the incident.
• Be willing and able to offer an apology, reassurance and feedback to service users and/or their representatives.
• Be culturally aware and informed about the specific needs of the service user and/or their representatives.
• Provide their contact details should the relevant person wish to contact them during the investigation.

8.2.3 Written notification

The duty of candour regulation requires the Trust to put in writing what has been disclosed and shared with the relevant person; during the initial contact and any other relevant information within 10 days from the time the incident was identified and reported.

The team associated with the incident guided by the Risk and Patient Safety Manager should prepare the written notification. A template is available for this purpose (Appendix 5)

The content must include:
• The factual information of the incident shared during the notification in person
• Details of the enquiries to be undertaken as suggested during the notification in person
• Results of any further enquiry undertaken (some enquiries may not yet be complete).
• An apology
• Information on next steps and how further contact /communication will be conducted. This is particularly to do with the investigation; ensuring that modes of communication are established or ongoing contact as necessary.

8.2.4 Communication with the Relevant Person or those acting on their behalf

• Information should only be disclosed to family members or carers where the relevant person has given their expressed or implied consent.
• The Trust (responsible person) must make every reasonable attempt to contact the relevant person through all available communication channels. All attempts made to establish contact must be recorded on RiO.

• If the relevant person cannot be contacted or does not wish to communicate with the Trust, their wishes must be respected and a record of this must be kept. In such a situation, sections 8.2.1 and 8.2.3 do not apply. However, a written record is to be kept of attempts made to contact the relevant person and/or the discussions that took place up to and including refusal to be contacted.

• If the relevant person has died and there is nobody who can lawfully act on their behalf, a record of this should be kept on RiO.

• Communication; verbal or written must be relevant, and in plain English.

• Complicated / scientific terms must be explained

• Account of the facts must be given in a manner that the relevant person can understand. Consideration should be given to securing interpreters, advocates or communication aids where indicated to facilitate this.

8.2.5 Ongoing Contact/Communication with the relevant person

Following the written notification, the responsible person would have informed the relevant person that an investigation is underway and:

• Establish the channels of communication on a regular basis but making it clear that all communication will be recorded, shared and stored as part of the investigation process and the duty of candour requirement.

• Give the approximate time for completion of the investigation and the process for sharing relevant information when the report is complete.

• The person/persons that would liaise with him/her and at what intervals, to update him/her on progress.

• Provide contact details should the relevant person wishes to make contact during the investigation.

8.2.6 Relevant Person / Service User Support
The Trust must give the relevant person all reasonable support necessary to help overcome the physical, psychological and emotional impact of the incident. The Responsible Person or staff dealing with the relevant person should refer to the Serious Incident Policy as well as consider these actions to facilitate that process:

- Treating the relevant person with respect, consideration and empathy.
- Offering the option of direct emotional support during the notifications, for example from a family member, a friend, a care professional or a trained advocate.
- Offering access to assistance with understanding what is being said e.g. via interpretative services, non-verbal communication aids, written information, Braille etc.
- Providing access to any necessary treatment and care to recover from or minimise the harm caused where appropriate
- Providing the relevant person with details of specialist independent sources of practical advice and support or emotional support/counselling.
- Providing the relevant person with information about available impartial advocacy and support services.
- Arranging for care and treatment to be delivered by another professional, team or provider if this is possible, should the relevant person make a request.
- Providing support to access the Trust's complaints procedure.

8.2.7 Staff Support (Appendix 3)

Patient safety incidents do have an impact on staff particularly those directly involved in such incidents. Arrangements for the provision of support to staff in potentially traumatic and stressful incidents, complaints and claims are described in Appendix 3. The support process will also assist in providing support for staff who may experience challenging situations when appearing as a witness or being interviewed.

There is also a staff support checklist for managers to ensure that all support mechanisms in place in the Trust and externally are explored (Appendix 4)

8.2.8 Completing the Process

Communication with the service user, their family, carer or representative
All lead investigators are required to include service users and their families in investigations and to feedback. Refer to the Serious Incident Policy for guidance.

After completion of the incident investigation, feedback should take the form most acceptable to the service user. Whatever method is used, the communication should include:

- the chronology of clinical and other relevant facts.
- details of the service user’s and/or their carer’s concerns and complaints.
- a repeated apology for the harm suffered and any shortcomings in the delivery of care that led to the service user safety incident.
- a summary of the factors that contributed to the incident.
- information on what has been and will be done to avoid recurrence of the incident and how these improvements will be monitored.

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 service user; where investigations are pending coronial processes; or where specific legal requirements preclude disclosure for specific purposes. It is expected that in such situations, the Caldicott Guardian will be consulted prior to feeding back.

**Continuity of care**
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 CPA plans addressed to designated individuals such as the referring GP when the patient safety incident has not occurred within the Trust.

Patients, their family, carer or 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 care team. They should also be informed that they have the right to continue their
treatment elsewhere if they have lost confidence in the care team involved in the patient safety incident.

**Communication with the GP and other community care service providers for patient safety incidents not occurring in the Trust**

Wherever indicated, it is advisable to send a brief communication to the service user’s GP or appropriate or an appropriate community care service. This situation will arise where the incident may impact on continuing care e.g. delay in discharge where the service user has other clinical appointments. :

- the current condition of the service user.
- key investigations that have been carried out to establish the patient’s clinical condition.

It may be valuable to consider including the GP in one of the follow-up discussions either at discharge or at a later stage.

**9.0 Other Issues to Consider**

**9.1 Advocacy and Support**

Patients, their families, carer or representative may need considerable practical and emotional help and support after experiencing an incident. The most appropriate type of support will vary and it is therefore important to discuss with the patient, their family, carer or representative their individual needs. Support may be provided by patient’s family, social workers, religious representatives, advocacy services or the Advice and Complaints Service. Where the patient needs more detailed long-term emotional support, advice should be provided on how to gain access to appropriate counselling and support services, for example, from Cruse Bereavement Care.

The Trust will provide:
- contact details of a staff member who will maintain an ongoing relationship with the patient, using the most appropriate method of communication from the patient’s, their family’s and carers’ perspective. Their role is to provide both practical and emotional support in a timely manner.

9.2 Particular service user circumstances
The approach to Being Open may need to be modified according to the patient’s personal circumstances. The following gives guidance on how to manage different categories of patient circumstances.

9.2.1 When a Service User dies
When an incident has resulted in a patient’s death, it is even more 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 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 state.

Usually, the Being Open discussion and any investigation occur before the coroner’s inquest. But 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, carer or representative. 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.

9.2.2 Withholding Information
The only circumstance in which it is appropriate to withhold incident information from a service user is when it would cause adverse psychological harm to him/her. However, such circumstances are rare and a second opinion (by another consultant psychiatrist) would be needed to justify withholding information from the patient. In the main, the Caldicott Guardian should be consulted if in doubt.
Apart from in exceptional circumstances, it is never appropriate to discuss patient incident information with a carer or relative without the express permission of the service user.

9.2.3 Patients with limited understanding
Some service users have conditions that may 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 that this extends to decision making and to the medical care and treatment of the patient. The Being Open discussion would be conducted 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, patients with 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.

9.2.4 Patients with different language or cultural considerations
The need for translation and advocacy services, and consideration of special cultural needs (such as for patients from cultures that make it difficult for a woman to talk to a male about intimate issues), must be taken into account when planning to discuss patient incident information. It is useful 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 the information by editing what is communicated.

9.2.5 Service Users 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. This involves focusing on the needs of the patient, their family and carers, and being personally thoughtful and respectful.
9.2.6 Service Users who do not agree with the information provided

Sometimes, despite the best efforts of healthcare staff or others, the relationship between the patient, their family and 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;

- Information on how to make a formal complaint and/or any other available means of giving positive or negative feedback to healthcare staff involved in their care.

- Where the patient agrees, ensure their family and carers are involved in discussions from the beginning;

- Ensure the patient has access to support service;

- 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.

- Write a comprehensive list of the points that the patient, their family and carers disagree with and reassure them you will follow up these issues.

10. Lessons learned from Incidents
Following an incident investigation, the Serious Incident Policy describes how lessons learned are disseminated across the organisation and how feedback is given to staff and service users/representatives.

11. Duty of Candour compliance/non/compliance
It is essential that all staff comply with the procedures within this policy as non-compliance is an enforceable action by the CQC.
The CQC will report on the duty of candour under the safety key question in their inspection reports. The CQC would want to know whether the Trust is meeting Regulation 20: Duty of Candour. When they identify a breach of the regulation, they will assess the impact on people and decide whether or not to take regulatory action, and what action to take, in accordance with their Judgement Framework and Enforcement Policy.

12.0 Dissemination and Implementation Arrangements

The Being Open and Duty of Candour Policy will be placed on the Trust intranet. Senior managers and team leads have a responsibility to ensure that all staff are made aware of it.

Staff requiring clarification or support with implementing this policy should contact the Risk and Patient Safety Manager.

13. Training

Training is available for staff on Root Cause Analysis for carrying out investigations. Staff are also supported by the Risk and Patient Safety Managers to respond to required actions from the time an incident occurs to the end of the investigation.

14. Review of the Policy

This policy will be reviewed in March 2018 or at any time before this date that a significant change is identified either by regulation or otherwise.
### 15. Monitoring and audit arrangements

<table>
<thead>
<tr>
<th>Elements to be monitored</th>
<th>Lead</th>
<th>How Trust will monitor compliance</th>
<th>Frequency</th>
<th>Reporting Which committee or group will the monitoring report go to?</th>
<th>Acting on recommendations and Lead(s) Which committee or group will act on recommendations?</th>
<th>Change in practice and lessons to be shared</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requirements of Being Open and the Duty of Candour: Acknowledgement, Apology, explanation, contact with Service User, information shared and timeliness</td>
<td>Risk and Patient Safety Manager</td>
<td>Audit of Being Open and Duty of Candour Requirements</td>
<td>6 monthly</td>
<td>Quality Committee</td>
<td>Quality Committee</td>
<td>Required actions will be identified and completed in a specified timeframe</td>
</tr>
<tr>
<td>Communication with Service User and record keeping</td>
<td>Clinical Directors</td>
<td>Audit of Service Users record</td>
<td>Quarterly</td>
<td>Quality Committee</td>
<td>Quality Committee</td>
<td></td>
</tr>
<tr>
<td>Support for Staff</td>
<td>Chief Operating Officer</td>
<td>Audit of Checklist</td>
<td>6 monthly</td>
<td>Quality Committee</td>
<td>Quality Committee</td>
<td></td>
</tr>
</tbody>
</table>
16. References

Mental Capacity Act 2005

Department for Constitutional Affairs: Mental Capacity Act 2005 Code of Practice

CQC Regulation 20:Duty of Candour; Guidance for NHS Bodies

Care Quality Commission (Registration Requirements) Regulations 2009


NHS National Patient Safety Agency, Being Open Framework provides guidance on communicating about patient safety incidents with patients, families and carers
http://www.nrls.npsa.nhs.uk/beingopen/?entryid45=83726

Definitions of levels of harm included in: National Patient Safety Agency, Seven Steps to Patient Safety
http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/?entryid45=59787

NHS Litigation Authority, Saying Sorry

General medical Council, Good Medical Practice 2001, Guidance on 'duty of candour'
http://www.gmc-uk.org/publications/24152.asp
17. Associated documents

The following documents should be referred to in conjunction with this policy:

- CL06 Consent to Treatment policy
- CL30 Care Programme Approach Operational Policy
- COR12 Claims Management Policy
- CO13 Advice and Complaints Policy
- HR04 Disciplinary Procedures Policy
- RM01 Prevention and Management of Violence and Aggression Policy
- RM03 Incident Reporting Policy
- Management of Serious Incidents Policy
- RM05 Management of Serious Incidents Policy
- RM12 Risk Management Strategy
# Appendix 1

## Equality Impact Assessment Tool

<table>
<thead>
<tr>
<th></th>
<th>Yes/No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Does the policy/guidance affect one group less or more favourably than another on the basis of:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Ethnic origins (including gypsies and travellers)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Nationality</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Culture</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Religion or belief</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Sexual orientation including lesbian, gay and bisexual people</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Disability - learning disabilities, physical disability, sensory impairment and mental health problems</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>2. Is there any evidence that some groups are affected differently?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>3. If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>4. Is the impact of the policy/guidance likely to be negative?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>5. If so can the impact be avoided?</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>6. What alternatives are there to achieving the policy/guidance without the impact?</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>7. Can we reduce the impact by taking different action?</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>
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 support the policy.

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 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 or trivialisation of a patient’s concerns will make future open and honest communication more difficult.

2) Principle of truthfulness, timeliness and clarity of communication

Information about a patient safety incident must be given to patients and/or their 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.

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 might 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.

3) Principle of apology

Patients and/or their 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 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. Although an apology should be given as soon as staff are aware an incident has occurred, it is essential that the episode is planned and some preparation undertaken. 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.
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.

4) 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 such as Action against Medical Accidents (AvMA) should be given to the patient as soon as it is possible. Appendix 8.

5) Principle of professional support

The trust’s ethos of openness and fairness creates an environment in which all staff, whether directly employed or independent contractors, 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, Royal Colleges, the Medical Protection Society, the Medical Defence Union and the Nursing and Midwifery Council.

Being Open and Duty of Candour Policy v4 21
6) 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 and audited for their effectiveness.

7) Principle of multidisciplinary responsibility

This policy 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 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.

8) Principle of clinical governance

“Being open” has the support of patient safety 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 trust 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 through managers’ feeding back locally and via the mortality and morbidity agenda of the Clinical Improvement Group.

These actions are monitored to ensure that the implementation and effects of changes in practice following a patient safety incident.

9) 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 multi-disciplinary 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.

10) Principle of continuity of care

Patients are entitled to expect 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 team, the appropriate arrangements should be made for them to receive treatment elsewhere.
Appendix 3

PROCESS for Staff Support

Immediate support / debriefing

In all cases, as soon as managers become aware that one of their staff has been involved in a potentially traumatic or stressful event, they should offer immediate support and reassurance to them. Much of the reassurance required by the member of staff can be provided by the manager informing them of the process and referring them to appropriate internal or external resources.

It is very important that the manager provides close support in the immediate aftermath of an event (24 – 48 hrs). This is a vital opportunity to help the individual involved in the situation keep the issues in perspective and not feel or become isolated.

The manager should ensure that the:

- Debrief is confidential and takes place in a suitable environment.
- Member of staff is given time to talk and is listened to and feels supported
- Arrangements are put in place for the staff member to receive any required medical assessment or treatment. For example, if they are in shock or suffer from a pre-existing medical condition that may have been exacerbated by the event.
- The 24 – 48 hour debrief meeting is discussed and appropriate arrangements put in place. The manager should discuss with her/his Service Manager and Associate Divisional Director to identify a suitable senior member of staff to conduct this session.
- Opportunity for referral to other sources of support is discussed and appropriate arrangements commenced, if required.
- Advice is offered concerning any requirement to write a statement. This may be provided by: the manager; a member of the Legal Services or Patient Safety teams. Staff may choose to discuss with their professional body.

Debriefing within 24 – 48 hours

This debriefing provides an opportunity to go over an event in a calm and rational fashion and also provides a further opportunity for the member of staff to explore their concerns.

As with the immediate debrief, this meeting should be used as an opportunity to plan further supportive meetings and to identify any other people with whom the member of staff should discuss the events.

Group debriefings

A group debriefing is sometimes useful when there are several members of staff who would value such a discussion. Such a session requires strong chairmanship to avoid an atmosphere of recrimination or blame. It can usefully be based around a presentation of the case and a reappraisal of the options, judgments and decisions that were made or could have been made. It must have primarily an educational focus. It is particularly helpful for it to take place as soon as possible following the event. Group debriefings do not substitute for individual care and support for the parties concerned.
Ongoing support
Managers should remember that, in the initial stages following an event, they or a staff member may be unaware of the impact of that event on their well-being or ability to undertake their full range of duties. For this reason, it is essential that on-going support is provided. This should involve a one to one meeting no later than 2 weeks after the event. At the meeting any follow up arrangements, for members of staff still experiencing difficulties should be put in place as a matter of urgency, if this has not already been commenced

It should be remembered that a complaint, claim or court appearance may arise some considerable time after the actual event occurred. This does not alter the fact that this may be equally traumatic for staff and support may be required at this stage

Action for managers or individuals to take if the staff member is experiencing difficulties associated with the event
It must be remembered that at any stage, either immediately following an event or in the longer term, staff may find themselves experiencing difficulties. In this case a number of actions may be considered.

- **Referral to Occupational Health**
  This may be made by the manager or the member of staff may self-refer. Occupational Health will assess the fitness of the staff member to continue to undertake their full range of duties and provide relevant advice. It is essential that the manager follows the advice given by Occupational Health.

- **Referral to the Trust’s Employee Assistance Service**
  Staff may be referred by the Occupational Health Department, their line manager or may self-refer. If the Counselling service deems it appropriate, a series of counseling sessions will be arranged. Staff offered such service have a responsibility to inform their manager. The manager may need to discuss arrangements should a staff member need to attend any of these sessions during working hours.

- **Change to work environment**
  It may be that following assessment by the Occupational Health Department or if the member of staff is finding it challenging to work in the same environment, and/or with others who have been involved in the event, that consideration must be given to temporary redeployment or to a restriction of duties.

Staff responsibilities
A staff member should:

- Inform their line manager if they are experiencing difficulties associated with an event, or as a result of being called as a witness, so that direct support can be provided
- Request to be referred or refer themselves to the Employee Assistant Service, or Occupational Health
- Inform their line manager of any change in the behaviour or conduct of a colleague, even if they were not directly involved in the event, as the change may indicate that support is required
• Keep their manager updated about their feelings affected by an incident

Human Resources
There may be occasions where, as well as Occupational Health, there is a requirement for involvement from the Human Resources team. This may be specifically the case where a member of staff feels they are unable to return to their post. In such cases the following policies should be referred to:
  • Management of Attendance and Absence Policy
  • Capability Policy and Procedure
  • Management of Stress at Work Policy

Staff Support Checklist (Appendix 4)
Managers should utilise the staff checklist to ensure that all staff are provided with timely, appropriate support; either internally or externally. The checklist should be completed and retained by the manager until the matter is at an end. Once finished, the checklist should be forwarded to the Human Resources for auditing purposes. The checklist can be used either on an individual basis or for a group of staff involved in the same incident, complaint, claim or as a witness.

Advice and support available to staff in the event of being called as a witness
The prospect of having to give evidence in a court of law or at a tribunal can be extremely daunting and appropriate support is essential, particularly if the staff member has not previously been a witness.

• Support provided

  The Risk and Patient Safety Manager and Compliant and Incidents Manager will provide the necessary support to staff.

• Prior to the event: a full briefing session should be held where supporting needs will be evaluated. Once the needs are established, the manager conducting the briefing will make arrangements to meet the needs of the member of staff.

• During the event: the member of staff will be accompanied at the court or tribunal by one or more of the staff above.

• After the event: a debrief meeting will be held to discuss the events surrounding the court appearance and the outcome. The Risk and Patient Safety Manager will arrange this.
# Appendix 4

## STAFF SUPPORT CHECKLIST

To be retained by manager, copy to Human Resources

<table>
<thead>
<tr>
<th>Employee Job title</th>
<th>Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of incident</td>
<td>Department/Ward</td>
</tr>
<tr>
<td>Reason for support</td>
<td></td>
</tr>
</tbody>
</table>

### Section 1 – To be completed by line manager

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Was immediate support/debriefing offered?</td>
<td>Yes/No/NA</td>
</tr>
<tr>
<td>2</td>
<td>Was a copy of internal and external support agencies highlighted to the employee(s)?</td>
<td>Yes/No/NA</td>
</tr>
<tr>
<td>3</td>
<td>Was referral to the Occupational Health discussed with the employee(s)?</td>
<td>Yes/No/NA</td>
</tr>
<tr>
<td>4</td>
<td>Was counselling support discussed and offered to the employee(s)?</td>
<td>Yes/No/NA</td>
</tr>
<tr>
<td>5</td>
<td>Have temporary role adjustments, redeployment or reassignment of duties been considered?</td>
<td>Yes/No/NA</td>
</tr>
<tr>
<td>6</td>
<td>Has a second debriefing (24 – 48 hours) been offered and held with the employee(s)?</td>
<td>Yes/No/NA</td>
</tr>
<tr>
<td>7</td>
<td>Has the need for ongoing or long term support been discussed?</td>
<td>Yes/No/NA</td>
</tr>
<tr>
<td>8</td>
<td>Has (have) a referral(s) to Occupational Health been made for assessment about fitness to return to work?</td>
<td>Yes/No/NA</td>
</tr>
</tbody>
</table>

### Section 2 – Witness appearances only. to be completed by line manager

*Has (have) the employee(s):*

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Been briefed about the process?</td>
<td>Yes/No/NA</td>
</tr>
<tr>
<td>11</td>
<td>Been offered support in statement writing?</td>
<td>Yes/No/NA</td>
</tr>
<tr>
<td>12</td>
<td>Been offered support in preparation for appearing as a witness?</td>
<td>Yes/No/NA</td>
</tr>
<tr>
<td>13</td>
<td>Have arrangements been made to ensure that the employee will be supported on the day of the hearing?</td>
<td>Yes/No/NA</td>
</tr>
<tr>
<td>14</td>
<td>On conclusion of the case, was the employee debriefed (if the information was in the public domain)?</td>
<td>Yes/No/NA</td>
</tr>
</tbody>
</table>
Dear XX,

I am writing further to our recent meeting to discuss the incident which occurred involving yourself / your relative on (insert date) at (ward/team/home). On behalf of the trust, I would like to again offer our sincere apologies for this incident and for the distress which it will have caused you / your relative. A brief outline, the incident is as follows:

The Trust aims to provide a quality service to you / your relatives and to investigate promptly any such incidents. It is essential that we share the findings of our investigation with all those involved, including trust staff, so that lessons can be learned and to make improvements to practice where necessary.

I agreed at our meeting on date, when we discussed the incident that I would write to you with an outline of our discussion which I have summarised below.

1. 
2. 
3. 
4. 

Since our meeting we have instigated a formal investigation into the incident which is being led by (insert name and job title). Upon completion of the investigation a further meeting will be arranged with you to share the findings and to review the lessons learned. Once again on behalf of the Trust, I apologise that this incident occurred.

Yours sincerely

Name
Job Title