# Being Open/Duty of Candour Policy

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Localities  
Service Experience Department  
Trust Solicitors |
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## Version History

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| 4       | Feb 2015 | 1. Reformatting to meet the requirements of the Policy, Procedure and Guidance for the Development and Management of Policy, Procedure and Guidance Documents;  
2. Updated to make explicit the requirements of the Duty of Candour. |
| 5       | June 2015| 1. Update Appendix 1. Regulation 20: Duty of Candour to reflect national changes  
2. Make explicit Managers responsibilities when the Duty of Candour is triggered.  
3. Include flowchart for the process as Appendix 2. |
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1. Policy Statement

In accordance with national guidance and legislation, the Trust is required to inform all service users and or their carers/families of notifiable safety incidents which lead to either moderate harm, severe harm or death. Notifiable safety incidents are defined in Appendix 1.

2. Introduction

Promoting a culture of openness is a prerequisite to improving service user safety and the quality of healthcare systems. It involves apologising and explaining what happened to service users who have been harmed in the course of their treatment. It ensures that communication is open, honest and occurs as soon as possible following an incident. It encompasses communication between healthcare organisations, teams and service users and/or their carers.

The Trust is committed to improving communication between service users and/carers when a service user has suffered a serious injury, has died or might die or come to harm as the result of a service user safety incident.

3. Purpose

This policy aims to improve the quality and consistency of communication when service users are involved in a notifiable incident by ensuring that, if mistakes are made, service users and/or their carers receive the information they need promptly, in order to enable them to understand what has happened; that an apology is offered; and that service users and/or carers are informed of the action the Trust will take to try and ensure that a similar type of incident does not recur. An apology is not an admission of liability.

The Being Open/Duty of Candour Policy should be read in conjunction with the Policy & Procedure for Reporting Incidents (Including the Management of Serious Untoward Incidents), the Policy & Guidelines for Investigating Incidents, Complaints and Claims, the Claims Policy & Procedure and the Complaints Policy & Procedure. It aims to create an environment where service users and/or their carers, care professionals and managers all feel properly supported when things go wrong.

4. Scope

This policy applies to all 2gether NHS Foundation Trust staff. There are no limitations on its circulation within the Trust and the wider NHS community, and it can be made available to service users, their families and the public on request.

5. Context

The Duty of Candour (CQC Regulation 20): came into force for NHS Bodies
on 27 November 2014 (updated March 2015) and is a direct response to recommendation 181 of the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust which recommended that a statutory duty of candour be imposed on healthcare providers. In interpreting the regulation on the duty of candour, we use the definitions of openness, transparency and candour used by Robert Francis in his report:

- **Openness** – enabling concerns and complaints to be raised freely without fear and questions asked to be answered.

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

- **Candour** – any patient harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it.

The regulation and its implementation reflect the approach proposed by the Dalton/Williams review, including defining a notifiable patient safety incident to include moderate harm, severe harm, death, and prolonged psychological harm. These definitions are contained within Regulation 20 itself. NHS bodies have been encouraged for some time to voluntarily report moderate incidents. Regulation 20: Duty of Candour is seen in full in Appendix 1.

The Being Open framework was updated in November 2009 by the National Patient Safety Agency (NPSA - The NPSA no longer exists, but its functions transferred to the NHS Commissioning Board Special Health Authority on 1 June 2012). It details how Being Open about what happened and discussing patient safety incidents promptly, fully and compassionately can help service users, their carers/families and professionals to cope better with the after effects.

### 6. Duties

6.1 Responsibility for the development, maintenance and review of this document lies within the Quality Management Team. The Director of Quality has board level responsibility for the development of this document and may delegate this responsibility to a subordinate.

6.2 **The Trust Board**

The Trust Board is responsible for actively championing the *Duty of Candour Being Open* process by promoting an open and fair culture that fosters peer support and discourages the attribution of blame.

6.3 **Chief Executive**

The Chief Executive is responsible for ensuring the infrastructure is in place to support openness between care professionals and service users and-or their
carers following an incident that led to serious harm, major harm, or death.

6.4 **Director of Quality**

The Director of Quality has responsibility for ensuring that an appropriate support mechanism is in place for staff involved in patient safety incidents.

6.5 **Service Directors**

Service Directors (in liaison with the Director of Service Delivery, Medical Director and Director of Quality) have responsibility to ensure that the most appropriate staff are identified to meet with the service user and/or relatives. For the purpose of this policy they are known as the nominated lead. In all instances consideration will be given to the characteristics of the person nominated to lead the *Duty of Candour/Being Open* process, ensuring that the lead is senior enough or has sufficient experience and expertise in relation to the type of service user safety incident to be credible to service users and carers.

6.6 **All members of staff**

All staff will be expected to adhere to this policy. Staff will also be aware of the relevant requirements regarding the Duty of Candour as set out in their relevant professional regulatory body's Codes of Conduct. All staff have a responsibility for ensuring that patient safety incidents are acknowledged and reported via DATIX as soon as they are identified. In cases where the service user and/or carers inform 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 staff.

It is not always appropriate for junior members of staff to be involved in *Duty of Candour/Being Open* discussions, particularly if they are distressed. However, when a junior member of staff who has been involved in a service user safety incident asks to be involved in the discussion, it is important they are accompanied and supported by a senior team member. It is unacceptable for junior staff to communicate service user safety information alone or to be delegated the responsibility to lead a *Duty of Candour/Being Open* discussion unless they volunteer and their involvement takes place in appropriate circumstances (i.e., they have received appropriate training and mentorship for this role).

6.7 **Managers**

All managers must review patient safety incidents reported via DATIX and check the details for completeness. In line with the Incidents Policy & Procedure, they must authorise the record and escalate the incident immediately if *moderate, severe* or potentially severe harm, *prolonged psychological harm*, or *death* is reported (having first determined if the
incident has been correctly recorded and the outcome in terms of harm to the service user is graded accurately).

When moderate or serious harm and/or death is reported, they have a personal duty to ensure that all actions as described in this policy are undertaken without delay (Sections 15-22), in line with the Principles of Being Open (Section 14).

6.8 Supportive Roles

The Assistant Director of Governance and Compliance, Patient Safety Manager and the Service Experience Manager can all be contacted for additional support as required, particularly in relation to the following:

- meeting with service users involved in a patient safety incident (and/or their carers);
- explaining what led to the incident occurring and any lessons learned;
- providing the service user (and/or carer) with an apology;
- ensuring that the service user has been provided with appropriate ongoing support;
- ensuring that the service user (and/or) carer has been provided with a contact name in the event of further queries or issues arising;
- documenting the details of all discussions with the service user (and/or carer);
- keeping in close communication with the incident investigation leads to enable regular and informed communication with the service user and/or carer;
- provision of written information relating to investigations to service users and/or their carers/families.

7. Definitions

*Being Open* is described by the NPSA as;

"Being open simply means apologising and explaining what happened to service users and/or their carers who have been involved in a service user safety incident"

A patient safety incident is described by the NPSA as

"Any unintended or unexpected incident(s) that could have or did lead to harm for one or more persons receiving NHS-funded healthcare. ‘Patient safety incident’ is an umbrella term which is used to describe a single incident or a series of incidents that occur over time."

A near miss is “any event which does not, but has the potential to result in injury, damage or loss”.

It is also important to consider the consequences of incidents; the following
are taken from Regulation 20: Duty of Candour and are used to describe the outcome to service users in terms of harm and mark the threshold for when the Duty of Candour must be enacted.

"Moderate harm" means—

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

(b) significant, but not permanent, harm;

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

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

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

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

“Prolonged psychological harm” means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

8. Ownership & Consultation

The Director of Quality has board level responsibility for the development of this document and may delegate the authority to a subordinate.

Trust Localities, Executive Directors, Service Experience Department & the Trust Solicitors (as a minimum) should be consulted with prior to ratification.

9. Ratification Details

This document will be ratified by the Governance Committee.

10. Release Details

This document will be made available to all staff and managers via the Trust’s policy section on the intranet.
The ratification and release of this document will be highlighted to managers and all staff via the weekly electronic news bulletin.

11. **Review Arrangements**

   This document will be reviewed as determined by changes in:
   - Legislation;
   - National guidance;
   - Local Trust needs.

   This document will be reviewed every 3 years.

12. **Process for Monitoring Compliance**

   Monitoring compliance with this policy is incorporated into the overall monitoring for incidents as described in *Incidents Policy and Procedure (Including the Management of Serious Incidents)*

13. **Training**

   The requirements of the Duty of Candour will be provided for new starters as part of Corporate Induction.

   For existing staff, the requirements of the Duty of Candour will be provided as part of Investigations/Root Cause Analysis Training.

   The Trust will also hold Duty of Candour awareness events no fewer than once per annum that staff can attend.

14. **Principles of Being Open**

   The Being Open Framework describes 10 principles which all Trusts must apply when supporting service users and/or carers who have been involved in care related incidents.

   14.1 **Principle of acknowledgement**

   All patient safety incidents should be acknowledged and reported as soon as they are identified. In cases where the user and/or their carers inform 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 staff. Denial of a service user’s concerns will make future open and honest communication more difficult.

   14.2 **Principle of truthfulness, timeliness and clarity of communication**

   Information about a patient safety incident must be given to users and/or
their carers in a truthful and open manner by the senior practitioner on duty. Users want a step-by-step explanation of what happened, that considers their individual needs and is delivered openly.

Communication should also be timely: users 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. Staff should explain that new information may emerge as an incident investigation is undertaken, and users and/or their carers should be kept up-to-date with the progress of an investigation.

Users 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, and using jargon which they may not understand should be avoided. It is accepted that on rare occasions, situations might arise where it might be inappropriate and/or not in the best interests of the user or carer to be informed. Where such concerns are evident advice should be sought from the Director of Quality or Assistant Director of Governance and Compliance. See section 22 in this regard.

14.3 Principle of apology

Users and/or their carers should receive a sincere expression of sorrow or regret for the harm that has resulted from a service user safety incident. This should be appropriately worded and in an agreed manner, as early as possible. Both verbal and written apologies should be given.

Verbal apologies are essential because they allow face-to-face contact between the user and/or their carers and the team. This should be given as soon as staff are aware an incident has occurred. It is important not to delay for any reason, including: setting up a more formal multidisciplinary *Being Open* discussion with the service user and/or their carers; fear and apprehension; or lack of staff availability. Delays are likely to increase the users and/or their carer’s sense of anxiety, anger or frustration. Evidence suggests that users are more likely to seek medico-legal advice if verbal and written apologies are not delivered promptly.

A written apology, which clearly states that the trust is sorry for the suffering and distress resulting from the incident, must also be given.

14.4 Principle of recognising service user and carer expectations

Users and/or their carers can reasonably expect to be fully informed of the issues surrounding a service user safety incident, and its consequences, in a face-to-face meeting with staff from the Trust. They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times. Users 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 service user requiring additional support, such as an independent service user advocate or
Where appropriate, information about the Patient Advisory and Liaison Service (PALS) and other relevant support groups like Cruse Bereavement Care should be given to the service user and/or their carers as soon as it is possible.

14.5 **Principle of professional support**

The Trust is responsible for creating an environment in which all staff, whether directly employed or independent contractors, are encouraged to report patient safety incidents. Staff should feel supported throughout the incident investigation process because 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.

The Trust should also encourage staff to seek support from relevant professional bodies such as the General Medical Council, Royal Colleges, the Medical Defence Union, the Nursing and Midwifery Council, and the Health and Social Care Professionals Council.

Where there is reason for the Trust to believe a member of staff has committed a punitive or criminal act, steps should be taken 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.

14.6 **Principle of risk management and systems improvement**

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

*Being Open* is one part of an integrated approach to improving service user safety following a patient safety incident. It needs to be embedded in an overarching approach to risk management which includes local and national incident reporting, analysis of incidents using Root Cause Analysis and decision making about staff accountability using the Incident Decision Tree.

14.7 **Principle of multidisciplinary responsibility**

These principles apply to all staff who have key roles in the service user’s care. Most care involves multidisciplinary teams and communication with users 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. To ensure multidisciplinary involvement in the *Being Open* process, all Heads of Profession are available for advice and support and their expertise may be requested as part of any incident investigation.
14.8 **Principle of clinical governance**

*Being Open* is supported though the Trust’s quality and risk management frameworks. Patient safety incidents are investigated and analysed, to find out what can be done to prevent their recurrence. And the Trust has a responsibility to share the findings from reviews of care to all staff so that they can learn from patient safety incidents. Where appropriate, learning programmes and clinical audit will be developed to monitor the implementation and effects of changes in practice following a patient safety incident. The Assistant Director of Governance & Compliance will coordinate all such activity.

14.9 **Principle of 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/practitioners involved in treating the provision of care. Where this is not practicable or an individual refuses to consent to the disclosure, disclosure may still be lawful if justified in the public interest or where those investigating the incident have statutory powers for obtaining information. Communications with parties outside of the clinical team should also be on a strictly need-to-know basis and, where practicable, records should be anonymous. In addition, it is good practice to inform the users and/or their carers about who will be involved in the investigation before it takes place, and give them the opportunity to raise any concerns.

14.10 **Principle of continuity of care**

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

15. **Timing of the meeting with service user and/or their carer(s)**

The initial discussion with the service user and/or carer/family should occur as soon as possible after recognition of the incident. The member of staff identified to make contact should consider the following:

- Clinical condition of the service user;
- Availability of key staff involved in the incident;
- Availability of the service user’s family and-or carers;
- Availability of support staff, for example a translator or independent advocate, if required;
- Service user preference (in terms of when and where the meeting takes place and which healthcare professional leads the discussion – if for any
reason during the initial discussion it becomes clear that the service user would prefer to speak to a different healthcare professional, the service user’s wishes should be respected and a substitute with whom the service user is satisfied should be provided;

- Privacy and comfort of the service user;
- Arranging the meeting in a sensitive location.

It is accepted that on occasions, the service user and/or carer/family may not wish to meet but may prefer to engage in a discussion via telephone.

16. **Content of initial discussions with service user and/or carers/families**

The identified member of staff has a number of responsibilities as detailed below. Advice can be sought from the Director of Quality or Assistant Director of Governance & Compliance regarding any aspect of these responsibilities:

1. They will advise the service user and/or carers of the identity and role of all people attending the discussion before it takes place. This allows them the opportunity to state their own preferences about which healthcare staff should be present.

2. They should express sympathy, regret and an apology for the harm that has occurred, when appropriate.

3. They will ensure that the facts that are known are agreed by the multidisciplinary team. Where there is disagreement, communication about these events should be deferred until after the investigation has been completed. The member of staff must inform the service user and/or carers/families that an incident investigation is being carried out and more information will become available as it progresses.

4. They should make it clear to the service user and/or carer that new facts may emerge as the incident investigation proceeds.

5. They must take into consideration the service user’s and/or carer’s/families understanding of what happened, as well as any questions they may have.

6. They should give consideration to the formal noting of the service user’s and/or carer’s/families views and concerns, and demonstrate that these are being heard and taken seriously.

7. They should ensure that appropriate language and terminology is used when speaking to service users and/or carers/families. For example, using the terms ‘incident’ or ‘adverse event’ may be at best meaningless and at worst insulting to a service user and/or carer. If a service user’s first language is not English, it is also important to consider their language needs – if they would like the discussion conducted in another
language, this should be arranged. Refer to the Translation & Interpretation Policy.

8. They should provide an explanation about what will happen next in terms of the long term treatment plan and incident analysis findings.

9. Information on likely short and long term effects of the incident (if known) should be shared with the service user and/or carer by the member of staff in conjunction with other members of the healthcare team as appropriate. The latter may have to be delayed to a subsequent meeting when the situation becomes clearer.

10. They should offer practical and emotional support to the service user and/or carer/families. This may involve signposting to third parties such as charities and voluntary organisations as well as offering more direct assistance. Information about the service user and the incident should not normally be disclosed to third parties without consent.

11. It should be recognised that service users and/or their carers/families may be anxious, angry and frustrated even when the discussion is conducted appropriately. It is essential that the following does not occur:

   - Speculation;
   - Attribution of blame;
   - Denial of responsibility;
   - Provision of conflicting information from different individuals.

12. They should ask the service user and/or carer if they are satisfied with the explanation and a note made of this in the service user's records.

13. They should provide the service user and/or carer with contact details so that if further issues arise later there is a conduit back to the relevant professionals or an agreed substitute.

17. **Written Records of the Discussion**

   The member of staff leading the meeting must ensure that a record is created of the discussion even if the discussion took place via telephone. The document should contain details of:

   - The time, place, date as well as the name and relationships of all attendees;
   - The plan for providing further information to the service user and/or carer/families and the timeliness of this feedback;
   - Offers of assistance and the service user's and/or carers/families response;
   - Questions raised by the family and/or carer or their representatives, and the answers given;
   - Plans for follow-up as discussed;
• Progress notes relating to the situation, and an accurate summary of all the points explained to the service user and/or carer;
• Copies of letters sent to service users, carers and the GP where appropriate.

Statements taken in relation to the incident should form part of the incident investigation. For completeness, a copy of all of the above documents should be provided to the lead incident investigator for inclusion with the incident investigation report. Refer to the Guidelines for Investigating Incidents, Complaints & Claims for details of incident investigation processes.

18. Involving staff who made mistakes

Some patient safety incidents that resulted in moderate harm, severe harm or death can result from errors made by healthcare staff while caring for the patient. In these circumstances, the member(s) of staff involved may or may not wish to participate in the Being open discussion with the patient, their family and carers.

Every case where an error has occurred needs to be considered individually, balancing the needs of the patient, their family and carers with those of the healthcare professional concerned. In cases where the healthcare professional who has made an error wishes to attend the discussion to apologise personally, they should feel supported by their colleagues throughout the meeting. In cases where the patient, their family and carers express a preference for the healthcare professional not to be present, it is advised that a personal written apology is handed to the patient, their family and carers during the initial Being Open discussion.

19. Continuity of Care

When a service user has been harmed during the course of treatment and requires further therapeutic management or rehabilitation, the lead should ensure that the service user and/or carer is informed of the on-going management plan.

Service users and/or their carers should be reassured that they will continue to be treated according to their assessed needs even in circumstances where there is a dispute between them and the team. They should also be informed that they have the right to continue their treatment elsewhere if they have lost confidence in the team involved in the service user safety incident. In cases where service users and/or carers request a transfer of care, the lead should seek advice and support from their lead professional to ensure that the transfer happens as safely and promptly as possible.
20. Completing the Communication Process Post Investigation

20.1 Communication with the service user and/or carers

After completion of the incident investigation, feedback on the results of the investigation must be offered to the service user and/or their carers/families. For Serious Incidents the lead must be an Executive Director and this is usually undertaken by the Medical Director and the Assistant Director of Governance & Compliance. Feedback should take place as soon as possible after the details are known, and be presented in the form most acceptable to the service user. Whatever method is used, the communication should include:

- Details 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;
- Notes of the internal review meeting;
- A copy of the serious incident investigation report;
- 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.

A written record of the discussions between the executive lead and the service user and/or carers/families will be kept and shared with all parties present. Any additional learning points and actions identified within this meeting will be added to the investigation action plan.

20.2 Communication with the GP and other care providers

Wherever possible, it is advisable to send a brief communication to the service user’s GP, and other care providers describing what happened.

When the service user leaves the care of the Trust, the lead must ensure that a discharge letter is forwarded to the GP or appropriate care provider. It should contain summary details of:

- The nature of the service user safety incident and the continuing care and treatment;
- The current condition of the service user;
- Key investigations that have been carried out to establish the service user’s clinical condition;
- Recent results;
- Prognosis.
21. Service users, Carers/Families who do not agree with the information provided

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

- Deal with the issue as soon as it emerges;
- Where the service user agrees, ensure their carers are involved in discussions from the beginning;
- Ensure the service user has access to support services;
- Where the senior health professional is not aware of the relationship difficulties, provide mechanisms for communicating information, such as the service user expressing their concerns to other members of the clinical team;
- Offer the service user and/or carers another contact person with whom they may feel more comfortable. This could be another member of the team or the individual with overall responsibility for clinical risk management;
- Use a mutually acceptable mediator to help identify the issues between the team and the service user, and to look for a mutually agreeable solution;
- Ensure the service user and/or their carers are fully aware of the formal complaints procedure and give them the Comment, Concern, Complaint, Compliment leaflet;
- Write a comprehensive list of the points that the service user and/or carer disagree with and reassure them you will follow up these issues.

22. Particular Service user circumstances

22.1 When a service user dies

When an incident has resulted in a service user’s death it is crucial that communication is sensitive, empathic and open. It is important to consider the emotional state of bereaved relatives and carers and to involve them in deciding when it is appropriate to discuss what has happened. The service user’s family and/or carers will probably need information on the processes that will be followed to identify the cause(s) of death. They will also need emotional support. Establishing open channels of communication may also allow the family and/or carers to indicate if they need bereavement counselling or assistance at any stage.

Usually the Being Open discussion and any investigation occur before the Coroner’s inquest. In any event an apology should be issued as soon as possible after the service user’s death, together with an explanation that the Coroner’s process has been initiated and a realistic timeframe of when the family and/or carers will be provided with more information and how this
relates to the Coronial process.

Where a death of a service user is investigated as a serious incident, a copy of the final report will be shared with the Coroner in order to assist them with their inquiry.

### 22.2 Children

The legal age of maturity for giving consent to treatment is 16. It is the age at which a young person acquires the full rights to make decisions about their own treatment and their right to confidentiality becomes vested in them rather than their parents or guardians. However, it is still considered good practice to encourage competent children to involve their families in decision making.

The courts have stated that younger children who understand fully what is involved in the proposed procedure can also give consent. This is sometimes known as Gillick competence or the Fraser guidelines. Where a child is judged to have the cognitive ability and the emotional maturity to understand the information provided, he/she should be involved directly in the Being Open process after a service user safety incident.

The opportunity for parents to be involved should still be provided unless the child expresses a wish for them not to be present.

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

More information can be found on the Department of Health’s website [www.dh.gov.uk](http://www.dh.gov.uk)

### 22.3 Service users with mental health problems

*Being Open* for service users with mental health problems should follow normal procedures, unless the service user also has cognitive impairment. The only circumstances in which it is appropriate to withhold service user safety information from a mentally ill service user is when advised to do so by a consultant psychiatrist who feels it would cause adverse psychological harm to the service user. However, such circumstances are rare and a second opinion (by another consultant psychiatrist) would be needed to justify withholding information from the service user. Apart from in exceptional circumstances, it is never appropriate to discuss patient safety incident information with a carer or relative without the express permission of the service user.

### 22.4 Service users with cognitive impairment

Some individuals have conditions that limit their ability to understand what is happening to them. They may have authorised a person to act on their behalf
by an enduring power of attorney. In these cases steps must be taken to ensure this extends to decision making and to the medical care and treatment of the service user. The Being Open discussion would be held with the holder of the power of attorney. Where there is no such person the clinicians may act in the service user’s best interests in deciding who the appropriate person is to discuss the incident information with, regarding the welfare of the service user as a whole and not simply their medical interests. However, the service user with a cognitive impairment should, where possible, be involved directly in communications about what has happened. An advocate with appropriate skills should be available to the service user to assist in the communication process.

22.5 Service users with learning disabilities

Where a service user has difficulties in expressing their opinion verbally, an assessment should be made about whether they are also cognitively impaired (see above). If the service user is not cognitively impaired they should be supported in the Being Open process by alternative communication methods (i.e. given the opportunity to write questions down). An advocate, agreed on in consultation with the service user, should be appointed. Appropriate advocates may include carers, family or friends of the service user. The advocate should assist the service user during the Being Open process, focusing on ensuring that the service user’s views are considered and discussed.

22.6 Service users with different language or cultural considerations

The need for translation and advocacy services, and consideration of special cultural needs (such as for service users 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 service user safety incident information. It would be worthwhile to obtain advice from an advocate or translator before the meeting on the most sensitive way to discuss the information. Avoid using ‘unofficial translators’ and/or the service user’s family or friends as they may distort information by editing what is communicated. Refer to the Translation & Interpretation Policy

22.7 Service users with different communication needs

A number of service users will have particular communication difficulties, such as hearing impairment. Plans for the meeting should fully consider these needs.

Knowing how to enable or enhance communications with a service user is essential to facilitating an effective Being open process, focusing on the needs of individuals and their families. The Head of Profession for Speech & Language Therapy and Dietetics can be approached for advice regarding appropriate communication with people who have complex communication difficulties.
23. **References**

*Department of Health - Building a Safer NHS for Service users (2001)*
*NPSA Being Open – Communicating service user safety incidents with service users and their carers (2005)*
*National Health Service Litigation Authority (2002) Circular No: 02/02. Apologies and Explanations*
*General Medical Council (2001). Good Medical Practice*
*NPSA Service user Safety Notice (2005). Being Open – saying sorry when things go wrong*
*Duty of Candour (CQC Regulation 20)2014 – March 2015*

24. **2gether NHS Foundation Trust policies:**

*Policy and Procedure for Reporting Incidents (including the Management of Serious Incidents)*
*Claims Policy*
*Complaints Policy and Procedure*
*Translation & Interpretation Policy*
*Guidelines for investigating Incidents, Complaints and Claims*
*Whistleblowing Policy & Procedures*
*Disciplinary Policy & Procedure*
*Disciplinary Procedures for Medical Staff*
*Risk Management Strategy*

25. **Associated Documentation**

*Equality Impact Assessment*
*Comment, Concern, Complaint, Compliment leaflet*
Appendix 1: Regulation 20: Duty of Candour

(1) Registered persons 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.

(2) As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a health service body must—

(a) notify the relevant person that the incident has occurred in accordance with paragraph (3), and
(b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

(3) The notification to be given under paragraph (2)(a) must—

(a) be given in person by one or more representatives of the registered person,
(b) provide an account, which to the best of the registered person’s knowledge is true, of all the facts the registered person knows about the incident as at the date of the notification,
(c) advise the relevant person what further enquiries into the incident the registered person believes are appropriate,
(d) include an apology, and
(e) be recorded in a written record which is kept securely by the registered person.

(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.

(5) But if the relevant person cannot be contacted in person or declines to speak to the representative of the registered person —

(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.

(6) The registered person must keep a copy of all correspondence with the relevant person under paragraph (4).

(7) In this regulation—

“apology” means an expression of sorrow or regret in respect of a notifiable safety incident;

“moderate harm” means—

(a) harm that requires a moderate increase in treatment, and
(b) significant, but not permanent, harm;

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

“notifiable safety incident” has the meaning given in paragraphs (8) and (9);

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

“prolonged pain” means pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

“relevant person” means the service user or, in the following circumstances, a person lawfully acting on their behalf—

(a) on the death of the service user,
(b) where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or
(c) where the service user is 16 or over and lacks capacity in relation to the matter;
“severe harm” means 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.

(8) In relation to a health service body, “notifiable safety incident” means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in—

(a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user’s illness or underlying condition, or
(b) severe harm, moderate harm or prolonged psychological harm to the service user.

(9) In relation to a registered person who is not a health service body, “notifiable safety incident” means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional—

(a) appears to have resulted in—
   (i.) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user’s illness or underlying condition,
   (ii.) an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of at least 28 days,
   (iii.) changes to the structure of the service user’s body,
   (iv.) the service user experiencing prolonged pain or prolonged psychological harm, or
   (v.) the shortening of the life expectancy of the service user; or

(b) requires treatment by a health care professional in order to prevent—
   (i.) the death of the service user, or
   (ii.) any injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a).
**APPENDIX 2**

**DUTY OF CANDOUR PROCESS**

1. **Patient Safety incident occurs**
   - Staff report incident on DATIX

2. **Has moderate/serious harm or death occurred?**
   - **Yes**
     - Manager/Team Leader to review grading of incident
     - If Serious Incident SIRI process begins
       - Meet with service user/family/carer ASAP
         - *AGREE BEST PERSON TO DO THIS*
   - **No**
     - Manager/Team Leader to review grading of incident
     - Is grading accurate
       - **Yes**
         - Regrade if harm is lower. Approve incident – no further action
       - **No**
         - Regrade if harm is moderate, serious or if death has occurred.

3. **Is grading accurate?**
   - **Yes**
     - Incident approved – no further action
   - **No**
     - Manager/Team Leader to review grading of incident
     - Is grading accurate
       - **Yes**
         - Document all actions taken
         - Review DATIX incident report and update with actions taken and lessons learned
         - On completion of the incident investigation feedback the findings to the service user/family/carer face to face within 10 working days and provide a copy of the investigation report. For serious incidents the lead must be an Executive Director
         - Follow up in writing to service user/family/carer
       - **No**
         - Document all actions taken

4. **Appropriate intervention/support provided**

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*Apologise in person*
*Explain what has happened*
*Explain what investigations are being undertaken & what the follow up process is*
*Follow up in writing to service user/family/carer*