TRUSTWIDE DIVISION CLINICAL SERVICE BASED POLICY DOCUMENT

BEING OPEN including DUTY OF CANDOUR

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2018 – Version 3

Striving for perfect care for the people we serve
Further information about this document:

<table>
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<tr>
<th>Document name</th>
<th>BEING OPEN POLICY including DUTY OF CANDOUR SA13</th>
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<tbody>
<tr>
<td>Document summary</td>
<td>Being open with patients, service users and carers following a patient safety incident is recognized as best practice and mandated by the national patient Safety Agency. The Duty of Candour is a legal duty on all NHS providers to inform and apologize to patients if there have been mistakes in their care that have led to significant harm</td>
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SUPPORTING STATEMENTS

SAFEGUARDING IS EVERYBODY’S BUSINESS

All Mersey Care NHS Trust employees have a statutory duty to safeguard and promote the welfare of children and adults, including:

- being alert to the possibility of child/ adult abuse and neglect through their observation of abuse, or by professional judgement made as a result of information gathered about the child/ adult;
- knowing how to deal with a disclosure or allegation of child/adult abuse;
- undertaking training as appropriate for their role and keeping themselves updated;
- being aware of and following the local policies and procedures they need to follow if they have a child/ adult concern;
- ensuring appropriate advice and support is accessed either from managers, 
  Safeguarding Ambassadors or the trust’s safeguarding team;
- participating in multi-agency working to safeguard the child or adult (if appropriate to your role);
- ensuring contemporaneous records are kept at all times and record keeping is in strict adherence to Mersey Care NHS Trust policy and procedures and professional guidelines. Roles, responsibilities and accountabilities, will differ depending on the post you hold within the organisation;
- ensuring that all staff and their managers discuss and record any safeguarding issues that arise at each supervision session.

EQUALITY AND HUMAN RIGHTS

Mersey Care NHS Trust recognizes that some sections of society experience prejudice and discrimination. The Equality Act 2010 specifically recognizes the protected characteristics of age, disability, gender, race, religion or belief, sexual orientation and transgender. The Equality Act also requires regard to socio-economic factors including pregnancy /maternity and marriage/civil partnership.

The trust is committed to equality of opportunity and anti-discriminatory practice both in the provision of services and in our role as a major employer. The trust believes that all people have the right to be treated with dignity and respect and is committed to the elimination of unfair and unlawful discriminatory practices.

Mersey Care NHS Trust also is aware of its legal duties under the Human Rights Act 1998. Section 6 of the Human Rights Act requires all public authorities to uphold and promote Human Rights in everything they do. It is unlawful for a public authority to perform any act which contravenes the Human Rights Act.

Mersey Care NHS Trust is committed to carrying out its functions and service delivery in line the with a Human Rights based approach and the FREDA principles of Fairness, Respect, Equality Dignity, and Autonomy.
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## APPENDICIES

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E Initial Being Open Discussion

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1 PURPOSE AND RATIONALE

Purpose

1.1 The purpose of this policy is to provide guidance for all Trust employees regarding the process for ensuring all communication is open, honest and occurs as soon as possible following an incident, complaint or claim and to ensure adherence to the Health and Social Care Act (2008) (Amendment) Regulations 2015, regulation 20; CQC Fundamental Standards relating to Duty of Candour; Recommendation 181 of the Mid Staffordshire NHS Foundation Trust public inquiry report.

1.2 Duty of Candour, Being Open provides a best practice framework for all Healthcare Organizations. This policy provides guidance on creating an environment where patients, service users and their carers feel supported when things go wrong and Healthcare Professionals have the confidence to act appropriately.

Rationale

1.3 The Trust’s Duty of Candour/Being Open Policy has been developed based on the Health and Social care Act 2008 (amendment Regulation 20 and the National Patient Safety Agency guidance to improve communications between Healthcare Organizations, patients, service users and carers when the patients or service user has been moderately harmed, severely harmed or has died as a result of a patient safety incident.

- The Trust fully endorses the Francis II report and the full implementation of a Duty of Candour.
- Duty of Candour, Being Open involves apologizing and explaining what happened to cause the incident and what action will be taken to prevent a further re-occurrence.
- This policy provides guidance to ensure communication is open, honest and occurs as soon as possible following an incident.
- For patients, service users and families effective communication starts from a healthcare need being identified and continues throughout their treatment. For healthcare professionals, there is an ethical and moral responsibility to maintain honest and open communication with service users and/or carers even when things go wrong.

This policy will help to:-

- Establish an environment where service users and/or their carers receive information they need to enable them to understand what happened and the reassurance that everything possible will be done to ensure that a similar type of incident does not reoccur.
- Create an environment where service users and/or their carers, healthcare professionals and managers all feel supported when things go wrong.
- Ensure that partner organizations, commissioners and performance managers are made fully aware of the incident and the actions that are being taken.
- Patient safety incidents have the potential to incur extra costs through litigation and further treatment; openness and honesty can help prevent such events becoming formal complaints or litigation claims.
The National Patient Safety Agency cites that many service users and/or their carers will often only make a litigation claim when they have not received any information or apology from the Multi Disciplinary Team or organizations when dealing with the patient safety incident.

Being Open when things go wrong is clearly fundamental to the partnership between patients, service users and those who provide their care.

Promoting a culture of openness is a prerequisite to improving patient safety and the quality of healthcare systems. It involves apologizing and explaining what happened to patients who have been harmed as a result of their healthcare treatment.

2. OUTCOME FOCUSED AIMS AND OBJECTIVES

AIMS

2.1 An organisational commitment to Being Open will help:-

- Establish a treatment and care environment where patients, service users and/or their carers receive the information they need to enable them to understand what happened and the reassurance that everything possible will be done to ensure that a similar type of patient safety incident does not recur.

- Create a treatment and care environment where service users and/or their carers, healthcare professionals and managers all feel supported when things go wrong.

- To ensure that the principles outlined in this policy are integrated with other risk management processes and policies, for example, adverse incident reporting and incident investigation approaches such as root cause analysis (RCA).

- To promote a culture of reporting and learning from patient safety incidents to reduce levels of harm, within an overarching safety culture that is open and fair.

- To ensure that the Trust has an infrastructure in place to support openness between multi disciplinary professionals and service users and/or their carers following a patient safety incident.

3. SCOPE

3.1 This policy is Trust wide and applies to all staff to varying degrees dependent on their role and responsibility. All staff have the responsibility to share their concerns regarding standards of care with senior staff with the aim of improving the standards of the services provided.

PRINCIPLES

3.2 Effective communication with service users commences upon their admission to the Trust and continues through to the point of discharge. This should be no different when a patient safety incident occurs. Openness when things go wrong is fundamental to the partnership between service users the Multi Disciplinary Team and the Trust.

3.3 The Trust has a responsibility to ensure that this Policy is integrated with local and national incident reporting and risk management policies. Adopting the principle of openness can
help to build a reputation of respect and trust for the Multi Disciplinary Team and the Organization.

3.4 Duty of Candour, Being Open means: -

- Acknowledging, apologizing and explaining when things go wrong.
- Conducting a thorough investigation into the adverse incident and confirming with patients, service users and/or their carers that lessons learned will help prevent the incident recurring.
- Improving the understanding of incidents from the perspective of the patient, service user and/or their carers.
- Providing support to cope with the physical and psychological consequences of what happened as a result of the safety incident.
- Acknowledging the distress that may have experienced as a result of the safety incident.
- Providing a sincere and compassionate statement of regret for any distress experienced.
- Providing a timely and factual explanation of what happened.
- Providing a clear statement of what is going to happen following the safety incident.
- Informing of the plan *(where appropriate)* regarding the repair or redress of the harm done.

Being Open can create: -

- Satisfaction that communication following a safety incident has been handled in the most appropriate way.
- The knowledge that lessons learned from incidents will help prevent the incident happening again.
- A good professional reputation for handling a difficult situation well and earning respect among peers and colleagues.

3.5 Research has shown that people are more likely to forgive healthcare errors when they are discussed fully in a timely and thoughtful manner and that Being Open can decrease the trauma felt by service users following a patient safety incident *(as cited in Being Open – NPSA 2005)*.

3.6 Ten Principles of Being Open

Being open is a process rather than a one off event. The NPSA states that Being Open is underpinned by ten key principles:-

**Principle of Acknowledgement**

All patient safety incidents should be recognized and reported as soon as they are identified. In cases where the service user and/or their carers inform Healthcare staff something untoward has happened, it must be taken seriously from the outset. Any concerns will be treated with compassion and understanding by all Healthcare staff. Denial of a service user’s concerns will make future open and honest communication more difficult.
Principle of Truthfulness, Timeliness and Clarity of Communication

Information about a patient safety incident must be given to the service user and/or their carers by an appropriately nominated person in a:-

- Truthful
- Jargon free
- Timely
- Factual
- Open manner

Service users will be given a step by step explanation of what happened, that considers their individual needs and is delivered openly. A commitment will be maintained to keep the service user updated regarding the incident investigation by a single point of contact to avoid conflicting information.

Principle of Apology

Service users and/or their carers will receive a sincere expression of regret for the harm that resulted from a patient safety incident. This will be in the form of both a verbal and written apology appropriately worded and in an agreed and timely manner. Any written apology, will clearly state that the Trust is sorry for the suffering and distress resulting from the adverse incident.

Both verbal and written apologies will be given. Based on local circumstances, Healthcare Organizations should decide on the most appropriate member of staff to issue these apologies to service users and/or their carers. The decision should consider seniority, relationship to the service user, and experience and expertise in the type of adverse incident that has occurred.

Principle of Recognizing Service user and Carer Expectations

Service users and/or their carers will be fully informed of the issues surrounding an adverse incident, and its consequences, in a face to face meeting with Senior Manager and/or Clinical representatives from the Trust. They will be treated in a caring manner, with respect and consideration. Confidentiality must be maintained at all times. Service users and/or their carers will also be provided with support in a manner appropriate to their needs, e.g.

- Easy read literature
- PALS support
- Advocacy services
- Legal representatives
- Interpreters
- Contacts with relevant support groups
- Provision of Psychological support

Principle of Professional Support

Developing the Being Open culture all staff will be supported in reporting all safety incidents and throughout the incident investigation process ensuring a robust and consistent approach to incident investigation and any necessary action.

Principle of Risk Management and Systems Improvement

Where serious and untoward incidents occur within the Trust the Root Cause Analysis (RCA) principles of investigation will be adopted in line with Trust Procedure ‘Policy & Procedure for the reporting, management and review of adverse incidents’. The investigation will be commissioned and co-ordinated by the Line and/or Clinical Director. A lead reviewer will be appointed who has been trained and has experience in using RCA techniques. The investigation process will focus upon learning lessons and improving systems of care with the aim of eliminating future reoccurrence of such incidents and not on apportioning blame.
Principle of Multi Disciplinary Responsibility
The Trust’s policy on Being Open extends to all staff who have key roles in the client's/patient's care. The Being Open process is consistent with the philosophy that incidents are usually a consequence of system failure and rarely from the actions of an individual. The process of Being Open will be supported and adopted by the Trust's Multi Disciplinary Teams.

Principle of Clinical Governance
The principle of Being Open will be supported by the Trust’s Clinical Governance Frameworks. The investigation and analysis of incidents will focus on the identification of learning lessons and preventing further reoccurrences.

Accountability extends from the Multi Disciplinary Teams interface with the patient, service users and their carers through to the Chief Executive and to the Trust Board, to ensure that organizational learning is identified and implemented. The use of clinical audit will enable the organization to monitor the implementation and effects of changes in practice following a patient safety incident.

Principle of Confidentiality
The identity of patients or service users and staff involved in any adverse safety incidents and the details will be considered confidential. Communications with parties outside of the Clinical Team will also be on a strictly need to know basis and, where practicable, records should be anonymous. It is recognized that there maybe circumstances where it is not practicable for details of an adverse incident to remain confidential, e.g. where those investigating the incident have statutory powers for obtaining the information such as the Police or where there is a public interest duty. In circumstances regarding public interest disclosure careful consideration to disclose such information will be given by senior managers or clinicians of the Trust after receiving legal advice. Communications with parties outside of the Trust will be on a strictly need to know basis. The Trust will inform the service user and/or their carers of any pending investigation before it takes place, who will be the investigation team and given them the opportunity to raise any objections.

Individuals have a right to confidentiality both when alive and after their death. In some circumstances, patients and service users will have stated that they do not wish their clinical information to be shared with certain family members or individuals. If this is the case, this should be clearly documented in case files. The patient’s and service user’s wishes should direct information sharing even though they are now deceased.

Principle of Continuity of Care
Where a concern is raised by a patient or service user or they are directly involved in an adverse incident regardless of the need for further investigation they can expect to continue to receive all usual treatment and care and be treated with respect and compassion. If a patient, service user or their carer/advocate expresses a preference for their healthcare or support needs to be provided by another Multi Disciplinary Team, the Trust will give careful consideration to all such requests.

Duty of Candour
The Department of Health’s policy on Duty of Candour adds a further legal intensity for health organizations and the staff who work for them to be open and honest about the quality of the services they provide.

- The Duty of Candour applies to patient safety incidents that occur during care provided and that result in moderate harm, severe harm or death.
- There should be an appropriate investigation to establish the facts of the incident.
- The service user or relative must be informed of the incident within 10 days of the incident being reported onto the local Risk Management System.
The notification to the service user must be verbal and ideally face to face and that an offer of written notification must be made. In addition documentation of the notification must be made for audit purposes.

An apology must be offered.

4 DEFINITIONS

Table 1: Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Duty of Candour</td>
<td>Legal duty to inform and apologize to patients if their has been mistakes in their care that have led to significant harm</td>
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<tr>
<td>Being Open</td>
<td>Acknowledging, apologizing and explaining when things go wrong</td>
</tr>
<tr>
<td>Apology</td>
<td>Saying sorry is not an admission of legal liability. it is the right thing to do.</td>
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<tr>
<td>Root Cause Analysis</td>
<td>Process used to investigate and identify root cause of incident</td>
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5 DUTIES

Board of Directors

The Board of Directors will ensure that all managers are accountable for the promotion and implementation of this procedure.

Responsible Executive Director

The Medical Director is responsible for strategically planning how Being Open is incorporated into all aspects of the Trust’s business. They will report on progress to the Board bi annually and lead developments and initiatives in relation to furthering the transparency of the organization as a whole.

Director of Patient Safety

Director of Patient Safety on a day to day basis, is directly responsible to the Medical director for ensuring that the Being Open Policy is fully implemented across the organization. They are also responsible for liaising with service directors and line managers for ensuring the most appropriate individuals are chosen to act as the lead for working with service users or carers.

Line Managers

Line managers are responsible for ensuring that their staff fully implement this policy and in particular communicate with service users/carers following an incident. Line Managers are responsible for choosing the staff from their services that attend the Being Open/Duty of Candour training and provide support and guidance during their involvement with this policy.

Lead Reviewer

The allocated lead to investigate the incident has the pivotal role of ensuring that:

- The patient, service user or carer is kept fully up to speed with the progress of the review.
- The patient, service user or carer has the opportunity to share their knowledge with the Review Team and raise any concerns.
- Ensure that liaison with the Review and the Being Open Service Representative is robust.
- Providing feedback to the service user/carer on the outcomes of the review.

**Team Leader / Ward Manager**

Team Leader / Ward Manager has responsibility for sharing the ideology with their staff and initially proffering them support following an incident. They will liaise with their line manager to plan who is the service / team being open representative and provide all relevant information to the person.

**Family Liaison Manager**

This individual will be responsible for making contact with patients, service users or carers who have been involved in an incident and they will liaise between the review team, service user or carer.

They will also be able to ask other senior staff to become involved and identify resources that are required to support the service users or carers.

- Ensure that the patient, service user or carer is ready for a Being open discussion
- Prepare thoroughly for the Being Open discussion
- Provide verbal and written apology or expression of regret
- Document the details, actions and service user concerns from Being open discussions and discuss ongoing communication
- Ensure ongoing communication is maintained with patient, service user or carer
- Delegate to an appropriate, trained suitable in exceptional circumstances if they cannot attend

**Healthcare professionals**

Healthcare professionals have a responsibility to challenge questionable practice and keep up to date with effective methods of care and have a duty to share their concerns regarding the quality of care, lack of care and failings in service provision.

They can use the Trust’s HR06: Concerns at work about patient care or business misconduct (whistleblowing) Policy to do this as well as completing an incident form and sharing concerns with their line manager.

**6 PROCESS / PROCEDURE**

**6.1 COMMUNICATION**

The Trust is committed to creating an environment that facilitates open and effective communication and will ensure that as part of the Trust’s commitment to developing open and effective communication regarding patient safety incidents it will:-

- Ensure that the patient, service user’s next-of-kin, nearest relative or preferred contact for communicating information about their treatment and care is informed.
- Ensure that the Multi Disciplinary Team identifies with the patient, service user any additional person[s] they may wish to be contacted to provide support for their practical and emotional needs.
• Provide repeated opportunities for the patient, service user and/or their carers to obtain information about the adverse incident.

• Provide information to the patient, service user or carer in verbal or written format.

• Provide assurance that an ongoing treatment and care will be developed in consultation with the patient, service user and/or their carers and the Multi Disciplinary Team and will not affect their access to care and treatment.

• Facilitate inclusion of the patient, service user’s carers or significant others in discussions about the adverse incident where the service user agrees.

• Determine whether information needs to be presented to the patient, service user and/or their carers in different formats and at different times to allow them to comprehend the situation fully.

• Ensure carers are provided with information known to the Trust if a service user has died as a result of an adverse incident. The carers will also be referred to the coroner for more detailed information.

• Ensure that discussions with the patient, service user and/or their carers are documented and that information is shared with them.

• Ensure the patient, service users or carers account of the events leading up to the patient safety incident are fed into the incident investigation, whenever possible.

• Ensure the patient, service user and/or their carers are provided with information on how improvement plans and lessons learnt derived from RCA will be implemented and their effects monitored.

Advocacy and Support

6.2 The Trust recognizes that practical and emotional support may be needed by the patient, service user and/or their carers following a patient safety incident. A nominated person from the Multi Disciplinary Team/Service will take responsibility for ensuring that the patient, service user/carer will be consulted to determine the type and extent of support they require.

6.3 The Trust is able to offer the service user/carer specific professional Psychological intervention. It will take the form of an initial assessment, followed by a series of therapeutic sessions. This service can be assessed via the Director of Patient Safety. Therapy will be fast-tracked and be undertaken by a skilled counselor or therapist.

Access to support services or organizations

6.4 The Trust will ensure that the patient or service user is provided with support continuity from a nominated member of the Multi Disciplinary Team, Service Team Leader, Line Manager. Their role will be to provide both practical and emotional support in a timely manner. Where it is not appropriate for the service/team to provide a point of contact, an individual will be nominated either from another service/team or from corporate services.

6.5 The Trust will ensure appropriate literature will be made available to the patient, service user or carer in order to identify or access appropriate additional support mechanisms

- Patient Advice Liaison Service (PALS)
- Commissioned Advocacy Service
6.6 It is important that the patient, service user and carers are informed that the adverse incident review will be conducted with the anticipation that it will answer any questions they have.

6.7 The Trust will ensure that information continues to be made available for patients, service users or carers on how to make a formal complaint and/or provide feedback on service delivery. The complaint process will then only be brought into action if they have further concerns.

6.8 CONSIDERING INDIVIDUAL SERVICE USER CIRCUMSTANCES

The Trust recognizes that communicating the Being Open principles and circumstances may be limited given the abilities of certain service users:-

The Trust will ensure that appropriate means of communicating with individuals are adopted and implemented. Additional support mechanisms may include the use of:-

- Easy read literature
- PALS
- Access to Independent Advocacy Services
- Nominated Multi Disciplinary Team Member
- Translation services
- Involvement of family or friends

6.9 Patients or Service User’s Cultural Needs

When planning to discuss an adverse incident, the Trust will give careful consideration to the needs of the person, considerations will include both language and specific cultural needs. The Trust’s equality and diversity manager will play a key role in facilitating appropriate Trust responses to individuals needs. Where appropriate specialist interpreters or advocacy services will be used.

6.10 Patients or Service Users with Different Communication Needs

The Trust acknowledges the need to ensure adequate provision is made for those service users or carers with additional communication needs. In order to enhance such communications with individuals the Trust will make provision for appropriate interpreters, advisors, specialist or advocates.

6.11 Patients, Service User or Carer Disagreement with the Information Provided

It is acknowledged by the Trust that sometimes, despite its best endeavors, the relationship between the patient, service user and/or their carers with the respective healthcare professional[s] may break down. The patient, service user and/or their carers may not accept the information provided by the Trust or may not wish to participate in the Being Open/Duty of Candour process.

In this situation the following strategies will be considered:-

- Dealing with the issue[s] as soon as these emerge
• Where the service user agrees, ensure their carers are involved in discussions from the beginning.

• Ensure the service user has access to support services, PALS, Advocacy.

• Where the Multi Disciplinary Team are unaware of the patient or service users perceived relationship difficulties, the Trust will ensure an alternative mechanism for communicating information and maintain dialogue is established with the patient, service user or carer, in addition to keeping the multi disciplinary team member[s] informed.

• Where appropriate the Trust will offer the patient, service user or carer another contact person with whom they may feel more comfortable, this will usually be a senior clinician/manager.

• The Trust can appoint a mutually acceptable mediator to help identify the patient, service user or carer’s issues of concern with the Trust and seek a mutually agreeable solution this will normally be done via the Director of Patient Safety. The Trust’s appointed mediator will identify with the patient, service user or carer their issues of concern and make a record of same and provide confirmation that these issues will be followed up in a timely manner.

• The Trust will ensure the patient, service user or carer is fully aware of the formal complaints procedures.

6.12 Individuals who have been Bereaved

When an adverse incident has resulted in the death of a patient or service user, the Trust recognizes that communication needs to be sensitive, empathic and open.

The emotional state of bereaved relatives or carers and their involvement in deciding when it is appropriate to discuss what has happened is of primary importance. The Trust will ensure that family and/or carers are informed of the processes that will be followed to identify the cause[s] of death. In these circumstances a fundamental aim of the Trust will be to establish open channels of communication.

The principle of Being Open/Duty of Candour advocates as good practice that discussions and any investigation takes place before the Coroner’s inquest. There may however be circumstances in which the Trust deems it appropriate to wait for the Coroner’s inquest before holding the Being Open/Duty of Candour discussion with the patient’s family and/or carers.

The Coroner’s report on post-mortem findings is a key source of information that will help to complete the picture of events leading up to the patient’s death. Within the communication process with relatives/carers there is a need to recognize the distress and concerns that they may have. It is also acknowledged by the Trust that the provision of an apology does not constitute an admission of either fault or legal liability. Therefore an apology can be given as soon as possible after the service user’s death. An explanation of the Coroner’s investigation process will be shared.

6.13 STAFF ISSUES

The Trust recognizes that when an adverse incident occurs, members of the Multi Disciplinary Team involved in the client’s/patient’s treatment and care may also require emotional support and advice. Both clinicians who have been involved directly in the incident and those with the responsibility for facilitating Being Open/Duty of Candour
discussions will be given access to assistance, support and any information they need to fulfill this role.

6.14 In responding to patient safety incidents and promoting the principles of Being Open the Trust will:-

- Actively promote an open and fair culture that fosters peer support and discourages the attribution of blame and developing a culture where safety is the primary factor in reporting and investigation errors. The Trust recognizes that blame impedes learning and creates stress, secrecy and anxiety.

- Provide facilities for formal and informal support mechanisms for the multi disciplinary team involved in the adverse incident, where appropriate, as part of the support system and separate from the requirement to provide statements for the investigation. Where appropriate, individual feedback regarding the final outcome of the patient safety incident investigation will be provided.

- Oxford Model and Dare to Share Events will be used to share incidents openly and gain staff's help in finding how a future similar incident can be prevented. These are events which are designed to engage staff in exploring incidents and developing actions that can be used to prevent re-occurrence (See Appendix F).

- Provide opportunities for members of the multi disciplinary team involved in the adverse incident to discuss their involvement and/or the circumstances leading up to the incident, inclusive of any report/statement they are required to make.

- Provide advice and training on the management of incidents, including the need for practical, social and psychological support, as part of a general training programme for key staff.

Training initiatives within the Trust will include:-

- Root Cause Analysis Courses

- Provision of access to the web based Incident Decision Tree

- Training workshops for Healthcare Professionals who have to communicate with patients, service users or carers following an incident

- 2 Days Report Writing Communication Skills

6.15 ORGANISATIONAL ISSUES

The NPSA in their Seven Steps to Patient Safety (2003) publication explains the requirement for Trust commitment to improving patient safety. This commitment is required throughout the whole healthcare organization, from the Trust Board through to clinical and non-clinical staff. In addition to the responsibilities described in Seven Steps to Patient Safety, the Trust will consider the following legal requirements when engaging in the Being Open process:-

- Appropriate confidentiality must be maintained at all times.
• Only anonymous data about patient safety incidents will be disseminated beyond the Multi Disciplinary Team and the investigation team.

• Where a service user makes information public it is permissible to confirm its accuracy or to make a simple statement that the information is incorrect.

• Where additional information is to be disclosed, for example, to correct statements made to the media, the service user/carer will be advised of any forthcoming statement and the reasons for it.

• Service user’s consent will be sought, but if it is not given disclosure may still be warranted in the public interest.

• All communications to the media will be co-ordinated via the Trust’s Communications Manager and approved as per Trust Policy.

• Where it is possible that an adverse incident occurred due to negligence on the part of the Trust, and/or there is an indication that legal proceedings may be brought against the Trust, the Claims and Legal Manager will be informed who will liaise with the NHS Litigation Authority.

The Trust will promote that the Being Open/Duty of Candour principle and that saying sorry to service users/carers is not an admission of liability and is both therapeutic and supportive to individuals.

7 CONSULTATION

This policy has been reviewed and updated taking into account current legislation. The divisional leads, service leads and leads for Duty of Candour have been consulted.

8 TRAINING AND SUPPORT

The day to day responsibility for the ensuring compliance with this policy and the implementation, training and support lies with the departmental managers and those with delegated responsibility and the Being Open/Duty of Candour training sessions are provided by the Trust and Divisional leads..

9 MONITORING

9.1 The Trust will monitor compliance with this policy through DATIX reporting process; references in SI reports, complaints reports, mortality reviews and by incorporating information on its implementation into the annual integrated claims, complaints and incidents information which is shared with the Board of Directors and in the bi-annual reports presented to the Quality Assurance Committee. Each incident report will be expected to clarify how Duty of Candour/Being Open has been facilitated in each case and this information will be monitored by the Divisional Safety Huddle meetings.

9.2 The monitoring process and information collated will include:

- Number of service users, carers or families corresponded with / liaised with following a serious adverse incident where Duty of Candour applies.
- Timescales between incident and contact with family.

10 SUPPORTING DOCUMENTS
List of Supporting Documents

<table>
<thead>
<tr>
<th>Ref No</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>SA03:</td>
<td>Reporting, management and review of adverse incidents</td>
</tr>
<tr>
<td>SA05:</td>
<td>Reporting, management and investigation of claims/potential claims including property expenses</td>
</tr>
<tr>
<td>SA06</td>
<td>Service user complaints Policy and procedure</td>
</tr>
<tr>
<td>HR06:</td>
<td>Concerns at work about patient care/business misconduct (whistleblowing)</td>
</tr>
</tbody>
</table>

**National Patient Safety Agency:** Being open - communicating patient safety incidents with patients and their carers

**Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry** Chaired by Robert Francis QC - Executive summary

**Mental Capacity Act (MCA) 2005 (amendments 2007)**

**Mental Health Act 1983**

**Health and Social Care Act 2008, Regulation 20 Duty of Candour**
Appendix A:

Regulation 20: Duty of Candour

20.— (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 registered person 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 provider 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 B

<table>
<thead>
<tr>
<th>Grade of Service user Safety Incident</th>
<th>NPSA Definition</th>
<th>Trust Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Harm</td>
<td>Incident prevented - any patient safety incident that had the potential to cause harm but was prevented, and no harm was caused to service users receiving NHS-funded care. Incident not prevented - any patient safety incident that occurred but no harm was caused to service users receiving NHS-funded care.</td>
<td>Incidents will be monitored through standard incident reporting mechanisms and be analysed centrally to detect high frequency events. Any investigation will be undertaken at a local service level. Where organisational learning has been identified, this will be communicated via the Line Manager to the Service’s Adverse Incident Group. The service user/carer should be informed of the incident. Should a report be received from a service user and/or their carers a response will be provided via the respective Multi Disciplinary Team/Line Manager?</td>
</tr>
<tr>
<td>Low Harm</td>
<td>Any patient safety incident that required extra observation or minor treatment* and caused minimal harm to one or more service users receiving NHS-funded care. * Minor treatment is defined as first aid, additional therapy, or additional medication. It does not include any extra stay in Hospital or any extra time as an out-patient, or continued treatment over and above the treatment already planned; nor does it include a return to surgery or re-</td>
<td>Unless there are specific indications or the service user request it, the communication, investigation and analysis, and the implementation of changes will occur at local service delivery level with the participation of those directly involved in the incident. This is termed a Reflective Practice Review. Communication will take the form of an open discussion between the staff providing treatment and care and the service user and/or their carers. Service user/carer should be informed of the incident. Reporting will occur through standard incident reporting mechanisms and be analysed centrally to detect high frequency events. Review will occur through aggregated trend data and local investigation. Where the trend data indicates a pattern of related events, further investigation and analysis may be needed.</td>
</tr>
</tbody>
</table>
Moderate Harm

Any patient safety incident that resulted in a moderate increase in treatment* and that caused significant but not permanent harm to one or more service users receiving NHS-funded care.

Moderate harm may also be caused by negligent acts or omissions by Clinicians.

* Moderate increase in treatment is defined as a return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in Hospital or an out-patient, cancelling of treatment, or transfer to another area such as intensive care as a result of the incident.

A higher level of response is required in these circumstances. The Line Manager will notify the Executive Director of Nursing & Care. A lead investigator will be appointed to investigate and analyse the incident. A Reflective Practice Review should be facilitated initially to identify immediate problems. Decisions can then be taken as to whether a further review is required.

The Trust’s Being Open Policy will be implemented.

<table>
<thead>
<tr>
<th>Grade of Patient Safety Incident</th>
<th>NPSA Definition</th>
<th>Trust Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>Any patient safety incident that directly resulted in the death* of one or more service users receiving NHS-funded care.</td>
<td>An initial Reflective Practice Review may be undertaken to establish initial concerns and actions required, particularly if the death is in an In-patient area.</td>
</tr>
<tr>
<td></td>
<td>* The death must be related to the incident rather than to the natural course of the client’s/patient’s illness or underlying condition.</td>
<td>A Lead Reviewer will be appointed, Terms of Reference developed and an RCA review commenced.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A Service Representative must be appointed and the Being Open process initiated.</td>
</tr>
</tbody>
</table>
Appendix C
DUTY OF CANDOUR – Explained

Doctors and health care professionals have a duty to be open with patients and their families if something goes wrong. Now you also need to be aware of your employer's duty of candour guidance and procedures.

Doctors are expected to play a major role in supporting their organization’s new contractual 'duty of candour' to patients. Under the new NHS standard contract all NHS healthcare providers, and private providers serving NHS patients, must disclose errors in treatment that result in moderate or severe harm, or death.

Any reportable or suspected patient safety incident falling within these categories must be reported to the patient, and any other 'relevant person', within 10 days. The organizations have a duty to provide patients and their families with information and support when a reportable incident has, or may have occurred.

When services are provided under the new NHS standard contract, if a provider breaches the contractual duty of candour, the commissioning body can recover either the cost of the episode of care, or up to £10,000 if the cost is unknown, from the provider.

The incident must be investigated and the duty of candour falls on the organization, not on individual doctors. But doctors already have an ethical duty to comply with investigations into actual or suspected patient safety events. Doctors must be open and honest and tell patients when something has gone wrong. Their account of the incident will be crucial and they will usually be the ones who tell the patient what happened.

Clause SC35 of the NHS contract specifies how the patient and any other relevant person should be notified of the incident. First, there is a duty to speak with the patient and this should be done by the provider's representative/s and, if possible, the clinician responsible. The explanation must include all the known facts and an appropriate apology. The patient or relevant person should be offered a written account, and the meeting minuted for audit purposes.

The National Patient Safety Authority (NPSA) defines the three levels of harm in Seven Steps to Patient Safety as:

- **Moderate** - any patient safety incident that resulted in a moderate increase in treatment and significant but not permanent harm
- **Severe** - a patient safety incident that appears to have resulted in permanent harm
- **Death** - an incident that directly resulted in the patient's death.

An example of a moderate incident is described as perforation of the bowel during surgery that is not picked up and results in septicemia and repair surgery. A severe incident would be bowel perforation that results in a temporary colostomy and further major operations.
Service providers are expected to use these definitions to create their own guidance. The MDU advises that if your organization does not already produce guidance on classification of patient safety incidents and investigating and reporting procedures, it will need to do so to ensure that all staff are aware when the duty of candour applies. It will also need to ensure that the guidance complies with the new duty of candour requirements.
Appendix D

RECORD KEEPING AND DOCUMENTATION REGARDING PATIENT SAFETY INCIDENTS AND THE BEING OPEN PROCESS

1. GENERAL

The information regarding the incident that will be available for reference includes:-

- A copy of relevant clinical notes
- Adverse Incident Report
- Investigation Report (information available to date)

The investigation report will be filed separately from medical records as an adverse incident record, and kept as part of the Trust’s clinical governance reports.

2. WRITTEN RECORDS OF THE BEING OPEN DISCUSSION

There will be documentation of:-

- The time, place, date, as well as the name and relationships of all attendees and apologies received;
- The plan for providing further information to the service user/carer;
- Trust offers of assistance and the service user/carer’s response;
- Questions raised by the family and/or carers or their representatives, and the answers given;
- Plans for follow-up as discussed;
- Progress notes relating to the clinical situation and an accurate summary of all the points explained to the service user/carers;
- Copies of letters sent to service users/carers;
- Copies of any statements taken in relation to the incident;
- A copy of the incident report.

A summary of the Being Open discussion should be shared with the service user/carer.
INITIAL BEING OPEN DISCUSSION

The initial discussion with the service user/carer is an important step in the Being Open process. The following guidelines should assist in making the communication effective:-

- The discussion should occur at the earliest practical opportunity;
- Consideration should be given to the timing of meeting, based on both the service user’s health and personal circumstances;
- Consideration should be given to the location of the meeting;
- Feedback should be given on progress to date and information provided on the investigation process;
- There should be no speculation or attribution of blame. Similarly, the healthcare profession communicating the incident must not criticize or comment on matters outside their own experience;
- The service user/carer should be offered an opportunity to discuss the situation with another relevant professional where appropriate;
- A written record of the discussion will be kept and copies sent to the service user/carer;
- All queries should be responded to in a timely manner and appropriately;
- The service user will be provided with contact details so that if further issues arise later there is a link back to the relevant multi-disciplinary or nominate.
### Equality and Human Rights Analysis

**Title:** SA 13 Being Open Policy including Duty Of Candour  
**Area covered:** Local Division Clinical Service Based Policy

<table>
<thead>
<tr>
<th>What are the intended outcomes of this work?</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Trust’s ‘Being Open’ Policy has been developed based on the National Patient Safety Agency guidance to improve communications between Healthcare Organisations and service users and carers when the service user has been moderately harmed, severely harmed or has died as a result of a patient safety incident.</td>
</tr>
<tr>
<td>- The Trust fully endorses the Francis II report and the full implementation of a Duty of Candour.</td>
</tr>
<tr>
<td>- Mersey Care NHS Trust believes that staff should be open with service users and carers when any incident has occurred. Service users/carers should be kept up to date when incidents occur.</td>
</tr>
<tr>
<td>- ‘Being Open’ involves apologizing and explaining what happened to cause the incident and what action will be taken to prevent a further re-occurrence.</td>
</tr>
<tr>
<td>- This ‘Being Open’ policy provides guidance to ensure communication is open, honest and occurs as soon as possible following an incident.</td>
</tr>
<tr>
<td>- For service users, effective communication starts from a healthcare need being identified and continues throughout their treatment. For healthcare professionals, there is an ethical and moral responsibility to maintain honest and open communication with service users and/or carers even when things go wrong.</td>
</tr>
</tbody>
</table>
The Trust Being Open Policy was subject to equality and human rights Analysis in 2010. This is a review. It is noted that the actions that were identified in the equality assessment of 2010 have all been completed.

Who will be affected?
All staff

<table>
<thead>
<tr>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>What evidence have you considered?</td>
</tr>
<tr>
<td>The policy</td>
</tr>
<tr>
<td>The previous equality and human rights analysis.</td>
</tr>
<tr>
<td>Disability inc. learning disability</td>
</tr>
</tbody>
</table>

Service Users with Different Communication Needs
The Trust acknowledges the need to ensure adequate provision is made for those service users/carers with additional communication needs. In order to enhance such communications with individuals the Trust will make provision for appropriate interpreters/advisors/specialist advocates.

Sex
See cross cutting below.

Race
Service User’s Cultural Needs
When planning to discuss an adverse incident, the Trust will give careful consideration to the needs of individuals, considerations will include both language and specific cultural needs. The Trust’s Equality and Diversity Manager will play a key role in facilitating appropriate Trust responses to individuals needs. Where appropriate specialist interpreters/advocacy services will be used.

Age
See cross cutting.

Gender reassignment (including transgender)
See cross cutting.

Sexual orientation
See cross cutting

Religion or belief
See cross cutting also see Race above.

Pregnancy and maternity
See cross cutting.

Carers: Objectives around carers identified.
As part of the Trust’s commitment to developing open and effective communication regarding patient safety incidents it will:

- Ensure that the service user’s next-of-kin, nearest relative or preferred contact for communicating information about their treatment and care is informed.

Other identified groups
Considerations are identified in relation to Mental Health and Criminal Justice Services.
See page 27 section 7.1

INVOLVEMENT / LIAISON WITH CRIMINAL JUSTICE SERVICES

7.1 Some incidents that involve mentally ill service users will require the intervention of the Police and Crown Prosecution Service. The Trust will share information with the Police as is allowed under the Data Protection Act Section 29.

It is important that where a homicide or suspicious death is the incident, the Police should be asked if it is acceptable for the Trust to continue with its investigation process. A senior manager should act as the Trust Liaison Officer and negotiate with the Police; Terms of Reference for an incident review that would not impede a Police investigation but would aid learning from a health care perspective.

Cross cutting:
Equality and Human Rights Statement included.

The Trust recognizes that communicating the Being Open principles and circumstances may be limited given the abilities of certain service users:-
The Trust will ensure that appropriate means of communicating with individuals are adopted and
implemented. Additional support mechanisms will include the use of:-

- Easy read Literature
- PALS
- Access to Independent Advocacy Services
- Nominated Multi Disciplinary Team Member
- Translation services
- Involvement of family/friends

<table>
<thead>
<tr>
<th>Human Rights</th>
<th>Is there an impact?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supports a human rights based approach This policy has been developed based on the National Patient Safety Agency guidance To improve communications between Healthcare Organisations and Service Users and Carers when the service user has been moderately harmed, severely harmed or has died as result of a patient safety issue.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Human Rights</th>
<th>How this right could be protected?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right to life (Article 2)</td>
<td>Supports human rights based approach.</td>
</tr>
<tr>
<td>Right of freedom from inhuman and degrading treatment (Article 3)</td>
<td>Supports human rights based approach.</td>
</tr>
<tr>
<td>Right to liberty (Article 5)</td>
<td>This article not engaged.</td>
</tr>
<tr>
<td>Right to a fair trial (Article 6)</td>
<td>Supports human rights based approach.</td>
</tr>
<tr>
<td>Right to private and family life (Article 8)</td>
<td>Supports human rights based approach.</td>
</tr>
<tr>
<td>Right of freedom of religion</td>
<td>Supports human rights based approach.</td>
</tr>
</tbody>
</table>
or belief (Article 9)

<table>
<thead>
<tr>
<th>Right to freedom of expression</th>
</tr>
</thead>
<tbody>
<tr>
<td>Note: this does not include insulting language such as racism (Article 10)</td>
</tr>
<tr>
<td>This article not engaged.</td>
</tr>
</tbody>
</table>

| Right freedom from discrimination (Article 14) |
| This article not directly engaged. |

Engagement and involvement

This policy has been reviewed and updated taking into account current legislation. The divisional leads, service users, service leads and leads for the Duty of Candour have been consulted.

Summary of Analysis

Eliminate discrimination, harassment and victimisation

This policy has been developed on the National Patient Safety Agency guidance to improve communications between Healthcare Organizations and service users and carers when the service user has been moderately harmed, severely harmed or has died as a result of a patient safety incident. A number of equality focused actions/objectives have been stated within the Policy.

Advance equality of opportunity

Equality is supported through the actions and objectives in relation to the Protected characteristics.

Promote good relations between groups
Culture and disability issues addressed.

**What is the overall impact?**
Intended to be positive. This policy applies to all carers, next of kin, important others.

**Addressing the impact on equalities** N/A

**Action planning for improvement**
N/A

**For the record**
Name of persons who carried out this assessment (Min of 3):
George Sullivan Equality and Human Rights Advisor
Collette Irving People Participation
Kim Guy PALS

Date assessment completed: 20.11.2015

Name of responsible Director:

Date assessment was signed: November 2015
### Action plan template

This part of the template is to help you develop your action plan. You might want to change the categories in the first column to reflect the actions needed for your policy.

<table>
<thead>
<tr>
<th>Category</th>
<th>Actions</th>
<th>Target date</th>
<th>Person responsible and their Directorate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitoring, evaluating and reviewing</td>
<td>Update on the monitoring of the policy should be provided to the Trust equality and human rights equality steering group on a yearly basis.</td>
<td>December 2015</td>
<td>Kim Guy</td>
</tr>
<tr>
<td>Transparency (including publication)</td>
<td>This equality and human rights analysis to be attached to this policy and placed on the Trust website.</td>
<td>2016</td>
<td>Kim Guy</td>
</tr>
</tbody>
</table>