BEING OPEN AND DUTY OF CANDOUR POLICY
COMMUNICATING OPENLY AND HONESTLY WITH PATIENTS AND THEIR CARERS FOLLOWING A PATIENT SAFETY INCIDENT, NOTIFIABLE SAFETY INCIDENT OR ANY RELATED COMPLAINT OR CLAIM

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1 INTRODUCTION

1.1 Rationale

Communicating honestly and sympathetically with patients and their families when things go wrong is a vital component in dealing effectively with errors or mistakes in their care.

It is both natural and desirable for those involved in treatment which produces an adverse result, for whatever reason, to sympathise with the patient or the patient’s relatives and to express sorrow or regret at the outcome.

Such expressions of regret would not normally constitute an admission of liability. In being open, NHS organisations can mitigate the trauma suffered by patients and potentially reduce complaints and claims (NHSLA 2012).

1.2 Definitions

Candour: The state or quality of being open, honest, frank and sincere.

Notifiable patient safety incident: Any unintended or unexpected incident that occurred during the provision of a regulated activity that did or could result in death or harm.

Relevant Person: The regulation defines the relevant person as the person using the service and, in certain situations, extends to people acting lawfully on their behalf. The patient may request that a suitable person acts on their behalf.

Moderate harm: Harm that requires a moderate increase in treatment, or significant harm which is not permanent.

Prolonged psychological harm: Psychological harm experienced for a continuous period of at least 28 days.

Severe harm: A permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb, organ or brain damage.

Moderate increase in treatment: An unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancellation of treatment, or transfer to another treatment area, such as ICU.

1.3 The Being Open Principles and Actions

There is evidence that openness is welcomed by patients who are more likely to forgive errors when they are discussed fully in a timely and thoughtful manner and that being open can decrease the trauma felt following an incident.

Being open is a process rather than a one-off event and is underpinned by 10 principles promoted in the publication;
‘Saying sorry when things go wrong: Being Open: Communicating patient safety incidents with patients, their families and carers (NPSA 2009)’

which informs the rationale for improving communication between NHS staff and patients.

The 10 Being Open Principles and 6 actions are shown in Appendix A.

1.4 Duty of Candour – An Introduction

When an incident is more serious, it is more important that the Being Open principles are followed, and the actions completed. Following the Francis Report into the Mid Staffordshire Hospital, the Government enacted the Duty of Candour. It is now a statutory duty for all NHS bodies to be open, honest and candid when a patient is harmed. There is now a new offence of giving false or misleading information. The duty will be overseen by The Care Quality Commission (CQC).

RDaSH has integrated the process of capturing, recording and managing a duty of candour into its Safeguard Risk Management System and all staff responsible for the Duty of Candour, or incident investigation, should be aware of how to undertake the Duty of Candour process using the system.

The criteria that must be met to fulfil the duty are listed in Appendix C.

2 PURPOSE

The purpose of this policy is to set out the arrangements for open and honest communication following an incident, complaint or claim in compliance with the Being Open principles and Duty of Candour requirements.

3 SCOPE

This policy applies to all clinical staff and staff who have a key role in patient care.

Being Open principles apply to all Patient Safety Incidents, the Duty of candour applies to all Patient Safety Incidents which have an Actual Impact of Moderate, Major or Catastrophic harm.

Incidents which come under the Serious Incident criteria are investigated under the Serious Incident Policy, which provides for an appropriate Duty of Candour, and is therefore not specifically covered by this policy. Although the requirements of the Duty of Candour are met within the Serious Incident process, the completed actions required by the Duty of Candour are recorded within the IR1 system.

4 RESPONSIBILITIES, ACCOUNTABILITIES AND DUTIES

4.1 The Board of Directors

The Board of Directors has responsibility for the implementation of this policy and
the monitoring of compliance.

4.2 Executive Director, Non-Executive Director with Lead Responsibility

The Executive Director of Business Assurance is the lead Executive Director for this policy.

4.3 Deputy Chief Executive/Director of Nursing and Partnerships

The Deputy Chief Executive/Director of Nursing and Partnerships is responsible for the effective management of clinical risk, liaising with Service Directors who are responsible for the effective management of clinical risk within the Trust’s Business Divisions.

This will include responsibility for ensuring Being Open principles and Duty of Candour are appropriately applied to the investigation and management of incidents, complaints and claims.

4.4 Directors, Assistant Directors, Service Managers and Matrons

All Directors, Assistant Directors, Service Managers and Matrons are responsible for the dissemination and implementation of this policy within their departments.

Managers are responsible for creating an environment within their services where open, timely and clear communication and information sharing is encouraged in line with the Being Open principles and Duty of Candour requirements.

4.5 Head of Patient Safety and Experience

The Head of Patient Safety & Experience is responsible for providing support to Directors, Assistant Directors, Managers, Lead Specialists and staff to facilitate the effective implementation and monitoring of this policy.

As chair of the Organisational Learning Forum they will ensure that the principles of Being Open and requirements of The Duty of Candour are discussed, embedded as part of the learning process for incident, complaints, and claims.

4.6 Organisational Learning Forum

The Organisational Learning Forum is responsible for developing and managing a structured approach to active organisational learning, where the Duty of Candour and the Being Open principles are routinely applied and lessons learned are embedded in the Trust’s culture and practice.

4.7 Investigator

Any member of staff nominated to investigate an incident, complaint or claim should comply with this policy and where appropriate, involve the patient and/or their carers and other relevant teams and organisations (for example where patient care extends beyond RDaSH) investigation. See Policy for the Investigation of Incidents, Complaints and Claims, including Analysis and
Improvement.

4.8 All Staff

All staff should comply with the principles of Being Open and the requirements of the Duty of Candour with patients and/or their carers as outlined in this policy.

Staff should report all incidents promptly and clearly to ensure that that the appropriate actions can be taken to ensure an open and honest culture.

5 PROCEDURE/IMPLEMENTATION

Although the Being Open and Duty of Candour requirements were implemented at different times, they are both part of communicating honestly and sympathetically with patients and their families when things go wrong, and are vital components in dealing effectively with errors or mistakes.

They form a set of principles and duties which support Trusts to create robust procedures for ensuring that the patient and/or significant others are kept fully informed when an error or incident occurs which did, or may have, caused them harm.

5.1 Reporting The Incident

The required process is outlined in the flow chart at Appendix I and Checklist at Appendix H.

When any incident occurs, the members of staff involved are to complete an incident report using the IR1 system (See the Incident Reporting Policy).

This report identifies whether the incident is a patient safety incident, and the level or harm that occurred as a result of the event.

In some cases, the incident may not initially involve our staff, and so the incident may be reported to staff by someone else, a patient, visitor or other organisation. These are also to be reported on the IR1 form, including in the report all information that is available.

5.2 Being Open Actions

The actions required to comply with the Being Open process are;

- Notify the patient, or relevant person, verbally, face to face where possible, unless the person cannot be contacted in person or declines notification, that the incident has occurred.
- This initial notification will include an apology and must be provided as soon as is practicable
- Provide all information directly relevant to the incident which will be step by step factual explanation of what has happened.
- Advise and, if possible, agree with the patient what further enquiries are appropriate.
- Provide reasonable support to the patient or service user, their families or carers.

See the flow chart at Appendix I and Checklist at Appendix H.

5.3 Duty Of Candour

Although the Trust has an ethical duty to be open and honest at all times, candour as a statutory duty applies when an incident occurs which is of such a severity, or potential severity, that it becomes a Notifiable Patient Safety Incident.

RDaSH has integrated the process of capturing, recording and managing a duty of candour into its Safeguard Risk Management System and all staff responsible for the Duty of Candour, or incident investigation, should be aware of how to undertake the Duty of Candour process using the system.

5.4 Notifiable Safety Incident

The definition of a 'notifiable safety incident' which will trigger the duty of candour is one which, in the reasonable opinion of a healthcare professional, could result in, or appears to have resulted in, moderate or severe harm or death or "prolonged psychological harm". The definitions of "moderate" and "severe" harm are consistent with those used within the NHS for reporting under the National Reporting and Learning System and the existing contractual duty under the NHS Standard Contract.

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<th>GRADE OF PATIENT SAFETY INCIDENT</th>
<th>DEFINITION</th>
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<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 patients receiving NHS-funded care.</td>
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<td>Incident not prevented – any patient safety incident that occurred but no harm was caused to patients receiving NHS-funded care.</td>
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<td>Low harm</td>
<td>Any patient safety incident that required extra observation or minor treatment* and caused minimal harm to one or more patients receiving NHS-funded care.</td>
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<td>Moderate harm</td>
<td>Any patient safety incident that resulted in a moderate increase in treatment* and that caused significant but not permanent harm to one or more patients receiving NHS-funded care.</td>
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<td>Severe harm</td>
<td>Any patient safety incident that appears to have resulted in permanent harm* to one or more patients receiving NHS-funded care.</td>
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<tr>
<td>Death</td>
<td>Any patient safety incident that directly resulted in the death* of one or more patients receiving NHS-funded care.</td>
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* 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 outpatient, or continued treatment over and above the treatment already planned; nor does it include a return to surgery or readmission.

* Moderate increase in treatment is defined as a return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another area such as intensive
care as a result of the incident.

* Permanent harm directly related to the incident and not related to the natural course of the patient’s illness or underlying condition is defined as permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of the wrong limb or organ, or brain damage.

* The death must be related to the incident rather than to the natural course of the patient’s illness or underlying condition.

Within the IR1 form is a record of the perceived actual impact (harm) caused. If this is recorded as Moderate Harm or above, then the incident has triggered the Duty of Candour.

However, the requirement to record "prolonged psychological harm" means that candour notifications will need to be made when a service user has experienced, or is likely to experience, psychological harm as a result of an incident, for a continuous period of at least 28 days. In many cases, the presence of psychological harm caused by the incident will not be recognised until after the 28 day period. In these cases, a new incident report is required documenting the presence of psychological harm from the original incident.

Incidents which come under the Serious Incident criteria are investigated under the Serious Incident Policy, however the incident continues to require the Duty of Candour process outlined in this policy. Although the Duty of Candour is met within the Serious Incident process, the completed actions required by the Duty of Candour are recorded within the IR1 system.

5.5 Duty Of Candour Actions

All patient safety incidents require the Being Open Actions detailed in Appendix A to be carried out. If, however, the incident is of such a severity that the Duty of Candour applies, then further actions are required. These further actions follow on from the Being Open Actions and are;

**AS SOON AS POSSIBLE AFTER THE INCIDENT**

- Provide support to the patient, their families or carers after the incident, throughout the investigation and ongoing as required.
- The manager is to meet the relevant person, in person, and inform them that he incident has occurred, apologise, inform them what happened as far as we are aware and what actions are to be taken next.

**WITHIN 10 WORKING DAYS OF THE INCIDENT**

- Share with the patient and/or Relevant Person, in writing, the original notification and the results of any further enquiries.
- This should include;
  - all the information given verbally during the face to face meeting,
  - the apology that was given
any further information that has come to light since the meeting and
an outline of the investigation that is in progress.

- Duty of Candour letter templates are available at Appendix D & E and on the Trust Intranet.

WITHIN 28 WORKING DAYS OF THE INCIDENT

- Investigate the incident and provide a report outlining an explanation of the events and circumstances which resulted in the incident. A report template is available at Appendix F
- Provide and maintain written records of the interactions with the patient or relevant person
- All final incident reports must be ratified by the Assistant Director for the Business Division, or the Delegated manager, as suitable and sufficient to outline the root cause of the incident.
- If the incident is being investigated as a Serious Incident (SI), or an external investigation is underway, then the 28 day limit may be exceeded to comply with the limits of the external investigation.

WITHIN 10 DAYS OF THE REPORT BEING ACCEPTED AND CLOSED

- All final incident reports must be shared with, and a copy provided for, the patient or relevant person.
- The actions taken, notifications given, letters sent and outcomes are to be recorded with the initial incident on the IR1 form

The final Duty of Candour report should be concise, easy to understand by the relevant person and restricted to the incident. It may be suitable to share the full Serious incident Report, although in most cases a shorter, clearer report would be more useful for the relevant person.

The timescales for each investigation will follow the standard requirements as identified in the policy for Investigation of Incidents, Complaints and Claims, including Analysis and Improvement unless agreement to extend the timeframe has been accepted by all concerned.

See the flow chart at Appendix I and Checklist at Appendix H.

5.6 Specific Guidance

5.6.1 Giving an Apology

Following any patient safety incident the patient and/or other relevant person should receive a sincere expression of sorrow or regret for any harm from the incident as early as possible. This is not an admission of liability, but an acknowledgment of the person’s distress at that time which may mitigate the trauma suffered and potentially avoid any complaint or claim being made.

The apology can be made by the member of staff involved in the error, but may
be made by any member of staff if it is decided this is more beneficial.

The leaflet ‘Saying sorry when things go wrong: Being Open: Communicating Patient Safety Incidents with Service Users and Their Carers’ (Appendix B) gives guidance on the saying sorry process.

Who does the patient want the apology from? Whom do they trust? The clinicians will be best placed to say what has changed “on the ground". The more you can include about lessons learned the better. Your response will be more meaningful if you can highlight changes in practice or other tangible improvements. What steps have been taken to stop this happening to another patient?

If the duty of candour applies, the initial apology should still be given, however the person designated to investigate the incident will provide a further apology within 10 days as outlined above and in the flow chart at Appendix I and Checklist at Appendix H.

The decision about who is most appropriate to provide the notification and/or apology will take into account seniority, their relationship to the service user/patient, and their experience and expertise in the type of notifiable incident that has occurred.

5.6.2 Provide an Explanation

For non-notifiable incidents (see section 5.4 and Duty of Candour), the member of staff involved should provide the patient or significant other with a full explanation of what is known at the time, including what further action is to be taken.

This can be given by another member of staff if it is decided that this would be more beneficial.

Staff should speak to their manager for advice about how to approach this if they are unsure.

5.6.3 Information to be shared

Communication should be timely, informing the patient and/or their carer what has happened as soon as is practicable.

A step by step account of all relevant facts known about the incident at the time should be given, in person, by one or more appropriate representatives of the Trust. This should:

- Include as much or as little relevant information as the relevant person/people want to hear
- Be jargon-free and explain any complicated terms
- Include an explanation of any further planned enquiries and investigations
- Be given in a manner that relevant person/people can understand. For example, staff should consider if appropriate interpreters, advocates,
communication aids etc. should be present, but should be conscious of any potential breaches of confidentiality in doing so.

5.6.4 Investigation of the Incident

All incidents should be investigated by an appropriate manager. (See Policy for the Investigation of Incidents, Complaints and Claims, including Analysis and Improvement).

This appropriate manager becomes the Lead for the Duty of Candour.

The level and depth of the investigation will be in line with the seriousness of the incident.

In many cases the investigation will be immediate and short with the apology, explanation and results of the investigation being delivered all at the same time.

In other cases these may be three distinct stages, the apology, the explanation and the results of the investigation.

The process for investigating the incident should be explained to the patient and/or their carer informing them that as any new information emerges as a result of any investigation they will be kept up to date.

The Investigator for the incident is responsible for liaising with and providing information in a timely, truthful and open manner to the patient and/or carer in line with the agreed investigation process.

5.6.5 Provision of additional support as required

Patients and or their carers should also be provided with support in a timely manner to meet their needs. This may involve an independent advocate or an interpreter. Information on the Patient Advisory and Liaison Service (PALS) and other relevant support groups should be given as soon as possible. The offer of additional support and the outcome should be recorded. It should be borne in mind that the need for support may change throughout the investigation process.

There should also be recognition of the traumatic effect that adverse outcomes and their aftermath might have on NHS staff as well as patients and their relatives.

5.6.6 Patients who do not agree with the information provided

Sometimes, despite the best efforts of staff, the relationship between the patient, their family and carers and the healthcare professional breaks down.

They may not accept the information provided, may desire a higher level of investigation or may not wish to participate in the process. In this case, the following strategies may assist:

- where the patient agrees, ensure their family and carers are involved in discussions from the beginning;
write a comprehensive list of the points that the patient, their family and carers disagree with and reassure them you will follow up these issues.

offer the patient, their family and carers another contact person with whom they may feel more comfortable. This could be another member of the team or a Manager from another team or service;

use a mutually acceptable mediator to help identify the issues between the healthcare organisation and the patient, and to look for a mutually agreeable solution;

ensure the patient, their family and carers are fully aware of the formal complaints procedures;

5.7 Special Considerations

The being open approach may need to be modified according to the individual patient or personal circumstances, for example (but not restricted to):

- When a patient dies
- Patients who have a cognitive impairment and may lack capacity
- Patients with a different language or cultural considerations
- Patients with different communication needs
- Children
- When there is a corresponding criminal enquiry

5.7.1 When a Patient Dies

When an incident has resulted in a patient death it is crucial that communication is sensitive, empathic and open. An apology will be given as soon as possible after the patient’s death. It is particularly important to consider the emotional state of bereaved relatives or carers and to involve them in deciding when it is appropriate to discuss what has happened.

A written notification and apology from the Modern Matron/AD should follow (See Letter Template - Appendix D - F)

Usually, the being open discussion and any investigation will occur before the Coroner’s inquest. In some circumstances the Trust may consider it more appropriate to wait for the coroner’s inquest before holding the being open discussion with the family and or carers. It is important to explain that they will be kept informed as information is released from the coroner’s office.

5.7.2 Patients Who Have a Cognitive Impairment and May Lack Capacity

Wherever possible the patient will be involved in communications about what has happened. An advocate with appropriate skills should be available to the person to assist in the communication process.

Some patients may have authorised a person to act on their behalf by an enduring power of attorney. In these cases steps must be taken to clarify the extent of this authority and the being open discussion would be held with the
holder of the power of attorney. This person would be the Relevant Person with regard to the Duty of Candour requirements. Where there is no such person staff may act in the patients' best interest in deciding who the appropriate person is to discuss information with, regarding the welfare of the patient as a whole and not simply their medical interests.

See Mental Capacity Act Policy

5.7.3 Patients with a Different Language or Cultural Considerations

The need for translation and advocacy services, and consideration of special cultural needs (such as for patients from cultures that make it difficult for a woman to talk to a male about intimate issues), must be taken into account when planning to discuss 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 patients and/or carers as they may distort information by editing what is communicated. Refer to the Policy for the Provision Of, Access To and Use of Interpreters for Service Users and Carers.

5.7.4 Patients with Different Communication Needs

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

5.7.5 Children

The Trust’s Safeguarding Children Team can provide advice related to assessing and managing risks in relation to children and child protection, including information-sharing with other agencies See also Trust Safeguarding Children Policy and multiagency safeguarding Children procedures.

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 (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 an 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.

5.8 Documenting All Communication

A clear and contemporaneous record must be maintained of all communication. It is important that throughout the Being open process that records of discussions with the patient and/or their carers as well as the incident investigation are maintained.

The initial apology and explanation given should be documented in the IR1 form, and in depth detail recorded in the patients notes.

The IR1 form will be the main record repository for Duty of Candour processes, with copies of letters and written notes being scanned and uploaded into the system.

Once the patient/relevant person has been told in person about the notifiable/patient safety incident, The Trust must provide the relevant person with a written note of the discussion, and copies of all correspondence must be kept by the Trust, along with any enquiries or investigations, and the outcome or results of those enquiries or investigations. A record of such communications should also be included in the patient record, IR1 and complaints and SI files where applicable.

Any routine day to day ‘being open’ communication such as an incident outside The Duty of Candour and the remit of the above policies will be recorded in the patient’s health record.

Staff should make every reasonable effort to contact the relevant people through various communication means. All attempts to contact the relevant people should be documented. If the relevant person declines to contact the Trust, their wishes should be respected and a record of this kept.

Good documentation is crucial. Discussions around the time of an incident should be recorded in the patient records. Any subsequent meetings should be minuted and followed up by letter.

The outcomes or results of any enquiries and investigations should also be provided in writing to the relevant people, should they wish to receive them. Any correspondence from relevant person(s) relating to the incident should be responded to in an appropriate and timely manner and a record of communications kept.

5.9 Next Steps

The relevant person should be advised on what further enquires are appropriate and they should be given all reasonable opportunities to be involved as much as they wish to be in the progress of any enquiries.

New information may emerge during the course of any inquiries into the incident, and the relevant people must be informed of new information as it arises. The
Trust must keep the relevant people informed about the conclusions of our enquiries, and provide them with a single point of contact for any questions and further opportunities to discuss the case:

- On an on-going basis throughout the course of their continuing recovery and/or treatment, and during any investigation or inquiry
- At times and amounts of their choosing until they are satisfied that all relevant information has been disclosed.

5.10 Continuity of Care

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

Patient or service users, their families and carers should be reassured that they will continue to be treated according to their clinical needs even in circumstances where there is a dispute between them and the 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 incident, complaint or claim.

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

5.11 Practical Support

In line with the expectations of all staff regardless of any incident, patients will be provided with all reasonable practical and emotional support necessary to help overcome the physical, psychological and emotional impact of the incident. At a direct level this will include:

- Treating all patients and their families with respect, consideration and empathy
- Offering the option of immediate emotional support during the notifications, for example from a family member, a care professional or a trained advocate
- Offering access to help with understanding what is being said e.g. via interpretative services, non-verbal communication aids, written information, Braille

In addition, staff will be supported by relevant process and individuals within the Trust to:

- Offer access to any necessary remedial treatment to minimise the harm caused
• Provide information about available impartial advocacy and support services, local Healthwatch and other relevant support groups, such as Cruse Bereavement Care and Action against Medical Accidents (AvMA), to help them deal with the outcome of incident

• Arrange for care and treatment to be delivered by another professional/team or provider as far as reasonably practical, should the relevant people wish.

6 TRAINING IMPLICATIONS

There are no mandatory training needs in relation to this policy, but the following staff will need to be familiar with its contents:

• All staff who during the course of their work will have direct contact with patients their carers
• Lead investigators who will have contact with patients, their families and carers during the course of their investigation
• Any other individual or group with a responsibility for implementing the contents of this policy.

Training sessions will be delivered by the Safety Team to raise awareness of the Duty of Candour for Managers, including how to record Duty of Candour compliance on the IR1 system.

As a Trust policy, all staff need to be aware of the key points that the policy covers. Staff can be made aware through a variety of means such as:

- Local Induction
- Team Brief
- One to one / Supervision
- Team meetings
- Posters
- Group supervision
- Weekly Newsletter
- Trust wide email notices

Please note that the Training Needs Analysis for the Investigation of Incidents, Complaints and Claims can be found in the Training Needs Analysis document which is part of the Trust’s Mandatory Risk Management Training Policy located under policy section of the Trust website.

The Investigation of Incidents, Complaints and Claims training will cover the principles and requirements of Being Open and The Duty of Candour.

7 MONITORING ARRANGEMENTS

<table>
<thead>
<tr>
<th>Area for Monitoring</th>
<th>How</th>
<th>Who by</th>
<th>Reported to</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Duty of Candour incidents</td>
<td>Safeguard output report</td>
<td>Head of Health, Safety &amp; Security</td>
<td>Risk Management Group</td>
<td>Monthly</td>
</tr>
<tr>
<td>Number not complying with the</td>
<td>Safeguard output exception report</td>
<td>Head of Health, Safety &amp; Security</td>
<td>Risk Management Group</td>
<td>Monthly</td>
</tr>
</tbody>
</table>
8  EQUALITY IMPACT ASSESSMENT SCREENING

The completed Equality Impact Assessment for this Policy has been published on the Equality and Diversity webpage of the RDaSH website [click here](#).

8.1  Privacy, Dignity and Respect

The NHS Constitution states that all patients should feel that their privacy and dignity are respected while they are in hospital. High Quality Care for All (2008), Lord Darzi's review of the NHS, identifies the need to organise care around the individual, *‘not just clinically but in terms of dignity and respect’.*

As a consequence the Trust is required to articulate its intent to deliver care with privacy and dignity that treats all service users with respect. Therefore, all procedural documents will be considered, if relevant, to reflect the requirement to treat everyone with privacy, dignity and respect, (when appropriate this should also include how same sex accommodation is provided).

<table>
<thead>
<tr>
<th>Indicate how this will be met</th>
</tr>
</thead>
<tbody>
<tr>
<td>No issues have been identified in relation to this policy.</td>
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</tbody>
</table>

8.2  Mental Capacity Act

Central to any aspect of care delivered to adults and young people aged 16 years or over will be the consideration of the individuals capacity to participate in the decision making process. Consequently, no intervention should be carried out without either the individuals informed consent, or the powers included in a legal framework, or by order of the Court. Therefore, the Trust is required to make sure that all staff working with individuals who use our service are familiar with the provisions within the Mental Capacity Act. For this reason all procedural documents will be considered, if relevant to reflect the provisions of the Mental Capacity Act 2005 to ensure that the interests of an individual whose capacity is in question can continue to make as many decisions for themselves as possible.

<table>
<thead>
<tr>
<th>Indicate How This Will Be Achieved.</th>
</tr>
</thead>
<tbody>
<tr>
<td>All individuals involved in the implementation of this policy should do so in accordance with the Guiding Principles of the Mental Capacity Act 2005.</td>
</tr>
</tbody>
</table>

9  LINKS TO ANY ASSOCIATED DOCUMENTS

- Policy on Supporting Staff Involved in a traumatic/stressful Incident, Complaint or Claim
- Speaking Out: Disclosure by Staff of Concerns on Healthcare Matters
- Policy for the Investigation of Incidents, Complaints and Claims, including Analysis and Improvement
- Incident Reporting Policy
- Policy for the Management of Serious Incidents (SIs)
- Claims Handling Policy
• Policy and Procedure in relation to the Handling of Formal Complaints
• Mental Capacity Act Policy
• Policy for Health Record Keeping Standards and Health Records Management
• Policy for the Provision Of, Access To and Use Of Interpreters for Service Users and Carers
• Patient Advice and Liaison Service (PALS) Policy (Raising Concerns)
• Policy for the Safe and Secure Handling of Medicines
• Health and Social Care Act

10 REFERENCES

• National Patient Safety Agency (NPSA) (2009) Saying sorry when things go wrong: Being Open
• NPSA (2009) Being Open: Communicating Patient Safety Incidents with patients their families and carers
• Department of Health (2003) Making Amends
• NHS Litigation Authority Risk Management Standards 2012
• NHS Litigation Authority (2009) Apologies and Explanations
• NHS Litigation Authority Press Release December 2013 [link]
• NHS Litigation Authority guidance on Candour [link]
• RDaSH Duty of Candour information sheet
• CQC guidance Regulation 5 and regulation 20, November 2014 [link]

11 APPENDICES

Appendix A - The Ten Being Open Principles and 6 Actions
Appendix B - NHSLA Saying Sorry Leaflet (link)
Appendix C - Duty Of Candour Criteria And Requirements
Appendix D - Letter Template: Incident resulting in death
Appendix E - Letter Template: Notifiable incident – Not Death
Appendix F - Letter Template: Closing letter
Appendix G - Incident Severity Grading Scale
Appendix H - Being Open Checklist
Appendix I – Being Open and Duty of Candour Process Flow chart
THE 10 BEING OPEN PRINCIPLES AND 6 ACTIONS

The Being Open framework has 10 guiding principles;

1. Acknowledgement
   - All patient safety incidents should be acknowledged and reported as soon as they are identified. In cases where the patient, their family and carers inform healthcare staff when something untoward has happened, it must be taken seriously from the outset.
   - Any concerns should be treated with compassion and understanding by all healthcare professionals.

2. Principle of truthfulness, timeliness and clarity of communication
   - Information about a patient or service user safety incident must be given to the individual and or their carers in a truthful and open manner by an appropriately nominated person.
   - Communication should also be timely: patients, service users and/or their carers should be provided with information about what happened as soon as practicable.
   - Patients, service 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 medical jargon which they may not understand should be avoided.

3. Principle of apology
   - Patients, service users and or their carers should receive an apology as soon as possible
   - Both verbal and written apologies should be given. Verbal apologies are essential because they allow face-to-face contact between the patient, service user and or their carers and the health or social care team.
   - A written apology, which clearly states the health social care organisation is sorry for the suffering and distress resulting from the incident, must also be given.

4. Principle of recognising patient, service user and carer expectations
   - Patients, service users and/or their carers should receive a full explanation of what led up to the patient/service user safety incident in a face-to-face meeting.
   - They should be provided with support in a manner appropriate to their needs.
   - Confidentiality should be maintained at all times.

5. Principle of professional support
   - Staff should feel supported throughout the incident investigation process.
   - Staff should be encouraged to seek support from relevant professional bodies such as the General Medical Council, Royal Colleges, the Medical Protection Society, the Medical Defence Union and the Nursing and Midwifery Council, Health and Care Professions Council.
   - Staff should be made aware of the Whistle blowing policy and procedure

6. Principle of risk management and systems improvement
• Root Cause Analysis (RCA), significant event audit (SEA) or similar techniques should be used to uncover the underlying causes of a patient or service user safety incident. 
• Investigations should focus on improving systems of care, which will then be reviewed for their effectiveness.

7. Principle of multidisciplinary responsibility

• Communication with patients or carers following an adverse incident should reflect the multi-disciplinary nature of the treatment received. 
• Senior managers, clinicians and health and social care leaders should champion the Being Open process.

8. Principle of clinical governance

• Being Open is part of the overall quality and governance frameworks within Rotherham Doncaster and South Humber NHS Foundation Trust (RDaSH)

9. Principle of confidentiality

• Policies and procedures for Being Open should give full consideration to the confidentiality of the patient, carer and member of staff. 
• Details of a patient safety incident should at all times be considered confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient.

10. Principle of continuity of care

• Patients should expect to continue to receive all usual treatment/ care and continue to be treated with respect and compassion. 
• If a patient expresses a preference for their health or social care needs to be taken over by another team, the appropriate arrangements should be made for them to receive treatment or care elsewhere.

The Being Open framework also has 6 specific actions which NHS Organisations must undertake, these are;

1. Policy:

• Review and strengthen local policy to ensure alignment with the Being open framework and embedded within our risk management and clinical governance processes.

2. Leadership:

• Make a board-level public commitment to implementing the principles of Being Open (via the Trust website).

3. Responsibilities:

• Nominate executive and non-executive leads responsible for leading our local policy. These can be leads with existing responsibilities for clinical governance.
4. Training and support:

- Identify senior clinical counsellors who will mentor and support fellow clinicians. Develop and implement a strategy for training these staff and provide on-going support.

5. Visibility:

- Raise awareness and understanding of the Being Open principles and local policy among staff, patients and the public, making information visible to all.

6. Supporting patients:

- Ensure Patient Advice and Liaison Services (PALS), and other staff have the information, skills and processes in place to support patients through the Being open process
Saying Sorry

Saying sorry when things go wrong is vital for the patient, their family and carers, as well as to support learning and improve safety. Of those that have suffered harm as a result of their healthcare, fifty percent wanted an apology and explanation. Patients, their families and carers should receive a meaningful apology – one that is a sincere expression of sorrow or regret for the harm that has occurred.

How should this happen?

Verbal apologies are essential because they allow face-to-face contact between the patient, their family and carers and the healthcare team. This should be given as soon as staff are aware an incident has occurred. A written apology, which clearly states the healthcare organisation is sorry for the suffering and distress resulting from the incident, must also be given.

Who should say sorry?

Information about a patient safety incident must be given to patients and their families in a truthful and open manner by an appropriately nominated person. Staff may be unclear about who should talk to patients when things go wrong and what they should say; there is the fear that they might upset the patient, say the wrong things, make the situation worse and admit liability. Having a local policy that sets out the process of communication with patients and raising awareness about this will provide staff with the confidence to communicate effectively. The local policy should state who is the most appropriate member of staff to give both verbal and written apologies to patients and their families; the decision should consider seniority, relationship to the patient, experience and expertise.

Most healthcare provision is through multidisciplinary teams so any local policy on openness should apply to all staff that have key roles in the patient’s care.

What if there is a formal complaint or claim?

Poor communication may make it more likely that the patient will pursue a complaint or claim. It is important not to delay giving a meaningful apology for any reason, including where there is a formal complaint or claim. It is also essential that any information given is based solely on the facts known at the time. Healthcare professionals should explain that new information may emerge as an investigation is undertaken, and that patients, their families and carers will be kept up-to-date with the progress of an investigation.
Is an apology the same as an admission of liability?

Saying sorry is not an admission of legal liability; it is the right thing to do. The NHS LA is not an insurer and will never withhold cover for a claim because an apology or explanation has been given. The NHS LA claims teams are always happy to provide support and advice where there is a potential claim.

What about the staff involved?

Healthcare organisations must create an environment in which all staff, whether directly employed or independent contractors of NHS care, are encouraged to report patient safety incidents. Staff should feel supported throughout the investigation process because they too may have been traumatised by being involved. Sometimes patients can suffer significant harm. In these circumstances, the member(s) of staff involved may find it hard to participate in the discussion with the patient and their family. Every case needs to be considered individually, balancing the needs of the patient and their family with those of the healthcare professional concerned.

In cases where the healthcare professional responsible wishes to attend the discussion to apologise personally, they should feel supported by their colleagues throughout the meeting. In cases where the patient and their family 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.

For more information

Being Open Guidance (National Patient Safety Agency)
www.npsa.nhs.uk

Reports and Consultations on complaint handling (Parliamentary and Health Service Ombudsman)
www.ombudsman.org.uk

Review of the NHS Hospitals Complaints System Putting Patients Back in the Picture (Clwyd and Hart)
www.clwyd.org.uk

Key messages

Timeliness: The initial discussion with the patient and their family should occur as soon as possible after recognition that something has gone wrong.

Explanation: Patients and their families should be provided with a step-by-step explanation of what happened, that considers their individual needs and is delivered openly.

Information: Patients and their families should receive clear, unambiguous information. They should not receive conflicting information from different members of staff. The use of medical jargon and acronyms, which they may not understand, should be avoided.

On-going support: Patients and their families should be given a single point of contact for any questions or requests they may have. They should also be provided with support in a manner appropriate to their needs. This involves consideration of special circumstances that can include a patient requiring additional support, such as an independent patient advocate or a translator.

Confidentiality: Policies and procedures should give full consideration of, and respect for privacy and confidentiality for the patient, their family and staff.

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

“Achieving timely and fair resolution, enhancing learning and improving safety.”

www.nhsla.com
DUTY OF CANDOUR CRITERIA AND REQUIREMENTS

In order to meet this duty the Trust must:

- Act in an open and transparent way with relevant persons in relation to care and treatment provided to people who use our services in carrying on a regulated activity.
- Tell the relevant person, in person, as soon as reasonably practicable after becoming aware that a notifiable Patient Safety Incident (PSI) has occurred, and provide support to them in relation to the incident, including when giving the notification.
- Provide an account of the incident, which to the best of its knowledge is true, of all the facts that it knows about the incident as at the date of notification.
- Advise the relevant person what further enquiries it believes are appropriate.
- Offer an apology.
- Follow this up by giving the same information in writing, and providing an update on the enquiries.
- Keep a written record of all communication with the relevant person.'

The CQC will monitor compliance with the key requirements with respect to the Duty of Candour:

- There should be a board-level commitment to being open and transparent in relation to care and treatment.
- Candour, openness and honesty should be encouraged at all levels, as an integral part of a culture of safety that supports organisational and personal learning.
- Providers should take action to tackle bullying, harassment and undermining, and must investigate any instances where a member of staff may have obstructed another in exercising their duty of candour.
- Staff should receive appropriate training, and there should be arrangements in place to support staff who are involved in a notifiable patient safety incident.
- There is no formal deadline under the Regulation for notifying the relevant person of an incident but the guidance refers to the NHS standard contract provision which requires notification within ten working days of the incident being reported and sooner where possible.
- Where the degree of harm is not yet clear but may fall within the criteria in the Regulation (death, severe harm, moderate harm or prolonged psychological harm) the relevant person must still be informed of the incident in line with the Regulations.
- Although there is a requirement to investigate incidents which ‘could result in’ harm as described above, the CQC state that there is no need to inform a person under the Regulation when a ‘near miss’ has occurred, resulting in no harm to that person.
- Where the incident relates to care delivered by another provider, RDaSH would work with others, and that provider would then be responsible for notifying the relevant person of the incident.
- There is guidance as to what constitutes ‘reasonable support’, e.g. third party emotional or advocacy support, arranging further treatment - where necessary by a different team or provider - and providing support to access RDaSH complaints procedure.
Appendix C

• Where, despite reasonable attempts, the relevant person cannot be contacted, or does not wish to communicate with the provider (including historic incidents) a written record should be kept of the attempts to contact or speak with them.
Appendix D

Rotherham Doncaster and South Humber
NHS Foundation Trust

Dear Patient/Relative (as appropriate)

You/Your ……………………. (insert relative) have/has been involved in an incident
.......................................................................................... describe event here..............................................

I wish to express my sincere apology that this event has occurred. The Trust aims to
provide a quality service to you/your (relatives as appropriate) and to investigate promptly
such incidents and share findings with those involved. To support anyone involved in an
incident the Trust follows the Being Open and Duty of Candour Policy, which lays out the
actions we will be taking.

We would like to invite you/your (relatives as appropriate), if you wish, to attend a meeting
to provide a step-by-step explanation of the events and circumstances. Prior to this going
ahead, I would appreciate your view on the following, in relation to this meeting.

- Your preference of time and date of meeting?
- Where would you wish to meet/proposed venue if there is any reason that this
cannot be at the hospital or Health care centre?

If you wish to do so, please feel free to bring along a friend or relative to offer you support
during this meeting. Also, if you wish, following the meeting you will be provided with
further information relating to the outcome of the investigation.

If you would prefer not to attend any meetings please let us know.

When our investigation is completed we will write to you to provide feedback regarding the
outcome.

I/ Staff member XXXXX is acting as your lead contact for the duration of the being open
process. I/they can be contacted on telephone number xxxx xxxxxxxx

Yours sincerely

Manager
Date XXXX

Dear Patient/Relative (as appropriate inserting title & name)

You/Your .................... (Insert relative) have/has been involved in an incident, which related to (brief description) ...................................on (date).

On behalf of the Trust and members of the team involved in the care of your son/daughter/father/mother, (insert name) please accept my sincere apology that this has occurred.

We aim to provide a quality service to patients/service users and families, and to investigate incidents promptly and share findings with those involved.

To support anyone involved in an incident, Rotherham Doncaster & South Humber NHS Foundation Trust has a Being Open and Duty of Candour policy. In line with this policy, you will be contacted by the investigating manager to discuss this with you. If you wish to talk about this beforehand, please do not hesitate to contact me on…….

When our investigation is complete you will be contacted with the findings.

Please be assured that it is not our intention to intrude upon you or your family at what may be a difficult time, however, it is important to keep you informed.

At this stage I/ Staff member XXXXX is acting as your lead contact for the duration of this process.

Yours sincerely

Manager
Date XXXX

Dear Patient/Relative (as appropriate inserting title & name)

As agreed following our initial letter dated, please find below a summary of the investigation findings into the incident/event/unexpected death of (name/relative) which happened on (date).

Description:

ENTER TEXT HERE

Immediate Action Taken:

ENTER TEXT HERE

Investigation findings:

ENTER TEXT HERE

Lessons Learned:

ENTER TEXT HERE

How these lessons learned will be shared across the Trust:

ENTER TEXT HERE

I hope that this will help assure you that appropriate steps have been taken to identify the care and treatment issues relevant to the incident, and that recommendations for action have been prioritised.

Yours sincerely

Manager
## Actual Harm Grading Scale

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No Harm</strong></td>
<td><strong>Minor</strong></td>
<td><strong>Moderate</strong></td>
<td><strong>Major</strong></td>
<td><strong>Catastrophic</strong></td>
<td><strong>Death</strong></td>
</tr>
<tr>
<td>Incident prevented – any patient safety incident that had the potential to cause harm but was prevented, and no harm was caused to patients receiving NHS-funded care.</td>
<td>Minor injury or illness, requiring minor intervention</td>
<td>Injury requiring a return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another area such as intensive care as a result of the incident.</td>
<td>Major injury leading to long-term incapacity/disability</td>
<td>Permanent harm directly related to the incident and not related to the natural course of the patient’s illness or underlying condition.</td>
<td>The death must be related to the incident rather than to the natural course of the patient’s illness or underlying condition.</td>
</tr>
<tr>
<td>Incident not prevented – any patient safety incident that occurred but no harm was caused to patients receiving NHS-funded care.</td>
<td>Minor treatment is defined as first aid, additional therapy, or additional medication.</td>
<td>Semi-permanent injury taking up to 12 months to recover.</td>
<td>Increase in length of hospital stay by &gt;15 days</td>
<td>Requiring time off work for &gt;14 days</td>
<td>Death as a result of an incident classified as a ‘never event’</td>
</tr>
<tr>
<td>Minimal injury requiring no/minimal intervention or treatment.</td>
<td>Increase in length of hospital stay by 1-3 days</td>
<td>Increase in length of hospital stay by 4-15 days</td>
<td>Increase in length of hospital stay by &gt;15 days</td>
<td>Requireing time off work for &gt;14 days</td>
<td></td>
</tr>
<tr>
<td>No time off work</td>
<td>Requiring time off work for &gt;3 days</td>
<td>RIDDOR Reportable incident</td>
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</tbody>
</table>
## Specific Actual Harm Guidance

<table>
<thead>
<tr>
<th>Specific Issue</th>
<th>2 Minor</th>
<th>3 Moderate</th>
<th>4 Major</th>
<th>5 Catastrophic</th>
<th>6 Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRESSURE ULCERS</td>
<td>Patient develops trust acquired pressure ulcer Category 1 or 2 or a moisture lesion</td>
<td>Trust acquired category 3 or 4 pressure ulcer. Multiple trust acquired category 2 pressure ulcers causing significant affects judged to be moderate</td>
<td>Multiple Trust acquired category 3 or 4 pressure ulcer</td>
<td>Pressure ulcer resulting in sepsis &amp; sepsis recorded on death certificate</td>
<td></td>
</tr>
<tr>
<td>FALLS</td>
<td>Fall causing harm that resolves within one month e.g. scalp laceration</td>
<td>Fall causing harm that takes 1-12 months to resolve e.g. fractured humerus. Seriousness of the incident or affects is judged to be moderate</td>
<td>As moderate, but judged to be a major harm.</td>
<td>Fall causing an injury which contributes to patient death e.g. recorded on Part 2 of death certificate OR causes permanent harm or permanent disability e.g. fractured neck of femur</td>
<td>Fall leading to injury that directly causes death of patient</td>
</tr>
<tr>
<td>MEDICATION ERRORS</td>
<td>Medication error resulting in patient harm which resolves within 1 month e.g. increased dose of antihypertensive administered in error which requires additional BP monitoring</td>
<td>Medication error resulting in patient harm that takes 1 to 12 months to resolve Seriousness of the incident or affects is judged to be moderate</td>
<td>As moderate, but judges to be a major harm.</td>
<td>Medication error which contributes to patient death e.g. failure to reconcile cardiac medication contributing to patient death</td>
<td>Medication incident directly resulting in patient death e.g. Medication administered to which the patient had a known allergy &amp; administration results in death</td>
</tr>
</tbody>
</table>
DUTY OF CANDOUR STEP BY STEP

Ensure the safety of those involved and the area. Provide assistance and aid as required.

Provide initial verbal apology and explanation of what happened as far as is known at that time.

Complete IR1 and record the conversation in the relevant section of the IR1 form.

Inform manager as soon as practicable.

Offer patient / relevant person support during and after the process, including, but not limited to, interpreters, advocates, counselling, self-help groups, transfer of care to another team, etc.

Within 10 Working Days the manager must;

Nominate a Lead to comply with the Duty of Candour.

This must be;
1. In person
2. Include an apology, what happened and what is going to happen next - investigation
3. Be delivered by a suitable manager from the service involved
4. Be followed by written notification
5. Be recorded in the Duty of Candour section of the IR1 form

Commence an investigation into the incident.

Within 28 working days of the incident (extended if SI or similar) the manager must;

Carry out an investigation and provide an explanation of the events and circumstances which resulted in the incident.

Provide and maintain written records of the interactions with the patient or relevant person.

Within 10 working days of the investigation being completed, the manager must;

Provide a copy of the investigation report to the patient or relevant person. This report has to be approved for release and suitably redacted if required.

Offer patient or relevant person support after the process, including, but not exclusively, counselling, self-help groups, transfer of care to another team, etc. Also the Your opinion Counts and complaints process. Incident is now complete.

The Incident is now complete.
Patient Safety Incident Occurs

BEING OPEN
At the time of the Incident

Ensure the safety of those involved and the area. Provide assistance and aid as required.

Provide verbal apology and explanation of what happened as far as is known at that time

Advise and, if possible, agree with the patient what further enquiries are appropriate.

Complete IR1 and record the conversation in the relevant section of the IR1 form

Provide reasonable support to the patient or service user, their families or carers.

Was The Severity Of Harm Moderate, Major, Catastrophic Or Death? OR Psychological Harm Over 28 Days?

NO

Duty of Candour Does Not Apply, But Being Open Initiative applies to ALL Patient Safety Incidents

YES

Within 10 Working Days
the allocated manager must;

Notify patient that incident has occurred. This must be;
1. Delivered by a suitable manager from the service involved
2. In person
3. Include all known facts about the incident
4. Include a repeat apology
5. Include next steps
6. Be followed by written notification
7. Be recorded in the Duty of Candour section of the IR1

Commence an investigation into the incident

Within 28 working days*
Of the incident the manager must;

Carry out an investigation to provide an explanation of the events and circumstances which resulted in the incident

Keep the Patient or relevant person informed of progress during the investigation

Provide and maintain written records of the interactions with the patient or relevant person

* If the incident is being investigated as an SI, or an external investigation, then the 28 day limit may be exceeded.

Within 10 working days of the investigation being completed;

Provide an explanation, and offer a copy, of the investigation report to the patient or relevant person. This report has to be approved for release and suitably redacted if required

Offer patient or relevant person support during and after the process, including, but not exclusively, counselling, self-help groups, transfer of care to another team, etc. Also the Your opinion Counts and complaints process. Incident is now complete

Appendix I

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