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| Associated Documents  | NCH&C Risk Management Strategy  
|                       | NCH&C Incident Reporting, Investigation and Management Policy  
|                       | NCH&C Complaints Policy  
|                       | NCH&C Claims Policy                                                                                                                               |
| Supporting References | National Patient Safety Agency (NPSA) NPSA/2009/Patient Safety Alert 003  
| NHSLA Risk Management Standards / CQC Regulation | NHSLA Standard 5 – Criterion 10  
|                       | NHSLA Standard 3 – Criterion 9  
<p>|                       | CQC Regulation 19                                                                                                                                     |
| Consultation or       | Executive Director Team                                                                                                                             |</p>
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| **Training Implications** | See section 4.2  
Training is included in Training Needs Analysis |
| **Process for Monitoring Compliance** | See Section 8  
This policy must be monitored following serious incidents |
| **Duties, Accountability and Responsibility** | See Section 3 |
| **Dissemination** | This policy will be published on NCH&C Intranet, and full details must be communicated to staff via Monthly Briefing Exchange and Weekly Messages  
Is there any reason why any part of this document should not be available on the public web site? ☐ Yes ☑ No |
| **Approval Process** | Clinical Policies Group 6th March 2012 |
| **Ratification Process** | Quality and Risk Assurance Committee 14th March 2012 |
| **Review Arrangements** | This policy must be reviewed in March 2014 or sooner if legislation or national guidance changes |
| **Date of issue** | March 2012 |
| **Archiving Arrangements** | This document must be archived in line with the Policy for Procedural Documents. |
# Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document Control</td>
<td>4</td>
</tr>
<tr>
<td>1 Introduction</td>
<td>5</td>
</tr>
<tr>
<td>2 Purpose</td>
<td>5</td>
</tr>
<tr>
<td>3 Duties, Accountability and Responsibility</td>
<td>6</td>
</tr>
<tr>
<td>3.1 Staff member involved in the incident</td>
<td>6</td>
</tr>
<tr>
<td>3.2 Line Manager of Staff involved in incident</td>
<td>6</td>
</tr>
<tr>
<td>3.3 Staff Member identified as the Lead for Communication</td>
<td>7</td>
</tr>
<tr>
<td>3.4 Quality and Risk Team</td>
<td>7</td>
</tr>
<tr>
<td>3.5 Complaints Team</td>
<td>8</td>
</tr>
<tr>
<td>4 Consultation and communication with staff groups</td>
<td>8</td>
</tr>
<tr>
<td>5 Process for encouraging open communication</td>
<td>9</td>
</tr>
<tr>
<td>5.1 Incidents</td>
<td>9</td>
</tr>
<tr>
<td>5.2 Complaints</td>
<td>10</td>
</tr>
<tr>
<td>5.3 Claims</td>
<td>10</td>
</tr>
<tr>
<td>6 Documentation of Open Communication</td>
<td>11</td>
</tr>
<tr>
<td>7 Provision of Additional Support for Patients, Families and Staff</td>
<td>11</td>
</tr>
<tr>
<td>8 Monitoring</td>
<td>13</td>
</tr>
</tbody>
</table>

## Appendices

|Appendix A | The ten principles of being open | 15 |
## Document Control

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1. **Introduction**

1.1 Promoting a culture of being open is a prerequisite to improving patient safety and the quality of healthcare systems. For patients, effective communication starts from a healthcare need being identified and continues throughout their treatment. For staff, there is an ethical responsibility to maintain honest and open communication with patients and carers even when things go wrong.

1.2 The effects of harming a patient may have devastating emotional and physical consequences for the patient and their families or carers. Being open involves apologising and explaining what happened, which can help patients and staff to cope better with the after-effects.

1.3 Being open and honest can prevent such events becoming formal complaints or litigation claims. It can also help support a ‘just culture’. Often patients will only pursue litigation following an incident if:

1.3.1 They received insufficient information

1.3.2 Where an apology was not given

1.3.3 Where they are not convinced that adequate learning or action has been taken.

1.4 This policy supports the government’s initiative to establish a safer and better health care service. Being open when things go wrong is fundamental to the partnership between patients and carers. It should be read in conjunction with the Trust’s Incident Reporting and Management Policy, Complaints Policy, Legal Policy and Whistleblowing Policy, which encourage staff to report incidents and provide mechanisms for raising concerns about patient safety issues.

2. **Purpose**

2.1 This policy describes the process to ensure that communication with patients and families, other organisations and between staff is open, honest and occurs as soon as possible following an incident, complaint or claim. It specifically considers events where harm may have been caused or where the patient or the patient’s family/carer believe that it has.

2.2 Being open helps to:

2.2.1 Establish an environment where patients receive the timely information they need to enable them to understand what happened

2.2.2 Create an environment where patients, their carers and staff feel supported when things go wrong

2.2.3 Create a culture where staff learn from adverse events and improve future practice
2.2.4 Assist in reassuring patients, families, staff and external agencies as appropriate, that everything possible must be done to ensure that a similar type of incident does not recur.

2.3 The Ten Principles of Being Open
Being open is a process rather than a one-off event. Ten principles underpin this policy:

1. Principle of acknowledgement
2. Principle of truthfulness, timeliness and clarity of communication
3. Principle of apology
4. Principle of recognising patient and carer expectations
5. Principle of professional support
6. Principle of risk management and systems improvement
7. Principle of multidisciplinary responsibility
8. Principle of clinical governance
9. Principle of confidentiality
10. Principle of continuity of care

See Appendix 1 for guidance on best practice on how to implement the principles.

3. Duties, Accountability and Responsibility
3.1 Staff member involved in the incident
It is the responsibility of the staff member involved in the incident to ensure the immediate safety of the patient/client and take any initial steps required to reduce harm. They must ensure that the relevant senior staff are informed of the incident as soon as possible and that appropriate remedial action is taken. If appropriate, they must contact the relevant medical team to assess the patient’s clinical condition and likelihood of any detrimental affect on their care, or immediate action required.

3.2 Line manager of the staff involved in the incident
3.2.1 The line manager of the staff member involved in the incident must identify the staff members who need to be informed of the incident and who need to be involved in communicating with the patient and his/her family.

3.2.2 The lead for communication with the patient about the incident may vary depending on the nature and severity of the incident. Consultation may need to take place with the patient’s consultant/lead healthcare practitioner. Advice and support may be sought from the Quality and Risk Team.
3.2.3 The line manager ensures that the staff member is supported following the incident.

3.2.4 They ensure that the incident is reported externally if appropriate.

3.2.5 Further information can be found in the Incident Reporting Investigation and Management Policy.

3.3 Staff member identified as the lead for communication

The staff member identified as the lead for communicating with the patient or the family must:

3.3.1 Ensure the patient/family is ready for any discussion and that the discussion takes place in an appropriate setting with due respect for confidentiality

3.3.2 Prepare for the discussion thoroughly

3.3.3 Provide a verbal/written apology or expression of regret, as appropriate, in line with the ten principles of being open

3.3.4 Ensure practical and emotional support in a timely manner to the patient

3.3.5 Document the details, actions and patient concerns from the discussion and ongoing plans in the patient’s health records.

3.3.6 Ensure that the date and time of the communication is recorded on the incident form (Datix).

3.3.7 Ensure truthful, timely and clear communication with all relevant parties.

3.3.8 Ensure ongoing communication is maintained with the patient and/or carer throughout the course of the investigation.

3.3.9 Delegate an appropriate substitute in exceptional circumstances if the lead is unable to attend.

3.4 Quality and Risk Team

It is the responsibility of the Quality and Risk Team to:

3.4.1 Support the incident investigation or root cause analysis where this is to be undertaken

3.4.2 To ensure that communication with the patient/family is ongoing throughout the investigation

3.4.3 Verify that the being open discussions have been recorded on the incident form

3.4.4 Update the Datix Incident Report Management System accordingly
3.4.5 To ensure that the incident has been reported internally to the relevant executive director and externally if necessary. This includes (but is not limited to) the MHRA, NPSA, the Strategic Health Authority, the Police, the Health and Safety Executive, Coroner as required.

3.4.6 If legal proceedings are instigated, to ensure that
   3.4.6.1 All relevant information is shared with claimant’s representatives.
   3.4.6.2 All communication with staff and with claimants is recorded in the Claim file.
   3.4.6.3 Comply with timescales for communication as identified in the Claims Policy

3.5 Complaints Team

It is the responsibility of the complaints team to:
   3.5.1 Ensure that any complaint is acknowledged within three working days
   3.5.2 Ensure that the acknowledgement identifies a lead investigator and provides a lead for communication for the complainant.
   3.5.3 Ensure that the response is factual
   3.5.4 Ensure that the response is provided within the agreed timescale and that appropriate communication takes place in the event of a delay
   3.5.5 Ensure that the response includes an apology or expression of regret as appropriate.
   3.5.6 Ensure that communication is truthful, timely and clear with all people involved.

4. Consultation and Communication with Staff Groups

4.1 Effective communication with staff is a vital step in ensuring that recommended changes resulting from the ‘Being Open’ process are fully implemented and monitored. It also facilitates the move towards increased awareness of patient safety issues and the value of an open culture.

4.2 Education and awareness of being open is raised via the following routes:
   4.2.1 Trust Mandatory Induction
   4.2.2 Local induction and refresher training
   4.2.3 Managing Incidents and Complaints Training.
   4.2.4 Quarterly Learning Events
4.2.5 Quarterly Incident, Complaints and Claims Report.

4.2.6 Annual Quality and Risk Report

4.2.7 Patient Safety Newsletters or other internal information sources
   all user and target emails

5. **Process for encouraging open communication**

Communication with patients and their families following incidents, complaints and claims should occur as soon as possible following identification of the problem. It may not always be possible to provide all of the necessary information at this time, but the incident should be acknowledged as soon as possible and the patient/family should be given an indication of when the investigation is likely to be complete.

5.1 **Incidents**

5.1.1 Following a patient safety incident staff should act to ensure the patient’s safety as a priority.

5.1.2 Where the patient has suffered harm as a result of a patient safety incident, the clinical team caring for the child identifies an appropriate clinical staff member to discuss the incident with the patient and/or their family. Appropriate clinical staff members include (but are not limited to) the: nurse in charge, ward sister, clinical site practitioner, modern matron, doctor caring for the patient, speciality lead or clinical unit chair. It may also be appropriate to involve senior managers from the relevant corporate departments.

5.1.3 In the event of a ‘prevented’ or ‘no harm’ patient safety incident, the clinical team caring for the patient determines the appropriateness of discussing the incident with the patient/service user and his/her family or carer where appropriate.

5.1.4 Staff must report patient safety incidents that were prevented and no harm incidents, to the Quality and Risk Team via the incident reporting system. Patient safety incidents that caused moderate, severe harm or death are also reported via this system, but are escalated promptly, usually by a direct phone call or page as per the NCH&C Incident Reporting, Investigation and Management Policy.

5.1.5 When a Root Cause Analysis (RCA) is undertaken by the Trust following an incident, it must be agreed who acts as the liaison point for the family regarding the progress with the RCA. The patient/service user must be provided with a copy of the full investigation report and must be offered the opportunity to meet with relevant clinical staff during or following the investigation.
5.1.6 Communication, whether verbal or written, regarding an incident must include a factual explanation, free, as far as possible, from medical terminology and an apology for any harm or suffering caused as a result of the incident.

5.1.7 The patient’s lead healthcare practitioner must identify in the event of an incident or near miss, any information which needs to be shared across the team or with other healthcare organisations. This may be internally by discussion at team meetings or more widely at quarterly ‘Learning Events’. They must identify any external agency such as the referring team or GP/consultant who may also need to be updated following any clinical incident.

5.2 Complaints

5.2.1 All formal complaints must be acknowledged within three working days of receiving the complaint. The acknowledgement provides the complainant with the name of the lead investigator and identify a point of contact within the Complaints Team to ensure that communication continues during the investigation period.

5.2.2 Where there are likely to be delays in communication or information, patients and their families must be advised of this by the Complaints Team.

5.2.3 When things go wrong it is important that the Trust is able to acknowledge this, adequately explain why things have gone wrong and apologise when it is appropriate.

5.2.4 Clinical teams may be involved in resolving complaints, both in providing information for the response, but also in meeting families where this is thought to be a more effective way to resolve a problem. They must liaise with other clinical colleagues both internal and external to the organisation as necessary.

5.3 Claims

5.3.1 The Complaints and Claims Manager must comply with the NHSLA requirements in respect of timescales for communication with relevant parties to a claim. They identify as part of the investigation into the claim where communication with other health care teams internal and external to the Trust is necessary.

5.3.2 As part of the claims management process the Trust acknowledges the right of a service user to make a claim for
compensation against the Trust should they feel this is appropriate.

6. Documentation of Open Communication
Staff are required to ensure that families and patients are informed when an adverse incident occurs. This discussion must take place promptly; give a truthful reflection of the situation, a realistic description of the potential harm if known, and a description of the process that must be followed going forward. This includes a description of the contact point for ensuring clarity of communication, the process for investigating why the event occurred and the feedback process to the family. This ensures continuity of the information provided and prevents mixed messages to all concerned. Staff may need additional senior support to do this.

6.1 Incidents
6.1.1 Staff must document on the incident form whether or not this discussion has taken place, including the date and time of the discussion. Clinical staff must also document all communication including the details of any discussion with the patient and/or family regarding a patient safety incident in the medical records.

6.1.2 A copy of all written correspondence with the patient/family regarding the incident must be held on file by the Quality and Risk Team. Communication with other clinical teams or agencies must be recorded in the patient’s records stating how and when this occurred and summarising the information given.

6.2 Complaints
6.2.1 The Complaints Team keep a file relating to each complaint. The file contains details of all correspondence and communication between staff, the patient, the family and any other agencies or healthcare organisations in relation to the complaint and actions taken to resolve it.

6.2.2 The Complaints and Claims Manager ensures that the person making the compliant and the staff involved are kept informed of progress

6.3 Claims
6.3.1 The Complaints and Claims Manager keeps a file relating to each claim. The file must contain details of all correspondence and communication with relevant parties to the claim in accordance with the Claims Policy and NHSLA requirements.

6.3.2 They ensure any clinical team or staff involved in a claim are up dated on progress within an agreed timescale.
7. Provision of Additional Support for Patients, Families and Staff

7.1 Patients and Carers

7.1.1 Patients or their carers who have been affected by an incident, complaint or claim should have a nominated contact within the Trust for communication. This may be a designated Doctor, Modern Matron, Therapy Manager, Member of Quality and Risk Team, or other nominated senior individual.

7.1.2 If additional support is required then patients/families should be directed to the Patient Advice and Liaison Service (PALS) in the first instance, who may be able to provide advocacy and support within the Trust. PALS will also be able to provide patients and families with details of external organisations who can provide support including Independent Complaints Advocacy Service (ICAS) and Action Against Medical Accidents (AvMA).

7.2 Staff

7.2.1 All staff involved need support from their peers, colleagues and managers. They may also require external support such as bereavement counselling or Trust Staff Counselling Service. Staff should be kept informed at regular intervals as to the progress of any investigation being undertaken. In some instances, for their own benefit, staff involved may require to be given time off work, this may include suspension on full pay, or offered the possibility of working in a different area of the Trust for a period of time. Efforts must be made to meet these needs. Further advice can be sought from the HR department, Occupational Health or Quality and Risk Team.

7.2.2 It is the responsibility of the manager of the staff member involved in an incident, complaint or claim to ensure that staff have access to appropriate support.

7.2.3 The Quality and Risk Team, including Complaints/Claims and the PALS Service are available to provide help and support to staff in being open with families and carers following incidents, complaints and claims. Support may include discussing the process for investigation of the incident, complaint or claim directly with the patient and/or family. This can be provided in person, on the phone or by letter, as close to the event occurring as possible.

8. Process for Monitoring Compliance

8.1 Incidents
8.1.1 Following completion of a Level 2 Root Cause Analysis (RCA) investigation, the report is reviewed by the Quality and Risk Manager to assess whether appropriate senior staff have been involved in the investigation, the level of staff support provided and involvement of the patient, family and carer in the process.

8.1.2 This is included in the report to the QRAC when the final report on the RCA is presented at the next available meeting following completion of the report.

8.1.3 Compliance with external reporting timescales for Serious Incidents Requiring Investigation (SIRIs) are monitored monthly and reported to the Quality and Risk Assurance Committee.

8.2 Complaints

8.2.1 A six monthly audit of complaint responses will identify:
   8.2.1.1 whether an apology/expression of regret has been given
   8.2.1.2 compliance with timescales for communicating with patients,
   8.2.1.3 informing the patient if there is going to be a delay
   8.2.1.4 and any offer of meeting the teams involved as it has been shown that this can assist in the resolution of complaints.

8.3 Claims

Claims files must be audited on a six monthly basis to check compliance with performance targets regarding the standard of filed correspondence and must be reported to the Quality and Risk Assurance Committee (QRAC).

Any deficit identified through the audit process is discussed in the first instance with the local team lead of the service involved and a summary report and any associated action plan presented to and monitored by QRAC.

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Being Open Policy
NCH&C
Version 2.0
15.03.12
13 of 17
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Appendix 1 - The ten principles of being open

Being open is a process rather than a one-off event. The following principles underpin this policy.

i. **Principle of acknowledgement**

All patient safety incidents should be acknowledged and reported as soon as they are identified using the Trust's incident reporting system. In cases where the patient and/or their carers inform healthcare staff when something untoward has happened, it must be taken seriously from the outset. Any concerns should be treated with compassion and understanding by all healthcare staff. Denial of a patient’s concerns could make future open and honest communication more difficult.

ii. **Principle of truthfulness, timeliness and clarity of communication**

An appropriate person must give information about a patient safety incident to patients in a truthful and open manner. Patients may want a step-by-step explanation of what happened, that considers their individual needs and is delivered openly.

Communication should also be timely. Patients should be provided with information about what happened as soon as practicable. It is also essential that any information given be based solely on the facts known at the time. Healthcare staff should explain that new information could emerge as an incident investigation is undertaken, and patients should be kept up-to-date with the progress of an investigation.

Patients should receive clear, unambiguous information and be given a single point of contact for any questions or requests they may have. They should not receive conflicting information from different members of staff. Medical jargon, which they may not understand, should be avoided.

iii. **Principle of apology**

Patients should receive an expression of sorrow or regret for the harm that has resulted from a patient safety incident. This should be in the form of an appropriately worded apology, as early as possible.

Both verbal and written apologies should be given. The relevant senior manager should decide on the most appropriate member of staff to issue the apology to patients based on individual circumstances. The decision should consider seniority, relationship to the patient, and experience and expertise in the type of patient safety incident that has occurred.

Verbal apologies are essential, because they allow face-to-face contact between the patient and the healthcare team. This should be given as soon as staff are aware an incident has occurred. It is important not to delay for any reason, including setting up a more formal multidisciplinary being open discussion with the patient, fear and apprehension or lack of staff availability. Delays are likely to increase the patient’s sense of anxiety, anger or frustration.

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

iv Principle of recognising patient and carer expectations
Patients can reasonably expect to be fully informed of the issues surrounding a patient safety incident, and its consequences, in a face-to-face meeting with representatives from the healthcare organisation.

They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times. Patients 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.

Where appropriate, information on the Patient Advisory and Liaison Service (PALS) and other relevant support groups like Cruse Bereavement Care (CRUSE) and Action against Medical Accidents (AvMA) should be given to the patient as soon as possible.

v Principle of professional support
We must create an environment in which all staff, whether directly employed or independent contractors, are encouraged to report patient safety incidents. Staff should feel supported throughout the incident investigation process because being involved may have also traumatised them. They should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration.

To ensure a robust and consistent approach to incident investigation, managers are advised to use the NPSA’s incident decision tree (IDT). The IDT has been developed as an aid to improve the consistency of decision-making about whether human error or systems failures contributed to an incident. It is designed for use by anyone who has the authority to exclude a member of staff from work following a patient safety incident.

Where there is reason for the trust to believe a member of staff has committed a punitive or criminal act, it should take steps to preserve its position, and advise the member(s) of staff at an early stage to enable them to obtain separate legal advice and representation.

Staff must be encouraged to seek support from relevant professional bodies such as the General Medical Council, Nursing and Midwifery Council, Health Professions Council, Royal Colleges, the Medical Protection Society, and the Medical Defence Union.

vi Principle of risk management and systems improvement
Root Cause Analysis (RCA) should be used to uncover the underlying causes of a patient safety incident. Investigations should focus on improving systems of care, which must then be reviewed for their effectiveness. An organisational approach that follows the Seven Steps to Patient Safety should be adopted.

The Trust’s Being Open Policy should be integrated into local incident reporting and risk management policies and processes.

vii Principle of multidisciplinary responsibility
Local policies on openness should apply to all staff that have key roles in the patient’s care. Most healthcare provision involves multidisciplinary teams, so communication with patients following an incident that led to harm, should reflect this. This ensures that the being open process is consistent with the philosophy that incidents usually result from systems failures and rarely from the actions of an individual.

To ensure multidisciplinary involvement in the process, it is important to identify clinical and managerial opinion leaders who must champion it.

**viii Principle of clinical governance**

Being open requires the support of patient safety and quality improvement processes through clinical governance and quality frameworks, in which patient safety incidents are investigated and analysed, to find out what can be done to prevent their recurrence.

It also involves a system of accountability through the Chief Executive to the Trust Board, to ensure these changes are implemented and their effectiveness reviewed. Findings should be disseminated to relevant staff and teams, so that they can learn from patient safety incidents.

Continuous learning programmes and audits should be developed that allow healthcare organisations to learn from the patient’s experience of being open and that monitor the implementation and effects of changes in practice following a patient safety incident.

**ix Principle of confidentiality**

Policies and procedures for being open should give full consideration of, and respect for, the patient’s and staff privacy and confidentiality. Details of a patient safety incident should at all times be considered confidential.

The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient. Where this is not practicable or an individual refuses to consent to the disclosure, disclosure may still be lawful if justified in the public interest or where those investigating the incident have statutory powers for obtaining information.

Communications with parties outside of the clinical team should also be on a strictly need-to-know basis and, where practicable, records should be anonymous. In addition, it is good practice to inform the patient about who will be involved in the investigation before it takes place, and give them the opportunity to raise any objections.

**x Principle of continuity of care**

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