Policy for Being Open and the Duty of Candour

Document ref. no: PP(16)394

For use in: Trustwide
For use by: All Staff
For use for: Being Open and the Duty of Candour
Document owner: Giles Thorpe
Approval Committee: Executive Team
Status: (date approved) 27th January 2016

The full document can be accessed through the Document Management System
**Document Title:** Policy for Being Open and the Duty of Candour

**Document Purpose:**
This policy aims to improve the quality and consistency of communication when incidents involving patients, staff or visitors occur and/or in situations which give rise to complaints. The policy will make sure that if mistakes are made the patient and/or their carer, relative, staff member or visitor will be given an opportunity to discuss what went wrong, that they will receive an apology and be informed of the action the Trust will take to prevent it happening again. This document also outlines the process by which staff must comply with the professional, contractual and statutory Duty of Candour to ensure that when harm events occur, patients and relatives are fully informed and are involved in the investigation process.

**Document Statement:**
The Board of Directors is committed to an open and honest approach in all matters. It fully endorses the principles of Being open and the Duty of Candour and it is the duty of all staff to follow this approach. The Trust is committed to an open, honest and fair culture and the overall approach expected within the organisation is one of help and support.

**Main imperatives of this document are:**

If potential harm has occurred as a result of a mistake or error in their care we as an organisation must:

- apologise for the harm caused;
- explain, openly and honestly, what has gone wrong;
- describe what we are doing in response to the incident;
- offer any support that might be of help;
- provide the name of a person to speak to;
- give updates on the results of any investigation/developments.
## CONTENTS

<p>| WHAT YOU NEED TO KNOW WHEN COMPLETING THE DUTY OF CANDOUR | 4 |
| 1. INTRODUCTION | 5 |
| 2. SCOPE | 6 |
| 3. DEFINITIONS | 7 |
| 4. ROLES AND RESPONSIBILITIES | 8 |
| 5. THE BEING OPEN PROCESS | 9 |
| 6. THE DUTY OF CANDOUR | 10 |
| 7. PATIENT ISSUES | 11 |
| 8. MONITORING | 13 |
| 9. TRAINING | 13 |
| 10. IMPLEMENTATION | 14 |
| APPENDIX A – PRINCIPLES OF BEING OPEN | 15 |
| APPENDIX B – FLOWCHART FOR UNDERTAKING THE DUTY OF CANDOUR PROCESS | 18 |
| APPENDIX C – DETAILED GUIDANCE FOR UNDERTAKING ACTIONS RELATED TO BEING OPEN OR DUTY OF CANDOUR | 19 |
| APPENDIX D – ILLUSTRATED EXAMPLES OF MODERATE HARM, SEVERE HARM AND DEATH REQUIRING DUTY OF CANDOUR | 24 |</p>
<table>
<thead>
<tr>
<th>Key Message</th>
<th>Detail</th>
</tr>
</thead>
</table>
| Review Incident – Verbal Duty of Candour OR Being Open | You are made aware/involved in an incident has occurred involving a patient? Do you suspect there is a possibility that the patient has suffered from harm?  
**YES**  
Provide an apology to patient (or relatives) and explain and that an initial investigation will be undertaken to find out what has occurred and that can be shared with the patient/relative.  
**NO**  
Provide an apology to patient (or relatives) for any aspect of poor patient experience, and provide contact details for PALS team if required |
| Document | Document clearly in the notes the following:  
- Reference incident number for tracking purposes  
- Identify who was present  
- Detail of apology made to patient/relative(s)  
- Explanation of investigation process (if potential of harm)  
- Explanation written follow up (if potential of harm)  
- Evidence of provision of contact details  
- Any questions raised and answers provided |
| Confirmation of moderate harm/SI/ Formal Duty of Candour | 24 Hour review will be reviewed at Executive SI Review Group |
| Written Duty of Candour | **Within 10 working days of SI being declared** - written apology and outline of process of Serious Incident investigation to be sent to patient/relative, with confirmed offer of sharing the investigation once it has been completed and approved by the Clinical Commissioning Group. (Template provided by Clinical Governance and Risk Department) |
| Incident investigation | Process of investigation of Serious Incident follows according to timeline as set within procedure. |
| Duty of Candour – sharing the report | **Within 10 working days of the Trust approving the report as closed** – written letter offering the opportunity to review the report, providing the opportunity to meet to discuss the report, and to provide any additional assistance required. |
| Meeting | Facilitate meeting with family to review the report, where this has been accepted, to ensure a clear understanding of the output and offer the opportunity to come back to evidence practice changes. |
| Document | Ensure that output from the meeting is documented and uploaded onto the Datix system, with an entry into the medical records. |
| Evidence of Compliance | The Divisional Management Team must ensure that all aspects of Duty of Candour have been evidenced and uploaded on the Datix system to meet contractual and legal responsibilities. |
1. Introduction

Colchester Hospital University NHS Foundation Trust is committed to the provision of high quality health care in all aspects of its services to patients, relatives, visitors, local community and staff. As part of this objective, the Trust has a duty to limit the potential impact of a wide variety of clinical and non-clinical risks and put in place robust and transparent systems to make sure that all incidents which might cause actual or potential harm to patients, visitors and staff are identified, investigated and rectified.

Promoting a culture of openness and truthfulness is a prerequisite to improving the safety of patients, staff and visitors as well as the quality of healthcare systems. It involves apologising and explaining what happened to patients who have been harmed as a result of their healthcare treatment as in-patients or outpatients of the Trust. It also involves apologising and explaining what happened to staff or visitors who have suffered harm. It encompasses communication between healthcare organisations, healthcare teams and patients and/or their relatives/carers, staff and visitors and makes sure that openness, honesty and timeliness underpins responses to such incidents.

1.1. Being Open

The culture of being open should be intrinsic throughout the Trust in relationships with and between patients, the public, staff and other healthcare organisations.

This policy is based on guidance from the National Patient Safety Agency (NPSA), ‘Being open: Saying sorry when things go wrong’ (2009) and the National Health Service Litigation Authority (NHSLA) communication of 1 May 2009 “Apologies and explanations”. The NPSA states that ‘Being Open’:

- is what patients want;
- is ethically and morally the right thing to do;
- it reduces litigation costs; and
- is a vehicle for winning back patient confidence.

Elements of the Being Open policy reflect other government initiatives and recommendations from major inquiry reports such as the 5th Shipman Inquiry Report (2004) and the NHS Litigation Authority’s Striking the Balance (NHSLA initiative 2003). These identify the need for clear and accurate documentation and the importance of providing support for healthcare professionals involved in a complaint, incident or claim.

1.2. The Duty of Candour

The Chief Medical Officer’s consultation document, Making Amends (2003), outlines processes to encourage openness in the reporting of adverse events, stating that there exists ‘a Duty of Candour’ which requires clinicians and health services managers to inform patients about actions which have resulted in harm. In addition, openness and honesty towards patients is actively encouraged by such professional bodies as the Medical Protection Society, the Medical Defence Union and the General Medical Council.

Since 2013 there has been a contractual requirement by NHS Trusts to ensure compliance with the Duty of Candour within the NHS Standard Contract for those incidents that result in moderate or severe harm, or death (utilising the National Patient Safety Agency (NPSA) definitions).
Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (located at [http://www.legislation.gov.uk/ukdsi/2014/9780111117613/pdfs/ukdsi_9780111117613_en.pdf](http://www.legislation.gov.uk/ukdsi/2014/9780111117613/pdfs/ukdsi_9780111117613_en.pdf)) is a direct response to recommendation 181 of the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust. This recommendation states that a statutory duty of candour should be imposed on healthcare providers. In interpreting the regulation on the duty of candour, the Care Quality Commission has published guidance on how this will be regulated and inspected. This guidance can be located at:


The CQC have used the definitions of openness, transparency and candour used by Robert Francis in his report:

- **Openness** – enabling concerns and complaints to be raised freely without fear and questions asked to be answered.
- **Transparency** – allowing information about the truth about performance and outcomes to be shared with staff, patients, the public and regulators.
- **Candour** – any patient harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it.

The regulation and its implementation reflect the approach proposed by the Dalton/Williams review (located at [http://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf](http://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf)), including defining a notifiable safety incident to include moderate harm, severe harm, death, and prolonged psychological harm. These definitions are contained within Regulation 20 itself. NHS bodies have been encouraged for some time to voluntarily report moderate incidents.

### 2. Scope

This policy relates to incidents, complaints and claims and details arrangements for communication with patients, relatives and/or their relatives/carers who have suffered harm within the Trust. The same principles and process should be applied if a member of staff or visitor suffers harm as a result of an incident within the Trust’s property.

It is aimed at any healthcare staff member, clinical or non-clinical, responsible for making sure that the infrastructure is in place to support openness between healthcare professionals and patients and/or their relatives/carers following an incident, complaint or claim. It describes the processes of ‘being open’ with patients and gives advice on the ‘dos and don’ts’ of communicating with patients and/or their relatives/carers following harm.

Whilst this Trust encourages staff to report all patient safety incidents, including no harm and near misses, this policy only relates to those incidents that cause moderate harm, severe harm or death on the actual impact grading scale below.
### Patient Safety Incident Severity Level

<table>
<thead>
<tr>
<th>Severity Level</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>No harm/near miss/no injury</td>
<td>Patients are not usually involved in investigations and these types of incidents are outside the scope of the Being Open and Duty of Candour policy. However, it is within the scope of the healthcare professional's accountability and responsibility to hold a discussion with the patient and/or relative, should this prove appropriate.</td>
</tr>
<tr>
<td>Minor/Low harm</td>
<td>Unless there are specific indications or the patient requests it, the communication, investigation, analysis and the implementation of changes will happen at service delivery level with the participation of those directly involved in the incident. Again it is within the scope of healthcare professional's accountability and responsibility to hold a discussion with the patient and/or relative, in the spirit of Being Open and transparent, including them in all aspects of care delivery and governance.</td>
</tr>
<tr>
<td>Moderate harm, Severe harm or death</td>
<td><strong>A higher response is required in these circumstances.</strong> Notification should be in accordance with the Incident Reporting procedure. A member of the Clinical Governance and Risk Department or Complaints Team will be available to provide support and advice during the Duty of Candour process. The patient (if possible) and their family/relatives/carer's must be kept informed of investigative procedures, outcomes and action planning.</td>
</tr>
</tbody>
</table>

### 3. Definitions

- **Being Open:** the process for communicating adverse events with patients, relatives, carers, staff and visitors.

- **Harm:** injury (physical or psychological), disease, suffering, disability or death.

- **Patient safety incident:** Any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS healthcare.

- **Risk:** the chance of something happening that will have an impact on individuals and/or organisations.

- **Root Cause Analysis:** a systematic process whereby the factors that contributes to an incident are identified.

- **Moderate harm:** ‘Moderate harm’ means harm that requires a moderate increase in treatment, and significant, but not permanent, harm, for example a “moderate increase in treatment” means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care).

- **Prolonged pain:** ‘Prolonged pain’ means pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

- **Prolonged psychological harm:** ‘Prolonged psychological harm’ means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

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

Chief Executive

The Chief Executive as the Accounting Officer has overall responsibility for the quality and safety of services provided by the Trust. In this respect, he/she is responsible for ensuring that the infrastructure required supporting the delivery and implementation of this document is available. He/she will delegate the full implementation of this document to a relevant Executive Director.

Medical Director

The Medical Director is responsible for ensuring that the necessary systems, processes, training and competency assessment (where appropriate) are available to ensure that all medical and dental staff are able to comply with the contents of this document. In addition, he/she is responsible for ensuring that the monitoring and audit of this document is undertaken and reported in the appropriate forum as indicated in the document.

Director of Nursing

The Director of Nursing is responsible for ensuring that the necessary systems, processes, training and competency assessment (where appropriate) are available to ensure that all non-medical staff (nurses, midwives and allied health professionals) are able to comply with the contents of this document.

Deputy Director of Nursing

The Deputy Director of Nursing is responsible for ensuring that there are systems and processes in place to communicate and implement this document in the clinical areas. He/she is also responsible for ensuring that information relating to compliance with the contractual and statutory Duty of Candour is analysed, to help identify requirements for further support and guidance, and provide relevant information to internal and external stakeholders, including commissioners and regulators.

Divisional Directors

The Divisional Directors are responsible for ensuring that systems and processes are in place throughout the Divisions to ensure that this document is disseminated appropriately and that monitoring of compliance is undertaken, with remedial action implemented as appropriate. In addition, the Divisional Directors are responsible for ensuring that all medical and dental staff complies with the contents of the document.

Associate Directors of Operations:

The Divisional Associate Directors of Operations are responsible for implementing the systems and processes required throughout the Divisions to ensure that this document is disseminated appropriately and that monitoring of compliance is undertaken, with remedial action implemented as appropriate.
**Associate Directors of Nursing/Head of Midwifery:**

The ADNs/HoM are responsible for ensuring that the policy is disseminated throughout the Division and that the required monitoring and audit are undertaken, with the resources provided to support this.

**Clinical Service Unit Leads/Managers:**

Clinical Service Unit Clinical Leads and Unit Managers are responsible for implementing this document in the Clinical Service Unit and for monitoring the impact on the service and reporting compliance with the document. They are accountable to the Divisional Clinical Director and General Manager in this respect.

**Matrons/Lead Nurses**

Lead Nurses are responsible for ensuring that all nursing staff (including Nurse Specialists, Practitioners/Advisors) within the Clinical Service Unit comply with the contents of this document and for taking action when this is not the case. The Lead Nurse will make sure that all necessary training is provided.

**Medical Staff**

The Consultant holds ultimate responsibility for ensuring that all members of the medical team follow the document contained within this document.

**Senior Sisters/Charge Nurses**

The Senior Sister/Charge Nurse is accountable for the safe care and management of patient on the ward. They are therefore responsible for ensuring that all staff within the ward comply with this document and for implementing a system to provide assurance that this is the case.

5. **The Being Open Process**

The Trust's process for encouraging open communication is reflected in the 'Ten Principles of Being Open' as identified in the National Patient Safety Agency's document 'Being Open: communicating patient safety incidents with patients and their relatives/carers' (NPSA, 2009). These can be found at Appendix A.

5.1. **Detecting and recognising an incident**

The Being Open process begins with the acknowledgement that a patient has suffered harm as a result of a patient safety incident. Please refer to the Trust's Incident Reporting Procedure for detail on the process of completing an incident form via the Datix system.

A patient safety incident may be recognised by a member of staff, patient and/or carer, as a result of a complaint or legal claim or other sources. In all cases the Trust's Incident Reporting Procedure must be implemented including identifying why there has been a delay in reporting an incident.

As soon as a patient safety incident is identified, the top priority is prompt and appropriate clinical care and the prevention of further harm. Where additional treatment is required, this should happen as soon as reasonably practicable after a discussion with the patient (or relative/carer if the patient is unable to participate in the discussion) and with appropriate consent.
A record of discussions must be made in the patient’s health record which must be descriptive but it does not need to be a verbatim record. The patient and/or carer response/reaction should also be recorded.

It may not be immediately evident to the patient and/or carer that an adverse event has taken place. However the adverse event must be advised to the patient as soon as possible after the event but certainly within a week of the incident occurring. At that time, an initial apology and explanation must be given. It is important that patients and/or their relatives/carer receive a meaningful apology. An apology does not constitute an admission of liability. Explanations should not contain admissions of liability.

6. The Duty of Candour

This contractual and statutory duty means that patients or their family/carer must be informed of a suspected or actual patient safety incident that has resulted in moderate or severe harm, or death, within 10 working days of the incident being reported on the incident reporting system. This notification must occur:

6.1. How to undertake Duty of Candour

When undertaken the Duty of Candour, the following steps must be taken – ensuring that:

- Duty of Candour is initially undertaken verbally (face to face where possible) unless the patient (or relative) declines.

- This verbal notification (or decline) must be documented in the patient’s medical record, including any responses by the patient (or relative if the patient is unable to be involved in the process themselves), ensuring that the associated incident number is documented.
  - An apology must be provided
  - A step by step explanation of what happened, in plain English, must be offered as soon as is practicable.

| Lack of clarity whether a patient safety incident, or the degree of harm, has occurred, is not a reason to avoid disclosure. |

- Follow up of the verbal notification must be in writing, outlining the process of the investigation, potential timescales and relevant contact details must be provided.

- Sharing the investigation report must be offered to the patient or relative/carer within 10 working days of the investigation being signed off as complete by the Trust.

A table outlining the process of Duty of Candour can be found at Appendix B.

Detailed guidance on undertaking the various aspects of Being Open and Duty of Candour can be found at Appendix C

Illustrative Examples of those notifiable incidents that would require the Duty of Candour (as provided by the Care Quality Commission) can be found at Appendix D.
7. Patient issues

The approach to Being open may need to be modified according to the patient's personal circumstances.

7.1. When a patient dies

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

Usually the initial discussion and any investigation will occur before the coroner's inquest. However it might be considered appropriate to wait for the coroner's inquest before holding the Duty of Candour discussion. The coroner’s report on post-mortem findings is a key source of information that will help complete the picture of events leading up to the patient’s death.

In any event an apology should be issued as soon after the patient's death along with an explanation of the processes that have been initiated.

7.2. Children

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

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.

7.3. Patients with mental health issues

Being open for patients with mental health issues should follow normal procedures unless the patient also has cognitive impairment (see Patients with cognitive impairments).

The only circumstances in which it is appropriate to withhold patient safety incident information from a patient with mental health issues is when advised to do so by a consultant psychiatrist who feels it would cause adverse psychological harm to the patient. However, such circumstances are rare and a second opinion (by another consultant psychiatrist) would be needed to justify withholding information from the patient.

Apart from in exceptional circumstances, it is never appropriate to discuss patient safety incident information with a carer or relative without the express permission of the patient.
7.4. Patients with cognitive impairment

Some individuals have conditions that limit their ability to understand what is happening to them. They may have authorised a person to act on their behalf by an enduring Power of Attorney. In these cases, steps must be taken to ensure that this extends to decision making and to the medical care and treatment of the patient.

The Being open or Duty of Candour discussion would be conducted with the holder of the power of attorney. Where there is no such person, the clinicians may act in the patient’s best interest in deciding who the appropriate person is to discuss incident information with, regarding the welfare of the patient as a whole and not simply their medical interests. However, patients with cognitive impairment should, where possible, be involved directly in communications about what has happened. An advocate with appropriate skills should be available to the patient to assist in the communication process. See ‘Patients with learning disabilities’ for details of appropriate advocates.

7.5. Patients with learning disabilities

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

7.6. Patients with different language or cultural considerations

The need for translation and advocacy services, and consideration of special cultural needs (such as for patients from cultures that make it difficult for a woman to talk to a male about intimate issues), must be taken into account when planning to discuss patient safety incident information. It would be worthwhile to obtain advice from an advocate or translator before the meeting on the most sensitive way to discuss the information. Avoid using ‘unofficial translators’ and/or the patient’s family or friends as they may distort information by editing what is communicated.

7.7. Patients with different communication needs

A number of patients will have particular communication difficulties, such as a hearing impairment. Plans for the meeting should fully consider these needs. Knowing how to enable or enhance communications with a patient is essential to facilitating an effective Being open process. This involves focusing on the needs of the patient, their family and carers, and being personally thoughtful and respectful.
7.8. Patients who do not agree with the information provided

Sometimes, despite the best efforts of healthcare staff or others, the relationship between the patient, their family and carers and the healthcare professional breaks down. They may not accept the information provided or may not wish to participate in the Being open or Duty of Candour process. In this case, the following strategies may assist:

- deal with the issue as soon as it emerges;
- where the patient agrees, ensure their family and carers are involved in discussions from the beginning;
- ensure the patient has access to support services;
- where the senior health professional is not aware of the relationship difficulties, provide mechanisms for communicating information, such as the patient expressing their concerns to other members of the clinical team;
- 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 the individual with overall responsibility for clinical risk management;
- 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;
- 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.

8. Process for monitoring compliance with this policy

Please see Appendix 1 for monitoring details. This will be led by the Divisions responsible for the delivery of Being Open and Duty of Candour within their monthly Governance meetings and with a synopsis of compliance against the agreed standards being reported through to Risk and Compliance Group. Further monitoring will be undertaken in line with the Trust’s Performance Management Framework.

9. Training

In line with the Being Open Patient Safety Alert from the NPSA and in line with the requirements for statutory Duty of Candour the Trust has nominated 4 senior people to act as champions to give support and guidance to fellow staff members on matters relating to Being Open or the Duty of Candour. These are the Medical Director, the Director of Nursing, the Associate Medical Director for Patient Safety and the Deputy Director of Clinical Governance.

In addition an awareness of the Being Open principles will be given at Corporate Induction. Further guidance will also be incorporated in Incident Investigation training for Managers.
10. **Implementation**

The *Being Open and Duty of Candour* Policy will be disseminated and made available by the Deputy Director of Clinical Governance. Clinical Directors, Associate Directors of Nursing and Quality and Associate Directors of Operations are expected to communicate the policy as part of local induction procedures. All staff are introduced to the principles during their incident reporting and risk management training. The policy will be available on the Hub (Trust Intranet) and in the hard copy document libraries.

The policy will be reviewed in line with any guidance/notices published by the NPSA pertinent to *Being Open* or Duty of Candour.
Appendix A - Principles of Being Open

Principle of acknowledgement

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

Principle of truthfulness, timeliness and clarity of communication

Information about a patient safety incident must be given to patients, family and/or carers in a truthful and open manner by an appropriately nominated person. Patients should be provided with a step-by-step explanation of what happened, that considers their individual needs and is delivered openly. Communication should also be timely; Patients, family and/or carers should be provided with information about what happened as soon as practicable.

It is also essential that any information given is based solely on the facts known at the time. Healthcare staff should explain that new information may emerge as an incident investigation is undertaken, and patients, family and/or carers will be kept up-to-date with the progress of an investigation.

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

Principle of apology

Patients, family and/or carers should receive a meaningful apology – one that is a sincere expression of sorrow or regret for the harm that has resulted from a patient safety incident. This should be in the form of an appropriately worded apology, as early as possible.

Both verbal and written apologies should be given. The decision on which staff member should give the apology should consider seniority, relationship to the patient, and experience and expertise in the type of patient safety incident that has occurred.

Verbal apologies are essential because they allow face-to-face contact between the patient and/or their carers and the healthcare team. 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.

It is important not to delay for any reason, including; setting up a more formal multidisciplinary Being open discussion with the patient and/or their carers; fear and apprehension; or lack of staff availability. Delays are likely to increase the patient's, family's and/or their carer's sense of anxiety, anger or frustration. Patient and public focus groups reported that patients were more likely to seek medico-legal advice if verbal and written apologies were not delivered promptly.

Principle of recognising patient and carer expectations

Patients, family and/or carers can reasonably expect to be fully informed of the issues surrounding a patient safety incident and its consequences, in a face-to-face meeting. They should be treated sympathetically, with respect and consideration. Patients, family and/or carers should also be provided with support in a manner appropriate to their needs. This involves consideration of special circumstances that can include a patient requiring additional support, such as an independent patient advocate or a translator.
When appropriate, information on accessing the Patient Advisory and Liaison Service (PALS) and other relevant support groups like Cruse Bereavement Care and Action against Medical Accidents (AvMA) should be given to the patient as soon as it is possible.

**Principle of professional support**

Organisations 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 as they too may have been traumatised by being involved. They should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration.

To ensure a robust and consistent approach to incident investigation, healthcare organisations are advised to use the National Reporting and Learning Service (NRLS) Incident Decision Tree.

Where there is reason for the organisation to believe a member of staff has committed a punitive or criminal act, the organisation 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 or representation.

**Principle of risk management and systems improvement**

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

Every organisation's *Being open* policy should be integrated into local incident reporting and risk management policies and processes. *Being open* is one part of an integrated approach to improving patient safety following a patient safety incident. It should be embedded in an overarching approach to risk management that includes local and national incident reporting, analysis of incidents using Root cause Analysis or Significant Event Audit, decision-making about staff accountability using the Incident Decision Tree and an organisational approach that follows the NPSA's “Seven steps to patient safety” (2009).

**Principle of multidisciplinary responsibility**

Any policy on openness applies to all staff that have key roles in the patient's care. Most healthcare provision involves multidisciplinary teams and communication with patients and/or their carers following an incident that led to harm, should reflect this. This will ensure that the *Being open* process is consistent with the philosophy that incidents usually result from systems failures and rarely from the actions of an individual.

To ensure multidisciplinary involvement in the *Being open* process, it is important to identify clinical, nursing and managerial leaders that will support it. Both senior managers and senior clinicians who are opinion leaders must participate in incident investigation and clinical risk management.

**Principle of clinical governance**

*Being open* has the support of patient safety and quality improvement processes through the clinical governance framework, in which patient safety incidents are investigated and analysed, to find out what can be done to prevent their recurrence. It also involves a system of accountability through the Chief Executive to the Board to ensure these changes are implemented and their effectiveness reviewed. These findings should be disseminated to staff so that they can learn from patient safety incidents.
These actions are monitored to ensure that the implementation and effects of changes in practice following a patient safety incident. Continuous learning programmes and audits should be developed that allow healthcare organisations to learn from the patients’ experience and that monitor the implementation and effects of changes in practice following a patient safety incident.

**Principle of confidentiality**

Full consideration of, and respect for, should be given to the patient’s and/or their carer’s and staff’s privacy and confidentiality. Details of a patient safety incident should at all times be considered confidential.

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

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

**Principle of continuity of care**

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

<table>
<thead>
<tr>
<th>Key Message</th>
<th>Detail</th>
</tr>
</thead>
</table>
| Review Incident – Verbal Duty of Candour OR Being Open | You are made aware/involved in an incident has occurred involving a patient?  
Do you suspect there is a possibility that the patient has suffered from harm? |                                                                                                                                   |
| YES                                             | Provide an apology to patient (or relatives) and explain and that an initial investigation will be undertaken to find out what has occurred and that can be shared with the patient/relative. |                                                                                                                                   |
| NO                                              | Provide an apology to patient (or relatives) for any aspect of poor patient experience, and provide contact details for PALS team if required |                                                                                                                                   |
| Document                                        | Document clearly in the notes the following:                                                                                                                                                   |
|                                                 | • Reference incident number for tracking purposes                                                                                 |
|                                                 | • Identify who was present                                                                                                           |
|                                                 | • Detail of apology made to patient/relative(s)                                                                                       |
|                                                 | • Explanation of investigation process (if potential of harm)                                                                      |
|                                                 | • Explanation written follow up (if potential of harm)                                                                               |
|                                                 | • Evidence of provision of contact details                                                                                           |
|                                                 | • Any questions raised and answers provided                                                                                           |
| Confirmation of moderate harm/SI/ Formal Duty of Candour | 24 Hour review will be reviewed at Executive SI Review Group                                                                          |
| Written Duty of Candour                         | Within 10 working days of SI being declared - written apology and outline of process of Serious Incident investigation to be sent to patient/relative, with confirmed offer of sharing the investigation once it has been completed and approved by the Clinical Commissioning Group. (Template provided by Clinical Governance and Risk Department) |
| Incident investigation                          | Process of investigation of Serious Incident follows according to timeline as set within procedure.                                   |
| Duty of Candour – sharing the report            | Within 10 working days of the Trust approving the report as closed – written letter offering the opportunity to review the report, providing the opportunity to meet to discuss the report, and to provide any additional assistance required. |
| Meeting                                         | Facilitate meeting with family to review the report, where this has been accepted, to ensure a clear understanding of the output and offer the opportunity to come back to evidence practice changes. |
| Document                                        | Ensure that output from the meeting is documented and uploaded onto the Datix system, with an entry into the medical records.        |
| Evidence of Compliance                          | The Divisional Management Team must ensure that all aspects of Duty of Candour have been evidenced and uploaded on the Datix system to meet contractual and legal responsibilities. |
Appendix C – Detailed guidance for undertaking actions related to Being Open or Duty of Candour

Organising a preliminary meeting for Being Open or Duty of Candour

The following factors should be taken into account when organising a preliminary meeting with a patient and their relative/carer.

- clinical condition of the patient;
- availability of key staff involved in the incident;
- availability of the patient’s family and/or carers;
- availability of support staff, e.g. translator/independent advocate, if required;
- patient preference (in terms of when and where the meeting takes place and which healthcare professional leads the discussion);
- privacy and comfort of the patient;
- arranging the meeting in a sensitive location.

Choosing the individual to communicate with patients/carers

This should be the most senior person responsible for the patient’s care and/or someone with experience and expertise in the type of incident that has occurred. This could either be the patient's consultant, nurse consultant, or any other healthcare professional, who has a designated caseload of patients.

If possible, the person should:

- be known to, and trusted by, the patient, relative/carer;
- have a good grasp of the facts relevant to the incident;
- be senior enough or have sufficient experience and expertise in relation to the type of incident to be credible to patients/carers;
- have excellent interpersonal skills, avoiding excessive use of medical jargon;
- be willing and able to offer an apology, reassurance and feedback;

In exceptional circumstances, if the relevant healthcare professional cannot attend, they may delegate to an appropriately trained substitute. The qualifications, training and scope of responsibility of this person should be clearly delineated. The substitute may be the clinician responsible for clinical risk (for example, the Clinical Lead for patient safety) or someone of similar experience.

The healthcare professional communicating information about an incident should be able to nominate a colleague to assist them with the meeting. Ideally this should be someone with experience or training in communication and Being Open procedures.
Responsibilities of junior healthcare professionals

Junior staff or those in training should not lead the process except when all of the following criteria have been considered:

- the incident resulted in low harm (and therefore does not fall within the Duty of Candour process);
- they have expressed a wish to be involved in the discussion;
- the senior healthcare professional responsible for the care is present for support;
- the patient, relative/carer agree.

Content of the initial discussion with the patient, relative/carer

- The patient or relatives/carers should be advised of the identity and role of all people attending the discussion before it takes place. This allows them the opportunity to state their own preferences about which healthcare staff should be present.
- There should be an expression of genuine sympathy, regret and an apology for the harm that has occurred.
- The facts that are known are agreed by the multidisciplinary team. The patient, relative/carer should be informed that an incident investigation is being carried out and more information will become available as it progresses.
- It should be made clear to the patient, relatives/carers that new facts may emerge as the incident investigation proceeds.
- The patient's/relative's/carer’s understanding of what happened should be taken into consideration, as well as any questions they may have.
- There should be consideration and formal noting of the patient’s/relative's/carer’s views and concerns.
- Appropriate language and terminology should be used when speaking to patients and relatives/carers.
- An explanation should be given about what will happen next in terms of the long term treatment plan and incident analysis findings.
- Information on likely short/long term effects of the incident (if known) should be shared. This may have to be delayed to a subsequent meeting when the situation becomes clearer.
- An offer of practical and emotional support should be made to the patient, relative/carer. Information about the patient and the incident should not normally be disclosed to third parties without consent.
- It should be recognised that patients and/or relatives/carers may be anxious, angry and frustrated even when the discussion is conducted appropriately.
• It is essential that the following does not occur:
  o speculation;
  o attribution of blame;
  o denial of responsibility;
  o provision of conflicting information from different individuals.

The initial discussion is the first part of an ongoing communication process. Many of the points raised here should be expanded on in subsequent meetings with the patient, relative/carer.

Written records of discussions with patients/carers

There should be documentation of:

• the time, place, date, as well as the name and relationships of all attendees;
• the plan for providing further information to the patient/carers;
• offers of assistance and the patient’s/carer’s response;
• questions raised by the carers or their representatives, and the answers given;
• plans for follow-up as discussed;
• progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient and/or relatives/carers;
• copies of letters sent to patients, carers and the GP;
• copies of any statements taken in relation to the incident;
• A copy of the incident report.

A summary of the discussion should be shared with the patient, family/carer.

Follow up meetings and completing the process

Follow-up discussions with the patient/carers are an important step in the Being open or Duty of Candour process once any investigation has been completed. The following guidelines should assist in making the communication effective:

• The discussion should occur at the earliest practical opportunity.
• Consideration should be given to the timing of meeting, based on both the patient’s health and personal circumstances.
• Consideration should be given to the location of the meeting e.g. the patient’s home.
• Feedback should be given on progress to date and information provided on the investigation process. If the investigation is complete, the communication should include:
  o the chronology of clinical and other relevant facts;
  o details of the patient’s/carer’s concerns and complaints;
  o a repeated apology for the harm suffered and any shortcomings in the delivery of care that led to the incident;
  o a summary of the factors that contributed to the incident;
  o information on what has been and will be done to avoid recurrence of the incident and how these improvements will be monitored.

• There should be no speculation or attribution of blame. Similarly, the healthcare professional communicating the incident must not criticise or comment on matters outside their own experience.
- The patient, relatives/carers should be offered an opportunity to discuss the situation with another relevant professional where appropriate.
- A written record of the discussion should be kept and shared with the patient/carers.
- If completing the process at this point, the patient/carers should be asked if they are satisfied with the investigation and a note of this made in the patient’s records.
- The patient should be provided with contact details so that if further issues arise later there is a conduit back to the relevant healthcare professionals or an agreed substitute.

It is expected that in most cases there will be a complete discussion of the findings of the investigation and analysis. In some cases information may be withheld or restricted, for example, where communicating information will adversely affect the health of the patient; where investigations are pending coronial processes; or where specific legal requirements preclude disclosure for specific purposes. In these cases the patient will be informed of the reasons for the restrictions.

**Continuity of care**

When a patient requires further management or rehabilitation they should be informed of the ongoing plan of care. Patients/carers should be reassured that they will continue to be treated according to their clinical needs. They should also be informed that they have the right to continue their treatment elsewhere if they have lost confidence in the healthcare team involved in the incident.

**Communication with the GP and other community care services**

Wherever possible, it is advisable to send a brief communication to the patient’s GP, before discharge, describing what happened. When the patient leaves the care of the Trust, a discharge letter should also be forwarded to the GP or appropriate community care service. It should contain summary details of:

- the nature of the incident and the continuing care and treatment;
- the current condition of the patient;
- key investigations that have been carried out;
- recent results;
- prognosis

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

**Incidents related to the environment of care**

In such cases a senior manager of the relevant service will be responsible for communicating with the patient, relative/carer. A senior member of the multidisciplinary team should be present to assist at the discussion. The healthcare professional responsible for treating the injury should also be present to assist in providing information on what will happen next and the likely effects of the injury.
Involving healthcare staff who made mistakes

Some incidents will result from errors made by staff while caring for the patient. In these circumstances the member(s) of staff involved may or may not wish to participate in the discussion with the patient, relative/carer. Every case where an error has occurred needs to be considered individually, balancing the needs of the patient, relative/carer with those of the healthcare professional concerned. In cases where the healthcare professional wishes to attend the discussion to apologize personally, they should feel supported by their colleagues throughout the meeting. In cases where the patient, relative/carer express a preference for the healthcare professional not to be present, it is advised that a personal written apology is handed to the patient, relative/carer during the first discussion.
### Appendix D – Illustrative examples and of Moderate Harm, Severe Harm or Death

<table>
<thead>
<tr>
<th>Surgery</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Examples</strong></td>
<td><strong>Interpretation</strong></td>
</tr>
<tr>
<td>A patient arrived for planned surgery but had not been given the correct advice to discontinue their Warfarin treatment. The surgery had to be postponed.</td>
<td>This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8)(b))</td>
</tr>
<tr>
<td>During a difficult appendectomy the patient’s bowel was accidentally perforated. This was recognised the day after surgery when the patient became increasingly unwell. The patient returned to theatre where the problem was fixed and the patient made a full recovery.</td>
<td>This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8)(b))</td>
</tr>
<tr>
<td>Wrong site surgery: The identities of two patients on the list are mixed up and one patient undergoes the wrong operation on the incorrect site. The patient is permanently harmed as a result.</td>
<td>This would be an example where an incident appeared to have resulted in severe harm (regulation 20 (8)(b))</td>
</tr>
<tr>
<td>An elderly patient undergoes a coronary artery bypass operation. The patient is appropriately consented for the risks of the operation, including stroke and death. Unfortunately, the patient sustained a large stroke during the operation, and subsequently died as a result.</td>
<td>This would be an example where an incident resulted in death (regulation 20 (8) (a))</td>
</tr>
<tr>
<td>A patient experienced pain during an elective Caesarean section due to incomplete anaesthesia from an epidural line. The patient found this experience traumatic and subsequently had an acute episode of severe anxiety and depression which lasted more than 28 days</td>
<td>This would be an example where an incident appeared to have resulted in prolonged psychological harm (regulation 20 (8)(b))</td>
</tr>
<tr>
<td>Medicine</td>
<td></td>
</tr>
<tr>
<td>---------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Examples</strong></td>
<td><strong>Interpretation</strong></td>
</tr>
<tr>
<td>A doctor causes a pneumothorax whilst placing a Central Venous Catheter (a recognised complication). The patient requires a chest drain to be inserted and a short stay on the Intensive Care Unit. The patient makes a full recovery</td>
<td>This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8)(b))</td>
</tr>
<tr>
<td>A patient developed a small grade 2 pressure ulcer during an admission to treat an acute cardiac problem. Although they were now fully mobile, they need district nursing visits after discharge home to check and dress the ulcer until healing was complete two weeks later</td>
<td>This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8)(b))</td>
</tr>
<tr>
<td>A patient incurs an extravasation injury (soft tissue burn) from an intravenous line causing irreversible scarring and bone damage.</td>
<td>This would be an example where an incident appeared to have resulted in severe harm (regulation 20 (8)(b))</td>
</tr>
<tr>
<td>A confused elderly patient was supposed to have 1:1 supervision on a medical ward. The patient was left unsupervised for a period of time whilst the shift change was occurring, and the patient fell out of bed, sustaining a severe head injury from which they later died.</td>
<td>This would be an example where an incident resulted in death (regulation 20 (8) (a))</td>
</tr>
<tr>
<td>A patient who is normally very shy sustains an extravasation injury (soft tissue burn) from an intravenous line. This causes irreversible and extensive scarring on her arm and as a result she becomes severely socially anxious for which she needs a prolonged period of therapy.</td>
<td>This would be an example where an incident appeared to have resulted in prolonged psychological harm (regulation 20 (8)(b))</td>
</tr>
</tbody>
</table>
### Maternity

<table>
<thead>
<tr>
<th>Examples</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A mother had significant post-partum haemorrhage after a difficult delivery, and there was some delay in obtaining blood for transfusion. As a result, she needed treatment in the high dependency unit for 24 hours before making a full recovery.</td>
<td>This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8)(b))</td>
</tr>
<tr>
<td>A pregnant woman was seen in A&amp;E at 12 weeks gestation with abdominal pain and PV bleeding. A high vaginal swab was taken by the Gynae SHO which grew Group B Streptococcus (GBS). When the woman went in to labour 28 weeks later, the midwife attending the birth did not check the laboratory results which showed the GBS growth and so the woman was not given intra-partum antibiotic prophylaxis as per national guidelines. The child then went on to develop GBS septicaemia in the days following delivery and required treatment in the Neonatal Intensive Care unit for 5 days before making a full recovery.</td>
<td>This would be an example where an incident appeared to have resulted in moderate harm (regulation 20 (8)(b))</td>
</tr>
<tr>
<td>An expectant mother who rang the maternity unit to report possible blood loss and reduced foetal movements was given inappropriate reassurance rather than asked to come for assessment. The baby later born with severe disabilities.</td>
<td>This would be an example where an incident appeared to have resulted in severe harm (regulation 20 (8)(b))</td>
</tr>
<tr>
<td>A woman requiring a blood transfusion for a post-partum haemorrhage received the wrong unit of blood after an error in labelling sample tubes. As a result the woman suffered a severe reaction leading to multi-organ failure and a fatal cardiac arrest.</td>
<td>This would be an example where an incident resulted in death (regulation 20 (8) (a))</td>
</tr>
<tr>
<td>An expectant mother with a past history of severe mental health problems was not appropriately assessed at her antenatal appointment. As a result she was not offered NICE recommended psychological therapies, prophylactic medications or specialist follow-up. After delivery she became symptomatic, and these errors led to delays to her diagnosis and treatment. This resulted in a prolonged deterioration in her mental health for more than 28 days.</td>
<td>This would be an example where an incident appeared to have resulted in prolonged psychological harm (regulation 20 (8)(b))</td>
</tr>
</tbody>
</table>
### MONITORING

The Trust will monitor compliance of the following:

<table>
<thead>
<tr>
<th>Minimum requirement to be monitored</th>
<th>Method of monitoring e.g. audit</th>
<th>Responsible individual/group/committee</th>
<th>Frequency of Monitoring</th>
<th>Responsible individual/group/committee (inc timescales) for:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Review of results</td>
<td>Development of action plan</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Monitored</td>
<td>Monitoring of action plan and implementation</td>
</tr>
<tr>
<td>How communication between healthcare organisations, healthcare teams, staff, patients, their relatives and carers is encouraged</td>
<td>Review in patient surveys and evidence of Duty of Candour.</td>
<td>Divisional governance feeding Risk and Compliance Group.</td>
<td>Annually</td>
<td>Associate Directors of Nursing and Divisional Directors.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>R&amp;CG</td>
</tr>
<tr>
<td>How staff acknowledge, apologise and explain when things go wrong</td>
<td>Duty of Candour compliance reports, incident reports</td>
<td>Divisional governance feeding Patient Safety Group.</td>
<td>Monthly</td>
<td>Associate Directors of Nursing and Divisional Directors.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PSG</td>
</tr>
<tr>
<td>Requirement for truthfulness, timeliness and clarity of communication</td>
<td>Complaint responses and feedback from Serious Incidents/DoC</td>
<td>Divisional governance feeding Risk and Compliance Group.</td>
<td>Annually</td>
<td>Associate Directors of Nursing and Divisional Directors.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>R&amp;CG</td>
</tr>
<tr>
<td>How additional support is provided</td>
<td>Incident investigations complaints. Staff support, SI debriefing.</td>
<td>Divisional governance feeding Risk and Compliance Group.</td>
<td>Annually</td>
<td>Associate Directors of Nursing and Divisional Directors.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>R&amp;CG</td>
</tr>
<tr>
<td>Author(s):</td>
<td>Giles Thorpe, Deputy Director of Nursing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------------</td>
<td>------------------------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other contributors:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Approvals and endorsements:</td>
<td>Executive Team</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consultation:</td>
<td>Trust Office Clinical Governance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Issue no:</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>File name:</td>
<td>PP394 – Being Open and Duty of Candour Policy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supercedes:</td>
<td>195 – Being Open and Duty of Candour Policy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equality Assessed</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implementation</td>
<td>See table above</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitoring: (give brief details how this will be done)</td>
<td>See table above</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Additional Information: