



THGPCG CIC DUTY OF CANDOUR AND BEING OPEN POLICY

Date Issued	
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Supersedes	All previous Policies
This policy will impact on	
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1. Introduction

The effects of harming a patient can have severe emotional and physical consequences for patients, families and their carers as well as being distressing for the professionals involved. Being open about events and having full, open and honest conversations in a timely and compassionate manner can help all those individuals involved cope better with the after effects.

Remember: saying sorry is not an admission of liability and is the right thing to do

The principles of Being Open are embedded in the NHS Constitution for England and supported by professional and indemnity bodies. A description of the Principles is at Appendix A.

It is a legal requirement to comply with the requirements of the Duty Of Candour process where this is applicable. The full regulation can be viewed at

<http://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour>

2. Scope

This policy applies to:

- Staff of any grades and role working within the THGPCG services, including self-employed contractors, locum and agency staff.
- Incidents that occur on any of the premises, including those that involve service users, employees, visitors or contractors.
- Incidents involving employees or service users that occur in any other setting, when an employee is carrying out his/her duties.

3. Purpose

This policy provides guidance on how to embed the Being Open Policy and details the process to ensure that the Duty of Candour requirements fulfilled and a framework to support staff to have the confidence to act appropriately when things go wrong. The Policy also offers guidance on how to communicate with patients, families and carers.

This guidance should be used when any event occurs whether as a result of a complaint or an adverse incident.

4. Definitions

Apology: a sincere expression of regret offered for harm sustained.

Being Open: open communication of events (adverse incidents, complaints or claims) that result in harm or death of a patient whilst receiving healthcare.

Duty of Candour: A statutory requirement to undertake volunteering all relevant information to persons who have or may have been harmed by the provision of services, whether or not the information has been requested and whether or not a complaint or a report about that provision has been made.



Claim:

Clinical claim: a claim for compensation in respect of adverse clinical incidents, which led to personal injury.

Employer's liability: claims for compensation for injury or ill health to staff arising out of work.

Public liability: claims for injuries to members of the public (including patients) following an accident on THGPCG property.

Complaint: an expression of dissatisfaction by one or more members of the public about the THGPCG's action or lack of action, or about the standard of a service, whether the action was taken by the THGPCG itself or by somebody acting on behalf of the THGPCG.

Harm: injury (physical or physiological), disease, suffering, disability or death.

Healthcare Professional: doctor, dentist, nurse, pharmacist, optometrist, allied healthcare professional or registered alternative healthcare practitioner.

Injury: damage to tissues caused by an agent or circumstance.

'Never Event': are defined as 'serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers.

Patient safety incident: any unintended or unexpected incident that could have or did lead to harm of any patient receiving healthcare within the THGPCG.

Root cause analysis (RCA): a systematic approach in which contributing factors to any event are identified, and in which understanding of the underlying causes and environmental context of the event is sought.

Serious Incident Requiring Investigation: one where serious actual harm or death has resulted.

Suffering: experiencing anything subjectively unpleasant. This may include pain, malaise, nausea and/vomiting, loss, depressions, agitation, alarm, fear, grief or humiliation.

5. Roles & Responsibilities

The **Director of Quality & Assurance** has responsibility for providing support and advice to Senior Staff to ensure the strategic and operational implementation of this policy across the THGPCG.

Service Leads have responsibility for fostering a culture of learning within team and ensuring that the Being Open and Duty of Candour requirements are appropriately implemented. They are also responsible for reporting on the outcomes and any learning as a result of the process.

6. Process

6.1 Event recognition and detection.

The Being Open process starts with the recognition that a patient has suffered harm or has died as a result of an unexpected event or omission in the course of their care. The first priorities once an event is identified are



- To ensure that the individual received prompt and appropriate clinical care
- To prevent any further harm, either to the individual or to others who may be at risk

If the incident is considered to have caused moderate or severe harm (please refer to the THGPCG Serious Incident Policy V3.0) or caused the death of a patient it will be subject to the Duty of Candour requirements (refer to appendix two).

Incidents are almost always unintentional, however if at any stage it is determined that the harm may have been the result of a criminal or intentionally unsafe act the Director of Quality & Assurance, or in her absence, the Senior Manager on call must be notified by telephone immediately.

6.2 Communication with patients, their families or carers

The role and seniority of the person given the role of communication will depend on the severity of the situation. The decision should be reached taking into account the following

- He/she should, wherever possible, be known to and trusted by the affected individuals
- He/she must have a good understanding of the facts relevant to the situation
- He/she must have enough experience and expertise to be credible to the patient or family members
- He/she should have excellent interpersonal skills and be able to communicate in ways that can be easily understood.
- He/she must be willing to offer a meaningful apology, provide reassurance and feedback
- He/she must be able to maintain a long term professional relationship with the patient, their family or carer if required.

Junior staff and those in training should not lead the Being Open process. If the appropriate senior healthcare professional is unavailable advice should be sought from the Service Lead and Director of Quality & Assurance.

Some events will have been as a result of an error made by healthcare staff. If staff wish to participate in the Being Open discussion to apologise personally they should be supported to do so by their colleagues. If the member of staff does not wish to do so consideration should be given to their providing a written apology to be given to the patient or carer during the initial discussion.

6.3 The Initial Being Open Discussion

The initial discussion should take place as soon as possible after the recognition of the event. It is the first part of an ongoing communication process. Where moderate or severe harm is deemed to have occurred this must take place within 10 working days of the event being recognized to satisfy Duty of Candour regulations (refer to appendix B for further details). This should be verbal or face to face wherever possible. The timing of the meeting should take into account

- Condition of patient
- Patient preference in terms of location, timing and healthcare professionals involved
- Privacy and comfort for the patient
- Availability of patient's family or carer
- Availability of key senior staff



6.4 First Meeting

The patient, family or carer should be advised of the identify and role of healthcare professionals attending the discussion in advance and be given the opportunity to state their preferences about individuals they wish to be present.

The discussion should encompass the following

- A meaningful apology and an expression of sympathy for the for the harm that has occurred
- That an investigation is being carried out and that information will be made available as the investigation progresses. An agreement communication should be reached to include a point of contact, how contact will be made and the frequency of contact.
- An explanation of what has happened and known facts that have been agreed by the multidisciplinary team (any facts which are disputed should not be discussed until the investigation has been completed)
- The patient's understanding of what has happened and any questions they may have should be noted and this information should be given to the investigator so that this can be included in the investigation and an informed response can be given
- An explanation of what will happen in terms of the short and long treatment plan for the patient where appropriate, this should include assurances about the continuity of care. They should also be informed that they have the right to continue their treatment under the care of an alternative healthcare professional or provider if they prefer
- An offer of practice and emotional support from appropriate national and local voluntary, charities and statutory organisations

It is essential that the following does not occur

- Attribution of blame
- Denial of responsibility
- Speculation
- Conflicting information from different individuals

There may be circumstances where the discussion should be modified, eg where the individual involved does not speak English as a first language or where a child is involved. Refer to Appendix C for further information.

6.5 Follow Up Discussion

Depending on the event a follow up discussion may be required. The patient, family or carer should be offered an update on known facts and a response to any queries raised in the first meeting.

6.6 Process Completion

If a formal investigation is required (refer to THGPCG Incident Management & Reporting Policy v.3.0) then feedback must be given to the patient, family or carer. This should be in a format acceptable to the recipients. The communication must include

- A repeated apology for the harm suffered
- The chronology of relevant facts and a summary of contributory factors
- Details of the patients, families and/or carers concerns
- Information on actions taken and/or planned to prevent the event happening again, and information about how this will be monitored



It is expected in most cases there will be a full discussion of the findings. Advice should be sought in accordance with the THGPCG Incident Management and Reporting Policy prior to the meeting being held.

For all events where moderate/severe harm or death has occurred a copy of the final investigation report must be provided to the patient, family or carer within 10 working days of completion in order to comply with the Duty Of Candour regulation. If the patient, family or carer has explicitly expressed a desire not to receive the report this must be recorded in Datix.

7. Documentation

Throughout the process it is important to record discussions with the patient, family or carer. The amount of documentation will depend on the severity of the event and the complexity of the investigation. Records should be kept using the document in appendix D and attached to the Datix incident record

8. Support During the Process

Establishing clear lines of communication and a single point of contact will facilitate the support for patients, carers and their families. Support for staff should also be facilitated by line managers. However there may be instances where increased support is appropriate.

Staff may be referred or self refer to the counselling service, contact details are on the THGPCG website (<http://www.gpcaregroup.org>)

Patients, families or carers Consideration should be given to offering specific support through the use of a patient advocate, facilitator or a national organization or charity who would be responsible for identifying the needs and communicating them back to the healthcare team.

9. Monitoring Compliance

Compliance with this policy will be monitored via monthly analysis of incident data and outcomes in the Datix system. Audit of Duty Of Candour will review compliance with timeframes and notification requirements and review outcomes for learning.



Appendices

Appendix A: Being Open Principles

<p>1. Acknowledgement All patient safety incidents should be acknowledged and reported as soon as they are identified. In cases where the patient, their family and carers inform healthcare staff when something untoward has happened, it must be taken seriously from the outset. Any concerns should be treated with compassion and understanding by all healthcare professionals.</p>	<p>2. Truthfulness, timeliness and clarity of communication Information about a patient safety incident must be given to patients, their families and 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, their families and 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 professionals should explain that new information may emerge as an incident investigation is undertaken, and that patients, their families and carers will be kept up-to-date with the progress of an investigation. Patients, their families and carers should receive clear, unambiguous information and be given a single point of contact for any questions or requests they may have. They should not receive conflicting information from different members of staff, and the use of medical jargon, which they may not understand, should be avoided.</p>
<p>3. Apology Patients, their families and carers should receive a meaningful apology – one that is a sincere expression of sorrow or regret for the harm that has resulted from a patient safety incident. This should be in the form of an appropriately worded and agreed manner of apology as early as possible. Based on local circumstances, healthcare organisations should decide on the most appropriate member of staff to give both verbal and written apologies to patients, their families and carers. 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, their family and carers and the healthcare team. This should be given as soon as staff are aware an incident has occurred. A written apology, which clearly states the healthcare organisation is sorry for the suffering and distress resulting from the</p>	<p>4. Recognising patient and carer expectations Patients, their families and 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 with representatives from the healthcare organisation. They should be treated sympathetically, with respect and consideration. They should also be provided with support in a manner appropriate to their needs. This involves consideration of special circumstances that can include a patient requiring additional support, such as an independent patient advocate or a translator. Where appropriate, information on PALS in England, the Community Health Councils (CHC) in Wales, 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.</p>

<p>incident, must also be given. It is important not to delay giving a meaningful apology for any reason, including: setting up a more formal multidisciplinary <i>Being open</i> discussion with the patient, their family and carers; fear and apprehension; or lack of staff availability. Delays are likely to increase the patient's, their family's and their carers' 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.</p>	
<p>5. Professional support Healthcare 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 because they too may have been traumatised by being involved. They should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration. To ensure a robust and consistent approach to incident investigation, healthcare organisations are advised to use the NRLS's Incident Decision Tree. It should be remembered that NCAS can be contacted for advice on handling the concern and whether an assessment of the individual's practice would be helpful. Where there is reason for the healthcare 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. Healthcare organisations should also encourage staff to seek support from relevant professional bodies such as the GMC, royal colleges, the MDU, the MPS and the Nursing and Midwifery Council.</p>	<p>6. Risk management and systems improvement Root Cause Analysis, Significant Event Audit (SEA) or similar techniques should be used to uncover the underlying causes of a patient safety incident. These investigations should focus on improving systems of care, which will then be reviewed for their effectiveness. Every healthcare organisation's <i>Being open</i> policy should be integrated into local incident reporting and risk management policies and processes. <i>Being open</i> 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 <i>Seven steps to patient safety</i>³. 17 Being open: saying sorry when things go wrong</p>
<p>7. Multidisciplinary responsibility Any local policy on openness should apply to all staff that have key roles in the patient's care. Most healthcare provision is through multidisciplinary teams. This should be reflected in the way that patients, their families and carers are communicated with when things go wrong. This will ensure that the <i>Being open</i> process is consistent with the philosophy that incidents usually result from systems failures and rarely</p>	<p>8. Clinical governance <i>Being open</i> requires the support of patient safety and quality improvement processes through clinical governance frameworks in which patient safety incidents are investigated and analysed to find out what can be done to prevent their recurrence. These findings should be disseminated to healthcare professionals so that they can learn from patient safety incidents. It also involves a system of accountability through the chief executive to the board to ensure these</p>



<p>from the actions of an individual. To ensure multidisciplinary involvement in the <i>Being open</i> process, it is important to identify clinical, nursing and managerial opinion leaders who will support it. Both senior managers and senior clinicians who are local opinion leaders must participate in incident investigation and clinical risk management.</p>	<p>changes are implemented and their effectiveness reviewed. Practice-based risk systems should be established within primary care. Continuous learning programmes and audits should be developed that allow healthcare organisations to learn from the patient's experience of <i>Being open</i>, and that monitor the implementation and effects of changes in practice following a patient safety incident.</p>
<p>9. Confidentiality Policies and procedures for <i>Being open</i> should give full consideration of, and respect for, the patient's, their family's and carers' and staff privacy and confidentiality in line with the CQC's guidance for Outcome 1924. 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, in line with the CQC's guidance for Outcome 2024. Where this is not practical, or an individual refuses to consent to the disclosure, it 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, their family and carers about who will be involved in the investigation before it takes place, and give them the opportunity to raise any objections.</p>	<p>10. Continuity of care Patients are entitled to expect that they will continue to receive all usual treatment and continue to be treated with dignity, respect and compassion. If a patient expresses a preference for their healthcare needs to be taken over by another team, the appropriate arrangements should be made for them to receive treatment elsewhere.</p>



Appendix B Duty Of Candour Regulations

Once a notifiable safety incident has been identified which meets the requirements of Regulation 20, a registered provider must:

- Make sure it acts in an open and transparent way with relevant persons in relation to care and treatment provided to people who use services in carrying on a regulated activity.
- Tell the relevant person in person as soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred, and provide support to them in relation to the incident, including when giving the notification.
- Provide an account of the incident which, to the best of the health service body's knowledge, is true of all the facts the body knows about the incident as at the date of the notification.
- Advise the relevant person what further enquiries the provider believes are appropriate.
- Offer an apology.
- Follow this up by giving the same information in writing, and providing an update on the enquiries.

<http://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour>



Appendix C Special Circumstances

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

When a patient dies

When an event has resulted in a patient's death, it is crucial that communication is sensitive, empathetic 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/or carers will probably need information on the processes that will be followed to identify the cause(s) of death. They will also need emotional support. Establishing open channels of communication may also allow the family and/or carers to indicate if they need bereavement counseling or assistance at any stage.

Usually the Duty of Candour/*Being Open* discussion and any investigation occurs before the coroner's inquest. But in certain circumstances the Trust may consider it appropriate to wait for the coroner's inquest before holding the *Being Open* discussion with the patient's family and/or carers. The coroner's report on post-mortem findings is a key source of information that will help to complete the picture of events leading up to the patient's death. In any event, an apology should be issued as soon as possible after the patient's death, together with an explanation that the coroner's process has been initiated and a realistic timeframe of when the family and/or carers will be provided with more information.

Children

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

The courts have stated that younger children who understand fully what is involved in the proposed procedure can also give consent. This is sometimes known as Gillick competence or the Fraser guidelines. Where a child is judged to have the cognitive ability and the emotional maturity to understand the information provided, he/she should be involved directly in the *Being Open* process. The opportunity for parents to be involved should still be offered unless the child expresses a wish for them not to be present.

Where children are deemed not to have sufficient maturity or ability to understand, consideration needs to be given to whether information is provided to the parents alone or in the presence of the child. In these instances the parents' views on the issue should be sought. More information can be found in the [Trust's Consent Policy](#) or the Department of Health's website: www.dh.gov.uk

Patients with mental health issues

Duty of Candour/*Being Open* for patients with mental health issues should follow normal procedures, unless the patient also has cognitive impairment (see below). The only circumstances in which it is appropriate to withhold information about an event from a mentally ill patient is when advised to do so by a consultant psychiatrist who feels it would cause adverse psychological harm. 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 information about any event with a carer or relative without the express permission



of the patient. To do so is an infringement of the patient's human rights.

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 a health and welfare lasting power of attorney. In these cases steps must be taken to ensure this extends to decision making and to the medical care and treatment of the patient. The Duty of Candour/*Being Open* discussion would be held with the holder of the power of attorney. Where there is no such person, the clinicians may act in the patient's best interest in deciding with whom is the appropriate person is to discuss information regarding the welfare of the patient as a whole and not simply their medical interests. However, the patient with a cognitive impairment should, where possible, be involved directly in discussions about what has happened. An advocate with appropriate skills should be available to the patient, to assist in the communication process.

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 above). If the patient is not cognitively impaired they should be supported in the Duty of Candour/*Being Open* process by alternative communication methods e.g. by being given the opportunity to write questions down. An advocate, agreed on in consultation with the patient, should be appointed. Appropriate advocates may include carers, the LD Liaison team family or friends of the patient and should focus on ensuring that the patient's views are considered and discussed.

Patients who do not agree with the information provided

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

- Deal with the issue as soon as it arises.
- Where the patient agrees, ensure their carers are involved in discussions from the beginning.
- Ensure the patient has access to support services.
- Where the senior healthcare professional is not aware of the relationship difficulties, provide the mechanisms for communicating information, such as the patient expressing their concerns to other members of the clinical team.
- Offer the patient and/or their carers another contact person with whom they may feel more comfortable. This could be another member of the nursing/medical team or the Patient and Customer Service team.
- Use a mutually acceptable mediator to help identify the issues between the healthcare professional and the patient, and to look for a mutually agreeable solution.
- Ensure the patient and/or their carers are fully aware of the complaints procedure.
- Write a comprehensive list of the points with which the patient and/or their carer disagree and reassure them you will follow up on these issues.

Patients with a different language or cultural considerations

The need for translation and advocacy services, and consideration of special cultural needs (such as for patients from cultures that make it difficult for a woman to talk to a male about intimate issues), must be



taken into account when planning to discuss information about any event. 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.

Patients with different communication needs

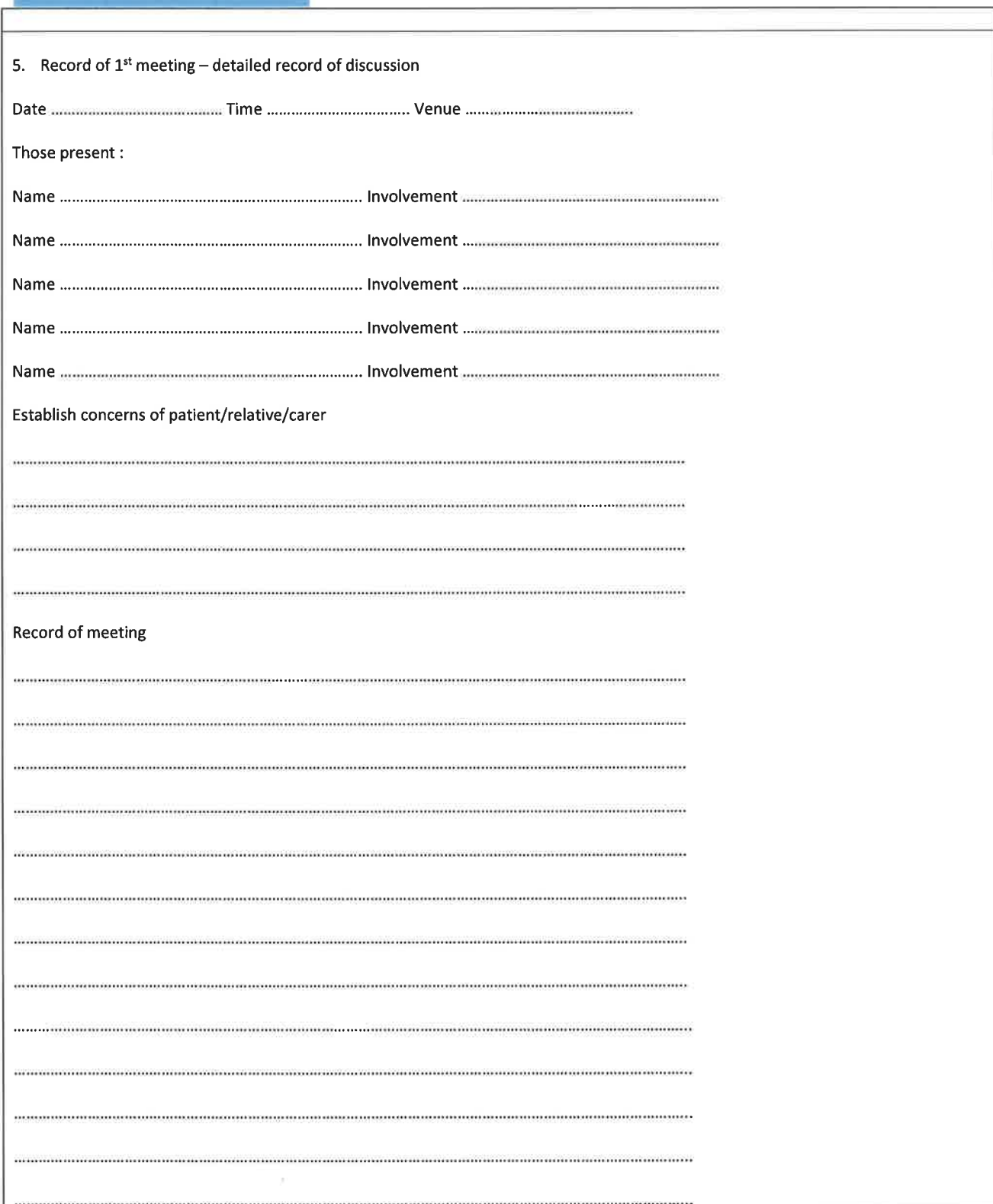
A number of patients will have particular communication difficulties, such as a hearing impairment. Plans for the meeting should fully consider these needs. Knowing how to enable or enhance communications with a patient is essential to facilitating an effective *Being Open* process, focusing on the needs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



Appendix D Record of Implementation of Being Open Policy

(provide copy to patient as each stage of record is complete)

<p>1. Patient Name Date of Incident Datix Incident Number</p> <p>NHS Number Service.....</p> <p>Nominated staff lead on <i>Being Open</i> for this incident</p> <p>Person responsible for communications with the patient</p>
<p>2. Brief overview of the incident</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>
<p>3. Additional people/organisations informed e.g. Coroner, Police, Safeguarding Team (please specify)</p> <p>.....</p> <p>.....</p>
<p>4. Record of initial discussion with patient</p> <p>Date Time Full apology given Yes <input type="checkbox"/></p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>



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Yes

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7. Completion of Process

Feedback on completion of process

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Appendix E Duty Of Candour Quick Reference Guide

