GP CARE GROUP CIC

LOCAL PEOPLE LOCAL HEALTH

# TOWER HAMLETS GP CARE GROUP (THGPCG)

## Being Open and Duty of Candour Policy and Procedure

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| Title | Being Open and Duty of Candour Policy and Procedure |
| Supersedes | All previous Policies |
| This policy will impact on | All staff |
| Links to other Policies | Risk Management Strategy<br>Incident Reporting Policy<br>Serious Incident Policy<br>Complaints Policy<br>Disciplinary Policy and procedure<br>Dignity and Respect Policy<br>Supporting Staff involved in an Incident/Complaint or Claim Policy<br>Whistle Blowing Policy<br>Patient Engagement Policy<br>Record Keeping Policy<br>Sharing Information Policy<br>Education and Development Policy |
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## ASSURANCE STATEMENT

Tower Hamlets GP Care Group (THGPCG) CIC (the Organisation) is committed to developing a safety culture dedicated to learning and improvement and continually striving to reduce avoidable harm. Being open and honest about patients or service users' treatment and care and adhering to the duty of candour guidance is a cornerstone to support good relationships with people we provide services to and to dispel the myth that staff cannot communicate openly when things go wrong and a moderate or severe harm is caused.

To achieve this, the Organisation will ensure that patients or service users, their families or carers receive a verbal apology, which includes an expressed 'Sorry' (face to face where possible) within 10 days from the reported incident when something has gone wrong in which the NPSA definition of moderate, severe harm or death has occurred. In addition, the Organisation will share the findings within 10 days of the final investigation receiving executive approval. Both patients, service users and carers will be supported throughout the process. Saying sorry is the right thing to do and is not an admission of liability. Patients or service users, their families or carers have a right to expect openness and honesty from the Organisation.

From 1 April 2014, there is a contractual Duty of Candour on health and social care organisations. The Government is committed to implementing a statutory Duty of Candour from 1 October 2014 across a wide range of providers and the Care Bill placed a specific duty on the Government to include Duty of Candour on providers registered with the Care Quality Commission (CQC). This means that as of 1st April 2015, a statutory duty of candour must always be one of the registration requirements placed on CQC registered providers. (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20)

## 1. Introduction

1.1 Following the Francis Report of the Mid Staffordshire NHS Foundation Organisation Public Inquiry in March 2013 plus a number of other reviews, a consultation on proposals to introduce a new CQC registration regulation commenced in March 2014, and subject to Parliamentary approval, this became part of a regulatory registration package which was introduced in October 2014.

1.2 As part of the Government's commitment to greater openness in the public sector, the Freedom of Information Act 2000 was passed through Parliament. The aim of the Act is to encourage the disclosure of information in order to:

- promote accountability and transparency of public bodies for decisions taken and the use of public funds
- highlight information affecting public health and public safety

1.3 In 2005, the National Patient Safety Agency (NPSA) issued a Safer Practice Notice advising the NHS to develop a local Being Open policy and to raise awareness of this with all healthcare staff. Since the release of the original Being Open policy in 2005, the NHS in England and Wales has undergone significant changes that have altered the context, infrastructure and language of patient safety and quality improvement. A review of the Being Open policy, undertaken in 2008, showed that more was needed to be done to strengthen the implementation of Being Open, particularly in light of these changes.

1.4 Based on the recommendations and feedback from a national listening exercise with healthcare professionals and patients, the National Reporting and Learning Service (NRLS – a division of the NPSA) developed an updated Being Open framework to demonstrate how to strengthen the culture of being open within healthcare organisations.

1.5 The framework is a best practice guide for all healthcare staff including boards, clinicians when managing incidents and complaints. It explains the principles behind Being Open and outlines how to communicate with patients, their families and carers following harm. Monitoring of the implementation of this policy will include feedback from the local population of patients, services users, carers and patient experience groups such as HealthWatch.

1.6 The policy seeks to reflect the changes within the revised Being Open framework (November 2009) and the NPSA's National Reporting and Learning Service's Patient Safety Alert 'Being Opencommunicating with patient or service users, their families and carers following a patient safety incident' NPSA/2009/PSA003).

1.7 Open and honest communication with patient or service users, their families and carersis at the heart of healthcare. Research has shown that being open when things go wrong, can help patient or service users, their families and carers and staff to cope better with the after effects of an incident, complaint or claim and the Organisation will ensure through its implementation and communication of this policy, that staff are aware and encouraged to be open in their communication with patient or service users, their families and carers.

1.8 Healthcare staff may be fearful of upsetting the patient or service user, their families and carers, by saying the wrong thing or admitting liability. The guidance and the associated actions outlined in the alert, provide reassurance that Being Open is the right thing to do, and encourage NHS boards to make a public commitment to openness, honesty and transparency.

1.9 Promoting a culture of openness is a prerequisite to improving patient or service user experience, safety and the quality of healthcare systems. It involves apologising and explaining what happened to patient or service users who may have been harmed as a result of their treatment or care. It ensures communication is open, honest and occurs as soon as possible following an incident, complaint or claim. It encompasses communication between healthcare organisations, healthcare teams and patient or service users and their families and carers.

1.10 The policy is aimed at all staff responsible for ensuring the infrastructure is in place to support openness between professionals and patient or service users, their families and carers when something goes wrong. This document sets up a process to be followed when communicating with patient or service users, their families and carers, following a reported patient safety incident report orcomplaint.

Clinicians have ethical duty of candour to inform patients about mistakes, For example the General Medical Council state the Good Medical Practice guide the following statement on a clinician's 'duty of candour',registration.

> *'If a patient or service user under your care has suffered serious harm or moderate harm, through misadventure, or for any other reason, you should act immediately to put things right, if that is possible. You should explain fully to the patient or service user what has happened and the likely long and short-term effects. When appropriate, you should offer an apology. If the patient or service user is under sixteen and lacks*

*the maturity to consent to treatment, you should explain the situation honestly to those with parental responsibility for the child. '*

The Nursing and Midwifery council to which all registered nurses are required to follow –'The Code' which is the foundation of good nursing and midwifery practice and a key tool in safeguarding the health and wellbeing of the public. With regard to duty of candour the following standards apply.

- *52. You must give a constructive and honest response to anyone who complains about the care they have received*
- *53. You must not allow someone's complaint to prejudice the care you provide for them*
- *54. You must act immediately to put matters right if someone in your care has suffered harm for any reason*
- *55. You must explain fully and promptly to the person affected what has happened and the likely effects*
- *56. You must cooperate with internal and external investigations*

## 2. Aims of the policy

2.1 The aim of this policy is to ensure that communication between health care providers, the Organisation staff and its patients, patient or service users, their families and carers, about their care and treatment is open, honest and that it takes place within 10 days of the moderate or severe harm or death being reported. The National Patient Safety Agency definitions for harms are as follows:

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

**Severe:** Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care.

**Death:** Any patient safety incident that directly resulted in the death of one or more persons receiving NHS-funded care.

Examples of incidents that should be managed via this process is attached at **Appendix 1**. Please note that this is not an exhaustive list and further clarification should be sought from your manager.

2.2 The National Patient safety definitions of harm will determine when a patient or patient or service user has been moderately or severely harmed, or when the incident it has resulted in a patient or service user's death. In addition, the policy aims to ensure all involved in the incident are supported when a patient safety incident occurs.

2.3 The Organisation recognises and acknowledges the importance of communication and openness at all times between staff, patients or service users, their families and carers. The Organisation complaints policy makes clear the Organisation's commitment and actions taken to actively seek the views of those who use our services.

2.4 This policy also aims to provide clear information for staff on what they do when they are involved and the support available to them to deal with the consequences of what happened and to how to communicate with patients, patient or service users, their families and carers. This policy should be read in conjunction with Care Groups' complaints Policy

## 3. Our Commitment to an Open and Honest Culture

3.1 A clinical or non-clinical error that has resulted in moderate or severe harm or resulted in a death is rarely caused wilfully. It is not in itself, evidence of carelessness, neglect or a failure to carry out a duty of care. Errors are often caused by a number of factors including process problems, systemic failings, human error, individual behaviour or a lack of knowledge or skills. Learning from such incidents can only take place when they are reported and investigated in a positive, open and structured way.

3.2 Determining safe practice is an important part of successful risk management. A stronger focus on learning from errors will promote a fair and open culture and safe practice throughout the organisation. This will enable the Organisation to identify trends and take positive action to prevent the error or adverse incident from happening again.

3.3 This has enabled the Organisation to take a non-punitive approach to investigations in relation to incidents, complaints, claims. Staff remain accountable to patient or service users, their families and carers, the Organisation and their professional bodies for their actions, but a non-punitive approach means that disciplinary action will not be taken against a member of staff involved in an incident, complaint or claim, except in the rare circumstances where there is evidence of:

- *gross professional or gross personal misconduct*
- *repeated breaches of acceptable behavior or protocol*
- *a resulting police investigation*

## 4. Duties & Responsibilities

4.1. The Organisation's Chief Executive Officer, Clinical Director, Executive Directors must ensure that mechanisms are in place to enable all staff to adhere to this policy which includes an Organisation wide program of training and awareness will support the implementation of this policy to ensure that responsible staff have the skills to confidently 'Say Sorry' and when required to conduct investigation of the root cause and contributory factors which are shared with the person affected in an open and transparent manner.

4.2. The Director of Quality & Assurance for Being Open and Honest must ensure that the policy is embedded and adhered to by staff involved in the being open and duty of candour process.

4.3. Deputy Clinical Director, Directors, Senior Managers, Service Leads must ensure that all staff are aware of and adhere to this policy.

4.4. The local line manager has a number of responsibilities, as follows:

- ensuring the duty of candour is implemented in the spirit it is intended

- deciding who will provide the initial notification to the patient or service user or their families or carers
- reporting data and evidence to commissioners via the contractual key performance indicator.
- Addressing non-compliance via the appropriate management route.

4.5 All staff involved in the being open and duty of candour process should familiarise themselves with this policy and ensure that the policy is fully implemented.

4.6 Temporary/bank staff (e.g. students on placement) or staff in training should not lead the Being Open and Honest of Duty of Candour process, unless authorised to do so by their manager.

4.7 If temporary/bank staff and staff in training have been involved in a patient or service user incident and are required to be involved in the Being Open and Honest or Duty of Candour discussion, they must be accompanied and supported by a senior team member. It is unacceptable for temporary/bank staff and staff in training to communicate to patient or service user safety information alone or to be delegated the responsibility to lead a discussion unless they volunteer and their involvement takes place in appropriate circumstances, i.e. they have received appropriate training and mentorship for this role. Qualified experienced staff should provide experiential learning opportunities to more junior staff in promoting the policy and professional practice.

4.8 Reporting of compliance/providing a robust risk management system from which reports and levels of policy compliance be monitored is the responsibility of the Quality, Safety & Governance Committee.

## 5. Guiding Principles

5.1 The NHS Constitution states pledges 'to ensure that patients are treated with courtesy and receive appropriate support throughout the handling of a complaint, and future treatment is not adversely affected'. NHS Constitution link here. Effective communication with patients and service users, their families and carers, begins at the start of their care, should continue throughout and should not change at any stage.

5.2 Openness about what happened and discussion with patients or service users, their families and carers, promptly, fully and compassionately can help patients or service users cope better with the after-effects. Openness and honesty can help prevent formal complaints and litigation claims and reduce costs incurred on the Organisation and is fundamental to the partnership between patients or service users, their families and carers and those who provide their care.

5.3 The Being Open and Honest process is as follows:

- acknowledging, apologising and explaining when things go wrong in a timely manner of the harm being reported, linking to the 'Saying Sorry' leaflet
- conducting a thorough investigation, the findings of which are shared with patients or service users, families or carers, highlighting that lessons that have been learned that will help prevent the incident recurring

- providing support to cope with the physical and psychological consequences of what happened
- Satisfaction that communication with patient or service users and their families and carers has been handled in the most appropriate way
- improving the understanding of errors from the perspective of the patient or service user, their families or carers
- the knowledge that lessons learned from errors will help prevent them happening again
- standards of professional practice are maintained and shared Organisation wide and that the needs of the patient, service user/ families and carers is always held centrally
- professionals being open to peer review

5.4 Patients or service users, their families and carers, who have been distressed or harmed will benefit from the effective implementation of the Being Open and Honest policy. Being listened to and understood and in return being provided with opportunity for open and honest discussions with suitably qualified staff is more likely to provide an understanding of why and how medical/clinical incidents occurred.

## 6. Ten Principles of Being Open and Honest

Being Open and Honest is a culture in which an organization operates rather than a one-off event. With this in mind, the following principles have been developed to support the policy.

### 6.1 Principle of acknowledgement

All incidents should be acknowledged and reported as soon as they are identified, and complaints and claims acknowledged when received (refer to THGPCG Complaints Policy). Any concerns should be treated with compassion and understanding by all staff. Denial of a patient or service user's concerns will make future open and honest communication more difficult.

### 6.2 Principle of truthfulness, timeliness and clarity of communication

Accurate and informed information about an incident must be shared with the patient or service user, their families and carers in a truthful and open manner. The Organisation has robust internal systems for dealing with concerns, and complaints and claims. Patient or service users expect a detailed explanation of what happened, that considers their individual needs and is delivered openly.

Communication should also be timely: patient or service users, their families and carers should be provided with accurate 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. Staff should explain that new information may emerge as an incident investigation is undertaken, and patient or service users and/or their carers should be kept up-to-date with the progress of an investigation.

Patient or service users, their families and carers will be given the opportunity to share their view of the events and that this information will be considered by the

investigation. The Organisation will share clear, unambiguous information and provide 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 may not be understood, should be avoided.

If for any reason it becomes clear during the initial discussion that the patient or service user would prefer to speak to a different professional, the patient or service user's wishes should be respected. A substitute with whom the patient or service user is satisfied should be provided.

### 6.3 Principle of apology

Patient or service users, their families and carers should receive a sincere expression of sorrow or regret for the harm and/or distress that has resulted from the incident, complaint or claim. 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 a staff member should give the apology should consider seniority, relationship to the patient or service user, and experience and expertise in the type of patient or service user safety incident that has occurred.

Verbal apologies are essential because they allow face-to-face contact between the patient or service user, their families and carers and the healthcare team. It is important not to delay giving an apology for any reason, including: setting up a more formal multidisciplinary 'Being Open and Honest' discussion with the patient or service user, their family and carers, fear and apprehension, or lack of staff availability, as this is likely to increase the patient or service user's, their families' and carer's sense of anxiety, anger or frustration. A written apology, which clearly states that the Organisation is sorry for the suffering and distress resulting from the error, must also be given. An apology is not an admission of liability.

### 6.4 Principle of recognising patient or service user, their families and carer expectations

Patient or service users, their families and carers can reasonably expect to be fully informed of the issues surrounding the error and its consequences in a face-to- face meeting. They should be treated sympathetically, with respect and consideration at all times.

Confidentiality must be maintained at all times.

Effective communication with patient or service users, their families and their carers should be established to provide support and information in a manner appropriate to their needs. This involves assessment and the provision of any required additional support, adaptations and resources to provide effective communication. Examples of this include: an independent patient or service user advocate or a translator, easy read resources or other technology to support communication.

When appropriate, information on accessing relevant support groups like Cruse Bereavement Care and Action against Medical Accidents (AvMA) should be given to the patient or service user as soon as it is possible.

### 6.5 Principle of professional support

Openness and honesty creates an environment in which all staff, whether directly employed or independent contractors, are encouraged to report patient or service user

safety incidents. Through clinical supervision staff should feel supported throughout the incident, complaint or claim 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 professional registration.

### 6.6 Principle of risk management, Learning and Practice improvement

The Organisation implements the National Patient Safety Agency (NPSA) Root cause analysis (RCA) methodology when undertaking incident investigations. In doing so the investigator will identify care and service delivery problems, analyses the information for contributory factors and identify any root causes. Action plans for learning and practice improvement are developed and monitored as per the Incident, complaints policy.

### 6.7 Principle of multidisciplinary responsibility

This policy applies to all staff who have key roles in the patient or service user's care. Some teams within the Organisation are multidisciplinary teams and communication with patient or service users, their families and carers following an incident, complaint or claim that led to harm, should reflect this. This will ensure that the Being Open and Honest process is consistent with the philosophy that incidents usually result from systems failures and rarely from the actions of an individual.

### 6.8 Principle of clinical governance

Being open and honest has the support of patient or service user safety and quality improvement processes through the clinical governance framework, in which incidents, complaints and claims 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. The findings are disseminated to staff so that they can learn from patient or service user safety incidents through manager's feeding back locally at team meetings. These actions are monitored to ensure that the implementation and effects of changes in practice following an incident, complaint or claim.

### 6.9 Principle of confidentiality

Full respect should be given to the patient or service user, their families' and carer's and staff's privacy and confidentiality. Details of an incident, complaint or claim 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 or service user. 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 or service user, their families and carers about who will be involved in the investigation before it takes place and give them the opportunity to raise any objections.

### 6.10 Principle of continuity of care

Patient or service users are entitled to expect they will continue to receive all usual treatment and continue to be treated with respect and compassion. The lead member of staff supporting the investigation provides supervision to staff and supports the continuity of care. If a patient or service user expresses a preference for their healthcare needs to be taken over by another team, the reasons for this should be openly discussed

and noted, Risks to the continuity of care must be negotiated and agreed before any individualised arrangements are made for them to receive treatment elsewhere.

## 7 Patient or service user safety 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 or service user, families and carers. A senior member of the multidisciplinary team should be present to assist at the initial Being Open and Honest discussion. The 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.

## 8 Involving Staff who have made mistakes

8.1. Where incidents, complaints or claims resulted in moderate harm, severe harm or death occurred as a result of an omission or error in carrying out a treatment intervention, consideration should be given as to the appropriate involvement of staff participating in the Being Open process.

8.2. Every case where an error has occurred needs to be considered individually, balancing the needs of the patient or service user, their families and carers with those of the healthcare professional concerned.

8.3. If staff require additional support i.e. counselling, Occupational Health, Human Resources department or support from other internal or external agencies, this should be made available as soon as possible.

8.4. In cases where the healthcare professional who has made an error wishes to attend the discussion to apologise personally, they should feel supported by their colleagues throughout the meeting. Staff can be referred for further psychological support if this is felt appropriate.

8.5. In cases where the patient or service user and/or their carers express a preference for the healthcare professional not to be present, it is advised that a personal written apology is handed to the patient or service user and/or their carers during the first Being Open and Honest discussion.

8.6. It is essential that the following does not occur:

- speculation
- attribution of blame
- denial of responsibility
- provision of conflicting information from different individuals

8.7. Individuals and individual circumstances may require additional support and care to support the process. Refer to Appendix 6 for further guidance.

## 9. The Being Open and Honest Process

The initial Being Open and Honest discussion with the patient or service user, their families and carers, should occur as soon as possible after recognition of the incident, complaint or carer. A suggested Duty of Candour letter template is available (Appendix 5).

9.1 Stage 1: Preliminary meeting with the patient or service user and/or their carers

Who should attend?

- a lead staff member who is normally the most senior person responsible for the patient or service user's care and/or someone with experience and expertise in the type of incident that has occurred
- ensure that those members of staff who do attend the meetings can continue to do so; continuity is very important in building relationships
- the person taking the lead should be supported by at least one other member of staff, such as risk manager, nursing or medical director, or a team member treating the patient or service user
- ask the patient or service user, their families and carers, who they would like to be present.
- Consider each team member's communication skills; they must be able to communicate clearly and effectively.
- hold a pre-meeting amongst the professionals so that everyone knows the facts and understands the aims of the meeting

When should it be held?

- as soon after the incident, complaint or claim as possible
- consider the patient or service user, their families and carer's home and social circumstances
- offer them a choice of times and confirm that chosen date in writing
- do not cancel the meeting unless absolutely necessary, always provide an apology and explanation for the cancellation.

Where should it be held?

- do not host the meeting near to the place where the incident occurred if this may be difficult for the patient or service user, their families and carers
- in some circumstances i.e. when a death has occurred or a patient or service user has mobility problems as a result of the incident, it may be appropriate to offer a home visit

9.2 Stage 2: Discussion

How should you approach the patient or service user, their families and carers?

- speak to the service, their families and carers as you would want someone in the same situation to communicate with a member of your own family
- do not use jargon or acronyms: use clear, straightforward language

- consider the needs of the patient or service users with special circumstances, for example, linguistic or cultural needs, and those with learning disabilities
- avoid disappointment and unmet expectations by being clear about what information you can tell them at that point in time

What should be discussed?

- introduce and explain the role of everyone present to the patient or service user, their families and carers and ask them if they are happy with those present
- acknowledge what happebed and apologise on behalf of the team and the organization. Expressing regret is not an admission of liability
- Invite and listen to the patient, service user / relative to share their understanding of the event to clarify any discrepancies
- Share the facts that are known at the time and provide assurance that if more information becomes available, it will be shared.
- do not speculate or attribute blame
- discuss sources of support that may be appropriate and acceptable
- check for understanding what has been shared and offer opportunity to answer any further questions
- provide a named contact who will be keeping in touch to provide updates on the investigation and who they can contact if they wish to.

9.3 Stage 3: Follow-up

- share in writing a summary of the meeting, providing details of the information given, key points, record action points and assign responsibilities and deadlines.• Provide a copy of the report, asking for confirmation that there is agreement or whether the patient/service user/carer would like to make additions or changes to the content of the above report
- the service user's notes should contain a complete, accurate record of the discussion(s) including the date and time of each entry, what the patient or service user and/or carers have been told, and a summary of agreed action points
- maintain proactive, supportive communications by addressing any new concerns raised and sharing new information once available.

9.4 Stage 4: Completion Process

- share the findings of the investigation reports with the patient or service user, their families and carers
- share the learning and how practice and or services are being improved as a result of the incident.

- inform on continuity of care and what the care plans are as appropriate
- share the reports and the key findings with staff involved in the investigation and being open process
- make arrangement to monitor the action plans and ensure that they have been implemented
- communicate the necessary requirements for learning the lessons and practice improvement with all staff using various formats

9.5 Documentation

Ensure that all discussions with the patient or service user, their families and carers are recorded throughout the being open process and held with the relevant incident, complaint or claim documentation.

## 10. Written records of the Being Open and Honest discussion

There should also be documentation held with the incident, complaints or claim of:

- the time, place, date, as well as the name and relationships of all attendees
- the plan for providing further information to the patient or service user, their families and carers
- offers of assistance and the patient or service user's, their families' and carers response
- questions raised by the family and 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 or service user, their families and carers
- copies of letters sent to patient or service users, their families and carers and the GP for patient or service user safety incidents not occurring within primary care
- copies of any statements taken in relation to the patient or service user incident, complaint or claim

## 11. Duty of Candour Requirements

The requirements outline where the harm threshold has been breached, as follows:

11.1 Notify the patient or service user, their families or carers (including someone lawfully acting on their behalf) verbally (face to face where possible) unless the person cannot be contacted in person or declines notification, that the incident has occurred.

11.2 The Clinical Director will decide who will provide this initial notification and this will be a senior member of staff.

11.3 This initial notification will include an apology and must be provided as soon as is practicable within 10 working days of the incident being reported, adhering to the Being Open and Honest process above.

11.4 Provide all information directly relevant to the incident which will be step by step factual explanation of what has happened

11.5 Advise and if possible, agree with the patient or service user what further enquiries are appropriate.

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

11.7 Share with the patient or service users, their families or carers in writing of the original notification and the results of any further enquiries. A suggested introduction and closing Duty of Candour letter template is available (Appendix 5 and 6).

11.8 All final incident reports must be shared with the patient or service user and families within 10 working days of being ratified by executive officer as complete and closed by the Quality, Safety & Governance Committee. The timescales for each investigation will follow the standard requirements as identified in the Complaints and Incident policies, unless agreement to extend the timeframe has been accepted by all concerned.

11.9 An audit tool will be used to ensure the Organisation is compliant with requirements. The Organisation will be required to provide evidence to the Commissioners regarding the incident in a six monthly contract review. The Organisation will seek the consent of complainants to share an anoymised version of the complaint and learning outcomes on the Organisation website.

## 12. Continuity of care

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

12.2 Patient or service users, their families and carers should be reassured that they will continue to be treated according to their clinical needs even in circumstances where there is a dispute between them and the team. They should also be informed that they have the right to continue their treatment elsewhere if they have lost confidence in the team involved in the incident, complaint or claim.

## 13. Prevented and 'No Harm' Incidents

The NPSA found from feedback on a draft version of Being open – which came from a range of healthcare staff, government agencies, professional bodies, patients and the public – that several problems were identified if no harm incidents were discussed with patients and / or their carers, including:

- added stress to patients and potential loss of confidence in the standard of care
- negative effects on staff confidence and morale
- decreased public confidence in the NHS

In addition, it was widely believed that communicating prevented and 'no harm' patient safety incidents was impractical, adding to staff workload and potentially interrupting their ability to provide patient care. The NPSA believe, however, that where an incident led to moderate or severe harm or death, the benefits outweigh these problems.

**14. Informed Consent and Disciplinary Processes**

Being open is based on concepts that should be broadly applicable to all healthcare settings. Informed consent and disciplinary processes are critical to this policy's successful implementation. (See section on Disciplinary Processes below.)

14.1 Informed Consent

Effective communication includes the provision of health information and discussion with patients of potential outcomes. There is already extensive recent guidance in this area from the Department of Health and the NHS Executive. Informed consent is an essential element in providing high quality services.

14.2 Disciplinary Processes

The taking of automatic punitive disciplinary action and inappropriate exclusion of staff from work following a patient safety incident may create a barrier to open reporting. THGPCG will strive to identify the underlying causes of patient safety incidents (i.e., systems failures or latent conditions) by using methods such as root cause analysis. This should ensure incident investigations do not focus exclusively on the last individual to provide care.

If it is deemed through investigation that there are staff conduct issues then the appropriate human resources processes will be followed.

To facilitate systematic assessment of the actions of staff and to determine the appropriate immediate action following a patient safety incident, the Organisation aims to use the NPSA's incident decision tree (IDT).

More information on the IDT can be found in *Seven steps to patient safety* and on the

NPSA website: www.npsa.nhs.uk/idt

Where concerns are identified about the performance of individual doctors, dentists or pharmacists the National Clinical Assessment Service (NCAS) can be contacted for advice on handling these issues and whether an assessment of the individual's practice would be helpful.

**15. Implementation of the Policy**

- all staff will be made aware of the policy via their line managers
- being Open and Honest and Duty of Candour to form part of Corporate Induction Programme

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- Local Induction for all staff
- Details of cases to be reported to Locality Quality and Safety Groups
- Learning t h e Lessons to be a standard agenda item on Quality and Safety Groups. Dissemination of learning is always a requirement of an investigation. Action plans are monitored to provide assurance that learning has been shared with local teams. The Organisation has developed framework for learning from serious incidents, complaints and claims.

## 16. Implementation process

16.1 Staff will be made aware of any new approved policies/ procedures/ guidelines via the monthly team brief. The Quality and Patient Safety team will be responsible for ensuring newly approved documents are sent to the communications team in order for them to insert into the team brief.

16.2 All senior managers/heads of service/team leaders will ensure new policies and procedures are placed on team meeting agendas for discussion. There is an expectation that the team leader will develop local systems to ensure their staff are instructed to read all relevant policies and to identify any outstanding training deficits.

## 17 Monitoring arrangements

Being open is a general concept and the specific delivery of Being Open communications will vary according to the severity, clinical outcome and carer arrangements for each specific event. In exceptional cases information may need to be withheld or specific legal requirements might preclude disclosure. Equally records of communications with patients and carers will not normally be shared within the public domain. For these reasons monitoring of compliance and effectiveness will be via a confidential planned audit using an appropriately sampled population. As a minimum the following elements will be monitored (see monitoring table below).

How well the Organisation performs in implementing the Being Open and honest (duty of candour) will require feedback through patient experience.

## 18. Equality statement

18.1 This policy reflects the organisation's determination to ensure that all parts of our community have equality of access to services and that everyone receives a high standard of service as a patient or service user, a carer or employee. This policy anticipates and encompasses the Organisation's commitment to prevent discrimination on any illegal or inappropriate basis and recognise and respond to the needs of individuals based on good communication and best practice. We recognise that some groups of the population are more at risk of discrimination or less able to access services than others and that services can often unintentionally put barriers in place that can limit or prevent access. The organisation is continually working to prevent this from happening.

18.2 One of the values of the Organisation is to value and respect individuals and effective communication. The Organisation will ensure that all staff embrace these values when working with patient or service users and makes a difference to their lives. The Organisation is committed in treating everyone individual equally and will not discriminate any groups of people, or treat them differently because of their race, gender, disability, age, religion or belief systems or their sexual orientation.

## 19. Reference

This policy should be read in conjunction with the following:


- THGPCG Complaints Policy
- "Being Open and Honest", National Patient or service user Safety Agency, 2005
- "Introducing the Statutory Duty of Candour", a consultation on proposals to introduce a new CQC registration regulation, Department of Health, March 2014
- Care Quality Commission (CWC) (2009): A Quality Service, a Quality Experience; London, CQC. Available at www.cqc.org.uk
- Department of Health (2009); Listening, Responding, Improving: A guide to better Customer Care. London, Department of Health. www.dh.gov.uk.
- Department of Health (2009); The NHS Constitution: The NHS belongs to us all. London; Department of health.
- Further information and e-learning module can be found at www.npsa.nhs.uk Elements of the Being Open and Honest policy are also related to other government initiatives and recommendations from major inquiry reports, including: Recommendations in the 5th Shipman Inquiry Report about appropriate documentation of patient or service user deaths.
- The NHS Litigation Authority's Striking the Balance initiative on providing support for National Safety Agency, Seven Steps to Patient or service user Safety, Involve and Communicate with Patient or service users and the public, the National Health Service Litigation Authority (NHSLA) circular 02/02.

**Appendix 1**

**Examples of incidents that should be managed under this Policy**

(Please note that this is not an exhaustive list and further clarification should be sought from your manager)

| Incident Category | Example |
|---|---|
| **Violence and Aggression** | |
| Threatening Behaviour | Damage to patient/service user or their |
| Bullying and/or Harassment | Persistent bullying and/or harassment causing distress to the victim |
| Verbal Attack | Verbal aggression with serious threat to harm or damage where imminent risk is perceived. |
| Physical Attack | Assault causing injury requiring some hospital treatment (but not as an in-patient) |
| Sexual Aggression | Inappropriate sexual behaviour and/or comments with perceived immediate threat |
| Allegation of Assault or Abuse | Following allegations of assault or abuse |
| **Harm to Self** | o Self-harm resulting in further intervention or treatment as agreed in care plan<br>o Attempted suicide<br>o Suicide of service user within 12 months of a contact with services |
| **Unexpected Death** | Sudden unexpected deaths of patients/service users in community or inpatient setting |
| **Physical Health Issue** | o Pressure ulceration obtained whilst under the care of THGPCG<br>o Patient/service user discharged from hospital and returned within 48 hours, presenting with continuation of same symptoms<br>o Failure to address the needs of a patient/service user refusing food and fluids resulting in further intervention<br>o Failure to address the needs of a patient/service user refusing insulin, as required |
| **Abscond and Absence Without Leave** | o Absconds/AWOL of service users detained under the Mental Health Act (1983) including Community Treatment Orders |

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| | |
|---|---|
| **Falls** | Where the slip, trip or fall resulted in harm that required medical attention and there was failure to identify the risk to the patient/service user or put inrequired safeguards to minimise risk |
| **Medication** | All prescribing, dispensing or administration errors |
| **Substance misuse** | Failure to manage the possession or consumption of alcohol or illicit drugs leading to intoxication and riskposed to self or others whilst on THGPCG property |
| **Health and Safety** | Any injury sustained whilst under the responsibilityof THGPCG services |
| **Fire** | For the disruption of services resulting from firerelated incidents |
| **Infection Control** | For the disruption of services and any inconvenience resulting from the outbreak of anotifiable illness |
| **Information governance, confidentiality and records management** | o Potential or actual breach of personal identifiable data to patients/service users and their families/carers<br>o Failure to maintain accurate patient records |
| **Breach of Mental Health Law or Human Rights** | Unlawful treatment or deprivation of liberty, not covered by the MHA(1983) or MCA/DoLs, and involving possible breach of Human Rights |
| **Loss of, or damage to property** | Failure to secure patient/service user or their families/carers personal possessions or property which THGPCG have accepted responsibility for |

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Appendix 2

| BEING HONEST AND OPEN PROCESS FLOW | |
|---|---|
| STAGE 1 | **Preliminary Team Discussion**<br><br>1. Appoint a member of staff (experienced and with expertise) to lead on communication with the patient or service user/carer<br>2. Established which other staff members should attend<br>3. Establish a time line<br>4. Establish the aims of the meeting<br>5. Offer support and counselling for staff involved if required |
| STAGE 2 | **Discussion**<br><br>1. Establish how to contact patient or service user/carer<br>2. Agree venue and time with patient or service user/carer<br>3. Introduce everyone in the meeting including what their roles are<br>4. Provide factual details to date<br>5. Offer practical and emotional support<br>6. Provide contact details of who to contact if patient or service user/carer have further questions<br>7. Identify next steps |
| STAGE 3 | **Follow Up**<br><br>1. Keep patient or service user/carer informed of how the investigation is going<br>2. Consider keeping in touch on a regular basis with the service user/carer<br>3. Respond to any queries as sufficiently as possible |
| STAGE 4 | **Completion Process**<br><br>1. Arrange to meet with Service user/carer to discuss the findings of the investigation<br>2. Give an apology to the service user/carer |

| | |
|---|---|
| | 3. Inform service user/carer how recommendations will be implemented and what continuity of care will be<br>4. Share the key findings/summary with all staff concerned<br>5. Make arrangements to monitor the action plans<br>6. Share the learning with staff within the organisation |
| All discussion with the services user, their family and carers should be documented at all times | |

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**Appendix 3**

## Being Open and Honest

## Checklist

1. Appoint a member of staff (experienced and with expertise) to lead on communication with the patient or service user/carer.
2. Establish which other staff members should attend.
3. Establish a time line.
4. Establish the aims of the meeting.
5. Offer support and counselling for staff involved if required.
6. Establish how to contact patient or service user/carer.
7. Agree venue and time with patient or service user/carer.
8. Introduce everyone in the meeting, including what their roles are.
9. Provide factual details to date.
10. Offer practical and emotional support.
11. Provide contact details of who to contact if patient or service user/carer have further questions.
12. Identify and agree next steps.
13. Keep patient or service user/carer informed of how the investigation is going.
14. Consider keeping in touch on a regular basis with the patient or service user/carer.
15. Respond to any queries as sufficientlyas possible.
16. Arrange to meet with patient or service user/carer to discuss the findings of the investigations.
17. Give an apology to the patient or service user/carer.
18. Inform patient or service user/carer how recommendations will be implemented and what continuity of care will be.
19. Share the key findings/summary with all staff concerned.
20. Make arrangements to monitor the action plans.
21. Share the learning with staff in the Organisation.

Appendix 4

**Incident, Complaint or Claim Consequence Grading Scale**

| Description | Impact on individual |
|---|---|
| **1. Insignificant** | No injury |
| **2. Minor** | First Aid<br><br>Minor Injury<br><br>Minor illness |
| **3. Moderate** | Temporary incapacity.<br>Short term monitoring.<br><br>Additional Medical treatment required up to 1 year |
| **4. Major** | Major Injury<br><br>Major clinical intervention |
| **5. Catastrophic** | Death |

Appendix 5

## Special Circumstances

The approach to Being Open and Honest may need to be modified according to the patient or service user's personal categories of patient or service user circumstances.

### a. When a patient or service user dies

When a patient or service user safety incident has resulted in a patient or service user's death it is 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 or service user'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 counselling or assistance at any stage.

Usually, the *Being Open and Honest* discussion and any investigation occur before the coroner's inquest. But in certain circumstances the Organisation may consider it appropriate to wait for the coroner's inquest before holding the *Being Open and Honest* discussion with the patient or service user'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 or service user's death. In any event an apology should be issued as soon as possible after the patient or service user'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.

### b. 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 and Honest* process after a patient or service user safety incident. The opportunity for parents to be involved should still be provided unless the child expresses a wish for them not to be present.

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

### c Patient or service users with mental health issues

*Being Open and Honest* for patient or service users with mental health issues should follow normal procedures, unless the patient or service user also has cognitive impairment (see below). The only

circumstances in which it is appropriate to withhold patient or service user safety incident information from a mentally ill patient or service user is when advised to do so by a consultant psychiatrist who feels it would cause adverse psychological harm to the patient consultant psychiatrist) would be needed to justify withholding information from the patient or service user. Apart from in exceptional circumstances, it is never appropriate to discuss patient or service user safety incident information with a carer or relative without the express permission of the patient or service user. To do so is an infringement of the patient or service user's human rights.

**d. Patient or service users 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 this extends to decision making and to the medical care and treatment of the patient or service user. The Being Open and Honest discussion would be held with the holder of the power of attorney. W here there is no such person the clinicians may act in the patient or service user's best interest in deciding who the appropriate person is to discuss incident information with, regarding the welfare of the patient or service user as a whole, and not simply their medical interests. However, the patient or service user with a 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 or service user to assist in the communication process.

**e. Patient or service users with learning disabilities**

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

**f. Patient or service users who do not agree with the information provided**

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

- deal with the issue as soon as it emerges.
- where the patient or service user agrees, ensure their carers are involved in discussions from the beginning.
- ensure the patient or service user has access to support services.
- where the senior health professional has failed to reflect or review their impact and effectiveness in working with the individual.,
- provide mechanisms for communicating information, such as the service user expressing their concerns to other members of the clinical team.

- offer the patient or service user and/or their 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 or service user, and to look for a mutually agreeable solution.

- ensure the patient or service user and/or their carers are fully aware of the formal complaints procedures.

- write a comprehensive list of the points that the service user and/or their carer disagree with and reassure them you will follow up these issues.

**g. Patient or service users with a different language or cultural considerations**

The need for translation and advocacy services, and consideration of special cultural needs (such as for patient or service users 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 or service user 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 or service user's family or friends as they may distort information by editing what is communicated.

**h. Patient or service users with different communication needs**

A number of patient or service users 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 or service user is essential to facilitating an effective Being Open and Honest process, focusing on the needs of individuals and their families and being personally thoughtful and respectful.

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**Appendix 6**

Duty of Candour Audit Tool

**Duty of Candour Tool**

| Name of nominated person to notify patient/carer: | |
|---|---|
| Job position of above: | |
| Director responsible: | |
| Date incident reported on Datix | |
| Date incident agreed by Trust as a moderate/severe/death harm | |
| Date patient/carer informed of incident, either Face to<br><br>Face or by other means<br><br>(unless patient/carer declined meeting, then please put declined) | |
| Date apology given? | |
| Date of professionals preliminary meeting: | |
| Attendance list of professionals preliminary meeting | |
| Was support offered to the patient? | Yes/No |
| Was the patient/carer involved in the plan? | Yes/No |
| Was support offered to staff? | Yes/No |
| Date report shared with patient/carer | Yes/No |
| Date report shared with QSC/Board | |
| Date report shared with Commissioners | |
| Date report shared with Team | |

## Appendix 7: Sample introduction letter

(insert contact address and telephone number)

**PRIVATE AND CONFIDENTIAL**

(insert date)

(insert name and address)

Dear

As you know (you/your….) have/has been involved in (briefly describe the event).

Firstly, I would like to express my sincere apologies that this event has occurred and that I am sorry if you have suffered any harm and or distress.

Second, I would like to assure you that the Organisation aims to provide a quality service to all our patients. We are therefore, undertaking a full investigation into your/your…'s care and treatment in an effort to understand exactly what happened and, in line with the Organisation's policy of "Being Open", we would like the opportunity to discuss our investigation with you and share our findings.

I would, therefore, like to invite you to come to a meeting, which is being organised as part of our investigation. I am, of course, more than happy for you to bring a relative or friend with you if this would help. I also recognise that you may wish to delay this meeting for a while and that is also perfectly fine. Alternatively, it may be that you do not feel a meeting would be of any help, either now or in the future and that is, of course, your choice: there is absolutely no pressure for you to come and talk to us. We just wanted to give you the opportunity, should you wish to do so.

I will be your lead contact during the investigation process and, whether you wish to attend a meeting or not, I should be grateful if you would ring me on the number at the top of this letter. We can then make any necessary arrangements. If you feel that you do not wish to telephone, I am more than happy to hear from you by letter.

It may be useful if you give the following some consideration:

1. With whom would you prefer to meet?
2. Where you would wish to meet?
3. Your preference of time and date for the meeting.

Whilst we cannot promise, we will make every effort to accommodate your wishes.

Yours sincerely

(insert name and designation)

**Appendix 8**

(Date)

Our Ref: xxxxxx

Dear

**Re (enter details of complaint)**

Further to our correspondence to you regarding (enter details of complaint) I am writing to advise that the investigation is now completed.

As part of the Organisation's policy of 'Being Open' we are sharing the outcome of the investigation regarding

(enter details of complaint including date when this occurred)

I would be more than happy to discuss any aspects of the report with you and please do not hesitate to contact me if you have any further questions or concerns you wish to raise regarding (list incident/complaint).

I wish to apologise for any distress caused to (name individual /family) as a result of this incident and assure you the Organisation will progress the actions identified in the report to reduce the risk of this happening in the future.

Yours sincerely,

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# Being Open

Our staff work hard to deliver the highest standards of healthcare. We provide safe and effective care to many thousands of people every year but sometimes, despite our best efforts, things can go wrong.

If you are not satisfied with the care that you, or a member of your family has received, please call the Organisation on xxxx and ask to speak to the designated administrator within each locality (the switchboard will put you through to the relevant member of staff).

When something goes wrong in our care, we will keep those involved fully informed about what has happened, answer their questions and let them know what is being done in response. This is something that we call *Being Open and Honest.*

We make a commitment to:

- apologise when things go wrong
- explain, openly and honestly, what has gone wrong
- describe what we are doing in response
- offer support and counselling services that might be able to help
- provide the name of a person to speak to
- treat all information in the strictest confidence
- share the results of any investigation.