

Duty of Candour and Being Open Policy

| Document Number | TAC/PD/6054 | Version | 3 | Page 1 of 23 |
|-------------------------------|---|---------------------|---|----------------------------|
| Date of Last Review | 01/02/23 | Date of Next Review | | January 2025 |
| Approved by Print Name | Signature Julie Wallace, Chief Nurse | | | |
| Executive Sign-Off Print Name | Signature Kenneth Park, Clinical Director | | | |

| Document control – revision history | | | |
|-------------------------------------|--------------------|--|-----------------------|
| Date amended | Version Revision | | Approved by & date |
| 08/10/18 | 2 | Audited and updated to include document number, new logo and footnote table – W. Sharp | A. Duncan 08/10/18 |
| 08/01/21 | 2 | Reviewed - no change | |
| 01/02/23 | 3 | Updated to include new logo and Incident Reporting and Review Process Flow | K. Park 03/02/23 |
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EXPLANATION OF TERMS USED IN THIS POLICY

Being Open - Process for explaining and apologising for what has happened to patients and/or their families/carers who have been involved in a complaint or patient safety incident

Duty of Candour - Legal requirement to inform patients and/or their family/carers if there has been an actual or suspected incident that resulted in moderate harm, severe harm or death. Failure to do this will result in the recovery of the cost of the episode of care, or £10,000 if the cost of the episode of care is unknown

Apology - Sincere expression of regret offered for harm sustained

Harm - Defined as an injury (physical or psychological), disease, suffering, disability or death

Incident - Any event or circumstance arising from or during, TAC activities that could have, or did lead to, unintended or unexpected harm, injury, distress, loss or damage to a person or property. This includes suspected suicides, homicides, (both victim and assailant) involving current patients of the Trust and of individuals who were patients of the Trust within 6 months prior to the incident

Notifiable Patient Safety Incident - Any unintended or unexpected incident that occurred in respect of a patient during the provision of a regulated activity that, in the reasonable opinion of a healthcare professional, could result in, or appears to have resulted in:

- a) Death of the patient, where the death relates directly to the incident rather than to the natural course of the patient's illness or underlying condition, or
- b) Severe harm, moderate harm or prolonged psychological harm to the patient

Complaint - Expression of dissatisfaction by an individual or persons who require a considered response from the company which addresses their concerns and attempts, by all reasonable means, to resolve them to the point of satisfaction.

Claim - Allegations of negligence and/or a demand for compensation made following an adverse incident resulting in personal injury, damage to property or any incident which carries significant litigation risk for the company.

Relevant person - The person receiving services or someone acting lawfully on their behalf in the following circumstances: on their death, or where they are under 16 and not competent to make a decision in relation to their care or treatment, or are 16 and over and lack the mental capacity in relation to the matter in accordance with Mental Capacity Act 2005

Severe Harm - Permanent lessening of bodily, sensory, motor, physiologic or intellectual functions including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.

Moderate Harm - Harm that requires a moderate increase in treatment (i.e. a prolonged episode of care or transfer to another treatment area such as the acute trust), the shortening of the life expectancy of the service receiver, requires treatment by a healthcare professional in order to prevent the death of a service receiver or any injury which left untreated would lead to the aforementioned outcomes



Prolonged Psychological Harm - Psychological harm which a patient has experienced or is likely to experience, for a continuous period of 28 days or more

Root Cause Analysis (RCA) - Systematic process whereby the factors which contributed to an incident are identified and recommendations made to prevent further recurrence

Risk - An uncertain event or set of events which should it occur, would have an impact on the objectives and/or values of the company

Risk Management - The process of identifying, controlling and eliminating risk



1. INTRODUCTION

1.1. Background

When a patient suffers harm as a result of the healthcare treatment, they have received they have to find a way of coping with the physical and psychological consequences of what happened. Discussing events promptly, fully, honestly and compassionately when things go wrong can greatly reduce their distress and is therefore a vital component in dealing effectively with errors or mistakes in their care.

The benefits of Being Open are widely recognised and supported by policy makers, professional bodies and regulators.

The introduction of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 Part 2 Duty of Candour and Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20 was as a direct response to recommendation 181 of the Francis Inquiry Report into the failings at Mid-Staffordshire NHS Foundation Trust, which recommended that a statutory Duty of Candour be placed on healthcare providers. Subsequent guidance was issued by the CQC and HIS and as it is a statutory requirement, non-compliance is a criminal offence.

It is both natural and desirable for those involved in treatment which produces an adverse result, to sympathise with the patient and/or their family/carer and to express sorrow or regret at the outcome. An apology is not an admission of guilt or liability and is the right thing to do. Openness and honesty towards patients are supported and actively encouraged by many professional bodies including the Medical Defence Union (MDU), the Medical Protection Society (MPS), the General Medical Council (GMC) and the Nursing and Midwifery Council (NMC).

TAC Healthcare Group Ltd (TAC) is committed to the principle of openness and having open and honest communication with patients, their families and carers when things go wrong. This policy is designed to provide the process for supporting patients, carers, healthcare staff and managers when things go wrong.

1.2. Key Principles of Part 2 Duty of Candour:

- Providing health and social care services is associated with risk and there are unintended or unexpected events resulting in death or harm from time to time.
- When this happens, people want to be told honestly what happened, what will be done in response, and to know how actions will be taken to stop this happening again to someone else in the future.
- There is a need to improve the focus on support, training and transparent disclosure of learning to influence improvement and support the development of a learning culture across services.
- Candour is one of a series of actions that should form part of organisational focus and commitment to learning and improvement.
- Transparency, especially following unexpected harm incidents is increasingly considered necessary to improving the quality of health and social care.



• Being candid promotes accountability for safer systems, better engages staff in improvement efforts, and engenders greater trust in patients and service users.

Duty of Candour can make an important contribution to creating a culture of openness and honesty which always places the safety and the needs of the patient and family above the reputation of the organisation.

What is needed is a culture of openness and honesty, stimulated by a duty of candour, which is wholeheartedly adopted by organisations and individuals. This will enable our patients to be reassured that when things go wrong, we will learn and we will improve. (Dalton & Williams 2014)

The commitment to candour has to be about values and it has to be routed in genuine engagement of staff building on their own professional duties and their personnel commitments to their patients.

2. PURPOSE

TAC has set out a commitment to transparency and being open and this document describes how we will implement and monitor adherence to this commitment by providing clear information to staff to enable them to have the confidence to communicate and act appropriately with patients, their families and carers when things go wrong.

- 2.1 Staff work hard to provide services which are safe and of a high quality. However, sometimes things go wrong.
- 2.2. This policy has been developed to ensure that staff are aware of the processes and steps to follow in supporting patients and carers following an incident meeting the requirements for provision of Duty of Candour. It sets out specific requirements to follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology.
- 2.3. Health professionals have a duty to be open and honest with patients when things go wrong as set out in the joint GMC / NMC document *Openness and honesty when things go wrong: the professional duty of candour*¹ supported by the *Joint statement from the Chief Executives of statutory regulators of healthcare professionals*²
- 2.4. The policy provides guidance to staff on how to undertake the Duty of Candour and support mechanisms available where staff are unsure how to proceed.
- 2.5. There are some specific incident types which have a defined pathway within the remit of Duty of Candour and these are set out in Section 8.
- 2.6. The policy also sets out how the TAC will ensure that such events are identified, recorded, and completion monitored.
- 2.7. Illustrative examples of incidents that trigger the thresholds for duty of candour are provided in Appendix 2

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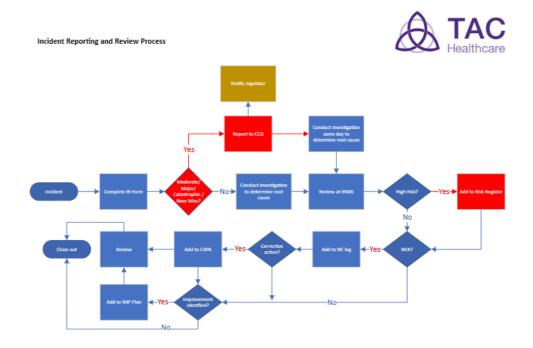
- 1. Openness and honesty when things go wrong: the professional duty of candour http://www.gmc-uk.org/static/documents/content/DoC_guidance_englsih.pdf
 - 2. http://www.gmc-uk.org/Joint statement on the professional duty of candour FINAL.pdf 58140142.pdf

3. SCOPE

- 3.2. TAC's <u>Accidents, Incidents, Adverse Incidents and Near Misses Management Policy</u> encourages staff to report all patient and service user safety incidents, including those where there was no harm or it was a 'near miss' event.
- 3.3. This 'Being Open The Duty of Candour' policy only relates to those incidents where actual harm has occurred and the consequences are graded as Moderate, Major or Catastrophic. Implementation of this policy will be an integral part of the management and investigation of these incidents.
- 3.4. However, there is flexibility to discuss incidents resulting in a lower level of harm (including no harm) with patients on an individual basis depending on local circumstance and the best interest of the patient. Where this does occur details of all communication must be documented.
- 3.5. Other disciplinary processes are outside the scope of this policy. Immediate disciplinary action can create a barrier to open reporting. The root causes of an incident should be the focus of the investigation, rather than the last individual to provide care.

4. PROCESSES

4.1 Process





Duty of Candour is a legal requirement for all care organisations to be open and honest with its patients and/or their families/carers when things go wrong. Duty of Candour applies to all notifiable safety incidents and requires a body to:

- Make sure it acts in an open and transparent way with the 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 health service body believes are appropriate.
- Offer an apology.
- Follow this up by giving the same information in writing and providing an update on the enquiries.
- Keep a written record of all communication with the relevant person.

Members of staff who are registered with a regulatory body must also ensure they are aware of and compliant with the requirements of Duty of Candour as set out in their body's Code of Conduct.

Duty of Candour focuses on incidents resulting in moderate or severe harm or death. As a result, incidents resulting in low, or no harm are not covered under statutory Duty of Candour requirements. Patients should still be informed of such incidents under the principles of Being Open.

Wherever possible patients/families or carers should be informed within 5 working days of the incident.

The initial notification must be verbal, and a face-to-face meeting offered. This must then be followed within 10 working days by a letter from the appropriate manager. Where it is not possible to adhere to the timescales all parties must be kept informed of new deadlines and the reason for the delay.

Once the facts are available an apology must be provided to the patient and/or their family/carer. A sincere expression of sorrow or regret for any suspected harm caused must be provided verbally and in writing by the appropriate manager as part of this process. An apology is not an admission of guilt or liability.

The appropriate manager must provide a step-by-step explanation of the facts as they are known at that point. This must be in terminology that the patient and/or their family/carer will understand, avoiding unnecessary jargon or medical terms. This may be only an initial view if the meeting takes place prior to investigations being undertaken. An explanation of the investigation process taking place and an offer to the patient and/or their family/carer must be provided with ongoing updates



provided as required.

The appropriate manager must ensure that full written documentation of any meetings are kept within the patient's files as well as creating an incident event with a summary and the relevant paperwork attached to the incident log as supporting evidence. It must also be recorded where meetings are offered but declined by the patient and/or their family/carer.

There may be exceptional circumstances where it is not possible to ascertain whether Duty of Candour applies until the Root Cause Analysis (RCA) investigation is complete e.g. following incidents of self-harm or where cause of death has not been established. These instances must receive agreement by the Chief Nurse prior to postponing Duty of Candour and the reasons for delay recorded on the incident log.

Where RCA investigation tools are used following a patient safety incident, the Lead Investigator must offer the patient and/or their family/carer an opportunity to contribute to the Terms of Reference (ToR), to answer any specific questions they have, a copy of the final investigation report (including action plan) and a meeting to discuss findings.

This should be as soon as practicable but no later than 10 working days after the Clinical Director being informed of approval of the report by the relevant Manager.

Copies of the final report and action plan must be delivered by the Investigator by hand to the Board of Directors and verbally feedback the case. All correspondence related to Duty of Candour outcomes should where possible be posted by Special Delivery so receipt can be confirmed.

4.2.1 Involving Healthcare Staff who have Made Mistakes

Some patient safety incidents that have resulted in moderate or severe harm or death will result from healthcare staff errors made while caring for the patient. In these circumstances, the member(s) of staff involved may or may not wish to be involved in the Duty of Candour discussions with the patient and/or their family/carer.

Every case where an error has been made should be treated individually, balancing the needs of the patient with those of the staff member(s). In cases where the member of staff who has made an error wishes to attend the discussions to make a personal apology, they should feel supported through the process by their colleagues throughout the meeting.

In cases where the patient and/or their family/carer express a preference for the member(s) of staff not to be present, their wishes should be respected and it is advised that a personal written apology is handed to the patient and/or their family/carer during the face-to-face meeting.



4.2.2 Content of the Initial Duty of Candour Discussions with the Patient and/or their Family/Carer

With the patient's agreement, carers and those close to the patient can be included in the discussions and decision making. If the patient is unable to participate or has died then their family and/or carer(s) can be provided with limited information regarding the incident, ensuring due regard to confidentiality and the patient's wishes is maintained. Carers and patient representatives can be referred to the Coroner for more information where required.

The following key principles must be adhered to when undertaking Duty of Candour disclosures:

- The patient and/or their family/carer should be advised of the identity and role of the staff members attending the Duty of Candour discussion beforehand. This allows them the opportunity to state their own preferences about which staff should be present
- There should be an expression of sincere sympathy, regret and an apology given for the harm that has occurred
- The known facts should be agreed by the multidisciplinary team before the meeting. Where there are disagreements, discussion of these items with the patient and/or their family/carer should be deferred until the facts have been established within the investigation. The patient and/or their family/carer should be informed that an investigation is ongoing and more facts may become available during its course
- The patient's and/or their family/carer(s) understanding of the incident should be taken into account and the investigation should seek to answer any questions they may have
- Appropriate language and terminology should be used when speaking to patients
 and/or their family/carer(s). For example, try to avoid medical terminology or
 abbreviations that may be meaningless to people outside of the healthcare sector. If
 the patient's first language is not English, or they have other communication issues,
 their language needs should be considered when making decisions on how to present
 material during and after discussions. These needs should also be communicated to
 the Lead Investigator to consider when feeding back the final report and action plan
- Information on likely short and long-term consequences of the incident (if known) should be shared with the patient. The latter may have to be delayed until a subsequent meeting if not known in the initial stages. Some patients may notwish to know every detail of an incident and these wishes should be respected. They should be reassured that should they change their mind in the future, this information will be available.
- An offer of practical and emotional support should be made to the patient and/or their family/carer e.g., contact details of third party support agencies. Patient information must not be given to third party agencies without their consent.
- The patient and/or their family/carer should be provided with the contact details of a member of staff they can contact during the investigation. This will be the Lead or



Support Investigator in the event of a RCA investigation taking place or the Service Lead if a RCA investigation is not occurring

- The patient should be reassured that they are entitled to continue receiving treatment and to be treated with dignity and respect. If the patient expresses a wish for their healthcare to be transferred to another team, arrangements should be made for this transfer to take place where possible.
- Patients and/or their family/carer should be given information on TAC's complaint process and offered assistance if they wish to make a complaint.
- It should be recognised that the patient and/or their family/carer may be anxious, angry, frustrated and distressed even when Duty of Candour disclosures are conducted appropriately.

It is essential that the following does not occur:

- Speculation
- Attribution of blame
- Denial of responsibility
- Provision of conflicting information from different individuals

4.2.3 Consequences of Non-Compliance

Failure to comply with the Act is a criminal offence.

4.3 Being Open Process

4.3.1 Principles of Being Open

In 2009, the (former) National Patient Safety Agency (NPSA) developed a framework consisting of 10 principles to help organisations create and embed a culture of Being Open. These principles are:

- Acknowledgement
- Truthfulness, timeliness and clarity of communication
- Apology
- Recognising patient and carer expectations
- Professional support
- Risk management and systems improvement
- Multidisciplinary responsibility
- Clinical governance
- Confidentiality
- Continuity of care

The principles of Being Open are separate to statutory Duty of Candour requirements, although there is likely to be considerable overlap between the two.



4.3.2 Acknowledgement

All patient safety incidents should be acknowledged and reported on DATIX as soon as they are identified. In cases where the patient, their family and carers inform healthcare staff that something has happened, their concerns must be taken seriously and should be treated with compassion and understanding by all staff. Denial of a person's concerns will make future open and honest communication more difficult.

4.3.3 Truthfulness, Timeliness and Clarity of Communication

Information about a patient safety event must be given in a truthful and open manner by an appropriately nominated person. Communication should also be timely, informing the patient, their family and carers what has happened as soon as is practicable, based solely on the facts known at that time. Explain that new information may emerge as the RCA investigation takes place and that they will be kept up to date. 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.

4.3.4 **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 event. This should be in the form of an appropriately worded agreed manner of apology as early as possible. Both verbal and written apologies should be given.

Saying sorry is not an admission of liability and it is the right thing to do. Verbal apologies are essential because they allow face-to-face contact. A written apology, which clearly states the organisation is sorry for the suffering and distress resulting from the patient safety event, must also be given.

4.3.5 Recognising Patient and Carer Expectations

Patients, their families and carers can reasonably expect to be fully informed of the issues surrounding a patient safety event, and its consequences, in a face-to-face meeting with representatives from the organisation. They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times. Patients, their families and carers should also be provided with support in a manner to meet their needs.

This may involve an independent advocate or an interpreter. Information on the Patient Advisory and Liaison Service (PALS) and other relevant support groups should be given as soon as possible.

4.3.6 **Professional Support**

The organisation must create an environment in which all staff are encouraged to report patient safety events. Staff should feel supported throughout the patient safety event investigation process; they too may have been traumatised by the patient safety event. Therefore it is vital that



managers, when investigating patient safety incidents, adopt a supportive approach.

Staff will invariably experience a range of emotions following their involvement in a safety incident or adverse event and should be offered independent support at the earliest possible opportunity e.g. through Staff Support Counselling Services, mentors or clinical supervisors.

It is essential that an objective and non-judgmental investigation of the incident takes place and staff involved should be kept informed of the progress and outcome of any investigation. Staff should feel confident that communication with patients, carers and family members following a patient safety incident has been handled in the most appropriate way and that the main focus of the investigation is improving the understanding of incidents from the perspective of the patient. 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. Staff should be encouraged to seek support from relevant professional bodies.

4.3.7 Risk Management and Systems Improvement

Root Cause Analysis (RCA) or similar techniques should be used to uncover the underlying causes of patient safety events. This investigation should focus on improving systems of care, which will be reviewed for their effectiveness.

4.3.8 Multi-Disciplinary Responsibility

Our services are provided by multi-disciplinary teams, and 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 Being Open process is consistent with the philosophy that patient safety events usually result from system failures and rarely from actions of an individual. To ensure multi-disciplinary involvement in the Being Open process, it is important to identify clinical, nursing and managerial leaders who will support it. Both senior managers and senior clinicians must participate in the patient safety event investigation and clinical risk management.

4.3.9 Clinical Governance

Being Open requires the support of patient safety and quality improvements through clinical/care governance frameworks, in which patient safety events 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 that these changes are implemented, and their effectiveness reviewed. These findings should be disseminated to staff so they can learn from patient safety events. Audits should be developed to monitor the implementation and effects of changes in practice following a patient safety.

4.3.10Confidentiality



Details of a patient safety event should at all times be considered confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient. Where this is not practicable or an individual refuses consent to the disclosure, disclosure may still be lawful if justified in the public interest or where those investigating the patient safety event have statutory powers for obtaining information. Communications with parties outside of the clinical team should also be on a need to know basis and, where practicable, records should be anonymous. It is good practice to inform the patient, their family and carers about who will be involved in the investigations before it takes place, and give them the opportunity to raise any objections.

4.3.11 Continuity of Care

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



4.4 Duty of Candour and Being Open Flowchart

For all other incidents causing Where an incident results in harm, an apology should be moderate or severe harm or provided and any relevant death, FULL Duty of Candour information shared with the requirements apply patient and/or family in line with being open Staff members registered with a regulatory body must also ensure they are compliant with Duty of Candour requirements as stipluated in the relevant body's Code of Conduct Appropriate manager informs the patient and/or their family/carer that an incident has taken place within 5 working days of the incident Face-to-face meeting offered with patient and/or their family/carer as soon as practicable; ideally within 5 days of the incident where possible A sincere apology must be provided to the patient and/or their family/carer as well as an explanation of the investigation process and all known facts relating to the incident. This must be followed-up with a letter of apology including a summary of discussions that have taken place Where there is to be a RCA investigation, the Lead Investigator must offer the patient and/or their family/ carer involvement, including in establishing the TOR The Lead Investigator should establish how the patient and/or their family/carer would like to receive the final report and action plan and offer a face-to-face meeting to present the report The Lead Investigator is responsible for providing the patient and/or their family/carer with a copy of the final report and action plan within 10 working days of commissioner approval - delivered by hand where possible or special delivery.



5. PROCEDURES CONNECTED TO THIS POLICY.

There are no standard operating procedures connected to this policy.

6. LINKS TO RELEVANT LEGISLATION

Public Interest Disclosure Act 1998

Public Interest Disclosure Act 1998 was created by parliament to protect whistle- blowers from detrimental treatment or victimisation from their employers after they have made a disclosure of information about malpractice. This will include criminal offences, failure to comply with legal obligations, miscarriages of justice, threats to health and safety of an individual, damage to the environment and a deliberate attempt to cover up any of the above. The Act covers all workers including temporary agency staff, persons on training courses and all persons working for the NHS but it not volunteers.

GDPR and Data Protection

Data Protection Act 1998 (DPA 1998) is an act of the United Kingdom (UK) Parliament defining the ways in which information about living people may be legally used and handled. The main intent is to protect individuals against misuse or abuse of information about them. The DPA was first composed in 1984 and was updated in 1998. The Act changed in May 2018 to GDPR which extends the rights of individuals to further protection from data breaches and offers the Right to be Forgotten.

Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 Part 2 Duty of Candour

The purpose of the new duty of candour provisions is to support the implementation of consistent responses across health and social care providers when there has been an unexpected event or incident that has resulted in death or harm that is not related to the course of the condition for which the person is receiving care.

7. LINKS TO OTHER KEY POLICY/S INCIDENT REPORTING POLICY

The purpose of this policy is to make clear the system used for reporting incidents involving patients, staff and others undertaking activities on behalf of TAC.



Complaints and Compliments Policy

The purpose of this policy is ensure the has in place arrangements that manages complaints effectively in an open and transparent way and in accordance with legal requirements.

Risk Management Strategy Policy and Process

The purpose of this Risk Management Strategy/Policy is to provide TAC with a framework for the development of robust risk management processes throughout the organisation.

Also links to:

- Whistleblowing Policy
- Disciplinary Policy
- Nursing and Midwifery Council (2010) The Code: Standards of conduct, performance and ethics for nurses and midwives

8. REFERENCES

- Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016
- Care Quality Commission (2015) Guidance for Providers on Meeting the Regulations
- Department of Health (2009) Listening, Responding, Improving: A guide to better customer care
- Department of Health (2009) The NHS Constitution: The NHS belongs to us all General Medical Council (2009) Good Medical Practice
- Health and Safety Executive (2001) A Guide to Measuring Health & Safety Performance
- National Patient Safety Agency (2009) Being Open: Saying Sorry When Things Go Wrong
- National Patient Safety Agency (2004) Incident Decision Tree NHS Litigation Authority (2009)
 Apologies and Explanations Letter



9. ROLES AND RESPONSIBILITIES OF THIS POLICY

| Title | Role | Responsibilities |
|------------------------------------|----------------|--|
| TAC Board | Strategic | - Ensure that a culture of Being Open is maintained and supported |
| | Accountable | - Ensure that there is a robust system in place for the reporting and managing of such events, which includes supporting staff in Being Open with patients and/or families/carers following a patient safety incident. Operational responsibility is delegated |
| Director of Nursing, | Executive Lead | - Lead the Duty of Candour and Being Open agenda |
| AHPs and | | - Escalate any non-compliance with Duty of Candour requirements to the TrustBoard |
| Governance | | - Ensure any serious concerns regarding the implementation of this policy are brought the Boards attention |
| Governance Risk | Governance | - Report all notifiable patient safety events |
| Management Committee | | - Record compliance with statutory Duty of Candour requirements |
| Quality Manager | Quality | - Ensure systems and events are audited to evidence compliance |
| Clinical Directors, Group, | Implementation | - Ensure staff are aware of and comply with this policy |
| Directors and Group Head | | - Ensure patient safety incidents are reported in line with the TACs Incident Reporting Policy |
| Nurses | | - Ensure compliance with statutory Duty of Candour requirements and escalate cases of non-compliance |
| Group | Implementation | - To act as point of contact for Duty of Candour queries |
| Governance | | - Ensure Duty of Candour requirements have been met following notifiable patient safety incidents |
| | | - Escalate any incidents of non-compliance with Duty of Candour requirements to the Clinical Director, Group Director and Head Nurse |
| | | - Ensure Datix is up to date with Duty of Candour compliance information |
| Group Managers, | Operational | - Ensure any staff member who is involved in a patient safety incident has access to support |
| Service Managers and Ward Managers | | - Meet with patients and/or families/carers involved in a patient safety incident in accordance with statutory Duty of Candour requirements and the principles of Being Open |
| | | - Explain what led to the event occurring and any lessons learned |
| | | - Provide the patient and/or their family/carer with a verbal and writtenapology |
| | | - Document details of all apologies made to the patient and/ or their family/carer or refusal of face-to-face meeting where relevant |
| | | - Ensure the patient has been provided with appropriate ongoing support |
| | | - Ensure the patient and/or families/carer are given a contact name in the event of further queries/issues |
| | | - Arrange for transfer of care where the patient and/or families/carer requeststhis |
| | | - Communicate the patient and/or their family/carers wishes in relation to investigation involvement to the nominated Lead Investigator in |
| | | the event of a RCA investigation |
| All employees | Adherence | - Comply with statutory Duty of Candour requirements |
| | | - Ensure that patient safety events are reported as soon as possible and no later than 24 hours after occurring |



10. TRAINING

| What aspect(s) of this policy will require staff | Duty of Candour | |
|--|---|--|
| training? | | |
| Which staff groups require this training? | Senior Managers/ Senior Clinicians/ Service | |
| | Managers/ Ward Managers | |
| Is this training covered in the Mandatory and Risk | Yes | |
| Management Training Needs Analysis document? | | |
| If no, how will the training be delivered? | N/A | |
| Who will deliver the training? | Training Team | |
| How often will staff require training | As identified as required by Head Nurse/ | |
| | Group Director/ General Manager/ | |
| | Clinical Director | |
| Who will ensure and monitor that staff have this | Group Heads of Nursing | |
| training? | | |

10 EQUALITY IMPACT ASSESSMENT

TAC is committed to ensuring that the way we provide services and the way we recruit and treat staff reflects individual needs, promotes equality and does not discriminate unfairly against any particular individual or group. Please contact us if you require this in a different format e.g. larger print, Braille, different languages or audio tape.

11 DATA PROTECTION AND FREEDOM OF INFORMATION

This statement reflects legal requirements incorporated within the GDPR and Freedom of Information Act that apply to all our staff who work within the public sector. All staff have a responsibility to ensure that they do not disclose information about TAC's activities in respect of patients in its care to unauthorised individuals. This responsibility applies whether you are currently employed or after your employment ends and in certain aspects of your personal life e.g. use of social networking sites etc. TAC seeks to ensure a high level of transparency in all its business activities but reserves the right not to disclose information where relevant legislation applies.

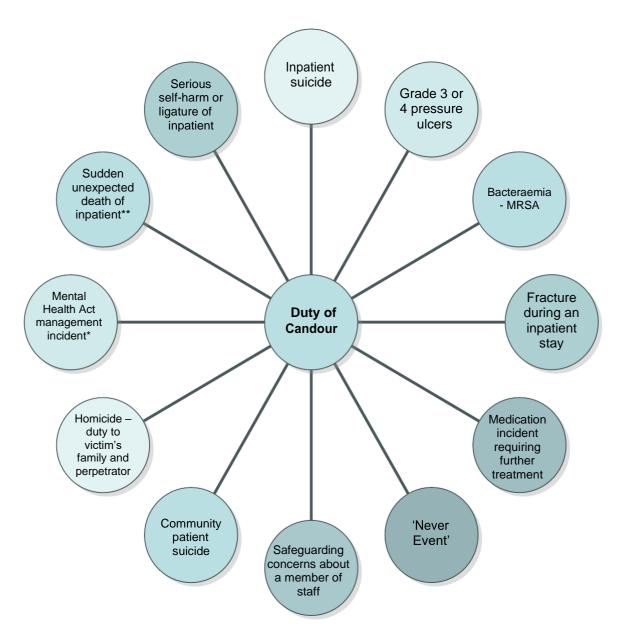


12 MONITORING THIS POLICY IS WORKING IN PRACTICE

| What key elements will be monitored? | Compliance with statutory Duty of Candour | |
|---|---|--|
| | requirements | |
| Where described in policy? | 4.0 Processes | |
| How will they be monitored? | Via Incident reporting through the Quality | |
| | Dashboard as a KPI | |
| Who will undertake this monitoring? | Management team | |
| How Frequently? | Monthly | |
| Group/Committee to receive and review results | IRMG and CGC | |
| Group/Committee to ensure actions are | Executive Board and Clinical Quality Review | |
| completed | Meetings | |
| Evidence this has happened | 100% compliance with requirements on | |
| | dashboard | |



APPENDIX 1: DUTY OF CANDOUR APPLICATION



It is important that the above is used alongside the definitions provided of 'relevant person', levels of harm and is based upon sound clinical judgment.

- * Maladministration, wrongful detention etc.
- ** If found to be result of natural causes, this would revert to Being Open principles rather than Duty of Candour



APPENDIX 2: EXAMPLES OF INCIDENTS THAT TRIGGER THE THRESHOLDS FOR DUTY OF CANDOUR.

Taken from: Regulation 20: Duty of candour Information for all providers: NHS bodies, adult social care, primary medical and dental care, and independent healthcare (March 2015)

These examples are to illustrate situations of notifiable safety incidents that trigger the threshold for the duty of candour regulation. This is not an exhaustive list. Where possible the examples used in this guidance are sourced or adapted from the following two documents: 'Seven steps to patient safety for primary care' (National Patient Safety Agency 2006) and 'Duty of Candour Threshold Review Group Review of Definitions' (Royal College of Surgeons 2014).

Surgery

| Examples | Interpretation |
|--|--|
| A patient arrived for planned surgery but had not been given the correct advice to discontinue their Warfarin treatment. The surgery had to be postponed. | This would be an example where an incident appeared to have resulted in moderate harm |
| During a difficult appendectomy the patient's bowel was accidentally perforated. This was recognised the day after surgery when the patient became increasingly unwell. The patient returned to theatre where the problem was fixed, and the patient made a full recovery. | This would be an example where an incident appeared to have resulted in moderate harm |
| Wrong site surgery: The identities of two patients on the list are mixed up and one patient undergoes the wrong operation on the incorrect site. The patient is permanently harmed as a result. | incident appeared to have resulted |
| An elderly patient undergoes a coronary artery bypass operation. The patient is appropriately consented for the risks of the operation, including stroke and death. Unfortunately, the patient sustained a large stroke during the operation, and subsequently died as a result. | This would be an example where an incident resulted in death |
| A patient experienced pain during an elective Caesarean section due to incomplete anaesthesia from an epidural line. The patient found this experience traumatic and subsequently had an acute episode of severe anxiety and depression which lasted more than 28 days | This would be an example where an incident appeared to have resulted in prolonged psychological harm |



Medicine

| Examples | Interpretation |
|--|--|
| A doctor causes a pneumothorax whilst placing a Central Venous Catheter (a recognised complication). The patient requires a chest drain to be inserted and a short stay on the Intensive Care Unit. The patient makes a full recovery | This would be an example where an incident appeared to have resulted in moderate harm |
| A patient developed a small grade 2 pressure ulcer during an admission to treat an acute cardiac problem. Although they were now fully mobile, they need district nursing visits after discharge home to check and dress the ulcer until healing was complete two weeks later | This would be an example where an incident appeared to have resulted in moderate harm |
| A patient incurs an extravasation injury (soft tissue burn) from an intravenous line causing irreversible scarring and bone damage. | This would be an example where an incident appeared to have resulted in severe harm |
| A confused elderly patient was supposed to have 1:1 supervision on a medical ward. The patient was left unsupervised for a period of time whilst the shift change was occurring, and the patient fell out of bed, sustaining a severe head injury from which they later died. | This would be an example where an incident resulted in death |
| A patient who is normally very shy sustains an extravasation injury (soft tissue burn) from an intravenous line. This causes irreversible and extensive scarring on her arm and as a result she becomes severely socially anxious for which she needs a prolonged period of therapy. | This would be an example where an incident appeared to have resulted in prolonged psychological harm |