

Duty of Candour Implementation

Recommendation:-

The Board is asked to note that NHS GG&C has in place the arrangements which ensure we meet the new legal duty described as the Duty of Candour.

Purpose of Paper:-

The paper describes the procedural adaptations and organisational support processes to ensure governance of the legal duty described as Duty of Candour (which applies when people experience significant harm as a consequence of healthcare).

Key Issues to be considered:-

The Boards approach to clinical risk management has operated a “being open” principle for over a decade. This has been a mandatory policy requirement for four years which has increased significantly the volume of reports being openly shared with patients or families affected by adverse events.

Implementation of the duty of candour builds on the culture of openness and supports consolidation of established practices.

The key issues in adapting existing arrangements are described, along with the ongoing monitoring process.

NHS GG&C is compliant with the new regulatory requirements and will continue work with the national agencies to further improve our response to and care of people affected by harm in healthcare.

Any Patient Safety /Patient Experience Issues:-

The Duty applies when patients experience significant harm in healthcare.

Any Financial Implications from this Paper:-

There are additional opportunity costs within the Clinical Governance Support Unit who are allocating additional time and administrative resource to ensure practice is appropriate.

Services will also have potential opportunity costs associated with staff training and support.

Any Staffing Implications from this Paper:-

There are staff support requirements identified in the policy and guidance with signposting to the available support arrangements.

Any Equality Implications from this Paper:-

The policy has been subject to an EQIA

Any Health Inequalities Implications from this Paper:-

None specified

Has a Risk Assessment been carried out for this issue? If yes, please detail the outcome:-

None specified

Highlight the Corporate Plan priorities to which your paper relates:-

Duty of Candour implementation and governance

Author – A. Crawford

Tel No – 0141 201 0814

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NHS BOARD MEETING

Dr Jennifer L. Armstrong
Medical Director

17th April 2018

Paper No: 18/19

Duty of Candour

Recommendation

The NHS Board is asked to note that NHS GG&C have prepared appropriately for implementation of the Duty of Candour (Scotland) Regulations 2018.

Purpose of Paper

To describe how GG&C have prepared for the new legislation and have processes in place to guide, train and support staff with the new requirements. To share the new policy which has been prepared and which provides the key operational principles and practice to reinforce and maintain the legal duty of candour within NHS GG&C

Context

The requirements for the Duty of Candour (DoC) procedure are set out in the regulations published on 13th February 2018 using the power in the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill (2016) for implementation in April 2018. The Healthcare, Quality and Improvement Directorate of Scottish Government notified the Board of the publication of further non-statutory guidance on 3 April 2018.

The legal Duty of Candour means apologising, acknowledging and explaining what happened to patients who have been harmed as a result of a notifiable safety incident. It ensures that communication is open, honest and occurs as soon as possible following an incident. The Duty of Candour encompasses communications between healthcare organisations, healthcare teams and patients and/or their carers.

Preparatory Development

GG&C established a formal requirement of “being open” for Significant Clinical Incidents (SCI) over four years ago. In Feb 2017 the SCI policy was updated to include a specific mention of Duty of Candour. In a recent review we confirmed 90% of Significant Clinical Incident Reports are now shared with patients or families. The long standing implementation of the “being open” principle means the NHS GG&C has approached a position where it was complying spirit of the Duty of Candour for Significant Clinical Incidents. Therefore this is not a major shift in practice but does require a modified structure of communication, confirmation and recording.

We have already completed a number of activities to create awareness of the Duty and its requirements. In the last two years our staff have actively contributed to national policy development and educational designs. Within NHS GG&C we have been generating awareness of the Act through direct communication with key groups. The core brief has been used to alert the organisation to the new legislation and for consultation on the new policy. There is now a

section of the Clinical Governance Support Unit Staffnet page which contains information on DoC, including general fact sheets and templates. The national resources are accessible via the internal Staffnet site which also contains the bespoke locally developed guidance.

A short life working group (SLWG) was established to develop a Duty of Candour Policy. This group involved staff from HSCPs, Acute Services Division and specialist support functions. The SLWG developed a draft document which was then submitted to broad consultation. It includes the policy position with explanation and guidance as to how to follow the legislative requirements for DoC. The comments along with Regulations were considered and further adaptations made to the policy before the SLWG signed it off as ready for final approval. The Corporate Management team have reviewed the policy and it is with the Board Clinical Governance for final approval at its meeting on 16th April 2018.

NHS GGC staff have developed training resources and contributed a new Learn Pro module created with NHS Education for Scotland. This is now available via our Learn Pro site and provides a comprehensive overview with example of cases and videos of DoC discussions. NHS GG&C has developed a DoC disclosure training half day event aimed at clinicians and managers who required further skills in discussing clinical incidents with patients / relatives. There have been five sessions to date with staff evaluating each session very positively.

Datix will be used to hold information on the procedural requirements and the information required for an annual report which the Board is obliged to publish. The coding changes within Datix have been completed.

Implementation

The policy will be issued via Directors and Chief Officers, who will be asked to ensure that all of their senior managers and clinicians read and become familiar with the policy. The policy is designed to provide clear guidance to those senior officers carrying a formal role. However bespoke awareness training will be available on request if senior teams experience any additional development needs. Further information and guidance will be developed and published via Staffnet, including worked examples of DoC cases.

A process to monitor the DoC policy using Datix has been trialled over the last three months. This will be finalised and will be used as a basis to provide feedback to our services on the level of policy adherence.

The implementation of the policy will be coordinated through the Clinical Governance Support Unit with update reports to the Medical Director at the Board Clinical Governance Forum, and linked to the Clinical and Care Governance Committee. Preparation and publication of an annual report on Duty of Candour compliance will be met through this monitoring process.

Conclusion

The Board has put in place the necessary adjustments to meet the new Duty of Candour. Implementation will be subject to ongoing monitoring via the Clinical Governance arrangements culminating in the publication of an annual report.



POLICY & PROCEDURE

DUTY OF CANDOUR

COMPLIANCE

Lead Manager:	Head of Clinical Governance
Responsible Director:	Medical Director
Approved by:	Board Clinical Governance Forum
Date approved:	(16/4/18 provisional)
Date for Review:	Three years from date of approval
Version:	Final for approval at Brd CG Forum

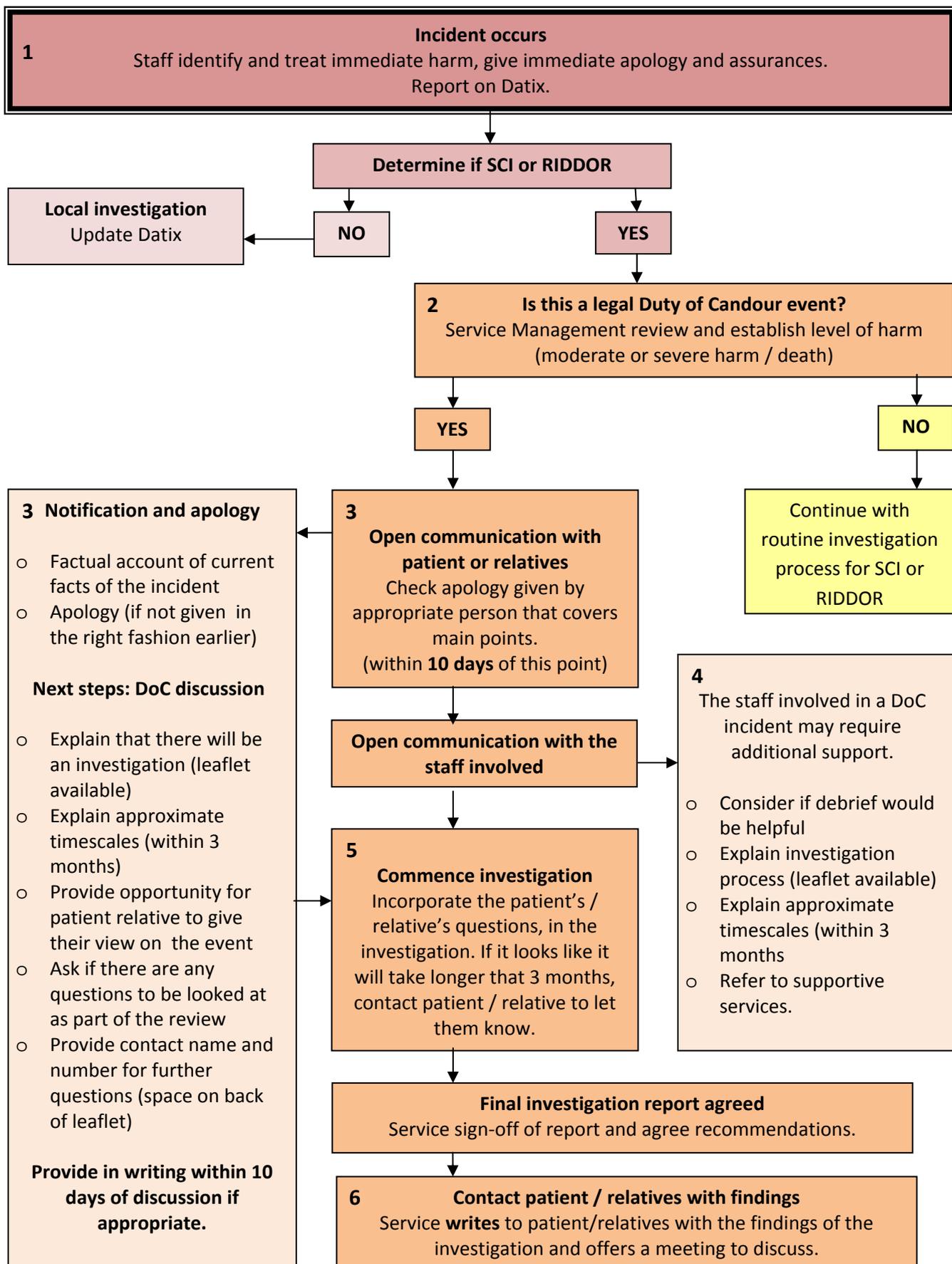
CONTENTS	Page
1. Definitions	3
○ Notifiable safety incident	
○ Incident	
○ Harm	
○ SCI	
○ RIDDOR	
2. Process Overview	4
3. Introduction & Purpose	5
4. Responsibilities & Accountabilities	6
5. Policy & Principles	8
○ Identifying the need for Duty of Candour	
○ Principles of Duty of Candour	
6. Process	10
○ Phase 1: Incident detection and reporting	
○ Phase 2: Assessment of Duty of Candour	
○ Phase 3: Patient and / or relevant person engagement	
○ Phase 4: Staff support	
○ Phase 5: Investigation	
○ Phase 6: Feedback to patient and / or relevant person (Process completion)	
7. Recording	15
8. Training	15
9. Monitoring Policy Implementation	16
10. Appendix 1 –Harm Parameters	18
11. Appendix 2 - Summary of key points	19
12. Appendix 3 – Particular patient circumstances for consideration	20
13. Appendix 4 – Training Plan	22

1. DEFINITIONS

It is important that there is clear understanding of the language used within the Duty of Candour regulations and this policy, therefore please note the section below with definitions.

Candour	The quality of being open and honest.
Notifiable safety incident	This is any unintended or unexpected incident caused by the organisation that in the reasonable opinion of a healthcare professional has resulted in moderate harm, severe harm, death or prolonged psychological harm (that is, psychological harm which a patient has experienced, or is likely to experience, for a continuous period of at least 28 days). The Duty of Candour applies equally to patient safety incidents and complaints.
Incident	This is any unintended or unexpected event that could have or did lead to harm. Serious Incidents are also likely to produce significant legal, media or other interest which, in addition to harm, loss or damage, may result in loss of the Board's reputation or assets.
Harm	This is defined as injury (physical or psychological), disease, suffering, disability, ill health or death to a person.
Significant Clinical Incident	Significant Clinical Incidents (SCI) are those events that have or, could have significant or catastrophic impact on the patient and may adversely affect the organisation and its staff and have potential for wider learning (i.e. learning that can be gained for future care delivery). See SCI policy for more information – http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Clinical%20Governance/Clinical%20Risk/SCI%20Policy%20and%20Toolkit/SCI%20Policy%20Final%202017.pdf
RIDDOR:	Reporting of Injuries, Diseases & Dangerous Occurrences Regulations 2013: Certain categories of work related accidents/incidents are required by law to be reported to the Health & Safety Executive timeously. See RIDDOR a guide for managers for more information - http://www.nhsggc.org.uk/media/237157/accident-reporting-riddor.pdf

2. **PROCESS OVERVIEW** (Numbers in boxes refer to process phases p10-15 in policy)



3. INTRODUCTION & PURPOSE

There is both an ethical responsibility, as well as a professional and statutory requirement for health care professionals and managers to inform patients who have suffered as a result of a safety incident that was caused by the organisation and has resulted in harm.

This is termed Duty of Candour and is included in health professional's codes of conduct instructing staff to be honest with patients concerning their care and treatment. This document outlines the specific requirements in relation to the new **legal requirement** of Duty of Candour and patient safety incidents that fall into this category are termed 'notifiable patient safety incidents' and specifically refers to apologising, acknowledging and explaining what happened to patients who have been harmed due to an act or omission by the organisation. This ensures that communication is open, honest and occurs as soon as possible following an incident. It may be that an investigation is required to establish if the event was avoidable and in these circumstances an apology should still be offered at the outset.

This Duty of Candour encompasses communications between healthcare organisations, healthcare teams and patient and / or relevant person. For clarity, when Duty of Candour is referred to in this policy it will be the legal Duty of Candour.

It is also recognised that being open and honest is a requirement to improving patient safety and the quality of health care systems.

The purpose of this policy is to:

- Improve the support, timeliness, quality and consistency of communication with patients and / or relevant persons when a notifiable safety incident occurs so that they receive prompt information to enable them to understand what happened; that a meaningful apology is offered; and that patients and / or relevant persons are informed of the action the Health Board or Health and Social Care Partnerships (HSCPs) will take to try and ensure that a similar event does not recur.
- Provide clear information to staff on what they should do when they are involved in a notifiable safety incident and the support available to them to cope with the consequences of what happened and to communicate with patient and / or relevant person effectively.

This policy has been informed by the requirements set out in:

- The Duty of Candour procedure, and regulations to be made using the power in the [Health \(Tobacco, Nicotine etc. and Care\) \(Scotland\) Bill \(2016\)](#) for implementation in April 2018.

Creating the environment where staff are open about what happened and discussing patient safety events promptly, fully and compassionately with patients and / or relevant persons can:

- Help maintain trust and confidence necessary for an effective therapeutic relationship.
- Help patients and / or relevant persons cope better with the after-effects.
- Promote a thorough investigation into the patient safety incident including the patient's and / or relevant person's perspective.
- Provide patients and / or relevant persons with assurance that lessons learned will be implemented to help prevent a similar type of incident.
- Provide an environment where patients and / or relevant persons, healthcare professionals and managers feel supported when things go wrong.

It is the intention that this policy will support NHSGGC's ambitions to meet its Public Sector Equality Duty as per the Equality Act (2010). In order to achieve this, the policy must be considered alongside the existing repository of anti-discriminatory documentation including the Clear to All Policy and other communication support resources including the NHSGGC Interpreting Service (including telephone interpreting) and translation services. Uptake of the policy will be monitored through appropriate patient engagement methodology to capture disaggregated data by protected characteristic and inform any future development.

4. RESPONSIBILITIES & ACCOUNTABILITIES

4.1 Greater Glasgow & Clyde Health Board

GG&C Health Board will monitor that the processes in place with regard to Duty of Candour work effectively and is committed to promoting a culture of openness within services.

4.2 The Chief Executive

The Chief Executive has overall responsibility for ensuring integrated governance, including risk management and clinical governance within the Board which includes the Duty of Candour Policy. The Chief Executive delegates the responsibility for patient safety to the Board Medical Director.

4.3 Medical Director

The Medical Director is the designated board member responsible for reporting to the Board on patient safety and clinical quality issues. The Medical Director will be accountable for ensuring that the policy is adhered to and that the relevant staff have access to Duty of Candour training.

4.4 Directors and Chief Officers

The senior management team of Acute Division Sectors and Directorates and the Chief Officers and Clinical Leads in HSCPs are responsible for ensuring Duty of Candour principles are followed for their services and will have day to day responsibility for ensuring that the policy is implemented.

4.5 General Managers, Heads of Department, Clinical Directors, Lead Nurses or equivalent

All managers working within the organisation are expected to follow the Duty of Candour Policy and have a responsibility for ensuring that all patient safety incidents are acknowledged and reported as soon as they are identified in line with the Significant Incident Policy. As commissioners of a Significant Clinical Incident investigation managers should seek assurance that the Duty of Candour policy has been followed. They should be aware that an individual member (or members) of staff might require support during the investigation and provide the appropriate help and guidance for them which may in some cases come from external agencies.

4.6 Incident Investigation Commissioner / Complaints Investigating Officer

The senior manager responsible for managing the incident or complaint is responsible for ensuring that Duty of Candour is discharged in line with the policy. They should ensure coordination of the communication with the patient and / or relevant person including that the opportunity has been given to incorporate patient and / or relevant person questions in the investigation process. They must also ensure that the patient and / or relevant person's concerns and issues are addressed as part of the investigation and feedback of the outcome given.

4.7 All those with Managerial & Supervisory Responsibilities for Clinical Staff.

All members of clinical staff with patient contact should be familiar with the procedural aspects of this policy. They should follow the guidance to achieve openness with patients and / or relevant persons as well as healthcare partners and other healthcare organisations where applicable.

When an error is made where harm has been caused by the care, treatment or service provided, the staff treating the patient should provide an immediate apology where possible and explain the issue will be raised with managers for investigation. These patient safety incidents must be reported on the incident reporting system (Datix) and escalated to the Manager on duty at the time of the incident for consideration for Significant Clinical Incident.

4.8 All Staff

All staff who have the potential to become aware of harm to patients require to be aware of the legal duty in relation to Duty of Candour. They should report any potential Duty of Candour cases to their line manager.

4.9 Independent Contractors

The Duty of Candour is the legal duty of any contractor, who must have arrangements in place which operate in accordance with the Act and any associated regulations or directions.

4.10 The Head of Clinical Governance

The Head of Clinical Governance is the policy lead for NHS GG&C. This involves a monitoring role, liaising with management teams to ensure that the need for Duty of Candour is recognised and implemented and documented as per the policy. The Clinical Governance Support Unit will provide support and guidance to those managers discharging Duty of Candour on behalf of the organisation.

The Head of Clinical Governance will also act as an arbitrator if any disagreements regarding disclosure arise to ensure compliance with the Duty of Candour legislation.

4.11 Monitoring Committees

The Acute Division Clinical Governance Forum, Partnership Clinical Governance Forum & Mental Health Clinical Governance Group will receive reports from the Clinical Risk Team on Duty of Candour to monitor compliance and identify any areas of concern, taking action where appropriate.

The corporate oversight of policy implementation will be maintained by the lead Executive, i.e. Medical Director, via regular reports at the Board Clinical Governance Forum.

The Non Executive oversight will be provided through the Clinical and Care Governance Committee, which is a standing sub-committee of the NHS Board and will seek assurance relating to systems and procedures required to meet the legal duty of candour. The Committee will receive reports relating to the Duty of Candour process and issues highlighted in order to provide assurance to the Board, or to raise concerns.

5. POLICY & PRINCIPLES

5.1 Identifying the Need for Duty of Candour

Effective communication between staff who recognise an incident and their management team is vital in order to ensure that the Duty of Candour process is implemented from the outset. As soon as a patient safety event is identified where harm has occurred, the top priority is to ensure appropriate clinical care is given and action taken to prevent further harm. Whenever practicable, appropriate discussion and patient consent should be gained prior to providing any additional treatment that is required.

There can be very rare occasions when an incident has been declared a Duty of Candour event and the management team responsible for the incident decide that it is inappropriate to disclose this to the patient and / or relevant person.

This is usually on the grounds that it is felt to be in the best interests of the patient and / or relevant person as the disclosure would cause harm.

This decision must be escalated to the senior management team of the area the incident occurred (Sector, Directorate, HSCP) for agreement. If there is any disagreement between those involved in the management of the incident and the management team, the Head of Clinical Governance will act as an arbitrator for the final decision to ensure compliance with the Duty of Candour legislation.

The reason disclosure has not been given would be recorded on the Datix system.

It may also be the case that despite best efforts the organisation is unable to communicate with next of kin for a patient who has died as there may be no family who has been in contact with the patient for example. In these cases as long as effort has been made to implement Duty of Candour, it would not be recorded as a failure to follow the process.

The table in appendix 1 outlines the parameters for implementing Duty of Candour in relation to the harm caused however one must remember that this is harm that in the opinion of a registered health professional is caused by an untoward incident, not natural progression of disease or an unavoidable complication.

If a harm event is not reported at the time but is identified through a complaint the management of the service responsible should consider if the incident element of the complaint should be investigated as a significant clinical incident rather than a complaint. This decision should consider the complexity of the investigation, the likelihood of organisational responsibility for the patient outcome and advice from complaints and clinical risk staff.

5.2 Principles of Duty of Candour Practice

The following are the main principles which should inform practice. This must not be considered a 'tick box' exercise but as a way of working to ensure openness, trust and good communication.

PRINCIPLE	Detail
Acknowledge	<ul style="list-style-type: none"> • Acknowledged and report notifiable incidents as soon as they are identified. • Concerns from the patient and / or relevant person must be taken seriously. • Denial of concerns will make future open communication more difficult.
Truthfulness Timeliness Clarity	<ul style="list-style-type: none"> • An appropriate person should be nominated for the communication. • Information must be given in an open and truthful manner. • Communication should also be timely giving information as soon as is practicable, based solely on the facts known at that time. • Explain that new information may emerge as the investigation takes place. • Patients, their families and carers should receive clear information and be given a single point of contact for any questions or requests they may have.

Apology	<ul style="list-style-type: none"> • Patients, their families and carers should receive a meaningful apology (defined as a sincere expression of sorrow or regret) for the harm that has resulted from the incident. Saying sorry is not an admission of liability and it is the right thing to do. • Both verbal and written apologies should be considered. Verbal apologies are desirable 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 incident, must also be considered. Some circumstances relating to the event dictate the best way to apologise. • The SCI leaflet for patients and relatives gives expressions of regret therefore use of this leaflet assists the Duty of Candour process. • Openness and honesty towards patients is supported and actively encouraged by many professional bodies including the Medical Defence Union, the Medical Protection Society the General Medical Council, General Pharmaceutical Council, the Nursing and Midwifery Council and the Health and Care Professions Council.
Recognising Patient and Carer Expectations	<ul style="list-style-type: none"> • Patients and / or relevant persons can reasonably expect to be fully informed of the issues surrounding a notifiable safety incident, and its consequences, in a face to face meeting with representatives from the organisation. • Patients and /or relevant persons should be advised on how to contribute questions or information for the review of an incident • They should be treated sympathetically, with respect and consideration and confidentiality must be maintained at all times. • Patients and / or relevant persons should also be provided with communication support in a manner to meet their needs. This may involve an interpreter. • Relevant information should be provided for example copies of SCI draft and final reports and access to case records.
Staff Support	<ul style="list-style-type: none"> • This organisation aims to create an environment in which all staff feel encouraged to report adverse events. • Staff will be supported throughout a significant clinical incident investigation process. The SCI toolkit contains: <ul style="list-style-type: none"> - A leaflet explaining the SCI process - A leaflet for staff support - A reflective exercise template to help learning from the event • Staff will be encouraged to seek support from Occupational Health • Counselling services are available to all NHS Greater Glasgow & Clyde employees. Face to face and telephone consultations are available. All appointments are confidential. • Staff are also encouraged to seek help from their relevant professional bodies.
PRINCIPLE	
Risk Management and Systems Improvement	<ul style="list-style-type: none"> • Root Cause Analysis methodology will be used to uncover the underlying causes of significant adverse events. This investigation will focus on improving systems of care, which will be reviewed for their effectiveness.
Multi-Disciplinary Responsibility	<ul style="list-style-type: none"> • The Duty of Candour policy applies to all staff involved in patient care. Healthcare provision involves multi-disciplinary teams. This should be reflected in the way that patients and / or relevant persons are communicated with when things go wrong. • Both senior managers and senior clinicians must participate in the safety incident investigation process.
Learning organisation	<ul style="list-style-type: none"> • Structures are in place to disseminate the lessons and actions taken from adverse event investigations in order to reduce the likelihood of their

	<p>recurrence.</p> <ul style="list-style-type: none"> • The Service Senior Management Teams are accountable for ensuring that processes are in place at Sector/Directorate and speciality level to monitor compliance with action plans developed as a result of notifiable safety incidents.
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6. PROCESS

Meeting the Duty of Candour is a process rather than a one-off event. There are a number of stages in the process; the duration of the whole process depends on the incident, the needs of the patient and / or relevant person, and how the investigation into the incident progresses. The flowchart in Appendix 1 provides an overview of the Duty of Candour process.

Phase 1 – Incident detection and reporting

The Duty of Candour process begins with the recognition of a notifiable safety incident which may be identified / reported by:

- a member of staff at the time of the incident;
- a member of staff retrospectively when an unexpected outcome is detected (such as at Morbidity and Mortality meetings);
- a patient and / or relevant person who express concern or dissatisfaction with the patient's healthcare either at the time of the incident or retrospectively such as in a complaint
- incident detection systems such as incident reporting or medical records review;
- Procurator fiscal following a post mortem or investigating on behalf of a family.

When a patient 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 a GP or care home, when the incident has occurred in acute care. Patients and / or relevant persons need to 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 healthcare team.

Phase 2 – Assessment of Duty of Candour

The assessment will include two specific elements and both must be in place for the event to be an organisational Duty of Candour event;

- **Was there significant harm?** (see table appendix 1) and outcomes below
- **Was the organisation responsible for the harm?** i.e. this is not a natural progression of disease or an unavoidable complication.

The Act describes the patient outcomes that would be applicable to Duty of candour as:

- A.** The death of a person.

- B.** Permanent lessening of bodily, sensory, motor, physiologic or intellectual functions (severe harm).
- C.** Harm which is not severe but which results in one or more of the following:
 - An increase in the person's treatment
 - Changes to the structure of the person's body
 - The shortening of life expectancy of the person
 - An impairment of the sensory, psychological, motor or intellectual functions of the person which lasted, or is likely to last, for a continuous period of at least 28 days.
- D.** The person requires treatment by a registered health professional in order to prevent:
 - The death of the person, or
 - An injury to the person which, if left untreated, would lead to one or more of the outcomes mentioned in B or C.

It may be in some cases the second question regarding responsibility, is not able to be answered until the investigation is concluded therefore service should act like the event is a duty of candour event until the investigation proves otherwise (as would be the normal course of investigation for a Significant Clinical Incident investigation).

With the exception of a few complaints alleging harm a legal Duty of Candour event will be a Significant Clinical Incident and should be managed through this well defined process. However, if a service management team do not wish to manage a Duty of Candour event through this process, all the criteria of this policy **must** still be met including the documentation of relevant Datix fields for inclusion in the annual report.

Phase 3 – Patient / family engagement

It is vital to be clear on what the patient and / or relevant person has been told to ensure all the elements of the process are met. Service should identify who will be responsible for discussion with the patient and / or relevant person. This could be a contact from the service or from the investigation team. This person will identify the patient's needs and communicate them back to the clinical and investigation team to ensure all ongoing care issues are identified and any questions the patient and / or relevant person may have about the incident are addressed in the investigation.

The person(s) communicating with the patient and / or relevant person should:

- have a good grasp of the facts relevant to the case;
- be a senior clinician/manager or have sufficient experience and expertise in relation to the case to be credible to patient and / or relevant person and colleagues;
- have excellent interpersonal skills, including being able to communicate with patients and/or relevant persons in a way they can understand and avoiding excessive use of medical jargon;
- be willing and able to offer an apology, reassurance and feedback to patient and / or relevant person;
- be able to maintain a medium to long term relationship with the patient and / or

relevant person, where possible, and to provide continued support and information;

- be culturally aware and informed about the specific needs of the patient and / or relevant person.

It is unacceptable for junior staff to be delegated the responsibility to lead a Duty of Candour discussion unless they volunteer and their involvement takes place in appropriate circumstances (i.e. they have received appropriate training and mentorship for this role).

Consideration should be given to the timing of communication. It is helpful if an apology can be given as soon as appropriate, even if the cause of the event is not known at this point.

It may be necessary to apologise in writing as the patient may not be an inpatient at the time the event is identified. It may be necessary to set up a meeting with the patient and / or relevant person before the investigation commences to explain the process and to gather their questions. If such a meeting takes place it can be helpful to follow this up with a letter confirming what was agreed at the meeting.

The leaflet regarding the SCI process for patients, relatives and parents provides an expression of regret and provides a space for the contact person from the organisational to be identified. The leaflet encourages the patient and / or relevant person to provide information or to ask any questions about the review. This information must be fed back to the investigation team so we can ensure any questions are answered as part of the investigation.

When deciding the time and form of communication the following should be considered:

- clinical condition of the patient
- mental capacity
- patient preference (in terms of when and where the meeting takes place)
- privacy and comfort of the patient;
- availability of key staff involved in the incident and in the Duty of Candour process;
- availability of support staff, for example a translator or independent advocate, if required;
- meeting location (appropriately supportive)

In certain patient circumstances i.e. when a patient dies; children or patients with different communication needs etc there will be particular considerations to be made in the Duty of Candour process see Appendix 2.

It is important to ensure there is a consistent approach by all team members around discussions with the patient and / or relevant person.

The Duty of Candour discussion with the patient and/or relevant person should take place within 10 working days of becoming aware that a notifiable safety incident has occurred. The member of staff who is leading the discussion must introduce themselves including their role in the process i.e. the manager of the service or the lead investigator or a member of the investigation team.

The patient and / or relevant person should be notified that an incident has occurred and provided with an account with all the facts known about the incident to date recognising

in some circumstances there may be little information to be given at this stage. Where there is disagreement about the facts, communication about these issues should be deferred until after the investigation has been completed.

There should be an expression of genuine sympathy, regret and an apology for the harm that has occurred.

The patient's and / or relevant person's understanding of what happened, views and concerns should be taken into consideration. Any questions that they have should be formally noted for inclusion in the investigation process and assurance given that these are being heard and taken seriously.

Appropriate language and terminology should be used when speaking to patient and / or relevant person. If a patient's and/or relevant person's first language is not English or if there are any other particular communication issues appropriate support should be made available.

If the patient is still receiving care, an explanation should be given about what will happen next in terms of the long term treatment plan and investigation findings.

The patient should be provided with contact details so that if further issues arise later there is a conduit back to the relevant healthcare professionals.

It should be recognised that patients and/or relevant persons may be anxious, angry and frustrated even when the Duty of Candour discussion is conducted appropriately.

Any information given relating to the patient's clinical condition or treatment planned should be recorded in the medical records.

It may be desirable to follow this initial Duty of Candour discussion with a written account of what has been discussed and agreed which could be given or sent to the patient and / or relevant person.

It is essential that the following does **not** occur:

- speculation and assumption;
- attribution of blame;
- criticism or comment on matters outside their own experience;
- denial of responsibility;
- conflicting information from different individuals.

Phase 4 – Staff Support

It is also acknowledged that staff involved in an incident involving requiring Duty of Candour implementation may require additional support. It is important that staff are informed regarding the investigation process and what will be expected from them in terms of recollection of events or interviews. Staff should also be reassured that the purpose of the investigation is for learning and not to apportion blame. Leaflets are available for staff to explain [Duty of Candour](#) and the [Significant Clinical Incident \(SCI\) Investigation process](#). Guidance is also available in the SCI toolkit on how to write a [recollection of events](#) and also a [template for reflective practice](#).

There is also a [staff support leaflet](#) in the SCI toolkit recognising the emotional response experienced by staff following an incident.

If additional support is required, this should be accessed initially through their line manager who will assess if a period of supervision, training or identifying a colleague for ongoing support would be helpful.

NHS Greater Glasgow and Clyde provides an Occupational Health Service which is a multi-disciplinary team. Our Occupational Health Service provide both physical and mental health support to staff who experience distress and counselling for our staff is an integral part of our service. The Occupational Health Service recognises that our staff are exposed to difficult and challenging clinical situations and by the virtue of their role may experience psychological and emotional distress as a result of their role.

The Occupational Health Service provides Counselling Services which are available to all NHS Greater Glasgow & Clyde employees within the Occupational Health Department. We offer face to face and telephone consultations. All appointments are confidential and staff are free to access the service on a confidential and individual basis.

Counselling is available for both work and personal stressors and this is an opportunity for staff to openly discuss their concerns in a safe and confidential environment.

Our Occupational Health Service further provides self help materials where staff can access on their terms information such as sleep deprivation, anxiety and depression which may result from experience or exposure to vicarious trauma or distress during their work. Our Staff Intranet site (HR Connect) provides a range of materials and details of support services outside of the NHS which can also provide staff with support they need, Information on mental health & wellbeing can also be found in our Resource Hub.

Phase 5 – Investigation

The investigation team should ensure they have been informed of any issues to be addressed in the investigation that have been raised by the patient and / or relevant person.

If it looks likely that the investigation will take longer than 3 months, the patient and / or relevant person must be contacted to let them explain and apologise for the delay.

Clinical Risk, Health & Safety and Complaints teams will liaise with each other to avoid confusion and duplication if there is likely to be overlap.

Where there are implications for continuity of care, it may be valuable to consider including the GP.

Phase 6 – Feedback to patient and / or relevant person (Process completion)

After completion of the incident investigation, and agreement by the commissioning management team, the service must feedback the findings to the patient and / or relevant person unless they have declared they do not want it. This feedback should take the form most acceptable to the patient which would normally be in a written format and may include the investigation report. Whatever method is used, the communication should

include:

- the chronology of clinical and other relevant facts;
- details of the patient's and / or relevant person's concerns and complaints;
- a repeated apology for the harm suffered and any shortcomings in the delivery of care that led to the incident;
- a summary of the factors that contributed to the incident;
- information on what has been and will be done to avoid recurrence of the incident and how these improvements will be monitored.

It is expected that there will be the offer of a face to face discussion of the findings of the investigation and analysis. In some cases information may be withheld or restricted, for example, in the rare instances where communicating information will adversely affect the health of the patient; or where specific legal requirements preclude disclosure for specific purposes. In these cases the patient must be informed of the reasons for the restrictions.

Any recommendations for system improvements and changes to be implemented will be monitored and shared with the service until completed. An overview report is provided to the Acute Services Division, the Partnerships Clinical Governance Forum and the Mental Health Clinical Governance Group.

7. RECORDING

All information in relation to a Duty of Candour event will be held on Datix within the incident and complaint modules. The same core information is required to be collected for all Duty of Candour events and it is a service responsibility to ensure this information is provided to either clinical risk or complaints staff to facilitate recording.

If a Duty of Candour event is discovered at a Morbidity & Mortality meeting and it has not been reported as an incident, it must be subsequently reported on the incident module of Datix to allow the appropriate collection of data to take place and to monitor the system. This event should be considered as a Significant Clinical Incident.

8. TRAINING

It is very important that clinical staff who are responsible for the implementation of the Duty of Candour legislation are fully aware of the new regulations and the NHSGGC Duty of Candour Policy and to support this awareness a comprehensive plan is in place to communicate and cascade the new policy throughout the organisation. This plan includes Core and Team Briefs, Hot Topics on Staff Net, articles in Staff news and a Pay slip message to all staff.

It is acknowledged that Clinical staff currently have a responsibility to ensure a professional duty of candour (generally being open and honest with patients regarding their care) and will already have a level of competence and understanding in this area which will facilitate implementation of this legislative Duty of Candour Policy.

For those staff who require additional training and support particularly with the interpersonal aspects of Duty of Candour Policy Implementation there are a range of

programmes which can be accessed depending on the specific needs of staff groups or individuals . Professional leads/managers may consider additional training in Duty of Candour an essential requirement for particular role or jobs and can add the relevant programme or module to Role Specific Induction or refresher training as deemed appropriate. A full list of available training with a descriptor and suggested target group is attached as Appendix 4.

This information will be promoted on HR Connect and through the Learning and Education calendar so that managers and staff will be able to easily access the required training and support.

In addition the requirements of the Duty of Candour regulations are embedded in existing relevant policy based programmes for example Root Cause Analysis and People Management programmes.

9. MONITORING

Services should review their duty of candour events to be assured that they are complying with this policy.

An annual Duty of Candour report will also be presented to the Board Clinical Governance Committee. The aspects of the policy listed below will be monitored by the Acute Services Division / Partnerships, Clinical Governance Forum as part of the quarterly clinical risk report.

Monitoring requirements:

- The number of duty of candour events reported
- The patient and / or relevant person receiving an apology
- The patient and / or relevant person are informed of the investigation process and given opportunity to contribute
- The patient and / or relevant person are given feedback on the outcome of the investigation and offered a meeting to discuss the findings
- The completion of the investigation within 3 months of awareness of the event

Appendix 1: Harm parameters

Grading of harm	Definition of grading	Level of response
Near miss	Any patient safety incident that had the potential to cause harm but was prevented/ avoided, and so no harm was caused to the patient.	Patients are not usually contacted or involved in investigations and these types of incident are outside the scope of this Duty of Candour policy. However, depending on the incident, health professionals may feel it appropriate to inform patients of these events if it is considered in the best interest of the patient.
No harm	Any patient safety incident that occurred but no harm was caused to the patient.	
Low harm (severity 1 & 2)	Any patient safety incident that required extra observation or minor treatment (e.g. first aid, additional medication) of the patient.	Unless there are specific indications or the patient requests it, the communication, investigation and analysis, and the implementation of changes will be led by the local area. Communication should take the form of an open discussion between the staff providing the patient's care and the patient and / or relevant person. It is important to note that whilst not essential under legislation, a professional duty of candour may apply and GG&C considers it best practice to inform the patient and / or relevant person of any harm caused and to apologise.
Moderate harm (severity 3)	A patient safety incident that resulted in a moderate increase in treatment and that caused significant but not permanent harm to the patient. This also includes prolonged psychological harm which has been experienced, or is likely to be experienced, for a continuous period of at least 28 days. Examples of this may include: return to surgery, unplanned readmission, prolonged episode of care, and transfer to another area such as ITU.	A higher level of response is required in these circumstances. Consideration should be given if this event would be reported as a Duty of Candour remembering that it is not only that there is harm but that the harm has been caused by the organisation and not part of the patient's disease process. If it is a notifiable safety incident it requires escalation and must be reported as a Significant Clinical Incident.
Severe harm (severity 4)	Any patient safety incident that appears to have resulted in permanent harm to the patient (i.e. permanent harm directly related to the incident and <i>not</i> related to the natural course of the patient's illness or underlying condition, e.g. permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of the wrong limb or organ, or brain damage.)	Duty of Candour is a statutory requirement. These are notifiable safety incidents. This type of event will be a Significant Clinical Incident and will require a Rapid Alert to be produced with immediate escalation.

Death (severity 5)	Any patient safety incident that directly resulted in the death of the patient (the death must be related to the incident rather than the patient's illness or underlying condition)	
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Appendix 2: Summary of key points

- Duty of candour – is a professional as well as now a statutory (legal) requirement for health professionals and managers to inform patients who have suffered as a result of a patient safety incident. The legal requirement relates to ALL staff.
- There are specific categories of incidents (defined as notifiable safety incidents) that are relevant to the new Duty of Candour legislation. However other incidents may also still fall into professional requirements for Duty of Candour.
- There are lots of situations where it is helpful to be open and honest with patients about incidents which have not caused harm and are not notifiable safety incidents. For example where a near miss has happened and telling the patient may prevent similar happening again (e.g. prescription of interacting medicines).
- The organisation supports staff to be open and honest with patients and to apologise at the outset about things that have or may have gone wrong and to explain what will happen next with investigations. The apology does not need to wait for a full investigation to be completed.
- It is helpful to patients and their relatives to have open and honest communication from the outset and staff are supported to share relevant information with patients and relatives e.g. it is acceptable to share draft and final SCI reports where appropriate. Further information is in the SCI policy.
- Patients and relatives should be encouraged to input into the SCI process where appropriate and advised on ways of doing this e.g. attending meetings, submitting questions, providing timelines from their viewpoint.
- The Duty of Candour policy is mainly about ensuring the new legal requirement is clear to staff and should be read in conjunction with the incident management, SCI and complaint policies.

Appendix 3: Particular patient circumstances that need to be considered in the Duty of Candour process

Other than the situations outlined below, information should only be disclosed to others when the patient has given their expressed or implied consent.

When a patient dies

When a notifiable safety incident has resulted in a patient's death, the person acting lawfully on behalf of the deceased patient must be notified. It is even more crucial in these circumstances that communication is sensitive, empathic and open. It is important to consider the emotional state of bereaved relatives or carers and to involve them in deciding when it is appropriate to discuss what has happened. The patient's relevant person should be informed about the investigation process that will be followed to identify the cause(s) of death. They will also need emotional support. Establishing open channels of communication will allow the family and/or carers to indicate if they need bereavement counselling or assistance at any stage.

Children

Although there is no legal age of maturity for giving consent to treatment, it is accepted practice that a child over 12 years may have the capacity to give consent. 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 Duty of Candour process after a patient safety event. The opportunity for parents to be involved should still be provided unless the child expresses a wish for them not to be present. Where children are deemed not to have sufficient maturity or ability to understand, consideration needs to be given to whether information is provided to the parents alone or in the presence of the child. In these instances the parents' views on the issue should be sought.

Patients with mental health issues

Duty of Candour for patients with mental health issues should follow normal procedures unless the patient also has cognitive impairment (see below). The only circumstances in which it is appropriate to withhold notifiable safety incident information from a patient with mental health issues is when advised to do so by a consultant psychiatrist who feels it would cause adverse psychological harm to the patient. However, such circumstances are rare and a second opinion (by another consultant psychiatrist) would be needed to justify withholding information from the patient. Apart from in exceptional circumstances, it is never appropriate to discuss notifiable safety incident information with a carer or relative without the express permission of the patient.

Patients with cognitive impairment

Some individuals have conditions that limit their ability to understand what is happening to them. They may have authorised a person to act on their behalf by an enduring Power of Attorney. In these cases, steps must be taken to ensure that this extends to decision making and to the medical care and treatment of the patient. The Duty of Candour discussion would be conducted with the holder of the power of attorney. Where there is no such person, the clinicians may act in the patient's best interest in deciding who the appropriate person is to discuss incident information with, regarding the welfare of the patient as a whole and not simply their medical interests. However, patients with cognitive impairment should, where possible, be involved

directly in communications about what has happened.

An advocate with appropriate skills should be available to the patient to assist in the communication process.

Patients with learning disabilities

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

Patients with different language or cultural considerations

The need for translation and advocacy services, and consideration of special cultural needs (such as for patients from cultures that make it difficult for a woman to talk to a male about intimate issues), must be taken into account when planning to discuss notifiable safety incident information. Advice on culturally sensitive issues can be given by the chaplains or other specialists.

Patients with different communication needs

A number of patients will have particular communication difficulties, such as a hearing impairment. Plans for the meeting should fully consider these needs. Knowing how to enable or enhance communications with a patient is essential to facilitating an effective Duty of Candour process. This involves focusing on the needs of the patient and / or relevant person, and being personally thoughtful and respectful.

Patients who do not agree with the information provided

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

- deal with the issue as soon as it emerges;
- where the patient agrees, ensure their family or relevant person are involved in discussions from the beginning;
- ensure the patient has access to support services;
- offer the patient and/ or relevant person another contact person with whom they may feel more comfortable. This could be another member of the team or a manager with a higher level of responsibility;
- consider a mutually acceptable mediator to help identify the issues between the healthcare organisation and the patient, and to look for a mutually agreeable solution;
- write a comprehensive list of the points that the patient and / or relevant person disagree with and reassure them you will follow up these issues.

What are the implications if a claim for compensation is made once the decision to follow the duty of candour procedure is made?

Whilst it would not be appropriate for an organisation to try to prevent the relevant person from making a claim, organisations can suggest to relevant person that they may wish to wait until the duty of candour procedure has concluded, when their case will have been investigated; they will have received an apology; the facts will have been established and any actions to improve the quality of care and/or learning will have been identified.

If a relevant person mentions that they are considering making a claim, the duty of candour procedure should continue. If a relevant person makes a claim (i.e. the organisation receives an appropriate notification of this), then some elements of the duty of candour procedure may need to be paused until the legal process reaches a conclusion. For example, internal reviews could still proceed and organisations should still try to identify any potential improvement and learning actions.

Appendix 4

Training & Development Opportunities in support of Duty of Candour

Title/content	Staff group	Descriptor
<p>NES E-learning module (Duration 45 mins) accessed via Learnpro: http://nhs.learnprouk.com/</p>	<p>Open to all staff</p>	<p>This module covers the new organisational Duty of Candour on health, care and social work services. The module content includes ways of ensuring that staff and Organisations are open honest and supportive when there is an unintended or unexpected incident resulting in death or harm</p>
<p>1/2 day Sage & Thyme Communication skills (accessed via L&E training catalogue)</p>	<p>Open to all staff</p>	<p>This 3 hour workshop is based upon evidence relating to core communication skills, psychological assessment and support. Attendees will learn how to use a structured approach for getting in and out of a conversation with someone who is upset or distressed, while providing basic psychological support. The workshop uses a mix of small group work, lectures and interactive rehearsals based on participant's scenarios to teach and demonstrate a structure approach to noticing distress, hearing concerns and responding helpfully.</p>
<p>1 Day Intermediate Communication Skills (accessed via L&E training catalogue)</p>	<p>Registered Nurses, AHPs (experienced band 5 and above) and Doctors who are involved in complex / difficult /necessary conversations with patients and / or relevant persons.</p>	<p>The training provides a structured evidence based approach to communication skills. This interactive day will include a variety of teaching techniques for example, scenario based group work, DVD skills exercises and interactive discussion.</p>
<p>2 day Advanced Communication Skills (accessed via L&E training catalogue)</p>	<p>As above + Particularly useful for senior staff and managers who are involved in significant conversations for example, around the complexities of care, breaking bad news or decision making.</p>	<p>The training provides a structured evidence based approach to communication skills. Over the 2 days the training builds and expands on the models and theories taught during the 1 day intermediate training session. It allows participants to refresh and review their current experience of communication issues through scenario base role play, reflective practice discussions and group experiential learning techniques. Each participant will be given an opportunity to use the models and techniques, to further develop their communication skills enabling them to deal more effectively with challenging/difficult conversations.</p>

Title/content	Staff group	Descriptor
<p>1/2 day Duty of Candour (accessed by contacting Clinical Governance Support Unit)</p>	<p>Senior Clinical staff ; Clinical Directors, Clinical Service Managers, Lead Nurses</p>	<p>This half-day training session specifically looks at disclosure communication immediately following an adverse event and follow-up meetings (which would also be suitable for meetings following a complaint). The course aims to enhance the skills of the individual to facilitate a successful interaction. The training will provide tools and techniques to improve the confidence of the staff who can find this type of meeting stressful and intimidating.</p>
<p>Bespoke on request Training (Contact Clinical Governance Support Unit or Learning & Education)</p>	<p>Clinical staff or Teams likely to be involved in adverse incidents or SCI's</p>	<p>Could range from Short 2 hour sessions to ½ day sessions and arranged by contacting the Clinical Governance Support Unit or Learning and Education</p>
<p>Managing Difficult Conversations (Part of the People Management programme and (accessed via L&E training catalogue))</p>	<p>Any manager in NHS Greater Glasgow and Clyde who has responsibility for managing NHSGGC staff in their teams. This includes managers employed in integrated Health and Social Care Partnerships who are not directly employed by NHSGGC.</p>	<p>The course is designed for those responsible for leading teams by developing personal skills in <u>handling difficult conversations with staff and peers</u>. The course will also explore good practice approaches to effective management of challenge.</p>