THE STATE HOSPITALS BOARD FOR SCOTLAND

DUTY OF CANDOUR POLICY

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Advisory Group	Duty of Candour Group	
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REVIEW SUMMARY SHEET

No changes required to policy (evidence base checked)	☐

Changes required to policy (evidence base checked) ☒

Summary of changes within policy:

- Included information on what steps to take if you are unable to contact relevant person (s).
- Clarity around the roles and responsibility of Corporate Management Team (CMT) and Lead Reviewer.
- Change in decision making of DoC incident, final decision lies with the DoC Group when deciding if an incident meets the criteria and will notify CMT.
- Updates to membership and hospital groups to reflect current hierarchy.
- Included further information on the support that the Patients Advocacy Service provide.
- Included a draft letter to be used when informing CMT that an incident has met the DoC criteria.
- Updated Duty of Candour Decision Making Process (Appendix 1) and Duty of Candour Timeline (Appendix 6) to reflect changes.
- Included a requirement that the report is circulated and reviewed by the DoC when the review is complete.

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1. Introduction

The Health (Tobacco, Nicotine etc. and Care) Scotland Act 2016 ("The Act") introduces an organisational Duty of Candour on health, care and social work services. The Act is supplemented by the Duty of Candour Procedure (Scotland) Regulations 2018, which highlights the procedure to be followed whenever a Duty of Candour incident has been identified.

The principles of Candour inform the approach that is taken within many health and social care professions, which is normally part of the requirements for practice by the various Professional Bodies.

The State Hospitals Board for Scotland ("The Board") is fully committed to the provision of high quality health care in all aspects of its service provision to patients. As part of this objective, we have a duty to limit the potential impact of a wide variety of clinical and non-clinical risks. We do this by developing and implementing robust and transparent systems to ensure that all incidents, which may cause potential or actual harm, are identified, investigated and where appropriate action taken to prevent a recurrence.

Promoting a culture of openness and truthfulness is a prerequisite to improving the safety of patients and the quality of our healthcare systems and provision. The principles of being open include:

- Acknowledgement and apology
- Truthfulness, timeliness and clarity of communication
- Recognising staff, patient, carer and volunteer expectations
- Support
- Risk management and systems improvement
- Multidisciplinary responsibility
- Clinical governance
- Continuity of care and confidentiality

However, when things go wrong (i.e. where there has been an unexpected 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) the focus of the Duty of Candour (DoC) involves notifying the person (and/or relevant person) affected, apologising and offering a meeting to provide an account of what happened, reviewing the incident and offering support to those affected (e.g. those delivering and receiving care).

The DoC not only encompasses communication between the patient and/or relevant person, but also other healthcare organisations, healthcare teams, and also individual members of staff to ensure that openness, honesty and timeliness underpin the State Hospital's response to such incidents.

Although the "Board" has an ethical duty to be open and honest at all times, Candour as a statutory duty applies 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 (i.e. Incident).

The State Hospital (TSH) has integrated the process of capturing, recording and managing an Incident within its Datix system, with all staff responsible for managing the process, being provided with suitable and adequate training/guidance.

Note: This Policy takes cognisance of the publication "Learning from adverse events through reporting and review: A national framework for Scotland: July 2018" and RR01 Incident Reporting & Review Policy

2. Definitions

Candour	The state or quality of being open, honest, frank and sincere
Incident	This is any unexpected or unintended incident that has occurred in respect of a patient during the provision of care that, in the reasonable opinion of a healthcare professional could or appears to have resulted in: • The death of the patient, where the death relates directly to the incident rather than to the course of the patient's illness or underlying condition, or • Severe harm, moderate harm or prolonged psychological harm to the patient. ***Note: The DoC applies equally to patient safety incidents and complaints.***
Datix Risk Management System	A risk management software programme currently used to electronically record all adverse events within TSH. Any member of staff can use Datix (or any subsequent system) to record an adverse event via the link on the hospital's intranet.
Harm	Injury (physical or psychologically), disease, suffering, disability or death.
Moderate Harm	Harm that requires a moderate increase in treatment, or significant harm which is not permanent.
Severe Harm	A permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, that is directly related to the incident and not related to the natural course of the patient's illness or underlying health condition.
Moderate Increase in Treatment	An unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, cancellation of treatment or treatment to another treatment area, such as a local General Hospital.
Prolonged Pain	Pain which a patient has experienced, or is likely to experience, for a continuous period of at least 28 days.
Prolonged Psychological Harm	Psychological harm which a patient has experienced, or is likely to experience, for a continuous period of at least 28 days.
Relevant Person	**"Relevant Person"** means the patient or in the following circumstances, a person lawfully acting on their behalf: • on the death of the patient, • where the patient is under 16 and not competent to make a decision in relation to their care or treatment, or • Where the patient is 16 or over and lacks capacity (as determined in accordance with Sections 2 and 3 of the 2005 Act) in relation to the matter.
Registered Health Professional	"**Registered Health Professional**" means a member of a profession to which section 60(2) of the Health Act 1999 applies
Responsible Person	Every organisation covered by the Duty of Candour legislation is regarded as a **"Responsible Person"** with the definition as set out within Section 25 of the "Act"
Lead Reviewer	Person managing a review of the Incident, via a Review Team on behalf of the "Board". The Lead Reviewer will also liaise with the relevant person(s) and be responsible for communication in line with the policy.
RIDDOR (Reporting of Injuries, Diseases & Dangerous Occurrences Regulations).	RIDDOR legislation states that The Board must report to the Health & Safety Executive any major injury, dangerous occurrence, occupational disease. Records must be kept of any absence lasting over three days following an injury at work, and absences lasting over seven days following an incident/accident at work must be reported to the Health & Safety Executive.

3. Purpose

The main purpose of this Policy is to ensure "The Board":

- Are open, honest and supportive (to both patients and members of staff) when there is an unexpected or unintended incident resulting in harm or death (as defined by the Act).
- Follow the DoC Procedure laid down within the Duty of Candour Procedure (Scotland) Regulations 2018 in a consistent manner throughout the organisation.
- Review the circumstances leading up to each Incident.
- Improve the support, timeliness, quality and consistency of communication with patients and/or the relevant person when an Incident occurs so that they receive prompt and clear information to enable them to understand what happened.
- Provide clear information to staff on what they should do when they are involved in an Incident and the support available to them to manage the circumstances of the Incident.
- Prepare and publish a DoC Annual Report.

4. Scope

This Policy is relevant to all care delivered by any of the "Board's" clinical services to patients and their families, including where the service is delivered by another provider on behalf of The Board in line with contractual arrangements. It therefore applies to all staff working / volunteers providing input within TSH and sets out the framework in place to support openness between healthcare professionals and patients, and/or the patient's relevant person, following an Incident. The words 'the patient's relevant person' in the context of this policy includes, however is not limited to next of kin, family, named person.

In line with regulatory and statutory requirements the specific DoC applies to actual or suspected Incidents and complaints that occur during care provision and that result in, or are suspected to have resulted in, moderate harm, severe harm or death.

There may be exceptions to implementing the DoC; however, there must be very sound reasons, which must be clearly recorded, for not having the DoC principles applied.

This Policy deals with the information and methods of sharing such information with the patient and/or relevant person. The amount of information and when this is provided will vary between patients and/or relevant persons, ranging from those who may request as much information as possible, to those who do not wish any information.

There will always be an element of professional judgement in determining what information should be given. However, the presumption must be that the patient and/or relevant person wishes to be well informed regarding the details surrounding an unexpected 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. Where the patient and/or relevant person makes clear (verbally or non-verbally) that they do not wish to be provided with any information, this should be documented within the Incident Review Notes.

5. Responsibilities

5.1 Chief Executive

The Chief Executive has overall responsibility for ensuring integrated governance including, risk management and clinical governance within the "Board", which includes the DoC Policy. They will delegate full implementation of this Policy to the Associate Medical Director.

5.2 Associate Medical Director

The Associate Medical Director is the Clinical lead for DoC in the Hospital and as such is responsible for ensuring that the necessary systems, processes, training and competency assessment (where appropriate) are available to ensure members of staff are able to comply with the contents of this document. In addition, they are responsible for ensuring that the monitoring and audit of this Policy is undertaken and reported to the appropriate Forums, as indicated within the Policy.

5.3 Director of Nursing & Operations

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

5.4 Lead Nurses/Responsible Medical Officer/Lead AHP/Head of Psychology/Skye Centre Manager/Lead Pharmacist/Person Centred Improvement Lead

All the above are responsible for following the DoC Policy and have a responsibility for ensuring that all Incidents are acknowledged and reported on Datix as soon as they are identified, in line with RR01 Incident Reporting & Review Policy. They should also seek assurance that the DoC Policy is being followed by local managers.

They should be aware that an individual member (or members) of staff may require support following an Incident and also during the investigation process, and therefore should provide the appropriate help and guidance, where required.

5.5. Senior Managers

The Senior Manager responsible for managing the incident or complaint is responsible for ensuring the DoC is discharged in line with this Policy. They should ensure there is regular communication with the patient and/or relevant person, including the incorporation of the patient's and/or relevant person's questions/ concerns within the Review process.

5.6 Local Managers

Local managers will:

- Ensure all adverse incidents/near misses occurring in their area of control are reported within Datix, together with any other issues of concern.
- Review the circumstances to determine causes and assess extent of injuries/ health issues sustained by the patient as a result of the incident, and where appropriate, complete the DoC section within Datix.
- Alert the Risk and Resilience Department to any potential "Incidents".
- Co-operate with the Lead Reviewer with regard to any review into the circumstances of the Incident.

All staff/volunteers with patient contact should be familiar with the procedural aspects of this Policy, in order to achieve openness with patients and/or the patient's relevant person 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 member(s) of staff/volunteer involved should provide an immediate apology, where possible and explain the issue will be raised with managers for investigation.

These Incidents must be reported within Datix and escalated to the Senior Manager on duty at the time of the Incident for consideration of an Enhanced Review (i.e. Category 1 or Category 2 Review.

5.7 Review Team/Lead Reviewer

A Review Team should be set up in accordance with the criteria set out within RR01 Incident Reporting & Review Policy (**Enhanced Review**). The Review Team will appoint a Lead Reviewer who will have completed appropriate investigation training to lead in the review of the Incident. Details of this person must be recorded within the Incident Review documentation.

5.8 Risk and Resilience Department

On behalf of the DoC Group the Risk and Resilience Department will monitor Datix for potential Incidents on a weekly basis and report these to the Group for consideration and confirmation that an Incident has occurred and requires further investigation under the Duty of Candour.

The Risk and Resilience Department will also produce a DoC Annual Report for consideration and approval by the DoC Group.

5.9 Corporate Management Team

The CMT will be notified by the DoC Group immediately once it has been agreed that an incident meets the criteria of DoC. CMT will decide the next steps in terms of review (Category 1 or 2 Review) and work with the Risk and Resilience Team to appoint an appropriate Lead Reviewer/Review Team. The CMT will also review and approve the final report once it has been completed.

6. Duty of Candour – Governance

The DoC Group will monitor activity relevant to the DoC process and report regularly to the CMT. The Group will also ensure any Incidents are identified and investigated in line with Scottish Government guidance and timescales.

The Group will operate a multi-disciplinary approach to the management of DoC and will comprise the following members or deputies:

- Associate Medical Director **(Chair)**
- Clinical Operations Manager
- Head of Psychology
- Lead AHP
- Head of Social Work
- Risk Management Facilitator

- Monitor and identify incidents that trigger the DoC and notify CMT of any decisions made. To do so they will consider a variety of information sources, e.g.
  - Incidents (Datix, RIDDORs, Category 1 & 2 Reviews)
  - Complaints
  - Claims
  - Whistleblowing
  - Adult Support & Protection Referrals

- Ensure that the DoC process is implemented in line with Scottish Government guidance, and this DoC Policy.

- Monitor compliance with agreed Action Plans following completion of an Incident Review.

- Ensure that relevant members of staff are appropriately trained to ensure compliance with this DoC Policy.

- Develop and monitor Policy on the DoC process to ensure that it aligns with the current RR01 Incident Reporting & Review Policy

- Ensure any organisational learning identified following a review of "Incidents" is acknowledged and is embedded in practice throughout TSH.

- Ensure a DoC Annual Report is forwarded to the Clinical Governance Committee for approval and thereafter published in a manner that is publicly accessible, e.g. within the TSH website.

- Notify the Scottish Government via dutyofcandour@gov.scot that a DoC Annual Report has been published.

7. Duty of Candour – Process

7.1 Being Open Principles

Being open and transparent with patients and/or relevant persons begins with the recognition that a patient has suffered harm (physical or psychological) as a result of their healthcare treatment. This may be as a result of an Incident, or may be related to some other kind of adverse event.

It involves explaining and apologising for what has happened to the patient and/or relevant person who has either being harmed or involved in an incident, ensuring that communication is open and honest, occurring as soon as possible following an incident. The following Principles (Table 1) should inform the DoC process and are considered essential components of the process, to ensure openness, trust and good communication.

Table 1

Principle	Detail
Acknowledgement	All Incidents" should be acknowledged and reported as soon as they are identified. In cases where the patient and/or relevant person, inform 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 or defensiveness will make future open and honest communication more difficult.
Truthfulness, Timeliness and Clarity of Communication	Information about an Incident must be given in a truthful and open manner by an appropriately nominated person. Communication should be timely, informing the patient and/or relevant person what has happened as soon as is practicable, based solely on the facts known at that time. It should also be explained that new information may emerge as the Duty of Candour review takes place. Patients and/or relevant persons and appointed advocates (where applicable) should receive clear, unambiguous information and be given a single point of contact for any questions or requests they may have.
Apology	Patients and/or relevant persons should receive a meaningful apology - one that is a sincere expression of regret for the harm that has resulted from an Incident. Both verbal and written apologies should be offered. **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, where this is possible or requested. A written apology, which clearly states the organisation is sorry for the suffering and distress resulting from the patient safety event, should also be given.
Recognising Patient and Carer Expectations	Patients and/or relevant persons can reasonably expect to be fully informed of the issues surrounding an Incident, and its consequences, in a face to face meeting with representatives from the organisation and/or in accordance with the local resolution process where a complaint is at issue. They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times. Patients and/or relevant persons, including family members should also be provided with support in a manner to meet their needs. This may involve an independent advocate or an interpreter. Information enabling to other relevant support groups will be given as soon as possible and as appropriate.

Principle	Detail
Risk Management and Systems Improvement	Root Cause Analysis (RCA) or similar techniques will be used to uncover the underlying causes of Incidents. Reviews at any identified level will however focus on improving systems of care, which will be reviewed for their effectiveness. *Being open* is integrated into Incident reporting and risk management policies and processes.
Multi-Disciplinary Responsibility	*Being open* applies to all staff who have key roles in patient care. This ensures that the *Being open* process is consistent with the philosophy that patient safety incidents 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 and managerial leaders who will support this across the health and care agencies that may be involved. Both senior managers and senior clinicians may be asked to participate in the investigation.
Clinical Governance	*Being open* involves the support of patient safety and quality improvement through the clinical governance framework, in which Incidents are reviewed and analysed, to identify what can be done to prevent their recurrence. It is a system of accountability to ensure that these changes are implemented and their effectiveness reviewed. Findings are disseminated to staff so they can learn from such incidents. Audits are also an integral process, to monitor the implementation and effects of changes in practice following an Incident.
Confidentiality	Details of an Incident should at all times be considered confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient. The "Board" will anonymise any Incident details it publishes, but still seek the prior agreement/approval of those involved. Where it is not practicable or an individual refuses consent to disclosure, disclosure may still be lawful if justified in the public interest or where those reviewing the incident have statutory powers for obtaining information. Communications with parties outside of those involved in the review will be on a strictly need to know basis. Where possible, it is good practice to inform the patient and/or relevant person about who will be involved in the review before it takes place, and give them the opportunity to raise any objections.
Continuity of Care	Patients will continue to receive all usual treatment and continue to be treated with respect and compassion.

7.2 Identifying and Reporting a Duty of Candour Incident

The DoC process begins with recognition of an Incident which may be identified/reported by:

- a member of staff at the time of the incident;
- a patient and/or the patient's 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; and
- incident detection systems such as incident reporting (Datix) or medical records review.

Any potential DoC incident must be reported as soon as practicable, by completion of the DoC section within Datix, after becoming aware that a patient has been the subject of an unintended or unexpected incident, and in the reasonable opinion of a registered health professional has resulted in or could result in:

- The death of a patient, where the death relates directly to the incident rather than to the natural course of the patient's illness or underlying condition.
- A permanent lessening of bodily, sensory, motor, physiologic or intellectual functions.
- An increase in the patient's treatment.
- Changes to the structure of the patient's body.
- Shortening of the life expectancy of the patient.
- Impairment of the sensory, motor or intellectual functions of the patient, which has lasted, or is likely to last for a continuous period of at least 28 days.
- The patient experiencing pain or psychological harm which has been, or is likely to be, experienced by the patient for a continuous period of at least 28 days.
- The patient requiring treatment by a registered health professional in order to prevent:
  - the death of the patient
  - any injury to the patient which, if left untreated, would lead to one or more of the outcomes listed above.

Note: Where the DoC process begins later than <u>one month</u> after the incident date, an explanation of the reason for this must be recorded within Datix.

Effective communication between staff who confirm that an Incident has occurred and their Local/Senior Managers is vital to ensure the process is successfully managed from the outset. As soon as an Incident where harm has occurred has been identified, the main priority is prompt and appropriate clinical care and the prevention of further harm. Where additional treatment is required, this should be provided as soon as reasonably practicable after a discussion with the patient (or relevant person if the patient is unable to participate in the discussion).

There may be rare occasions when an incident has been declared a DoC event and the Clinical Team responsible for the Incident decide that it is inappropriate to disclose this to the patient and/or relevant person. This decision is usually based on the best interests of the patient and/or the patient's relevant person if the disclosure would cause harm. For example, in the opinion of the Lead Reviewer that disclosure would cause adverse psychological harm to the patient. Such circumstances may be rare and it would be good practice to seek further opinion from the patient's Responsible Medical Officer (RMO) in these circumstances to justify withholding information.

The RMO (supported by the Patients' Advocacy Service) will assess if the patient is well enough to be involved in the process. If there is any disagreement between those involved in the management of the Incident, the Associate Medical Director will act as the arbitrator for the final decision to ensure compliance with the DoC requirements. ***Note: The reason disclosure has not been given must be recorded within the final Report and also on Datix.***

Following confirmation of an Incident this must be recorded on Datix. Refer to the RR01 Incident Reporting & Review Policy for details on reporting incidents. CMT will be noted immediately after an incident has been confirmed by the group that it has met the DoC criteria.

7.3 Duty of Candour – Assessment

The initial facts of the Incident should be established and an assessment of the level of harm to the patient should be carried out (**Appendix 1: Duty of Candour – Decision Making Process**). The assessment will include the following specific elements, which must be in place for the incident to be confirmed as a DoC event:

- Was there moderate/severe harm or death?
- Was TSH responsible for the harm/death? i.e. this is not a natural progression of a disease or an unavoidable complication.

The DoC Group will through its weekly review of the Datix system consider whether in their opinion any incident reported by a member of staff as a "DoC Incident" meets the relevant criteria. Any further assessment at this stage will be led by the DoC Lead (or deputy in their absence). Where the DoC Group deems it necessary to obtain further details on the Incident, there will be involvement at an early stage with those directly providing care to the affected patient within this assessment process.

Once the DoC Group decides an Incident meets the relevant criteria, the DoC Lead (or deputy in their absence) will make the CMT aware of this through an identified CMT email inbox. The CMT will be responsible for deciding what type of review should take place and decide who should take on the role of Lead Reviewer.

It is possible that the question of responsibility for harm will not be answered until the Review is concluded therefore it should be assumed that the Incident is a DoC event until the Review proves otherwise.

With the exception of a few complaints alleging harm a DoC event will be a Category 1 or 2 incident and should be managed in accordance with the RR01 Incident Reporting & Review Policy (**Enhanced Review**), final decision on this will be made by CMT.

7.4 Duty of Candour – Communication (Patient/the Patient's Relevant Person)

The DoC requires TSH to inform the patient and/or the patient's relevant person of a suspected Incident, which has resulted in moderate or severe harm, or death as soon as is reasonably practicable following the incident. Consequently, it is important there is a consistent approach by all members of staff around communications/ discussions with the patient and/or relevant person.

A meeting should be offered to the patient and/or the patient's relevant person within **10 working days** of becoming aware that an Incident has occurred and should be led by the person nominated by the Review Team (i.e. Lead Reviewer). Prior to this meeting the patient and/or the patient's relevant person must be afforded the opportunity to ask questions in advance.

The Lead Reviewer should have/be:

- A good grasp of the facts relevant to the case.
- A senior clinician/manager or have sufficient experience and expertise in relation to the case to be credible to patient/relevant person and colleagues.
- Excellent interpersonal skills, including being able to communicate with patients / patients' relevant persons in a way they can understand and avoiding excessive use of medical jargon.
- Willing and able to offer an apology, reassurance and feedback to patient and/or the patient's relevant person.
- Able to maintain a medium to long term relationship with the patient/the patient's relevant person, where possible, and to provide continued support and information.
- Culturally aware and informed about the specific needs of the patient and/or the patient's relevant person.

Prior to any meeting taking place the following should be considered:

- Clinical condition/mental capacity of patient.
- If the patient is unable to participate in the meeting or future discussions who should be involved on their behalf? (e.g. because the incident was fatal or the patient lacks capacity or the patient wishes to nominate someone else to act on their behalf).
- Who from TSH has already been in contact with the patient and/or the patient's relevant person?
- What discussions or exchange of information has previously taken place?
- What is the patient's and/or the patient's relevant person's current understanding of the incident and TSH response to this?
- Is the information provided based on the facts known at the time?
- Location of the meeting, taking into account the cost of travel for the patient's relevant person, in addition to the privacy and comfort of patient and/or the patient's relevant person.
- Who should be part of and who should lead the meeting?
- What support should be available to the patient and/or the patient's relevant person during the meeting (e.g. interpreter, advocate, etc.), ensure patient has been informed of right to have independent advocacy service present to support if they wish.
- Has a "single point of contact" following the meeting been identified to ensure all on-going care issues are addressed if the patient and/or relevant person has any further questions/concerns/requests?

The meeting should be accessible to the patient and/or the patient's relevant person having regard to their needs, e.g. disability requiring reasonable adjustments, travel issues, barriers to communication etc. and in certain circumstances it may be necessary to invite an interpreter

and/or advocate. If the patient's relevant person declines a meeting or is unable to attend, the responsible person must provide the patient's relevant person with the information detailed below if they wish.

In certain patient circumstances, i.e. when a patient dies; or the patient experiences barriers to communication; including intellectual disability, individual needs require to be considered within the DoC process (**Appendix 2**).

During any arranged meeting, the following must be included:

- The provision of an account of the incident.
- The provision of an explanation of any further steps that will be taken to investigate the circumstances which TSH considers led or contributed to the incident.
- An opportunity for the patient and/or the patient's relevant person to ask questions about the incident.
- An opportunity for the patient and/or the patient's relevant person to express their views about the incident.
- The provision of information to the patient and/or the patient's relevant person about any legal or review procedures that are being followed in respect of the incident in addition to the DoC process.

Where there is a disagreement about the facts presented at this meeting, these should be documented within the Incident Review Notes and deferred until completion of the Review process.

Note: It is important to be clear on what the patient and/or relevant person has been told to ensure all elements of the DoC process are met.

Following the meeting any identified patient needs should be communicated to the Clinical and Incident Review Teams to ensure all ongoing care issues are addressed.

Any patient and/or patient's relevant person's questions/concerns must be documented within the Incident Review Notes and assurance given that these will be addressed during the Review process. Following, the meeting it is helpful to follow this up with a letter confirming what has been discussed and agreed (**Appendix 3**).

Written follow-up communications should include:

- An apology.
- As much or as little information as required to update the patient and/or the patient's relevant person on the incident details and on the progress of the Review.
- Details of any further enquiries to be undertaken.
- Results of any further enquiries into the incident.
- Be jargon free, contain no acronyms and explain any complicated terms.
- Be given in a manner that the patient/the patient's relevant person can understand, with consideration to the need for interpreters, advocates, communications aids, whilst being conscious of any breaches of confidentiality in doing so.

Records of the Review meetings should include the following:

- Date, time, place, the names, relationships or job roles of those who attended.
- Discussion/topics covered.
- Questions/concerns of the patient and/or the patient's relevant person.
- The plan for further communication and contact.
- A summary of agreed actions.

A record of all communications (verbal and written) with the patient/the patient's relevant person must be inserted onto the Datix system, linked to the event. It may also be appropriate under certain circumstances to keep some relevant notes and copies of communications within the patient's Case Notes or Care Records.

Where the issue is the subject of a complaint, the Complaints & Claims Officer will be notified and thereafter receive copies of all documentation.

If in respect of an incident the responsible person is unable to contact the patient's relevant person or the patient's relevant person declines to communicate with the responsible person:

- A record should be kept which must include information about the attempts made to contact or to communicate with the patient's relevant person
- Any requirement to provide information to, or communicate with the patient's relevant person does not apply in respect of that incident until communication is made

7.5 Duty of Candour – Incident Review

The process followed will be a case-by-case decision made by the Lead Reviewer taking into account the following factors:

- Nature of the Incident or complaint.
- Degree and nature of harm sustained (physical or psychological).
- Needs and wishes of the patient and/or the patient's relevant person.
- Capacity of the patient, and whether this is likely to change.
- Involvement of the patient's relevant person.
- Diversity issues relating to delivering effective 'being open' communication and support to the patient/ the patient's relevant person.
- Confidentiality issues.

However, in general, the Review into the circumstances leading to the Incident will take the form of existing review processes currently undertaken within TSH e.g. a Category 1 or Category 2 Review.

If it is likely that the Review process will not be completed within 3 months of the process start date, the patient and/or the patient's relevant person must be contacted and an explanation and apology for the delay provided to them.

On completion of the Review process a written Report must be prepared, which should include the following:

- A description of the manner in which the review was carried out
- A statement of any actions to be taken by TSH for the purpose of improving the quality of service it provides and sharing learning with others (persons or organisations) in order to support continuous improvement in the quality of service provided
- Details of the agreed actions, including a timescale for implementation

Following completion of the Review process and approval by CMT. The findings will be communicated to the patient and/or the patient's relevant person unless they have declared they do not wish any feedback. If no feedback is required by the patient and/or the patient's relevant person, details should be noted within Datix.

Feedback should be provided within 30 days of being approved by CMT and in a format most suitable to the patient and/or the patient's relevant person, which would normally be in a written format and may include the Review Report, if requested. (**Appendix 4**).

Whatever method is used the communication should include the following:

- The chronology of clinical and other relevant facts.
- Details of the patient's and/or the patient's relevant person's concerns and complaints.
- An apology for the harm suffered and any shortcomings in the delivery of care that led to the adverse event.
- A summary of the factors that contributed to the adverse event.
- Information on what has been done and will be done to avoid a recurrence of the adverse event and how these improvements will be monitored.

Note: It is important to think about how the Review Report is written if this is to be shared with the patient and/or the patient's relevant person. It should <u>not</u> contain jargon or acronyms which are difficult to understand and should be clear and unambiguous.

It is anticipated that there will be the offer of a "face to face" discussion with the patient/the patient's relevant person to communicate the findings of the review. In some cases, information may be withheld or restricted, for example, in rare instances where the communication of information will adversely affect the patient's health or where specific legal requirements preclude disclosure for specific purposes.

With regard to these circumstances the patient and/or the patient's relevant person must be informed of the reasons for the information being withheld and/or restricted.

The report will be circulated to the DoC Group for discussion and review at the next available meeting.

7.6 Duty of Candour – Apology

In addition to any apology provided at the time of the Incident, as part of the DoC process, the patient and/or the patient's relevant person should be offered a written apology (this can be by

electronic communication if that is the patient and/or the patient's relevant person's preferred means of communication) in respect of the Incident.

The written apology should be personal and provided at an appropriate time during the DoC process, taking account of the facts and circumstances in relation to the particular Incident.

There may still be misconceptions and misunderstanding that the provision of an apology equates to an admission of liability and that organisations should never offer apologies for this reason. However, Section 23(1) of the "The Act" sets out that "an apology" or other step taken in accordance with the DoC process does not of itself amount to an admission of negligence or a breach of a statutory duty. Any apology is an acknowledgement of the patient's distress at that time, which may mitigate any trauma/distress suffered at this time. The apology should come directly from the Chief Executive (or Deputy in his absence)

Further guidance on making an apology as part of the DoC process is set out in **Appendix 5**.

7.7 Duty of Candour – Provision of Support

In line with the expectations of all staff regardless of the cause or outcome of any Incident, patients and/or relevant persons will be provided with all reasonably practical support necessary to help overcome the physical, psychological and emotional impact of such an incident. This includes:

- Treating the patient and/or the patient's relevant person with respect, consideration and empathy.
- Offering the patient, the option of direct emotional support during any notification of an "Incident (e.g. from a family member, a friend, a care professional or a trained advocate.
- Offering access to assistance with understanding what is being said, e.g. through interpreting services, non-verbal communication aids, written information.
- Providing access to any necessary treatment or care to recover from or minimise the harm caused by the adverse event, where appropriate.

When an Incident occurs, members of staff involved in the patient's clinical care may also require emotional support and advice. Any members of staff who have been directly involved in the incident and those with the responsibility for undertaking the Review process and communicating with the patient and/or the patient's relevant person should be given access to assistance, support and necessary information, where required.

To support staff involved in Incidents, the following arrangements are in place within TSH:

- A 'fair blame and open' culture that discourages the apportion of blame and, following adverse incidents, focuses on "what went wrong" and what can be done to prevent a recurrence.
- De-briefing arrangements are in place for members of staff involved in patient safety incident.
- Counselling and support services are available via the Occupational Health Service.

Note: The DoC Process is summarised within Appendix 6.

8. Duty of Candour - Training

A DoC e-learning resource has been produced by NHS Education for Scotland, The Scottish Social Services Council, The Care Inspectorate and Healthcare Improvement Scotland. Members of staff should complete the module, which is located within LearnPro. Further information and guidance is available via the following:

Risk & Clinical Quality intranet site - Duty of Candour Little Things Make a Big Difference

9. Duty of Candour - Annual Report

"The Act" legislates that TSH must prepare a DoC Annual Report, as soon as reasonably practicable at the end of each financial year. Within TSH, the Annual Report will be submitted to the Clinical Governance Committee for approval.

This DoC Annual Report must include the following:

- Information about the number and nature of "Incidents" to which the DoC process has applied within the previous financial year.
- An assessment of the extent to which TSH has carried out its DoC requirements.
- Information about TSH policies and procedures in relation to the DoC, including information about procedures for identifying and reporting "Incidents", and support available to staff and to persons affected by such "Incidents".
- Information about any changes to TSH policies and procedures as a result of learning points identified from incidents, to which the DoC has applied.
- Such other information as TSH believes relevant to include within the Report.

The Report must not include the name of any individual, or contain information that could identify any individual involved in the DoC process. The Report must also be published in such a manner that is accessible, e.g. on TSH web-site through which people can request adapted formats of the report in their preferred mode of communication e.g. large print, translated version.

When the DoC Annual Report has been published TSH must notify the Scottish Government via the following e-mail address dutyofcandour@gov.scot

The Scottish Government may, for the purpose of monitoring compliance with the DoC provisions, serve a notice on TSH, requiring information about any matters related to the DoC, within a specified timescale. As a result, the Scottish Government may publish a Report on TSH compliance with the DoC provisions.

10. Equality and Diversity

The Board is committed to valuing and supporting equality and diversity, ensuring patients, carers, volunteers and staff are treated with dignity and respect. Policy development incorporates consideration of the needs of all Protected Characteristic groups in relation to inclusivity, accessibility, equity of impact and attention to practice which may unintentionally cause prejudice and / or discrimination.

The Board recognises the need to ensure all stakeholders are supported to understand information about how services are delivered. Based on what is proportionate and reasonable, we can provide

information/documents in alternative formats and are happy to discuss individual needs in this respect. If information is required in an alternative format, please contact the Person-Centred Improvement Lead.

Line Managers are responsible for ensuring that staff can undertake their role, adhering to policies and procedures. Specialist advice is available to managers to ensure that reasonable adjustments are in place to enable staff to understand and comply with policies and procedures. The EQIA considers the Protected Characteristic groups and highlights any potential inequalities in relation to the content of this policy.

Patient pre-admission assessment processes and ongoing review of individual care and treatment plans support a tailored approach to meeting the needs of patients who experience barriers to communication (e.g. Dementia, Autism, Intellectual Disability, sensory impairment). Rapid access to interpretation / translation services enables an inclusive approach to engage patients for whom English is not their first language. Admission processes include assessment of physical disability with access to local services to support implementation of reasonable adjustments. Patients are encouraged to disclose their faith / religion / beliefs, highlighting any adapted practice required to support individual need in this respect. The EQIA considers the Protected Characteristic groups and highlights any potential inequalities in relation to the content of this policy.

Carers / Named Persons are encouraged to highlight any barriers to communication, physical disability or anything else which would prevent them from being meaningfully involved in the patient's care (where the patient has consented) and / or other aspects of the work of the Hospital relevant to their role. The EQIA considers the Protected Characteristic groups and highlights any potential inequalities in relation to the content of this policy".

The volunteer recruitment and induction process supports volunteers to highlight any barriers to communication, physical disability or anything else which would prevent them from contributing meaningfully to patient care and / or engage in other aspects of the work of the Hospital relevant to their role. The EQIA considers the Protected Characteristic groups and highlights any potential inequalities in relation to the content of this policy.

11. Stakeholder Engagement

Key Stakeholders	Consulted (Y/N)
Patients	Y
Staff	Y
TSH Board	Y
Carers	N
Volunteers	Y

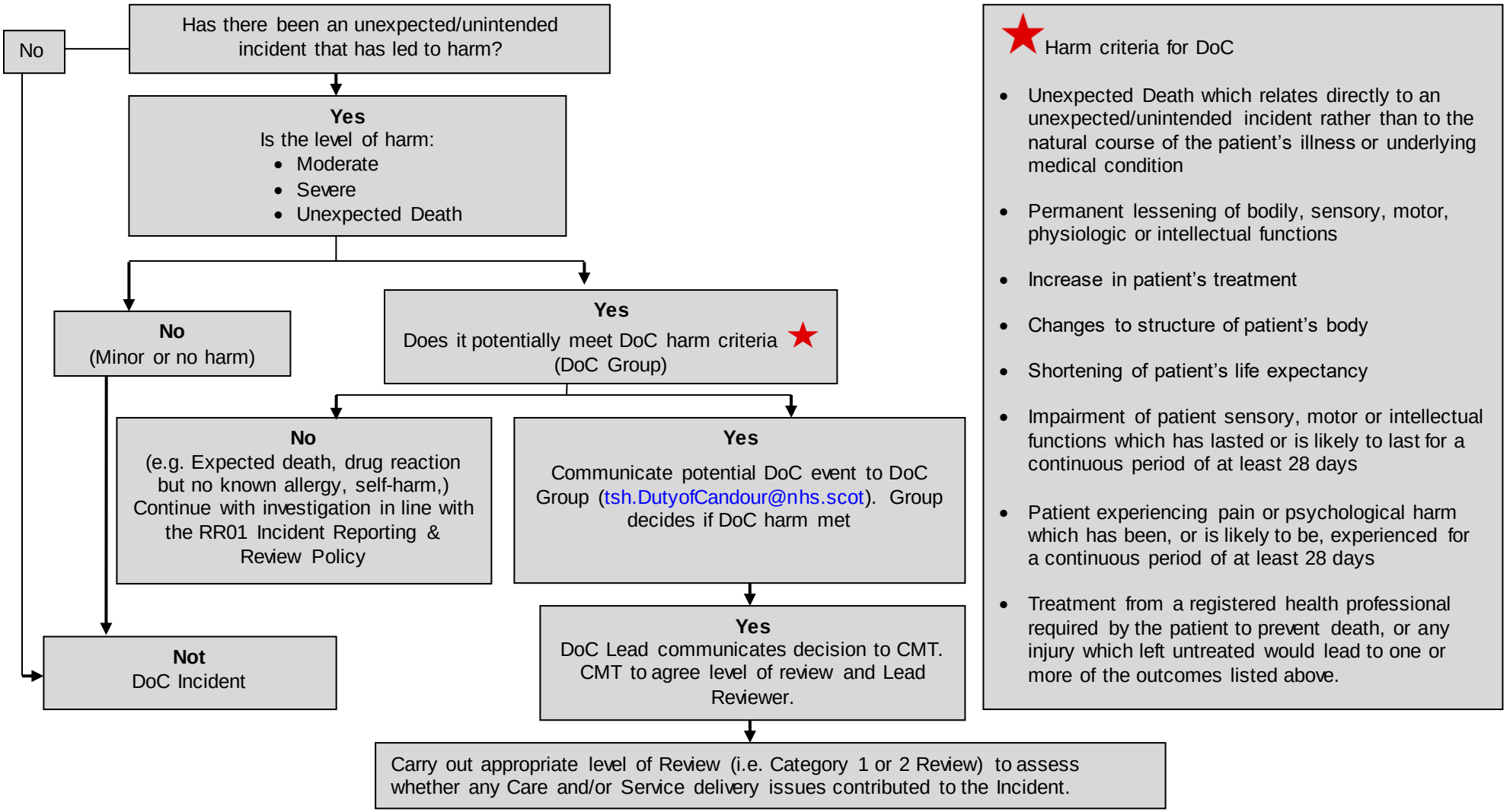
12. Communication, Implementation, Monitoring and Review of Policy

This policy will be communicated to all TSH staff via the intranet and through the staff bulletin. Volunteers will receive a copy of the Policy via e-mail and the Policy will be displayed in the Carers' Reception.

The DoC Group will be responsible for the implementation and monitoring of this policy.

This policy will be reviewed every three years or earlier if required.

Duty of Candour (DoC) - Decision Making Process



Individual patient needs required to be considered within 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 an 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 require bereavement counselling or assistance at any stage.

Patients with mental health issues

DoC for patients with mental health issues should follow normal procedures unless the patient also has cognitive impairment (see below). The only circumstances in which it is appropriate to withhold information from a patient with mental health issues is when advised to do so by the RMO who feels it would cause adverse psychological harm to the patient. However, such circumstances are rare and a second opinion (by another consultant psychiatrist) would be needed to justify withholding information from the patient. Apart from in exceptional circumstances, it is never appropriate to discuss patient 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 DoC 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 intellectual 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 DoC 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 DoC process, focusing on ensuring that the patient's views are considered and discussed.

Patients whom experience barriers to communication

Individual patient needs must be taken into account when communicating with patients whom experience barriers to communication and / or require a discrete approach in order to support them to engage meaningfully e.g. sensory impairment, Autism, Dementia, language barriers, cultural values/beliefs.

The Person Centred Improvement Team should be contacted in the first instance in relation to seeking support from the Hospital Chaplains or other specialists required to support cultural / faith related needs: tsh.personcentredimprovementteam@nhs.scot.

TSH 'Supporting Patient and Carer Involvement Policy' should be accessed via the intranet for details of the process required to engage interpretation / translation services.

Patients who disagree with the information provided

Sometimes, despite the best efforts of staff or others, the relationship between the patient and/or the patient's relevant person and the healthcare professional breaks down. They may not accept the information provided or may not wish to participate in the DoC process. In this case, the following guidance should be followed:

- 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/the patient's 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 the patient's 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 DoC process is made?

Whilst it would be inappropriate for TSH to try to prevent the patient and/or the patient's relevant person from making a claim, they can suggest to the patient and/or the patient's relevant person that they may wish to wait until the DoC process has concluded, when the Incident 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 patient and/or the patient's relevant person makes it known they are considering making a claim, the DoC process should still continue. If a patient and/or the patient's relevant person makes a claim (i.e. TSH receives an appropriate notification of this), some elements of the DoC process may need to be paused until the legal process reaches a conclusion. For example, internal reviews could still proceed and the Review Team should still try to identify any potential improvement and learning actions.

Appendix 3

Letter template following conversations with Patient/Patient's Relevant Person.

Note: To be tailored and personalised to suit individual cases.

PRIVATE AND CONFIDENTIAL

Patient's/Patient's Relevant Person's Name
Address

Your Name
Title
TSH address
Date

Dear ……(insert name)

I am writing to follow up on the conversation that we had on (insert date).

Again I would like to express my sincere apologies that you/ your …...(insert name) has been involved in a ……..….. (provide appropriate factual details here).

I would like to assure you that the State Hospital aims to provide a quality service to all our patients. We have listened to your immediate concerns and as explained we are undertaking a full Review into you/your …...(insert name) care and treatment in an effort to understand exactly what happened and, once completed, we would like the opportunity to discuss our findings with you.

The initial Review will take up to ….. weeks to complete and there may be a number of actions that come out of the Review. As discussed there may also be additional information that comes to light as the Review proceeds and we have agreed that we will……(insert relevant information) to ensure that you are kept informed. If you have any specific questions you would like our Review to address, please do not hesitate to contact me.

When our Review is completed we will write to you again to ask how you would like us to provide feedback regarding the outcome, if you feel able to arrange a mutually convenient time to meet (in advance of the completion of the Review) please let us know. I understand ……(insert name) is acting as your "Relevant Person" for the duration of the Review and they can be contacted on telephone number ……, email ……. or on the address provided.

I also understand that you may not feel any further communication would be of help and if this is the case I again, would be grateful if you could contact me to inform me of your decision.

Just as importantly, if there is anything else you would like to mention at this stage to assist with the Review then please do not hesitate to contact me.

Please let me know if you have a preferred means of communication so that I can ensure that you are enabled to be involved fully in the process.

Yours sincerely

Appendix 4

Letter template on conclusion of Incident Review.

Note: To be tailored and personalised to suit individual cases.

PRIVATE AND CONFIDENTIAL

Insert Patient's/Patient's Relevant Person's Name
Address

Insert Your Name
Title
State Hospital Address
Date

Dear ……(insert name)

I am writing to inform you that we have now conducted the Review into…….(provide details of the incident).

Either
As discussed earlier we have arranged to meet on (date and time) and the meeting has been planned to take place at (insert venue). I would be grateful if you could contact ……..(insert name) on number ……., email …….. or at the above address to confirm that you are still able to attend. ……..(insert name) can also explain who will be present at the meeting. You may also wish to consider whether you would like to bring a friend or family member along with you.

Or
I would, therefore, like to invite you/your ……(insert name) to meet with me to discuss the findings of the Review and would be grateful if you would contact …….(insert name) on number …… email …… or at the above address, so that we can organise an appropriate day, time and venue should you wish to meet. ……..(insert name) can also explain who will be present at the meeting. You may also wish to consider whether you would like to bring a friend or family member along with you.

If however you do not wish to attend a meeting, I can arrange for the final report to be sent directly to you. Additionally, if you wish to discuss any aspect of the incident or investigation please contact ……(insert name) on number …….

Finally, myself and the staff at the State Hospital are very sorry for any suffering and distress caused as a result of this incident. I wish to assure you that we have taken into account your concerns and will take on board any learning points identified from the Review into the events surrounding ……(insert incident details).

Yours sincerely,

Making an Apology

For the purposes of "The Act", an "apology" means a statement of sorrow or regret in respect of the unintended or unexpected incident that caused harm or death. "The Act" sets out that an apology or other step taken in accordance with the DoC process does not of itself amount to an admission of negligence or a breach of a statutory duty.

Sometimes clinical and care staff find it difficult to say sorry when something has gone wrong and harm has occurred. People may be unclear if they can say sorry and worry that the timing for doing this will not be right or that they will make things worse. The 'Four Rs' are an easy way to remember how we can get this right:

Reflect - stop and think about the situation

Regret - give a sincere and meaningful apology

Reason - if you know, explain why something has happened or not happened and if you don't know, say that you will find out

Remedy - what actions you are going to take to ensure that this won't happen again and that the State Hospital learns from the Incident

It is important that an open and honest apology is provided from the outset as this can reassure an individual and/or their family and will also set the tone for moving things forward from here.

By making an apology following an Incident, you are acknowledging that harm has been caused, a mistake has been made and you may be acknowledging emotions that are felt by the individual and/or their family. A meaningful apology can help to calm a person who has become angry or upset. ***An apology is not an admission of liability.***

What is a meaningful apology?

An apology is often the first step in putting things right and can help to repair a damaged relationship and restore dignity and trust. To make an apology meaningful you should:

- Acknowledge what has gone wrong.
- Clearly describe what has gone wrong to show you understand what has happened and the impact for the person affected.
- Accept responsibility, or the responsibility of TSH for the harm done.
- Explain why the harm happened.
- Show that you are sincerely sorry.
- Assure the individual and/or their family of the steps you or TSH have taken, or will be taking to make sure the harm does not happen again (where possible).
- Make amends and put things right where you can.

How should I make an apology?

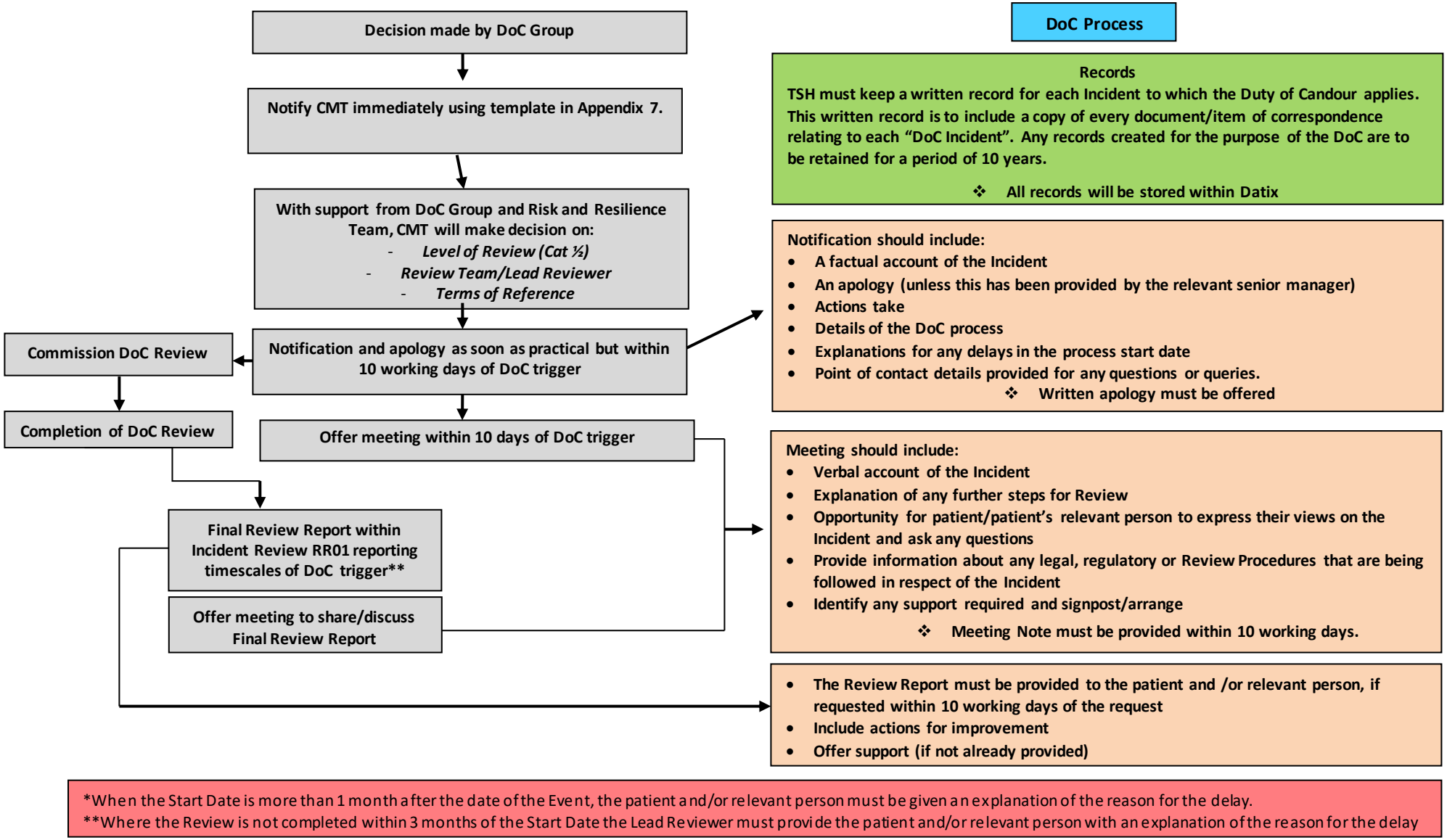
Your apology should be based on the individual circumstances. There is no 'one size fits all' apology, but there are some general good practice points.

- The timing of the apology is very important and should be done without delay.
- To make the apology meaningful do not distance yourself from the apology or let there be any doubt that you or TSH accept any wrongdoing.
- The language you use should be clear, plain and direct.
- Your apology should sound natural and sincere.
- Your apology should not question the extent of harm suffered by the person affected.
- Your apology should not minimise the effects of the Incident.
- It is very important that you apologise to the right person or people.

Who should apologise?

"The Act" states that the responsibility for the apology rests with the "Responsible Person", which is TSH who are delivering the service. However, in practical terms this will be carried out by the Associate Medical Director, or may be delegated to the Lead Reviewer.

Duty of Candour – Timeline of Process



*When the Start Date is more than 1 month after the date of the Event, the patient and/or relevant person must be given an explanation of the reason for the delay.
**Where the Review is not completed within 3 months of the Start Date the Lead Reviewer must provide the patient and/or relevant person with an explanation of the reason for the delay

Appendix 7

Letter Template to Notify CMT of Duty of Candour Incident

Dear Corporate Management Team

The Duty of Candour Group have reviewed incident (insert TSH number) and have agreed that it meets the criteria set out within the policy.

The incident resulted in (Insert short description of incident and the reason incident meets criteria, refer to section 7.2 or Appendix 1).

The Duty of Candour Group are asking CMT to review the incident and agree on:

- The level of review required (Category 1 or 2)
- The appointment of a Lead Reviewer and/or review team
- Terms of Reference

The Duty of Candour Group and Risk and Resilience Team are available to support in the any of the above decisions.

The Duty of Candour Policy states that TSH is required to offer a meeting with the patient/relevant person within 10 days of becoming aware that an incident has occurred.

For further information, please refer to RRO6 Duty of Candour Policy.

Kind regards

The Duty of Candour Group