Manx Care

Duty of Candour Procedure

Operational Policy

Date: 01-April-2021

Version: 1.0

1. Summary

1.1. The Duty of Candour is our legal responsibility to be open and transparent with individuals and their families when something goes wrong with their care.

1.2. It is part of our commitment to placing the safety and needs of those we serve above everything else, to ensuring we learn from mistakes, and to improving our health and care services.

1.3. This duty extends to all service areas and all staff who are involved in an individual's care.

1.4. This policy is designed for all Manx Care and DHSC staff and all patients, carers, and relatives affected by an adverse incident connected to one of our services.

1.5. Where third parties are contracted by Manx Care to deliver services, this process applies equally to those organisations and their employees, unless they have an equivalent duty in their local jurisdiction, in which case the regulations and procedures in that jurisdiction will apply.

1.6. This policy should be read in the context of our broader processes for managing serious incidents, complaints, and for driving improvement.

2. Introduction

2.1 The introduction of the Duty of Candour is one of the core recommendations of Sir Jonathan Michael's Independent Review of our health and social care system and becomes law as part of the Manx Care Act 2021.

2.2 Health and social care professionals already have a duty to be open and honest with patients when things go wrong. This duty is as described in the Professional Standards Authority for Health and Social Care *Duty of Candour* and joint General Medical Council and Nursing & Midwifery Council document "*Openness and honesty when things go wrong: the professional duty of candour*".

2.3 Section 11 sub-section 2 of the Manx Care Act makes this also the responsibility of all organisations involved in health and social care on behalf of the Island. The Act states:

"The Department must, by regulations, make provision as to the information to be provided by a relevant service provider in a case where an incident of a specified description, or a prescribed degree of severity, affecting a service user's safety occurs in the course of the service user being provided with a health service or a social care service."

2.4 Further to this Act of Tynwald, the Manx Care (Duty of Candour Procedure) Regulations 2021 set out the regulations which apply to Manx Care from 1st April 2021 in relation to upholding our new legal Duty of Candour.

2.5 This policy takes those regulations as the starting point and explains what we all need to do to ensure we are compliant.

2.6 We recognise that providing health and care services and treatments involves a level of risk, and that this is reflected in the principle of the "informed consent" of service users.

2.7 However, the Duty of Candour reflects the need for us to be open and honest when something happens during the course of delivering care which is **unintended** and / or **unexpected** and **causes harm** to a service user.

3. Purpose of the Policy

3.1 We are committed to providing high-quality, safe services to everyone who needs them, but we know that unfortunately sometimes things will go wrong.

3.2 This policy is designed to support:

3.2.1 staff to understand what they need to do; and

3.2.2 patients and service users, carers and families to understand what to expect

in the event that a serious incident occurs.

3.3 This includes our responsibility to:

3.3.1 inform the individual (or, where appropriate, the person's advocate, carer or family) when something has gone wrong;

3.3.2 apologise to them;

3.3.3 offer an appropriate remedy or support to put matters right (if possible);

3.3.4 explain what has happened and understand the impact;

and how we support each other to be open and honest in reviewing, understanding, and acting upon lessons to be learnt.

3.4 Regulations specify the types of incidents which are covered by the Duty of Candour and these are set out in section 4 of this policy.

3.5 This policy also sets out how we will ensure that incidents are appropriately identified, recorded and that the process for managing them is being correctly followed, in each and every case, as part of our commitment to those we care for.

3.6 This policy provides guidance to all staff on how to uphold the Duty of Candour and details the support available where they are unsure how to proceed.

3.7 This policy includes illustrative examples in Appendix A taken from the CQC guidance for all providers (CQC 2015).

4. Scope

4.1 All staff are required to report safety incidents, including those where there was no harm or there was a "near-miss".

4.2 **The Duty of Candour applies where unintended or unexpected incidents (including errors of omission) in the provision of a relevant service has resulted in, or is likely to result in, actual or likely harm occurring; and where that harm results in:**

4.2.1 the death of the individual;

4.2.2 a permanent lessening of the individual's bodily, sensory, motor, physiologic or intellectual functions;

4.2.3 harm which is not listed in 4.2.1 or 4.2.2 but which results in —

4.2.3.1 an increase in their treatment;

4.2.3.2 changes to the structure of their body;

4.2.3.3 the shortening of their life expectancy;

4.2.3.4 an impairment of the sensory, motor or intellectual functions which has lasted, or is likely to last, for a continuous period of 28 days;

4.2.3.5 the individual experiencing pain or psychological harm which has been, or is likely to be, experienced by the service user for a continuous period of 28 days;

4.2.4 the individual requiring treatment by a registered health professional in order to prevent —

4.2.4.1 their death; or

4.2.4.2 any injury which, if left untreated, would lead to one or more of the outcomes mentioned above.

4.2.5 if the person is under the age of 18, significant harm that results in the impairment of their mental or physical health or physical, intellectual, emotional, social and behavioural development compared with that which could reasonably be expected of a similar child.

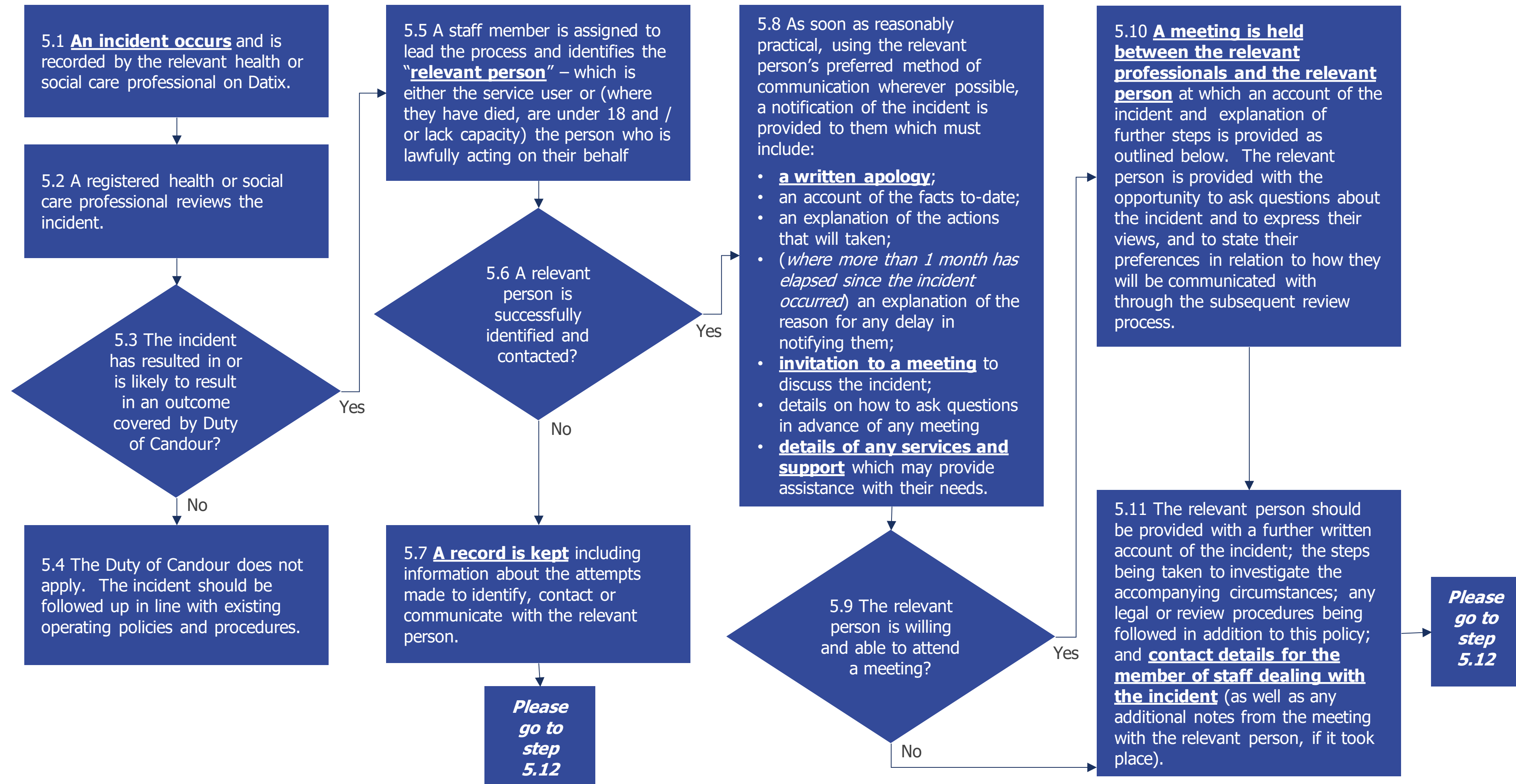
4.3 **Incidents which must be reported under the Duty of Candour are those which in the reasonable opinion of a registered health or social care professional either have, or are likely to, directly result in one of the outcomes mentioned above.**

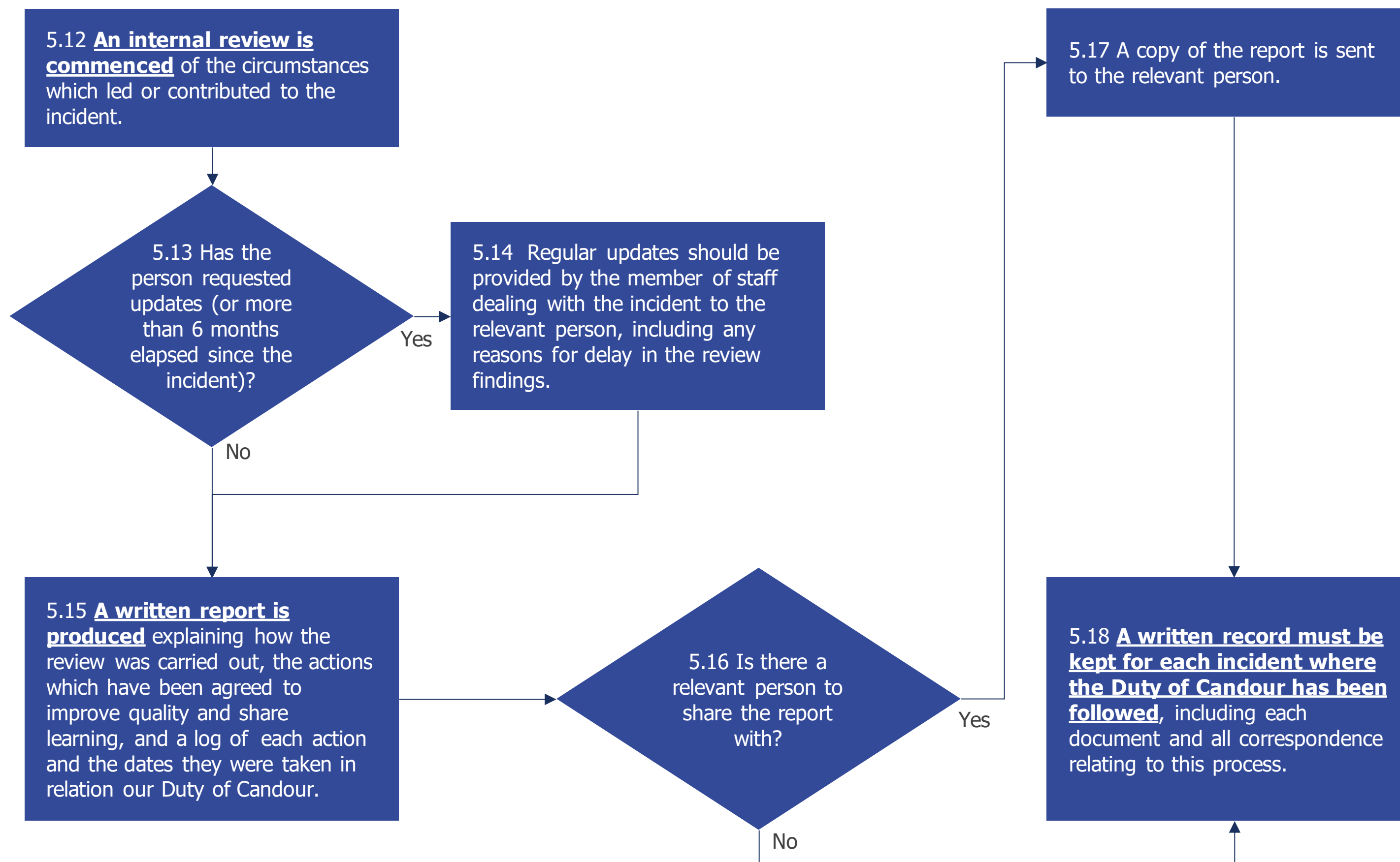
4.4 We have flexibility to discuss incidents resulting in a lower level of harm (including no harm) with people on an individual basis depending on individual circumstances and their best interests. Where this does occur, all details of all communication must be documented in accordance with this policy.

4.5 All reviews under this policy will focus on the root causes of the incident and our responsibilities as organisations and as a system providing health and social services, rather than simply the actions of those providing care.

5. Process for handling incidents under the Duty of Candour

Please note this process flow should be read in conjunction with the accompanying notes, set out in this section 5 below.




5.12 An internal review is commenced of the circumstances which led or contributed to the incident.
5.13 Has the person requested updates (or more than 6 months elapsed since the incident)?
Yes
No
5.14 Regular updates should be provided by the member of staff dealing with the incident to the relevant person, including any reasons for delay in the review findings.
5.15 A written report is produced explaining how the review was carried out, the actions which have been agreed to improve quality and share learning, and a log of each action and the dates they were taken in relation our Duty of Candour.
5.16 Is there a relevant person to share the report with?
Yes
No
5.17 A copy of the report is sent to the relevant person.
5.18 A written record must be kept for each incident where the Duty of Candour has been followed, including each document and all correspondence relating to this process.

Initial incident assessment and response

5.1 An incident that triggers the Duty of Candour is one as defined in the Manx Care (Duty of Candour Procedure) Regulations 2021 and as set out in section 4.2 of this policy. All incidents should be recorded in the first instance on Datix. Please note that our incident management policy requires us to report serious incidents within 24 hours.

5.2 At this point, Datix will prompt to consider the Duty of Candour. This should not prevent earlier conversations with, or apologies to, the service user or their representatives. However, a registered health or social care professional must review the incident to confirm if the Duty of Candour regulations formally apply.

5.2.1 A "registered health or social care professional" in this context means:

5.2.1.1 a registered health professional, a person who is regulated in accordance with any of the following: Dental Act 1985, Health Care Professionals Act 2014, Medicines Act 2003 or Opticians Act 1996;

5.2.1.2 a registered social worker, a person registered under a UK Care Act or regulations under section 161(2)(a) of the Regulation of Care Act 2013 to perform work of any type (however described) that is social work;

5.2.1.3 a registered manager of a service provider, as per section 39 of the Regulation of Care Act 2013.

5.3 The professional will make an assessment of whether the incident is likely to result in one of the outcomes of actual harm set out in the regulations.

5.4 If it is judged that the Duty of Candour would not apply, the Datix record should be updated to indicate that Duty of Candour does not apply and the reason(s) why. The incident should continue to be followed up as per standard procedures for incident management within the service area concerned.

5.5 If it is judged that the Duty of Candour does apply, the Datix record should be updated to indicate that Duty of Candour has been triggered. A named staff member should be asked to oversee the Duty of Candour process and the "relevant person" identified, who will be:

5.5.1 either the service user affected by the incident;

5.5.2 or a person lawfully acting on that service user's behalf if:

5.5.2.1 the service user has died.

5.5.2.2 the service user is under the age of 18 and is not able to make a decision in relation to his or her own care or treatment; or

5.5.2.3 the service user is aged 18 or over and for whatever reason lacks capacity in relation to the matter.

5.5.2.4 the service user does not for any reason wish to act on their own behalf, a person having written authority to act for them.

5.5.3 Where no individual is identifiable as the relevant person as per 5.5.1 or 5.5.2 above, or where there is some dispute as to who the relevant person might be, for the purpose of the Duty of Candour the staff member will attempt to identify the relevant person where, having regard to any information in our records, we believe the person has both sufficient interest in the service user's welfare; and is suitable to act on the service user's behalf. Any further disagreements in relation to this determination should be resolved through the Complaints process and it is our responsibility to explain to the individuals concerned how to raise a Complaint in this situation.

5.5.4 **As soon as is reasonably practicable after the incident, the staff member overseeing the incident must offer to supply the relevant person with details of any services or support** which they consider may provide assistance to the relevant person, taking into account that person's needs.

5.5.5 This includes proactively providing the relevant person with details of the Complaints procedure as well as explaining to them how the Duty of Candour process applies.

5.6 If the relevant person is not be contactable or declines to speak with us, this does not remove our responsibilities under the Duty of Candour, but does change the way in which the subsequent process operates as outlined below.

5.7 In the case that the relevant person is not contactable or declines to speak with us, this should be documented in Datix along with a record of the attempts to identify, contact or communicate with the individual. The next step will be to commence the review, as detailed in process steps 5.12 onwards below.

5.8 It is important that once we have identified that the Duty of Candour applies, that we follow up in a timely way. This includes the staff member responsible identifying with the relevant person how they would prefer to be communicated with; making sure that when we do communicate, all communications are fully understandable and in line with Isle of Man Government best-practice guidance; and as soon as practical, we write to them with:

5.8.1 **An apology.** An apology is an expression of sorrow or regret to those affected by a notifiable safety incident. It is not an admission of guilt. The Manx Care Act makes clear that: *"Apology" means a statement of sorrow or regret in respect of an incident referred to in subsection two and an apology or other step taken in accordance with the duty of candour does not of itself amount to an admission of negligence or a breach of a statutory duty.* This is in addition to any verbal apology issued at the time of the incident.

5.8.2 **An account of the facts to-date.** This is an account of what happened, based on the facts as we have established them at that point.

Please note that the regulations do not permit or require us to disclose any information which would prejudice any active criminal investigation or prosecution; or to contravene any restriction on disclosure, arising from any other legislation that is in place.

5.8.3 **An explanation of the actions that we will take.** This is as explained in more detail below.

5.8.4 **An invitation to a meeting.** This should include how the person may raise any questions they might have in advance of the meeting, and their right to be accompanied by an individual of their choosing.

5.8.5 **Details of services and support.** These should be appropriate to the needs of the person, as we understand them at the time.

5.8.6 **Please note that when more than one month has elapsed** since the date on which the incident occurred, we must provide an explanation of the reason for the delay in writing to the relevant person around the above.

5.9 Following the written notification, we will ascertain with them whether the relevant person is willing and able to attend a meeting with us. We should make all reasonable accommodations to enable their attendance should they wish to attend, including the timing of and venue for the meeting.

5.10 It is important that when a meeting is held, it is organised in an appropriate venue, with relevant professionals in attendance, and with the time and space to engage with the relevant person, recognising that they or their loved one may have been subject to significant harm or loss as a result of the original incident. The relevant person has the right to be accompanied by an individual of their choosing to support them during the meeting. The meeting with the relevant person is an opportunity to:

5.10.1 **Provide an in-person apology** if this has not occurred already.

5.10.2 **Provide an account of the incident**, including any details we are able to provide at this stage in addition to what was supplied in the initial written notification.

5.10.3 **Explain next steps** in relation to the process which is being followed.

5.10.4 **Enable the person to ask questions**, including around the original incident and the process being followed. Staff should make all reasonable efforts to answer the questions being asked, within the limits of what is known at the time.

5.10.5 **Enable the person to express their views and feelings** including in their own words the impact that the incident has had on them and / or the person they are representing.

5.10.6 **Enable the person to tell us how they would like to be communicated with and engaged** throughout the review process.

5.11 Whether or not a meeting is possible, Datix must be updated with:

5.11.1 any further details in relation to the incident;

5.11.2 a record of the steps being taken to investigate the incident, including any legal or review procedures being followed in addition to this policy;

5.11.3 and contact details for the staff member dealing with the case.

5.11.4 A written copy of this information should be sent to the relevant person.

5.11.5 If a meeting has occurred, this should also include the record of any additional notes or actions from the meeting, including in relation to the views of the relevant person, and any questions which were asked but remain unanswered.

5.11.6 If the relevant person is not happy with the record of the meeting, their concerns should be recorded alongside the original record.

Incident review and findings

5.12 Under the Duty of Candour regulations we are required to conduct an internal review of serious incidents, whether or not a relevant person is identified and has consented to be part of the review. Our incident management policy specifics that investigations of serious incidents should ideally be completed within 60 working days.

5.13 **If a relevant person has been identified, and they have requested updates** (**or if more than six months have elapsed since the original incident**) it is our responsibility to update them, including on any reasons for delays in the review process.

5.14 Updates should be provided by the member of staff responsible for reviewing the incident, who should also ensure that the relevant person is appropriately consulted and engaged throughout the review.

5.15 At the end of the review we must produce a written report which will include how the review was carried out, the actions which have been agreed as a result, and how we will share learning. This report should also include a log of each of the actions we have taken as part of fulfilling our responsibilities under the Duty of Candour regulations, the dates they were completed, and by whom.

5.16 If there is a relevant person to share the report with, a copy will be sent to that person.

5.17 In sharing the report we will take all reasonable steps to do so in a way which respects their preferences and needs, and presents findings in an understandable way.

5.18 Whether or not it is possible to share the outcome with a relevant person, we must ensure a written record is kept of all review findings alongside all documents and correspondence, for each incident. At the end of the process it is the responsibility of the staff member overseeing our response to ensure that Datix is updated to reflect this and to confirm that the process has been completed successfully, and that the lessons learnt are appropriately shared as part of our broader improvement systems.

6. How we will ensure we uphold the Duty

6.1 All our staff and managers will be provided with formal training on the Duty of Candour. The training includes our legal responsibilities, how to respond when a suspected incident occurs, and examples of different scenarios which might be encountered in our work.

6.2 The Datix system will be used as a repository for managing all incidents and to record what we do at each stage where the Duty of Candour applies.

6.3 We will ensure as an organisation that all employees, contracted persons or organisations involved in delivering health and care services for the Island are aware of our and their obligations under the Duty of Candour, will fulfil these obligations and can provide formal assurance that they are being met.

6.4 We will produce a written record for each incident in respect of which the duty of candour procedure is followed.

6.5 This will include a copy of every document and piece of correspondence relating to the application of the Duty of Candour procedure to the incident.

6.6 As soon as is reasonably practicable after the end of each financial year, we will prepare an annual report on the Duty of Candour during that year which includes:

- 6.6.1 information about the number and nature of incidents to which the duty has applied, in all relevant services;
- 6.6.2 an assessment of the extent to which the duty has been carried out in each of the relevant services;
- 6.6.3 information about the policies and procedures in relation to the duty, including our procedures for identifying and reporting incidents;
- 6.6.4 support available to staff and to persons affected by incidents;
- 6.6.5 information about any broader changes to policies and procedures as a result of incidents to which the duty has applied.

6.7 The report will not contain the name of any individuals or any information likely to identify an individual, but will help us and others to ensure that we are meeting our obligations under the Duty of Candour.

6.8 The report will be submitted formally by the Manx Care Board to the Department of Health & Social Care and will be made available publicly.

7. Responsibilities

7.1 **All staff:** To complete relevant training in the Duty of Candour when offered in a timely matter, to seek support and guidance whenever necessary, to work with our service users and each other to identify relevant incidents and to use the Duty of Candour to improve the way in which we work and the outcomes we deliver.

7.2 **Clinical / Professional Leads:** To support colleagues to be candid when things go wrong and to provide objective clinical and professional input into the identification and the review of incidents which do occur, to ensure that staff have the time to complete training and to conduct their responsibilities in relation to the Duty of Candour, to lead by example.

7.3 **Head of Patient Safety & Effectiveness:** To conduct regular assurance that this policy is being followed including through the use of Datix and other systems, and to make such recommendations as may be required to improve the implementation of the Duty of Candour within Manx Care and our contracted service providers.

7.4 **Medical Director / Director of Nursing / Director of Social Care:** To take overall responsibility for ensuring that processes, systems and culture within their areas of professional responsibility are supporting staff and managers to deliver on our responsibilities to service users and each other under the Duty of Candour.

7.5 **Chair / Chief Executive / Board Secretary:** To ensure that the Board takes a lead in overseeing the operation of the Duty of Candour; establishing and reinforcing a culture which supports individuals and teams carrying out this duty; assuring adherence to the associated regulations; sharing and taking appropriate action in relation to all resulting lessons learnt.

Appendix A

The following examples are taken from the CQC Duty of Candour guidance for providers (CQC 2015). These examples were designed to be illustrative only and not an exhaustive list.

The examples provided by the CQC were sourced and adapted where possible from “Seven steps to patient safety for primary care” (National Patient Safety Agency 2006) and “Duty of Candour Threshold Review Group Review of Definitions” (Royal College of Surgeons 2014).

Surgery

Example 1: A patient arrived for planned surgery but had not been given the correct advice to discontinue their Warfarin treatment. The surgery had to be postponed.

- This would be an example where an incident appeared to have resulted in **harm** and would trigger the Duty of Candour.

Example 2: During a difficult appendectomy the patient's bowel was accidentally perforated. This was recognised the day after surgery when the patient became increasingly unwell. The patient returned to theatre where the problem was fixed and the patient made a full recovery.

- This would be an example where an incident appeared to have resulted in **harm** and would trigger the Duty of Candour.

Example 3: Wrong site surgery: The identities of two patients on the list are mixed up and one patient undergoes the wrong operation on the incorrect site. The patient is permanently harmed as a result.

- This would be an example where an incident appeared to have resulted in **permanent harm** and would trigger the Duty of Candour.

Example 4: An elderly patient undergoes a coronary artery bypass operation. The patient is appropriately consented for the risks of the operation, including stroke and death. Unfortunately, the patient sustained a large stroke during the operation, and subsequently died as a result.

- This would be an example where an incident resulted in **death** and would trigger the Duty of Candour.

Example 5: A patient experienced pain during an elective Caesarean section due to incomplete anaesthesia from an epidural line. The patient found this experience traumatic and subsequently had an acute episode of severe anxiety and depression which lasted more than 28 days.

- This would be an example where an incident appeared to have resulted in **prolonged psychological harm** and would trigger the Duty of Candour.

Medicine

Example 1: A doctor causes a pneumothorax whilst placing a Central Venous Catheter (a recognised complication). The patient requires a chest drain to be inserted and a short stay on the Intensive Care Unit. The patient makes a full recovery.

- This would be an example where an incident appeared to have resulted in **harm** and would trigger the Duty of Candour.

Example 2: A patient developed a small grade 2 pressure ulcer during an admission to treat an acute cardiac problem. Although they were now fully mobile, they need district nursing visits after discharge home to check and dress the ulcer until healing was complete two weeks later.

- This would be an example where an incident appeared to have resulted in **harm** and would trigger the Duty of Candour.

Example 3: A patient incurs an extravasation injury (soft tissue burn) from an intravenous line causing irreversible scarring and bone damage.

- This would be an example where an incident appeared to have resulted in **permanent harm** and would trigger the Duty of Candour.

Example 4: A confused elderly patient was supposed to have 1:1 supervision on a medical ward. The patient was left unsupervised for a period of time whilst the shift change was occurring, and the patient fell out of bed, sustaining a severe head injury from which they later died.

- This would be an example where an incident resulted in **death** and would trigger the Duty of Candour.

Example 5: A patient who is normally very shy sustains an extravasation injury (soft tissue burn) from an intravenous line. This causes irreversible and extensive scarring on her arm and as a result she becomes severely socially anxious for which she needs a prolonged period of therapy.

- This would be an example where an incident appeared to have resulted in **prolonged psychological harm** and would trigger the Duty of Candour.

General practice

Example 1: A young man falls over whilst playing badminton and presents to his GP the next day with a swollen and painful foot and ankle. His GP decides not to order an x-ray and sends him home with advice to rest, ice, compress and elevate the leg. He tells the man he can weight-bear fully. Over the following week, the pain and swelling does not improve and the man re-presents at the GP surgery and sees a different doctor who sends him for an x-ray. He is found to have a fracture of the base of 5th metatarsal which should have been managed in a plaster cast and non-weight bearing. Due to this mismanagement, the patient develops a non-union over the following 6 weeks which causes him ongoing pain and eventually requires surgical intervention in hospital.

- This would be an example of an incident leading to a service user **requiring further treatment** to prevent the service user experiencing prolonged pain and would trigger the Duty of Candour.

Example 2: A patient who is a heavy smoker with a persistent cough is noted to have a suspicious lesion on a chest x-ray. The GP messages the practice reception to arrange an urgent appointment with the patient, although there is no answer on the patient's home telephone as he is on holiday. The message to follow up is missed. Two months later the patient presents with shortness of breath and haemoptysis. He is admitted to hospital via MAU and is diagnosed with lung cancer. His chances of survival were believed to be significantly reduced due to the delay.

- This would be an example of an incident leading to the **shortening of the life expectancy** of a service user and would trigger the Duty of Candour.

Example 3: A patient is on a repeat prescription for morphine sulphate 10mg twice a day for chronic pain. The patient requests a prescription and, in error, a prescription is issued for morphine sulphate 100mg twice a day. The medication is dispensed and the patient's wife, who looks after his medicines, gives her husband 100mg tablets of morphine sulphate. He takes 2 doses over the next day and then his wife is unable to rouse him in the morning. He is admitted to hospital where he has a cardiac arrest and dies.

- This would be an example where an incident resulted in **death** and would trigger the Duty of Candour.

Example 4: A patient's discharge summary from a recent inpatient episode for pneumonia described how an x-ray showed signs of a 'suspicious lung lesion' requiring a follow-up with their GP. The GP practice carried out further tests but failed to follow normal processes for relaying the results to the patient. The patient consequently spent several weeks in a state of extreme upset, concerned about the possibility of cancer and developed symptoms of anxiety and depression which lasted more than 28 days. Eventually he discovered his test results were normal.

- This would be an example where an incident appeared to have resulted in **prolonged psychological harm** and would trigger the Duty of Candour.

Mental health

Example 1: A prescribing error on a mental health ward resulted in a patient being given twice her normal dose of Lithium for several days. She became symptomatic for Lithium toxicity which required inpatient admission. She made a full recovery.

- This would be an example where an incident appeared to have resulted in **harm** and would trigger the Duty of Candour.

Example 2: A distressed, aggressive patient required physical restraint whilst receiving an injection of anti-psychotic medication. During the restraint, the patient's arm was broken which required manipulation and treatment in plaster for 6 weeks. He made a full recovery from the injury.

- This would be an example where an incident appeared to have resulted in **harm** and would trigger the Duty of Candour.

Example 3: A 9 year old boy was prescribed methylphenidate for the treatment of ADHD. At no point was an assessment made of his cardiac status nor enquiry into a family history of cardiac problems. He suffered several episodes of syncope thought to be due to extreme anxiety before collapsing with an arrhythmia, resulting in cardiac arrest and resultant permanent cognitive impairment.

- This would be an example where an incident appeared to have resulted in **harm that results in the impairment of development** and would trigger the Duty of Candour.

Example 4: A patient on a mental health unit committed suicide after lapses in risk assessment and observation.

- This would be an example where an incident resulted in **death** and would trigger the Duty of Candour.

Example 5: A 71 year old woman with apathy and memory loss is diagnosed with dementia. She is treated for several months in the memory service before she is re-evaluated and diagnosed with depression which responds to antidepressant treatment.

- This would be an example where an incident appeared to have resulted in **prolonged psychological harm** and would trigger the Duty of Candour.

Maternity

Example 1: A mother had significant post-partum haemorrhage after a difficult delivery, and there was some delay in obtaining blood for transfusion. As a result, she needed treatment in the high dependency unit for 24 hours before making a full recovery.

- This would be an example where an incident appeared to have resulted in **harm** and would trigger the Duty of Candour.

Example 2: A pregnant woman was seen in A&E at 12 weeks gestation with abdominal pain and PV bleeding. A high vaginal swab was taken by the Gynae SHO which grew Group B Streptococcus (GBS). When the woman went in to labour 28 weeks later, the midwife attending the birth did not check the laboratory results which showed the GBS growth and so the woman was not given intra-partum antibiotic prophylaxis as per national guidelines. The child then went on to develop GBS septicaemia in the days following delivery and required treatment in the Neonatal Intensive Care unit for 5 days before making a full recovery.

- This would be an example where an incident appeared to have resulted in **harm** and would trigger the Duty of Candour.

Example 3: An expectant mother who rang the maternity unit to report possible blood loss and reduced foetal movements was given inappropriate reassurance rather than asked to come for assessment. The baby later born with severe disabilities.

- This would be an example where an incident appeared to have resulted in **harm that results in the impairment of development** and would trigger the Duty of Candour.

Example 4: A woman requiring a blood transfusion for a post-partum haemorrhage received the wrong unit of blood after an error in labelling sample tubes. As a result the woman suffered a severe reaction leading to multi-organ failure and a fatal cardiac arrest.

- This would be an example where an incident resulted in **death** and would trigger the Duty of Candour.

Example 5: An expectant mother with a past history of severe mental health problems was not appropriately assessed at her antenatal appointment. As a result she was not offered NICE recommended psychological therapies, prophylactic medications or specialist follow-up. After delivery she became symptomatic, and these errors led to delays to her diagnosis and treatment. This resulted in a prolonged deterioration in her mental health for more than 28 days.

- This would be an example where an incident appeared to have resulted in **prolonged psychological harm** and would trigger the Duty of Candour.

Dentistry

Example 1: A patient was undergoing a dental procedure in a Primary Dental Care setting requiring conscious sedation with midazolam. The patient was inappropriately given too much sedation resulting in an overdose which required admission to hospital. The patient made a full recovery.

- This would be an example of an incident where a service user has required **further treatment to prevent death** and would trigger the Duty of Candour.

Example 2: A patient undergoing root canal treatment sustained irreversible tissue and nerve necrosis due to severe hypochlorite extravasation occurring during the procedure.

- This would be an example of an incident where a service user has suffered **a change in the structure of the body** and would trigger the Duty of Candour.

Example 3: A patient with a severe allergy to latex went for a dental procedure. The nature of the allergy had been stated in the medical history questionnaire. The dentist did not check this history before starting the procedure and was wearing latex gloves. The patient developed an anaphylactic reaction which required hospitalisation. The patient made a full recovery.

- This would be an example of an incident where a service user has required **further treatment to prevent death** and would trigger the Duty of Candour.

Adult social care

Example 1: An OT completed an assessment with a care home resident whose mobility was deteriorating. The OT advised that grab rails were needed in a person's bathroom before it was safe for them to use the bath and that in the meantime staff should assist the person to have a strip wash each morning. The manager failed to update the person's care plan or inform the care staff of this change, so staff supported the person to take a bath the following morning as usual. The person slipped when getting out of the bath and sustained a broken arm. The arm was put in a plaster cast and the person needed full assistance for all aspects of their care for 6 weeks until the cast was removed. The person made a full recovery.

- This would be an example of an incident leading to a service user requiring **further treatment to prevent the service user experiencing prolonged pain** and would trigger the Duty of Candour.

Example 2: A new member of staff on induction was shadowing another care worker delivering care to a person who needed to be hoisted. Two trained members of staff were required to operate the hoist safely and the new member of staff had not yet been trained in moving and handling. The new care worker was asked to assist with the manoeuvre and did not attach one of the loops of the sling to the hoist properly. As a result, during the manoeuvre, the person slid out of the sling and onto the floor. The person sustained a broken hip requiring emergency surgery.

- This would be an example of an incident leading to a service user experiencing **changes to the structure to the body** and would trigger the Duty of Candour.

Example 3: A person with a learning disability was prescribed antipsychotic medicines. They were assessed as needing full staff support in the management of their medicines. Over a period of two weeks they became increasingly anxious and distressed. When the person's medicines were checked it was discovered that their antipsychotic medicines had not been ordered the previous month and did not show on the MAR chart. This was because the correct procedure for ordering and the checking in of medicines had not been followed and the error had gone unnoticed for 18 days. This resulted in a prolonged deterioration in the person's mental health for more than 28 days.

- This would be an example where an incident appeared to have resulted in **prolonged psychological harm** and would trigger the Duty of Candour.