ISLE OF MAN GOVERNMENT

DEPARTMENT OF HEALTH AND SOCIAL CARE

DUTY OF CANDOUR

Summary of responses to the Consultation on the Manx Care (Duty of Candour Procedure) Regulations 2021

Issue date: 12 March 2020

We Asked

The purpose of this consultation was to gather views regarding the Manx Care (Duty of Candour Procedure) Regulations 2021 which will require organisations providing people with health and care services to follow a set procedure where a person's safety has been, or is likely to be, affected as a result of using a health or social care service, including what information must be provided and when.

You Said

52 responses were received: six from organisations (Crossroads, Graih, the Health Services Consultative Committee, Hospice Isle of Man, the Isle of Man Dental Association and the Stroke Association) and 46 from individuals:

- 11 gave permission to publish their response in full,
- 34 gave permission to publish anonymously, and
- seven did not give consent to publishing their responses on the consultation hub.

We Did

All responses received during the consultation have been considered and have helped to make improvements to the Regulations, including:

- clarification that the definition of "incident" includes omissions;
- definition of "relevant person" changed to provide more flexibility on who can act on someone else's behalf in receiving the information to be provided under the procedure;
- Clarification added to confirm that any questions asked by the service user should be answered by the service provider;
- Timescales added for publishing the annual report in relation to the duty of candour; and
- Additional requirements added to cover publicity of the duty of candour requirements and operational policy.

The responses have also led to further detail being included in the draft operational policy for the duty of candour, which is being worked on alongside the Regulations.

It is intended that these Regulations will be introduced to Tynwald in March with the aim that they should take effect at the same time as the establishment of Manx Care.

1. Summary

The Manx Care Bill 2020 will establish Manx Care as the new organisation responsible for the delivery of health and care services on the Island. Manx Care will be instructed by the Department of Health and Social Care on what services are to be delivered, to what standard and for what budget and will then deliver services in the way it deems best. The Department will hold Manx Care to account for Manx Care's performance.

It is anticipated that the Manx Care Bill 2020 will bring in a new legal duty for health and social care services to be open and transparent ("duty of candour") with service users from 1 April 2021. The intention in bringing in a duty of candour is to provide patients and service users with greater confidence in the providers of health and social care services as well as encouraging a culture of openness, improvement and learning from mistakes.

The duty of candour in the Manx Care Bill 2020 does not provide any detail on how the duty should operate in practice. For that, a new set of Regulations is needed.

This new duty applies to the organisation providing care rather than the individual, but sits alongside and supports the professional duty of candour that is already in place for health and social care professionals under the codes set by their professional regulator.

A public consultation on the draft Manx Care (Duty of Candour Procedure) Regulations 2021 was undertaken from 18 December 2020 to 22 January 2021. In addition to publishing the consultation on the Government's consultation hub, hard copies were made available on request and the consultation was advertised through the Transformation Programme's webpage on the government website as well as via press release and social media. Staff of the Department of Health and Social Care were also encouraged to review and comment on the provisions of the draft Regulations during the public consultation.

Responses received during the public consultation have provided a useful feedback on the proposals and the wording of the initial draft Regulations for the duty of candour procedure. There were also many comments that did not relate specifically to the duty of candour but which relate to the wider Transformation Programme. These comments will not result in a change to the Manx Care (Duty of Candour Procedure) Regulations 2021 but will be considered in other areas of work carried out by the Programme. As an example, several comments related to the current complaints procedure for health and social care services in the Island, which is distinct from any duty of candour procedure, but is due for full review as part of the planned National Health and Social Care Service Bill which will focus on modernising current health and social care legislation.

We are grateful to all those who took the time to submit their views to this consultation. Please note that the comments *in italics* used in this report are copied directly from the consultation hub.

2. Feedback

i. Harm threshold for the duty of candour procedure to be activated

The Regulations define thresholds for harm that will activate the duty of candour procedure.

Question Do you have any comments on the proposed harm threshold for when the duty of candour procedure would be triggered?

Several of the respondents did not feel that there should be any threshold for harm and expressed the view that honesty and transparency should apply during normal practice, not just after an incident of a specified description of harm. Others agreed that a threshold is needed and that harm needs to be defined in detail in the legislation in order to allow for clarity in regard to the legal requirements for everyone concerned.

> *"Why is there a minimum of 28 days for impairment or harm? This limit should be removed."*
>
> *"I find the idea that there should be a threshold for honesty odd! Surely a duty of candour should apply to all interactions with health and social care providers. That said in order to trigger a formal procedure the proposed threshold seems reasonable."*
>
> *"Agree that there should be a materiality threshold. It should cover errors of omission such as failure to identify a problem in a test or scan, as well as errors of commission. I am not sure whether it addresses that clearly enough. Is not doing something, or missing something an incident?"*

Inclusion of a threshold in the Regulations provides a trigger for the prescribed procedure to be followed by the service provider. This sits alongside the broader statutory duty of candour in the Manx Care Bill 2020 that applies to all functions of Manx Care, and of the Department of Health and Social Care, whether there has been an incident of harm or not.

There is already a "being open policy" in place within the Department of Health and Social Care which will apply to Manx Care from 1 April 2021. This policy requires staff to report **all** safety incidents including near-misses (where no harm was caused) to the organisation even though the organisation would then not be required to follow the duty of candour procedure. In those circumstances the communication, investigation and analysis, and the implementation of changes will occur at service delivery level.

The need for harm to last (or be likely to last) for a continuous period of 28 days in order to activate the duty of candour was questioned by some respondents. However, this time period is consistent with the duty of candour legislation in both England and Scotland as harm that is of such a level to necessitate the duty of candour procedure to be followed. As mentioned above, other policies are in place to ensure that incidents that lead to shorter term harm are documented, reviewed and that learning is taken from such events.

Some useful feedback was provided around an accumulation of smaller mistakes that may ultimately amount to serious harm and a lack of availability of services which may result in harm. In both cases, where harm thresholds have been met, the duty of candour procedure would be triggered.

> *"I would want to see that duty of candour should also be triggered at a point when a clinician becomes aware that a number of smaller cumulative failings that may have happened over several years have subsequently resulted in the above noted harm thresholds as well as any one larger specific instance."*

> *"What about a situation where harm is done because of a lack of Service EG shortage of dentists, doctors and podiatrists?"*

Regular reviews of safety incidents recorded will occur through aggregated trend data and local investigation. Where the trend data indicates a pattern of related events, further investigation and analysis will be required to identify shortfalls and issues that need to be addressed.

Changes have been made to the wording in the Regulations to remove any reference to "severe harm", as this terminology gave the impression that the impact of certain types of harm was greater than others, which was not the intention. Therefore, the description of the types of harm remains, but without any reference to whether it is severe or not.

> *"According to the above definitions, shortening someones life expectancy is not severe harm. So if a cancer diagnosis is missed or an operation goes wrong which will result in the patient dying of the condition needlessly, it is not considered serious harm? I think most patients would find this unacceptable."*

Additional wording has also been added to the description of an incident that would activate the duty of candour procedure to clarify that an incident may include where an error of omission has occurred, such as failure to identify a problem in a test or scan.

Other feedback to this question related to issues that would be covered by the complaints procedure. This feedback will be considered in relation to the operational policy for duty of candour and its interactions with the complaints policy as well as in developing future legislation for complaints.

ii. The steps to be taken in the duty of candour procedure

The proposed Regulations set out the procedure to be followed in the event of an unintended incident which has resulted in or is likely to result in harm to the service user. The steps to be taken in that procedure, in summary, are:

a) the service user (or their representative) is informed about the incident,

b) an apology is provided,

c) support services are offered to the service user affected,

d) a meeting is offered to explain what has happened,

e) the organisation investigates what went wrong, and

f) the details of that investigation are provided to the service user.

Question Do you agree with the steps that Manx Care will be required to take under the duty of candour procedure?

Support for introducing a duty of candour procedure

Most of the general feedback was in favour of the steps that must be followed in the event of a duty of candour procedure being triggered. Some examples of the comments received are provided below:

> *"Whilst the steps appear sensible and the requirement to keep the service user informed is good, it is also important that the process is not unduly onerous particularly for more minor issues. The process needs to be efficient enough not to disincentivise its use."*

> *"Yes. Having recently lost a relative as a result of what appeared to be a catalogue of negligent incidents, communications about investigations into what happened and why and a sincere apology are the actions that would have been most helpful."*

> *"I believe they don't go quite far enough because the Joint Guidance of the GMC/NMC requires practitioners to apologise both verbally and in writing.[1] "Offering" a written apology is in conflict with this and may also dilute the power of an early apology, as well as being at odds with the Professional requirements of medical and nursing registrants. As an apology is not an admission of guilt, IMHO the definition and actions taken to apology should be amended, especially as an apology can have a profound and positive effect on what will almost always be an unsettling time."*

> *"Yes, this is a welcome culture change with the focus on learning and prevention of further harm."*

However, many comments also provided useful and specific feedback about whether the steps should require something slightly different or go further than what had been proposed.

Providing the apology

Some of the feedback was around the provision of an apology, in particular whether:

[1] The GMC guidance in respect of health professionals providing an apology is in line with the duty of candour procedure as specified in the Regulation and states: *"You should record the details of your apology in the patient's clinical record. A verbal apology may need to be followed up by a written apology, depending on the patient's wishes and on your workplace policy."*

- a written apology should always be provided irrespective of the service user's wishes,
- the apology would always be meaningful and sincere, and
- the apology would amount to an admission of negligence or breach of statutory duty.

"We like the wording in this paragraph because it specifies not just the offer but the actual apology, and gives the service user a choice and control. Again, no time scale is given - should there be one, or at least an 'as soon as practicable' clause?"

"I feel that the written apology should be provided regardless of whether or not that offer of an apology has been accepted."

"I think that it is especially important that service users who receive an apology are reminded that an apology does not amount to an admission of negligence or breach of statutory duty."

"Apology should be genuine, not just a tick box apology."

"Meaningless. What use is an "apology" that is only a process that has to be followed, without any true engagement? Hollow words."

Internal guidance will be made available to staff on how an apology should be provided to the service user or their representative to ensure that it is as meaningful as possible.

The Regulations allow for the written apology to be offered at a later stage in the procedure, when the service provider will be better informed of the impact of the harm on the service user, thereby allowing for the apology to be more meaningful, and at a time when the service user may be in a better position to receive and digest the information and apology being offered.

The Regulations have been clarified by adding in the word "verbal" within the paragraph that deals with apologies, so that the procedure requires that a written apology must be offered in addition to any verbal apology which is given when first communicating with the service user or their representative about the incident.

The Manx Care Bill 2020 explicitly states that the provision of an apology does not amount to an admission of negligence or of a breach of duty. This was identified as very important to cover in the legislation so as to encourage reporting and openness and avoid any culture of blame which would undermine the duty.

<u>Timeframes for actions</u>

Several comments focussed on introducing time limits for some of the requirements in the draft Regulations:

"The duty of Candour procedure MUST be started within a month of the incident occurring. Any delays required during the procedure must be agreed with the service user."

"para 9 'Tell the service user what has happened' We believe this should include an aim to tell them as soon as possible, or as soon as the event is known, or a specified time, notwithstanding the following sentence about what happens if a month passes (which we support). para 10 Again, a specified time frame for the meeting invitation would be better, or at least an imperative to hold it as soon as practicable… para 12 A similar comment - should there be time scales on updates?"

"The Duty of Candour procedure additionally must provide a timescale which must be adhered to. Excuses such as "being busy" and absence of staff should not impact on the procedure which is stressful to those involved and impacts negatively on their well-being too."

"No more reports buried in intrays at Suite C. And ensure the Duty of Candour regulation states annual report, EVERY YEAR. DHSC are not currently filing complaints reports before Tynwald because the law states annual reports to be laid before Tynwald, but because the original draftsman didn't say annual reports every year, DHSC do not lay annual reports every year ! Regular updates ? How often and what will they contain ? Standard sorry it's taking longer than we thought and no substance ?"

Within the draft Regulations there is a timeframe stated for the initial notification to be given to the service user (or their representative) which is within one month of the incident taking place, otherwise an explanation must be provided to the service user for why it has taken longer. It may take longer than a month in some cases for a variety of reasons, including where it is not immediately clear that unexpected and unintentional harm has resulted from an incident. Another time limit already in the draft Regulations requires that the review must be completed within six months, and again flexibility is given for the service provider to explain to the service user if it has not been able to complete the review within that time frame as full investigations may include external parties and incorporate one of a range of review processes.

Taking on board feedback from the consultation, the wording has been changed in respect of the publishing of the annual report on the duty of candour so that Manx Care will be required to publish the report within three months after the end of each financial year instead of "as soon as reasonably practicable".

<u>Independent advocacy and support</u>

There has been strong support for the idea that no one should have to go through any of the process, especially the meeting, alone or without any support. It was suggested that there should be an independent advocacy service for service users:

"Re the meeting, it would be useful to include who the person or the person's representative could have with them. It reads a bit as if they would be in their own, which I'm sure is not your intention but it reads as if it could and therefore a bit cold."

"There needs to be clear information on advocacy support services available and an introduction to those services, something along the lines of the police family liaison officer and victim support were a patient or their representative can be told of what their rights are and how the process works, what questions they may want ask. Who are there as both support and to advocate for the patient (or their representative) both inside and outside of the Manx care remit."

"Services and support: this again should come in the form of a patient/family support officer who can arrange access and ensure that the patient is receiving the support they need. It is very hard to fight for support and access when you are grieving or very poorly, it takes a great amount of both physical and emotional effort."

"Some individuals who have attended expert patient courses in the past and/or have previous/current experiences should be invited onto the panel to ensure that the layperson is not overwhelmed or intimidated with the medical/legal professions".

Although it is not a requirement of the Regulations, Manx Care is committed to the development and introduction of an independent advocacy service, which will provide invaluable support to those that need it. In addition, the operational policy document will be clear that service users or their representatives will be entitled to have someone attend meetings with them through the duty of candour procedure and that this is something that should be discussed with the service user.

Failure to comply with Regulations

Respondents commented on the need to have some accountability for failure to comply with Regulations.

Leaders and managers within Manx Care (and other service providers) should ensure that the implementation of the duty of candour procedure forms a key part of the learning systems and is integrated and aligned with organisational processes and procedures. The central emphasis on communication, support, learning focused reviews and transparency in publishing duty of candour annual reports should be reflected throughout Manx Care.

Work is ongoing to set the organisational policy and consider how monitoring of the effective implementation of the actions required by the duty of candour legislation can be integrated into existing frameworks, processes and procedures. Assurance will need to be sought to confirm that all elements of the procedure are being implemented when they should be, and that there are ways of supporting continuous improvements and refinements in the way that the organisation discharges its legal responsibilities.

At an organisational level, the Manx Care Bill 2020 gives the Department of Health and Social Care the ability to issue directions to Manx Care if Manx Care is failing in any of its duties.

It is also expected that the external inspectors brought in as a result of the Manx Care Bill 2020 will review the operation of the duty of candour procedure as part of those inspections and report on any issues discovered.

Other feedback

Some additional views were expressed in relation to:

- ensuring that there is involvement of the service user or their representative throughout the process,
- agreeing the minutes taken from the meeting with the service user or their representative,
- having accurate record keeping, and
- incentivising self-reporting by staff to build a transparency culture.

The operational procedure and associated guidance will include consideration of these points.

iii. The service user's representative in case of death or lack of capacity

An important aspect of the duty of candour procedure is ensuring that the information is communicated to the appropriate person. Feedback was invited about the best approach for determining the appropriate person (or "relevant person") to communicate with about an incident which has triggered the duty of candour procedure.

Two proposals were set out in the consultation document and alternative suggestions were also requested. The first proposal was to include the wording *"a person acting lawfully on their behalf",* which in practice would mean;

- if the service user is under 18 then a person with parental responsibility (subject to a Gillick competency test[2]),
- if the service user lacks capacity then a person who has been given an appropriate power of attorney (the Department of Health and Social Care is currently working on a draft Capacity Bill which is proposed to modernise this), or
- if the service user is deceased then a person who is the personal representative of the deceased (which would include the executor or administrator of the individual's estate).

[2] Children can consent to their own treatment if they're believed to have enough intelligence, competence and understanding to fully appreciate what's involved in their treatment. This is known as being Gillick competent. For more information see https://www.nhs.uk/conditions/consent-to-treatment/children/

The second proposal was alternative wording, which would allow for any person to represent the service user if they were considered a suitable person to act as a representative and had sufficient interest in the person's welfare:
"In the case of a person who has died or who lacks capacity, the representative must be a relative or other person who, in the opinion of the registered health or social care professional had or has a sufficient interest in his or her welfare and is a suitable person to act as representative. If in any case the registered health or social care professional is of the opinion that a representative does or did not have a sufficient interest in the person's welfare or is unsuitable to act as a representative, he must notify that person in writing, stating his reasons".

Two questions were asked in this section of the consultation and the responses to both questions are considered together in this document.

Question Which approach would you prefer? Please give a reason for your view.

Question Alternatively, is there a different approach that you feel would work better?

The feedback on the two proposals was mixed, with some preferring the first approach, some suggesting a preference for the second approach and others in favour of a combination of elements from both. Most of those who voiced support for an approach also provided suggestions about what should be added to the wording, taken away or adjusted.

The first approach of using a person acting lawfully on someone's behalf was generally seen as better defined than the second approach and was felt to be less open to abuse by a health or social care professional, who might be perceived to be biased. On the other hand, there was a lot of support for the flexibility provided by the second approach

> *"I prefer the first. It's certainly a bit narrow and prevented me from acting on behalf of my family member when next of kin were not in a fit state to do so. However my concern is that the second approach, whereby the health service assesses if the person has sufficient interest, could lead to a real or perceived conflict of interests. The body being complained against should definitely not be deciding who is allowed to complain".*
>
> *"The second approach devolves a lot of power on to the registered Health or Social Care professional, I suggest some form of safeguard be built into this provision in order to keep the professional within bounds".*
> *"there needs to be a definition of what a registered healthcare person or social care professional can deem as "sufficient" and how they will be qualified to deem whether someone is "suitable". What is this definition of suitable? what the appeal procedure is for these decisions."*
>
> *"We would recommend that the alternative wording is used because it applies in a wider variety of situations, including the service user having nobody with power of attorney or dying intestate."*

"In our experience of dealing with vulnerable adults it is often the case that people (perhaps from Graih or simply a friend) become some of the most trusted contacts in a person's life without having any legal powers or duties. A broader definition allowing someone trusted to represent an individual would be very helpful. A narrow definition risks excluding those vulnerable people who have trusted non-family friends but are simply too vulnerable or chaotic to sort out legal matters such as Power of Attorney."

"I would prefer the alternative approach in principle in that it caters better for situations where there are no formal powers of attorney in place. This would be likely to be the case if an incident has resulted in a lack of capacity unexpectedly."

One suggestion which was made a number of respondents was for the service user to be given the ability to elect to act on their behalf:

"not every service user is up to dealing with the complex health care complaints system and therefore the service user should be able to appoint someone to act on their behalf"

"anyone who cares about the service user and has legal capacity should be able to represent the patient, deceased or otherwise if they are willing to take on the responsibility."

Two respondents also questioned the age threshold being set at 18 for the service user to be considered as an adult in respect to capacity to act for themselves without the need for a 'Gillick competency' consideration. Using the age of 18, rather than 16, is consistent with the Children and Young Persons Act 2001 definition of a child and was applied within these Regulations to provide more flexibility and discretion in who can act for the benefit of older children who may struggle to comprehend the impact of any unexpected and unintended harm.

After considering all of the feedback, further changes have been made to the wording in the draft Regulations in relation to who should be considered to be a relevant person:

"relevant person" *means —*
(a) the service user referred to in regulation 4(2); or
(b) in a case where the service user referred to in paragraph (a) does not wish to act on his or her own behalf, a person with written authority to act on the service user's behalf; or
(c) a person lawfully acting on the service user's behalf —
(i) if the service user has died;
(ii) if the service user is under the age of 18 and is not competent to make a decision in relation to his or her own care or treatment; or
(iii) if the service user is aged 18 or over and lacks capacity in relation to the matter; or

(d) if no person is identified as the relevant person under paragraphs (a), (b) or (c), a person who the service provider considers, having regard to any information in the service provider's records with respect to the service user, —

(i) has sufficient interest in the service user's welfare; and

(ii) is suitable to act on the service user's behalf;"

The changes mean that the person to be communicated with in the first instance is the service user themselves. If the service user wants to elect someone else to act on their behalf, then they have the ability to do so. If the service user has died or lacks capacity, then the service provider would be required to communicate with "a person lawfully acting on the service user's behalf". As this person has legal responsibility for acting for the service user, it was considered that it would not be helpful or appropriate to override this legal responsibility.

Finally, should it still not be possible to identify someone as the relevant person, flexibility is included for the service provider to nominate a person to become the relevant person. Consideration was also given to the perceived conflicts of interest raised if the service provider is able to nominate a person to become the relevant person. The Regulations require the service provider to have regard to any records in its possession when considering whether a person is appropriate to be a relevant person and so could use information available to it (such as a documented next of kin) when making this decision. Additionally, the reasonableness of the actions of a service provider under the Regulations are open to challenge in the court and the court would have to determine the matter on the facts before it on an application.

We believe that this approach takes the best qualities of the two proposals put forward in the consultation document and provides flexibility where needed to ensure that an appropriate person is able to act on behalf of the service user.

iv. Equality of opportunity

An initial assessment of the duty of candour procedure had shown that communications made to service users would need to be tailored appropriately in order to ensure that everyone is given the same opportunity to receive, digest and question the information shared with them as part of the procedure (for example, providing information in alternative formats, such as large font, Braille or audio CDs, in easy read formats or in a different language), as well as necessary adjustments being made for people to attend meetings. A question was asked in the consultation inviting further feedback about other areas in the implementation of the duty of candour procedure where adjustments may be required:

Question – Are there any other areas where this policy has the potential to adversely affect equality of opportunity?

Several additional aspects of the duty of candour procedure were identified for consideration for adjustments to be made as appropriate, including:

- being flexible in respect to the location of the meeting or providing transport to the meeting, and
- ensuring that those who require it are given sufficient support and the opportunity to be accompanied and represented.

Some examples of the feedback are provided below:

> *"Representation in the event of disadvantaged individuals not having the mental capacity to 'state their case'!*
>
> *"please add to this what sources of support a person/representative can access for neutral, external support and state they can if they wish request for support/accompaniment from them in meetings if desired."*
>
> *"Attendance at any meeting… needs to be facilitated for individuals who cannot easily travel to place of meeting. Eg those who cannot drive - disabled etc. Perhaps use of patient transport buses. Someone's ability to attend can deeply affect outcomes"*
>
> *"It may be necessary for the meeting to be held at a venue of the service users choosing, provided such place is appropriate. For example, if the service user is unwell or less able, consideration should be given to the meeting being held in the service user's home."*
>
> *"Simple language without jargon for everybody."*
>
> *"I think careful thought needs to be given to the way in which communication takes place with those who are particularly vulnerable. We often find that our guests simply do not understand what is happening even when a professional thinks they have 'communicated'. This is not merely a matter of literacy (or getting the information, as alluded to in your example above of Braille etc) as much as cognitive ability: the capacity to really grasp and understand and comprehend what is being said and done. I don't think that there are easy answers to this but I would urge careful consideration of how communication happens, where it happens and how to check that everything is being understood. It should be emphasised that this is often a very time-consuming and potentially frustrating process with those who are vulnerable."*

All of this feedback has been of great value to the work to ensure that everyone is given equal opportunity in respect to accessing and understanding the information made available under the duty of candour procedure and comments in response to this part of the consultation have been provided for consideration when putting together the operational policy which will support the Manx Care (Duty of Candour Procedure) Regulations 2021 when they take effect from the 1 April 2021.

vi. Other comments

A final question was asked at the end of the consultation inviting any other comments regarding the draft Regulations that were not covered by the specific questions asked earlier.

Question - Do you have any other comments regarding the draft Regulations?

The majority of the comments submitted in response to this question suggested that respondents wanted to see change with respect to the existing complaints process in relation to health and social care services. Some of these comments were highly critical of how they believe they, or their loved ones, were dealt with and others commented more specifically about issues they perceive with the actual complaints process, such as timeframes and a lack of information and transparency.

Whilst issues may come to light through the complaints process, which could trigger the duty of candour procedure. The complaints process is separate from the duty of candour procedure, which is about informing a service user or their representative when an incident has occurred which has resulted in unexpected and unintended harm, and the two shouldn't be confused.

The operational policy for the duty of candour procedure will make it clear that service users and representatives should always be given information about how to make a complaint, if they wish to do so, along with information about support services available to them. A full review of the complaints process for health and social care services and of the legislation that supports that process, is planned to be carried out as part of the work to be completed on the planned National Health and Social Care Services Bill. A public consultation will be carried out around the proposals for a new complaints procedure at that time.

Examples of some of the comments made about the complaints process are copied below:

> *"There are differences between these proposals and the current complaints process. Nobles hospital has great difficulty adhering to the timescales laid down in its complaints booklet, social care and mental health services complaints procedures are impenetrable/ non existent. These should all be unified and managed by an independent team. The exception would be GP complaints, as independent contractors."*
>
> *"Patients and their relatives need to understand that this is a procedure to acknowledge that an 'incident' has taken place. The written apology of sorrow or regret does not prevent a formal complaint being made through the usual procedure. Patients and their representatives should be made aware of the standard complaints procedure and given contact details for the isle of Man Health and Care Association."*
>
> *"I feel the complaints process has not been addressed. Unfortunately people will complain and sometimes an apology will not suffice. There has to be a clear time line*

to when a complaint is properly resolved. Two and half years down the line and my complaint has not been resolved, in fact we have had 3 or 4 resolution meetings and an independent review and still no answers to relevant questions. This is to long to wait and causes stress and anxiety, coming from the Health and Social care department is ironic. Most of the answer to the questions I asked by the way should be recorded and they aren't. Have a complaints process that's fit for purpose."

"I am currently partly through an ongoing complaint at Nobles Hospital where poor treatment was a contributing factor in my elderly father's death. I possess various skills which enable me to analyse reports and documents and draw information and conclusions. However, this has been a very time consuming and arduous process, additionally the emotional toll has been exacerbated by delays, lack of information and a lack of openness, transparency and candour."

A few of the other responses commented on the importance of culture in the organisation when introducing a change such as the duty of candour procedure:

"The need for these regulations could be seen as an unwelcome reflection on the existence of a blame culture within Health and Social Care. However positive implementation of the regulations should help to change this. It is however important that this is a trigger for a more transparent and supportive culture rather than simply another burdensome bureaucracy."

"I think this is only part of what is needed. It would involve a cultural approach. Management should recognise that zero errors is not achievable, but that openness is the best way to improve. Staff should be confident that self-reporting is recognised as good behaviour and incentivised. And patients should not have to go through the courts or prove negligence to get compensation."

It is recognised that the culture of the organisation is a key component to ensuring transparency and honesty in our health and social care services. The new Regulations are only one part of the changes that will need to occur to ensure that the implementation of the duty is successful. The implementation of these requirements is being given serious consideration by the Transformation Programme and the Department of Health and Social Care with a focus on ensuring that there is no blame culture and instead embedding a culture of learning from mistakes.

Other comments in response to this question expressed concerns about ensuring that inspections are carried out by the CQC, a lack of appendices referencing relevant work by professional and regulatory bodies in the UK and about whether this duty of candour procedure is going to be just another piece of transformation that is ultimately ignored or comes to nothing in terms of benefits for the end-user:

"The CQC have previously said they would inspect on the Island, and have visited before (as the Health Care Commission). Will this be something Manx Care will implement to ensure compliance with the Fundamental Standards, etc?"

"I want to welcome these regulations but sadly I have no faith that they will be upheld. There may be a chance of this regulation being meaningful if you commission UK Care Quality Commission to regulate and monitor the service and quality of care provided, the DHSC does not have the skills to do this. You also need to ensure that there are fines for failure to comply with the Duty of Candour Regulation."

"I would have like to have seen references and appendices, particularly as much work has been done by the CQC, GMC, NMC, RCN, AvMA, etc. and would have liked to have seen if, for example, Appendix 5 of the NHS Standard Contract was referred to, as well as the Joint Guidance referred to earlier and numerous documents on the CQC website."

"Please ensure this is not just another tokenistic procedure that will be written presented as a proactive piece of transformation and then ignored. Please also consider robust measures to ensure compliance as compliance to current Duty of Candour regulations such as Nobles Hospital Directorate Being Open Policy and Professional Duty of Candour does not happen: no one monitors it and there is no consequences for a lack of adherence to the duty of candour."

The Manx Care Bill 2020 requires that regular inspections of health and social care services mandated to Manx Care are carried out. The Department of Health and Social Care will be contracting the Care Quality Commission in the UK to carry out these inspections on its behalf and the CQC will report to the Department of Health and Social Care on its findings. Inspection reports will be published and Manx Care will be required to prepare an action plan in respect to each matter, which will also be published.

In respect to the suggestion that appendices should be included in the duty of candour procedure, whilst not appropriate to include this information as part of secondary legislation in the Island, the duty of candour operational policy will include appendices with relevant guidance, case studies and supporting information. It is anticipated that the operational duty of candour procedure will be published so that service users know what to expect and the Regulations require that it is made available on request.

The duty of candour procedure is not a tokenistic piece of transformation, but is part of a broader programme of change being led by the Transformation Programme which sits outside of the Department of Health and Social Care. Things are already happening - for example, the move of Public Health into the Cabinet Office, which was one of Sir Jonathan Michael's clear recommendations, took place at the start of April 2020; and the approach being taken is designed explicitly to learn the lessons from earlier reviews and to ensure that the Transformation Programme delivers sustainable change.

Manx Care will be required to adhere to the duty of candour procedure as set out in the Regulations. Possible consequences for non-compliance includes direction notices that the Department of Health and Social Care has power to issue under the Manx Care Bill 2020 and

ultimately powers held by the Council of Ministers to hold Manx Care to account. However, it is anticipated that Manx Care will embrace a culture of learning and transparency and that the duty of candour procedure will be a key component to that culture.

3. Next Steps

Feedback received through this consultation exercise has helped make improvements to the Regulations and it is intended that these Regulations will be introduced to Tynwald in March with the aim that they should take effect at the same time as the establishment of Manx Care on 1 April 2021.