The Duty of Candour –

Consultation Response to Welsh Government

December 2022

Question 1

Is the Guidance on when the Duty of Candour applies clear? - **Yes.**

Please provide any comments or further explanation (in particular if response is no).

We believe the guidance is largely clear.

We welcome the confirmation within the guidance that health care may have been a factor in an adverse outcome, rather than having to be proven as a factor. We also welcome the focus on training within this consultation. For clarity, it will be important that health care only having possibly been a factor is given a focus in training to ensure that this is understood.

We welcome consideration that staff need additional training in this area in the 'amendments and updates to putting things right' guidance to assist with embedding procedures in everyday working practice.

Is the flowchart at Annex A, a useful tool for determining whether the Duty has been triggered? **Yes, in the main.**

Please provide any comments or further explanation (in particular if response is no).

The flow chart is clear in determining whether the duty of candour is triggered in circumstances where health care has been provided. What is less clear is whether duty of candour is triggered when <u>not</u> providing health care may be a factor. Whilst the Duty of Candour Statutory Guidance includes that once diagnosed then some care has been provided, this is not the case for some patients.

In our annual surveys of older people's experiences of the pandemic over the last three years,[1] older people have told us of delays in access to treatment,

[1] www.agecymru.org.uk/covid19survey

repeated cancellation of appointments and treatment stopping with no communication at all from health services. How and when duties may be triggered in those circumstances need considerations. We would like to see reference to this within the flow chart for clarity.

Question 3

Are the guidance and case studies useful in determining what is meant by harm that 'could' be experienced? **Yes**

Please provide any comments or further explanation (in particular if response is no).

The case studies included in appendix H do provide useful case studies for a variety of medical conditions and circumstances. Case studies include instances where delay is access to care is a factor, but they do not definitively breakdown what level of delay in access to care would trigger the duty of candour procedures for different conditions. Whilst a definitive list may not be possible owing to the differences in conditions and wider circumstances, it will be important for NHS bodies to have greater detail for training and procedures to ensure that cases do not get missed where the duty of candour should be triggered.

The Duty of Candour was introduced in England in 2014 and evidence from 2020 shows that in some cases the Duty of candour appears to have been a tick box exercise for some bodies, rather than providing Health professionals the support and resourcing to use the duty to improve quality of care.[2]

Question 4

Do you agree that setting the threshold for triggering the Duty of Candour at moderate harm, severe harm or death reaches the right balance between informing Service Users and not overburdening NHS providers?
Yes

Please provide any comments or further explanation (in particular if response is no).

As previously stated, we welcome the inclusion of an adverse outcome not being proven as resulting from health care. With the ongoing retention and recruitment crisis it is important that the introduction of the Duty of Candour is not too burdensome.

[2] https://www.professionalstandards.org.uk/news-and-blog/blog/detail/blog/2020/01/30/the-duty-of-candour-where-are-we-now

It is vital that trust in NHS bodies is restored for those who have lost it and this Duty will assist health bodies in achieving this aim at this level.

Question 5

Does the harm framework at Annex B provide useful guidance on the type of harm that will fall into the categories of moderate, severe harm or death?
Yes
No
Please provide any comments or further explanation (in particular if response is no).

The definitions of moderate, severe harm and death do make sense for the purposes of the duty of candour in medical terms. We are unsure whether these categories will be understood by older people in the same way as to them what is moderate and severe harm can include social factors. It is therefore important that the reasoning for these definitions are communicated clearly to patients.

Question 6

Do you consider the case study examples set out in Annex H to be sufficiently comprehensive to explain when the Duty of Candour would be generated?

Yes, in the main
No
Please provide any comments or further explanation (in particular if response is no).

The case studies included in annex H are clear. A range of scenarios are included that also include the same scenarios with different circumstances that are helpful in understanding when the duty of candour process would be triggered.

An example is included where there was an excessive wait for diagnosis in relation to cancer screening. It would be helpful to have more detailed information on whether excessive delays are considered to trigger the duty of candour in other diagnostic and treatment areas and what length of delay would be considered excessive. This will assist busy health professionals assess a case more quickly as to whether it meets the Duty of Candour criteria.

Question 7

Is the relationship between the professional Duty of Candour that many health professionals are subject to and the statutory Duty of Candour clear?

Yes
Please provide any comments or further explanation (in particular if response is no).

Question 8

Is the guidance on the operation of the Duty of Candour procedure at page 11 of the guidance clear?

Yes
No
Please provide any comments or further explanation (in particular if response is no).

Question 9

Are the flow charts at Annexes C and F1 useful as an aid to understanding how the procedure will operate?

Yes
No
Please provide any comments or further explanation (in particular if response is no).

Question 10

Is the guidance clear on how the Duty of Candour applies to commissioned services?

Yes
No
Please provide any comments or further explanation (in particular if response is no).

The guidance is clear in that it does not hold commissioned services to the same procedures as an NHS body except through contracting arrangements, which can take a number of years to catch up. It is disappointing that the same duties cannot be applied at the same time as for NHS bodies. With the delays in access to health care before, during and peri-pandemic, we are concerned that the quality of care provided by non-NHS bodies may not be held to the same standards.

We have heard increasingly through our annual surveys, at face-to-face engagement sessions with older people and increasing calls to our Advice and Information service how they are turning to private care as they simply can not wait for NHS services as their quality of life is so badly affected. It is important that when Duty of Candour procedures are introduced, NHS bodies have robust monitoring arrangements with outside agencies to ensure quality of care is overseen on an ongoing basis and that processes are in place to address any issues where they are identified.

Question 11

The procedure flow chart at Annex A1 shows the procedure to follow when services are commissioned. Is the process clear?

Yes
Please provide any comments or further explanation (in particular if response is no).

Question 12
Is the guidance clear when harm to Service Users that occurs whilst waiting for diagnostics and treatment triggers the Duty of Candour?
Yes
No
Please provide any comments or further explanation (in particular if response is no).

Please see our response to questions 3 and 6 above.

Question 13
What further clarification do you consider would be helpful for NHS organisations and service users with regards to harm sustained whilst waiting for diagnostics and treatment?

Please provide any comments or further explanation

Please see our responses to questions 3 and 6 above

Question 14

Is the requirement for Local Health Boards, NHS Trusts, and Special Health Authorities, to publish their Candour reports clear?

Yes
No
Please provide any comments or further explanation (in particular if response is no).

Question 15

In relation to the reporting flow chart set out in Annex G, is the process clear?

Yes

No
Please provide any comments or further explanation (in particular if response is no).

Question 16

Are the annual reporting dates of 30th Sept for primary care providers and 31st October for Local Health Board's, NHS trusts and Special Health Authorities' reasonable?

Yes, in the main
No
Please provide any comments or further explanation (in particular if response is no).

Whilst annual reporting ensures that learning can be taken from reported incidents going forward, it is also important that Duty of Candour procedures have clear lines of reporting that can be escalated when things have gone very wrong at any time of the year.

Question 17

Is it reasonable to suggest the Duty of Candour report should be aligned to the existing annual PTR report already in place to avoid duplication?
Yes
No
Please provide any comments or further explanation (in particular if response is no).

Question 18

Is the explanation of 'on first becoming aware' in the guidance sufficiently clear to enable NHS organisations to know when the Candour procedure must start?

Yes
No
Please provide any comments or further explanation (in particular if response is no).

Question 19

In circumstances where the service user is unable or unwilling to be notified the Duty of Candour has been triggered, are the provisions setting out who may act on the service user's behalf sufficiently comprehensive?

Yes

No
Please provide any comments or further explanation (in particular if response is no).

8.7 of the Duty of Candour guidance simply states that where the service user has decision-making capacity that consent for the representative to act on their behalf should be obtained in writing. We welcome the inclusion that consent is kept under review. It is important that the guidance also includes appropriate reference to ensuring that the service user with capacity understands what this may mean in practice and how they may call for a review themselves.

More detail is required on who can be contacted when the patient is not willing to be notified, which should take into account those with power of attorney for various matters and any advance care plan that is in place.

Question 20

Are the provisions at regulation 7(3) which allow an NHS organisation to record when it will not be engaging with a service user or a person acting on their behalf, either because:

(i) they have made reasonable attempts to contact them and failed; or

(ii) where the service user has determined, they do not wish to communicate about the Duty, proportionate?

Yes
No
Please provide any comments or further explanation (in particular if response is no).

Question 21

Do regulations 7(2) and 7(3) strike the right balance between the needs of Service Users or persons acting on their behalf and level of burden placed on NHS organisations?
Yes
No
Please provide any comments or further explanation (in particular if response is no).

Question 22

Do you agree that 'in person' notification is appropriate and proportionate when informing a service user or their representative that the Duty of Candour has been triggered?
Yes

Please provide any comments or further explanation (in particular if response is no).

Please see question 23 below.

Question 23

Do you agree that it is appropriate and proportionate that the NHS organisation has the choice of which form of 'in person' notification is most appropriate, considering these factors above?

Not sure
Please provide any comments or further explanation (in particular if response is no).

To members of the public, an 'in person' notification would normally be expected to be a face-to-face communication. In practical terms this will not be possible for all cases and would slow down the notification to the patient and/or their representative. However, where something has gone wrong, then face to face communications are clearer for patients and their representatives. We have heard from older people where verbal communications from health professionals have not been understood due to the volume of information they are trying to take in at a stressful time. We therefore welcome that the written follow up includes the point of contact for patients to be able to ask questions after the notification has taken place.

We have concerns that patient records may not have sufficient detail with which to make the decision on how the Duty of Candour is communicated. We have heard repeatedly through our Dementia Advocacy service and our Helping Others Participate and Engage project (HOPE) where both patients and loved ones with and without Powers or Attorney have not been communicated with on relevant matters, even in cases where records clearly include them as being involved.

The guidance says that the NHS body must take reasonable steps to establish the preferred method of communication. It is vital that this takes into account whether patients and their representative are digitally literate, their preferred language and any other communication needs.

Question 24

Does the guidance on how to make a meaningful apology set out at section 7e and Annex E of the guidance provide sufficient information and advice to ensure a personal, meaningful apology is conveyed?

Yes
No
Please provide any comments or further explanation (in particular if response is no).

The guidance is clear on how and when an apology should be made.

Question 25

Do you agree that 'in person' notification should be followed up by a written notification?
Yes
No
Please provide any comments or further explanation (in particular if response is no).

We believe the written follow up is absolutely vital to older people who may suffer more than minimal harm. We hear repeatedly from older people where they have not been able to take information in fully during stressful times when hearing it for the first time, and so a written follow up is essential.

We would like to see further detail on how carers and loved ones can be part of this procedure at what can be an incredibly stressful time for a patient. UK evidence from older people's interactions with health care shows how poor communication contributes to negative experiences.[3] It is important that NHS bodies carefully consider what works for patients in written communications and make changes to existing systems.

Question 26

Do you agree the requirement placed on NHS organisations to take all reasonable steps to send the written notification within two working days from the date of the in-person notification is reasonable and proportionate?

Yes
No
Please provide any comments or further explanation (in particular if response is no).

Question 27

Do the training requirements cover all the staff that require training?
Yes
No

Please provide any comments or further explanation (in particular if response is no).

We welcome that staff at high to lower level will receive training. It is important that the training developed in relation to the Duty of Candour is sufficiently

[3] 2021, Chit Selvarajah, Helen Harrison, Meg Stapleton, Patiently Waiting: Older People's experiences of waiting for surgery' https://www.independentage.org/policy-and-research/patiently-waiting

resourced to be rolled out to all health staff needing it in a timely fashion. In England where the duty has already been introduced, it appears that the level of training was a contributing factor in the Duty not resulting in the cultural change expected to make a difference to older patients. Learning from England should be considered in the training roll-out.

Question 28

What type of training do you think would be required by NHS staff in addition to the current NHS training for the Duty of Candour to be successful?

Please provide any comments or further explanation.

Health care staff should be provided with wider training to assist with a more holistic treatment approach to help improve patient outcomes. Particularly for working with older people, it is important that staff have received human rights, dignified care and dementia training. This should include respectful communication, protecting privacy, promoting autonomy in a sensitive manner. We are aware of older people who have struggled to communicate with health staff in hospitals through hearing, sight and memory impairments. It is therefore vital that staff are aware of these additional needs to ensure patients are fully informed and involved in their treatment.

Question 29

Are the provisions related to staff support proportionate?

Yes

Please provide any comments or further explanation (in particular if response is no).

We welcome additional support for staff in relation to the Duty of Candour. This is essential to enable the cultural shift needed. Good quality health care relies on staff that are supported to do their jobs well. It is important that consideration is given on whether the existing volume of resources available to staff is sufficient to meet the level of need expected through the introduction of the Duty of Candour. Appropriate support for staff is vital at any time, but particularly now with the effects on staff because of the pandemic, additional support may be required to assist with staff retention.

Question 30

Do Regulations 10 and 11 assist NHS organisations in establishing an effective governance structure to ensure compliance with the Duty of Candour procedure?

Yes

No

Please provide any comments or further explanation (in particular if response is no).

We welcome the levels of seniority under Regulations 10 and 11. It is vital that those with responsibilities for overseeing quality are resourced to oversee the roll out of the Duty of Candour and have ongoing resourcing to give them time to comply with their duties.

In England where the Duty of Candour has been in place for 8 years, issues still remain in underreporting and compliance with the Duty.

Four years after implementation, a quarter of CQC inspection reports included little or no evidence to show that NHS trusts improved compliance with the duty.[4] Later research demonstrates their Care Quality Council inspections were still inconsistent and could be superficial.[5]

As such it is vital that HIW in Wales have the appropriate levels of training and resourcing to carry out their duties effectively in relation to the Duty of Candour.

Question 31

Do the regulations assist an organisation in providing the right level of leadership to fulfil its Duty of Candour responsibilities?
Yes
No
Please provide any comments or further explanation (in particular if response is no).

Question 32

Do you agree the time limits under the PTR Regulations should, when the Duty of Candour is triggered, run from the date of the in-person notification rather than the date the NHS Organisation would have been notified of the incident?

Yes
No
Please provide any comments or further explanation (in particular if response is no).

Question 33

Do you think changing the 'Putting Things Right' rules like this will cause problems?

[4] https://www.enablelaw.com/news/latest-news/duty-of-candour-4-years-on/

[5] https://journals.sagepub.com/doi/pdf/10.1177/0141076818815509

For example, do you think it would be better to not tell the person what has happened if it is in their best interest?

Yes

No

Please add any other comments you have.

It is not for health bodies to determine whether telling a patient what has happened is or is not in their best interests. In circumstances where the stress of knowing what has happened may in some circumstances be the right thing to do at that precise moment in time, all patient records should include details of family, carers and other loved ones who can help professionals make the right decision that will be in the best interests of the patient.

Question 34

Is the link between the Duty of Candour and the PTR process clear in the guidance and Annex F1?

Yes
No
Please provide any comments or further explanation (in particular if response is no).

Question 35
Are the proposed changes to the PTR guidance in respect of the Duty of Candour and PTR Amendment Regulations clear?

Yes
No
Please provide any comments or further explanation (in particular if response is no).

Question 36

Do you think that the changes made to the PTR guidance are sufficient to provide clarity on how Duty of Candour interacts in the PTR procedures?

Yes
No
Please provide any comments or further explanation (in particular if response is no).

Question 37

What are your views on how the proposals in this consultation might impact?

- on people with protected characteristics as defined under the Equality Act 2010[6];
- on health disparities; or on vulnerable groups in our society.

Please provide your comments here:

We are pleased to see that the consultation already identifies that older people are more likely to have more interactions with health services and so in this way will be affected. Older people are not a homogenous group and so it is also important to consider how intersectionality affects older people (as well as younger age groups).

For example, as well as being more likely to be in receipt of health care, older people are more likely to have caring responsibilities. In circumstances where they are the main carer for another patient, it is important that patient records are able to identify these relationships so that notification happens in the best way possible for the patient and their carer(s).

Impact on Welsh language

Question 38

We would like to know your views on the effects that the Duty of Candour proposals would have on the Welsh language, specifically on opportunities for people to use Welsh and on treating the Welsh language no less favorably than English.

For example, what effects do you think there would be? How could positive effects be increased, or negative effects be mitigated?

Please provide your comments:

Question 39

Please also explain how you believe the proposed Duty of Candour policy could have positive or negative effects on opportunities for people to use the Welsh language or treat it no less favorably than the English language?

Please provide your comments:

In cases where the patient's first language is Welsh, and particularly for older people who may be living with dementia as well as a range of other health conditions, it is vital that NHS bodies have enough Welsh speaking staff to notify patients when the Duty of Candour is triggered. In some cases, this may

[6] The following characteristics are protected characteristics from the Equality Act 2010—age; disability; gender reassignment; marriage and civil partnership; pregnancy and maternity; race; religion or belief; sex; sexual orientation.

be through advocacy services where there is an existing relationship with the patient and their representatives.

Question 40

We have asked several specific questions. If you have any related issues which we have not specifically addressed, please use this space to report them:

Please provide your comments:

In order for the duty of candour procedure to be effective, it is vital that health bodies are resourced and supported to roll this out effectively. Whilst in some ways the procedure may be seen as an add on to Putting Things Right, it is important that appropriate training for all staff and leaders is clear and comprehensive in order for this to be effective.

We also have concerns that the current levels of advocacy services will not be sufficient to help older people with no close relatives to be supported through the process fully. It is important that the impact assessment considers what resources are needed by support services to make roll out successful.

Annex D provides a very useful list of useful national contact details for organisations that can support the service user or person acting on their behalf. It is important that at local level, NHS bodies utilise local knowledge on support and information to supplement this list. For example, at Age Cymru our Dementia Advocacy project would be well placed to support older people affected by dementia through the Duty of Candour process but we are not included on this list.

Consultation Response Form
Your name: Helen Twidle

Organisation (if applicable): Age Cymru

Option to designate citizen or service user rather than organisation

email / telephone number: helen.twidle@agecymru.org.uk / 02920 431571

Your address: Ground floor, Mariners House, Trident Court, East Moors Road, Cardiff CF24 5TD

Please enter here:

Responses to consultations are likely to be made public, on the internet or in a report. If you would prefer your response to remain anonymous, please tick here: