The Duty of Candour Consultation Questions

The Health and Social Care (Quality and Engagement) (Wales) Act 2020,

Date of issue: 20th September 2022

Action required: Responses by 13th December 2022

The Duty of Candour

The Duty of Candour means NHS organisations have a Duty to be open and honest with people they are caring for when things go wrong, and harm has occurred. And they should try and put things right if they have caused harm.

The Candour process will build on the work that has already been started in Wales as part of the 'Putting Things Right' (PTR) process to embed candid behaviour by making openness and transparency with people in relation to their care and treatment a normal part of their culture across these organisations in Wales. It also adds to the existing individual professional Duty of Candour that clinicians already have as part of their professional regulations.

The purpose of this consultation is to invite views on the guidance and Regulations that are necessary to implement the Duty of Candour namely:

- the Duty of Candour Guidance, and
- the Duty of Candour Procedure (Wales) Regulations 2023 ("the Candour Procedure Regulations"),

When the Duty of Candour is applied

The Act provides that the Duty of Candour will apply when two conditions are met:

i. firstly, a service user to whom health care is being or has been provided by a NHS organisation has suffered an adverse outcome; and
ii. secondly, the provision of health care was or may have been a factor in the service user suffering that outcome.

Part 4 of the guidance describes when the Duty of Candour procedure applies.

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).

Agree that the guidance is clear about the two conditions that need to be met.

Annex A explains the Duty of Candour trigger review process as a flow chart

Question 2

Is the flowchart at Annex A, a useful tool for determining whether the Duty has been triggered?

Yes

Please provide any comments or further explanation (in particular if response is no). A condition that needs to be satisfied before the Duty applies is the service user must suffer an adverse outcome. A service user suffers an adverse outcome if the user experiences, or if the circumstances are such that they could experience; any unexpected or unintended harm that is more than minimal.

Practical guidance in relation to this in the Guidance at pages 8-9 and Annex H case study 9.

It is a useful tool to easily identify whether the Duty has been triggered.

Local internal processes must be clear that the Duty isn't triggered at the point when the incident is entered on to DATIX (DATIX is the IT system we use to input concerns or complaints information) but when the organisation has reviewed the DATIX entry in a timely way and determined that the trigger has been met.

We would recommend that the flowchart; in the box which states:

"Has the service user to whom healthcare is being or has been provided by the NHS body suffered an adverse outcome?"

adds the phase *'or could suffer' an adverse outcome* to the main question and not only be referred to in the subsequent "i.e." section.

Add a final box on the flowchart, so if the clinician and patient do not agree that the Duty of Candour has not been triggered in this instance, the patient is informed that they still have the option to raise a concern under PTR.

We would recommend that additional wording is added to the statutory guidance on page 19, point 8.27. As above, we would recommend that additional details about what the process is, should the clinician and the patient disagree with the level of harm caused. For example, the clinician should tell the patient that they are entitled to raise a concern via Putting Things Right process if the clinician is of the view that none or low harm is evident, but the patient or representative feels moderate or severe harm is evident.

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 Act, states that more than minimal harm is necessary to trigger the Duty of Candour. The proposal is that the meaning of more than minimal harm is 'moderate harm, severe harm and death'

Annex B explains what is meant by moderate harm, severe harm, and death

There are varied useful case studies which help the reader to understand what is meant by harm that 'could' be experienced.

We would value the intention for additional case studies to be provided as they happen, to provide relevant up to date examples.

We would welcome the inclusion of a case study about maternity services.

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).

Should the clinician and patient not agree on the level of harm experienced, it should be clear that the patient is entitled to raise a concern under PTR.

We welcome that the guidance is clear about the Health Board's responsibility.

We would like to see what interim assurances will be provided from independent providers, until the independent provider Duty of Candour is introduced in April 2024.

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

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

It provides useful guidance to understand the categories.

We also value that it aligns with the English and Scottish guidance, for a consistent approach and application of the Duty in the UK.

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

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

We would value the intention for additional case studies to be provided as they happen, to provide relevant up to date examples.

We would welcome the inclusion of case study about maternity services.

The relationship with professional duties

Part 2 of the guidance also explains how the Duty of Candour under the Act interrelates with the professional duties of Candour that many clinicians (including GPs, hospital doctors, dentists, nurses, pharmacists, ophthalmic practitioners, allied health professionals etc.) are obliged to follow

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).

We are satisfied that these align.

The Duty of Candour procedure

- Part 7 of the guidance provides some further explanation of the intended operation of the Duty of Candour procedure

Annexes C and F1 explain the process.

Question 8

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

Yes

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

Add to second orange box:

We would like to see additional details about what the process is, should the clinician and the patient disagree with the level of harm caused. For example, the clinician should tell the patient that they are entitled to raise a concern via Putting Things Right process.

Add to second yellow box:

We would like to see additional details about what the process is, should the clinician and the patient disagree with the level of harm caused. For example, the clinician should tell the patient that they are entitled to raise a concern via Putting Things Right process.

Question 9

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

Yes

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

We welcome that the flowcharts prompt and remind staff about reporting near misses for learning and improvement purposes.

Commissioned Services
an NHS organisation is responsible for complying with the Duty of Candour in relation to all health care which it actually provides:

- Where a local health board enters into arrangements with a primary care provider (such as a GP) for the provision of NHS services, it is the primary care provider that is subject to the Duty

If a local health board entered into an arrangement with an independent provider for the provision of services, the Duty would remain with the local health board.

Section 11 of the guidance clarifies which organisation will be responsible for complying with the Duty of Candour in situations where health services are provided by one organisation on behalf of another.

Question 10

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

Yes

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

We support that independent commissioned services will come under their own duty of candour in April 2024.

We also support that the responsibility for Candour in regard to Independent providers will remain with the local health board.

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).

Harm that occurs to Service Users whilst waiting for diagnostics or care from the NHS

There will be occasions when the Duty of Candour is triggered because of moderate, severe harm or death being suffered by people waiting for treatment on waiting lists. This would be where the harm caused that was 'unintended or unexpected'

1) which goes over and above what might reasonably be expected or intended considering factors such as the person's condition, the number of people waiting for treatment and the availability of resources to provide that treatment.
   or
2) for the purposes of Duty of Candour an error occurred in the process of administration or in the admission to the list or subsequent care during the waiting list process.

For more detailed information read the section in the guidance on page 20

Question 12
Is the guidance clear when harm to Service Users that occurs whilst waiting for diagnostics and treatment triggers the Duty of Candour?

No

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

We do not support this section of the guidance. The guidance does not refer to patients waiting over their referral to treatment time target (RTT) and the harm these people may suffer as a result of waiting longer than "intended" in line with clinical and national guidance on target times.

This document does not align with the Welsh Government's transforming and modernising planned care services where deadlines have been set for local Health Boards to work though their first outpatient appointment and treatment lists.

Whilst the backlogs caused by the pandemic are expected at this time, "unintended harm" should apply here as people are waiting longer than intended against RTTs in many cases. People's clinical risks of deterioration are always present, hence the reason for their referral, waiting time targets for urgent and routine care are set so that avoidable harm is prevented if treated within set time periods. Anyone waiting over their RTT

either as an urgent or routine patient has an increased risk of suffering harm as a result of waiting too long.

Clinical list management and monitoring is not a suitable caveat against this current (unintended) service pressure.

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

As above, we do not support this section of the guidance.

We would expect the guidance to be much clearer about unintended harm caused as a result of excessive waiting times, which could have been avoided if the person was treated in line with the RTT for their condition.

Annual reporting of Duty of Candour:

The Act also provides for NHS organisations to report annually on whether the Duty of Candour has come into effect in relation to the NHS organisation during the reporting year (each financial year). Guidance in relation to the reporting requirements is set out in part 11 of the Guidance, with an explanatory flow chart at Annex G.

Question 14

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

Yes

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

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

Add the Citizen Voice Body to the flowchart.

The Act states that reports on Candour must be published as soon as practicable we have said for primary care providers this is no later than 30th Sept and for Health Boards, Trusts, and Special Health Authorities no later than 31st Oct.

This is in line with the 6 months of investigation time for incidents under ‘Putting Things Right’.

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

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

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

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

Notification of Duty of Candour

The Regulations require the NHS organisation to notify the service user or someone acting on their behalf at the point it first becomes aware that the Duty of Candour has been triggered.

Guidance on what is meant by ‘on first becoming aware’ is set out at pages 11 of the guidance. This is the point, at which it is known that harm (moderate, severe or death) to a service user during their NHS care has occurred, or may do, and the care is likely to have been the cause.

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

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

The notification may be made to a person who is acting on the service user’s behalf, where the:

- service user has died
- or in the opinion of the NHS organisation, lacking in capacity or otherwise unable to make decisions about the service provided
- or where a service user with capacity has asked for someone else to act on their behalf.

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

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

When you cannot get hold of the service user or they do not want to be contacted Regulation 7(2 & 3) requires the NHS organisation to make a record of attempts to contact or communicate with the service user and keep records.

Read more detail on regulation 7 in the Regulations

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

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

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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

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

The ‘in person notification’

Regulation 4 of the Regulations requires an NHS organisation to make an ‘in person notification’ to the service user or a person acting on their behalf.

This is ‘communication that is made by telephone call, audio visual communication or a face-to-face meeting’.

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 but please see comments below.

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

When deciding which method to use the Regulations specify the criteria to be considered when making this decision such as:

- the severity of the harm caused
- the nature and complexity of what has happened
- the personal circumstances of the service user and their preferred method of communication.

We are concerned that in some instances this may not be appropriate or sufficient.

We would like to see in the guidance a prompt to offer patients the option of having someone accompany them at the 'in person' notification, for example, a chaperone approach or an offer for a family member to attend.

This is to ensure that the person can take this information in, especially in a stressful situation. We believe that appropriate support for an individual when they are being told is important. We support this being a patient focused process.

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?

Yes but please see comment below

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

It would be helpful for the guidance to state that the organisations choice should reflect the individual circumstances, for example what is best for the patient not the clinician/notifier.

The apology

To support NHS organisations in saying sorry, the guidance (section 7e) provides some further guidance to NHS organisations on how to make a personal, meaningful apology.

Additional resources are available in Annex E

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

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

We welcome the guidance in Annex E. A meaningful apology is very important.

We would like to see that Annex E is linked to staff training and examples of good practice shared with staff, so refresher training and continued development of staff is meaningful and relevant to their role.

Written notification

In accordance with Regulation 5, the NHS organisation must follow the in-person notification with a written notification within 2 working days. This is to ensure the service user or person acting on their behalf has a written record of what was discussed which will aid their understanding of the process.

Question 25

Do you agree that ‘in person’ notification should be followed up by a written notification?

Yes

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

We agree that it the ‘in person’ notification should be following up by a written notification. We know that sometimes in stressful situations, people do not retain all the information given to them.

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

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

We welcome the intent in the guidance to make letters personal (not a standard template used) and the inclusion of a personal signature.

Training and support of staff

Regulation 8 details the requirements for staff training and support. Regulation 8(1) sets out which staff must receive training on the Duty of Candour.

Further information on the type of staff that will be trained is in the Regulations

Question 27

Do the training requirements cover all the staff that require training?

Yes

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

We would welcome mandatory training for all staff and acknowledge the different levels of training required depending on staff involvement with the candour and complaints process.

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.

We would like to see regular refresher training for all staff, including the use of new, relevant and up to date examples of good practice.

Using the information gathered in the annual reports including lessons learned, we would like to see where further training and development of staff is identified and implemented.

Annual reports should include training compliance percentages.

Regulation 8(2) provides that an NHS organisation must provide staff who are involved in a notifiable adverse outcome with details of services which may aid the member of staff – taking account of the circumstances of the notifiable adverse outcome and the staff member's needs.

Further information on the support of staff involved is in the Regulation 8

Question 29

Are the provisions related to staff support proportionate?

Yes

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

Organisational governance and oversight of the Duty of Candour

Regulations 10 and 11 set out the requirements to assist NHS organisations in devising a governance structure to ensure compliance with the Duty.

Further detail on these requirements are in Regulations 10 and 11.

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

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

We are content that the Duty of Candour can be integrated into existing corporate governance frameworks, processes and procedures, and that the corporate lead responsible for the monitoring of the Duty of Candour is also responsible for PTR.

Question 31

Do the regulations assist an organisation in providing the right level of leadership to fulfil its Duty of Candour responsibilities?

Yes

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

We are content that the Duty of Candour can be integrated into existing corporate governance frameworks, processes and procedures, and that the corporate lead that is responsible for the monitoring of the Duty of Candour is also responsible for PTR.

It is very important for this to be aligned in terms of lessons learned and impact and improving patient safety.

Duty of Candour and the PTR procedure

The PTR Regulations are extended to apply from the date the NHS organisation makes the in-person notification, rather than the date that the NHS Organisation received notification of the concern. This designed so that the Duty of Candour being triggered and the link to the 'Putting Things Right' process work in sequence and avoid duplication.

An overview of the Candour procedure and review process steps that need to be followed is in Annex C in the guidance and the PTR Regulation amendments.

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

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

We agree that the PTR timeframe of 30 working days to respond should start the day that the Duty of Candour is triggered.

‘Putting Things Right’ says that you can decide not to tell someone if harm was caused if it is in their best interest. The NHS would still need to write up details of this. And say why they decided not to tell the person.

Now ‘Putting Things Right’ says that the person must be told if something went wrong with their care, and Duty of Candour is being used.

But they do not need to be involved in the process or the investigation, if that is what is best for them.

Question 33

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

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

No, we are content the Duty of Candour aligns with PTR. It will speed up the process and reduce the risk of a number of time critical cases and complaints being dismissed as out of time.

Please add any other comments you have.

A flow chart is available in Annex F1

Question 34

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

Yes

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

Duty of Candour and the PTR Amendment Regulations

A summary of the changes to be made to the guidance in relation to the Duty of Candour and the PTR Amendment Regulations

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

Yes

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

We support the amendments to the regulations, especially where the Health Board can consider whether it is appropriate to take the concern back and consider it through PTR following the conclusion of a PSOW investigation.

We also agree with the "representative" definition included.

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

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

We are comfortable with how the Duty of Candour interacts with PTR procedures since and when the Duty of Candor is triggered, PTR begins.

Integrated Impact Assessments

It is fundamental to the policy making process to consider health disparities and to assess and understand how different groups are impacted differently by the policies that we implement.

Our consideration to date suggests that the proposals could have a disproportionate indirect impact (but not a negative impact) on people with certain characteristics – notably disability and age. The reason for this indirect impact is that people in these groups have more frequent interactions with the health care system and, as a result, more likelihood of the Duty of Candour being triggered.

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[1];
- on health disparities; or on vulnerable groups in our society.

Please provide your comments here:

It is important to consider how people with protected characteristics or those in vulnerable groups in society may require additional support such as chaperone services or communication support, so they are not negatively impacted.

Impact on Welsh language

[1] 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.

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:

We are supportive of the view that people should be able to state their preferred method of communication and language (i.e. Welsh) needs and that they should not be negatively affected and it should not lead to a delay in responding to that individual.

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:

Positive - if more Welsh language resources are made available.

Negative - There may be a delay in triggering the Duty of Candour while trying to obtain translation or communication support services.

The implementation of the Duty of Candour to Welsh NHS organisations is complex however your views are essential to help us do this successfully.

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:

The useful contacts literature refers to the Community Health Councils but needs to include reference to the new CVB as the new body will be launched at the same time that this Duty comes into force.

The clinician may need to start the conversation with the patient before the Duty of Candour is triggered, as other policies would expect them to do so. Framing those conversation, the org will need to consider whether the duty of candour will be triggered.

Consultation Response Form
Your name:

Organisation (if applicable):

Option to designate citizen or service user rather than organisation

email / telephone number:

Your address:

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: