

Duty of Candour Consultation 2022: RCGP Cymru Wales Response

Introduction:

RCGP (Royal College of General Practitioners) Cymru Wales has consulted with its members and patient forum regarding the Duty of Candour. Our members were encouraged that the Duty applies to institutional bodies, rather than individuals. As previously noted in the College's 2014 response to the UK government and our response to the Northern Irish Consultation, we held concerns that any duty conveyed on individuals would lead to targets around reporting causing potentially harmful outcomes.

From our discussions, our members noted an improvement in the culture of accountability already becoming more commonplace in the NHS in Wales and are in cautious support of these regulations.

A common theme among both patients and members was the appetite for using the data gathered by the Duty of Candour to identify common issues, which cause patient harm and to ensure these are closely monitored, that staff are supported, and training is provided to reduce occurrence of these issues from the NHS. Patients noted that their primary concern while either receiving notification under these regulations or having made a complaint under the current Putting Things Right system, would be to ensure the same thing did not happen to another person. Therefore, RCGP Cymru Wales would encourage more guidance relating to staff support and training, not just in implementing the Duty of Candour but in using the information to inform best practice. The College would also encourage robust data collection following the implementation of the regulations to focus on areas and procedures most in need of change.

Question 1: Is the Guidance on when the Duty of Candour applies clear?

No

The Duty of Candour applies when two conditions are met:

"Firstly, a Service User to whom health care is being or has been provided by a NHS body 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."

Page 11 of the statutory guidance provides that, *'The meaning of health care is deliberately widely drawn to capture all of the services provided in Wales under the NHS umbrella.'* and that *'It need not, however, be certain that the health care caused the harm. It is sufficient that the health care may have been a factor.'* The example given in the consultation document is that of a patient on a waiting list, not necessarily triggering the Duty as it would be their condition which caused the harm rather than the health care.

The above are unclear for the following reasons; there are few examples given of what constitutes health care, for example would administrative errors leading to harm constitute health care?

Also, as time spent waiting to be seen does not constitute health care causing harm, would other omissions also fail to meet the conditions of this two-part test. The legislation is not prescriptive enough and therefore could be subject to misinterpretation. Under the specific section regarding waiting times, the guidance states that being missed from a list or added to the wrong list could constitute an action causing harm, but this is specific to only that circumstance. Elsewhere the guidance is silent on omissions.

Question 2: Is the flowchart at Annex A, a useful tool for determining whether the Duty has been triggered?

No,

A flowchart such as this could be helpful, however the language in the flowchart encounters the same issues as above.

Question 3: Are the guidance and case studies useful in determining what is meant by harm that 'could' be experienced?

No

The case study document itself is not user-friendly. It is not clear how health care professionals could use it to support themselves when complying with the Duty.

Taking the 'GP to secondary care' example, the case study states that the duty is triggered because 'of baby B's condition not being fully appreciated.' However, it would be difficult to apply this to other examples where the condition was worse than it appeared. Does this mean all conditions that are in fact worse than they appear on first visit to the GP would trigger the duty or is there a 'but for' test that needs to be applied as in the law of negligence? It is not clear, and this will lead staff to draw their own conclusions about the causes of the harm.

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

RCGP Cymru Wales agrees that the threshold should be set at moderate harm. This is consistent with existing guidance from the National Patient Safety Agency. The NPSA's 'Being open' framework sets 'moderate harm' as the threshold requiring open disclosure.

'Moderate harm' is defined by the NPSA as: "Any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care." While the NPSA identified difficulties in defining moderate harm, the levels of harm diagram provided by Welsh Government, in Annex B, are clear, appropriate, and proportionate.

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

The categories of harm are explicit and easy to understand. There are a variety of examples of the types of which fall under the category. It is clear the list is not exhaustive, but it would be simple to compare a real-life situation to the examples given.

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

As above

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

The Duty of Candour here is a duty conveyed on healthcare bodies and that it complements the professional duties which already apply to many healthcare professionals.

Question 8: Is the guidance on the operation of the Duty of Candour procedure at page 11 of the guidance clear?

Yes: While page 11, discusses the aims and application of the duty of candour, it also provides that the procedure is outlined by Annex C. While, as above we would encourage more clarity on the first condition to trigger duty of candour, the procedure is clear and easy to follow.

Question 9: Are the flow charts at Annexes C and F1 useful as an aid to understanding how the procedure will operate?

Yes, as above

Question 10: Is the guidance clear on how the Duty of Candour applies to commissioned services?

Yes

If a contract is awarded to a healthcare body such as a GP practice, the duty remains with the practice, if it were not a health body it would remain with the health board. The College queries if social care provisions arranged by health boards would trigger the duty of candour, should a patient suffer harm, as this distinction is not made by the documents.

Question 11: The procedure flow chart at Annex A1 shows the procedure to follow when services are commissioned. Is the process clear?

Yes, however please see our above comment regarding social care.

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

No

At page 27 the guidance that while a waiting on a waiting list who suffers harm because of their condition will not necessarily trigger the duty *'if the Service User had been missed off the list or incorrectly prioritised and this therefore created a delay resulting in harm then the Duty would*

apply since the resulting harm would be unexpected.' It is not clear if this list is an exhaustive list of the patients who may trigger the duty whilst on waiting list or if these are examples, it also not clear if the duty will be triggered if a person who seemed to be on the correct waiting list, suffered and harm and, with hindsight, they should have been put on this list or if it would be trigger simply in the case of pure clerical error.

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?

While an exhaustive list of examples which trigger the duty is not possible, RCGP Cymru Wales would support an accessible database, searchable by keyword and NHS discipline, of cases which triggered the duty and why. It will be helpful if this could be added to following the reporting of incidents to help staff decide if the duty has been triggered.

Question 14: Is the requirement for Local Health Boards, NHS Trusts, and Special Health Authorities, to publish their Candour reports clear?

Yes

Question 15: In relation to the reporting flow chart set out in Annex G, is the process clear?

No,

Annex G does not state the format the report should be delivered in, or, for example if there will be a proforma to minimise error.

Question 16: Are the annual reporting dates of 30th September for primary care providers and 31st October for Local Health Boards, NHS trusts and Special Health Authorities reasonable?

Yes

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

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?

No,

Page 16 provides: *'The requirement to notify the service user/person acting on their behalf on first becoming aware the duty has been triggered means that the NHS body should reflect and make a considered decision as to whether the conditions as set out in part 4 above have been met.'*

Once determined that the conditions as set out in part 4 above have been met, this would be considered to be the point at which the NHS body 'first becomes aware' that the duty has been triggered. 8.9 This is the start date for the duty of candour procedure (referred to in this Guidance and the appendices as "the procedure start date"), which must be followed, starting with the 'in person' notification to the service user/person acting on their behalf.'

The above does not provide how long this period of reflection should be, only that it will not be necessary to undertake a full investigation. It does not specify if the reflection should be done by an individual or by committee. There is also no maximum time limit for the period of reflection, after which the 30-day period should start.

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

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:

- they have made reasonable attempts to contact them and failed; or
- where the service user has determined, they do not wish to communicate about the Duty, proportionate?

No

The regulations do not provide for how many attempts to contact would be reasonable.

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?

No

While recording the number of failed contact attempts is sensible, without clarity as to what reasonable looks like we cannot say if is proportionate. The College feels three attempts over three weeks would be reasonable and proportionate in most circumstances. If a healthcare body felt it was appropriate to deviate from any prescribed number of attempts, they should be required to report the reasons for that decision to the health board.

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

After consulting with our patient forum, RCGP Cymru Wales feels it would be appropriate and proportionate for both patient and healthcare provider for the notification to take place in person. The College feels that training material regarding how to empathetically notify of a mistake should be made available if it is not already.

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

However, following the implementation of the regulations there should be room for discussion around how a notification in its various forms was perceived by the patient.

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, the information in Annex E would be useful to staff, but a training video showing examples of effective apologies would also be welcome.

Question 25: Do you agree that 'in person' notification should be followed up by a written notification?

Yes, this should be the case to record what has been said for patients and staff members.

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

Question 27: Do the training requirements cover all the staff that require training?

No, regulation 8 states the following:

‘(2) For the purposes of paragraph (1), the members of staff are— (a) those involved in the provision of health care; (b) those involved in investigating or managing notifiable adverse outcomes; (c) any other relevant members of staff who are involved in performing or exercising functions in connection with the candour procedure.’

As above, it is not clear which activities constitute healthcare, to satisfy the first condition. Therefore, the term here also lacks clarity. It is not clear whether more administrative tasks, such as the booking of appointments for in-patients or hospital transport, could constitute healthcare and whether staff, such as ward based clerical staff would need to be trained or if their actions could satisfy the first condition.

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?

The statutory guidance states that, the training that will be provided will be *‘The guidance will be complemented by an online training package devised by NHS Shared Services Partnership and Welsh Government to support NHS bodies with the implementation of the duty.’*

RCGP Cymru Wales supports an online training package and feels this should include video examples of notification and apology.

Question 29: Are the provisions related to staff support (regulation 8(2)) proportionate?

This is unclear as the provisions are minimal, regulation 8 states: *‘(3) The responsible body must provide a member of staff who is involved in a notifiable adverse outcome with details of any services of which the responsible body is aware which may provide assistance or support to any such member of staff, taking into account— (a) the circumstances relating to the notifiable*

adverse outcome, and (b) the member of staff's needs.'

Regulation 8b, regarding the member of staff's needs, is too wide a provision and may either leave staff unsupported or leave them open to not facilitating the Duty of Candour because they believe they have not been given proper support.

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. In the case of GP practices, the regulations are clear that one person, most likely a partner in the practice, would be responsible for ensuring compliance with the duty.

Question 31: Do the regulations assist an organisation in providing the right level of leadership to fulfil its Duty of Candour responsibilities?

Regulations 10 and 11 provide that the responsible can either perform functions relating to the duty themselves or delegate them to another party, however it is not clear how the duty of candour should be promoted internally in organisations. While the regulations state that all those staff members involved with the Duty of Candour must be trained to complete reports, to notify and apologise, RCGP Cymru Wales would welcome training for responsible officers in dealing with and supporting staff members to whom the duty applies.

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,

This is sensible due to the additional duties conveyed on bodies by the duty of candour,

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,

A patient has the right to know of an action taken on their behalf which has led to an adverse outcome. According to the Mental Capacity Act 2005, a person's best interests can only be served if their wishes and feelings are considered, therefore the person must be consulted if that is possible. If a person lacks the capacity to understand what has happened, an agent acting on behalf of the affected person should be informed.

Question 34: Is the link between the Duty of Candour and the PTR process clear in the guidance and Annex F1?

Yes

Question 35: Are the proposed changes to the [PTR guidance](#) in respect of the Duty of Candour and PTR Amendment Regulations clear?

Yes

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

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 2010¹⁴;
- on health disparities; or
- on vulnerable groups in our society.

The provisions of the regulations may impact the elderly, and those with a learning disability or neurodivergence as it provides for social interactions, that they may struggle with for a variety of reasons.

The training and support provided to staff should account for how to provide apologies and notify anyone who may struggle to understand. In addition, any ongoing record of case studies following implementation of the regulations should include how people from these groups perceive interactions relating to the duty, with a view to improving the experience for all parties.

The use of an in-person apology may also have an effect for those who do not understand spoken or written English, such as foreign nationals, migrants, or those from ethnic minorities (particularly women). In these cases, an in-person interaction with an interpreter may be a

more effective communication than a letter as the healthcare provider will be able to gauge understanding and take any questions.

The experience may be different for those with physical disabilities. For example, if a health board deems a face-to-face meeting the most appropriate way of engaging with a patient, any issues with transport or access should be considered and alternatives, such as video calls, should be offered.

In the case of deaf people any in-person interaction should accommodate any need for a signing language interpreter to be present, while members of staff should be mindful of lip reading.

In the case of the protected characteristic of maternity, it should be considered that a face-to-face meeting or telephone conversation the presence of a child, who cannot be in childcare, may be distressing, whether that conversation relates to the parent or child, and accommodations should be made to prevent this occurring.

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?

As the regulations provide for an in-person notification, it should be possible for a Welsh speaker to receive this notification in Welsh. Therefore, it should be provided that enough Welsh-speaking staff are trained according to the provisions above.



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