Browne Jacobson

Duty of Candour review: Submission to the Department of Health and Social Care

07 May 2024 Katie Viggers

The Department of Health and Social Care (DHSC) made a call for evidence as part of its review of the statutory duty of candour for health and social care providers in England. The DHSC requested feedback (including examples of good and poor practice) in relation to 10 specific questions. This document details Browne Jacobson's response to that call for evidence, which was submitted to the DHSC on 29 May 2024.

Question 1: Do you agree or disagree that the purpose of the statutory duty of candour is clear and well understood?

Disagree.

This response has been prepared by Browne Jacobson LLP, a leading UK law firm. We are health and social care sector experts and advise a wide range of national and international NHS and independent health and social care providers, commissioners and regulators.

We know that many of the health and social care organisations we represent have strong views on the statutory duty of candour and how this operates in practice. We therefore held an online forum on 7 May 2024 (the forum). We invited representatives from our clients to share their thoughts and views on the questions in the duty of candour review. The forum was attended by 69 individuals from over 40 different organisations, with attendees predominantly from NHS and independent healthcare providers, NHS commissioning bodies and local authorities. This response incorporates views expressed by delegates at the forum, on an anonymous basis.

While not specifically in scope for question 1, we note the recent conclusions of the Infected Blood Inquiry and the inclusion of a statutory duty to review candour laws in the Victims and Prisoners Bill (which was granted Royal Assent on 24 May 2024). Any wider changes to candour laws that impact on health and care services may also impact on the existing statutory duty of candour. It will be important for this to be considered as part of the current review, noting the views expressed below regarding the difficulties created by the existing differences in approach between the statutory duty of candour; professional duties of candour; and other specific duties to notify of certain incidents. It would also be helpful to consider the impact of the transition to the Patient Safety Incident Response Framework and way in which the different approach to incident monitoring and reporting interacts with the statutory duty of candour.

During the forum, we took a live poll on question 1. Of those who responded, 51% disagreed, 22% agreed and 26% neither agreed nor disagreed (hence we have responded to this question with the majority view).

Delegates spoke of the statutory duty of candour being challenging to understand and implement in practice alongside the professional duty. The duty of candour legislation, CQC guidance and terminology create confusion and internal debate about whether an incident triggers the statutory duty and specific requirements under Regulation 20. This can detract from the purpose of the duty of candour. As a result, some providers simply now ask themselves whether informing the patient/family about the incident is the right thing to do. If it is, they will do so in a way that meets the requirements of duty of candour, even if not required to. It was suggested that the statutory duty should be simplified, with that question at its core, since the duty of candour is primarily about openness and honesty.

Regarding “notifiable safety incidents”, many delegates found it difficult to determine whether the requisite harm threshold had been met to trigger the duty of candour. This is discussed in more detail in response to Question 6.

Question 2: Do you agree or disagree that staff in health and/or social care providers know of, and understand, the statutory duty of candour requirements?

Neither agree nor disagree

Delegates felt that individuals with specific roles relating to the duty of candour understand its requirements, however it is quite variable as to whether those directly providing care do. Again, it was noted that some professionals do not follow the process of determining whether an incident is a notifiable safety incident, but instead decide whether informing a patient or family about the incident is the right thing to do – and follow the process for the statutory duty of candour even if the incident does not meet the relevant criteria. This can result in inconsistencies.

One experienced delegate said that healthcare professionals generally are compassionate, kind and honest. It is only when they begin to look at the legislation and the specific requirements of the duty of candour that they become confused and anxious, and start to worry that apologising for an incident that does not meet the statutory criteria may land them in trouble.

There is also still fear and confusion among healthcare professionals about the duty of candour and liability for clinical negligence claims. Many organisations want to engender a culture of candour. However, staff on the ground can find it difficult to comply with the duty as they are concerned about inadvertently making admissions of liability, criticising others or being criticised themselves. It was felt that the duty of candour needs modernising and its language should be simplified and aligned with NHS Resolution’s approach, which simply says that apologising is “always the right thing to do” and “not an admission of liability”. Another delegate spoke of having an “openness” policy in place, and having open conversations with patients and families and conducting care reviews regardless of whether the incident is a notifiable safety incident or not.

Question 3: Do you agree or disagree that the statutory duty of candour is correctly complied with when a notifiable safety incident occurs?

Neither agree nor disagree

Delegates considered that the verbal duty of candour requirements are usually complied with, particularly in a healthcare setting. However, compliance can be variable in some social care settings. Further, professionals are not always proficient at appropriately evidencing or recording compliance with the duty of candour requirements. While the initial sharing of information is generally good, written follow ups and documentation of what has happened are less so.

Delegates from social care and community trusts spoke of difficulties in obtaining next of kin details or contacting next of kin following an incident. As a result, written follow up with next of kin can be challenging.

Some delegates reported that correspondence can be too “corporate” and difficult for patients or families to understand. Efforts are being made to simplify letters, to ensure they are accessible and compassionate.

One delegate said that smaller care providers, such as small care homes, often lack the systems that larger organisations have, making it difficult for them to comply with the requirements.

Question 4: Do you agree or disagree that providers demonstrate meaningful and compassionate engagement with those affected when a notifiable safety incident occurs?

Neither agree nor disagree

During the forum, a live poll was taken on this question. 33% of respondents agreed, 33% neither agreed nor disagreed, 22% disagreed and 10% didn't know.

It was felt that staff are under significant clinical pressure and have limited time and resources, and that fulfilling the duty of candour in a meaningful and compassionate manner takes time. This may not be fully appreciated by the regulator, CQC. Some delegates expressed the view that CQC seems more concerned with whether the duty of candour has been complied with rather than the quality of the response or whether it is compassionate. This can make it feel like a mere tick-box exercise. Additionally, larger organisations often have high volumes of notifiable safety incidents, which shifts the focus towards compliance with the duty rather than scrutinising the quality of responses.

One delegate pointed out that, in practice, the duty of candour is not fulfilled by the "provider" as a whole, but rather by individuals working within the provider. Given the typically large number of staff employed by healthcare providers, many of whom could be engaging in candour conversations or correspondence, it can be difficult to monitor the quality of engagement.

However, some good practices were noted in terms of compassionate and meaningful engagement, and family or patient liaison leads were deemed valuable in this regard.

Question 5: Do you agree or disagree that the 3 criteria for triggering a notifiable safety incident are appropriate?

Disagree

Many concerns were expressed about the criteria, and specifically the lack of consistency in the CQC's guidance on this. One delegate pointed out that the first criterion – "unintended or unexpected" – was previously understood to include unintended or unexpected outcomes, before a significant shift in CQC guidance in 2022 to clarify that "unexpected or unintended" in the context of the statutory duty of candour relates to "an incident which arises in the course of the regulated activity, not to the outcome of the incident". This has led to confusion and some delegates were uncomfortable with the new approach. Questions were raised as to whether this distinction accorded with the principles behind duty of candour.

In particular, one delegate expressed concern over the "surgery" example given by CQC in its guidance (example 3 under "Examples of notifiable safety incidents"). According to the guidance, this fictional example is not a notifiable safety incident because nothing unexpected or unintended occurred during the course of treatment, despite the unexpected outcome (the patient's death). However, the example caused confusion since it was considered a notifiable safety incident in the previous version of the guidance. In practice, it can also be challenging to distinguish between unintended or unexpected occurrences during treatment and unintended or unexpected outcomes, particularly within mental health care.

Connected to this, it was acknowledged that it can sometimes be difficult to determine if an 'incident' has occurred at all. This is particularly the case when considering whether harm that arises whilst patients are on waiting lists for care can trigger the duty of candour, even in the absence of any issues of prioritisation.

The delegates present did not raise concerns about the second part of the test (i.e. identifying whether an incident occurred during the provision of regulated activities), but it was acknowledged that this can be more challenging for certain types of service. For example, in learning disability and autism services that provide both CQC regulated and non-regulated care, there has previously been confusion, including from CQC inspectors themselves.

Difficulties in identifying harm thresholds are discussed elsewhere.

Question 6: Do you agree or disagree that the statutory duty of candour harm thresholds for trusts and all other services that CQC regulates are clear and/or well understood?

Disagree

Delegates expressed confusion over the varying definitions of harm, dependent on whether the provider is an NHS Trust or an independent service provider (ISP). Many ISPs deliver care under an NHS contract and operate under the assumption that the harm thresholds for NHS bodies (as set out in Paragraph 8 of Regulation 20) apply to them. However, technically, they should be following the other harm thresholds specified in Paragraph 9 of Regulation 20. In practical terms, there may be little difference between the two definitions, as something falling within the definition of harm for an NHS body is also likely to fall within the definition of harm for an ISP. Nevertheless, the differing definitions is confusing for healthcare providers – particularly ISPs.

Many delegates also found it difficult to determine whether the requisite harm threshold had been met to trigger the duty of candour, particularly in a mental health setting, largely because the levels of harm are not clearly defined in the Regulations. For instance, “moderate harm” means (in part) “significant, but not permanent, harm”, yet “significant” is not further defined. This makes it challenging for staff to determine whether the harm meets the required threshold. Additionally, delegates believed that the definitions were subjective and dependant on local interpretation. The harm thresholds were also deemed more difficult to apply in a social care setting than a clinical one. Social care professionals are expected to use clinical judgment to assess the level of harm caused, which they are not necessarily able to do. If the harm thresholds are to remain, then terms such as “moderate harm”, “significant harm” and “prolonged psychological harm” require clearer explanations and examples.

Question 7: Linked to the previous question, do you agree or disagree that the statutory duty of candour harm criteria that the incident must have been unintended or unexpected is clear and/or well understood?

Disagree

Please see our response to question 5.

Question 8: Do you agree or disagree that notifiable safety incidents are correctly categorised and recorded by health and/or social care providers, therefore triggering the statutory duty of candour?

Disagree

We took a live poll on this question. 68% of delegates who responded disagreed, for all of the reasons set out in response to the previous questions.

Question 9: Do you agree or disagree that health and/or care providers have adequate systems and senior level accountability for monitoring application of the statutory duty of candour and supporting organisational learning?

Neither agree nor disagree

The overall view was that staff members want to do the right thing, but they lack adequate support to do so. The statutory duty of candour has been transformed into a challenging and sometimes confusing process that providers find difficult to adhere to and execute, rather than being an intuitive, compassionate response simply because it is the right thing to do.

Question 10: Do you agree or disagree that regulation and enforcement of the statutory duty of candour by CQC has been adequate?

Disagree

A live poll was taken for this question. 48% of respondents disagreed, 27% neither agreed nor disagreed and 23% said they did not know.

Delegates thought that, in larger settings, there tends to be a focus by the CQC on self-reported figures, and in smaller settings on very specific incidents. Consequently, there is a lack of focus on the quality of duty of candour responses in larger services.

It was considered that the current regulation and enforcement arrangements by the CQC could be improved. As mentioned in the response to question 4 above, delegates reported that the CQC approach to enforcement was more of a tick box exercise, checking that compliance was recorded in the correct way, rather than looking at the quality of duty of candour engagement with patients and families. It was also reported that it could be difficult to engage in constructive dialogue with the CQC about compliance and that fear of prosecution could lead to defensiveness by organisations.

Some delegates suggested that CQC could develop its duty of candour guidance further and, in particular, include a “FAQ” section. A “learning log” was also considered to be a good idea.

Related expertise

Key contact

Katie Viggers

Professional Development Lawyer

katie.viggers@brownejacobson.com

+44 (0)330 045 2157