Open call for evidence

Duty of candour review

Published 16 April 2024

Applies to England

Summary

This call for evidence forms part of a review by the Department of Health and Social Care (DHSC) to consider the operation (including compliance and enforcement) of the statutory duty of candour ('the duty') for health and social care providers in England. The review was announced in the government's response to the Hillsborough disaster report on 6 December 2023. The terms of reference for the review were published on the same day.

We are committed to a review that can consider a wide range of evidence and views from across the health and care system in relation to the real-life application of the duty of candour. This call for evidence will be particularly relevant to those who are, or have been, engaged in the duty:

- patients and service users
- families and caregivers
- registered providers
- health and care professionals
- registered managers (known as 'registered persons')
- health and social care regulators

Together with other evidence and insights, we will use your responses to this call for evidence to help us assess the effectiveness of the duty and shape recommendations for the review.

Introduction

Those who use any type of health or social care service have a right to be informed about all elements of their care and treatment. Health and social care providers have that fundamental responsibility to be open and honest with those who are under their management and care.

In particular, when things go wrong during the provision of care and treatment, patients and service users and their families or caregivers expect to be informed honestly about what happened, what can be done to deal with any harm caused, and to know what will be done to prevent a recurrence to someone else.

In November 2014, the government introduced a statutory (organisational) duty of candour for NHS trusts and NHS foundation trusts via Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 ('regulation 20'). In essence, the duty places a direct obligation upon trusts to be open and honest with patients and service users, and their families, when something goes wrong that appears to have caused or could lead to moderate harm or worse in the future (known as a 'notifiable safety incident'). From April 2015, the duty extended to all other health and social care providers registered with the Care Quality Commission (CQC), including care homes.

The duty of candour is enforced by CQC with consequences for health and care providers who are found to be non-compliant. This can include CQC's ability to:

- impose conditions
- issue warning notices and fines
- remove a provider's registration
- bring criminal prosecutions without needing to first serve a warning notice

The duty of candour arose from recommendations by the Mid Staffordshire NHS Foundation Trust Public Inquiry (2013). This high-profile failure in NHS healthcare led to important questions about ways in which harm during healthcare can be prevented and about how, when this does not happen (for whatever reason), it can be acknowledged and act as a source of learning and improvement.

As such, the duty of candour is a crucial, underpinning aspect of an open and transparent culture which supports staff to be candid. The duty permits a level of scrutiny to be applied, which gives an opportunity to consider each situation objectively, look at what could have been done better and implement any necessary changes in order to advance patient safety.

The most significant consequence of the duty of candour is the extent to which leaders within health and care organisations create and support the systems and cultural conditions by which mistakes and errors enable learning and support a process of continuous improvement.

The duty

The statutory duty of candour is contained in regulation 20 and applies to all health and social care organisations registered with CQC. 'Notifiable safety incident' is a specific term defined in regulation 20 and must meet all 3 of the below criteria in order to qualify as one:

- it must have been unintended or unexpected
- it must have occurred during the provision of an activity that CQC regulates
- in the reasonable opinion of a healthcare professional, the incident already has, or might, result in death or severe or moderate harm to the person receiving care. This element of categorisation varies slightly depending on the type of provider, as set out in the next 2 paragraphs

Regulation 20 defines the harm thresholds for health service bodies (NHS trusts and NHS foundation trusts) as follows:

> In the reasonable opinion of a healthcare professional, the incident could result in or appears to have:
>
> - resulted in the death of the person - directly due to the incident, rather than the natural course of the person's illness or underlying condition
> - led to the person experiencing severe harm, moderate harm or prolonged psychological harm

Regulation 20 defines the notifiable safety incident harm threshold for all other services that CQC regulates as follows:

> In the reasonable opinion of a healthcare professional, the incident appears to have resulted in, or requires treatment to prevent:
>
> - the death of the person - directly due to the incident, rather than the natural course of the person's illness or underlying condition
> - the person experiencing a sensory, motor or intellectual impairment that has lasted, or is likely to last, for a continuous period of at least 28 days
> - changes to the structure of the person's body
> - the person experiencing prolonged pain or prolonged psychological harm
> - a shorter life expectancy for the person using the service

After becoming aware that a notifiable safety incident has occurred, all registered organisations must as soon as reasonably practicable:

- notify the relevant person of the incident - this should be done in person and:
    - provide an explanation of what is known at the time and what further enquiries or investigations will be made
    - offer an apology
    - be recorded in a written record that is kept securely

- offer the person reasonable support - this could be practical support such as providing an interpreter or emotional support (for example, counselling)
- provide the person with written notes of the initial discussion and of the notification, including details of further enquiries, their results and an apology. The organisation is also required to keep copies of all correspondence relating to the incident

For further details, see CQC's guidance for providers on the duty of candour.

Why we are reviewing the duty

A fundamental element of high-quality care is honesty. Patients and service users, and their loved ones, place a large amount of trust in health and social care providers. They must feel confident that should anything untoward occur, they will be entitled to an open and honest response.

Although the statutory duty of candour should be practised by everyone working in health and social care, we know of concerns within independent reports that the duty is not always met as intended in regulation 20.

Such failures to comply with the duty not only constitute a breach of a legal obligation but can lead to a breakdown in trust between patients and service users and their health or care providers. Patients and service users may also distance themselves from vital services they require in the future.

DHSC's review is being conducted to understand to what extent the duty of candour is honoured, monitored and enforced. We will also consider to what extent the policy and its design are appropriate for the health and care system and have met their objectives. We are clear that limited or non-compliance with the duty cannot be justified. Our aim is to deliver recommendations for better meeting the policy objectives of the duty and which can be implemented at pace.

The review is not considering the professional duty of candour. This places an obligation on healthcare professionals to be open and transparent with patients and service users when things go wrong. Although the statutory duty of candour and professional duty of candour have similar aims, the professional duty is different as it is regulated by professional regulators such as the General Medical Council (GMC), Nursing and Midwifery Council (NMC) and the General Dental Council (GDC).

Call for evidence questions

Please provide us with your feedback (including examples of good and poor practice where appropriate) in relation to any or all of the below questions.

Please do not include any personally identifiable information when providing your answers to these questions.

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

- Agree
- Neither agree nor disagree
- Disagree
- Don’t know

Please provide your views, evidence or experience to explain your answer. (Maximum 500 words)

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

- Agree
- Neither agree nor disagree
- Disagree
- Don’t know

Please provide your views, evidence or experience to explain your answer. (Maximum 500 words)

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

- Agree
- Neither agree nor disagree
- Disagree
- Don’t know

Please provide your views, evidence or experience to explain your answer. (Maximum 500 words)

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

This refers to the way providers engage with patients or service users, and families or caregivers.

- Agree
- Neither agree nor disagree

- Disagree
- Don’t know

Please provide your views, evidence or experience to explain your answer. (Maximum 500 words)

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

- Agree
- Neither agree nor disagree
- Disagree
- Don’t know

Please provide your views, evidence or experience to explain your answer. (Maximum 500 words)

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?

- Agree
- Neither agree nor disagree
- Disagree
- Don’t know

Please provide your views, evidence or experience to explain your answer. (Maximum 500 words)

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?

- Agree
- Neither agree nor disagree
- Disagree
- Don’t know

Please provide your views, evidence or experience to explain your answer. (Maximum 500 words)

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?

- Agree

- Neither agree nor disagree
- Disagree
- Don’t know

Please provide your views, evidence or experience to explain your answer. (Maximum 500 words)

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?

- Agree
- Neither agree nor disagree
- Disagree
- Don’t know

Please provide your views, evidence or experience to explain your answer. (Maximum 500 words)

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

- Agree
- Neither agree nor disagree
- Disagree
- Don’t know

Please provide your views, evidence or experience to explain your answer. (Maximum 500 words)

What challenges, if any, do you believe limit the proper application of the statutory duty of candour in health and/or social care providers?

Please provide your views, evidence or experience to explain your answer. (Maximum 500 words)

Provide any further feedback that you feel could help shape our recommendations for better meeting the policy objectives of the duty of candour.

Please provide your views, evidence or experience as part of your feedback. (Maximum 500 words)

How to respond

This call for evidence closes at 11.59pm on 29 May 2024. You can respond by completing the online survey. DHSC will review all of the feedback that we receive. This will help to inform the outcome of our review which we will be publishing this year.

If you are experiencing any technical difficulties accessing the survey please contact dutyofcandourreview@dhsc.gov.uk.

An easy read version of this call for evidence will be made available shortly.

Privacy notice

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