action against medical accidents

Call for evidence
Duty of candour review – AvMA response

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

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

AvMA provides comprehensive training to staff and organisations on 'Implementing the Duty of Candour with Empathy', delivered by our former Chief Executive Peter Walsh and C&C Empathy Training. This course has been attended by hundreds of NHS staff members, giving AvMA an understanding of the challenges that staff have in implementing the duty in a way which meets the statutory requirements and does so in a meaningful way.

It is not widely understood by delegates that the Duty of Candour applies both before and during an investigation not just after, as shown by our Inquest casework client experiences. So, although there are also some concerns from delegates about the bureaucracy involved in sending a Duty of Candour letter, it ensures that patients and families have a timely explanation in writing that there has been an incident and that it is subject to an investigation. Delegates are unaware that the regulation guidance suggests that patients and families are offered sources of support through the Duty of Candour, such as making reference to AvMA. Furthermore, in case papers that clients send us, we rarely find a Duty of Candour letter included and the duty is usually only mentioned briefly in the body of some SIRs that we have sight of. However, we see regular client referrals through PALS and the complaints process, with AvMA routinely mentioned in formal response letters.

The most common worry heard during training is an anxiety about having to make an apology very soon after an incident, when it is not fully clear what has happened yet. There is a fundamental misunderstanding that an apology is tantamount to admission liability, and this is therefore a problem. The CQC updated its guidance to providers in 2022 to 'make clear that the apology required to fulfil the duty of candour does not mean accepting liability and will not affect a provider's indemnity cover'. We suggest that there needs to be much better guidance about what a meaningful apology entails, and a review of when it would be most appropriate to make an apology. Staff may feel more empowered to make a sincere and regretful apology when they understand more about what has happened later in the investigation process.

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

In September 2009 AvMA committed resources to providing a specialist pro bono inquest service in England and Wales. The service was officially launched in July 2010. The service aims to find representation where possible for people who have been affected by the death

of a loved one where the death occurred in a medical setting. The information below is based on our experience of inquests which arise because of deaths where acts and/or omissions in healthcare provision may, or have caused, or contributed to the death. Our evidence is therefore confined to our experience of healthcare inquests.

AvMA has an inquest new client form that clients complete, and we routinely analyse the information we receive from the public to identify how much they understand and know about coronial and inquest services. This includes questions about the Duty of Candour. In 2020-2023 inclusive, AvMA advised 315 clients who had completed our inquest new client form. We found that 19% of these clients had heard of the Duty of Candour. 39% of clients were certain that they had not. Just over 3% of these clients had received a Duty of Candour letter, however, 48% were certain that they had not.

In 2021, the Justice Committee noted that health and social care bodies were failing to fulfil their Duty of Candour to bereaved people during Coroner's investigations and inquests, and in November 2023 they launched a new inquiry to examine progress in the Coroner's Service. The Committee recommended that the Coroner's Rules should be amended to make clear that the Duty of Candour extended to the Coroner's Service. AvMA's year-on-year statistics show no improvement in the number of Inquest clients receiving a Duty of Candour letter over the past four years and show a decline in clients' awareness of the Duty of Candour.

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.

AvMA finds that Trusts do not provide enough information to patients regarding the Duty of Candour, even alongside their complaint procedures. This extends to independent NHS complaints advocacy providers whose remit includes outlining procedures. Patients cannot challenge a failure to comply with regulations or raise concerns with the CQC if they are not aware of the duty existing. This indicates a 'defensive' stance from Trusts as suggested by the PHSO that could be resolved through further NHS training. Online information tends to come from regulatory bodies, there are only a few examples from Trust patient resources.

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

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?

A common misunderstanding is that it only needs to 'appear' that the threshold of harm has been reached for the statutory procedure to apply. The CQC provided further clarification on qualifying a notifiable patient safety incident in 2022. The wording of the regulations and comprehensiveness of the guidance is still a concern and can still be improved to make it clearer and simpler for NHS staff to follow. Complex wording can also encourage a pre-occupation with defining the threshold of harm, creating a systematic approach to the Duty of Candour that disregards the over-arching duty to be open and transparent that has no threshold of harm and is unrelated to set procedures.

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?

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?

At the time of contacting AvMA, 20% of Inquest clients were aware of the hospital preparing a Serious Incident Report (SIR) or other investigation report into the death of their loved one, but only 17% of these clients expecting a report had received prior formal notification of this via a Duty of Candour letter, enabling them to be fully involved and of primary focus in an open and honest process. It may be worth envisaging just how many of the 27% of Inquest clients who thought that the hospital had not prepared an investigation report had just not been told about the investigation or their right to be informed or involved.

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?

AvMA finds that it is crucial for more NHS staff to receive training on the ongoing Duty of Candour, how to communicate with families with empathy and how to investigate effectively. Training should include learning from those with lived experience of avoidable harm. When AvMA's NHS delegates have been asked whether they had received any previous training on the Duty of Candour through their role, over 90% had not. The minority that had received any training found that it focused on avoiding breaches rather than exploring the value of the regulation. In their feedback, delegates stated that they had learned a lot that they had previously not known or understood from AvMA's training, and most importantly, the training had helped them reframe the Duty of Candour as an essential aspect of their professional commitment to treating patients well.

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

AvMA campaigned for a statutory Duty of Candour for over two decades before the regulation was introduced in November 2014 for NHS bodies in England. Our former Chief Executive Peter Walsh worked with government ministers and officials to draft the legislation and guidance on how the statutory duty would be both delivered and regulated. We then published a report in 2016 and an updated version in 2018 reflecting on how the CQC had been regulating the statutory Duty of Candour and made several recommendations. AvMA were encouraged to see improvements following the 2016 report, but we were still concerned that regulation required improvement in 2018. Many recommendations are yet to be addressed.

We can see examples where the CQC have fined Trusts a fixed penalty in July and October 2021 for failing to comply with Duty of Candour regulations, relating to two incidents in 2018. £1250 is the maximum punitive amount that the CQC can fine per breach, and the chief inspectors involved in the enforcement acknowledge that the limitation of this amount is in no way a reflection of the value of the lives lost in these cases. As illustrated, AvMA have been informed by our clients that it is many more than two patients at two Trusts that have been

let down in this way by 'failing to notify the family as soon as reasonably possible that an incident had occurred' and that 'the trust did not provide the family with an account of the incident or offer an appropriate apology to them in a timely manner'. AvMA believes that more robust enforcement from the CQC to ensure the duty is applied as intended remains vital.

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

With the phasing out of SIRs and the introduction of the Patient Safety Incident Response Framework (PSIRF) underway, AvMA anticipates that Duty of Candour is going to be more vital than ever for families to understand their statutory rights and hold the respective Trust accountable, as a PSIRF investigation will only be triggered when a patient safety incident falls within the remit identified by the Trust itself. Providing there has been a notifiable patient safety incident, the regulations make it clear that the Duty of Candour still applies.

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

As the PHSO found in their report Broken Trust, there remain issues with the application of the Duty of Candour in practise, 'it is unacceptable that Trusts still fail in this duty nearly a decade after it was introduced… this is symptomatic of a defensive culture in some Trusts' (pg. 38), as illustrated in the inconsistent experiences of our Inquest casework clients nationwide. The Duty of Candour remains as important as ever to normalise transparency, openness, accountability, and honesty which are integral to the public's trust in the NHS, for both patients and staff. Failure to communicate with empathy can compound the original harm, an experience so prevalent that AvMA launched a Harmed Patient Pathway with the Harmed Patient Alliance in 2021, with the intention of piloting the pathway with Trusts in 2024.

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