Department of Health and Social Care

Duty of Candour review – call for evidence

A response by the Association of Personal Injury Lawyers

May 2024

Introduction

APIL is grateful for the opportunity to respond to this call for evidence on the review of the statutory duty of candour for health and social care providers in England.

APIL supports an open and transparent culture in healthcare, where admissions are made to patients when things go wrong. Often, people who have been injured by medical mistakes simply want to know what happened, that lessons have been learnt to prevent a recurrence to someone else and to be offered an apology. Our members' feedback is that compliance with the statutory duty of candour is currently sporadic, with an inconsistent approach across different trusts. The framework and the provisions in the regulations are clear, proportionate, and mostly well understood by healthcare staff, but in reality, the requirements in the duty are not being complied with consistently. While the existence of the duty is a step in the right direction, and members report that apologies and openness around what went wrong are more forthcoming in clinical negligence cases than in other areas, there is still a lack of transparency, which we attribute to a fear of repercussions from those in leadership positions or in-house legal teams. There is more work to be done around education and training to address this.

We believe that for the duty to be implemented correctly, the wider issues behind the lack of transparency must be addressed and change needs to happen inside the trusts and within the healthcare profession.

Question 1: Do you agree or disagree that staff in health and/or social care providers know of, and understand, the statutory duty of candour requirements?

Question 2: Do you agree or disagree that the statutory duty of candour is correctly complied with when a notifiable safety incident occurs?

We believe that the statutory duty and its requirements are understood by most staff in health and/or social care providers. However, compliance with the duty and with the requirements in the regulations has been sporadic and inconsistent since its implementation.

Some APIL members reported that the NHS has improved openness and transparency in relation to incidents involving birth injuries. The work carried out by the Healthcare Safety Investigation Branch (HSIB) (now the Maternity and Newborn Safety Investigations (MNSI) programme) has in some cases led to patients/families receiving early admissions of poor care and avoidable harm and seeing the requirements of the statutory duty of candour complied with. Members reported that the families valued the honesty of the staff.

APIL members have provided the positive case studies of compliance of the duty below.

Case study 1

The patient was incorrectly diagnosed with breast cancer following a confusion with another patient's histology results. Consequently, the patient underwent unnecessary surgery and treatment for breast cancer. According to our member's feedback, the duty of candour was fully complied with in this case. The NHS trust produced an incident report, provided adequate support to the claimant, and promptly admitted liability.

Case study 2

The patient suffered laser burns reducing vision in one eye significantly as a result of a failure to apply laser to correct area of the eye during a laser treatment for proliferative diabetic retinopathy. Our member's feedback is that the duty of candour was fully complied with in this instance, with a prompt admission of liability by the NHS trust.

Others reported that it is fairly rare for their clients to be told where there has been a failure in their treatment.

On several occasions, trusts have a written record of a 'duty of candour discussion', but the patient is still unaware of what actually happened during care. When apologies are provided, they seem superficial and lack an explanation of the events, what could be done to address the harm caused, and do not provide sufficient emotional support. Furthermore, trusts are slow and reluctant to disclose investigation details or fail to investigate when a safety incident occurs. Members report that even with threats of pre-action disclosure, the trusts still ignore their correspondence. The case studies below are an example of the impact of lack of compliance with the duty on the patient.

Case study 3

A claimant suffered a spinal cord injury. During their treatment in the NHS, there was a series of failures by healthcare providers. The ambulance failed to immobilise the claimant, the emergency department incorrectly diagnosed them with just a broken nose, and there were other failures in the care provided in the intensive care unit. Our member reports that it has taken over 5 years for the claimant to get an apology and a recognition of the failings in treatment by the NHS. For 5 years the claimant was denied an account of what happened, recognition of mistakes and the trust just denied any failures in care. The psychological impact has been immense, and similar to this example, many other patients harmed during care are facing the same challenges. The NHS must not underestimate the power of an apology and effective compliance with the statutory duty.

Case study 4

In this case the treating team for the client's husband (the widow of the deceased patient) did not disclose findings of features of sarcoma in imaging taken in 2006. Nothing was done about the sarcoma at the time and the client only found out about it by reading her late husband's medical records. The deceased continued to be under the care of the same consultant and in 2012, he underwent a thoracic operation for removing the sarcoma. The sarcoma then returned in 2016, but again the client and her husband were kept in the dark about its return. Delayed action in relation to the sarcoma on both occasions affected her late husband prognosis and shortened his life span. The client and her husband were kept in the dark about these errors on both occasions causing additional distress.

The treating consultant said verbally to the client that the duty of candour did not come into play in 2006, so he was under no obligation to inform his patient. Even before the statutory duty was introduced in 2014, doctors already had an ethical duty to be open and honest when things go wrong, and he failed to be transparent on both occasions.

Case study 5

The patient experienced a very distressing removal of retained products of pregnancy following a traumatic miscarriage. Multiple points of complaint were raised. The NHS trust's internal incident review supported parts of the allegations. However, no section 20 notice was issued and the duty of candour was not complied with. The trust has not made admissions and, four and a half years later the failures in care are still being denied.

Question 3: Do you agree or disagree that providers demonstrate meaningful and compassionate engagement with those affected when a notifiable safety incident occurs?

As mentioned above, staff and trusts' approach to the duty varies greatly, and some are much better than others at engaging with harmed patients and their families.

We have concerns that people affected by a patient safety incident are not getting access to clear, independent information about their rights and options. Part of the problem lies in the power imbalance between organisations and patients and their families. Too often, those who are injured feel left in the dark about what has happened, and that they are unable to have confidence in what the hospital trust tells them. Many would benefit from speaking to an independent advocate who can understand their needs and offer detailed advice and guidance. Some will go on to seek independent legal advice from a lawyer, but most patient safety incidents will not be actionable as a claim. Families in these cases would benefit from independent support, advice and guidance in ensuring that the duty of candour is complied with and that they are able to engage meaningfully in discussions.

We believe that the emotional and psychological support provided to patients and families as part of the duty of candour requirements should be improved. In case studies 3 to 5, claimants suffered significant psychological impact due to their injuries and the lack of compliance with the duty of candour. Following the incidents no arrangements or offers of psychological support or counselling were made by trusts. Where the duty of candour was complied with and support was offered, such as remedial treatment, it was only provided at the trust where the injuries occurred. After such incidents claimants have often lost trust in their care. We believe that following a failure in treatment, trusts should offer to arrange suitable remedial treatment at an alternative healthcare provider. Claimants often have to wait to bring a claim to be able to fund private treatment because they do not want further treatment from the negligent trusts.

Question 4: Do you agree or disagree that the 3 criteria for triggering a notifiable safety incident are appropriate?

We agree that the three criteria for triggering a notifiable safety incident are appropriate. However, we believe the challenge lies in the interpretation of these criteria. It is crucial that all healthcare professionals are able to clearly distinguish between what is and is not notifiable.

While the criteria themselves are well-defined, the application in practice can be subjective, particularly concerning the third criterion "In the reasonable opinion of a healthcare professional, already has, or might, result in death, or severe or moderate harm to the person receiving care.". The subjective interpretation of what qualifies as a notifiable event is leading to inconsistencies in reporting and may undermine the overall effectiveness of the

duty of candour. We recommend that additional training and guidance be provided to healthcare staff to ensure a consistent understanding and application of the criteria. Specific examples of notifiable safety incidents should be included in the guidance to clarify what constitutes a reportable event. Further clarity and training will help to ensure that the duty of candour is applied consistently and effectively.

Question 5: 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?

We do not agree. While the harm threshold of moderate to severe harm or death is a proportionate threshold, it is not being applied properly and is being interpreted subjectively. We believe the moderate to severe harm threshold strikes the balance between providing the patient with an apology if something has happened to them, without requiring the doctors to divulge every “near miss” which could result in adverse effects on patients. However, our members’ perception is that the threshold is being misinterpreted and that only very severe incidents are being reported.

While the framework for the statutory duty of candour is sound, there needs to be further consistent training on when the duty applies. It is key that staff receive training to understand what qualifies as moderate harm to trigger the duty. The guidance for health care staff should include examples of what is considered moderate harm for the purposes of the duty of candour. Given that the duty relies on self-reporting, healthcare professionals must be clear on when it applies.

Question 6: 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?

We strongly believe that one of the main challenges to the proper operation and compliance of the duty is the lack of senior-level monitoring of its application.

Often healthcare professionals involved in care are honest and open when explaining that there was a mistake in the treatment, but when the incident gets reported and senior managers and in-house legal teams become involved, there is a tendency to discourage disclosure, due to fears or reputational damage, professional repercussions, and sometimes fear of litigation. Our members have frequently encountered this pattern where healthcare staff make admissions, provide an apology and are transparent early on but as the investigation progresses, liability is denied, and it then takes years for there to be an admission that there was a breach of duty.

The case study bellow illustrates our concerns.

Case study 7

In this case, there was a failure to manage the claimant’s major hemorrhage to adequate standard. This resulted in periods of hypotension despite fluid resuscitation during the claimant’s shoulder replacement surgery, causing total blindness (Non-Arteritic Anterior Ischemic Optic Neuropathy).

The trust underwent an investigation and produced a comprehensive investigation report. The result was that the investigation had not identified any failings. The trust fully denies liability.

The claimant in this case submitted a complaint including the following allegations:

"…visited by surgeon and anaesthetist who both apologised…no other information, nor an explanation of their actions has been forthcoming".

"Despite numerous requests from me, to date nobody has had a conversation with my wife and all the conversations have been had with me alone without any support or advocacy at all".

"At no point has anyone actually acknowledged the complete devastation this has caused to me and my whole family".

"I told staff I couldn't see. Despite me continuing to tell staff that I could not see, nobody accepted how serious this was, nor was any explanation forthcoming".

The duty of candour will only make meaningful changes in patient safety and patients/ their families once the NHS cover-up culture, often incentivised by those in leadership roles, is addressed. We note that while there has been an improvement in the perception of fair treatment of staff involved in errors, near misses and incidents[1], the most recent NHS staff survey still indicated that 40 per cent did not think that staff were treated fairly. There is still work to do. The cultural issues that prevent individual clinicians from reporting incidents to patients must be addressed. Leaders must demonstrate fair treatment of staff so that they feel safe to comply with the duty requirements.

Question 7: Do you agree or disagree that regulation and enforcement of the statutory duty of candour by CQC has been adequate?

We believe that enforcement by the Care Quality Commission (CQC) regarding breaches of the duty of candour should be stronger. Since the duty's implementation in 2014, the frequency of prosecutions for breaches has remained notably low.

The first recorded prosecution to reach court was as recently as October 2020, underscoring the pressing need for a more robust enforcement mechanism. The current leniency in enforcement fails to sufficiently uphold the principles of honesty and openness that the duty of candour seeks. Strengthening enforcement measures will not only serve as a deterrent against non-compliance but also reinforce public trust in the healthcare system's commitment to transparency and patient safety.

Question 8: What challenges, if any, do you believe limit the proper application of the statutory duty of candour in health and/or social care providers?

While the framework itself is sound, as stated in question 6, we have concerns that one of the main challenges to the proper operation and compliance of the duty is the lack of senior-level monitoring of its application and the cover-up culture still present in the NHS. Most responses we received from members highlighted a lack of compliance with the duty and a feeling that organisations do not support their clinicians in admitting medical error when it arises. Such systemic features are suppressing transparency in healthcare.

[1] 59.45 per cent of staff agreed or strongly agreed that staff involved in errors, near misses and incidents were treated fairly in 2023, compared to 43 per cent in 2015.

We strongly believe that these issues can be tackled through further education for healthcare teams, including practice managers, senior health leaders and health service commissioners. Alongside their mandatory training on clinical governance, such professionals should be encouraged to engage in ethical training in order to support their clinicians in being more open and honest with their patients. Clinicians must feel supported by their healthcare teams. We note that the NHS Constitution is currently under review. We suggest consideration should be given to amending the leadership section of the Constitution to include the need to comply with the duty of candour and support teams in doing this.

Training is also essential for all healthcare professionals to feel confident when being open and honest with patients. They must be capable of delivering bad news compassionately to preserve a strong professional relationship between clinician and patient while complying with the statutory duty obligations. There must also be more training and further improvement of the perception of how staff are treated when they are involved in errors, near misses and incidents, to encourage people to open up when things go wrong.

Staff, managers and those in leadership positions must be aware of the benefits of being upfront, transparent and open. Better compliance with the duty could potentially prevent litigation, as those with more minor injuries may choose not to sue if they receive an explanation of what happened and a reassurance that lessons have been learned. Often, the only way to obtain an explanation of what went wrong currently is via litigation.

Most patient safety incidents will not result in claims, but where they do, they would be resolved more efficiently and at a lower cost for the benefit of all the parties involved if the duty of candour is complied with.

Staff must also be made aware of the significant psychological burden that injured people face after a patient safety incident. These people will be dealing with potentially life-changing injuries and will be left distressed and unable to move forward should NHS trusts refuse to accept responsibility and provide an explanation of what has gone wrong.

Any questions in the first instance should be addressed to Ana Ramos, legal affairs assistant at APIL ana.ramos@apil.org.uk