Department of Health Northern Ireland

Duty of Candour and Being Open – Policy Proposals

A response by the Association of Personal Injury Lawyers

July 2021

Introduction

APIL believes that the introduction of a duty of candour within the healthcare system in Northern Ireland is long overdue. Often, people who have been injured by medical mistakes simply want to know what went wrong and why, and that lessons have been learned. A statutory duty of candour will help to achieve this.

While it is a step in the right direction towards an improved culture of openness and learning from mistakes, however, a duty of candour is not enough in isolation. Lessons can and must be learned from the introduction of the duty of candour in England and Scotland, where a statutory duty of candour has been in place since 2015 and 2018 respectively. Compliance with the duty in both jurisdictions has been sporadic at best, with an inconsistent approach across the different Trusts and Health Boards, and it is evident that the duty alone does not always lead to openness when things go wrong. Consideration must be given to addressing the wider issues behind why there is not already a culture of openness within the healthcare profession – not only the fear of litigation, but the fear of speaking out leading to job loss, and/or reputational damage. Sanctions for non-compliance with the duty of candour must also be used to their full effectiveness – something which does not currently happen in England or Scotland.

Scope

We are pleased to note that the scope of the proposed statutory duty is wide. It is positive that the duty will cover every healthcare organization in Northern Ireland. It is important that the duty is as wide as possible – there is no justification for any organization or individual working within the healthcare system in Northern Ireland to be excluded from the duty of candour.

Requirements when care goes wrong

We have a number of concerns about the proposed threshold for the duty of candour when things go wrong.

<u>"Unintended or unexpected incident"</u>

Paragraph 3.13 of the consultation document sets out that the duty of candour will apply where there has been an unintended or unexpected incident that occurred in respect of a patient or service user during the provision of health and social care services, that has or may have resulted in: a) The unexpected or unexplained death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition; or b) Moderate harm, serious harm, or prolonged psychological harm to the service user. We question why only "unintended" incidents fall within the scope of the duty, and thus if someone intended harm, they would not need to be honest about this.

"Harm"

At paragraph 3.15 of the consultation document, "harm" includes "prolonged psychological harm", defined as psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days. There are no such timing requirements for physical harm, and we do not believe there should be a distinction between physical and psychological harm. It is nonsensical that those suffering psychological harm must suffer for a "prolonged" period before the duty of candour is triggered. We suggest that instead of differentiating between physical and psychological harm, the duty should apply where there has been any reasonably moderate harm, or worse.

It is right that near misses will not be included within the scope of the duty. Telling patients about every slight incident, even if there was no harm, may result in adverse effects on the patient, causing them to lose confidence in their healthcare providers. This is not to say near misses and slight incidents should not be taken seriously and addressed to ensure that they do not occur again, but this is a separate issue to the duty of candour. In addition, the duty of candour should not be so overbearing as to exacerbate the culture of fear within the healthcare profession. Healthcare professionals must be encouraged to embrace this new culture of openness and including near misses may hinder that.

Apologies

We agree that the requirement for an apology should be included within the regulations.

Reporting and monitoring

We welcome that the duty will include the requirement to publish an annual report which assesses the organisation's performance in respect of the duty of candour; how many incidents there have been that have triggered the duty of candour, as well as information about what processes the organisation has put in place in relation to the duty of candour. We also welcome paragraph 3.29 of the consultation which provides that statements made to the regulator must be truthful and not misleading by omission, and any public statements about the organisation's performance must be truthful and not misleading by omission. We are concerned, however, that depending on how the legislation is drafted, organisations may be able to satisfy the requirement to be truthful, but may put out statements in such a way as to disguise the full extent of the mistake triggering the duty of candour.

Regulation and enforcement

Criminal sanctions are welcomed to ensure that healthcare professionals take the duty of candour seriously. We are concerned however, that the criminal sanctions that are available may not be used in practice. In England since the duty of candour was introduced in 2015, there has been only one prosecution. In order to give teeth to the regulations, the criminal sanctions must be used effectively.

We also question how prosecutions will be brought. The consultation paper states that one of the recommendations of the Inquiry into Hyponatremia Related Deaths Report was that the Regulation and Quality Improvement Authority (RQIA) should ensure overall compliance and consideration should be given to granting it the power to prosecute. We question, however whether the RQIA will have sufficient standing to bring these prosecutions, and whether the prosecutions will need to be brought privately. It is also unclear who will be responsible for issuing fixed penalty notices.

Further, we are concerned that prosecution by the RQIA would only take place in cases of "serial non-compliance or serious and wilful deception". This gives the impression that

prosecution and criminal sanctions will only apply in these limited circumstances. This is confusing and surely incorrect. At paragraph 3.36 of the consultation document, it is stated that the following breaches will be classed as a criminal offence:

- failure to notify the relevant person that a notifiable safety incident has occurred;

- failure to provide the notification in line with the legislative requirements;

- provision of a false or misleading statement to a regulator or other individual acting pursuant to the statutory duty or

- publication of a false or misleading public statement by an organisation about its performance

It cannot be said that these breaches will be classed as "serious and wilful deception" – "serious and wilful deception" is surely too high a threshold. If a breach of the duty of candour attracts criminal sanctions, there should not be a requirement that the breach also be a serial breach, or that the breach be serious or wilful deception. There is also a question as to who will decide what is classed as a "serious and wilful deception" and what will be classed as "serial non-compliance". If there is a large organisation that has been in breach, are several breaches by several different departments classed as "serial non-compliance" by the organisation?

Whoever the prosecuting authority in these cases is, they must be required to publish the data on how many prosecutions have taken place. Data on how often checks are made that sufficient reporting is taking place under the duty of candour, and the regularity of fixed penalty notices and prosecutions should be published and independently audited for themes.

It is also important that there is correlation between the duty of candour and the organisation's complaints process. In England, in most cases the duty of candour and the complaints processes of the various organisations falling within the duty operate separately. Some complaints procedures have the duty of candour incorporated within them; some fail to mention the duty at all. There is an opportunity to address this before the duty of candour is implemented in Northern Ireland, with efforts made to ensure that the duty of candour is fully integrated within the various complaints processes of the healthcare system.

Individual duty of candour

We welcome that in addition to the organisational duty of candour, there will be an individual duty to be open and honest. We believe that an individual duty with sanctions for non-compliance is necessary, to avoid the duty of candour simply becoming a "tick box exercise" for organisations. Individuals must be held to account for non-compliance with the duty of candour. There must, however, be a balancing act, proper guidance to the prosecuting authority and discretion must be exercised to ensure that criminal sanctions are not used as a witch hunt. Sanctions must also be proportionate – people should not be subject to criminal sanctions simply for not saying sorry, for example.

It is important that changes to individual employment contracts – as detailed within the footnote on page 45 of the consultation document take place before the duty of candour is introduced. There are already protections for those who make a formal disclosure in the public interest ("whistle-blowers")[1], and these should be referred to in the employment contract alongside changes relating to the duty of candour. Guidance must be available to

[1] https://www.nidirect.gov.uk/articles/blowing-whistle-workplace-wrongdoing

employees on how to make a disclosure in a manner which will protect against job loss and victimisation. As mentioned above, the duty of candour cannot be introduced in isolation. The reasons behind the culture of secrecy must be acknowledged and addressed. One of the key drivers for people to not speak out when something has gone wrong is the fear of job loss, and contracts must be amended to ensure that speaking out when things have gone wrong and compliance with the duty of candour does not automatically lead to disciplinary action.

Guidance

There must be detailed guidance issued to healthcare providers with information on how to comply with the duty of candour. There must also be guidance for the RQIA, or whoever else is the prosecuting body, so that they know the line to tread when prosecuting, and what the appropriate actions to take in different circumstances would be.

The “Being Open Framework” set out in the consultation document seems unnecessarily complicated. If the first level, of simply being open across the board, were developed and implemented, then the other two levels would fall into place automatically. Again, healthcare professionals need to feel safe to divulge issues with patients and colleagues in order to be open.

In order for guidance and education to be most effective, the concept of a duty of candour should be raised and discussed as early as possible within a healthcare professional’s career - at degree level, for example, with medical students and nursing students being introduced to the concept of openness and candour, and trained on how to comply with the duty of candour – both routinely and when things go wrong – from the earliest stage.

It must also be acknowledged that the relationships and hierarchy of staff in hospitals and healthcare settings may be hindering the duty of candour in other jurisdictions, with more junior members of the profession in particular perhaps feeling unable to speak out if they do or see something which would trigger the duty of candour. There may also be tensions between different specialisms, for example between midwifery teams and obstetricians in maternity care, with midwives feeling unable to speak out if an obstetrician has triggered the duty.

About APIL

The Association of Personal Injury Lawyers (APIL) is a not-for-profit organisation which has worked for over 30 years to help injured people gain the access to justice they need, and to which they are entitled. We have around 3,000 members who are committed to supporting the association’s aims, and all are signed up to APIL’s code of conduct and consumer charter. Membership comprises mostly solicitors, along with barristers, legal executives, paralegals and some academics.

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