Royal College of Surgeons of England

IN NORTHERN IRELAND

Royal College of Surgeons of England response to the Duty of Candour & Being Open – Policy Proposals for consultation

The Royal College of Surgeons of England welcomes the opportunity to respond to the consultation on the Duty of Candour and Being Open policy proposals developed by the Inquiry into Hyponatraemia-Related Deaths (IHRD) Programme Duty of Candour Workstream and Being Open Sub-Group.

The Royal College of Surgeons of England is a professional membership organisation and registered charity, which exists to advance patient care. We support nearly 30,000 members across the UK and internationally. In Northern Ireland, the College is represented by a Professional Board that reflect the following specialties: Neurosurgery, ENT, Paediatrics, General Surgery, Trauma and Orthopaedics, Plastics, Urology, Vascular, Cardiothoracic and OMFS. The Board includes 10 elected regional specialty advisors, the Association of Surgeons in Training (ASiT), QUB Medical School Surgical Society, NIMDTA Head of the School of Surgery and an RCS England Council member. The purpose of the Board is to improve surgical outcomes for patients, advocate locally and support the dissemination of good practice and professional guidance. Throughout the COVID-19 pandemic, we have been determined in our efforts to ensure that surgeons and surgical teams are supported in delivering vital patient care and are not exposed to unnecessary risk.

Summary Position

We support the introduction of a statutory duty of candour for healthcare providers similar to that introduced in England in 2014. Candour and openness are a fundamental part of what it means to be a healthcare professional. The College is **opposed to duty of candour with criminal sanctions attached and to the introduction of criminal sanctions for individuals**. We believe that such measures are counter-intuitive to creating an environment of full disclosure, honesty and transparency and can lead to the opposite of what the report aims to achieve, i.e. to a culture of fear that suppresses open, honest admission and discussion of mistakes. To drive up standards of care, professionals and organisations need to be honest about their mistakes in order to quickly deal with errors and learn from them. Candour also allows the public to understand why decisions have been made, encouraging patients to be involved in their care.

Introduction

As surgeons, we were greatly saddened by the findings of Justice O'Hara's Inquiry into Hyponatraemia-related Deaths (IHRD[1]) and our heartfelt sympathies go to the families of the children who died. The 14-year inquiry into the deaths of the five children found that their deaths were avoidable. These families have shown great dignity and bravery throughout what has been a very difficult and traumatic time for them.

The journey to this point has been very long for the families involved and we agree with Quintin Oliver (Chair Duty of Candour Workstream IHRD Programme) that "we owe it to the bereaved families to see this assignment through to its conclusion."[2]

The IHRD commenced its work in 2004 and concluded its considerations in 2018. After hearing evidence from over 100 doctors and other medical professionals and 179 witnesses, the IHRD concluded that the five deaths had been avoidable. It also concluded that the culture of the health service at the time, the arrangements in place to ensure the quality of services and the behaviour of individuals had all contributed to those unnecessary deaths[3].

In their investigations the Inquiry found "*a Health Service that had been largely self-regulating and unmonitored" (See O'Hara report* [4]1.14).

Above all the report makes clear that: "*This has not been an investigation into allegations of criminal wrongdoing. It has been an investigation into deficiencies in clinical performance and shortcomings in governance control and response*."

It adds (See point 1.76): "*The purpose of identifying underperformance is to highlight acts or omissions, attitudes or assumptions to be avoided in the future. Whilst it is proper that individuals be accountable, it is also better to learn than to punish. To place undue emphasis on blame is to encourage the cycle of defensiveness, concealment, indifference to learning and further harm. There is much for all who work in the Health Service to reflect upon and learn from in the sad narratives of this Report*."

In his report, Justice O'Hara acknowledged that progress had been made in hyponatraemia practice and guidance but that a more comprehensive approach for learning from error was needed for further unnecessary harm to be avoided. He set out 96 recommendations across 10 themes where he had identified failings in "*competency in fluid management, honesty in reporting, professionalism in investigation, focus in leadership and respect for parental involvement*".

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[1] IHRD website: https://www.health-ni.gov.uk/hip

[2] Duty of Candour Consultation document, Foreword p2 https://www.health-ni.gov.uk/sites/default/files/consultations/health/doh-duty-of-candour-being-open-consultation-document.pdf

[3] IHRD website summary: https://www.health-ni.gov.uk/topics/hyponatraemia-implementation-programme/ihrd-background-inquiry

[4] IHRD report http://www.ihrdni.org/Vol1-01-Introduction.pdf

In receiving the report Department of Health (DOH) Permanent Secretary, Richard Pengelly apologised for the distress, hurt and loss suffered by the families[5] and stated a commitment to the vital work needed to address serious past failings and provide safe and accountable care in future.

He further stated that it was "*essential that those of us with leadership responsibilities now take concerted and prompt action to address the issues raised in the Report, and reassert the primacy of patient safety and work diligently to rebuild public confidence in the care provided, whether in hospitals, the community or primary care*[6]".

It is important to acknowledge that the majority of health professionals aim to provide the best care for patients. We completely understand that a patient or their family who have experienced trauma or injury as a result of a mistake, simply want answers. As surgeons, we are committed to a culture of openness and integrity in our working lives and in our engagements with patients and families. When things go wrong, it is a difficult position for all involved. This is referenced in the IHRD report (See point 1.75) that "*untoward clinical incidents can cause terrible suffering, not only for patients and their families but also to the clinical professions"*.

We are mindful that the recommendation of IHRD goes further than relevant legislation in England, Wales and Scotland, and proposes that the duty of candour should apply to individuals as well as organisations, and that any breaches should attract criminal sanctions.

The College is opposed to the criminalisation of candour and to the introduction of criminal sanctions for individuals. We believe that such measures are counter-intuitive to creating an environment of full disclosure, honesty and transparency and can lead to the opposite of what the report aims to achieve, i.e. to a culture of fear that suppresses open, honest admission and discussion of mistakes.

Any deliberate attempt to cover up, to tamper with or hide evidence, or to deliberately lie or to conceal information or fact should be addressed appropriately and punished according to existing law which provides sufficient criminal recourse without the need for further layers of legislation.

In addition, there is existing regulatory requirement set out by the General Medical Council in Good Medical Practice (GMP) that doctors must be honest and open with patients and must promote and encourage a culture that allows staff to raise concerns openly and to take prompt action if patient safety has been compromised.

In section 55, GMP states: "*You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress, you should put matters right (if that*

[5] http://www.health-ni.gov.uk/news/department-healths-response-report-inquiry-hyponatraemia-related-deaths

[6] IHRD Implementation Plan Programme Initiation Document: https://www.health-ni.gov.uk/sites/default/files/publications/health/IHRD%20Programme%20Initiation%20Document%20%28Programme%20Brief%29%20March%2018.pdf

is possible), offer an apology, and explain fully and promptly what has happened and the likely short-term and long-term effects." (GMC, 2013).

In 2015, the GMC, jointly with the Nursing and Midwifery Council, further published the document *Openness and Honesty When Things Go Wrong* (GMC, 2015) to elaborate on the professional duty of candour for all healthcare professionals.

As outlined above there are already a number of robust sanctions that patients, employers, regulators and others can draw on to hold staff to account.

Adding an individual statutory duty of candour with criminal sanctions would not add anything substantive to the existing routes and would add to the confusion about who is accountable. If the existing mechanisms are not used effectively or not understood, additional advice and guidance should be provided, rather than adding another provision, which could have the unintended consequence of worsening the existing culture of fear that prevents staff speaking out.

When it comes to surgeons, the main principles of the professional and ethical duty to be open and honest are also outlined in the College's *Good Surgical Practice* (RCS, 2014, section 3.5.4) which requires surgeons to:

- Inform patients promptly and openly of any significant harm* that occurs during their care, whether or not the information has been requested and whether or not a complaint has been made.
- Act immediately when patients have suffered harm, promptly apologise and, where appropriate, offer reassurance that similar incidents will not reoccur.
- Report all incidents where significant harm has occurred through the relevant governance processes of your organisation.

We agree with a statutory duty of candour for healthcare organisations, described in the Care Quality Commission's *Regulation 5 and Regulation 20: Guidance for NHS Bodies* (CQC, 2014) in England.

We note the consultation discusses **scope** of the organisational duty of candour (3.8) and agree that it should apply to all health and social care providers. We recognise that when unexpected or unintended incidents occur during the provision of treatment or care, openness and transparency is fundamental. This promotes a culture of learning and continuous improvement.

We believe that legislation in itself is not enough to prevent medical errors or bad behaviours. Openness and transparency needs to be led by the top of the organisation to engender real culture change and drive professionalism. Raising concerns early, before they become a serious patient safety threat, combined with a strong relationship between clinicians and managers, is vital to patient safety - and staff need to be supported to deliver this honesty without fear of reprisal.

Discussions via the Francis report[7] and recommendations on ***Freedom to Speak Up Guardians*** would be most useful in this regard. The Francis report concluded that a culture of fear prevented staff from speaking up and which was a lost opportunity to improve patient safety.

Importantly the O'Hara report flags reticence from clinicians to speak up about colleagues when things go wrong (See point 1.77) and this is where a more open culture and freedom to speak guardians could play an important role.

In England, The National Guardian's Office[8] was established in 2016 as an independent, non-statutory body with the remit to lead culture change in the NHS so that speaking up becomes business as usual.

We therefore agree with the consultation's recommendation to develop a framework around the following five key principles, based on the work of Sir Robert Francis, to achieve the cultural change that is needed for openness and honesty to prevail:

1. Routine openness
2. Openness to promote learning
3. Candour when harm or death has occurred
4. Support for openness and candour
5. The governance of openness and candour

These principles envisage a continuum between routine openness, openness to promote learning, and candour when something has gone wrong, and can be further broken down at each level on what they means in practice for the organisation, the patient and staff.

We welcome the consultation's focus on practical steps at Trust level to enable the creation of an open and transparent culture (Point 3.27 p31). We particularly support this element:

> "Any successful organisational Duty of Candour will depend on each organisation providing adequate support and protection for staff to enable them to work within an open and honest culture. Therefore, it will be a statutory requirement for organisations to ensure that all employees who carry out the Duty of Candour procedure on its behalf receive:
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> - Relevant training and guidance on the Duty of Candour procedures; and
> - Support to enable them effectively to adhere to their statutory individual Duty, and contribute to the organisation's statutory Duty of Candour requirements.

"Proposed examples of the types of support and protection to be provided by organisations include, but are not limited to:

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[7] Francis Report 2013: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/279124/0947.pdf

[8] National Guardians Office website: https://www.cqc.org.uk/national-guardians-office/content/national-guardians-office

- Opportunities for reflective practice;
- Leadership to ensure the implementation of an open and just culture;
- Provision of adequate training on an ongoing basis in response to the needs of staff;
- Clear guidance on the requirements of the statutory Duty of Candour and how it should be fulfilled; and
- Clear systems in place to identify and disseminate learning in order to improve practice."

We support the consultation's proposal to impose a statutory duty on organisations to publish an annual report on Duty of Candour incidents and to share with RQIA and DOH (Point 3.30 p33).

RCS England has guidance on the Duty of Candour (RCS, 2015[9]) that gives advice on how to implement the principles of duty of candour in everyday practice. In this document, we outline steps that doctors, surgeons and their employers can take to ensure that the principles of the duty of candour are at the forefront of everyday work. Specifically, we outline the following considerations and would welcome the opportunity to shape the policy supporting the duty of candour in Northern Ireland:

- How to nominate an individual to carry out the disclosure discussion
- The process for apologising and understanding liability
- Details on timing, location and persons to notify should an error occur
- How to ensure that the patient is well supported
- How to facilitate an open dialogue with patients
- What documentation is required
- What to do if the error occurred in a different organisation
- The support that should be available for surgeons and surgical teams who have been involved in harm
- How to report the incident and ensure lessons are learnt
- Ensuring that there is a culture of openness, focusing on patient safety.

We note the consultation discusses situations where Duty of Candour should apply - for example where unintended or unexpected incidents happen and which cause death, moderate harm, serious harm or prolonged psychological harm. They also potentially apply in circumstances where harm '**may have resulted'**. This is a nuanced departure from the English Duty of Candour wording in relation to the threshold of a 'notifiable safety incident':

> "any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, **could result in**, **or appears to have resulted in**: the death of the service user, where the death relates directly to the incident rather than to the natural

[9] RCS Duty of Candour guidance https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/good-practice-guides/duty-of-candour/

course of the service user's illness or underlying condition, or severe harm, moderate harm or prolonged psychological harm to the service user.[1011]"

The consultation document (Point 3.14 p25) further explains that the inclusion of the term '**may have resulted in'** is "*intended to bring incidents which have the potential to cause significant harm in the future within the scope of these requirements. However "potential harm" in this context would not include near misses, which are acts of commission or omission that could have harmed a patient but did not cause harm as a result of chance, prevention or mitigation*."

Finally, we note recommendations flowing from the Independent Medicines and Medical Devices Safety Review (known as the Cumberledge Review 2020[12]) looking into the response of England's healthcare system to patient reports of harm from drugs and medical devices. The review primarily focused on use of pelvic mesh, sodium valproate and hormone pregnancy tests. The report focused on Duty of Candour (Theme 6) concluding[13]:

> *We believe that barriers to being open and honest must be minimised. We share concerns with others that litigation, which is blame-based and focusses on the actions of individual doctors, inhibits disclosure. It has been known for decades that the majority of mistakes are system errors, yet litigation deals with the culpability of individuals. Over twenty years ago in 'To Err is Human' the Institute of Medicine wrote, 'The focus must shift from blaming individuals for past errors to a focus on preventing future errors by designing safety into the system. This does not mean that individuals can be careless. People must still be vigilant and held responsible for their actions. But when an error occurs, blaming an individual does little to make the system safer and prevent someone else from committing the same error.'*

As surgeons, we support a cultural shift away from blame in order to create a healthcare system where people are open and honest. We believe this is essential to deliver a safer health service where healthcare professionals have no reason to fear being candid and telling the truth to their patients. We wholeheartedly agree with the Duty of Candour workstream Chair's aspiration for "inspirational leadership from our managers whom we ask to champion the values outlined across the HSC[14]."

If you would like any further information or to arrange a meeting to discuss the issues raised in this response, please contact Áine Magee, Royal College of Surgeons of England, Policy and Public Affairs Manager Northern Ireland amagee@rcseng.ac.uk

[10] Duty of Candour UK Gov web version: https://www.gov.uk/government/publications/nhs-screening-programmes-duty-of-candour/duty-of-candour
[11] The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 https://www.legislation.gov.uk/ukdsi/2014/9780111117613
[12] Independent Medicines and Medical Devices Safety Review: https://www.immdsreview.org.uk/Report.html
[13] Ibid: page 31
[14] Duty of Candour consultation document p2