Response to Department of Health Consultation on the introduction of a statutory Duty of Candour and Being Open Framework in Northern Ireland

July 2021

1. About the RCPCH

The Royal College of Paediatrics and Child Health (RCPCH) is responsible for training and examining paediatricians. The College has over 20,000 members in the UK and internationally and sets standards for professional and postgraduate education. We work to transform child health through knowledge, research and expertise, to improve the health and wellbeing of infants, children and young people across the world.

The voices of children and young people are at the heart of everything we do. Guided by the UNCRC, the RCPCH &Us Network facilitates children and young people to have their voices heard in decisions that affect them (Article 12) and work with them to help shape services so they have the best healthcare possible (Article 24).

2. Introduction

The RCPCH welcome the opportunity to respond to the consultation on the introduction of a statutory Duty of Candour for Northern Ireland (NI).

The RCPCH welcome and acknowledge the utility of an organisational Duty of Candour. We agree in the most part with the proposed scope, requirements and procedure as detailed in the consultation document as well as the staff support and reporting and monitoring proposals. The RCPCH also welcome the proposal on the development of a 'Being Open' Framework. We support the stated purpose of the proposed Framework to viz. set out the mechanisms through which cultural change can be facilitated and the key principles of; routine openness, openness to promote learning, candour when harm or death has occurred, support for openness and candour and, the governance of openness and candour. The College's considerations are set out at Section 4 of this response.

The RCPCH does not believe that a statutory individual Duty of Candour, in any form, is necessary in addition to a new statutory organisational Duty of Candour and Being Open Framework. The College notes that paediatricians are already rigorously regulated by way of the professional, regulatory Duty of Candour placed upon them by the General Medical Council (GMC) and their employer. The RCPCH believe that an additional, individual duty would be cumbersome, duplicative, and disproportionate in terms of achieving the stated aims of implementing candour legislation. The RCPCH also believe that an individual duty with criminal sanctions attached would have the potential to create fear and defensive practice. The College's considerations are detailed at Section 5 of this response.

The RCPCH has also included the voice of children and young people at Section 6 of this response which covers the skills, attitudes and attributes identified through engagement processes that children and young people have stated are needed in order for information and communication to be effective and understood. The RCPCH makes it clear that in moving forward, under UNCRC, children and young people would need to be effectively and meaningfully involved in the development of any implementation actions and their input sought for the purposes of training staff and organisations on how to communicate effectively.

3. Background

The RCPCH undertook a methodology to appropriately capture the wide scope of considerations, particularly potential unintended consequences, needed to accurately assess the impact of implementing the proposed aspects of a statutory Duty of Candour in NI on paediatricians and paediatric care at an operational level and from an ethical perspective. The RCPCH launched a member's survey in June 2021 to elicit direct, on the ground insight. The College also conducted a review which covered; the statutory Duty of Candour in the UK and Ireland, existing remedies and sanctions relating to candour and, how the threat of criminal sanction in medical practice can have a chilling, paradoxical effect.

4. Statutory Organisational Duty of Candour and the Being Open Framework

Multiple reviews and reports have acknowledged that candour, as it relates to openness and transparency within care settings must be developed and delivered in a way which maximises the ability of individual practitioners to; discharge their obligations, deliver the best care based on expert clinical analysis and ensure patient safety, and that ultimately, a blame culture is detrimental to these aims.

Sir Robert Francis QC stated that services need to get away from the culture of blame and the fear that it generates, to one which celebrates openness and commitment to safety and improvement which in turn will reduce patient risk and improve confidence in the NHS.[1] Professor Sir Liam Donaldson highlighted that when a quality or safety problem arises in the NI care system, the tendency is to point to the individuals or services involved, when in reality, the greatest threats to quality and safety, come from the way in which the system as a whole operates. In order to promote a culture of openness, Donaldson stated that there would be considerable advantages in NI introducing an organisational Duty of Candour to match the duty that doctors come under from their professional regulators.[2] More recently, Baroness Cumberlege stated that a cultural shift away from blame is needed to create a healthcare system where people are open and honest, a systems-based approach to delivering redress as a substitute for litigation could drive this shift which is essential to deliver a safer NHS where healthcare professionals have no reason to fear being candid and telling the truth to their patients.[3]

The RCPCH notes that the 'Routine Requirements' and 'Requirements when things go wrong' set out in Section 3 and expanded upon at Section 5 which sets out the proposed three Levels of openness the Workstream have considered within the consultation document. The RCPCH welcomes the proposed provisions that staff can expect at Level 1, viz. the expectation that clear guidance, time and space to reflect and feedback, training and leadership who exhibit candour will all be forthcoming. The RCPCH response expands further on these points at Section 4.3.

In terms of Level 2 openness (Openness to promote learning), the RCPCH believes this should be the key driving aim of the organisational Duty of Candour and welcome the proposal that when staff report a mistake where no harm has been caused, their organisation will respond appropriately to capture the learning from the mistake and disseminate that learning where appropriate. The RCPCH asserts that systemic processes must be such as to facilitate paediatricians to have the time to learn

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[1] Francis, R (2015) *Freedom to Speak Up: An independent review into creating an open and honest reporting culture in the NHS* available at: https://webarchive.nationalarchives.gov.uk/20150218150953/https://freedomtospeakup.org.uk/wp-content/uploads/2014/07/F2SU_web.pdf

[2] Donaldson (2014) *The Right Time, the Right Place,* available at: https://www.health-ni.gov.uk/topics/health-policy/donaldsonreport#:~:text=The%20Right%20Time%2C%20The%20Right%20Place&text=Sir%20Liam's%20report%20was%20published,areas%20across%20the%20health%20service

[3] Cumberlege (2020) *First do no harm; The report of the Independent Medicines and Medical Devices Safety Review*, available at: https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf

from errors which did not cause harm but had the potential to. The RCPCH note, as already highlighted by the Medical Defence Union (MDU), that 'Level 2 openness' as currently drafted in the consultation document requires the 'immediate' reporting of a patient safety incident caused by them or witnessed by them. This may not be possible in most cases; staff will still need to prioritise patient care before the opportunity to report the incident is possible. We agree with the MDU that staff should instead be expected to make such reports as soon as is reasonably practicable.[4]

The RCPCH note that the Level 3 (openness when things go wrong) requirements for staff are intrinsically linked to the GMC mandated professional Duty of Candour which paediatricians work to routinely. The GMC sets out that every healthcare professional must be open and honest with patients when something goes wrong with their treatment or care, or has the potential to cause harm or distress. This means that healthcare professionals must: tell the patient when something has gone wrong; apologise to the patient; offer an appropriate remedy or support to put matters right if possible; explain fully to the patient the short and long-term effects of what has happened; be open and honest with their colleagues, employers and relevant organisations and; take part in reviews and investigations when requested. They must also be open and honest with their regulators, raising concerns where appropriate and support and encourage each other to be open and honest, and not stop someone from raising concerns.[5]

4.1 Definition of harm

In terms of the threshold on definitions of harm, these are fairly consistent with the commensurate legislation in England[6] and Scotland.[7] However, the MDU note that it can be difficult in practice to work out whether something has met the definition threshold and consequently, there are potentially legitimate differences of opinion between healthcare professionals about whether the threshold for something being a notifiable incident is met.[8] This outlook has been echoed by RCPCH members who have raised the question of what the threshold for reporting an incident will subsequently be, and some anticipate "frequent debates" on whether or not a threshold has indeed been met.[9] The Department of Health should pay cognisance to these ambiguities if drafting candour legislation and associated guidance.

4.2 Apologies

In terms of procedure as detailed at Section 3.26 of the consultation document, the RCPCH welcome the proposed legal protection of apologies within the anticipated candour procedure which clarifies that an apology or other step taken in accordance with the Duty of Candour procedure should not, of itself, amount to an admission of negligence or a breach of a statutory duty. Indeed, some protection in terms of litigation would somewhat align NI with the rest of the UK.[10] RCPCH members in acute

[4] Medical Defence Union (2021) Response to NI Department of Health Duty of Candour and Being Open consultation

[5] GMC 'The Professional Duty of Candour' available at: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/candour---openness-and-honesty-when-things-go-wrong/the-professional-duty-of-candour

[6] Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, available at: https://www.legislation.gov.uk/ukdsi/2014/9780111117613/regulation/20

[7] Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 and The Duty of Candour Procedure (Scotland) Regulations 2018 available at: https://www.legislation.gov.uk/ssi/2018/57/contents/made

[8] Medical Defence Union (2021) Response to NI Department of Health Duty of Candour and Being Open consultation

[9] RCPCH (July 2021) NI Member's Survey on Statutory Duty of Candour

[10] Compensation Act 2006, available at: https://www.legislation.gov.uk/ukpga/2006/29/contents and Apologies (Scotland) Act 2016, available at: https://www.legislation.gov.uk/asp/2016/5/body respectively

settings reported that instances of misconstrued apologies have happened within their services when staff have expressed that they were sorry for a particular diagnosis and/or suffering.[11] It should be noted that surveys have consistently shown that, among other things, what patients want from a complaints system is an apology.[12]

"[Sic] as in sorry for their diagnosis, suffering etc. in case misconstrued as apologising for something wrong. Has happened in our service already."[13]

4.3 Support for staff

In terms of the support for staff aspect of the proposals in the consultation paper, the RCPCH believe that robust support mechanisms are crucial in achieving the desired effect of the organisational Duty of Candour. The RCPCH are content with the principles set out at section 3.28, viz. 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; Opportunities for reflective practice; 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. RCPCH members told us that:

> *"We work in a system and do not practice as 'individuals' very often. Increasingly teams take care of children and they are cared for across community and acute settings … I feel that learning and sharing information without fear and blame would be the best way forward. If we could be really focused on improvement and sharing system learning and have time [sic] and learning events this would create a much happier and more open culture."*
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> *"It will require new training approaches in terms of very clear documentation and will likely require more engagement with management colleagues."*[14]

The newly updated NHS England 'Framework for Involving patients in patient safety' reiterated that organisations must have systems in place to uphold the Duty of Candour and do so in a sensitive and effective way. Organisations should encourage, train and support staff to apologise to and be open with patients or those close to them when something has gone wrong. Organisations need to have clear policies setting out how the process of open disclosure will be initiated and who it will be led by. Those people should be; trained in 'duty of candour' and 'being open' principles, be able to establish a relationship with those affected, identify what support is needed, help people get access to that support, and set expectations about the response to the incident.[15] The NI Department of Health should consider the impact of this contemporary, updated guidance.

However, it should be noted that in an already over-stretched system, where there are too few career and trainee grade paediatricians[16] protecting time to fulfil these principles will not necessarily be straightforward. RCPCH members have stated that there must be protected time to allow for team

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[11] RCPCH (July 2021) NI Member's Survey on Statutory Duty of Candour

[12] Donaldson (2014) *The Right Time, the Right Place*, available at: https://www.health-ni.gov.uk/topics/health-policy/donaldsonreport#:~:text=The%20Right%20Time%2C%20The%20Right%20Place&text=Sir%20Liam's%20report%20was%20published,areas%20across%20the%20health%20service

[13] RCPCH (July 2021) NI Member's Survey on Statutory Duty of Candour

[14] Ibid

[15] NHS England (June 2021) 'Framework for involving patients in patient safety', available at: https://www.england.nhs.uk/wp-content/uploads/2021/06/B0435-framework-for-involving-patients-in-patient-safety.pdf

[16] RCPCH (2019) 'Workforce census: Focus on NI' available at: https://www.rcpch.ac.uk/sites/default/files/2020-01/Workforce%20census%20Northern%20Ireland%202019%20v1.8.pdf

reviews and that essentially, the services need more staff in order to have the time to look after patients and record what they do properly. RCPCH members also noted that in general, complaints processes are stressful, time consuming and expensive to manage and stated that the NI Executive will need to commit to financing the additional pressure this will put on Trusts and individual staff by providing paid time for staff to provide responses to complaints and also by providing pastoral support for staff through the complaints process. RCPCH members have stated that they expect that service providers will feel they need to provide "very lengthy verbal and written information which will increase the time for consultations and involve managers". It is paramount that capacity is built into the system to ensure the protections are adhered to.[17]

4.4 Reporting and monitoring

In terms of the reporting and monitoring requirements commencing at Section 3.29 of the consultation document, the RCPCH can only comment insofar as possible given the limited detail i.e., that information on compliance with the reporting and monitoring requirements will be included within the accompanying guidance issued by the Department of Health to support the implementation of the statutory organisational Duty of Candour in due course. The RCPCH welcome the proposed statutory requirement that organisations must publish a report on the Duty of Candour as soon as practicable after the end of the financial year which includes statistics regarding the number and type of incidents in which the Duty of Candour process was invoked, and an assessment of the organisation's performance in respect of the Duty of Candour.

The RCPCH do not have a specific, preferred approach in terms of compliance for breach of a future organisational Duty, we endorse the approach which gives way to the most holistic method of identifying problems where candour failures assist in the identification of patient safety patterns and best promotes safety and learning. It follows that the efficacy in the reporting and monitoring aspects of the proposed organisational Duty of Candour is crucial.

The RCPCH note that in England, the Care Quality Commission (CQC) are impowered by Regulation 20[18] to regulate the operation of the organisational statutory Duty of Candour which applies to every health and social care provider that CQC regulates. The CQC can use their powers of enforcement to prosecute breaches of the Regulation including; warnings and requirement notices, imposition of conditions and, criminal prosecution.[19] The efficacy of the Duty was questioned by Baroness Cumberlege in the *First do no harm* report, but the main thrust of her deliberations were soundly centred upon a shift away from blame culture[20], which creates a dichotomy between the proposed approach of an individual Duty of Candour with criminal sanction for breach and the stated aim of creating an open culture in NI. Nonetheless, although the CQC prosecutorial power was slow to start, several successful prosecutions have been brought during 2019/20.[21] However, the efficacy of the prosecutorial approach remains to be seen.

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[17] RCPCH (July 2021) NI Member's Survey on Statutory Duty of Candour

[18] Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, available at: https://www.legislation.gov.uk/ukdsi/2014/9780111117613/regulation/20

[19] Care Quality Commission; 'Regulation 20: Duty of Candour' https://www.cqc.org.uk/guidance-providers/all-services/regulation-20-duty-candour

[20] Cumberlege (2020) *First do no harm; The report of the Independent Medicines and Medical Devices Safety Review*, available at: https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf

[21] Care Quality Commission, University Hospitals Plymouth NHS Trust (Sept 2020) available at: https://www.cqc.org.uk/news/releases/care-quality-commission-prosecutes-university-hospitals-plymouth-nhs-trust-breaching and Bradford Teaching Hospitals NHS Foundation Trust (January 2019) available at: https://www.cqc.org.uk/news/releases/bradford-teaching-hospitals-fined-failure-comply-duty-candour

The statutory organisational Duty of Candour[22] came into effect in Scotland on 1 April 2018 and applies to health, care and social work organisations. The implementation of the Duty of Candour in Scotland follows the same process as was introduced in England in 2014. However, there are some slight differences e.g., in Scotland the person determining whether a notifiable incident has occurred must not have been involved in the incident itself.[23] The MDU also points out that a unique feature of the statutory Duty in Scotland is the recognition of the need to support healthcare staff that goes beyond the training needed to help staff understand and fulfil their responsibilities.[24]

In order to assist with monitoring the extent to which the organisational Duty of Candour procedure has been followed in Scotland, there is a power for certain bodies to require responsible persons to provide them with information. These same bodies are to be notified when the annual reports are published. The bodies with the power to require information (and who are to be notified) vary depending on the responsible person. Health Boards, for example, are linked to Scottish Ministers.[25]

The recently enacted Health and Social Care (Quality and Engagement) (Wales) Act 2020 enshrines the statutory organisational Duty of Candour in to law in Wales. Regulations are to be drafted but there is currently no intention to attribute fault in order to enable a focus on learning and improvement.[26] The Act requires NHS providers to report annually about when the Duty has come into effect, how often the Duty has been triggered, a description of the circumstances leading to the event and the steps taken by the provider with view to preventing any further occurrence.[27]

In response to a proposed amendment to the Duty of Candour provisions in the now Health and Social Care (Quality and Engagement) (Wales) Act 2020 which sought to invoke escalation action toward providers for breach, the then Minister for Health and Social Services, Vaughan Gething stated that taking a punitive approach to try to change culture and behaviour, where the aim is openness and transparency, is unlikely to achieve all the intended results. *"You're unlikely to hold your hand up and say, 'I have breached a duty', if you realise that your whole organisation is then going to be punished in some way … we want to have the reports on the Duty of Candour, including where breaches have taken place, to be highlighted, to be open and transparent"*.[28]

As previously iterated, the RCPCH endorse the most effective mechanism which would promote learning and patient safety and note the utility of exploring the efficacy of mechanisms in operation in other jurisdictions. However, in general terms, regarding criminal sanction for candour failures, a member made an apt observation:

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[22] Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 and The Duty of Candour Procedure (Scotland) Regulations 2018 available at: https://www.legislation.gov.uk/ssi/2018/57/contents/made

[23] BML Law, 'The Duty of candour in Scotland' https://www.blmlaw.com/news/the-duty-of-candour-in-scotland-8211-what-you-need-to-know

[24] Medical Defence Union, 'Duty of Candour in Scotland' available at: https://www.themdu.com/guidance-and-advice/guides/duty-of-candour-scotland

[25] Scottish Government (2016) Explanatory notes; Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016, available at: https://www.legislation.gov.uk/asp/2016/14/pdfs/aspen_20160014_en.pdf

[26] The Medical and Dental Defence Union of Scotland, 'Statutory Duty of Candour' available at: https://www.mddus.com/advice-and-support/advice-library/statutory-duty-of-candour

[27] The Health and Social Care (Quality and Engagement) (Wales) Act; summary, available at: https://gov.wales/health-and-social-care-quality-and-engagement-wales-act-summary-html

[28] Health, Social Care and Sport Committee - Fifth Senedd (23/01/2020) at: https://record.assembly.wales/Committee/5969#A700000107

"I find the punitive stance a bit off putting. We are in medicine to provide care and we work hard for it. If mistakes happen, we should be able to support each other but not cover up mistakes. It is important to promote candour - not criminalise its absence"[29]

5. Statutory Individual Duty of Candour

The RCPCH have reviewed the original O'Hara Inquiry into Hyponatremia related deaths (IHRD) recommendation that an individual Duty of Candour be enacted with criminal sanctions attached for breach and the two alternative recommendations proposed by the Workstream; (a) statutory individual Duty of Candour without criminal sanction attached for breach and (b) statutory individual Duty of Candour without criminal sanction for breach, and separate criminal offences for withholding information, destroying information, or providing false or misleading information as detailed at Section 4 of the consultation document. Ultimately, the RCPCH asserts that a statutory individual Duty of Candour in any form is unnecessary, as at best it would duplicative and at worst, incongruent with the overarching aim of creating an open culture where blame is minimised and learning is key. The introduction of a statutory organisational Duty of Candour, alongside a regulatory, professional Duty of Candour against a backdrop of a new Being Open Framework ideally should be sufficient. Our rationale regarding the individual statutory Duty of Candour is detailed in sections 5.1 – 5.3.

5.1 The General Medical Council Professional Duty of Candour

As is the case across the UK, paediatricians in NI are strictly regulated by the GMC as empowered by the Medical Act 1983,[30] as amended by Medical Act 1983 (Amendment) Order 2002.[31] The GMC can take action to ensure the protection of patients, maintain confidence in the medical profession and uphold the standards expected of doctors.[32] Among the obligations and expected standards is the professional Duty of Candour, an explicitly detailed process for doctors to follow when something goes wrong.[33] As identified by the Cumberlege Review,[34] the professional Duty of Candour to be open and honest with patients if things go wrong was reinforced with a joint statement from regulators of healthcare professionals in 2019.[35]

The available sanctions the GMC can levy are; warnings, agreeing undertakings with doctors and referral to the Medical Practitioners Tribunal Service, which has the power to restrict, suspend, or revoke a doctor's registration in the UK. Furthermore, the GMC advise that a fitness to practise panel is likely to consider a more serious sanction if there is evidence of a failure to raise a concern, or of an

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[29] RCPCH (July 2021) NI Member's Survey on Statutory Duty of Candour

[30] Medical Act 1983 available at: https://www.legislation.gov.uk/ukpga/1983/54/contents

[31] The Medical Act 1983 (Amendment) Order 2002 available at: https://www.legislation.gov.uk/uksi/2002/3135/contents

[32] GMC 'Our Sanctions' available at: https://www.gmc-uk.org/concerns/information-for-doctors-under-investigation/our-sanctions

[33] GMC (updated 2019) 'Openness and honesty when things go wrong: the professional duty of candour' available at: https://www.gmc-uk.org/-/media/documents/openness-and-honesty-when-things-go-wrong--the-professional-duty-of-cand pdf-61540594.pdf?la=en&hash=EEB52EBEDBFA0EA421F4736F4C36BAB730A9E567

[34] Cumberlege (2020) *First do no harm; The report of the Independent Medicines and Medical Devices Safety Review*, available at: https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf

[35] Joint statement from the Chief Executives of statutory regulators of healthcare Professionals (2019) available at: https://www.pharmacyregulation.org/sites/default/files/joint_statement_on_the_professional_duty_of_candour.pdf

attempt to cover up.[36] It follows that doctors are already rigorously regulated in terms of individual candour.

The RCPCH also wishes to point out that our Progress training programme curriculum sets out that patient safety and quality improvement needs to encapsulate all aspects of patient care - not just the clinical experience but service development, review and evaluation. We inform our training grade paediatricians that they have a Duty of Candour to the patient and their parents to be honest about errors and inform service users of the format and timescale of investigation of the error. We advise that paediatricians must answer any questions the service user may have and direct questions they are unable to answer to an appropriate colleague or patient advice and liaison service. The error must be reported on the relevant local reporting system and the relevant, local patient safety lead must be invited to be involved in the investigation. The College encourages paediatricians to think about why the error may have happened, learn how to disseminate learning to colleagues and, prevent it happening again.[37]

RCPCH members have reported that they act in accordance with their professional Duty of Candour as a matter of course and already work in an open and honest way with patients and families in line with associated GMC guidance. Some members alluded to a fear of "double jeopardy" in terms of both GMC and new legislative criminal sanction if they are "perceived to have not been candid".[38] Our members also cited their awareness of their responsibility to speak up, despite the fact NI does not currently have the protective mechanisms such as Freedom to Speak Up Guardians, that exist in other UK jurisdictions.

> *"I view myself as having GMC and Trust responsibilities to speak up if I see something untoward happening…"*[39]

The 2018 civil *Bawa-Garba* appeal case highlighted that the sanction of erasure from the GMC register may occur even where a doctor does not present a risk to patient safety, but where this action may be felt necessary to maintain public confidence in the profession. Examples cited included; blatant disregard for the safeguards designed to protect members of the public, maintaining high standards within the profession and, dishonesty.[40] We believe further individual regulation and sanction relating to candour is therefore unnecessary. In the same vein, as identified by the MDU, a failure by a Health and Social Care NI employed practitioner to offer their employer reasonable cooperation with a Duty of Candour investigation could result in either contractual disciplinary action by the employer, or referral to the regulator, or both. The potential outcome of these is loss of employment and loss of the ability to practice in a regulated profession. In any case, this is a hefty price to pay for professional accountability and these outcomes are already in place.[41]

5.2 Potential impact of a statutory individual Duty of Candour with criminal sanctions attached on paediatricians and paediatric care

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[36] GMC 'Our Sanctions' available at: https://www.gmc-uk.org/concerns/information-for-doctors-under-investigation/our-sanctions

[37] RCPCH 'Progress domain resources: Patient safety and quality improvement' (updated 22 November 2019), available at: https://www.rcpch.ac.uk/resources/rcpch-progress-domain-resources-patient-safety-quality-improvement#closing-the-gaps---case-study

[38] RCPCH (July 2021) NI Members Duty of candour proposals survey

[39] Ibid

[40] *Hadiza Bawa Garba v the General Medical Council* [2018] EWCA Civ 1879 available at: https://www.judiciary.uk/wp-content/uploads/2018/08/bawa-garba-v-gmc-final-judgment.pdf

[41] Medical Defence Union (2021) Response to NI Department of Health Duty of Candour and Being Open consultation

5.2.1 Recruitment and retention

The RCPCH notes that at section 4.7 of the consultation document, the Workstream have already acknowledged feedback regarding the potential impact on the recruitment and retention of regulated health professionals if NI were perceived to be a less attractive location to work as a consequence of the implementation of an individual statutory Duty of Candour, and in particular, the introduction of individual criminal liability for breach.

RCPCH members in NI have indicated that they "will seriously consider leaving clinical paediatrics"[42] should criminal liability attached to individual candour come to pass citing that legal sanctions would be "intolerable".[43] This is indicative of the chilling effect described by the MDU and others[44] created by the threat of criminalisation in clinical practice where uncertainty and risk are omnipresent.

RCPCH members in NI reported that they believe the impact of criminal sanctions will be detrimental and far-reaching, citing that the anxiety created by the additional threat of criminalisation may encourage practitioners to leave practice. Members cited a potential increase in early retirements due to the additional stress of risk of criminalisation on top of the current stress of multiple bodies interrogating paediatric work.[45] Members note that impact on recruitment and retention will be exacerbated by the O'Hara Inquiry recommendation that Foundation doctors should not be employed in children's wards[46] which the RCPCH fundamentally disagree with because Foundation doctors are valuable additions to the paediatric workforce.[47] The potential manifest effect of these cited issues is increased pressure and workload upon those who continue to practice, who in turn may reconsider paediatrics as a career or NI as a place to work.

> *"Already I have had instances of junior staff - mainly from overseas who when mentioned in a clinical incident are afraid they will lose their job or be punished. We already struggle to recruit and NI currently pays … consultants less than the rest of the UK [sic] (Lack of merit awards) funds our health service less …"*
>
> *"This will make attracting staff even more difficult than it already is. What incentive would there be for staff to come to NI when there is a chance of prosecution here and not anywhere else in the UK - I have been told by colleagues elsewhere in the UK that they feel that NI is a toxic place to work. The criminal sanction part of this will not improve this".*[48]

The most recent RCPCH paediatric workforce census published in 2019[49] identified that NI had 2.4 headcount consultant paediatricians per 10,000 children, lower than the UK average rate of 2.8. The census also detailed that NI had a slightly older paediatric workforce compared to the UK as a whole,

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[42] RCPCH (July 2021) NI Member's Survey on Statutory Duty of Candour
[43] Ibid
[44] MDU (September 2019) 'Statutory duty of candour in NI: MDU submission', available at: https://www.themdu.com/about-mdu/our-impact/our-impact-archive/statutory-duty-of-candour-in-northern-ireland-mdu-submission
[45] RCPCH (July 2021) NI Member's Survey on Statutory Duty of Candour
[46] O'Hara, J (2018) *Inquiry into Hyponatremia Related Deaths* (Recommendation 13) available at: http://www.ihrdni.org/
[47] RCPCH et al (2018) Hyponatremia Related Deaths Inquiry Report; A joint response, available at: https://www.rcpch.ac.uk/sites/default/files/2018-05/hyponatremia_related_deaths_inquiry_report.pdf
[48] RCPCH (July 2021) NI Member's Survey on Statutory Duty of Candour
[49] RCPCH (2019) 'Workforce census: Focus on NI', available at: https://www.rcpch.ac.uk/sites/default/files/2020-01/Workforce%20census%20Northern%20Ireland%202019%20v1.8.pdf

22% were in the 50-54 age category and 15.3% were aged 55 or over. Furthermore, our *Facing the Future: Standards for Paediatric Services*[50] states that there should be 10 whole time equivalent posts on general paediatric training rotas; 88.9% of training rotas in NI did not meet this standard.[51] It is not unreasonable to extrapolate that any reduction in paediatric staffing levels, either via discouraging entry in to paediatrics to train, or invoking career grade paediatricians to reconsider maintaining their practice as a result of unnecessary punitive candour legislation, will be detrimental to the delivery of paediatric services in NI.

5.2.2 Open and learning culture and defensive practice

The RCPCH assert that creating any new criminal offence in the context of individual candour failures is problematic. Sir Francis noted that an incident or a series of incidents may be attributable to poor performance by an individual clinician or a team or there may be a systemic cause for the concern. In cultures where blame is an accepted method of explaining a concern, those implicated by a concern are likely to react in a defensive manner. Working relationships with colleagues may suffer, and organisations may default to hierarchical solutions.[52]

RCPCH members have reported significant concerns that attaching criminal sanctions to a statutory individual Duty of Candour will discourage doctors and nurses from reporting incidents and also from being honest with patients by creating a blame culture. Our members have noted their strongly held belief that being open and honest with patients is important for trust and mutual respect, however, they have warned that a balance must be struck between the increasing bureaucracy of the procedural aspects of care and actually providing care.[53]

> *"I already work in an open and honest way with patients and families in line with GMC guidance. I am worried about criminalisation being part of this as it makes me anxious about how issues will be dealt with in the years ahead. I feel it will require new training approaches in terms of very clear documentation and will likely require more engagement with management colleagues".*
>
> *"[Sic] not criminal sanctions. This will decrease openness, increase defensive medicine and increase fear".*
>
> *"It will mean that we will work in fear of being convicted of a crime every time we interpret a result and seek to explain to families. It will affect our clinical care and judgement. It will further demoralise an already demoralised work force. I am an honest doctor, as most are".*
>
> *"Additional stress, an environment of fear and constantly looking over my shoulder. Think it will be very counterproductive, people will be scared to be open and honest".*

RCPCH members in NI cited a range of negative observations around potential unintended consequences indicating that, despite the assurance from the Workstream that criminal sanction will

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[50] RCPCH (2010) 'Facing the Future: Standards for Paediatric Services', available at:
[51] RCPCH (2019) 'Workforce census: Focus on NI' available at: https://www.rcpch.ac.uk/sites/default/files/2020-01/Workforce%20census%20Northern%20Ireland%202019%20v1.8.pdf
[52] Francis, R (2015) *Freedom to Speak Up: An independent review into creating an open and honest reporting culture in the NHS*, available at: https://webarchive.nationalarchives.gov.uk/20150218150953/https://freedomtospeakup.org.uk/wp-content/uploads/2014/07/F2SU_web.pdf
[53] RCPCH (July 2021) NI Member's Survey on Statutory Duty of Candour

only happen in the most egregious circumstances, the psychological effect of threatened criminalisation persists. Our members cited fears of bullying and harassment, potential subtle changes in clinical practice to a focus which places too much emphasis on legality, poorer relationships with patients and colleagues, and increased anxiety and stress. Members have reported that subconsciously, they will feel less safe in their practice and will be much more guarded. They also noted the potential for more entrenched silo mentality with some staff possibly deflecting risk by refusing multi-disciplinary team approaches to working.[54]

In the same thread, the Cumberlege Review concluded that barriers to being open and honest must be minimised and noted concerns that litigation, which is blame-based and focusses on the actions of individual doctors, inhibits disclosure. The Cumberlege Report noted that 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*.'[55]

Building on the potential paradoxical and psychological effect of proposed criminal sanction for candour failures, RCPCH members noted a confusion around what actually constitutes a candour failure noting the potential of wrongful whistleblowing because staff may report others for what *they* perceive as wrongdoing so that they will not be "seen as covering up for others" and warned that it "must be proven that mistakes were deliberately hidden-not just misrepresented by hindsight" and therefore misconstrued.

5.2.3 Patient / provider relationship

Paediatrics is a unique specialty because patients are children ranging from infancy to adolescence, and paediatricians not only communicate with the patient but also, in almost all circumstances, their parents or carers. The dynamics between a child patient and an adult patient and their doctors are very different and a high degree of situational awareness and communication skills are required to balance the need to disclose, the timing of disclosure and the content. Paediatricians recognise that parents need information but heightened states of anxiety and proximity to the situation can often create additional concerns for a paediatrician to work through.

RCPCH members have elucidated upon a range of operational and management level considerations where the patient / doctor relationship may be adversely impacted by criminal sanctions attached to individual candour in practice. Members worry that explaining every detail of substandard care to families could diminish trust in the profession. They have reported their concerns that external legal implications may violate patient / physician confidentiality and erode trust given the sensitivity of healthcare information sharing. Members have said that they fear that their clinical practice and working life will be significantly negatively affected in terms of their "ability to do what is best for the patient". Our members anticipate a "negative effect on how they communicate with families" and worry that managing care where "parents don't agree with medical opinion/advice" or "where safeguarding" is an issue and "social complexity" will all become much more difficult.[56]

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[54] Ibid

[55] Institute of Medicine (2000) *To Err is Human; Building a Safer Health System* at: https://pubmed.ncbi.nlm.nih.gov/25077248/

[56] RCPCH (July 2021) NI Member's Survey on Statutory Duty of Candour

"It will mean that we will work in fear of being convicted of a crime every time we interpret a result and seek to explain to families. It will affect our clinical care and judgement. It will further demoralise an already demoralised work force…".[57]

While the RCPCH fundamentally disagrees with the need for a statutory individual Duty of Candour, in the interests of completeness, and the fact that the consultation document at Section 4.44 details that beyond high level feedback, insufficient information has been received to allow the Workstream to develop a policy position around possible inclusion of exemptions in circumstances where clinical or professional judgement or other extant legal obligations determined that candour may not be appropriate in certain contexts, RCPCH members from emergency and critical care settings have indicated potential instances for exemption.

Members have stated that it is unethical to divulge inappropriate types or amount of information in the case of critically unwell or potentially dying children in the Intensive Care Unit or the Emergency Department. They also pointed out the sensitivities around suspected child abuse of unknown perpetrators which means that candour in this context would not be apposite[58] or could hinder future investigations. The RCPCH also updated our Perplexing Presentations guidance and in terms of illness induction, there could be signs of interfering with specimens, unexplained results of investigations etc., where paediatricians may have concerns that an open discussion with a parent might lead them to harm the child.[59] In such contexts, candour will come secondary to the protection and wellbeing of a child.

5.2.4 Resource and capacity

RCPCH members have raised a range of concerns around increased need for resource in a system which is stretched beyond capacity. Members have relayed that they feel implementation will require new training approaches in terms of very clear documentation and will likely require more engagement with management colleagues. Some members alluded to subconsciously feeling less safe in their practice, and thusly will not perform optimally and will take longer to make complex decisions which in turn will have a knock-on effect on waiting times etc. Members described the possibility of increased risk aversion medical care with increased risk of investigations and over investigation for patients, ultimately utilising scarce resource on potentially unnecessary investigations, the impact of which could be detrimental in a region of the UK with some of the worst waiting times for diagnostics and elective care. Members cited that children are already being transferred to paediatric centres as local teams feel unqualified to deal with some presentations and worry that fear of additional legal sanction will exacerbate this.[60]

Members also raised the issue of potential increased medical protection fees and the impact of paid time for paediatricians to reflect and receive pastoral care adding that the NI Executive must commit to financing the pressure this will put on Trusts and individual staff should it come to pass because clinical care budgets cannot suffer to absorb any further financial pressure. At the very crux of this concern is that RCPCH members articulated that NI needs more staff so that paediatricians can have the requisite time to look after patients the way they want to and to record what they do properly. Further legal sanction will worsen this situation.

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[57] Ibid

[58] Ibid

[59] RCPCH (updated February 2021) 'Perplexing Presentations (PP) / Fabricated or Induced Illness (FII) in Children RCPCH guidance', available at: https://childprotection.rcpch.ac.uk/resources/perplexing-presentations-and-fii/

[60] RCPCH (July 2021) NI Member's Survey on Statutory Duty of Candour

5.3 Other measures which could foster open and learning culture

RCPCH members have advised that they support a Duty of Candour wholeheartedly but have reported that they do not think NI has exhausted the non-legal framework to support candour as yet. Suggestions around the need to implement mitigating mechanisms as seen in England and proposed in Scotland such as Freedom to Speak Up Guardians, an independent investigative statutory body and the forthcoming Patient Safety Commissioner[61] were made. RCPCH members also noted that NI requires a Knowledge Matrix Strategy and robust collecting and collating of data across operational delivery, all clinical audits, Quality Improvement, learning from Serious Adverse Incidents (SAIs), and proper implementation of a Child Death Review Panel which can be benchmarked with the rest of the UK.[62] Indeed, in the *Right Time, Right Place* report, Donaldson noted that whilst data are available on SAI types, the categories and classifications used do not make it easy to aggregate data in a way that enables systemic weaknesses to be identified. Opportunities are therefore being lost for surveillance of patient safety across NI.[63] The RCPCH have consistently called for the implementation of meaningful child death review processes in NI,[64] a call echoed by O'Hara at Recommendation 88 of the Inquiry into Hyponatremia Related Deaths[65] and the Jay Review of the Safeguarding Board NI[66] and despite this, remains unimplemented.

6. What Children and Young People told us they want from paediatricians in terms of communication and openness

In addition to Article 12 (voice in decisions) and Article 24 (best health/healthcare) in the UNCRC, children and young people also have a right to freedom of expression including seeking information (Article 13) and access to appropriate information including working with the media and creating wider guidelines to prevent harm from information shared (Article 17).

This needs to be reviewed and considered into relation to the Duty of Candour legislative framework, to ensure that all stakeholders have fully explored the legislation and implementation in relation to these rights, with an appropriately resourced plan as to how to meet these rights for all children and young people in NI. Of particular concern is the need to maintain confidence in the profession as explored in section 5.1 and 5.2.3, where in paediatrics there is a dual role to ensure that both patient and parent have their communication and information needs met, particularly at pivotal time in a child's development where intervention, support and monitoring by medical professionals ensure children are able to grow into being healthy adolescents and adults. Furthermore, should there ever be criminal prosecutions under the Duty of Candour, care must be taken so that any media reporting does not undermine the trust that children and young people have in their clinicians (as per Article 17). Children and young people will be exposed to media reporting, but in some cases may not be able to critically analyse this.

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[61] Medicine and Medical Devices Act (2021) Part 1 available at: https://www.legislation.gov.uk/ukpga/2021/3/part/1 and Scottish Government (2021) Patient Safety Commissioner role for Scotland: consultation, available at: https://www.gov.scot/publications/consultation-patient-safety-commissioner-role-scotland/

[62] RCPCH (July 2021) NI Member's Survey on Statutory Duty of Candour

[63] Donaldson (2014) *The Right Time, the Right Place*, available at: https://www.health-ni.gov.uk/topics/health-policy/donaldsonreport#:~:text=The%20Right%20Time%2C%20The%20Right%20Place&text=Sir%20Liam's%20report%20was%20published,areas%20across%20the%20health%20service

[64] RCPCH (2020) State of Child Health, available at: https://stateofchildhealth.rcpch.ac.uk/evidence/nations/northern-ireland/

[65] O Hara, J (2018) *The Inquiry into Hyponatremia Related Deaths*, available at: http://www.ihrdni.org/

[66] Jay, A (2016) *Independent Review of the Safeguarding Board for Northern Ireland*, available at: https://www.health-ni.gov.uk/publications/independent-review-safeguarding-board-northern-ireland-sbni

The RCPCH children, young people and family network, RCPCH &Us, has explored the key attributes that need to be developed, practiced, reviewed and continuously improved through training, CPD, mentoring and coaching, in order for their communication and information needs as patients and parent/carers to be met. In 2019[67], a guidance document was provided to paediatric trainees by children and young people outlining their views, wishes and needs on professional values and behaviours, patient safety, communication and meeting their needs within procedures, all of which is transferable to further Duty of Candour legislation. Themes include:

- **Professional values and behaviour:** *be age appropriate, talk to you not at you, be aware of their own actions*
- **Patient safety:** *communicate with other carers and healthcare professionals about the child, remembering which medication to give and when*
- **Education and training:** *children and young people have to be involved, the most important thing for us is that doctors are taught how to understand what I am **not** saying, especially as a teenager!*
- **Communication:** *Services need us to be part of them to help them be what we need and this means you need to ask us and then do something with what we say, communication is about building up trust, I want to feel that I understand my doctor and what he is saying, so that I don't have to ask mum afterwards*
- **Procedures:** *changes are needed so we can understand what you are saying like: using easier words and did a drawing to explain what was going to happen, work with play specialists to use play, activities and role play to explain, a young person with cerebral palsy and limited speech likes it when they are talked to directly and when the consultant emails before with questions and information*

It is important to think about how the needs of children, young people and families highlighted in this resource is transferred into thinking about the Duty of Candour. There needs to be adequate time within training to explore how to share information with paediatric patients and parents/carers, who will have different levels of understanding, different communication and information preferences, what has happened and what the next steps are, so that the Duty of Candour can be fully discharged. It is not appropriate and is in contravention to the UNCRC to expect this to be successfully discharged without further training, support, advice and resources being made available for medical professionals to be able to meet the needs of patients and families. As clearly expressed above, children, young people and families need to also be part of the development of training and resources, supporting Articles 12, 13, 17 and 24 as well as being able to support patients and families of the future in times where there are concerns about medical practice.

Further work on the knowledge, skills and attitudes needed when health professionals are working with children and young people was carried out from 2019-2021 as part of the RCPCH Paediatrics 2040[68] work programme, with children and young people in NI identifying the following core elements:

- 34.8% of NI responses related to doctors being respectful, kind, supportive and friendly: *understanding, good attitude and manners, helpful, caring about all of us, truthful, trustworthy, patient, have empathy and awareness, be compassionate in their approach, calm and confident, not dismissive of our questions or concerns, not patronising, listens well and acts, adapts to our ages and needs*

[67] RCPCH (2019) 'What do the RCPCH Progress domains mean to children, young people and families?', available at: https://www.rcpch.ac.uk/sites/default/files/2019-05/progress_domains_-_what_do_cyp_think.pdf 2019

[68] RCPCH (2021) 'Paediatrics 2040 Voice Matters', available at: https://paediatrics2040.rcpch.ac.uk/voice-matters/

- 23.4% of NI responses related to communication: *listens, talks things over, speaks to me and my parents/carers, good eye contact, uses different ways to explain things, talk to me like my age, doesn't use big words or language you can't understand, makes us feel comfortable, summarises and simplifies so we can understand, makes it easy to talk to them and easy to understand, explains what has happened and what will be happening, takes time to talk it through*
- 14.7% of NI responses related to good medical conduct: *gives the right medication, has good medical skills, keeps practicing, has experience with children and young people, is knowledgeable on different child and youth needs or experiences, doesn't make mistakes, is clever and smart, gives advice, tells you the truth, willing and determined to help, explain what is wrong, focused on the whole person, positive and careful, good people skills, confident, makes good medical decisions*

In addition to the NI voice, RCPCH &Us young people analysed the voices of children and young people across the UK in relation to knowledge, skills and attitudes which highlighted the need for paediatricians to be supported to '*continue to love their job and to do the best for children and young people*'.[69] Wider analysis highlighted the need to provide more support to health professionals on how they work with children and young people[70] including the need to find new ways to show they are listening and explaining things, which in this context will need to be refined for discussions around concerns and issues related to medical practice in how this is explored and explained to all ages of patients.

There is also a specific request from children and young people about having a 'youth doctor' to deal with complaints, highlighting the need from children and young people to have a different person involved in supporting their understanding when things go wrong, similar to the Scotland Duty of Candour approach outlined in section 4.4 of this response. A 'youth doctor' in this context is a doctor who has the appropriate training and skills to communicate effectively and appropriately with children and young people about the medical issue that has occurred but is not the doctor directly involved.

There is a clear mandate from children, young people and families for medical professionals to be well supported and trained in how they communicate with, involve and support children and young people within their medical practice. This needs to be resourced and factored into any discussions, decisions and planning in relation to legislative frameworks around Duty of Candour in order for the needs of paediatric patients to be met in all health settings.

7. Conclusion

The RCPCH assert that it is essential that paediatricians are able to practice within organisations where openness and transparency are the norm. Our members therefore welcome the introduction of a statutory organisational Duty of Candour in principle. Not only will this bring NI into line with the rest of the UK, it will emphasise the polycentricity of candour, learning and patient safety. The RCPCH note that ensuring that the focus of the Duty must be placed on promoting patient safety is paramount and any subsequent legislation and guidance must have this at its core. Indeed, candour is integral to a 'just culture' and it is vital that providers get this right. Candour cannot be an 'add on' or a simple matter of compliance - it will only be effective as part of a wider commitment to safety, learning and improvement.[71]

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[69] RCPCH (2021) 'Paediatrics 2040 youth presentation' available at: https://youtu.be/7BklOoUfDUo

[70] RCPCH (2021) 'Paediatrics 2040 working with us' available at: https://paediatrics2040.rcpch.ac.uk/voice-matters/#page-section-18

[71] Care Quality Commission (March 2021) 'Updated guidance on meeting the duty of candour', available at: https://www.cqc.org.uk/news/stories/updated-guidance-meeting-duty-candour

The RCPCH welcome, in the most part, the limited detail contained in the proposed Being Open Framework which will provide the context for, and give way to, the organisational candour procedure. The three Levels of openness ('routine', 'to learn' and 'when things go wrong') as described in the consultation document presents the opportunity to ensure that a culture of openness and learning is embedded in NI. This must be meaningfully co-produced with service users (including children, young people, parents and carers) paediatricians and other Health and Social Care NI staff.

The RCPCH believes that a statutory individual Duty of Candour is unnecessary and duplicative given the sanctions associated with candour failures and dishonesty available to the GMC as the professional regulator to all doctors including paediatricians, which was strengthened in 2019, post-O'Hara's IHRD Report. A fit for purpose Being Open Framework, coupled with an organisational Duty of Candour enacted in a way which promotes learning and patient safety and bolstered by professional regulators may be considered sufficient.

The RCPCH believes there are a raft of potential unintended consequences if a statutory individual Duty of Candour with criminal sanctions attached were to be enacted in NI. These include; negative impacts on recruitment and retention in paediatrics, decreased openness around patient safety incidents and defensive practice resulting in less disclosure and thusly less opportunity to learn from error, detrimental impact on the doctor / service user relationship, and a need for increased resource to (a) support implementation both in terms of support to staff and management structures and (b) to support the possibility of heightened fear of legal sanction which results in unnecessary investigations such as diagnostics and the centralisation of paediatric care toward the Royal Belfast Hospital for Sick Children because local teams in DGHs fear such sanctions.

The RCPCH iterate that children and young people's rights must be considered with a view to upholding these in the context of a Duty of Candour. In particular these relate to the UNCRC Articles, 12, 24, 13 and 17. Children and young people have informed the RCPCH how their communication and information needs can be met and a specific focus, along with resources, will be important in further unpacking the range of approaches and skills, across all health care settings, that will be necessary to ensure staff can uphold their duty when working with children, young people and parents.

For further information on this response, please contact RCPCH Policy and Public Affairs staff anna.mcdaid@rcpch.ac.uk or john.mcbride@rcpch.ac.uk