

16 Cromac Place
Cromac Wood
Ormeau Road
Belfast BT7 2JB

T 02890269687

E jcross@bma.org.uk

BMA

Northern Ireland

IHRD Implementation

Department of Health
Room D1
Castle Buildings
Belfast BT4 3SQ

lhrd.implementation@health-ni.gov.uk

5 August 2021

Duty of Candour and Being Open: BMA NI Response

Dear Sir/Madam

The British Medical Association (BMA) is a professional association and trade union representing and negotiating on behalf of all doctors and medical students in the UK. It is a leading voice advocating for outstanding health care and a healthy population. It is an association providing members with excellent individual services and support throughout their lives.

BMA NI welcomes the opportunity to respond to this important consultation on the implementation of the first recommendation of the O'Hara Report. We submitted evidence to the workstream in March 2019 and ask that this is also included for analysis alongside this response. BMA NI has, like others, deep concerns about the recommendation to embed additional criminal elements into the provision and the delivery of health and social care in Northern Ireland, at both organisational and individual levels. We are fully supportive of the organisational duty of candour but do not believe the addition of the criminal element will enable the creation of the cultural change that is needed for openness and honesty to flourish; indeed, evidence would suggest that the opposite will happen.

National director (Northern Ireland): Claire Armstrong

Chief executive officer: Tom Grinyer

Registered as a Company limited by Guarantee. Registered No. 8848 England.
Registered office: BMA House, Tavistock Square, London, WC1H 9JP.
Listed as a Trade Union under the Trade Union and Labour Relations Act 1974



British Medical Association
bma.org.uk/northernireland

The three options as outlined in relation to the individual statutory duty of candour, with or without criminal sanctions or the creation of a separate criminal offence, adds an additional layer of statutory regulation, and is also unlikely to create the conditions which would promote openness and honesty. We believe that this would only add to confusion for patients and staff in an already complex system. And as noted above the evidence suggests that this will not result in a supportive and open environment.

An observation by Baroness Julia Cumberlege in her report *First Do No Harm*, was that the healthcare system was “*siloed, disjointed, unresponsive and defensive*”. Sir Liam Donaldson found a similar pattern in Northern Ireland in his report, *The Right Time, The Right Place*, where he stated that, “*Openness and transparency, blame and fear: these are multi-dimensional, issues that cannot be improved directly by legislation, rules or procedures alone.*”

Donaldson similar to Baroness Cumberlege, recommended the establishment of an independent body to hold the system to account. This will enable the full realisation of candour in the system. BMA NI’s preferred approach would be for this issue to be located in an overarching patient safety framework which would challenge the current culture of blame and sanction, working towards a culture of learning and openness. This must be led by patient safety and clinical experts who understand how the system works and how to identify the most appropriate interventions to achieve these goals. This would provide patients, services users and staff with a much safer and positive experience, rather than implementing punitive legislation that has no basis in evidence and could do more harm than good.

“It is well explained in safety literature that fear is a barrier to learning and hence patient safety. If a legislation like this is passed it will only increase fear. If the bottom line is to make patient safety better, then the introduction of this would be completely counterproductive. Personally, I am working hard to implement a Just and Restorative culture in our organisation and this would be an immense blow to the work we are trying to achieve.”

Consultant, obstetrics and gynaecology. Aged 35-44

Once again, we would like to thank the department/workstream for the opportunity to respond to this important consultation. Should you have any questions in relation to it, please contact Judith Cross, head of policy and committee services, in the first instance via jcross@bma.org.uk

Yours sincerely

A handwritten signature in black ink, appearing to read 'Dr Tom Black', written in a cursive style.

Dr Tom Black
Chair
BMA NI Council

Duty of Candour and Being Open: BMA NI Response

August 2021

Executive Summary

BMA Northern Ireland's mission is that '*we look after doctors, so they can look after you,*' and patient safety defines the work of doctors as they strive to do no harm when treating patients. Modern medicine is complex and can transform the lives of patients, but this is not without risk. We do all we can to minimise these risks, but it is not possible to eliminate them fully.

We do know that most harm in healthcare results from problems within the systems and processes that determine how care is delivered, and there is a need to identify the contributory factors that have led to harm or the potential for harm to patients.

We also know that culture and the environment that we all work in has an impact that affects patient safety and the quality of care. A duty of candour with a meaningful apology when things go wrong is vital for everyone involved in an incident, including the patient, their family, carers, and the staff that care for them. To have sensitive, clear and candid conversations with patients, these need to be carried out in an environment where doctors and healthcare professionals are not fearful of being penalised or punished and lessons are learnt to continuously improve care.

Our response is based on evidence from key patient safety experts, the themes from our *Better Culture Better Care* conference and importantly through directly engaging with our membership. BMA Northern Ireland believes that:

- the statutory organisational duty of candour to embed a culture of openness and honesty will be a welcome addition to the long-established existing professional duties. But we do not agree with the addition of criminal sanctions to this duty
- we do not support the additional individual statutory duty of candour as doctors are already subject to a duty of candour, criminal and civil sanctions and other regulatory and employment sanctions
- the evidence suggests that criminalising healthcare and staff will not enable the creation of the culture needed for openness and honesty
- implementing this in isolation of the current processes, procedures and the lack of understanding of clinical practice will cause irreparable damage
- there is now need in Northern Ireland to position this within a wider patient safety framework that reflects BMA NI's model of cultural change to include:
 - freedom to speak up guardians
 - extending the work of the HSSIB to Northern Ireland
 - fit and proper person's test
 - regulation of medical managers.

Duty of Candour and Being Open: BMA NI Response**August 2021**

Contents	Page
Introduction	6
Overarching patient safety framework	7
Organisational duty of candour	9
The case of Dr Hadiza Bawa-Garba	18
Individual duty of candour	20
Professional duties and criminal and civil sanctions	23
Being open framework	33
Additional issues	40
<ul style="list-style-type: none">• Process: co-production• Northern Ireland polling survey	

Section 1 Introduction

- 1.1 As a profession, we were greatly saddened by findings of the Inquiry and our heartfelt sympathies go out to the families of the children who died. These families have shown great dignity and bravery throughout what has been a very difficult and traumatic time for them.
- 1.2 It is important to acknowledge that an overwhelming majority of health professionals aim to provide the best care for our patients. We completely understand that the patient or their loved ones who have experienced trauma or injury as a result of a mistake, simply want answers. They want someone to take responsibility for what has happened to them or to their loved one and to ensure that where possible, no other family has to experience what they are going through. A critical test then for the trust that exists between doctors and patients (or their families) is how we deal with mistakes when they happen.
- 1.3 However, BMA NI has, like others, deep concerns about the recommendations embedding additional criminal elements into the provision and the delivery of health and social care in Northern Ireland, both at organisational and individual levels. We are fully supportive of the organisational duty but do not believe the addition of the criminal element will enable the creation of the cultural change that is needed for openness and honesty to flourish; indeed evidence would suggest that the opposite will happen.

Section 2 Overarching patient safety framework

- 2.1 In order to influence the debate on patient safety in Northern Ireland, BMA NI held a major UK wide conference in Belfast in December 2019, '*Better Culture, Better Care: Creating Trust, Learning and Accountability within Health and Social Care*¹'. The aim of the conference was to position key patient safety debates within the themes of creating a better culture, to hear from experts on what a caring and trusting environment would look like for patients and doctors, and what needs to happen for this to become the norm. We are concerned that this has largely been ignored by the department and the workstream as there is no indication that the development of a just and fair culture has influenced the consultation document. Indeed, the initiatives that we highlighted in our evidence paper to the workstream in March 2019 have also not been included, such as the Fit and Proper Persons Test or Freedom to Speak Up Guardians². This leaves us with the view, which was also expressed at the primary care event held on 29 September 2020, '*that this is a done deal.*'

Learning from errors

- 2.2 BMA NI is concerned that the proposed introduction of this statutory duty is limited and the focus is to be punitive Throughout the sections relating to the organisational duty of candour, nowhere does it suggest that the overarching purpose of this is to promote learning and subsequently, improve patient safety. Paragraph 3.8 simply refers to, '*public accountability for the delivery of open and honest health and social care.*' Paragraph 3.34 refers to the role of the RQIA in terms of compliance, but again we see the absence of organisations learning from mistakes or suggesting mechanisms where learning can be captured across the system.
- 2.3 In looking to the current process of reporting concerns, in particular the Serious Adverse Incident (SAI) reporting mechanisms, we asked members to outline their experiences of using this process. They reported that:
- The lack of involvement of staff is detrimental not only to them but their patients.
 - The lack of expertise of the investigators is also a cause for concern and the failure to follow through with learning.
 - The length of time to conduct an SAI exacerbates the distress for the patient, the family and the doctor.
 - The number of SAIs due to system pressures such as poor estates, red flag referrals or unsafe discharges, leaves doctors with a loss of faith in the process.

¹ <https://www.bma.org.uk/media/2560/bma-better-culture-better-care-conference-report-june-2020.pdf>

² <https://www.bma.org.uk/media/1698/bma-ni-briefing-duty-of-candour-aug-2019.pdf>

- 2.4 In addition,
- The questions on effectiveness, measurability and sustainability become largely irrelevant in a service with waiting lists of up to and sometimes beyond 5 years
 - The system is in chaos, it communicates poorly and does not learn or change easily.
 - Simply sending out volumes of emails and alerts does not change practice and therefore the learning opportunity is lost.
- 2.5 Fundamental to a duty of candour is the ability to learn from errors and improve patient safety but this cannot happen unless staff feel safe to report errors and raise concerns. We are concerned that the current process of reporting errors, capturing learning etc has not been explored or presented alongside this work. With so many layers of governance of quality standards across the HSC in Northern Ireland, we are concerned that this new duty may simply become another mechanism, rather than embedding the concepts of candour such reporting and raising concerns within current structures.
- 2.6 It is important that the RQIA is appropriately resourced with the necessary level of expertise to ensure that the organisational duty is effectively ingrained into the regulatory, inspection and improvement functions.
- 2.7 BMA NI's preferred approach would be for this to be located in an overarching patient safety framework, rather than implementing this in isolation of current process and procedures.

Section 3 Organisational Duty of candour

- 3.1 BMA NI welcomes and believes that a statutory organisational duty of candour is necessary to ensure that registered providers of health and social care are open and transparent when things go wrong. Doctors are already accountable, as per the principles of the GMC's *Good medical Practice*, to be open and honest, but many HSC bodies operate a defensive culture, with little means for them to be held to account. Therefore, this organisational duty will complement the professional duty of candour that individual doctors are subject to that they too must be open and honest with patients when something goes wrong³. Again, this should be introduced and viewed in the context of not apportioning blame but to contribute to a culture of learning and enhancing patient safety.
- 3.2 We welcome the adoption of the definition of candour that was used by Sir Robert Francis in 2013. The main elements of this organisational duty should ensure that risk is acknowledged up front and that honesty and transparency are core with a focus on the development of a learning culture to improve the quality of services. **We do not agree that criminal sanctions should attach to this duty as we are of the view that this is counterproductive to creating these conditions.** In addition, we would be concerned that a culture of perverse incentives would be created by shifting the blame to individuals to avoid criminal sanctions for the organisation.
- 3.3 Despite these concerns, we would reiterate our support for the general approach of introducing an organisational duty of candour (without criminal sanctions) which we feel could support the need to engender a culture in which reporting and raising of concerns is encouraged and learning captured.
- 3.4 However, we do have concerns with the potentially burdensome impact of the duty as presented on primary care providers. General practice is experiencing long-term challenges in the form of excessive workload, depleting workforce and inadequate funding and therefore we should be wary of introducing policies, procedures and regulations that would increase the pressure on already pressurised and fragile service. Notwithstanding such concerns, we do support the principle that the duty of candour should apply within primary care.
- 3.5 Implemented appropriately, we feel the organisational duty could play an important role in helping to create an HSC with an operational culture that is not rooted in blame but supports and encourages learning and improvement. The House of Commons Health Committee Inquiry into *Complaints and Litigation* noted that an open culture around complaints amongst staff is

³ NMC/GMC (2015) *Openness and honesty when things go wrong: the professional duty of candour*. GMC, NMC. London

essential and notes a previous report that recommended that attempts to improve patient safety should not focus on punishing individuals for errors. They noted that the ‘blame culture’ encourages covering up incidents and fails to identify underlying causes and lessons to prevent repetition⁴.

- 3.6 The report published by the National Advisory Group on the Safety of Patients in England, *A Promise to Learn – a commitment to act*, also recognised that even apparently simple human errors almost always have multiple causes, many beyond the control of the individual who makes the mistake and *‘therefore it makes no sense at all to punish a person who makes an error, still less to criminalise it.’*⁵
- 3.7 BMA NI believes that adding a criminal element to the organisation duty of candour is out of step with patient safety initiatives across the world and will reinforce a culture of fear and blame, rather than one that promotes openness and learning. We believe that the department of health’s approach to patient safety has not been robust and Northern Ireland is now behind in bringing forwards initiatives and developments that have happened in the UK and Ireland that would go some way to creating the conditions for a safer health and social care system.

Developments across the UK

- 3.8 In looking to developments in England, Scotland and Wales we can see that only England has introduced the criminal sanction element into its organisational duty of candour, through Regulations 20 and 22 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The 2014 regulations impose a duty to notify a service user or their representative when a *‘notifiable safety incident has occurred’* and there is a corresponding criminal offence for failing to make such a notification, punishable by summary conviction and a fine.
- 3.9 It is important to note that Scotland and Wales have not introduced the criminal component within their organisational duty. A failure to make the necessary notification in Scotland through the Health (Tobacco, Nicotine etc and Care) (Scotland) Act 2016 requires that a responsible person must follow the duty of candour procedure. The Scottish duty does not have criminal sanctions attached. However, Health Improvement Scotland, the Scottish Ministers and Social Care and Social Work Improvement Scotland can serve a notice on an organisation requiring them to provide further information relating to the matters on which an organisation must report.
- 3.10 The Welsh organisational duty of candour due to come into force in 2023, through the Health and Social Care (Quality and Engagement) (Wales) Act 2020, does not have a criminal component within the Act.

⁴ <https://publications.parliament.uk/pa/cm201012/cmselect/cmhealth/786/78602.htm>

⁵ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf

The Cumberlege report and candour

3.11 The recent report led by Baroness Cumberlege, *'First do no harm: The Independent Medicines and Medical Devices Safety Review,'* (2020⁶) examined the response of England's healthcare system to patients' reports of harm from drugs and medical devices. Commissioned in 2018 and published in July 2020, the review was conducted through the lens of three medical treatments: hormone pregnancy tests (mainly the drug Primodos), alleged to cause serious birth defects; the anti-epileptic sodium valproate, which can cause birth defects and developmental delays; and pelvic mesh, a surgical material (technically a medical device) implanted in thousands of women to treat organ prolapse and urinary incontinence.

3.12 Theme 6 of the report focused on the *'Duty of Candour – preventing future errors,'* concluded that:

*"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.'***

*We endorse this approach. **We believe that a cultural shift away from blame is needed to create a healthcare system where people are open and honest.** We outline how we feel a no-blame, systems-based approach to delivering redress as a substitute for litigation could drive this shift in paragraphs 2.37 – 2.39 (see also Appendix 3). We believe this shift is essential to deliver a safer NHS where healthcare professionals have no reason to fear being candid and telling the truth to their patients. Whilst we support the new emphasis on supporting whistle-blowing we are not convinced that this in itself will solve this problem".⁷*

3.13 We can see from this recent report that criminalising healthcare will only reinforce the blame and sanction culture that exists and will prevent the creation of a culture of learning and transparency. This report also reinforces

⁶ <https://www.immdsreview.org.uk/Report.html>

⁷ Ibid: page 31

the findings and recommendations from other major reports^{8 9 10} into breaches of patient safety such as Mid Staffordshire, and from patient safety experts, such as Don Berwick¹¹.

3.14 In determining its response to patient safety failings, the Government in England set out a number of steps to take forwards the recommendations from the above reports. In *'Learning not Blaming'*,¹² they identified the need for the NHS to be less defensive and to embrace a culture of listening and learning. They identified the following initiatives as helping in creating this cultural change:

- Freedom to speak up guardians
- The establishment of an independent statutory body, *The Health Service Safety Investigations Body*
- A review of the Fit and Proper Persons requirement.

3.15 BMA NI is of the view that the department of health must consider these reports and their recommendations alongside the recommendations from the IHRD report. We remain concerned that the IHRD recommendations are being treated in isolation not only from the current system but also from tried and tested developments elsewhere.

Specific comments on the document – Organisational duty

3.16 **Q1: Candour:** BMA NI prefers the term candour as this links to the professional duty of candour that doctors are subject to and is now common parlance within the patient safety community.

3.17 **Q5 and 6, Routine Requirements:** At 3.10, states *'that staff will be required and supported to give full and honest answers to any question reasonably asked by a patient about their treatment.'* This is problematic as it does not detail who the staff member should be and at what level. Is this the conversation that doctors have with patients and/or carers about treatment on an ongoing basis, or is this something different? This is not clear and would need to be clarified. The organisational duty does not apply to individuals and therefore this responsibility needs to lie with the organisation. As such, this should be an appropriate and knowledgeable senior member who provides information to the patients or their representative.

⁸ Francis, R. (2015) *Freedom to Speak Up. An independent review into creating an open and honest reporting culture in the NHS.*

⁹ <https://publications.parliament.uk/pa/cm201415/cmselect/cmpubadm/886/88602.htm>

¹⁰ <https://www.gov.uk/government/organisations/morecambe-bay-investigation>

¹¹ National Advisory Group on the Safety of Patients in England (2013) *Improving the safety of patients in England.* NAGSP London

¹² <https://www.gov.uk/government/publications/learning-not-blaming-response-to-3-reports-on-patient-safety>

3.18 In addition, it would be inappropriate to require a person to disclose any information which could prejudice any criminal investigation or prosecution or contravene any restriction on disclosure that would be prohibited.

3.19 BMA NI carried out a survey of doctors across Northern Ireland in June 2021 seeking their views on candour and the impact this will have on them. Although the following question is related to the individual duty of candour with criminal sanctions, this is relevant for the organisational duty with criminal sanctions. *“How would the introduction of an individual duty of candour with criminal sanctions impact on your relationship with your patients?”*

- Most responses note fear, additional time for discussions, additional and confusing information being given to patients, the impact of defensive medicine on the patient and the HSC system.
- In answering this question, a number of respondents have stated that they are unsure or need more time/information in order to form an opinion on the impact on patient relationships.
- More stated that they already feel that they are open/honest with patients and therefore feel there will be no impact on their patient relationships.

“Making already difficult conversations seem fraught with more danger for fear of missing some point which could later be used in criminal proceedings”

Junior Doctor, paediatrics, aged 35-44

“In General practice, medical uncertainty, safety netting and good communication are core to our everyday practice. When the fear of criminal prosecution is hanging over every decision made, it can only erode this relationship.”

GP, aged 45-54

“Consent forms will be huge to cover anything that I can think of that may go wrong and more! I’m sure certain procedures may not even be considered as too risky re adverse outcome. I will never consider saying how sorry I feel if someone has a bad time as I cannot risk it being perceived as apology for wrongdoing, and this would take the heart out of my job and I would leave.”

Consultant, paediatrics, aged 55-64

3.20 **Q7 and 8, Requirements when care goes wrong:** The definition of a ‘notifiable incident’ is *“any 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.”* (para 3.13)

- 3.21 The phrase ‘may have resulted in’ is said to include incidents which have the potential to cause significant harm in the future, but to exclude near misses, where a patient could have been harmed but in fact was not (para 3.14).
- 3.22 We would suggest more precise wording such as ‘may result in’ or ‘could result in.’ This could apply to something that has yet to become apparent.
- 3.23 Some further consideration is needed on the term ‘severe’ as other jurisdictions in the UK use the term ‘serious’ and this would give clarity for those who move and work across the UK.
- 3.24 At 3.17 the document refers to looking at the potential impact on existing patient safety review mechanisms. We assume this is referring to the current SAI process. BMA NI and others have outlined their concerns about the SAI processes and how ineffective we believe it is in promoting patient safety and capturing learning. We would have expected this document to detail how this duty will impact on the existing frameworks and find this statement unhelpful and believe it points to the lack of linkages or understanding of the current system.
- 3.25 **Q9 and 10, Procedure:** There may be issues that will need to be clarified in relation to involving the family of the patient in respect of confidentiality.
- 3.26 **Q11 to 14, Apologies:** Providing an apology when something goes wrong is the right thing to do and research from the NHS Resolution’s publication, ‘*Saying Sorry*¹³, outlined how a meaningful apology when things go wrong is vital for everyone involved in an incident, including the patient, their family, carers, and the staff that care for them. At our conference, Better Culture, Better Care,¹⁴ we outlined that a duty of candour with a meaningful apology when things go wrong is vital for everyone involved in an incident, including the patient, their family, carers, and the staff that care for them. To have sensitive, clear and candid conversations with patients, these need to be carried out in an environment where doctors and healthcare professionals are not fearful of being penalised or punished and lessons are learnt to continuously improve care.
- 3.27 Paragraph 3.26 refers to an apology not being seen as an admission of negligence or a breach of the statutory duty of candour. **Members have told us that they have been forbidden by Trust solicitors and senior managers, not to discuss or engage in conversations about cases that they have been involved in where harm had happened.** BMA NI welcomes this inclusion, but we would need further clarification at the drafting stage that this provided the protection

¹³ <https://resolution.nhs.uk/wp-content/uploads/2018/09/NHS-Resolution-Saying-Sorry.pdf>

¹⁴ <https://www.bma.org.uk/media/2560/bma-better-culture-better-care-conference-report-june-2020.pdf>

for staff to disclose when something has gone wrong, including the provision of ‘safe spaces.’

- 3.28 **Q15 and 16, Support for staff:** We welcome this proposal to provide adequate support and protection for staff as this is an essential component in this regard. We have detailed in this paper, and in previous papers, a number of initiatives that need to be put in place to ensure that staff feel confident and safe when reporting errors or mistakes.
- 3.29 Again, the language in this section suggests a lack of linkages to the current systems and process in place. Paragraph 3.28 gives a list of examples of how staff will be supported and what is missing from this list is ‘time.’ If healthcare professionals are open and report errors, this should lead to an increase in investigations and a greater understanding of where errors are made and ultimately lead to changes in practice.
- 3.30 This is in addition to the current pressures that doctors and others face in terms of trying to provide high quality and safe care in this environment. For example, figures for June 2021 revealed that the waiting list for planned admission to hospital or a first outpatient appointment had reached almost 450,000, equivalent to almost a quarter of the population. In England, where services have also been hit hard by the pandemic, the waiting list was equivalent to just 9% of the population.¹⁵ The reality for doctors in secondary care is that they are now being asked to undertake additional work to reduce the waiting lists, in addition to their current Programmed Activities (PA)
- 3.31 Surveys by BMA have shown that doctors are having to prioritise direct clinical care, with many saying that their workload hinders their ability to provide patient care at a level they are happy with. 59% of Consultants and SAS doctors in Northern Ireland reported that they were not confident that the health service will be able to manage patient demand when ‘normal’ service eventually resumes.¹⁶
- 3.32 BMA has developed a number of resources to assist our members to speak up and raise concerns. We believe that it is in everyone’s interests – patients, staff and managers to identify when something is not right. We offer support and can guide members through this process.¹⁷ **It is vital that doctors and all healthcare staff feel able to speak up for patient safety without risking hostility from management, departmental solicitors, colleagues or the media.**

¹⁵ <https://www.ria.ie/news/arins-analysis-and-research-ireland-north-and-south/new-research-cross-border-co-operation>

¹⁶ BMA Tracker Surveys

¹⁷ <https://www.bma.org.uk/advice-and-support/complaints-and-concerns/raising-concerns-and-whistleblowing/raising-a-concern-guide-for-doctors>

- 3.33 **Q17 and 18, Reporting and monitoring:** Annual reporting and monitoring are commonplace within the HSC NI, but consideration needs to be given to amalgamating the reporting and monitoring linked to this duty within existing reporting frameworks to ensure that this is embedded within the organisation. There is a lack of reference to capturing learning from mistakes; no sense of reporting how staff have been supported and protected – it feels like a formulaic tick-box exercise. We are not convinced that this will enable the ‘system’ to learn.
- 3.34 Reports from the Northern Ireland Audit office in 2012 and subsequently Sir Liam Donaldson in 2015, highlighted the lack of a reliable means of tracking the improvements in patient safety. We are not convinced that the organisational duty as outlined will be able to provide a means of tracking patient safety until the metrics, data and analysis are in place.
- 3.35 **Q19 to 22, Criminal sanctions:** As outlined above we do not believe that introducing criminal sanctions for breaches of the organisational duty is the right approach and will be counterproductive to creating the conditions for openness and honesty to flourish.
- 3.36 We do not understand why the department and the workstream have proposed higher level of fines in Northern Ireland? There is no rationale or evidence for this. Has consideration been given to the impact on patient care if a Trust is fined, reducing the finance available overall?
- 3.37 In addition, we have not been provided with evidence that applying criminal sanctions will work to achieve the aims of openness and transparency, nor has the department implemented initiatives that are known to work, as outlined in this response, in our initial evidence paper submitted in March 2019 and as outlined in our conference, *Better Culture, Better Care*.

Leadership within the HSC

- 3.38 During our engagement with the department and the workstream, there was reference to the importance of leadership, which has been recognised as vital in creating the conditions for openness and honesty to flourish. **The term, ‘a fish rots from the head’ was frequently used to refer to the failures of senior leadership which we believe is extremely unhelpful.** We welcome the publication of the HSC Handbook for Board Members¹⁸ as a useful resource, however, we question whether this goes far enough, given the centrality and importance of leadership. There are no mechanisms for monitoring whether board members or non-executive directors are abiding by this resource and no indication of monitoring its effectiveness. It is unclear just how far the organisational duty of candour with criminal sanction would apply to board

¹⁸ <https://www.health-ni.gov.uk/publications/hsc-board-member-handbook>

members and non-executive directors. A more appropriate mechanism would be the development of the Fit and Proper Persons Requirement.

– Board members and non-executive directors - Fit and Proper Persons Requirement (FPPR)

- 3.39 The Health and Social Care Act 2008 (regulated Activities) Regulations 2014 required NHS trusts to ensure that all executive and non-executive directors (or those in equivalent roles) are suitable and fit to undertake the responsibilities of their role. The purpose of these requirements is not only to hold board members to account in relation to their conduct and performance but also to instill public and patient confidence in those who have lead responsibility for NHS organisations and the services they provide. The CQC holds NHS trusts to account in relation to FPPR as part of their regulatory assessment framework.¹⁹
- 3.40 In his review of the FPPR in 2019, Tom Kark QC concluded that the current operation of the FPPT does not ensure that directors have the competency and skills required for this role and there are no mechanisms in place for sharing information on directors.²⁰ One of the recommendations is for the establishment of a body *“which has the power to bar directors where serious misconduct is proved to have occurred. We have suggested that this body be called the Health Directors’ Standards Council (HDSC) and that it should have the powers to investigate, require the production of information and, following a fair hearing, to bar directors from director level appointments in the health service.”* (13.2.1, pg 128)

Regulation of non-clinical health service managers

- 3.41 We would recommend that as well as the Fit and Proper Persons Requirement for board members and non-executive directors, that non-clinical managers are subject to a system of regulation in the same way that clinical staff are regulated by professional bodies. A doctor who is subject to breaches of their professional duties, runs the risk of being struck off, and thereby prevented from working again as a doctor, whilst a manager who presides over significant failure may go on to secure a new management position in a different part of the HSC.
- 3.42 Sir Robert Francis, when giving evidence to the Health and Social Care Committee, recently reinforced the need to consider the regulation of senior

¹⁹ The current Fit and Proper Persons Requirement is designed to ensure that senior staff who are responsible for quality and safety of care, are fit and proper to be in their roles.

²⁰

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/787955/kark-review-on-the-fit-and-proper-persons-test.pdf

managers and leaders in order that they are held to account in the same way as doctors and nurses.²¹

- 3.43 As such, we advocate that additional provisions are included to address the regulatory imbalance between clinical staff and non-clinical managers. Such provisions could ensure that where a manager has presided over failure of sufficient magnitude, and which can be directly attributed to their performance in their role, they could then be prevented them from taking up a new management position elsewhere within the HSC. This could be a useful safeguard that could lead to more effective management of the HSCNI. It could also create a system where non-clinical managers share in the risks that clinicians must accept, and therefore become more accountable for the role that they play in health care delivery.

²¹ <http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/health-and-social-care-committee/patient-safety-and-gross-negligence-manslaughter-in-healthcare/oral/91923.html>

Section 4 The case of Dr Hadiza Bawa-Garba

- 4.1 We highlighted the case of Dr Bawa-Garba in our evidence to the workstream in March 2019 and provided a number of links to further briefings and information on this. We were taken aback at a meeting, organised by NICON on 26th May '21, that the department and the workstream considered that this had no relevance to the criminal sanctions being proposed. This once again displays a significant lack of knowledge or an understanding of the impact that this case has had on the medical profession.
- 4.2 Trainee paediatrician Dr Hadiza Bawa-Garba was convicted of manslaughter in 2015 on the grounds of gross negligence over the death of 6-year-old Jack Adcock in 2011. This court ruling resulted in her suspension from the medical register for 12 months. The GMC appealed this and applied to have her permanently struck off the medical register. However, the Medical Practitioners Tribunal Services (MPTS) refused this application, stating “erasure would be disproportionate” in January 2018. The GMC controversially appealed against the MPTS decision in the High Court. The appeal was successful and resulted in Dr Bawa-Garba being struck off the GMC medical register, preventing her from working as a doctor. In March 2018, Dr Bawa-Garba was granted leave to challenge the erasure from the medical register in the Court of Appeal of which she won, and the original 12-month suspension was reinstated. **The MPTS determined Dr Bawa-Garba to be a low risk to patients, and she was cleared to begin practising again.**
- 4.3 **The hospital carried out an internal review, which identified multiple systematic failures rather than a single root cause. No charges were brought against the hospital.** It should be noted that prior to this, Dr Bawa-Garba had an exemplary record. She had just come back from maternity leave and was not given a return-to-work induction. Whilst mistakes were made by Dr Bawa-Garba and she was open and candid about these, there were also issues within the hospital’s system which contributed to the negligence in care provided. Notably, these are:
- Dr Bawa-Garba was carrying out the work of two Doctors and the hospital was extremely understaffed.
 - Senior consultants were not on-site and therefore Dr Bawa-Garba had no one to report to.
 - There were not enough senior nurses on the ward.
 - The failings of the hospital computer system prolonged blood testing results.
 - There was no system in place to notify Dr Bawa-Garba that the x-ray was ready for analysis.
 - Nurses did not notify Dr Bawa-Garba that Jack was deteriorating.
 - The administration of medication for Jack’s heart condition was not carried out by Dr Bawa-Garba.

- 4.4 **Dr Bawa-Garba bore the brunt of system failures and the GMC.** The GMC have subsequently reflected on their role and commissioned an independent review of their role and are looking at this within the context of systematic pressures.²²

²² <https://www.gmc-uk.org/about/how-we-work/corporate-strategy-plans-and-impact/supporting-a-profession-under-pressure/responding-to-the-case-of-dr-bawa-garba/dr-bawa-garbas-appeal>

Section 5 Individual duty of candour

- 5.1 In our initial submission to the workstream in March 2019 we clearly stated that we do not agree that an additional individual statutory duty of candour with criminal sanctions is necessary. The additional proposals as outlined in the document do not change this view. There are already a number of robust sanctions that patients, employers, regulators and others can draw on to hold staff to account and these are outlined below. Adding an individual statutory duty of candour would not add anything substantive to the existing routes and we believe would only 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. If the criminal sanctions are to be applied to the organisational statutory duty of candour (we do not agree that they should be attached) and if the additional individual statutory duty of candour is introduced, with or without, or separate criminal sanctions, the interplay between criminal and regulatory processes will need to be examined more closely.
- 5.2 It is not clear what the trigger for a criminal investigation would be. For example, could a service user or family member ask the police to investigate? Would the police await the outcome of the internal or regulatory processes to be completed first? Assuming the criminal investigation takes precedence, how will this interact with the internal / regulatory processes? What if the criminal investigation finds that no breach has taken place? Therefore, when the document states at paragraph 4.18 that, *“criminal prosecutions for breach are likely only when investigation has found evidence of deliberate and intension breach of the Duty,”* displays a lack of understanding of the interplay between the criminal justice system and health. We assume that engagement has taken place with the Department of Justice and that legal advice has been sought from the departmental solicitor’s office in advance of the development of these proposals?

BMA member survey

- 5.3 BMA has been engaging with our membership since the publication of the IHRD report in 2018 and carried out a survey with members in 2021. Over 95% of respondents were largely aware of the IHRD report. However, when we asked if they were aware that the department is consulting on the introduction of an individual duty of candour and to attach criminal sanctions to this duty, only 56.3% answered yes. When asked the following,

5.4 *“The introduction of an individual duty of candour with criminal sanctions would mean that as well as your current duty of candour, criminal sanctions will apply to you if you breach this duty. What are your thoughts on this?”*

5.5 The majority of responses to this question were short one word or one sentence responses stating that the respondent found the proposals scary/frightening/chilling/etc

“I appreciate Justice O’Hara met obstructions from doctors in his enquiry but rather than a more open culture being achieved, the addition of criminal sanctions will result in the closing down of an already nervous junior doctor cohort. Poor working conditions, staff shortages, increased patient pressures etc in addition to risk adverse AHP will see junior doctors have increased workload and ultimately increase the mass exodus that is ongoing. We are still working in fear following the persecution of Bawa-Gaba for doing her best in a broken system. More fear will see closed culture in an already broken system. I for one am seeking alternative career options”

Junior Doctor, surgery, aged 35-44

5.6 Additionally, we engaged with 4th and 5th year medical students, the future of our profession. 100% of respondents were unaware of this proposal. Three quarters of them were worried about the potential impact on their future medical career. Perhaps most worryingly for the future the introduction of a duty of candour with criminal sanctions would make 75% of respondents less likely to enter certain specialties.

5.7 We also asked, **“How would the introduction of an individual duty of candour with criminal sanctions impact on your medical practice?”**

5.8 Overview of responses

- The vast majority of respondents mentioned, fear, worry and defensive medicine. Examples of the comments are included below:
 - Almost 50% of responses felt that they would practice defensive practice
 - Of this 50% many noted the knock-on impact defensive practice will have referral numbers and waiting lists
 - A smaller number of respondents stated they would seek to avoid complex cases if an individual duty of candour with criminal sanctions were to be introduced
- Additionally, a number of responses note the fear and stress that would be added to daily working under the threat of criminal prosecutions and the impact that this would have on performance
- Many responses noted relief at being close to retirement age, leaving frontline medicine or moving to work elsewhere.

“As GPs we deal with uncertainty every day, we try to balance risk and benefit and explain these to patients. I think the introduction of individual duty of candour with criminal sanctions will skew our decision making and make us practice more defensive medicine. This will inevitably result in increased referrals to secondary care which will stretch an already struggling system. It is also likely to increase the number of investigations patients undergo which may do more harm than good.”

GP, Aged 35-44

“I feel like I will begin to practice “defensive medicine” whereby I am so worried about the consequences of potentially making the wrong decision that I will end up being overly cautious and over investigating or overtreating patients. I also feel that learning from serious adverse incidents will be less of a fact finding mission and feel more like a blaming exercise”

Junior Doctor, paediatrics, aged 25-34

“An individual duty of candour in a creaking, chronically underfunded health service where professionals carry most of the responsibilities but little power to change structures makes no sense. It would curtail multidisciplinary work, teaching and recruitment. It will create an atmosphere of suspicion and defensive practice and greatly increase stress levels”

Male, Consultant, aged 45-54

Section 6 Professional Duties and Criminal and Civil Sanctions

- 6.1 Throughout our engagement with the workstream we, as have others, outlined the existing professional duties and criminal and civil sanctions that doctors are subject to. The following section provides an overview and as this shows this is extensive. We were surprised that this detail was not provided within the documentation, either as part of the work of the workstream or within this consultation document. The onus is on those responsible for this consultation exercise to provide this information to enable respondents to make an informed response based on all the available evidence.

Regulating bodies

- 6.2 The GMC is the regulator of all doctors in the UK and is an independent, accountable regulator whose responsibilities are set out in the Medical Act 1983. All doctors must be registered with the GMC and hold a license to practise. To keep their license to practise, doctors must undergo revalidation once every five years and achieve a positive recommendation from their responsible officer to the GMC on their fitness to practise. Evidence from doctors' annual appraisals is used by responsible officers to make the revalidation decision. Trainee doctors must go through the Annual Review of Competence Progression (ARCP) process, rather than have annual appraisals.

Good medical practice

- 6.3 The General Medical Council's Good Medical Practice (2013), states:²³

Respond to risks to safety:

(24) You must promote and encourage a culture that allows all staff to raise concerns openly and safely.

(25) You must take prompt action if you think that patient safety, dignity or comfort is or may be seriously compromised:

- a) If a patient is not receiving basic care to meet their needs, you must immediately tell someone who is in a position to act straight away*
- b) If patients are at risk because of inadequate premises, equipment or other resources, policies or systems, you should put the matter right if that is possible. You must raise your concern in line with our guidance and your workplace policy. You should also make a record of the steps you have taken*
- c) If you have concerns that a colleague may not be fit to practise and may be putting patients at risk, you must ask for advice from a colleague,*

²³ https://www.gmc-uk.org/-/media/documents/good-medical-practice---english-1215_pdf-51527435.pdf

your defence body or us. If you are still concerned you must report this, in line with our guidance and your workplace policy, and make a record of the steps you have taken.

Maintaining trust:

(55) 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:

- a) put matters right (if that is possible)*
- b) offer an apology*
- c) explain fully and promptly what has happened and the likely short-term and long-term effects.*

- 6.4 Good Medical Practice clearly sets out the principles and values on which good practice is founded and directs the professionalism of doctors. Not only is the guidance addressed to doctors, but it is also intended to let the public know what they can expect from their doctors. Breaching this guidance can lead to a doctor's removal from the medical register and a loss of their ability to practice medicine.
- 6.5 The GMC and the Nursing and Midwifery Council (2015) published joint guidance on Openness and Honesty when things go wrong: the professional duty of candour.²⁴ This guidance complements the joint statement²⁵ from healthcare regulators and reinforces the professional duty of candour for doctors, nurses and midwives.

Regulation of the profession by others

- 6.6 Health and Social Care Board (HSCB): regulates GP practices in Northern Ireland and carries out inspections. (The 2004 Standard General Medical Services [Contract](#) refers to inspection on p161)
- 6.7 Northern Ireland Primary Medical Performers List, as per [The Health and Personal Social Services \(Primary Medical Social Services Performers Lists\) Regulations \(Northern Ireland\) 2004](#): the HSCB is required to maintain a list of medical practitioners who may perform primary medical services in Northern Ireland. To stay on the performers list, doctors must abide by rules set in legislation.
- 6.8 Northern Ireland Medical and Dental Training Agency (NIMDTA), established under the [Northern Ireland Medical and Dental Training Agency \(Establishment](#)

²⁴ GMC and NMC (2015) *Openness and Honesty when things go wrong: the professional duty of candour*. London. GMC/NMC

²⁵ General Chiropractic Council, General Dental Council, General Medical Council, General Optical Council, General Osteopathic Council, General Pharmaceutical Council, Nursing and Midwifery Council, Pharmaceutical Society of Northern Ireland (2014) *The professional duty of candour*

and Constitution) Order (Northern Ireland) 2004: from 2021, the GMC has required NIMDTA to submit a declaration which demonstrates that Deaneries and local education providers (LEPs) are meeting GMC standards. As part of its quality management work, NIMDTA conducts deanery visits to ensure that LEPs are meeting GMC standards of training provision.

Complaints process

- 6.9 The GMC only investigates complaints about registrants that meet their fitness to practise thresholds (complaints may be from patients, the public or colleagues). If complaints do reach these thresholds, then they may be referred for provisional enquiries or a full investigation. More information on how the GMC decides whether to investigate or close a case is available [here](#).
- If cases do not reach the GMC threshold then they are dealt with via local processes (see below). At the beginning of the GMC's investigation, depending on the seriousness of concerns registrants' practice may be restricted or suspended immediately. If this happens, registrants are referred to an interim orders tribunal. These are run by the Medical Practitioners Tribunal Service (MPTS).
 - After the investigation, senior GMC decision makers decide whether to conclude the case, issue a warning to the registrant, agree undertakings, or refer the case to the MPTS for a medical practitioner tribunal.
 - The medical practitioner tribunal decides if a doctor's fitness to practise is impaired and what action is needed. The GMC brings a case against the doctor and tribunal members consider the evidence and make decisions accordingly.
 - More information about the GMC investigation process is [here](#), and about the MPTS tribunals [here](#).
- 6.10 Complaints about doctors that do not reach GMC thresholds can be addressed through local disciplinary processes.
- 6.11 All health and social care services are required to have a complaints policy, and individuals are encouraged to use this in the first instance to complain about a service so that the issue can be resolved locally. If this is not satisfactory a complaint can be raised with the Trust. If a satisfactory resolution is still not reached, then the concern can be raised with the Northern Ireland Public Services Ombudsman (NIPSO). NIPSO will review the complaint and review the response from the service and trust so far. More information on raising a concern to these different organisations is [here](#).
- 6.12 Complaints about services can also be raised to the RQIA. Unlike NIPSO, the RQIA does not have legal power to investigate individual complaints about health and social care services but will use this information to inform their inspection/review work.

Other bodies involved in doctors' activities

- 6.13 Northern Ireland Health and Social Care Trusts: all Trust staff are held to their Trust's disciplinary policy. Trusts can carry out investigations onto staff behaviour and employees are expected to participate fully in the disciplinary process. A disciplinary policy template is available [here](#).
- 6.14 Trusts staff are also bound by the Maintaining High Professional Standards, a framework for the initial handling of concerns about doctors and dentists in the HSC -
https://webarchive.nationalarchives.gov.uk/20130123204228/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4103586

Criminal and civil liabilities for medical practitioners in Northern Ireland

- 6.15 Medical practitioners in Northern Ireland are subject to a number of potential criminal and civil liabilities which may arise in connection with the practice of medicine. These are obligations which arise in addition to the regulatory requirements for practising doctors, such as the requirement to comply with guidance issued by the General Medical Council. An overview of the types of potential criminal and civil liabilities arising are set out below. This section gives a broad overview of the types of liability arising, this is not intended to be an exhaustive list of all such liabilities.
- 6.16 This includes reference to numerous offences which may be committed by any member of the public but, to which medical practitioners are additionally vulnerable due to the nature of their clinical roles. There are a number of ways in which medical practitioners may be at increased risk of criminal penalty over and above the average member of the public. For example, a requirement to undertake intimate examinations of patients can lead to medical practitioners being particularly vulnerable to allegations of sexual assault. The inherent risks involved with the provision of medical care increases the possibility of a medical practitioner being subject to an allegation of gross negligence manslaughter, should a patient die. Whilst the risk of being subject to such allegations is low overall, medical practitioners are nonetheless at greater risk of exposure to such allegations than the average member of the public.
- 6.17 Medical practitioners are also more likely than the average member of the public to become subject of a civil claim for damages or to be required to give evidence to an inquest or potentially a statutory inquiry. Any medical practitioner who becomes involved in such proceedings will then be subject to various legislative requirements which may include to a requirement to give truthful evidence and/or participate in such proceedings.

Criminal Liability

Misuse of Drugs legislation

6.18 Most medical practitioners' actions will, to some extent, be subject to the provisions of the misuse of drugs legislation, which governs the safe custody and use of controlled drugs. There are a number of potential offences that can arise under this legislation which include:

- That it is an offence to fail to comply with the Department of Health's directions for the safe custody of controlled drugs (Section 11, Misuse of Drugs Act 1971); and
- Any breach of regulations made under the Act, or any deliberate or reckless provision of false information in response to a requirement to provide information under regulations made under the Act (Section 18, Misuse of Drugs Act 1971).

6.19 In addition to the above offences, there are a number of circumstances in which directions may be given to prohibit individual medical practitioners from having in their possession, prescribing, administering, manufacturing, compounding and/or supplying controlled drugs. For example, practitioners who are convicted of certain offences. It is an offence to fail to comply with any such direction (Sections 12 and 13 of the Misuse of Drugs Act 1971).

6.20 There are also a number of circumstances in which practitioners may be required to provide information in connection with the use of controlled drugs. For example, under Section 17 of the 1971 Act, the Secretary of State can require the provision of information about the prescription, administration and supply of drugs, if there appears to be extensive misuse of dangerous or otherwise harmful drugs in a specific area.

Record Keeping/Production of Information

– *Common Law*

6.21 At common law there are various offences in connection with the administration of justice that could potentially cover any failure by a medical practitioner to maintain an accurate record and/or give an accurate account of events in judicial proceedings. These include the common law offences of fabricating evidence with intent to mislead a judicial tribunal or using a false instrument to pervert the course of justice.

– *Fraud Offences*

- 6.22 Whilst not specifically directed to medical practitioners, a number of fraud offences would potentially cover any deliberate making of false records by a medical practitioner. Depending on the precise circumstances, this could include false patient records or false administrative records made, kept and/or used by a medical practitioner. Offences which could potentially be levied against practitioners include:
- 6.23 Offences under the Fraud Act 2006 including
- An offence under Section 1, which may be committed by:
 - Making a false representation with the intention of securing a gain for himself or another, or causing loss to another or exposing another to risk of loss (Section 2);
 - Failing to disclose information which a person is under a legal duty to disclose with the intent of making a gain for themselves or cause a loss to another or exposing them to a risk of loss (Section 3); or
 - By abuse of a position of trust (Section 4).

Northern Ireland Public Services Ombudsman's Investigations

- 6.24 Medical practitioners providing NHS care are subject to the remit of the Northern Ireland Public Services Ombudsman.
- 6.25 Pursuant to Section 33 of the Public Services Ombudsman Act (Northern Ireland) 2016 it is an offence to obstruct the Ombudsman, or any member of their staff, in the performance of their instructions under the Act. It is also an offence to do any act in connection with an Ombudsman's investigation that would equate to contempt of court.

Inquiries established under the Inquiries Act 2005

- 6.26 There is an obligation on medical practitioners, as with all individuals, to produce evidence for an inquiry established under the Inquiries Act 2005, failure to do so is an offence (Section 35).
- 6.27 It is also an offence under Section 35 if, during the course of an inquiry, an individual intentionally suppresses or conceals a document that he knows, or believes to be, a relevant document, or intentionally alters or destroys any such document.
- 6.28 Whilst relevant to all individuals, there have been a number of inquiries specifically related to the provision of medical care.

RQIA

- 6.29 Medical practitioners engaged in the provision of private healthcare may fall under the regulatory scope of the Regulation and Quality Improvement Authority ('the RQIA'). For those who are registered persons under RQIA legislation they are under a statutory obligation to provide notification to the RQIA of certain events. These include, but are not limited to:
- The death of a patient in a registered establishment, during treatment provided by a registered establishment or agency or within seven days of such treatment
 - Any serious injury to a patient
 - The outbreak in any registered establishment of an infectious disease, which in the opinion of a medical practitioner employed in the establishment is sufficiently serious to be so notified
 - Any event in an establishment or agency which adversely affects the well-being or safety of any patient
 - Any allegation of misconduct resulting in actual or potential harm to a patient by a registered person, any person employed in or for the purpose of an establishment or agency, or any medical practitioner with practising privilege
 - Any accident in the establishment or agency.
- 6.30 Such notice shall be given within 24 hours beginning with the event in question. It is an offence to fail to comply with the above notification requirements.
- 6.31 It is also an offence to fail to comply with various regulations which govern aspects of the running of RQIA registered establishments and agencies, this includes issues such as failure to maintain records as required.

Notification of deaths

- 6.32 There are a number of offences that can arise in the context of death notifications. These include the following offences which arise under the Coroners Act (Northern Ireland) 1959, namely:
- It is an offence for a medical practitioner who has reason to believe that a deceased person has died, either directly or indirectly, as a result of violence or misadventure or by unfair means, or a result of negligence or misconduct or malpractice on the part of others, or from any cause other than natural illness or disease for which he had been seen and treated by a registered medical practitioner within 28 days prior to his death, or in such circumstances as may require investigation (including death as the result of the administration of an anaesthetic) to fail to immediately notify the coroner within

- whose district the body of such deceased person is of the facts and circumstances relating to the death (Section 7);
- A Coroner may impose a fine on any person who, without reasonable excuse, fails to give evidence to an inquest, to produce requested documents or provide evidence to the Coroner about any specified matters (Section 17A);
 - Doing anything intended to have the effect of distorting or otherwise altering any evidence or document produced for the purposes of a Coroner's investigation or inquest, or preventing any evidence or document being given or produced (Section 17C);
 - Intentionally suppressing, concealing or destroying a document that is relevant to a Coroner's investigation or inquest (Section 17C); or
 - Contempt in face of the Coroner's court (Section 34).

Perjury

6.33 Medical practitioners are subject to the same provisions as all individuals in terms of the perjury offences. Offences in this respect include the following under the Perjury (NI) Order 1979:

- Perjury in judicial proceedings (Article 3)
- Perjury by making a false statement under oath in non-judicial proceedings (Article 7)
- Making a false statement re a birth or death registration (Article 9)
- Making a false statutory declaration (Article 10)
- Wilfully making a false declaration to procure professional registration (Article 11).

Specialised areas of practice

6.34 There are a number of specialised areas of practice, which are subject to additional legislative control and which, therefore, expose practitioners to potential criminal sanctions. For example, the Human Fertilisation and Embryology legislation makes it an offence to undertake the unlicensed creation, keeping or use of an embryo.

6.35 There is legislation which governs the use of human tissues. Pursuant to the Human Tissue Act 2004 it is an offence to undertake certain activities in relation to the use of deceased bodies or relevant human cells without consent. This includes offences at Sections 5, 8, 30, 31 and 45 of the 2004 Act.

6.36 There are a number of potential offences that may be committed under the Mental Health (Northern Ireland) Order 1986. These would include a practitioner:

- Without lawful authority or excuse having in their possession, custody or control a document which he knows to be false, relating to making certain applications or recommendations under the Order (Article 119)
- Wilfully making a false entry or statement in any application, recommendation, report or other document required or authorised to be made under the Order or, with intent to deceive, using such false entry or statement (Article 119)
- Unlawful detention of a patient (Article 120)
- Ill-treatment or wilful neglect of a patient receiving treatment for mental disorder (Article 121)
- Without reasonable cause refusing to allow an inspection of premises, visiting, interviewing or examination of any person, failing to produce any document or record as required by a person authorised under the Order or obstructing such a person in the exercise of their functions (Article 125).

6.37 A number of the above offences will in due course be substituted by equivalent offences under the Mental Capacity Act (Northern Ireland) 2016, once fully in effect.

Involuntary Manslaughter

6.38 A medical practitioner may be subject to an allegation of involuntary manslaughter, that is an allegation of unlawful killing without intent to kill, or cause grievous bodily harm, by reason of gross negligence.

Sexual Offences

6.39 As referred to above, medical practitioners may be at increased risk of facing of allegations of sexual offences. This can include an allegation of sexual touching without consent pursuant to Article 7 of the Sexual Offences (NI) Order 2008. Such offences can arise in the context of misconstrued intimate examinations.

Civil Liability

6.40 Dependent on the nature and context of the care provided, medical practitioners are potentially subject to a range of civil claims – this may include clinical negligence claims, claims for breach of contract and/or product liability claims.

6.41 In broad terms, to succeed in a clinical negligence claim, a Plaintiff will need to demonstrate that:

- They were owed a duty of care by the practitioner

- The practitioner has failed to provide a reasonable level of skill and care. (This is assessed by reference to the standard of a responsible body of medical opinion)
 - The alleged negligent act has caused the Plaintiff an injury or loss.
- 6.42 There is also an obligation on medical practitioners to ensure that a patient is aware of any material risk involved in any recommended treatment and or any reasonable alternative or variant treatments.
- 6.43 To succeed in a breach of contract claim, a Plaintiff must demonstrate that there is a valid contract in existence, that the medical practitioner has failed to fulfil their obligations under the contract and that the Plaintiff has suffered some loss as a result.
- 6.44 A product liability claim may arise if a patient has suffered an injury as a result of a defect in a medical product. Such claims can potentially be brought against the manufacturer and/or supplier of that product.
- 6.45 As mentioned earlier this is not an exhaustive list and displays the range of regulation, criminal and civil sanctions that doctors are under. We were surprised that this list did not form part of the consultation documents, as an appendix for example, to illustrate what is currently in place already for healthcare professionals. This would have given a more complete picture and enabled informed responses. We believe this again highlights the disconnect and failure to locate this information and evidence within the wider framework.

Specific comments on the document – Statutory individual duty of candour with criminal sanctions

- 6.46 **Q24 to 30, Statutory individual duty:** BMA does not believe that this the introduction of a statutory individual duty of candour is necessary. There is no evidence to support it, indeed the evidence presented in this paper and presented by others show the negative adverse impact of this approach and the many unintended consequences that could result in its introduction. During this process we have continually and consistently asked the workstream to provide evidence where this approach, of criminalising the provision and delivery of healthcare has worked and led to an end to the blame and sanction culture. To date they have not produced any evidence to support these policy proposals.
- 6.47 This is a significant divergence in policy across the UK and Ireland, indeed globally and to our knowledge this does not exist anywhere else in the world. Dr Nagpaul²⁶, in his keynote address to our conference, *Better Culture, Better Care*, highlighted that In Norway, 76% of health and education sector employees raise

²⁶ Dr Chaand Nagpaul, keynote address, *Better Culture, Better Care*, 4 December 2019. Belfast

concerns; 83% of Norwegian employees had a positive reaction to raising concerns; and 64% reported improvements in their workplace after raising a concern. Both operate a 'no fault' scheme, similar to other high-risk industries.

- 6.48 Consideration needs to be given to the movement of doctors across the UK and Ireland and the potential impact on recruitment, retention and patient care. Doctors may be deterred from working in a punitive environment in favour of moving to work elsewhere in the UK and / or the Republic of Ireland, exacerbating an already dire workforce situation.
- 6.49 **Q28 and 29, Routine requirements and requirements when care goes wrong:** It appears that the scope and extent of this duty as outlined extends to every investigation arising from the notifiable incident. It is not clear who is to be informed of notifiable incidents? The patient and/or their representative, an employer, a regulator, a Coroner? Do all employees have the same duty to notify and to the same people? Would, for example, a cleaner employed by a hospital Trust have the same duty as a doctor? Why? How would an employee with no medical expertise be expected to assess the concepts of serious harm, moderate harm or prolonged psychological harm?

Section 7 Being Open Framework

- 7.1 BMA believe that the Being Open Framework was the right approach to creating the conditions where openness and honesty flourished and an effective mechanism to end the blame and sanction culture that currently exists. Embedding the criminal components within this framework is counterproductive and we would suggest that this is reframed and located within a wider patient safety framework. As globally patient safety experts have testified, criminalising healthcare will not change the culture: Peter McBride, the previous chair of the Being Open sub-group stated at our conference, '*Better Culture ,Better Care*', "*that **people** change culture not legislation,*" and he reiterated that there is an organisational responsibility to create the environment that facilitates learning.²⁷
- 7.2 We believe that combining the Being Open framework and the proposed legislation (which we were told originally were intended to work separately with the being open work creating more immediate positive change in challenging the blame culture that exists) is a huge, missed opportunity to achieve real and immediate benefits to a system that is not conducive to learning.
- 7.3 There are a number of immediate actions that could be implemented to begin the process of embedding a just culture within the HSCNI, such as Freedom to Speak-Up Guardians. This could be achieved by extending the role of the National Guardians office to NI. We also note that the establishment of the patient safety institute as recommend by Sir Liam Donaldson has been stalled. This was also one of the recommendations from the Cumberlege Report where they recommend the appointment of a Patient Safety commissioner (recommendation 2).²⁸ Consideration could also be given to extending the operations of the HSSIB to Northern Ireland.²⁹
- 7.4 The aim of the conference ***Better Culture, Better Care*** was to position key patient safety debates within the themes of creating a better culture, to hear from experts on what a caring and trusting environment would look like for patients and doctors, and what needs to happen for this to become the norm.

Better Culture Better Care – A model of cultural change

- 7.5 The conference heard from expert speakers, all of whom have experience in leading initiatives to improve culture and patient safety in health and social care. The '*Better Culture, Better Care*' conference gave an overview of evidence based good practice from various areas where improving culture and patient safety have been viewed as priorities for change. BMA Northern Ireland has

²⁷ <https://www.bma.org.uk/media/2560/bma-better-culture-better-care-conference-report-june-2020.pdf> pg 11

²⁸ https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf pg 187

²⁹ <https://www.bma.org.uk/media/1698/bma-ni-briefing-duty-of-candour-aug-2019.pdf>, section 9

developed a model of cultural change for health and social care in Northern Ireland:

- Development of a model of cultural change for Northern Ireland based on learning from best practice elsewhere including: the development of a fair and Just Culture, creation of safe and protected spaces for disclosure; development of a Civility Saves Lives implementation programme; and Freedom to Speak Up Guardians
- Genuine development of a learning culture in which staff are fully engaged and feel able to raise concerns without fear or blame, knowing that these will be promptly acted on to improve care and safety for patients
- Safe staffing mechanisms so that no one has to work in a consistently understaffed and under-resourced health and social care environment and clinical teams are able to provide care within manageable workloads
- Effective accountability procedures and mechanisms in place to escalate concerns, with a genuine focus on improving patient care, not hitting financial or political targets
- A shift in culture to recognise that staff wellbeing is essential to good patient care and the development and implementation of a comprehensive occupational health and wellbeing service for doctors in Northern Ireland
- Creation of a compassionate working environment in which staff treat each other with civility, kindness and respect
- Development of an investigation process that is effective for patients, families and doctors with safe spaces for disclosure and implementation of improvement and learning from situations
- Having a fair and proportionate system of individual and service wide regulation that understands context and systemic pressures and is part of a culture of learning and improvement

Specific comments on the document – Being Open Framework

- 7.6 We support the general concepts and levels of openness and candour as outlined in the document. However, as pointed out earlier, the lack of linkages to existing mechanisms and processes, leaves us sceptical of how this can be achieved. It also assumes that none of this is happening currently, which is misleading.

7.7 The consultation document details how the Being Open Framework links to the organisational and individual duty over three levels. One of the criticisms from members when they have engaged with the workstream, is the lack of understanding of clinical practice and the relationships healthcare professionals have with patients and colleagues. Information was usually presented as a simple interaction with a singular issue to deal with. Medicine is rarely that simple – it is complex, difficult, risky and patients are not a simple homogenous group often presenting with many co-morbidities at any one time.

7.8 Comments such as ‘if the IT system does not work – fix it’ is a very simplistic and naive view of how the current system works and again shows the lack of understanding about how the current system operates. For example, we still have patients queuing outside their local surgeries to pick up their paper prescriptions to bring to the pharmacy to be fulfilled despite GPs calling for an automated service for many years.

“As GPs we are also continually reflecting on the best way to treat our patients and this is done in consultation and it is not a binary approach, but one of multiple discussions and interventions to get the best outcome for the patient and over time. We were slightly disappointed that this complexity was not presented at the workshop and left us feeling concerned that decisions are being made by those who have no direct, frontline experience of working in a healthcare setting – primary or secondary care. The case study is a point in question.

“It is important that the experiences of those making clinical decisions and the environment in which those decisions are made are central to this process. It is also crucial that those driving the IHRD implementation programme are also aware of the clinical decision-making process in primary care.³⁰”

7.9 When we referred to the long waiting lists, staff shortages and other patient safety risks at various engagements with the department and with the workstream leads, we were told that this was not part of their work. This silo working, isolation and disconnection from the day to day working of the health services and the complexity of medicine is a significant concern for BMA NI. The Being Open Framework is an opportunity to be a vehicle for improving patient safety and the quality of care overall.

7.10 There must be a clear link between service quality and the provision of appropriate staff levels. BMA NI is currently working with the department to ensure that the forthcoming safe staffing legislation includes medical staff. Importantly there must be implicit links with safe staffing and any organisational

³⁰ Correspondence to the IHRD programme from the LMC officers after the event for primary care, 1 October 2020

duty of candour, otherwise this will be a missed opportunity. Be in no doubt, high quality and safe care are compromised by staff shortages.

“Decisions on what a treatment plan will be will have many variables that need to be taken into account and these can change quite quickly too. These will be discussed with patients and or their family, but at times we need to react quickly and change our course of treatment. We are trained for this – this is what we do. Keeping a continuous record, especially in intensive care is simply unrealistic. I see that the proposals state that I have to report immediately – this just will not work nor possible without causing adverse impact on patient care.³¹”

- 7.11 Also, the current pressures in the system means that our members struggling to provide safe care and as such It is unclear how the detail at 5.12 can be achieved without significant restructuring of current services.
- 7.12 For example, if we look at level two, openness to promote learning for staff and the organisation, we can see that if a mistake has been made that causes no harm and this is due to a system or procedural weakness or human error, staff will report immediately and also report when others have made errors, that the organisation will remedy this and staff will be supported and training will be provided. When we presented this to members, they used the example of staff vacancies and shortages as system and procedural weakness and that these are raised on a continual basis, in both primary and secondary care through various avenues. But despite these issues being raised at various forums, nothing is remedied. Do we assume that under the organisational duty of candour that this will now be rectified? We could apply the failure to restructure the health service in Northern Ireland as a system and procedural weakness, but yet despite various reports, nothing is done.
- 7.13 In relation to requiring staff to report immediately where they believe others have made such errors (5.21), we asked doctors,

“How would the introduction of an individual duty of candour impact on your relationship with colleagues?”

- 43% of responses stated that an individual duty of candour was likely to result in less support and trust amongst colleagues and teams.
- Many responses were worried that this would result in reduced learning opportunities as people would be less open.
- There were repeated concerns about the impact on the HSC system and the ability to recruit and retain staff.
- Just 0.5% of respondents felt there would be no impact on their relationship with colleagues.

³¹ A view from a member at BMA Member engagement events

“It will hamper open discussion about cases – we all learn from each other’s reflection on difficult cases and complications, both formally at M&M, and informally during private discussions. The fear of being reported or misrepresented, will cut this line of learning off as we become wary of discussing what we might have done better”

Consultant, surgery, aged 35-44

“I see it causing fear, mistrust and suspicion amongst colleagues. 360-degree feedback will be a thing of the past. How can annual appraisal be an open, supportive discussion if an appraiser fears criminal sanctions from non-disclosure? How can the appraisee trust the appraiser knowing that this pressure is on them? It will invalidate the appraisal process and make medical practice less safe as issues of concern will not be brought to appraisal.”

Female, GP, aged 45-54

“It is possible to unintentionally breach the duty of candour as you believe that information you have shared with patients is complete and at a later date further information is available and was not known to you at the time. You may also believe that another doctor has given information to a patient and this may be true or partially true and as you hold consultant responsibility it be considered that you have breached the duty of candour.”

Consultant, paediatrics, aged 45-54

Employment contracts

- 7.14 Paragraph 5.37 states that employment contracts will be amended in line with the IHRD recommendation 5 to reflect the statutory individual duty of candour. As outlined below this is already contained in the employment contracts. In addition, doctors are heavily regulated as detailed above and we believe that this is unnecessary.
- 7.15 The following are excerpts from the various contracts that are currently in existence. As pointed out earlier in this paper, this consultation exercise would have benefited from this level of detail being made available in advance and shared with members of the workstream, as well as the public and key stakeholders.

Existing contractual requirements

General practitioners – Performers List

- 7.16 The Health and Personal Social Services (Primary Medical Services Performers Lists) Regulations (Northern Ireland) 2004³² detail how **general practitioners** are included on the performers list and the conditions attached for inclusion.

³² <https://www.legislation.gov.uk/nisr/2004/149/contents/made>

- 7.17 All GPs must be on the Performers List to practice in Northern Ireland. GP Appraisal and revalidation is managed and co-ordinated by NIMDTA in partnership with the department and the board, under the guidance of a central management board.³³
- 7.18 [Appraisal Forms \(Forms 1 to 6\)](#). These forms reflect the GMCs Good Medical Practice for appraisal and revalidation.

Terms and conditions of service for consultants in Northern Ireland 2004

Associated Duties and Responsibilities

- 7.19 A consultant has continuing clinical and professional responsibility for patients admitted under his or her care or, (for consultants in public health medicine) for a local population. It is also the duty of a consultant to:
- keep patients (and/or their carers if appropriate) informed about their condition
 - involve patients (and/or their carers if appropriate) in decision making about their treatment
 - maintain professional standards and obligations as set out from time to time by the General Medical Council (GMC) and comply in particular with the GMC's guidance on 'Good Medical Practice' as amended or substituted from time to time.

Terms and conditions for associate specialists and speciality; Terms and Conditions of Service Specialist – Northern Ireland (2021); Terms and Conditions of Service Specialty – Northern Ireland (2021)

Associated Duties and Responsibilities

- 7.20 Whilst on duty a doctor has clinical and professional responsibility for their patients or, for doctors in public health medicine, for a local population. It is also the duty of a doctor to:
- keep patients (and/or their carers if appropriate) informed about their condition
 - involve patients (and/or their carers if appropriate) in decision making about their treatment
 - maintain professional standards and obligations as set out from time to time by the General Medical Council (GMC) and comply in particular with the GMC's guidance on 'Good Medical Practice' as amended or substituted from time to time (Doctors only).

³³ <https://www.nimdtg.gov.uk/general-practice/gp-appraisal/>

Junior doctors - Hospital medical and dental staff and doctors in public health medicine and the community health service - terms and conditions

Foundation curriculum professional capabilities

7.21 The 20 'foundation professional capabilities' in the syllabus reflect key generic aspects of professional and clinical medical practice. These 'foundation professional capabilities' are the educational outcomes of foundation programme training.

- **Has demonstrated the knowledge, skills and behaviours necessary to apply the professional duties, principles and responsibilities set out in Good Medical Practice, Generic Professional Capabilities Framework, other professional guidance and statutory legal requirements.**
 - acts professionally (FPC 1)
 - delivers patient centred care and maintains trust (FPC 2)
 - behaves in accordance with ethical and legal requirements (FPC 3)
 - makes patient safety a priority in clinical practice (FPC 19)
 - contributes to quality improvement (FPC 20)

Section 8 Additional Issues

Process: Co-production

- 8.1 BMA engaged with this process on the understanding that it was an open and honest process where the views and evidence presented by us and others would be taken on board as part of the co-production process. Throughout this process, we have had, on occasion, to raise concerns in relation to the role and function of the duty of candour workstream. These have been raised with the deputy CMO, the permanent secretary and the IHRD programme director. Our members who attended early engagement meetings with the duty of candour workstream, (June 2019) raised issues with us that the introduction of a statutory individual duty of candour with criminal sanctions was being presented as a ‘fait accompli,’ rather than a genuine attempt to consult and listen to the views of those who work in health and social care. We were reassured that this was not the case from the Permanent Secretary in his letter of 11 July 2019, where he stated that, *‘no policy decisions have been taken regarding how the duty of candour recommendations will be implemented.’*
- 8.2 We raised concerns recently (21 July 2021) around the process and sought clarity on who was leading on this consultation and particularly in relation to co-production. We were reassured that co-production as outlined in this process was between the department and the workstream and not with the wider stakeholders. For the document to claim in the introduction that a comprehensive co-production process was undertaken is somewhat disingenuous.
- 8.3 Also, before the consultation was released, the Minister announced to the House that he accepted all the recommendations the O’Hara Inquiry had proposed, before taking account of the consultation responses.³⁴ It is unusual for new policy proposals to be presented in such a way in that they have been determined elsewhere and outside the normal co-production/consultation processes. Indeed, many previous reports to the Department of Health have made recommendations that have never been implemented.
- 8.4 *The Co-Production Guide*³⁵ and *The Practical Guide to Policy Making*³⁶ all point to the need to create the opportunity for people to work in genuine partnership and to take shared responsibility for improving health and social care outcomes

³⁴ “My Department accepts the recommendations of the O’Hara Report in their entirety” .

<http://www.niassembly.gov.uk/assembly-business/official-report/written-ministerial-statements/department-of-health--inquiry-into-hyponatraemia-related-deaths-ihrd-implementation-programme-update/>

³⁵ <https://www.health-ni.gov.uk/sites/default/files/publications/health/HSCB-Co-Production-Guide.pdf>

³⁶ https://www.executiveoffice-ni.gov.uk/sites/default/files/publications/ofmdfm_dev/practical-guide-policy-making-amend-nov-16.PDF

with a view to finding solutions **from those directly involved**. Evidence is also crucial in this regard.

“It is crucial that policy decisions should be based on sound evidence. Good quality policy making depends on high quality information, derived from a variety of sources - expert knowledge; existing local, national and international research; existing statistics; stakeholder consultation; evaluation of previous policies; new research, if appropriate; or secondary sources, including the internet. To be as effective as possible, evidence needs to be provided by, and/or be interpreted by, experts in the field working closely with policy-makers.”³⁷

- 8.5 In addition, *The Practical Guide to Policy Making* also refers to ‘evidence from the front line,

“Very often these groups will have a clearer idea than the policy-makers about what the problems are, why the situation is as it is and why previous initiatives did or did not work. They are also well placed to advise on how a new policy can be put into practice on the ground and what pitfalls need to be avoided.”³⁸

- 8.6 BMA NI believes that in order for this co-production approach to have been genuine, and in-line with departmental guides and best practice, healthcare professionals should have been involved in working to produce the policy proposals rather than the workstream tasked with implementing what was recommended by the report.
- 8.7 When Justice O’Hara delivered his report and the work of the workstreams concluded, we expected the department would then consider the evidence/recommendations and determine the best approach and consult on any new proposals in due course. This was not the case. The purpose of consultation events is to enable individuals and organisations to make informed decisions on the validity or not of the policy proposals presented by the department and to share their opinions on the impact of proposals based on their knowledge and experience. However, the events organised by the department were not conducted in the usual way. Usually, information will be presented in a nuanced and balanced way, with evidence to support the policy proposals, this not what we experienced throughout this process.
- 8.8 Indeed, there was a distinct lack of evidence to support the case that the proposed recommendations would make the system better and safer for patients. **In addition, the views of the workstream were presented as a fixed position meaning that there was an unwillingness to consider the opinions and experience of those working in the system that the opposite may be true.** If the workstream was only tasked with implementing the IHRD recommendations, then the views and opinions of key stakeholders were unable to be considered. This would appear to be at odds with the principles underpinning co-production and policy making.

³⁷ Ibid page 17

³⁸ Ibid page 18

8.9 We accept that changes were put forward for the individual statutory duty, but this was due to the efforts of organisations such as ourselves, co-ordinating with other similar professional bodies, royal colleges and trade unions. Many of the organisations we spoke to initially stated that they found this difficult to engage with and were not aware of the potential impact on their members. In light of this we co-ordinated a joint meeting with the workstream leads in which organisations reiterated their concerns over this approach. This was subsequently repeated and as such many of these organisations will now be making submissions to the departmental consultation. We believe that if we had not co-ordinated this, many of these organisations would have been unaware of the impact.

Northern Ireland polling survey

8.10 We welcome that the department and the workstream carried out polling to capture the views of the public. We note that the majority of respondents stated that they are currently satisfied with the care that they receive and their involvement in shared decision making.³⁹

8.11 Paragraph 4.8 of the document states that:

- Many patients and service users do not routinely experience openness and honesty when something has gone wrong with their care or treatment; and
- Respondents to the survey also strongly favoured the criminalisation of deliberate actions which prevent candour and honesty in these circumstances

8.12 BMA NI has a number of concerns with this survey. We believe it is leading as it does not set out any alternatives, does not explain what is meant by 'wrong,' and only asks about recent bad experiences. For example, does this mean that patients did not like what they have been told, even if it was correct; did the doctor not follow best practice or was the doctor clinically negligent? This also confuses clinical negligence and deliberate cover-ups which is misleading.

8.13 Overall, it is difficult to determine if the 31% who reported that '*they experienced something that has gone wrong with the health and/or social care service being provided, which impacted on the treatment or care received*' experienced a problem without some examples of what was meant by 'wrong.' The answers could be picking up a massive spectrum of possible issues, and tighter definitions /illustrations would have elicited more robust and factually correct data. The same applies to the follow-up-question to this question as we do not know if respondents were aware of the process of making a complaint

³⁹ <http://www.health-ni.gov.uk/publications/niview-openness-health-survey>

- 8.14 In addition, the tone of question 4 is leading and respondents should have been asked about a range of options, of which criminal liability was one. It is also not possible to distinguish if criminal liability points to individuals or organisations.
- 8.15 We remain seriously concerned about the use of the public confidence criterion in cases involving clinical error. We have previously suggested that this criterion could lead to 'trial by media' and called for guidance that properly relates 'public confidence.'
- 8.16 On a more subtle note, the questions imply an example of criminal negligence and then combine that with a cover-up and criminal action. Conflating these two very separate issues is not helpful and adds confusion around the understanding of the lack of candour vs malpractice. It would have been preferable to ask about the merits of disclosure and the penalties for not doing so in a broader context. Therefore, we are not convinced that the above conclusions as outlined in the consultation document can be drawn from this survey.
- 8.17 In addition, reliance on the public confidence criterion may, if it results in outcomes that are too severe, have consequences which are contrary to the public interest, such as: encouraging defensive practice; discouraging remediation, candour and openness as the best means of promoting patient safety; and deterring new entrants to the profession.

Ends

5 August 2021