

BMA Northern Ireland's briefing paper on the duty of candour: submission to workstream 1: duty of candour

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Executive summary

BMA Northern Ireland's aspiration is for doctors to provide care in a safe and well-run healthcare system. And while the focus on candour in Justice O'Hara's report is welcome and will help us achieve this aspiration, criminalising doctors and other healthcare professionals will not help us to get there. Those who are responsible for causing harm to patients due to neglect or wilful misconduct should be held to account and sanctioned.

On 18 November 2004 Mr John O'Hara QC was appointed chair and asked to conduct an Inquiry into the events surrounding and following the deaths of children due to hyponatremia. The report into hyponatremia related deaths was published on 31 January 2018¹.

This report and recent failures in patient care, such as the neurology recall in the Belfast Trust and most recently the review into the safety and treatment of vulnerable adults at Muckamore Abbey hospital, have brought the issue of patient safety to the fore. However as in the past, there is a tendency to target the blame on individual health care professionals.

Patient safety debates over the last decade have recognised that it is the way that healthcare systems are organised, alongside the financial and staffing pressures that are responsible for breaches in patient safety and rarely the responsibility of individuals. The emphasis is on creating the conditions and culture where reporting becomes the norm and, importantly lessons are learnt and disseminated across the healthcare system.

Embedding protections for healthcare professionals who disclose can act as a mechanism to develop the supportive structures and processes needed to support open disclosure and to build patient and public trust in the healthcare system.

¹ LJ O'Hara. (2018) The Inquiry into Hyponatraemia-related Deaths: Report. Belfast. DoF

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BMA Northern Ireland's briefing paper on the duty of candour**March 2019****1. Introduction**

- 1.1 The 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.
- 1.2 BMA Northern Ireland welcomes the opportunity to present for consideration a briefing paper on the duty of candour.
- 1.3 Patients and their families have the right to an apology and explanation when things go wrong. We welcome the emphasis placed on candour in the report and fully support the principle underlying a duty of candour for organisations. Doctors must be open and honest in everything that they do to provide high quality and safe care to their patients.
- 1.4 The existing professional duties on doctors is governed through their professional code, *Good Medical Practice*², which determines their fitness to practice. Breaching this code can lead to their removal from the medical register. In addition to this there are a number of avenues such as criminal and civil proceedings that can be used in connection with dishonest behaviour or neglect or wilful misconduct that endangers patients.
- 1.5 Our evidence refers to:
 - Context in which doctors are working
 - Developments elsewhere
 - Candour – organisational and individual
 - Protection for doctors

² https://www.gmc-uk.org/-/media/documents/good-medical-practice---english-1215_pdf-51527435.pdf

2. Background

2.1 There have been several high-profile inquiries into breaches of care across the UK, most notable was Mid Staffordshire in 2013. Whilst there were errors on the part of staff, the underlying cause of breaches in patient safety at Mid Staffordshire were due to the working conditions of staff, too much of a focus on targets, warning signs not heeded and no clear lines of accountability. Sir Liam Donaldson (2104) in his report acknowledged that the responsibility for patient safety in Northern Ireland is often confusing and complex,

*"There is currently a complex interweaving of responsibilities for patient safety amongst the central bodies responsible for the health and social care system in Northern Ireland."*³

2.2 Don Berwick and Professor Bruce Keogh were subsequently invited to produce reports and recommendations on patient safety and quality of treatment and care. *Improving the safety of patients in England*⁴, published in August 2013 and *Review into the quality of care and treatment provided by 14 hospital trusts in England*, July 2013.⁵ Both point to the blame culture that exists and how this prevents the creation of an environment where learning and improvement are embedded.

2.3 Don Berwick (2013) in his report on patient safety, stated that '*NHS staff are not to blame*', He also distinguished between three types of unnecessary harm:

- Risk of harm due neglect or wilful misconduct
- Risk of harm due to failures in the system
- Risk of harm from error.

2.4 Sir Robert Francis (2013) in his report on Mid Staffordshire⁶ also recognised the differences and how each of these warrant different responses. Human error is normal and by definition, is unintended and is usually the result of multiple causes, many beyond the control of individuals. Those who are responsible for causing harm by neglect or wilful misconduct do warrant sanctions.

³ Donaldson, L. et al (2014) *The Right Time, The Right Place: An expert examination of the application of health and social care governance arrangements for ensuring the quality of car provision in Northern Ireland*. Pg 46

⁴ National Advisory Group on the Safety of Patients in England (2013) *Improving the safety of patients in England*. NAGSP London

⁵ Keogh, B., (2013) *Review into the quality of care and treatment provided by 14 hospital trusts in England*. NHS London

⁶ Francis, R. (2013) Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry February 2013. London. TSO

- 2.5 Alongside the publication of the O’Hara report, the case of Dr Bawa-Garba was processing through the courts and this in many respects highlighted how the ‘system’ failed both Jack Adcock and Dr Bawa-Garba and brought into sharp relief the culture of blame that doctors are working under. Addressing errors needs to consider the system, rather than targeting individual doctors who are often doing their best in difficult circumstances in a HSC system which is under pressure, without adequate staff, beds and facilities. For more information on this please see the following link – <https://www.bma.org.uk/collective-voice/influence/key-negotiations/training-and-workforce/the-case-of-dr-bawa-garba/the-case-and-appeal>
- 2.6 As a result of this case the Secretary of State in England instigated a review into gross negligence manslaughter and appointed Sir Norman Williams to carry this out. The GMC subsequently initiated their own review into how gross negligence manslaughter and culpable homicide (in Scotland) are applied to medical practice. For more information on this please see the following link - <https://www.bma.org.uk/collective-voice/influence/key-negotiations/training-and-workforce/the-case-of-dr-bawa-garba/gross-negligence-manslaughter>
- 2.7 NHS Improvement have recently concluded a consultation on *Developing a patient safety strategy for the NHS*⁷ and this strategy connects different parts of the system such as quality, death certification, IT infrastructure and data to set clear expectations and better support for patient safety. The overarching themes echo the need to focus on structures and culture, to create the conditions for openness and transparency rather than individual blame, similar to developments elsewhere on patient safety.
- 2.8 BMA has contributed to and responded to the above and has consistently argued that there should be a process where all errors are acted upon and used to improve the system. Emphasis should be on systemwide lessons and not individuals. There should also be a recognition that the current lack of resources and staffing crisis in the HSC NI is a major patient safety risk.

3. Context for doctors

- 3.1 The provision of care and treatment of patients is rarely the sole responsibility of one doctor or another healthcare professional as multidisciplinary working is now the norm.

⁷ NHS Improvement, *Developing a patient safety strategy for the NHS*, December 2018.

- 3.2 Whilst, doctors are clinically responsible for their patients, they are working within a system that is overstretched and under resourced, with too few staff. They see first-hand the pressures to prioritise financial targets over clinical need and those who have no clinical expertise nor direct responsibility for clinical outcomes can hold the balance of power, thereby potentially compromising quality and safety.
- 3.3 BMA launched '*Caring, supportive, collaborative: Doctors views on working in the NHS*⁸', in September 2018. This landmark survey provided a clear picture of the challenges and opportunities facing doctors in the NHS today. The results, extrapolated for Northern Ireland, highlight that members are reporting an absence of a supportive culture and that this is having a detrimental effect on doctors.
- 3.4 Key findings from the survey on culture, quality and safety show that:
- 56% of doctors fear being unfairly blamed for errors due to pressures in the workplace and systems failing
 - 48% of doctors agreed with the statement, '*I believe there is insufficient protection and support for those reporting errors*'
 - *38% of doctors are cautious about recording reflective practice for fear it could be used against them, while 26% are significantly worried.*
- 3.5 Our own local surveys for GPs (2016), consultants (2017) and doctors in training (2018) painted a picture of doctors working above and beyond, which had a negative impact on their work-life balance. Morale was low, and they felt that they are working in a non-supportive environment, where patient safety can at times be jeopardised and learning and reflection discouraged. Of concern was that over 40% of doctors in training would not recommend Northern Ireland as a place to undertake medical training⁹.
- 3.6 What we are conveying is that doctors do not work in a vacuum and go to work to do their best for patients in a system that has been recognised as being in need of transformation, is underfunded and under resourced with too few staff. As a result, patient care is compromised. Within this situation, when things go wrong, and an issue of quality or safety is identified there is a tendency to point to the individuals or the service involved. The report published by the National Advisory Group on the Safety of Patients in England, *A Promise to Learn – a commitment to act*,¹⁰ also

⁸ <https://www.bma.org.uk/collective-voice/policy-and-research/nhs-structure-and-delivery/future-vision-for-the-nhs>

⁹ BMA NI Surveys

¹⁰ National Advisory Group on the Safety of Patients in England (2013) *Improving the safety of patients in England*. NAGSP London

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*'¹¹.

- 3.7 BMA produced guidance for our members on, '*Working in a System that is Under Pressure*'¹² where we highlighted that doctors are working in a system which is under immense pressure to meet rising patient demand and is unable to recruit and retain the necessary staff required to deliver services. Individual staff feel that they bear the brunt of these workforce pressures. Operating in understaffed and under resourced environments makes it more difficult for doctors to meet their professional standards and sadly, mistakes can happen. We also highlighted that the current fragmented regulatory system assesses an individual's fitness to practise without always sufficiently recognising the challenges presented by systemic failures.
- 3.8 In order to address an underlying culture that may discourage health professionals from speaking up, employers should have a duty to listen to staff when they do report concerns, and to protect them. Staff should be encouraged and recognised for following their professional guidelines. More training may be necessary to help people communicate more effectively when, for example, treatment has not gone as well as expected or an error has occurred in the process of their care.

4. Key Reports

- 4.1 A number of reports were pivotal in determining the government's response to patient safety since the publication of the Mid Staffordshire report in January 2013¹³:
- *A promise to learn- a commitment to act*, Don Berwick in 2013¹⁴
 - *Hard Truths: The Journey to Putting Patients First*, the department of health's response to the mid-Staffordshire report, in 2014¹⁵
 - *Building a culture of candour: A review of the threshold for the duty of candour and incentives for care organisations to be candid*, Dalton and Williams in 2014¹⁶

¹¹ Ibid, page 12

¹² <https://www.bma.org.uk/collective-voice/influence/key-negotiations/nhs-pressure/working-in-a-system-under-pressure>

¹³ Sir Robert Francis, 2013, Report of the Mid Staffordshire NHS Foundation Trust, Public Inquiry

¹⁴ National Advisory Group on the Safety of Patients in England (2013) *Improving the safety of patients in England*. NAGSP London

¹⁵ Department of Health (2003) *Hard Truths: the journey to putting patients first*. DoH London

¹⁶ Dalton, D., Williams, N., (2014) *Building a culture of candour: A review of the threshold for the duty of candour and incentives for care organisations to be candid*. RCS London

- *The Freedom to Speak up Review*, by Sir Robert Francis QC in 2015¹⁷
- The Public Administration Select Committee report, *Investigation clinical incidents in the NHS* in 2015¹⁸
- General Medical Council and Nursing and Midwifery Council, *Openness and honesty when things go wrong- the professional duty of candour* in 2015¹⁹
- *A review of the fit and proper person test* by Tom Kark QC and Jane Russell, Barrister in 2018²⁰
- *Telling patients, the truth when something goes wrong: Evaluating the progress of professional regulators in embedding professionals' duty for be candid to patients*, by the Professional Standards Authority in January 2019.²¹

4.2 The Government's response to patient safety, *Learning not Blaming*²², set out a number of steps to address the issues raised:

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

5. Organisational statutory Duty of candour

5.1 BMA NI 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. This will also 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 wrong²³.

5.2 In our response to the Donaldson report, *The Right Time, The Right Place: An expert examination of the application of health and social care governance arrangements*

¹⁷ Francis, R. (2015) *Freedom to Speak Up. An independent review into creating an open and honest reporting culture in the NHS*.

¹⁸ In <https://publications.parliament.uk/pa/cm201415/cmselect/cmpubadm/886/88602.htm>

¹⁹ <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/candour---openness-and-honesty-when-things-go-wrong/about-this-guidance>

²⁰ Kark, T., Russell, J., (2018) *A review of the fit and proper person test*. DHSC London

²¹ https://www.professionalstandards.org.uk/docs/default-source/publications/research-paper/telling-patients-the-truth-when-something-goes-wrong---how-have-professional-regulators-encouraged-professionals-to-be-candid-to-patients.pdf?sfvrsn=100f7520_6

²² <https://www.gov.uk/government/publications/learning-not-blaming-response-to-3-reports-on-patient-safety>

²³ NMC/GMC (2015) *Openness and honesty when things go wrong: the professional duty of candour*. GMC, NMC. London

for ensuring the quality of care provision in Northern Ireland in 2015²⁴, we stated our support for the introduction of a statutory duty of candour for all providers of health and social care. BMA NI believes that a statutory organisational duty of candour should be comprehensive with robust sanctions in place to ensure providers are fulfilling their duties.

- 5.3 **England**²⁵ introduced an organisational duty of candour in November 2014, through the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The Care Quality Commission (CQC) is responsible for monitoring compliance and publishes guidance to ensure providers are aware of the requirements.
- 5.4 The requirement in England is that registered persons act in an open and transparent manner after a notifiable incident. The definition of a notifiable incident includes those which result in death, serious or moderate harm, or psychological harm that lasts at least 28 days. Once triggered, a number of steps must be taken, including an apology and involving the relevant person.
- 5.5 **Scotland's** duty of candour came into effect in April 2018, with guidance and e:learning modules published²⁶. The main elements of this organisational duty are that risk is acknowledged up front, honesty and transparency are core with a focus on the development of a learning culture to improve the quality of services. Organisations must publish an annual report to include the number and nature of incidents and assessment and information on changes to policies and procedures as a result of the incidents. They must also notify their relevant oversight body.
- 5.6 **Wales**²⁷ is currently looking at introducing an organisational duty of candour. There were some earlier discussions by the Welsh Government in 2015 on legislating for a statutory duty of candour, but to date this has not progressed²⁸. The complaints process in Wales has a section relating to raising concerns, *Putting Things Right: Raising Your Concerns*. The legislative base for this is the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.
- 5.7 **Northern Ireland:** BMA met with Sir Liam and his team in December 2014, and we highlighted that the overarching message from our members was that HSC organisations had not yet fully embraced the potential for learning from the Critical

²⁴ BMA NI (2015) Response to, *The Right Time, The Right Place: An expert examination of the application of health and social care governance arrangements for ensuring the quality of care provision in Northern Ireland*. BMA. Belfast

²⁵ <http://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour>

²⁶ <https://www.gov.scot/Topics/Health/Policy/Duty-of-Candour>

²⁷ <http://www.wales.nhs.uk/news/37950>

²⁸ <http://www.wales.nhs.uk/news/37950>

Incident Reporting process and the lack of leadership shown by some managers was deeply concerning to clinicians. We also highlighted that the pressure of workloads in both primary and secondary care means that doctors are not given the necessary time or training to undertake and conduct investigations.

- 5.8 In the report, *The Right Time, The Right Place*²⁹, it was noted that when an issue of quality or safety arises the tendency is to point to the individuals or the service involved. The report published by the National Advisory Group on the Safety of Patients in England, *A Promise to Learn – a commitment to act*,³⁰ 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*'³¹.
- 5.9 Donaldson (2014) recommended the introduction of an organisational duty of candour, similar to other parts of the UK and better regulation as well as the establishment of a Northern Ireland institute of patient safety. This recommendation was actioned in Health and Wellbeing 2026 where the report calls for the completion of the initial design work for the Improvement Institute.³² As of January 2018, some areas of practice have been identified to test and model.³³
- 5.10 Due to the Donaldson report and developments elsewhere in the UK, the then Minister, Mr Jim Wells, MLA, made an oral statement to the Assembly on 27th January 2015 confirming that a statutory duty of candour will be introduced in Northern Ireland. In his statement, the Minister referred to the creation of a statutory duty of candour, '*supported by professional codes of conduct that already exist*'³⁴.
- 5.11 Common themes from the above reports identify the importance of regulation and adherence to standards for quality and safety. But quality assurance nor continual improvement can be achieved through regulation based purely on technically specific standards. Berwick (2013) stated that,

²⁹ Donaldson. L., et al (2014) *The Right Time, the Right Place: An expert examination of the application of health and social care governance arrangements for ensuring quality of care provision in Northern Ireland*.

³⁰ National Advisory Group on the Safety of Patients in England (2013) *Improving the safety of patients in England*. NAGSP London

³¹ Ibid, page 12

³² DoH (2016) *Health and Wellbeing 2026: Delivering Together*. DoH Belfast

³³ <https://www.health-ni.gov.uk/sites/default/files/publications/health/dlt-latest-action-point-jan-18.pdf>

³⁴ Mr Jim Wells, Minister, Oral Statement to the NI Assembly, *Quality of Care in Northern Ireland*, 27 January 2015.

“In the end, culture will trump rules, standards and control strategies every single time, and achieving a vastly safer NHS will depend far more on major cultural change than on new regulatory regime.³⁵”

6. Freedom to Speak up Guardians

- 6.1 The Francis report on *Freedom to Speak Up* (2015), concluded that the culture of fear that pervades the NHS prevents staff from speaking up and this is a lost opportunity to improve patient safety. His report documented horrific treatment of staff and highlighted the distinct issues faced by students and doctors in training.
- 6.2 In England, The National Guardian’s Office³⁶ was established in 2016 as an independent, non-statutory body with the remit to lead culture change in the NHS so that speaking up becomes business as usual. The National Guardian office provides leadership, training and advice for Freedom to Speak Up Guardians. Freedom to Speak up Guardians have been appointed within Trusts. The national office also has a challenge, learning and support function to the healthcare system as a whole by reviewing trusts’ speaking up culture and the handling of concerns where they have not followed good practice.

7. Regulation of medical managers - Fit and Proper Persons Test (FPPT)

- 7.1 The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014,³⁷ 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 FPPT as part of their regulatory assessment framework.
- 7.2 Sir Robert Francis when giving evidence to the Health and Social Care Committee recently reinforced the need to consider the regulation of senior managers and leaders in order that they are held to account in the same way as doctors and nurses³⁸.

³⁵ National Advisory Group on the Safety of Patients in England (2013) *Improving the safety of patients in England*. NAGSP London. Page 10

³⁶ <https://www.cqc.org.uk/national-guardians-office/content/national-guardians-office>

³⁷ <http://www.legislation.gov.uk/ukdsi/2014/978011117613/contents>

³⁸ <http://data.parliament.uk/writtenEvidence/committeeEvidence.svc/evidencedocument/health-and-social-care-committee/patient-safety-and-gross-negligence-manslaughter-in-healthcare/oral/91923.html>

7.3 The FPPT was reviewed recently by Tom Kark and Jane Russell examining the effectiveness the FPPT.³⁹ In their report, Kark and Russell (2018) noted that culture and management flows directly from the management team and thus has the greatest impact on the ethos, the working conditions and ultimately the care comfort and safety of patients. In other words, the senior management should be the greatest force for improvement. Whilst acknowledging the great work of those management teams who are performing well, the FPPT is not consistently applied and there is a lack of central information about the people who manage health trusts.

7.4 They make 5 core recommendations and central to these is an assessment of whether a director has the necessary skills and competencies for their role:

- All directors (executive, non-executive and interim) should meet specific standards of competence to sit on the board of any health providing organisation. Where necessary, training should be available
- That a central database of directors should be created holding relevant information about qualifications and history
- The creation of a mandatory reference requirement for each Director.
- The Fit and Proper Persons Test (FPPT) should be extended to all commissioners and other appropriate Arms-Length-Bodies
- The power to disbar directors for serious misconduct.⁴⁰

8. Individual professional duty of candour for doctors

8.1 Doctors have an existing professional duty to be open and honest with patients about their care. Doctors are strictly regulated under the Medical Act 1983⁴¹ and by the General Medical Council (GMC) which is an independent, accountable regulator and has a duty to ensure proper standards in the practice of medicine.⁴²

8.2 The General Medical Council's *Good Medical Practice (2013)*, states:⁴³

Respond to risks to safety:

³⁹https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/777336/kark-review-on-the-fit-and-proper-persons-test.pdf

⁴⁰ Ibid, pg 133

⁴¹ <http://www.legislation.gov.uk/ukpga/1983/54/contents>

⁴² Guidance to the GMC's Fitness to Practise Rules 2004 (as amended) - https://www.gmc-uk.org/-/media/documents/DC4483_Guidance_to_the_FTP_Rules_28626691.pdf

⁴³ https://www.gmc-uk.org/-/media/documents/good-medical-practice---english-1215_pdf-51527435.pdf

(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, 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.

8.3 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.

8.4 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.*⁴⁴

⁴⁴ GMC and NMC (2015) *Openness and Honesty when things go wrong: the professional duty of candour.* London. GMC/NMC

This guidance complements the joint statement⁴⁵ from healthcare regulators and reinforces the professional duty of candour for doctors, nurses and midwives.

- 8.5 BMA met with Sir Liam and his team in December 2014, and we highlighted that the overarching message from our members was that HSC organisations had not yet fully embraced the potential for learning from the Critical Incident Reporting process. Members have suggested that the system is not easy to use and frequently when incidents are reported no action is taken and the doctor is not informed of progress. The pressures in primary and secondary care means that doctors are not given the necessary time or training to undertake and conduct investigations.
- 8.6 Junior Doctors in particular raised a number of issues pertinent to them at the start of their careers. They highlighted a reluctance in reporting incidents as they perceived it could potentially impact negatively on their career progression. There is a need for this to be part of the core curriculum for medical students and doctors in training as it may go some way to reducing this fear and also contribute to the necessary cultural shift needed to enable doctors to speak up.
- 8.7 The report by the Professional Standards Authority in 2019 evaluating the professional duty of candour⁴⁶ found that, similar to their advice in 2013 to the Secretary of State, ‘fear’ was still a common thread when identifying barriers to being candid. This could be fear of isolation from colleagues, litigation or a detrimental impact on careers. These findings complement our own survey results from Caring, Supportive, Collaborative, outlined earlier.
- 8.8 They do conclude that the regulators could strengthen the relationships that they have with range of stakeholders to further embed the concepts of being candid, particularly across all professions.

Protection for Disclosure/Raising Concerns

9. The Health Services Safety Investigations Bill

⁴⁵ 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*

⁴⁶ https://www.professionalstandards.org.uk/docs/default-source/publications/research-paper/telling-patients-the-truth-when-something-goes-wrong---how-have-professional-regulators-encouraged-professionals-to-be-candid-to-patients.pdf?sfvrsn=100f7520_6

- 9.1 The Public Administration Select Committee in 2015 called for an independent body to be established to conduct patient safety investigations in the NHS. The Health Services Safety Investigations Bill⁴⁷ is currently going through the legislative process in Westminster and will establish a statutory investigative body for England to look into patient safety and the risks for the sole purpose of learning and not to attribute blame or individual fault for England.
- 9.2 The Health Services Safety Investigation Body (HSSIB) will conduct investigations into incidents which appear to evidence serious patient safety risks and develop standards on best practice in carrying out investigations. Importantly the HSSIB will conduct investigations using ‘safe spaces’ which prohibit the disclosure and protect certain information held in connection with an investigation.
- 9.3 The Joint Committee on the Draft Health Service Safety Investigations Bill published its findings in August 2018 on the Department of Health and Social Care in England’s plans to establish the Health Service Safety Investigations Body (HSSIB). The report supported the planned ‘safe space’ approach to investigating incidents which will reduce the fear of talking openly and not apportion blame.⁴⁸ The report was also clear in that, “*Healthcare professionals will remain subject to their professional duties, not least the duty of candour. The ‘safe space’ will have no impact on these duties.*” (par 21)

10. Open disclosure and patient safety in Ireland

- 10.1 Doctors in Ireland are bound by the ‘*Guide to professional conduct and ethics for registered medical practitioners*’⁴⁹ and they like their counterparts in Northern Ireland, have a duty to be open, honest and transparent with patients, to reflect on adverse events and to take steps to ensure that such incidents are not repeated. This guide supports open and honest communication with patients when things go wrong.
- 10.2 Doctors in Ireland are provided with protection when they disclose to a patient when something goes wrong. The provision of ‘*Open Disclosure*’ for doctors in Ireland is contained in the Civil Liability (amendment) Act 2017.⁵⁰ Section 10 of this Act protects doctors when being open and honest. This means that an apology and

⁴⁷ <https://www.gov.uk/government/publications/health-service-safety-investigations-bill>

⁴⁸ https://publications.parliament.uk/pa/jt201719/jtselect/jthssib/1064/106411.htm#_idTextAnchor183

⁴⁹ Comhairle na nDoctúirí Leighis. Guide to Professional Conduct and Ethics for Registered Medical Practitioners. 8th Edition, 2016.

⁵⁰ <http://www.irishstatutebook.ie/eli/2017/act/30/section/7/enacted/en/html>

expression of regret cannot be interpreted as an admission of liability and therefore cannot be used in litigation against the person making the disclosure.

- 10.3 Protections are also built in to ensure that the insurance or indemnity of the doctor is not affected by an apology made as part of an open disclosure as well as records created solely for the purpose of the disclosure to patients are not admissible as evidence in civil proceedings relating to liability for injury or death.
- 10.4 The Commission on Patient Safety and Quality Assurance recommended a framework for improvement in patient safety⁵¹. They recommended mandatory reporting of adverse incidents which result in death or serious harm; the voluntary reporting of other less serious incidents and ‘near misses; the need for clinical audit to improve patient care and outcomes and extend the Health Information and Quality Authority (HQIA) remit to private health services.’ **The Patient Safety Bill**⁵² will enact these recommendations. It also does not affect the provisions of open disclosure outlined above and maintains the protection of doctors engaging in the open disclosure of patient safety incidents. The Commission recognised that many adverse events and poor outcomes in healthcare stem from several service wide factors acting together and rarely attributable to shortcomings or failures on the part of individuals.
- 10.5 The HQIA and the Mental Health Commission will jointly develop standards on the notification of reportable incidents and this will require Ministerial approval. The National Clinical Effectiveness Committee in conjunction with the Minister will be involved in developing guidance for the clinical audit aspects of the Bill and will tailor these depending on the provider.
- 10.6 BMA NI would be supportive of similar provision in Northern Ireland as this can provide doctors with medico-legal clarity, but also reinforce the right of patients to an explanation, an apology and assurance that such incidents are not repeated. Protections for healthcare professionals are not about apportioning blame but about being open and honest when things go wrong. Embedding protections for healthcare professionals who disclose can act as a mechanism to develop the supportive structures and processes needed to support open disclosure and to build patient and public trust in the health system.

⁵¹ https://health.gov.ie/wp-content/uploads/2014/03/en_patientsafety.pdf

⁵² https://health.gov.ie/wp-content/uploads/2018/07/General-Scheme_Patient-Safety-Bill_5-July-2018.pdf

11. Northern Ireland Department of Health's response to patient safety

- 11.1 Chapter 8 of the O'Hara reports examines the current position in relation to patient safety to note the changes that have taken place over the years. The changes reported by the relevant statutory bodies show that guidance, training and reviews were instigated in relation to the provision of IV fluids to children. Reviews were undertaken by RQIA into age appropriate settings, followed by guidance from the HSCB. Other changes resulted in the Chief Medical Officer establishing the HSC Safety Forum in 2007.
- 11.2 The department of health (DoH) created the Guideline and Audit Implementation Network (GAIN) in 2007 to scrutinise quality improvement through auditing and to train staff in clinical audit and systematic review. The DOH issued its first regional guidance on Serious Adverse Incidents (SAIs) in 2004 and developed the '*Safety First Strategy*' in 2006. *Quality 2020*⁵³ was published in 2011 to raise standards, measure improvement and transform culture. The recent implementation plan (2017) associated with Quality 2020 shows that many of the actions have not yet been implemented⁵⁴.
- 11.3 In 2010 responsibility for the management and follow-up of SAIs was transferred from the DoH to the Health and Social Care Board (HSCB) and the Public Health Agency (PHA) working collaboratively with the Regulation, Quality and Improvement Agency (RQIA). Assurance frameworks were published by the HSCB in 2010, 2013, 2016. The RQIA undertook a review of how the Trusts handled SAIs and reported in 2014 and found that some cases were not reported as SAIs, some were breaching the 12-week timeframe, some failed to involve families and there was difficulty in obtaining independent expertise for more complex investigations.
- 11.4 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.

⁵³ DHSSPS (2011) Quality 2020 - a ten-year strategy to protect and improve quality in health and social care in Northern Ireland. Belfast DHSSPS

⁵⁴<https://www.health-ni.gov.uk/sites/default/files/publications/health/Q2020%20Strategic%20Implementation%20Plan.pdf>

12. Conclusions

- 12.1 Our focus in this paper is on the duty of candour, an examination of system wide pressures and how these impact on patient safety. The benefits of an organisational statutory duty of candour are twofold. As well as addressing individual errors, it can promote greater openness which would benefit all patients. 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. 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.
- 12.2 What is clear from this paper is that other jurisdictions have responded to patient safety by attempting to implement measures across their healthcare systems that create the culture where reporting becomes the norm and ending the blame culture. An Audit Report in 2012 and the report of Sir Liam Donaldson in 2014 recognised that patient safety in Northern Ireland was complex and there were no systems in place to track improvements in patient safety.
- 12.3 BMA Northern Ireland does not accept that an individual statutory duty of candour with criminal sanctions as proposed by O'Hara is necessary or beneficial in achieving improved patient safety. There are already a number of robust sanctions that patients, employers, regulators and others can draw on to hold staff to account. Adding an individual statutory duty of candour with criminal sanctions would not add anything substantive to the existing routes and would add to the confusion about who is accountable. If the existing mechanisms are not used effectively or not understood, additional advice and guidance should be provided, rather than adding another provision, which could have the unintended consequence of worsening the existing culture of fear that prevents staff speaking out.
- 12.4 Embedding protections for healthcare professionals who disclose can act as a mechanism to develop the supportive structures and processes needed to support open disclosure and to build patient and public trust in the health system. BMA NI believes that this would provide doctors with medico-legal clarity, but also reinforce the right of patients to an explanation, an apology and assurance that such incidents are not repeated. Protections for healthcare professionals are not about apportioning blame but about being open and honest when things go wrong.

- 12.5 The House of Commons Health Committee Inquiry into *Complaints and Litigation*⁵⁵ noted that an open culture around complaints amongst staff is essential and 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 repetition.⁵⁶
- 12.6 Doctors and other healthcare staff work in and across multidisciplinary teams and sites, in a system that is under severe pressure with simply not enough staff. Even where a staff member was confident that no single individual was to blame for the action that endangered or misled a patient, concern about criminal prosecution may discourage them from speaking out,

‘Make sure pride and joy in work, not fear, infuse the NHS.’

(Don Berwick, 2013)

Judith Cross
Head of policy and committee services
29 March 2019

⁵⁵ Health Committee, *Complaints and Litigation*, Sixth Report of Session 2010-12, HC 786-1

⁵⁶ Ibid 138

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