General Medical Council

Department of Health (Northern Ireland) consultation on Duty of Candour and Being Open policy proposals

18 August 2021

Summary

1 We welcome the opportunity to comment on the Duty of Candour and Being Open Framework consultation.

2 Our thoughts and sympathies remain with the families who tragically lost children to hyponatraemia in Northern Ireland (NI). Healthcare professionals and organisations must learn from these terrible mistakes and make sure that they are open and honest with patients and their families when things go wrong.

3 We are committed to continuing to work with the Department of Health and others to implement the recommendations of the Inquiry into Hyponatraemia-related Deaths Report ('the Report'). We very much welcomed the emphasis placed on the importance of the Duty of Candour within Justice O'Hara's report.

4 We also welcome the Duty of Candour working group's commitment to co-producing these policy options with a wide range of stakeholders and the focus on involving patients, service users and carers.

5 We are committed to working with and for patients. Patient safety is our priority, and we encourage doctors and employers to foster transparent behaviours that allow for concerns about care to be effectively raised and addressed in partnership with patients.

6 In our *Corporate Strategy 2021-2025*[*], we have committed to 'work with partners across the UK health services to improve working environments and cultures, making them supportive, inclusive and fair for medical professionals. In doing so, patients will

[*] General Medical Council (2021) Corporate Strategy 2021 -2025. Available online

benefit from safer and better care, and the workforce will retain and attract more professionals.'

7 We would welcome the introduction of a statutory Duty of Candour for organisations, as we think that it will support the cultural change needed to ensure openness within the Health and Social Care (HSC) service. This duty needs to be supported by strong and effective leadership in organisations. We have previously endorsed recommendation nine of the Report, which sets out that the 'highest priority should be accorded the development and improvement of leadership skills'. We recognise that this, and the development of cultures where candour is encouraged and learning from errors is enabled, are interdependent.

8 The Freedom to Speak up Guardians network in England is supporting healthcare organisations to create open and transparent cultures. A similar initiative in NI would support the implementation of an organisational Duty of Candour.

9 Doctors already have a professional Duty of Candour [*]to be open and honest with patients when things go wrong. We are unconvinced that a statutory Duty of Candour for individuals with criminal sanctions will deliver the fundamental changes in attitudes and behaviour in relation to openness and honesty that are needed. We believe that the threat of criminal sanctions to individual doctors would work against the culture of openness we need in healthcare. Instead, we believe that organisations must lead and develop open cultures, in which candour is encouraged and learning from errors is enabled.

10 As some of the questions in the consultation fall outside our regulatory remit, we have restricted our comments to relevant areas.

Our response is structured as follows:

- **i** Our role;
- **ii** Terminology and definitions *(Questions 1 and 2);*
- **iii** Our view on a Statutory Organisational Duty of Candour *(Questions 3, 9, 10, 15);*
- **iv** Our view on a Statutory Individual Duty of Candour *(Questions 24 - 29);*
- **v** Engaging the profession, patients and the public *(Question 31)*;
- **vi** Leadership and culture *(Question 31);*

[*] General Medical Council & the Nursing and Midwifery Council (Published June 2015) *Openness and honesty when things go wrong: the professional Duty of Candour*. Available online

vii Approaches in other jurisdictions *(Question 31);*

viii The Being Open Framework *(Question 32);*

ix Additional support measures *(Question 52).*

11 Our previous submissions on this, and related issues, are included as Annexes:

i **Annex A:** Inquiry into Hyponatraemia-related Deaths - GMC response, May 2018;

ii **Annex B:** Inquiry into Hyponatraemia-related Deaths: Duty of Candour - GMC submission, April 2019;

iii **Annex C:** Donaldson report (2014) – GMC submission, May 2015;

iv **Annex D:** Relevant extracts from our guidance for doctors.

Our role

12 The General Medical Council (GMC) is an independent organisation that helps to protect patients and improve medical education and practice across the UK.

- We decide which doctors are qualified to work here and we oversee all stages of UK medical education and training;
- We set the standards that doctors need to follow, and make sure that they continue to meet these standards throughout their careers;
- We take action to prevent a doctor from putting the safety of patients, or the public's confidence in doctors, at risk.

13 Every patient should receive a high standard of care. Our role is to help achieve that by working closely with doctors, their employers and patients, to make sure that the trust patients have in their doctors is fully justified.

14 We are independent of government and accountable to Parliament. Our powers are given to us by Parliament through the Medical Act 1983.

Terminology and definitions (Questions 1 and 2)

- *Question 1: Do you agree with the terminology and definitions adopted by the Workstream in respect of "openness" and "candour"? If yes, please provide any additional information and / or insights;*

- *Question 2: If not, do you suggest a preferred terminology that should be used to describe this policy and the statutory duty? Please provide evidence to support any alternative proposal.*

15 It is important to define 'Candour' and 'Openness' in the context of the delivery of healthcare services and place a focus on better patient safety outcomes and positive working environments for staff.

16 To improve wider understanding of openness and transparency in healthcare settings, we suggest it would be helpful to outline the conditions that should be in place;

- a culture that encourages openness, information sharing and learning from reflection at all times;
- the freedom to speak up and raise concerns; and
- collective clinical leadership.

17 The GMC's *Corporate Strategy 2021-2025* is designed to support all doctors in delivering high standards of care and moving away from acting only when things have gone wrong. Themes of openness, learning and reflection are key to this and we see our Corporate Strategy as a core reflection of the values of the health and social care system in which doctors work.

18 Our joint guidance [*]with the Nursing and Midwifery Council (NMC), *Openness and honesty when things go wrong: the professional Duty of Candour*, highlights that every healthcare professional must be open and honest with patients when something that goes wrong with their treatment or care causes, or has the potential to cause, harm or distress. We also set out a duty for doctors, nurses, midwives and nursing associates to be open and honest with their employer, and to encourage a learning culture by reporting errors openly and honestly.

19 Our guidance on professional standards is necessarily broad so it can be widely applicable to all doctors in the UK, regardless of their specialty, grade and area of work. As it can't cover all the situations they might face in practice, we expect doctors to use their professional judgment to apply the principles in our guidance.

20 GMC decision makers and tribunals are encouraged to consider how a doctor has complied with their professional duty of candour as part of considering any concerns about their Fitness to Practise. In our guidance *Making decisions on cases at the end of the investigation stage: Guidance for the Investigation Committee and case*

[*] [*] [*] General Medical Council & the Nursing and Midwifery Council (Published June 2015) *Openness and honesty when things go wrong: the professional Duty of Candour*. Available online

examiners[*], we say that 'a key factor in whether a doctor is found impaired will relate to how they have responded to the concern. Even where there has been a serious failing that may have harmed patients, if a doctor has been honest about the failing including apologising to any patient harmed, reflected on what happened, demonstrated insight, taken steps to put it right and repetition is unlikely, this is likely to address the risk to the public.' (paragraph 67).

21 In our *Sanctions guidance*[†], tribunals are reminded that when a doctor is presenting evidence that they have attempted to address or remediate a concern, Good Medical Practice (GMP) states that doctors "*must be open and honest with patients if things go wrong*" and respond promptly, fully and honestly to complaints and apologise where appropriate (see paragraphs 55 and 61 of GMP and paragraph 26c of the Sanctions guidance).

Our view on a Statutory Organisational Duty of Candour (Questions 3, 9, 10, 15)

- *Question 3: Do you agree with the proposed scope of the statutory organisational Duty of Candour? If yes, please provide any additional information;*
- *Question 9: Do you agree with the proposed requirements under the statutory organisational Duty of Candour when things go wrong? If yes, please provide any additional information or insights;*
- *Question 10: If not, do you have a preferred approach for the requirements under the statutory organisational Duty of Candour when things go wrong? Please provide evidence to support any alternative proposal;*
- *Question 15: Do you agree with the proposals for support for staff under the statutory organisational Duty of Candour? If yes, please provide any additional information or insights.*

22 We support a statutory Duty of Candour for organisations in Northern Ireland to drive a change in culture required to deliver openness and transparency in the HSC service.

23 Doctors in NI have told us about the barriers to raising concerns:

- The fear of recrimination and feeling like nothing will change;

[*] General Medical Council (Updated March 2021) Making decisions on cases at the end of the investigation stage: Guidance for the Investigation Committee and case examiners. Available online

[†] General Medical Council & Medical Practitioners Tribunal Service (MPTS) (2021) *Sanctions guidance.* Available online

- The impact of the Jack Adcock/Dr Bawa-Garba case and concern amongst doctors about what will happen to them if they do speak up;
- Unfamiliar reporting systems and not knowing who to speak to about concerns, particularly after moving to a new Trust;
- The impact on long term employment in NI if doctors do raise concerns; and
- The impact of the small size and the closeness of the health service in NI.

24 A legal duty on organisations will require them to support professionals in being open and transparent, where those in their care suffer harm or distress.

25 We believe the professional duty of candour required of doctors by the GMC and the statutory organisational Duty of Candour are mutually reinforcing and should not be viewed in isolation. Fostering a working culture in which all staff value the opportunity to put things right and learn from mistakes if things go wrong, in a non-punitive manner, will support health professionals to be open and honest when such events arise.

26 For this reason, we believe that introducing an organisational Duty of Candour would support existing guidance to strengthen both patient safety and transparency within the HSC service, which could encourage a culture of quality improvement.

27 A statutory Duty of Candour is already in place in England, Scotland and is planned for implementation in Wales.

28 We believe it will be important that organisations make sure staff are aware of the organisation's Duty of Candour, and, if they are subject to professional regulation, how the organisational duty aligns with their own professional duty.

29 To support the effective implementation and enforcement of the organisational Duty of Candour we recommend enhancing the range of enforcement and improvement powers available to RQIA as recommended in the Review of Leadership and Governance at Muckamore Abbey Hospital.*

30 We set standards that apply to doctors equally regardless of their practice environment and believe that, if introduced, an organisational Duty should be applied consistently across all health and care settings.

* The Muckamore Abbey Hospital Review Team (2020) A Review of Leadership and Governance at Muckamore Abbey Hospital. Available online

Our view on a Statutory Individual Duty of Candour (Questions 24 - 29)

- *Question 24: Please provide comments on the policy proposal for the statutory individual Duty of Candour;*
- *Question 25: Please provide comments on the alternative policy proposals for the statutory individual Duty of Candour;*
- *Question 26: If you do not agree with any of the three high-level policy proposals, do you have a preferred alternative policy approach for implementation of the recommendations relating to the statutory individual Duty of Candour? Please provide evidence to support an alternative proposal;*
- *Question 27: What is your preferred policy approach in respect of the scope of the statutory individual Duty of Candour? Please outline the reasons for your preference and provide evidence to support your reasoning;*
- *Question 28: Do you agree with the proposals in relation to the requirements under the statutory individual Duty of Candour? If yes, please provide reasons for your agreement;*
- *Question 29: If not, do you have a preferred approach for the requirements under the statutory individual Duty of Candour? Please provide evidence to support any alternative proposal.*

31 In April 2019, we set out our view on an Individual Duty of Candour in response to the DoH (NI)'s Duty of Candour Working Group (see Annex A). We remain unconvinced that a statutory Duty of Candour for individuals with criminal sanctions attached is likely to deliver the fundamental changes in attitudes and behaviour in relation to openness and honesty that are needed in the health and social care system.

32 Research commissioned by the Department of Health and Social Care in England found [*]that the wider health system still contains 'conflicting signals about the risks and benefits of openness', and widely publicised criminal convictions, along with cases of 'blacklisting' of whistle-blowers, sustain the message that openness was not risk free[†].

[*] Martin, G et al. (2018) '*Senior stakeholder views on policies to foster a culture of openness in the English National Health Service: a qualitative interview study*', Journal of the Royal Society of Medicine. Available online

33 We share the Professional Standards Authority's (PSA) view that professionals need to 'take candour to heart', making candour a professional strength to be valued, not just a regulatory requirement to be complied with. [*]

34 The 2013 Berwick review into patient safety [†]in England, highlighted that poor leadership behaviours such as blame, sanctions attached to errors, and a culture of fear, increase risk and make healthcare less safe. Instead, Berwick emphasised that blame should be 'abandoned', transparency should be 'insisted upon' and warnings of problems should be welcomed.

35 A culture of fear, particularly a fear of the consequences of being candid, may be a strong influencing factor in doctors' decision-making. Our serious concern is that the introduction of individual criminal sanctions for failures in candour would add to the climate of fear, driving staff to weigh up the perceived personal risks to them of disclosing information (e.g. fear of litigation, or being scapegoated) versus the perceived risks of not doing so (e.g. fear of criminal prosecution). Instead we need to ensure a culture of openness from the outset.

36 A focus on self-protection is also not in line with our professional standards for doctors. We expect doctors to be open and honest to patients and those close to them. Where there is a strong just culture, individuals can feel confident about being open when things have gone wrong.

37 Penalising individuals' failure in an institutional culture which does not support candour and openness may prove counterproductive. We are not persuaded that introducing a statutory individual Duty of Candour is an effective way forward and indeed may be seriously counter-productive.

Engaging the profession, patients and the public (Question 31)

- *Question 31: Is there any additional feedback that you wish to provide in respect of the policy proposals for the statutory individual Duty of Candour? If so, please provide evidence to support alternative proposals, if possible.*

38 Concerns about the effectiveness of an individual statutory duty makes it all the more important to support doctors to fulfil their professional duty. For that reason, we proactively encourage candour through our engagement with doctors.

[*] Professional Standards Authority (2019) *'Telling patients, the truth when something goes wrong.'*
[†] Don Berwick (2013) A promise to learn – a commitment to act: Improving the Safety of Patients in England. Available online

39 GMC Liaison Advisers based in NI deliver workshops covering a variety of themes, including a doctors' duty to raise a concern, maintaining and improving standards of care, and encouraging a learning culture by routinely reporting errors or near misses.

40 Each year, we run professionalism workshops for doctors, which include sessions on our guidance for raising and acting on concerns about patient safety and openness and honesty when things go wrong. In 2019 we delivered this workshop to 1149 doctors in Northern Ireland.

41 In the event an individual Duty of Candour is introduced, it will be important to have clarity about how this interacts with existing processes, including regulatory action by professional regulators.

42 It would also be important to provide clarity for individual doctors on the thresholds for breaching an individual Duty of Candour, and how this interacts with existing professional guidance.

43 There should also be consideration to providing accessible information for patients on the introduction of an individual Duty of Candour and how it will operate in practice.

Leadership and culture (Question 31)

- *Question 31: Is there any additional feedback that you wish to provide in respect of the policy proposals for the statutory individual Duty of Candour? If so, please provide evidence to support alternative proposals, if possible.*

44 We know that the cultural environment within which health professionals work is by far the biggest determinant of quality and patient outcomes. There is a direct association between working cultures that are cohesive, supportive, collaborative and inclusive and measurably better outcomes for patients (Braithwaite et al., 2017).*

45 We recognise that it is through strong and effective leadership that organisations will develop a culture in which candour is encouraged and learning from errors is enabled. When doctors are practising, they need to feel they are part of a supportive and just culture, and that they are getting appropriate support that is consistent.

46 We are committed to strengthening our collaboration with healthcare partners across the HSC to create environments where doctors feel confident and supported to raise concerns.

* Braithwaite et al. (2017) *Association between organisational and workplace cultures, and patient outcomes: systematic review,* Available online.

47 Our guidance, *Leadership and management for all doctors* (2012) (see Annex D), outlines that doctors in leadership positions should actively foster a culture of learning and improvement. The GMC recognises that all doctors are leaders, not only those in specific leadership positions. Doctors must lead by example, valuing each other, reflecting on mistakes and speaking up when something is not right.

48 We are strongly supportive of the development of clinical leadership skills in NI as set out in the *Health and Social Care (HSC) Collective Leadership Strategy*[*]. We welcome the commitment to establish shared learning for improvement rather than blaming for mistakes because this will help to support a culture of candour.

49 Another welcome development to drive cultural change and create openness, is the establishment of the *Collective Leadership Community of Practice*. We are supportive of its ambition to create a new generation of leaders across the HSC which fosters 'better staff well-being and commitment, improved care quality and fairer, more transparent and kinder workplaces'.

50 In 2018 we commissioned Professor Michael West and Dame Denise Coia to carry out a UK-wide review to help tackle the causes of poor wellbeing faced by medical students and doctors.

51 Their report, *Caring for doctors, Caring for patients*, [†]concluded that in organisations where leadership was remote from staff, the standard response to safety failures was to blame individuals rather than develop systems to avoid recurrence. The report highlighted that effective and engaged leadership is the key to creating an environment free of unfair blame, where a culture of candour and learning can flourish.

52 In 2019, our Liaison Advisers facilitated 14 sessions on our *Leadership and management for all doctors* [‡]guidance, which were attended by over 750 doctors in NI.

Approaches in other jurisdictions (Question 31)

- *Question 31: Is there any additional feedback that you wish to provide in respect of the policy proposals for the statutory individual Duty of Candour? If so, please provide evidence to support alternative proposals, if possible.*

[*] Department of Health (NI) (2017) Health and Social Care (HSC) Collective Leadership Strategy. Available online

[†] Professor Michael West & Dame Denise Coia, *Caring for doctors, caring for patients* (2019), Available online.

[‡] General Medical Council (2012) Leadership and Management for all doctors. Available online

53 There is an opportunity for NI to learn from the approaches to increasing openness in healthcare systems in other countries, which has resulted in improved patient safety outcomes.

54 For example, *The safety of maternity services in England* report cited evidence from the Swedish no-blame compensation scheme for medical injuries. This approach has improved patient safety outcomes by promoting openness from clinicians. The model is designed to "remove obstacles, actual or imagined, that are there [to openness]". [*]

The Being Open Framework (Question 32)

- *Question 32: Do you agree with the policy proposals in respect of the Being Open Framework? If yes, please outline your reasoning.*

55 We are supportive of the Being Open Framework proposals. We welcome the focus on routine openness rather than the exceptional circumstances when mistakes may lead to harm or death.

56 We welcome the provision of clear and accessible guidance for patients about what they can expect and what support is available to them.

57 The focus on support mechanisms for staff involved in adverse incidents is key and we support the promotion of routine reflection and learning.

Additional support measures (Question 52)

- *Question 52: Is there any additional feedback that you wish to provide in respect of the policy proposals for the Being Open Framework? If so, please provide evidence to support alternative proposals, if possible.*

58 We believe that establishing a network of Freedom to Speak Up Guardians in NI would be a beneficial addition to this framework. The National Guardian leads, trains and supports the network of Freedom to Speak Up Guardians in England and provides challenge and learning to the healthcare system on matters related to speaking up.

59 Since the introduction of Freedom to Speak Up Guardians [†]in England in 2016 the Freedom To Speak Up Index has improved. This matrix is drawn from four questions in the NHS Annual Staff Survey and measures whether staff feel knowledgeable, encouraged and supported to raise concerns, and if they agree they would be treated fairly if involved in an error, near miss or incident.

[*] *The safety of maternity services in England, Fourth Report of Sessions 2021-22,* Ordered by the House of Commons to be printed 29 June 2021. Available online.

[†] NHS National Guardian (2021) *Freedom to Speak Up index report 2021*. Available online.

Annex A: Inquiry into Hyponatraemia-Related Deaths - GMC response [partial], May 2018

The Inquiry into Hyponatraemia-related deaths

Introduction

Mr Justice O'Hara's report highlights serious failures in the care of five young children. It levels profound criticisms at both individual doctors who were charged with their care and at the culture and conduct of the institutions in which they worked. Although much time has passed, and much has changed, since the tragic events described by Justice O'Hara, it remains vital that all concerned consider the lessons that can still be learned and the actions that should now be taken.

Although none of the report's 96 recommendations is directed specifically at the GMC in our role as the regulator of doctors, we are committed to learning lessons from what occurred and to making sure that patients are protected. This response to the Inquiry report sets out our conclusions so far.

A statutory Duty of Candour should now be enacted in Northern Ireland (recommendation 1)

The report describes a lack of candour at both individual and institutional level and Mr Justice O'Hara rightly concludes that the failure to report and instead conceal certain failings should not have happened. We therefore very much welcome the emphasis placed on the importance of the Duty of Candour within his report. In particular, we wish to endorse the recommendation that 'Any statement made to a regulator or other individual acting pursuant to a statutory duty must be truthful and not misleading by omission' (recommendation 1(iv)).

Our own regulatory approach to the professional Duty of Candour has developed over the course of the Inquiry's investigations, building on the recommendations of Sir Robert Francis' report on the Mid-Staffordshire Inquiry.

At the level of institutions, we welcome a statutory Duty of Candour for organisations as this would bring Northern Ireland into line with England, Wales and Scotland.

Linked to that, we fully endorse the report proposal that the 'highest priority should be accorded the development and improvement of leadership skills' (recommendation 9) as it is through strong and effective leadership that organisations will develop a culture in which candour is encouraged and learning from errors is enabled. Where that culture is strong individuals can feel confident about being open when things have gone wrong. But penalising individuals' failure in an institutional culture which does not support candour and openness may prove counterproductive. We are not persuaded, therefore, that a

statutory Duty of Candour for individual professionals with criminal sanctions attached is likely to be the most efficacious way forward. In particular:

- It would limit doctors' ability to apply professional judgement in handling a particular situation, and risk binding them to specific actions which in some cases may not be appropriate;
- It would potentially create confusion by introducing new legal duties in addition to existing professional duties;
- It would undermine other professional guidance principles which are not similarly legally enforced;
- It is inconsistent with the legal Duty of Candour adopted in England, Wales and Scotland.

Our current guidance, *When things go wrong - The professional Duty of Candour,* was developed in collaboration with the Nursing and Midwifery Council. It imposes on doctors, nurses and midwives a professional duty to be open and honest with patients when things go wrong. It also places duties on managers to ensure there are systems and a culture that supports open reporting of adverse incidents. Placing a punitive duty backed by criminal sanctions on individuals who are working in an unsupportive environment may be counterproductive. This is not to say that individuals should not be accountable where there is a lack of candour, but a regulatory response rather than criminalisation may be more effective and proportionate.

In recent years, we have invested additional resources in working with local healthcare organisations across the UK to increase awareness and understanding of our standards. In Northern Ireland we have a dedicated member of staff who takes forward an extensive programme of interactive and scenario-based programmes and workshops in this area. Our programmes in Northern Ireland include, but are not limited to:

- Dedicated Professionalism days for all Foundation Year 2 (FY2) doctors in partnership with the Northern Ireland Medical and Dental Training Agency (NIMDTA).
- Compulsory professionalism module for all early years doctors in training (ST1-ST3, CT1-CT2) in partnership with NIMDTA. This includes specific sessions on raising and acting on concerns.
- GMC guidance workshops and programmes in partnership with all five Health and Social Care Trusts. These include sessions on *Raising and acting on concerns*, *Leadership and management*, *0-18: Guidance for all doctors* and many other aspects of GMC guidance.

- Our Welcome to UK Practice programme which highlights the standards expected of doctors new to practice in Northern Ireland/UK. It has recently been agreed with HSC Trusts that all doctors new to Northern Ireland will be offered the opportunity to attend one of these sessions within three months of taking up post. We are the process of putting this in place with the Trusts.

Raising and acting on concerns (see recommendations 1(vii) and 31-42)

Linked to the Duty of Candour is the need for doctors to raise and act on concerns. We were therefore pleased to note within recommendation 1 the statement that healthcare professionals who believe that treatment or care provided to a patient has caused death or serious injury to the patient 'must report their belief or suspicion to their employer'. Our guidance *Raising and acting on concerns about patient safety* sets out managers' responsibilities to ensure there are systems in place to allow concerns to be raised and investigated and that staff who raise concerns are protected from unfair criticism or action.

Our confidential helpline (established in 2012) gives doctors across all four countries of the UK a means to raise serious concerns with us. Since 2014 we have received over 200 calls to the helpline from across the UK, the majority of which have led to further investigation.

Leadership- the highest priority should be accorded to the development and improvement of leadership skills at every level of the health service (recommendation 9)

Our Employer Liaison Service (ELS) (established 2012) provides support and advice to Medical Directors (Responsible Officers) to assist them in fulfilling their statutory responsibilities. This includes support on investigating concerns about a doctor's practice. The support provided by the ELS includes discussing cases of potential concern with us and advising Responsible Officers on the appropriate course of action. A robust local response supports patients, doctors and healthcare providers and we believe is the foundation for effective and proportionate systems to deal with concerns. We were therefore also pleased to see recommendations in the Report intended to strengthen the reporting and investigation of serious adverse clinical incidents at a local level.

Although much progress has been made since the tragic events that led to Mr Justice O'Hara's Inquiry, we are keen to support the further development of effective and timely local investigation processes as this will be in the interests of both patients and healthcare professionals. The candour of the profession at all levels will be critical to making progress with stronger local processes and promoting a wider safety culture.

In addition, we are collaborating with a number of system & professional regulators and healthcare improvement agencies across the UK to update the Governance Handbook – which is guidance for Boards, governing bodies, and medical leaders on creating organisation-wide commitment to creating an environment that fosters good professional practice and high-quality patient care. Providers of healthcare services have a duty of care

to patients. To satisfy this duty, they must ensure that all doctors they engage are supported in keeping up to date and are fit to practise, and that where a doctor's performance is in question there are effective mechanisms for investigating and managing this. Well-led and committed Boards and governing bodies will embed the core elements of the Governance Handbook in their local governance systems and will use them within their monitoring of the on-going effectiveness of those processes.

Incorporating Good Medical Practice (GMP) into doctors' contracts (Recommendations 73 and 75)

We were pleased to note the prominence given in the report to our guidance to doctors, *Good Medical Practice*. GMP sets out the standards of conduct and behaviour that we expect of doctors. Serious or persistent failure to comply with the guidance may put a doctor's registration at risk. This would not change if it was a contractual requirement.

However, it is important to understand that GMP is not a mechanistic code which must be precisely and rigidly followed in every circumstance. Rather, it provides a set of principles which doctors must use when applying their professional judgement to everyday practice. There may, therefore, be situations where doctors can properly justify not following every letter of the guidance. For this reason, we are concerned that the recommendation for the 'GMP Code' to be incorporated into doctors' employment contracts may result in an inappropriately mechanistic application of GMP. Similarly, the recommendation that 'breaches of professional codes' should be treated as 'disciplinary matters' may encourage behaviours more focussed on compliance with rules than patients best interests.

This is not to suggest that doctors need not adhere to the principles of GMP in the way they practise. In 2012 we introduced a system of revalidation through which all licensed doctors are required to demonstrate on a regular basis that they are up to date and fit to practise. Revalidation and the system of doctors' annual appraisal which supports it are structured around the principles of GMP. Failure to participate meaningfully in revalidation would put a doctor's licence to practise at risk. Participation in appraisal is now a contractual requirement and a review published in 2017 showed that the number of doctors being appraised annually is now at 90% or above in four of the five HSC Trusts. In our view, therefore, revalidation provides a more appropriate means of ensuring that doctors follow the principles of GMP than the imposition of employer disciplinary action for any breach.

We would, however, support a statement in contracts that doctors must follow our guidance. This would help to ensure that our core guidance, GMP, and all its explanatory guidance, such as *openness and honesty, and raising and acting on concerns,* is made explicit to doctors.

There are other measures too, that employers could take to reinforce the importance of GMP. Our Welcome to UK Practice Programme is a free half-day workshop to help doctors new to practice, or new to the country, to understand the ethical issues that will affect them and their patients on a day to day basis. We therefore welcome the decision by HR

Directors of the HSC Trusts in Northern Ireland to recommend that all doctors new to practising in Northern Ireland will be recommended to attend one of these sessions within three months of joining the NI HSC service. We are working with HSC Trusts to take this forward. Participation is voluntary but we would welcome employers mandating participation for all doctors who are new to UK practice and making the time available as part of their induction to attend. This would help to embed the importance of GMP as a tool to support good practice rather than simply a stick for employers to punish poor practice.

Trusts should ensure health care data is expertly analysed for patterns of poor performance and issues of patient safety (Recommendation 80)

For several years the GMC has been working to review, clarify and publish the data that we hold about doctors on the register. The State of Medical Education and Practice (SoMEP) annual report, which was first published in 2014, is where we provide current data about the register but also wider themes and issues impacting on patient care. In addition to SoMEP, the GMC has two new data sources that are available to Trusts:

- RO dashboard – provides data to healthcare leaders about their organisation. The systems regulator, RQIA, also has access to this data - for all organisations.
- GMC data explorer – publicly available data on the GMC website - shows data at a country and sector level.

Annex B: Inquiry into Hyponatraemia-Related Deaths: Duty of Candour - GMC submission, April 2019

1 We welcome the opportunity to further participate in this important debate. We are committed to working with the Department of Health and others to implement the recommendations of the Hyponatraemia-Related Deaths Report ('the Report'). The deaths of the children investigated by Justice O'Hara are tragic and complex cases. We recognise how difficult and distressing the deaths continue to be for all the families involved.

2 We very much welcomed the emphasis placed on the importance of the Duty of Candour within Justice O'Hara's report. At the level of institutions, we welcomed a statutory Duty of Candour for organisations as this would bring Northern Ireland into line with England, Wales and Scotland. We endorsed many of the recommendations, particularly recommendation nine which set out that the 'highest priority should be accorded the development and improvement of leadership skills' (recommendation 9). We recognise that it is through strong and effective leadership that organisations will develop a culture in which candour is encouraged and learning from errors is enabled. Our full response to the publication of the Report is attached as Annex A.

3 We remain unconvinced however that a statutory Duty of Candour for individual professionals with criminal sanctions attached is likely to deliver the fundamental changes in attitudes and behaviour in relation to openness and honesty that are needed. Our reasons for this are as follows:

A statutory Duty of Candour on the individual with criminal sanctions attached is unlikely to drive the culture change that's needed to support doctors in being open and honest

4 We know that the cultural environment within which health professionals' work is by far the biggest determinant of quality and patient outcomes. Our Corporate Strategy 2018-20 sets specific aims around strengthening our collaboration with healthcare partners and in particular how we can work with others to create environments where doctors feel confident and supported to raise concerns. We want a positive working environment, where doctors feel encouraged to be candid and raise issues, to be one of the lasting impacts of the work we are undertaking as an organisation. We believe that this approach is consistent with present thinking around human factors and other cognitive and behavioural methods for seeking cultural change in working environments.

5 Feedback from our frontline engagement teams suggest that the following factors continue to present barriers to doctors behaving candidly:

- organisational cultures in the work environment which do not actively encourage and incentivise candour with patients or between professionals
- fear of litigation; continuing perception that apologising is an admission of liability
- lack of communication skills amongst some doctors to know how to effectively deliver the apology
- systems not supporting candour – for example, inadequate support for putting explanations and apologies in writing.

6 This is supported by recently published research commissioned by the Department of Health in England, Senior stakeholder views on policies to foster a culture of openness in the English National Health Service: a qualitative interview study. This found that the wider system still contains 'conflicting signals about the risks and benefits of openness', and widely publicised criminal convictions, along with cases of 'blacklisting' of whistle-blowers, sustained the message that openness was not risk free*.

7 It therefore seems that culture of fear, particularly a fear of the consequences of being candid, is already a strong influencing factor in doctors' decision-making. Our concern is that the introduction of individual criminal sanctions for failures in candour would add to the climate of fear, driving staff to weigh up the perceived personal risks to them of disclosing information (e.g. fear of litigation, or being scapegoated) versus the perceived risks of not doing so (e.g. fear of criminal prosecution). Such a focus on self-protection is a long way from the spirit of openness and honesty and focus on the interests of patients and those close to them, that we seek to encourage through our professional standards.

8 We therefore actively promote and support doctors to exercise their professional Duty of Candour. Some examples are as follows.

- We have published joint Duty of Candour guidance with the Nursing and Midwifery Council in order to support doctors, nurses and midwives to fulfil their duty to be open and honest if they make mistakes. The guidance sets out the standards expected of all doctors, nurses and midwives practising in the UK.
- We include the Duty of Candour under the requirements for professional values and behaviours within our *Generic Professional Capabilities* framework, which seeks to embed common generic outcomes and content across all

* Martin, G et al. Senior stakeholder views on policies to foster a culture of openness in the English National Health Service: a qualitative interview study, Journal of the Royal Society of Medicine, 2018

postgraduate medical curricula. These will need to be embedded in every postgraduate curriculum by 2020. The duty is also included within the *Outcomes for graduates*, which sets out what newly qualified doctors from all medical schools who award UK primary medical qualifications must know and be able to do.

- We require education providers to promote a culture of honesty and openness. In our standards for medical education and training, *Promoting excellence*, we say that, 'Organisations must demonstrate a learning environment and culture that supports learners to be open and honest with patients when things go wrong – known as their professional Duty of Candour – and help them to develop the skills to communicate with tact, sensitivity and empathy' (R1.4).

- We highlight the Duty of Candour in our updated *Guidance on supporting information for appraisal and revalidation*, *Information sharing principles* and our *Governance handbook*. This, and other revalidation guidance, emphasises the importance of transparency and candour in sharing information and decisions as part of appraisal and clinical governance.

- We encourage candour through our engagement with doctors. Our liaison services across the UK deliver workshops on raising concerns which incorporate the Duty of Candour. We have also provided a number of case studies on our website to support doctors in applying the Duty of Candour in practice.

- We proactively highlight our support for candour, insight and remediation. For example, we regularly liaise with the medical defence organisations where we promote the positive way in which we view candour. Where a doctor has been honest in their reflections, has shown insight and has apologised for an error this may result in no regulatory action being taken as there is less likely to be an ongoing risk to public safety.

9 This approach is in-line with those of other regulators, as detailed in the Professional Standards Authority's (PSA) *Telling patients the truth when something goes wrong* (2019). We share the PSA's view that professionals need to 'take candour to heart', and that the encouragement of organisations across healthcare can enable that, making candour a professional strength to be valued, not just a regulatory requirement to be complied with' (para 7.6).

10 There is also likely to be considerable value in addressing continuing misconceptions about risks of litigation arising from openness and honesty when things go wrong. Recent research from NHS Resolution and the Behavioural Insights Team investigated the factors which lead patients to consider a claim for compensation when something goes wrong in their healthcare. The research confirmed that claims for compensation

can sometimes be made in the search of answers, which could have been provided when the incident occurred.*

* NHS Resolution and The Behavioural Insights Team (2018), *Behavioural insights into patient motivation to make a claim for clinical negligence* (accessed 20 March 2019).

Annex C: The Donaldson report, 'The right time - the right place' recommendations (2014) – GMC submission, May 2015

1 The GMC believes that raising concerns is central to protect patients and providing good medical care. Both Good Medical Practice and our guidance on Raising and acting on concerns about patient safety make this duty unambiguously clear.

2 We welcome the proposal for RQIA to review the whistleblowing policy in the HSC service. In February 2015, Sir Robert Francis QC, published Freedom to Speak Out which looked at whistleblowing in the NHS in England. The review highlighted that while there was some good practice of organisations supporting whistle-blowers that many staff continue not to raise concerns because they do not believe they will be listened to or fear for victimisation in their own careers. The recommendations is being taken forward by Department of Health in England and any review in Northern Ireland may benefit from considering the issues considered by Sir Robert.

3 The GMC is aware from our engagement with doctors across the UK that many front-line staff can feel under enormous pressures and that the culture of the institutions in which they work is vital in creating the conditions for openness and honesty.

4 The health service should provide a learning culture where everyone in the healthcare team feeling able to raise concerns.

5 An analysis of complaints received by the GMC from Northern Ireland between 2010 and 2013 indicates that doctors and employers in Northern Ireland are more likely to make referrals to the GMC than in other parts of the UK.

6 From 2010-13, we received 21,097 complaints in total of which 413 came from Northern Ireland. Of the 413 complaints:

- **a** 80 came from a doctor;
- **b** 31 from employer;
- **c** 220 from public;
- **d** 82 sourced as other.

7 In Northern Ireland, the proportion of complaints from doctors (19%) was higher than the UK average (11%), the proportion from employers (7.5%) was higher than the UK average (6.6%) and the proportion of complaints from the public (53%) was lower than the UK average (64%).

8 Our National Trainee survey (NTS), as acknowledged by Sir Liam in his report, also provides insight into the level of patient safety concerns experienced by doctors in training in Northern Ireland. While trainees, like all other doctors, must raise these concerns through local procedures, NTS provides important information for the HSC management, RQIA and the on areas within training programme where concerns exist.

9 The GMC has very clear guidance in this area for doctors. They must raise concerns. Good Medical Practice states in Paragraphs 24-25 that:

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

- You must take prompt action if you think that patient safety, dignity or comfort is or may be seriously compromised;
- 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;
- 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;
- 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.

11 This is supplemented by our specific guidance on Raising and acting on concerns about patient safety which expands on this area and highlights the responsibilities of all doctors as well as the additional responsibilities on those in leadership positions to promote a culture where concerns can be raised, and action is taken where concerns have been raised. This highlights how doctors can overcome perceived obstacles they face and highlights the protection available to whistle-blowers in law, through systems regulators such as the RQIA and support available across the UK from for whistle-blowers through Public Concern at Work.

12 The GMC has also developed a number of tools to support doctors in this areas including our GMC Confidential helpline and an online decision-making tool on raising concerns to support doctors on how and where to raise concerns. We have also published specific guidance for whistle-blowers (www.gmc-uk.org/DC5900_Whistleblowing_guidance___for_publication.pdf_57107304.pdf)

13 As part of a pilot programme of promoting professionalism events in Northern Ireland since June 2014, the GMC has delivered 8 training sessions on our Raising and acting on concerns guidance in partnership with a number of HSC Trusts and the Northern Ireland Medical and Dental Training Agency (NIMDTA). This has enabled us to engage directly with 202 doctors/doctors in training. During that same period we have also distributed 262 copies of Raising and Acting on Concerns guidance. Following a successful evaluation of the pilot, we will continue to deliver these, and other, workshops on our guidance to doctors in the future in partnership with HSC organisations.

14 Our engagement in Northern Ireland (and other part of the UK) suggests that doctors do not know where to turn to and there is a perception that raising a concern could have an impact on their career development or relationships with colleagues and employers. The feedback we receive from our engagement with doctors suggests there could be further progress in this area. Some doctors are not confident they would be supported if they raised a concern, while others need to know where to take their concerns.

15 We believe that the support available to whistle-blowers through RQIA and Public Concern at Work should be promoted further.

16 The GMC will do more in this area. We commissioned Sir Anthony Hooper, a retired Lord Justice of Appeal, to conduct an independent review of how the GMC deals with doctors who raise concerns in the public interest. (www.gmc-uk.org/Hooper_review_final_60267393.pdf)

17 The report, published in March 2015, said that there is evidence that those who raise concerns may suffer, or believe that they suffer, reprisals from their employer or from colleagues. It added that the key to minimising the risk that the GMC unwittingly becomes the instrument of the employer in a campaign against a doctor is an understanding of the background to the allegation. He proposes a series of recommendations for GMC investigations to make sure that such whistle-blowers are treated fairly.

18 The GMC is clear that organisations should not refer a doctor to the GMC on the basis of an allegation which is unjustified, or because that individual has raised concerns about patient safety. Doctors must be able to raise concerns without fear of reprisal.

19 The GMC is currently considering the recommendations of the review and after further discussion with key interest groups will publish an action plan about how we will take them forward.

Serious Adverse Incident (SAI)

20 It is important that any concern relating to a doctor's fitness to practise is raised with the GMC as soon as it is identified. Under our legislation, the GMC has the power to

take action to suspend a doctor's licence to practise if they are a potential risk to patient safety. This means that they cannot take up a post elsewhere in Northern Ireland or anywhere else in the UK. Any such action would also be communicated to other European and international organisations regulating doctors.

21 The GMC's Employer Liaison Service works with local responsible officers (usually medical directors), supporting them to manage doctors where a fitness to practise concern exists or where they have concerns about making recommendations about an individual doctors' revalidation. Evidence from evaluations of our service show complaints referred to GMC via ELAs are more likely to reach our thresholds than those received from other sources.

22 Any revised SAIs system should ensure that any incidents that involve consideration of a doctor's fitness to practise should be raised with the GMC for discussion through our Employer Liaison Adviser for Northern Ireland at the earliest stage. This enables us to give adequate consideration if any further action is required from the regulator in order to protect patient safety.

23 DHSSPS should consider the introduction of risk quality summits or similar to review

24 Incidents involving all key interests including providers, systems regulators and professional regulators including the GMC. The GMC participates in risk summits and Regional Quality Surveillance Groups in other parts of the UK enabling sharing of relevant information between partners.

Annex D: Relevant extracts from our guidance for doctors

Good medical practice (2013)

Paragraph 23

To help keep patients safe you must:

- **a** contribute to confidential inquiries
- **b** contribute to adverse event recognition
- **c** report adverse incidents involving medical devices that put or have the potential to put the safety of a patient, or another person, at risk
- **d** report suspected adverse drug reactions
- **e** respond to requests from organisations monitoring public health.

When providing information for these purposes you should still respect patients' confidentiality.

Paragraph 24

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

Paragraph 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.

Paragraph 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.

Leadership and management for all doctors (2012)

Paragraph 24

Early identification of problems or issues with the performance of individuals, teams or services is essential to help protect patients.

All doctors

Paragraph 25

You must take part in regular reviews and audits of the standards and performance of any team you work in, taking steps to resolve any problems.

Paragraph 26

You should be familiar with, and use, the clinical governance and risk management structures and processes within the organisations you work for or to which you are contracted. You must also follow the procedure where you work for reporting adverse incidents and near misses. This is because routinely identifying adverse incidents or near misses at an early stage, can allow issues to be tackled, problems to be put right and lessons to be learnt.

Paragraph 27

You must follow the guidance in Good medical practice and Raising and acting on concerns about patient safety when you have reason to believe that systems, policies, procedures or colleagues are, or may be, placing patients at risk of harm.

Doctors with extra responsibilities

Paragraph 23

Leading by example, you should promote and encourage a culture that allows all staff to contribute and give constructive feedback on individual and team performance. You should make sure that systems are in place to achieve this.

Paragraph 28

If you have a management role or responsibility, you must make sure that systems are in place to give early warning of any failure, or potential failure, in the clinical performance of individuals or teams. These should include systems for conducting audits and considering patient feedback. You must make sure that any such failure is dealt with quickly and effectively.

Paragraph 29

If you are managing or leading a team, you should make sure that systems, including auditing and benchmarking, are in place to monitor, review and improve the quality of the team's work. You must work with others to collect and share information on patient experience and outcomes. You must make sure that teams you manage are appropriately supported and developed and are clear about their objectives.