

Inquiry into Hyponatraemia-Related Deaths: Duty of Candour - GMC submission

Our role

- 1** 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 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.
- 2** 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.

Our submission

- 3** 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 Hyponatremia-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.
- 4** 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](#).

- 5 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

- 6 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.
- 7 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.
- 8 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*.

- 9** 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.
- 10** 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 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.

* 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

- 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.
- 11** 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).
- 12** 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.*

We deliver proportionate responses to concerns raised with us about a doctor's candour

- 13** If we receive a concern about a doctor's candour, we will investigate.
- 14** The table below outlines how we responded to allegations relating to a lack of candour since 2014 (when the statutory duty of candour upon NHS organisations was introduced in England). There have been 575 cases investigated since 2014 where there has been an allegation relation to duty of candour (Paragraphs 23, 24 and 55 of *Good medical practice* 2013; see [Annex B](#)).
- 15** Of these, 424 cases have been closed following an investigation with no further action. Cases can be closed following an investigation for a number of reasons including insufficient evidence to support the allegations. 88 have been closed

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

following an investigation with advice, a warning or undertakings; and 63 have been referred to hearing.

16 We only hold data about the enquiries we have received involving duty of candour allegations for 2017 and 2018 because this is when we began recording the allegations on receipt of enquiries – a separate table has been provided for this data. 482 enquiries received in 2017-2018 had an allegation related to ‘duty of candour’ attached and of these, 262 (54.36%) were closed at triage. This means that 220 proceeded to an investigation.

Year of receipt of complaint	Cases closed	Cases closed following an Investigation				
	Total	No Further Action	Advice	Warning	Undertaking	Refer to tribunal
2014	145	113	13	1	5	13
2015	151	116	11	2	8	14
2016	116	81	9	2	7	17
2017	93	64	10	2	8	9
2018	69	50	2	2	5	10
Total	575	424	45	10	33	63

Year of receipt of complaint	Total Number of Enquiries	Closed following initial assessment (triage)	Cases subject to an investigation

2017	273	145	128
2018	209	117	92
Total	482	262	220

Note: Enquiries and cases may have multiple allegations, any of which can be closed at any point during the triage/investigation process and may not form part of the reason for any sanction applied to a case.

A statutory duty of candour with criminal sanctions attached would limit doctors' ability to apply professional judgement in handling a particular situation

- 17** If a statutory duty of candour were to be imposed upon the individual healthcare professional, we would strongly suggest that the threshold for its application would need clarification.
- 18** Recommendation 1(i) in the O'Hara report broadly states healthcare professionals must be 'open and honest in **all** their dealings with patients and the public'. However 1(ii) states, 'Where death or serious harm has been or may have been caused to a patient by an act or omission of the organisation or its staff, the patient (or duly authorised representative) should be informed of the incident and given a full and honest explanation of the circumstances'.
- 19** The latter (1.ii) is in line with our [professional guidance on the duty of candour](#) - where we say doctors should be open and honest when things go wrong. However, in some circumstances, patients may not need to know about a near miss that has not caused (and will not cause) them harm. This is a matter for doctors' professional judgement. Recommendation 1(i) as it's currently drafted could limit doctors' professional judgement, and result in actions that are not in the overall interests of the patient.
- 20** Secondly, as discussed in the research paper, *Human Rights and Legal Issues*, provided by the working group, being candid may risk the doctor incriminating themselves if they have been accused of a crime (for example, medical manslaughter). It is outside of our remit to comment upon the complexities of this, however we feel this matter would need further consideration before a statutory duty of candour could be imposed upon individuals.

Conclusion

21 As the Duty of Candour workstream has already observed, there is currently no other jurisdiction which imposes a statutory duty of candour upon the individual, and from which the Department of Health could learn. Given the lack of robust evidence to indicate that imposing this statutory duty upon individuals is an effective way forward, we would advise caution against doing so. This is because, as we have outlined above, there is a risk that the statutory duty with criminal sanctions attached would have an adverse impact upon candour, and contribute to the culture of fear.

Annex A: Our previous submission on this matter

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.

Annex B – Relevant Paragraphs of *Good medical practice*

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 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.