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.

Our role

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.

Doctors’ fitness to practise

The report criticises the conduct of a number of doctors who were responsible for the care of the children or who gave evidence to the Inquiry. We are currently considering whether there are grounds for us to take action against any of those named in the report in relation to their fitness to practise. We have established a dedicated team to take this
work forward. It would not be appropriate to provide further details of individual cases within this response.

It should be noted that 24 of the doctors criticised by Mr Justice O’Hara have so far independently brought this to our notice as they are expected to do under our guidance to the profession, *Good Medical Practice* (paragraph 75). However, even where doctors named in the report have not contacted us we can, and will, consider whether there are grounds for further investigation and action by us where they remain registered with the GMC.

*Doctors who are no longer registered with the GMC*

Only doctors who are registered with the GMC may work as a doctor in the UK. The GMC may only investigate and take action against doctors on the GMC register - we have no powers to investigate or take action in respect of doctors not on the register. Some of the doctors criticised in the Report are no longer registered as doctors with the GMC; we have no powers, therefore, to take action against the registration of these doctors.

However, if any of these doctors were ever to apply to come back on the GMC register, no decision to restore their registration would be taken without first considering whether the criticisms of them in the Report are compatible with their restoration to the register.

In addition, we are mindful that while a doctor may no longer have GMC registration and so no longer be working in the UK, they could be registered to work in a jurisdiction outside the UK. For this reason we are engaging with the regulators of other countries so that they are aware of the Report, and can make their own assessment regarding doctors registered with them.

*Police proceedings*

We understand that the Police Service of Northern Ireland (PSNI) is also considering whether any individuals will be subject to investigation for a potential breach of criminal law. In the event of us being made aware by the PSNI that a doctor is under criminal investigation we would discuss with them whether our fitness to practise processes need to be placed on hold until the criminal process is complete. If we identify a current risk to patient safety, the Medical Practitioner Tribunal Service can take action on a doctor’s registration through our Interim Orders Tribunal.

We will be in contact with PSNI to discuss this further.

*Policy recommendations*

The recommendations in the report are wide ranging and touch upon both detailed operational matters and broader policy issues. We do not wish to comment on every one of the 96 recommendations, though there is much that we would support. In particular:
The emphasis on the importance of the duty of candour for both individuals and organisations;

- The need to prioritise the development and improvement of leadership skills;
- The need for healthcare professionals to raise and act on concerns where the care provided has caused harm;
- The importance of strengthening arrangements for local reporting and investigation of serious adverse incidents;
- The prominence given to our guidance to doctors, *Good Medical Practice*.

This response will focus on those recommendations directly relevant to our regulatory role and we will work with our partners in Northern Ireland on how they should be addressed. We consider these recommendations in the following paragraphs.

*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
opportunities 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.

**Handling conflicts of interest**

We have, in conjunction with eight other health and care regulators, published a statement on handling conflicts of interest. This sets out our expectations for how doctors and other professionals should act in relation to avoiding, declaring and managing actual or potential conflicts of interest. A key message is that health professionals must put the interests of people in their care before their own interests, or those of any colleague, business or organisation.

**Foundation doctors should not be employed in children’s wards (recommendation 13)**

It is clearly vital that doctors in training who are caring for sick children work in an environment, and with the level of support and supervision, that enables them to do so safely as they develop their knowledge and skills. In the years since the tragic events that led to this Inquiry much has changed in the way that medical education and training is organised, managed and quality assured. The GMC has taken over responsibility from PMETB* for setting and overseeing the standards for postgraduate training, a new framework of standards has been put in place, and the mechanisms for monitoring and enforcement have been strengthened. Other developments have also helped put us in a stronger position to identify and act on emerging concerns and protect both patients and doctors. These include the introduction of revalidation, the work of our Regional Liaison Service† and ELS with doctors on the frontline and with employers, and better sharing of data and other intelligence with our regulatory partners.

We are therefore concerned that the recommendation for Foundation trainees to be removed from paediatric wards does not sufficiently acknowledge the systems that are now in place to support safe medical practice within doctors’ education and training and that it risks undermining the general objective of training (as well as increasing the pressure on an already stretched health service).

The Foundation Programme is intended to ensure that doctors in training develop the capabilities and experience to deal with complexity and risk in the healthcare environment. Excluding them from particular environments will make this more difficult. Indeed, failing to prepare Foundation doctors to work in paediatrics will simply shift any perceived risk, and the addressing of knowledge gaps, to later in doctors’ training. It could also impact on

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* The Postgraduate Medical Education and Training Board
† And our national offices in Northern Ireland, Scotland and Wales
Northern Ireland’s ability to attract doctors from other parts of the UK to the Northern Ireland Foundation programme as it could affect their future career choices.

Therefore, rather than denying doctors these training opportunities in the early stages of their careers it is better to ensure that appropriate standards for education and training are in place and that robust arrangements exist to check that those managing and delivering training are meeting those standards. This includes making sure that trainees receive the supervision and support necessary for them to provide safe care within the limits of their capabilities and the requirements of their training programme.

Promoting excellence: standards for medical education and training sets out our requirements for the management and delivery of undergraduate and postgraduate medical education and training. These standards are given force through our Quality Assurance Framework (QAF) and the statutory powers that underpin it. The QAF makes clear what we expect of organisations responsible for managing and delivering training and what they must do to demonstrate they are meeting our standards. Their adherence to our standards is monitored through a suite of quality assurance activities, including (but not limited to) data collection, our National Training Survey (NTS), inspections and enhanced monitoring. Where organisations fail to comply with our standards we have statutory powers to place conditions on, or withdraw approval of, the training provided. By us exercising these powers trainees can, where necessary, be removed from a particular training location until problems are addressed.

As our 2017 National Training Survey data has shown, support and supervision of trainees is an ongoing issue in a health system under pressure. However, it is an issue best addressed in the particular environments where it arises, rather than a general withdrawal of all paediatric training from the Foundation Programme which, in the long run, would benefit neither patients nor trainees.

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 – publically available data on the GMC website - shows data at a country and sector level.
If you wish to discuss any aspect of our response, our named contact is Alan Walker, Head of Northern Ireland Office, (Alan.Walker@gmc-uk.org)