

Independent review of gross negligence manslaughter and culpable homicide

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Foreword

This independent review, commissioned by the General Medical Council (GMC), has its origins in the tragic death of a child and the subsequent conviction for gross negligence manslaughter (GNM) of the senior paediatric trainee involved in his care.

The decision of the GMC to seek this doctor's erasure from the medical register following her criminal conviction caused consternation and outrage across large sections of the medical profession in the United Kingdom (UK) and overseas. Some described it as a 'toxic fear'. Many questioned why an individual trainee working under pressure should carry the blame for what they considered to be wider systemic failings within her working environment. They recognised her situation in their own working lives and felt that 'there but for the grace of God, go I.'

The criminal conviction and the actions of the GMC provided the immediate focus for doctors' fears and sense of injustice, but this was part of a more fundamental loss of confidence in the GMC and in the operation of a fair and just culture in medicine. In the minds of many doctors, the fear begins when things go wrong in the workplace and with the belief that the 'system' is structured to apportion individual blame rather than to learn from events and prevent future harm. It continues through coronial inquests, criminal investigation and the regulatory process which, some doctors feel, does not sufficiently recognise the realities of medical practice. In England and Wales, it is not necessary to be wilfully reckless or intend harm to become the focus of a criminal investigation. This adds to the sense of vulnerability felt by a profession dedicated to caring for its patients. The blame culture can be real enough, but perceptions about vulnerability to criminal investigation are not always well founded. Out of approximately 250,000 licensed doctors in the UK, the number likely to be brought into these processes is extremely small, although any criminal prosecution will come at the end of a much longer chain of investigations which inevitably takes its toll on the individual doctor. But the fact the perceptions exist at all is symptomatic of the embattlement felt by many in the profession. Such an atmosphere does not serve the interests of doctors or, more importantly, their patients.

The healthcare services have woken to the need for just and fair treatment of staff, but the practical application of the principles has so far been patchy, at best. The public also recognises the pressures under which healthcare professionals labour to care for them and that recklessness or deliberate harm are extremely rare and need to be viewed differently from unintended failings. But they also, rightly, expect candour and action when their loved ones have come to harm. Doctors are trusted to care for their patients to the highest possible standards, so bad doctors cannot be shielded. To meet these expectations, personal and system accountability must be balanced with learning and prevention of future harm. But local, coronial, judicial and regulatory processes operate independently and are directed at achieving different goals. Criminal justice and a just culture do not seek the same outcome.

In this report we aim to shine a light on how the system currently operates and how it is seen by those working within it. We make recommendations aimed at the better application of a just and fair culture when things go wrong. Ultimately, that is what is best for patients.



Leslie Hamilton

Chair of the Independent Review of Gross Negligence Manslaughter and Culpable Homicide

Executive summary

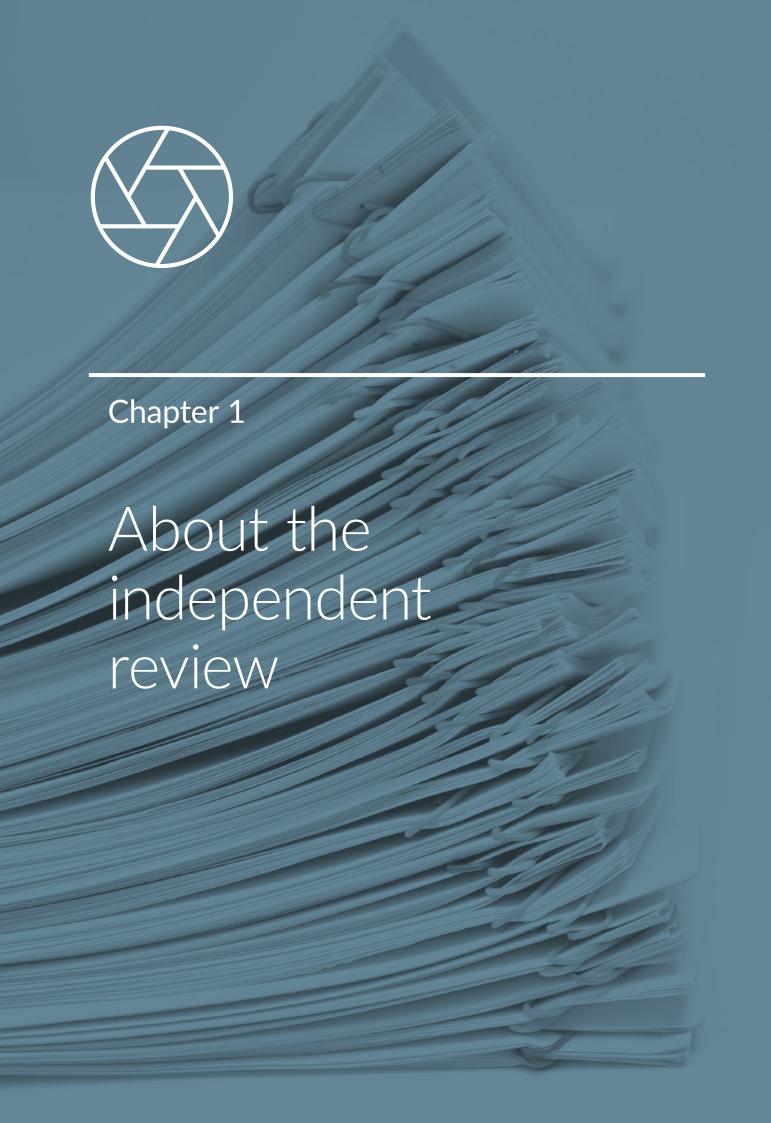
- Over the last year there has been much discussion about the importance of a just and fair culture in medicine and the need to learn, not blame, when things go wrong. Fundamentally, this report is about how to achieve that aim, for the benefit of both patients and the doctors who care for them.
- For some, realising a just culture means changing the law surrounding gross negligence manslaughter (GNM) and culpable homicide (CH). That was not within the remit or competence of this review. Instead, our focus has been on how the systems, procedures and processes surrounding the criminal law and medical regulation are applied in practice and how they can be improved to support a more just and fair culture. In doing so, we have listened carefully to all those who have a part to play. We have heard from doctors and doctors' organisations, patients and their families, patient organisations, lawyers, academics, coroners, healthcare service providers, regulators and many others. We have also examined the approach taken in the different countries of the UK. In Scotland, where the law relating to CH is different from the law on GNM which applies in the rest of the UK, we have not identified any convictions of a doctor for culpable homicide linked to the discharge of their medical duties. Indeed, many of the concerns reported to us do not seem to arise in the Scottish context.
- Although the criminal investigation and prosecution of doctors is extremely rare, the effect of just one case has been palpable and profound across the medical profession. Many doctors feel unfairly vulnerable to criminal and regulatory proceedings should they make a mistake which leads to a patient being harmed. The depth of this feeling has resulted in a breakdown in the relationship between many doctors and their regulator, the GMC. The GMC must take urgent steps to repair that relationship so that it is better able to work with and support doctors in delivering a high standard of care for their patients [Recommendations 1-2].
- But the decisions of a regulator when things go wrong are only the final stage of a complex series of processes which begin with the healthcare service provider and which may stretch over many years. Those processes often do not serve the needs of doctors or patients and their families. Although all four countries of the UK have developed robust frameworks to enable good quality, fair and just investigation of incidents, they are inconsistently applied, poorly understood and inadequately resourced [Recommendations 15-16]. Not only doctors, but also patients and their families can feel unsupported and excluded from these processes [Recommendations 3-4].

^{*} https://improvement.nhs.uk/resources/just-culture-guide/#h2-what-do-we-mean-by-just-culture

- Some groups of doctors feel particularly at risk. Although the statistical data is limited, research evidence points clearly to the increased risk for Black, Asian and Minority Ethnic (BAME) doctors being referred into regulatory proceedings and the dangers of professional isolation and lack of support. This is an issue for healthcare services and regulators alike to address [Recommendations 5-9].
- The vulnerability felt by many doctors reflects their sense of working in healthcare services that are under considerable strain and where individuals trying to do their best for their patients can too easily be blamed for mistakes arising from wider system failures. Although many doctors told us that these pressures were not sufficiently understood by the wider public, the evidence we heard suggests that the public are, in fact, acutely aware of the challenges faced by those caring for them. Even so, healthcare service providers have a responsibility for the environments in which doctors practise and when things go wrong to the extent that a doctor faces criminal investigation, the appropriate external authorities should scrutinise the systems within the department where the doctor worked. This is particularly relevant where the doctor involved is a trainee [Recommendation 10].
- Once an investigation is underway, much reliance will be placed on the opinions of those who are commissioned to provide medical expert evidence about the actions of the doctor or doctors involved. Invariably, it is other doctors who provide these expert opinions. We heard repeated concerns about how those who put themselves forward as experts are selected, how their opinions are calibrated and how their work is quality assured. The weight of concern expressed to us points to a widespread lack of confidence in a system which relies on the confidence placed in experts [Recommendations 11-14].
- The lack of consistency seen in the quality of local healthcare service provider investigations is mirrored in the processes of the coroner service in England and Wales. The local nature of the coroner service, coupled with the rarity of potential GNM cases, means it is difficult for individual coroners to develop experience in handling such cases and knowing when the police should be notified. The Chief Coroner and his Deputies have a role in supporting greater consistency of decision making [Recommendation 17]. These are not issues we encountered when looking at the system in Scotland.
- Doctors appearing at coroners' courts also need better support. Although inquisitorial in nature, the process can feel adversarial and accusatory. Healthcare service providers have a responsibility to provide support and guidance for doctors involved in these processes so that they are better prepared [Recommendation 18].

- 10 The rarity of potential GNM and CH cases is also an issue for the police. The police are under close scrutiny and pressure to investigate fully whenever there are allegations of serious criminal conduct in a healthcare setting. Investigating officers should have early access to independent medical advice to inform their understanding of what is alleged to have taken place. Responsible Officers are well placed to co-ordinate the provision of suitable independent advice for the police in the initial stages of an investigation [Recommendation 19]. This will give the police greater confidence over whether a full investigation is required and families' confidence in the independence of the advice given to the police.
- Lack of confidence in organisations and processes is a theme which pervaded much of the evidence we heard. Sometimes this reflected individuals' perceptions rather than facts; families perceptions that doctors and healthcare service providers wish to conceal the truth of wrong-doing; doctors' perceptions that they are regarded as guilty until proven innocent. Sometimes perceptions can be well founded. At other times they are not. For example, we heard of doctors' belief that the CPS recruits experts who will support the case for prosecution rather than provide a balanced view on the doctor's conduct. Whether or not perceptions are well-founded in fact, they are powerful in influencing behaviours. Greater transparency is needed to aid understanding about how decisions are made and improve confidence in the integrity of key processes [Recommendation 20].
- 12 Doctors' loss of confidence in the GMC was at the heart of this review. Our final suite of recommendations is aimed at helping the GMC to tackle this issue so as to support better and fairer regulation. To that end we have recommended that the GMC examine the processes which contributed to doctors' loss of confidence. We also support the UK Government's plan to remove the GMC's power to appeal decisions of the Medical Practitioners Tribunal Service [Recommendation 21].
- The GMC regulates doctors on behalf of society and has a statutory duty to regulate so as to promote and maintain public confidence in the medical profession. We commissioned independent research to help us better understand public expectations, particularly where a doctor has been convicted of a criminal offence. The results of that research are complex and nuanced, and point both to an understanding of the pressures under which doctors work, but also an expectation of accountability when patients are harmed. There is work for the GMC to do to improve understanding of its role and its responsibility not to punish doctors for past mistakes but to ensure their ongoing fitness to practise. The GMC and Medical Practitioners Tribunal Service must consider how this is reflected in their guidance to tribunals [Recommendations 22-23]. There is also work for the UK Government in bringing forward planned legislative reform that will enable the GMC to take a more proportionate approach to its handling of concerns about doctors' fitness to practise [Recommendations 24-25].

- But even with legislation that is fit for purpose, some of the changes that are needed cannot be delivered by the GMC alone. There is much that doctors can do to help themselves. This includes using the tools that have been developed to help them engage in reflective practice in a way which will support their learning and limit their perceived vulnerability to the misuse of their reflective notes in other proceedings [Recommendation 26]. Doctors' professional bodies, medical defence organisations, healthcare service providers and others should work with the GMC to explore how doctors under investigation can be better supported [Recommendation 27]. Healthcare service providers can do more to provide induction and support for those doctors who are new to medical practice or returning to clinical practice after a significant absence [Recommendation 28].
- 15 The recommendations contained in this report are directed at a number of different organisations. Although these are independent bodies, we hope they will recognise the need for change to enhance public and professional confidence in the processes over which they preside. As the GMC commissioned our review, we also hope that the GMC will monitor the adoption and implementation of our proposals [Recommendation 29].







- The independent review of gross negligence manslaughter and culpable homicide (GNM/CH) was commissioned by the GMC in January 2018. The Chair of the review and the working group that has taken forward the review are independent of the GMC, although the GMC has provided the secretariat. The members of the group were appointed by the Chair for the range of knowledge, experience and perspectives they personally could bring to the issues. They were not selected to represent the views of particular organisations or interest groups. Their task has been to bring a truly independent analysis of the evidence collected during the review and to report their findings. This report sets out their conclusions and recommendations. The members of the working group, and their biographies, are listed on the review webpages.
- 17 The law in Scotland relating to culpable homicide (CH) is different from the law on GNM which applies in the rest of the UK. A separate Scotland task and finish group was therefore set up to advise the main working group on the issues as they applied in the Scottish legal and healthcare context. The members of the task and finish group are listed on the review webpages. Its report to the working group setting out its advice is also on these webpages.

Terms of reference

- 18 Our terms of reference are set out on the review webpages.
- 19 The decision to commission the review followed widespread concern among the medical profession about the treatment of Dr Hadiza Bawa-Garba (a graduate of Leicester medical school and a senior trainee paediatrician) who was convicted of GNM and subsequently erased from the medical register in 2018. The focus of that concern was the GMC's appeal against the Medical Practitioners Tribunal Service (MPTS) decision to suspend rather than erase Dr Bawa-Garba from the medical register. Mid-way through this review, the Court of Appeal overturned the High Court's decision to erase Dr Bawa-Garba from the medical register and reinstated her suspension. Although Dr Bawa-Garba's case provided the catalyst for this review, we have not considered the details or merits of that case or other cases where doctors have been convicted of GNM. Rather, we have examined the broader issues raised by those cases in which serious incidents leading to patient deaths are brought into the criminal and the regulatory arena and the wider system in which they occur.

^{*} A number of steps were taken to ensure the independence of the working group and the review. Working group members were identified and appointed by the review Chair. The written evidence collated by the secretariat to assist the group was reviewed both through sampling by members of the working group and by independent audit. In addition, when drawing up its conclusions and recommendations the working group initially met separately from the secretariat.

[†] Dame Clare Marx was initially appointed to lead the review in January 2018. In July 2018 she was appointed by the Privy Council as the next Chair of the GMC. She immediately stood down as Chair of the review to avoid any conflict of interest. She was succeeded as Chair of the review by Mr Leslie Hamilton who was already a member of the working group.

- 20 Our review had its origins in doctors' concerns about their perceived vulnerability to criminal prosecution for GNM/CH as a result of medical mistakes, and the risk of regulatory action by the GMC. But it was also a review about patients, their families and protecting the public when things have gone wrong. Our terms of reference required us to look at how we understand and maintain public confidence in the doctors to whom patients must entrust their lives.
- Our remit was intentionally wide to investigate all processes which might be engaged following an unexpected death. It included the arrangements for local healthcare service provider investigations following unexpected patient deaths, the coronial process (and, in Scotland, the work of the Crown Office and Procurator Fiscal Service (COPFS)) and the criminal and regulatory proceedings that may follow. We needed to understand how cases are brought into the criminal and regulatory arena, and how this may be affected by the handling of events and treatment of individuals within the healthcare setting in the immediate aftermath of an unexpected death. We recognised that if existing local systems do not work well, there is a risk that the wrong cases may go forward or that cases which should be prosecuted may be missed. That is not in the public interest or in the interests of the medical profession. We also wanted to understand the effect of these traumatic events on the individuals involved, both families and doctors.
- It was not within our remit to propose changes in the law surrounding GNM* or CH, although many of those who provided evidence to our review did express views on the state of the law. Instead, we were asked to look at the application of the existing law and whether there needed to be changes to how it is understood and applied. Nobody believes that doctors should be above the law or immune from regulatory investigation. But, at the same time, the interests of patients and doctors are not best served if doctors fear being unfairly criminalised. A blame culture does not encourage candour when things have gone wrong and is inimical to learning. Our aim, as set out in our terms of reference, has therefore been:

"...to encourage a renewed focus on a fair and just culture, reflective practice, individual and systemic learning (with a view to enhancing patient safety) and the provision of support for doctors in acting on concerns."

To fulfil our terms of reference, we have had to look into matters that fall within the remit of others. Some have been keen to keep our tanks off their lawns. We make no apology for trespassing. But we recognise that we cannot fetter the autonomy of other agencies such as local healthcare service providers, the police, the coroner service and the prosecuting authorities. Nor would we wish to do so. Our aim has been to shine a light

^{*} The Law Commission last reviewed the law surrounding GNM in 1996. See further; Law Commission, Legislating the Criminal Code Involuntary Manslaughter (Law Com No 237, 1996).

on the issues and make recommendations that will help those with the power to deliver change to develop processes and procedures that have the confidence of both the public and the medical profession.

What we did and who we heard from

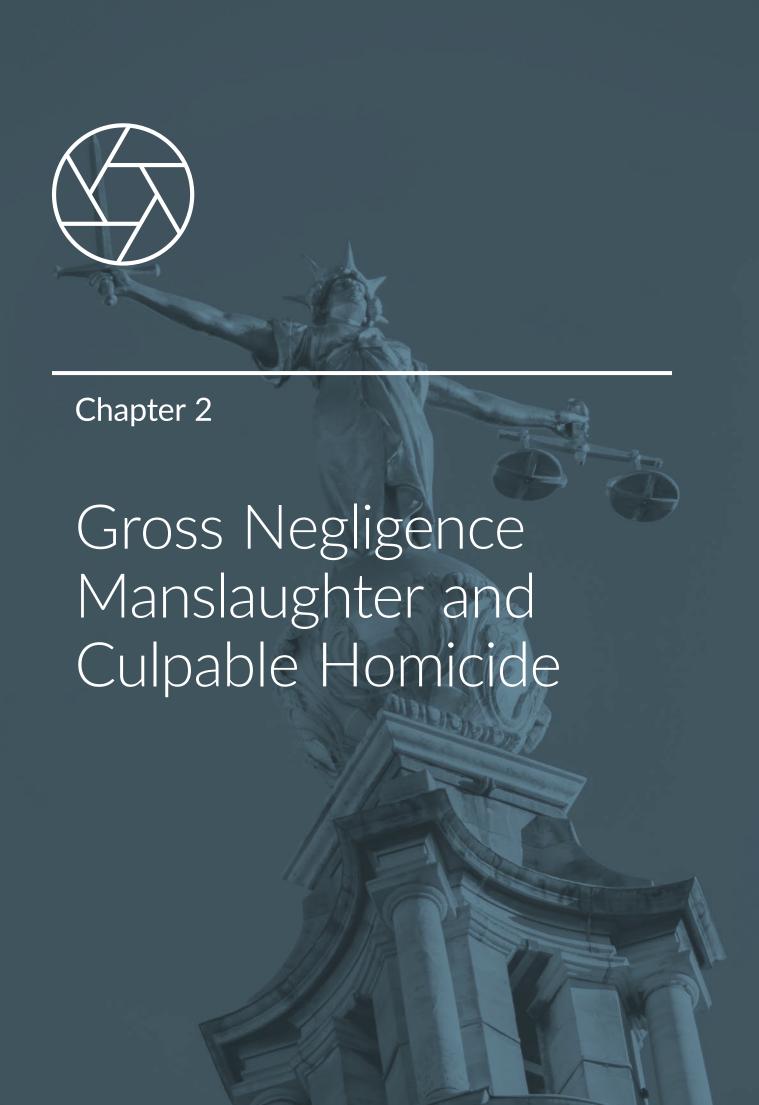
- Our terms of reference defined four broad areas for us to consider: local healthcare service provider processes; investigations undertaken by police, coroner service and COPFS; decisions to prosecute; and the professional regulatory process.
- 25 To inform our understanding of these areas we carried out research, analysis, consultation and engagement with key audiences and diverse stakeholders. This included:
 - A literature review and other desk-based research
 - A call for written evidence. This resulted in approximately 750 responses from a range of individuals and organisations. A summary report of the written submissions received can be found on the review webpages
 - Eight workshops for doctors and other stakeholders across all four countries of the UK (attended by around 250 participants)
 - A separate workshop for patients and their families
 - A roundtable discussion with patient organisations
 - A roundtable discussion with senior members of the legal community which included representatives from prosecution, defence, former judicial office holders and the coroner service
 - 19 oral evidence sessions with organisations and individuals
 - 39 additional one-to-one meetings with stakeholders across the UK
 - Commissioned research into public confidence in the medical profession and how
 this should be understood and applied by the GMC within the regulatory process.
 This research canvassed views from over 2000 members of the public. The final report
 of that research can be found online
- Overall, we have been able to draw on submissions from, among others, families of patients, patient organisations, doctors, doctors' organisations, the police, Crown Prosecution Service (CPS), coroners, COPFS, lawyers who prosecute and defend, medical defence organisations, employers and organisations with responsibility for policing standards in healthcare. A full list of the organisations which contributed to our review is on the review webpages.

- 27 We have also benefited from research commissioned by others. In particular, we are grateful for the insights of Griffiths and Quick* arising from their research into CPS case files 'Managing medical manslaughter cases: improving efficiency and transparency'.† The ongoing research of Professor Roger Kline and Dr Doyin Atewologun into the referral of Black, Asian and Minority Ethnic (BAME) doctors by trusts and boards across the UK to the GMC has also helped to inform our understanding of these issues.
- We also drew on the inquiry and report prepared for the Secretary of State for Health and Social Care by Professor Sir Norman Williams.[‡] We have endeavoured to build on the helpful foundations that report has provided.

^{*} Danielle Griffiths, Lecturer in Law, University of Sussex, and Dr Oliver Quick, Reader in Law, University of Bristol.

[†] The paper is expected to be published shortly and will be found at http://www.bristol.ac.uk/law/research/legal-research-papers/

[‡] Gross negligence manslaughter in healthcare: the report of a rapid policy review June 2018.



Chapter 2: Gross Negligence Manslaughter and Culpable Homicide



- 29 The criminal offence of GNM applies in England, Wales and Northern Ireland. In the medical context, it is sometimes referred to as 'medical manslaughter'. For a doctor to be convicted of GNM, the following elements have to be proven:
 - a The doctor owed a duty of care to the patient
 - **b** The doctor breached that duty of care
 - c The breach caused (or significantly contributed to) the death of the patient; and
 - **d** The breach that caused the death of the patient was 'grossly negligent' and therefore a crime.*
- 30 Conviction for GNM requires there to have been a truly exceptional degree of negligence. In other words, the defendant's breach of their duty of care towards the victim (what they did or didn't do) has to have been 'truly, exceptionally bad'.† That breach of duty of care by the defendant must itself have caused (or have significantly contributed to) the early death of the victim, albeit that there was no intention to cause harm or death. But a mistake, or even a serious mistake, should not amount to GNM, notwithstanding the catastrophic outcome for the victim.

'Mistakes, even very serious mistakes, and errors of judgment, even very serious errors of judgment, will not have themselves sufficed.' (Misra 2005 and confirmed in Oliver 2016)

- 31 GNM does not, however, require proof of wilful recklessness or intentional harm.
- 32 Before the CPS will proceed with a GNM case, it must be satisfied that the case passes both an evidential test and a public interest test. The evidential test involves considering whether it is more likely than not that the prosecution will be successful.
- 33 Although our terms of reference required us to look at how the law of GNM is applied, it was outside our terms of reference to seek a change in the law itself. We have therefore not taken a view on the matter. Nevertheless, it is right to record that many of those who provided evidence to the review thought the law should be changed. They argued that for an act or omission to constitute a criminal offence it should involve either a deliberate act leading to harm or reckless indifference to the consequences of an action.

The jury will have to consider whether the extent to which the defendant's conduct departed from the proper standard of care incumbent upon him, involving as it must have done a risk of death to the patient, was such that it should be judged criminal. It is true that to a certain extent this involves an element of circularity, but in this branch of the law I do not believe that is fatal to its being correct as a test of how far conduct must depart from accepted standards to be characterised as criminal. This is necessarily a question of degree and an attempt to specify that degree more closely is I think likely to achieve only a spurious precision. The essence of the matter which is supremely a jury question is whether having regard to the risk of death involved, the conduct of the defendant was so bad in all the circumstances as to amount in their judgment to a criminal act or omission.'

R v Adomako [1994] UKHL 6, (Lord Mackay of Clashfern LC) at page 7.

[†] R v Sellu [2016] EWCA Crim 1716.

- 34 Professor Alan Merry is one of a number of commentators who has sought to distinguish between genuine errors in medical practice and 'rule violations'.* He argues that criminalising errors is not a deterrent and does nothing to prevent the same errors happening again.
- 35 Other commentators, such as Sir Robert Francis QC and Professor Ian Kennedy have also taken the view that the Iaw on GNM should be changed. In his October 2018 evidence to the Health and Social Care Select Committee, Sir Robert argued that in a case of alleged GNM:

'the jury...are being asked to decide what is or is not a criminal offence. For instance, if a person is charged with theft, it is very easy to work out what the definition of theft is: if you took someone else's property without permission, you did so dishonestly and you intended to keep it. Those are facts we can look at.

If you ask "Is this so serious that it deserves criminal sanction?" you are asking the jury to make the law for a particular case. I would suggest that is a flaw in the law...'

However, we also heard from those who felt that the problem was not wholly with the way the current law is framed; it was also a matter of it not being properly and consistently applied in the early stages of an investigation. Among them, the Medical Defence Union (MDU) said:

'The MDU's view is that the law as it stands today is better than in recent times in terms of providing clarity about how a jury should be properly directed. However, the problem for doctors is not just with the courts but very much with the procedures that precede a decision about prosecution, with such a high proportion of cases being investigated unnecessarily.'

37 This was echoed by other concerns we heard about the application of the law; in particular whether proper understanding and focus is routinely applied to the 'truly, exceptionally, bad' standard which must be present in any proceedings for GNM.

^{*} A Merry, 'How does the law recognise and deal with medical errors?' (2009) JRSM 265.

- 38 At the roundtable discussion we held with senior members of the legal community, the clear consensus was that the law, if properly applied, did not require change. Legal academic Dr Oliver Quick noted that the broadness of the test for GNM is beneficial as it can be applied to all scenarios where a duty of care is owed*. He argued that attention should be paid to the use of experts and how they are instructed. We discuss the role of experts in chapter 4.
- In Scotland, there is no offence of GNM. The closest to it is culpable homicide (CH). In the medical context, this would most likely fall into the category of 'involuntary culpable homicide' where a death occurs as a result of 'lawful conduct' on the part of the accused. What distinguishes CH from GNM is that CH requires the presence of a mental element ('mens rea'). The death may have been caused by an act or conduct in the face of obvious risk which was, or should have been, appreciated and guarded against, but to constitute mens rea there must have been a total indifference to or reckless disregard of the potential dangers and consequences which might result.† Mere carelessness or negligence are not sufficient to constitute mens rea for the purposes of CH. No convictions of a doctor for culpable homicide in Scotland in relation to the discharge of their medical duties have been identified.‡ We noted that in its submission to the Williams review the Medical Protection Society advocated that the law on GNM should be reformed and moved towards the Scottish legal test for culpable homicide.
- We will discuss the role of the prosecuting authorities in more detail in chapter 7 of this report. However, it is important at this stage to say something about the nature and scale of the perceived problem surrounding GNM and CH. Recent cases where doctors have been prosecuted for GNM and faced subsequent action by the GMC have sent shock waves through the medical profession. They have provoked debate in the UK and internationally.§ The anxiety and stress caused among conscientious and caring doctors has been palpable and profound. As one doctor described it in response to our call for evidence:

'I fear making an error every day. I spend much of my time second-guessing and worrying about my clinical decisions. I have nightmares about inadvertently causing patients harm. Often there are too many patients for one person to deal with and things get missed.'

(Anonymous, medical professional)

^{*} As stated in an oral evidence session attended by Danielle Griffiths and Oliver Quick on 13 September 2018.

[†] Cameron v Maguire 1999 JC 63.

[‡] Information provided by the Crown Office and Procurator Fiscal Service.

[§] Ameratunga et al, 'Criminalisation of unintentional error in healthcare in the UK: a perspective from New Zealand' (2019) BMJ 364.

- 41 Such fears are very real for doctors on the frontline. Increasingly, they are caring for frail, older patients with multiple conditions where the treatment of one condition may adversely and sometimes unpredictably affect another. All doctors are treating patients within healthcare systems that are under significant pressure. We have heard repeated reference to doctors resorting to defensive medicine and refusing to engage in learning and reflection following incidents for fear that this could be used in evidence against them. Such an atmosphere is bad for doctors and bad for their patients. That is because it may lead to unnecessary medical interventions carried out so as to avoid risk of criticism; interventions which may not be in the patient's best interests and which also have consequences for NHS resources.
- And yet data demonstrates that the NHS is a very safe place for patients to be treated.*

 Other data also shows that investigation and prosecution of doctors for GNM is extremely rare (around one prosecution a year). Although a number of commentators have reported that prosecutions against doctors have increased and that this is having a detrimental effect on the profession†, the most recent research from Griffiths and Quick shows their continued rarity. Data from their examination of 192 CPS cases for the period January 2007 to March 2018 identified twelve cases where healthcare professionals were charged with GNM (ten of whom were doctors) just 6% of the cases investigated.‡ These figures need to be seen in the context of approximately 250,000 licensed doctors in the UK.
- 43 But these figures cannot diminish the impact of even the small number of cases that have occurred and the perception among doctors that they are unfairly vulnerable to investigation, prosecution and regulatory action. The number of convictions is small but the number of investigations much greater (see chapter 3). In any event, statistics are of no comfort to the individual who is facing the reality of criminal investigation. One doctor who had been the subject of a GNM investigation shared their diary entries from the time:

'I am now crying inconsolably and quite frankly feel like walking under the nearest bus. I seem to spend every waking hour on the phone.

I felt like I was being hunted in a game in which I didn't know the rules – not having control or an understanding is the worst part.'

44 Part of the task of our review has been to understand the factors behind both the perception and the reality of GNM/CH, and make recommendations for how the very real concerns may be addressed.

^{*} In 2014, the <u>Commonwealth Fund</u> declared that in comparison with the healthcare systems of 10 other countries (Australia, Canada, France, Germany, Netherlands, New Zealand, Norway, Sweden, Switzerland and the US) the NHS was rated as the best system in terms of efficiency, effective care, safe care, co-ordinated care, patient-centred care and cost-related problems.

[†] J Vaughan, 'Gross negligence manslaughter and the healthcare professional' (2016) RCS Bulletin 60.

[‡] At the time of finalising our report, the Griffiths and Quick research was awaiting publication.



Chapter 3

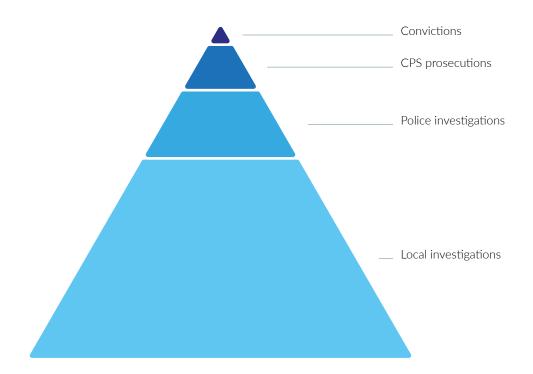
The roots of concern

Chapter 3: The roots of concern



A pyramid effect

45 Although the number of prosecutions and convictions for GNM is extremely small, such cases represent the end of a long process of investigation in a variety of settings. There is a 'pyramid effect' caused by the larger number of local, coronial and criminal investigations which have the potential to culminate in prosecution and conviction.* Too often we have heard of local hospital investigations into unexpected deaths which focus on blame rather than learning and future prevention. More than once we heard of local processes which referred to the 'perpetrator' of an incident. It is not surprising that this lexicon of blame can leave doctors feeling vulnerable when things have gone wrong.



46 That sense of vulnerability is compounded by the knowledge that any investigation can become a criminal investigation in which the police are involved. Although the Griffiths and Quick research identified only ten doctors who were prosecuted between 2007 and 2018, this was out of a total of 192 cases involving healthcare professionals (not just doctors) where there had been CPS involvement following a police investigation.[†] The overall number of police investigations relating to clinical care provided by doctors is unknown. The effect on a doctor of being brought into the criminal arena in such circumstances cannot be overstated. It is worth remembering that investigation and

^{*} The same principle applies to CH, although we know from the COPFS that cases reaching the criminal prosecution stage are rare.

[†] Based on research data from April 2019, unpublished at the time of finalising this report.

- prosecution for GNM in particular does not require there to have been any intention to harm or, indeed, recklessness on the part of the doctor. Yet the response to our call for written evidence and independent research commissioned for this review show a view among the public and the medical profession that these factors are among those that should or could be present for errors to become criminal.
- The concern expressed by many in the medical community over the treatment of Dr Bawa-Garba points to a perception that any mistake could land them in court, or at least in front of the GMC. 'We are all Hadiza Bawa-Garba' announced a headline in the Guardian on 7 February 2018. Some claim that such cases have had a chilling effect on the profession. Commentators such as Dr Jenny Vaughan in the UK, and Professor Alan Merry in New Zealand,* argue that this may lead to individuals being unfairly criminalised in a profession where risks are ever present, that criminalisation prevents learning and may encourage a form of defensive medicine which is not in the interests of patients, doctors or the wider healthcare systems.
- 48 In their responses to the review, many doctors drew attention to the role of the media. We heard frequent reference to 'trial by media' in cases where there had been an unexpected death. Again, these cases add to doctors' sense of vulnerability. However, doctors' perceptions may be at odds with the actual views of the public. Our research suggests that the public exercise a healthy degree of scepticism over the details of reports they read in the press, recognising that these probably do not give the full picture. Extensive media coverage does not necessarily influence the public in the way that doctors imagine. For example, amongst those who took part in the research there was virtually no awareness of the case of Dr Bawa-Garba.

Rebuilding the GMC's relationship with the profession

There was, nevertheless, a strong perception among doctors that it was media headlines that had driven the GMC's decision to seek the removal of Dr Bawa-Garba from the medical register as part of its remit to maintain public confidence in the medical profession. We discuss the regulatory process in detail in chapter 8 of this report, where we also consider public expectations and public confidence. But it is important to acknowledge here the damage done to the GMC's relationship with the medical profession as a result of the case of Dr Bawa-Garba. This report is not about that case, but the wider issues arising from it. And, as we have shown above, the problem begins with what happens locally in the immediate aftermath of an unexpected death and the processes that follow, long before the regulator becomes involved.

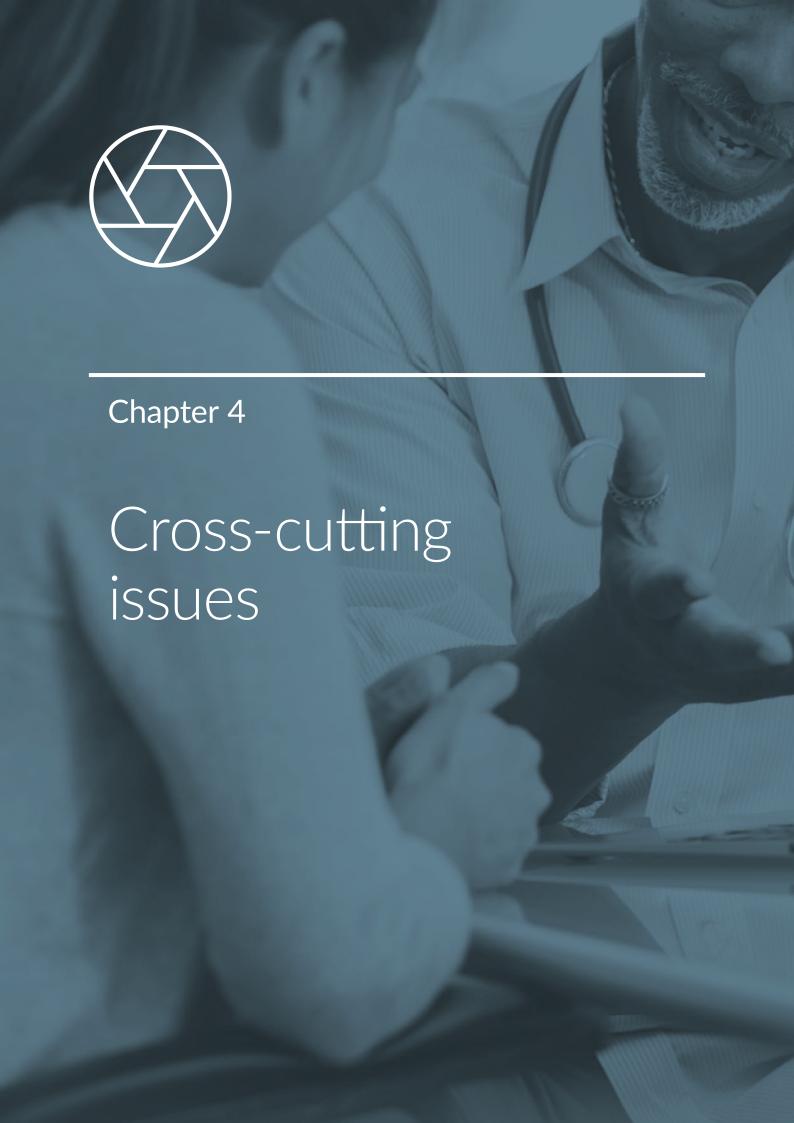
^{*} A Merry, 'How does the law recognise and deal with medical errors?' (2009) JRSM 265.

50 Nevertheless, a breakdown in the relationship between the GMC and the medical profession is of great concern. We recognise that the GMC seeks to work with doctors by supporting them to deliver good medical practice for patients. But it can only do that if doctors feel able to engage constructively with their regulator, confident that its culture and processes will be proportionate, fair and just. The evidence we have heard is very clear that this is not how many doctors currently view the GMC. We commend the steps the GMC is taking to repair its relationship with doctors, for example through its programme of work to support a profession under pressure, but fully learning the lessons of recent events will take time and will need to be accompanied by evidence of change and a degree of humility on the organisation's part:

Recommendation 1: Effective medical regulation is dependent on doctors' confidence in, and constructive engagement with, their regulator. The GMC must acknowledge that its relationship with the medical profession has been severely damaged by recent events and then the GMC must learn from those events in the way it regulates.

Recommendation 2: The GMC must take immediate steps to re-build doctors' trust in its readiness to support them in delivering good medical practice for patients. This should include examining the processes and policies that have contributed to doctors' loss of confidence and considering how it can better support a profession under pressure as well as promoting a fair and just culture.

^{*} https://www.gmc-uk.org/about/how-we-work/corporate-strategy-plans-and-impact/supporting-a-profession-under-pressure



Chapter 4: Cross-cutting issues



Many of the issues discussed in this report relate to particular parts of the process that may lead to a doctor being prosecuted for GNM or CH. For example, the way local hospital investigations are conducted, the proceedings in coroners' courts or the decision making of the CPS or COPFS in Scotland. However, some issues are cross-cutting. For example, the treatment of families following a bereavement, the position of BAME doctors, and issues linked to the use of medical expert evidence in different types of proceedings. This chapter deals with these issues.

The experience of patients and their families

52	This review arose out of the medical profession's concern that doctors are unfairly
	vulnerable to investigation and prosecution for GNM and CH. But it is not possible
	to examine the position of doctors without also considering the vulnerability and
	expectations of patients and their families. As the British Medical Association (BMA)
	noted in its observations to us:

'Families and carers can offer a vital perspective in helping to fully understand what
happened to a patient as they see the whole pathway of care the patient experienced,
which clinicians conducting the investigation may not have seen.'

- Recent years have seen a steady stream of reports highlighting shortcomings in the way that local healthcare service provider investigations are carried out when a patient has come to harm. They have already made recommendations for the way patients and their families are treated following such incidents.* It is not the job of this review to repeat the often excellent work of those reports which focus on learning, candour and accountability when things have gone wrong. But they are relevant to our review because we have heard repeatedly about the failure of local systems to engage effectively and inclusively with families. The principles and frameworks for doing so exist, but implementation is, at best, variable across the countries of the UK.
- This matters in the context of GNM/CH because the longer that families feel they are denied the answers they are seeking, and the more they feel excluded from the investigatory process, the greater their sense that the truth is being concealed from them, and that there has been a cover-up. This came through strongly in our engagement with patients and families who have lost loved ones. In such circumstances, families are more likely to seek answers through legal processes. One bereaved family member we

^{*} See further; National Quality Board, 'National Guidance on Learning from Deaths;
A Framework for NHS Trusts and NHS Foundation Trusts on Identifying, Reporting, Investigating and Learning from Deaths in Care' (2017); CQC, 'Learning Candour and Accountability a review of the way NHS trusts review and investigate the deaths of patients in England (2016); Regulation Quality Improvement Authority, A review of the Handling of Serious Adverse Incidents (SAIs) across the five Health and Social Care Trusts (2015); Professional Standards Authority, 'Candour disclosure and openness; learning from academic research to support advice to the Secretary of State' (2013).

interviewed told us that if the person and the NHS Trust responsible for his son's care had shown insight early on, neither criminal nor regulatory action would have been necessary.* The Right Reverend James Jones described the feelings of families in his foreword to the 2018 report on deaths at the Gosport War Memorial Hospital:†

'The anger is also fuelled by a sense of betrayal. Handing over a loved one to a hospital, to doctors and nurses, is an act of trust and you take for granted that they will always do that which is best for the one you love. It represents a major crisis when you begin to doubt that the treatment they are being given is in their best interests. It further shatters your confidence when you summon up the courage to complain and

.....

This was reinforced by responses to our own call for written evidence:

then sense that you are being treated as some sort of 'troublemaker'.[‡]

'Trusts tend to bring up the drawbridge rather than involve families in the process.' (Anonymous, bereaved family member)

'The initial lack of openness and legalism engenders a mistrust so deep that their conviction of the concealment of wrongdoing can never thereafter be displaced.' (Anonymous, legal professional)

It is, of course, entirely appropriate that where there have been potentially criminal actions by healthcare workers these should be the focus of criminal investigation. Engagement with families should not prevent that. Although we have seen evidence about the low conversion rate of investigations to convictions, we have heard of variation among coroners in referring cases for police investigation, some of which may have little prospect of prosecution for a criminal offence. It should be remembered that the threshold for a GNM conviction is very high. And, as we discuss in chapter 7, we have also heard from the police in England about the difficulties they encounter when trying to decide whether a case merits full investigation. Against that background, effective and early engagement with families may help to avoid those cases being referred into the criminal justice system which have little prospect of prosecution, thus avoiding families having false expectations raised.

^{*} Of course, although the individual's insight would have no bearing on whether their actions were deemed criminal by the courts, it was key to the family's perception of events and their desire to take matters further.

[†] Gosport Inquiry Panel, 'Gosport War Memorial Hospital: The report of the Gosport Independent Panel (June 2018). † ibid vii

[§] The study of CPS case files by Griffiths and Quick showed that just 6% of investigations involving healthcare professionals resulted in prosecutions.

- 57 We believe that effective engagement with families is particularly important in the hours immediately following an unexpected death. Healthcare service providers must have procedures in place for communicating clearly with them about what is happening and what the next steps will be. It is also vital that they ensure there is a named individual who can be contacted should the family need further information or have questions they feel the investigation should address. That channel of communication should continue throughout the investigation and afterwards, to assure families that any learning has been disseminated and recommendations implemented. Those responsible for co-ordinating this communication must have the necessary time, experience and skill to carry out the role required of them. It is not the task of this review to prescribe how that should be done. Others are better placed to do that.
- We also note that the implementation of the medical examiner role in England and Wales* will go some way in ensuring that families are engaged within the first 24 hours. This will give them the opportunity to raise any concerns they might have with the treatment or care their family member received. We hope that there will be an evaluation of the effectiveness of the new system once it has been fully rolled out.
- 59 We also acknowledge that, in Scotland, families can contact the Death Certification Review Service and request an interested person review if they have questions or concerns about the content of a Medical Certificate or Cause of Death.

Recommendation 3: Following an unexpected death, there should be close adherence to the professional and statutory duty of candour to be open and honest with the family of the deceased. They need to be told as fully as possible what has happened, why it happened and be assured that they will be kept involved and informed throughout the investigation.

Recommendation 4: Involvement of, and support for, families and staff is often deficient in the period between and unexpected death and the start of a patient safety investigation. All healthcare service providers should have clear policies and a named lead to ensure consistent implementation of policies in line with the relevant national frameworks.

^{*} In response to a number of public inquiries, most notably the Shipman Inquiry (third report), Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry (vol 2) and the Morecambe Bay Investigation, the Government is reforming the process of death certification in England and Wales. These reforms include the recruitment of medical examiners and medical examiner officers across England and Wales. The role of the medical examiner will be to conduct independent medical scrutiny of cause of death in all non-coronial cases. In October 2017 Lord O'Shaughnessy, Parliamentary Under Secretary of State for Health, announced that a national system of medical examiners will be introduced from April 2019.

Equality, diversity and inclusion issues

- 60 Our terms of reference required us to consider whether some groups of doctors with protected characteristics, in particular BAME doctors, are disproportionately vulnerable to allegations of GNM/CH.
- Recent high-profile cases involving BAME healthcare workers prosecuted for GNM (Dr Hadiza Bawa-Garba, Mr David Sellu and Ms Honey Rose) have fuelled concerns that BAME doctors are more vulnerable to prosecution than other doctors. An analysis of media reports relating to doctors accused of GNM after deaths due to errors in drug treatment or anaesthesia in the UK suggested that between 1970 and 1999 almost three quarters of those accused were from BAME groups.* There is, however, very little hard data to show whether BAME doctors are more vulnerable to investigation and prosecution than other groups. Although a study by Dr Oliver Quick in 2006 suggested this might be the case, a later report by Dr Quick appeared to cast doubt on his earlier findings.† As Professor Sir Norman Williams' review has previously noted, the number of cases is too small to be able to draw statistically meaningful conclusions‡. Better data on the ethnicity of doctors at all stages of the investigative processes would be valuable, though we recognise the challenges of achieving this across the UK.
- 62 Nevertheless, there is good evidence of BAME doctors' vulnerability to complaints and investigation more generally. For example, GMC data shows that BAME doctors are disproportionately represented in the GMC's fitness to practise processes. Successive independent audits of the GMC's fitness to practise processes have found no evidence of racial bias.§ But BAME doctors are referred to the GMC by their employers more frequently and employer referrals are more frequently investigated. The reasons for this are complex. We welcome the research the GMC has commissioned from Roger Kline and Doyin Atewologun to help understanding of the reasons behind this pattern of referrals. Emerging findings from that work highlight a number of interacting factors operating at individual and organisational level. These include an avoidance of difficult conversations about performance which is particularly marked across socio-demographic difference; the exclusion of some doctors from ongoing socialisation support; and unfamiliarity with the unspoken rules of medical practice in the UK. Other emerging findings point to problems where leadership teams are unapproachable and do not model openness and transparency, the existence of blame cultures, and environments where some groups of 'outsiders' experience bias. When things go wrong, these factors can combine so that the

^{*} RE Ferner: 'Medication errors that have led to manslaughter changes,' (2000) BMJ 2000; 1212-1216.

[†] O Quick, 'Prosecuting 'gross' medical negligence: manslaughter, discretion and the Crown Prosecution Service (2006) JLS 421. Quick (2017) Medical manslaughter – time for a rethink? http://journals.sagepub.com/doi/pdf/10.1177/0025817217727363.

[‡] Gross negligence manslaughter in healthcare: the report of a rapid policy review (June 2018) page 43.

[§] General Medical Council, State of medical education and practice (2018) page 129. See further; Plymouth University Peninsula, 'Review of decision making in the General Medical Council's Fitness to Practise procedures' (2014) https://www.gmc-uk.org/-/media/about/review-of-gmc-decision-making-infitness-to-practise-procedurespdf?la=en&hash=C8B5E48CACB63B0D772B445C8FE33564798D880A accessed 16 April 2019.

finger of blame is likely to be pointed at the individual rather than the system and negative stereotypes held about certain groups may reinforce assessments relating to their fitness to practise. Once that stage is reached, the concern relating to a doctor may be sufficiently robust and amplified that, on reaching the GMC, there is little doubt about the need to investigate. We look forward to the publication of the full findings of this work.

- 63 The valuable contribution to the NHS of doctors from BAME backgrounds has been widely acknowledged. So too has the evidence of racial inequalities in the NHS workforce. There are likely to be a range of factors contributing to this. For example, the recruitment of international medical graduates (IMGs) into jobs in unsupported environments with poor induction and development opportunities; prejudice or unconscious bias affecting decisions; lack of a sense of affinity between decision makers and BAME doctors when things go wrong; and isolation and lack of peer support for BAME doctors.
- We heard evidence from the British Association of Physicians of Indian Origin, and others about the importance of support for doctors who are new to UK practice. The same applies to doctors returning to practice after a significant absence. The nature of the support required will depend on the individual but there should, at the very least, be a standard national approach to induction. There should also be recognition of the need for support and pastoral care for an extended period (perhaps up to 12 months) to help with adjustment and integration with the NHS and local communities. The GMC, through its Welcome to UK Practice Programme (WtUKP), already provides a half day course to help new registrants familiarise themselves with some of the challenges and expectations facing doctors in the UK. However, its scope is limited. Attendance at WtUKP is voluntary and although the GMC is attempting to increase participation, the current law means it cannot be mandatory for new registrants. Therefore, we believe that a wider suite of support is needed and, in the meantime, healthcare service providers and others must also play their part as an investment in the quality of their workforce.
- This is not to suggest any correlation between the support provided for overseas doctors and the likelihood of investigation or prosecution for GNM but it may be part of the explanation for their over representation in GMC investigations. Even so, the Roger Kline and Doyin Atewologun research and other evidence does suggest a heightened perception of isolation and vulnerability for BAME groups (many of whom will be overseas doctors) within the systems overall. Better support and guidance when doctors start practice may, in part, help to address this, though it is clearly not the whole answer.

Recommendation 5: The GMC should work with healthcare service providers, national bodies and representatives of overseas doctors to develop a suite of support for doctors new to UK practice. This should include information about cultural and social issues, the structures of the NHS, contracts and organisation of training, induction, appraisal and revalidation, professional development plans and mentoring.

- A sense of relative isolation within the working environment and distrust of the system can be seen in the reported reluctance of BAME doctors to raise concerns when things go wrong. A BMA survey of its members reported that BAME doctors were nearly twice as likely as white doctors to say they would not feel confident about raising concerns. Furthermore, 57% of BAME doctors said they would be afraid they would be blamed or suffer adverse consequences, compared to 48% of white doctors.
- 67 That anxiety, across all groups of doctors, about blame and punishment does not sit well with the professional duty of candour, the responsibility to raise and act on concerns and the need to learn when things have gone wrong. And, as we have seen, it is when patients and their families perceive these behaviours to be absent that they are more likely to seek answers and action through recourse to the law.
- 68 Clearly, these are not just matters for the GMC. But the GMC can use its influence to work with others in helping to tackle the issues.

Recommendation 6: The GMC should work with stakeholders across the healthcare systems to ensure that the importance of an inclusive culture within the workplace, education and training environments is understood.

Recommendation 7: The GMC, in supporting the profession, should ensure it continues to demonstrate a commitment to understanding the experiences and contributions of international doctors practising in the UK and shares the insight with the wider healthcare systems.

Recommendation 8: To ensure confidence in fair decision making, relevant healthcare sector organisations (including the GMC) should have published measures and aspirations for diverse workforce representation in key roles and at all levels involved in decision making.

Recommendation 9: Relevant healthcare sector organisations (including the GMC) should have in place appropriate methods of assurance of fair decision making, including (but not limited to) equality, diversity and inclusion training, unconscious bias training, auditing and monitoring.

The environment of medical practice

System pressures

69 We consistently heard about the impact of system pressures on doctors' ability to provide the standard of care expected of them. Alongside this, we heard of doctors' fears of being blamed and prosecuted for making a mistake. They repeatedly voiced concerns that the public was unaware of these pressures and did not understand the impact on the care they and their families receive. Yet the evidence we heard from the public told a different story. They were sympathetic to doctors working under pressure and quick to link errors

to the effects of long hours, poor communication and under-staffing rather than the inadequacy of individuals. That was confirmed by the research commissioned for this review.

.....

'With regards to system pressures, media coverage (and some personal experience) of issues such as waiting times and understaffing (especially in A&E) meant that they were less confident doctors would be able to provide the best care. They felt that – while doctors would do the best they could – system pressures might force errors... A small minority of participants said that media coverage of some system pressures did make them question care they would receive from doctors in hospitals (especially A&E), but again – they blamed this on the system, not the individual doctor."

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Humans and human factors

70 Catastrophic harm to patients is very rarely the result of an error made by a single individual. Typically, it involves the alignment of a series of weaknesses and failures across a whole system of activity (James Reason's Swiss Cheese model). Blaming an individual for those wider failings is unlikely to encourage candour when things go wrong. Nor does it support learning and prevention of future harm. NHS Improvement's Just Culture Guide, which has been adopted widely in the UK,†‡ recognises that an organisation must treat human error and deliberate harm caused by an individual clinician very differently if lessons are to be learned. This came through clearly in the evidence we received:

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'Very rarely do such events have a single or 'root' cause. Done properly, incident analysis usually reveals a combination of multiple factors. Systems, processes, equipment, resources, organisational culture and normal human fallibility are often interlinked factors in the chain of causation. People working in healthcare generally set out each day to do the very best for their patients, but they work in complex and often challenging circumstances where the functioning of wider systems, processes and the support around them play a crucial role in the overall quality and safety of care they are able to provide. In this context, the issue of accountability can become fraught with difficulty.§'

(James Titcombe)

^{*} Community Research, 'Promoting and maintaining public confidence in the medical profession' (06 June 2019) page 20.

[†] NHS Improvement, 'A just culture guide' 2018.

[‡] Healthcare Improvement Scotland, 'Learning from adverse events through reporting and review: A national framework for Scotland' (July 2018) Appendix 6.

[§] Patient Safety Learning, 'Reflecting on the Bawa-Garba case' https://www.patientsafetylearning.org/blog/reflecting-on-the-bawa-garba-case accessed 4 April 2018.

'Those in the healthcare provider organisation have a responsibility to recognise that any system of work which relies on human infallibility is not a safe system of work... Where a mistake or mistakes have been made by an individual the initial focus should be on the provider organisation investigating whether the individual lacks competence and whether the context in which the task was being carried out (including the task method) was not as safe as reasonably practical.'

(Anonymous, patient or family member of a patient)

71	The problem was highlighted by Sir Ian Kennedy QC, speaking at the Royal College of Surgeons of Edinburgh's triennial conference on 22 March 2018, who said
	'medical manslaughter means that you can pick someone, blame them, and imagine that you've solved the problem. And what you have actually done is exacerbated it."

- Understanding human factors (also known as ergonomics) is increasingly prominent in organisations' thinking about how to manage risk and respond to harm. However, as NHS Providers noted in its comments to the review, the commitment to human factors has 'not in most part been matched with action towards delivery'. One human factors expert who responded to our call for evidence suggested that this was to some extent because staff turnover meant constantly expecting staff to re-learn and embed human factors in their local system. Perhaps, more fundamentally, understanding of human factors was not sufficiently targeted at governance or senior management so that there was no 'trickle down' effect to other parts of the organisation. There were mixed views about the relative merits of human factors over root cause analysis as methodologies for understanding system failure. But there was consensus that there is an essential need for a more professional approach to investigation.
- investigations into serious incidents. But it is equally relevant to investigations in the criminal and regulatory arenas. We recognise that the GMC, for example, has built human factors principles into its frameworks for undergraduate and postgraduate training and is incorporating it into the training of experts and decision makers within its fitness to practise procedures.† We believe that they should also play an important part in the criminal arena where the test for GNM requires consideration of 'all the circumstances' in which the events occurred. In order to take account of 'all the circumstances,' decision makers and those providing expert advice should have an understanding of human factors.

^{*} A Rimmer, 'The role of medical manslaughter must be reconsidered, says leading lawyer' (2018) BMJ 360.

[†] British Medical Journal, 'Will human factors restore faith in the GMC?' (2019) 364.

Systemic failures, corporate accountability and embedding a just culture

Corporate manslaughter charges

- 74 Our terms of reference have required us to consider the lack of corporate manslaughter prosecutions against healthcare service providers.
- 75 We have not found any record of a healthcare service provider being successfully prosecuted for corporate manslaughter. In view of the system pressures many doctors described to us, they wanted to know why individual doctors could be prosecuted for GNM while organisations and those in leadership positions were not held similarly to account.

'More emphasis on Trusts liability / trust should have been charged
with manslaughter.'
(Anonymous, medical professional)

- 76 Our legal advisors on the working group told us that in the context of large healthcare service providers, it is extremely difficult to prove a direct causal link between high level policy decisions and the death of an individual patient so as to secure a corporate manslaughter conviction. Organisations were more likely to face prosecution under health and safety legislation. Similar challenges arise in the Scottish context where the Corporate Homicide Act 2007 sets a very high bar for prosecution.
- 77 The law is, in any event, a blunt instrument in such cases. As some commentators pointed out to us, if blaming individual clinicians is seen as unfair and a barrier to candour and learning, shifting the blame in order to criminalise managers is no better. If we truly wish to learn, not blame, we cannot simply point the finger at a different individual and imagine the problem is solved. We do not, therefore, feel that calling for more prosecutions for corporate manslaughter is the answer. Other investigatory mechanisms may provide a greater opportunity for learning and prevention of future harm. Fatal Accident Inquiries in Scotland provide such opportunities, for example. But in the aftermath of a serious incident leading to an unexpected death, the more immediate learning opportunity must be through properly focussed and just investigation by the healthcare service provider. We discuss this is chapter 5.
- 78 There must, however, be an impetus for corporate accountability and learning.

 Rejecting a blame culture should not mean lack of accountability. In her evidence to the Health and Social Care Select Committee hearing on GNM in November 2018,

 Dr Suzanne Shale said:

"...The thing I really want to emphasise now is that if we move away from blaming individual members of staff inappropriately, which is right, we have to think very carefully about how we hold the system accountable; otherwise it ends up that no one is accountable."

.....

- 79 This is reflected in the National Confidential Enquiry into Patient Outcome and Death, which looked at deaths from sepsis and highlighted that more cases had room for improvement in organisational factors than in clinical care.[†]
- 80 Some of our respondents have called for the regulation of hospital managers. This was a view shared by Sir Robert Francis QC, who led the public inquiry into failings at Mid-Staffordshire NHS Foundation Trust. We are not aware that the UK Government is yet minded to introduce further regulation. However, the recently published Review by Tom Kark QC of the 'Fit and Proper Person Test' for directors of NHS bodies in England has made a number of recommendations aimed at strengthening quality and accountability at senior levels within NHS organisations.[‡]
- Government decisions on the full suite of the Kark recommendations are still awaited. Governments in Northern Ireland, Scotland and Wales may also take a view on these in due course. But, regardless of the outcome, it seems fundamental that where there has been an incident which has resulted in a doctor being charged with GNM or CH, the environment within which the incident occurred should be subject to external scrutiny. This will be particularly important where the doctor concerned is a trainee to ensure that the training environment is safe and supportive for other trainees and their patients. In England, consideration should be given to whether the newly established Healthcare Service Safety Investigation Branch should be part of any scrutiny to help ensure that lessons are learned and disseminated. The governments in Wales, Scotland and Northern Ireland should consider the most appropriate organisations to undertake this task in their countries. The extreme rarity of GNM cases should mean that the resource implications for organisations and external authorities are not significant.

Recommendation 10: Where a doctor is being investigated for gross negligence manslaughter or culpable homicide, the appropriate external authority should scrutinise the systems within the department where the doctor worked. Where the doctor is a trainee, this should include scrutiny of the training and education environment by the bodies responsible for education and training.

^{*} Health and Social Care Committee: 'Oral evidence: Patient safety and gross negligence manslaughter in healthcare (2018) HC 1582 response to question 13.

[†] National Confidential Enquiry into Patient Outcome and Death, 'Just say sepsis! A review of the process of care received by patients with sepsis' (2015).

[‡] Two recommendations have so far been accepted by the Government. We understand that the remaining recommendations are being considered as part of the work on the NHS Long Term Plan.

Balancing accountability and learning

Much of this section of our report has been concerned with personal and corporate accountability and how to embed a just culture. In the wake of the Mid Staffordshire Inquiry Professor Don Berwick wrote of the need to 'abandon blame as a tool and trust the good intentions of the staff'.* Before leaving this theme we wish to note the reflections of one medical respondent to our call for evidence:

'...There is a sense that the medical culture is moving along a path of valuing openness and tolerance of individual error as a vehicle for greater safety through improvements in individual and team functioning. By contrast the legal culture continues at present to maintain a culture of individual culpability as the guardian of safety. The medical culture must reasonably accept that there must at some point be individual accountability, and the legal culture that there is value in learning. The difficulty is that at present the tipping point between both is indistinct. It would be very helpful to reach a point where both cultures subscribe to a shared culture of balanced accountability whereby responsibility continues to be apportioned but there is a greater value placed on the potential for remediation and with it forgiveness of error, even those with major consequences.

The question should be less about what has happened before, and more about how we make things safer in the future. We must censure, remove licences and even convict some individuals, and we must remediate, supervise and support others. Both extremes of response are appropriate in some circumstances; our task is to work out which to use and when. Within this we must consider the impact on the collective of perceived unfairness on an individual and the risk that safety will be compromised by a nervous and defensive workforce just as it may from malpractising individuals.' (Anonymous, medical professional)

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83 In the later chapters of this report we consider how we might address this challenge.

^{*} National Advisory Group on the Safety of Patients in England, 'A promise to learn – a commitment to act Improving the Safety of Patients in England' (2013).

Medical expert evidence

- Where a doctor is facing investigation over clinical matters, the opinions of medical experts regarding the standard of care provided can be pivotal to the outcome of the case. This is true regardless of whether matters are being considered as part of a local healthcare service provider investigation, as part of the coronial or COPFS process, within the criminal arena or as part of the regulatory process.
- 85 Throughout our review, and across the UK, we have heard concerns expressed about the arrangements for obtaining good quality and objective expert medical opinion. These concerns have included the difficulty of finding suitable experts, questions about the genuine expertise of those who put themselves forward for such roles and complaints about their objectivity and familiarity with the reality of practice in the relevant field at the relevant time. Those who gave evidence to us also referred to the readiness of experts to tailor their opinions according to clients' needs, failure to understand their role in the legal process, and the lack of quality assurance of their work. We have noted that Professor Sir Norman Williams' review into GNM in healthcare heard similar concerns. The following is typical of the observations we received about the quality of expert opinion:

'My experience of medical experts, and the credence given to them by the coroner, is variable. I have encountered an expert who wasn't qualified to give a view in the particular case, but who was given credence by the coroner. It doesn't look to me as if there are enough checks in the system to deal with this type of situation.' (Anonymous, medical professional)

- While we have no doubt that there are many well-qualified, capable and conscientious doctors who provide high quality expert opinion, the scale of the concerns voiced to us cannot be ignored. They point to a widespread lack of confidence among doctors in a system that is reliant on the confidence placed in experts. A survey of experts across a wide range of fields (both healthcare and non-healthcare) has confirmed these concerns, even among those acting as experts.*
- 87 Some who gave evidence to us have called for a register or registers of accredited experts to be established by organisations such as the medical royal colleges or the GMC. However, this is not universally supported by those who would need to keep such registers, although some already maintain lists of specialists who are willing to provide expert opinion. In submissions to the review, it was also argued that those seeking expert opinions (such as coroners, prosecuting authorities, regulators and defence organisations) must not be fettered in their choice of experts.

^{*} The Times, 'Bond Solon and the Times Annual Expert Witnesses Survey' (2018).

- The judiciary in all four countries have set out in their respective process rules what is required of experts. The GMC also has well established guidance to doctors about their responsibilities when giving expert opinion. In the absence of a system of accreditation, Sir Norman Williams has recommended that the Academy of Medical Royal Colleges (the Academy) should lead work to promote and deliver high standards and training for healthcare professionals providing expert opinion or appearing as expert witnesses. We fully support that recommendation and welcome the publication of further guidance from the Academy. In this review we have sought solutions which would reinforce the standards expected of those providing expert evidence, while making the pool of available expertise more widely available and accessible.
- 89 One of the difficulties for those seeking and considering expert evidence is to know, in the absence of a common standard, who is expert in the relevant field and how their views sit on the spectrum of possible expert opinion within their specialty. The practice of medicine involves professional judgement and different experts may view a doctor's actions in relation to the same events more or less harshly. This can be particularly acute in coroners' courts where coroners may have access to only one opinion which is not subject to cross examination or other scrutiny from a medical professional.

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[Coroners are] 'Often heavily dependent on reports from the referring hospital, with reluctance to use external expert[s], and often treating the pathologist as the all-purpose expert witness.'

(Anonymous medical professional)

90 The language deployed by experts in giving evidence can also be influential. In the case of Mr Sellu (2016) the Court of Appeal identified concerns arising from the many different forms of expression used by the experts (and advocates) when assessing the standard of care provided by Mr Sellu. A more standardised approach to the structure and lexicon of expert reports may also help to mitigate the potentially distorting effects of exaggerated rhetoric and support a more measured analysis of the care provided.

Recommendation 11: Those providing expert witness reports and evidence should be required:

- To state in a specific section of their report the basis on which they are competent to provide an expert opinion on the matters contained within the report or evidence.
- To state in a specific section of the report where their views fit on the spectrum of possible expert opinion within their specialty.
- To calibrate their reports to indicate whether an individual's conduct was, in all the circumstances, within the standards that could reasonably have been expected, below

the standard expected; far below the standard expected; or whether the individual's conduct was truly, exceptionally bad.* They should also give their reasons for the views reached.

- 91 While these principles are already contained within the relevant court rules and regulatory guidance, we have heard that they are not always followed. The aim, therefore, is to ensure that experts are uniformly and routinely instructed by reference to an agreed standard as set out in the agreed statement of the law (see chapter 7 of this report). They should also express their views using uniform and routine calibration of their views and giving clear reasons for their views.
- We have also considered the currency of expertise and doctors giving opinions even though they have been out of medical practice for many years or were not in clinical practice at the time of the events under consideration. We read about one coroner inquest where the conclusion was quashed because the expert witness had not practised in the relevant field for 15 years.† Those providing expert opinion must have a proper understanding of the realities of medical practice for those being judged. At the same time, we are mindful that the pool of relevant expertise in a particular field may be small (particularly in criminal cases) and it would not help if the practical effect of our recommendations resulted in making access to suitable expertise even harder. We have therefore tried to strike a balance. However, we are clear that when the stakes are so high, the expert must have a proper understanding of the clinical situation.

Recommendation 12: Doctors should only provide expert opinion to the coroner, procurators fiscal, police, CPS, GMC or to the criminal court on matters which occurred while they were in active and relevant clinical practice.

- 93 In his review, Professor Sir Norman Williams recognised the importance of the role of the expert and recommended that colleges and specialty associations should encourage their members to participate in providing expert opinion. We endorse that view and have considered what other steps might be taken to improve access to a pool of suitably qualified experts.
- 94 Within its fitness to practise processes the GMC makes extensive use of expert opinion and has well established criteria and systems for recruiting, appraising and quality assuring the work of the experts it uses. However, these processes are not widely known or understood. Although we are aware of commercial bodies which run training for those wishing to act as experts, the GMC is the only organisation we have seen which operates a systematic means of assuring the quality of its experts. While we understand there will be some scepticism among doctors over GMC processes, it is worthy of mention that

^{*} In Scotland, a different calibration would be needed to reflect the law on CH.

[†] R (on the application of John Duffy v HM Deputy Coroner for Worcestershire & Worcestershire Acute Hospital Trust (Interested Party) [2013] EWHC 1654 (Admin).

early use of expert input in cases referred to the GMC results in 67% of those cases being closed without further investigation.

95 We believe that the GMC's acquired expertise in its use of experts should be available to others. We cannot mandate the use of the GMC system by others, but this may be a valuable resource that they could draw on.

Recommendation 13: The GMC should make transparent its processes for recruitment and quality assurance of those doctors providing expert reports. It should also explore how it can support just decision making in other parts of the system by giving access to its pool of medical experts to the police, procurator fiscals, coroners, defence and prosecutors.

- In its recent consultation on consent, the GMC wrote that 'Exercising judgement means different doctors may come to different conclusions faced with the same situation.' This is equally true for expert medical opinion. Obtaining a second opinion to assist with difficult decisions is very common in medicine. There are also situations where, because of the high-stakes involved, the law considers it necessary to have two concurring medical opinions before a decision is taken. Examples include the detention of a patient under the Mental Health Act, a person's fitness to stand trial, signing cremation certificates and termination of pregnancy. We were told by the COPFS that although there is no legal requirement in Scotland to obtain two expert opinions before pursuing a criminal prosecution against a doctor, in practice this would happen if a case arose. Those in favour of requiring two concordant expert opinions argue that it is unjust that a doctor could be prosecuted and convicted on the basis of one adverse opinion from an expert in their specialty.
- 97 However, the arguments for requiring two expert opinions are finely balanced and some who gave evidence to us took a different view. For patients' families, the fact that there is at least one expert who supports the prosecution's case would point to the need for their concerns to be properly tested before a court or tribunal. Defence organisations may feel the need to obtain a second opinion supportive of their case to balance the views of the prosecution. There are also practical considerations such as cost and availability of suitable experts, though the small number of GNM cases means these issues might not be insurmountable.

^{*} General Medical Council, Decision making and consent supporting patient choices about health and care: Draft guidance for consultation (2018) page 2. https://www.gmc-uk.org/-/media/ethical-guidance/related-pdf-items/consent-draft-guidance/consent-draft-guidance.pdf

This is an area where we cannot mandate what approach independent organisations must take. Working group members feel, however, that in view of the potential seriousness of the outcome, there would be value in exploring the efficacy and cost-effectiveness of having two concurring expert opinions in criminal or regulatory prosecutions. Above all, just as medicine is an evidence-based discipline, we should find out whether a two expert approach in cases involving doctors' clinical competence produces evidence of more reliable outcomes. We therefore recommend that our proposal is tested by the GMC and that other organisations take cognisance of the outcome to inform their own practice.

Recommendation 14: Any decision to bring a misconduct case about clinical competence to the MPTS reliant on expert evidence should require the support of two expert opinions. The GMC should assess the efficacy and cost-effectiveness of using concurring expert opinion from two relevant medical experts to inform its fitness to practise investigations in cases raising questions about clinical competence.



Processes leading up to a criminal investigation

Chapter 5: Processes leading up to a criminal investigation



Local investigations

- What happens in the immediate aftermath of an unexpected death is crucial. We saw in chapter 4 that inadequate local processes and 'Poorly conducted investigations can make a bad situation worse and damage relatives and healthcare professionals.' Yet despite the existence of frameworks and guidance in all four countries of the UK, we heard repeatedly that the quality of investigations carried out is inconsistent and often poor with damaging consequences for the staff involved. We heard similar concerns about the consistency of local processes from our Scotland task and finish group.
- 100 Many doctors associate local investigations with the apportioning of individual blame rather than learning and prevention of future harm. We were told that 'full admission of mistakes and causality is seen as dangerous and likely to result in blame and personal damage to career, reputation and livelihood.' Another anonymous medical professional wrote in their submission that:

'in an adversarial system it is for the doctors, their defence societies and the Litigation Authority to fend off actions if they can. No one can seriously believe this encourages clinicians to admit mistakes.'

(Anonymous medical professional)

101 Poor initial handling of incidents may make it more likely that a case will result in criminal investigation. Although the number of such cases is very small, the lack of confidence in local processes contributes to a more general sense of embattlement in an already hard pressed medical profession. In their evidence to us, doctors overwhelmingly reflected a perceived threat of criminal sanctions or litigation for getting something wrong. At best this creates an atmosphere of mistrust. At worst it gets in the way of good patient care.

'I have been a Consultant surgeon for nearly 19 years and have never been sued. Have I made mistakes? Of course. Am I so good I will never find myself talking to the Police about the death of a patient? Well we shall see how LUCKY I am. I spend my days in the NHS doing one thing - protecting myself. Any sensible doctor does the same. We practice [sic] very defensive medicine and that is VERY expensive.' (Anonymous medical professional)

^{*} Royal College of Pathologists written submission to the review.

Support for staff

102 We have already discussed how local investigations may not meet the needs of patients and their families. The distress of the healthcare team involved must also be recognised. Often the issues for families and staff are the same; exclusion from the process, lack of information about the process to be followed or access to advice about their rights. We heard frequent reference to the phenomenon of the 'second victim' and the perceived lack of support for staff involved in investigations. We heard of instances where this has led to mental breakdown and even the suicide of individuals under investigation. One doctor who had been subject to an investigation stated that they did not feel 'empowered to reply to the allegations presented in the SI [Serious Incident] report'. This doctor reported that they were not interviewed as part of the SI process, and that information about what was happening was provided to them inconsistently. For example, they were only given sight of the relevant expert opinion in a meeting. On the other hand, we also came across examples of good practice, such as instances of where doctors had access to mentors within their trust to support them through an investigation.

The investigators

- **103** Two of the key issues identified in the evidence we received were the composition of the local investigation team and the training of investigators.
- 104 Doctors Association UK (DAUK) wrote of investigators 'seemingly being selected on the basis of whoever is available'. NHS Improvement referred to the lack of consistency in the way investigations were undertaken with 'different approaches in different organisations'. It reported that some organisations have 'dedicated investigators but too often, investigators are clinicians or managers (with other 'day jobs') and who have had limited training in the science and art of investigation' and 'limited time to spend on this task'. Lack of training and lack of time, coupled with lack of dedicated professional resource, led to the view of some Responsible Officers that 'the investigation function usually needs to be re-built every time'. These factors all contribute to delays in what is often seen as a protracted investigation process. By the time it is over, particularly for trainees who may have moved on to another department or hospital, the opportunity for feedback and learning is lost.

- 105 The independence of the investigating team was also seen as key by respondents. 'Because the process is local, there is no getting around the feeling by patients and relatives that the investigation is biased.' There must, however, be proportionality in the way investigators demonstrate their independence. It is not practical or affordable to institute a full external inquiry after every significant incident, but in the case of an unexpected death there is a need for greater externality. As one respondent to our call for written evidence observed: 'There should be external reviews as well, but this can't be kneejerk as this disempowers the trust from owning its problems.' Externality from the department where the incident happened is vital, but as one medical professional noted: 'The people best placed to find a resolution are near-peers, but they must be far enough removed to be impartial and reassure all stakeholders that they are impartial. A nearby trust perhaps.'
- **106** We might compare healthcare with the approach taken in some other industries:

'Investigations in industries such as nuclear power are typically conducted by dedicated in-house teams of professionally trained investigators; routinely incorporate rigorous human factors and systems analysis; are separated entirely from any management processes that seek to allocate blame; and typically produce actions that focus on strong, systemic safety improvements such as redesigning equipment."

- 107 In England, the Healthcare Safety Investigation Branch (HSIB) offers an approach to investigation that brings expertise, independence and a focus on learning and prevention of future harm that is separate from the process for examining individual or corporate accountability. We note that HSIB aims to develop the capability of healthcare organisations in England to improve the quality of their own local investigations.
- investigation of patient safety incidents exist in all four countries of the UK. For example, NHS Improvement's (NHSI) new *Patient Safety Principles for Local Investigations* address all of the issues we have so far highlighted in this report: the need for a just culture focused on learning not blaming, independence of the investigation, staff and family involvement, human factors, organisational governance and accountability. Healthcare Improvement Scotland's *Learning from Adverse Events* also addresses these issues, as does the Health and Social Care Board Northern Ireland in *Procedure for the reporting and follow up of serious adverse incidents* 2016, and NHS Wales in *Putting things right: raising a concern about the NHS in Wales* 2013.

^{*} C Macrae and K Stewart, 'Can we import improvements from industry to healthcare?' (2019) BMJ 364.

109 Bearing in mind the concerns we heard from the profession about the risk of local investigation leading to criminal investigation, we should remember the clear distinction that NHSI's *Just Culture Guide* draws between the way an organisation should respond to error and how it deals with deliberate harm or recklessness. In the case of the former, the focus must be on learning and prevention of future harm to patients. In the case of the latter, disciplinary or criminal proceedings may be appropriate. However, this points to a disconnect between the aims of the just culture ethos and the current state of GNM which does not require recklessness or deliberate harm for the law to be invoked.

Recommendation 15: Improvements in patient safety are most likely to come through local investigations into patient safety incidents which are focused on learning not blame. We strongly endorse recent developments in the frameworks for investigations. These emphasise the need for the investigation team to have the time and the appropriate experience, skills and competence (including understanding of human factors) to undertake investigations, and the necessary degree of externality to command confidence in the process. We also stress the need to involve and support families and staff.

110 As we have also noted, although such frameworks exist, local implementation of national policies is patchy. We therefore recommend that the appropriate authorities in each of the four UK countries take responsibility for ensuring they are consistently and effectively applied.

Recommendation 16: The appropriate authorities in the four UK countries should quality assure the effective application of local investigation frameworks for patient safety incidents.* This external scrutiny should include a specific focus on how healthcare service providers address human factors issues within their investigation processes.

^{*} We acknowledge and support the parallel Williams review recommendation (4.2) for the Care Quality Commission in England.



Chapter 6

Investigations by coroners or procurators fiscal

Chapter 6: Investigations by coroners or procurators fiscal



Role of the coroner and the coroner service

- 111 The role of the coroner in England and Wales is to investigate deaths which are not due to natural causes. If initial investigations do not reveal a natural cause of death (or there are any concerns about the healthcare given to the deceased) an Inquest will be held. The Inquest is a fact finding process and the coroner is required to answer four questions: who the deceased was, and how, when and where they came by their death. It is not the role of the Inquest to determine criminal or civil liability for that death. If the coroner considers that a criminal offence may have been committed they will notify the police and adjourn the Inquest to await the outcome of police enquiries. It should be noted that the only relevant criminal offence relating to a doctor is GNM (which is a high threshold for conviction). There is an offence of wilful neglect but this has only been used in the context of care homes and, by definition, has an element of intent.
- 112 If the coroner considers that the conduct or performance of a doctor raises concern, they should notify the GMC. If, during their investigation, the coroner identifies circumstances which would create a risk of further deaths in the future, they have a duty under Regulation 28 of the Coroners (Investigations) Regulations 2013 to produce a Report to Prevent Future Deaths.
- 113 Northern Ireland has its own coroner service (with, uniquely, a full time Medical Advisor), although the function is broadly the same as in England and Wales.

Crown Office and Procurator Fiscal Service

- **114** In Scotland, the Lord Advocate is the independent head of the prosecution system and has constitutional responsibility for investigating all sudden, suspicious, unexpected and unexplained deaths. This responsibility is exercised on his behalf by the Crown Office and Procurator Fiscal Service (COPFS).
- 115 COPFS is Scotland's sole prosecution service. COPFS receives reports about crimes from the police and other reporting agencies and decides what action to take in the public interest, including whether to prosecute. COPFS also investigates deaths that need further explanation. Within COPFS, the Scottish Fatalities Investigation Unit (SFIU) is a specialist unit responsible for investigating all sudden, suspicious, accidental and unexplained deaths.

Variation between coroner jurisdictions

116 As the fifth annual Report of Chief Coroner to the Lord Chancellor 2017–2018 notes, the coroner service in England and Wales is 'essentially a local service'.' It is funded locally, including the provision of courts and other accommodation and IT systems. Coroners' officers and support staff are employed locally by police and local authorities. In his report, the Chief Coroner has supported calls for a national service, arguing that there is much to be gained in terms of standardisation, consistency and implementation of reform. The report notes:

.....

'the localised nature of the present service produces inevitable inconsistencies between coroner areas. Coroners have to an extent worked in isolation, unsupported by a sound framework and network of coroner resilience. The Chief Corner has continued to work towards greater consistency...'

.....

- 117 In working towards greater consistency, the Chief Coroner's main responsibilities under the Coroners and Justice Act 2009 include providing support, leadership and guidance for coroners and setting national standards for all coroners. Despite this, the anecdotal evidence from respondents to our review has tended to support the Chief Coroner's comments about the variability of the service. We repeatedly heard about coroners adopting their own local policies, including which deaths should be referred to them by doctors. We heard of coroners seeking 'someone to blame' or following an 'inappropriately adversarial model', while a minority of other respondents described a service which was fair, robust and 'works well'.
- **118** Given the extreme rarity of GNM cases in a healthcare setting, this makes the task of achieving consistency among coroners particularly challenging.

GNM guidance for coroners

119 Part of the role of the Chief Coroner is to 'provide support, leadership and guidance for coroners'. The relevant guidance in relation to GNM is the 'Law sheet No. 1' which contains a one page summary of GNM. This law sheet was last updated in January 2016 and it does not make reference to the most recent case law. The inadequacy of the guidance for coroners was picked up by the Williams review which recommended that:

^{*} According to the Chief Coroner Annual Report 2017-2018, England and Wales is divided up into 88 coroner areas (as of June 2018 with further mergers planned to reduce to 75).

[†] The Chief Coroner's Guide to the Coroners and Justice Act 2009.

'The Chief Coroner should consider revising the guidance on gross negligence manslaughter in Law Sheet no 1 in light of the explanatory statement [on GNM] set out by the working group under 1.1 [of the Williams review recommendations]. We expect coroners will routinely consider this guidance in assessing the facts on whether or not a referral for a criminal investigation should be made.'

120 We would go further. In view of the gravity and rarity of GNM cases and the need for consistent decision making and proper use of police resources, any case where a coroner feels that a doctor's conduct might reach the threshold for GNM should be discussed with the Chief Coroner's Office before the police are notified. As the Medical Defence Union argued:

'All cases should be referred through or only after consultation with the Chief Coroner. That would mean someone with comparators and in a senior position is able to filter cases. It has the advantage of establishing consistency, which is plainly not evident at present.'

121 The judicial independence of individual coroners means that the Chief Coroner (or Deputies) would not be expected to 'sign-off' the decision to notify the police, but the Chief Coroner's Office would provide expert guidance consistent with the Chief Coroner's role. The rarity of such cases should mean that the resource implications are minimal.

Recommendation 17: In order to ensure a consistent approach, if a coroner feels that a doctor's conduct might reach the threshold for GNM, they should discuss this with the Chief Coroner's Office before the police are notified.

122 In Scotland, where there have been no convictions for culpable homicide in a medical setting, and where the COPFS carries out the functions performed separately in England and Wales by the coroner and CPS, we heard no evidence of inconsistency. We also received evidence of a generally positive relationship between doctors and the Procurators Fiscal regarding the reporting of cases.

Guidance and support for doctors involved in the coronial process

and

23	this may also reflect a lack of preparedness about what to expect at coroner inquests a lack support before and during an inquest.
	'Healthcare staff worry hugely about their attendance at coroners court as they worry it is the first step towards them being struck off or sent to jail.'
	'Personally I have attended several Coroners hearings and have prepared and given evidence at a greater proportion of these. I observe that there is a lack of familiarity amongst other doctors of how to interact with the Coroner and how they should represent themselves.'
	'In my experience [a trust advocate of approximately 20 years] doctors from all branches of the profession, except pathologists who regularly appear at Inquests, need help to prepare, and require personal support during and after the proceedings. It is always a source of anxiety to be called to give a factual account of one's actions in what is deliberately, a very serious and formal setting. In my view at least it is right and proper that this should be so. However, it was also my experience that many professionals are left to their own devices, and not adequately supported when they do have to go to Court."

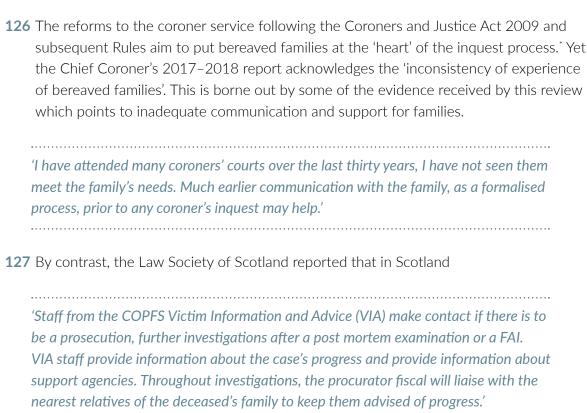
124 Doctors appearing before a coroner's court are not on trial. But, as we have seen, some clearly find the experience adversarial rather than inquisitorial and see it as the first step to possible criminal investigation. It should be the duty of a healthcare service provider to ensure that when its staff are involved in coronial proceedings they are properly prepared and supported. Practice across organisations varies, but there are examples of innovate approaches. For example, the Royal Brompton and Harefield Hospital NHS Foundation Trust employs a doctor full time to deal with medico-legal issues and attend all inquests.

Recommendation 18: Healthcare service providers should provide support and guidance for doctors who are involved in an inquest or fatal accident inquiry so that they have an appropriate understanding of the process and their role in proceedings.

^{*} G Meijer, 'Live And Learn, I dreaded my day in court'(2014). In the comments section, anonymous, retired, 'employing trust's advocate in court for 20 years approximately'. https://www.bma.org.uk/connecting-doctors/b/live-and-learn/posts/justifying-your-decisions accessed 10 July 2018.

Support for the family through the process

125 In chapter 4 of this report we described how, too often, the process of local investigation inadequately involves, supports and communicates with families. That can also be true of the coroner service.



128 Some of the bereaved families who attended our review workshop recounted poor experience and loss of faith in the coroner service, leaving them looking for resolution through other legal channels. It is perhaps not surprising, therefore, that some doctors perceive coroner proceedings as the prelude to civil or criminal action against them.

^{*} Bereaved families at the heart of the coroner system, 24 February 2014, Press statement from the Ministry of Justice. https://www.gov.uk/government/news/bereaved-families-at-the-heart-of-the-coroner-system-accessed 11 July 2017.

Dissemination of learning

129 Any learning from an inquest which is applicable to other trusts should be highlighted via a Prevention of Future Deaths report* – these are published on the Chief Coroner's website and all trust quality improvement departments should be reviewing these regularly. Consideration should be given to whether the functionality of the website could be improved to make information more accessible.

130	But trusts themselves could do more. The evidence we received was mixed. One told t
	In our trust all the outcomes of coroners are sent back to all clinical staff with the rerdict and a small paragraph about the learning.'
131	However in direct contrast, another doctor told us:
a n v	I have given evidence at coroners inquests as a clinician involved in the case, and also as a serious incident investigator. The outcomes of coroners inquests should be shared more robustly with clinical teams, for example, the coroner's office should send a written summary to the hospital for review in clinical governance sessions. In my Trust, we never hear the outcome of coroners inquests unless we have attended personally purselves.'

- 132 It is clearly the role of the trust to disseminate outcomes with clinical teams. We believe that someone from the trust should be at any inquest into the death of a patient which has been subject to an internal investigation.
- 133 In Scotland, our task and finish group expressed concern about the lack of a body to oversee implementation of recommendations arising from Fatal Accident Inquiries (FAI). It also noted that there is no organisation with responsibility to disseminate learning from FAIs to boards across Scotland in order to help prevent the recurrence of issues. The group was of the view that there should be a Scotland-wide approach to consider all learning from FAIs and to aid and promote a prioritised implementation of learning nationally.

^{*} Following the inquest, the coroner can write a report in cases where the evidence suggests that further avoidable deaths could occur and that, in the coroner's opinion, preventative action should be taken. The report will be sent to the person or authority who may have the power to take the appropriate steps to reduce the risk, and they have a mandatory duty to reply within 56 days. These reports, known as Regulation 28 Reports (formerly known as Rule 43), are now routinely published on www. judiciary.gov.uk.

Other issues considered

- 134 In looking at the work of the coroner service, police and prosecuting authorities, we explored several other possibilities aimed at helping just and informed decision making in cases where a doctor's clinical decisions may have contributed to the death of a patient. One suggestion was that where the coroner, police or prosecuting authorities are notified of a case they should, in the first instance, refer the matter to the GMC before any criminal investigation or prosecution is considered. It was argued that as the statutory role of the GMC is to determine a doctor's fitness to practise it had the experience and expertise necessary to assess the doctor's actions and that its decision should, therefore, inform the decisions of those other authorities. Indeed, the Appeal Court in the case of Dr Bawa-Garba highlighted that a specialist adjudicative body, such as the MPTS, usually has greater experience in the field in which it operates than the courts. It was also argued that since the GMC is required to consider cases using the civil standard of proof (beyond reasonable doubt), any case which failed to meet the GMC's threshold for action must, by definition, fail to meet the criminal standard. It was suggested that this might help reduce the high proportion of criminal investigations which do not lead to conviction.
- obstacles to such an approach. Although we would expect the coroner and police to notify the GMC of any case involving a doctor, those authorities have legal duties to investigate which cannot be fettered by the regulator. Furthermore, the GMC and the criminal law need to address fundamentally different questions. Whereas the criminal law is concerned with a doctor's actions (or alleged actions) in the past and whether these amount to a criminal offence, the GMC (and MPTS) is concerned with a doctor's current and future fitness to practise. The two things are related, but must not be conflated. Because they are related it is vital that those conducting criminal and regulatory investigations co-operate, as this will help to reduce duplication of effort, the time taken to reach decisions, and the stress felt by doctors and others involved.
- **136** We have therefore had to look for other solutions. These are covered in the next two chapters of this report.

^{*} If a criminal investigation identifies wider system failures then other relevant authorities, such as the CQC in England, would need to be notified.



Chapter 7

Police investigations and decisions to prosecute

Chapter 7: Police investigations and decisions to prosecute



Application of the law in the medical context

137	As we make clear at the beginning of this report, it is not the task of our review to examine the state of the law on GNM and CH or call for changes to the law. Our concern is with how the law is applied and how it is perceived to be applied by those affected.
138	Although Sir Robert Francis argued in his evidence to the Health and Social Care Select Committee that the law on GNM was 'flawed', he also noted:
	'whatever the law is, it should focus on the surrounding context in which the medical practitioner is working, and there should be an understanding of how those circumstances impact on people's behaviour and their ability to make rational decisions in particular circumstances. In my view, most of the cases go wrong, if they go wrong, because of lack of attention to that.
139	In other words, he saw the problem being as much with the application of the law and the failure to understand all the circumstances in which doctors work, as with the law itself. The need for a realistic understanding of the circumstances of medical practice is a frequently heard refrain, as illustrated by some of the responses we received.
	'GNM cases in healthcare are multi factorial and very complex.' Juries are highly likely to find it difficult to get a clear grasp of all the circumstances given a lack of personal experience of working in healthcare and a potential lack of understanding of system pressures.' (British Medical Association)
	'Medicine is mostly 'statistics' and 'likelihood' not certainty , which the public mostly does not understand, and most of medicine is about balancing completing risks and likelihoods, with insufficient information to do this well.' (Anonymous, medical professional)

^{*} Manslaughter can only be tried in the Crown Court. This means it will be tried by a judge with a jury. In jury trials, the judge bears responsibility for directing the jury as to the relevant law, but the jury decide the facts of the case. A jury can only convict if the prosecution makes them sure of guilt.

'Although no one is above the law, the nature of our profession, where every act from a prescription to a diagnosis or mis- diagnosis, to a minor or major invasive procedure inflicts actual or potential harm to an individual is very different. We are tasked with doing potentially dangerous and fatal things to members of the public on a daily basis, as an integral part of our professional roles unlike any other profession and this must be legally recognised. We incise, operate, insert and inject but then suddenly we are deemed to be assaulting and inflicting grievous harm - but only when it suits...' (Anonymous, medical professional)

140 Part of our task, therefore, has been to examine how the context of medical practice can be better understood when it comes into contact with the criminal law.

Agreed statement on the law

141 Recourse to criminal sanctions should be, and is, extremely rare. Following the recommendations of the Williams review, the CPS in England is leading on work to develop an agreed statement of the existing law on GNM and is also updating its website. We strongly encourage an agreed statement of the law which must include reference to the 'truly, exceptionally bad' standard necessary for GNM. We hope that this will provide clarity and contribute to greater consistency in the way that the police, coroners and expert witnesses approach GNM and how the threshold for prosecution is applied.

Police investigations: training, guidance and support for Senior Investigating Officers

- **142** The Williams review also sought to consolidate police expertise in the investigation of GNM by healthcare professionals through the creation of a virtual specialist unit. This was in recognition of the fact that such cases are so rare that investigating officers are unlikely to have built up knowledge or expertise in this area.
- 143 This was borne out by the feedback to our own review. The Medical Protection Society reported 'an alarming lack of awareness of the specialist issues at play when investigating a death in a medical setting'. It noted that with 43 police forces across England and Wales, each may only deal with a single GNM investigation every few years. The Medical Defence Union was similarly critical of the Senior Investigating Officer (SIO) guidance which, it claimed, 'fails to appropriately explain the law itself and the complexities of gross negligence manslaughter.'

- 144 Our interviews with police representatives were particularly instructive in helping us understand the challenges they face in dealing with such cases. The police are under close scrutiny and pressure to investigate fully whenever there are allegations of serious criminal conduct in a healthcare setting. The threshold for investigation is low. They must establish whether a crime has been committed; would what is alleged have caused the death of the patient and, if so, would it reach the threshold for prosecution for GNM? The complexity of modern healthcare described by other commentators, coupled with the rarity of cases, shows how challenging this can be. Understanding of human factors is no doubt important at this stage as it is in local healthcare service provider investigations. The police will sometimes seek guidance from the CPS. However, they also identified the value of receiving early, independent medical advice to inform their understanding of what is alleged to have taken place. The independence of that advice is important as advice obtained from the healthcare service provider where the death occurred may lack credibility in the eyes of the family.
- 145 We believe that Responsible Officers (RO) would be well placed to co-ordinate the provision of suitable independent advice for the police or COPFS in the initial stages of an investigation into GNM or CH. In England, the appropriate RO would be the High-Level RO for the region. They would help identify a clinician in the relevant specialty, but from a different region to provide the advice. In Scotland, Wales and Northern Ireland the appropriate RO would be from a different trust or health board from the one in which the death occurred. Provision of advice should be part of a doctor's professional duty (and recognised as such by employers) rather than a commercial arrangement which might cause families to question the independence of the advice. The advice obtained would not be a substitute for any separate expert medical opinion that might be required at a later stage of an investigation or prosecution, but it would provide an initial filter and guidance to assist the police. Indeed the clinical advisor should not be involved if the case was investigated further. The bereaved family could be given the opportunity to meet with this independent clinician, especially if the advice was that no further investigation was necessary.
- 146 Since we know from the work of Griffiths and Quick that only 6% of police investigations result in a prosecution for GNM, this should help to ensure police resources are directed appropriately. We also understand from their findings that a number of factors combine to extend the timeline of police investigations including (but not limited to) the complexity of the case, police unfamiliarity with the healthcare context, police resources and prioritisation, the process of gathering evidence and the availability of expert advice. Therefore, an early decision on whether it is necessary to proceed with a full investigation should help to shorten the timeline for investigations, manage the expectations of families

^{*} PSNI told us that although the burden of proof for culpability is high, the threshold for investigation is significantly lower. This level of scrutiny for all those on the front line of public service was, inevitably, uncomfortable for individuals but, they argued, enabled them to justify their actions and be exonerated where unfounded allegations are made.

and reduce unnecessary stress and anxiety for both families and the doctors concerned. The GMC's experience of using early expert input to inform decisions about the need for further investigation within its own fitness to practise procedures shows how valuable such an approach can be. Early expert appraisal of the facts demonstrated that there was no case to proceed further in 67% of cases. This speeds up the resolution of cases and reduces the impact on the doctors and patients involved.

147 The small number of cases across the UK should mean that the resource implications for ROs and those providing medical advice to the police are minimal. We envisage, however, that medical advisors in these cases would need 'just-in-time' training on the law of GNM to guide them in assisting the police. We propose that NHS Improvement should develop a pilot study to explore the practicalities and efficacy of involving High-Level ROs in England in securing suitable advice for the police before such an approach is considered for the rest of the UK.

Recommendation 19: When the police, or procurators fiscal in Scotland, receive notification of an unexpected death they should have early access to appropriate, independent medical advice to help determine whether an investigation is warranted. To assess how best this can be arranged we recommend that a pilot study is taken forward in England to explore the feasibility of involving high-level Responsible Officers in identifying suitable doctors to provide this advice.

Process of decision making and scrutiny

148 The perception of what happens in the investigation of GNM can be as powerful in influencing attitudes and behaviours as what actually happens. A number of individual doctors and organisations responding to our call for written evidence expressed the view that because of media pressure the police and CPS are more likely to pursue a prosecution where the victim is white or vulnerable (a baby, for example). We have seen no convincing evidence that this is the case. We were also told of the perception that the aim of the CPS is to win its case and that it uses medical experts who will give an opinion likely to support that aim. There was a further perception that the CPS does not take sufficient account of 'all the circumstances' affecting a doctor's practice, including human and environmental factors, when making a decision on whether to prosecute. Yet that is certainly not how CPS perceives its role and we received detailed evidence from CPS about its decision making process and use of expert evidence.

149 In the light of some of the adverse perceptions, however, we believe that CPS should consider whether there is more that it could do to enhance the transparency and understanding of its decision making process. This may help to provide some reassurance about how decisions are made. We note, for example, the good practice highlighted in the report of the Lammy Review: An independent review into the treatment of, and outcomes for Black, Asian and Minority Ethnic individuals in the criminal justice system* in relation to CPS transparency, quality assurance and peer review processes.

Recommendation 20: The CPS (England and Wales) should consider what measures it could take to enhance the transparency and understanding of its decision-making process (including how experts are recruited and the use and disclosure of expert evidence) so as to provide reassurance about how decisions are made.

150 Perhaps because of the lack of criminal prosecutions in Scotland we did not hear a similar weight of concern in relation to the Crown Office and Procurator Fiscal Service in Scotland. Some respondents have suggested to us that the Director of Public Prosecutions in England and Wales should sign-off any decision to prosecute a doctor for GNM, thus mirroring the requirement in Scotland for the Lord Advocate to authorise prosecutions for CH.[†] However, in practice both systems involve a process of delegation to senior decision makers so we are not persuaded that such a change would make any practical difference.

^{*} D Lammy, 'Lammy Review: An independent review into the treatment of, and outcomes for Black, Asian and Minority Ethnic individuals in the criminal justice system' (2017) https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/643001/lammy-review-final-report.pdf accessed 5 April 2019.

[†] As the Medical Protection Society stated in their oral evidence session on 21 November 2018.



Chapter 8

The GMC







151 The catalyst for this review was the action of the GMC in appealing against the MPTS decision in the case of Dr Hadiza Bawa-Garba. As this report has shown, the actions of the regulator in response to a GNM conviction come at the end of a long line of local, coronial, criminal and judicial investigation, often stretching over many years. This stepwise process, involving the COPFS rather than the coroner service, would equally apply to a doctor found guilty of CH in Scotland. While it is important to recognise that failures can happen at any point in the process, it is the actions of the GMC that have caused most concern among the medical profession and damaged confidence in the GMC's ability to work with doctors for the benefit of patients. Elsewhere in this report we have identified a number of areas where the GMC could use its influence to contribute to improvements in the system overall. This chapter focuses on the GMC's own processes. We will begin with the matter of appeals and public confidence in the medical profession as it was the maintenance of public confidence in doctors that was the basis of the GMC's appeal in the case of Dr Bawa-Garba.

Regulator appeals

- 152 Section 40A of the Medical Act 1983 gives the GMC a right to appeal decisions of the MPTS where it considers the decision is 'not sufficient to protect the public'. In considering this issue the GMC must have regard to whether the decision is sufficient to protect the health, safety and wellbeing of the public; the need to maintain public confidence in the medical profession; and maintain proper professional standards and conduct for members of the profession.
- 153 The Williams review examined the background to the GMC's right of appeal and how it had been used. It concluded that the Medical Act should be amended to remove the GMC's powers to appeal MPTS decisions. There is no need to rehearse the detail of that work in our report. We support the Williams review's recommendation and note, once again, the importance of perceptions in this area. To regulate effectively the GMC (like any regulator) must command the confidence of those it regulates and the current state of mistrust is hampering its ability to do so. We note that the UK Government has accepted the recommendation and intends to bring forward the necessary legislative changes at the earliest opportunity. We understand that the GMC has acknowledged that it will lose its current right of appeal and will not argue for its retention.
- 154 Williams further recommended that pending a change in the law the GMC should review its processes for deciding when to appeal a decision of the MPTS so that they are transparent and understood by all parties. Again, we support the Williams recommendation. We note that some commentators have called for a pause on GMC appeals until the law is changed, but we appreciate that the GMC cannot lawfully disregard or delegate the powers and responsibilities given to it by Parliament. It must

- await a change in the law, although we also note that the GMC has not exercised its right of appeal in any case since the case of Dr Bawa-Garba.
- 155 We have been told that the GMC has, though, taken steps to change its processes for deciding when to appeal. Decisions to appeal will now be taken by a panel comprising the Registrar of the GMC, the Medical Director and Director of Standards and Education, and the Director of Fitness to Practise. We understand that the panel will consult with the Professional Standards Authority before taking a decision to appeal and panel decisions will be published to aid transparency.* We welcome the steps that have been taken.

Recommendation 21: We agree with the Williams review recommendation (at 6.1) to remove the GMC's right to appeal Medical Practitioners Tribunal Service (MPTS) decisions as an important step towards rebuilding the profession's relationship with its regulator. We urge the Government to introduce the legislative reform necessary to achieve this without delay. We commend the GMC's recent steps to review and reform its processes for decisions to appeal in the meantime.

Public confidence in the medical profession

- 156 One of the GMC's statutory objectives is to promote and maintain public confidence in the medical profession.† Our terms of reference required us to explore the 'meaning, appropriateness and measurement of public confidence as an objective of the regulatory process'. This would include understanding patient and public expectations of regulatory processes after a doctor has been convicted of a criminal offence.
- 157 Some, such as the BMA, expressed concern that the public confidence criteria could lead to 'trial by media'. It was the view of a number of doctors who responded to our call for evidence, stating that GMC fitness to practise action was too often driven by a desire to appease the press. One doctor wrote to us of the GMC 'mak[ing] examples of doctors to satisfy the mob/media'. We noted with interest the media coverage of two different cases; the first where the GMC was criticised for its supposed leniency towards a GP following the death of a child; the second where it was criticised for what was perceived to be the harshness of its actions. In fact, the way in which public confidence should be understood by the regulator is set out in the final judgement of the Dr Bawa-Garba case where it refers to a 'fully informed and reasonable member of the public' and 'ordinary, intelligent citizens who appreciate the seriousness of the sanction, as well as other issues involved in the case'.[‡]

^{*} Letter from Charlie Massey to Sarah Wollaston MP (20 December 2018). https://www.gmc-uk.org/-/media/documents/gmc-letter-to-sarah-wollaston-mp---20-dec-2018---final.pdf accessed 5 April 2019.

[†] The over-arching objective of the General Council in exercising their functions is the protection of the public. The pursuit by the General Council of their over-arching objective involves the pursuit of the following objectives: (a) to protect, promote and maintain the health, safety and well-being of the public, (b) to promote and maintain public confidence in the medical profession, and (c) to promote and maintain proper professional standards and conduct for members of that profession.

[†] https://www.judiciary.uk/wp-content/uploads/2018/08/bawa-garba-v-gmc-final-judgment.pdf

- 158 To understand these issues better, we commissioned independent research to explore with members of the public how they would expect the GMC to respond to specific behaviours, acts and omissions by doctors. We were particularly interested in how such actions were perceived when criminal sanctions against a doctor are involved. The full research report can be read online. In the following paragraphs we consider some of the key findings and implications for the GMC. What is immediately clear is that the issues are complex and nuanced, both for the public and the regulator.
- 159 As might be expected, the research showed high-levels of public confidence in doctors, with 87% agreeing or strongly agreeing that 'the majority of doctors can be trusted to do a good job'. However, knowledge of how doctors are regulated was low. While 74% had heard of the GMC prior to participating in the research, only 14% felt they 'already knew quite a lot' about its role.
- 160 The qualitative elements of the research highlighted that individual cases of wrong doing by doctors were generally regarded as 'one-offs' and had little impact on confidence in the medical profession overall. There was awareness of some notorious, historic cases, such as that of Dr Harold Shipman, but only three participants recalled (after some prompting) the case of Dr Bawa-Garba. None remembered her name. Participants were more likely to recall media stories about system pressures in the NHS and local cases of misdiagnosis. Overall, this does not point to a public whose confidence in the medical profession has been poisoned by media stories.

Clinical error and the criminal law

161 The most fundamental issue raised by respondents to this review was whether it is appropriate for errors by doctors, even truly, exceptionally bad errors that would therefore meet the threshold for GNM, to be subject to the criminal law. The researchers asked the public what would turn an error by a doctor into a criminal act. For most members of the public there were two elements; the act and its consequences. It was not enough for there to have been a mistake. The doctor's actions must have been intentional or reckless and the outcome for the patient resulted in lasting harm or death. Any attempt by a doctor to cover up, falsify or blame others for clinical errors also implied criminality. This was the very clear view of many of those who took part in our review through our call for written evidence or by taking part in workshops.

Clinical error and medical regulation

- 162 The research indicates that, patient outcomes being equal, the public generally responded less severely to a series of clinical errors set in a wider context (including mention of the doctor being very busy) than they did to a one-off clinical error made by a doctor in a position of authority. But the consequences of the error for the patient were the single most important factor in shaping the public view. The proportion of respondents who said that the GMC should erase or suspend a doctor involved in a one-off clinical error rose from 19% to 67% when they were told that the error led to the patient's death.
- 163 This difficulty in disentangling action from outcome presents challenges for regulator and public alike. As the courts have established, the purpose of the fitness to practise process is essentially forward looking. It seeks to determine whether a doctor is fit to continue practising medicine. The focus is not on punishing a doctor for past actions, though it will inevitably feel like that to the doctor whose registration is at stake. But the research suggests the public may view matters differently; serious errors which do not result in harm may be viewed more leniently than more minor failings that have catastrophic consequences. This does not sit comfortably with an emphasis on learning not blaming and the need for the GMC and MPTS to be concerned with the risk of future harm to patients and the public. These tensions point to a need for greater dialogue between regulators and the public about the role of regulation, public expectations and the realities of medical practice.

Recommendation 22: The GMC should work with the public and patient organisations to support better understanding of its role in regulating the medical profession within a system under pressure. The GMC must demonstrate how that understanding has shaped, and continues to shape, its policies.

- 164 Despite the apparently harsher view taken by the public where an error results in a patient's death, this does not mean they expect the doctor to be automatically erased from the GMC register. Reasons for preferring a lesser sanction included; lack of malicious intent; because mistakes are seen as a natural part of learning; a recognition that medicine is a high-stakes profession, and where system pressures were a factor in what has happened.
- 165 But the existence of a criminal conviction hardened public views. Where a doctor had been convicted of GNM or CH, well over half of respondents thought the doctor should be erased from the register. Presented with scenarios involving a series of clinical errors committed against a backdrop of system issues resulting in a conviction for GNM, 62% of the sample in England, Wales and Northern Ireland felt that a doctor should be erased. But even here there were shades of opinion. A GNM conviction carrying a suspended sentence could be viewed more leniently because, in the words of one respondent, 'If the sentence was suspended then there would be mitigating factors which led to what happened.'

- 166 Overall, the research paints a picture of subtlety, and sometimes inconsistency, in the public view of medical error, wrong-doing and criminal conviction. The research shows that public confidence is primarily maintained by patients' interactions with their doctors. So part of the GMC's duty in fulfilling its statutory objectives must be to support doctors to perform at the top of their capabilities.
- 167 But public expectations are not always what might be expected. In our opinion, the role of the GMC and the MPTS is not to react to the public mood of the moment (insofar as that can even be understood). Nevertheless, they must be cognisant of public expectations in the way they calibrate their regulatory sanctions if they are to maintain confidence in the profession. This must be reflected in the fitness to practise sanctions guidance produced by the GMC and the MPTS to provide the framework for the way decisions are made.

Recommendation 23: The GMC and MPTS should review the Interim Orders Tribunal and Medical Practitioners Tribunal Guidance to ensure that the guidance takes proper account of the findings of the research commissioned by this review regarding the maintenance of public confidence in the medical profession. This should include consideration of the appropriate handling of cases involving clinical incidents, including those that result in a criminal conviction such as GNM.

168 The GMC and MPTS should continue to ensure that full data on the outcomes of all stages of the fitness to practise process and the sanctions imposed is publicly available.

Timeliness and reform

- 169 Our call for evidence produced repeated complaints from doctors about the time taken to deal with fitness to practise cases. One wrote that 'my mental health was in jeopardy for some 6 months due to the FTP proceedings which dragged out afterwards'. Another said that it took 12 months to conclude the investigation and they only heard from the GMC at the beginning and end of the investigation. We have been advised that the GMC aims to conclude 90% of its investigations in 6 months. Where a case proceeds to a hearing, the target is to conclude 90% of cases in 12 months. Even with effective case management processes designed to ensure the efficient progress of cases, the mental, emotional and professional toll on doctors' lives while they are within the GMC's fitness to practise processes cannot be overstated.
- 170 However, there are statutory requirements within the fitness to practise process which affect how quickly an investigation can proceed. These requirements exist to ensure fairness for all parties. For example, doctors must be given time to respond to allegations against them.

- 171 Often there are also external factors which affect timescales. For example, where the police are involved and there is a criminal prosecution the regulatory process must not contaminate or usurp the criminal investigation. While there are obstacles to joint investigations, we have been told that the GMC liaises closely with the police where there are parallel criminal and regulatory investigations. This enables the GMC to proceed with those aspects of its investigation which do not hinder the criminal investigation. We are also aware that there are escalation protocols in place to prevent the GMC's investigation from stalling where there is police involvement.
- 172 Like other professional regulators in healthcare, the GMC's performance in managing its fitness to practise processes is subject to external scrutiny by the Professional Standards Authority. Both the GMC and MPTS are also required to report annually to Parliament. Nonetheless, the GMC must, in any event, continue to focus on improving the targets for the timely resolution of cases. It must also ensure regular communication with doctors and their representatives, patients and families, so that they remain informed about progress.

Recommendation 24: The GMC should strive to reduce the timescales for progressing fitness to practise cases to Medical Practitioner Tribunals. Where a case does not progress within target timescales, it should be subject to senior level review within the GMC.

- 173 We believe that the GMC's capacity to improve its fitness to practise processes in ways which might reduce the impact on doctors is currently constrained by outdated and inflexible legislation. For example, the legislation is framed so as to require the GMC to initiate an investigation* when it receives an allegation about a doctor's fitness to practise. The lack of discretion not to investigate contributes to around 6000 investigations a year† which ultimately result in no action. This is not just a waste of resources which could be better directed elsewhere, the adverse effects of the investigation on the exonerated doctor can be profound and for patients' or their relatives' expectations may have been falsely raised. We hope that the intended reform of the legislation surrounding the regulation of healthcare professions will allow the GMC to reduce the number of unnecessary investigations it is currently required to undertake.
- 174 In fitness to practise cases where some action is required, we think more could be done to reduce the adversarial nature of the proceedings. The GMC currently has some limited powers to resolve cases consensually where the facts and proposed sanction against a doctor are agreed. This achieves the goal of protecting the public, without the need for a public hearing which may prove stressful for the complainant and doctor alike. Such hearings should only be necessary where the facts and outcome are contested. We

^{*} Section 35C of the Medical Act 1983 provides that the GMC 'shall investigate [an] allegation' and decide whether it should be considered by a Medical Practitioners Tribunal.

[†] Based on 2016 figures.

- understand that the GMC is seeking to extend its powers for consensual disposal to those cases which might require the suspension or removal of a doctor's name from the register and we would support this.
- 175 The need for legislative reform has been acknowledged by successive governments for at least the last 6 years, without any practical progress being achieved. In 2017, the Department of Health in England consulted on proposals for the reform of professional regulation. The results are still awaited.

Recommendation 25: The UK Government has signalled its intention to reform the legislation surrounding healthcare professionals' regulation, including fitness to practise. We urge the Government to bring forward legislative reform at the earliest opportunity to give GMC greater discretion to determine which cases are appropriate for investigation and greater scope for disposing of fitness to practise cases efficiently and consensually.

176 On the subject of legislative reform, there is one other matter requiring clarification. We received a number of comments that the GMC was seeking a change to the Medical Act that would introduce automatic erasure from the register for doctors convicted for gross negligence manslaughter.* We have been advised by the GMC that while it supports a presumption of erasure for certain crimes which are incompatible with being a doctor, such as murder, rape and sexual abuse, it specifically does not wish to include GNM and CH within that category.

Reflective practice

- 177 The GMC has stated that reflection is 'central to learning and to safe practice and fundamental to medical professionalism'.[†] Nevertheless, in the wake of the Dr Bawa-Garba case many doctors reported unwillingness to engage in reflection for fear that their written reflections may be used against them in court or in regulatory proceedings.
- 178 Although the GMC has stated that it will never ask for doctors' reflective records as part of its fitness to practise processes and we note that it did not do so in the case of Dr Bawa-Garba its relationship with the medical profession has become so damaged that many doctors simply do not believe these assurances. One respondent to our call for written evidence wrote that the GMC 'should make no further comment on the subject at all' while another wrote that 'GMC assurances aren't believable'.
- 179 We understand that reflective records are opinion, not facts, and therefore likely to be of little evidential value in any proceedings. Prosecutors nevertheless argue that they should not be prevented from accessing any document which might be relevant as criminal evidence. Regardless of the GMC's position, therefore, doctors' recorded reflections are

^{*} For example, GNM Review Workshop Northern Ireland September 2018.

[†] General Medical Council, 'Williams Review into gross negligence manslaughter in healthcare – GMC written submission' (2018).

not subject to legal privilege and the GMC does not control the conduct of the courts. We note that the Williams review supported the status quo in respect of the criminal law but recommended that the Medical Act be amended to prevent the GMC seeking reflective material.* We are aware that the GMC has categorically stated that it will never seek reflective material and would support this position.

180 In September 2018, the GMC, Medical Schools Council, the Conference of Postgraduate Medical Deans (CoPMeD) and the Academy of Medical Royal Colleges jointly published new guidance intended to support doctors in being reflective practitioners.[†] To accompany this, the Academy and COPMeD have published a reflective practice toolkit to support the practical application of the guidance. Further learning materials are planned for medical students and educators as well as a range of case studies to help doctors apply the guidance.[‡] It is our view that by following this guidance doctors will be less vulnerable to having their reflective notes used in court or other proceedings. However, we would go further. The UK Parliament and the devolved governments should consider how doctors' reflections should be given legal protection, as this is the only way to ensure that doctors will reflect on incidents in a totally open and honest way. This is in no way intended to assist suppression of the truth or absolve doctors from their duty of candour, but simply to ensure that reflective notes are used for their proper purpose.

Recommendation 26: Doctors' reflective practice is fundamental to their professionalism. We recommend that doctors use the Reflective Practitioner guidance and supporting toolkit to help them engage in reflective practice. This will support doctors' learning whilst limiting the possible relevance of any recorded reflections in other proceedings. UK Parliament and the devolved governments should consider how these reflections could be given legal protection.

Support for doctors

- 181 As we discussed in chapter 5, the impact of an unexpected death is devastating for the patient's family and also for members of the healthcare team. The ensuing investigations can leave members of the team feeling like second victims if they are handled poorly. That applies to local investigations, criminal investigations and the regulatory process. We heard throughout our review that the support available for doctors under investigation varies both in accessibility and quality.
- 182 The question of what support the GMC should provide is a difficult one. Any doctor facing the prospect of a GMC investigation is likely to be under considerable stress. But as one respondent to our call for written evidence wrote, 'I do not think...that the GMC can be supporter and investigator'. Another wrote that it was not the regulator's

^{*} Gross negligence manslaughter in healthcare: the report of a rapid policy review (recommendation 5.3) (2018)

[†] General Medical Council, 'New guidance to help you with reflection (2018) help-you-with-reflection> accessed 4 April 2019.

[‡] Academy of Medical Royal Colleges, 'Academy and COPMeD Reflective Practice Toolkit Guidance Note' (2018).

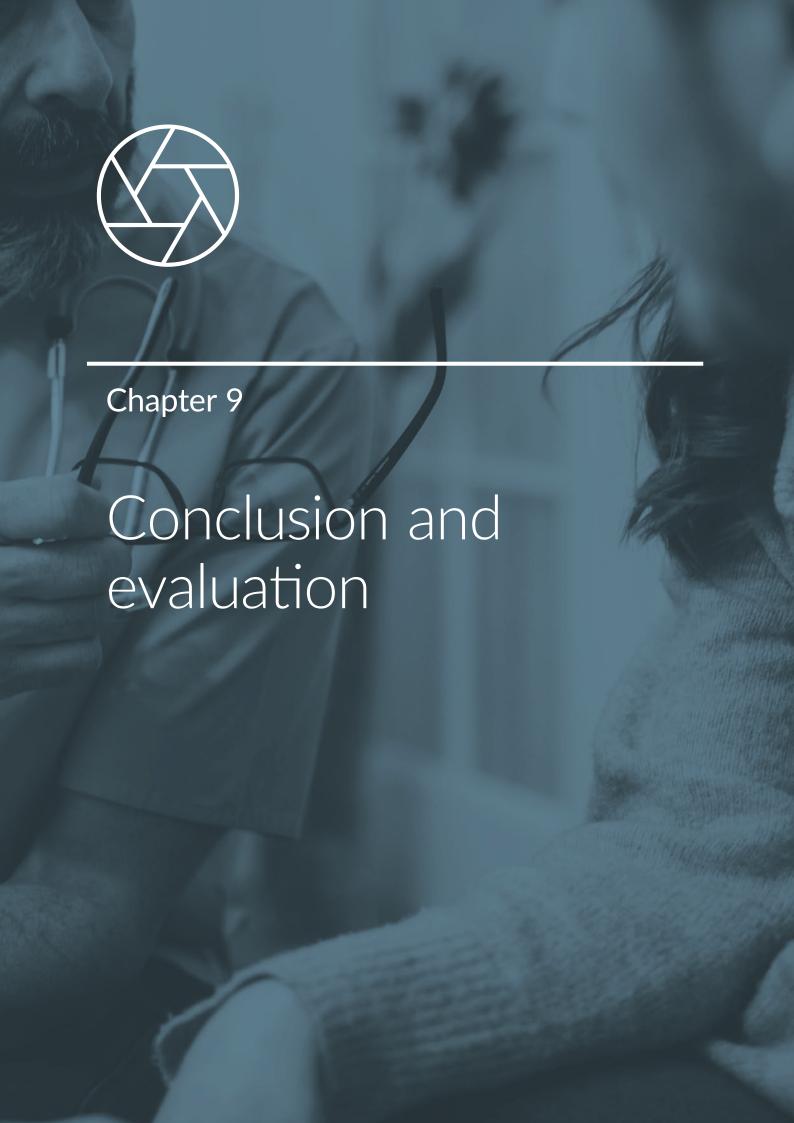
role to provide support for doctors under investigation as 'it may end up causing conflict of interest'. Indeed, there is an inevitable measure of distrust: 'the GMC processes, investigations and prosecutions of clinicians cause the problem.' However, the GMC does have a duty to make sure its processes are fair and sensitive in the way they deal with both respondent doctors and patients and the public. Both are vulnerable in the arena of an investigation.

- 183 The GMC commissions the independent GMC Doctor Support Service (currently delivered by the BMA) to provide support for doctors under investigation but its reach is limited in terms of the number of doctors who have used it (approximately 100 a year) and the nature of the help available.
- 184 Through our workshops and our call for written evidence we received a range of suggestions about further action the GMC could take to support doctors. For example, one medical director felt that the impact of a fitness to practise investigation on a vulnerable individual might be cushioned if the employer or Responsible Officer was made aware of the outcome before the doctor was notified so that local support mechanisms could be put in place. The BMA pointed to fuller use of the GMC's liaison services around the UK as a means of gathering evidence to highlight local issues and identify emerging risks and concerns for medical practice. Arguably, this would help to identify systemic issues before they become individual problems.
- 185 The GMC needs to re-gain the trust of doctors. In doing so it must engage with the profession about the steps it has taken, and is intending to take, to better support doctors both within its own fitness to practise processes and also in the wider context of medical practice. But given its prosecutorial function, we feel that any support GMC can provide will necessarily be limited. We believe that others also have a role to play. In England, the NHS Practitioner Health Programme, for example, provides an important and highly commended service to support doctors with mental health problems. Therefore, while the GMC itself cannot provide all that might be needed, it should work with others who might be better placed to do so.
- 186 Finally in this section, we were surprised to find that many doctors facing GMC and MPTS proceedings are not legally represented. In these stressful circumstances medical defence organisations can provide helpful legal and pastoral support.

Recommendation 27: The GMC should work with the medical trade unions, medical defence organisations, healthcare service providers, education and training bodies and other professional bodies to explore how doctors under investigation might be better supported. Doctors should be made aware that NHS basic indemnity for clinical negligence claims does not cover legal advice and support for any other processes (GMC, coroner or criminal).

187 That need for support is not confined to when things have gone wrong. Just as doctors entering the UK workforce for the first time require proper induction and mentoring, it is equally important for those returning to clinical practice following lengthy absence due to illness, maternity leave, service breaks or for other reasons. They too will need time and support to re-adjust to the realities of front line medical practice and get up to speed again. This was highlighted for us by many of the respondents to our call for evidence. We are also reminded that this review arose from the case of a doctor who found herself in just that situation. Our aim, after all, is to ensure that measures designed to prevent harm are put in place, rather than merely improving processes once a serious safety incident has occurred.

Recommendation 28: Healthcare service providers should provide induction and support for all doctors returning to clinical practice after a period of significant absence. These doctors should have a return to work meeting and appropriate supervision and support during the induction period tailored to the needs of the individual.



Chapter 9: Conclusion and evaluation

- 188 This review arose from a single case in which the GMC sought to have removed from the medical register a doctor who had been convicted of GNM. It was an action which has had a profound effect on the medical profession in the UK and overseas. The impact extended well beyond the individual case and exposed other long-standing tensions in the relationship between the GMC and the doctors it regulates. As we have highlighted, those tensions need to be addressed if the GMC is to regulate effectively and support doctors in providing high quality care for patients, as it aspires to do. Our report recommends a number of actions the GMC must take in order to repair its relationship with the medical profession. Regaining the trust of doctors will not be a quick process. It will require the proof of concerted actions, not just words.
- 189 We are also cognisant of the effect an unexpected death can have on relatives and carers when significant failings in care are involved. They are not always well-served or supported by the investigations which follow. They have a right to expect candour and be given the opportunity to remain informed and involved in the process of understanding what went wrong.
- 190 As we have also shown, the application of the law of GNM in healthcare is not, at its root, simply a GMC problem. GNM is a serious criminal offence and where a doctor is convicted of that offence the regulator is bound by law to consider the matter and the public would rightly expect nothing less. By this point a series of often protracted local, coronial and criminal processes will have run their course and taken their toll on the doctor, the healthcare team and, above all, on the family of the patient whose life has been lost. Too often the application of those processes is flawed. Too many doctors now fear being drawn into a criminal system which they perceive as having little understanding of, or interest in, the realities of medical practice in healthcare systems under pressure. Doctors and others we have heard from feel that it is too easy to blame the individual for what has gone wrong, rather than examine and learn from the wider system failures in which a tragedy has occurred.
- 191 Those perceptions are not always accurate. Some of the anecdotes and allegations that we have heard during the course of this review have not been borne out by the facts. But the perceptions are real enough and doctors have told us they are affecting medical practice. We have therefore directed many of our recommendations beyond the GMC and towards others in the process who have a duty to support a just and fair culture. In doing so, we know that we cannot force those organisations to act. However, we have endeavoured to shine a light on what we believe needs to be done and hope they will give serious consideration to our recommendations. As it was the GMC that commissioned this review, we end by urging the GMC to monitor, evaluate and report on the implementation of the recommendations we have made.

Recommendation 29: The GMC should encourage and support the implementation, monitoring and evaluation of the above recommendations, working closely with the agencies to which they are directed.

List of recommendations

Rebuilding the GMC's relationship with the profession

Recommendation 1: Effective medical regulation is dependent on doctors' confidence in, and constructive engagement with, their regulator. The GMC must acknowledge that its relationship with the medical profession has been severely damaged by recent events and then the GMC must learn from those events in the way it regulates.

Recommendation 2: The GMC must take immediate steps to re-build doctors' trust in its readiness to support them in delivering good medical practice for patients. This should include examining the processes and policies that have contributed to doctors' loss of confidence and considering how it can better support a profession under pressure as well as promoting a fair and just culture.

Families and healthcare staff

Recommendation 3: Following an unexpected death, there should be close adherence to the professional and statutory duty of candour to be open and honest with the family of the deceased. They need to be told as fully as possible what has happened, why it happened and be assured that they will be kept involved and informed throughout the investigation.

Recommendation 4: Involvement of, and support, for families and staff is often deficient in the period between an unexpected death and the start of a patient safety investigation. All healthcare service providers should have clear policies and a named lead to ensure consistent implementation of policies in line with the relevant national frameworks.

Equality, Diversity and Inclusion

Recommendation 5: The GMC should work with healthcare service providers, national bodies and representatives of overseas doctors to develop a suite of support for doctors new to UK practice. This should include information about cultural and social issues, the structures of the NHS, contracts and organisation of training, induction, appraisal and revalidation, professional development plans and mentoring.

Recommendation 6: The GMC should work with stakeholders across the healthcare systems to ensure that the importance of an inclusive culture within the workplace, education and training environments is understood.

Recommendation 7: The GMC, in supporting the profession, should ensure it continues to demonstrate a commitment to understanding the experiences and contributions of international doctors practising in the UK and shares the insight with the wider healthcare systems.

Recommendation 8: To ensure confidence in fair decision making, relevant healthcare sector organisations (including the GMC) should have published measures and aspirations for diverse workforce representation in key roles and at all levels involved in decision making.

Recommendation 9: Relevant healthcare sector organisations (including the GMC) should have in place appropriate methods of assurance of fair decision making, including (but not limited to) equality, diversity and inclusion training, unconscious bias training, auditing and monitoring.

System scrutiny and assurance

Recommendation 10: Where a doctor is being investigated for gross negligence manslaughter or culpable homicide, the appropriate external authority should scrutinise the systems within the department where the doctor worked. Where the doctor is a trainee, this should include scrutiny of the education and training environment by bodies responsible for education and training.

Expert reports and expert witnesses

Recommendation 11: Those providing expert witness reports and evidence should be required:

- To state in a specific section of their report the basis on which they are competent to provide an expert opinion on the matters contained within the report or evidence.
- To state in a specific section of the report where their views fit on the spectrum of possible expert opinion within their specialty.
- To calibrate their reports to indicate whether an individual's conduct was, in all the circumstances, within the standards that could reasonably have been expected, below the standard expected; far below the standard expected; or whether the individual's conduct was truly, exceptionally bad. They should also give their reasons for the views reached.

Recommendation 12: Doctors should only provide expert opinion to the coroner, procurators fiscal, police, CPS, GMC or to the criminal court on matters which occurred while they were in active and relevant clinical practice.

Recommendation 13: The GMC should make transparent its processes for recruitment and quality assurance of those doctors providing expert reports. It should also explore how it can support just decision making in other parts of the system by giving access to its pool of medical experts to the police, procurator fiscals, coroners, defence and prosecutors.

Recommendation 14: Any decision to bring a misconduct case about clinical competence to the MPTS reliant on expert evidence should require the support of two expert opinions. The GMC should assess the efficacy and cost-effectiveness of using concurring expert opinion from two relevant medical experts to inform its fitness to practise investigations in cases raising questions about clinical competence.

Local investigations into patient safety incidents

Recommendation 15: Improvements in patient safety are most likely to come through local investigations into patient safety incidents which are focused on learning not blame. We strongly endorse recent developments in the frameworks for investigations. These emphasise the need for the investigation team to have the time and the appropriate experience, skills and competence (including understanding of human factors) to undertake investigations, and the necessary degree of externality to command confidence in the process. We also stress the need to involve and support families and staff.

Recommendation 16: The appropriate authorities in the four UK countries should quality assure the effective application of local investigation frameworks for patient safety incidents.* This external scrutiny should include a specific focus on how healthcare service providers address human factors issues within their investigation processes.

Coroner service in England and Wales

Recommendation 17: In order to ensure a consistent approach, if a coroner feels that a doctor's conduct might reach the threshold for GNM, they should discuss this with the Chief Coroner's Office before the police are notified.

Preparedness for Coroner and Procurators Fiscal proceedings

Recommendation 18: Healthcare service providers should provide support and guidance for doctors who are involved in an inquest or fatal accident inquiry so that they have an appropriate understanding of the process and their role in proceedings.

^{*} We acknowledge and support the parallel Williams review recommendation (4.2) for the Care Quality Commission in England.

Police, Crown Prosecution Service and Procurators Fiscal

Recommendation 19: When the police, or procurators fiscal in Scotland, receive notification of an unexpected death they should have early access to appropriate, independent medical advice to help determine whether an investigation is warranted. To assess how this can best be arranged we recommend that a pilot study is taken forward in England to explore the feasibility of involving high-level Responsible Officers in identifying suitable doctors to provide this advice.

Recommendation 20: The CPS (England and Wales) should consider what measures it could take to enhance the transparency and understanding of its decision-making process (including how experts are recruited and the use and disclosure of expert evidence) so as to provide reassurance about how decisions are made.

GMC policies and processes

Recommendation 21: We agree with the Williams review's recommendation (at 6.1) to remove the GMC's right of appeal of Medical Practitioners Tribunal Service (MPTS) decisions, as an important step towards rebuilding the profession's relationship with its regulator. We urge the Government to introduce the legislative reform necessary to achieve this without delay. We commend the GMC's recent steps to review and reform its processes for decisions to appeal in the meantime.

Recommendation 22: The GMC should work with the public and patient organisations to support better understanding of its role in regulating the medical profession within a system under pressure. The GMC must demonstrate how that understanding has shaped, and continues to shape, its policies.

Recommendation 23: The GMC and MPTS should review the Interim Orders Tribunal and MPT Sanctions Guidance to ensure that the guidance takes proper account of the findings of the research commissioned by this review regarding the maintenance of public confidence in the medical profession. This should include consideration of the appropriate handling of cases involving clinical incidents, including those that result in criminal convictions, such as GNM.

Recommendation 24: The GMC should strive to reduce the timescales for progressing fitness to practise cases to Medical Practitioner Tribunals. Where a case does not progress within target timescales, it should be subject to senior level review within the GMC.

Recommendation 25: The UK Government has signalled its intention to reform the legislation surrounding healthcare professionals' regulation, including fitness to practise. We urge the Government to bring forward that legislative reform at the earliest opportunity to give the GMC greater discretion to determine which cases are appropriate for investigation and greater scope for disposing of fitness to practise cases consensually.

Reflective practice

Recommendation 26: Doctors' reflective practice is fundamental to their professionalism. We recommend that doctors use the Reflective Practitioner guidance and supporting toolkit to help them engage in reflective practice. This will support doctors' learning whilst limiting the possible relevance of any recorded reflections in other proceedings. UK Parliament and the devolved governments should consider how these reflections could be given legal protection.

Support for doctors

Recommendation 27: The GMC should work with the medical trade unions, medical defence organisations, healthcare service providers, education and training bodies and other professional bodies to explore how doctors under investigation might be better supported. Doctors should be made aware that NHS basic indemnity for clinical negligence claims does not cover legal advice and support for any other processes (GMC, coroner or criminal).

Recommendation 28: Healthcare service providers should provide induction and support for all doctors returning to clinical practice after a period of significant absence. These doctors should have a return to work meeting and appropriate supervision and support during the induction period tailored to the needs of the individual.

Independent Review of GNM/CH evaluation

Recommendation 29: The GMC should encourage and support the implementation, monitoring and evaluation of the above recommendations, working closely with the agencies to which they are directed.



Independent review of gross negligence manslaughter and culpable homicide

June 2019

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