

Gross negligence manslaughter in healthcare

The report of a rapid policy review

June 2018

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1. Letter from Professor Sir Norman Williams to Jeremy Hunt, Secretary of State for Health and Social Care

Dear Secretary of State

Thank you for asking me to lead this important review into gross negligence manslaughter in healthcare settings. Those of us who have never experienced the unexpected death of a family member or friend receiving healthcare cannot fully appreciate the enormous sense of loss and grief that will be inevitable in such circumstances. This must never be underestimated and my review panel has kept this very much in mind throughout its deliberations and it has been essential in shaping the report.

What families and loved ones want in such circumstances is transparency, a thorough investigation, an explanation of what went wrong and reassurance that measures are put in place to prevent similar tragedies. If this does not happen and they are ignored or worse provided with explanations that are inaccurate in some way, then trust will be lost and concerns will remain.

It also has to be appreciated, however, that healthcare professionals go to work to alleviate suffering not to add to it. They work in complex, high-risk environments, invariably as part of a team, and when things go wrong it is rarely the result of one individual's error. When a patient dies due to one or more errors, it has a profound effect on that healthcare professional and the entire team, both psychologically and in terms of their confidence. Such effects can then be compounded by an investigation which may seek to blame, rather than to understand the factors that have led to the tragedy so that lessons can be learnt to prevent future incidents. At all stages of any investigation the stress levels for those involved, including the professionals, can be overwhelming. For the healthcare professionals a sense of fear pervades and patient safety is jeopardised as they become cautious about being open and transparent, impeding the opportunity for lessons to be learnt.

Despite reports to the contrary, investigations of gross negligence manslaughter in healthcare are unusual, prosecutions are rarer and guilty judgements rarer still. There is no doubt, however, that recent cases have led to an increased sense of fear and trepidation, creating great unease within the healthcare professions. This has been compounded by a perceived arbitrariness and inconsistency in the investigation and subsequent prosecution of gross negligence manslaughter.

During our deliberations the evidence we received led us to conclude that these inconsistencies must be addressed. The panel was clear that healthcare professionals could not be, or be seen to be, above the law and needed to be held to account where necessary. It was equally evident, however, that for the sake of fairness, the complexity of modern healthcare and the stressful environment in which professionals work must be

taken into consideration when deciding whether to pursue a gross negligence manslaughter investigation.

Testimony to our panel also raised concerns about the regulatory system which had wider implications than those limited to gross negligence manslaughter. The panel felt that in order to fulfil its obligations it was important to consider these relevant issues. One issue that the panel considered very carefully was the right of the General Medical Council to appeal the fitness to practise decisions of the Medical Practitioner Tribunal Service. On balance it was felt that removing this right was appropriate. Such action will hopefully mitigate the distrust felt by doctors about their professional regulator, while maintaining effective public protection through the Professional Standards Authority's right of appeal.

There was evidence also to suggest that in both criminal and regulatory investigations there was a disproportionate number of Black, Asian and Minority Ethnic professionals involved. Although the causes were by no means certain, there was enough unease from panel members to ensure that we made recommendations to address any perceived injustice.

We hope our recommendations will change the environment by establishing a just culture and providing reassurance to healthcare professionals, patients and their families that gross negligence manslaughter cases will be dealt with in a fair and compassionate manner. The implementation of our recommendations should, we believe, dispel fear within the healthcare professions and improve patient safety. By seeking to remove inconsistencies in the approach to gross negligence manslaughter, fewer investigations will be pursued and only those rare individuals whose performance is so "truly exceptionally bad" that it requires a criminal sanction will be indicted. By so doing, we very much hope that the public will be reassured that patients' families will be treated fairly, with respect and will receive honest explanations for their loved ones' deaths. In addition, the public will see effective action by the police, courts and regulators, where appropriate.

I would like to thank all those who gave evidence either in writing, in person or both. I am also very grateful to members of the panel for their expertise, engagement and diligence in this review. I would particularly like to thank my Vice Chair, Mr Ian Stern Q.C., for his outstanding support both to me personally and to the panel. Tribute should be made also to the Secretariat who have worked tirelessly on our behalf: they have gone that extra mile to assist in producing this report in a relatively short timescale.

The review panel has worked extremely well together and our findings and recommendations have been agreed unanimously. We commend them to you.

A handwritten signature in black ink, appearing to read "Norman Will", followed by a long, sweeping horizontal flourish.

2. Overview

- 2.1. On 6 February 2018 the Secretary of State for Health announced a rapid policy review into gross negligence manslaughter in healthcare, chaired by Professor Sir Norman Williams. The review was set up to consider the wider patient safety impact resulting from concerns among healthcare professionals that simple errors could result in prosecution for gross negligence manslaughter, even if they occur in the context of broader organisation and system failings. In particular, there was concern that this fear had had a negative impact on healthcare professionals being open and transparent should they be involved in an untoward event, as well as on their reflective practice, both of which are vital to learning and improving patient care.
- 2.2. The panel heard from many individuals and organisations. This included bereaved families, healthcare professionals and their representative bodies, regulators, lawyers, investigatory and prosecutorial authorities, as well as members of the public.
- 2.3. The recommendations made in this report aim to support a just and learning culture in healthcare, where professionals are able to raise concerns and reflect openly on their mistakes but where those who are responsible for providing unacceptable standards of care are held to account. This will lead to improved patient safety.
- 2.4. Healthcare professionals will see the following changes:
- Though the legal bar for conviction for gross negligence manslaughter is high, investigations that have little prospect of conviction cause uncertainty and distress. Revised guidance to investigatory and prosecutorial bodies and a clearer understanding of the bar for gross negligence manslaughter in law should lead to criminal investigations focused on those rare cases where an individual's performance is so "truly exceptionally bad" that it requires a criminal sanction; and
 - Systemic issues and human factors will be considered alongside the individual actions of healthcare professionals where errors are made that lead to a death, ensuring that the context of an incident is explored, understood and taken into account.
- 2.5. Bereaved families will be provided support through:
- Being informed, in a timely manner, of any untoward event which might have contributed to the death of a family member or loved one;
 - Being provided with the opportunity to be actively involved throughout investigative and regulatory processes; and
 - An expectation that, for all bodies with a role in investigation and regulatory action, families and loved ones are supported, treated at all times with respect and receive honest explanations when things have gone wrong.
- 2.6. Finally we make recommendations for regulatory bodies:

- The General Medical Council should have its right to appeal fitness to practise decisions by its Medical Practitioner Tribunal Service removed. This will help address mistrust that has emerged between the GMC and the doctors that it regulates. The Professional Standards Authority will retain its right to appeal these cases to ensure public protection, in the same way that it does for the other eight regulatory bodies for healthcare professionals;
- The General Medical Council and General Optical Council will no longer be able to require registrants to provide reflective material when investigating fitness to practise cases. This change will help ensure healthcare professionals are not afraid to use their notes for open, honest reflection which supports improvements in patient care; and
- Concerns about the over representation of Black, Asian and Minority Ethnic healthcare professionals in fitness to practise cases to be investigated, understood and addressed.

3. Why was the review commissioned?

- 3.1. On 6 February 2018 the Secretary of State for Health announced a review into the application of gross negligence manslaughter in healthcare led by Professor Sir Norman Williams. This review was not set up to recommend changes in the law but to look at how decisions are made within the current legal framework. The review's terms of reference can be found at Annex C. They focus on three key areas:
- information on and understanding of gross negligence manslaughter and the processes which apply to possible cases of gross negligence manslaughter involving healthcare professionals;
 - reflective learning; and
 - lessons for healthcare professional regulators.
- 3.2. This review was not set up to consider the detailed facts in relation to any specific death or individual case of gross negligence manslaughter. Nor does the review provide any comment on decisions made by the courts and tribunals in relation to any case.
- 3.3. However, the panel was keen to understand the impact of investigative, criminal and regulatory processes on bereaved families, how they navigate a complex system, and how they are assisted in doing so. The panel heard oral evidence from families affected by gross negligence manslaughter convictions and from those who had suffered other unexpected deaths in circumstances that caused them great concern. The panel also received further evidence in writing from bereaved families. It was important to the review to hear this evidence to inform its understanding of the issues.
- 3.4. The panel also considered the impact of gross negligence manslaughter cases in healthcare on attempts to achieve a just and learning culture. A just culture considers wider systemic issues where things go wrong, enabling professionals and those operating the system to learn without fear of retribution.
- 3.5. The panel was concerned to identify the effects of gross negligence manslaughter prosecutions on this culture. In particular, it sought to understand the origins of perceptions reported by medical and other staff that it would be all too easy to find oneself the subject of a criminal investigation and that a defensive style of clinical practice would be the only protection. In doing so, the panel hoped to identify changes and to make recommendations which would better support a just culture, in which the processes for accountability are both understood and correctly balanced with the ability of both individuals and the system to learn from error and improve patient safety.

Territorial Extent

- 3.6. The review recommendations relating to healthcare apply to England only. Healthcare is devolved in Scotland, Wales and Northern Ireland. The regulation of healthcare

professionals is, generally, a reserved matter and so our recommendations relating to professional regulation apply to England, Scotland, Wales and Northern Ireland.

- 3.7. It is also important to note that the review has considered only the criminal justice system in England and Wales and our recommendations for the criminal justice system are therefore only directly applicable in these two countries (for example, there is no term such as “manslaughter” in Scots Law).
- 3.8. While many of our recommendations do not therefore relate to the whole of the UK, we would encourage the Governments of Scotland, Wales and Northern Ireland to consider our recommendations in full.

4. Gross negligence manslaughter

What is gross negligence manslaughter?

4.1. Gross negligence manslaughter is a common law criminal offence. The concept of gross negligence manslaughter was set out in the case of *R v Adomako* (1994) 3 WLR 288. This outlined a four stage test for gross negligence manslaughter. The stages are:

- the existence of a duty of care to the deceased;
- a breach of that duty of care which;
- causes (or significantly contributes) to the death of the victim; and
- the breach should be characterised as gross negligence, and therefore a crime.

4.2. In the recent case of *R v Rose* [2017] EWCA Crim 1168¹, the Court of Appeal set out the principles that apply to gross negligence manslaughter. These were summarised as

(1) the offence of gross negligence manslaughter requires breach of an existing duty of care which it is reasonably foreseeable gives rise to a serious and obvious risk of death and does, in fact, cause death in circumstances where, having regard to the risk of death, the conduct of the defendant was so bad in all the circumstances as to go beyond the requirement of compensation and to amount to a criminal act or omission;

(2) there are, therefore, five elements which the prosecution must prove in order for a person to be guilty of an offence of manslaughter by gross negligence:

(a) the defendant owed an existing duty of care to the victim;

(b) the defendant negligently breached that duty of care;

(c) it was reasonably foreseeable that the breach of that duty gave rise to a serious and obvious risk of death;

(d) the breach of that duty caused the death of the victim;

(e) the circumstances of the breach were truly exceptionally bad and so reprehensible as to justify the conclusion that it amounted to gross negligence and required criminal sanction;

(3) the question of whether there is a serious and obvious risk of death must exist at, and is to be assessed with respect to, knowledge at the time of the breach of duty;

(4) a recognisable risk of something serious is not the same as a recognisable risk of death, and

¹ <https://lexisweb.co.uk/cases/2017/july/r-v-rose>

(5) a mere possibility that an assessment might reveal something life-threatening is not the same as an obvious risk of death: an obvious risk is a present risk which is clear and unambiguous, not one which might become apparent on further investigation.

4.3. There is no separate offence of medical manslaughter; this is merely a description of gross negligence manslaughter in a medical context.

Trends in gross negligence manslaughter involving healthcare professionals

4.4. Prosecutions for gross negligence manslaughter occur infrequently. Data on gross negligence manslaughter cases is not routinely collected and it has not been possible for the Crown Prosecution Service (CPS) to identify an accurate number of such cases referred to them, though they estimate that they receive about 200 referrals a year nationally. These are referrals for all categories of gross negligence manslaughter, not just those involving healthcare professionals. The CPS has been able to identify the number of prosecutions for medical health care professionals since 2013, in order to assist the review.

4.5. Prosecutions of healthcare professionals for gross negligence manslaughter are even more unusual (see annex A). The review has looked at prosecutions of health care professionals for gross negligence manslaughter since the Adomako case in 1994. In this time, the deaths of 38 patients have led to gross negligence manslaughter prosecutions of 47 healthcare professionals (37 doctors, nine nurses and one optometrist). Twenty-three of these healthcare professionals were convicted, with four prosecutions subsequently overturned on appeal.

4.6. The most recent cases have seen a marked decline in conviction rates. Since 2013, 15 healthcare professionals have been prosecuted for gross negligence manslaughter in relation to the death of nine patients. These resulted in just six convictions, relating to five of those patients, two of which were subsequently overturned on appeal. These figures suggest two things. First, prosecutions of healthcare professionals for gross negligence manslaughter are very rare. Second, a relatively small number of prosecutions result in a conviction.

Crown Prosecution Service investigations of suspected gross negligence manslaughter involving healthcare professionals

4.7. It is important to consider not just those cases that result in a trial, but also how many cases of suspected gross negligence manslaughter by healthcare professionals are investigated. Investigations themselves can be distressing for both bereaved families and the healthcare professionals involved.

4.8. Since 2013 the CPS has been involved in 151 cases of suspected gross negligence manslaughter involving a healthcare professional. In most of these cases (85) no further action was taken by the police after advice had been provided by the CPS at an early stage of the investigation. In a further 43 cases, the CPS decided to take no

further action after a full case had been submitted for a charging decision. Seven of these cases referred to the CPS resulted in a prosecution, leading to four convictions and three acquittals. A further 16 cases are still being considered by the CPS.

5. Professional regulation

5.1. The primary purpose of professional regulation is to protect the public from harm by providing assurance that professionals providing health and care have the skills and competence to do so safely. Professional regulation is part of the wider regulatory infrastructure that seeks to ensure patient safety. For the most part, regulation of healthcare professionals is carried out on a UK-wide basis. However, some professions are regulated in some UK nations but not all.

5.2. There are nine regulators that regulate health and care professionals in the United Kingdom (UK) and social workers in England². They are independent of Government but are accountable to the UK Parliament. The regulators are:

- General Chiropractic Council (GCC)
- General Dental Council (GDC)
- General Medical Council (GMC)
- General Optical Council³ (GOC)
- General Osteopathic Council (GOsC)
- General Pharmaceutical Council⁴ (GPhC – Great Britain only)
- Health and Care Professions Council (HCPC)
- Nursing and Midwifery Council (NMC)
- Pharmaceutical Society of Northern Ireland (PSNI)

A tenth body, Social Work England, is being established and will take over the regulation of Social Workers in England from the Health and Care Professions Council.

5.3. These bodies regulate approximately 1.5 million professionals across 32 professions, at a total cost of around £300m a year. A further 85,000 professionals across 54 occupations are covered by 25 accredited voluntary registers, held by the Professional Standards Authority (PSA). The PSA oversees the work of the nine regulators.

5.4. The regulators' over-arching objective is the protection of the public, and, in particular, to:

- protect, promote and maintain the health, safety and well-being of the public;
- promote and maintain public confidence in health and care professionals;
- and

² Not all healthcare professionals are subject to statutory regulation. Professional regulation should be both effective and proportionate, imposing the least cost and complexity, whilst securing the confidence of the public.

³ The GOC also regulates optical businesses.

⁴ The GPhC and the PSNI also regulate pharmacy business premises.

- promote and maintain proper professional standards and conduct for members of those professions.

5.5. They do this by:

- maintaining a publicly available register of qualified professionals who are fit to practise;
- setting the standards of training and education required to gain entry to the register and approving and inspecting education and training providers;
- setting the standards of conduct and performance expected of a registered professional;
- operating a system to ensure that registered professionals continue to meet those standards and remain fit to practise; and
- taking disciplinary action where the fitness to practise of the registered professional is impaired as a result of misconduct, deficient performance, health or following a conviction.

5.6. Each regulator has a fitness to practise process for handling complaints about health and care professionals. The most serious cases are referred to formal hearings in front of fitness to practise committees or panels or, in the case of doctors, the Medical Practitioners Tribunal Service⁵ (MPTS). While the regulators' approach to fitness to practise processes are broadly similar, differences in the legislation underpinning the regulators mean that there are some differences in processes, guidance and sanctions for different professional groups.

5.7. Each regulator provides guidance for its panels⁶, including on sanctions, mitigating and aggravating circumstances and how to consider criminal convictions.

⁵ The Medical Practitioners Tribunal Service is the adjudication function for UK doctors, which makes independent decisions about a doctor's fitness to practise, measured against professional standards set by the GMC. MPTS has the power to impose sanctions against the doctor's registration where necessary to protect the public

⁶ The MPTS provides this guidance to its tribunals in the case of doctors.

6. Investigations and prosecutions for gross negligence manslaughter

- 6.1. While it is not within the terms of reference of this review to recommend changes to the law which sets out the offence of gross negligence manslaughter, the panel nonetheless heard a number of views as to how the offence might be altered. All of these comments were based on a view that the bar for the offence is set too 'low'. Some who provided evidence suggested that the definition should be set to encompass an element of intent through the inclusion of words such as 'wilfulness' or 'recklessness', while others favoured the adoption of the Scottish offence of culpable homicide. There was, however, a strong, although not universal, consensus that healthcare professionals must not be, or be seen to be, above the law, and that the offence of gross negligence manslaughter should continue to apply to healthcare professionals in the same way that it applies to everyone else.
- 6.2. The view of the panel is that the recent Court of Appeal judgment in the Rose case has clarified the test for gross negligence manslaughter and that the bar for a conviction is set appropriately high. However, we heard evidence from those who felt that the test has not been applied consistently. In addition, there was general misunderstanding of court proceedings and decisions.
- 6.3. All referrals to the CPS that resulted in a conviction were referred by the police. The relatively low rate of convictions resulting from investigations and prosecutions (Annex A) suggest that some healthcare professionals are facing investigation for gross negligence manslaughter in cases where the realistic prospect of a prosecution may be small. The investigations are necessarily complex and take a long time to complete. They cast a long shadow and, in the view of the panel, it is the investigations as much as convictions that have led to genuine if misplaced concern among healthcare professionals that they may be one mistake away from a gross negligence manslaughter investigation.
- 6.4. Healthcare professionals who meet the high threshold set for gross negligence manslaughter should be investigated and prosecuted. It is equally important that cases where there is no realistic prospect of the test being met are resolved at the earliest opportunity. This would allow bereaved families to understand as soon as possible the circumstances of their relative's death, because a police investigation can lead to the suspension of any internal investigation. It would also remove the threat to individual professionals of prosecution and allow them to continue to provide healthcare. The delays caused by drawn out investigations and failed prosecutions have a detrimental effect on patient confidence and expectations, as well as on healthcare professionals and the health service. The cost to all involved both financially and emotionally, calls for an early resolution of cases that clearly do not meet the threshold for gross negligence manslaughter.

6.5. The panel has identified a number of areas where improvements can be made to the way that investigations into gross negligence manslaughter are carried out. These are set out in the following sections.

7. Developing an agreed and clear understanding of the law on gross negligence manslaughter

- 7.1. A shared and accurate understanding of the law and how the threshold for gross negligence manslaughter is applied to healthcare professionals is the starting point for improving the consistency of investigations of suspected gross negligence manslaughter.
- 7.2. A common understanding of the law and the high level at which the bar for gross negligence manslaughter is set should provide reassurance to healthcare professionals that the offence only arises in the most serious cases of "truly exceptionally bad" breaches of a duty of care that result in death (see legal test at 4.2). In such cases families, the public and healthcare professionals themselves rightly expect individuals or their organisation to be held to account. No-one is above the law.
- 7.3. The panel believes that a shared understanding of gross negligence manslaughter would result in only those cases where there is a realistic prospect of prosecution being reported to the CPS. It would also help families to understand why a prosecution might, or might not, be appropriate in specific cases.
- 7.4. The value of developing such a shared understanding will only be realised if it is widely disseminated. Guidance from bodies with a role in investigating or referring suspected cases of gross negligence manslaughter will need to be updated to reflect the shared understanding of the law. This will include, but is not limited to, guidance from the Chief Coroner, guidance to senior investigating officers in police forces around the country and guidance to prosecutors from the CPS. This agreed understanding of the law will also need to be promulgated to healthcare professionals.

Recommendations

- A working group should be set up to set out a clear explanatory statement of the law on gross negligence manslaughter. This working group should involve, at a minimum, representatives from the Crown Prosecution Service (CPS), the coroner services, Treasury Counsel and healthcare defence organisations.
- All relevant organisations, including, if appropriate, the Director of Public Prosecutions, should produce or update guidance on gross negligence manslaughter in light of the explanatory statement set out by the working group. This will promote a consistent understanding of where the threshold for prosecution for gross negligence manslaughter lies.

8. Improving assurance and consistency in the use of experts in gross negligence manslaughter cases

8.1. Expert opinion is central to prosecutions of healthcare professionals for gross negligence manslaughter as well as to other offences related to clinical practice. The importance of expert opinion was made clear in the report *Bearing Good Witness* by Sir Liam Donaldson, former Chief Medical Officer, which said:

... The Courts need to be confident both that an appropriate witness will be available when needed and the evidence provided is of the highest quality, is based on high-quality research and represents the current state of knowledge about the issue in question⁷.

- 8.2. Expert opinion is also key to fitness to practise cases considered by the healthcare professional regulators. The panel heard a number of concerns about the quality and consistency of opinion provided by healthcare professionals acting as experts or expert witnesses.
- 8.3. Every investigation for suspected gross negligence manslaughter by healthcare professionals requires an expert opinion at an early stage. The police will be alerted to a suspected case of gross negligence manslaughter involving a health care professional from one or more of a number of sources – these include coroners, Clinical Commissioning Groups, the Care Quality Commission, NHS England, families of the deceased patient or possibly journalists. The police will appoint a senior investigating officer (SIO), set up an incident advisory group and the SIO will make a decision as to whether there is a possible homicide. It is at this stage that the police will usually seek advice from the CPS and the views of an expert.
- 8.4. The expert will usually be appointed by the police, often on the advice of the CPS. Ideally they will have recent, relevant experience related to the incident that is being investigated. Such an expert might be sourced through the CPS or the National Crime Agency.
- 8.5. The terms of reference for the opinion of an expert will be drawn up jointly by the police and the CPS. These should include an explanation of the law relating to gross negligence manslaughter and of the requirement on experts to provide objective and unbiased opinion, rather than to support a prosecution.
- 8.6. The CPS was clear that where the opinion of the expert, taken with the surrounding evidence, suggests that there is no case to answer that will usually signal the end of

⁷http://webarchive.nationalarchives.gov.uk/+f_/http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_4140132

the investigation. While the role of the expert is central in determining whether an investigation goes ahead, and indeed whether such a case proceeds to prosecution, there was general consensus that finding the right expert, with relevant clinical experience, knowledge and expertise, can be difficult and time consuming.

- 8.7. Recent cases that have been considered by the courts suggest difficulties with expert witnesses. In one case⁸, for example, a conviction was successfully appealed in part due to the manner in which expert witness evidence was used during the trial⁹. In other cases and investigations questions were posed about the quality and use of expert witness evidence¹⁰. These suggest that problems with expert testimony may not be uncovered until a trial or appeal.
- 8.8. The role and expectation of expert witnesses is set out in the court procedure rules. There is also guidance from, among others, the British Medical Association and the GMC. Despite this, the evidence that the panel received highlighted problems with the conduct and ability of expert witnesses in cases of suspected gross negligence manslaughter involving healthcare professionals. Although our terms of reference were limited to gross negligence manslaughter, the panel heard evidence of more general concerns about medical experts.
- 8.9. The police and the CPS spoke about the particular difficulty of finding suitable experts for cases in specialised areas of healthcare. Medical defence organisations and healthcare professionals raised concerns about the use of experts who did not have sufficient understanding of current healthcare practice, as they had retired or worked primarily in an area that was not directly relevant to the case under consideration. In addition, there were concerns that in some cases experts provided opinion based on a 'text-book' approach, which failed to recognise the realities of current frontline healthcare practice. It should be noted that human factors science refers to the difference between theoretical practice and practice in reality as the difference between "work as imagined" and "work as done".
- 8.10. Other concerns raised were that expert witnesses did not have an adequate understanding of the law or their duties to the court in providing expert opinion. There was also a suggestion that the CPS engaged in 'expert shopping', seeking further views if the initial expert did not support a prosecution. This assertion was rejected by the CPS. In its evidence to the panel, the CPS said that it would only seek further expert views if the evidence of two experts were contradictory. In any case, the CPS would be required to disclose to the defence all of the expert evidence it had received.
- 8.11. The panel is clear that a number of steps are needed to improve the quality and availability of healthcare experts in both criminal and regulatory settings.

⁸ R v Sellu [2016] EWCA Crim 1716

⁹ http://www.qebholliswhiteman.co.uk/cms/document/establishing_threshold_gross_negligence_in_medical_cases.pdf

¹⁰ R v Cornish (Errol) [2016] EWHC 779; R v Rudling [2016] EWCA Crim 741

- 8.12. In terms of improving quality, it is important that healthcare professionals providing an expert opinion have experience that is directly relevant to the area in which they are providing such an opinion. Ideally this should include both being in current practice or having practised in a relevant discipline at the time that the incident under consideration occurred. The panel believes that this would support an understanding of routine healthcare practice in both investigations and subsequent prosecutions and reduce the possibility of the test of 'grossness' being applied against an idealistic view of clinical practise.
- 8.13. It is also vital that experts should have an appropriate understanding of their role in the legal process and of their responsibility to provide objective and unbiased opinion in an investigation or to the court. The panel believes that training should be improved in order to better prepare healthcare professionals who provide an expert opinion or appear as an expert witness. There are many examples of similar training, such as the training for Home Office approved forensic pathologists¹¹. All professionals require training to practise in the fields in which they operate and knowledge of the standards needed to do so. It is a notable omission that those putting themselves forward as suitable to provide expert evidence do not need to undergo any training or accreditation in that role.
- 8.14. The panel heard concerns that there is a shortage of professionals prepared to appear as experts. As well as increasing the quality of healthcare professionals providing expert opinion or appearing as an expert witness, the panel recognises that steps need to be taken to encourage more professionals to undertake such work. Acting as an expert needs to be recognised as a valuable part of a healthcare professional's working life. The professions themselves need to encourage their members to take on this role. Professional regulators, responsible officers and healthcare professional bodies need to recognise professionals' work as expert witnesses as a valuable contribution to their continuing professional development.

Recommendations

- The Academy of Royal Medical Colleges, working with professional regulators, healthcare professional bodies and other relevant parties, should lead work to promote and deliver high standards and training for healthcare professionals providing an expert opinion or appearing as expert witnesses. These standards should set out what, in the Academy's opinion, constitutes appropriate clinical experience expected of healthcare professionals operating in such roles.

Healthcare professionals providing an expert opinion or appearing as an expert witness should have relevant clinical experience and, ideally, be in current clinical practice in the area under consideration. Additionally, they should understand the legal requirements associated with being an expert witness (including the requirement to provide an objective and unbiased opinion).

¹¹ <https://www.gov.uk/government/publications/pathology-delivery-board-criteria-registration>

- Healthcare professionals should be supported and encouraged to provide an expert opinion where it is appropriate for them to do so. Healthcare professional bodies, including Royal Colleges and professional regulators, should encourage professionals to undertake training to become expert witnesses, and employing organisations should be prepared to release staff when they are acting as expert witnesses.
- Professional representative bodies and regulators should recognise acting as an expert witness as part of a healthcare professional's revalidation or continuous professional development (CPD) process.
- Although our terms of reference were limited to gross negligence manslaughter, we heard evidence of more general concerns about experts. This should be reflected in the Academy's work to develop training for healthcare professionals acting in this capacity.

9. Consolidating expertise in relation to investigations of gross negligence manslaughter by healthcare professionals

- 9.1. Recent prosecutions of healthcare professionals for gross negligence manslaughter have caused genuine fear among healthcare professionals about the risk of prosecution for what many might see as an understandable error. However, the panel heard that the rates of investigations and prosecutions for gross negligence manslaughter are low. The CPS advised that it investigates around 30 cases a year and the number of prosecutions averages just one a year. Objectively speaking, the risk of a healthcare professional being prosecuted for gross negligence manslaughter is very small.
- 9.2. However, it was clear from the evidence given by medical defence organisations that healthcare professionals' fear of being prosecuted is not just a response to the number of investigations and prosecutions but also to a sense of arbitrariness in which cases result in a prosecution. The recommendations about developing an agreed explanatory statement of the law on gross negligence manslaughter and improving the quality of expert opinion will go some way to address these concerns while making clear that gross negligence manslaughter should apply to truly exceptionally bad cases of negligence that result in death.
- 9.3. The panel believes however that further measures are required to achieve greater consistency in the consideration of suspected cases of gross negligence manslaughter by healthcare professionals. All such cases are handled by the special crime and counter-terrorism team within the CPS which has developed a degree of expertise in this area. However, similar expertise is not brought to bear in how either the coronial service or the police consider potential gross negligence manslaughter cases. The view of the panel is that greater consistency, and fewer inappropriate referrals to the CPS, would be achieved by a similar pooling of expertise in the coronial and police services.

Coroner

- 9.4. Coroners are independent judicial officers appointed by the local authority and are responsible for investigating the cause of death in certain circumstances. There are 98 coroners in England and Wales covering approximately 109 areas. There is no power available for the coroner to frame their determination in such a way as to appear to determine criminal or civil liability on the part of a named individual or organisation.
- 9.5. The Office of the Chief Coroner was created by the Coroners and Justice Act 2009, with the first Chief Coroner being appointed in September 2012. The Chief Coroner

heads the coronial service, and has overall responsibility and national leadership for coroners in England and Wales¹².

- 9.6. Many cases of suspected gross negligence manslaughter by healthcare professionals are reported to the police by the coroner. Where suspicion arises that a death was caused by a criminal act, the coroner may adjourn an inquest until the conclusion of any criminal proceedings. Similarly, where a jury returns a conclusion of unlawful killing the case may subsequently be investigated or reconsidered by the police.
- 9.7. The panel heard from the medical defence organisations and solicitors who represent health professionals that there is a lack of consistency about which cases coroners report to the police. A more consistent approach could reduce the number of such investigations which would enable the resources of the police and the CPS to be focused on those ‘truly exceptionally bad’ cases that might constitute gross negligence manslaughter.
- 9.8. The Chief Coroner has issued guidance for coroners on delivering a verdict of unlawful killing in Law Sheet No 1¹³, this covers gross negligence manslaughter. This sets out the Adomako test together with some revisions reflecting subsequent cases. This guidance should be updated to reflect the explanatory statement on gross negligence manslaughter that will be developed as part of our previous recommendation in chapter 7.
- 9.9. Updated guidance will help to improve the consistency with which suspected cases of gross negligence manslaughter involving healthcare professionals are reported by coroners to the police. Since coroners are likely to have considered very few cases involving suspected gross negligence manslaughter by a healthcare professional, we would expect coroners to routinely consider relevant guidance as to whether the facts of a case meet the threshold for a police investigation before making such a report.

Recommendation

- The Chief Coroner should consider revising the guidance on gross negligence manslaughter in Law Sheet no 1 in light of the explanatory statement set out by the working group under the previous recommendation in chapter 7. 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.

Police investigations

- 9.10. Police investigations consider the circumstances in which a death occurred and assess the extent to which it may have been caused by the actions of individual

¹² <https://www.judiciary.gov.uk/related-offices-and-bodies/office-chief-coroner/guidance-law-sheets/coroners-guidance/>

¹³ <https://www.judiciary.gov.uk/wp-content/uploads/2016/02/law-sheets-no-1-unlawful-killing.pdf>

healthcare professionals. Given that investigations into gross negligence manslaughter are rare, police experience of undertaking these cases is limited.

- 9.11. In spite of this, steps have been taken to promote consistency in police investigations into gross negligence manslaughter. The police were clear that, in their view, the senior investigating officers (SIOs) form the cadre of specialists that has the expertise to investigate all complex cases, including those of suspected gross negligence manslaughter. The National Policing Homicide Working Group (HWG), which is part of the Violence Portfolio within the National Policing Crime Business Area, develops national policy and practice for the investigation of homicide, major incidents and other serious crimes. The HWG publishes a twice-yearly journal on homicide¹⁴. It has also produced guidance for SIOs on investigating unexpected death and serious harm in healthcare settings. This was last revised in 2015. This guidance should be updated in the light of the explanatory statement of the law on gross negligence manslaughter and any organisational changes.
- 9.12. In addition, a 2006 memorandum of understanding between the NHS, the Association of Chief Police Officers (ACPO) and the Health and Safety Executive (HSE) set out arrangements for liaison and communication in investigating patient safety incidents involving unexpected death or serious untoward harm. This Memorandum of Understanding (MoU) stated that “the police may conduct initial investigations into matters of concern reported to them and the threshold for taking these forward is usually set at a high level. This means that such investigations should take place only where there is clear evidence of a criminal offence having been committed.”
- 9.13. The principles of this MoU, and the relationship that it set out between police investigations and local safety investigations, is as relevant today as it was in 2006. However, the MoU has not been renewed since the demise of ACPO in 2015¹⁵. The panel believes that a similar MoU should be developed to set out the respective roles of the police, CPS, HSE and health service bodies (such as the Care Quality Commission, the Healthcare Safety Investigation Branch and healthcare professional regulators) in investigating unexpected deaths in healthcare settings in order to ensure that patient safety lessons can be understood and acted upon.
- 9.14. A number of people and organisations that provided evidence to the review suggested that the police should establish a national specialist unit in order to develop expertise in investigating suspected cases of gross negligence manslaughter by healthcare professionals. The police themselves did not support this proposal, arguing that there are too few cases and that it would result in the loss of important local knowledge in investigations. The panel felt that the networking approach taken by the

¹⁴ <https://www.app.college.police.uk/app-content/major-investigation-and-public-protection/homicide/homicide-journal/>

¹⁵ For the Police, SIO Guidance for Investigating Unexpected Deaths is available: <http://library.college.police.uk/docs/NPCC/2015-SIO-Guide-Investigating-Deaths-and-Serious-Harm-in-Healthcare-Settings-v10-6.pdf>

Homicide Working Group could be built upon to ensure expertise in gross negligence manslaughter is made available to local senior investigating officers.

Recommendations

- Building on the work of the Homicide Working Group, police forces across England should consolidate their expertise on gross negligence manslaughter by a healthcare professional through the creation of a virtual specialist unit. This unit would support senior investigating officers by making available the experience of previous gross negligence manslaughter cases in the early stages of an investigation.
- Advice to senior investigating officers should be updated to reflect the explanatory statement on gross negligence manslaughter set out by the working group in the recommendation in chapter 7 and the standards for healthcare professionals providing an expert opinion or appearing as expert witnesses recommendation in chapter 8.
- A new memorandum of understanding (MoU) should be agreed between relevant bodies, including the College of Policing, the CPS, the Care Quality Commission (CQC), Health and Safety Executive (HSE) the Healthcare Safety Investigation Branch (HSIB) and professional regulators, in relation to the investigation of deaths in a healthcare setting. As a minimum this MoU should establish a common understanding of the respective roles and responsibilities of the organisations involved, support effective liaison and communications between these organisations, and cover what is expected of expert witnesses, in particular that they should consider the role of systemic and human factors in the provision of healthcare.
- Signatories to the MoU should disseminate its contents in order to promote a greater understanding of legal issues among healthcare professionals and of healthcare issues (including systemic and human factors) among prosecuting authorities, the police and coroner services. This would help support the development of a “just culture” in healthcare, which recognises both systemic factors and individual accountability.

Local NHS and independent sector investigations

9.15. The importance of effective local incident investigations in identifying and driving improvements in the quality of healthcare has long been understood. In 2000, the

Department of Health report *An organisation with a memory*¹⁶ identified the absence of learning from failure as a weak link in driving safety improvements in the NHS:

- *The NHS has no reliable way of identifying serious lapses of standards of care, analysing them systematically, learning from them and introducing change which sticks so as to prevent similar events from recurring. In this respect the NHS is behind some other sectors where there are risks in service delivery and where human safety is at stake.*

9.16. This point was again made in Sir Robert Francis's report into the Mid Staffordshire Hospitals NHS Foundation Trust¹⁷ and in Dr Bill Kirkup's Morecambe Bay Investigation¹⁸.

9.17. While the importance of good local investigations is crucial in improving the quality of care and communications with patients and relatives about failings in care, this area of practice in the NHS in England has proved resistant to change. The panel heard from family members about their poor experiences of NHS investigations in which they felt that they were either not provided with full or, more alarmingly, accurate information. This led to concerns that there was a 'cover-up'. NHS Improvement and the Care Quality Commission told the panel that the quality of local investigations was extremely variable.

9.18. In every case of suspected gross negligence manslaughter involving a healthcare professional, there will nearly always be factors in the delivery of healthcare beyond the actions of individual professionals. An effective local investigation, operating in conjunction with a police investigation, is essential to establish a full understanding of all the causal factors. This provides an understanding of the broader and system context in which the actions of an individual took place.

9.19. This is not about healthcare professionals avoiding accountability for their actions, including those that may constitute gross negligence manslaughter, but it is important to understand the actions of individuals in the context in which they were operating. In relation to gross negligence manslaughter, Lord Mackay set out that whether the breach of a duty of care should be characterised as gross negligence, and therefore as a crime, "will depend on the seriousness of the breach of duty committed by the defendant in all the circumstances in which the defendant was placed when it occurred".¹⁹

9.20. The police and CPS were clear that they will investigate suspected cases of gross negligence manslaughter 'in all the circumstances' – that is, taking account of the circumstances in which the professional was operating at the time. However, other

¹⁶http://webarchive.nationalarchives.gov.uk/+/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_4098184

¹⁷ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/279124/0947.pdf

¹⁸https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/408480/47487_MBI_Accessible_v0.1.pdf

¹⁹ <http://www.e-lawresources.co.uk/R-v-Adomako.php>

people who gave evidence raised concerns about the ability of investigating bodies to assess and understand the complex interaction of multi-disciplinary healthcare teams operating in circumstances that are often challenging.

- 9.21. In particular, given the scarcity of such cases and the complexity of healthcare, there is likely to be a very limited understanding of the influence of human factors and system design on the decisions and behaviours of professionals involved in a healthcare incident. The panel recognised that there might be significant benefit derived from the assistance, not only of 'technical' medical experts, but also from the understanding which could be brought to bear by Human Factors and Ergonomics (HFE) experts, both at the investigation stage and should a case go to trial.
- 9.22. In the transport industry, the Air Accident Investigation Branch and the Rail Accident Investigation Branch carry out safety investigations in parallel to a police investigation. Witness statements made as part of such a safety investigation are confidential to the investigation in order to encourage co-operation and to allow lessons to be learned to improve safety.
- 9.23. In the healthcare context, the Healthcare Safety Investigation Branch (HSIB) was established in April 2017 as a national body which would carry out selective safety investigations, develop a body of expertise in healthcare investigation, and support improvement and professionalisation of NHS safety investigation at all levels.
- 9.24. The panel considered whether HSIB should be asked to work alongside a police investigation to help assess the context in which a suspected case of gross negligence manslaughter occurred. While the panel believes that the implementation of the legislative framework in support of HSIB should go ahead as quickly as possible, it was felt that it was too early in the development of HSIB to understand how it could undertake such a role. The influence of HSIB on improving the local investigation process will primarily benefit health service users by increasing the safety and effectiveness of care. A welcome side effect may be that the police gain confidence in the professionalism of the healthcare investigation, as is the case with those carried out by the transport investigation branches. This would benefit all parties in any gross negligence manslaughter investigation.
- 9.25. The panel felt the CQC would be better placed to provide an assessment of the broader system context in which a suspected case of gross negligence manslaughter occurred. The CQC could provide evidence from its latest inspection report of the quality of care provided by a particular organisation. In addition, the organisations registered with the CQC are required to notify it of deaths that may have been the result of the way care was provided – this would include any deaths that may result in a gross negligence manslaughter investigation. CQC should consider such a notification in deciding whether to carry out a parallel inspection of the provider to identify system factors involved in the case and to assess the context in which the professional was operating. It should also consider such a notification in considering whether to carry out a more general inspection of the provider.

- 9.26. However, the need to learn from errors and failures in patient care goes beyond those incidents where there may be an investigation for suspected gross negligence manslaughter. The context of the aviation or rail industries is very different to health care. There are very few deaths in the aviation and rail industries, whereas managing and dealing with illness and death is an intrinsic part of healthcare and unexpected death during treatment is not unusual. This makes it impossible for any single national organisation to be able to carry out investigations into all unexpected deaths. This reinforces the need for and importance of high quality local investigations.
- 9.27. NHS Improvement (NHSI) publishes a Serious Incident Framework (SIF) which NHS organisations are expected to follow when things appear to go wrong in patient care. It is currently running an engagement exercise to make improvements to the SIF²⁰. NHSI acknowledges that there is strong evidence from patients, families, carers and staff of weaknesses and variation in the way NHS organisations investigate, communicate and learn when things go wrong. Similar evidence was heard as part of this review.
- 9.28. The review of the SIF provides an opportunity to make improvements to local investigations. In order to be widely adopted, the panel believes that the SIF needs to be available in a short form. The panel identified a number of particular issues that should be stressed in any revisions to the SIF. This includes the need for the close involvement of patients and family members in investigations, including how to support their involvement, possibly through a family liaison approach. The revised SIF should also set out the requirement that any investigation is expertly overseen and independently-led wherever appropriate. The findings of any investigation should be shared with relevant regulatory, statutory, advisory and professional bodies.
- 9.29. NHSI informed the panel that, despite the clear SIF, most healthcare providers were not managing to follow some key sections of the guidance. In order to increase use of the SIF, the panel believes that a member of the Board of NHS healthcare provider organisations should be accountable for its use in local investigations. Each Trust has one Board member responsible for safety, and it would make sense for this to be part of their role.
- 9.30. In addition, the SIF should provide guidance on how to consider equality and diversity considerations in investigations, including whether the investigations should include Black, Asian and Minority Ethnic (BAME) representation. At a minimum, healthcare providers should ensure that all people conducting investigations have been appropriately trained, including in equality and diversity issues (further discussion and recommendations on the issues of diversity, equality and representation are included in chapter 13).
- 9.31. The Government is introducing a system in England and Wales, where all non-coronial deaths are subject to a medical examiner's scrutiny. The introduction of medical examiners is designed to deliver a more comprehensive system of assurance for all non-coronial deaths. While not specifically concerned with gross negligence

²⁰ <https://improvement.nhs.uk/resources/future-of-patient-safety-investigation/>

manslaughter, the introduction of medical examiners aims to improve the quality and appropriateness of referrals of deaths to coroners and to increase transparency for the bereaved and offer them an opportunity to raise any concerns. The panel supports this aim and the introduction of medical examiners.

9.32. The panel also recognised that serious incident investigations, like other criminal and regulatory investigations, are highly stressful for those healthcare professionals involved. This review has not considered in any detail the support that is available to staff involved in such processes. However, the panel believes that there would be value in the Royal Colleges, in conjunction with NHS Employers and Health Education England, conducting a review of this area, with a view to improving the support available to staff.

Recommendations

- Where a suspected gross negligence manslaughter case in a healthcare setting has been referred to the CPS, the CQC must be informed so that it can consider whether to carry out a parallel, but separate, investigation of the healthcare provider to determine the role of systemic and human factors in the incident and to identify any changes which might need to be made. The CQC should also consider the findings of its inspection in deciding whether to undertake any follow up action in relation to the provider and/or any wider review of system issues. The relationship between a criminal investigation and any parallel CQC inspection should be set out in the MoU (recommendation in chapter 9).
- There must be a thorough local investigation of all unexpected deaths in healthcare settings, both in the NHS and in the independent sectors. The CQC should consider the effectiveness of such investigations as part of its inspection programme of healthcare providers.
- In the case of NHS organisations, investigations into unexpected deaths should be carried out in line with NHS Improvement's Serious Incident framework (SIF). In particular family members, carers or advocates must be involved and supported (e.g. through family liaison) from the outset and be kept informed of progress and the outcome. Investigations must be expertly and objectively overseen and, where appropriate, independently-led. A member of the healthcare provider's Board must be appointed to be responsible for ensuring the SIF is followed in relevant investigations. The outcome of such investigations should be reported to the Board and shared with the relevant regulatory, statutory, advisory and professional bodies. A similar methodology for investigations should be adopted by private healthcare providers.
- Healthcare providers should ensure that people conducting investigations have received appropriate training, including on equality and diversity. NHS Improvement's SIF should include guidance on how to consider equality and

diversity considerations in investigations, including adherence to appropriate equality and diversity standards such as WRES²¹ (Workforce Race Equality Standards) standards for the NHS. Wherever possible the investigation team should include Black, Asian and Minority Ethnic (BAME) representation.

- Proposals for the establishment of Healthcare Safety Investigation Branch as an Executive Non-Departmental Public Body should be implemented at the earliest opportunity. HSIB will support improved practice across the NHS by undertaking exemplar investigations and supporting the development of skilled NHS investigations.
- Royal Colleges, professional representative bodies and healthcare providers should review the availability of independent support for staff involved in legal and regulatory proceedings.

²¹ WRES is currently a requirement for NHS commissioners and NHS healthcare providers including independent organisations through the NHS standard contract.

10. Reflective material

- 10.1. Reflective practice is an intrinsic part of being an effective healthcare professional. The expectation that healthcare professionals prioritise learning through reflection is set out in revalidation and continuing professional development systems. On a personal level, reflection and taking action to address any issues leads to personal insight, improved practice and greater professionalism. On a system wide basis, this leads to more engaged and effective staff, improved standards and better patient safety.
- 10.2. The panel heard widespread fears from healthcare professionals and representative groups that personal reflection where things have gone wrong, and in particular written reflection, might be used as evidence against them in criminal or regulatory proceedings.
- 10.3. There has been much speculation about the role of reflective material in a recent case against a doctor, and this has led to heightened concerns among healthcare professionals about carrying out reflective practice. The panel heard from the Medical Protection Society (MPS), the doctor's medical defence organisation, that there were misconceptions about the use of reflective material in this case²². The MPS stated that at no point during the criminal trial was their e-portfolio reflective statement presented to the court or jury as evidence. The doctor shared some personal reflection with the panel in the fitness to practise hearing to demonstrate the steps she had taken to remediate her practice.
- 10.4. Nevertheless, the fear felt by healthcare professionals about the use of reflective practise is present and real. The panel was concerned to learn that some clinicians are choosing not to engage with reflective learning for fear it could be used against them.
- 10.5. The CPS advised that reflective material is unlikely to be used in prosecuting a healthcare professional for gross negligence manslaughter – but that it is possible. The panel heard suggestions from a number of sources that reflective material should be given legal 'privilege', protecting it from admission in Court. This was not considered workable or appropriate. Where any evidence is material to a case, it is right that it should be considered. No other sectors or professions have equivalent privilege, and to provide an exemption for reflective practice material would rightly cause concern that healthcare professionals are above the law.²³

²² <https://www.medicalprotection.org/uk/about-mps/media-centre/media-gallery/mps-blogs/blogs/good-medical-practice/gmc-issues-blog-posts/gmc-issues/2018/02/05/the-use-of-e-portfolios-and-reflections>

²³ The draft Health Service Safety Investigations Bill, published in draft in September 2017, makes provision for the prohibition on disclosure of information held by the investigation body in connection with an investigation. This power is not absolute: it has significant exceptions allowing for information to be disclosed, such as where there is evidence of criminal activity, where there is an ongoing safety risk or safeguarding concern and where there are concerns about professional misconduct. There is a further exception to prohibition on disclosure in court proceedings - information can also be disclosed on application

- 10.6. However, we believe that a number of steps can be taken to provide reassurance to healthcare professionals about the confidentiality of reflective practice. The panel heard from a number of sources that it is possible to carry out reflection in a way that minimises the likelihood of it being used by either prosecuting authorities or professional regulators. The panel also heard that reflective notes are far more likely to be used in support of an individual rather than against them. Existing guidance on reflective practice should be reviewed to ensure that healthcare professionals are carrying out reflective practice in a way that supports continued professional development.
- 10.7. All healthcare professions have a duty to cooperate with their regulator. They also have a duty to be open with patients and their families when things go wrong in their care – the professional duty of candour²⁴. However, two regulators – the General Medical Council (GMC) and the General Optical Council (GOC) – have powers to require registrants to provide any information, which would include reflective material, to assist with a fitness to practise investigation²⁵. In the case of the GMC, this power allows it to refer a case to a tribunal where a doctor fails to comply with such a request. The tribunal can then consider whether to suspend or impose conditions on the doctor for non-compliance.
- 10.8. When this power was introduced in 2015 it was intended that it would ‘enable the GMC to take swifter action, to ensure the protection of patients, where a fitness to practise concern has been raised about a doctor but it is unable to ascertain whether that doctor is safe because the doctor has failed to respond to requests for information’.²⁶ It was argued that the power would discourage non-cooperation with fitness to practise investigations, and reduce costs and length of fitness to practise hearings by ensuring all relevant information was presented at the appropriate time, reducing the need for additional hearings. In the case of the GOC in 2005, the intention was that power would ‘modernise’ regulation, making it ‘faster, fairer and more effective’.
- 10.9. However, the panel heard concerns among doctors that this power could be used to force them to provide reflective material that could be self-incriminatory, though no examples were given to support this view. However, the panel heard that some groups are so concerned that they are no longer reflecting on their practice or recording such reflection.

to the High Court. Where such an application is made, the judge will apply a test balancing the “interests of justice” against the effect of disclosure on future investigations and the ability of the SofS to improve services.

²⁴ To 'provide to the service user and any other relevant person all necessary support and all relevant information' in the event that a 'reportable patient safety incident' occurs

²⁵ Provision for the GOC to require information was provided in 2005 and for the GMC in 2015.

²⁶ <https://www.gov.uk/government/consultations/changing-how-the-gmc-decides-on-doctors-fitness-to-practise>

- 10.10. The rationale for regulators having different powers to require information from registrants is not clear. Seven regulators operate effectively without a power to require information from registrants for fitness to practise purposes. However, all the regulators that gave evidence to the panel were clear that they would not request reflective material in the investigation of fitness to practise cases. There was no suggestion that either the GMC or GOC had used this power to request reflective material when investigating fitness to practise concerns. Indeed, the GMC has been clear that it will not do so.
- 10.11. The panel was clear that the misunderstanding of this power has had a detrimental effect on the willingness of doctors to reflect on their practice. Given that regulators would not use the power to request reflective material for the purposes of investigating a registrant's fitness to practise, the panel believes that the power to require registrants to provide reflective material should be removed.

Recommendations

- The Royal Colleges, through the Academy, and professional regulators working with appropriate professional bodies should review and, if necessary, amend guidance on how healthcare professionals carry out reflection, stressing the value of reflective practice in supporting continuous professional development. Guidance on carrying out reflection should take a consistent approach across all healthcare professional groups.
- Both prosecuting authorities and professional regulators have been clear that they would be unlikely to use a healthcare professional's reflective material either for a criminal investigation or in considering a registrant's fitness to practise. The professional regulators should clarify their approach to reflective material through guidance.
- Those professional regulators that have a power to require information from registrants for the purposes of fitness to practise procedures should have this power modified to exclude reflective material. Registrants will still be expected to co-operate with their regulator in line with their code of practice and to be open and honest with patients (or where appropriate the patient's advocate, carer or family) when something goes wrong with their treatment or care (the professional duty of candour).

Professional regulation

The review began its consideration of professional regulation in the context of cases of gross negligence manslaughter. However, such cases are rare and consequently organisations and individuals invariably presented evidence about regulation in the context of other serious cases.

As fitness to practise processes are the same for those convicted of gross negligence manslaughter and those facing other fitness to practise allegations, the panel concluded that, in order to discharge its duty effectively, it should consider professional regulation issues in the round.

11. Right of appeal against fitness to practise decisions

11.1. The GMC has the power to appeal to the High Court a decision of the MPTS which it considers to be insufficient for the protection of the public. The GMC is the only UK health regulator that has such a right of appeal²⁷, because of its unique arrangements for fitness to practise (see 11.3). Decisions about whether to appeal are made by the GMC's Registrar, taking into account legal advice. When determining whether to take an appeal the GMC considers:

- protecting the health, safety and well-being of the public;
- maintaining public confidence in the medical profession;
- maintaining proper professional standards and conduct for members of that profession²⁸.

11.2. The MPTS was set up in June 2012 with the aim of providing separation between the GMC's investigative and adjudicative fitness to practise functions²⁹. The MPTS provides independent decision making, which is separate from the GMC's investigatory function. However, the MPTS is a statutory sub-committee of the GMC, is funded by the GMC and is accountable to the GMC Council. It also reports to Parliament on an annual basis.

²⁷ Known as a S40A appeal.

²⁸ https://www.gmc-uk.org/-/media/documents/dc8221-guidance-for-decision-makers---s40a-appeals_pdf-64121775.pdf

²⁹ The 2004/5 Shipman Inquiry by Dame Janet Smith recommended that there should be a clear separation between the investigation of doctors and the process for adjudicating on whether they should be allowed to practise. This was originally envisaged as a wholly separate organisation – the Office of the Health Professions Adjudicator (OHPA) – which would eventually take over Fitness to Practise adjudication for all the regulated health professions. OHPA was established but never operational, and was disbanded in 2012.

- 11.3. The GMC took up its right to appeal MPTS decisions on 31 December 2015 to coincide with the MPTS being made a statutory sub-committee of the GMC. It was argued that the GMC, having already acted in the prosecution role before the tribunal would be well placed to appeal due to its detailed knowledge of the case. The Professional Standards Authority has, since its inception in 2003, always had a power to refer fitness to practise decisions of the nine healthcare professional regulators to the High Court where it has a concern that such a decision is insufficient to protect the public.
- 11.4. The PSA can also join a GMC appeal, or take over the conduct of an appeal with which the GMC decides not to proceed. The GMC similarly has the power to join PSA appeals of MPTS cases, or to take over an appeal from which the PSA withdraws. PSA appeals have two respondents, the regulator and the registrant – whereas the registrant is the only respondent in a GMC appeal. In addition the MPTS cannot oppose a GMC appeal, but the GMC could respond to an appeal by the PSA.
- 11.5. The PSA has put in place a clear process for reaching a decision on whether to refer fitness to practise cases to the High Court. It reviews each fitness to practise decision and those which may be considered insufficient to protect the public are considered by its legal team. If the decision is still considered to be insufficient, a case meeting is called at which a three-member panel, supported by an independent legal adviser, decides whether to refer the case to the High Court. These case meeting decisions are recorded and published.
- 11.6. Any PSA decision whether to refer decisions of fitness to practise committees or the MPTS to the High Court is reviewed by its Scrutiny Committee, which reviews and monitors the work of the PSA. The Scrutiny Committee reviews the case meeting outcomes for quality assurance purposes. It also sample reviews cases where the PSA did not refer a decision or join a GMC appeal.

GMC referrals of MPTS decisions, 31 December 2015 – 30 April 2018

Number of MPTS hearings	559	This figure includes all MPTS decisions new and review, non-compliance and restoration cases.
Number of cases where MPTS imposed sanction lower than recommended by GMC	197	This shows only those cases the sanction imposed by the MPTS was less severe than that recommended by the GMC.
Number of hearings appealed*	25	The number of doctors with decisions that the GMC has appealed.
Appeals allowed (GMC successful) following court judgment	15	Where the appeal has been allowed by the court after hearing the appeal and giving judgment on the case.
Unsuccessful appeals at court hearing	2	Where the appeal has been dismissed by the court after hearing the appeal and giving judgment on the case.
Appeals allowed (GMC successful) by consent	2	Cases where appeal allowed by consent either before or at a hearing.
Appeals withdrawn	4	Appeals withdrawn before hearing. This includes cases where a doctor is granted voluntary erasure before the hearing.
Appeals outstanding	2	Appeals not yet heard

* 27 issued in total as second appeals were issued for two doctors who had had review hearings

PSA referrals of fitness to practise decisions for all nine regulators, 31 December 2015 – 30 April 2018

Number of decisions appealed	30	This figure includes all appeals against MPTS and fitness to practise panel decisions across the nine UK healthcare professional regulators
Successful PSA appeals at court hearing	8	Where the appeal has been allowed by the court after hearing the appeal and giving judgment on the case.
Unsuccessful appeals at court hearing	1	Where the appeal has been dismissed by the court after hearing the appeal and giving judgment on the case.
Cases agreed by consent	17	Cases where appeal allowed by consent either before or at a hearing.

Appeals withdrawn	3	Appeals withdrawn before hearing.
Appeal outstanding	1	Appeals not yet heard

- 11.7. The principle of a right of appeal against fitness to practise decisions that are considered insufficient to protect the public was universally accepted. However, there were significant concerns about whether it was appropriate for this appeal right to be held by the GMC where such a right is also held by the PSA, which oversees all of the health profession regulators.
- 11.8. The review heard concerns that the GMC’s power to appeal MPTS decisions is inconsistent with other healthcare professional regulators. While the MPTS is a statutory subcommittee of the GMC rather than a panel within the organisation like the other healthcare regulators, it is still part of the GMC. This has led to the perception that the GMC is in effect appealing against itself and having two opportunities to make its case – first in putting its case for a sanction to the MPTS and then appealing the MPTS decision if it doesn’t ‘agree’ with the GMC’s view. The panel heard evidence that this perception has led to fear in the medical community and a lack of confidence in the GMC.
- 11.9. While the GMC and PSA cannot lodge separate appeals in relation to the same case, they each have a separate decision making process to determine whether to exercise their right to appeal, but the grounds for any appeal are the same. Doctors, therefore, may be subject to two appeal decisions where other healthcare professionals are only subject to one. This is seen by professionals as unfair and disproportionate. Duplication of the right and of the processes involved extends the conclusion of fitness to practise proceedings by 28 days which adds further stress and uncertainty to families and professionals involved.
- 11.10. Some witnesses also felt that the GMC had used its right of appeal excessively with the intention of seeking to make case law rather than to protect public safety.
- 11.11. On the other side of the argument, the GMC and the MPTS argued that the GMC’s right of appeal was appropriate and conferred public safety benefits. The view expressed by the GMC is that, given the operational separation between its investigative and adjudicative functions, it is appropriate that the GMC has a right to appeal MPTS decisions. It pointed out that it has a high success rate in appealing MPTS decisions, which, it argued, demonstrates that the power is being used appropriately to protect patients and the public from unfit doctors. The MPTS itself considers the outcomes of successful appeals in order to improve its work. Both the GMC and MPTS said that they expected the number of appeals to fall over time. A family member who spoke to the Chair of the panel said that they agreed with the GMC’s decision to appeal a decision in a specific case, although they were not asked about the general principle of the GMC having an appeal right.
- 11.12. The panel looked at the Department of Health’s rationale for giving the GMC a right of appeal in 2015. Public consultation at the time revealed little appetite for the GMC to

be given this appeal right with 70% of respondents opposing the proposal. Notable concerns raised in the consultation – that the PSA is better placed to undertake appeals, that doctors face two appeal decisions where other professionals face only one, and that the GMC is in effect appealing its own decisions – remain issues today.

- 11.13. The tables above show that the GMC has exercised its power proportionately more often than the PSA (the GMC has appealed 25 MPTS decisions since 2015 while the PSA appealed 30 decisions across all nine regulators in the same time). Of the 197 cases where the MPTS imposed a sanction lower than that recommended by the GMC the GMC decided to appeal 25. Of the 25 cases the GMC has appealed, just two have been unsuccessful. The panel's view was that GMC's use of appeals is not excessive. Taken together with the high rate of successful appeals there can be no suggestion that the GMC has used its appeal power inappropriately. Indeed it can be argued that these successful appeals have improved patient safety.
- 11.14. An MPTS decision may be insufficient to protect the public as a result of how the GMC presents its case. For instance the GMC may fail to provide a full picture of a professional's conduct to the Tribunal, which may then reach a decision that is insufficient to protect the public. It would be wrong in principle for the GMC to appeal in such circumstances. The PSA can appeal such cases as it was not involved in presenting the case to the tribunal. In addition, the fact that the PSA reviews decisions across all nine regulators means that it is able to take a fair and consistent approach across the regulatory field. Such consistency encourages confidence in the system.
- 11.15. Since the GMC was granted a power to appeal, the PSA has assessed that it would not have appealed nine cases which were appealed by the GMC. Four of these appeals were upheld by the High Court. In two of these four cases, the High Court imposed a more severe sanction than that originally passed down by the MPTS. In one of these cases the registrant has subsequently been given leave to appeal the High Court's decision. This appeal is pending. Conditions were imposed by the MPTS in the other two cases. The High Court referred one back to the tribunal, which found no impairment and lifted the conditions. In the other case, part of the appeal was upheld by the High Court although the sanction was not changed.
- 11.16. It is the view of the panel that the decision to give the GMC an appeal right has had significant unwelcome and unintended consequences. The panel was concerned about the level of fear and mistrust that the medical community reported about the GMC. This is heightened by the right of appeal against MPTS decisions, which has undermined doctors' trust in the GMC and has had a significant impact on their ability and willingness to engage with the regulator. This is deterring reflection and learning from errors to the detriment of patient safety.
- 11.17. The panel also considered what might be lost if the GMC's right of appeal were to be removed. Since the PSA has a near identical right of appeal to MPTS decisions, it is clear that there would be no gap in the law where regulatory action is being taken as a result of a serious criminal conviction. This then becomes a question about how the two bodies have used their appeal rights. There is an argument that the GMC has taken a more active approach to bringing appeals. However, when the panel

considered those nine appeals which the GMC has brought where the PSA would not have done so, just two appeals resulted in a more severe sanction, and one of these is subject to appeal.

- 11.18. On balance, the panel believes that, in the interest of patient safety, the GMC's right of appeal should be removed. This will help address the mistrust of the GMC amongst doctors and contribute to cultivating a culture of openness that is central to delivering improved patient safety. The PSA would continue to have a right to appeal MPTS decisions that were insufficient for public protection and such decisions would be made in a consistent manner for all healthcare professionals.
- 11.19. The PSA has previously indicated that it intended to review the GMC's use of its power of appeal with a focus on policy, process, procedure and transparency. This review will commence in summer of 2018. The panel accepts that removing the GMC's right of appeal will be dependent on the availability of Parliamentary time. In the meantime, the GMC should review its processes for deciding when to appeal a decision of the MPTS to ensure greater transparency. This review should be informed by the PSA's review of the GMC's right of appeal as well as from the PSA's processes for taking decisions on appeals.

Recommendations

- The Professional Standards Authority (PSA) should retain its right to appeal a decision of a fitness to practise panel to the High Court on the grounds of insufficient public protection. The duplicate power provided to the General Medical Council (GMC) to appeal decisions of the Medical Practitioners Tribunal Service (MPTS) to the High Court should be removed. This will ensure a consistent approach to appeals across healthcare professions that are statutorily regulated.
- Ahead of the legislative change needed to remove its power of appeal, the GMC should review its processes for deciding when to refer a decision of the MPTS so that it is transparent and understood by all parties and involves a group or panel decision, as opposed to lying solely with the Registrar.

12. Consistency of fitness to practise decisions across professional regulators

- 12.1. The professional health regulators' over-arching objective is the protection of the public. This includes the promotion and maintenance of public confidence in the health and care professions. This duty to maintain public confidence in the profession is part of the regulators' consideration of fitness to practise cases and, in the case of the GMC, the exercise of its appeal right.
- 12.2. The panel heard concerns about a perception of inconsistency in the professional regulators' decision making, with a sense that decisions made on similar facts by different regulators result in different sanctions. However, there was insufficient evidence provided to substantiate this.
- 12.3. It is difficult to establish whether there is inconsistency in outcomes for what seem to be similar cases. Even in a single case where multiple professionals are involved, the actions and responsibilities of individual professionals will be different. This may explain some of the perceived variation in outcomes. However, such a perception of inconsistent outcomes can undermine confidence in the regulatory system, both from within the professions and the public as a whole, and merits further consideration.
- 12.4. The panel heard that there is an appetite among regulators to work together to support greater clarity and consistency. Some regulators have investigated incidents jointly, but it is a legal requirement that the fitness to practise processes relating to different professions is separate. The Government has consulted on proposals to streamline the regulation of healthcare professionals in *Promoting Professionalism; Reforming Regulation*. These include proposals to encourage greater joint working between regulators.
- 12.5. The panel heard particular concerns about the regulators' role in taking fitness to practise action on the grounds of securing public confidence in the healthcare professions. It heard that there was little understanding about the type of behaviours and failings that might lead to the public losing confidence in the profession and which therefore constitute grounds for regulatory action. This needs to be better understood in order for the professional regulators to give proper consideration to their duty to protect the public.
- 12.6. Given the short-time frame of this rapid policy review it was not possible to reach definitive conclusions about the inconsistency of regulatory outcomes or about how the regulators assess public confidence in the professions. However, we recognise that these issues are important for effective regulation and believe that further work should be carried out on these issues by the PSA.
- 12.7. In addition, the issues relating to expert opinion provided by healthcare professionals are equally relevant to where they are providing such opinion in a regulatory rather than criminal context.

Recommendations - Consistency of fitness to practise decisions across professional regulators

- Among professionals there is little understanding of what actions by a healthcare professional might lead to the public losing confidence in the profession. The PSA, working with professional regulators, should review how the impact on public confidence is assessed in reaching fitness to practise decisions about individual healthcare professionals, and develop guidance to support consistent decision making in this area.
- The PSA should review the outcomes of fitness to practise cases relating to similar incidents and circumstances considered by different regulators. This review should seek to determine the extent and reasons for different fitness to practise outcomes in similar cases and, if appropriate, recommend changes to ensure greater consistency.
- We recommend that professional regulators ensure that the healthcare professionals they rely upon for an expert opinion in fitness to practise cases have satisfied the requirements set out in the recommendations in chapter 8.

13. Diversity in fitness to practise proceedings

- 13.1. The panel heard that Black, Asian and Minority Ethnic (BAME) registrants are over-represented in the fitness to practise processes of a number of healthcare professional regulators. There is some evidence that this also applies to prosecutions for gross negligence manslaughter, although the numbers of cases are too small from which to draw meaningful conclusions.
- 13.2. Research undertaken by the GMC and NMC has shown that while rates of referral to the regulators of BAME registrants are higher than expected, there is no evidence that the fitness to practise processes of the regulators themselves are discriminatory. This was supported by the evidence heard by the panel.
- 13.3. Regulators have taken steps to ensure that fitness to practise processes are fair. For example, the panel heard that the GMC has improved BAME representation on fitness to practise panels. In 2000 there was BAME representation on just two per cent of panels, whereas by the time the role was transferred to the MPTS in 2015 this had increased to 80 per cent. The GMC is committed to working with employers to better understand and address the reasons for the over-representation of some groups in the cases referred to it. It has also commissioned a review to better understand why some doctors with certain characteristics, including Black, Asian and Minority Ethnic doctors, are referred to the regulator for fitness to practise issues more than others³⁰. In addition, the PSA has consulted on proposals to include equality and diversity standards in its Standards of Good Regulation.
- 13.4. These are welcome steps, and the panel recognises that progress has been made to ensure that regulatory processes are sensitive to potential unconscious bias about certain groups of professionals. The panel recognises that the factors which lead to the over-representation of BAME professionals in fitness to practise proceedings are complex and are not solely within the control of the regulators. However, the regulators should continue to take steps to ensure that their processes are fair to all registrants.

Recommendations – Diversity in fitness to practise proceedings

- We support the PSA's intention to introduce, as part of its Standards of Good Regulation, equality and diversity standards for professional regulators.
- Professional regulators should ensure that fitness to practise panel members have received appropriate equality and diversity training.

³⁰ <https://www.gmc-uk.org/news/media-centre/media-centre-archive/gmc-commissions-new-research-into-fitness-to-practise-referrals>

Legal representation

- 13.5. The panel also heard that some professional groups were more likely than others to have legal representation during fitness to practise proceedings. The assumption was that those higher paid professionals would be more likely to afford legal representation. There was concern that professionals who are not represented might be at a disadvantage in what is an adversarial process. This is all the more important in light of the evidence we heard regarding the inconsistency in the quality of expert evidence. Unrepresented professionals are likely to be less able to respond to such evidence further supporting the need for high standards in healthcare professionals providing expert advice and evidence (see recommendations in chapter 8).
- 13.6. Figures from the GMC show that 54 per cent of doctors who appeared before the MPTS in 2016/17 were legally represented. In 2017/18, 35 per cent of Health and Care Professionals Council registrants were represented at a final hearing (this may include legal representation, but also Union or professional body representatives, McKenzie friends or colleagues). Seventy-nine per cent of registrants who faced fitness to practise proceedings before the General Osteopathic Council had legal representation. Data on legal representation in fitness to practise proceedings is not gathered by all the regulators. It is therefore difficult to understand the degree of variation of legal representation and the impact that this might have on the outcomes of fitness to practise hearings.
- 13.7. The panel also considered whether there was a correlation between legal representation and the ethnic identity of registrants. Again, insufficient data was available for the panel to consider this issue in full.
- 13.8. In light of this the panel believes that further work is needed to understand to extent of legal representation in fitness to practise proceedings and the impact on the outcome of such proceedings. This should be taken forward alongside work on reforming fitness to practise to make it a more inquisitorial and less adversarial process, as consulted on in *Promoting Professionalism; Reforming Regulation*³¹.

Recommendations – Legal representation in fitness to practise proceedings

- The PSA should review whether the outcome of fitness to practice procedures is affected by the availability of legal representation of registrants. This needs to be considered alongside broader proposals for the reform of professional regulation which seek to establish a less adversarial approach to fitness to practise issues through the use of undertakings and consensual disposal.

³¹ <https://www.gov.uk/government/consultations/promoting-professionalism-reforming-regulation>

Support for patients and families during fitness to practise proceedings

- 13.9. The panel's Chair heard from two families that they felt marginalised and poorly communicated with by the regulators during fitness to practise cases concerning healthcare professionals involved in the death of a family member. These cases echo some of the concerns in the recent PSA report on how the NMC handled the fitness to practise cases of a number of midwives at Morecambe Bay NHS Foundation Trust³².
- 13.10. Fitness to practise processes are by their nature concerned with individual healthcare practitioners. They do not seek to 'punish' a practitioner, offer retribution to patients who have experienced poor care or provide a forum to better understand what went wrong in an episode of treatment beyond the immediate question of the individual's fitness to practise.
- 13.11. In addition, the fitness to practise process and any appeals can lengthen the time taken to conclude proceedings relating to a healthcare associated death. One family member who spoke to the panel has been waiting over seven years for the conclusion of criminal and regulatory proceedings associated with the death of their family member.
- 13.12. While the fitness to practise process is about the professional rather than the bereaved relatives, it is understandable that families are interested in the process and its conclusions. The panel believes that regulators could and should do more to engage with and inform families in a compassionate and consistent manner about fitness to practise processes.

Recommendation

- Professional regulators should review and where necessary improve the support they provide to patients and family members whose care and treatment is an issue in fitness to practise proceedings against a healthcare professional.

³² <https://www.professionalstandards.org.uk/publications/detail/nmc---lessons-learned-review-may-2018>

14. Automatic erasure offences

- 14.1. In 2014 the Government commissioned the Law Commissions of England and Wales, Scotland and Northern Ireland to undertake a comprehensive review of the legal framework for professional regulation.
- 14.2. The Law Commissions recommended that there should be a presumption of erasure for registrants convicted of some serious criminal convictions that they considered to be incompatible with continued registration – so-called automatic erasure offences. The Law Commissions made the following recommendation:
- *A regulator must remove automatically any registrant who has been convicted of murder, trafficking people for exploitation, blackmail (where a custodial sentence is imposed), rape and sexual assault, and certain offences against children. There should be a right to make representations to the regulator and right of appeal to the higher courts on the factual basis of an error in law or finding of fact.*
- 14.3. Subsequently the UK Government, along with the Governments of Scotland, Wales and Northern Ireland, consulted on wide ranging proposals to reform the regulation of health and social care professionals. While automatic erasure was not specifically consulted on, the principles of providing flexible and efficient fitness to practise processes, which is central to proposals for the reform of professional regulation, are consistent with such a development. The Governments have not yet set out their plans for reform following this consultation.
- 14.4. A number of respondents to the review expressed views as to whether a conviction for gross negligence manslaughter should become an automatic-erasure offence. In general it was felt that gross negligence manslaughter should not constitute grounds for automatic erasure. The panel agrees with this view.

15. Recommendations

Allegations of gross negligence manslaughter against healthcare professionals

1. An agreed and clear position on the law on gross negligence manslaughter

1.1 A working group should be set up to set out a clear explanatory statement of the law on gross negligence manslaughter. This working group should involve, at a minimum, representatives from the Crown Prosecution Service (CPS), the coroner services, Treasury Counsel and healthcare defence organisations.

1.2 All relevant organisations, including, if appropriate, the Director of Public Prosecutions, should produce or update guidance on gross negligence manslaughter in light of the explanatory statement set out by the working group in 1.1. This will promote a consistent understanding of where the threshold for prosecution for gross negligence manslaughter lies.

2. Improving assurance and consistency in the use of experts in gross negligence manslaughter cases

2.1 The Academy of Royal Medical Colleges, working with professional regulators, healthcare professional bodies and other relevant parties, should lead work to promote and deliver high standards and training for healthcare professionals providing an expert opinion or appearing as expert witnesses. These standards should set out what, in the Academy's opinion, constitutes appropriate clinical experience expected of healthcare professionals operating in such roles.

Healthcare professionals providing an expert opinion or appearing as an expert witness should have relevant clinical experience and, ideally, be in current clinical practice in the area under consideration. Additionally, they should understand the legal requirements associated with being an expert witness (including the requirement to provide an objective and unbiased opinion).

2.2 Healthcare professionals should be supported and encouraged to provide an expert opinion where it is appropriate for them to do so. Healthcare professional bodies, including Royal Colleges and professional regulators, should encourage professionals to undertake training to become expert witnesses, and employing organisations should be prepared to release staff when they are acting as expert witnesses.

2.3 Professional representative bodies and regulators should recognise acting as an expert witness as part of a healthcare professional's revalidation or continuous professional development (CPD) process.

2.4 Although our terms of reference were limited to gross negligence manslaughter, we heard evidence of more general concerns about experts. This should be reflected in the Academy's work to develop training for healthcare professionals acting in this capacity.

3. Consolidating expertise of gross negligence manslaughter in healthcare settings in support of investigations

3.1 The Chief Coroner should consider revising the guidance on gross negligence manslaughter in Law Sheet no 1 in light of the explanatory statement set out by the working group under 1.1. 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.

3.2 Building on the work of the Homicide Working Group, police forces across England should consolidate their expertise on gross negligence manslaughter by a healthcare professional through the creation of a virtual specialist unit. This unit would support senior investigating officers by making available the experience of previous gross negligence manslaughter cases in the early stages of an investigation.

3.3 Advice to senior investigating officers should be updated to reflect the explanatory statement on gross negligence manslaughter set out by the working group (1.1) and the standards for healthcare professionals providing an expert opinion or appearing as expert witnesses (2.1).

3.4 A new memorandum of understanding (MoU) should be agreed between relevant bodies, including the College of Policing, the CPS, the Care Quality Commission (CQC), Health and Safety Executive (HSE) the Healthcare Safety Investigation Branch (HSIB) and professional regulators, in relation to the investigation of deaths in a healthcare setting. As a minimum this MoU should establish a common understanding of the respective roles and responsibilities of the organisations involved, support effective liaison and communications between these organisations, and cover what is expected of expert witnesses, in particular that they should consider the role of systemic and human factors in the provision of healthcare.

3.5 Signatories to the MoU should disseminate its contents in order to promote a greater understanding of legal issues among healthcare professionals and of healthcare issues (including systemic and human factors) among prosecuting authorities, the police and coroner services. This would help support the development of a "just culture" in healthcare, which recognises both systemic factors and individual accountability.

4. Improving the quality of local investigations

4.1 Where a suspected gross negligence manslaughter case in a healthcare setting has been referred to the CPS, the CQC must be informed so that it can consider whether to carry out a parallel, but separate, investigation of the healthcare provider to determine the role of systemic and human factors in the incident and to identify any changes which might need to be made. The CQC should also consider the findings of its inspection in deciding whether to undertake any follow up action in relation to the provider and/or any wider review of system issues. The relationship between a criminal investigation and any parallel CQC inspection should be set out in the MoU under 3.4.

4.2 There must be a thorough local investigation of all unexpected deaths in healthcare settings, both in the NHS and in the independent sectors. The CQC should consider the effectiveness of such investigations as part of its inspection programme of healthcare providers.

4.3 In the case of NHS organisations, investigations into unexpected deaths should be carried out in line with NHS Improvement's Serious Incident framework (SIF). In particular family members, carers or advocates must be involved and supported (e.g. through family liaison) from the outset and be kept informed of progress and the outcome. Investigations must be expertly and objectively overseen and, where appropriate, independently-led. A member of the healthcare provider's Board must be appointed to be responsible for ensuring the SIF is followed in relevant investigations. The outcome of such investigations should be reported to the Board and shared with the relevant regulatory, statutory, advisory and professional bodies. A similar methodology for investigations should be adopted by private healthcare providers.

4.4 Healthcare providers should ensure that people conducting investigations have received appropriate training, including on equality and diversity. NHS Improvement's SIF should include guidance on how to consider equality and diversity considerations in investigations, including adherence to appropriate equality and diversity standards such as WRES³³ (Workforce Race Equality Standards) standards for the NHS. Wherever possible the investigation team should include Black, Asian and Minority Ethnic (BAME) representation.

4.5 Proposals for the establishment of Healthcare Safety Investigation Branch (HSIB) as an Executive Non-Departmental Public Body should be implemented at the earliest opportunity. HSIB will support improved practice across the NHS by undertaking exemplar investigations and supporting the development of skilled NHS investigations.

³³ WRES is currently a requirement for NHS commissioners and NHS healthcare providers including independent organisations through the NHS standard contract.

4.6 Royal Colleges, professional representative bodies and healthcare providers should review the availability of independent support for staff involved in legal and regulatory proceedings.

Reflective material

5.1 The Royal Colleges, through the Academy, and professional regulators working with appropriate professional bodies should review and, if necessary, amend guidance on how healthcare professionals carry out reflection, stressing the value of reflective practice in supporting continuous professional development. Guidance on carrying out reflection should take a consistent approach across all healthcare professional groups.

5.2 Both prosecuting authorities and professional regulators have been clear that they would be unlikely to use a healthcare professional's reflective material either for a criminal investigation or in considering a registrant's fitness to practise. The professional regulators should clarify their approach to reflective material through guidance.

5.3 Those professional regulators that have a power to require information from registrants for the purposes of fitness to practise procedures should have this power modified to exclude reflective material. Registrants will still be expected to co-operate with their regulator in line with their code of practice and to be open and honest with patients (or where appropriate the patient's advocate, carer or family) when something goes wrong with their treatment or care (the professional duty of candour).

Professional regulation

6. Right of appeal against fitness to practise decisions

6.1 The Professional Standards Authority (PSA) should retain its right to appeal a decision of a fitness to practise panel to the High Court on the grounds of insufficient public protection. The duplicate power provided to the General Medical Council (GMC) to appeal decisions of the MPTS to the High Court should be removed. This will ensure a consistent approach to appeals across healthcare professions that are statutorily regulated.

6.2 Ahead of the legislative change needed to remove its power of appeal, the GMC should review its processes for deciding when to refer a decision of the Medical Practitioners Tribunal Service so that it is transparent and understood by all parties and involves a group or panel decision, as opposed to lying solely with the Registrar.

7. Consistency of fitness to practise decisions across professional regulators

7.1 Among professionals there is little understanding of what actions by a healthcare professional might lead to the public losing confidence in the profession. The PSA, working with professional regulators, should review how the impact on public confidence is assessed in reaching fitness to practise decisions about individual healthcare professionals, and develop guidance to support consistent decision making in this area.

7.2 The PSA should review the outcomes of fitness to practise cases relating to similar incidents and circumstances considered by different regulators. This review should seek to determine the extent and reasons for different fitness to practise outcomes in similar cases and, if appropriate, recommend changes to ensure greater consistency.

7.3 We recommend that professional regulators ensure that the healthcare professionals they rely upon for an expert opinion in fitness to practise cases have satisfied the requirements set out in recommendation 2.1.

8. Diversity in fitness to practise proceedings

8.1 We support the PSA's intention to introduce, as part of its Standards of Good Regulation, equality and diversity standards for professional regulators.

8.2 Professional regulators should ensure that fitness to practise panel members have received appropriate equality and diversity training.

9. Legal representation in fitness to practise proceedings

9.1 The PSA should review whether the outcome of fitness to practise procedures is affected by the availability of legal representation of registrants. This needs to be considered alongside broader proposals for the reform of professional regulation which seek to establish a less adversarial approach to fitness to practise issues through the use of undertakings and consensual disposal.

10. Support for patients and families during fitness to practise proceedings

10.1 Professional regulators should review and where necessary improve the support they provide to patients and family members whose care and treatment is an issue in fitness to practise proceedings against a healthcare professional.

16. Annex A - Gross Negligence Manslaughter Data

Table 1: Special Crime unit gross negligence manslaughter cases (January 2013 to March 2018) – Breakdown by referral year

Date of referral to CPS	No further action by police after early investigative advice from CPS	No further action decision by CPS after full case submitted for charging decision	Prosecuted and convicted	Prosecuted and acquitted	Ongoing as of March 2018	Total
2013	11	5	2	1	0	19
2014	26	15	1	2	1	45
2015	21	4	0	0	2	27
2016	15	11	1	0	3	30
2017	12	6	0	0	5	23
2018	0	2	0	0	5	7
Total	85	43	4	3	16	151

Note: Cases dated and carried through from conviction date

18. Annex B – Panel members

- Professor Sir Norman Williams – chair
- Ian Stern QC – vice chair
- Martin Bromiley (Chair, Clinical Human Factors Group) / Dr Nick Toff (Principal National Clinical Investigator, Healthcare Safety Investigation Branch) - member
- Harry Cayton (CEO, Professional Standards Authority) - member
- Professor Jacqueline Dunkley-Bent (Head of Maternity, Children and Young People, NHS England) - member
- Professor Carrie MacEwen (Chair, Academy of Medical Royal Colleges) – member
- Lesley Watts (Chief Executive, Chelsea and Westminster Hospital NHS Foundation Trust) – member

Secretariat – Department of Health and Social Care

- William Vineall – Director, Acute Care and Quality Policy
- Claire Armstrong – Deputy Director, Professional Regulation
- Mark Bennett – Deputy Branch Head, Professional Regulation
- Rhian Wells – Section Head, Professional Regulation
- Harriet Askew – Policy Officer, Quality, Patient Safety and Investigations

Additional legal support

- Jacqueline Carey – Barrister and legal support for Ian Stern QC

19. Annex C – Terms of reference

Background/Context

- The Secretary of State for Health and Social Care announced on 6 February that he was asking Professor Sir Norman Williams to conduct a rapid policy review into the issues pertaining to gross negligence manslaughter in healthcare. This will not consider any changes to the law of gross negligence manslaughter or the autonomy of the decision making of the Crown Prosecution Service or the courts.

Purpose of the Review

Working with stakeholders, the Review will consider:

- how we ensure healthcare professionals are adequately informed about:
 - where and how the line is drawn between gross negligence manslaughter (GNM) and negligence;
 - what processes are gone through before initiating a prosecution for GNM;
- In addition, provide any further relevant information gained from engagement with stakeholders through this review about the processes used in cases of gross negligence manslaughter;
- how we ensure the vital role of reflective learning, openness and transparency is protected where the healthcare professional believes that a mistake has been made to ensure that lessons are learned and mistakes not covered up;
- lessons that need to be learned by the General Medical Council (GMC) and other healthcare professionals' regulators in relation to how they deal with professionals following a criminal process for gross negligence manslaughter.

The Review will not be commenting on the specifics of any particular case although it will consider questions raised by such cases and whether lessons may be learned.

20. Annex D – Meetings held by the Williams Review

The Williams Review panel, in full or in part, has heard oral evidence from the following:

- AvMA
- British Association of Physicians of Indian Origin
- British Medical Association
- Care Quality Commission
- Conference of Postgraduate Medical Deans
- Crown Prosecution Service
- David Sellu
- Friends of David Sellu
- General Medical Council
- General Optical Council
- General Pharmaceutical Council
- Health and Care Professions Council
- Health and Safety Executive
- Health Education England
- Healthcare Safety Investigation Branch
- Margaret Hughes
- MDDUS
- Medical Defence Society
- Medical Defence Union
- Medical Practitioners Tribunal Service
- Medical Protection Society
- Murray Anderson Wallace
- National Police Chief's Council
- NHS Confederation
- NHS England
- NHS Improvement
- Nicola Adcock
- Nick Ross
- Nursing and Midwifery Council
- Professional Standards Authority
- Professor Iqbal Singh
- Rail Accident Investigation Branch
- Royal College of Anaesthetists
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Obstetricians and Gynaecologists
- Royal College of Paediatrics and Child Health

- Royal College of Psychiatrists
- Royal College of Physicians
- Royal College of Surgeons Edinburgh
- Royal College of Surgeons England
- Sir Robert Francis QC
- Sid Herbert
- Steve Shorrocks
- Treasury Counsel
- Will Powell

We are also very grateful to the following groups and organisations that provided written evidence to the review:

- Doctors4Justice
- Institute of Biomedical Science
- Association of Optometrists
- The Doctors' Association UK
- UK Public Health Register (UKPHR)
- Association of Surgeons of Great Britain & Ireland (ASGBI)
- Royal College of Pathologists
- The Doctors' Association UK
- Royal College of Physicians and Surgeons of Glasgow
- Community Pharmacy Patient Safety Group
- Association of Anaesthetists of Great Britain & Northern Ireland
- Difficult Airway Society
- Royal College of Physicians of Edinburgh
- Hospital Consultants and Specialists Association
- Royal College of Emergency Medicine
- College of Optometrists
- Academy of Medical Royal Colleges
- Centre of Excellence in Safety for Older People (CESOP)
- NHS Providers

We would like to extend our thanks to the numerous others who sent in written evidence in an individual capacity, including families, healthcare professionals, academics, and medico-legal professionals.

21. Annex E – Glossary of terms

Terms used in the Review report³⁴.

Clinical Commissioning Groups	Clinical Commissioning Groups (CCGs) commission most of the hospital and community NHS services in the local areas for which they are responsible. Commissioning involves deciding what services are needed for diverse local populations, and ensuring that they are provided.
Crown Prosecution Service	The Crown Prosecution Service is the principal public prosecuting agency for conducting criminal prosecutions in England and Wales. It is headed by the Director of Public Prosecutions.
Director of Public Prosecutions	See Crown Prosecution Service
Duty of candour	The statutory duty of candour placed on all health service bodies and all other care providers registered with the CQC, as introduced by the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. This duty requires providers to be open and honest with patients, or their representatives, when unintended or unexpected harm has occurred during their treatment.
Gross negligence manslaughter	A criminal offence where death has been caused as the result of a grossly negligent (though otherwise lawful) act or omission on the part of the defendant. A type of involuntary manslaughter.
Healthcare professional	Any professional working in the healthcare system
Human Factors/Ergonomics	The two terms are interchangeable. This refers to environmental, organisational and job factors, and human and individual characteristics, which influence behaviour at

³⁴ Some of these terms may be open to interpretation. The glossary explains the context that these terms are used within this report.

	work in a way which can affect health and safety -
HSE	The Health and Safety Executive (HSE) is the body responsible for the encouragement, regulation and enforcement of workplace health, safety and welfare, and for research into occupational risks in Great Britain
Just Culture	A culture that many safety critical industries aspire to but which is also subject to academic debate. However generally in a just culture inadvertent human error, freely admitted, is not normally subject to sanction to encourage reporting of safety issues. In a just culture investigators principally attempt to understand why failings occurred and how the system led to sub-optimal behaviours. However a just culture also holds people appropriately to account where there is evidence of gross negligence or deliberate acts.
Medical Defence Organisations	Mutual non-profit making organisations, with the primary functions of indemnifying doctors for incidents arising from their clinical care of patients and providing members with medico-legal advice for issues arising from clinical practice.
Medical Practitioners Tribunal Service	The adjudication service for doctors, established in 2012.
Professional regulators	The regulators of registered healthcare professionals in the UK and Northern Ireland. This includes the General Medical Council (GMC), Nursing and Midwifery Council (NMC), General Chiropractic Council, General Dental Council (GDC), General Optical Council, General Osteopathic Council, General Pharmaceutical Council, Health and Care Professions Council, and the Professional Standards Authority.

Prosecuting authorities	Any authority involved with the investigation and prosecution for criminal offences. Includes the police and the CPS
Reflective practice	The self-reflections of a healthcare professional. Reflective practice is a requirement as part of the General Medical Council's revalidation process for doctors.
Revalidation	Every licenced doctor must revalidate with the General Medical Council to keep their licence to practise.
Royal Colleges	The medical Royal Colleges across the UK whose primary interests are post graduate education and training and standards of clinical practice. They also have general interest in healthcare policy.
Serious Incident investigation	The investigation of a serious incident (see glossary term 'Serious Incident') that is commissioned by a Trust to determine learning from the incident.
Serious incidents	Serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.
Serious untoward incidents	See Serious Incidents.
The Panel	The review panel.
The Review	The Williams Review into gross negligence manslaughter in healthcare.

22. Annex F – Abbreviations used in the report

Abbreviation	Name in full
AAIB	Air Accident Investigation Branch
BAPIO	British Association of Physicians of Indian Origin
CCG	Clinical Commissioning Group
CPS	Crown Prosecution Service
CQC	Care Quality Commission
DPP	Director of Public Prosecutions
GMC	General Medical Council
GNM	Gross negligence manslaughter
GOC	General Optical Council
GPhC	General Pharmaceutical Council
HCPC	Health and Care Professions Council
HEE	Health Education England
HSIB	Healthcare Safety Investigation Branch
HWG	Homicide Working Group
MDDUS	Medical and Dental Defence Union of Scotland
MDO	Medical Defence Organisation
MDU	Medical Defence Union
MoU	Memorandum of Understanding
MPS	Medical Protection Society
MPTS	Medical Practitioners Tribunal Service
NHSE	NHS England

NHSI	NHS Improvement
NMC	Nursing and Midwifery Council
NPCC	National Police Chief's Council
PSA	Professional Standards Authority
RAIB	Rail Accident Investigation Branch
SI	Serious Incident
SUI	Serious Untoward Incident