ROYAL COLLEGE OF PHYSICIANS AND SURGEONS OF GLASGOW

Royal College of Physicians and Surgeons of Glasgow
Submission to Dame Clare Marx's
Review into Gross Negligence Manslaughter and Culpable Homicide
For the General Medical Council

The Royal College of Physicians and Surgeons of Glasgow was founded in 1599 to improve the quality and practice of medicine and surgery.

Based in Glasgow, the College has 14,000 Fellows and Members who work as senior clinicians throughout the United Kingdom and across the world. Unlike our sister Royal Colleges, we have a multidisciplinary membership.

Ensuring the safety of our patients is at the forefront of every clinician's practice. That is why we welcome this review and are committed to engaging with this issue in order to promote and uphold the best practice in patient care and professional practice amongst our membership and throughout the medical profession.

Our College remains concerned, however, about the negative impact that recent cases in the Courts (GMC v Bawa-Garba 2018 EWHC 76, R v Sellu 2016) have had on our profession and on our membership, and in particular on medical trainees. As resources within the health service in every part of the UK are squeezed, workforce issues including staff shortages have intensified, and the wellbeing of our membership continues to deteriorate.

This has been brought into focus by the recent results of "Focus on Physicians 2017 – 18", the annual census of consultant physicians and higher specialty trainees across the UK commissioned by the Federation of Medical Royal Colleges of the United Kingdom, and the "National training survey results 2018" published by the GMC in July.

The key findings from these reports make stark reading.

- Half of all consultants and two thirds of trainees who responded to the physicians' census reported frequent gaps in trainees' rotas
- **One in five respondents saying these are causing significant problems for patient safety in hospitals**
- Three quarters of respondents have highlighted the workaround solutions they are regularly having to find.

Other findings included the fact that **consultants and trainees are working around 10 per cent more than their contracted hours**. This equates to trainees working an extra six weeks and consultants an extra month unpaid a year.

The GMC survey found that:

- **Nearly a quarter of doctors in training and just over a fifth of trainers reported that they're burnt out because of their work**.
- **Almost a third of trainees said that they are often or always exhausted at the thought of another shift**. And well over a half of trainees, and just under a half of trainers, reported that they often or always feel worn out at the end of their working day.

- **Two in five trainees and two thirds of trainers rated the intensity of their work as very heavy or heavy**; and nearly half of trainees reported that they work beyond their rostered hours on a daily or weekly basis.
- And around a third of doctors in training and trainers said that training opportunities are lost to rota gaps.

There is increasing evidence that human factors affect performance of doctors and medical staff. This means that doctors in difficult situations may not be functioning at an optimal level. There is good evidence from the airline industry that stress needs to be reduced, breaks and meals are important. Hierarchical structures may not allow sensible criticism and advice.

We believe that it is vital to acknowledge this challenging context when trying to understand and address issues relating to medical negligence in the contemporary health service.

As we stated in our response to the Williams Review earlier this year, our members have highlighted the difficulty that the current environment does not allow mistakes to be acknowledged, reflection made and learning to take place to prevent further mistakes without blame.

The College believes that:

- We should adopt a proactive approach to promoting an open, transparent clinical culture which is designed to reduce the number of avoidable deaths
- We must create a safe environment where individual mistakes can be acknowledged and reflected upon in a way which is designed to improve practice, not to apportion blame
- This discussion must also recognise and be able to address systematic failures in the system, and the impact these have on individual practice
- We are concerned that health care providers and Commissioners are not held to account for their decisions and there is no regulator for non-medically (in its broad sense) qualified NHS managers

The Submission continues with the format of the Call for Evidence.

<u>This section focuses on what you consider to be 'criminal acts' by doctors</u>

9. What factors turn a mistake resulting in a death into a criminal act?

In general, doctors should not be prosecuted for deaths that result from mistakes when they are acting in good faith. The focus should be on learning from mistakes to improve patient safety, rather than apportioning blame.

The College considers that the context in which a death takes place is of paramount importance. In particular, account needs to be taken of the system in which those involved were working. This applies to local enquiry, judicial situations and regulatory fitness to practice processes.

The College considers a human factors assessment approach should be taken as part of any investigation.

There needs to be greater standardisation in terms of expert training and selection, investigation and decision to prosecute.

10. What factors turn that criminal act into manslaughter or culpable homicide?

There are certainly a small minority of doctors whose actions may merit being charged with a criminal offence. What should distinguish these individuals from those who are put in an impossible situation and have made a mistake or mistakes? **It is surely intent to do harm.** If someone prescribes a treatment which has no proven benefit (either measured by research or practice), this would potentially produce harm. If the intent was worse such as to cause death this would fulfil the definition. If the intent was to relieve distressing symptoms and led to earlier death, this would not fulfil the criteria (the argument often used to justify use of opiates in terminal illness).

The intent to do harm could be from pre-meditated malice or from wilful negligence that is unaccounted for by the situation within which care is provided. It has to be recognised as more than an error and not the result of the lack of experience alone.

It remains a concern that legal terminology is not well understood by most clinicians. If we are to make progress in this area as a profession, we need to ensure that clinicians are fully up to date with the law as it impacts on their work.

Doctors are not lawyers. There are very few clinicians who could give a reliable description of or define the difference between gross negligence manslaughter, culpable homicide and manslaughter. The possibility of a prosecution for gross negligence manslaughter may cause doctors and other health professionals to lose self-confidence such that they perform their duties at a lower standard resulting in suboptimal care. We also question whether these definitions are clearly understood by juries under the present system (R v Sellu Appeal 2016, where the appeal was allowed on the grounds that the jury was given no guidance on the meaning of "gross negligence" [Dyer C, Br Med J 2016;355:i6274]).

There is a strong argument to be made that gross negligence manslaughter or culpable homicide in Scotland should not be an offence. Sir Ian Kennedy QC (Br Med J 2018;360:k1376) has stated that "we need to rethink the role of the criminal law and medical manslaughter. Does it have any place in how we deal with things going wrong... because medical manslaughter means you can pick someone, blame them and imagine you have solved the problem. And what you have done has exacerbated it". The College believes where the situation excludes malice or intent, this should be actively considered. It also notes that the threshold for each offence is different at present, being higher for culpable homicide.

ROYAL COLLEGE OF PHYSICIANS AND SURGEONS OF GLASGOW

This section focuses on the experience of patients and their families

11. Do the processes for local investigation give patients the explanations they need where there has been a serious clinical incident resulting in a patient's death? If not, how might things be improved?

Current practice varies. There is always the ability for senior clinicians to have a discussion with families. However, there is no defined national structure, no formalised training of staff or support for staff in relation to dealing with these enquiries It can be a long and unwieldy process for both families and hospital staff. Many Trusts and Health Boards do not have adequate numbers of trained individuals to carry out this type of investigation.

Local investigation using techniques such as root cause analysis allows for investigations of serious untoward incidents in the health setting. Patients and their families should be an essential part of this investigation with evidence being taken from them, and regular communication and a final conclusion and action plan communicated to them in clear language. They should be integrated into the process. However wherever possible these often-harrowing experiences must not be confrontational. These processes should be seen to be timely, impartial and independent. Their findings should be part of any future processes.

12. How is the patient's family involved in the local trust/board/hospital investigation process and in feedback on the outcome of the investigation?

The families need to be in the centre of the process and feel they are being heard. This may mean they need an advocate such as the PALS (Patient Advice and Liaison Service) service. Anyone acting this way must have an intimate knowledge of how the NHS works, be trained and have adequate time in their job plan. There is however no defined standard of process, quality and family support.

There will always be vexatious complainers and systems should be in place to provide adequate controls

13. What is the system for giving patients' families space for conversation and understanding following a fatal clinical incident? Should there be a role for mediation following a serious clinical incident?

The College believes that involvement of people whom the family know and trust is vital if this is to succeed. Mediators may be helpful but must have the trust of all concerned. They are currently under used. It should be remembered that hospital staff may have also be traumatised mentally by the incident.

Standards need to be devised and their quality reviewed. This would mean appropriate communication, training of staff, support and information for families. This will require local resources.

14. How are families supported during the investigation process following a fatal incident?

There is a lack of a standard approach to the provision of appropriate communication support and information to families. An equivalent team to that provided for complaints should be considered. National minimum standards and quality review would be required.

15. How can we make sure that lessons are learned from investigations following serious clinical incidents?

The College believes this is key to successful management of these situations. Any investigation needs to have messages for everyone with reassessment after an interval. This should involve cultural change of any organisation as well as personal, technical or scientific change.

Conventional risk management processes will address learning from serious incidents and 'near misses'. However, when clinically led, these commonly focus on identifying clinical decisions which could have resulted in an alternative outcome, rather that identifying system-derived factors e.g. staffing, filing of results, computerised processes. Systematic analysis of ***all*** contributory factors is needed, clinical and non-clinical. Processes are also needed that allow for collation and review of multiple low-level concerns and for sharing information about matters learned at trust or board level. This will require appropriate resourcing of clinical governance and clinical risk by Trusts and boards.

<u>This section focuses on processes leading up to a criminal investigation</u>

16. Do you think that the current arrangements for reporting and investigating serious clinical incidents within healthcare settings are effective and fair? If not, what is wrong and how might they be improved?

The internal processes such as a Serious Untoward Incident (SUI) (also known as a Serious Clinical Incident) meeting should take place and an action plan initiated. Any enquiry has to be fair to all sides and should not be adversarial. The current investigations may not be seen as independent to both patients and their families and also clinicians. If gross negligence manslaughter (GNM) and Culpable Homicide continue to be criminal offences, the Crown Prosecution Service or Procurator Fiscal must take independent expert advice before proceeding. There needs to be greater standardisation of expert training and selection, investigation and decision to prosecute. This College would consider helping to provide this training.

It is also critical that where a system failure may have occurred, this must form part of the assessment.

Commissioning bodies (e.g. Clinical Commissioning Groups [CCGs]), NHS Trust and Boards must have an obligation to take an active part in this process and non-medical managers must also engage. At present the trigger for a prosecution is not clearly defined (current criteria include a realistic prospect of conviction and that the prosecution is in the public interest). **It could be argued that the current cases may not be in the public interest and could therefore have the opposite effect.**

We understand, having taken advice, that the threshold for prosecution in the Scottish jurisdiction may be higher and definitions may differ.

For individual doctors and hospital staff, this process will require significant education, and the Royal Colleges may have a role to play in this. Over and above this, the GMC needs to balance its educational role with its regulatory role. Its guidance needs to be framed constructively in an educational manner.

Current processes are often not perceived as fair. Morbidity and mortality meetings at department level can be handled supportively, but more formal risk management processes are often perceived as operating within a blame culture.

Doctors involved in Inquests or Fatal Accident Enquiries are not usually supported personally by their board or trust and commonly report depression and anxiety. Some leave their place of work as a result.

Formal steps to provide structured support of medical and other clinical staff are needed. An all-cause analysis of the factors leading to death should replace that which focusses only on the actions of one or a few individuals. Identification of the contextual contributing factors is needed e.g. decanted patients, staffing, misfiled results.

Protocols and training should be standardised nationally, including QA with fairness and impartiality for black, minority and ethnic doctors.

17. Would there be benefits in ensuring a human factors assessment approach is used in local investigations as opposed to a root cause analysis? 'Human factors' refer to the environmental, organisational and job factors, and human and individual characteristics which influence behaviour at work in a way which can affect health and safety. A 'root cause' analysis is a systematic process for identifying 'root causes' of problems or events and an approach for responding to them.

The College believes that human factors must be taken into account at all stages of an investigation at local, judicial and regulatory level. It is of note that root cause analysis may not have been part of the evidence in recent legal cases.

18. Typically, who is involved in conducting investigations following a serious clinical incident in hospital/trust/board or other healthcare settings and what training do they receive?

The College believes that any health care provider should have publicly transparent operational policies for Serious Untoward Incidents which has appropriate independence from the body itself. The first Gosport enquiry for instance was never published yet had very similar conclusions to the recent one (2018).

Some trusts provide risk-management training for senior staff, but training to lead Morbidity and Mortality meetings or Schwartz Rounds is not provided, nor is training regarding appropriate family communication relating to such incidents. The Scottish Morbidity and Mortality Programme has recently produced a guidance document with clear recommendations for best practice in this area.

Reference: Mortality and Morbidity Reviews Practice Guide (Working Version) – May 2017 published by The Improvement Hub (ihub) [part of Healthcare Improvement Scotland]

19. How is the competence and skill of those conducting the investigations assessed and assured?

Standard methods of training and support need to be instituted at a national level**.** Royal Colleges may have a role in this provision

20. In your hospital/trust/board or other healthcare setting, is there a standard process/protocol for conducting investigations following a serious clinical incident leading to a fatality? If so, please email a copy to ClareMarxReview@gmc-uk.org

Copy of Mortality and Morbidity Reviews Practice Guide (Para 18) enclosed.

21. What measures are taken to ensure the independence and objectivity of local investigations in hospital/trust/board or other healthcare settings?

Current investigations are not necessarily seen as independent of the Trust or Health Board.

22. What is the role of independent medical expert evidence in local investigations?

Currently this can be idiosyncratic. The expert may not expertise in the correct field. They may not have experience of considering evidence impartially. Training and experience is important to maintain the trust of all parties.

23. How are independent experts selected, instructed and their opinions used? Is access to appropriate expertise always available? Do they have training in unconscious bias?

None of this applies at a local level.

24. Are there quality assurance processes for expert evidence at this stage, if so, what are they?

No

25. How can we make sure that lessons are learned from investigations following serious clinical incidents? (please respond here if you haven't already responded to this question in the patients and families section)

See above

26. What support is provided for doctors following a serious clinical incident that has resulted in the death of a patient (including emotional, educational, legal, professional support)? Could this be improved? If so, how?

Trust and Health Boards often fail to support their staff. This should be an obligation. Little or no guidance is given. Doctors are often simply asked to write a statement and not given guidance on how to do so. There is no mentorship, no 'senior counsel', no psychological support.

There is a need to develop systems to support individuals in the situation where someone has died under their care. The blame culture in the past has led to individuals being ostracised by their employer when they need support in all the facets of the questions. Medical defence organisations are more supportive to individuals. The GMC does not support doctors in this difficult period. There is a conflict between its educational and supportive role and its regulatory role.

27. How and when are decisions made to refer a fatality to the coroner, or in Scotland, to the police? Who does it? Who do you think should do it?

A senior experienced clinician should be responsible for referring fatalities onwards for further review. It would be good practice to have all deaths reviewed by a consultant in the department but not involved in the case with a view to highlighting to the medical director where there is cause for concern.

28. What evidence is there that some groups of doctors (by virtue of a protected characteristic) are more or less likely to be subject to investigations leading to charges of GNM/CH than other groups? What are the factors that may be driving a greater likelihood for certain cohorts of doctors to be subject to investigations leading to charges of GNM/CH?

This is an area for more research. There is no evidence in this area. There is some circumstantial opinion. It is possible that those with protected characteristics may lack confidence or have more or increased stress in certain situations. There may be issues of communication culture or self-esteem.

29. Do you think there are barriers or impediments for some groups of doctors to report serious incidents and raise concerns? More specifically are there additional barriers for BME doctors? If so which groups are affected by this and how can those barriers be removed?

The introduction of a no blame culture in these investigations would improve safety. Comparison should be made with the aviation industry**.**

ROYAL COLLEGE OF PHYSICIANS AND SURGEONS OF GLASGOW

This section focuses on inquiries by a coroner or procurator fiscal

30. What is your knowledge or experience of cases involving clinical fatalities that have been referred to the police or procurator fiscal? What can we learn from the way those cases have been dealt with?

The current systems in the UK are adversarial and as such will always consider blame. There is no pastoral or procedural support, only formal legal advice. It is a very alien environment for clinicians. Many who have experienced this process regard it as hostile and report a greater assumption of guilt than they anticipated.

We need look at causes and prevention of future deaths. Systems rather than just individuals need to be part of the review. Is the current system the correct way to look at fatalities? Should a non-legal method be considered?

31. To what extent does an inquest or fatal accident inquiry process draw on or rely on the evidence gathered in the post incident investigation by the hospital/trust/board or other healthcare setting?

This is often used, especially in respect of conclusions drawn, or in reference to lack of action by Trusts after an earlier similar event.

32. What is the role of independent medical expert evidence in inquest or fatal accident inquiry processes?

To provide impartial, evidence-based advice, drawing on relevant clinical experience, on causality and the likely outcome had certain events not happened

33. How are independent experts selected, instructed and their opinions used? Is access to appropriate expertise always available? Do they have training in unconscious bias?

There is no standard approach to selection or instruction or as to how such opinions are used. Experts are not always available or released by their employers. They do not have consistent training

34. Do the same standards and processes for experts apply regardless of whether they are providing their opinion for a local investigation, an inquest or fatal accident inquiry process? If not, why not? For example, is there a higher level or different type of expertise or skill set required?

They should have the same standards and be independent. Health Boards and Trusts must make their staff available for independent expert opinions

35. Are there quality assurance processes for expert evidence at this stage, if so, what are they?

None known

ROYAL COLLEGE OF PHYSICIANS AND SURGEONS OF GLASGOW

This section focuses on police investigations and decisions to prosecute

36. To what extent does the criminal investigation and/or prosecution process draw on or rely on the evidence gathered in the post incident investigation by the hospital/trust/board or other healthcare setting?

Our current knowledge is that post incident investigatory evidence may not be used in a criminal investigation whereas it is the College's view that it should be mandatory.

37. What is the charging standard applied by prosecuting authorities in cases of GNM/CH against medical practitioners? How does the charging standard weigh the competing public interest in improving patient safety?

Clearer definitions should be made of GNM and CH if they are to remain offences. Police, legal staff, experts and juries must be clear on the definition and thresholds.

Lowering the threshold of evidence so that it is easier to bring a criminal case for manslaughter would be detrimental. If this was to be the case then it would promote a culture of risk averse medicine, defensive medicine and a culture of silence and non-transparency. Trainees would not wish to go into areas of high risk medicine.

38. Are there factors which potentially hamper key decision makers in making fully informed decisions at each stage of the process, taking into account all the circumstances that the medical practitioner found themselves in at the time of the fatality, such as system pressures and other factors?

There is a lack of an all cause analysis / awareness of systemic factors.

39. Do the key decision makers (the police senior investigating officers (SIOs), and/or prosecuting authorities) have the necessary support to enable them to make fully informed decisions on whether or not to charge a doctor of GNM/CH? Is there a need for detailed prosecutorial guidance for this offence (similar to that for assisted suicide)?

There is a need for clear definitions and there is also a case to be made for independent expert (medical) advice.

40. Why do some tragic fatalities end in criminal prosecutions whilst others do not?

As we have already asserted, our College believes that the key determining factor in this case must be intent to do harm. However, the lack of a standardised system with training and quality assurance means that some cases proceed whereas others do not. Family pressure is also relevant.

41. Under what circumstances would it be more appropriate to consider cases involving fatal clinical incidents within the regulatory system rather than the criminal system?

This would be appropriate when mistakes are made, but there is no intent to do harm. However, there will need to be changes in how the regulator carries out its business. There is a conflict between its educational and its regulatory roles While we agree public protection is important, prevention of mistakes and learning from them is as important. We need to move away from a culture of blame unless there is intent to harm or evidence of malice. System derived factors must be taken into account.

42. What is the role of independent medical expert evidence in criminal investigations and prosecutions?

See above

43. How are independent experts selected, instructed and their opinions used? Is access to appropriate expertise always available? Do they have training in unconscious bias?

See above

44. Do the same standards and processes for experts apply with regards to evidence provided for the police or prosecuting authorities as they do for a local investigation, an inquest or fatal accident inquiry process? If not, why not? For example, is there a higher level or different type of expertise or skill set required?

Yes

45. Are there quality assurance processes for expert evidence at this stage, if so, what are they?

No but there should be.

46. What lessons can we take from the system in Scotland (where law on 'culpable homicide' applies) about how fatal clinical incidents should be dealt with?

We believe that the higher threshold for prosecution for Culpable Homicide under Scots Law may be a more appropriate standard for the rest of the UK to follow.

Culpable homicide implies liability at an individual level. In many cases, individual action or lack of action is not of itself the cause of death.

ROYAL COLLEGE OF PHYSICIANS AND SURGEONS OF GLASGOW

This section focuses on the professional regulatory process

47. What is your experience of the GMC's fitness to practise processes in cases where a doctor has been convicted of a serious criminal offence?

Our membership remain concerned over the GMC's actions in recent such cases.

For example, in the recent case of GMC v Bawa Garba (2018 EWHC 76) we have found it difficult to reconcile how the GMC chose to pursue this case despite having discretion in this area. We do not believe that this action was in the best interests of patients or the profession. It has alienated trainees and has done harm to a group where stress is high and there are increasing numbers leaving the profession. We do not consider they have supported doctors, particularly in those in training who are in a stressful environment. The process is unnecessarily protracted.

48. The GMC has a statutory duty to: promote and maintain public confidence in the medical profession and promote and maintain proper professional standards and conduct for doctors. What factors do you think the GMC should balance when trying to fulfil both these duties where there have been mistakes that are 'truly, exceptionally bad' or behaviour/rule violations resulting in serious harm or death?

It is only by upholding the highest professional standards that we can engender proper public confidence in our profession. This should be the first priority of the regulator. Recent cases brought by the GMC could be interpreted as reducing public confidence.

There is a big difference between a bad mistake and a behavioural /rule violation – one implies human error, the other wilful intent, behaviour significantly out of keeping with that of other practitioners.

Any mistake needs to be carefully evaluated in the context of both the systems and the overall performance of that doctor – was it a "one off", was it due to illness or extreme fatigue, was it a system problem (lack of senior support, too many patients, poor staffing, IT infrastructure etc.) or was it after many more subtle concerns, complaints or performance issues?

49. What information would you like to see from the GMC and others about the role of reflection in medical practice and how doctors' reflections are used?

Reflective practice is a positive and rewarding process. However, if there is a perception that it is going to be used against an individual in a fitness to practise or criminal case it is likely to be of poor quality. Many doctors have changed their practice and do not detail events requiring reflection. We need to move away from blame and into prevention of incidents.

If reflection is truly to be used as a learning tool, it needs to be totally honest and reflective. If this can be used against an individual then there are many learning points that will not be disclosed. All significant events should involve reflection and discussion of that with an experienced colleague.

Moreover, reflection is a recording made after the event and its legal weight is questionable. It is inappropriate and counter-productive to require view of reflective material in legal or GMC contexts, but it could be provided by individuals, should they choose.

50. What emotional, pastoral and other support is available for doctors who have an allegation or charge of gross negligence manslaughter or culpable homicide and are being investigated by the GMC?

Very little. Medical defence organisations and the BMA provide some services

The College considers this very important. Very few people experience such situations on account of deliberate action. Their whole lives can be devastated by what has happened, especially when investigations take a long time or there is public awareness of the situation. Robust support must be freely and readily available This needs to be improved at all levels from Trusts and Health Boards, Royal Colleges and the GMC. This is a role that the regulator could facilitate.

51. How can the learning from a fatal incident best be shared? Should the regulator have a role in this?

Yes. This is part of its educational role and could be disseminated by regular communication. However, its style needs to change considerably. It also needs to be responsible to those it regulates

<u>Finally…</u>

52. Do you have any other points that you wish the review to take into account that are not covered in the questions before?

Measures to consider the patient's voice have been developed. However, we often hear the voice of the loudest patient, but not the most important voice to hear. The present patient complaint system has not improved services to enhance safety.

Dr Richard Hull FRCP Glasgow
Honorary Secretary
Royal College of Physicians and Surgeons of Glasgow

25 July 2018