Dame Clare Marx's review of gross negligence manslaughter and culpable homicide
Comments from the Royal College of Physicians of Edinburgh

The Royal College of Physicians of Edinburgh ("the College") was founded in 1681. We support and educate doctors in the hospital sector throughout the UK and the world with over 12,000 Fellows and Members in 91 countries, covering 30 medical specialties. Our UK Fellows and Members work across the NHS in the four nations, with more than 50% in the NHS in England, and we welcome the opportunity to submit evidence to the Marx Review into gross negligence manslaughter and culpable homicide. The College is committed to promoting the highest clinical standards and the implementation of robust, evidence-based medical practice to ensure the highest quality of care for patients.

This response has been informed by the views of senior College Office Bearers; our Trainees and Members' Committee; our Recently Appointed Consultants' Committee and our Lay Advisory Committee. We recently responded to the *Williams Review into Gross Negligence Manslaughter in Healthcare* and note that significant areas of the review overlap with the Marx Review. There is currently wide-ranging activity on this subject involving different organisations, and it is vital that workstreams are not looked at in isolation.

This section focuses on what you consider to be 'criminal acts' by doctors

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

Our Fellows and Members feel strongly that providing safe, patient-centred, high quality medical care is their prime concern: no clinician comes to work with the intention of doing a bad job or harming patients. Sadly errors in care can and do occur, but in order to address these, the College and others have highlighted the need for all healthcare professionals to learn from serious failings in care. No doctor, regardless of grade, should be made to practise in an environment of fear and retribution. Such an environment can only lead to defensive and poor medical practice.

Views from College Fellows and Members indicate that clinicians have limited knowledge of the legal definitions and boundaries of gross negligence manslaughter/manslaughter/culpable homicide/murder. The College recommends clear guidance for employers, the accused and those investigating where this is not already consistently offered or applied. Fellows suggest that where there is clear evidence of deliberate intent to inflict harm or damage; intent to disrupt processes or malice shown then these would indicate a criminal act had taken place. Additionally, evidence of premeditation; self-interest; clear attempts to fabricate/alter or cover up evidence; attempts to implicate or intimidate others would also indicate that a there was a serious incident which may be criminal. Lack of insight or empathy are also issues, however

these are perhaps 'greyer' or more subjective areas and may not indicate a criminal act has taken place without other factors also coming into play.

There also needs to be clarity of how a criminal prosecution may come about - what is the relationship between coroner's court and criminal charges? Who brings the charges against the doctor? Such incidents should be thoroughly investigated by the institution's Serious Incident process and possibly through the legal team defending a claim.

Adequate teaching of medical and all healthcare staff on risk and patient safety, and heightened focus on medicine, ethics and the law must be mandatory and commence early in undergraduate or apprenticeship training. There is no doubt that many staff have the belief that they are protected by their employer and by the law unless they commit a deliberate act of harm. There should be increased emphasis on the importance of good quality note keeping throughout training. Defence organisations currently provide training on this subject, and this knowledge needs to be rolled out across the NHS as a whole.

Staff must also have access to clear information setting out defence and/or insurance options. The College has been advised that few clinicians have a clear understanding of what the NHS as an employer will cover and the clinician's options need to be clearly laid out. There needs to be recognition of the fact that there are multiple different contracts, including honorary contracts in particular, where the legal status / provision is much less clear than in the standard Junior Doctor contract and the Consultant contract. Doctors must understand what protection is available and can be afforded to them, and employers should have an obligation to provide access to information such as the level of NHS indemnity provided and signposting to defence unions.

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

Feedback from College Fellows and Members indicates that this terminology is not clear or widely understood: a key challenge is the lack of alignment between terms and definitions used by employers and the GMC and those used by the legal profession. There needs to be uniform terminology and clearly defined distinctions between poor performance, misconduct, negligence and criminality. This is fundamental to any review into GNM/CH in healthcare. There also needs to be a clear understanding of the potential consequences of both GNM/CH and negligence legalistically and professionally.

The College's response to question 9 above outlines features that we feel distinguish an unintended error with severe consequences from a criminal act and the different grades of criminality. Fellows have suggested that murder implies intent to kill which is quite deliberate; manslaughter implies death has ensued, but was not what the perpetrator intended, however, some deliberate act of recklessness or lack of acknowledgement of limitations has resulted in death, so the individual still bears responsibility- for example, performing a surgical procedure not fully trained to, but quite deliberately and without coercion from seniors or system pressures. There may also be situations where an error has occurred without intent, but then staff have covered this up- which may not be classified as murder or manslaughter but is still extremely serious.

How GNM/CH is applied to an individual must be made clear, as must whether or not it can be applied to a system. For example, what would make the police investigate an individual without investigating the employer? Healthcare professionals and their employers must be clear on the processes to deal with each circumstance. This should be included in the remit of the employer and encompass induction as standard. It should also be publicised by the GMC, Royal Colleges and through postgraduate training bodies.

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?

No, or at least not consistently and universally. This is currently very much dependent on individual doctors/nurses and hospital policy. There should be consistency in what is offered to patients and families, for example, written information about processes with a timeline, perhaps invitation to parts of investigation or debrief/conclusion. It is of great concern that lack of consistency exists, and that it is down to individuals to report and escalate- often wading through unnecessary bureaucracy and delays themselves. Fellows and Members have expressed concern that some cases may not be taken further because of the barriers faced by concerned staff.

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 experience of College Fellows and Members from across the UK has been that this is very variable- as outlined above. Case examples included families not being involved or up-dated at all, other than by clinicians who have taken a personal interest in the case and pursued this on behalf of the family members.

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?

This is certainly worth consideration. There should, as above, be consistency around this process. It is remarkable that it is not mandatory for all boards/trusts to have policies- though perhaps they do, they are simply not always accessible or put into practice. Policies/processes should be monitored and audited. There should be a clear and distinct method for clinicians/healthcare staff to raise concerns where death has resulted- not simply via the same reporting system for 'less serious' errors. It is also important to recognise that staff too need feedback and mediation.

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

As described above: this is entirely variable.

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

There is a need for clear processes to be in place. Transparent reviews of cases in a timely manner and with involvement of all affected, with mediated discussion is required. It would also be useful to have hospital newsletters or webpages with anonymised feedback and other clear avenues for raising concerns which have no stigma attached and staff are encouraged to participate in by senior management.

This section focuses on processes leading up to a criminal investigation

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?

No, as above this is due to lack of consistency and is too dependent on individuals. Current arrangements also tend to be subject to complicated bureaucracy and indistinct timelines.

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 feels that the crucial point is that an open and no-blame culture is encouraged, where focus is on identifying and addressing system and, where appropriate, individual failures and risks; where staff feel empowered to raise concerns over standards of care and confident that action will be taken to address these and improve quality.

There should be a set of standards for which data is collected and assessed for every prosecution in a healthcare setting. These should include but not be limited by: number and skill mix of staff; number and complexity of patients; presence or not of safety procedures including safety brief, multidisciplinary huddle, escalation policy; has individual/s accused recently returned from career break and if so, what support/induction was offered; were all staff present familiar with the unit or had they been adequately inducted; availability of senior decision maker/s and their communication with team if not on site.

Complaints, litigation, negligence and Gross Negligence Manslaughter (GNM) all have potentially devastating effects on the individual(s), teams and the institution involved. All of these groups need significant support, rehabilitation and supported re-training when such instances arise. Fellows and Members have advised the College that they feel that regulatory bodies and institutions have a considerable way to go to achieve this supportive environment. The College suggests that there is a fundamental need for reflection on how we have reached this point, and how circumstance, culture, context and system structures have contributed to this position. In this regard a "human factors" approach would be of benefit and the College suggests this should in fact be mandatory.

~~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?~~
~~19. How is the competence and skill of those conducting the investigations assessed and assured?~~
~~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~~
~~21. What measures are taken to ensure the independence and objectivity of local investigations in hospital/trust/board or other healthcare settings?~~
~~22. What is the role of independent medical expert evidence in local investigations?~~
~~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?~~
~~24. Are there quality assurance processes for expert evidence at this stage, if so, what are they?~~
~~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)~~

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?

The experience of College Fellows and Members is that there is no consistent approach to the provision of support for doctors. Support should be provided, however at present this appears to be dependent on the individuals involved and lacks constancy.

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?

The College is aware that NHS trusts and boards have clear guidelines in place, some of which are available online for reference[i]. There is also guidance available such as *Reporting deaths to the Procurator Fiscal: Information and Guidance for Medical Practitioners*[ii] (Produced by Crown Office and Procurator Fiscal Service). We also note that "in Scotland, deaths that may have been related to adverse effects of medical or surgical treatment, or to standards of care, or about which there has been any complaint, are reportable to the procurator fiscal. While this is not a requirement in England and Wales, it is anyway advisable to refer such deaths to the coroner[iii]" and consider this an example where parity could be beneficial across the UK.

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?

The GMC have stated that "doctors with certain characteristics – including those who obtained their primary medical qualification outside the UK and/or those who are from a black and minority ethnic

background – are more likely to be referred to us for fitness to practise concerns than their peers. Similarly, such doctors are more likely to end up being investigated by us and, ultimately, to receive a sanction"[iv]. Previous academic publications have referred to factors including cultural differences particularly related to verbal and non-verbal communication, and learning environment[v].

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 (black, minority and ethnic) doctors? If so, which groups are affected by this and how can those barriers be removed?

The College suggests that all healthcare staff should undergo unconscious bias training- not just for staff-staff interactions, but for staff-patient interactions. More research needs to be done, specifically looking at evidencing potential reasons for cultural differences.

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?~~
~~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?~~
~~32. What is the role of independent medical expert evidence in inquest or fatal accident inquiry processes?~~
~~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?~~
~~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?~~
~~35. Are there quality assurance processes for expert evidence at this stage, if so, what are they?~~

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?~~
~~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?~~

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?

A number of factors may be influential in this regard, including bias; knowledge of those involved; personal experience; lack of understanding of terminology/processes and lack of support.

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)?

Yes, there should be detailed guidance. The College is concerned that key decision makers lack adequate support.

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

There are a number of issues which contribute to this, largely rated to inconsistency in processes. This could be processes vulnerable to individual bias or competence. Media involvement is also likely to play a large role and public and political interest.

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?

Recent cases have highlighted that local systems e.g. IT, do not always provide the necessary support to healthcare staff. If a system such as IT is not functioning as intended, then vital tests, results, notes and other communications are not able to be accessed by individuals. In cases where a local system fails and a serious incident follows, then it would be beneficial to have input from regulatory bodies e.g. NHS Improvement to review when the governance system of having a reliable infrastructure falls down.

~~42. What is the role of independent medical expert evidence in criminal investigations and prosecutions?~~
~~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?~~
~~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?~~
~~45. Are there quality assurance processes for expert evidence at this stage, if so, what are they?~~

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?

The College notes that the Medical Protection Society (MPS) has suggested that the law that is applied in gross negligence manslaughter (GNM) cases in healthcare in England and Wales should move towards Scotland's comparable offence of Culpable Homicide, where charges are only brought against doctors if an act is proved to be intentional, reckless or grossly careless. The MPS has stated that the legal bar for conviction in England and Wales – which does not require intent or recklessness or a public interest test – is too low and is resulting in good doctors being criminalised for unintentional and often system-wide mistakes that are devastating for all involved. It said the law and its application in Scotland - which has seen one attempted prosecution resulting in acquittal - is better suited to determining the culpability of a doctor in a patient death and whether a prosecution is in the public interest[vi].

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?

There needs to be much clearer understanding of the impact of a clinical conviction. Are all doctors with a criminal conviction removed from the register? When the regulator makes a decision on registration, what factors are taken into consideration – the conviction, the issues and events surrounding the circumstances of conviction? Peer/senior experiences of the doctors? All of this is now essential knowledge for clinicians and must be clearly set out.

The recent cases have perhaps highlighted the differing roles of the GMC and the criminal justice system and it is important that one does not try to replicate the job of the other. For the most part the sanction imposed by the GMC would be commensurate with the conviction but it is entirely reasonable that the response to an incident would differ in some circumstances. However, in one recent case it has become apparent that many consider the resulting conviction to be unreasonable and, given that, have difficulty comprehending why the regulator acted as they did.

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?

The College suggests that the GMC could have a greater role in public education, and also in highlighting the reality of the stresses that the profession works under. It does of course publish its annual review of trainees and trainers with comment, however Fellows and Members of the College feel this could be more vocal.

Greater public understanding that individuals rarely work in isolation, and are subject to a host of system/team/patient/public expectations and pressures would allow the public to have a more realistic, informed view of doctors' working lives. Similarly, there is presumably work underway to capture the public's views on these issues to help healthcare staff know how best to respond.

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?

Our Fellows and Members are primarily clinicians; clinical / educational supervisors; clinical / medical directors and training program directors and generally do not have specific expertise or training in medico-legal issues. Those who have additional roles, for example in postgraduate deaneries, have been engaging in discussions about the reflection process for trainees. Clear guidance is essential. The legitimacy of individual reflections being used as evidence has been queried with concerns including validity and difficulty with corroboration.

Reflection is critical for doctors in daily practice and it is essential that reflection on both good and poor outcomes continues. This should be emphasised as part of good medical practice, and the College suggests there should be a renewed focus on teaching of reflective practice, report writing and best practice. Openness and candour must not be discouraged, and it is important to recognise that different personalities and communication styles can lead to very different outcomes of reflection, making it a complex process. Therefore it can be difficult to draw conclusions from submissions.

There should also be regard given to the likely bias of reflective practice towards negativity, such is the nature of training regarding reflective practice, for example through questions such as "what have you learnt?" or "what could you improve upon for next time?" However notwithstanding this, there is recognition that reflection is essential and must continue to be an intrinsic part of daily practice.

The College has received a variety of views on whether verbal or written reports are most appropriate in situations where the healthcare professional believes that an error has been made. The crucial point is that an open and no-blame culture is encouraged, where focus is on identifying and addressing system and, where appropriate, individual failures and risks; where staff feel empowered to raise concerns over standards of care and confident that action will be taken to address these and improve quality.

The College suggests that the aviation industry model is worthy of further examination, as this has delivered full disclosure for learning by valuing reflective practice and, to a certain extent, excluding it as a record available to other agencies. If reflective practice documents are readily available to the courts they should be documented with that in mind such that practitioners should still be encouraged to reflect but should be advised around how those reflections are recorded: this will of course be likely to make reflection less full. If the NHS Board/Trust has other procedures (for example Mortality and Morbidity meetings and event reporting) to promote safety culture and how events are recorded, this should be encouraged and supported from board/trust level. Board/Trust level processes should also be clear on confidentiality, recording and sharing of outcomes and should similarly encourage candour rather than promote defensiveness.

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?

The College has no particular evidence on this issue, however notes that recent cases featured in medical press and journals would suggest that support is suboptimal.

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

This is discussed in greater detail in the response to question 49. And yes, the regulator should be an active participant and contributor.

Finally…

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

Investment in our current and future workforce is essential to create a culture where colleagues have the time to care, time to train and the time to research. The medical workforce faces significant challenges. The College supports improved medical workforce planning across the UK to recruit and retain the highest quality doctors. There are workforce shortages across the country with rota gaps creating additional pressures in an already difficult environment. There is a pressing need to value healthcare professionals at every stage in their careers, to ensure that medicine remains an attractive career choice and offers support for medical professionals as they progress throughout their careers.

We need to ensure that we continue to recruit and retain a world class workforce to deliver the best possible patient care. The College is committed to working with Government and other allied organisations to address issues around recruitment and retention such as consultant vacancies, rota gaps and trainee attrition rates, as a matter of priority. The College is concerned that workforce morale is low and that new medical graduates continue to leave the profession[vii] .

Our Fellows and Members feel strongly that providing safe, patient-centred, high quality medical care is their prime concern: no clinician comes to work with the intention of doing a bad job or harming patients. Sadly errors in care can and do occur, but in order to address these, the College and others have highlighted the need for all healthcare professionals to learn from serious failings in care. Doctors of all grades should not be made to practice in an environment of fear and retribution, leading to defensive and poor medical practice.

To enable such learning and thereby improved patient care, the College encourages an open and no-blame culture where focus is on identifying and addressing system and, where appropriate, individual failures and risks; where staff feel empowered to raise concerns over standards of care and confident that action will be taken to address these and improve quality. It is important to note the introduction of the Duty of Candour (Scotland) Regulations 2018 and Apologies (Scotland) Act 2016 have been intended to help enable this kind of environment. Only by doing so can we ensure that learning and improvement occur, and that similar incidents are prevented from occurring. This has been highlighted by Ian Kennedy QC, speaking at the Royal College of Surgeons of Edinburgh's triennial conference on 22 March 2018, who said "…*medical manslaughter means that you can pick someone, blame them, and imagine that you've solved the problem. And what you have actually done is exacerbated it".*[viii]

There is a wide-ranging activity on this subject, such as the Williams Review, involving different organisations and it is vital that workstreams are not looked at in isolation. The College President, Prof Derek Bell OBE, met the Lord Advocate to discuss these matters on 12 April 2018 and is leading a Scottish Academy of Medical Royal Colleges workstream, which is likely to examine many issues of interest to the Marx Review.

[i] *For example*: Northern Lincolnshire and Goole Hospitals NHS Foundation Trust: Guidelines to doctors on reporting deaths to the Coroner https://www.nlg.nhs.uk/content/uploads/2013/12/Guidelines-to-Doctors-on-Reporting-Deaths-to-the-Coroner.pdf

[ii] *Reporting deaths to the Procurator Fiscal: Information and Guidance for Medical Practitioners*[ii] (Produced by Crown Office and Procurator Fiscal Service) http://www.copfs.gov.uk/images/Documents/Deaths/Reporting%20Deaths%20to%20the%20Procurator%20Fiscal%202015.pdf

[iii] P.4 Office for National Statistics' Death Certification Advisory Group**:** Guidance for doctors completing Medical Certificates of Cause of Death in England and Wales https://www.gro.gov.uk/Images/medcert_July_2010.pdf

[iv] GMC Terms of reference–A research study to understand better why some groups of doctors are referred to the GMC by employers or healthcare providers for fitness to practise concerns more, or less, than others. https://www.gmc-uk.org/-/media/documents/terms-of-reference-for-circulation-final_pdf-75387349.pdf

[v] University of Bradford: The Involvement of Black and Minority Ethnic Staff in NHS Disciplinary Proceedings (2010) https://www.brad.ac.uk/research/media/CfID-Briefing-9-BME-disciplinaries.pdf

[vi] English law on gross negligence manslaughter in healthcare must move towards Scottish position - Medical Protection Society (13 March 2018) https://www.medicalprotection.org/uk/about-mps/media-centre/press-releases/press-releases/english-law-on-gross-negligence-manslaughter-in-healthcare-must-move-towards-scottish-position

[vii] *Most junior doctors leave after training* (16 March 2018): The Times https://www.thetimes.co.uk/article/9cb272d4-28ac-11e8-acc5-262aff1ca7a6

[viii] The role of medical manslaughter must be reconsidered, says leading lawyer https://doi.org/10.1136/bmj.k1376 (Published 23 March 2018) BMJ 2018;360:k1376