Clare Marx Review

Questionnaire: written submissions to inform Dame Clare Marx's review of gross negligence manslaughter and culpable homicide

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

- • What factors turn a mistake resulting in a death into a criminal act?

  Genuine mistakes which are a one off where a death is the end result should not be considered "criminal acts" unless the doctor attempts to cover up the error, falsify documentation around the error, or shift the blame for the error onto another member of the team. When there has been an act of malice this should be considered criminal. Repeated errors of the same type over a sustained period of time where interventions have been made but where learning has demonstrably not taken place, should be viewed as a criminal act. When a systems failure has been identified by the doctor but this knowledge not been communicated appropriately or the recording of such has been falsified should be also viewed in this way.

- • What factors turn that criminal act into manslaughter or culpable homicide?

  The Williams Report succinctly describes this as: 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.

  We think it needs to take into account being open and honest about failure, not covering up / falsifying records, and no act of commission or omission to conceal or shift blame.

  This section focuses on the experience of patients and their families

- • 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?

  Patients often believe that if someone has died there must be a "fault" or "someone directly responsible". Serious Untoward Incidents (SUIs) are designed in a no blame culture to look at faults in processes where learning can occur rather than specifically identify individuals at fault. So, the expectations of the process between groups are not always fully aligned. Although the framework around SUI is national, each trust / locality has a slightly different process and paperwork to fill in. Adding "patient" or "family" questions to the SUI process locally can help align agendas and allow patients to get the explanations they need from the local investigation.

  An SUI investigation has a defined timetable but often this slips due to difficulty in getting the clinicians to be interviewed together with the clinicians who are doing the interviewing as part of an investigation (again SUIs should require 2 investigators but often they do not need to interview a witness together - which can be a mistake as it can be seen as a possible cover up by the family). The number of clinicians trained

to undertake investigations within an organisation is usually limited and all have a full time day job in addition to occasional (one hopes) SUI investigations. Allowing busy clinicians the time to undertake or participate in reviews could improve the veracity of investigations and subsequently, the experience of the patient. The commissioners should hold the trust to account if a timetable slips.

Assigning a member of the PALs team (or similar) to support the family / complainant who can give clear explanations of the process and timetable and to manage expectations is often employed and can be useful. Regular updates on progress can also be invaluable. Often an incident occurs in a pressurised situation, documentation is often scanty and response is based on stressed memories which end up being related as "I would normally", "I see no reason why I would not, but I cannot recollect what I did in this situation" which can frustrate families. If their loved one has died as a result of a possible error, and a clinician appears not to remember the scenario in minute detail, it does not suggest the appropriate gravity is being given to the fatality.

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

  Again this varies between trusts. Some only acknowledge that the investigation is ongoing and then send the results to the family. Others adopt a more holistic approach meeting with the family to find out what their questions are and incorporating these in the report. Assigning a member of the e.g. PALs team to keep the family up to date and reassure them that "their" investigation has not been lost can be very useful. Inviting the family to a meeting rather than simply sending them the SUI report can also help explain findings in lay terms and achieve alignment of outcomes.

- • 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?

  See above. There is a national framework but each trust / locality interprets this differently. Clinical incidents resulting in fatality are generally not handled differently to other incidents. At the time of death the incident may / not be recognised as such, and the usual facilities are made available to relatives e.g. quiet room on the ward. Some trusts will invite families to a meeting of clinicians and managers at the start of the investigation to find out what questions they would like answered specifically. Some trusts invite them at the end to feedback on findings, the learning points and action plan but as far as I am aware there is no national system / framework for this. Mediation implies a trained mediator which has a significant cost implication. Most trusts keep families informed and meet with them to achieve this without trained personnel being involved. If the thought is that trained mediation would prevent some families pursuing a financial settlement, we are not sure that this tracks. The result of an SUI can be relayed to families but there is currently no mechanism for compensation outside legal means. The question is, do you believe that mediation helps understanding (which it might) or does mediation reduce financial legal claims (which is highly unlikely).

- • How are families supported during the investigation process following a fatal incident?

  Varies from trust to trust. Most usually via PALs. Sometimes by a senior team member who could be either one of the investigators or more likely not.

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

  This is paramount but, unfortunately, inherently problematic as embedding learning and enacting change is the most difficult ask of any large organisation. On an individual level, those who have made an error need to be able to reflect and be supported to change their behaviours / access extra training as required. The department needs to promote the lessons learned and facilitate a culture shift to embed this change. Highlighting learning points is difficult to do in a "no blame" fashion. Generally, this is meant to be done anonymously, but most staff learn about SUIs on the grapevine (which is often infected with misinformation). The organisation needs to transfer learning across siloed working. If a department has not been party to the error - "this never happens here" - then there is resistance to change.

  The trust governance structure should be robust, and routine reviews of incidents / trends / good practice / learning should naturally occur, but often the learning from a serious incident is taken out of this structure as "something special" which gives learning itself the wrong focus. Some organisations publish patient safety matters looking at trends or lessons from incidents/deaths, this practice should be encouraged.

  Finally who holds the department or trust to account about implementing the learning outcomes from an SUI? Is it the governance team (not clinical but at board level or equivalent) or is it the CCG who commission the service?

  This section focuses on processes leading up to a criminal investigation

- • 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?

  Current arrangements for investigating are not fair as they largely depend on the skill / training of the investigators which can vary. Training investigators should be a standardised role. Inclusion of patient questions may assist the outcome to address family as well as organisational concerns.

  Current arrangements for reporting are also unfair due to variance from trust to trust. There is a national framework but this is interpreted differently in each setting so are prone to bias, e.g. local arrangements for assigning SUI versus IRI vary. Also, reporting back to CCG process is variable from locality to locality so again prone to bias. Clear national definitions are required as some trusts require every minor incident/near miss to be recorded which has a significant impact on time available for clinical work, and has the potential to stifle reporting of more serious incidents. Reporters should be given whistleblowing protections and not be reported for highlighting unsafe practice themselves.

- • 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.

  This would be eminently sensible. Root cause analysis often does not uncover the system failures which lead up to an individual event, tending to focus on simple issues and blame, overlooking many mitigating elements.

- • 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?

  Usually two employees, most commonly senior clinicians from different disciplines, run the investigation. They have full time clinical roles, so this is fitted in as an added extra, usually with no administrative support to set up interviews / take notes / type statements / produce report and action plan. This means that investigations often do not get the "brain space" they require. Ideally, both should be trained in the organisation's processes, but sometimes there is simply not enough trained staff resulting in an experienced clinician being paired with an untrained one.

- • How is the competence and skill of those conducting the investigations assessed and assured?

  Mostly it is not. Often there will have been an in-house training process. Updating training / registers of competence are not the norm. External assessment of competence is not the norm; in fact, we are unaware if this actually happens anywhere.

- • 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

  Serious incidents with or without fatality are investigated in the same way within the trust of one of the respondents, others were unsure of the protocols.

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

  Generally, the investigations are undertaken by senior clinicians not directly involved with the incident. In larger organisations this can be someone from the same directorate (e.g. surgery) but in a different discipline (e.g. breast rather than vascular). However, most investigators are known to those they investigate. The investigation is reported and presented to the commissioner, so the scrutiny of the end product should be independent.

- • What is the role of independent medical expert evidence in local investigations?

  Not sure – there does not appear to be a defined recognised role. In our experience, investigators can choose who they interview so they could ask to interview another uninvolved member of the team with specialist knowledge if that is deemed appropriate. If there are no uninvolved local experts, it is unsure what would happen, but we suspect expert input from an adjacent trust could be obtained.

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

  No knowledge of this.

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

  No knowledge of this.

- • 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. Regular robust governance meetings to ensure dissemination of learning points. Trusts being held to account to embed lessons learned by commissioners.

- • 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?

  There is no definite support for anyone involved in a serious clinical incident. The investigative process allows the interviewee to bring a friend / supporter along. Most trusts have confidential employee support (usually outsourced) but these are often not well publicised - especially to doctors in training who are often very transitory. Professional support is available via the BMA, but only to members. Legal support can be obtained via a medical defence society, but again this requires the doctor to be a member. Drawing on personal experiences, there seems to be a distinct divide between the support offered by BMA and that offered by a defence society. We are concerned that a doctor in this situation may fall through those gaps.

  Who to turn to and how to access assistance should be explicitly stated and sent to anyone involved in a serious clinical incident. Any structured support provided would be an improvement.

- • 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?

  There are clear guidelines for referring deaths to the Coroner. Usually this is done by the doctor certifying death. This is commonly a junior trainee but in suspicious

circumstances it is generally a more senior doctor. I think an unexpected / suspicious / worrying death should be referred by a Consultant level practitioner.

- • 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?

  The GMC publicise data confirming this for BME doctors, and the Williams report. We are unsure of evidence relating to other protected characteristics.

- • 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?

  Any doctor who has a transitory relationship with their employer is more at risk – this includes doctors in training, locums and those in a new substantive post who have never worked for that organisation before. Those with a PMQ from outside the UK may be more at risk due to cultural and organisational factors. This could be mitigated by improved mentorship and induction procedures. An acclimatisation period with less responsibility with a named supporter could be useful.

  Lack of robust governance and feedback through organisational structures render those nearing the end of their career (who may have reduced sessions and thus be less aware of altered organisational structures) are more open to this discrimination. They also may be more prone to being seen as "old fashioned" and also by extrapolation "risky".

- • 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?

  Being new to a department either as a trainee or in a substantive post can act as an impediment, as you can be seen to "not to understand how things are here". There is the possibility that doctors from BME backgrounds may feel marginalised and not part of the core of the department so feel reluctant to raise concerns in case they would be seen as troublemakers.

  Generally, concerns may not be raised because of fears around the impact on future career or issues of 'power' if someone more senior and/or respected is involved.

  This section focuses on inquiries by a coroner or procurator fiscal

- • What is your knowledge or experience of cases involving clinical fatalities that have been referred to the police or procurator fiscal?

  One RCR officer has referred cases to the coroner and the procurator fiscal but only as routine. The same officer has: submitted a significant number of reports on expected mesothelioma deaths to the coroner; given evidence at a coroner's court about a patient treated some five years previously, and on the likely long term side effects as they related to the patient's unexpected death; been involved in certifying

a death in suspicious circumstances in hospital residences as the consultant on call when the police had been called in – giving a statement to the police.

- • What can we learn from the way those cases have been dealt with?

  No formal feedback mechanism from coroner's procedures. Feedback at trust level was from investigations only. No mechanism for identifying and feeding back on the quality of the local investigations.

- • 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?

  Appears to be vital - hence the requirement to keep accurate contemporaneous records. However, we would expect the investigation to be rerun by the police and the primary source evidence reviewed (rather than just the evidence gathered through the incident investigation).

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

  No knowledge of this.

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

  No direct knowledge about this. We do understand independent experts advertise their services, and there are abundant training courses to enhance the skills of expert witnesses available publicly.

- • 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?

  While our knowledge is limited, intuitively it is felt these should be the same standards.

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

  No knowledge of this but we suspect there is no quality assurance process except what the legal team use normally.

  This section focuses on police investigations and decisions to prosecute

- • 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?

No knowledge but assume it would used with an independent enquiry also undertaken.

- •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?

  No knowledge but would hope it would not be higher than other types if GNM / CH.

- • 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 will always be general factors that influence decision making e.g. staff availability, other competing high priority patient decisions, lack of beds, lack of support/mentoring. A potential risk for key decision makers could be that they examine the case in isolation rather than in full context of the systemic, organisational or national factors (such as vacancy rates). A decision maker's lack of awareness around what the skill levels and knowledge base of someone of a particular grade should be, could hamper results. Using an expert witness does not always guarantee that the appropriate benchmarking level is chosen. Lack of national agreed safe staffing levels/skill mix will act as another barrier.

- • 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?

  Not sure – it is suspected they look at it from the "provable" aspect (how likely to secure a conviction) than how important or negligent the error was. Are they trained to avoid bias such as in cases with a high media profile?

- • Is there a need for detailed prosecutorial guidance for this offence (similar to that for assisted suicide)?

  Yes

- • Why do some tragic fatalities end in criminal prosecutions whilst others do not?

  Some cases are more 'evocative' – such as deaths involving children. Some referrals may be malicious. Some families are more vociferous – seeking answers/looking for someone to blame. Fatality may be in someone who was near death anyway, or of perceived less worth to society, so do not attract the same societal/media condemnation. Some fatalities will be the demonstrable result of "bigger" errors which may be a repetitive trait of the doctor involved or they will have tried to cover the error up.

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

All fatal clinical incidents should be considered within the regulatory system. Only where there has been deliberate commission/omission should they be considered under the criminal system.

- • What is the role of independent medical expert evidence in criminal investigations and prosecutions?

  They should be experts and give balanced evidence for both the prosecution and the defence. They should not be expected to be able to benchmark skills of those in training unless they have specific expertise in that area.

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

  They nominate themselves and are selected by the legal team - instructed and used by them. Appropriate expertise may not always be available. Training is available, however, although we have no knowledge of content and it is not mandatory, but it should include recognising conscious & unconscious bias.

- • 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?

  We are unsure, but would assume they are the same - perhaps local investigation may have more holistic systems view of the situation rather than purely medical view.

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

  We do not think there are currently, but feel that there should be.

- • 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?

  Not enough knowledge to answer.

  This section focuses on the professional regulatory process

- • 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?

  No personal experiences to report.

- •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?

We feel it is very difficult for anyone to identify a "truly, exceptionally bad mistake", especially in the context of a potentially stressed system which can be undermanned outright or has the wrong skill mix. The context of the error including organisational factors needs to be taken into consideration.

It needs to take into consideration mitigating factors that have resulted in death unless the individual, by their own deliberate commission or omission, caused the death. In the majority of cases, it is by 'accident' that an individual doctor was in charge of a particular case that, because of human factors and the multiple stresses in the NHS, died. Generally, apart from a few high profile exceptions, clinicians do not seek to deliberately harm or kill patients.

Doctors are human and doctors make errors. If you are going to have an arbitrary level of "badness" of an error which can be subject to different interpretations by different people then you will discourage doctors from covering absences or providing cover in any other potentially stressful situations.

- • 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?

  Reflection is a necessary part of medical learning.

  Reflection is currently not being used as intended because of the fear that it may be used in court. However, it is an essential part of learning to reflect on where things might not have gone so well as well as where things have gone well. We all need to learn from our own, and others, mistakes to try and prevent them occurring in the future. The threat of having to release records of reflection or discussion of errors, has the potential to exacerbate unsafe practices. The GMC and others need to be clear and precise about how reflections could be used.

- • 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?

  At present there is no defined support for doctors being investigated by the GMC. The unifying feature of everyone we have been in contact with who has undergone any GMC process, is a complete lack of care and support for someone who has yet to be found guilty. The individual may have a defence union but generally this provides legal support only. The employer may have an employee support programme but this may not be available to those who have been suspended. This needs to be improved. All doctors under investigation, particularly for these charges will require mentoring and support; emotional, pastoral, legal, and professional.

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

  Sharing learning is extremely important. Learning from all incidents, fatal or non-fatal, is hugely powerful. Changes in practice implemented as a result of investigations should be made widely available in a non-attributable blame free culture. Possibly facilitated as a function of NHS Employers who hold the trusts to account.

Finally…

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

Errors should not be viewed as a crime in the same framework of the criminal justice systems. The view of an error as a single stand alone event which is entirely down to one person is simplistic at best in the increasingly complex medical systems we work in.

If the type and magnitude of errors is not fully codified and left open to the interpretation of others, or seen to be at the whim of the press and societal disapproval, then the "no blame culture" (such as it is) will be lost and essential learning will not take place. Also, marginalised doctors will be at the mercy of colleagues who will cry wolf on them with no route for reciprocal reproach.