THE ASSOCIATION OF ANAESTHETISTS

of Great Britain & Ireland

Association of Anaesthetists formal response to the independent review of gross negligence manslaughter and culpable homicide

The Association of Anaesthetists (the Association) represents the medical and political views of over 11,000 anaesthetists in the United Kingdom and the Republic of Ireland. The Association has a broad remit including education, safety and research in anaesthesia, as well as the professional aspects of the specialty and the welfare of individual anaesthetists.

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

While difficult to provide an exact definition, we believe the important factors are:

- Wilful recklessness;
- Intent to cause harm;
- Deliberate cover up/falsifying records.

Different factors about organisational behaviour are relevant when considering a possible charge of corporate manslaughter.

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

It is difficult to give a precise definition, but we believe a key factor is the presence of 'intent' to cause harm.

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?

We believe that 'local processes' are of variable quality. In addition, patient (or next of kin) expectations may not be met (for example, they may be expecting apportionment of individual blame, but this may not be appropriate). The key features of a high-quality investigation are: transparency, timeliness, independence, thorough/systematic, and with learning as a key outcome.

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

Such family involvement is variable. Delivery of a clear timeline, along with a single point of contact would assist.

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?

We believe mediation (using trained facilitators) and conversations can be helpful. Again, a more standardised approach would assist. However, with the threat of later, or on-going, criminal investigation the opportunity for an open, free discussion may not be grasped.

How are families supported during the investigation process following a fatal incident?
We believe this is variable and may, on occasion, be non-existent. This is harmful to the family and unhelpful to the process. While structures such as PALS exist, they are not always involved.

How can we make sure that lessons are learned from investigations following serious clinical incidents?
Learning is best facilitated by a 'no-blame' culture. The parallels with investigations in the airline industry are well-known. The opportunities are often lost by attempts at confidentiality, time delays for multiple investigations, and by the fear of a criminal investigation. The public good is often not served, and may be harmed, by prolonged and semi-secretive investigations, instead of a time-limited investigation from which the lessons are widely and rapidly disseminated.

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?
There remains a risk of investigations concentrating on the behaviour of individuals, rather than systematic or organisational failures. Many investigations are undertaken by subject matter experts, who have little or no training in investigating, analysing or reporting their findings. This almost certainly reflects a lack of investment in investigating teams. We believe the use of trained investigators is likely to improve the quality of local investigations.

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.
We are unaware of any evidence of the benefit of one approach over the other, though Root Cause Analysis tends to look for a single root cause, when, in fact, medical error is complex and commonly involves multiple errors. A combination of both methodologies is likely to be best. Whichever is used (including use of a combination), requires training in the methodology within the context of medical error.

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?
Most investigations are undertaken by senior medical and other clinical staff, sometimes with support from a manager. We believe the training is variable, and sometimes non-existent. We would welcome any initiative that defined and provided suitable training.

How is the competence and skill of those conducting the investigations assessed and assured?
Quite simply, it usually isn't. Given the seriousness of the matters being investigated, this is a significant failure of the current arrangements.

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
Not answered

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

There is very little, if any, oversight of local processes.

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

The use of independent experts, who might otherwise be very useful in many local investigations, is ad-hoc and usually reserved for the most serious incidents. We note that independent medical experts are not required to undergo formal training (or assessment of their abilities) for their role.

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

The choice of whether to use an independent medical expert, and which one is chosen (and their degree of independence), is often at the whim of the medical director or other senior managers. We are unaware of any requirement for such an expert to have any training in unconscious bias (or in anything else).

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

None that we are aware of.

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)

As previously described, to benefit from the lessons learnt from investigations requires openness, transparency, timeliness and adoption of a no-blame culture – all of these are rare in the more serious incidents, especially those where there are parallel or likely criminal investigations.

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 usually no local support after more serious incidents, leaving the clinical staff involved unsupported, isolated and sometimes 'quarantined'. The second victim(s) effect is very significant. Furthermore, the length of time to complete the various investigations and the risk of double-jeopardy may leave staff in a vulnerable state.

Outside bodies, such as the Association of Anaesthetists (and equivalent professional and membership organisations) are able to offer confidential, independent support. We are very saddened to hear repeatedly of colleagues under great psychological and emotional stress and who develop serious mental health illness. We have developed guidance (*Catastrophes in Anaesthetic Practice – dealing with the aftermath, AAGBI, 2005)* to assist colleagues at this time. We offer confidential mentoring support to individuals in this circumstance. Informal feedback is that discussion with a mentor who is not involved with the case is very helpful, particularly when there is multiple jeopardy with the Trust/Board, GMC, and police all investigating.

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?

This is variable at present. We believe there should be a senior, trained figure within each Trust/Health Board with responsibility to review all deaths and decide on referral to the Coroner, police, GMC, etc.

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?

We are aware of significant concerns that some groups of doctors (as determined by ethnicity or place of primary qualification) are more likely to be referred to the GMC, for example. This matter needs urgent investigation and analysis. The causes are not yet clear.

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?

There are understandable barriers for trainee doctors who feel that reporting serious incidents or raising concerns may damage their career progress. Overcoming this suspicion is problematic.

BME doctors, particularly in the SAS grade and for similar reasons to trainees feel that their concerns are less likely to be listened to especially if those concerns relate to a consultant. Despite a willingness to protect whistle blowing, there is still a suspicion that speaking out will get you into trouble.

Locum and locally employed doctors can also find it difficult to raise concerns. They are often new to the organisation and can be less certain as to how to report incidents and raise concerns.

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?

As an organisation we do not have 'corporate' experience. However, as individuals we are aware of many inconsistencies. A more systematic approach, using a defined process would help both the quality of each investigation, and assist the individuals involved – both the family and the staff involved.

One element that is particularly stressful for the doctor is the immediate exclusion from work and from contacts with colleagues, who are often also personal friends. It would be helpful if a way could be found to keep them at work.

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 variable, but we are aware that both the evidence and analysis from prior local investigations are declared and, presumably, used. Unfortunately, such local investigations may be of poor quality.

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

A medical expert should be a subject matter expert, with training or significant experience in providing independent, unbiased opinion. They need to understand both the medical and legal

issues and have recent and regular clinical experience in the area that they are providing expert comment.

How are independent experts selected, instructed and their opinions used? Is access to appropriate expertise always available? Do they have training in unconscious bias?
Too often medical experts are chosen because of availability, reputation or word-of-mouth recommendation. For example, the availability of retired colleagues is often much 'better' than those in current practice, yet their knowledge and experience of contemporary practice may be less.

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?
We believe the same standards should apply irrespective of the type of investigation being undertaken.

Are there quality assurance processes for expert evidence at this stage, if so, what are they?
We are not aware of any QA processes.

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?
We are unable to comment.

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?
We are unable to comment on the charging standard. However, we see no link between the charging standard and improving patient safety.

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?
The decision makers should be required to consider all factors – individual and system-based. It is very rare for a clinician to make a significant mistake leading to harm without the presence of system factors and pressures. To artificially differentiate these, and investigate an individual's actions in isolation, risks harm to natural justice and will fail to find the real, remedial cause.

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)?
We believe that at present there is not enough support. We believe there should be detailed guidance. In addition, Senior Investigating Officers should have access to a national resource to assist them in assessing evidence and applying the tests described in the charging guidance.

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

Perhaps the crux of the current problem - there is much inconsistency. While we know this occurs, its causes are less clear – but possible factors include: public, family or political pressure; lack of experience in the police or CPS; and, variable quality of expert advice.

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

When there is no evidence of intent or wilful recklessness

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

As above – to offer independent, unbiased subject matter expertise, with experience and knowledge of the relevant legal issues.

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

As previously described in relation to local investigations

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?

In theory yes, but in practice this may not be possible, and experts chosen to assist the police/CPS should be required to have some experience or understanding of the relevant legal issues.

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

None that we are aware of.

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 are unable to comment.

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?

We presume this question refers to FtP processes where the clinician has been convicted of a serious criminal offence in relation to the same incident (and not an unrelated matter)?

We have limited experience of such cases. However, the perception is of a long-drawn out process, the risk of double-jeopardy, the lack of openness, the isolation of the individual, the failure to consider system problems, and the lack of support (with ensuing psychological stress and consequent mental illness). We have considerable experience of assisting individuals who are subject to local investigations, regulatory processes or police investigations. The common features are the lack of local support, a feeling of 'nowhere to turn', and isolation. Shamefully, there is at present, no universally available physician health programme.

We believe it is necessary for processes to be streamlined, run wherever possible in parallel, and to use the same sources of information and expertise. The GMC should be required to assess and assist with the welfare of the professionals they regulate. Patient safety and protection rely on a

healthy and motivated workforce who believe the investigatory and regulatory processes are designed to help them perform to the highest standards.

Like any other investigation of a poor outcome, the GMC's processes should provide learning and recommendations for improvement, as well as ensuring clinicians are practicing as least to a minimum standard.

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?

If a criminal conviction concerns a single act and there is no evidence that it represents a pattern of poor behaviour and practice, then protection of future patients should be the main concern and the Fitness to Practice hearing should focus on whether there are on-going concerns. It is important that the GMC's actions are not punitive

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?

Reflections should be privileged in the same way as 'safe space'. The opportunity for both individual learning and the benefit of a 'no-blame' discussion outweigh the possible benefits of such material being admissible to the regulator. We also understand that reflections are being considered as part of the draft Health Service Safety Investigations Bill and hope that this may provide more clarity on their legal status. It is important that any guidance issued is consistent with the draft legislation. However, clear breaches of the criminal law should not be protected. Similarly, those responsible for reading reflections (e.g. appraisers, educational supervisors) have an overriding responsibility to protect patients and active patient safety issues require immediate action.

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?

In our experience, such support is variable. As described above, we believe that the GMC should be required to assess and provide support as a component of the FtP process. The Practitioner Health Programme (PHP) should be extended and made available to all practitioners working in the UK. We note the new Secretary of State's priority for action on workforce issues and believe the extension of the PHP, and, specifically, attention to the welfare issues of clinicians subjected to such allegations or investigations, would be consistent with acting as a caring 'employer'.

The suicide rate amongst doctors reported to the GMC is significantly raised. Of note, it should be the potential supporter who makes the initial contact with the doctor who faces the allegation.

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

Yes, the opportunities for learning are often too great for investigations to remain hidden. To some extent this will depend on the adoption of a no-blame culture.

Yes, the regulator can only fulfil its obligation to protect patients by promoting such learning. Of note, this responsibility does not lie with the regulator alone. For example, we welcome the increasing use by Coroner of the 'Prevention of Future Deaths' notices.

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

The recent case that precipitated this review led to concerns about the actions of the GMC and about the inconsistent criminal justice system that led to the criminal prosecution and conviction of a healthcare worker who made errors when there were also clear systematic and organisational problems which contributed significantly to those errors.

Changes to investigatory and regulatory processes should focus on efficiency, natural justice, limitation of variation, enhancement of opportunities for learning, use of both system and individual-based approaches, and mandatory assessment of the individual's welfare (with referral to appropriate support). For avoidance of doubt, similar welfare safeguards should apply to other healthcare occupations (and their regulators), not just doctors.