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

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<tr>
<th>This section focuses on what you consider to be 'criminal acts' by doctors</th>
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| 9. What factors turn a mistake resulting in a death into a criminal act?  
A degree of recklessness going significantly beyond clinical negligence that has a causative link to the death of a patient.  |

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<td>10. What factors turn that criminal act into manslaughter or culpable homicide?</td>
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<td>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?</td>
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Each NHS board has their own process for learning from adverse events however each process has been developed in line with the [national approach to learning from adverse events](#). Healthcare Improvement Scotland developed this national approach which provides a clear, consistent governance framework for managing adverse events. The national approach has been developed in conjunction with colleagues from across NHSScotland.

The national framework was originally published in September 2013. This was later refreshed in April 2015 after taking the opportunity to refine and clarify areas based on feedback and comments from stakeholders and is currently being refreshed again in 2018/2019 to align with the [Duty of Candour Procedure](#).

One of the key principles of the framework is openness about failures, that errors are identified, reported and managed in a timely manner, and patients, service users and their families are told what went wrong and why. Supporting cultural change is at the heart of the framework. The aim is a positive safety culture that is open, just and informed, in which reporting and learning from error is the norm. Achieving cultural change is challenging and will take time, but this approach and the tools developed will support the behavioural changes we want to see across Scotland.

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<th>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?</th>
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| The national framework suggests that the person involved in the incident/adverse event must be cared for, theirs and other people’s health and welfare secured and further risk mitigated. The person’s family or carers must be similarly cared for and involved where a person has been harmed. Compassion and understanding should be shown at all times even if simply making regular contact to keep people involved and informed.  
Communicating effectively with people is a vital part of dealing with errors or problems in the delivery of care. Saying sorry, providing an explanation and keeping them informed will help people cope when things have gone wrong. The national framework advocates that the organisation should give early consideration to the provision of information and support to patients, service users, families, carers|
and staff involved in the adverse event, including details on available support systems. We have developed a suite of national leaflets which can be used as a support tool. We have also published a reference document for Scotland that builds on the principles within the National Patient Safety Agency’s (NPSA) Being Open Framework (2009) to support care providers develop their approach to communicating and engaging with people who have suffered harm following an adverse event. These tools are available on our Community of Practice website.

This approach aligns with the Duty of Candour procedure. The duty of candour requires all organisations providing care in Scotland to tell people if there has been an event involving them where the organisation has recognised that there has been physical or psychological harm as a result of their care or treatment. More information about this aspect of the Duty of Candour procedure can be found here.

Individuals involved in the adverse event (for example patients, family, carers, staff) must be invited to contribute and informed throughout the review process. This includes asking them if they have any questions that they would like to be explored during the review process.

A report presenting the findings, conclusions and recommendations of the review should be produced and shared with everyone involved in the event. The organisation should ensure engagement and involvement with all people involved in the adverse event during the review process and as the report is finalised.

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?

Please refer to our answer to question 12.

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

In addition to our answers to previous questions, the Adverse Events team at HIS encompasses the Suicide Review and Learning System, which was created to help boards learn from suicides. Sadly, some people in contact with mental health services do complete suicide. The numbers are small but the effects are devastating for relatives, friends and the staff involved. When a suicide takes place NHS boards need to understand what happened and learn from any lessons identified. The lessons learnt are important to improve services and help staff recognise where risk exists. Suicide reviews are the way that NHS boards, and their mental health services, analyse what happened and recognise where anything can be done to make things safer for other people at risk.

The SRLS have created a Community of Practice to provide staff with useful information in this resource, including guidance or tools to assist staff through the review process. Guidance on the process of suicide reviews can be found in the Learning and Development section and includes a section on communication and provides guidance to staff on supporting families following a suicide.

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

The Adverse Events Community of Practice website has been set up to support NHS boards to share learning for improvement following adverse events reviews. The aim is to widen the scope to sharing learning from other patient safety sources, such as complaints and claims, across both health and social care. NHS boards use the learning summary template to share learning about: service improvements following recommendations and actions that have come from reviews with potential national application improvements in the management of adverse events e.g. in relation to the process of reporting, reviewing and learning from adverse events, and risk awareness notices. Published learning summaries and further guidance and information can be found here: http://www.knowledge.scot.nhs.uk/adverse-events/sharing-learning.aspx.
Healthcare Improvement Scotland (HIS) has agreed with the Procurator Fiscal to share the learning points from particular reviews into deaths more widely across NHSScotland, in order to facilitate national learning and improvement. The aim of this process is to ensure that learning from death investigations is shared in the most efficient and effective way possible, and ensuring that this is done in collaboration with the NHS board in which the review took place. Please see the following link for the process: http://www.knowledge.scot.nhs.uk/media/CLT/ResourceUploads/4089731/0d5b7acc-189f-410f-96c9-3cb6cde4a444.pdf

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?

The national approach to learning from adverse events provides a clear, consistent governance framework for reporting, managing and reviewing adverse events.

The Duty of Candour Act sets out that a responsible person that provides a health, care, or social work service during a financial year must prepare an annual report, as soon as reasonably practicable after the end of that financial year, which must include information about the number and nature of incidents to which the duty of candour procedure has applied in relation to a health service, a care service or a social work service provided by the responsible person.

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 national framework recommends that all events are subject to review. The basic process of adverse event review and analysis should be essentially the same. However, some events due to the complexity or the potential for learning require a more formal, extensive review making full use of all associated techniques to comprehensively examine the chronology, care delivery problems and contributory factors. Reviews should seek to understand what happened, how and why it happened and recommend what systems or processes should be put in place to prevent future occurrence using a human factors approach.

Adverse event reviews should use a structured and consistent approach by using defined tools and techniques to identify the contributory factors, details of the care provided and any lessons that could inform service improvement or reduce the risk of recurrence. A variety of tools, such as cause and effect charts, fishbone diagrams and contributory factor frameworks can be used. At least one member of the review team should be trained in review methodologies and their application. Where this is not possible, support from central clinical governance and risk management teams should be sought.

A human factors approach is critical to undertaking a review. Awareness of human factors can help to:

- understand why events happen and, in particular, which ‘systems factors’ threaten safety
- improve the safety culture of teams and organisations
- enhance teamwork and improve communication between care staff
- improve the design of care systems and equipment
- identify ‘what went wrong’ and predict ‘what could go wrong’ (in the future)
- help to identify events which went well, and
appreciate how certain tools can help to lessen the likelihood of harm.

The 2019 review of the framework will increase emphasis on human factors/systems approach.

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?

Information on this can be found in the national approach to learning from adverse events. Individual NHS board processes for suicide reviews can be found here: http://www.knowledge.scot.nhs.uk/suicidereviews/qa-flowcharts.aspx

The national framework advises that:

- Staff leading adverse event reviews should have up-to-date training and be competent in investigative methodologies, techniques and analysis, including human factors and report writing.
- The review team must be multidisciplinary and should include professionals with experience relevant to the event being reviewed.
- For Level 1 significant reviews, the review team should be sufficiently removed from the event, have no conflict of interest (real or perceived) to be able to provide an objective view.
- The roles and responsibilities of each member of the review team must be clear, including identifying a lead reviewer, and should be documented.
- A lead director or senior manager (band 7 and above) should be assigned to ensure a thorough and appropriate review is undertaken.

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

Information on this can be found in the national approach to learning from adverse events.

Individual NHS board processes for suicide reviews can be found here: http://www.knowledge.scot.nhs.uk/suicidereviews/qa-flowcharts.aspx

Additional processes and guidance can be found here: http://www.knowledge.scot.nhs.uk/suicidereviews/learning-and-development.aspx

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

See answers to previous questions

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

See answers to previous questions

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)

The Adverse Events Community of Practice website has been set up to support NHS boards to share learning for improvement following adverse events reviews. The aim is to widen the scope to sharing learning from other patient safety sources, such as complaints and claims, across both health and social care. NHS boards use the learning summary template to share learning about: service improvements following recommendations and actions that have come from reviews with potential national application improvements in the management of adverse events e.g. in relation to the process of reporting, reviewing and learning from adverse events, and risk awareness notices. Published learning summaries and further guidance and information can be found here: http://www.knowledge.scot.nhs.uk/adverse-events/sharing-learning.aspx

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?

There is information available on our Adverse Events Toolkit on our Community of Practice website.

The SRLS Community of Practice provides mental health services staff with a shared space where they can find guidance on the process of suicide reviews. Including support and guidance for staff. This guidance encourages staff to think about their own support. It encourages them to identify where in your organisation they would get support in dealing with their own emotional and professional responses to a suicide. Each NHS board will have their own support available.

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?

In Scotland there is a professional obligation to report incidents to the Procurator Fiscal, and advice can also be sought from the Death Certification Review Service.

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?

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?

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?
Healthcare Improvement Scotland (HIS) has agreed with the Procurator Fiscal to share the learning points from particular reviews into deaths more widely across NHSScotland, in order to facilitate national learning and improvement. The aim of this process is to ensure that learning from death investigations is shared in the most efficient and effective way possible, and ensuring that this is done in collaboration with the NHS board in which the review took place. Please see the following link for the process: [http://www.knowledge.scot.nhs.uk/media/CLT/ResourceUploads/4089731/0d5b7acc-189f-410f-96c9-3cb6cde4a444.pdf](http://www.knowledge.scot.nhs.uk/media/CLT/ResourceUploads/4089731/0d5b7acc-189f-410f-96c9-3cb6cde4a444.pdf)

| 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? |
| 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)?

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

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?

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?

**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?

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?

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?
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<th>Question</th>
<th>Answer</th>
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