

Consultation Response

Review of gross medical negligence manslaughter and culpable homicide

10 August 2018





Introduction

The Law Society of Scotland is the professional body for over 11,000 Scottish solicitors. With our overarching objective of leading legal excellence, we strive to excel and to be a world-class professional body, understanding and serving the needs of our members and the public. We set and uphold standards to ensure the provision of excellent legal services and ensure the public can have confidence in Scotland's solicitor profession.

We have a statutory duty to work in the public interest, a duty which we are strongly committed to achieving through our work to promote a strong, varied and effective solicitor profession working in the interests of the public and protecting and promoting the rule of law. We seek to influence the creation of a fairer and more just society through our active engagement with the Scottish and United Kingdom Governments, Parliaments, wider stakeholders and our membership.

Our Criminal Law Committee welcomes the opportunity to consider and respond to the call for written submissions in relation to the (formerly named) Dame Clare Marx Review of gross negligence manslaughter (GNM) and culpable homicide (CH) (Review).

In relation to Question 7, the members of the Criminal Law Committee include practising solicitors as well as academics in criminal law at various Scottish universities.

As far as Question 8 is concerned, none of the Committee members are doctors but there may well be some of our members who are also medically qualified.

The wider membership of the Society includes solicitors who work:

- as Procurator Fiscals for the Crown Office and Procurator Fiscal Service (COPFS)
- in criminal defence
- specialise in delict (tort) in relation to medical negligence cases
- in regulatory capacities in relation to Tribunal hearings such as the Medical Practitioners Tribunal Service (MPTS)¹
- for the medical defence unions such as Medical Dental Defence Union for Scotland (MDDUS)
- for the NHS in Central Legal Office²
- in Government Service



Executive Summary

We discuss what happens in Scotland in relation to any medical-related deaths.

We outline the roles of COPFS in relation to medical-related deaths in Scotland. COPFS decides whether any such death should be subject to criminal prosecution or form the basis of a Fatal Accident Inquiry (FAI).

There has only been one case prosecuted for a charge of CH in Scotland to date where the circumstances were rather different from the GNM successful prosecutions in England and Wales. That Scottish case provides no real insight into Scottish processes.

We set out the legal test for CH under Scots Law and highlight that the Scottish Law Commission is undertaking a review of homicide whose remit may include medical-related CH deaths.

FAIs may be held in Scotland in relation to medical-related deaths. We consider how FAIs work and differ from the English and Welsh coroner system. Better public awareness of the processes of FAIs would enhance the public awareness and understanding of what the purpose of a FAI is.

We support the promotion of no-blame culture to encourage doctors to reflect on mistakes where they arise so that lessons can be learnt for all concerned. There would be benefit in making clear what the status of the doctors' e-portfolio reflections are for all concerned. This would prevent doctors from being inhibited or concerned about making full timeous reflection because it could be used in any criminal process to follow.

There are a range of factors which may be relevant when considering what lessons can be taken from the Scottish system on how fatal clinical incidents are dealt with.

Prosecution will only take place if there is sufficient admissible evidence according to the Scottish evidential requirements and that prosecution is justified in the public interest. Public interest is fully discussed in relation to the role of the Lord Advocate as the head of the COPFS in instructing any criminal prosecution. Similar considerations apply in assessing the circumstances of any death in deciding that the death is of significant public concern to justify the holding of a FAI.

The broad Scottish approach allows COPFS to fully investigate any medical-related death before any decision as to any proceedings, criminal or otherwise, is taken. Decisions are fully informed once the whole facts and circumstances of the death and expert opinion has been obtained and assessed. There may well be considerable benefit in that approach to maintain an open mind as to any future action that may be appropriate in the public interest.



General

The Role of COPFS

COPFS³ is Scotland's prosecution service who is solely responsible for prosecuting in Scotland in the public interest. It considers case reports received from the police and other reporting agencies. These are assessed to decide whether there is sufficient admissible evidence in accordance with Scots law and that prosecution is merited in the public interest. Their role includes investigating the circumstances of any death caused because of medical procedures or processes that could potentially result in a prosecution for CH (GNM is the English crime).

Any cases prosecuted for CH would be most likely to proceed in the High Court of Justiciary, Scotland's highest first instance court. Such cases would be competent to prosecute in the sheriff court but given the level of public interest that such cases generate, this would be thought to be extremely unlikely. However, the imposition of any sentence, certainly considering the sentencing in English cases, have not attracted the level of sentencing that would be outwith the range in the sheriff court, namely up to five years imprisonment. There are no sentencing guidelines in Scotland; sentencing on conviction would be a matter for the judge to decide based on the factors involved.

Indictments in solemn (more serious) proceedings would run in the name of the Lord Advocate⁴ who is the chief legal officer of the Scottish Government and the Crown in Scotland for both civil and criminal matters that fall within the devolved powers of the Scottish Parliament under the Scotland Act 1998.

COPFS has a further responsibility in that sudden, unexpected and unexplained deaths occurring in Scotland are reported to it for investigation; similar to the role of the coroner in England and Wales.

Within COPFS, the Scottish Fatalities Investigation Unit (SFIU) is a specialist unit responsible for investigating such deaths (and if required the Homicide team). A designated SFIU team is based across each area of Scotland which are described and include the North, East and West. These deaths are dealt with by a small number of specialist lawyers. The work of these teams is ultimately overseen by the Deputy Crown Agent, Serious Casework. There are no local deaths investigations carried out by the procurator fiscal. Everything is undertaken by the national specialist units.

When a person dies in Scotland, they cannot be buried or cremated until a medical certificate giving the cause of death has been issued. This certificate must be completed by a doctor and must show the time, place and cause of death. Once a death which requires to be reported to the Procurator Fiscal, the Procurator Fiscal has legal responsibility for the deceased's body, usually until a death certificate is written

³ http://www.copfs.gov.uk/about-us/about-us

⁴ https://beta.gov.scot/about/who-runs-government/cabinet-and-ministers/lord-advocate/



by a doctor and given to the nearest relative. All deaths where the circumstances are thought to be suspicious must be reported to the Procurator Fiscal. The Procurator Fiscal will then instruct the police to investigate the circumstances and consider whether criminal charges should be brought which may lead to a prosecution. The COPFS booklet sets out "*The role of the Procurator Fiscal in the investigation of deaths*⁵" in detail.

Fatal Accident Inquiries (FAI)

To deal with circumstances where there is no criminality in a death, a death can still result in a public inquiry such as FAI being held. This is a type of court hearing held in public into the circumstances of a death. The remit, conduct and scope of FAIs is set out in the Inquiries into Fatal Accidents and Sudden Deaths etc. (Scotland) Act 2016 (2016 Act). There are both mandatory⁶ and discretionary FAIs. Discretionary inquiries⁷ can be instructed into in all manner of deaths where the Lord Advocate considers that the death:

"(i) was sudden, suspicious or unexplained, or (ii) occurred in circumstances giving rise to serious public concern, and (b) decides that it is in the public interest for an inquiry to be held into the circumstances of the death."

Medical related deaths (which are relatively small in number) are only one category of deaths which may be the subject of a discretionary FAI⁸. In effect any death can give rise to a FAI such as the Dunblane Primary School and Lockerbie disasters.

Lord President Hope9 said:

"There is no power ... to make a finding as to fault or to apportion blame between any persons who might have contributed to the accident.. It is plain that the function of the Sheriff at a [FAI] is different from that he is required to perform at a proof in a civil action to recover damages. His examination and analysis of the evidence is conducted with a view only to setting out in his determination the circumstances, in so far as this can be done to his satisfaction. He has before him no Record or other written pleading, there is no claim of damages by anyone and there are no grounds of fault upon which his decision is required."

⁵ Information for bereaved relatives. The role of the Procurator Fiscal in the investigation of deathshttp://www.copfs.gov.uk/investigating-deathtps://www.gmc-uk.org/news/news-archive/responding-to-the-case-of-dr-bawa-garbaths/our-role-in-investigating-deaths

⁶ Effectively deaths arising in custody and those during employment

⁷ Section 4 of the 2016 Act

⁸ The Glasgow Bin lorry case was an example of a FAI ([2015] FAI 31

⁹ Black v Scott Lithgow 1990 S.L.T. 612



Civil proceedings for medical negligence may follow a determination that has been issued in a FAI. (Commonly because of time bar implications, such actions are raised earlier and sisted pending the conclusion of the FAI). FAIs do therefore have their limitations as Sheriff Derek CW Pyle stated:

"[Later] litigation [can be pursued] where the normal rules apply of advance notice in writing of each party's case and control of the manner evidence is presented to the court."¹⁰

A FAI has a distinct role; it is neither designed to be an all-encompassing inquiry into a death as the scope of the framework of the FAI is limited by statute nor necessarily to offer a panacea to the deceased's relatives. Section 5 of the Inquiries Act 2005 offers a wider scope for any inquiry as it allows it to set its own terms of reference as happened with the original Dunblane inquiry into the shooting at the primary school. That type of inquiry would not seem appropriate in relation to an isolated medical death. It could be relevant to an inquiry into multiple deaths such as contaminated blood from a blood-bank.

How many deaths?

It is relevant to consider the number of deaths reported in Scotland to COPFS each year. 56,728 deaths were registered in Scotland in 2016¹¹ but only a relatively small proportion of those will be reported to COPFS. The number of deaths dealt with by COPFS does vary year on year (but is estimated annually as between 10,000 and 11,500), with 11,000 deaths dealt with in 2016-17¹².

Post mortem examinations, which are instructed by COPFS where necessary, are carried out in relation to approximately half the number of deaths dealt with by COPFS. There are a number of categories of deaths that do require to be reported to the COPFS but for the purposes of this Review, those concerned fall within the following category:

"Deaths associated with medical or dental care.13

9.1 Most deaths under medical care represent an unfortunate outcome where every reasonable care has been taken. However, some deaths associated with the provision of medical care may involve fault or negligence on the part of medical or paramedical staff and may give rise to questions of public safety and, in rare cases, may be associated with criminality.

¹⁰ Inquiry into the circumstances of the death of Michael Dodds at Dundee (11 August 2009)

¹¹ https://www.nrscotland.gov.uk/statistics-and-data/statistics/statistics-by-theme/vital-events/general-publications/births-deaths-and-other-vital-events-preliminary-annual-figures/2016

¹² http://www.gov.scot/Publications/2018/02/5184/4

¹³ Reporting deaths to the Procurator Fiscal Information and Guidance for Medical Practitioners 2015



9.2 Medical care includes surgical, anaesthetic, nursing or other care/treatment whether provided in a healthcare or non-healthcare setting.

9.3 The procurator fiscal may decide to instruct an independent expert in the relevant field to provide an opinion on the circumstances of the death. The expert may wish to discuss the circumstances of the death with the doctor/(s) involved in the treatment of the deceased."

For COPFS to be aware of any death that requires to be investigated, the death must of course have been reported. (Question 27 of the Review refers to the reporting of deaths).

The FAI into the death of Norma Haq¹⁴ illustrates the circumstances (though of course not amounting to any allegation of criminal conduct) where a death was not reported to COPFS at the time. It came to COPFS's attention much later. It was decided that the circumstances of the case merited the instruction of a discretionary inquiry in terms of the then Fatal Accidents and Sudden Deaths Inquiry (Scotland) Act 1976 (1976 Act)¹⁵.

The sheriff's determination at paragraph (4) outlines concerns about the death not having been reported at an earlier stage (and illustrates the role of the Scottish Audit of Surgical Mortality):

"4) In terms of Section 6(1)(e) of the [1976 Act] the <u>death ought to have been reported</u> to the procurator fiscal in terms of the literature "Death and the Procurator Fiscal".....; in any event Mr Hansell <u>should have known such a report was required from his own NHS consultant practice</u>; it <u>would have been appropriate to report to the Scottish Audit of Surgical Mortality (SASM)</u>, and effort should be made to encourage the participation of surgeons in private practice in SASM, a voluntary scheme; there should be a system of review of cases in a private hospital such as Ross Hall Hospital where a patient's stay in hospital is longer than expected following an elective procedure; there should be participation in managed clinical networks in specialist areas by consultant surgeons in a private hospital such as Ross Hall Hospital;Mr Hansell should have made a <u>full and frank disclosure</u> from the outset to the patient, the family and other doctors involved with the patient, that the cause of perforation was instrumental, which in itself is a recognised complication of the ERCP procedure and is not considered medical negligence." (The underlining represents our emphasis)

We turn now to the questions that have been posed in the Review when we refer to the law of Scotland unless otherwise mentioned.



Consultation

Questions 1 – 6 deal with the Society and contact details.

Questions 7 and 8 are answered above.

What may be considered 'criminal acts' by doctors

The Review's background lies in the recent high-profile English cases of Dr Bawa-Garba¹⁶ and David Sellu¹⁷ where both were convicted of GNM. The Review is not concerned with circumstances where doctors commit offences in their everyday lives.

This Review is focused on the doctors' culpability for actions/decisions/processes taken within the medical treatment context that could result potentially in prosecution for GNM/CH. On conviction, they then face criminal sanctions for what are of course very serious crimes¹⁸. Rule 5(1) of the General Medical Council (Fitness to Practise) Rules 2004 contains specific provisions regarding the management of cases which result from a conviction, police caution or a determination from another regulatory body. Under Rule 5(1), the Registrar shall refer all convictions resulting in a custodial sentence, whether immediate or suspended, directly to a MPTS.

We recognise that these cases of GNM have received extensive publicity. They also follow significant public disquiet relating to the Inquiry into the mistreatment and neglect of patients in the Mid Staffordshire NHS Trust.¹⁹ That highlighted concerns regarding deaths, injuries and neglect. There have been calls for legislation specifically to deal with such cases:

*"where serious harm or death has resulted to a patient as a result of a breach of the fundamental standards, criminal liability should follow."*²⁰

The Review is considering cases where a charge of GNM/CH could result. The Crown Prosecution Service (CPS) defines medical manslaughter as '*medically qualified individuals who are performing acts within their*

16 https://www.gmc-uk.org/news/news-archive/responding-to-the-case-of-dr-bawa-garba

¹⁷ http://www.pulsetoday.co.uk/news/gp-topics/legal/gmc-fails-in-case-against-surgeon-exonerated-of-manslaughter/20036298.article

¹⁸ Sentencing Guidelines are understood to exist in England and Wales. There are no such guidelines in Scotland. Any judge would sentence according to the facts and circumstances arising in such a case.

¹⁹ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/279115/0898_i.pdf

²⁰ Francis Report (2013) Vol.3, p1439 Recommendation 28



*duty of care when the act or omission occurs*²¹. COPFS has no such definition and would consider if the conduct amounted to CH as discussed below.

The case of $R \vee Adomaku^{22}$ provides guidance on the issue of when a doctor's conduct might be considered criminal:

"[it] is necessarily a question of degree ...the essence of the matter which is supremely a jury question is whether having regard to the risk of the death involved the conduct of the defendant that was so bad in all the circumstances as to amount in their judgment to a criminal act or omission.²⁴²³

CH in Scotland

Were a medical case to arise in Scotland such as Dr Bawa-Garba's and to be considered for prosecution, the relevant charge under the current law would be one of CH (otherwise referred to as lawful act involuntary culpable homicide). For these purposes, we leave aside the issue that the rules of evidence regarding sufficiency are different in Scotland with the need for corroboration.

The charge would narrate that the accused has caused the death of another because of the grossly careless way in which they performed some other not unlawful act.²⁴

The criminal law does not apply to an individual who has acted without mental fault (mens rea). The criminal law distinguishes between conduct that is meant and conduct which is not deliberate. There is a focus on intent and recklessness in considering if actions are criminal and consider negligence only in passing. Ordinary negligence (which may result in a civil action for delict (tort) in respect of medical negligence) will not suffice to attract criminal liability. The courts in Scotland more recently have made a conscious effort to avoid using '*negligent or negligence*' when considering the required mental element for establishing a crime. There may be a practice to avoid using the term negligence when dealing with criminal cases. This is due to the use of the technical legal connotations of 'negligence' in civil law as it means different things to different people.

The difference whether actions are criminal lies in the degree of carelessness exhibited. Examples where this can be seen include dangerous driving cases²⁵, folding up of a bed which had a child in it at the time²⁶ and a conviction for CH after fitting a gas fire without providing for flues to remove toxic fumes²⁷. For a

21 https://www.cps.gov.uk/legal-guidance/homicide-murder-and-manslaughter

23 Lord Mackay

- 25 McDowall v HMA 1998 SCCR 343 and HMA v Purcell 2007 SCCR 520
- 26 Williamina Sutherland (1856) 2 Irv 455

^{22 [1995] 1}AC1

²⁴ Criminal Law Timothy H. Jones and Ian Taggart 6th edition W Green 2015 Edinburgh at Page 226

²⁷ See 24 above. Ross Fontana Unreported - High Court Kirkcaldy 1990 cited in Jones and Taggart paragraph 9-65



more recent example, a boy was killed when a spooler machine (used to raise and lower subsea cables) was started when he was in it. Criminal prosecution followed with convictions for breaches of the relevant health and safety legislation²⁸

The mental element is crucial and is a necessary and significant element in the crime of lawful act culpable homicide. The case of *Transco*²⁹ provides the best discussion of the issue where the decisions of two judges – Lord Hamilton and Osbourne set out the Scottish position. Referring to mens rea, that element may be proved in various ways including inference from the external facts. It is a mistake as stated by Lord Hamilton:

"to suppose that the actual state of mind can be ignored, and guilt or innocence determined on the basis of proof that the conduct in question fell below an objectively set standard."³⁰

This approach does indicate that there must be an awareness of risk which refers back to the concept that CH cannot be committed inadvertently. This may be an important difference from the GNM in England because it implies that a person cannot be guilty of [lawful act] CH unless they are aware of the risk and choose to run it. English prosecutions are rarely if ever based on an allegation that the doctor *knowingly ran an unjustified risk* (rather than inadvertent gross negligence). The Review may want to consider whether criminal liability based on inadvertence is appropriate.

Lord Osbourne refers too to mens rea as:

"a complete disregard of potential dangers or an utter disregard of what the consequences of the act in question may be so far as the public, or recklessness so high as to involve an indifference to the consequences for the public generally."³¹

What is clear is that inferences can be drawn from the lack of care exhibited by the accused '*against the standards of conduct to be expected of persons carrying on operation of the relevant kind.*'³² The accused may always be able to provide an explanation which could offset any lack of care. (Please see answer in relation to Question 46 regarding any explanation by a doctor tin Scotland as to the reasons for their conduct.)

We consider that it is important for the Review to note that the Scottish Law Commission has recently commenced a project examining the law of homicide³³. Though the scope is not yet confirmed, we would anticipate that it will include consideration of such cases of lawful act involuntary culpable homicide.

²⁸ https://www.bbc.co.uk/news/uk-scotland-north-east-orkney-shetland-44413548 Man acquitted in teenagers Inverurie Workplace death trial

²⁹ Transco v H.M.Advocate 2004 JC 69

³⁰ Transco- Lord Hamilton at para 54

³¹ Lord Osbourne - Transco v H.M. Advocate 2004 JC 69

³² Transco v H.M.Advocate 2004 JC 69

³³ https://www.scotlawcom.gov.uk/files/7515/2586/0369/e-Bulletin_Spring_2018.pdf



Medical CH prosecutions in Scotland

There has only been one unreported prosecution regarding medical CH in Scotland in July 2017. Its circumstances are somewhat different from the English GNM cases. We mention the case details to differentiate.

Katy McAllister³⁴ was acquitted of causing the death of her friend in May 2015 by giving her a cocktail of powerful painkillers. The deceased had felt 'anxious' about having her body inked at a tattoo parlour and died of a cardiac arrest a day later. Dr McAllister was however convicted of drug offences of supplying a fellow doctor with diazepam while employed at NHS Tayside and possession of magic mushrooms. She received a sentence of 150 hours community service and was subsequently suspended from practice for a year at a disciplinary hearing MPTS hearing³⁵

The CH charge never reached the jury as the judge ruled that the Crown had failed to provide sufficient evidence to establish a case to answer on a charge of CH.

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

We refer to our response above in setting out the Scottish legal basis for considering prosecutions for CH. We agree that doctors' actions should not be immune from prosecution. Exactly when a mistake resulting in a fatality should result in a prosecution for a death for a criminal act is unclear. Mistakes will commonly be dealt with through litigation for medical negligence.

Cases alleging medical manslaughter in England and Wales appear to have risen over the last twenty years though conviction rates have remained low. A review³⁶ found that 85 doctors had been charged with medical manslaughter since 1795 with 38 of them charged since 1990. Such cases will always be subject of a high level of media and public interest.

Successful prosecutions may provide examples which highlight the factors that have been considered as meeting the criminal standard of conduct. These may also identify areas of medicine that may be more likely to arise which may include 'cutting edge' medical procedures. In other cases, actions may have been considered as potentially criminal, but no person or organisation could be held as responsible to justify any prosecution proceeding. Examples where prosecutions have successfully taken place for illustrative purposes³⁷ include:

³⁴ https://www.bbc.co.uk/news/uk-scotland-tayside-central-40057847

³⁵ https://www.scotsman.com/news/doctor-is-suspended-after-acquittal-over-friend-s-drug-death-1-4619591

^{36 2006} Ferner and McDowell Ferner RE, McDowell SE. Doctors charged with manslaughter in the course of medical practice, 1795–2005: A literature review. J R Soc Med 2006; 99: 309–14.

³⁷ Medical manslaughter: Simon Edwards Deputy Director of Communications, https://publishing.rcseng.ac.uk/doi/pdf/10.1308/rcsbull.2014.96.4.118



- 2003 A teenage patient died after a toxic cancer drug was wrongly injected into his spine
- 2007 A patient received an injection of six times the required dose of diamorphine for migraine, following a call to an out-of-hours general practice service.
- 2013 A patient died from diabetic ketoacidosis, having been erroneously diagnosed with depression following a call to an out-of-hours general practice service.

These were cases where the doctor tendered a plea of guilty rather than facing a trial. These examples provide a useful starting point when reflecting what common factors in such prosecutions may be. More generally, we would envisage that those cases will sit on a spectrum which comprises at one end cases where the mistake leads to a fatality due to a momentary lapse of concentration or a misheard instruction to the other extreme where actions are not mistakes such as cases where deliberate harm is inflicted on a patient such as the cases of Harold Shipman³⁸ and Beverley Allitt³⁹.

Each case, of course, depends on its own facts and circumstances so that no hard and fast rules can necessarily be drawn. Unless a case is appealed and is reported, the exact facts and circumstances establishing the conduct that gave rise to the finding of GNM are difficult to ascertain. Dr Bawa- Garba's case, at least from the press reporting, seemed to have much by way of mitigation such as working arrangements and late test results which could be thought to have formed more of a systemic failure lying at the door of the hospital trust where no prosecution took place. Instead, she was convicted, presumably, due in part to the expert reports on her conduct falling within the requisite category of GNM.

Much will depend on the evidence of any expert witnesses. Their role is crucial since they speak to training, normal practices, training and complications that arise in relevant cases.

Patients die despite the best endeavours of those involved. The fact of their underlying condition cannot be ignored as even with the best medical care, the patient may still have died. In ascertaining what factors are relevant to considering CH, the following are questions to be considered and answered:

- What is the cause of death established by the post mortem?
- What did the doctor do or not do in the given case that resulted in the death?
- Did the act or omission cause the patient's death?
- Was that doctor responsible for that act or omission?



- What was the mental state of the doctor at the time?
- Is there evidence to allow the inference to be drawn that this mistake meets the 'legal' requirement for lawful act CH?
- Is there corroborated evidence of the key facts?

If the foregoing can be proved to the criminal standard of proof of beyond reasonable doubt, consideration must be given to whether it is in the public interest to prosecute.

The mental element of the doctor who it is alleged caused the death lies at the heart of the answer to this question. There will often be no dispute as to the facts or to the identity of the person who made the mistake or that the mistake caused the death. The question is whether the act or omission which caused the death goes beyond simply being an error of judgement or an accident, albeit with catastrophic consequences and was sufficiently reckless to meet the test as discussed above.

It is difficult to envisage a situation in which a mistake resulting in a death may be a criminal act but not amount to CH.

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

We refer to our answer to Question 9.

For GNM/CH, the mistake needs to have resulted in the death of the patient having been directly caused by the mistake, whether by commission or omission. The action causing death would generally require to be the responsibility of one doctor. Where, as indicated above, there were multiple failures by doctors that would be indicative of a systemic failure the organisation (such as the hospital trust) might be prosecuted under section 1(1) of the Corporate Manslaughter and Corporate Homicide Act 2007:

"An organisation to which this section applies is guilty of an offence if the way in which its activities are managed or organised—

(a)causes a person's death, and

(b)amounts to a gross breach of a relevant duty of care owed by the organisation to the deceased".



Another factor to consider is why bring a common law charge such as CH when there may well be breaches of statutory contraventions relating to the relevant health and safety legislation. Criminal proceedings may be said by some to be symbolic, and more about denunciation⁴⁰ rather than the penalty. There is a perception that a conviction for CH is worse than for a specific statutory offence. It is hard perhaps to envisage a statutory offence being applicable against an individual doctor but certainly that could apply to a hospital trust.

For Scotland, there would require to be corroborated⁴¹ evidence sufficient for the Crown to prove that:

- the accused committed an unlawful act
- the act was intentional, reckless or grossly careless and
- the death was a direct result of the unlawful act.

It is immaterial whether death was a foreseeable result or not. The bar for criminal proceedings is set very high. Each case will turn on its own facts and circumstances and the strength of the admissible evidence but if that evidence does not show that the accused person demonstrated the required degree of recklessness, there will not be a prosecution.

The experience of patients and their families

Question 11: Do the processes for local investigation give the 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?

Question 12: How is the family involved in the local trust/board/hospital investigation process and in feedback on the outcome of the investigation?

These are questions best answered by the hospital trusts and patients and their relatives who can provide feedback. Our position is if these are not dealt with appropriately and effectively, there may be more likelihood for greater COPFS involvement as matters will not have resolved at the first opportunity.

⁴⁰ James Chalmers Corporate Culpable Homicide: Transco plc v H M Advocate Edin L R Vol 8 pp262- 266

⁴¹ Corroboration is a unique feature of Scots criminal law. The requirement for corroborating evidence means at least two different and independent sources of evidence are required in support of each crucial fact before an accused can be convicted of a crime.



By 'local', we assume that this refers to the hospital processes immediately after the serious clinical incident resulting in the patient's death. Before considering the role of local investigation, it may be helpful to remember the context. As is recognised by NHS Education for Scotland:

"the management of a sudden or unexplained death can be challenging for professionals. The responses required may be complex and come at an extremely difficult time for those who are bereaved. This may be further compounded by the conflicting interests of <u>all the agencies</u> (our emphasis) involved. Empathetic handling and knowledge of the <u>multi agency processes</u> (our emphasis) which will occur can reduce unnecessary stress for all concerned."⁴²

Providing explanations is vital. At the actual time of the death, this is not the best time as all involved will be emotionally challenged. All agencies involved at that time have a role and it is important too to understand that role in relation to the background of the death investigation.

There has to be investigation into deaths which is the role of the State.⁴³ Article 2 of the European Convention on Human Rights (ECHR) states:

"Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law."

The State is required to facilitate an effective independent judicial system to determine the cause of any death and, if necessary, to hold accountable those responsible for it. Scotland provides that system through the reporting of deaths and subsequent investigation to the COPFS as outlined above. There is a balance to be obtained as the death of a loved person is a private matter but there must be investigation into the death to provide explanations about the death but also to allow lessons to be learnt. That effective investigation requires to be independent, reasonably prompt, open to a sufficient element of public scrutiny and one in which the next-of-kin must be involved to an appropriate extent.

Article 2 rights also apply to the hospital trusts as they have an over-arching obligation to protect the lives of patients in their hospitals. To fulfil that obligation and depending on the circumstances, they may be required to fulfil a number of obligations to ensure that the hospitals for which they are responsible employ competent and trained staff to a high professional standard. Hospitals too must adopt systems of work which will protect the lives of patients⁴⁴.

As well as hospital procedures at the time of the death, in Scotland both Police Scotland and COPFS are included within '*the agencies*' in their respective roles. Setting out the various steps involved in the investigation of deaths may be helpful when considering these roles:

44 Courses y South Essay Dorthorphin NUC Foundation Trust [2000] UKUL 74

44 Savage v South Essex Partnership NHS Foundation Trust [2008] UKHL 74

⁴² http://www.sad.scot.nhs.uk/media/15996/transcript-of-understanding-the-processes-following-a-sudden-or-unexplained-death-script.pdf 43 http://www.sad.scot.nhs.uk/atafter-death/faith-spirituality-and-cultural-considerations/



Investigation of a hospital death

A death occurs. There are practical steps to take.

Prior to release of the Deceased Body

- 1. The death is reported to the COPFS as discussed above. (We would envisage that most of the deaths falling into the context of the Review would require to be reported.)
- 2. The death will most likely require a post mortem to be instructed by the Procurator Fiscal. There can be a 'view and grant' of the body but this is unlikely in relevant medical cases. If criminal proceedings are being contemplated, a post mortem in Scotland would be carried out by two pathologists (for the purposes of corroboration.)
- 3. The deceased's body will not be released until COPFS permits. That will take place as soon as practical, but any delay is stressful for the family. Furthermore, where the deceased is of a different culture, observance of funeral procedures may well be hindered through such a delay.
- 4. The police will be involved in the investigation which may be distressing for the families. Paragraph 1.2 of the Police Scotland's Standard Operating Procedures recognises that deaths occur in society on a very regular basis and arise in hospital settings. Paragraph 1.4 recognises that the deceased relatives must be treated with dignity, compassion, and respect throughout.⁴⁵ The police will take statements and submit a report as part of the investigation process with initial findings to COPFS as part of that process. The procurator fiscals themselves do not investigate a sudden or unexplained death at this stage as they will normally instruct the police to investigate deaths, regardless whether the death is suspicious. In reported cases, contact will be made either by telephone or in person. Information regarding the circumstances of the death and views on any further examination will be requested and made known to the procurator fiscal in a police report.
- 5. If there was obvious criminality with a doctor identified and arrested, consideration would need to be given to a defence post mortem.
- 6. Once these initial investigations are completed, the body will be released to the family for the funeral arrangements.

Next steps

- 7. Post release of the body, COPFS process will continue to investigate the circumstances of the death. This will involve statements, perusal of medical records and the instruction (most likely) of professional expert medical reports. These will be crucial in determining how and what proceedings may follow. It is a matter for the procurator fiscal to determine what investigations to instruct.
- 8. Whilst some death investigations conclude once a cause of death is known, other deaths may require further detailed and sometimes lengthy investigation, involving complex technical and medical issues and expert opinions.



- At the end of such investigations, a FAI may be instructed. The families' views on the holding of any FAI will be considered by the COPFS but are not paramount to the decision which is made at the discretion of the Lord Advocate⁴⁶.
- 10. In medical cases, COPFS will seek to hold FAIs as soon as practicable after a death. The purpose of the FAI is to assess the circumstances surrounding the death and to identify any issues of public concern or safety and to prevent future deaths or injuries.
- 11. The procurator fiscal has responsibility for calling witnesses and leading evidence at a FAI, although other interested parties may also be represented and question witnesses. At the end of a FAI, the sheriff will make a determination. The determination⁴⁷ (where (a) and (b) are mandatory findings) will set out:
- a. where and when the death occurred
- b. the cause of death
- c. any precautions by which the death might have been avoided
- d. any defect in systems that caused or contributed to the death
- e. any other facts which are relevant to the circumstances of the death.

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

We refer to our answer to Question 12.

There is not much time for giving the families space since there are practical arrangements that need to be made about post mortems and the release of the body. Good information and communication channels need to be available so that relatives can understand the practical implications as well as being involved and understand what is happening.

We recognise that communication at this stage is vital and may well shape how the subsequent procedures pan out.

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

46 Paragraph 29 Emms v Lord Advocate [2011] CSIH 7.

47 Section 26 of the 2016 Act



We have already referred to the role of the police. Support for families is also provided through COPFS. Staff from the COPFS Victim Information and Advice (VIA) make contact if there is to be a prosecution, further investigations after a post mortem examination or a FAI.

VIA staff provide information about the case's progress and provide information about support agencies. Throughout investigations, the procurator fiscal will liaise with the nearest relatives of the deceased's family to keep them advised of progress⁴⁸.

If the family has employed a solicitor to represent them this forms another means of support.

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

• Why do lessons need to be learnt?

We would suggest that There are three reasons why lessons must be learnt from serious clinical incidents which are:

- to strive to improve standards
- to learn from what has happened
- to identify responsibility if relevant

Investigations, be it by the hospital or COPFS, need to have a public facing focus to ensure that the public has confidence in the conclusion of the investigation process that has been undertaken. Families will need to have the outcome of the investigation into the death explained to them, including what any experts' opinions may have said, specifically addressing any issues worthy of exploring further.

Some investigations will stop there with hospital processes.

There has been a death which is tragic but there is need for further investigation once all hospital adverse outcomes reviews have been undertaken. There is still a need for those involved in such processes to be and to feel supported. Any recommendations made because of the hospital investigations should be put into force to avoid the problems recurring on another occasion. The outcome of such investigations requires to be communicated effectively to the relatives. That is supported by the duty of candour.

Regarding the duty of candour, the Scottish Government has set out the key principles which include provision of healthcare and medical services associated with risk as the unexpected can and will happen. The public want to be told honestly what happened, what will be done in response and to know how actions will be taken to stop this happening again to someone else in the future.

http://www.copfs.gov.uk/images/Documents/Deaths/The%20role%20of%20the%20Procurator%20Fiscal%20in%20the%20investigation%20of%20deaths%20-%20Information%20for%20bereaved%20relatives.pdf



Candour is one of various actions forming part of organisational focus and commitment to improved learning and improvement. Being candid promotes greater accountability for safer systems, engages staff in efforts made to improve healthcare and promotes greater trust in patients and those using medical services⁴⁹.

• How can they be learnt?

There is the role played by FAIs which we highlighted above. We do not suggest that FAIs are a cure-all. There does need in our view to be a greater understanding of the role of a FAI.

Families' concerns are inevitably motivated by them wanting answers as to why the death occurred. If the Lord Advocate decides not to hold a FAI, that decision may be very upsetting for the family⁵⁰. That upset can tend to be based on an unrealistic understanding and expectation of what a FAI is about and can achieve.

Sheriffs have made comments about the role of medical FAIs: The interests of a particular family in a death do not necessarily coincide with the public interest. There is a need to balance interests between the family and the medical staff. Medical professionals whose actions are under scrutiny need to continue working and caring for patients while a FAI is taking place. This subjects medical staff to "*the strain inevitably associated with the prospect of having to give evidence at a [FAI] and perhaps being made the subject of any public criticism at the end*"⁵¹

Things may go wrong. If such mistakes are made, the person, or persons, responsible may be sued in a civil litigation. The family has a right to know why their relative has died, to be informed of the conclusion of any investigations and provided with access to the medical records.

The independence of the COPFS' investigation in Scotland in this regard must be stressed.

Any concerns expressed by the family justifying the public interest in holding a FAI must be based on the relevant evidence and not conjecture. In considering the facts and circumstances of each case, possible allegations of medical negligence may well arise. Such actions for negligence lie in a different forum and do not justify a FAI. The public interest in FAIs is wider, aimed at systemic failures but, crucially, where changes were not made, other deaths might follow.

FAIs are not a general inquiry into procedures, irregularities, acts, or omissions of an organisation. FAIs are neither criminal nor civil proceedings (and are described as in a class of their own). They are inquisitorial in nature and not adversarial. Representation for parties including the family interested in a FAI

⁴⁹ http://www.gov.scot/Topics/Health/Policy/Duty-of-Candour

⁵⁰ Though it can be subject to judicial review- PETITION OF FRASER SUTHERLAND FRCS FOR JUDICIAL REVIEW [2017] CSOH 32

⁵¹ Inquiry into the circumstances of the death of Mrs Eileen Peterson. Paragraph 9. https://www.scotcourts.gov.uk/search-judgments/ judgment?id=da3d87a6-8980-69d2-b500-ff0000d74aa7 (accessed 24/11/16). 13 Inquiry into



is optional. Legal aid is not automatically available and is subject to the statutory test of reasonableness which considers:

• why the applicant needs separate legal representation at the inquiry, in addition to the role of the Crown

• any potential areas of dispute with the Crown in relation to the approach taken to the inquiry or the evidence to be led

• any areas of concern in relation to any other party involved in the inquiry that might result in the need for representation

• any areas of inquiry the applicant wants to pursue which will not be addressed by the Crown or should be pursued in a different way

• why these different areas of inquiry are appropriate and reasonable to be taken forward at the inquiry, having regard to the purpose of an inquiry

• any other factors that should be taken into account in assessing the need for representation⁵².

FAIs are a means of inquiry which provide a framework that allows for investigation, but it is worth observing now that where a sheriff does make a recommendation under section 28 of the 2016 Act the organisation has to give a response to the recommendation within a statutory timescale. Such responses require to be published in most circumstances. That provide a route to ensure that recommendations require to be publicly acknowledged. In the FAI into the death of Norma Haq the findings in fact highlight shortcomings such as:

"(101) There was no full and frank disclosure of the true cause of the duodenal perforation by Mr Hansell given to Mr Haq, the family, the GP and doctors treating her.^{*753}</sup></sup>*

Processes leading up to a criminal investigation

Question 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?

This question is best answered by the families and the hospital trusts.

Question 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

52 https://www.slab.org.uk/providers/handbooks/Civil/part4chp4#4.89

53 https://www.scotcourts.gov.uk/search-judgments/judgment?id=4c5386a6-8980-69d2-b500-ff0000d74aa7



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 can understand the definition of the 'human factors' in healthcare. Much of medicine is about teamwork which can make it difficult to identify an individual in any circumstances where the standard of medical care is such that the death gives rise to consideration of a charge of CH.

There will be factors to be considered such as the respective roles, tasks, equipment, workspace, culture and organisation that arise in a clinical setting when staff are working under pressure. Difficult decisions need to be made at times that can be very challenging. That will inevitably impact on the quality of care and may cause harm to the patient.

'Human Factors' assessments are used in other safety industries such as civil aviation and rail and focus on human performance. This provides a way to consider how to mitigate the effect of human decision-making. We understand that the NHS England has begun a process of using this approach:

"This means acknowledging that [h]uman [f]actors is not a separate agenda or programme, but a way of thinking that should be incorporated as part of the design of processes, jobs and training"⁵⁴

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

These questions are all best answered by the relevant hospital/trust/board.

⁵⁴ Human Factors in Healthcare A Concordat from the National Quality Board



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

This is a question best answered by the hospital trust or board.

We would merely stress the independence of COPFS when it is investigating such a case. The investigation process will review all reports that were obtained at the time of the local investigation. Those involved in the commission and writing of such reports if a FAI were to be instructed would be anticipated to be witnesses. They could then be subject to challenge as to their reports' conclusions in court.

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

This is a vital role as it is their evidence in many cases which will confirm or deny at the outset if there has been a mistake that has led to the fatality. With the advancing science that is medicine, there may well require to be more one expert report obtained. What is essential is the independence of that report. It needs to command the respect and trust of those within the medical profession and then strike a balance with those that may also see the report later such as the family. Their role, just as with any other case, is that of an expert witness so the following aspects can be stressed regarding their role:

- Expert witnesses will be doctors with sufficient experience in their speciality to provide a reliable and informed opinion about specific issues in a case. Only an expert can give opinion evidence. That differs from other witnesses such as the clinician treating a patient who provides factual evidence about what they did.
- The duty of the expert witness is:

"to furnish the judge or jury with the necessary scientific criteria for testing the accuracy of their own independent judgement by the application of these criteria to the facts proved in evidence..."

The expert witness must provide an entirely independent opinion on the case in question and would be expected to have the relevant training, skill and experience which would be set out in a CV in future for court purposes.

There are various registers of expert witnesses including by the Law Society of Scotland⁵⁶. The GMC provides guidance on acting as an expert witness⁵⁷. 'The GMC makes clear that doctors who act as an expert witness must ensure that the instructions they are given are clear and unambiguous and that they

⁵⁵ Davie v Magistrates of Edinburgh 1953 SLT 54

⁵⁶ https://www.lawscot.org.uk/members/business-support/expert-witness/

⁵⁷ Acting as a witness in legal proceedings (2013)



restrict any statements to areas where they have relevant knowledge or direct experience, and which fall within the limits of their professional competence. The expert witness is expected to include all relevant information and give a balanced opinion. However, if there is not enough information to reach a conclusion on a point, this should be made clear.

Question 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?

We refer to our answer to Question 22. There can be problems with the appropriate expert especially where the medical speciality itself may be very small in providing an expert report. That Report must be independent. In the FAI into Sharman Weir⁵⁸, to provide the necessary transparency, an expert witness was needed in the field of pre-eclampsia with relevant academic seniority, educated, trained and worked outside of Scotland. Concerns had been expressed by the family into the medical practice on delivering patients with pre-eclampsia.

Problems with experts have been seen in cases involving:

- Sir Roy Meadow where his statistical evidence on the incidence of cot deaths was found fundamentally flawed in the case of Sally Clark⁵⁹
- Declan Hainey's death where his mother Kimberley Hainey was acquitted on appeal of his murder⁶⁰.

The evidence in the case of Hainey rested on the expert evidence from two scientists and their examination of the child's bones with findings regarding Harris lines and cortical erosion. The expert evidence was criticised heavily alleging that the scientists did not have the requisite expertise on which such evidence could or should have been given:

"Any prosecution of such an alleged crime.....must require the most careful and sensitive consideration by those responsible for bringing the prosecution. If the case, as this one was, is to be based, to a material extent, on expert evidence, it is of the utmost importance that the experts chosen by the prosecutor to provide evidence supportive of the charge of murder should have the relevant qualifications, competence, expertise and experience to speak to the matters they are invited to give evidence about. The matters about which they are to be invited to give evidence about must themselves be clearly defined so that their competence to speak to them can be readily identified and confirmed.....It is true that in our system of criminal procedure there is no procedure set down for the judge to operate a gatekeeper's role whereby,

⁵⁸ https://www.scotcourts.gov.uk/search-judgments/judgment?id=13c286a6-8980-69d2-b500-ff0000d74aa7

⁵⁹ https://www.independent.co.uk/news/uk/crime/scientists-claim-on-cot-death-is-flawed-appeal-court-hears-81246.html

⁶⁰ Kimberley Mary Hainey v H M Advocate (2013) HJAC 47



during some procedure or hearing, prior to trial, he can determine whether or not a person who is to be invited to give evidence at the trial has the necessary expertise and qualifications to give that evidence. Putting matters colloquially it cannot be right for a trial judge to allow an obvious "quack" doctor to speak to a subject in a supposed expert way in relation to which he has no qualifications, and to allow his evidence to be placed before a jury with the simple direction that it is a matter for them to assess his competence".

Where expert evidence is crucial, there are analogies with experts in relation to the prosecution of doctors. In Dr Bawa-Garba's case, the expert assessed that her standard of care fell significantly below what was required. Prosecutions need to rely on the expert's medical assessment of what went wrong and their opinion as to the seriousness of such errors. As medicine advances so do medical procedures. Concerns with prosecutions of doctors for GNM/CH may well arise that they will be inhibited from such practices through fear of potential prosecution.

We are not aware of any specific questions about training on unconscious bias being asked. We would imagine in a case dealing with any of the 'protected characteristics' under the Equality Act 2010 that these aspects would be specifically considered. (We are aware of the challenges that were made on behalf of different ethnic groups regarding the Royal College of GPs examinations.⁶¹)

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

This is an issue that has been discussed between the solicitors and the Scottish Legal Aid Board (SLAB) who are responsible in Scotland for paying for expert reports in publicly funded cases. There are few controls (though there are challenge possible with SLAB) on what experts may seek to charge for providing and the quality of these reports as well as the timescale in which they are produced. Where reports deal with highly technical areas of medicine, it can be hard to judge the expertise of the expert providing the report.

We refer to our comments on Question 23.

Introduction of quality assurance procedures would be beneficial however it can be achieved.

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)



We refer to our answer to Question 15.

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?

This is a question best answered by the NHS, British Medical Association⁶² and the medical defence unions.

We refer to recommendation (f) in the FAI into the death of Sharman Weir (a death of a pre-eclampsia woman) which referred to:

(f)That there should be an opportunity for all junior staff to de-brief after a fatal outcome in relation to a patient in relation to whose care they have been involved.⁶³

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?

We refer to our comments above outlining the procedures adopted in Scotland for reporting of deaths to COPFS.

The reporting of deaths will on most occasions be undertaken directly by the hospital to the relevant SIFU office depending where the death has occurred. (Glasgow may well be the place of death as several hospitals provide highly specialist service for patients across Scotland though original care may have started elsewhere in Scotland.) The police will be instructed by the COPFS to report on the circumstances of the death. Remember that many deaths reported in the hospital context will proceed based on the death certification by that doctor. The actual cause of death will not be the actual issue as it will be the care or what led to the death which is relevant.

There are procedures for amending the death certificate after a FAI or on information received if required. Paragraph 42 of the Guidance for doctors completing medical certificates of the cause of death and its quality assurance advice from the Chief Medical Officer and National Records of Scotland (Guidance) refers⁶⁴.

⁶² https://www.bma.org.uk/advice/work-life-support/your-wellbeing/sources-of-support

⁶³ https://www.scotcourts.gov.uk/search-judgments/judgment?id=13c286a6-8980-69d2-b500-ff0000d74aa7

⁶⁴ http://www.sehd.scot.nhs.uk/cmo/CMO(2014)27.pdf published October 2014



As far as who is best placed to report the death, there is a useful diagram included in the Guidance at page 31. From the COPFS perspective, it is helpful if a doctor at senior or consultant level reports the death where there have been complications, unusual or unexpected circumstances as they are usually best placed to explain details of the death. Leaving this to junior doctors, except where the death may be routine, causes stress to junior doctors and may cause delay to COPFS as their ability to make decisions on instructing a post mortem or post mortems may be instructed unnecessarily.

Guidance to medical practitioners as to when to report a case to the procurator fiscal has been provided⁶⁵.

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?

Since there have been no relevant prosecutions in Scotland, we are unable to answer this question from the Scottish perspective. We are aware of comments that have been made regarding these issues in England and Wales.

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?

65

http://www.copfs.gov.uk/images/Documents/Publications/Reporting%20Deaths%20to%20the%20Procurator%20Fiscal/Reporting%20Deaths%20to%20the%20Procurator%20Fiscal/%20-%20Info%20for%20Medical%20Practitioners%2002FEB18.pdf



We refer to our earlier comments about the Society, our members and the role of COPFS. Our members as procurator fiscals and defence agents in Scotland are involved in all prosecutions of CH in Scotland. That would include, if relevant, any medical CH cases. Separately, our members work for the Medical Defence Unions, the private firms who specialise in representation of doctors at FAIs and in 'fitness to practise' tribunals and the NHS National Service Scotland⁶⁶ who specialise in public sector law, providing legal advice and representation including:

- clinical negligence
- information governance
- consent
- withdrawal of treatment
- interpretation of policy documentation and circulars.

Some of our members are academics involved in teaching and research in the related field of criminal and medical law. Within our committees we have representation from academia too.

From the legal perspective when learning from such cases, we depend on those involved advising about such issues. As we highlight, only a few medical deaths progress to a FAI where the practice is now for such determinations at the inquiry's conclusion to be published. This was not historically the practice when it was a matter for the individual sheriff to decide whether it should be published. Some FAIs such as the death of Norma Haq, took a considerable number of years before publication was achieved. Publication of FAIs is the responsibility of the Scottish Courts and Tribunal Service⁶⁷. Where determinations are published, these can be studied to ascertain the area of speciality of medicine and the findings especially where discretionary findings have been made under section 26 of the 2016 Act.

With criminal cases, the case decisions will only be published on appeal where there is a point of law that exists, and the judges have decided that the judgment should be published. As there have been no such medical CH cases in Scotland to date, this does not provide a source. We have referred earlier to the case of Katy McAlister⁶⁸where there was no appeal so that we cannot establish exactly why the charge of CH failed.

We do note that the majority of FAIs will be covered by the press. An example of an unpublished FAI relates to Stephen Miller.⁶⁹ This was the death of an asthmatic 16-year-old teenager where the sheriff stated that:

"the public will be surprised to learn that the all-important burden of recognition rested upon the least qualified least experienced and- after a 56-hour shift- the most exhausted member of staff"

⁶⁶ https://nhsnss.org/services/legal/litigation/

⁶⁷ https://www.scotcourts.gov.uk/search-judgments/fatal-accident-inquiries

⁶⁸ https://www.bbc.co.uk/news/uk-scotland-tayside-central-40057847

⁶⁹ http://www.heraldscotland.com/news/11905612.Sheriff_makes_scathing_attack_on_hospital_where_asthmatic_teenager_died/



As such criticisms go the heart of public concerns, ensuring all FAI determinations are published seems appropriate if that is not already being achieved.

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?

We refer to our answers above.

We have stressed that the procurator fiscal's investigation of a death is independent. It does not rely solely on material gathered because of the initial review of the hospital by the NHS. Where the procurator fiscal investigates a death, typically the police will be instructed to take statements from all material witnesses and to seize documents and items that are relevant to the investigation. Whilst evidence gathered by the NHS will form part of the investigation by the procurator fiscal, that forms part of the information considered in deciding about the case as opposed to evidence from the hospital/trust/board or other healthcare setting providing the sole information.

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

We refer to our answers above.

Where a patient dies during an operation or there is a suggestion that the standard of care provided to a patient is inadequate, expert witnesses will be instructed to provide an opinion in the case. The expert witness's role depends upon the facts of a given case and will be very important. Given that there requires to be an assessment of the standard of care, expert evidence will be required to consider that. Often the expert will give reassurance that the standard of care given to the patient was reasonable and appropriate. The procurator fiscal's investigation can then be competed without any FAI. However, expert evidence is never determinative and can be rejected. It is important to stress the decision making which is required in undertaking a FAI.

For instance, the FAI into the death of Sharman Weir⁷⁰ included six experts in the field of pre-eclampsia all instructed by different interests in the inquiry.

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?

We refer to our earlier answers.

In selecting an expert witness, it must be considered firstly whether as a matter of law expert evidence is permissible in a case and secondly whether the expert is suitably qualified to give an opinion according to the law. The first stage in selecting an expert witness is to establish that an expert is in fact required. It is not possible to say definitively what constitutes legitimate subject matter for expert opinion.

The subject matter must be necessary for the proper resolution of the dispute and be such that a judge or jury (and in the first instance the procurator fiscal) without instruction or advice in the particular area of knowledge or experience would be unable to reach a sound conclusion without the help of a witness who had such specialised knowledge or experience. The subject matter must be part of a recognised body of science or experience which is suitably acknowledged as being useful and reliable, properly capable of reaching and justifying the opinions offered, and the witness must demonstrate a sufficiently authoritative understanding of the theory and practice of the subject. It is essential that a court could be satisfied that the witness is an expert.

Thereafter, in consultation with expert witnesses, the matter of their accreditation must be covered carefully and fully. This elicits from the witness their qualifications and experience which confirms the status and experience of the chosen expert - or otherwise. Once the evidence achieves the status of 'expert', it can carry a weight over and above that of ordinary evidence. The expert is there to give opinions. This clearly puts them in a very different position from the ordinary witness.

The legal rules as to who can be an expert were most recently considered authoratively (in a criminal context) in the Scottish case of *Young*⁷¹ where the court said,

"Evidence about relevant matters which are not within the knowledge of everyday life reasonably to be imputed to a jury or other finder of fact may be admissible if it is likely to assist the jury or finder of fact in the proper determination of the issue before it. The expert evidence must be relevant to that issue (and so not concerned solely with collateral issues), and it must be based on a recognised and developed academic discipline. It must proceed on theories which have been tested (both by academic review and in practice) and found to have a practical and measurable consequence in real life. It must follow a developed methodology which is explicable and open to possible challenge, and it must produce a result which is capable of being assessed and given more or less weight in light of all the evidence before the finder of fact. If the evidence does not meet these criteria, it will not assist the finder of fact in the proper determination of the issue; rather, it will risk confusing or distracting the finder of fact, or, worse still, cause the finder of fact to determine the crucial issue on the basis of unreliable or erroneous evidence. For this reason, the court will not admit evidence from a "man of skill" or an "expert" unless satisfied that the



evidence is sufficiently reliable that it will assist the finder of fact in the proper determination of the issue before it."

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?

We refer to our earlier answer. The standard is the same.

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.

We refer to our answer to Question 24 above.

Police investigations and decisions to prosecute

Question 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?

We refer to our answer to Question 31. The determination of what evidence is relevant is made on a case by case depending on the facts and circumstances.

Question 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?

It is not clear if the reference here to 'charging' is a reference to the English criminal procedural concept of charging by the police. Any case reported to COPFS by the police may well refer to caution and charge for



an offence such as CH. No matter what offence a person may be charged with, the police cannot bind the prosecutor (COPFS) as to taking proceedings or to what charge is appropriate.

There is a reference to 'prosecuting authorities' which of course in relation to deaths in Scotland can only mean COPFS. In England, we understand that prosecutions may be undertaken by different prosecutors such as health and safety.

The Lord Advocate has published a COPFS Prosecution Code⁷² (Code) outlining the test for criminal proceedings instructed in Scotland. This guidance to prosecutors, which is not offence specific, sets the factors which favour, or militate against, prosecution. There is a two-stage test:

- the evidential stage which concerns the legal sufficiency of the evidence according to Scottish evidential rules
- public interest stage (which is echoed too when considering if to instruct a FAI in the public interest). This addresses whether, even if there is a sufficiency, it is in the public interest to prosecute. This involves the exercise of the Lord Advocate's discretion.

On the assumption that the report discloses sufficient admissible, reliable and credible evidence of a crime having been committed by the accused, the public interest often includes consideration of competing interests, including the interests of victims, the accused and the wider community. The factors requiring to be considered in assessing the public interest vary according to the circumstances of each case. Page 06 of the Code lists thirteen factors to consider when considering the public interest. These include:

- (i) The nature and gravity of the offence
- (ii) The impact of the offence on the victim and other witnesses
- (iii) The age, background and personal circumstances of the accused
- (iv) The age and personal circumstances of the victim and other witnesses
- (v) The attitude of the victim
- (vi) The motive for the crime
- (vii) The age of the offence
- (viii) Mitigating circumstances
- (ix) The effect of prosecution on the accused
- (x) The risk of further offending



- (xi) The availability of a more appropriate civil remedy
- (xii) Powers of the court
- (xiii) Public concern

Not all factors apply in every case and the weight to be attached to any factor depends on the circumstances of each case. The assessment of the public interest involves a careful consideration of all the factors relevant to a particular case. These factors are not exclusive.

Criminal proceedings may be taken in Scotland if it can be assessed that there is sufficient credible and reliable evidence that a crime has been committed, it was committed by the accused and it is in the public interest to take proceedings. There must be sufficient corroborated evidence.

If there is sufficient evidence consideration will be given as to whether it is in the public interest to take proceedings.

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

There are no systemic barriers of which we are aware.

Question 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)?

In COPFS, these cases are dealt with by specialists and therefore sufficient expertise exists to undertake appropriate investigations. These can be supported if required by Crown Counsel who is responsible for instructing whether cases are to proceed on indictment.

All have a wide range of experience of cases prosecuted for CH including any reports in medical related cases. There is no specific detailed prosecutorial guidance in Scotland. Such cases are unusual and therefore very detailed guidance is unlikely to be helpful given the breadth of scenarios that may arise (in contrast to 'assisted suicide').



Whilst, due to differences in the law in England and Wales detailed prosecutorial guidance regarding what is in the public interest is often promulgated by the Director of Public Prosecution, this is not the case in Scotland. The Lord Advocate makes decisions as to what amounts to public interest⁷³.

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

This is difficult to answer. It depends on the evidence in each case. We note that there has only been one CH prosecution in Scotland to date which failed. The circumstances of that case rather differ from the GNM cases.

Question 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?

It is not clear if the regulatory system referred to means the GMC. If so, it may be observed as a generality, that whilst the regulatory system has a role investigating the competence and fitness to practice of doctors which is important and in the public interest, it is there to complement, rather than supplant the public interest in the State in ensuring an independent and impartial investigation into deaths in furtherance of Article 2 of ECHR as highlighted above.

There is no evidence to suggest that the current balance in Scotland is wrong.

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

Question 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?

Question 44: Do the same standards and processes for experts apply with regards

⁷³ Bearing in mind in decisions as to FAIs, there can be recourse to judicial review of his decision.



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?

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

We refer to our answers to Questions 33-35 inclusive. There is a role for quality assurance as the evidence will be available and presented in court as part of the proceedings most likely from the Crown in establishing their case.

Question 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 question tends to infer that there is at least something to be preferred or at least different about the Scottish system. We assume that this relates to the absence of substantial numbers of prosecutions for medical CH cases in Scotland but is not explained further. We do not understand this to suggest any criticism of the Scottish procedures or processes.

We would suggest that the wider context of investigation into deaths in Scotland needs to be factored in so that inevitably includes discussing COPFS's role both in relation to prosecution as well as FAIs.

There does seem to be a perceived vulnerability of doctors to face prosecution in England and Wales especially when considering the NHS with its alleged under-resourcing as well as systemic failures such as in Dr Bawa- Garba's case. This does not seem to be the same case in Scotland though Scotland wants to ensure that there is also a suitable promotion⁷⁴ of a learning, no-blame culture involving reflective practice (the role of which we discuss below) and provision of support for doctors undergoing investigations when fatalities occur.

What may be relevant is to discuss are what factors which may be relevant to consider in relation to Scotland's processes:

Prosecution:

As we have highlighted homicide is a matter under review by the Scottish Law Commission as part of its reform programme. (We would note for reference that there was a proposal for a Bill⁷⁵ to redefine the

⁷⁴ Reviewing criminal responsibility of doctors 2018 Crim. L.B.1

 $^{^{75}\} http://www.parliament.scot/parliamentarybusiness/Bills/84553.aspx$



offence of culpable homicide in terms of causing death by recklessness or gross negligence, and to define the circumstances in which office-holders in organisations (including certain public bodies) can be guilty of the offence. This did not proceed further. This is not relevant to an individual doctor's circumstances but could have been relevant to the hospital trust. In any event we would assume that the scope of that Bill will be covered under the Scottish Law Commission's review.) The Scottish Law Commission is the best place for the law relating to CH to be fully considered and if necessary, clarified in the wider homicide context. The prosecution of Katy McAlister failed for reasons that are not clear, but the circumstances of her case do rather differ from that of Dr Bawa-Garba.

There is no suggestion that medical CH cases are not appropriately reported or investigated by the police or COPFS. Indeed, recent press coverage has referred to a recent MPTS hearing in relation to Dr Laxman who was cleared of any serious misconduct for the death of an unborn baby delivered by way of an emergency caesarean operation. She was not prosecuted nor was the case the subject of a FAI. The decision to deliver vaginally was clinically justified. With the benefit of hindsight that was the wrong decision but that does not justify criminal prosecution or indeed a FAI as there was neither systemic failure nor suggestion that hospital or other processes needed to be improved.

"The tribunal was satisfied that throughout the attempted delivery of baby B, Dr Vilvanathan Laxman believed that she was acting in both patient A's and baby B's best interests, and that she genuinely believed that proceeding with a vaginal delivery was the optimum course to take in the circumstances which existed at the time.⁷⁶"

Scottish processes and procedures:

Approach: The way in which medical deaths are reported to the procurator fiscal means that the procurator fiscal is responsible for investigating all deaths including those that may give rise to potential CH proceedings. To a large extent the process of investigation at the earlier stage is substantially similar. The results of these inquiries will then determine what route the case will take if at all. That may allow an early broad-based approach where nothing is ruled out. For instance, if there is insufficient evidence for any criminal prosecution, the death may still be instructed as a FAI but this would not be inevitable.

The circumstances in which a FAI can be instructed: Discretion as to what is in the public interest lies with the Lord Advocate in criminal cases as well as FAIs. 'Significant public concern' in relation to FAIs is undefined. Exactly what sudden, unexplained, or suspicious death would not merit the instruction of a public inquiry by the Lord Advocate may be hard to identify since every such death to those involved such as relatives will be distressful and of concern. Clearly, a public inquiry cannot be held into every death for expediency reasons alone as the courts would grind slowly to a halt.



The purpose of the FAI: This is strictly defined and is held in front of a judge and not a jury. That differs from the inquest system. That may also allow for a full examination of the circumstances which is in everyone's interests.

Scottish criminal evidential factors: This relates to the requirement for corroboration in Scots criminal law which may affect consideration as to when there is sufficient evidence to allow criminal cases to proceed.

There is also a need to highlight the difference between Scotland and England and Wales in relation to police interviews. In Scotland, the caution means that there tend rarely to be any circumstances where a doctor accused of CH would be advised to provide an explanation as to their conduct. In England and Wales with the adverse inference then it may well be in the doctor's best interests to provide an explanation or that may harm their defence.

FAIs:

We consider that there is merit in considering carefully if a FAI is the best place to consider medical type cases. Where there are systemic failures, a FAI seems appropriate but not if the case relates to a mistake by one doctor and there is satisfaction that all hospital internal/external processes have been carried out. FAIs "are armed with the benefit of hindsight, the evidence led at the Inquiry and the Determination of the Inquiry [that] may be persuaded to take steps to prevent any recurrence of such a death in the future."⁷⁷

That context is important when we recognise that it is difficult to be prescriptive about the nature of deaths that justify the holding of a FAI and the Lord Advocate of course has the requisite discretion. That reflects that the FAI legislation is deliberately broad brushed. A recent judicial review into a determination in the FAI into Robert Baird's death⁷⁸ highlights the problems when the FAI seems to relate to one doctor's care which was then criticised⁷⁹.

There could be consideration as to a call for the issue of guidance on the factors to consider when considering the holding of a FAI into a medical death. That could identify any 'additional criteria [required] before the balance is tipped into instructing an inquiry⁸⁰. Better awareness for all concerned in the process/procedure of FAIs could engender and promote their more efficient use.

Question 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?

⁷⁷ https://www.scotcourts.gov.uk/search-judgments/judgment?id=13c286a6-8980-69d2-b500-ff0000d74aa7

^{78 [2016]} FAI 4

⁷⁹ Sutherland v Lord Advocate 2017 S.L.T. 333

⁸⁰ Judicial review and the death of Robert Baird 2017 S.L.T. 159



Solicitors are involved in advising and representing doctors at the GMC fitness to practise processes. We understand that doctors will tend to be members of the one of the medical defence unions such as the Medical Dental Defence Union of Scotland⁸¹ which offers access to expert medico-legal and professional indemnity for doctors across the UK.

As recognised in the FAI into the death of Norma Haq, there is an inevitable overlap in the evidence which will be heard in any criminal case and/or FAI and/or any future disciplinary proceedings:

The separate roles of the various organisations should be respected. The findings of guilt or otherwise in criminal proceedings or findings in any determination are quite separate, cannot and should not be relied on to any disciplinary proceedings which fall to be taken or indeed, considered in line with the GMC regulatory procedures.

The Scottish system allows for a wide independent process for full investigation to take place. That is before any decision as to any proceedings, criminal or otherwise takes place. With the safeguard of judicial review, this approach works.

Question 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?

We have no comment. The GMC as the medical regulator set out the standards and procedures for the profession.

Question 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?

The role of reflection is important in relation to lessons learnt and the training of doctors and features prominently in relation to assessment procedures. This includes the Annual Review of Competence Progression (ARCP) which trainee doctors undertake each year to progress. Since reflection is fundamental and intrinsic to the medical training process, the ability to reflect honestly must be preserved. Otherwise doctors cannot be encouraged to be honest in their reflection. Honesty is what families



interviewed in connection with the FAIs want- which is for this not to happen again or for the death not to be in vain as processes will have been reviewed and steps taken to avoid such outcomes in the future.

How to preserve that balance is more problematic.

There will be different opportunities or times for the doctor to reflect. There will be the individual process within the doctor's own e-portfolio and as part of a medical team reviewing the case such as adverse outcomes. The doctor's own e-portfolio should be personal to the doctor accessible only to clinical and educational supervisors and to a panel at the ARCP. The notes of the medical team's review would be wider where we can envisage that these may well be referred to at a FAI to show that changes in practice have been made in response to any death.

There is difficulty in Dr Baba-Garba's case in understanding exactly what role was played by her reflection on the case since much of the criminal process is not fully reported. The fact that there was material contained within the e-portfolio seems not to be in dispute. The e-portfolio should not be able to be used in a criminal case, but it seems to have been used in the expert's opinion, for instance, in assessing factors such as what went wrong, the standards of care displayed by the doctor and any appreciation of risk.

What this case highlights is the need for the role of the e-portfolio with any personal reflection to be clear. That should be put in guidance for the profession. If the true reflection is being encouraged and supported, as part of training, then it must not be available for other purposes such as criminal prosecution.

It may be appropriate to remember in criminal processes that the accused has the right to remain silent which is also reflected in the ECHR Article 6. If the position of reflection is not made clear and the timing of any reflection is important, any doctor would be well advised not to reflect until a decision is taken that there are to be no criminal proceedings.

Question 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?

We refer to our answer to Question 47. We are aware that there is professional support available through the BMA and the medical defence unions.

We refer to our answer to Question 26 in relation to the absence of support for junior staff in the Sharman Weir⁸² FAI.



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

When a death occurs, lessons where possible should be learnt. Extending the criminal law to take an increased role in regulating healthcare may not be the best means to share learning from a fatal incident. We would endorse the view that "the adversarial nature of the criminal trial does not lend itself to the task of identifying what lessons can be learnt from a tragic and unexpected medical death."⁸³ Any death as required by Article 2 of the ECHR should be fully investigated. That holds good no matter the process whether in Scotland or otherwise.

We have set out the roles of the various organisations throughout our responses which include COPFS and the GMC. They do not overlap in their respective remits. The regulator should tend only have a role when the other processes have been concluded whether in relation to COPFS in decisions as to prosecution or the holding of a public inquiry. The problem if the regulator acts earlier is that the other decisions such as criminal prosecution (highly likely) or a FAI (less likely) could be prejudiced. In practice the regulator tends to wait though of course interim suspension of a practising certificate could take place pending a full hearing.

We have identified the regulatory role already which is in relation to regulation of conduct of the medical profession. That does not and should not trespass on the jurisdiction of the prosecution service or the Lord Advocate in relation to the holding or remit of any public inquiry.

- If the death results from criminal conduct subject to the relevant rules of evidence, prosecution can be affected if and only if it is justified in the public interest.
- If the death raises issues of public concern, then a FAI can be held.
- If neither of these apply, it is open to the GMC to conduct proceedings.

What does seem important is to ensure that these processes once concluded all feed into a mechanism for improving medical training or hospital procedures where relevant. That indeed is part of the purpose in the determinations issued by sheriffs and the process for recording them under the 2016 Act.

What is also clear is that the public must be able to find out what has happened so transparency of process is also crucial. That may be a further factor for the Review to consider. To be judged by the media is not the best place for any of the parties who may be involved. There are suggestions indeed that any apparent increase in GNM prosecutions has come about from '*media content* [*which*] *is of course highly selective driven by consumer, social, political and economic interest.*⁸⁴ Ensuring public understanding seems to be a benefit of the public scrutiny being undertaken as part of the Review.

⁸³ Brazier, Devaney, Griffiths, Mullock and Quirk 'Improving healthcare using 'medial manslaughter'? Facts, fears and the future https://doi.org/10.1177/1356262217696623



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

It is important to stress that we are dealing with very difficult issues. No matter what the law is, we must not forget that every death is tragic for the relatives to whom all sympathy must be and should be expressed. By seeking to remember that, the need to ensure that all *lessons are learnt* from a death is not diminished.

We trust these responses are helpful for your purposes and would be happy to provide any further information hat may be required.



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