RCOG Submission GMC Dame Clare Marx Review

Introduction

The issues raised in relation to the recent Bawa-Garba case have led to a significant response from RCOG members, particularly its trainees. The RCOG welcomes this opportunity to share its views with the review group and hopes that this review will help to address some of the uncertainties that clinicians are currently experiencing. It is not the RCOG's position to comment on either the specific facts of the case or the judgement that was reached by the high court.

The RCOG notes the overwhelming response to the case, both from the clinical community and from the media. The complexity of the issues in the Bawa-Garba case has fuelled the misinformation and anxiety in the profession. As a medical royal college, the RCOG feels that it is important to support its members with clear information and signpost them to guidance on the issues that have been raised in relation to this case.

Since the judgement the RCOG has been actively engaging with its members, particularly its trainees, to explore the issues and to support clinicians to regain the confidence with reflective practice and the regulator, which some have expressed has been lost. The RCOG is aware that social media has been a primary source of information for many, again particularly trainees. In response the President of the RCOG has met specifically with the RCOG Trainees' Committee on this matter, to direct and encourage them to access the publicly available information and guidance. The RCOG is providing regular updates in response to the developing external landscape on the issues that have been raised and it has communicated the scope of this review with its members, highlighting the opportunity for individuals to comment.

The RCOG is committed to sustaining a high level of engagement with its members and will support a continued dialogue during the review and once the findings and recommendations are published and implemented.

This response was developed with RCOG members, drawing on evidence from the RCOG Supporting Our Doctors Task Group, its Trainees' Committee, and its Patient Safety Committee, and from anecdotal feedback. The RCOG also asked its patient involvement panel, the Women's Network, for their views and experiences. The RCOG has also submitted the following supporting documentation to the review email address as examples of best practice from O&G:

- *Supporting Our Doctors Task Group remit and terms of reference*
- *Human factors training video, RCOG Each Baby Counts programme*
- *Bullying and undermining toolkit*

The RCOG wishes to highlight that obstetrics is a particularly high-risk specialty and it is highly likely that most obstetricians will be involved in the care of women and babies with adverse outcomes at some point in their careers. Clinicians, therefore, need to be clear about the purpose and impact of all investigation processes and how and where Gross Negligence Manslaughter and culpable homicide are considered in relation to medical error. Equally clinicians need to be provided with clear guidance on what is expected of them and of the organisations that they work for when a process has been started for a suspected GNM charge. Obstetrics is also a high-litigation specialty and there are several

investigation processes and routes already in place for addressing medical error in maternity care. It is critical that employers and individual clinicians working in obstetrics are clear about the circumstances and, importantly, the process in which a serious incident may be escalated into a charge of GNM.

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

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

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

This section focuses on the experience of patients and their families

11. Do the processes for local investigation give patients the explanations they need where there has been a serious clinical incident resulting in a patient's death? If not, how might things be improved?

The RCOG understands patients and their families experience huge variation in local investigations following serious clinical incidents. In the worst cases, the RCOG has anecdotally heard that families have been unaware of an investigation's aims, its outcomes and recommendations, and even sometimes the investigation itself. Due to this large variation, patients and their families are often sceptical about the effectiveness of reviews, and can perceive them as biased and not independent.

The RCOG's Women's Network has highlighted that the best examples of processes for local investigation involve relatives at all levels, actively engage and are honest and transparent throughout the process. The RCOG fully supports the need for patient involvement in local investigations and calls for all investigations of stillbirth to ensure that patients are offered the opportunity to contribute to a serious investigation. The MBRRACE National Standardised Perinatal Mortality Review Tool is a good example, setting out what a good quality hospital review should look like following the death of a baby. Designed around the principles of high quality parent involvement throughout, the tool asks local investigations to acknowledge any specific questions from patients and families which should then be clearly incorporated into any future investigation tools and processes. The RCOG encourages the review panel to assess the tool as a best practice example of how patients and families can be involved throughout the process to increase trust and transparency, as well as the strength of the review itself.

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

Feedback the RCOG has received on the Duty of Candour shows that it is well known and understood as a formal way of speaking to families after a serious incident has occurred. However, Duty of Candour alone is not a sufficient driver for the involvement of families in an investigation to understand what went wrong.

In order to fully engage patients and their families during an investigation, departments and clinical staff need to be properly resourced and receive training into how to facilitate an open and

transparent conversation. This will enable clinicians to approach issues of clinical error with more confidence and skill and ensure that they understand the value to their working practice.

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

The RCOG believes there are some instances were mediation would be welcome and appropriate following a serious clinical incident, and that this could be developed as a skillset within trusts and health boards. However, it will sometimes be important that clinicians and families have space away from the hospital to discuss incidents, and there may also be occasions where there has been a breakdown of communication between a family and a trust or health board. In these situations external mediation would be welcome, especially if it can reassure families of the robustness of a local investigation and prevent it escalating into a criminal or regulatory investigation where it otherwise might not have been.

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

Trust Patient Safety Teams and non-involved senior clinicians are often allocated to support families during any investigation and communicate with them about the outcome of the investigation. Whilst these relationships are crucial to maintaining openness and trust between the hospital and families, the RCOG Women's Network has expressed that they would like to see families supported further with signposting to other services that can support them, for instance counselling services and relevant charities. Trusts and health boards should work together with charities to be able to coordinate and signpost patients to appropriate, high quality support.

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

Establishing the difference between error and criminal negligence is important. The Bawa-Garba case at its heart has highlighted the lack of knowledge and confidence on the issue of medical error and has exposed the significant lack of understanding about where the line between medical error and criminal error is drawn.

A learning culture must consider the wider factors which affect the outcomes in a case, and thorough review of those factors is critical to driving improvements in care.

The RCOG understands that outcomes from serious investigations are not always communicated fully with teams. Junior doctors often struggle to attend Morbidity and Mortality meetings due to pressures within the trust and shift patterns, and this leaves the potential for them to miss important lessons. Safety reports and newsletters can be helpful, but these need to be shared through a wide variety of media to ensure that all clinicians can access them.

Lessons learned need to be communicated with teams regularly and without blame, through better management processes and better team development. Various methods need to be employed to ensure that clinicians have the time and space to understand and respond to lessons. Reinforcing and sustaining lessons relies on clear recommendations and action plans to achieve those

recommendations from local investigations. Ensuring staff involvement in open investigations is also crucial as this allows people to reach their own conclusions which leads to more effective life-long learning.

This section focuses on processes leading up to a criminal investigation

16. Do you think that the current arrangements for reporting and investigating serious clinical incidents within healthcare settings are effective and fair? If not, what is wrong and how might they be improved?

The RCOG is concerned about the lack of consistency in the processes for reporting and investigation of serious clinical incidents at a local level. This lack of consistency also results in doctors being unclear about the processes for investigation, and when an investigation might escalate further.

The role that leaders play is critical in ensuring a positive workplace culture. The RCOG has found huge variability in the ways in which local leaders (for example Clinical Directors and Medical Directors) manage complaints. The RCOG recommends that more work is done to standardise the quality of support and response to issues arising from complaints. Clinical Directors are not provided with any formal support and may not be experienced in managing complaints. Standardised training on dispute resolution would help with variation in managing complaints and conducting investigations.

The RCOG believes more work should be done "upstream" to prevent complaints escalating. With proper training and standardisation across trusts and health boards, a large number of complaints could be managed more effectively at a local level with appropriate support for professionals. The RCOG's Supporting our Doctors Task Group is specifically working with the GMC to raise awareness of the support available to clinicians who are being investigated by the GMC as the result of a complaint (GMC Fitness to Practise Complaints - top tips for doctors), and the RCOG is particularly concerned about the impact an investigation can have on an individual going through this process.

The RCOG also has concerns about the grounds under which a trust may initiate an investigation for Gross Negligence Manslaughter. Greater clarity is required about the role of the Serious Incident (SI) process, in light of the updated standards and the proposed bespoke SI framework for maternity care. It is important that those processes are informed by this findings from this review.

Both patients and doctors have made it clear to us during our engagement with them on this issue that investigations of serious clinical incidents are often perceived as using individuals as scapegoats, and assume that attributing blame on an individual will fix the problem. However, both patients and doctors desire a more exploratory approach from reporting and investigations that consider the contribution of wider system factors.

17. Would there be benefits in ensuring a human factors assessment approach is used in local investigations as opposed to a root cause analysis? 'Human factors' refer to the environmental, organisational and job factors, and human and individual characteristics which influence behaviour at work in a way which can affect health and safety. A 'root cause' analysis is a systematic process for identifying 'root causes' of problems or events and an approach for responding to them.

The RCOG's Each Baby Counts programme is a national quality improvement programme to reduce the number of babies who die, or are left with severe disability, as a result of incidents occurring during term labour. The programme investigates both the quality of SI reports and the factors affecting care for all intrapartum stillbirths, neonatal deaths and brain injuries. It aims to drive up the quality of SI reports and is a good example of how doctors can be supported to learn from mistakes and be open when things go wrong.

Establishing the difference between error and criminal negligence is important, particularly where a case is focusing on a single event rather than being considered as part of a complex system of related factors. The Each Baby Counts programme found that an average of six contributory factors could be attributed to the outcome of care in each case of stillbirth, neonatal death and brain injuries. This demonstrates the complex association between individual, system and organisational factors and the importance of assessing all factors within an investigation, including human factors.

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?

As well as variation in the process and standards of local investigations, the RCOG understands from its membership that there is variation in who is involved in conducting the investigation and their training. These range from senior staff such as clinical directors and medical directors, to clinicians within the departments in which the incident happened, and in-house patient safety teams. Training is reported as often being only half a day, with no top-up training. The RCOG would like to see greater value placed on training, where employers view it as an investment to improve skills and culture. This would include better resourcing of training but also employers being much more willing to release staff to participate.

19. How is the competence and skill of those conducting the investigations assessed and assured?

Often, those involved in investigations at a hospital, trust and board level have little and limited training that would assure their competence. The RCOG believes that standardised training on dispute resolution at a local level would help address the variation among investigations and would also increase the publics, and doctors', trust in the process.

20. In your hospital/trust/board or other healthcare setting, is there a standard process/protocol for conducting investigations following a serious clinical incident leading to a fatality? If so, please email a copy to ClareMarxReview@gmc-uk.org

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

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

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

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

The variable quality of medical experts has been problematic for a long time.

The RCOG feels it is important that any "accredited" Medical Expert is supported by processes and resources to ensure that the role is appealing and that clinicians are motivated to provide this service. The RCOG has previously offered Expert Witness training courses to members in order to ensure they had the right skills, this included training in expert report writing and court room skills.

Following the Sir Norman Williams Review, the RCOG fully supports the work the Academy of Medical Royal Colleges is taking forward to promote and deliver high standards and training for healthcare professionals providing an expert opinion or appearing as expert witnesses.

25. How can we make sure that lessons are learned from investigations following serious clinical incidents? (please respond here if you haven't already responded to this question in the patients and families section)

26. What support is provided for doctors following a serious clinical incident that has resulted in the death of a patient (including emotional, educational, legal, professional support)? Could this be improved? If so, how?

The RCOG recognises the adverse impact and personal cost of investigations on individuals and welcomes initiatives which seek to keep professionals in work where appropriate, such as offering alternative clinics or teaching opportunities to reduce the risk of absolute exclusion. Evidence has shown the highly detrimental impact that arrangements for removing clinicians from the workplace can have on mental wellbeing in the longer term.

The RCOG believes there is support available for doctors but that more needs to be done in order to promote this. For instance the GMC's Health Systems Liaison Service and Employer Liaison Service are positive examples of how this support can work locally, but many doctors and employers are unaware of it.

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?

28. What evidence is there that some groups of doctors (by virtue of a protected characteristic) are more or less likely to be subject to investigations leading to charges of GNM/CH than other

groups? What are the factors that may be driving a greater likelihood for certain cohorts of doctors to be subject to investigations leading to charges of GNM/CH?

29. Do you think there are barriers or impediments for some groups of doctors to report serious incidents and raise concerns? More specifically are there additional barriers for BME (black, minority and ethnic) doctors? If so, which groups are affected by this and how can those barriers be removed?

This section focuses on inquiries by a coroner or procurator fiscal

30. What is your knowledge or experience of cases involving clinical fatalities that have been referred to the police or procurator fiscal? What can we learn from the way those cases have been dealt with?

31. To what extent does an inquest or fatal accident inquiry process draw on or rely on the evidence gathered in the post incident investigation by the hospital/trust/board or other healthcare setting?

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

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

34. Do the same standards and processes for experts apply regardless of whether they are providing their opinion for a local investigation, an inquest or fatal accident inquiry process? If not, why not? For example, is there a higher level or different type of expertise or skill set required?

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

This section focuses on police investigations and decisions to prosecute

36. To what extent does the criminal investigation and/or prosecution process draw on or rely on the evidence gathered in the post incident investigation by the hospital/trust/board or other healthcare setting?

37. What is the charging standard applied by prosecuting authorities in cases of GNM/CH against medical practitioners? How does the charging standard weigh the competing public interest in improving patient safety?

The anxiety within the medical profession created by the Bawa-Garba case has emphasised that clinicians are uncertain about the charging standard applied by prosecuting authorities, and how and when a charge might be brought against them. Greater clarity and reassurance is required to support doctors to understand when and how the criminal law applies to medicine when a patient dies, including processes for initiating a prosecution.

Clinicians need to be clear about the purpose and impact of all investigation processes and how and where gross negligence manslaughter and culpable homicide fits in. Equally clinicians need to be provided with clear guidance on what is expected of them and of the organisations that they work for when a process has been started for a suspected gross negligence manslaughter or culpable homicide charge.

The RCOG would welcome the publication of resources from the GMC to enable doctors and the public to better understand the various routes of investigations (whether they are coronial, SI, criminal or charges of gross negligence manslaughter and culpable homicide) following serious clinical incidents, for example through a process map.

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

39. Do the key decision makers (the police senior investigating officers (SIOs), and/or prosecuting authorities) have the necessary support to enable them to make fully informed decisions on whether or not to charge a doctor of GNM/CH? Is there a need for detailed prosecutorial guidance for this offence (similar to that for assisted suicide)?

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

The RCOG is concerned that the complexities and realities of healthcare (as demonstrated by the Each Baby Counts findings), when coupled with a lack of a clear definition regarding the *severity or extent* of negligence for gross negligence manslaughter and culpable homicide, leaves clinicians with inadequate support and guidance on this important issue. This has resulted in a lack of confidence in the regulator which affects the morale and welfare of the workforce. This could likely lead to doctors becoming more risk-averse in their practice, which would be to the detriment of patient safety.

The process and threshold for referral, investigation and decision to charge is heavily inconsistent, and focus should be on tackling this issue. The RCOG supports the need for greater consistency in the process that is taken before a charge of gross negligence manslaughter or culpable homicide is made. Little evidence exists to demonstrate how a charge of gross negligence manslaughter and culpable homicide is bought or the circumstances in which a referral for these charges is to be made (coronial referral, CPS route, police route, trust reporting routes). The lack of clear guidance on the criteria that must be met for a case to be escalated and investigated as a charge of gross negligence manslaughter is something that needs to be addressed urgently.

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?

Give how much work is being undertaken by the GMC and CQC in supporting staff in relation to patient safety, it is vitally important that work such as NHS Improvement's "a just culture guide" are better joined up and promoted. In light of the Sir Norman Williams Review, it is understood that this tool will be reviewed. The RCOG would urge that this is updated with any changes made to regulators and that there is consistency with all arm's-lengths bodies, trusts and health boards about the correct processes following clinical incidents.

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

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

44. Do the same standards and processes for experts apply with regards to evidence provided for the police or prosecuting authorities as they do for a local investigation, an inquest or fatal accident inquiry process? If not, why not? For example, is there a higher level or different type of expertise or skill set required?

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

46. What lessons can we take from the system in Scotland (where law on 'culpable homicide' applies) about how fatal clinical incidents should be dealt with?

This section focuses on the professional regulatory process

47. What is your experience of the GMC's fitness to practise processes in cases where a doctor has been convicted of a serious criminal offence?

The RCOG recognises the adverse impact and personal cost of all levels of investigations on individuals and has been working with members to better understand this impact. Research by Tom Bourne and colleagues, in a seminal study of nearly 8000 doctors involved in investigations that may or may not have involved criminal offences, reports high rates of psychological morbidity in doctors facing all types of complaints. Unsurprisingly, the impact was greatest on those undergoing GMC investigation.

Bourne and his team also examined how doctors changed their clinical practice in response to complaints. Over 80% of doctors reported changing the way they treat patients after complaints against themselves or others. The most common changes were "hedging" behaviours, such as over-investigation, over-referral, and over-prescribing. Just under half of doctors described avoiding high-

risk patients and procedures, 23% reported suggesting invasive procedures against their professional judgement, and 16% reported abandoning procedures early[1]. This undermines the use of professional judgement and demonstrates the worry and lack of confidence that professionals experience when dealing with fitness to practise investigations[2].

The RCOG understands that referrals to the GMC are high, and that the GMC has a legal duty to investigate. Reasons for high referrals are not always well understood and the RCOG believes that many incidents could be better dealt with at a local level to avoid escalation.

The RCOG has developed five principles for good complaints management and learning. The RCOG suggests that these principles have application to the work of both the services regulator, CQC, and the professional regulator, GMC, as investigations are often as much a service quality issue as a regulatory issue. The principles aim to clarify the standards of complaints management and motivate greater resolution, learning and leadership to take place locally.

The RCOG believes that following these guiding principles will reduce a reactionary, short-termist response to incidents and encourage local trusts and health boards to take a more consistent and considered approach.

48. The GMC has a statutory duty to: promote and maintain public confidence in the medical profession, and promote and maintain proper professional standards and conduct for doctors. What factors do you think the GMC should balance when trying to fulfil both these duties where there have been mistakes that are 'truly, exceptionally bad' or behaviour/rule violations resulting in serious harm or death?

The role of the regulator in balancing public confidence and the confidence of doctors is hugely important. There is a perception within the medical profession that the regulator is too heavily on the side of patients, often to the detriment of the profession.

Both members of the public and doctors have highlighted to the RCOG that adopting a human factors approach and considering system-wide factors in investigations will go some way to demonstrating to the public and the profession that concerns are being dealt with appropriately and fairly.

Mistakes that are 'truly, exceptionally bad' are rare events where the regulator needs to be consistent, transparent and fair. Whilst the confidentiality of patients and clinicians involved is vital, there is currently a perception that the GMC is not transparent enough in its rationale when dealing with doctors involved in these incidents. For instance, when approaching our membership, one clinician highlighted "currently it is easier to access the court proceedings to understand [the rationale] than it is the GMC conduct investigations". The RCOG believes that increasing the transparency of the GMC's processes and rationale would help rebuild the trust and confidence of the profession in the regulator.

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?

[1] Bourne T, Wynants L, Peters M, van Audenhove C, Timmerman D, van Calster B, et al. The impact of complaints procedures on the welfare, health and clinical practise of 7926 doctors in the UK:a cross-sectional survey. *BMJ Open* 2014;4:e006687.

[2] http://careers.bmj.com/careers/advice/Can_I_avoid_complaints_by_practising_defensively%3F

RCOG trainees have reported taking a more defensive attitude towards the written process of reflective learning in e-portfolios in response to the reporting of the Bawa-Garba case and, specifically, the reported use of reflective notes as evidence within the criminal proceedings. The RCOG supports the suggestion of an education/communication campaign aimed at trainees, to reiterate the value of reflective learning and the risk to their development of not undertaking reflection.

Considering the current distrust regarding reflection, timely and better guidance is vitally needed at all levels to communicate the value of learning within healthcare. As well as highlighting the importance of reflection, and what good reflection should look like, the guidance should include information on what reflection can and cannot be used for in investigations. The guidance should also address what a doctor should do when they have made a mistake.

RCOG trainees have suggested that reflective practice and learning from mistakes are wider issues and more work should be done to communicate how to support a learning culture across the career course, rather than just on the e-portfolio tool and only addressed at trainees. There is an appetite to produce more on learning from mistakes and creating an open culture. This was why the RCOG set up the Supporting our Doctors working group.

The RCOG recognises that reflective practice notes is just one aspect and is committed to supporting all members across all career stages to engage when mistakes are made and to collectively learn from them and use them to improve future ways of working. The RCOG is actively working across O&G to understand and create the ways of working which are needed to support clinicians and their employers to improve the learning culture.

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?

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

Finally…

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