

GMC response to the Review of Gross Negligence Manslaughter and Culpable Homicide

Summary of our response

- 1** We understand that the terms of reference for the Review are intentionally broad in their scope so that they encompass the local investigation of fatalities following serious clinical incidents, the role of the coroner service and the prosecuting authorities, and the role of the regulator where there has been a criminal conviction. Although the spotlight of recent cases has been on the actions of the GMC, the GMC's interventions have come at the end of lengthy local and criminal processes over which the regulator has no control. It therefore seems absolutely necessary for the Review to look first at how and why those processes operate as they do and whether improvements can be made within the existing laws that would support a fair and just culture.
- 2** In our response below we cover a number of areas, including some of the following key messages:

 - There is great variation in how local investigations are carried out across the UK.
 - We understand from the experience of our Employer Liaison Service that the use of independent expert evidence is very varied across providers, and that providers can struggle to access appropriate expert evidence, especially in small specialities.
 - Within our own regulatory processes we have well established and quality assured arrangements in place for securing expert input. This has helped us to close a significant number of cases at an early stage of our fitness to practise investigations. We also fully recognise the value of exploring a human factors approach and have

met with leaders in the field of human factors to consider how we might ensure that our response to systemic issues is effective and reflects best practice.

- Black, Asian and Minority Ethnic (BAME) doctors are overrepresented in our fitness to practise processes and those of other medical regulators, and in the referrals we receive from public bodies such as employers and the police. We have also noticed an overrepresentation of BAME doctors in other aspects of our work.
- We have commissioned a more detailed research project to understand the factors that influence the referral of doctors into GMC fitness to practise processes by employers/healthcare providers.
- Employers/healthcare providers have critical responsibilities in providing workplaces that enable learning where things go wrong or that may drive unfairness in cohorts of doctors most at risk.
- Involvement and support of patients and family members in investigations is paramount. In relation to GMC investigations, we operate a Patient Liaison Service, which is for anyone who is a patient, relative of a patient or a member of the public who has raised concerns about whether a doctor is fit to work and we have decided to investigate those concerns.
- More can be done to improve the support offered to doctors in challenging circumstances, and we are committed to working with our partners in healthcare to address this.
- Reflection is a key component of [Good Medical Practice](#) (highlighted in Domain 2).
- Reflection is also an overarching principle of our requirements for revalidation as outlined in our Guidance on supporting information for appraisal (including the Annual Review of Competency Progression (ARCP) for doctors in training) and revalidation. The ability of doctors to reflect during appraisals as a supportive and developmental forum, is central to their ability to improve the quality of their care.
- We are jointly publishing guidance in September with the Academy of Medical Royal Colleges, Medical Schools Council and the Conference of Postgraduate Medical Education Deans. The guidance explains how medical students and doctors should engage with, and demonstrate, reflection.
- Ultimately, embedding openness and transparency is critical to culture change amongst the healthcare profession and we will be working with others across the sector to create environments where doctors feel confident and supported to raise concerns.

Background

- 3** The case that has given rise to this review has been a tragedy; a little boy lost his life and a family lost a loving son. Further to this, a doctor lost her career and the wider medical profession now feels less supported and more vulnerable in its efforts to care for patients and the public in a system under intense pressure. The outcome of the case has served to highlight issues that have been present for a long time, but that are either insufficiently understood or inadequately addressed. They include (but are not limited to):
- The enormous challenges facing all doctors working in a system under pressure, and where accountability lies when things go wrong.
 - The involvement of the criminal justice systems where fatalities occur in a medical setting and whether the procedures and processes surrounding the investigation and prosecution of alleged gross negligence manslaughter (GNM) or culpable homicide ((CH) although noting that we are not aware of any prosecutions of doctors for CH to date) are sufficient to support fair and consistent decision making.
 - The use of expert witnesses within criminal, coronial and regulatory proceedings.
 - The role of human factors and system issues - expertise in which is still being developed and understood.
 - The role of reflection in good medical practice and how this should be used to support learning and safe practice.
 - How public confidence in the profession is maintained.
 - The role of professional regulation in relation to these issues.
 - The extent to which the case of Dr Bawa-Garba has served to act as lightning-rod for many of the underlying systemic pressures facing the health service and the medical profession.
- 4** It is to help us all better understand and address these issues, that we commissioned this independent, UK wide review of GNM and culpable homicide (the Review) and consider what might be done to improve the application of the existing law in cases involving doctors.
- 5** The learning from this Review must support fair and just decision making and the application of the law, procedures and processes where allegations of GNM or culpable homicide have arisen so that accountability is appropriately apportioned between healthcare systems and individual doctors.

- 6 We are keen to stress the importance of the independence of the Review and that the GMC will not seek to interfere with its autonomy or influence its conclusions. We write this submission in response to the call for evidence, as we believe we are best placed as the professional regulator of the medical profession to provide some factual information in relation to previous learning we have had from reviews and research reports and to advise on the professional regulatory part of the process relating to cases of medical professionals with allegations of gross negligence manslaughter or culpable homicide. We will only seek to provide answers to some questions in the questionnaire where we feel we can potentially make relevant contributions.

Questions 11 – 13

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?

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

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

- 7 We are aware that there is great variation in how local investigations are carried out across the UK. Last year we commissioned an initial study to find out more about what happens with investigations locally before concerns are referred to us by employers. The review's working group may find this research helpful in their work - [Understanding employers' referrals of doctors to the GMC](#).
- 8 We have also this year commissioned a further detailed research project, to be led by Roger Kline and Dr Doyin Atewologun. This research project is to better understand why some doctors are referred to us for fitness to practise issues more than others and to understand the factors that influence the referral of doctors into GMC fitness to practise processes by employers/healthcare providers. This research is intended to identify ways in which the GMC, clinical leaders, and management can work together to help develop workplaces in which doctors' interactions with the GMC and local processes are fair. The ultimate aim of this research is to increase understanding about the pattern of referrals to the GMC of different groups of doctors, and to increase assurance about the systems for and the approach to referrals of such groups. The research is due to report in February 2019. (More information about this research project is included in answer to question 28 below) It is worth stressing here, the critical responsibilities that employers/healthcare providers have in

providing workplaces that enable learning where things go wrong or that may drive unfairness in cohorts of doctors most at risk.

- 9 Last year, we also developed a document entitled 'Principles of a good investigation' to provide overarching guidance to Responsible Officers on what is needed for a good investigation (due to be published shortly but can be shared with the Review). This includes a principle about the handling and sharing of information and highlights that 'appropriate updates should be shared with patients whose quality of care is the subject of concerns, and the relatives and carers of those unable to represent themselves'.
- 10 Information on the role of Responsible Officers in relation to clinical governance and responding to concerns about doctors can be found here - [NHS England » Responsible officers](#) and here - [Medical regulation: responsible officer guidance - GOV.UK](#) although regulations do differ across the four countries and are listed [here](#) on our website.

Question 14

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

- 11 In relation to GMC investigations, we operate a Patient Liaison Service, which is for anyone who is a patient, relative of a patient or a member of the public who has raised concerns about whether a doctor is fit to work and we have decided to investigate those concerns. Meetings are offered at the outset of the investigation process to:
 - Ensure we understand the complainant's concerns
 - Explain the investigation process and the outcomes available at the end of our investigation
 - Make sure they understand what we do
 - Signpost them to other organisations that may be able to help where we can't

Meetings are also offered at the end of the process to explain the outcome of an investigation.

- 12 As part of our ongoing Witness Experience Review, we have introduced a range of changes based on feedback obtained through detailed surveys of GMC witnesses. These changes will improve the experience of all GMC witnesses and ensure good witness care, contact and support throughout our processes, including increased levels of telephone contact and frequency of updates. We have introduced a new witness management tool which guides colleagues through our policies and

processes, as well as conversations and interactions with witnesses. It includes early assessment of each witness's needs with signposting to our independent Witness Support Service where the witness is vulnerable or has emotional support needs. Our Legal Team and MPTS have worked to improve our approach to witness care during hearings, including clear and frequent updates to witnesses and plans for improved witness facilities at the hearing centre. Before the end of the year, we plan to introduce a feedback mechanism for all witnesses to complete, through which we'll regularly review the effectiveness of our witness care and support provision.

- 13** We have also recently introduced a process to communicate with family, next of kin or those close to the care of a patient where we are investigating concerns about the care of a patient who would otherwise lack a voice in our process because they have died, lack capacity or are underage.

Questions 15

How can we make sure that lessons are learned from investigations following serious clinical incidents? (and repeated at Question 25)

- 14** Our guidance document [Good medical practice](#) describes the professional values and behaviours we expect from any doctor registered with us. It sets out the expectation that doctors will contribute to and comply with systems to protect patients, including responding constructively to the outcomes of reviews and regularly reflecting on the standards of care they provide. We provide further guidance in [Leadership and management for all doctors](#).
- 15** We support the establishment of a Health Service Safety Investigations Branch in England on a statutory basis and the proposed 'safe space' approach to investigations. It reflects the aim of our 2018-2020 Corporate Strategy to move regulation upstream, to promote a learning culture which identifies and addresses risks at the earliest possible point and to help prevent avoidable harm from occurring in the future. It is also consistent with our guidance to doctors about their responsibilities to learn from mistakes and reflect on their practice, and their duty to take part in systems of quality assurance and quality improvement to promote patient safety.
- 16** The extent of a doctor's insight into the concerns raised about their fitness to practise and any steps they have taken to remediate concerns is an important part of our decision making about a doctor's fitness to practise. Our decision makers are provided with guidance to assist them in determining the most appropriate outcome at the end of an investigation or at a hearing, which includes how insight and remediation can be taken into account in certain types of cases. For example, where a doctor has been honest in their reflections, has shown insight and has apologised for an error this may result in no regulatory action being taken as there is less likely to be an ongoing risk to public safety. It is also worth drawing attention to our work

(as outlined in our answers to questions 16 and 17) in training our decision makers in human factors so that they are well equipped to recognise the impact of systems on human conduct.

- 17** We are currently piloting an extension of our provisional enquiries process to include concerns arising from a single clinical incident. Provisional enquiries seek to ensure we only carry out a full investigation where necessary and speed up the handling of concerns to enable us to respond to complaints more effectively. Rather than initiating a full investigation in all cases, provisional enquiries enable us to obtain key pieces of information at an early stage so that we can make an earlier assessment of whether allegations are serious enough to raise a question of impaired fitness to practise. In the case of single clinical incidents, our provisional enquiries include seeking information from the doctor's responsible officer to establish the level of insight the doctor has shown to the incident, and obtain information about any remediation and learning that the doctor has already undertaken. In cases where appropriate insight and remediation can be demonstrated, it will be much less likely that there is an ongoing risk to the public and therefore no need for a case to progress to a full investigation. It is possible that a by product of this new approach could be to encourage a local learning culture by demonstrating the benefits of candour and learning lessons at an early stage.
- 18** We also proactively highlight our support for candour, insight and remediation. We regularly liaise with the medical defence organisations where we promote the positive way in which we view candour. We also highlight the positive role of insight in the meetings our decision makers hold with doctors before deciding the outcome of an investigation. We run promotional campaigns to help doctors better understand how we work. In June 2017 we ran a 'GMCexplained' campaign that included blogs to help doctors better understand what we do when we receive a concern about a doctor and how we assess fitness to practise concerns in the context of a system under pressure. Both of these [blogs](#) touched on the role of candour, insight and remediation. We also worked with the Scottish Government before they implemented the organisational duty of candour in April 2018.
- 19** We want to continue to work with stakeholders and doctors to explain how we work and to promote candour and we are open to other ways we can do this.

The role of revalidation in making sure that lessons are learned from investigations following serious clinical incidents

- 20** Medical revalidation is based on doctors' collection of supporting information from across their practice, and their reflection and discussion on it at regular appraisals. Our requirements, are set out in our [Guidance on supporting information for appraisal and revalidation](#). Revalidation through engagement in appraisal aims to create an ongoing supportive forum in which doctors can review and evaluate the quality of their work and, together with support from their appraiser, identify the elements of their practice that work well, and those areas where doctors could and should make

changes. Appraisal discussions also allow doctors to reflect on whether the changes they have made have improved their practice, or whether they should take further action to make changes to their practice.

- 21** Of particular relevance is the requirement to collect evidence about what we term 'significant events', and participation in quality improvement activities. At every appraisal, doctors must discuss and reflect on evidence of 'significant events' from their whole practice. Our guidance defines these as 'any unintended or unexpected event, which could or did lead to harm of one or more patients. This includes incidents which did not cause harm but could have done, or where the event should have been prevented.' Doctors will be able to identify any patterns in the types of significant events recorded about their practice, and consider what further learning and development actions they have implemented, or plan to implement, to prevent such events happening again.
- 22** Doctors must also participate in quality improvement activities at least once in their revalidation cycle, and again, collect, reflect on and discuss these at their appraisals. However, in addition we say that a doctor must discuss with their appraiser or responsible officer the extent and frequency of the activity that is appropriate for their work. We recognise that for some specialties, it is appropriate for them to carry out activity more frequently. Our guidance advises doctors to contact their college or faculty for guidance to better understand the type of quality improvement activity that would be most appropriate for their practice. Our requirements also make clear that doctors 'should participate in any national audit or outcome review if one is being conducted in your area of practice... [and] reflect on the outcomes of these audits or reviews, even if you are unable to participate directly.'
- 23** Doctors must also collect, reflect on and discuss compliments and complaints relating to the period covering their appraisal (including declaring all formal complaints received about their practice) and obtain feedback from their patients and colleagues. These may also highlight valuable learnings from doctors' practice, including in relation to serious clinical incidents.
- 24** As part of our work to support the delivery of revalidation locally we have produced, in collaboration with system regulators/improvement bodies across the UK, a handbook for Boards and Governing Bodies called [Effective governance to support medical revalidation](#). It sets out a view of the core elements required to support revalidation in recognition of the importance it plays in driving improvements in the quality and safety of healthcare across the UK. One of the core elements of the Handbook is that... 'There is corporate or organisation-wide commitment to creating an environment that fosters good professional practice' and describes organisations as having 'Quality improvement programmes [that] will deliver activities that result in improvement actions and derived learning that is put in place and audited.' As well as outlining five core elements of governance the Handbook also sets out questions for Boards and Governing Bodies to consider including 'How does your organisation ensure it can and does respond when things go wrong?'. We are currently reviewing

the Handbook and planning to publish a revised version in the autumn. It is worth stressing again here, the critical responsibilities that employers/healthcare providers have in providing workplaces that enable learning where things go wrong or that may drive unfairness in cohorts of doctors most at risk.

Questions 16 and 17

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?

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.

- 25** Focussing on root cause analysis may not always be the best way of dealing with all investigations and we understand that exploration of a human factors approach is underway at several NHS Trusts in England. We too recognise the value of exploring a human factors approach and have met with leaders in the field of human factors to consider how we might ensure that our response to systemic issues is effective and reflects best practice. There are two main areas of interest for us which we propose to explore further:
- Training our decision makers in human factors so that they are well equipped to recognise the impact of systems on human conduct
 - Increasing our knowledge and carrying out some influencing work with local systems in order to ensure that local systems take account of human factors. This is upstream work to reduce the incidence of mistakes and improve safety.
- 26** Several high profile patient safety inquiries and our own fitness to practice data have identified major deficits in basic areas of professional practice. These underline the importance of and a need for specific training to address individual, team and organisational deficiencies, as well as addressing wider systemic failures. That is why the GMC is specifically including human factors principles in the outcomes it requires for students and doctors - at all stages of UK medical education and training - in areas which are critical to the delivery of effective clinical care e.g. safety and quality improvement, teamwork, communication, the use of equipment.
- 27** In our outcomes for graduates we require that newly qualified doctors must be able to *'...describe basic human factors principles and practice at individual, team, organisational and system levels and recognise and respond to opportunities for*

improvement to manage or mitigate risks'. In [domain 6 of our Generic professional capabilities framework](#), covering Capabilities in patient safety and quality improvement, we say that: 'Doctors in training must demonstrate that they can participate in and promote activity to improve the quality and safety of patient care and clinical outcomes.' To do this, they must... 'raise safety concerns appropriately through clinical governance systems... demonstrate and apply basic Human Factors principles and practice at individual, team, organisational and system levels.'

- 28** It is also worth highlighting that the GMC is one of several organisations which signed the National Quality Board's, [Concordat on human factors](#), in 2013.

Questions 22 and 23

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

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

- 29** We understand from the experience of our Employer Liaison Service that the use of 'independent expert evidence' is very varied across providers, and that providers can struggle to access appropriate expert evidence, especially in small specialities.
- 30** It is worth recognising that there is not currently a shared/agreed understanding or definition of what 'independent expert evidence' is or who should be recognised as an 'expert'.
- 31** Within our own regulatory processes we have well established and quality assured arrangements in place for securing medical expert input. This has helped us to close a significant number of cases at an early stage of our fitness to practise investigations. There may be learning that we can bring to the way that the wider system uses expert medical evidence, including an understanding of human factors issues alongside clinical expertise. As mentioned in the answer to question 17, we are also exploring the need to build training in human factors into the training of our case examiners and our pool of medical experts.
- 32** We have focussed on ensuring that our staff and associates have equality and diversity and unconscious bias training, particularly our decision makers in our fitness to practise processes, (to note: E&D training sessions are also standard induction sessions and delivered at regular intervals for tribunal members of the Medical Practitioner Tribunal Service). We are also aware that there are all sorts of other bias which can influence decision making. Therefore, it will be important for us all to consider assessing those biases to ensure fairness in decision making.

Question 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?

- 33** An online survey carried out by Harrison et al (2014)^[1] found that 76.5% of doctors who had been involved in an adverse patient safety event felt the experience affected their personal or professional lives. The effects most commonly reported were stress and anxiety, reduction in job satisfaction, difficulties sleeping and loss of professional confidence.
- 34** Doctors involved in such incidents and undergoing GMC investigations have access to a confidential support service that we commission and is currently delivered by the BMA – the Doctor Support Service. The Medical Protection Society offers a counselling service specifically to assist members suffering from stress as a result of complaints, clinical negligence claims, disciplinary matters, and other medicolegal issues. In addition, the BMA also provide a telephone counselling service for all doctors - BMA Counselling – which is available 24 hours a day, 7 days a week.
- 35** We have been working to improve the way we support doctors through the difficult experience of facing a complaint or investigation. Since 2015 we have been working with Professor Louis Appleby, a professor of psychiatry, to review our investigation process to see what changes could be made to better identify and support doctors, some of whom might be vulnerable. We have made a range of improvements as a result, including speeding up the process of notifying doctors of the outcome of a complaint and tailoring our approach for doctors who are, or who become, unwell.
- 36** However we believe there is more that could be done to improve the support offered to doctors in these circumstances, and we are committed to working with our partners in healthcare to address this. We have already commissioned a project on the mental health and wellbeing of the medical profession, chaired by Dame Denise Coia and Prof Michael West. The project will research and analyse the working conditions that contribute to stress amongst doctors, and the support currently available for doctors in the workplace. This project may identify how we can collaborate further to improve the professional and emotional support available to doctors in the workplace who have been involved in a serious clinical incident.

^[1] Harrison, R et al. Doctors' experiences of adverse events in secondary care: the professional and personal impact, 2014 available at <http://www.clinmed.rcpjournals.org/content/14/6/585.full.pdf+html>

Question 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?

- 37** We are acutely aware that Black, Asian and Minority Ethnic (BAME) doctors are overrepresented in our fitness to practise processes and those of other medical regulators, and in the referrals we receive from public bodies such as employers and the police. And, it is because of this awareness, and because we recognise the importance of addressing this issue, that we have undertaken research to examine our decision making procedures in relation to fitness to practise - which has found no evidence that our processes are in themselves discriminatory. The most recent was carried out by Plymouth University in 2014 - *Review of decision making in the GMC's FTP procedures*. As set out earlier in this response, in view of the over-representation of BAME doctors in referrals from employers/healthcare providers, last year we commissioned some initial research - *Understanding employers' referrals of doctors to the GMC* - to understand more about what happens with investigations locally before concerns are referred to us by employers. And this year we have commissioned a further more detailed research project to understand the factors that influence the referral of doctors into GMC fitness to practise processes by employers/healthcare providers, the ultimate aim of which is to better understand what drives the over-representation of BAME doctors in referrals from employers/healthcare providers and to increase assurance about the systems for and the approach to referrals of different groups of doctors to the GMC.
- 38** The rapid review undertaken by Professor Sir Norman Williams into Gross Negligence Manslaughter in healthcare found some evidence that this applies to prosecutions for GNM but that the numbers are too small to draw meaningful conclusions.
- 39** We agree that due to the rarity of GNM cases, identifying any link to protected characteristics can be problematic. These are very small numbers and drawing inferences about the relative likelihood of different cohorts undergoing investigation leading to GNM/CH charges can be risky and potentially misleading. Whilst we have some data such as age, gender and ethnicity available for what are a very small number of cases, we only started collecting data on religion, disability and sexual orientation in January 2016 and most cases of GNM were prior to that.
- 40** Previous results of analysis and research in this area have been published in our annual publication, [State Of Medical Education and Practice](#). There is also some emerging work on 'fairness' in fitness to practise overall currently underway that may help to inform us in future. We may also need to look into qualitative research to fully understand the risks that may lead specifically to charges of GNM/CH for doctors.

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?

- 41** As mentioned in answer to questions 11-13 above, in April 2018 we announced that we have commissioned Roger Kline and Dr Doyin Atewologun to lead a major project to better understand why some doctors are referred to us for fitness to practise issues more than others. This is a significant issue which we recognise requires more evidence and understanding in order to effect change. Roger and Doyin will head up a programme of work of research, analysis and advice, which is due to conclude in February 2019. Their research will enable the GMC to work with clinical leaders to properly develop supportive and open workplaces, where doctors' interactions with the GMC, and their processes, are appropriate and fair.
- 42** Below is the list of potential characteristics which may influence referrals from healthcare organisations (others may be identified) that are being considered (and are included in the Terms of Reference) for the Roger Kline Review:
- perceived/ actual individual level differences between doctors (e.g. educational qualifications, cultural capital (e.g. knowledge of NHS), English language skills, training outside the UK)
 - the working environment they are employed within
 - the formal and informal support available for those doctors
 - the nature of their role or contract
 - the support available for clinical leaders and/or the overall leadership and clinical governance within that environment.
- 43** The Community Research, [Understanding employers' referrals of doctors to the GMC](#) mentioned above, has contributed to shaping the scope of the commission for Roger Kline and his work intends to build on this. This referred to a number of factors:
- Some participants suggested the likelihood of issues coming to light was not the same for all groups of doctors. For example, some felt that concerns were more likely to be raised against locums, doctors who qualified overseas, doctors approaching retirement and doctors that worked in specialisms that are easy to benchmark. Conversely, some felt that concerns were less likely to be raised (or more carefully considered) against trainee doctors, popular doctors and doctors from non-white backgrounds.
 - Promising approaches (that enabled trusts to deal with concerns more effectively) included clear organisational values, targeted appraisals, having a wide pool of case

investigators, reviewing previous cases, having two case investigators per case and providing unconscious bias training.

- Ideas for the future (individuals' thoughts on dealing with concerns more effectively) included developing an integrated professional support unit, a forum for case investigators, sharing of legal/HR expertise (for smaller trusts), having a 'faculty' of case managers, sharing case investigators at a regional level, establishing an expert witness database, developing terms of reference for expert witnesses and reverting to a single employer for doctors in training.

Question 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?

44 Feedback from our frontline engagement teams suggest that the following factors present barriers to doctors behaving candidly:

- Organisational cultures in the environment doctors work within which do not actively encourage and incentivise candour with patients or between professionals
- Lack of awareness of existing guidance and resources
- Fear of litigation; continuing perception that apologising is an admission of liability
- Time to do so in a manner up to the expected standard
- Confusion about who should apologise, when and how
- Fear that they will be seen as a 'trouble maker' if they report concerns
- Lack of communication skills amongst some doctors to know how to effectively deliver the apology
- Systems not supporting candour - e.g. mix of paper and electronic systems, inadequate support for putting explanations and apologies in writing.

45 We have no direct measure of doctors' attitudes to duties of candour, but we did observe a significant increase in the number of sessions delivered by our Regional Liaison Service in England between 2016 and 2017 (12 in 2016; 53 in 2017) on the topic of candour, at the request of healthcare providers. These sessions cover both the professional duty and the organisational duty, the aim is to helping professionals

and organisations understand what they are required to do. This could indicate increased engagement with the issue.

- 46** However, a consistent finding in these sessions was low awareness overall of the professional and statutory duties (and confusion between the two). There are also many misconceptions about the duty. In particular there is still fear of litigation and a perception that saying sorry will lead to negligence claims. In recent sessions particular anxiety has been expressed that the duty of candour could result in criminal prosecution as mistakes are being conflated with the events in recent high profile cases. Within this context, comments on social media have been referring to the 'death of candour', indicating that the GMC needs to restore doctors' trust in their regulator; in part by emphasising that apologising is not the same as admitting legal liability.
- 47** We would recommend that key players in the sector (regulators, employers and doctors) work collaboratively to influence a cultural shift from 'blame' to 'learning' and to encourage doctors to talk openly about things which go wrong. Our Liaison Advisors throughout the UK are seeking to encourage this in our raising concerns workshops – where all doctors regardless of career stage are encouraged to consider what they personally can do to create a culture of openness and learning. We have heard feedback during these sessions that doctors feel this cultural shift needs to be led from the top. It would therefore be helpful for us to work together to achieve this, and to raise awareness of smaller behavioural changes which could contribute to this culture - for example improving communication skills amongst healthcare professionals, and engaging patients and their families in feeding in ideas for improvement.
- 48** The Healthcare Safety Investigation Branch (HSIB) also aims to encourage learning as part of their investigation process as well as openness and honesty. HSIB wants to drive positive change to improve patient safety, and their investigations look at whether there is a new perspective so that they can develop meaningful, influential and effective recommendations. It is important to note that HSIB's work relates to England only, and that there is currently no equivalent body in Northern Ireland, Scotland or Wales.
- 49** One of our key strategic aims for 2018-20 is to strengthen collaboration with our regulatory partners across the health sector. The action we will take forward in relation to this aim will build on our constructive collaboration with partners around issues of quality. For example our national reviews of training environments in Scotland and Northern Ireland in 2017 ensured close collaboration with deaneries, medical schools and employers in the name of quality assurance, and built on ongoing and constructive joint work with our partners in this area around the UK. Culture is defined by the shared values and behaviours of society or an organisation and ultimately, embedding openness and transparency is critical to culture change amongst the healthcare profession. Therefore, we will be working with others across the sector to create environments where doctors feel confident and supported to

raise concerns. All organisations, not just professional regulators need to work collaboratively in embedding and encouraging a culture of candour.

- 50** As mentioned in response to question 17, we are exploring what we can do to encourage local systems to take into account human factors. We understand from leaders in this field that taking a human factors approach can increase confidence in staff about reporting concerns.
- 51** As noted in the Review's terms of reference, we agree it is important to encourage and support a 'fair and just culture' in which learning is readily enabled but also ensuring there is appropriate individual and/or system accountability. Often a 'fair and just culture' is confused or conflated with 'a no blame culture,' but as James Reason, (the safety expert- famous for propounding the Swiss Cheese model of accident causation) highlights in a report on culture in aviation '*.. the 'no-blame' concept had two serious weaknesses. First, it ignored—or, at least, failed to confront—those individuals who wilfully (and often repeatedly) engaged in dangerous behaviours that most observers would recognise as being likely to increase the risk of a bad outcome. Second, it did not properly address the crucial business of distinguishing between culpable and non-culpable unsafe acts.*'^{*} This important distinction between a 'just culture' and a 'no-blame' culture was also highlighted by Sir Robert Francis QC in the [Freedom to Speak up report](#) (para 29). This report also identified that the '*primary need is to move from a culture which focuses on 'who is to blame?' to one focused on 'has the safety issue been addressed?' and 'what can we learn?'*'.
- 52** In Reason's report a 'just culture' is described as '*an atmosphere of trust in which people are encouraged, even rewarded, for providing essential safety-related information, but in which they are also clear about where the line must be drawn between unacceptable behaviour and blameless unsafe acts.*' It may be that public and the profession's perceptions of where that line ought to be drawn may differ, which may be something that the Review may wish to consider.

Public interest concerns and fitness to practise

- 53** We commissioned an independent review from Sir Anthony Hooper to examine our handling of cases involving whistleblowers. Sir Anthony reported in March 2015 - [The handling by the GMC of cases involving whistleblowers](#). He made a number of recommendations including that the GMC ought to have more understanding about the circumstances surrounding referrals from organisations and the timeline of events leading to the referral. As a result we have been piloting a series of measures which are designed to give us this greater understanding.

^{*} 'A roadmap to a just culture: enhancing the safety environment, GAIN Working Group E', September 2004.

- 54** The pilot commenced on 11 July 2016, with the introduction of a new referral form which requires senior individuals acting on behalf of an organisation to make their referral using the new form, and asks them to:
- State whether the doctor has raised concerns about patient safety or systems and if so, how and when it was investigated locally.
 - Confirm when they made the doctor aware of their concerns about the doctor's practice.
 - Answer a statement to confirm that the referral has been made in good faith and that the doctor's Responsible Officer has taken reasonable steps to make sure that the referral is fair and accurate.
- 55** If the referral involves a doctor who has raised concerns and the information provided does not contain objective evidence to support it (evidence that is not solely based on the views of those who are employed by the organisation about which the doctor raised concerns), we will seek to gather more information about the complaint using our provisional enquiry process. This will help us assess whether an investigation is necessary.
- 56** If we need to open a full investigation, the background information from the referral form will be given to the investigator and decision makers, so that it continues to be taken into account throughout our decision making. New procedures ensure that the investigation will focus on gathering evidence that is not solely based on the views of those who are employed by the organisation about which the doctor raised concerns and new guidance helps decision makers weigh up the evidence.
- 57** It is also worth noting that Sir Robert Francis QC's, [Freedom to Speak Up Review report](#) covers this point in relation to barriers for staff from black and minority ethnic (BME) background in raising concerns – the executive summary is quoted below and full detail relevant to this question is on page 64-67:

'The experiences of BME staff were broadly similar to those of other staff, but without doubt they can feel even more vulnerable when raising concerns.

This was partly because the culture can sometimes leave minority groups feeling excluded, and cultural misunderstandings may exacerbate difficulties. This sense of vulnerability appears to be supported by the evidence of our independent research. There is also a perception that BME staff are more likely to be referred to professional regulators if they raise concerns, more likely to receive harsher sanctions, and more likely to experience disproportionate detriment in response to speaking up.'

- 58** Suggestions from BME staff to improve raising and handling concerns were in line with suggestions from other contributors such as:

- 'culture change
- clarification of the process
- a named contact in each organisation to act on concerns raised
- stronger leadership
- better accountability
- more transparency.'

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?

59 We set out the factors for decision makers to consider when determining what action to take when a doctor has put patients at risk or undermined confidence in the profession in our [Sanctions guidance](#). The guidance is based on the values and standards contained in our core guidance, [Good medical practice](#) and seeks to ensure that decision making is fair, proportionate and consistent.

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?

60 Reflection is a key component of [Good Medical Practice](#) (Domain 2) and an overarching principle of our requirements for revalidation as outlined in our [Guidance on supporting information for appraisal and revalidation](#). The ability of doctors to reflect during appraisals (including ARCP's for doctors in training) as a supportive and developmental forum, is central to their ability to improve the quality of their care. Regardless of the nature or scope of a doctor's practice, ongoing reflection is an important part of being able to learn from their practice. It is not enough for a doctor to simply collect supporting information.

61 Responsible officers can recommend that a doctor's revalidation is deferred if they do not believe they have sufficiently reflected on or discussed their supporting information, and ultimately, if a doctor is persistent in not meeting that requirement, the responsible officer can make a recommendation of non-engagement.

- 62** We told the Williams Review into Gross Negligence Manslaughter that doctors' reflections are so fundamental to their professionalism that the UK and devolved governments should consider providing legal protection. We also reiterated this position in [our evidence](#) to the Joint Committee on the Draft Health Service Safety Investigations Bill.
- 63** We are jointly publishing guidance in September with the Academy of Medical Royal Colleges, Medical Schools Council and the Conference of Postgraduate Medical Education Deans. The guidance explains how medical students and doctors should engage with, and demonstrate, reflection.
- 64** Some key messages from this guidance are:
- Reflection is personal and there is no one correct way to reflect.
 - The quality of reflections is more important than the quantity. A variety of different experiences can be reflected on.
 - Having and taking time to reflect on both positive and negative experiences – and being supported to reflect – is important for individual wellbeing and development.
 - Group reflection often leads to ideas or actions that can improve patient care.
 - The healthcare team should have opportunities to reflect and discuss openly and honestly what has happened when things go wrong - see Openness and honesty when things go wrong: the professional duty of candour.
 - Doctors should keep notes to demonstrate they are a reflective practitioner, this does not need to capture full details of an experience but show awareness of how to learn and develop from both good and bad experiences.
 - Doctors in training should discuss the experiences they have been reflecting on with their supervisor. They should include in their learning portfolio insights gained and any changes made to their practice. The supervisor should in the portfolio confirm the experience has been discussed, and agree appropriate learning outcomes and what actions are planned. They should share original, non-anonymised information with supervisors but should not record factual details in the learning portfolio.
 - Doctors undertaking appraisal should discuss the experiences that have been reflected on with their appraisers, and maintain a note of these discussions. These notes should focus on the learning identified and any planned actions. No factual details should be recorded in the appraisal portfolio.
 - When keeping a note, doctors should anonymise it as far as possible. Our guidance on confidentiality explains what is expected.

- The GMC will not ask for reflective notes as part of a fitness to practise investigation – though doctors can choose to offer them as evidence of insight.
- Reflective notes can currently be required by a court - if doctors have followed the advice on anonymising data in reflective practice notes and considering the learning from experiences, this should not be a cause for concern. It's important to note that as reflective notes are not contemporaneous records of an incident, they are less likely to be of interest to the courts.
- Tutors, supervisors, appraisers and employers should support time and space for reflection, individually and collectively.

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?

- 65** We recognise that being investigated can be a stressful experience, and we commission the independent GMC Doctor Support Service (currently delivered by the BMA) to provide support to doctors under investigation. The service offers emotional support from another doctor and is independent of the GMC and completely confidential. It is free to doctors and available to all doctors, not just BMA members. Further information can be found on our website - [Doctor Support Service](#). In addition to relevant written information which is sent to doctors at each stage of the investigation process, we also provide information for doctors on our website to explain our investigation processes - [How we investigate concerns](#). Our Investigation Officers are also available to doctors under investigation to answer any questions about the process. On the MPTS website, there is a dedicated section for self represented doctors with comprehensive guidance, and information about sources of support, including a telephone information line, and the Doctor contact service, which is offered by the MPTS to doctors attending a hearing to help lessen isolation and stress, signpost useful support materials and services and provide information about the hearing process - [Information for self represented doctors](#). It is also worth acknowledging here the important role that medical defence organisations and representative bodies play in providing doctors with impartial support.
- 66** A recent programme of our work to support doctors, (some of whom might be vulnerable) involved 26 changes to the fitness to practise process to reduce impact and increase sensitivity and support. Changes included:
- A single point of contact for any doctor under investigation and co-ordination of correspondence with these doctors
 - A specialist team with enhanced communication training for cases involving doctors who are unwell, and the development of communication plans for doctors

- A process to pause investigations to enable doctors who are very unwell to get treatment.

67 We hope that the information included in this submission will be helpful for the purposes of the review and please let us know if any further information may be of use. We look forward to the review's findings early next year.