ORGANISATIONAL MODULES 2024

MUCKAMORE ABBEY HOSPITAL INQUIRY
WITNESS STATEMENT

Statement of Charles Hamilton Massey
Dated 28 June 2024

I, Charles Hamilton Massey, make the following statement for the purpose of the Muckamore Abbey Hospital ("MAH") Inquiry ('the Inquiry'). This is my second statement to the Inquiry having previously provided a statement to the Inquiry dated 08 March 2024 (MAHI – STM – 210 1).

The statement is made on behalf of the General Medical Council, 350 Euston Road, London, NW1 3JN, in response to a request for evidence by the Inquiry Panel.

There are no documents to exhibit with this second statement.

1. I have been asked to address a number of further questions for the purpose of my second statement. I will address those questions in turn.

Q1. Are responsible officers for revalidation required to be of the same specialism as the doctor seeking revalidation?

2. Responsible officers ('RO') are not required to be of the same specialty as the doctor seeking revalidation. The Medical Profession (Responsible Officer) Regulations (Northern Ireland) 2010, published by the Department of Health (Northern Ireland), determine which designated body[1] a doctor has a prescribed

[1] A **designated body** is a UK organisation that has established clinical governance processes including appraisal systems that support doctors with their revalidation and promote and protect the interests of patients.

connection to.[2] Each designated body can only appoint a single RO for all of the doctors connected to them, so most doctors will have an RO who does not practise in the same specialty. A doctor cannot choose which RO to connect to and ROs cannot choose whether to connect to a doctor. We provide an online connection tool and guidance on our website to help doctors identify their designated body and RO.[3] I have provided further details on revalidation in my first statement to the Inquiry.[4]

Q2. If a doctor has been involved in a significant event or complaint, how is this managed through revalidation, would it be on the record that is sent to the GMC?

3. Incidents and complaints should be reported and managed through relevant local clinical governance[5] systems which include processes for responding to concerns. These processes run independently of revalidation and providers should not wait until a doctor's annual appraisal or revalidation to address concerns. Where concerns are identified that could meet the GMC threshold for fitness to practise investigation, the organisation's RO should discuss it with their GMC Employer Liaison Adviser ('ELA') who will advise on referral to the GMC. I provide further information on the RO referral process in response to question seven.

4. Doctors are required to reflect on all significant events and complaints they have been involved in as part of revalidation. These should be collated and discussed at their annual appraisal with a focus on any learning, changes to practice, and professional development. The GMC does not receive the portfolio of information collected by individual doctors for their appraisals or revalidation. The outputs of appraisals, alongside other clinical governance information, are reviewed by the RO when making the revalidation recommendation to the GMC. ROs have a role and responsibility to support doctors to collect their supporting information for

[2] The Medical Profession (Responsible Officers) Regulations (Northern Ireland) 2010 No. 222, Section 2(2).
[3] Online connection tool and guidance.
[4] Witness Statement of Charles Hamilton Massey, 8 March 2024 (MAHI – STM – 210 – 1) paragraphs 18-25.
[5] **Clinical governance** is an overarching term for the processes and systems used by healthcare organisations to monitor and improve the safety and quality of clinical services. It encompasses a range of activities, including (but not limited to) pre-employment checks for clinicians, risk monitoring, clinical audits, effective information governance, and responding to patient safety incidents.

revalidation. I provide more information on how we support ROs to fulfil their responsibilities as part of an effective local clinical governance system in my response to question seven.

5. To further support ROs we reviewed our guidance on supporting information for appraisal and revalidation. This followed recommendations 57 and 58 in the Independent Neurology Inquiry ('INI') report (2022) and was aimed at ensuring that the guidance is clear and accessible for all audiences, including doctors, so that they understand the data they are required to consider as part of their appraisal. We sought and received feedback from a wide range of organisations and stakeholders, including ROs, appraisers, and all the organisations that are cosignatories to the GMC's Clinical Governance Handbook.[6] Our updated guidance, published in January 2024, applies to doctors, and will apply to anaesthesia associates and physician associates in the future and reflects this year's version of *Good medical practice*.[7]

6. The updated guidance also clarifies how doctors must declare and reflect on every significant event they were involved in since their last appraisal, including those that happened in a team they were part of. We also acknowledge that different organisations may use a different term for these events (for example, serious incident, adverse event, serious adverse incident, or patient safety incident) or that some organisations may have defined the term more broadly to include learning events other than those that result in harm. We say that doctors should focus on their learning from any events and incidents that have or could have harmed their patients, to meet our requirements.[8]

Q3. Are doctors required to discuss treatment decisions and prescriptions with patients?

[6] Effective clinical governance to support revalidation.
[7] Guidance on supporting information for revalidation, (2024).
[8] Guidance on supporting information for revalidation, (2024).

7. Yes. We set out our expectations about supporting patients to make decisions about their treatment and care at *paragraphs 24 to 27* of *Good medical practice*.[9] We say that doctors must start from the presumption that all adult patients have capacity to make decisions about their treatment and care. It is a duty of a doctor registered with the GMC to work in partnership with patients supporting them to make informed decisions about their care, and to listen to them.

8. We make clear that the exchange of information between doctors and patients is central to good decision making, and we say that doctors must give patients the information they want and need in a way they can understand. *Paragraph 28* sets out that this includes information about:
   - their condition(s), likely progression, and any uncertainties about diagnosis and prognosis;
   - the options for treating or managing the condition(s), including the option to take no action;
   - the potential benefits, risks of harm, uncertainties about, and likelihood of success for each option.

9. We say doctors must listen to patients and encourage an open dialogue about their health, ask questions to allow them to express what matters to them, and respond honestly to their questions. We say the information given to patients must be clear, accurate and up to date and based on the best available evidence.[10] Doctors must check patients' understanding of the information they have been given and do their best to make sure the patient has the time and support they need to make an informed decision.[11] And we set out the importance of taking steps to meet their communications needs and make reasonable adjustments.[12]

10. Our more detailed guidance, *Decision making and consent,* expands further on these principles. All patients have the right to be involved in decisions about their treatment and care and to make informed decisions if they can.

[9] GMC, *Good medical practice*, (2024).
[10] GMC, *Good medical practice*, (2024), paragraph 30.
[11] GMC, *Good medical practice*, (2024), paragraph 31.
[12] GMC, *Good medical practice*, (2024), paragraphs 32-33.

11. We say that doctors must give patients the information they want or need to make a decision. This will usually include:
    - diagnosis and prognosis;
    - uncertainties about the diagnosis or prognosis, including the options for further investigation;
    - options for treating or managing the condition, including the option to take no action;
    - the nature of each option, what would be involved, and the desired outcome;
    - the potential benefits, risks of harm, uncertainties about and likelihood of success for each option, including the option to take no action. By harm we mean any potential negative outcome, including a side effect or complication.[13]

12. In our guidance on *Good practice in prescribing and managing medicines and devices* we further set out principles for establishing a dialogue with patients, assessing their needs, and giving information to patients.[14] The amount of information doctors give to patients will vary according to the nature of their condition, the potential risks and side effects, and the patient's needs and wishes.[15]

13. We also provide guidance on exceptional circumstances where doctors may decide not to share all relevant information.[16]

14. We provide further advice to doctors on supporting patients' decision making[17] and guidance on circumstances where a patient does not want to be involved in making a decision.[18]

Q4. If a patient lacks capacity, is a doctor obliged to keep next of kin informed of their health and progress? Is failure to do so considered poor practice by the GMC?

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[13] GMC, *Decision making and consent*, (2020), paragraph 10.
[14] GMC, *Good practice in prescribing and managing medicines and devices,* (2021), paragraphs 34-49.
[15] GMC, *Decision making and consent*, (2020), paragraph 45.
[16] GMC, *Decision making and consent*, (2020), paragraph 14.
[17] GMC, *Decision making and consent*, (2020), paragraphs 27-29.
[18] GMC, *Decision making and consent*, (2020), paragraphs 65-68.

15. We cannot provide specific answers to these questions as it would depend on the factors to be considered in the circumstances of any individual case. We are also unable to comment on the actions of individual registrants outside of our fitness to practise process. Broadly, we expect doctors to make decisions based on their professional judgement in the context of the situation they find themselves in and doctors must be prepared to explain and justify their actions and decisions. We outline this in the professional standards and guidance we publish for doctors which I summarise below.

16. We would expect a doctor in this situation to adhere to the relevant principles in our guidance on *Confidentiality: good practice in handling patient information*.

17. We make clear that doctors may disclose relevant information about a patient who lacks the capacity to consent if it is of overall benefit to the patient. We provide specific guidance for doctors on disclosures about patients who lack capacity to consent, including what the doctor must consider when making the decision to disclose information.[19]

18. We say that the doctor must consider the views of anyone the patient asks them to consult, or who has legal authority to make a decision on their behalf or has been appointed to represent them. We provide guidance on sharing personal information with the patient's relatives, friends or carers to allow an overall benefit assessment to take place, with the caveat that this does not mean a general right of access to the patient's records or giving irrelevant information.[20]

19. When providing information for these purposes, if the patient has previously asked that personal information about their condition or treatment ***not*** be shared with those close to them, we say that the doctor should abide by the patient's wishes whilst still doing their best to be considerate, sensitive and responsive to those close to the patient, giving them as much information as they can.

[19] GMC, *Confidentiality: good practice in handling patient information*, (2018), paragraphs 41-49.
[20] GMC, *Confidentiality: good practice in handling patient information*, (2018), paragraph 46.

20. We would also expect the doctor to apply the relevant high-level principles provided in our *Decision making and consent* guidance. As stated before, we say doctors must start from the presumption that all adult patients have capacity to make decisions about their treatment and care. A patient can only be judged to lack capacity to make a specific decision at a specific time, and only after assessment in line with legal requirements.[21] The choice of treatment or care for patients who lack capacity must be of overall benefit to them, and decisions should be made in consultation with those who are close to them or advocating for them.

21. We provide guidance to doctors on supporting patients' decision making (*from paragraph 27*) which includes accommodating a patient's wishes if they would like anyone else – a relative, partner, friend, carer or advocate – to be involved in discussions and/or help them make decisions.[22] We also say doctors should anticipate situations where the patient's capacity or insight may be impaired by their condition or the effects of an intervention, and plan accordingly. We say that if a patient has a condition that is likely to impair their capacity as it progresses, doctors should sensitively encourage the patient to think about what they might want to happen if they become unable to make healthcare decisions; which includes whether the patient would like anyone else – relatives, friends, carers or representatives – to be involved in decisions about their care. We say doctors must record a summary of their discussion with the patient about their future care and any decisions they make, including as much detail as practical about the patient's wishes and fears, their preferences about future options for care, and the values and priorities that influence their decision making.[23] If possible, they should make this record while the patient has capacity to review and understand it.

22. We set out guidance on making decisions when the patient lacks capacity from *paragraph 87* of *Decision making and consent*. If there is no evidence of a legally binding advance refusal of treatment, and no one has legal authority to make the

[21] GMC, *Decision making and consent*, (2020), paragraphs 77-79. We also provide a legal factsheet for doctors on our website.
[22] GMC, *Decision making and consent*, (2020), paragraph 27(d).
[23] GMC, *Decision making and consent*, (2020), paragraph 37.

patient's decision for them, then the doctor is responsible for deciding what would be of overall benefit to the patient. We use the term 'overall benefit' to describe the ethical basis on which decisions are made about treatment and care for adult patients who lack capacity to decide for themselves. We say that doctors should consult with those close to the patient, take account of their views about what the patient would want, and aim to reach agreement with them. We say that the doctor should allow enough time for discussions with those who have an interest in the patient's welfare, and they should aim to reach agreement about how to proceed.[24]

23. The doctor would be expected to take these factors into consideration when deciding whether to keep the next of kin of a patient who lacks capacity informed about the patient's health and progress.

24. All references to our guidance in this statement relate to the editions in effect at the time of submission. We have included a list of the previous editions of guidance which would have been in effect during the period referred to in the terms of reference (December 1999 to 14 June 2021).
    - Good medical practice 1998-2001
    - Good medical practice 2001-2006
    - Good medical practice 2006-2013
    - Good medical practice 2013-2024
    - Seeking patients' consent: the ethical considerations 1998-2008
    - Consent: patients and doctors making decisions together 2008-2020
    - Good practice in prescribing medicines 2006-2008
    - Good practice in prescribing medicines 2008-2013
    - Good practice in prescribing and managing medicines and devices 2013-2021
    - Confidentiality 1995-2000
    - Confidentiality: protecting and providing information 2000-2004
    - Confidentiality: protecting and providing information 2004-2009
    - Confidentiality 2009-2017

[24] GMC, *Decision making and consent*, (2020), paragraphs 87-91.

Q5. What are the consequences if a doctor observes poor practice of abuse and does not speak up?

25. In my first statement to the Inquiry, I wrote that when a serious or persistent concern is raised about a doctor's performance, behaviour, or health, we can take action to prevent a doctor from putting the safety of patients, or the public's confidence in doctors, at risk. I also described when and how we investigate concerns about doctors in accordance with our obligations under the Medical Act 1983 ('The Act').[25]

26. As I explained, we have a legal duty under the Act to protect the public. The Act splits public protection into three distinct parts. It says that we must act in a way that:
    - protects, promotes and maintains the health, safety and wellbeing of the public;
    - promotes and maintains public confidence in the profession;
    - promotes and maintains proper professional standards and conduct for members of the profession.

27. The purpose of our fitness to practise proceedings is not to punish or discipline doctors but to assess if the doctor may pose any current and ongoing risk to one or more of the three parts of public protection outlined above. An allegation that a doctor observed abuse occurring and did not speak up may be considered as misconduct and may pass our threshold for an investigation if it raises a question of impaired fitness to practise.

28. As with any other allegation of misconduct, our decision makers will consider all the relevant circumstances to decide whether the concern meets our thresholds at different stages of the FTP process (as set out in our Thresholds guidance),[26] focusing on the following:
    - The seriousness of the concern – this includes looking at how far a doctor has departed from the professional standards set out in *Good medical practice* and

[25] Witness Statement of Charles Hamilton Massey, 8 March 2024 (MAHI – STM – 210 – 1) paragraphs 60-69.
[26] GMC, *Thresholds guidance*, (2024).

our other guidance (see below for the standards relevant to failing to raise concerns);

- Any relevant context – we consider any relevant context that we are aware of. By 'context' we mean the specific setting or circumstances that surround a concern;
- How the doctor has responded to the concern – we examine the evidence available to establish if the doctor has insight into their own practice and behaviour – as this helps us assess the likelihood of repetition and therefore any current and ongoing risk to the public.

29. Our information document, *What we mean by fitness to practise*,[27] provides further detail on the decisions made about fitness to practise, how we assess if a doctor poses any current and ongoing risk, and sets out what may amount to a fitness to practise concern and why. This guidance includes descriptions of certain types of cases in the fitness to practise process and how these relate to our guidance, including sexual misconduct, dishonesty and lack of integrity, violent or abusive behaviour, discrimination, clinical concerns, impact of a health condition, insufficient knowledge of English language, and convictions, cautions and determinations.

30. In considering what action to take if a doctor has observed abuse but not spoken up, the decision maker would consider the extent of the doctor's departure from the professional standards set out in our ethical guidance on candour and speaking up.

31. On responding to safety risks, our professional standards explain that doctors must act promptly if they think that patient safety or dignity is, or may be, seriously compromised. In the revised version of *Good medical practice,* we included a new paragraph to emphasise the roles of doctors who are in formal leadership and management positions. If doctors hold these roles, they must take active steps to create an environment in which people can talk about errors and concerns safely. This includes making sure that any concerns raised with the doctor are dealt with

[27] GMC, *What we mean by fitness to practise*.

promptly and adequately in line with their workplace policy and our more detailed ethical guidance on *Raising and acting on concerns about patient safety*.[28] I provided further details on the revised version of *Good medical practice* in my first statement.[29]

32. *Raising and acting on concerns about patient safety* says, 'All doctors have a duty to raise concerns where they believe that patient safety or care is being compromised by the practice of colleagues or the systems, policies and procedures in the organisations in which they work. They must also encourage and support a culture in which staff can raise concerns openly and safely.'[30]

33. We would also consider the extent of any departures from our supplemental guidance on the professional duty of candour referenced in my first statement to the Inquiry.[31]

34. Further information on how we assess concerns can be found either on our website or in our guidance for decision makers on deciding whether an investigation is needed.[32]

35. If it is determined that our threshold is met in respect of a concern then it is promoted for full investigation. At the conclusion of our investigation our Case Examiners[33] will consider what, if any, action is needed. Such action will depend on the seriousness of the concern and whether the doctor poses a current and ongoing risk to one or more of the three parts of public protection. We may therefore need to take action if a doctor's behaviour poses a risk to patient safety,

[28] GMC, *Good medical practice*, paragraph 76, (2024).
[29] Witness Statement of Charles Hamilton Massey, 8 March 2024 (MAHI – STM – 210 – 1) paragraph 43.
[30] GMC, *Raising and acting on concerns about patient safety*, paragraph 7, (2012).
[31] Witness Statement of Charles Hamilton Massey, 8 March 2024 (MAHI – STM – 210 – 1) paragraph 51.
[32] How we assess and respond to fitness to practise concerns.
[33] **Case Examiners** are our fitness to practise statutory decision makers. They comprise both medical and non-medical members in various fields and their primary role is to make a decision at the end of a fitness to practise investigation. They can also assist with the investigations process and make recommendations on the progression of a case. At the end of an investigation the case examiners must decide unanimously on an appropriate outcome based on the evidence according to the relevant burden of proof, taking into account our statutory objective to protect the public.

to public confidence or to the professional standards and conduct expected of doctors.

36. As outlined in my first statement, we can give doctors a warning when their behaviour or performance has significantly departed from the standards expected and should not be repeated, but when restricting a doctor's practice is not necessary. In certain cases, we can agree undertakings with the doctor about their future practice (for example, limiting a doctor's practice in some way or restricting the doctor to only working while supervised). We can also refer the concern to the Medical Practitioners Tribunal Service ('MPTS') to arrange a medical practitioners tribunal ('MPT'). Where a referral to a MPT is made, further evidence may need to be gathered prior to the hearing.

37. At the MPT hearing, if a doctor's fitness to practise is found to be impaired, the MPT then decide whether to impose a sanction, and if so, what sanction to impose. MPTs have the power to restrict a doctor's registration by way of conditions or suspension and, in the most serious cases, can remove a doctor's registration. We provide sanctions guidance for MPT.[34]

Q6. How did GMC work with other regulators to protect the public prior to 2023? Has MAH been discussed at the Northern Ireland Joint Regulators Forum?

38. The GMC regulates doctors as one part of a much wider healthcare and regulatory system. This includes, but is not limited to, other professional regulators (such as the Nursing and Midwifery Council); system and quality assurance regulators which regulate and inspect healthcare providers (in Northern Ireland, the Regulation and Quality Improvement Authority – ('RQIA')); healthcare providers themselves; and individual regulated professionals. These separate elements or layers must be individually robust, collaborate and share information effectively for regulation to work properly.

[34] Sanctions guidance: for members of the medical practitioners tribunals and for the General Medical Council's decision makers.

39. We collaborate closely with other health and social care regulators throughout the UK and internationally. We have offices in England, Northern Ireland, Scotland, and Wales. Through them we build and maintain relationships with relevant organisations and partners, including professional associations, regulators, health bodies, and government departments. This helps us be clear on the differences between the UK's healthcare systems, hear the views of our stakeholders, and develop relevant policy and guidance.

40. We have continuously taken steps to improve collaboration with other regulators and to ensure the collective ability of healthcare regulators to respond to emerging concerns and support effective local clinical governance. For example, I highlighted our work on the Northern Ireland Joint Regulators Forum ('the Forum') in my first statement to the Inquiry.[35] The Forum is comprised of several regulators and enables regulators to share information to improve the identification of patient safety issues; support continuous improvement; and inform policy development within healthcare systems.

41. I also mentioned that we participated in an exercise held by the RQIA to scope a framework for sharing intelligence among regulators of health and social care in Northern Ireland ('the Framework'), and commented on their proposed model for an emerging concerns protocol for Northern Ireland. Along with members of the Forum we are a signatory of the Framework which launched on 1 May 2024. We welcome the development of this process for health and social care regulators to share information and improve collective consideration of issues at an early stage.

42. We have over 160 data sharing agreements, around 35 Memoranda of Understanding, and 25 joint working operational protocols in place with organisations across the UK. These organisations include system and quality assurance regulators, public protection bodies, NHS agencies and others, to share knowledge and escalate emerging concerns to reduce patient safety incidents.

[35] Witness Statement of Charles Hamilton Massey, 8 March 2024 (MAHI – STM – 210 – 1) paragraphs 39-42.

43. We commenced a memorandum of understanding with RQIA in January 2014 and it was reviewed and renewed in October 2021. Our agreement is to share information around concerns or information about a healthcare organisation where doctors practise or are trained, and any concerns or information about a doctor which may call into question their fitness to practise. In addition, our agreement also covers any concerns or information about an organisation that may call into question the organisation's suitability as a learning environment for medical students or doctors in training.

44. As Chief Executive of the GMC, I also meet regularly with the chief executives of the other UK health professional regulators to discuss areas of mutual concern and collaboration.

45. Since 2012 and the introduction of revalidation, our outreach team has worked across the UK in frontline care, to explain how our processes work and promote our standards. Our outreach advisers[36] also help us make sure our approach to regulation is well informed. They achieve this by working with doctors, healthcare providers, educators, and other regulators to:
    - improve understanding of the role and value of the GMC;
    - promote and support excellence in medical education, training, and practice;
    - learn about the environments in which doctors practise to identify and address risks to patients and doctors before harm occurs;
    - work with ROs to address concerns about doctors and support management of concerns at a local level;
    - support the continuous development of local clinical governance systems.

46. I answer the second part of this question in my response to question eight of this statement.

Q7. How should employers investigate concerns about doctors before considering a referral to the GMC?

[36] Our outreach team include the ELAs referred to earlier in this statement.

47. Our outreach team works across the four countries of the UK to improve understanding of our regulatory role and when fitness to practise action is necessary. They discuss concerns and, where appropriate, support employers to address them at a local level before anything is referred to us.

48. We regularly promote our guidance to support employers and ROs when they are considering raising a concern with us. It explains that they must tell us:
    - about all the steps they have taken to make sure referrals are fair and inclusive;
    - what checks have been carried out to ensure local investigation processes were impartial and how they have considered whether systemic issues might have played a part in a concern;
    - what support they have provided locally to the doctor in question; and,
    - what induction international medical graduates have received, so they understand what is expected if things go wrong.

49. I provided an overview of when and how we investigate concerns about doctors and how concerns can be raised in my first statement to the Inquiry.[37] We have updated our approach to investigations, so that we no longer open a case where there is an ongoing local investigation and no immediate risk to public protection requiring an interim order[38] to restrict or suspend the doctor's registration pending further investigation. In cases where no immediate GMC action is necessary, we wait for the outcome of local processes before opening a case.

50. We have strengthened how we share information with employers on the outcomes of investigations. This helps build awareness and understanding with ROs and employers about what we can and cannot investigate.

51. We continue to work with partners to help make sure local investigation processes are fair and consistent. We are capturing examples of good practice in local

[37] Witness Statement of Charles Hamilton Massey, 8 March 2024 (MAHI – STM – 210 – 1) paragraphs 60-74.
[38] **Interim orders tribunals** decide if a doctor's practice should be restricted, either by suspension or imposing conditions on their registration, while an investigation takes place. At any point during our investigations, the GMC can refer a doctor to an interim orders tribunal at the MPTS.

complaint handling and we are exploring how we can share these to encourage organisations to embed them in their own local processes.

Outreach and referral of concerns at the local level

52. In 2012, we set up a team of ELAs to facilitate more effective working between the GMC and healthcare providers, predominately in connection with fitness to practise and revalidation.

53. ELAs work in partnership with employers to improve patient safety and ensure high standards of medical practice through:
    - providing advice on GMC thresholds and revalidation recommendations;
    - improving the quality and fairness of fitness to practise referrals; and
    - encouraging robust local investigation of concerns, managing risks to patient safety, and clinical governance.

54. One of the primary roles of an ELA is to provide ROs with advice on whether the thresholds for referral of concerns to the GMC are met. The role of the RO was established by the UK government to enhance the effectiveness of local handling of concerns. Our ELAs work closely with ROs to support effective local handling and referral to the GMC in appropriate cases. New legislation on 13 December 2023 allowed for the statutory regulation of physician associates and anaesthesia associates by the GMC under a new framework. When the legislation comes into force on 13 December 2024, it will, amongst other things, further support local handling of concerns in appropriate cases. This legislation provides the template for future reforms for the regulation of doctors.[39]

[39] We have been working with government on wide-ranging reforms to the legislation governing professional regulation. The first part of these reforms was laid before the UK Parliament in December 2023 and will bring physician associates and anaesthesia associates into a new model of statutory regulation under the GMC. This model is expected to provide the statutory template for reforms to the regulation of doctors and other regulated healthcare professionals over the next few years. The new statutory framework is intended, among other things, to provide greater operational flexibility for regulators, support better co-operation between regulators and the wider system, and adopt a more agile, compassionate, and less adversarial approach to regulation.

55. Many local concerns do not result in a referral to the GMC, but our guidance emphasises that ELAs are there to offer advice and support at any stage. We have published RO referral guidance,[40] which includes:
    - what ROs should consider before making a referral;
    - details of the referral form which they are strongly encouraged to use;
    - the steps they must take when making a referral;
    - factors they need to consider in the process to ensure the referral is fair;
    - specific considerations relating to any doctors who have raised patient safety concerns;
    - encouraging ROs to seek advice from their ELA on how to proceed if a doctor connected to their organisation appears to have reached, or be close to, any of the thresholds.

56. When filling out a referral form, we ask ROs to include information such as the doctor's details, an account of the events or incidents with dates, copies of any relevant papers and/or any other evidence. They are also expected to provide details of any local action that has been taken already.

57. Once they have filled out the form and are ready to make their referral, we ask ROs to make a referral declaration. This confirms the referral was made in good faith, based on the information available at the time, and that the RO has taken reasonable steps to ensure that the information contained is accurate and fair.

58. Our thresholds guidance aims to provide clarity for ROs, medical directors and others involved in the employment, contracting and management of doctors about what matters we can and cannot take action on.

59. Paragraphs 9 and 28 of our RO referral guidance[41] state:

    '(9) Our employer liaison advisers are expert in advising on whether a doctor should be referred to the GMC. We always ask that you seek their advice when

[40] GMC, *RO Referral Guidance*, (2024).
[41] GMC, *RO Referral Guidance*, (2023).

concerns arise and before making a referral, unless delaying the referral would present an imminent risk to patient safety […].

(28) Our employer liaison advisers are available to help you and your team understand our thresholds and procedures by providing support and advice at any stage, on a wide range of issues. If you have concerns about a doctor or a query about our thresholds or procedures, you should discuss this with your designated employer liaison adviser at the earliest opportunity. If a doctor connected to your designated body or working for or contracted by your organisation appears to have reached, or be close to, any of the thresholds you must contact your designated employer liaison adviser for advice on how to proceed.'

60. The role of the RO when making referrals is set out at paragraph three[42] and states:

'(3) The *Responsible Officer Regulations* give you responsibility for the evaluation of the fitness to practise of every doctor with a prescribed connection to your designated body. Additionally, doctors have a duty to protect patients under *Good medical practice.* If a concern is raised about the fitness to practise of a doctor connected to your designated body (that is if you believe that a doctor's behaviour poses a risk to patients, public confidence in the profession or to proper professional standards and conduct), you have a responsibility to take all reasonable steps to investigate those concerns, and where appropriate, refer those concerns to us.'

61. The ELA maintains a relationship with the RO through regular meetings and responds to ad-hoc requests for support. The frequency of these meetings depends on a range of factors including, but not limited to, the level of experience of the RO, the presence of any concerns or unusual fitness to practise issues or patient safety issues. ROs will discuss with their ELA emerging concerns about doctors that are being handled locally. These discussions provide the RO with an opportunity to discuss local problems, thresholds for referral to the GMC, local management, and patient safety issues.

[42] GMC, *RO Referral Guidance*, (2023).

62. The GMC is not responsible for local clinical governance or investigation processes. We encourage ROs to reflect on the effectiveness of the systems for which they are responsible and local responses to concerns. The responsibility for taking action on issues, whether by referring to the GMC or dealing with the matter locally, sits with the RO. Paragraph eight of the guidance to RO's[43] states:
    - 'you must exercise your professional judgement when considering whether to make a referral;
    - any referral should be made in good faith, based on all the information that is available to you;
    - you should take reasonable steps to ensure that any referral you make is accurate and fair;
    - you may choose to delegate the administration of the referral, but you remain accountable for the referral.'

63. The guidance to ROs[44] also states that they should seek advice from the ELA before making a referral, unless delaying the referral would present an imminent risk to patient safety. To make sure that referrals are accurate and fair ROs may first need to:
    - complete their own local investigation and consider the conclusions;
    - understand the outcomes of any external investigation; and/or,
    - take any other reasonably practicable steps necessary to understand whether the concerns raise a question about the fitness to practise of the doctor.

64. To further enhance our relationship with ROs, we organise reference groups and events to engage with them on a range of issues and provide training where we have identified a gap in knowledge through the outreach team.

Improvements to our fitness to practise processes following the Independent Neurology Inquiry (INI) report

[43] GMC, *RO Referral Guidance*, (2023), paragraph 8.
[44] GMC, *RO Referral Guidance*, (2023), paragraph 10.

65. We have reflected on the recommendations and made improvements to some of our functions since the publication of the INI report in 2022. We are continuing to work with the Department of Health (Northern Ireland) who are leading on the implementation of the Inquiry's recommendations. We have offered our ongoing support for, and contribution to, the work of their Independent Neurology Inquiry Implementation Board. The recommendations for us arising from the report mainly concerned three key themes: raising concerns; revalidation and local clinical governance; and sharing of information related to fitness to practise concerns.[45]

66. For example, the INI recommended that we review our practice in relation to the retention of historical information we hold on individual clinicians.[46] We have committed to reviewing this as part of our programme of regulatory reform. We are also developing, and have consulted on, a new suite of policy guidance to support our decision makers to assess whether a medical professional poses any current and ongoing risk to one or more of the three parts of public protection: patient safety, public confidence and the maintenance of professional standards. We have also identified operational improvements, such as how we can inform a doctor more quickly whether historical information is considered as part of their case. We have since made changes to some of our procedures as a result.

67. The report also recommended that we disclose to ROs all the information we hold about a doctor to enable the RO to make a fully informed judgement about their recommendation for revalidation.[47] We are considering how to improve on this by using our existing 'Notify RO' process, where we close a concern but notify the doctor's RO so that the concern can be considered as part of the doctor's annual appraisal.[48] We have already had initial conversations with ROs from Northern Ireland and in other parts of the UK to understand what information might be helpful. There was general agreement by ROs that there may be value in proportionately sharing more relevant information. We are currently scoping out

[45] GMC response to the Independent Neurology Inquiry Report, (2022).
[46] Recommendation 66 of the INI report.
[47] Recommendation 59 of the INI report.
[48] Guidance for decision makers on Provisional enquiries - Part E – Deciding the outcome of a provisional enquiry.

what additional information we should share with ROs and will update our processes once an approach has been agreed.

68. Finally, the report recommended that the GMC should hold doctors who fail to raise concerns to account. Finally, the report recommended that the GMC should hold doctors who fail to raise concerns to account. Across the four UK countries between 2008-2022, we identified 243 cases where we investigated allegations about doctors which included a failure to report concerns. Of these cases, we took action on 21 doctor's registration which demonstrates that we have and do investigate doctors who fail to report concerns.[49]

Q8. Was MAH ever discussed as a risk to patient safety on the Northern Ireland Joint Regulators forum ('the Forum') either prior to 2017 (if it existed) or post?

69. No. MAH was not discussed as a risk to patient safety at the Forum, however respective members have noted their engagement with the Inquiry. The Forum was established as a platform to share information, new approaches and ideas about improving the impact and effectiveness of regulation. It was not intended to be the mechanism for regulators to discuss specific patient safety incidents.

70. As referenced in my answer to Question 6, along with members of the Forum, we are a signatory of the framework for sharing intelligence among regulators of health and social care in Northern Ireland, which launched on 1 May 2024. Via this framework, members can share information relating to specific patient safety concerns.

71. The Forum was set up in 2014, in response to a recommendation in the Professional Standards Authority's 2012-13 annual report. The report recommended that regulators should consider whether they can learn and improve from each other's practices.[50] The initial Forum primarily focused on public affairs

[49] The actions would have included a warning, undertaking, condition, suspension, or erasure from the register. It may be that these investigations featured additional allegations not related to reporting concerns.
[50] Professional Standards Authority, *Annual Report and Accounts and Performance Review Report 2012-2013*, (2013).

engagement and communications. It ceased to meet regularly in 2017.

72. The Forum was re-established in 2021 with the following membership: RQIA, Nursing Midwifery Council, General Dental Council, Health Care Professionals Council, Pharmaceutical Society of Northern Ireland and General Medical Council.

Q9. What is the current position on the statutory duty of candour in Northern Ireland?

73. The Department of Health (Northern Ireland) is responsible for healthcare policy in Northern Ireland and are best placed to comment on the current position.

74. In our response to the Department of Health (Northern Ireland)'s consultation in August 2021, we expressed our support for a statutory duty of candour for organisations to drive a change in culture required to deliver openness and transparency in the Health and Social Care ('HSC') service.[51]

75. The professional duty of candour we set for doctors and any future statutory duty of candour are mutually reinforcing and should not be viewed in isolation. The duty for doctors outlines how we expect doctors to be open and honest with patients and those close to them. We believe that doctors are best supported to be open when things have gone wrong where there is a strong, just culture, which is crucial to exercising a duty of candour.

76. We welcome the development of the Department of Health (Northern Ireland)'s Being Open Framework, with the focus on routine openness rather than the exceptional circumstances when mistakes may lead to harm or death. Our position is that establishing a network of Freedom to Speak Up Guardians in Northern Ireland would benefit the Being Open Framework. The Freedom to Speak up Guardians network in England supports healthcare organisations to create open and transparent cultures. A similar initiative in Northern Ireland would support the

[51] GMC response to Department of Health (Northern Ireland) consultation on Duty of Candour and Being Open policy proposals, (2021).

implementation of an organisational duty of candour. I include more information on how we interact with the Freedom to Speak Up Guardian system in England in my response to question 10.

How we support raising concerns and enabling a professional duty of candour

77. In my first statement, I provided an overview of the professional standards and more detailed guidance for doctors that explains the professional duty of candour, expectations around discharging the duty, how to raise concerns, and some of the support available to them.[52] This included how we support whistleblowing.

78. Following the INI report and its recommendations, we have either revised existing guidance or introduced new guidance and resources, to support doctors who raise concerns and enable a professional duty of candour.

79. We launched the speaking up ethical hub on our website which includes information and resources to support doctors to raise concerns within their organisations. We also signpost to our existing confidential helpline on the hub. Doctors can use the confidential helpline to raise concerns, including when they have concerns about colleagues.[53]

80. We have also reinforced the expectations around a doctor's professional duty to report concerns as part of the implementation of the updated version of *Good medical practice* (2024). This version emphasises the role of all doctors in helping to create cultures where all staff can ask questions, talk about errors, and raise concerns safely. There is also a new duty for those in leadership positions to take active steps to create such cultures, and to act on concerns when raised.

81. Implementation of the updated professional standards has included a range of communication methods including through an e-bulletin which goes out to all doctors on our register, trade and national media, social media, video content, and

[52] Witness Statement of Charles Hamilton Massey, 8 March 2024 (MAHI – STM – 210 – 1) paragraphs 51-54.
[53] Speaking up ethical hub.

features in content from other healthcare organisations. We run events at every RO Network and have engaged with over 9000 doctors so far in 2024 to raise awareness of the new standards. Our ELAs also regularly speak with ROs to explore progress with implementation.

82. Our outreach teams will continue to deliver targeted sessions on raising concerns to doctors in Northern Ireland and work actively with them to bring about the open cultures we want to see.

Q10. What evidence is there that the Freedom to Speak up Guardian system is working in England?

83. The Freedom to Speak Up process is managed by the National Guardian's Office ('NGO') in England. The NGO leads, trains and supports the network of Freedom to Speak Up Guardians in England and provides challenge and learning to the healthcare system on matters related to speaking up. They also collect and publish statistics on speaking up in England. Since the establishment of the National Guardian the Freedom to Speak Up Index has continued to show improvement in England.[54]

84. We work with the NGO nationally and engage with local processes to support the system. We hold relationships with the NGO and Freedom to Speak Up Guardians across England, many of which join our Regional Liaison Advisers ('RLA')[55] at workshops where they can introduce themselves, their role and how they can support doctors to raise concerns within their organisation. RLAs also routinely promote Freedom to Speak Up and the Guardians when delivering workshops. I described the other ways our outreach team support doctors at the local level, including the Professional Behaviour and Patient Safety Workshops that we run across the UK, in my first statement to the Inquiry.[56]

[54] National Guardian's Office, *Freedom to Speak Up Index*, (2021).
[55] RLAs are part of our outreach team and work alongside the ELAs referred to earlier in this statement.
[56] Witness Statement of Charles Hamilton Massey, 8 March 2024 (MAHI – STM – 210 – 1) paragraph 58.

85. Since the National Guardian role and local Freedom to Speak Up Guardians were established, our outreach teams have fostered a relationship with both the central office and at regional level. We are also part of the Speak Up Partnership Group ('the Group').

86. The Group was brought together by the NGO 'to develop an aligned, consistent and supportive response when workers speak up to them.'[57] In 2023 the Group coproduced a set of speaking up principles to strengthen consistency in how regulators respond to workers who speak up.[58] The group also enables regulators to share good practice. For example, the NGO asked us to showcase our speaking up ethical hub and processes for capturing and following up intelligence.

87. The Group also identified themes that may require a speaking up review and as part of this, identified the disparity experienced by internationally qualified workers speaking up as compared to UK qualified colleagues. As a result, the NGO has commissioned an expert advisory group, which we sit on, to improve speaking up for overseas trained workers.

88. Dr Jayne Chidgey Clarke, the current National Guardian for Freedom to Speak Up in England, also gave a presentation to our Council. Dr Chidgey Clarke shared some of the barriers to speaking up and the role of regulators in understanding these.

Q11. Is the GMC aware of any complaints against doctors generated through the freedom to speak up guardian system? If so, how many and with what result?

89. Our electronic case management system in fitness to practise does not currently record if a complaint about a doctor was generated through the freedom to speak up guardian. Therefore, we are unable to provide an accurate figure for the number of complaints that we have received in this way.

[57] National Guardian's Office, *Making Speaking Up business as usual: annual report*, page 35, (2022).
[58] Further information can be found at: Principles - National Guardian's Office.

90. We do hold information on the number of whistleblowing disclosures we receive. I shared in my first statement to the Inquiry that we produce an annual whistleblowing report[59] with the other professional health regulators.[60] Between 1 April 2022 and 31 March 2023, we received 48 disclosures and regulatory action was taken in 47 cases and the other case was referred to an alternative body.[61]

Declaration of Truth

91. The contents of this witness statement are true to the best of my knowledge and belief. I have produced all the documents which I have access to and which I believe are necessary to address the matters on which the Inquiry Panel has requested me to give evidence.

Signed:

Date: 28 June 2024

[59] A copy of the report can be found at: Healthcare regulators annual whistleblowing report published.
[60] Witness Statement of Charles Hamilton Massey, 8 March 2024 (MAHI – STM – 210 – 1) paragraph 36.
[61] *Whistleblowing disclosures report 2023: Health and social care professional regulators*, (2023).