

Witness Name: Charles
Hamilton Massey
Statement No.: 1
Exhibits: CM/1 –
INQ0007321 to CM/33 –
INQ0007344
Dated: 4 March 2024

THIRLWALL INQUIRY

WITNESS STATEMENT OF CHARLES HAMILTON MASSEY

I, Charles Hamilton Massey, of the General Medical Council, 3 Hardman Street, Manchester, M3 3AW, will say as follows: -

1. My name is Charles Hamilton Massey. I am the Chief Executive and Registrar of the General Medical Council ('the GMC'), and I have held this role since 1 November 2016.
2. I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 6 November 2023 and a request under section 21 of the Inquiries Act 2005 dated 15 December 2023.
3. This is my first witness statement for the Thirlwall Inquiry ('the Inquiry') into the events at the Countess of Chester Hospital ('CoCH') and their implications.

About the GMC and our response to the Inquiry

4. The GMC is the independent regulator of doctors in the UK. We work with doctors, their employers, their educators, and others to:
 - a. set the standards of patient care and professional behaviours doctors need to meet;
 - b. make sure doctors get the education and training they need to deliver good, safe patient care;
 - c. check who is eligible to work as a doctor in the UK and check they continue to meet the professional standards we set throughout their careers;
 - d. give guidance and advice to help doctors understand what is expected of them;
 - e. investigate where there are concerns that patient safety, or the public's confidence in doctors, may be at risk, and take action if needed.
5. The UK government has recently brought forward legislation that will extend our remit to include the regulation of physician associates and anaesthesia associates. This will come into force towards the end of 2024.

6. The GMC is independent of government and the medical profession and accountable to Parliament. Our powers are given to us by Parliament through the Medical Act 1983 ('the Act'). The Act sets out the requirements for us to publish and submit to the Privy Council an annual report, annual fitness to practise statistics, and a strategic plan.¹
7. We welcome the opportunity to contribute information to the Inquiry's investigation into the events at the CoCH as well as consideration of wider factors involved with keeping babies in hospital safe. We would like to extend our deepest sympathies to all the families and healthcare staff affected by these tragic events. We remember the babies who sadly lost their lives or were harmed by the terrible crimes committed by Lucy Letby.
8. This statement sets out the following information:
 - a. **Section one:** an overview of the GMC's governance systems and the way we work with partners across the UK.
 - b. **Section two:** our professional standards for doctors to support a culture of raising and acting on concerns about patient safety.
 - c. **Section three:** how we protect patients by listening to their concerns and taking action where necessary and an overview of our fitness to practise data relating to the events at the CoCH.
 - d. **Section four:** our reflections on the key themes in the Inquiry's Terms of Reference and suggestions to address these issues.

Section one: an overview of the GMC's governance structures and the way we work with partners across the UK

Our governance structures

9. Our current powers and duties are contained in the Act and in statutory rules and regulations. The GMC is a corporate body and is registered as a charity with the Charity Commission in England and Wales and the Office of the Scottish Charity Regulator. The GMC's activities in Northern Ireland do not currently fall under the auspices of the Charity Commission for Northern Ireland.
10. Our current corporate structure can be separated into three main areas: Council governance, executive governance, and formal engagement. We have provided a summary of these areas below. Further details on our current governance structure can be found in our governance handbook (2023) at exhibit one [CM/1 – INQ0007321]. We have attached tables depicting our structures from 2013 to present at exhibit two [CM/2 – INQ0007329].

¹ Section 52(A) of the Act.

Council governance

11. Council is the governing body of the GMC and it sets the strategic direction of the organisation. It holds the Chief Executive and their team to account for the proper management of the GMC and ensuring that the GMC fulfils its statutory and charitable purposes. The Council comprises 12 members, six of whom are doctors and six of whom have no medical background. Members of Council, including the Chair, are appointed by the Privy Council through a process which follows the Professional Standards Authority's guidance for making appointments to healthcare regulatory bodies. This guidance incorporates principles based on those identified by the Commissioner for Public Appointments.
12. Council members are members of three committees that advise Council on a number of areas including audit and risk, remuneration, and investment.
13. The Medical Practitioners Tribunal Service ('MPTS')² statutory committee is responsible for providing a hearings adjudication service when, following investigation by the GMC, there are allegations that a doctor's fitness to practise is impaired. The MPTS is operationally separate from the investigatory role of the GMC. The committee oversees the delivery of the hearing service for doctors and ensures that the hearings service meets its responsibilities under the Act. It is led by the chair of the MPTS and four other appointed MPTS Committee members (two medical and two non-medical).

Executive governance

14. The GMC's executive takes forward the operational work of the organisation in line with our statutory purpose, and according to the strategic aims, business plan, policies and schedule of delegated authority agreed by Council. The executive team comprises of the Chief Executive and the directors. The Chief Executive is responsible for the performance of the executive and is accountable to Council.
15. The Chief Executive chairs the Executive Board. The Executive Board is a decision making and oversight forum established to provide strategic direction, scrutiny, and reporting to Council by the GMC's senior management team³ on significant policy, strategy, finance, performance, operational delivery, and resource management issues. Its work is reported

² The MPTS is an independent tribunal service which makes independent decisions about whether doctors are fit to practise medicine. They are separate from the investigatory role of the GMC. They are overseen by a committee and their role is defined by legislation.

³ The senior management team is comprised of directors from each of the GMC's directorates, including: corporate; education and standards; fitness to practise; registration and revalidation; resources; strategic communications and engagement; and strategy and policy.

to Council through the Chief Executive's reports and an annual report on the Board's activities.⁴

Formal engagement

16. We seek advice and discuss the work that we do by engaging with key healthcare stakeholders through bilateral conversations and through our advisory forum meetings. In our UK-wide advisory forums which meet twice yearly in Northern Ireland, Scotland, and Wales, we seek advice on the work we do and try to understand how people experience our regulation on the ground. We use this information to reflect on how we can continuously improve our work.⁵
17. Our Strategic Equality, Diversity, and Inclusion ('ED&I') Advisory forum provides us with the opportunity to listen and respond to the experiences of doctors from a diverse range of backgrounds and interests. Membership of the forum includes organisations that represent doctors who share protected characteristics. The forum helps us meet our ED&I objectives by:
 - a. raising relevant issues and concerns to allow us to develop appropriate responses;
 - b. commenting and advising on the development of our policies and strategies to enable us to be a fair regulator; and
 - c. seeking views on, and raising broader awareness of, our priorities and progress.
18. The Education Advisory Forum helps us engage widely and effectively with our key interest groups on education, training, and assessment matters, ensuring we can best develop and promote a strategic approach to this work across all countries of the UK.
19. We also have an Advisory Forum on GMC Procedures and Doctors' Health, which was set up to provide expert advice to the Executive Board on how we engage with vulnerable doctors in GMC processes.

Changes to our governance structures during the relevant period

20. We have made several changes to our governance structures during the relevant period (2015 to present).
21. Changes from 2019 to 2021 included formally adding the Senior Management Team and Programme Boards to our Executive Governance, as well as including Strategic ED&I and GMC Procedures and Doctors' Health to our advisory forums.
22. Our 2017-2019 governance structure included the Board of Pension Trustees. The Board was previously shown as part of our governance structure, but as the GMC Staff

⁴ Copies of each of these reports can be found on our website.

⁵ Further information on each of our individual forums can be found on: <https://www.gmc-uk.org/about/how-we-work/governance/advisory-forums>.

Superannuation Scheme is a separate entity, it is no longer shown as part of it. Some Council members continue to serve on the Board.

23. Our 2013-2017 governance structure included the Strategy and Policy Board, the Assessment and Advisory Board, and the Performance and Resources Board as part of our Executive Governance. These were replaced by the Executive Board in April 2017. The Strategy and Policy Board and Performance and Resources Board were replaced by the Executive Board in 2017 to promote collective executive decision-making by the senior management team. The structure makes sure that the Chief Executive leads significant discussions on strategy, policy, performance, and risk.
24. The 2013-2017 governance structure also included advisory boards on assessment and revalidation and education and training, with the latter only continuing after 2017 in the form of an advisory forum. The assessment and revalidation forums were disestablished once the policy they advised on had been implemented.

GMC and the wider healthcare systems: collaborating with stakeholders

25. 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); systems regulators which regulate and inspect healthcare providers (in England, the Care Quality Commission); healthcare providers themselves; and individual regulated professionals. For regulation to work properly these separate elements or layers must be individually robust and collaborate and share information effectively.
26. 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.
27. 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.⁶
28. 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.

⁶ 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.

These organisations include system regulators, public protection bodies, NHS agencies, and others to share knowledge and escalate emerging concerns to reduce patient safety incidents.

29. One of these initiatives, the Emerging Concerns Protocol, is an agreement to provide a mechanism for organisations with a role in the quality and safety of care provision to share information that may indicate risks to people who use services, their carers, their families, or healthcare professionals.⁷ Areas of information sharing include: concerns about individuals or groups of professionals; concerns about healthcare systems and the healthcare environment (including the learning environments of professionals); and concerns that might have an impact on trust and confidence in professionals or the healthcare professions generally. This agreement was introduced in 2017 and was reviewed in January 2023.
30. We are also part of a shared data platform with the Nursing and Midwifery Council ('NMC') and the Care Quality Commission ('CQC') to identify risks in maternity departments to tackle patient safety concerns. This includes registration, fitness to practise, education, inspection, and maternity related data. We identified the latter as a priority risk area. A joint database is now in place to pool data about places and registrants to support risk analysis, share data, and identify concerns. This provides a small number of indicators about maternity departments in England that, used as part of a wider suite of data and intelligence, can help us identify areas of potential regulatory concern. At the time of writing, we are considering next steps for its development which will include considering disparities in fitness to practise referrals between cohorts of nurses and doctors and whether specific locations tend to see greater disparities.
31. The Joint Oversight Group framework provides a forum for healthcare regulators (including the CQC and NMC), NHS England, and NHS Improvement to share and discuss intelligence on emerging risks to patient safety and to develop common approaches to address them.
32. 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.
33. Our corporate strategy says that we will 'work with diverse groups of patients and members of the public to shape our work, so we can continuously improve our interactions and processes.'

⁷ Signatories to the protocol include: the GMC, the Care Quality Commission (CQC); the General Dental Council (GDC); the General Pharmaceutical Council (GPhC); the Health and Care Professions Council (HCPC); NHS England; the Local Government and Social Care Ombudsman; the Nursing and Midwifery Council (NMC), and the Parliamentary and Health Service Ombudsman.

34. We use a range of tools to involve patients in our work, including commissioning independent research, conducting public consultations, and bringing together patient organisations from around the UK twice a year at our patient roundtables to discuss our emerging thinking about our policies and services. We also provide support for our policy staff to enhance their approach to public and patient involvement in policy development. We have a team that is dedicated to supporting patients when they make a complaint about a doctor⁸ and we are investing in new technology that will help us monitor patients' experiences of receiving help and support from our contact centre. We are committed to improving our involvement of patients and the public in policy development, the experience they have of our services, and our engagement with them through the organisations and networks that represent their needs and interests.
35. In frontline care, our outreach team works across the UK to explain how our processes work and promote our standards. The team also collaborates with service providers to understand the issues faced at a local level. Our outreach advisers 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:
- a. improve understanding of the role and value of the GMC;
 - b. promote and support excellence in medical education, training, and practice;
 - c. learn about the environments in which doctors practise to identify and address risks to patients and doctors before harm occurs;
 - d. work with responsible officers⁹ ('RO') to address concerns about doctors and support management with concerns at a local level;
 - e. support the continuous development of local clinical governance systems.
36. Further information about the role of our outreach team and how they support doctors and protect patient safety is in section three of this statement.

Section two: our professional standards for doctors to support a culture of raising and acting on concerns about patient safety

37. Our standards define what makes a good doctor by setting out the professional values, knowledge, skills, and behaviours required of all doctors working in the UK. We work closely with doctors, patients, groups representing their interests, and other stakeholders to develop and agree on the professional standards.

⁸ Further information on how patients are supported when they raise a complaint about a doctor is in section three of this statement.

⁹ A responsible officer is an experienced senior doctor. They are responsible for making sure their doctors review all their work each year at an appraisal and they take action if there are any serious problems.

38. Within our guidance, we make clear that all doctors, whatever their role or level, have a professional duty to promote and encourage a culture that allows all staff to raise concerns openly and safely. Prompt action must be taken by doctors if there are concerns that patients may be put at risk by the practice of colleagues, or as a result of any organisational systems, policies, and procedures.

Good medical practice

39. During the events at the CoCH, *Good medical practice* (2013) exhibited at [CM/3 – INQ0007314], was the document which set out our core professional standards and described what is expected of all registered doctors. Over the past couple of years, we have worked with doctors and other healthcare professionals, patients, relatives and carers of patients, and stakeholder organisations across the UK to update *Good medical practice*. A revised version of the guidance was published in summer 2023 and came into effect on 30 January 2024. This is attached at exhibit four [CM/4 – INQ0007315]. We expect doctors to use their professional judgement and expertise to apply the principles outlined in the guidance to the various situations they might face. The guidance includes doctors' responsibility to raise concerns and respond to risks and issues that could impact the safety of their patients. We do not publish a separate code of conduct for our registrants.
40. Our professional standards highlight that 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. Doctors must promote and encourage a culture that allows all staff to raise concerns openly and safely. They must take prompt action if they think that patient safety, dignity, or comfort is or may be seriously compromised. This expectation includes:
- a. immediately telling someone who is in a position to act right away if a patient is not receiving basic care to meet their needs;
 - b. raising concerns in line with our guidance (further outlined below) and their workplace policy if patients are at risk because of inadequate premises, equipment, other resources, policies, or systems;
 - c. asking for advice from a colleague, their defence body, or the GMC if they have concerns that a colleague may not be fit to practise and may be putting patients at risk. They must report this in line with our guidance and their workplace policy if they are still concerned.

41. Doctors also need to record all steps that they have taken in raising concerns under points (b) and (c) above.¹⁰
42. The 2024 version of *Good medical practice* [CM/4 – INQ0007315], introduces some new expectations on doctors in relation to responding to safety risks and raising concerns. This document is divided into domains.
43. In domain two of the revised *Good medical practice* [CM/4 – INQ0007315], where we outline the duties of a doctor in relation to their patients, partnership and communication, we have highlighted the need for doctors to act promptly on any concerns that they might have about a patient. We have also strengthened expectations on how all doctors must act on when they have *any concerns* about a patient – or someone close to them – who may be at risk of abuse or neglect or being abused or neglected.¹¹
44. Domain three focusses on colleagues, culture and safety. This introduces a greater emphasis on the important role that doctors have to create a working and training environment that is compassionate, supportive, and fair, where everyone feels safe to ask questions, talk about errors, and raise concerns.
45. It also states that if a patient is not receiving basic care to meet their needs, all doctors ‘*must act*’ to make sure the patient is cared for as soon as possible. For example, by asking ‘*someone who delivers basic care to attend to the patient straight away.*’¹² This is an improvement from the 2013 version which stated that, under the same circumstances, all doctors were under a duty to immediately ‘*tell someone*’ in a position to act.
46. 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* [CM/4 – INQ0007315], 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 promptly and adequately in line with their workplace policy and our more detailed guidance on *Raising and acting on concerns about patient safety* which is available at [CM/5 – INQ0007316].¹³

More detailed ethical guidance

¹⁰ GMC, *Good medical practice*, paragraphs 24-25, (2013).

¹¹ GMC, *Good medical practice*, paragraph 42, (2024).

¹² GMC, *Good medical practice*, paragraph 75a (2024).

¹³ GMC, *Good medical practice*, paragraph 76, (2024).

47. We have published more detailed guidance that expand upon the principles covered in *Good medical practice*. Those we consider most closely relate to the subjects covered in the Inquiry's Terms of Reference are exhibited to this statement as follows:
- a. *Leadership and management for all doctors* (2012) at [CM/6 – INQ0007317];
 - b. *Raising and acting on concerns about patient safety* (2012) at [CM/5 – INQ0007316];
 - c. *Protecting children and young people: The responsibilities of all doctors* (2012) at [CM/7 – INQ0007318];
 - d. *Good practice in prescribing and managing medicines and medical devices* (2021) at [CM/8 – INQ0007319];
 - e. *Openness and honesty when things go wrong: Professional duty of candour* (2022) at [CM/9 – INQ0007320].
48. Recognising the role that medical leaders have to play in challenging and addressing unprofessional behaviour, we published *Leadership and management for all doctors* [CM/6 – INQ0007317] in 2012. This sets out the wider management and leadership responsibilities of all doctors in the workplace, reiterating that all doctors, whatever their role, must raise and act on concerns about patient safety. Our guidance also sets out that those with leadership and management responsibilities should lead by example, promote, and encourage a culture that allows all staff to contribute and give constructive feedback on individual and team performance, ensuring that there are systems in place to achieve this.¹⁴
49. To reinforce this guidance, we have developed advice, online practical tools, and resources, published on our online ethical hub,¹⁵ to support doctors at various stages of their career. The target audience for these resources includes doctors in leadership positions and those working across multiple settings to raise and act on concerns.
50. Our guidance on *Raising and acting on concerns about patient safety* [CM/5 – INQ0007316] provides advice on raising concerns if patients might be at risk of serious harm. It also sets out the help and support available to the doctor raising a concern and explains doctors' responsibilities when their colleagues or others raise concerns to them. The guidance states that 'If you have a management role or responsibility, you must make sure that: [...] all other staff are encouraged to raise concerns they may have about the safety of patients, including any risks that may be posed by colleagues or teams'.¹⁶ The guidance also outlines some potential obstacles that doctors might experience while raising a concern, including fear that there will not be action taken on the concern or that

¹⁴ GMC, *Leadership and management for all doctors*, paragraph 23, (2012).

¹⁵ Further information can be found at <https://www.gmc-uk.org/ethical-guidance/ethical-hub>.

¹⁶ GMC, *Raising and acting on concerns about patient safety*, paragraph 22(d), (2012).

reporting a concern could damage working relationships. We also provide advice on how doctors can raise their concerns so that they are listened to and to ensure that concerns are acted upon.

51. Protecting children and young people is the responsibility of all doctors. We recognise that child protection is a sensitive and complex issue and can be personally challenging. We publish more detailed guidance on *Protecting children and young people* [CM/7 – INQ0007318] which explores how doctors can ensure that children and young people receive the care and support that they need. The guidance helps doctors know what to do if they identify children at risk of, or suffering from, abuse and neglect. It also encourages doctors to work in partnership with parents and others and provides a framework to follow when they need to share information.
52. Our guidance on *Good practice in prescribing and managing medicines and medical devices* [CM/8 – INQ0007319] sets out our expectation for doctors to report adverse reactions, incidents, and near misses involving medicines and devices via relevant schemes across the UK.

Our guidance on the professional duty of candour

53. In 2015 we published joint guidance with the NMC on *Openness and honesty when things go wrong: the professional duty of candour*. This guidance highlights that every healthcare professional must be open and honest with patients when something goes wrong with their treatment or care, and causes, or has the potential to cause, harm or distress. It also places duties on managers to ensure there are systems and a culture that supports open reporting of adverse incidents. The guidance outlines professional obligations to report a colleague whose working practices and/or behaviour are a matter of concern. The guidance draws on other GMC and NMC guidance, including *Good medical practice*, *Raising and acting on concerns about patient safety*, and *Leadership and management for all doctors*.
54. The guidance was updated in 2022 to reflect the introduction of the statutory duty of candour in England, Scotland, Wales, and the proposals for this in Northern Ireland. We also set out the latest arrangements and terminology for reporting adverse incidents and near misses across the UK. A copy of the guidance is attached at exhibit nine [CM/9 – INQ0007320].
55. It is important for medical students to understand the requirements of candour and raising concerns early on in their education, so we require education providers to promote this. In our standards for medical education and training, *Promoting excellence* (2016) [CM/10 – INQ0007322], we say that, 'Organisations must demonstrate a learning environment and culture that supports learners to be open and honest with patients when things go wrong

– known as their professional Duty of Candour – and help them to develop the skills to communicate with tact, sensitivity and empathy.¹⁷ Similarly, we set expectations for newly qualified UK medical graduates to be able to ‘raise and escalate concerns through informal communication with colleagues and through formal clinical governance and monitoring systems about: patient safety and quality of care; bullying, harassment and undermining.’¹⁸

56. We collect doctors' views and provide an opportunity for them to tell us safely and formally about their experiences of working in healthcare environments across the UK. We have also published a speaking up topic on our ethical hub¹⁹ which contains a toolkit to help doctors tackle unprofessional behaviour and case studies showing the positive impact that raising concerns has on patient safety.

Working with partners to support an open culture

57. We aim to foster a culture in which openness and honesty is the norm and where concerns are shared and acted on as soon as possible. To achieve this, we are working with partners in the health services in England, Northern Ireland, Scotland, and Wales to ensure that doctors at all career stages feel supported to raise and act on concerns.

58. Over the past 12 months, we have delivered 439 sessions to 15,929 doctors, which covered raising and acting on concerns and how to speak up. Our raising and acting on concerns workshops explore our guidance and some practical steps to empower those working in healthcare environments to know when and how to raise concerns. We know that raising concerns is not easy, so we use case studies and practical skills application to help doctors to build their skills in giving feedback, calling out unprofessional behaviour, looking at what they can do to effect change, or where needed, escalating a concern.

59. We hold relationships with the National Guardians Office and Freedom to Speak Up Guardians across England, many of which join our regional liaison advisers at workshops where they can introduce themselves, their role and how they can support doctors in raising concerns within their organisation.

60. We have also run 45 half day Professional Behaviour and Patient Safety workshops for 4,925 doctors this year. These workshops enable doctors to consider and discuss their perceptions of unprofessional behaviours, how to identify them with the use of case studies and consider their impact on patient safety. The sessions also give participants an opportunity to practise using the verbal and behavioural skills needed to challenge these behaviours. We worked closely with a number of medical royal colleges which have run

¹⁷ GMC, *Promoting excellence*, paragraph R.14, (2016).

¹⁸ GMC, *Outcomes for graduates*, paragraph 2.O, (2020).

¹⁹ Further information can be found at: <https://www.gmc-uk.org/professional-standards/ethical-hub/speaking-up>.

initiatives in this area, and with workplace culture experts to design a workshop that gives doctors the space to focus on this important and challenging aspect of their work.

61. We engage with around 45,000 doctors each year. We feel encouraged that 94% of doctors find our workshops very good or good, with 79% reporting that they will change their practice as a result.

Section three: how we protect patients by listening to their concerns and taking action where necessary and an overview of our data relating to the events at the CoCH

When and how we investigate concerns about doctors

62. 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.
63. 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:
- a. protects, promotes and maintains the health, safety and wellbeing of the public;
 - b. promotes and maintains public confidence in the profession;
 - c. promotes and maintains proper professional standards and conduct for members of the profession.²⁰
64. We can act on information we receive from any source that raises a question about a registered doctor's fitness to practise. Common sources of information include patient complaints, referrals from ROs, employers, media reporting, and notifications from the police and other bodies acting in a public capacity.
65. As set out in the Act, we will only take forward a concern if it falls into one of the following:
- a. misconduct²¹;
 - b. deficient professional performance;
 - c. a criminal conviction or caution in the British Isles (or elsewhere for an offence which would be a criminal offence if committed in England or Wales);
 - d. adverse physical or mental health;
 - e. not having the necessary knowledge of English;
 - f. a determination (decision) by a regulatory body either in the UK or overseas to the effect that fitness to practise as a member of the profession is impaired.²²

²⁰ Section 40A(4) of the Act.

²¹ Examples include but are not limited to: sexual assault; violence; improper sexual or emotional relationships; serious clinical concerns; knowingly practising without a licence; unlawful discrimination; dishonesty; gross negligence or recklessness.

²² Section 35C(2) of the Act.

66. We will take action where the matter raised is sufficiently serious to raise a question about a doctor's fitness to practise. There are a variety of ways that we can take action and these are further outlined below. Further information on what we can and cannot investigate can be found on our website²³ and in our GMC threshold guidance available at [CM/11 – INQ0007323].
67. When we receive a concern, we are legally required 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. We do this by considering the following, which is often referred to as an assessment of a doctor's fitness to practise:
- a. a doctor's overall ability to perform their individual role;
 - b. their professional and personal behaviour;
 - c. the impact of any health condition on their ability to provide safe care.
68. As part of assessing fitness to practise concerns, and to reach a decision on whether a doctor poses any risk to public protection, we consider:
- a. 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*. Or, if relevant, it includes considering if a health condition is having an impact on their ability to practise safely;
 - b. any relevant context – we consider any relevant context of which we are aware. By 'context', we mean the specific setting or circumstances that surround a concern;
 - c. how the doctor has responded to the concern.
69. Further information on how we assess concerns can be found either on our website²⁴ or our guidance for decision makers on deciding whether an investigation is needed available at [CM/12 – INQ0007324].
70. We can take action to make sure we protect patients, maintain confidence in the medical profession, and uphold the standards we expect of doctors. We can give doctors a warning when a doctor's behaviour or performance is significantly below the standards expected of doctors and should not be repeated, but when restricting a doctor's practice is not necessary. In certain cases, we can agree undertakings, which are agreements between us and a doctor about the doctor's future practice (for example, limiting a doctor's practice in some way or committing to only working while supervised). We can also refer them to the MPTS, which has the power to restrict by way of conditions, suspend, or erase a doctor's registration in the UK.

²³ Further information can be found at: <https://www.gmc-uk.org/concerns/supporting-you-with-your-concern/can-we-help-with-your-concern>.

²⁴ Further information can be found at: <https://www.gmc-uk.org/concerns/information-for-doctors-under-investigation/fitness-to-practise-explained/how-we-assess-and-respond-to-fitness-to-practise-concerns>.

71. If a doctor's fitness to practise is found to be impaired, tribunal members have to decide whether to impose a sanction, and if so, what sanction to impose. Our sanctions guidance sets out further advice for decision makers available at [CM/13 – INQ0007325].

How patients, families, and the public and employers can raise concerns about patient safety and managing concerns locally

72. Anyone can raise a concern with the GMC. Those raising concerns might include patients or their families, employers, doctors or other healthcare professionals. It is vital that anyone can raise concerns about patient safety promptly, easily, and feel listened to. We provide a range of channels and support (further described below) to help anyone who raises a concern to understand how to disclose information so we can consider whether action needs to be taken.

73. As signalled earlier in this statement, there are many organisations responsible for the health, safety, and wellbeing of patients in England, including employers, the NHS and CQC. Over the past several years, we have received a high number of enquiries from patients and the public that do not meet our fitness to practise thresholds and/or are not issues the GMC can address. For example, since 2017 approximately 23% of complaints raised with us were not promoted to an investigation since they were not about a doctor. Often these concerns do not raise questions about a doctor's fitness to practise and should be more appropriately dealt with locally by the doctor's employer or contracting body.

74. We provide advice for patients, families, and the public on our website²⁵ to make sure that we are the right organisation to deal with their concern. We also signpost to other organisations who may be better suited to help. This includes, where appropriate, the doctor's employer, trust, or other regulators, such as the CQC.

75. To support patients and the public raising their concerns, we have implemented several initiatives, including updating the Local Help pages²⁶ on our website to help patients direct their complaint to the relevant organisation.

76. Patients and the public can raise concerns with us by completing our online form or by speaking to one of our contact centre advisers. We are also able to provide a leaflet to help people decide where and how to raise their concern. This includes information about the support available to them. A copy of this leaflet is included at exhibit 14 [CM/14 – INQ0007326]. If we decide to investigate a concern raised by a patient, we will invite them to a meeting either online or in person at one of our offices in Belfast, Cardiff, Edinburgh,

²⁵ Further information can be found at: <https://www.gmc-uk.org/concerns/supporting-you-with-your-concern/local-help-services/help-services-in-england>.

²⁶ Further information can be found at: <https://www.gmc-uk.org/concerns/supporting-you-with-your-concern/local-help-services>

London or Manchester to explain our investigation process and answer any questions they might have. Once we have finished our investigation, we offer another meeting to talk to the patient about the outcome.

77. Every licensed doctor who practises medicine must revalidate. Revalidation supports doctors to develop their practice, drives improvements in clinical governance, and gives their patients confidence that their knowledge and skills are up to date. The revalidation system is based around the annual appraisal of doctors in the workplace leading to recommendations from the RO, normally every five years, on whether the doctor remains fit to practise. In 2012, we set up a team of Employer Liaison Advisors ('ELAs') to facilitate more effective working between the GMC and healthcare providers, predominately in connection with fitness to practise and revalidation.²⁷
78. ELAs work in partnership with employers to improve patient safety and ensure high standards of medical practice through:
- a. providing advice on GMC thresholds and revalidation recommendations;
 - b. improving the quality and fairness of fitness to practise referrals; and
 - c. encouraging robust local investigation of concerns, performance management, and clinical governance.
79. 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 allows for the statutory regulation of physician associates and anaesthesia associates by the GMC under a new framework. It will, among other things, further support local handling of concerns in appropriate cases. This legislation provides the template for future reforms for the regulation of doctors (further information on regulatory reform is in section four of this statement).
80. Many local concerns do not result in a referral to the GMC, but our guidance emphasises that our ELAs are there to offer advice and support at any stage. We have published RO referral guidance exhibited at [CM/15 – INQ0007327], which includes:
- a. what ROs should consider before making a referral;
 - b. details of the referral form exhibited at [CM/16 – INQ0007328] which they are strongly encouraged to use;
 - c. the steps they must take when making a referral;
 - d. factors they need to consider in the process to ensure the referral is fair;

²⁷ ELAs are now part of our outreach team referred to in section one of the statement.

- e. specific considerations relating to any doctors who have raised patient safety concerns;
 - f. 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.²⁸
81. 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.
82. 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.
83. Our thresholds guidance at [CM/11 – INQ0007323], 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.
84. Paragraphs 10 and 29 of our RO referral guidance at [CM/15 – INQ0007327] state:

'(10) 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 concerns arise and before making a referral, unless delaying the referral would present an imminent risk to patient safety [...] (29) 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.'

85. The role of the RO when making referrals is set out in [CM/15 – INQ0007327] at paragraph three 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.

²⁸ GMC, *RO Referral Guidance*, paragraphs 9-29 (2021).

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.'

86. 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 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.
87. 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 nine of the guidance to RO's at [CM/15 – INQ0007327] states:
- a. 'you must exercise your professional judgement when considering whether to make a referral;
 - b. any referral should be made in good faith, based on all the information that is available to you;
 - c. you should take reasonable steps to ensure that any referral you make is accurate and fair;
 - d. you may choose to delegate the administration of the referral, but you remain accountable for the referral.'
88. The guidance to ROs 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. In order to make sure that referrals are accurate and fair ROs may first need to:
- a. complete their own local investigation and consider the conclusions;
 - b. understand the outcomes of any external investigation; and/or
 - c. take any other reasonably practicable steps necessary to understand whether the concerns raise a question about the fitness to practise of the doctor.

The operation and management of our fitness to practise investigations

89. When we receive a complaint or concern our triage team first identifies whether the concern is about a registered doctor and, if it is, consider whether it meets our threshold for investigation.
90. If the concern does not meet the threshold for investigation, we may consider that the complaint should be disclosed to the doctor and the doctor's RO to be reflected on as part of their workplace annual appraisal (this is called the 'Notify RO process').
91. For some concerns we conduct a provisional enquiry.²⁹ This is done where the issue raised is potentially serious, but we need to gather one or two more discrete and easily obtainable pieces of information or get expert opinion that may resolve the issue. If the concern meets the threshold it is promoted to a full investigation.
92. Full investigations are disclosed to the doctor, the doctor's RO and any other employers or contracting bodies. The nature of the concerns will determine what investigatory steps need to be undertaken. Most commonly these involve obtaining:
- a. expert report(s);
 - b. witness statement(s);
 - c. any other documentary evidence that may be available (e.g. information from police files, health assessments, or local investigation reports).
93. At the conclusion of the majority of investigations, draft allegations are sent to the doctor. Doctors are given 28 days to respond with any comments or supporting evidence that they would like us to be aware of, after which our Case Examiners³⁰ will make a decision. Investigations can be referred to the Case Examiners for a decision without draft allegations being sent to the doctor if, for example, we are unable to collect the evidence to support the concerns raised to us.
94. Where the Case Examiners consider that action is needed this may be through voluntary undertakings by the doctor (referred to in paragraph 65 above), issuance of a warning, or referral of the case to a Tribunal. Where a referral to a Tribunal is made further evidence may need to be gathered prior to the hearing at the MPTS.

A summary of changes made to our fitness to practise process from 2015 to present

²⁹ Provisional enquiries are defined on page 20.

³⁰ The 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.

95. We are continuously looking for ways to improve our fitness to practise processes. We have provided details below of recent changes we think are most relevant to the Inquiry's Terms of Reference.

Supporting vulnerable doctors

96. In 2015, we commissioned Professor Sir Louis Appleby to undertake an independent review to identify how we can improve our investigation process to reduce the impact and stress for doctors, particularly those with health concerns. In response to the review findings, we implemented our safeguarding vulnerable doctors programme. This includes:

- a. coordinating our approach so doctors under investigation have a single point of contact throughout the process;
- b. new guidance for staff to help them recognise signs that a doctor may be unwell and manage interactions with doctors displaying challenging behaviour;
- c. establishing a specialist team to handle cases where doctors are unwell, with a process to pause an investigation to allow a very unwell doctor to get treatment;
- d. introducing procedures to identify and address health concerns more quickly and reduce the number of unnecessary investigations through the effective use of provisional enquiries.

Expansion of the provisional enquiries (PE) process

97. A provisional enquiry involves obtaining limited, targeted information at triage to help inform a decision about whether the concern raised amounts to an allegation that a doctor's current fitness to practise is impaired and therefore requires a full investigation. This helps us to be proportionate in our regulatory activity and mitigate the risk of unfairness, for example to prevent employers using our fitness to practise procedures to retaliate against whistleblowers. The use of provisional enquiries was tested in a pilot in 2014 and subsequently implemented soon after. It has been extended in phases from 2015 onwards.

98. We now undertake provisional enquiries where:

- a. the doctor who is the subject of the complaint has a history of whistleblowing³¹;
- b. it is likely that one or two pieces of information can be swiftly obtained which will clarify the seriousness of the matters raised;

³¹ If a concern is promoted for an investigation and we later learn from the doctor that they are a whistleblower, we would focus our investigation on independently corroborating the allegations to avoid unfairly disadvantaging that individual in our procedures. Further information on how we support doctors with whistleblowing can be found in section four of this statement.

- c. the concerns relate to a single clinical incident (one-off clinical mistake) or a single clinical concern (more than one incident about a single patient involving a single course of treatment);
- d. there are concerns about a doctor's health (concerns relate solely to a doctor's health and we need more information about their condition); or
- e. events that arose during the Covid-19 pandemic (concerns relating to a doctor's practice and/or conduct in a clinical setting during the pandemic and the circumstances of the pandemic are likely to be a key factor in explaining the doctor's actions).

Embedding Learning from Sexual Abuse Cases

99. We conducted a review in 2017 of our historic child sexual abuse cases that occurred between 1945 and 2016 in line with current best practice on child protection. We reflected on the wider lessons from the review and in 2018 established the Embedding Learning from Sexual Abuse cases ('ELSA') programme of work to:

- a. improve how we identify, evidence and progress cases involving sexual misconduct and sexual harassment;
- b. improve our support for complainants and vulnerable witnesses to understand and participate in our investigation of sexual misconduct cases, as well as our support for doctors, employers, and our staff in identifying and raising concerns about sexual misconduct and sexual harassment;
- c. raise awareness with our staff, doctors, and the public about our professional guidance and how we deal with cases involving sexual misconduct and sexual harassment.

100. As a result of the ELSA programme we have delivered the following changes to date:

- a. we updated our guidance on anonymous and confidential complaints to ensure a doctor's fitness to practise history is appropriately considered;
- b. we updated our guidance on dealing with complaints relating to events more than five years ago to introduce clear criteria on when it may be in the public interest to investigate. This gives decision makers greater flexibility to consider factors where a complainant may delay reporting their concerns in, for example, cases involving sexual misconduct, harassment or other traumatic events. We also updated our systems to make it easier to track and report these decisions;
- c. we identified areas of good practice in our use of expert reports in clinical cases that involve allegations of inappropriate clinical examinations or behaviour and introduced new guidance to ensure this happens consistently;

- d. in response to new research, which revealed concerns about the extent to which chaperones can protect patients from a doctor under investigation, we updated our guidance on imposing interim orders for the Interim Order Tribunal³² and Medical Practitioners Tribunal. This encourages decision makers to give greater consideration to the circumstances where temporary measures requiring the use of a chaperone (conditions) may not be effective.

Fair to Refer

- 101. In 2019, we commissioned independent research to help us understand why some groups of doctors are disproportionately referred by employers to the GMC. The *Fair to refer?* report pointed to workplace environments and cultures as the causes of this disproportionality. We have committed to eliminating disproportionality in fitness to practise referrals from employers based on ethnicity and place of primary medical qualification by 2026.
- 102. To address inequalities in how concerns are handled at a local level effectively, commitment from employers and other key stakeholders is required. To achieve this, we are making changes to our own procedures and working with our partners to create more inclusive, supportive, and fair local environments.
- 103. We have completed phase one of our programme to support delivery of the target and our activity so far includes:
 - a. fairness conversations with all employers to emphasise their duty to provide supportive and inclusive working environments and to explore how they are implementing the findings of the *Fair to refer?* research;
 - b. changes to our RO referral form, to include additional questions about how employers have considered systemic issues, the support that they have provided locally, and the impartial checks that have been made to ensure the referral is fair and inclusive;
 - c. new training for our staff on the specific risks of bias in employer referrals;
 - d. introduced new feedback channels for employers to share information about the outcome of concerns referred to us at the end of an investigation;
 - e. we are also developing a mechanism to provide feedback to employers about concerns that do not meet our threshold for investigation;

³² 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.

- f. we support NHS Resolution's Being Fair programme which brings together a range of stakeholders to collaborate on ED&I matters and support a just and learning culture;
 - g. we support the work of our partners to standardise local investigation processes and how these might address disproportionality at the early stages of a concern being raised, to avoid unnecessary GMC referrals. For example, we worked with Health Education England (prior to its merger with NHS England) to launch a standardised induction process for international medical graduates in 2022.
104. We also introduced a feedback loop between Case Examiners and our outreach team in May 2022 to identify learning where employer referrals do not meet our criteria to open an investigation at triage. This process helps to identify and share lessons for any ELAs who provided advice and support prior to the referral, and lessons for the employer where referrals were made without advice.

Changes introduced during Covid-19 pandemic which we have permanently retained to enable better use of resources and more targeted regulatory action to protect patients

105. During the pandemic, it was crucial that we continued to protect patients and investigate serious concerns whilst being sensitive to the exceptionally challenging circumstances in which doctors may be working. We also introduced measures to reduce face to face contact to protect everyone involved in our fitness to practise procedures. Some of those changes delivered additional long-term benefits by allowing us to make better use of resources and deliver more targeted regulatory action. For example, the greater use of remote engagement should enable us to progress cases more quickly and improve the accessibility of these meetings by removing the need to travel. As a result, we have decided to permanently embed these changes in our fitness to practise processes. These include:
- a. new guidance for our decision makers on how to take into account the unique context of the pandemic. It also seeks to ensure that decision makers understand and consider the specific context and individual circumstances surrounding a complaint consistently and fairly, together with the wider system or environmental pressures that are beyond a doctor's control;
 - b. expediting how we obtain independent opinion on a doctor's performance and fitness to practise through the introduction of short form performance assessments when appropriate;

- c. holding medical supervision and health assessment³³ appointments remotely to allow for greater flexibility;
- d. transitioning to remote meetings with doctors and GMC staff where we draw attention to the issues we are most concerned about in the case;
- e. changing our triage guidance to enable us to close matters relating to lower level violence or dishonesty that occurred outside professional practice and has been investigated by another body, such as an employer or the police, without formal action being taken. This allows us to have a more flexible and proportionate approach where the doctor's behaviour does not pose a risk to patients, to public confidence in the profession, or to proper professional standards and conduct.

Introductory phone calls between investigation caseworkers and doctors who are the subject of concern

106. To reduce anxiety for doctors who are the subject of a concern, we have put in place a new process where the person dealing with the investigation will first email the doctor to arrange a phone call and introduce themselves as the doctor's contact. Our staff will then explain what the immediate next steps in the investigation will be and signpost the doctor to relevant support services and representation. This is aimed at taking a more compassionate approach to our interactions with those who are subject to our fitness to practise processes and reducing the impact of our investigations on doctors.
107. We then follow up the call with written correspondence confirming the details outlined in the initial call and containing the documentation we currently hold relating to the concerns we are investigating. A bespoke communication plan is also created for the doctor during the call, factoring in their communication preferences. The pilot, carried out last year, found doctors felt more supported when initial phone calls were made. A post implementation review is currently ongoing at the time of writing to ensure the process continues to be effective and tailor our approach where necessary.

Providing ongoing support for people who provide witness statements as part of our investigations

108. Our Legal team introduced the witness needs assessment process in 2017, which is designed to continually assess the communication preferences and/or vulnerabilities of people who provide witness statements as part of our investigations (either in written or oral form). This is particularly valuable for those involved in cases that are referred to a

³³ Medical supervision is how we monitor a doctor's health progression during a period of restricted practice. A health assessment is one part of a wider investigation into a doctor's fitness to practise. It helps us understand any concerns about a doctor's health before considering measures we may need to take to protect patients.

hearing, as these cases generally take longer to resolve and involve more frequent engagement between the GMC and the witness. This new process also aids the transfer of witness contact between investigations and legal colleagues once a decision has been made for an allegation to be referred to a hearing.

Chronology of events related to the CoCH

109. As part of our response to the Inquiry's work, we have conducted an internal review of our fitness to practise data to determine whether we received any concerns or complaints about doctors who worked on the CoCH's neonatal unit between the specified period of June 2015 and June 2016.
110. It is important to note that we do not routinely record or hold details of the units that doctors work on. To answer this question, we carried out a search of all complaints we have received that have a recorded connection to CoCH from 2012 to present. In this context, a recorded connection is defined as the incident location, the referring body,³⁴ the designated body,³⁵ or a doctor's current or previous employment history. Through this, we have not identified any complaints relating to the neonatal unit between 2015 and 2016.
111. We also searched the meeting notes from ELAs assigned to the CoCH between 2012 to 2017. These are recorded centrally in our database. Our records show that concerns about the neonatal unit were first raised with our ELA on 30 September 2016.
112. On 20 July 2018, we received an emailed complaint about Mr Ian Harvey from **I&S** **I&S** supported by a number of consultant paediatricians at the CoCH. Ordinarily we aim to make a triage decision on an enquiry within seven days from opening. However, in some instances the Assistant Registrar will require further information to assist in making the triage decision. In respect of the referral pertaining to Dr Harvey, further information was sought from the complainant to try and understand the concerns raised. This included the Royal College of Paediatrics and Child Health ('RCPCH') service review report and the review conducted by Jane Hawdon on the neonatal unit. These are attached at exhibit 17 [CM/17 – INQ0007312] and 18 [CM/18 – INQ0007313] respectively. The documents were received from the complainant on 8 August 2018 and were considered as part of our investigation.
113. Subsequently, internal advice was sought from a Medical Case Examiner about the concerns raised. A copy of the Medical Case Examiner Advice is exhibited as 19 [CM/19 – INQ0006777]. On the 29 August 2018, an Assistant Registrar made the decision that the complaint should be promoted for investigation.

³⁴ Where the CoCH was the referrer of a fitness to practise complaint.

³⁵ 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.

114. On 10 October 2018, as part of our employer disclosure process³⁶, we contacted the CoCH RO, Professor Susan Gilby. On the same date Professor Gilby advised she had recently taken the role of Chief Executive Officer and directed us to Dr David Semple as RO. Correspondence between the GMC and Professor Gilby and/or Dr Semple is included within the case documents disclosed to the Inquiry in response to their section 21 request, dated 15 December 2023.
115. The GMC's investigation in respect of Dr Harvey coincided with Cheshire Constabulary's investigation into the tragic deaths which occurred at CoCH and the subsequent prosecution of Lucy Letby. As is routine in all investigations where there are, or may be, criminal investigations ongoing, we considered at the outset whether our investigation may need to be paused in light of the ongoing police investigation. On 17 September 2018 we contacted Cheshire Constabulary ('the Police') to understand the scope of their ongoing enquiries. By way of email on 3 October 2018, the Police informed us that they had made an arrest, and they have not, nor would they, confirm the identity of any individual associated with the ongoing investigation. They also confirmed that they were not at this time investigating Dr Harvey or his conduct. A copy of this correspondence is exhibited at 20 [CM/20 – INQ0007330].
116. After our initial contact with the Police, we decided to continue our investigation but faced delays obtaining information to support this. We liaised with the CoCH to obtain relevant documents and liaised with the Police to confirm what was disclosable to us. During this time, we also took steps to obtain a witness statement from [I&S] and an expert report, as referenced at paragraph 117. On 12 May 2021, the Police wrote to us and advised that in light of the ongoing criminal proceedings, the prosecution team would not wish any of their witnesses to be approached by the GMC at this time. A copy of this correspondence is exhibited at 21 [CM/21 – INQ0007332].
117. During the course of our investigation the GMC obtained a witness statement from [I&S] [I&S]. This witness statement is exhibited as 22 [CM/22 – INQ0006890]. The GMC also proceeded to obtain an expert report in respect of the allegations. The initial report, dated 30 September 2020, is exhibited at 23 [CM/23 – INQ0007171]. Documentation was also sought from CoCH, which included a copy the RCPCH report [CM/17 – INQ0007312] and Jane Hawdon report [CM/18 – INQ0007313]. We also received a copy of the draft RCPCH report [CM/24 – INQ0007336]. These documents were received by the GMC on 28 June 2021. A supplemental expert report was then

³⁶ Where we decide to progress a full investigation into concerns raised, we will disclose details of the concerns, including the place of the incident, to the doctor's current employers. If it is relevant and necessary to do so, we will also disclose information to the doctor's previous employers.

subsequently obtained, dated 8 February 2022, and is exhibited at 25 [CM/25 – INQ0007276].

118. Once the investigation was complete, we decided that we did not need to take any action against Dr Harvey's registration. By way of a decision dated 29 April 2022, the case was closed with no further action. A copy of the Case Examiners decision is exhibited to this statement as 26 [CM/26 – INQ0007337].
119. Dr Harvey applied for voluntary erasure from the medical register in February 2020. This was considered under our guidance on making decisions on voluntary erasure applications and advising on administrative erasure. The application was refused given the potentially serious nature of the concerns related to Dr Harvey. Dr Harvey's fitness to practise investigation concluded in April 2022. At the time of writing, Ian Harvey is currently not registered having relinquished his registration as of 17 June 2022. I exhibit here to a copy of Dr Harvey's entry on the GMC's List of Registered Medical Practitioners ('LRMP') as 27 [CM/27 – INQ0007338].
120. The Inquiry has also asked whether concerns were raised with the GMC about any other senior manager who worked at the CoCH between June 2015 and June 2016. From our initial searches, we did not find any complaints against any other senior manager who worked at the CoCH between June 2015 and June 2016. It is important to note that we do not routinely record detailed information about a doctor's role and therefore could not rely on this information to inform our search.
121. Finally, at the request of the Inquiry we conducted further searches of named individuals and the results of these searches were disclosed to the Inquiry in January 2024.

Section four: our reflection on the key themes in the Inquiry's Terms of Reference and suggestions to address these issues

122. Modern professional regulation has a vital role to play in promoting excellent leadership, fostering an open culture, and protecting patients when things go wrong. However, as outlined at the beginning of this statement, effective regulation requires collaboration across national and local bodies to support and strengthen local clinical governance systems, as well as encourage an open and honest culture where patient safety is prioritised.
123. Since 2015, we have received queries or responded to publications on various areas related to the Inquiry's Terms of Reference. This includes the details of the events at the CoCH, our position on whistleblowing and raising concerns, and on the number of times that doctors who raise a concern are subsequently referred to us. Our responses to these queries and publications are contained within various parts of this statement. We have

attached copies of our previous press statements to this statement at [CM/28 – INQ0007339].

Existing structures and governance to support a culture of raising concerns

124. Robust local clinical governance systems are imperative to a flourishing patient safety system. These systems require appropriate quality assurance, effective information sharing, and management and investigation of risk. Previous reviews and public inquiries have identified failings in these systems.
125. Clinical governance is also key to the effectiveness of medical regulation and the system of revalidation in which all practising doctors must participate. The GMC has no formal responsibility in relation to the operation of local clinical governance, but we play a supportive role in the quality and operation of these systems. This is one of the reasons why the interface between our outreach team and ROs described earlier in this statement is so important. It is also why we are keen to support the strengthening of those local systems wherever we can.
126. We are currently reviewing our revalidation guidance to reflect the updated version of *Good medical practice* [CM/4 – INQ0007315]. This includes duties for all medical professionals to be aware of the clinical governance arrangements where they work and to continuously engage with them. We will also soon be publishing an updated Clinical Governance Handbook. A copy of the current Clinical Governance Handbook is exhibited to this statement as [CM/29 – INQ0007340]. [CM/29 – INQ0007340] was first published in 2013 and updated in 2018 following the Taking Revalidation Forward improvement programme.³⁷

Barriers to doctors raising concerns

127. Since 2022, we have included questions in our annual barometer survey around the experience of doctors raising concerns about patient safety and workplace culture. Our data suggests that there is a largely positive picture about the reporting of patient safety and educational concerns for doctors in training. For example, 85% of respondents indicated that they agree or strongly agree that they have been made aware of how to report patient safety incidents and near misses. Meanwhile, three-quarters of respondents (75%) thought that there was a culture of proactive reporting concerns and learning lessons from concerns raised (78%) in their training environments.³⁸

³⁷ The Taking Revalidation Forward improvement programme was created to action the recommendations of an independent review, commissioned by the GMC in 2017, to assess the impact of revalidation after its nationwide implementation in 2012.

³⁸ Further data can be found on the GMC Data Explorer: <https://www.gmc-uk.org/about/what-we-do-and-why/data-and-research/gmc-data-explorer>.

128. Despite this, we highlighted in a recent report that a substantial minority of doctors may be hesitant to raise concerns. While six out of ten (62%) doctors felt confident raising concerns about patient care, almost one out of five did not (18%) and specialists were particularly likely to not feel confident in raising concerns (23%).³⁹
129. Working and learning environments for doctors must be free of bullying and harassment to create a safe environment to deliver patient care. It is the responsibility of healthcare providers and employers of doctors to ensure that they are creating a positive culture where concerns can be raised with confidence. The purpose of this is to ensure that doctors at all stages in their careers do not hesitate to act openly and honestly if something has gone wrong.
130. Despite our work to encourage doctors to raise concerns, we know many remain reluctant to do so. The 2015 review by Sir Robert Francis QC, *Freedom to speak up: an independent review into creating an open and honest reporting culture in the NHS* outlined some of the reasons for this. We are also concerned that independent sector organisations, which do not provide NHS services, are not required to establish freedom to speak up processes or appoint freedom to speak up guardians.
131. Good leadership is crucial in creating a workplace environment where patients' interests are prioritised, and staff are supported in maintaining standards. Our outreach team and devolved offices have picked up significant anecdotal evidence that confidence in raising concerns is not consistent. This highlights the need for leaders to work proactively on ensuring just cultures where concerns can be raised easily, without fear, and where appropriate learning or action can happen. This issue, if not addressed, can have serious consequences for the wellbeing of doctors and the quality of care that patients receive.
132. We are committed to playing our part in engendering a culture of speaking up across the healthcare sector. We have a pivotal role to play in helping to make the health service a place for learning, not blaming.

Supporting whistleblowing

133. Our guidance on *Raising and acting on concerns about patient safety* is clear that doctors must take prompt action if they think that patient safety, dignity, or comfort is or may be seriously compromised. If doctors have concerns about a colleague's ability to carry out their professional duties and believe it may compromise patient safety, our advice is to seek guidance. They may decide to reach out to a colleague, a defence body, or

³⁹ GMC, *The state of medical education and practice: workforce report*, page 30, (2023).

consult the GMC for advice. Alternatively, they may opt to speak to their local NHS Freedom To Speak Up Guardian, if their Trust has one.

134. Doctors who wish to raise a concern about a registered doctor may refer to our *How to raise a concern about a doctor* booklet. A copy of this leaflet is exhibited at [CM/14 – INQ0007326]. Support is also available from the GMC confidential helpline and the NHS Whistleblowing helpline. There have been 562 complaints made to us via our confidential helpline since 2015. Where doctors still have concerns, it is important that they follow our guidance and their workplace policy by reporting the matter and documenting the actions they have undertaken. We have a speaking up hub on our website, which provides practical advice and tools to doctors who wish to raise patient safety concerns. Our whistleblowing policy at [CM/30 – INQ0007341] also sets out in detail what doctors should do if they wish to raise a concern with the GMC as a whistleblower.
135. We understand that doctors may hesitate to speak up due to concerns about potential consequences and the risk of facing detrimental outcomes, such as being referred to the GMC for raising patient safety concerns. We would, however, only take action under our fitness to practise procedures where a doctor has seriously or persistently breached our guidelines. When a referral is made to us, the employer is required to confirm whether the doctor in question has previously raised concerns in the public interest, and whether those concerns have been investigated. The referrer must also declare that the referral is made in good faith and is both accurate and fair. This declaration of good faith was specifically introduced following the recommendations that were made following the independent Hooper review. A copy of the report is exhibited to this statement as [CM/31 – INQ0007342].⁴⁰
136. In situations where we are aware that a doctor has previously raised concerns about patient or public safety, we seek independent corroboration of the allegations stated in the employer's referral before deciding whether to open an investigation (as set out in section three on changes to our fitness to practice processes). This helps us to determine whether there is a legitimate concern about the doctor's fitness to practise which could pose a risk to patients, undermine public confidence in the profession, or breach proper professional standards and conduct. If we decide to investigate, we inform our decision makers about the doctor's history of raising patient/public interest safety concerns, so they can consider this information when deciding the appropriate course of action. In addition, the law provides legal protection against victimisation or dismissal for individuals who reveal

⁴⁰ We commissioned the independent Hooper review (2015) so that we could assess how we engaged with individuals who identify as whistleblowers.

information to raise genuine concerns and expose malpractice in the workplace, where they have raised concerns in the public interest.

137. We also produce an annual whistleblowing report⁴¹ with the other professional health regulators, which shows the number of whistleblowing disclosures we receive. In 2022, we received 62 disclosures and in the vast majority (60 cases), regulatory action was taken in response to the issue raised. In one case, no action was taken because of a lack of information. Regulatory action was taken on the other remaining case, and it was then referred onward to an alternative body.

Promoting learning and reflection to reduce blame and foster a more positive speaking up culture

138. It is part of our role to support medical professionals and promote learning and improvement where concerns arise. We have put in place a range of measures to reflect this. These measures include, but are not limited to, the following:

- a. taking evidence of learning, insight and remediation into account when considering whether a doctor who is subject to fitness to practise concerns poses any ongoing risk to the public;
- b. ensuring that any fitness to practise referrals to us by employers are not vexatious by asking the RO to confirm if the doctor has previously raised concerns and whether any concerns raised have been investigated;
- c. using our provisional enquiries process to consider single clinical incidents so that we can close them as soon as possible where the concern has been remediated and there is no risk to public protection – in 2022 we closed over 80% of these.

Changes to our regulatory model to better support the profession and protect patients

139. As noted at the beginning of this statement, the legislation which governs the constitution, functions, and activities of the GMC is the Medical Act 1983. Although the Act has been amended piecemeal on several occasions, it is outdated, inflexible, and overly prescriptive in ways which inhibit us from responding swiftly to our changing needs and changes in the healthcare systems within which we operate.
140. For this reason, 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

⁴¹ A copy of the report can be found at: https://www.gmc-uk.org/-/media/documents/whistleblowing-report_2022.pdf.

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.

Accountability and regulation of senior managers in the NHS

141. Recent years have seen a number of calls for increased accountability of senior managers and leaders, including for them to be brought into regulation. We are aware that these have grown louder in the immediate aftermath of the events at the CoCH. Ultimately, this will be a matter for government to decide. We have no position on the matter. However, those examining the issue will need to address a number of considerations.
142. First, it is important to be clear about the purpose of regulation and the problems it is intended to solve as that will determine the type of regulation needed, if any, and the design of the model. As I hope this witness statement shows, most modern professional regulation is concerned with protecting patients by supporting the majority of practitioners in practising to high standards, rather than simply acting against the small minority who fall below the expected standards. This model of statutory regulation involves a complex infrastructure of education and training; setting and maintenance of professional standards; registration and licensing; and systems for investigating and adjudicating on instances of impaired fitness to practise. Crucially, it also requires financial and operational independence if it is to have public credibility. Whilst this system brings many benefits both for the public and the regulated professions, it is also complex, resource intensive and imposes regulatory burdens on individuals and the wider system. If, on the other hand, the principal aim is to identify and act where things have gone wrong, then other regulatory models may be more appropriate, such as negative registers or barring lists.
143. In addition, statutory regulation is not the only available model. Many of the currently regulated healthcare professions began under systems of voluntary regulation. The Professional Standards Authority, which oversees the work of professional healthcare regulators, also operates a scheme for accrediting voluntary registers.
144. The Inquiry may be aware that in 2022, the UK government consulted publicly on the principles that should be used when determining whether a professional group should be brought into statutory regulation. In our response, exhibited to this statement at [CM/32 – INQ0007343], we identified a number of considerations. These included the risk posed by, and complexity of, the activity to be regulated, and the associated need to command public confidence. In addition to this, we highlighted the importance of a defined body or knowledge and skills for the professional group and the need for supporting educational and standards infrastructure.

145. The Inquiry will also be aware that as recently as August 2023, following the recommendations of the 2019 Kark Review, NHS England published the fit and proper person test framework for board members. We wait with interest to see the impact of this and understand that the DHSC will be keeping the efficacy of the framework under review. That evaluation will help to clarify where additional accountability mechanisms may be needed.
146. We should also note that many senior managers within the NHS are also senior clinicians, and therefore already subject to professional regulation by bodies such as the GMC and NMC. We understand this to have been the case at the CoCH. Thought would need to be given to the value of additional layers of accountability and dual regulation for these individuals and how standards across different systems of accountability are aligned.
147. In September 2023, The Rt Hon Wes Streeting MP, Shadow Secretary of State for Health and Social Care, wrote an open letter to NHS Providers and NHS Confederation, calling for regulation for non-medical managers in the NHS. In response, and to share our experience as a professional regulator, we wrote to him and set out the GMC's role in supporting an open culture of speaking up and raising concerns. A copy of this correspondence is available at [CM/33 – INQ0007344].

Concluding remarks

148. We want to thank the Inquiry for the opportunity to provide information and would be happy to discuss any of the information contained within this statement. We hope that the information that we have provided will assist the Inquiry in its work and contribute towards ensuring such tragic events never happen again.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

PD

Signed: _____

Dated: 4 March 2024 _____

Annex A

Table of exhibits: (33 exhibits)

	Date	Notes/Description	Exhibit number
1.	March 2023	GMC Governance Handbook	CM/1 – INQ0007321
2.	November 2023	Diagrams of GMC governance structures from 2013 to present	CM/2 – INQ0007329
3.	April 2013	Good medical practice	CM/3 – INQ0007314
4.	January 2024	Good medical practice	CM/4 – INQ0007315
5.	March 2012	Raising and acting on concerns about patient safety	CM/5 – INQ0007316
6.	March 2012	Leadership and management for all doctors	CM/6 – INQ0007317
7.	September 2012	Protecting children and young people: The responsibilities of all doctors	CM/7 – INQ0007318
8.	April 2021	Good practice in prescribing and managing medicines and medical devices	CM/8 – INQ0007319
9.	2022	Openness and honesty when things go wrong: Professional duty of candour	CM/9 – INQ0007320
10.	January 2016	Promoting excellence	CM/10 – INQ0007322
11.	July 2021	GMC Thresholds	CM/11 – INQ0007323
12.	March 2022	Guidance for decision makers on deciding whether an investigation is needed	CM/12 – INQ0007324
13.	February 2018	Sanctions guidance: for members of medical practitioners tribunals and for the General Medical Council's decision makers	CM/13 – INQ0007325
14.	February 2021	How to raise a concern about a doctor (England)	CM/14 – INQ0007326
15.	December 2021	RO Referral Guidance	CM/15 – INQ0007327
16.	2023	RO fitness to practise referral form	CM/16 – INQ0007328
17.	November 2016	Royal College of Paediatrics and Child Health (RCPCH) service review report	CM/17 – INQ0007312
18.	[no date]	Jane Hawdon review on Neonatal Unit at CoCH	CM/18 – INQ0007313
19.	17 August 2018	Medical Case Examiner Advice	CM/19 – INQ0006777
20.	September – October 2018	Correspondence with Cheshire Constabulary	CM/20 – INQ0007330
21.	12 May 2021	Correspondence with Cheshire Constabulary	CM/21 – INQ0007332
22.	17 January 2019	Witness statement of Dr Stephen Brearey	CM/22 – INQ0006890
23.	30 September 2020	GMC Expert Report	CM/23 – INQ0007171
24.	October 2016	(Draft) Royal College of Paediatrics and Child Health (RCPCH) service review report	CM/24 – INQ0007336

25.	2 February 2022	GMC Supplemental Expert Report	CM/25 – INQ0007276
26.	29 April 2022	Case Examiner Decision	CM/26 – INQ0007337
27.	December 2023	Dr Ian Harvey's entry on the LRMP	CM/27 – INQ0007338
28.	Various	GMC Press statements	CM/28 – INQ0007339
29.	November 2018	Effective clinical governance for the medical profession: A handbook for organisations employing, contracting or overseeing the practice of doctors	CM/29 – INQ0007340
30.	May 2018	GMC policy on whistleblowing	CM/30 – INQ0007341
31.	March 2015	The handling by the General Medical Council of cases involving whistleblowers (The Hooper Review)	CM/31 – INQ0007342
32.	March 2022	GMC response to DHSC consultation on Healthcare regulation: deciding when statutory regulation is appropriate	CM/32 – INQ0007343
33.	6 October 2023	Letter from Charlie Massey to Wes Streeting regarding the regulation of NHS non-medical managers	CM/33 – INQ0007344