Witness Name: Colin Melville
Statement No.: WITN7248001
Exhibits: WITN7248002 -
WITN7248014
Dated: 21/10/2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF COLIN RANDOLPH MELVILLE

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 08 September 2022.

I, Colin Randolph Melville, will say as follows: -

Section 1: Introduction

1. My name is Colin Randolph Melville, MB ChB PGDip FRCA FFICM FRCP SFHEA HonFAcadMEd. My date of birth is GRO-C 1959 and my address is known to the Inquiry. I am a medical doctor, registered and licensed with the General Medical Council (No: 2806806). I am the Director of Education and Standards at the General Medical Council ('GMC') and have held this role since January 2017.

2. This is my first witness statement for the Infected Blood Inquiry. Previous witness statements provided by the GMC consist of those from Chief Executive Officer, Charles Hamilton Massey [WITN3365001, WITN3365011, WITN3365032, WITN3365035, WITN3365039, WITN3365043 respectively] and are respectively dated 17 July 2019, 30 August 2019, 10 February 2020, 3 April 2020, 26 October 2020, and 16 December 2021.

3. The Rule 9 notice dated 08 September 2022 posed 12 questions (noted in italicised text). They are answered below.

4. *Please describe, in broad terms, your role and responsibilities as the Medical Director and Director of Education and Standards at the General Medical Council (GMC).*

4.1. As Director of Education and Standards, my role is to lead the GMC's regulatory Education function (the responsibilities of which are described below) and the GMC's Standards function. The latter sets the professional standards and behaviours the GMC expects of doctors registered with us and advises doctors on professional conduct, performance, and medical ethics.

4.2. As the GMC's Medical Director, I provide advice to the Executive on matters which are clinically relevant and provide contextual interpretation of clinical and ethical issues in relation to our regulatory powers. I am also a member of the GMC appeals panel that considers Tribunal[1] outcomes that may be insufficient to fulfil our overarching powers (i.e., to protect patients, maintain public trust in the profession and maintain the reputation of the medical profession). I also manage a number of key external stakeholder relationships.

4.3. As the GMC's Responsible Officer[2], I oversee the appraisal and revalidation of doctors who hold a connection with the GMC. In this role I am accountable to the Higher-Level Responsible Officer ('HLRO') at NHS England (London region). Further information can be found at paragraphs 26-28.

[1] 'Tribunal' refers to the Medical Practitioners Tribunal Service ('MPTS'). The MPTS run hearings, which can make independent decisions about whether doctors are fit to practise medicine. The MPTS is a statutory committee of the GMC and are accountable to the GMC Council and the UK Parliament. The Tribunal operates separately from the investigatory role of the GMC and is therefore independent in its decision making.

[2] Responsible Officers are senior clinicians in specific organisations (known as Designated Bodies) that ensure that the doctors for whom they act in this nominated capacity, continue to practice safely, and are properly supported and managed in maintaining their professional standards. They are governed by the Medical Profession (Responsible Officer) Regulations 2010 [WITN7248002], amended in 2013 [WITN7248003].

5. *Please describe in broad terms the role of the GMC in the training and education of medics.*

5.1. Under our current legislative framework, the GMC has the following responsibilities for medical education and training:

5.1.1. We set overarching requirements for providers of undergraduate medical education and the outcomes medical students must achieve in order to graduate and be granted provisional registration with the GMC. We do not set or approve the content within undergraduate curricula for medical students; this responsibility sits with individual medical schools.

5.1.2. Within postgraduate medical education, we approve training programmes, curricula, and assessments to confirm that our standards are being met. This includes approving the curriculum for the UK Foundation Programme which is a two-year training programme for newly qualified doctors. Further information can be found in the response to question 3.

5.2. Our key education and training guidance consists of:

5.2.1. *Outcomes for graduates*[3] [WITN7248004] which sets out what newly qualified doctors must know and be able to do;

5.2.2. Our *Generic Professionals Capabilities Framework*[4] [WITN7248005] which sets out the essential generic professional capabilities needed for safe, effective, and high-quality medical care in the UK. We have translated these into educational outcomes so that they can be incorporated into medical curricula;

[3] Available at: https://www.gmc-uk.org/-/media/documents/outcomes-for-graduates-2020_pdf-84622587.pdf?la=en&hash=35E569DEB208E71D666BA91CE58E5337CD569945

[4] Available at: https://www.gmc-uk.org/-/media/documents/generic-professional-capabilities-framework--2109_pdf-70417127.pdf

5.2.3. *Promoting excellence standards for medical education and training*[5] [WITN7248006] which sets out the 10 standards that we expect organisations responsible for educating and training medical students and doctors in the UK to meet; and

5.2.4. *Excellence by design: standards for postgraduate curricula*[6] [WITN7248007] which set out the requirements for postgraduate medical curricula in the UK.

5.3. We will introduce a new Medical Licensing Assessment ('MLA') for all final year students graduating from a UK medical school from academic year 2024/25 and doctors from overseas who currently take our Professional and Linguistic Assessment ('PLAB') test. The MLA will consist of an applied knowledge test and a clinical professional skills assessment. The MLA will test the core knowledge, skills and behaviours needed to practise safely in the UK. This assessment will ensure that medical professionals are ready for safe practise, able to manage uncertainty, and can deliver person centred care.

5.4. We also set Continuing Professional Development ('CPD') requirements for revalidation[7] [WITN7248008] to promote high standards of medical education. *Good medical practice*[8] [WITN7248009] places a duty on doctors to keep their knowledge and skills up to date throughout their working lives by regularly taking part in activities that maintain and further develop their competence and performance. Doctors are responsible for identifying their own CPD needs, planning how those needs should be addressed, and undertaking CPD that will support their professional development and practice. Since CPD activities must be tailored to their whole scope of practice and individual needs, we do

[5] Available at: https://www.gmc-uk.org/-/media/documents/promoting-excellence-standards-for-medical-education-and-training-2109_pdf-61939165.pdf

[6] Available at: https://www.gmc-uk.org/-/media/documents/excellence-by-design---standards-for-postgraduate-curricula-2109_pdf-70436125.pdf

[7] Available at: https://www.gmc-uk.org/-/media/documents/cpd-guidance-for-all-doctors-0316_pdf-56438625.pdf

[8] Available at: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice

not mandate what types of CPD doctors should engage in or the number of CPD points doctors should collect for revalidation.

5.5. The Inquiry may find it helpful to engage with other organisations involved in setting guidance on how CPD should be carried out. All medical royal colleges and faculties have published guidance on how CPD should be conducted in their specialty. Most of the medical royal colleges and faculties also have formal CPD schemes.

5.6. Lastly, our *Good medical practice*[9] [WITN7248009] guidance sets out the professional standards for all medical professionals registered with us to meet. Earlier this year, we consulted on this guidance in relation to a number of themes of relevance to the Inquiry:

5.6.1. Duty to effectively communicate within teams when supporting patients with complex care needs and ensuring patients' language communication needs are met;

5.6.2. Duty to find out what matters to a patient so that relevant information about the benefits and harms of proposed treatment options is raised as part of the consent process, with a renewed focus on honesty throughout; and

5.6.3. Strengthened expectations on medical leaders and managers to support staff to raise concerns.

5.7. We are reflecting on the responses to these issues following our consultation and will address the feedback we get in a revised version of our standards. Any revisions will also be reflected in our guidance on education and training standards and outcomes.

5.8. We proactively promote our standards through our engagement with the medical profession. For example, the GMC Outreach team annually delivers a

[9] Available at: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice

range of workshops and sessions to doctors including on raising concerns, duty of candour and professional behaviours. Further information relating to Outreach services can be found at question 6.

6. *Please set out your membership, past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference, including the dates of your membership and the nature of your involvement.*

6.1. Please find a table below that summarises my involvement and memberships in various organisations. I am also involved in ongoing research into assessment methods, geospatial analysis of student/doctor training, and aspects of patient safety in collaboration with academic colleagues in Manchester, Imperial College (London), York, Anglia Ruskin and Lancaster Universities.

Organisation	**Role**	**Nature of involvement**	**Dates of involvement**
Manchester University	Honorary Professor of Medical Education	Contribution to medical education research	2018 - current
Royal College of Anaesthetists	Fellow	*[in line with expectations of a Fellow role]*	1992 - current
Faculty of Intensive Care Medicine	Fellow	*[in line with expectations of a Fellow role]*	2011 - current
Royal College of Physicians	Fellow	*[in line with expectations of a Fellow role]*	2017 - current
Higher Education Academy	Senior Fellow	*[in line with expectations of a Senior Fellow role]*	2014 - current
Academy of Medical Educators	Honorary Fellow	*[in line with expectations of a Honorary Fellow role]*	2016 - current
Intensive Care Society	Member	*[in line with expectations of a member role]*	>20yrs

Medical Protection Society	Member	*[in line with expectations of a member role]*	1983 - current
British Medical Association	Member	*[in line with expectations of a member role]*	1983 - current
GMC Services International	Director	*[in line with expectations of a Director role]*	2021 - current
NHS England Clinical entrepreneurs programme	Support Provider	Selection of applicants, mentoring of entrepreneurs	2016 - current
Anglia Ruskin University	Visiting Professor	Contribution to institutional leadership and medical education	2022 - current

7. *Please confirm whether you have provided evidence to, or have been involved in, any other inquiries, investigations or criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. Please provide details of your involvement and copies of any statements or reports which you provided.*

7.1. I have not previously provided evidence to, or been involved in, any other inquiries, investigations or criminal or civil litigation in relation to anything described above.

Section 2: Training

8. *What is the current system for ensuring that clinicians are kept up to date with new guidelines, guidance and best practice? How effective is this? Please provide any audits or evaluations that have assessed this. What can be done to improve this?*

8.1. There are several ways in which we ensure clinicians are kept up to date with GMC guidance and best practice. These include:

8.1.1. Our outreach services

8.1.2. Our expectations of organisations delivering medical education and training

8.1.3. Our online guidance offering

8.1.4. Our revalidation requirements.

8.2. As part of our engagement approach, our Outreach service promotes and supports local implementation of GMC guidance and standards through its engagement with medical students (and their professors), doctors, Responsible Officers and their teams.

8.3. Outreach services offer learning and development opportunities to help doctors understand ethical guidance and apply it to their day-to-day work. This includes work with employers and others to tailor content in a way that's relevant and interesting for staff. Interactive workshops can be anything from one-hour sessions to half or full days and use a range of tools, case studies and doctors' own reflections to create an innovative learning experience. We regularly provide sessions on candour, consent and effective communication to registrants which we know will be of particular interest to the Inquiry.

8.4. Outreach services also deliver our ongoing programme of Welcome to UK Practice educational sessions for overseas doctors. These short induction sessions introduce UK ethical and professional standards to doctors new to practising in the UK.

8.5. We also engage with medical students to deliver presentations and workshops that introduce students to our guidance and help bring it to life with learning resources.

8.6. Within our *Promoting excellence standards for medical education and training*[10] [WITN7248006], we require organisations to regularly evaluate and review the curricula and assessment frameworks, education and training programmes and placements they are responsible for to make sure standards are being met and to improve the quality of education and training.

8.7. In *Excellence by design*[11] [WITN7248007], we state that organisations developing curricula must demonstrate the mechanisms they use to keep their curricula up to date and relevant. This includes how they incorporate innovation in training or practice and remove elements that are out-of-date. We make it clear that they must review their curricula regularly and have processes in place to make sure they are monitored and improved to keep up to date.

8.8. In Domain 9 of the *Generic professional capabilities framework*[12] [WITN7248005], we make it clear that doctors in training must demonstrate that they can keep up to date with current research and best practice in their area through appropriate continuing professional development activities and their own independent study and reflection. We also expect them to practise in line with the latest evidence.

8.9. We regularly review our guidance and educational outcomes to ensure they keep up to date with new information and developments in healthcare, adapting to the needs of society and reflecting changing patient needs.

8.10. We publish all our guidance online and proactively promote new or updated guidance through an email e-bulletin to all registrants.

[10] Available at: https://www.gmc-uk.org/-/media/documents/promoting-excellence-standards-for-medical-education-and-training-2109_pdf-61939165.pdf
[11] Available at: https://www.gmc-uk.org/-/media/documents/excellence-by-design---standards-for-postgraduate-curricula-2109_pdf-70436125.pdf
[12] Available at: https://www.gmc-uk.org/-/media/documents/generic-professional-capabilities-framework--2109_pdf-70417127.pdf

8.11. We are also proactively engaging with our registrants to better understand how they prefer to access our guidance and what sorts of training and educational resources they find most helpful in tackling their daily challenges. We will use this to improve our guidance related products and our promotional activities.

8.12. All doctors are required to revalidate as a condition of maintaining a licence to practise. The GMC is responsible for setting out the UK wide framework for revalidation and approving revalidation recommendations about individual doctors from Responsible Officers. These recommendations are based on information collected through local governance systems, including appraisal. All doctors subject to revalidation will participate in an annual cycle of appraisal, run by a trained appraiser. At each appraisal, the doctor will need to demonstrate that they have undertaken sufficient and relevant CPD for their current role(s). A revalidation recommendation confirms that in the view of the Responsible Officer, the doctor is up to date and fit to practise.

8.13. We set out the types of supporting information we expect doctors to reflect on and discuss at appraisal in the following guidance: *Supporting information for appraisal and revalidation*[13] [WITN7248010]. This guidance clarifies that each doctor must tailor their CPD to the role(s) they carry out and ensure that this is relevant to the emerging knowledge and skills they will need within their area of work or specialty.

8.14. Further information about how we monitor and work with others to improve medical revalidation can be found here: Monitoring and evaluating revalidation[14] [WITN7248011].

9. *How do educators embed best practice into clinicians' practice? What can be done to improve this?*

[13] Available at: https://www.gmc-uk.org/-/media/documents/rt---supporting-information-for-appraisal-and-revalidation---dc5485_pdf-55024594.pdf?la=en&hash=1CA018A10A29AEEA7CDE433E0B901B97DFE96402

[14] Available at: https://www.gmc-uk.org/-/media/documents/rev----taking-revalidation-forward---working-with-others-to-improve-revalidation---dc11687_-76860097.pdf

9.1. As outlined above, we set standards for education and training organisations and postgraduate medical curricula which educators need to take account of.

9.2. Undergraduate and postgraduate training programmes must give students and doctors in training the opportunity to develop their practical skills and generic professional capabilities.

9.3. In Domain 9 of the *Generic professional capabilities framework*, *Capabilities in research and scholarship*[15] [WITN7248005], we state that doctors in training must demonstrate that they can keep up to date with current research and best practice in their area through appropriate continuing professional development activities and their own independent study and reflection. They must also practise in line with the latest evidence.

10. *Is the GMC involved in providing training on candour, consent and effective communication to non-clinical senior leaders working in the NHS such as executive directors, chief executives, and trustees? If so, please outline who it is delivered to, what the training consists of and any details of any audits or evaluations to assess how effective the training is.*

10.1. As our standards and guidance only apply to doctors (and will, in future, also apply to physician associates and anaesthesia associates[16] [WITN7248012]), our routine engagement is with medical professionals rather than non-clinical senior leaders.

10.2. Through the GMC's Outreach function, we regularly provide sessions on candour, consent and effective communication to medical professionals.

[15] Available at: https://www.gmc-uk.org/-/media/documents/generic-professional-capabilities-framework--2109_pdf-70417127.pdf Page 25

[16] Further information about our future role as regulator for physician associates and anaesthesia associates can be found on our website. Available at: https://www.gmc-uk.org/pa-and-aa-regulation-hub

10.3. The Inquiry may also wish to liaise with organisations such as The King's Fund in relation to this question as they may offer this type of training.

Section 3: Response to the recommendations of the Psychosocial Expert Group

11. *Does the duty of candour form part of medical training or continuing professional development? Please give details including as to which students/ clinicians are trained on these matters, what the training consists of, and any details of any audits or evaluations to assess how effective the training is.*

11.1. We require education providers to promote a culture of candour. In our standards for medical education and training, *Promoting Excellence*[17] [WITN7248006], 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'. Our *Good medical practice* [WITN7248009] guidance also takes account of the diverse approaches to the duty of candour across the UK.

11.2. For doctors already registered with us, our joint guidance with the Nursing and Midwifery Council, *Openness and honesty when things go wrong: the professional Duty of Candour*[18] [WITN7248013], 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.

11.3. We also set out a duty for doctors to be open and honest with their employer, and to encourage a learning culture by reporting errors openly and honestly. Our guidance on professional standards is necessarily broad to ensure that it's widely applicable to all doctors in the UK, regardless of their specialty,

[17] Available at: https://www.gmc-uk.org/-/media/documents/promoting-excellence-standards-for-medical-education-and-training-2109_pdf-61939165.pdf
[18] Available at: https://www.gmc-uk.org/-/media/documents/openness-and-honesty-when-things-go-wrong--the-professional-duty-of-cand____pdf-61540594.pdf

grade and area of work. As it can't cover all the situations they might face in practice, we expect doctors to use their professional judgement to apply the principles in our guidance.

11.4. As mentioned earlier, it is for medical schools to determine how they meet the requirements that we set out. We do, however, evaluate training programmes against our standards and carry out quality assurance activities related to the requirements in our *Promoting Excellence* and *Outcome for Graduates guidance* [WITN7248006]. Part of this evaluation is gathering feedback from students, doctors in training and teachers about whether education and training prepares individuals effectively for life as a doctor. Within this, we ask for feedback about the duty of candour-related learning they experienced.

12. *Does effective patient communication form part of medical training or continuing professional development? Please give details including as to which students/clinicians are trained on these matters, what the training consists of, and any details of any audits or evaluations to assess how effective the training is.*

12.1. Effective patient communication is a crucial skill for doctors and forms part of all our requirements for medical education and training[19] [WITN7248014].

12.2. In our *Generic Professional Capabilities* [WITN7248005] guidance, we say that due to the complex nature of medical practice, doctors in training must develop high levels of communication and interpersonal skills. We make clear that doctors in training must demonstrate they can communicate effectively and be able to support patients in making decisions, while maintaining appropriate situational awareness, professional behaviour and professional judgement. This covers behaviours such as: demonstrating effective consultation skills; sharing decision making by informing the patient and respecting the patient's concerns; demonstrating cultural and social awareness; communicating effectively and sensitively when breaking bad

[19] Available at: https://www.gmc-uk.org/-/media/documents/welcomed-and-valued-how-can-postgraduate-training-organisations-apply-their-duties-20210329-78514518.pdf Pages 94 - 102

news; and delivering an honest apology and offering an effective explanation where appropriate.

12.3. In the MLA content map, we say that final-year students will be assessed on their ability to communicate effectively with health care professionals, patients, relatives, carers and other advocates, as well as demonstrating person-centred consultation and management skills.

13. *Do the ways in which implicit and explicit biases affect interactions with patients and families (including increasing awareness of the nature of stigma and its impacts on both patients and families/carers) form part of medical training or continuing professional development? If so, please give details including as to which students/clinicians are trained on these matters, what the training consists of, and any details of any audits or evaluations to assess how effective the training is.*

13.1. Recognising and accounting for bias is an important issue for doctors. We have prioritised this as part of our work on *Generic Professional Capabilities* and now require bias to be covered in all medical training as part of behaviours that affect patient safety.

13.2. In the *Generic Professional Capabilities* [WITN7248005] framework, we define cognitive and unconscious bias, and fixation error (an error which occurs when the practitioner(s) concentrate solely upon a single aspect of a case to the detriment of other more relevant aspects of the case), and how these may impact on patient care. We encourage doctors to take a 'Human Factors' approach to understanding the complex factors which influence behaviour at work in a way that can affect patient safety. Human Factors approaches aim to reduce error bias through better understanding of how systems and processes affects human behaviour and culture and applying this knowledge to clinical practice and clinical settings.

13.3. *Good Medical Practice* [WITN7248009] contains a section on treating patients and colleagues fairly and without discrimination which states:

You must give priority to patients on the basis of their clinical need if these decisions are within your power. If inadequate resources, policies or systems prevent you from doing this, and patient safety, dignity or comfort may be seriously compromised, you must follow the guidance in paragraph 25b.

13.4. Doctors must also give priority to patients based on their clinical need and must base investigations or treatment on an assessment of the patient's needs and priorities, and on the likely effectiveness of the treatment options. Doctors must not refuse or delay treatment because they believe that a patient's actions or lifestyle have contributed to their condition.

13.5. Doctors must not deny treatment to patients on the grounds that a patient's medical condition may put them at risk. If a patient poses a risk to a doctor's health or safety, they should take all available steps to minimise the risk before providing treatment or making other suitable alternative arrangements for providing treatment.

13.6. When we quality assure training programmes, we collect information from learners and educators about professionalism. When evaluating teaching on professionalism, we may ask learners about how prepared they are to recognise and manage bias.

13.7. Recognising and accounting for bias and stigma may also form part of a doctor's CPD activities if a doctor has identified it as an area where they need or wish to develop.

14. *Do you have any comments to make on the recommendations made, or any recommendations to add to those of the Expert Group listed above in relation to the two questions posed by Sir Brian to the Psychosocial Expert Group?*

14.1. I do not have anything further to add.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed GRO-C

Dated 21 October 2022

Table of exhibits

Date	Description	Exhibit number
2019	First Written Statement of Mr Charles Hamilton Massey	WITN3365001
2019	Second Written Statement of Mr Charles Hamilton Massey	WITN3365011
2020	Third Written Statement of Mr Charles Hamilton Massey	WITN3365032
2020	Fourth Written Statement of Mr Charles Hamilton Massey	WITN3365035
2020	Fifth Written Statement of Mr Charles Hamilton Massey	WITN3365039
2021	Sixth Written Statement of Mr Charles Hamilton Massey	WITN0365043
2010	The Medical Profession (Responsible Officers) Regulations 2010	WITN7248002
2013	The Medical Profession (Responsible Officers) (Amendment) Regulations 2013	WITN7248003
2020	Outcomes for graduates, General Medical Council	WITN7248004
2017	Generic professional capabilities framework	WITN7248005
2015	Promoting excellence: Standards for medical education and training	WITN7248006
2017	Excellence by design: Standards for postgraduate curricula	WITN7248007

2012	Continuing professional development: Guidance for all doctors	WITN7248008
2020	Good Medical Practice, General Medical Council	WITN7248009
2020	Guidance on supporting information for appraisal and revalidation	WITN7248010
2018	Taking revalidation forward: Working with others to improve revalidation	WITN7248011
2022	PA and AA Regulation, General Medical Council	WITN7248012
2022	Openness and honesty when things go wrong: the professional duty of candour	WITN7248013
2019	How can postgraduate training organisations apply their duties?	WITN7248014