Witness Name: Professor Ramani Moonesinghe
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UK COVID 19 INQUIRY

FIRST WITNESS STATEMENT OF PROFESSOR RAMANI MOONESINGHE

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I, Professor Ramani Moonesinghe, National Clinical Director for Critical and Perioperative Care at NHS England of Wellington House, 133-135 Waterloo Road, London, SE1 8UG, will say as follows:

STATEMENT OVERVIEW

1. I make this statement in response to the UK Covid-19 Inquiry's Rule 9 request to me dated 25 June 2024 in relation to Module 5 of the Inquiry ("**the Rule 9 Request**"), which focuses on the procurement and distribution to end-users across the four nations of the United Kingdom of key healthcare related equipment and supplies, including PPE, ventilators and oxygen, between 1 March 2020 and 28 June 2022 ("**the Relevant Period**").

2. This statement is structured as follows:

    a. **Section 1** provides an overview of my professional background.

    b. **Section 2** outlines my roles during the Relevant Period.

    c. **Section 3** details my involvement in relation to ventilators, by particular reference to procurement.

    d. **Section 4** details my involvement in relation to oxygen supplies, by particular reference to procurement.

    e. **Section 5** details my involvement in relation to critical care, by particular reference to procurement.

    f. **Section 6** details my involvement in relation to PPE, by particular reference to procurement.

    g. **Section 7** sets out my reflections on challenges, good practice and lessons learned.

3. Throughout this statement I have set out my reflections and the challenges that we faced.

4. This witness statement does not seek to duplicate the related evidence provided to the Inquiry in Module 5, particularly the witness statement of Julian Kelly for Module

5. I have adopted certain definitions and approaches as follows:

    a. definitions of the waves of the pandemic:

Wave and dominant variant	Dates (approx.)
Wave 1 – Wuhan variant.	February – May 2020
Wave 2 – emergence of Alpha variant.	September 2020 to January 2021
Wave 2 - reducing and the emergence of Delta variant.	February 2021 to September 2021
Wave 3 – emergence of Omicron variant.	September 2021 to end of the Relevant Period.

b. referring to the Department of Health and Social Care ("**DHSC**") and the Secretary of State for Health and Social Care ("**SSHSC**") in accordance with how they are structured today, but such references include all predecessor organisations and roles as the context may require; and

c. collectively referring to NHS Trusts and NHS Foundation Trusts as "**Trusts**" unless otherwise stated.

SECTION 1: MY PROFESSIONAL BACKGROUND

6. I am a doctor who has worked in the NHS for 27 years, including 20 years of working clinically in critical care. I was appointed as a Consultant in critical care, anaesthesia and perioperative care at University College London Hospitals (**"UCLH"**) in 2009. As a consultant on the UCLH critical care unit, I worked in a multidisciplinary team providing care for critically ill patients in one of the largest services in the UK.

7. I graduated from UCL, first with an intercalated degree in Physiology (1994), then Medicine (1997) and finally a research doctorate, MD(Res) (2014). I am a Fellow of the Royal College of Physicians, the Royal College of Anaesthetists (**"RCoA**") and the Faculty of Intensive Care Medicine, and a Senior Fellow of the Faculty of Medical Leadership and Management. I was awarded the honour of Officer of the Order of the British Empire (OBE) in the 2021 New Year's Honours for services to anaesthesia, perioperative and critical care medicine.

8. I am the National Clinical Director for Critical and Perioperative Care at NHS England ("**NHSE"**) and have held this role since 19 March 2020. Prior to this date, I was in the

role of National Specialty Advisor for Perioperative Care at NHS England (from 1 October 2019), and prior to that, the role of Associate National Clinical Director for Elective Care (2016 – 2019).

9. I was an elected Council member of the **RCoA** between 2008 and 2012.

10. I am a clinical academic, with research activity accounting for half of my job plan. I am Professor of Peri-Operative Medicine at University College London (**"UCL"**) where I am also head of my research department. Between 2016 and 2022 I was the Director of the Health Services Research Centre **("HSRC")** at the RCoA, and was the Deputy Director of the HSRC between 2012 and 2016. I am now Director of the National Institute for Health Research's Central London Patient Safety Research Collaboration and the Chair of the National Institute for Academic Anaesthesia. I include, at Annex 1, a brief overview of my career history to date.

SECTION 2: MY ROLE DURING THE RELEVANT PERIOD

11. Over the course of the pandemic, and with specific reference to the Relevant Period, I held roles at NHS England, UCL, UCLH and the RCoA. This section sets out my role in those organisations during the Relevant Period. I took maternity (adoption) leave between 2 July 2020 and 1 November 2020, although I returned to work for NHS England from mid-August 2020 to assist with the pandemic response. During the 6 weeks I was away from NHS England, my role was covered by clinical fellows and members of the NHSE EPRR and specialised commissioning teams, including the Incident Directors and the Lead Commissioner for Adult Critical Care.

Role at NHS England during the Relevant Period

12. I was appointed as a National Specialty Advisor for Perioperative Care at NHS England in 2019. I started providing input on clinical and operational matters related to the NHS England Covid-19 response on 2 March 2020. On 19 March 2020, I was formally appointed to the role of National Clinical Director for Critical and Perioperative Care, to provide national clinical leadership for adult critical care.

Role at UCL during the Relevant Period

13. I continued to undertake limited research activities alongside my work for NHS England, focusing on Covid-19 research.

14. I stepped down from my role as Head of the Research Department for Targeted Intervention to create time for NHS England work.

Role at UCLH during the Relevant Period

15. During Wave 1, from approximately 19 March 2020, I stepped down from clinical duties to enable me to work full-time for NHS England in my national leadership role. After I returned from maternity leave, alongside university and NHS England roles I undertook ad hoc shifts outside my job plan at UCLH for the remainder of the Relevant Period, including outpatient clinic work reviewing high-risk surgical patients before surgery, and a small number of shifts on the critical care unit, including care of patients with Covid.

Role at the RCoA during the Relevant Period

16. I led the HSRC at the RCoA throughout the Relevant Period, however, almost all research activity, apart from that related to Covid-19, was suspended between the start of the first lockdown (around 23 March 2020) and approximately March 2021.

17. As a result of my various national leadership roles in anaesthesia and critical care, I have had regular interactions with senior clinical and academic leaders for these specialties, and, in a range of professional settings, over the past 16 years. As a result, my colleagues in professional bodies and I are very accustomed to working together and managing any potential conflicts.

SECTION 3: VENTILATORS AND RELATED MEDICAL EQUIPMENT AND SUPPLIES

Introduction

18. The following paragraphs provide an overview of the resources (equipment, medicines and consumable items) which are required to treat patients who are critically ill or at risk of critical illness. These paragraphs also outline some of the challenges with procurement of these items in March 2020, in the context of the global Covid-19 pandemic.

19. Critically ill patients are those who are at risk of organ failure (these patients are termed Level 2 or high dependency patients), or in whom at least one organ has failed (these patients are termed Level 3 or intensive care patients). Critical Care services care for both level 2 and level 3 patients.

20. Organ failure is treated with medicines, specialist equipment, and a wide range of 'consumable items'.

21. Examples of specialist equipment for critically ill patients include:

a. Machines providing invasive positive pressure ventilation **("IPPV")**; also known as mechanical ventilation **("MV")** – to treat severe respiratory failure in patients who are usually sedated. Mechanical ventilators are used in critical care (the most complex and versatile machines); they are also used to provide IPPV to anaesthetised patients having surgery (as part of an 'anaesthetic machine'); there is a further category of mechanical ventilator which is portable and can be used when moving patients inside or between hospitals ("transport ventilators") – these vary in quality and complexity, but are usually built to a lower specification than critical care or anaesthetic machine ventilators.

b. non-invasive respiratory support devices to treat less severe respiratory failure: for example:

i. continuous positive airway pressure ("**CPAP**"); these provide fresh gas to patients via a mask or helmet at a single fixed (adjustable) pressure. Some CPAP machines can provide an adjustable blend of air and oxygen; others can provide oxygen-enrichment via a separate tube feed of oxygen into the device;

ii. non-invasive ventilators (**'NIV")**; also known as Bi-level non-invasive ventilation ("**BiPAP"**); these provide fresh gas to patients via a mask, at two specified pressures (one inspiratory pressure, and one, lower, expiratory pressure). These devices usually provide an adjustable blend of oxygen and air, and can also be used as CPAP (single level of pressure) machines;

iii. high-flow nasal oxygen devices ("**HFNO$_2$**") – provide humidified, warmed oxygen to patients at very high flow rates (over 50litres/minute of fresh gas flow);

c. syringe drivers (which are used to administer continuous intravenous medications, such as medicines to treat circulatory failure or sedatives);

d. volumetric pumps (which are used to administer fluids intravenously or liquid feed enterally, at a controlled rate for patients who are sedated or otherwise unable to eat and drink normally);

e. renal replacement therapy machines – for example haemofiltration machines or haemodialysis machines: used to treat patients with renal (kidney) failure;

f. equipment to support endotracheal intubation and bronchoscopy of patients in respiratory failure or who for any other reason require sedation and ventilation (laryngoscopes, bronchoscopes);

g. extra-corporeal membrane oxygenation ("**ECMO**") machines and associated equipment: used in five highly specialised severe acute respiratory failure centres; and

h. ultrasound machines to support siting of invasive lines.

22. Examples of consumable items used in hospitalised patients include:

a. Loose fitting face masks, "venturi" devices, oxygen tubing and nasal cannulae – all used to administer oxygen to ward-level patients;

b. Tight-fitting oxygen masks to administer CPAP or non-invasive ventilation to patients requiring level 2 support;

c. Endotracheal tubes, tracheostomy tubes, ventilator tubing, heat-and-moisture exchange bacterial and viral filters for patients on invasive ventilators (level 3 support);

d. Cannulae, tubing and pressure bags for continuous monitoring of blood pressure in patients with circulatory failure; and

e. Equipment for sampling of bodily fluids for monitoring of organ function and detection of infection (e.g. blood, sputum, urine).

23. Examples of medicines used in hospitalised and specifically critically ill patients include:

a. Oxygen;

b. Intravenous fluids to provide hydration, particularly if the patient is sedated or at risk of organ failure;

c. Medicines to sedate and (in the most severely ill) paralyse the muscles of patients requiring IPPV;

d. Antibiotics; and

e. Renal replacement therapy fluids.

24. The severity of respiratory illness determines the level of support required to maintain oxygen delivery and carbon-dioxide removal, and therefore all physiological functions. The most basic support is oxygen delivered via nasal cannulae or a loose-fitting face mask. The next level up of support is either $HFNO_2$ or CPAP or BiPAP. In normal acute care providers, the highest level of respiratory support which can be offered is IPPV. In the five specialised severe acute respiratory failure centres, ECMO is offered, for a minority of the most critically ill patients.

25. During the pandemic, ventilators (and related equipment, medicines and consumables) were used to treat patients with Covid-19 in the same way as in normal practice: to provide escalating levels of support in order to maintain or replace organ function. Differences between the medicines and devices which were used during the pandemic and in normal practice were all related to either the volume of patients requiring treatment, and/or the specifics of Covid-19 disease. The higher volume of patients meant that the demand for some of these machines, medicines and consumable items outstripped our usual supply and/or existing stock, and as a consequence, less familiar, or repurposed, or second-choice items were used. For example, anaesthetic machine ventilators were used to treat critically ill patients, whereas in normal times, these would only be used to treat patients with largely normal physiology, having general anaesthesia for surgery.

26. Ventilators are complex medical devices, which are expensive and therefore usually made to order, rather than being manufactured and then warehoused until sale. This means that the lead-in time between placing an order and the item being delivered, is usually 6 to 8 weeks. In February / March 2020, this meant that there was significant global competition for both ventilators, and their component manufacturing parts. Furthermore, all mechanical ventilators being used in UK critical care units prior to the pandemic were manufactured abroad.

27. I set out below my involvement in relation to the production and procurement of ventilators, and any related medical equipment or supplies, during the Relevant Period. I do so by reference to dates of key actions or decisions in which I was personally involved.

My role in relation to procurement of ventilators, and the "Ventilator Challenge" during the Relevant Period

28. I provided clinical leadership to the DHSC ventilator supply team, the Oxygen / Concentrators / NIV task and finish group, and the Cabinet Office Ventilator

Challenge. I also provided clinical advice as required to procurement teams working across NHS England and DHSC, including other medical equipment, medicines, consumable items and the Nightingale Hospitals programme. I worked closely with Dr Emily Lawson, Senior Responsible Officer ('**SRO**') for the cross-organisational Oxygen, Ventilation and Consumables programme, Mr Chris Stirling, DHSC civil service lead for ventilator procurement, and Mr Gareth Rhys-Williams, Cabinet Office Chief Commercial Officer who was SRO for the Ventilator Challenge.

29. Procurement of ventilators was led by DHSC. My involvement began on 2 March 2020.

30. From the outset of my involvement, DHSC were focused on procurement of mechanical ventilators, non-invasive ventilators (which would provide both NIV/bi-level support and CPAP) and oxygen concentrators. Specifically, there was no emphasis on procurement of additional $HFNO_2$ devices because of concerns that the high consumption of oxygen by these devices could cause imbalance in oxygen flow between beds or clinical areas in NHS hospitals.

31. A report describing the Ventilator Challenge, on which I was consulted, has been previously published by the National Audit Office. The topic of ventilator procurement and innovation has also been covered by a Public Accounts Committee review.

32. The Ventilator Challenge concept was developed between 10 and 15 March 2020, in recognition of the concern that despite exhaustive efforts by DHSC's ventilator supply team, there was a significant risk that there would be insufficient ventilators to meet patient demand. In parallel, an increasing number of innovation proposals were being received by NHS England, DHSC and professional bodies, necessitating the development of a systematic approach to evaluating such approaches.

33. To that end, we considered multiple unusual and innovative ideas to increase ventilator capacity, for example:

    a. Using ventilators usually designed for veterinary practice;

    b. Splitting one ventilator between more than one patient; and

    c. Manufacturing new ventilators, including basic designs which would provide a means of short-term stabilisation of patients who would otherwise be at risk of death from hypoxia.

34. In addition to discussion with me and the National Clinical Director for Respiratory Medicine, DHSC reached out to a range of stakeholders, including via the National Institute for Health Research, to gauge the level of support for these ideas.

35. A draft of the initial "Rapidly Manufactured Ventilator Specification" (**"RMVS"**) [**RM1/001 INQ000508305**] was co-developed on 13 March 2020 by me and by Edward Pennington-Ridge, my husband.

36. Edward is an independent design consultant, who has previously undertaken work funded by the Defence Science and Technology Laboratory (Ministry of Defence) and numerous charities and fulfilled a role of 'inventor in residence' at UCLH. I initially introduced (via email) Edward to DHSC to consider if his expertise could help with evaluating the potential role for the rapid manufacture of ventilators. I suggested Edward because of his extensive and relevant design experience and because there was insufficient time to source this expertise through wider consultation. Edward was able to draw on his knowledge and experience to advise on the technical complexity associated with different features of a ventilator and work with clinicians to ensure that the design specification could be realistically achieved by potential manufacturers while also being as safe as possible for patients and staff. DHSC approved his involvement and his appointment to the panel referred to below. Notwithstanding the personal relationship between me and Edward, I believe he gave appropriate independent and professional advice that was within his area of expertise while he carried out his role.

37. DHSC asked me and Edward to provide a draft specification within one working day (on Friday 13 March 2020); this was duly provided.

38. This initial draft also had clinical input from two other clinicians:

    a. Dr (now Professor) Dan Martin, Consultant in Intensive Care and at that time, clinical lead for the High Consequence infectious Disease centre at the Royal Free Hospital and a member of the NERVTAG sub-group on aerosolization; and

    b. Dr Jim Down, Consultant in Intensive Care and Anaesthetics, UCL Hospitals.

39. The initial draft specification was developed based on the following assumptions, using the information that was available to us in early- to mid-March 2020:

a. That the number of ventilators required would be in the thousands, to meet the potential demand. Paragraphs 776 onwards of the Second Witness Statement of Amanda Pritchard for Module 3 provides more information on ventilator modelling numbers at this time. However, modelling shared with me on 15 March 2020 indicated that NHS England's modelling of a Reasonable Worst Case Scenario ("**RWCS**") on the NHS would require at least 30,000 patients to have invasive ventilation (and many thousands more to have non-invasive ventilation or CPAP, and many thousands more to require basic oxygen therapy) [**RM1/002 INQ000508283**].

b. An audit of ventilator capacity in the NHS was undertaken between late February and early March 2020. Details of the relevant numbers are set out in the witness statement of Julian Kelly for Module 5 but it was clear that there were insufficient numbers of ventilators of the right kind to meet the expected demand.

c. That the priorities were to provide access to ventilatory support for the maximum number of people possible, while minimising risks to healthcare workers. Therefore, if at all possible, the aim was to provide machine-delivered ventilation using a medical device, rather than a healthcare support worker manually ventilating a patient, which would both be unreliable, and also potentially expose many more support workers to risk.

d. That the expected peak in demand would arrive within 2 to 3 weeks, with a rising demand which would quickly outstrip the supply of ventilators we either had in the system or which we had secured through new procurement (as there remained a significant time lag between ordering and receiving new items); therefore the device would need to be designed, manufactured and delivered within that timeframe.

e. That it would be impossible to manufacture high specification critical care mechanical ventilators to meet the potential demand, in the time which was available; therefore the aim should be to develop a very basic device - which was feasible from a manufacturing perspective

f. The initial draft RMVS specification was forwarded to MHRA by the DHSC on 15 March 2020, and subsequently iterated using input from MHRA, myself, Edward and the independent clinical team who subsequently formed the Technical Design Authority **("TDA")**, based on the considerations set out

above. The initial published version was published by MHRA on 18 March 2020 [**RM1/004 INQ000508406**]. Over the days and weeks following the initial release, the specification was updated multiple times, led by the MHRA, and involving wider input from other stakeholders (e.g. the second specification [**RM1/003 INQ000508306**]). Version control, iteration and final confirmation of all published versions of the RMVS specification was the sole responsibility of the MHRA.

40. A fourth, final version was published by MHRA on 10 April 2020 [**RM1/043 INQ000513357**]. The updates were based on evolving forecasting of the number of patients who might require treatment with ventilators and on evolving clinical understanding of Covid-19 respiratory failure. These factors impacted on decisions around how complex the specification could or should be. Greater complexity would mean the ventilator could be more useful but build and training in its use would take longer. Decisions on the design was therefore informed by the level and timing of the forecasted demand.

41. Between 15 and 18 March 2020, I assembled an independent expert advisory panel who could review proposals and provide feedback to companies. This panel formed part of the membership of the TDA. The panel were:

    a. Professor Mike Grocott, Professor of Intensive Care Medicine, University of Southampton;

    b. Dr Max Jonas, Consultant in Intensive Care Medicine, Southampton University Hospital;

    c. Dr James O'Carroll; clinical fellow working on secondment with NHS England and ST7 anaesthetist in training at St, Thomas' Hospital, London;

    d. Dr Charlotte Summers (now Professor Summers); Consultant and Senior Lecturer in Intensive Care Medicine (respiratory physician background) – Cambridge University and Addenbrookes Hospital; and

    e. Edward Pennington-Ridge; given his expertise as an independent design consultant and his involvement in developing the specification.

42. I provided clinical leadership for the Ventilator Challenge and specifically the TDA, including accountability for the independent expert advisory panel to the Cabinet

Office. I was the primary means of communication between the panel and the other members of the TDA, including Cabinet Office and MHRA.

43. The clinicians were selected on the basis of clinical expertise, and availability. Professor Grocott, Dr Jonas and Dr Summers were not paid for their time advising the TDA.

44. I provided assurance to DHSC, MHRA and the Cabinet Office on the suitability of these clinicians to fulfil this role; however, no formal appointments process was undertaken, due to the speed with which we needed to assemble the panel. Other clinicians who were approached were unable to help because of local clinical commitments to the pandemic response. Edward joined early meetings to support the clinical discussions from a design perspective, the rationale being that he could provide a perspective on the complexity (and therefore the likely feasibility) of specific aspects of the design given the timeframes and scale-up requirements we were working within.

45. Other members of the TDA included representatives of the MHRA, PA Consulting, Cabinet Office and DHSC. There was no formal sign-off from the Cabinet Office on the clinical panellists in the TDA; however, as stated above, I invited membership from individuals who were either already in roles at NHS England (myself and Dr O'Carroll) or who represented a range of relevant clinical and academic expertise.

46. The clinicians on the TDA provided feedback on the proposals which were submitted by potential manufacturers, so that the manufacturers could consider these perspectives when iterating their designs. The clinicians also advised on whether, given the current set of circumstances in the pandemic, the designs which were being developed remained suitable for further development and patient use. Specifically, as detailed above, because of the rapidly changing pandemic situation (number of machines required, speed with which they would be required, improved understanding of the clinical disease) the specifications of the machines being considered were also required to change. We thankfully moved over time from the situation we were in at the start (when anything better than a human bagging oxygen into a patient would have been acceptable) to a position where we could afford (in terms of time) to demand more sophisticated machines, which would therefore be better for patients.

47. The ventilator challenge was coordinated by the Cabinet Office. A series of TDA meetings were held, beginning on 18 March 2020, where commercial companies

presented their proposals. Companies fielded questions from the TDA, and later, the independent expert advisory panel above, would meet to discuss the proposals, and make recommendations to the TDA.

48. In total, the TDA met 12 times between 18 March and 21 May 2020.

49. The recommendations of the TDA, and the subsequent decision-making on whether to continue to work with individual companies vs. withdrawing support (including financial) were based on multiple factors:

    a. Forecasting of numbers of machines required and in what timeframe; originally, the ambition was 20,000 RMVS in 6 to 8 weeks; by 27 March 2020 this had been modified to 8,000 in 2 weeks;

    b. Actual and forecasted inbound machine numbers sourced through new procurement;

    c. Viability of design, including the timeframe with which products were likely to be produced; for example, products which were already in use, but on which manufacture could be scaled up quickly were favoured over completely novel designs;

    d. Design specification, mapped to the current version of the RMVS specification;

    e. Clinical acceptability and device functionality, based on discussion and reports from the independent Medical Devices Testing and Evaluation Centre ("**MD-TEC")** in Birmingham. A fuller explanation of the role of, and my interaction with, MD-TEC is set out later in this Statement; and

    f. Evolving evidence and clinical experience regarding Covid-19, including the clinical characteristics of patients with Covid-19, patient safety considerations, and structural factors (e.g. oxygen delivery challenges).

50. I conveyed the TDA's discussions and recommendations to the Cabinet Office, who were responsible for decision-making on which products to take forward to the next stage of the process and the funding envelope available to support the Ventilator Challenge.

51. In addition to the TDA meetings, I attended meetings and had correspondence with Cabinet Office civil servants and ministers where individual proposals were discussed.

52. On or around 22 March, the clinicians involved in the TDA, in conjunction with Professor Tom Clutton-Brock of MD-TEC, proposed to the Cabinet Office that a specification be developed for a rapidly manufactured CPAP device in response to growing clinical understanding about the potential value of CPAP in the treatment of Covid. This was subsequently developed and published by the MHRA on 29 March 2020.

53. Aside from my role within the TDA, I did not have direct contact or provide advice to companies, individuals or other entities on procurement or the Ventilator Challenge, with the following exceptions:

    a. I received multiple individual approaches from companies, either directly or via other stakeholders including professional bodies; in all cases I directed these to the formal process led by the Cabinet Office and the generic email address.

    b. I provided some informal clinical advice to Vobster Medical Ltd, who were developing a low-flow CPAP machine which entered the rapidly manufactured CPAP device challenge. My husband Edward had come across Vobster on an online forum of diving experts that were discussing developing solutions to oxygen challenges. I considered their solution to have an important role to play in the overall response, as it had a much lower oxygen demand than any other CPAP device on the market or under consideration by the Ventilator Challenge, and we continued to have concern about oxygen delivery when hospitals had large numbers of Covid patients being treated in surge wards. I therefore referred the company's solution to the Ventilator Challenge. Although neither Edward nor I had any connection or financial interest in this company, we had referred them and informally liaised with them prior to the referral. As such whenever Vobster designs were considered by the TDA, we excused ourselves from the process. I understand that Vobster received approximately £40,000 from the Ventilator Challenge to further develop their offering but that they were not subsequently contracted to produce ventilators.

    c. I was approached on multiple occasions by UCL colleagues developing a CPAP device, which became known as the UCL Ventura, for support with various aspects of the project including procurement of essential parts,

support with commissioning, support with distribution. On all occasions that I was approached individually, I liaised with relevant others (e.g. other members of the TDA, MD-TEC and MHRA) in order to develop a consensus on how to proceed. I understand that UCL was subsequently contracted to provide I&S Ventura devices for an investment (as recorded in the NAO report) of £20.3 million.

54. In my opinion, the Ventilator Challenge and the approach to procurement of ventilators and other medical equipment had sufficient regard to equality and diversity, including the public sector equality duty. Different ventilators may be required for children and adults, and this was considered in procurement decisions, based on forecasts of the impact of Covid on children; however, ventilators do not need to be adapted to suit adults' different personal characteristics. There are known challenges with providing advanced respiratory support to patients with morbid obesity, but it would be the responsibility of clinicians at local level to ensure that such patients were treated with the machines most suitable for their individual needs, that were available to them at the time.

Engagement with other agencies

55. The approach to procurement of ventilators was a cross-government effort, albeit led by DHSC, and involved multiple stakeholders during the Relevant Period. My interactions with those various agencies and entities, insofar as they arose in connection with my specific role, are covered in this section.

56. I worked directly with NHS England, DHSC and the Cabinet Office providing clinical advice on procurement decisions regarding ventilators and other medical equipment.

57. I attended separate daily meetings on procurement and the Ventilator Challenge and corresponded daily with multiple colleagues within NHS England, NHS Supply Chain, DHSC and Cabinet Office in order to progress this work.

58. On procurement: a subset of the same small team of clinicians who contributed to the Ventilator Challenge TDA, and were accountable to me, supported me in providing clinical oversight of procurement of ventilators and non-invasive respiratory devices – specifically Dr James O'Carroll, Professor Mike Grocott and Dr Max Jonas. An example of how we worked is available [**RM1/005 INQ000508307**] and further detail provided in the paragraphs below.

59. My team and I were responsible for reviewing lists of devices which were already on the NHS procurement framework, and other device lists provided by DHSC through their engagement with sales teams internationally. No indication was provided to me that the list of devices were 'recommendations' for devices to be procured and I was not part of any other types of review or due diligence carried out on the devices. From my perspective, what was required, was a clinical review of the suitability of the devices on these lists for use in the pandemic, given the available information about the disease, and our projections of demand. The expected output was a recommendation (as set out below) back to the DHSC team.

60. This clinical review involved categorising devices (according to whether they provided IPPV, NIV or other respiratory support, and for which age groups), and evaluating the potential for them being used to treat Covid-19 patients. The information we were provided with was usually from open sources such as marketing materials from manufacturers' websites, Instructions for Use and so on. The clinical review could not involve putting the devices to actual use, as we had to make rapid procurement decisions because of the high international demand. If it was identified at any stage that a device did not have a 'CE' mark, the MHRA were involved, and the devices would be required to go through their 'exceptional use' process. I provided a "go/no-go" recommendation to the commercial team on procurement. This recommendation was relevant only to the clinical review, i.e. an indication that my team and I considered the device to be clinically appropriate or not based on the materials we had reviewed. A "go" recommendation was therefore a recommendation that the device could proceed to the next review or due diligence stage. A "no go" recommendation was a recommendation that it should not proceed. All "go/no-go" recommendations that I made in regard to both procurement and innovation (the Ventilator Challenge) were based on clinical grounds and with no consideration of commercial factors. The ultimate decision on whether to contract with a particular supplier was made by the DHSC team responsible for that particular product.

61. Given the urgent need for ventilators at the time, the clinical review had to be undertaken at speed, collating and reviewing large amounts of information in a short space of time. A quick recommendation was needed, often within hours of the ask, which was challenging for all involved. I consider that the clinical review process and the provision of "go/no go" recommendations were appropriate given the pandemic pressures at the time. The urgent need for ventilators at that time meant any device that could do the job regardless of whether it also had other desirable features was

given a "go" recommendation in relation to the clinical review. It was very different to the level and nature of consideration that would be given by Trust clinicians to the purchase of a ventilator outside of pandemic times. My overall reflections on this process are detailed in Section 7 of this Statement but the lack of 'surge stock' of critical care ventilators, as opposed to anaesthetic machines and transport ventilators, was the key reason why we were required to act in this way.

62. These efforts to procure manufactured devices continued into mid-April, with regular reviews undertaken by me and the team of clinicians around me, of product descriptions [**RM1/006 INQ000508285]**.

63. I worked with MHRA representatives on the Ventilator Challenge: specifically, on the development of all versions of the RMVS specification, on the TDA, and via regular correspondence, in order to provide coherent advice to the Cabinet Office.

64. With regard to procurement and supply of ventilators and other medical equipment, I worked with the Royal College of Anaesthetists, Association of Anaesthetists, Faculty of Intensive Care Medicine and Intensive Care Society, and individual experts, where my clinical team and I lacked specific knowledge or expertise on the type or number of medical device which might be required for a specific indication. In this scenario, I approached the appropriate professional partners for advice – this included, for example, advice on video laryngoscopes and on ultrasound machines for placing invasive lines [**RM1/007 INQ000508308**].

65. In the early part of the pandemic, the approach taken by myself and procurement teams was that we should attempt to secure as many as possible of any and all ventilators and non-invasive ventilators. With regard to other medical devices, I advised on how many devices we should be aiming to procure within categories, based on modelling assumptions for the number of patients who would be treated in the NHS at different levels of disease severity (from ward level through to Level 3 care). For example, we aimed for four additional video laryngoscopes (which assist safe airway intubation for patients requiring mechanical ventilation) per hospital site to meet predicted surge requirements, and seeking the advice of experts in the field, we sought to procure the best available / most familiar to UK clinicians) **[RM1/032 INQ000513352]**.

66. I had ongoing discussions with professional leaders (representing the Faculty of Intensive Care Medicine, Intensive Care Society, Royal College of Anaesthetists and Association of Anaesthetists) and MHRA which began in mid-March, regarding the

need for pragmatism in terms of ventilator and other equipment design. I particularly emphasised the need to consider the forecasted pandemic timelines and the design challenges around ventilator design, in order to balance the potentially competing interests of ventilator quality and design/manufacturing speed. An unrealistic specification for a ventilator would not have been deliverable in the timeframes we were working with, and traditional "peacetime" views (e.g. "a bad ventilator is worse than no ventilator at all") required challenge. Through discussion we were able to reach consensus which supported rapid progress with ventilator procurement, the ventilator challenge and working collaboratively to support clinicians using novel equipment under pressure.

67. I was invited to meetings hosted by the Intensive Care Society, named the "National Emergency Critical Care Committee" from 1 April 2020 onwards. At these meetings I was able to give brief updates on NHS England work and to take questions. These meetings were held weekly and I attended intermittently when able to around other commitments.

68. My one interaction with the Rapid C-19 Oversight group was to present the results of a Process Audit of the uptake of evidence-based Covid-19 treatments which I had initiated with the Intensive Care National Audit & Research Centre (**"ICNARC"**) on 8 December 2021.

69. Throughout the relevant periods, I liaised with the ICNARC team to discuss the potential for changes to their data collection methods, including the inclusion criteria (to ensure that patients being treated in surge critical care units could be included, and to discuss the feasibility of "level 2" patients being included).

70. In December 2020, supported by the National Medical Director, I commissioned ICNARC to develop an audit of compliance with Covid-19 treatments. ICNARC was already collecting a dataset from patients admitted to all participating critical care units, and our request was to add questions to their routine audit, which could help us understand if there was unwarranted variation in administration of therapies with some therapeutic benefit in Covid-19: specifically, dexamethasone, remdesivir, interleukin-6 inhibitors (tociluzimab) and different doses of anticoagulation.

Safety and efficacy considerations

71. In this section, I outline my involvement, and where requested, my views, on the adequacy of interventions which were implemented to support safety and efficacy with regard to ventilator procurement, innovation and distribution / implementation.

72. Prototypes for non-CE marked devices which were developed either within the Ventilation Challenge, or through other routes, were delivered to MD-TEC for formal testing.

73. A testing protocol was developed by MD-TEC which involved bench testing at their lab in Birmingham, and clinical testing at hospitals which volunteered – these included Southampton and Cambridge (Addenbrookes). The evaluations were designed to map to the minimum requirement/standard for the ventilators as set out in the current version of the RMVS specification.

74. The testing protocol was intended to be a pragmatic evaluation, to determine:

a. If the device met the standard (i.e. did it do what it was supposed to do); and

b. usability: categorised to promote safe deployment (for example, estimating the level of training and prior clinical experience required for staff initiating and managing treatment using these devices)

75. Formal reports of testing of prototypes were fed back to the TDA to assist in decision-making at each stage gate of the process [**RM1/008 INQ000508309**]. PA consulting, acting on behalf of the Cabinet Office, compiled reports summarizing the evaluations, our clinical feedback, feedback from the regulator and other key information, for ease of decision-making [**RM1/009 INQ000501921, RM1/010 INQ000508286, RM1/011 INQ000478796, RM1/012 INQ000508289 and RM1/013 INQ000508299**].

76. The level of testing which devices underwent at MD-TEC was necessarily more limited than in normal times. However, in my opinion, MD-TEC device evaluations were of good quality, robust, and easy to understand, providing the clinicians with important information to support recommendations and decision-making.

77. I was not involved in supply chain analysis of component parts of ventilators.

78. All comments/feedback to developers / manufacturers of ventilators were limited to the discussions at formal meetings hosted by PA Consulting/Cabinet Office with the following exceptions:

a. I received multiple personal communications from individuals hoping to enter the Ventilator Challenge, or to offer services for related products. Some came directly to me, and others via Royal Colleges, FICM or other professional stakeholders; in all cases I directed these individuals to the Cabinet Office or DHSC as appropriate [**RM1/014 INQ000508284**];

b. I received multiple personal communications from the team responsible for the development of the UCL Ventura CPAP device. These included colleagues at UCL and UCLH where I work academically and clinically. The summary of the interactions is that the UCL team were keen to ensure that the device was commissioned, manufactured and distributed as soon as possible. They sought my help on these matters. I provide further information on these interactions, including safety discussions below.

79. In the later stages of the Ventilator Challenge we specifically turned our attention to the potential for devices which were not required to support the UK Covid-19 response to be deployed internationally, to support low- and middle-income settings, either for Covid-19 or for general use. We engaged military experienced anaesthetists and surgeons to help us with this task [**RM1/015 INQ000508298**].

80. All the clinical members of the TDA were being approached to help with / support different projects. We were meticulous about declaring conflicts of interest and ensuring that direct approaches to us were directed appropriately through official channels [**RM1/014 INQ000508284 and RM1/015 INQ000508298**].

81. The clinical team on the TDA were asked on 6 May 2020 if they would be prepared to offer support to the final five teams in the Ventilator Challenge through support for clinical trials (one of the final steps required to achieve regulatory approval). On consultation with the team, we declined to provide this, on the basis of wanting to remain impartial should further advice to DHSC, NHS England or government be required on the relative merits of different devices [**RM1/016 INQ000508300**].

Quality, safety and appropriateness of equipment procured or developed

82. Dozens of different devices, including mechanical ventilators, non-invasive respiratory support devices and other equipment such as syringe drivers, feeding pumps and so on, were procured (and in the case of ventilators and CPAP devices, manufactured) as part of the ventilation procurement effort and Ventilator Challenge.

83. The quality of these devices varied significantly, including:

a. Machines which would be procured and used in 'normal times';

b. Machines which would have been unlikely to have been used in 'normal times' due to concerns about quality or versatility; and

c. Machines manufactured for one purpose (e.g. delivery of mechanical ventilation during general anaesthesia for surgery, or during transport) which were used to support critically ill patients (either with Covid-19 or other diagnoses).

84. In some cases, the limitations of the devices we had available for patient care necessitated specific guidance, and/or adaptation of the devices and/or the indications for which they were used. Some examples (not an exhaustive list) are provided below.

Anaesthetic machines used as critical care ventilators

85. The immediate availability of anaesthetic machines in all acute hospitals with operating theatres, and the cessation of planned surgery, meant that anaesthetic machines were the initial source of surge ventilator capacity across the NHS.

86. Anaesthetic machines include simple ventilators which are designed predominantly for use in patients with healthy lungs for short periods (up to 24h) while patients are anaesthetised for surgery.

87. Clinicians quickly adopted their use for treating Covid-19 patients, but challenges became apparent with early clinical experience; we gathered information from sites with experience and published national guidance to support safer care on 29 April 2020 [**RM1/017 INQ000508310**].

AeonMed 510 Shangri-La

88. One of the devices for which I provided a "go" recommendation was the Aeonmed 510S Shangri-La ventilator. I was asked to carry out the clinical review of the device (as described in paragraph 60 of this Statement), as one device on the list of devices provided by DHSC colleagues. I was not part of any other review or due diligence undertaken on the device before then. The documents considered for the clinical review were those that were publicly available (as explained in paragraph 60 of the Statement), or had been provided by the device's manufacturer. I provided a "go" recommendation (see paragraph 61 of this Statement for clarity on what this meant) on the basis of the manufacturer's materials which stated that it was a machine which

could provide six different ventilatory modes, oxygen levels between 40 and 100%, and a variety of other features – therefore significantly higher specification than a basic transport ventilator, and higher specification than anything which would be likely to be produced by the ventilator challenge. Procurement was approved on 18 March 2020 and devices arrived in the UK in early April 2020.

89. On 6 April, through one of the regular calls we had with the seven NHSE regional medical directors or their designates, I became aware of a potential risk associated with this device, related to the tubing provided not being immediately compatible with UK cylinder/piped gas supplies. NHSE regional medical directors typically work within their given NHSE regions, and engage with the wider NHS system on their patch. They are not medical directors within individual NHS Trusts; during Covid they had multiple roles, which included supporting coordination within and between regions of care and resources (including people and equipment). I requested further information from Portsmouth hospital which had been allocated some of the devices in question, which I received on 6 April 2020 and we worked the information provided into the quick start guides we were concurrently producing (see later in this Statement for more detail on these) to assist local teams in safe introduction of new equipment to practice. Where the allocation process indicated that a particular Trust needed ventilators, neither the regional medical directors nor local Trust leaders could specify the make or model of ventilator they would like. Allocation was a fair system based on clinical need, demands of patient care and the available devices within the warehouse.

90. On 8 April 2020, we received an offer from Professor Daniel Clark at Nottingham University Hospitals, via the Institute of Physics and Engineering in Medicine, to offer support to our allocation process – in the form of a single test site for new stock which was unfamiliar to the NHS.

91. The offer was made because Professor Clark had received feedback from colleagues in the West Midlands, who had voiced their concerns regarding the challenges with adapting new kit for UK use, specifically related to the Shangri La device. We accepted this offer and the efforts to do this were coordinated by the DHSC/Cabinet Office team. The Nottingham team led by Professor Clark were geographically close to the Donnington Warehouse which received inbound stock, and where such stock was then packaged up for distribution to the NHS in accordance with our established allocation and distribution system.

92. On 12 April 2020, I received a request from the Regional Medical Director for the Midlands to hear concerns from critical care consultants regarding the Shangri-La ventilators. This call took place on 13 April 2020 and I subsequently requested and received a written statement from the clinicians summarising the concerns they had and the issues we had discussed [**RM1/018 INQ000508291, RM1/019 INQ000508292, RM1/020 INQ000508293, RM1/021 INQ000508294, RM1/022 INQ000508295 and RM1/023 INQ000508296**]. In particular, it was evident that the clinical experience of using the devices suggested significant differences in the capabilities of the ventilator when used in practice, compared with the manufacturer's specifications. I also received correspondence from Portsmouth voicing further concerns with these machines [**RM1/024 INQ000508297**]

93. The same day, 13 April 2020, I formally alerted DHSC and the Ventilator Procurement team about these concerns and made three recommendations – to stop further procurement of these machines and try to recoup the cost; to replace the machines allocated via our National Allocation Process; and to ensure that any machines which had already been received by Donnington were checked by the Nottingham medical engineering team. I cannot recall updating the regional medical directors of my actions, however, given that we were meeting daily I am quite certain that an update would have been provided verbally to them. I would have expected that the regional directors would have, in turn, updated the clinicians working in Trusts who had initially alerted them. In addition, as described further below, all hospitals with these devices were quickly contacted directly by DHSC.

94. The DHSC team approached all hospitals where these devices had already been allocated and asked them to undertake an urgent clinical and engineering review. The reports we received confirmed that the machines were not reliable, and some had failed basic engineering testing undertaken on site. Via the Cabinet Office we also sought information from the devolved nations and Crown Territories. I submitted a report [**RM1/025 INQ000508311**] summarising the issues, which included all concerns raised to me, information from sites, and discrepancies between the manufacturer's literature and the NHS experience of using the actual device, to the NHS England/DHSC team on 19 April 2020 with four key recommendations:

    a. Stop using devices which had been distributed

    b. Stop further distribution

    c. Undertake an independent bench evaluation of machines

d. Stop further procurement until the report from the independent evaluation received

95. Cabinet Office followed up on these recommendations to further alert clinicians not to use the devices and over the subsequent week these devices were recalled.

96. I am not aware of any operational or clinical impact of removing these machines from service at that time. Similarly, I cannot recall any other instances of devices which failed in this way. I am aware that Philips recalled some CPAP devices in June 2021 due to a potential safety issue.

97. As described in paragraph 91 of this Statement, Professor Clark began carrying out checks on the actual devices prior to Trust allocation. This was an additional check added once procured ventilators had arrived at Donnington for allocation. It was separate to, and much later in the procurement process, than the clinical reviews I and others provided prior to any buying decision. As ventilators had not been procured at the clinical review stage, it was not possible to check whether a ventilator actually worked in accordance with its specification. Most (if not all) of the ventilators we procured were manufactured overseas; therefore, unless they were a device which was already familiar to UK clinicians, we were entirely dependent on the quality of information provided by manufacturers.

Non-invasive respiratory support devices

98. From the outset of my involvement with procurement, our strategy included the procurement of any and all devices which could be of potential use to treat patients with Covid-19. This included non-invasive respiratory support devices, which as detailed in paragraph 21 of this Statement includes CPAP machines. As early as 9 March 2020, I was advocating for the procurement of CPAP hoods as it was clear we would require multiple options to manage patients with respiratory failure.

99. Sufficient turbine-driven devices became available via procurement to meet the demand for CPAP in NHS patients during Wave 1 (and therefore subsequently). Turbine driven devices carried a lower risk to oxygen infrastructure than gas-driven devices, although some modifications were required to some of these devices, to repurpose them from their usual indications for use (e.g. home ventilation or obstructive sleep apnoea) to Covid-19 respiratory support. For some devices, we sought support from academic experts (clinical and engineering) at the Royal Brompton Hospital, to modify and improve the functionality of turbine-driven devices

for use in patients with Covid [**RM1/033 INQ000513355**]. We also asked these experts to provide advice on off-label use of non-invasive respiratory support devices which we had secured through mass procurement, to support safe deployment in different clinical scenarios [**RM1/034 INQ000513362**].

UCL Ventura device

100. A team from UCL, co-led by engineers and intensive care doctors, worked with the Mercedes Formula 1 engineering team to rapidly develop an updated version of a CPAP device (originally known as the "Whisperflow") which had previously been CE marked and widely used, but which had largely been withdrawn from use in the NHS. The original Whisperflow was a gas (oxygen) driven device which would attach directly to a piped oxygen wall outlet, providing CPAP to patients via standard ventilation tubing and a fitted mask. The advantage of trying to rapidly develop this device was that the team were planning to copy and then modestly modify an existing design, which would simplify the manufacturing and regulatory approvals process. However, a disadvantage of this particular design was the high oxygen demand required when it was used; it was a gas-powered mechanical device which required high oxygen flow rates to generate the continuous pressure required, as well as the oxygen which the patient would breathe. We had previously discouraged (through procurement strategy and clinical guidelines) other high-oxygen demand devices (such as high-flow humidified nasal oxygen therapy).

101. The team, which were based in my academic and clinical institutions, approached me on several occasions to seek support for development. I facilitated early conversations with colleagues at DHSC and then stepped back from further involvement with the exception of providing advice to them, and to colleagues at DHSC and Cabinet Office on my concerns about:

    a. Safety:

        i. high oxygen demand which could disrupt oxygen delivery in hospitals;

        ii. high ambient oxygen levels which could pose a risk to ward safety (explosion risk);

    b. distribution:

i. concern about circumventing the National Ventilator Allocation Process which had been established to allocate and distribute the centralised stock of critical care equipment procured by DHSC / manufactured through the Ventilator Challenge.

102. We were able to mitigate these risks by managing the distribution of these devices centrally, in keeping with all other equipment procurement and distribution, and sense-checking with regional teams that the oxygen infrastructure would be sufficient to meet the demand that these devices placed.

103. I have been asked whether I was involved in the 'recommendation' of GE R860 ventilators; UCL Ventura CPAP devices; Flo-Ox Oxygen Monitors; and Visionaire 5 Portable Oxygen Concentrators. I reiterate here my earlier comments on the nature of the "go/no go" recommendations provided as part of the clinical review of devices. In relation to these devices: the GE R860 was already being used in the NHS, and therefore I would have provided a "go" decision if asked. While I cannot find a specific record of approving the oxygen concentrator, it is very likely that I would have approved if it met a basic standard, as these devices were potentially able to give us significant additional capacity for patient care: they extract oxygen from ambient air and therefore would enable patients requiring oxygen via a face mask to be treated anywhere (including care homes) even without piped or cylinder oxygen supply.

104. I did not provide a clinical opinion on whether the UCL Ventura device should be procured. This was a ministerial decision [**RM1/035 INQ000513363**] which I understand was made over the weekend between 3 and 5 April 2020, and which did not go through the processes established for the Ventilator Challenge or more general DHSC led procurement. I believe that clinical input was provided by NERVTAG, but I was asked to check the clinical content of the submission for approval of DHSC funding for 10,000 devices [**RM1/036 INQ000513353**].

105. The Flo-Ox oxygen monitors were provided as part of the kit of parts required to use the Ventura device and therefore, again, I was not involved in decision-making on these. The monitor was needed to show how much oxygen was being received by the patient (rather than driving the device).

106. I have been provided with comments from the draft witness statement of the Royal Surrey NHS Foundation Trust in relation to these devices. It is not clear when these devices were provided to the Trust and so I cannot be clear whether these devices were provided as part of the ventilator allocation programme. I was aware, for

example, that UCL were providing some its Ventura devices direct to Trusts rather than via the ventilator allocation programme. I was also aware that some devices, including the UCL Ventura device were provided to a small number of Trusts as part of the 'Recovery-RS' clinical trial. I am also aware that early in the pandemic, the Royal Surrey was one of the small number of hospitals which offered to trial the Ventura device as part of the MHRA approvals process.

107. I was not aware of concerns being raised in respect of these devices at that time. I make reference above to the concerns I raised as to the high oxygen usage of the UCL Ventura CPAP device. As referred to above, this relates to concerns, early in the pandemic, as to the capacity of the infrastructure within certain Trusts of getting oxygen to the bedside. See Section 4 of this Statement for more detail on this. It is unclear to me whether the comments from Royal Surrey relate to safety concerns of the device itself or safety concerns relating to oxygen capacity as a consequence of using the device.

108. In relation to the provision of appropriate consumables and competency training relating to these devices, the allocation team strived to provide a week's worth of consumables alongside any new devices where possible. As explained below quick start guides accompanied allocated devices. Other organisations (and this includes UCL in relation to the Ventura CPAP device) also developed user guides for new devices.

General quality and safety considerations relating to procurement, deployment and use of ventilators and other specialist equipment or medicines

109. Critically ill patients are usually cared for in accordance with staffing and clinical guidance which specifies specific ratios of nurses, doctors and allied health professionals, to patients with different levels of critical illness. Such ratios have been set by professional bodies and implemented by the NHS to maintain patient safety and the quality of care – specifically to reduce the risk of inadvertent harm (medical accidents) and to ensure that care is individualised to the patient's clinical needs.

110. During surges in critical care demand, as occurred in some centres during the pandemic, the ratios of critical care trained staff to patients were diluted. I commissioned and contributed to national guidance, produced both by NHS England and professional stakeholders which aimed to support local teams in the following approaches to maintain patient safety; relevant guides included:

a. Training of non-critical care staff in the basics of critical care e.g. https://icmanaesthesiacovid-19.org/cross-skill-training-for-pandemic-covid-19;

b. Redeployment of staff to support the critically ill – how many, how to allocate, how to prepare, how to deploy;

c. management of critically ill Covid-19 patients and those requiring non-invasive respiratory support; and

d. oxygen housekeeping (actions for clinicians to reduce the risk of oxygen delivery failure).

111. In addition, a team of clinicians worked with DHSC and the Cabinet Office to produce 2-page quick start guides for all new ventilators, whether sourced through procurement or through the Ventilator Challenge. These were intended to supplement Instructions For Use provided by manufacturers, providing information in a concise format which would support deployment. An example complete set of documents available for one device (the Penlon ESO2) is provided [**RM1/037 INQ000513356, RM1/038 INQ000513358, RM1/039 INQ000513359, RM1/040 INQ000513360**]; an example of a training video can be accessed here: https://portal.e-lfh.org.uk/LearningContent/Launch/620844.

112. My work in the procurement of ventilators or other equipment was not informed by any research regarding the protected characteristics of NHS staff as these do not affect operating requirements.

My views on the provision and adequacy of procurement and distribution of ventilators, other equipment, medicines and other supplies

113. Working collaboratively, NHS England, DHSC and the Cabinet Office undertook a multi-faceted programme which aimed to ensure that patients who required treatment with oxygen, non-invasive respiratory support and/or mechanical ventilation were able to access it at all times. This included:

a. Procurement;

b. Innovation (the Ventilator Challenge);

c. Oxygen provision and infrastructure works, and guidance to clinicians and engineers to reduce the risk of oxygen flow failures; and

d. Moving patients between hospitals to alleviate surge pressures in particularly hard-pressed services; however, this was predominantly undertaken to alleviate workforce challenges as opposed to mitigate equipment shortages.

114. In March 2020, the government set a target of an additional 30,000 ventilators to be made available for use in the NHS. This target was achieved by 3 August 2020, through a combination of procurement by DHSC and new manufacture through the Ventilator Challenge.

115. Although the target number of machines was achieved, the quality of the machines and their suitability for use in the NHS, to treat Covid-19 or other conditions was variable. There were also shortages of other essential items, including some medicines and consumable items. These limitations meant that clinicians were not always able to treat patients with their first choice of interventions.

116. In some situations, the surge of patients requiring care beyond the usual capacity of critical care and acute respiratory services led to a combination of pressures arising from:

a. the use of unfamiliar or adapted clinical interventions; and

b. workforce pressures, including the dilution of ratios of trained critical care staff (nurses, doctors, allied health professionals and pharmacists) and the consequent need to train, supervise and support staff who were not used to working in these clinical settings.

117. An example of unusual clinical practice necessitated by surge demand, related to renal replacement therapy in critically ill patients. In normal times, this would usually be provided using continuous venous-venous haemofiltration (**"CVVH"**) which requires an access line, some specialist consumable items (filter, fluid) and a complex machine (the haemofilter). Nursing staff setting up and supervising CVVH therapy have received specific training to be able to do so and the establishment and maintenance of CVVH is a specialist critical care skill for doctors and nurses.

118. The high demand for renal replacement therapy placed pressure on all aspects of the delivery of this intervention – the consumable items, hardware and technical skills required.

119. NHS England established an incident cell to manage this problem which was multifaceted and included auditing, procurement, distribution and clinical guidance.

NHS England published guidance to support clinicians in how to manage the excess demand, which included alternative approaches to renal replacement therapy (e.g. slow low efficiency dialysis or peritoneal dialysis) **[RM1/041 INQ000513354]**. NHS England also supported clinicians to consider how to use expertise from outside critical care (specifically renal dialysis services) to support renal replacement therapy in the critically ill.

120. I am not aware of any specific incident where a patient who needed a ventilator was not able to access one. However, I cannot be sure that individual decisions, made when clinicians were under current or anticipated pressure, did not lead to a change in clinical decision-making or behaviour, compared with normal practice. Such a change in clinical decision-making may have meant that patients who would have otherwise had their treatment escalated, did not. This may have led to patient safety incidents and/or psychological harm to staff.

121. To some extent, clinical decision-making can be affected by demand even during more modest surges in NHS demand, such as over the Winter. For example, I have published research which demonstrates that critical care capacity (the availability of a bed) exerts a small but significant effect on the likelihood of a high-risk patient being admitted to critical care after surgery, all other things being equal;[1] furthermore, we know that some patients may have elective surgery postponed if a critical care bed is essential, but not available.[2] However, the Covid surges were unprecedented, for two reasons: first, the sheer numbers of emergency admissions, and second, the impact on capacity for emergency care, even after reducing elective activity.

122. In early April 2020, it was brought to my attention that there was a marked difference between centres in one English region, in the proportion of renal transplant patients being admitted to critical care with Covid-19 disease, and that there may also be differences in admission patterns for patients who were on immunosuppressant therapy for other indications. Concern was also raised that in at least one centre there was a blanket rule that renal dialysis or transplant patients should not be admitted to critical care. I received correspondence about this on 7 April 2020 and responded that clearly blanket rules were inappropriate, and that individual decision-making based on the patient's overall clinical condition remained the approach which should be taken (as is always the case with critical care

[1] https://associationofanaesthetists-publications.onlinelibrary.wiley.com/doi/10.1111/anae.16383

[2] https://www.bjanaesthesia.org/article/S0007-0912(18)30565-8/fulltext

decision-making) [**RM1/026 INQ000508290**]. I further confirmed that while there may be concerns about critical care capacity, there were plenty of beds available nationally, although it might be necessary for patients to be transferred between hospitals to access one. Clinical guidance available at that time, and which was regularly updated, confirmed that decision-making regarding critical care admission and treatment escalation should follow usual ethical, legal and clinical frameworks.

123. There is some evidence to suggest clinical practice varied according to changes in demand. For example, data from ICNARC which was published as a peer-reviewed research paper, indicates that during times of surge, the age and premorbid health of patients who received critical care interventions was lower (i.e. patients admitted to critical care were younger and healthier) than when services were under less pressure [**RM1/027 INQ000508312**]. As discussed in the research paper, this may reflect changes in the population demographics of patients with Covid during times of surge or may reflect access to or treatment escalation decisions related to critical care.

124. NHS England monitored critical care capacity, including a quantitative evaluation of capacity (bed numbers, including occupancy) and the service-level 'Critcon' score, which provides a qualitative evaluation of 'strain' on the service, incorporating features such as workforce capacity. This is set out in detail in the Second Witness Statements of Amanda Pritchard and Mike Prentice, both in Module 3.

125. Daily meetings with regional medical directors or their delegates, managed the critical care capacity of the country as 'one NHS' and therefore supported transfer of patients between centres, in order to alleviate pressure on staff and other resources, and provide the best available care to individual patients.

SECTION 4: OXYGEN

Introduction

126. The clinical nature of Covid-19, being a respiratory virus, and the necessary therapies and treatments required as a result, meant that oxygen supply was a key consideration and challenge throughout the pandemic. It is also important to understand the infrastructure for delivery of oxygen to patients which existed throughout the NHS coming into the pandemic.

127. The principal reason for hospital admission of patients with Covid-19 was for oxygen therapy. The mechanisms by which oxygen can be administered to hospitalised patients are detailed in paragraph 24 of this Statement.

128. Although overall hospital occupancy during Covid may have been lower than normal, the proportion and absolute numbers of patients requiring oxygen therapy were far higher during surges of Covid-19 occupancy. This therefore placed significant pressure on oxygen infrastructure as described below.

129. Oxygen is predominantly transported to hospitals in tankers in liquid form. Liquid oxygen is transferred into a Vacuum Insulated Evaporator ("**VIE**") which is a large cylindrical store, usually situated directly outside a hospital. Here, the liquid oxygen is warmed in a controlled process, to convert it to oxygen gas. This gas is transported via pipework to multiple wall outlets inside the hospital, whereby a tube connects the outlet to an oxygen administration device (e.g. face mask, CPAP device or ventilator).

130. VIEs have a maximum flow rate capability. If oxygen demand is unusually high, there is a risk that this capability will be exceeded. The consequence of this could be failure of oxygen delivery to patients, due to ice build-up on the exterior of the vessel leading either to an unexpected flow drop (compromising supply to patients) and/or permanent damage to the system.

131. The architecture of the pipework most proximal to the wall outlet will determine the maximum flow rate it is possible to achieve. Clinical areas where oxygen demand is generally low (e.g. normal wards) have pipework which supports oxygen delivery at an average of 10 litres/minute. High demand areas (e.g. critical care units, operating theatre suites, emergency departments) have pipework which supports oxygen delivery at a much higher average flow rate (up to perhaps 100 litres/min). This is set out in further detail in the Health Technical Memorandum (HTM) 02-01 Medical Gas Pipeline Systems, which is mandatory guidance issued by DHSC in May 2006.

132. Hospitals with older estates were therefore faced with a significant challenge when considering how to expand their critical care capacity, or even to care for larger numbers of ward-based patients on face-mask oxygen.

133. A further source of risk is that flowmeters, when fully opened, provide a flow rate of gas which is far higher than that recorded on the meter. For example, clinicians would generally consider an oxygen flow rate of 15 litres/minute to be the maximum which would be required for administration to a patient wearing a loose fitting face mask,

and indeed the highest level on a wall flow meter is usually 15 litres/min; however, if the tap is fully opened, flow rates of around 60 litres/minute may be possible. This risks excess oxygen flows being delivered, to no patient benefit, but to significant clinical and operational risk (of flow failures if the ward is subject to higher than usual demand) and of fire risk if ambient oxygen levels rise.

134. A Covid-19 ward design guide was (initially) published by NHS England on 22 March 2020 which included advice for hospitals on oxygen supply considerations when converting normal wards to Covid-19 wards or critical care surge units. It was subsequently updated and re-published on 2 April 2020, to include an appendix which described the lessons learned from setting up the London Nightingale hospital [**RM1/028 INQ000508303]**.

Urgent patient safety notice issued on 31 March 2020

135. On 31 March 2020 I, in conjunction with NHS England's National Clinical Director for Respiratory Medicine and the National Estates Operational Lead/Covid-19 Estates Lead, sent an urgent patient safety addressed to all NHS CEOs, Medical Directors, Critical Care Directors and Respiratory/Acute Medicine Directors **[RM1/044 INQ000226891]**. This notice related to the use of high flow oxygen therapy devices, including wall CPAP and high flow face mask or nasal oxygen, mindful of the pressure the use of such therapies was placing on oxygen supply and delivery across the NHS.

136. This notice was sent because we were concerned about oxygen delivery failures or challenges for two reasons:

    a. Increasing actual, and anticipated, numbers of Covid-19 admissions to general wards, requiring high oxygen flow rates, and therefore a higher than usual demand on VIEs and oxygen pipework infrastructure; and

    b. updated clinical guidance issued by NHS England on 26 March 2020, which advocated treatment with CPAP as a key part of the pathway for patients with respiratory failure.

137. Wall-mounted CPAP devices which use piped oxygen as a driving pressure, tend to consume higher amounts of oxygen than turbine-driven devices, normal oxygen delivery systems (loose fitting face or Venturi masks) or mechanical ventilators, and therefore we considered there to be a risk of oxygen flow failures.

138. The alert was labelled an Estates and Facilities Alert and addressed to CEOs, and Medical, Critical Care, Respiratory and Acute Medicine Directors; it was further disseminated with the assistance of professional bodies (e.g. medical Royal Colleges and specialist societies to their members and fellows).

139. The alert provided the background to the risks and mitigation actions, including the need for clinicians to work with hospital engineering teams to ascertain their VIE's maximum flow rate, the safest physical location to open surge wards which would treat patients with high oxygen flow requirements, and to consider limiting the number of high flow CPAP or similar devices available to reduce the risk of unanticipated oxygen failures

140. The 31 March alert also highlighted the risks of using cylinder oxygen to drive ventilators or provide bedside oxygen, including trip hazards and undetected oxygen failure due to supply depletion.

141. A further alert was issued via the Central Alerting System (CAS) on 6 April 2020 highlighting the specific risk of icing on the VIE which could lead to sudden, unexpected oxygen delivery failure. This was in response to the incident at Watford General Hospital which necessitated the evacuation of critically ill patients, and which is described in greater detail in Part 2, Section 5 of the witness statement of Julian Kelly for Module 5.

142. A number of safety incidents related to oxygen delivery and demand occurred during the Relevant Period; those which were declared major, or critical, incidents are also detailed in the witness statement of Julian Kelly for Module 5, as referenced above.

143. Following the incident in Watford, I supported a proposal from the Healthcare Safety Investigation Branch (**"HSIB"**) to undertake a rapid investigation, with a view to quickly understanding and learning lessons to prevent future similar events. Further information on how this was undertaken and the outcomes communicated are within the witness statement of Julian Kelly for Module 5, as referenced above.

144. NHS England's estates team, working with BOC and Air Liquide (the commercial providers of liquid oxygen to the NHS) undertook a coordinated review of hospital oxygen infrastructure and demand and prioritised several estates for priority engineering work to improve their capacity to meet surge demand of oxygen to patients. This began in early April 2020 and was completed in waves over the course

of the pandemic, as detailed in the witness statement of Julian Kelly for Module 5, again as referenced above.

145. As the pandemic progressed, more respiratory support equipment, which was less 'oxygen hungry' became available for hospitals to use, and via our centralised mechanisms we preferentially allocated devices (such as turbine driven non-invasive respiratory support devices, rather than UCL Ventura Devices) to hospitals via the National Ventilation Allocation Panel.

146. In addition, clinical guidance on treating critically ill patients and those requiring non-invasive respiratory therapy was regularly updated and included guidance on managing oxygen supply/demand challenges, referencing the CAS alert from 6 April 2020.

Procurement/provision of oxygen supplies

147. The specific role of NHS England in relation to the procurement of oxygen supplies is set out in the witness statement of Julian Kelly for Module 5. That statement also sets out the major incidents which occurred during the Relevant Period, and the role of NHS England in managing them.

148. Insofar as my own involvement in such matters is concerned, I provide commentary below on the procurement/provision of oxygen supplies.

149. I do not have any concerns about the procurement of oxygen to the NHS during the pandemic. DHSC had worked with BOC to ensure that liquid oxygen for storage and use in VIEs at main hospital estates had been sufficient to mean that supply was not a concern; further, oxygen supplies were delivered to new sites (e.g. Nightingale facilities) in such a way that these were not a limiting factor in developing the estates that were planned to meet surge demand.

150. The oxygen infrastructure within NHS estates limited the safe delivery of surge demand to the point that clinicians and local engineers in some (particularly older) estates were required to undertake mitigation activities related to oxygen husbandry which were exceptional, and created an additional pressure on these staff, in order to avoid patient safety events.

151. The incidents at Watford in Wave 1, and at Grimsby, Epsom and St Helier and Morecambe Bay in Waves 2 and 3 were examples of where despite attempts at prevention/mitigation of risks associated with the extremely high oxygen demand,

potential risks to patient safety occurred. The measures taken in response to those incidents by NHS England are outlined in the witness statement of Julian Kelly for Module 5.

SECTION 5: CRITICAL CARE

Introduction

152. The challenges posed by the Covid-19 pandemic, and in particular the strain it placed on critical care, meant that it was necessary to make certain changes to standard models of care. This included changes to staffing ratios, which has been addressed in detail in section 10 of the Second Witness Statement of Amanda Pritchard for Module 3. On that basis I therefore focus on my own reflections relating to standards of care during the pandemic.

Reflections on standards of care for critical care patients vs. surgery patients

153. Throughout the pandemic, there were system-wide changes in the provision of healthcare. This included reducing the volume of non-emergency surgery, to free up capacity (beds, staff, equipment) to care for surges in numbers of Covid-19 patients, while also providing care for other emergency and urgent patients, including surgical patients.

154. NHS England issued guidance to support anaesthetic teams (who provided the first line of surge support staff for critical care) in ensuring that the provision of essential care for non-Covid patients, could continue with as little disruption as possible; for example, through support to maternity units and non-elective surgery. NHS England also issued guidance to support local teams in prioritising which types of elective surgery should continue to take place.

155. There was no change in guidance regarding which surgical patients should be admitted to critical care after their operation.

156. NHS England sought to ensure that the highest priority non-emergency surgery, for example cancer surgery, could continue with minimal disruption. Measures which they undertook included the use of the independent sector, as set out in paragraphs 1145 to 1233 of the Second Witness Statement of Amanda Pritchard for Module 3 and the broader strategies as set out in paragraphs 44 to 207 of the Fourth Witness Statement of Steve Powis also for Module 3.

157. The National Emergency Laparotomy Audit (**"NELA"**) published a special "Covid-19 report" in early 2021, which analysed data on patients undergoing this high-risk type of emergency abdominal surgery [**RM1/029 INQ000508301]**. The report noted a drop in the proportion of high-risk patients (defined as those with a 30-day mortality risk prediction of >5%) which met the national standard of being admitted to critical care after surgery; the report discussed that this fall in standards may have been related to critical care capacity, due to Covid-19 admissions.

158. In addition, analysis of Hospital Episode Statistics data compared admission rates, treatment patterns and clinical outcomes for patients with a broad range of acute abdominal conditions which might require surgery, between the first peak of Covid in March/April 2020 and the same time window in 2019 [**RM1/030 INQ000508313**]. This analysis found that during the First Wave, fewer patients with these conditions were admitted to hospital. In addition, of the patients who were admitted to hospital with these conditions, fewer underwent surgery (that is, more had 'medical' or 'conservative' management). For some of these conditions, mortality after emergency surgery was higher and mortality after 'conservative' management was also higher, during the First Wave when compared with 2019. Whatever the precise underlying reasons, this indicates that there were differences in patient characteristics and clinical decision-making for emergency surgery during the First Wave and the equivalent time period in the previous year.

My reflections on guidance for staff and professionals who did not normally work in critical care.

159. The surge in critical care admissions necessitated the redeployment of staff who did not normally work in critical care, to support critically ill patients. This diluted the usual staffing ratios of trained critical care staff, but was necessary to ensure that all critically ill patients had a healthcare worker at their bedside at all times.

160. We published multiple guidance documents as detailed in paragraph 110 of this Statement. These documents were updated regularly, either by the team which I led at NHSE, or by a multi-professional working group which I had convened, which updated clinical guidance on the management of Covid.

161. The guidance set out key aspects which we considered to be important to protect patient and staff safety given that the ratios of trained critical care staff to patients were to be extended. This included different tiers of supervisory roles, use of other services (e.g. anaesthetics, radiology, renal, pharmacy) to provide specialty specific

support (for example for airway management, line insertion, aspects of renal replacement therapy and the preparation of intravenous infusions) to enable critical care trained staff to focus on specialised tasks.

162. We provided resources for staff new to critical care via the e-learning for health ("**e-lfh**") platform; this included putting into a single repository information which was sourced from external sources, such as individual Trusts, which could be of value to the healthcare community.

163. The e-lfh platform also included guidance on implementing new equipment, including the ventilators procured and made through the DHSC and Cabinet Office programmes; this included everything from how to unbox new deliveries of devices through to the "quick start" guides produced by our clinical team, and the manufacturers' instructions for use.

164. We worked closely with professional partners (for example specialist societies, medical royal colleges) to identify themes for challenges in providing safe patient care, and to produce guidance to support safe care. In particular, I worked closely with individuals representing a four-party collective of the Royal College of Anaesthetists, Association of Anaesthetists, Faculty of Intensive Care Medicine and Intensive Care Society, which published professional guidance for doctors working in critical care and anaesthesia, on a specific website which they developed and curated.

165. Critical care staff have undertaken specialist training to deliver the care required to support patients with organ failure. No guidance document or suite of documents can substitute for the months or years of training and experience which experienced critical care staff have. However, the guidance which was produced was comprehensive. In my view the guidance was also timely, and updated as regularly as practicable, when new information became available.

166. We also sought to address the clear risks to the mental health of staff working in critical care through multiple approaches. I worked with the Strategic Incident Commander Professor Willett, to secure an allocation of £10million approved by the NHSE CFO Julian Kelly, to support staff working in critical care. This money was distributed in November 2020 via regional teams on a 'fair shares' basis across the NHS in England; £5million was allocated to support training for surge staff in the practical duties of working in critical care; £5million was allocated to support the pastoral care of staff – with a specific suggestion that this funding will be used by

providers to support the pastoral care of clinical teams with dedicated supernumerary clinical facilitators that can provide hands on practical support to staff on a day to day basis **[RM1/042 INQ000513361]**.

Concerns regarding procurement and staffing ratios

167. Procurement of healthcare equipment and supplies was challenging throughout the pandemic. Availability of equipment, medicines and consumables varied, both as a result of global competition for resources, challenges for manufacturers because of supply chain constraints and border controls, and our own unusually high demand.

168. Examples of these challenges include those already discussed regarding ventilators, but also extended to other areas. For example, the supply of the drug propofol was constrained at different times in the pandemic. Propofol is an intravenously administered medicine usually used to induce anaesthesia, and to maintain sedation for critically ill patients. NHS England published a supply disruption alert ("**SDA**") and I worked in collaboration with professional partners to produce supporting advice for clinicians to help prioritise the indications for using propofol, and guidance on alternatives. This was particularly important to ensure that the Commercial Medicines Unit at NHS England were able to predict and mitigate "knock-on" impacts in demand for other medicines.

169. My experience during the Relevant Period, is that the NHS and DHSC worked closely together to predict and mitigate risks of supply shortages (the Ventilator Challenge being a prime example of this). We established mutual aid processes, and central coordination of resources, so that equipment, medicines or consumable items which were in very short supply were allocated in the fairest way possible to the Trusts in the greatest need. This is addressed in NHS England's corporate witness evidence for Module 3.

170. However, the unique circumstances of the global pandemic, the surge in UK patient numbers requiring respiratory and critical care, and the lack of capability of the UK to undertake or scale up manufacturing capacity for multiple high demand items, all had an impact on patient care and on the teams delivering that care.

171. In summary, my opinion is that, despite the best efforts of those involved across all agencies, the outcome of procurement of equipment and supplies was not sufficient to enable healthcare workers meet the same standards of care afforded to patients treated during surges of Covid-19 demand, compared with non-surge, or

pre-pandemic conditions. Despite the efforts of teams responsible for procurement, and clinicians, managers and other colleagues who developed guidance to support delivery of patient care, patients were treated with equipment or medicines which were either not designed for that purpose, or did not provide best practice, and were treated by staff who were not necessarily fully trained to do so. These risks would have been cumulative and would potentially have had an impact on patient safety.

172. For example, in the case of propofol as described above, the alternative medicines used for critical care sedation, had disadvantages, such as a longer half-life, which meant that patients might take longer to regain consciousness after a long period of sedation. The alternatives would also have been less familiar to even experienced critical care staff, with the potential for patient safety and other risks.

173. A further example is described in a Prevention of Future Deaths report issued by the East London Coroner on 7 July 2021 which described the misconnection of filters used in breathing systems. While there is no conclusion about whether this contributed directly to the patients' deaths, these are patient safety incidents which nonetheless should not occur [**RM1/031 INQ000508302**].

174. Concerns regarding the generic risks associated with increased demand, staffing constraints and equipment or medicines constraints were discussed at internal meetings, where mitigations were developed and actioned. Where appropriate, concerns were escalated via the Incident Directors or directly by me to the National Incident Response Board or other relevant senior decision-makers. However, in my view, the only way to definitively address such concerns would be to reduce demand, which would have been a governmental decision in terms of non-pharmaceutical or other interventions aimed at reducing the number of hospitalised Covid-19 patients.

SECTION 6: PPE

175. My role at NHSE did not involve any responsibility for Personal Protective Equipment ("**PPE**") procurement or advice on PPE suitability. However, I have been asked to provide a viewpoint on some aspects of PPE, and this is set out in the following paragraphs.

176. On the potential benefits and drawbacks of reusable non-surgical gowns: if the gown was designed to be reusable, and facilities existed on site or through local contracting for cleaning them, then there would be clear advantages in terms of environmental sustainability, supply/demand balance and clinical confidence of the staff that they

(and their patients) were being adequately protected. If the gown was not designed to be reusable, then early research in the pandemic could have evaluated the potential for such gowns to be reused, and the results published openly to support clinical and public confidence.

Suitability of PPE for all

177. The NHS benefits from being an employer of individuals from diverse backgrounds, and PPE provision, stockpiling, procurement and design should take into consideration the needs of all NHS and social care staff, and patients, including individuals' ethnicity, shape, size and all protected characteristics.

178. I did not work with any organisation on evaluating the differences in infection rates and/or clinical outcome for healthcare workers. However, I was asked to represent NHS England to the Joint Health and Social Care, and Science and Technology Committee review of the pandemic "Lessons Learned" on the specific topic of the impact of Covid on Black, Asian and Minority Ethnic communities in November 2020. For this I undertook significant preparation and research.

179. It is clear from objective evidence that there were significant disparities in critical illness and mortality rates from Covid in patients according to ethnicity. I am aware of research published in 2022[3] which highlights that healthcare workers from ethnic minorities in the UK accounted for 64% of deaths of nursing and support staff, and 95% of medical staff.

180. In my evidence to the Lessons Learned inquiry I stated that to my knowledge, there was at that time, no clear evidence whether these ethnic disparities in healthcare workers' clinical outcomes were in part or wholly attributable to workplace related risk, including the fit of PPE or Respiratory Protective Equipment ("**RPE**"). I am now aware of research which has been published since then, which highlights a number of matters of concern regarding PPE and RPE design, specifically when considering the needs of staff from diverse ethnicities. For example, a systematic literature review published in 2021[4] found that there is a paucity of evidence regarding respirator fit for individuals of non-white or non-male background; prospective research undertaken at

[3] Healthcare Workers From Diverse Ethnicities and Their Perceptions of Risk and Experiences of Risk Management During the COVID-19 Pandemic: Qualitative Insights From the United Kingdom-REACH Study published 1 July 2022

[4] The influence of gender and ethnicity on facemasks and respiratory protective equipment fit: a systematic review and meta-analysis published in BMJ Global Health

a single NHS hospital during the pandemic[5] also found that the likelihood of RPE fit test success was significantly higher in men and those of white ethnicity. While not conclusive evidence, this does raise a concern that staff from ethnic minority backgrounds may have been at higher risk of contracting Covid if the RPE was not suitably fitted.

[5] Prospective observational study of gender and ethnicity biases in respiratory protective equipment for healthcare workers in the COVID-19 pandemic published in BMJ Open

181. In my role as National Clinical Director for Critical and Perioperative Care at NHSE, or as a clinician and academic, I did not receive any contemporaneous reports of specific incidents where healthcare workers were pressured to work in care settings with inadequate PPE, where aerosol generating procedures were carried out, and which may have exposed them to risk of Covid infection. In these roles, I was also not made aware of any disparity between ethnic groups of healthcare workers or professionals in this regard. However, I am aware that such concerns were expressed to others, for example, through surveys conducted by the British Medical Association; these reports were widely discussed in the media and on social media, throughout the pandemic. However, in my role for NHSE, despite the regular interaction I had with clinicians and operational leads at local, system, regional and national level, I did not have such concerns flagged to me.

182. Over time it became clear that there were patterns of risk to healthcare workers which had not been previously anticipated. For example, clinicians working in critical care and anaesthesia practice were prioritised for PPE because of the risk of being exposed during aerosol-generating procedures ("**AGPs**"). However, evidence emerged[6] that their risk of contracting Covid or serious harm from it, was lower than that of colleagues working elsewhere in healthcare. Postulated reasons for this include that patients who were coughing, and at an earlier stage of their illness, may have been more likely to transmit Covid than those who were already intubated. Furthermore, research undertaken during the pandemic[7], supported the re-thinking of which procedures or situations should be considered aerosol-generating.

183. I reiterate that I am not an expert on PPE or infection prevention and control; however, I have been asked for my view on whether black, Asian and minority ethnic staff, and female NHS staff were adequately supported when it came to PPE. My opinion, for what it is worth, is that there is some evidence that they were not, examples of which are given above. Whatever the case, ethnic minority staff for whom Fit testing repeatedly failed may have felt, and indeed may have been, more exposed to risk than staff for whom Fit testing was successful. What I do not know, is

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[6] The safety of anaesthetists and intensivists during the first COVID-19 surge supports extension of use of airborne protection PPE to ward staff published in ScienceDirect in March 2021

[7] A rapid review of aerosol generating procedures (AGPs) An assessment of the UK AGP list conducted on behalf of the UK IPC Cell 9 June 2022

to what extent this may have contributed to different health outcomes from Covid for our staff of different ethnicities.

184. I am not an expert on High Consequence Infectious Diseases but I have been asked to comment on the downgrading of Covid from HCID status, the consequent acceptance therefore of PPE rather than RPE, and therefore the impact that this may have had on exposure to covid of healthcare workers (including differential exposure according to protected characteristics). I have cited evidence above which indicated that ward level staff may have been at higher risk than intensive care or anaesthetic staff from Covid, and that this may have been because they were less likely to use RPE when treating Covid patients who were not undergoing AGPs. This raises concern about occupational exposure which could potentially have been mitigated; however, I do not feel I have sufficient evidence on which to make a conclusion.

SECTION 7: CHALLENGES, GOOD PRACTICE AND LESSONS LEARNED

185. The NHS England corporate statement for Module 5 provides detail on the reviews and/or lessons learned exercises which have taken place in relation to the scope of this particular Module. In addition, I was involved in multiple workstreams to understand and learn lessons from the first wave in order to support patients, clinicians and other healthcare staff to deliver the best possible care to future hospitalised patients with Covid-19. These included:

a. Analysis and interpretation of data submitted to ICNARC on the risk profile and outcomes of critically ill Covid-19 patients;

b. Regular meetings with clinicians to hear qualitative first-hand experiences. For example, every one of the seven NHSE regions developed a critical care cell which provided oversight of the service; these meetings were attended by clinical and operational leads, and provided an opportunity for two-way communication; and

c. Attendance at NECCC.

186. I focus in this statement on my own reflections, which take account of those broader lessons learned exercises. My own reflections, based on my role and specific experience during the pandemic, are as follows.

Challenges

187. I do not consider that there was a robust system in place to ensure an adequate supply of key healthcare equipment and supplies to the NHS during the initial phase of the pandemic. As far as those areas in which I was involved – specifically, equipment, consumables, medicines and oxygen, the efforts made by DHSC, Cabinet Office and NHS England were remarkable and effective in many ways; however, because of a lack of availability of resources to meet the demand in the first wave, clinicians were required to use unfamiliar or less than ideal equipment, medicines and consumables, which will have augmented the pressure under which they were working. These factors combined posed a potential risk to patient safety and may have added additional psychological burden to staff who were working under conditions of unprecedented challenge.

Good practice

188. The geographical variation in Covid-19 hospital and critical care admissions meant that some parts of England were under extreme pressure while others were relatively quiet, at different time points during the period in question. NHS England quickly established mutual aid systems to move equipment or consumable items to areas of need, and/or handled the allocation of inbound stock centrally, in order to ensure fairness and that resources were allocated to the sites in most need.

189. Related to this, NHSE also established systems to enable safe transfer of patients from hospitals under high pressure to those which had more capacity. These transfers were predominantly undertaken to alleviate workforce pressures and therefore reduce the risk of harm to patients. However, there were also instances where patients were transferred because of oxygen demand. The demand which necessitated transfers related to hospital infrastructure, rather than the provision of liquid oxygen from manufacturers, the procurement and delivery of which was, in my view, exemplary.

190. Prior to the pandemic, we had little understanding of the true capacity of critical care in the NHS, in relation to actual beds, equipment and workforce. We rapidly established regular reporting to understand the day-to-day operational capacity, and since 2020, we have also conducted an annual deep dive 'census and stocktake' which enables us to track workforce patterns, vacancies and major equipment stocks (particularly ventilators and renal replacement therapy machines).

Lessons learned

191. The circumstances of a global pandemic, with international competition for medical resources (equipment, medicines, consumables) and challenges with supply chains due to border controls, was unprecedented. However, a future response, and our preparedness for it, could learn from this experience to build a more resilient system.

192. Module 3 has already featured discussion about the low number of critical care beds in the NHS compared with similar health economies, and even in normal times, this is a source of inequity which affects health outcomes for patients. For example, previous research has demonstrated:

a. The proportion of high-risk emergency abdominal surgery patients being admitted to critical care after surgery has fallen short of national standards for over 10 years;

b. There is unwarranted variation in the proportion of high-risk elective surgical patients who are admitted to critical care after surgery which has also not changed significantly over the past 5 years;

c. That a key determinant of whether or not a patient is admitted to critical care is the availability of a bed. This means that in places with fewer beds, patients are less likely to have access, and that this is a source of inequity between hospitals and for patients.

Thus, as with so many other aspects of the pandemic, Covid simply shone a spotlight on problems which predated 2020, and which persist today.

193. Furthermore, data from the NHSE census and stocktake of critical care workforce and resources indicates that we remain unable to fill even our current staffing establishment, particularly of nurses. Prior to the pandemic, vacant shifts were commonly filled by staff working overtime; the impact of the pandemic has led to staff being reluctant to do this. An additional challenge has been the exodus of more senior staff, and this has led to a dilution of the experience and know-how of the overall critical care team. These factors combined means that despite an increase in the overall number of funded and equipped critical care beds since the pandemic, that we are not much better resourced from an overall capacity perspective than we were pre-Covid.

194. Legacy interventions such as the introduction and establishment of critical care transfer services are important and will improve our resilience going forward, but in

my view are insufficient: should a pandemic of similar impact on critical care happen again, we risk many of the same challenges as we saw in 2020/21.

195. Increasing the number of beds and addressing the workforce challenges we have would develop greater resilience for predictable fluctuations in demand (winter pressures for example, and protecting elective activity) as well as short-term emergencies such as major incidents, and once-in-a-generation events such as a pandemic.

196. The NHS has supported the introduction of enhanced care services, which provide a level of care in between normal ward standards, and critical care. It has been proposed that such services could support particular activities, such as elective surgery. The benefits would include improved access to a higher standard of care for patients, improved flow through the hospital and reduced capacity pressures on critical care services. In addition, this would provide an additional source of surge staff for critical care emergencies such as a future pandemic, who have at least some of the skills which fully trained critical care staff have. Enhanced care areas could also have much of the equipment which would be required on a full critical care unit such as monitors, ventilators, syringe drivers and feeding pumps. Despite some targeted investment funding associated with the Elective Recovery Fund, the overall expansion of enhanced perioperative care has been slow, limited predominantly by financial constraints. Wider implementation of enhanced care would provide important resilience both for usual times and surges in activity, including enabling elective work to continue despite emergency pressures.

197. Referencing the findings at paragraph 4.29 in the Module 1 report, and the opinions of the Chief Medical Officer and previous Government Chief Scientific Officer, there is note of requiring 'the building blocks of lots of different capabilities' and acknowledging 'generic capabilities which are important across the piece'.

198. Recommendation 4 of the Module 1 report suggests the introduction of a UK-wide whole system civil emergency strategy, which should have a range of features. In my opinion, this should include consideration of how we would rapidly scale up critical care capacity, address procurement and manufacturing challenges and learn lessons from our experience in 2020. The following paragraphs set out some examples.

199. There is a notable difference between the preparedness of the NHS, academia and the regulators (specifically the MHRA) for innovation of "Ventilator Challenge" type, as opposed to traditional research (e.g. RECOVERY, ISARIC and REMAP-CAP). An

important step, therefore, would be to identify a list of research questions which might need to be answered for range of scenarios, and a consider the methodologies which might be used, so that hibernating protocols could be developed. For example, this could include:

a. PPE design, safety, re-usability;

b. Studies of fluid dynamics and aerosol generation which would improve air safety and potentially improve the deployment of respiratory protective equipment;

c. Equipment development – not just ventilators, but also other pieces of equipment which may have high demand such as syringe drivers, volumetric pumps etc – all of which were at risk of 'running out' if our surge demand reached the levels predicted in early March 2020; and

d. Rapid, formative evaluations of safety in training and deployment of new staff and equipment which could be used to quickly inform guidelines and protocols, therefore improving the approach we had to take of simply receiving 'soft intelligence' about safety concerns.

200. Regarding complex medical equipment, such as ventilators:

a. Consideration could be made of having a further stockpile of ventilators and associated hardware (syringe drivers, feeding pumps, haemofiltration machines etc) which are stored at Trust, system or regional level, and for which the responsibility for maintenance rests with the systems. This would also facilitate training exercises for local staff;

b. There was unhelpful narrative in the Press and disagreement between professionals and professional bodies which focused on the quality and quantity of ventilators and other items which were procured or manufactured to meet surge demands. This could be avoided through better preparation and advanced planning and agreement on the potential risks and benefits of different approaches with all relevant stakeholders – including the general public;

c. In advance of any future emergency, a panel of experts including engineers and clinicians should be commissioned to develop the minimum acceptable specifications for a range of scenarios, based on the demand and the

timeframe for manufacture (e.g. we need 10,000 machines within 2 weeks vs. 5000 machines within 6 weeks). This would improve the feasibility and effectiveness of our response to a significant surge in demand because:

i. Regulators could satisfy themselves in advance of the emergency that the proposed specifications were appropriate for different scenarios;

ii. Key components which would be difficult to source in an emergency and may therefore constrain production could be procured and stored e.g. oxygen sensors;

iii. Hibernating contracts could be considered with UK-based manufacturers which would enable production to begin according to a pre-specified protocol;

iv. The clinical community would have increased confidence in the process to develop and deliver these products. This may have knock-on benefits including avoidance of behaviour changes due to perceived risk of equipment not being available;

v. It would be possible to plan for training healthcare workers on unfamiliar devices and a safer expansion of the workforce required to care for high risk or critically ill patients; and

vi. The financial investment required to deliver these plans would be focused and likely lower than the 'spread betting' approach which the Ventilator Challenge was required to take.

201. Regarding consumable items: consideration of the need to stockpile a wider range of items than just PPE, and have the manufacturing capability for others. This would reduce our reliance on international procurement, with all the associated challenges, and also enable regulatory and safety factors to be considered and agreed in advance of the emergency.

202. The lack of manufacturing capability for medical devices, consumables and medicines within the UK was a key limitation of our response. Consideration should be given to whether this requires review, including having systems in place to enable manufacturing capacity to be safely pivoted towards items which may be predictably in demand – e.g. specific fluids, medicines and consumables.

203. The aim of the procurement efforts with which I was involved, including the Ventilator Challenge, was to try, as far as possible, to prevent medical equipment or supplies being the limiting factor in the ability of the NHS to treat patients during the pandemic. While this was broadly achieved, we should not underestimate the impact on the workforce of treating surging numbers of patients, relying on non-specialist staff for support, and in many cases having to treat patients with equipment or supplies which would not have been their first choice.

204. It therefore follows that in the future, staff preparedness must be considered in greater depth and in parallel, both from a clinical/operational perspective and also from a psychological perspective. The psychological trauma associated with treating surging numbers of Covid patients, with a high mortality and out of many healthcare workers' usual scope of practice, would have been compounded by the stress of using unfamiliar equipment and/or equipment, consumables and medicines which were below usual standards. In order to improve patient safety and reduce harm to staff, better preparation for this eventuality, including of a similar nature to that which military personnel have for far-forward operations, may be warranted.

205. My overall reflection is that given the circumstances, the procurement and innovation efforts with which I was involved (medical equipment, oxygen, consumables and medicines) were remarkable and successful, due to the focused and collaborative efforts of multiple agencies, and the provision of clinical advice which reduced the risk of procurement or innovation which would result in products which were not fit for purpose.

206. However, for the future, better preparation, for a range of scenarios, would ensure not only that the quality of the products which were made available for clinical use would be higher, but also that surge demand would be met more quickly, clinicians would be better prepared and able to use the products provided, and the overall investment in surge capacity would provide better value for the taxpayer.

STATEMENT OF TRUTH

I believe that the facts stated in this witness statement are true. I understand that proceedings for contempt of court 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 in its truth.

Signed:

Dated: 28 October 2024

ANNEX 1

Career History

The key roles I have held during the Relevant Period are set out in the table below:

Date	Role
March 2020 – current	National Clinical Director, Critical and Perioperative Care, NHS England.
September 2019 -March 2020	National Specialty Advisor, Perioperative Care, NHS England
March 2016 – September 2019	Associate National Clinical Director, Elective Care, NHS England
2009 – current	Consultant in Anaesthetics, Critical and Perioperative Care, University College London Hospitals NHS Foundation Trust
2018 – current	Professor of Perioperative Medicine, University College London
2023 - current	Director, NIHR Central London Patient Safety Research Collaboration, UCL/UCLH
2016 - 2022	Director, Health Services Research Centre, Royal College of Anaesthetists
2024 - current	Chair, National Institute for Academic Anaesthesia