**IN THE MATTER OF THE INQUIRIES ACT 2005**
**AND IN THE MATTER OF THE INQUIRY RULES 2006**

**UK COVID-19 INQUIRY**

---

**FOURTH WITNESS STATEMENT OF MATTHEW STYLE**

---

MODULE 5 CORPORATE STATEMENT CONCERNING OXYGEN AND VENTILATION

## INTRODUCTION

1. I, Matthew Style, Director General of Secondary Care and Integration, at the Department of Health & Social Care, 39 Victoria St, Westminster, London SW1H 0EU, will say as follows:

2. I make this statement in response to a request from the UK COVID-19 Public Inquiry (the Inquiry) dated 19 April 2024 made under Rule 9 of the Inquiry Rules 2006 (the Request) asking for a draft response on behalf of the Department of Health and Social Care (the Department).

3. I first became a civil servant in 2001 and first joined the Senior Civil Service in 2008. I have been Director General of the NHS Policy and Performance Group, now known as the Secondary Care and Integration Group, since I joined the Department in November 2021.

4. As this is a corporate statement on behalf of the Department, it necessarily covers matters that are not within my personal knowledge or recollection. I was neither employed by the Department, nor responsible for the matters addressed in this statement, for the majority of the relevant period, although the Medical Technologies Directorate did transfer to my responsibility in October 2022, after the closure of the COVID-19 Oxygen, Ventilation, Medical Devices and Clinical Consumables (O2VMD&CC) Programme. This statement is to the best of my knowledge and belief, accurate and complete at the time of signing. Notwithstanding this, it is the case that the Department continues to prepare for its involvement in the Inquiry, in line with responding as far as possible within the Inquiry deadlines. As part of these

preparations, it is possible that additional material will be discovered. In this eventuality, additional material will of course be provided to the Inquiry, and a supplementary statement will be made if need be.

5. This statement provides an overview of the role, function, and responsibilities of the Department in relation to the procurement of ventilators and related medical equipment and supplies in the period between 1 January 2020 and 28 June 2022.

6. This statement has been structured into seven sections that set out the information that addresses the Inquiry's questions:

a. **Section 1: Corporate Overview** sets out key decision makers, the Department's role in the procurement of ventilators during the COVID-19 pandemic. It also describes key agencies, boards, committees and the Department's interaction with these.
b. **Section 2: Ventilators and their Purpose** provides an explanation of what ventilators are and their role in clinical settings.
c. **Section 3: Modelling and Pre-pandemic Stock** explains the various modelling processes undertaken before the pandemic. It also highlights the Department's efforts to understand how many ventilators were available to the NHS at the start of the COVID-19 pandemic and how this was used a baseline for future procurement decisions.
d. **Section 4: Ventilator Procurement** provides an overview of the creation of the O2VMD&CC programme, its responsibilities and evolving governance structure, which reflected the Department's collaboration with NHSE/I and the Cabinet Office (CO), as well as the overall efforts of that programme to procure ventilators from multiple sources. This section also discusses the CO-led Ventilator Challenge and technical standards of ventilators.
e. **Section 5: Securing Long-term Supply of Ventilators** provides information on the second phase of the O2VMD&CC programme, which focussed on consolidating the supply of ventilators across the NHS estate. It also covers facilitating the donation of ventilators to other countries.
f. **Section 6: The Cost of the O2VMD&CC Programme** provides a breakdown of the total cost of procuring, storing and distributing the ventilators secured through the programme.
g. **Section 7: Lessons Learned** covers what lessons the Department has identified from its work on procuring and distributing ventilators and other medical supplies. This

includes lessons around the structure of the programme, communications and work processes and what might be improved next time.

## SECTION 1: CORPORATE OVERVIEW

7. This section sets out key decision makers and the Department's role in the procurement of ventilators and related medical equipment. It also describes key agencies, boards and committees and the Department's role in relation to these.

### Key Decision Makers

8. A list of key decision makers in the Department in respect of the topics outlined in the Provisional Outline of Scope for Module 5 was provided to the inquiry on 19 January 2024. **(MS4/1 - INQ000514287)**

9. For ease, the key decision makers with most involvement in the procurement of oxygen and ventilators have been listed below. Later sections of this statement will provide more detail of how those people were involved in the procurement of ventilators and other Departmental activities during the time in question.

*Ministers*

10. Relevant ministers within the Department between January 2020 – 28 June 2022 were:

a. Secretary of State for Health and Social Care – Rt Hon Matt Hancock MP from the start of the period considered to 26 June 2021.
b. Secretary of State for Health and Social Care – Rt Hon Sajid Javid MP from 26 June 2021 to 5 July 2022.
c. Minister of State for Health – Rt Hon Edward Argar MP from the start of the period considered to 6 July 2022.
d. Parliamentary Under-Secretary of State for Public Health and Primary Care - Jo Churchill MP from 26 July 2019 to 16 September 2021.
e. Parliamentary Under-Secretary of State for Public Health and Primary Care including Patient Safety – Maria Caulfield MP from 17 September 2021 to 7 July 2022.

*Key Officials*

11. Relevant officials in the Department are listed here:

a. Sir Christopher Wormald has been the Permanent Secretary from May 2016 to the present.
b. David Williams was the Second Permanent Secretary from March 2020 to April 2021.
c. Shona Dunn was the Second Permanent Secretary from April 2021 to May 2024.
d. Professor Sir Chris Whitty has been the Chief Medical Officer (CMO) for England from October 2019 to the present; and was also the Departmental Chief Scientific Advisor (CSA) from January 2016 to August 2021.
e. Deputy Chief Medical Officers (DCMO) included:
    i. Professor Sir Jonathan Van-Tam, who was the DCMO from October 2017 to March 2022. His role covered emergency response and preparedness, infectious diseases, vaccines, and therapeutics.
    ii. Professor Dame Jenny Harries was the DCMO for health improvement from July 2019 to April 2021.
    iii. Professor Thomas Waite was interim DCMO for COVID-19 in July 2021 and was substantively appointed DCMO leading on health protection in April 2022 (until the present). His responsibilities cover emergency response and preparedness, infectious diseases, vaccines, and therapeutics.
f. I (Matthew Style) have been the been Director General of the NHS Policy and Performance Group, now known as the Secondary Care and Integration Group from November 2021 to the present.
g. Clara Swinson was the Director General for Global and Public Health from November 2016 to 13 September 2024.
h. Steve Oldfield was the Chief Commercial Officer from October 2017 to October 2022.
i. David Williams was the Director General, Finance and Group Operations from March 2015 to April 2021.
j. Andy Brittain has been the Director General for Finance from April 2021 to the present, having been Director for Finance from August 2020 to April 2021.
k. Christopher Young was the Director for Finance from 1 March 2020 to April 2020, and Joint Director of Finance (with Jon Fundrey) from April 2020 to 21 July 2020.
l. Jon Fundrey was Joint Director of Finance (with Christopher Young) from April 2020 to 21 July 2020.

m. Chris Stirling was the Programme Director for COVID-19 Oxygen, Ventilation, Medical Devices and Clinical Consumables from 1 March 2020 to 31 March 2021; and later the Director, Medical Technology from 1 April 2021 to end of October 2022.

12. As the O2VMD&CC Programme was jointly run by the Department and NHSE/I, another key official was Emily Lawson, who at different times fulfilled the roles of Chief Commercial Officer and National Director for Transformation and Corporate Development, from NHS England and NHS Improvement (NHSE&I). She was the Senior Responsible Officer (SRO) for the joint NHSE/The Department programme 'Supply of Oxygen, Ventilation and Clinical Consumables'.

**Arm's Length Bodies**

13. I am asked to provide an overview of the Arm's Length Bodies that the Department is regularly involved with and with which the Department collaborated with during the COVID-19 pandemic.

*The Medicines & Healthcare products Regulatory Agency (MHRA)*

14. The MHRA regulates medicines, medical devices, and blood components for transfusion in the UK. It is an executive agency of the Department. Regarding the procurement of ventilators, MHRA's responsibilities were to provide the minimum acceptable technical standards to enable legal use of ventilators in the UK and investigate any concerns around devices meeting these standards.

*NHS England*

15. NHSE leads and oversees the NHS in England. It is an Executive Non-Departmental Public Body (ENDPB) of the Department. It was established on 1 April 2013 and has various statutory functions and duties in relation to the health service in England. NHSE is accountable to the Secretary of State and is responsible for allocating budgets to Integrated Care Boards ("ICBs", formerly Clinical Commissioning Groups (CCGs)), holding them to account, as well as leading on commissioning specialised services and primary care. During the relevant period the Board was chaired by Lord David Prior (until March 2022) and then by Richard Meddings. The CEO was Sir Simon Stevens (April 2014 - July 2021) and then Amanda Pritchard from August 2021. Ms Pritchard had previously been the Board's Chief Operating Officer as well as the CEO of NHS Improvement (NHSI).

16. NHS Improvement ("NHSI") was the operational name given to the umbrella organisation including Monitor and the NHS Trust Development Authority. NHSI operationally merged with NHSE in 2018. From the point of that operational merger, until NHSE and NHSI formally merged on 1 July 2022 under the Health and Care Act 2022, this merged entity was known as NHS England and Improvement or NHSEI. Since that merger, NHSE also has regulatory functions in relation to NHS providers.

17. Consistent with their statutory duties, NHSE/I provided operational leadership to the NHS throughout the pandemic, which involved gathering information within the healthcare system regarding COVID-19 and issuing guidance in relation to treatment for patients **[pages 9-14 in] (MS4/2 - INQ000022859).**

18. NHSE/I collected and published data on activity relating to COVID-19, including data about numbers of patients in hospital, numbers of patients receiving mechanical ventilation, consumables to deliver it to the bedside, and numbers admitted, diagnosed and discharged from hospital.

*NHS Supply Chain*

19. NHS Supply Chain manages the sourcing, delivery and supply of healthcare products, services and food for NHS trusts and healthcare organisations across England and Wales. Supply Chain Coordination Ltd (SCCL) is the legal entity through which NHS Supply Chain undertakes its procurement services and oversees operational management of the NHS Supply Chain and its service providers.

20. Pre-pandemic, the procurement of ventilators and other clinical consumables fell under the responsibility of individual NHS Trusts, with many choosing to utilise NHS Supply Chain **(MS4/3 - INQ000514288)**. During the pandemic, NHS Supply Chain remained responsible for procuring ventilators through Supply Chain Coordination Limited (SCCL). NHS Supply Chain also helped deliver ventilators to Scotland and Northern Ireland. There was a large increase in demand from NHS Supply Chain users, and additional NHS Trusts also sought the help of NHS Supply Chain when their usual providers could not deliver their requests. The Department's involvement in procuring ventilators started when the NHS Supply Chain could not manage the demand.

21. NHS Supply Chain lacked the resources to respond adequately to the increased demand, in the context of a globally disrupted supply chain; as explained in further detail in paragraph 60 below, the COVID-19 Oxygen, Ventilation, Medical Devices and Clinical Consumables (O2VMD&CC) programme was jointly established and funded by the Department and NHSE/I to enable NHS organisations to meet demand for oxygen, ventilators and consumables during surges of COVID-19. **(MS4/4 - INQ000514285)**

## SECTION 2: VENTILATORS AND THEIR PURPOSE

22. Before describing the activities around procurement and distribution of ventilators in later sections of the statement, I will provide a brief explanation in this section of what they are.

23. I am also asked what resources and other equipment were required to treat COVID-19 patients. It should be noted that the Department was not responsible for determining what equipment and treatment methods were required; it was the responsibility of clinical staff to decide what treatment methods were best suited in each situation.

### Description of Ventilators

24. Mechanical ventilation is a form of life support. Before the patient gets to the stage where the use of a mechanical ventilator is considered, NHS clinical practice requires consideration of a series of escalating interventions. These are described below at paragraph 27.

25. A mechanical ventilator is a machine that takes over the work of breathing when a person is not able to breathe sufficiently well on their own. **(MS4/5 - INQ000494416)**.

26. Non-invasive ventilation involves use of a machine that delivers oxygen to support breathing through an external device (such as a face mask). This type of ventilation is mostly used for patients with mild to moderate difficulty breathing due to an acute or chronic medical condition. The two types of non-invasive ventilators generally available are bilevel positive airway pressure (BiPAP) ventilators and continuous positive airway pressure (CPAP) ventilators. BiPAP and CPAP devices differ primarily in their air pressure delivery, with BiPAPs providing distinct air pressure levels for inhalation and exhalation, whereas CPAPs maintain a constant fixed pressure throughout each breath.

27. Patients with an acute illness who require non-invasive ventilation will always need monitoring to ensure their breathing difficulty does not worsen. Patients with an acute illness who require invasive mechanical ventilation would be monitored in an intensive care unit (ICU). Invasive mechanical ventilation is a serious procedure in which an endotracheal tube is connected to a machine that delivers a prespecified amount of oxygen and volume of air, along with a set number of breaths per minute. These are adjusted according to a patient's oxygen and carbon dioxide levels. **(MS4/6 - INQ000494415)**.

28. The Department was not responsible for determining which of these specific treatments and interventions were clinically required to treat patients with COVID-19 as this would have been determined by qualified clinical staff.

## SECTION 3: PRE-PANDEMIC STOCK AND EARLY MODELLING

29. This section of the statement will cover the Department's position regarding oxygen and ventilators pre-pandemic, as well as the Department's modelling work in response to the outbreak of the pandemic, which informed decisions about the procurement of ventilators. It will also provide baseline information on the number of available ventilators and the demand for ventilators across the NHS at the start and throughout the pandemic, as well as modelling analysis that influenced decision making.

### Pre-Pandemic Ventilator Demand

30. Previous modelling had been undertaken that included estimating ventilator demand at various periods before the pandemic to improve the Department's knowledge and understanding. This included, for example, consideration of recommendations about bringing ventilators that had been placed in storage back into use. **[pages 33-34 of] (MS4/7 - INQ000514140)**

31. I am asked to set out the number of patients in the NHS that required a ventilator from June 2009 to January 2020. As holders of the data, the NHS are better placed to answer this question.

**Pre-Pandemic Ventilator Capacity**

32. Immediately before the pandemic, the Department and NHSE/I had limited understanding about the number of ventilators that were available at that time, based on previous studies undertaken.

33. A paper produced by NHSE in 2017/18, for example, on NHS escalation capabilities during an influenza pandemic stated that, at that time, the NHS's baseline ventilator capacity was around 3,500 ventilated beds, with a maximum surge capacity to 7,000 beds, which could be maintained for a maximum of two weeks. As such an increase in capacity was not required during the 2009/10 swine flu pandemic, and ventilator baseline capacities were not tested further beyond the stated existing capacities. An increase in the baseline capacity of ventilators was not considered necessary in a pandemic influenza scenario. **[pages 3-5 in] (MS4/8 - INQ000057495).**

**Early Pandemic Demand and Supply Modelling**

34. Data from modelling studies supported key decision-making on the government's response to the pandemic, including procurement of ventilators. This included modelling data provided by the Scientific Pandemic Influenza Group on Modelling (SPI-M). SPI-M was a working group that supported the Department in the development of flexible responses to pandemic disease risks, including reviewing evidence, maintaining a 'modelling summary', and developing policy guidance. In an emergency, such as the COVID-19 pandemic, SPI-M becomes an operational subgroup of the Scientific Advisory Group for Emergencies (SAGE) (SPI-M-O). **(MS4/9 - INQ000514286)**. This section provides further detail on the modelling that supported decision-making about early pandemic procurement.

35. After considering the experiences of European countries such as Italy in the early stages of the pandemic, the Department estimated that far more mechanical ventilators would be needed than those available to the NHS **(MS4/10 - INQ000514145)**. Based on reasonable worst-case scenario (RWCS) planning assumptions for an Influenza pandemic that was undertaken in November 2018 and mentioned in paragraph 33, it was estimated in early 2020 that up to 90,000 adult ventilated beds would be needed to care for COVID-19 patients **(MS4/11 - INQ000023027).** Using this analysis as a basis, the Government's strategy was to increase ventilator capacity from UK and global suppliers to manage a potential surge of need.

36. Additional modelling by the NHSE from 24 February 2020, based on the RWCS by SPI-M for a flu pandemic, provided estimates of the potential impact on the NHS of COVID-19. The reasonable worst-case scenario for such an event showed the total number of occupied ventilated beds peaking at around 51,000 by the eighth week of such a pandemic. It was pointed out, however, that none of the results of this modelling should be interpreted as a forecast of the impact of COVID-19, or even as reasonably likely scenarios **(MS4/12 - INQ000494392)**. This modelling was approved by NHSE and shared with the SPI-M group in the Department on 26 February 2020 **(MS4/13 - INQ000494391).** Such considerations shaped the thinking and modelling of ventilator requirements at the start of the COVID-19 pandemic.

37. NHSE/I also ran a demand model in March 2020, using the Imperial College Covid-19 epidemic model assumptions, which focused on the need for ventilated beds, and considered different infection reduction measures that would affect the requirement for such ventilators. This model provided a scenario in which implementing a policy of home isolation, household quarantine and wider social distancing measures and school closures would have resulted in a peak demand for ventilators of between 2-3,000 by the end of the first month of a pandemic, dropping to almost no additional ventilators after three months. However, the modelling also suggested that implementing only home isolation and household quarantine might, according to the model, result in a ventilator demand of over 70,000 between the second and third month of a pandemic. **(MS4/12 - INQ000494392; MS4/14 - INQ000494396)**

38. The Department also received projections for oxygen and ventilator demand that considered the impact of compliance with infection reduction measures. Demand was modelled at 40%, 60% and 75% compliance rates for each region of England. **(MS4/15 - INQ000514194)**

39. In the early stages of the O2VMD&CC programme, demand from Trusts was very large, but often reflected their desire to build capacity and contingency, rather than an immediate clinical need. Transparently working through all requests with regional representatives and comparing actual need with desired provision increased clarity and reasonable consistency of what was, and was not, considered as 'immediate clinical need' for additional ventilators.

40. Operational activities in support to this panel and process were carried out by a team of individuals of various grades from across the Department, NHSE, Cabinet Office, other government departments and external contractors, which collected daily information from NHS Trusts across the UK, regarding their respective ventilator capacity and requirements. Decisions regarding the allocation of ventilators were made by the National Ventilator

Allocation Panel, a decision-making body whose membership is provided in the exhibit in paragraph 93. In parallel, NHSEI set up the technical infrastructure to support the process logistically by creating a data collection and visualisation **(MS4/16 - INQ000514204).**

41. The Department was kept up to date through daily situation reports (sitreps) from NHS Trusts, which were collated by NHSE/I, and which contained data on the use of ventilators in clinical settings. This included, for example, the number of available or occupied beds with mechanical or non-invasive ventilation support, as well as differentiating between COVID and non-COVID cases **(MS4/17 - INQ000514234)**. This data was collected daily and was used to inform the estimates of clinical need for additional ventilators and allocation priorities **(MS4/18 - INQ000514158; MS4/19 - INQ000514176; MS4/20 - INQ000514178)**.

42. The RWCS provided by SAGE on 26 March 2020 suggested that, if infection limitation measures were poorly adhered to, there would be around 2,300 ICU beds occupied in the week of 30 March 2020. This ICU occupancy rate was projected to rise to 4,900 by the week of the 13 April 2020, before gradually falling to around 2,500 beds occupied by the 31 August 2020. In the context of the COVID-19 pandemic, a bed occupied in ICU is most likely to have involved the use of a ventilator. The RWCS also assumed that, based on poor public compliance with infection limitation measures, 30% of patients hospitalised with COVID-19 symptoms would require ventilation, although this was highly age-dependent (**MS4/21 - INQ000514209)**.

43. On the 27 March 2020, the Cabinet Office circulated an internal update presentation on ventilator modelling and expected supply. The long-term projections outlined in this presentation suggested that demand for mechanical ventilators would increase to around 17,500 by mid-April 2020, which would outpace the availability of NHS stock and procurement capabilities. Ventilator availability was projected to catch up with modelled demand again by late April, at which point demand as predicted to be around 12,000 mechanical ventilators. The modelling showed a predicted continuous increase of ventilator procurement throughout the first half of 2020, culminating in a potential total number of around 109,000 mechanical ventilators being available by early June 2020 **(MS4/22 - INQ000514153).**

44. As our understanding of the pandemic and models of care for COVID-19 patients developed during the time period covered by this statement, and infection control measures started to have an impact, the expected future demand for mechanical ventilators reduced.

**Early Pandemic Ventilator Stock Levels**

45. This sub-section provides information on the number of ventilators available to the NHS at the outset of the COVID-19 pandemic. As outlined in paragraph 33, previous studies regarding the impact of an influenza pandemic had not considered the necessity to increase the UK's capacity for ventilators, based on the specific learning around how many ventilators were needed for events such as the 2009 Swine Flu pandemic. Ventilator availability was not therefore identified early on as a priority given the exercises that fed into pandemic planning. This was also the reason why data on ventilator availability was not available until the end of February 2020, as the Department did not receive regular data on equipment stock levels from NHSE prior to the pandemic. In Section 7 of this statement, I refer to the lesson that the Department learned on records of available stock.

46. The Department has not been provided with information on the number of ventilated beds in use, or the number of patients requiring a ventilator for the 1 January 2020. The Department does not hold data for the number of ventilated beds in use or the number of patients requiring a ventilator prior to the start of the COVID-19 pandemic. The earliest information regarding ventilator availability is from February 2020.

47. This information shows that on 27 February 2020 NHSE and NHSE/I undertook an assessment of the preparedness of the NHS regarding critical care capacity for COVID-19. 96.6% of Acute Trusts responded by 6 March 2020, informing the Department that there were 4,954 adult and 878 paediatric ventilators available; and an additional 1,362 adult and 163 paediatric ventilators could be brought online **(MS4/23 - INQ000494407).**

48. Starting from March 2020, the Department relied on daily bed-occupancy data provided by the NHS, including the number of ventilated beds occupied. As stated in paragraph 164, the Department should learn the lessons of the COVID-19 pandemic and enable a more consistent and overarching supply and analysis of NHS data, especially regarding the available stockpile of key equipment.

49. By 30 March 2020, there were a total of 8,721 ventilators available in England, including 1,200 that could be loaned from the private sector **(MS4/24 - INQ000514163; MS4/25 - INQ000514179; MS4/26 - INQ000494406)**. By this point, on top of the 8,721 existing ventilators, the Department had placed orders for an additional 10,221 mechanical ventilators, including 4,649 through the existing NHS Supply Chain procurement route and 4,520 from international orders, managed by the Hard to Source team. In line with delivery schedules, it

was assumed that these ordered ventilators would be fully in place by the end of May 2020 **(MS4/27 - INQ000494398)**.

50. Based on available NHSE/I data, between 2 April 2020 and 31 July 2020, an average of 2,765 mechanically ventilated beds across the NHS were occupied daily, with the highest number of 4,014 being occupied on 12 April 2020. Of these, an average of 1,007 mechanically ventilated beds were occupied by confirmed COVID-19 patients in the same time period, with the number of COVID-19 patients occupying such a bed on 12 April being 2,881 across England **(MS4/28 - INQ000494743)**.

51. By 9 April 2020, there were a total of 9,600 ventilators available **(MS4/ 29 - INQ000514166).** We also know that by the 14 April 2020, the Department had procured a total of 10,993 mechanical ventilators and 19,338 non-invasive ventilators, although many of these had not yet arrived in the UK. Both types of ventilators were delivered to the UK in a steady stream from different countries around the world **(MS4/ 30 - INQ000514186)**, including Germany, the United States, China, Taiwan and Hong Kong, as well as from UK suppliers **(MS4/31 - INQ000514168)**.

52. A stocktake of ventilators circulated by the Department on 20 May 2020 showed that the total number of ventilators available to the NHS at that point was around 34,800. This comprised approximately 13,000 mechanical ventilators, ~11,700 bilevel positive airway pressure (BiPAP) ventilators and ~10,100 continuous positive airway pressure (CPAP) ventilators. This compared to a pre-pandemic stock of 4,954 ventilators (**MS4/26 - INQ000494406)**.

**Ventilator Stock Levels After August 2020**

53. From 1 August 2020 to 6 April 2021, the average number of occupied mechanically ventilated beds was 3,591, with the high point being on 13 March 2021, with 6,664 mechanically ventilated beds occupied. Of these occupied beds, an average of 1,194 were occupied by confirmed COVID-19 patients in that time period, with the number on 13 March 2021 being 1,000. **(MS4/32 - INQ000494742)**

**SECTION 4: VENTILATOR PROCUREMENT**

54. This section of this statement describes the development of the Oxygen, Ventilation, Medical Devices and Clinical Consumables (O2VMD&CC) Programme in its earliest stages.

It will cover its actions to increase the number of available ventilators through domestic and international procurement. It will also cover the safety and technical standards of ventilators, the Government's decision not to implement export controls for ventilators, the distribution of ventilators, how the Department worked with the Devolved Administrations and other government departments and how the programme met the Public Sector Equality Duty. The later phases of the O2VMD&CC Programme are described in Section 5.

**Ventilator Procurement Prior to the Pandemic**

55. Prior to the start of the COVID-19 pandemic, the Department was not involved in the procurement of ventilators or other medical equipment. All orders of ventilators and related medical supplies were placed by NHS Supply Chain, or directly by Trusts themselves.

**The start of the O2VMD&CC Programme**

56. During the pandemic, NHS Supply Chain remained responsible for procuring ventilators through the normal SCCL route. The Department only became involved in procuring ventilators from domestic and overseas suppliers at a time when a significant spike in global demand meant NHS Supply Chain lacked the resources and was unable to respond adequately to the increased demand. As a result, the Department became the main organisation through which ventilator demand was assessed and from where the distribution of ventilators across the UK was coordinated. The government's strategy was to rapidly increase UK ventilation capacity by buying as many ventilators as possible from both UK and global suppliers. Once it became clear that sufficient ventilators had been procured, processes returned to business as usual, with the Department no longer engaged in procurement.

57. One of the Department's main roles on the procurement of ventilators and related medical supplies during the pandemic was as budget holder; we became a commercial contracts partner for orders of these devices, outside the SCCL supply chain. The Department undertook the responsibilities of SCCL in carrying out ventilator procurement. This included ordering such equipment according to the needs of NHS Trusts and the wider health and care system. The unprecedented situation and need required OGD collaboration, and in this case, we worked with the Foreign, Commonwealth and Development Office (FCDO) and the Department for International Trade (DIT) to arrange overseas orders, and we also later followed up on ensuring these orders were delivered appropriately. The Department also liaised with the Devolved Administrations as discussed below at paragraphs 96 and 97.

58. The COVID-19 Oxygen, Ventilation, Medical Devices and Clinical Consumables (O2VMD&CC) programme began on the 3 March 2020. It was set up to ensure that there were sufficient oxygen and ventilation devices in the NHS to enable an effective clinical response to COVID-19.

59. The Programme was a collaboration between the Department and NHSE/I, with respective roles split between these two organisations, but it reported its activities as a single entity. It reported to and coordinated with NHSE/I and ministers in the Department, as well as reporting delivery information to the COVID-19 Delivery Group in the CO and the National Incident Response Board of NHSE/I. The programme received its funding from HM Treasury and policy direction and accounting oversight from the Department, with NHSE/I leading on clinical and NHS operational matters.

60. During the initial stages of the pandemic, when we were faced with an exceptional surge in need, the focus of the programme was on improving ICU capabilities, as well as rapidly purchasing equipment and upgrading hospital infrastructure to ensure the effective supply of oxygen to the bedside **(MS4/33 - INQ000514193)**.

61. Over the following few months, the focus of the programme shifted, from managing this surge in demand, to improving capabilities and the quality of available devices. This also included moving the programme's stance from a 'crisis response' model to one designed to handle a more enduring situation. The overall objectives of the programme, as regards the procurement and distribution of ventilators, in this stage were as follows:

a. To oversee and manage the procurement, storage, allocation and distribution of nationally purchased oxygen therapy devices to the NHS; and
b. Ensuring devices were procured appropriately, that contracts and financial commitments were reported and managed, that devices were made available where most needed and were transferred permanently to the NHS or utilised to support the broader global response to the COVID 19 pandemic **(MS4/34 - INQ000514191)**.

62. The O2VMD&CC programme was the primary route through which the Department procured ventilators on behalf of the NHS. It is distinct from the Ventilator Challenge (see paragraphs 75-80), which was a CO-led programme to encourage domestic suppliers to manufacture ventilators. It also received and acted upon modelling information, (see paragraph 34-44) and figures jointly between the Department and NHSE/I.

**Development of the O2VMD&CC Programme**

63. By June 2020 the scope of the O2VMD&CC Programme had evolved to include the following workstreams:

a. **Oxygen Production and Distribution** – The objective of this workstream was to ensure that sufficient medical oxygen was produced and distributed to NHS Trusts' premises ensuring prioritisation of oxygen for medical use.
b. **Trust oxygen plumbing** – The objective was to make sure sufficient oxygen would get through from storage tanks to the bedside as COVID-19 demands often exceeded Medical Gas Pipeline System (MGPS) design capacity.
c. **Conventional Procurement** – The objective of this workstream was to procure and provide a wide range of medical devices necessary including mechanical ventilation devices. Global competition meant many potential offers of procurement opportunities were received; however, there was a significant challenge around determining which offers were supported by viable infrastructure and capability and risks around fraud. It was important to procure equipment in line with clinical requirements underpinned by evidence.
d. **ICU Consumables** – The objective was to make sure all necessary associated consumables were available be used effectively to support patients in COVID-19 ICU care. This included connectors, tubes and filters, some of which were machine specific.
e. **Supply Chain Management** – The objective was to manage the operational receipt, storage, management and national distribution of devices to the NHS across the Home Nations, British Overseas Territories and Crown Dependencies as required.
f. **Allocation Process** – The objective was to agree and implement the process for allocation of equipment based on clinical need. A clinically driven National Ventilator Allocation Panel (NVAP) was established to provide strategic direction and oversight of the allocation of ventilators and ICU equipment within England regions. This process was informed by a daily review of data on ventilator supply and demand within England, alongside regional intelligence, and enabled clinically informed decisions about ventilator allocation across the country.
g. **Hard to Source Items** – A combination of increased demand (COVID) and instability in the global supply chain meant that it was difficult to ensure that all required items were available. A global supply shortage meant certain 'hard to source' consumables were identified such as enteral feed pumps, syringe pumps, suction pumps, and syringe drivers. **(MS4/35 - INQ000494409)**

64. Overall policy and strategic decisions were made by ministers in the Department, with advice on financial decisions being given by the Accounting Officer of the Department. Clinical and NHS operational decisions were led by NHSE/I. Furthermore, the final structure of the programme **(MS4/36 - INQ000494410)** included the following boards:

65. A monthly Programme Oversight Board, chaired by Emily Lawson as SRO, was responsible for providing advice and guidance to the Programme to support effective delivery, alignment of activities, and understanding of the programme across senior stakeholders **(MS4/37 - INQ000471091; MS4/38 - INQ000514212; MS4/39 - INQ000514219; MS4/40 - INQ000514222; MS4/ 41 - INQ000514251; MS4/ 42 - INQ000514255; MS4/ 43 - INQ000514258; MS4/44 - INQ000514261; MS4/45 - INQ000514264)**.

66. A Programme Delivery Board, which met every fortnight, was chaired by Chris Stirling as Programme Director. This managed the delivery of regular progress reporting, resolved cross-cutting issues and ensured the programme was aligned with the programme priorities **(MS4/46 - INQ000471090; MS4/47 - INQ000514199; MS4/48 - INQ000514208; MS4/49 - INQ000514214; MS4/ 50 - INQ000514218; MS4/ 51 - INQ000514220; MS4/ 52 - INQ000514223; MS4/ 53 - INQ000514232; MS4/ 54 - INQ000514236; MS4/ 55 - INQ000514241; MS4/ 56 - INQ000514246; MS4/ 57 - INQ000514250; MS4/ 58 - INQ000514253; MS4/ 59 - INQ000514254; MS4/ 60 - INQ000514256; MS4/ 61 - INQ000514257; MS4/ 62 - INQ000514259; MS4/ 63 - INQ000514260; MS4/ 64 - INQ000514262; MS4/ 65 - INQ000514272; MS4/ 66 - INQ000514268; MS4/ 67 - INQ000514266; MS4/ 68 - INQ000514269; MS4/ 69 - INQ000514271; MS4/ 70 - INQ000514273; MS4/ 71 - INQ000514274; MS4/ 72 - INQ000514276; MS4/ 73 - INQ000514277)**.

67. Weekly project checkpoint meetings, also chaired by Chris Stirling, were intended to action key decisions and purchasing agreements, as well as resolve any issues that arose in the process **(MS4/74 - INQ000471089; MS4/75 - INQ000514207; MS4/76 - INQ000514206; MS4/77 - INQ000514211; MS4/78 - INQ000514216; MS4/79 - INQ000514217; MS4/80 - INQ000514228; MS4/ 81 - INQ000514227; MS4/ 82 - INQ000514226; MS4/ 83 - INQ000514225; MS4/ 84 - INQ000514231; MS4/ 85 - INQ000514233; MS4/ 86 - INQ000514237; MS4/ 87 - INQ000514238; MS4/ 88 - INQ000514239; MS4/ 89 - INQ000514242; MS4/ 90 - INQ000514244; MS4/ 91 - INQ000514245; MS4/ 92 - INQ000514247; MS4/93 - INQ000514249)**.

**02VMD&CC Programme Procurement**

68. The Department started contacting established suppliers of ventilators to the NHS at the beginning of March 2020 and placed orders for as many oxygen concentrators and ventilators as suppliers could provide. The Department placed its first set of orders on 9 March 2020, using existing NHS Supply Chain framework agreements, which are designed to ensure competitive pricing **(MS4/ 94 - INQ000514142; MS4/ 95 - INQ000514143; MS4/ 96 - INQ000514141)**.

69. From 13 March 2020, the Department explored various options for the purchasing of ventilators directly from non-established manufacturers and distributors, with support from the FCO, now FCDO, and DIT to purchase ventilators directly from overseas manufacturers and their accredited distributors. Officials from FCO and DIT, based in-country at British diplomatic stations, made use of their local knowledge to understand local supply arrangements, whether devices were genuine, could be exported and normal country contracting arrangements. **(MS4/97 - INQ000514184).** The Department was involved in the process of authorising payments for ventilator contracts, as well as seeking assurances regarding the reputations of the companies involved and that the products in question met NHS clinical specifications and quality standards **(MS4/98 - INQ000514149; MS4/99 - INQ000514147)**.

70. The Department's initial focus was on the procurement of mechanical ventilators, as clinicians had determined that these were of the highest priority. Soon after, the focus also included procuring non-invasive ventilators, following additional clinical recommendations.

71. Devices that met specified criteria, but were not previously used within the UK, were procured based on paper specifications. The purpose of any paper specification was to provide purchasing personnel with clear guidelines for how the product should perform, and to provide vendors with firm criteria of minimum product or service acceptability. Upon receipt, some of these devices were rejected by UK clinicians as not fit for purpose **(MS4/100 - INQ000514224; MS4/101 - INQ000514198; MS4/102 - INQ000514167)**. Additional details about the devices rejected can be found in paragraph 109.

72. This process differed from the business-as-usual approach, which would normally involve much longer timelines for testing and evaluating samples of products before purchasing in larger quantities. Instead, following the arrival of procured ventilators in the UK, a sample would be inspected by the clinical due diligence team and, for mechanical ventilators,

additionally by the technical due diligence team. These reviews would determine if a certain ventilator model met the UK standard and could be used within a clinical setting.

73. The Shangrila 510S ventilator presented operational challenges for medical staff. This device operated differently to UK models and required extensive training to allow the staff to be proficient in using the device. **(MS4/103 - INQ000514240)**. This device was therefore not used within clinical settings and some of these devices were subsequently replaced by VG70 ventilators. The Department secured a partial refund on this procurement **(MS4/ 104 - INQ000514215; MS4/ 105 - INQ000514275)**. In other cases, the funds used for the procurement of cancelled ventilator deliveries were sometimes repurposed to procure urgently needed PPE **(MS4/106 - INQ000514200)**.

74. On 30 March 2020 the Department outlined its intention to enter into a contract with University College London (UCL) for a recently developed CPAP device subject to necessary approvals (including MHRA approval) to enable the device to be used in the NHS. **(MS4/107 - INQ000494408)**

75. On 4 April 2020, information was sent to ministers regarding arrangements for the purchase of the recently developed UCL CPAP device **(MS4/108 - INQ000514162)**. This information contained an explanation that UCL, working with Mercedes and Oxford Optronix, had developed a CPAP machine for use by the NHS as part of the COVID-19 response. This device, called UCL-Ventura, was based on an optimised version of a previous design. UCL-Ventura received time-limited and emergency approval from MHRA on the 2 April 2020 **(MS4/109 – INQ000514156)**, with an initial expiry of this authorisation set for 14 October 2021 **(MS4/110 - INQ000514283)**, with a subsequent extension agreed until 14 July 2022 **(MS4/111 - INQ000514284)**. The information set out that there were some risks associated with all CPAP devices, specifically the high volume of oxygen required for their use, but it was considered that these risks could be mitigated. UCL was seeking the support of the Department to mass produce UCL-Ventura and make them broadly available across the UK. Ministers approved this approach on 8 April 2020 **(MS4/112 - INQ000494400)**. UCL subsequently published their own announcement on the distribution of these devices on 9 April 2020 **(MS4/ 113 - INQ000494401)**.

76. On the 16 November 2020, NHSE was made aware of a delivery of UCL Ventura ventilators to Glenfield Hospital in Leicester. It was communicated that one of the Flo-Ox monitors associated with these ventilators was not working properly when tested **(MS4/114 - INQ000514243)**. The UCL Ventura devices also used more oxygen than comparable

ventilators, which required considered planning and staff awareness to ensure reliable oxygen supply in clinical settings. **(MS4/115 - INQ000514270)**

77. Based on the Department's current knowledge, no technical faults or issues with the UCL Ventura ventilators themselves were reported. However, they were labelled as 'not for clinical use outside of the COVID-19 pandemic'. This labelling was included because MHRA had only provided a time limited authorisation for the use of these devices, in line with regulation 12(5) of the Medical Devices Regulations 2002. These regulations allow for devices to be used under special circumstances under authorisation of the Secretary of State.

**The Ventilator Challenge**

78. I am asked to provide information about the Ventilator Challenge, which was run by the CO, and the Department's involvement therein. The CO will be best placed to provide information about how companies were selected to become part of the Ventilator Challenge UK, and what criteria were applied to their selection.

79. A target of 30,000 ventilators was set on 13 March for delivery by the end of June 2020. As it was clear that it would not be possible to procure enough ventilators for 30,000 beds, a manufacturing drive for ventilators and related equipment was initiated, including a national call to action to deliver the extra ventilators required. This resulted in the creation of the Ventilator Challenge, the objective of which was to produce 20,000 new ventilators, as part of the overall target of 30,000. The Ventilator Challenge was led by Gareth Rhys Williams, Government Chief Commercial Officer **(MS4/ 116 - INQ000279904; MS4/ 117 - INQ000106555; MS4/ 118 – INQ000106203; MS4/ 119 - INQ000106234; MS4/ 120 - INQ000106519; MS4/121 - INQ000514195)**.

80. On 16 March 2020 the Prime Minister announced a "call to arms" to British industry and organisations to help the UK step up production of vital medical equipment. He asked manufactures to rise to this challenge by offering skills and expertise as well as manufacturing the components themselves.

81. The Ventilator Challenge had two strands, one focusing on offers from established suppliers and one focusing on new suppliers of ventilators. The Department was responsible for managing the offers from established ventilator suppliers, whilst the CO held responsibility for managing new suppliers.

82. The Department for Business, Energy and Industrial Strategy (BEIS) managed a triage process on behalf of the Department, to narrow down the offers received to those that were most credible **(MS4/122 - INQ000514185)**. The challenge at this point was to ascertain which of the offers of equipment made were viable and backed up with genuine infrastructure and capability **(MS4/119 - INQ000106234)**.

83. Potential suppliers through the Ventilator Challenge would present their ventilators to a group of clinicians and staff from MHRA, CO and PA Consulting. These clinicians would then make assessments of these presentations and make recommendations whether to select certain ventilators for use **(MS4/123 - INQ000514196; MS4/124 - INQ000514197)**.

**Export Controls of Ventilators**

84. I am asked if the Department was aware of any export control in relation to ventilators. The Department is not aware of any controls on UK exports of ventilators prior to the pandemic and is therefore unable to confirm if any ventilator supplier exported ventilators outside of the UK at the start of the pandemic. The Department made the decision not to request any export controls for ventilators, following the start of the pandemic, given the low initial production capacity of the UK and the risk of such controls being imposed by other countries **(MS4/125 - INQ000514144)**.

**Procurement of Ventilators from Overseas**

85. In an internal email on 24 March 2020, officials from the Department indicated that they would be asking HMT for delegated authority to allow the Department to order ventilators on the condition that:

a. There was an assessment of the international suppliers in writing from the FCO and Department commercial were satisfied with the level of risk;
b. There was certification that the products were fit for purpose (CE/ kitemarking as well as clinical assessment);
c. There would be a process of inspection on delivery so that no product would go to the NHS without it being confirmed as fit for purpose and;
d. The unit price of products did not exceed "normal" market value by more than 25% **(MS4/126 - INQ000514151; MS4/127 - INQ000514152; MS4/128 - INQ000514282).**

86. Whilst there was an official process to monitor and manage the spending of the Department on ventilators, such processes were designed to be compatible with the need to satisfy the reality of having to swiftly procure as many ventilators as possible in a highly competitive environment **(MS4/129 - INQ000514150; MS4/130 - INQ000514169)**. As the pandemic response progressed, global shortages meant ventilator unit prices increased, and as a result, the unit price expectation set out in paragraph 82.d above was breached to secure ventilator stock.

87. As the pandemic progressed, international demand for ventilators increased, resulting in highly dynamic prices for ventilators. SCCL would be best placed to provide accurate information on pre-pandemic prices of ventilators bought for use in the NHS, as the Department was not involved in the pre-pandemic procurement of ventilators and has no data on prices paid for such ventilators. The included exhibit provides an overview of the often-extreme fluctuations in per-unit prices between different contracts for identical ventilator models **(MS4/31 - INQ000514168)**.

88. The final version of the funding agreement and ministerial conditions letter set out the pre- and post-procurement conditions with which the Department had to comply, including:

a. Taking all reasonable action to ensure all equipment had the appropriate medical certification and commercial colleagues had sought and taken all reasonable action to review time-stamped pictures of the equipment; and
b. Confirming that all stock would be inspected as medically fit for purpose before distribution to NHS Trusts, that any kit failing that test was notified to HMT within 24 hours, and that actions were undertaken to recover payment where contractually possible. When ventilator stock was procured at speed, the inspection did not take place in the country from which the ventilators were being delivered; instead, the stock was photographed at point of origin as proof of its existence. Tests were conducted on ventilators once they reached the UK, and any failures reported immediately to HMT (see paragraphs 106-107) **(MS4/131 - INQ000514248).** The tests were carried out by both the Clinical and Technical due diligence teams concurrently. The process of due diligence is outlined in paragraphs 105-109.

89. I will now provide some examples of contracts and the Department's efforts to procure ventilators from overseas suppliers, including the factors that were considered as well as any issues faced during this process.

90. On the 23 March 2020, the Department sought approval for the procurement of 630 ventilator devices from China and Taiwan **(MS4/132 - INQ000514148)**.

91. On the 26 March 2020, the Department was made aware by the FCO in Malta of an offer of ventilators from a company based in Malta. The communication between the Department and FCO confirmed that the devices in question had been cleared by the clinical review team and that the FCO had completed due diligence on the company. In total, 3,000 ventilators were being offered to the Department **(MS4/133 - INQ000514155)**.

92. However, upon receiving a deposit payment of almost €40 million, the company informed the Department that the deal had changed, and that the manufacturer of the devices had increased the prices and required an immediate letter of credit to hold the stock. The Department initially proceeded with this contract and began drafting a letter of credit, alongside a letter demanding an inspection of the devices. The Department raised concerns regarding the lack of a delivery schedule from the company and stated that it was unable to proceed without such a schedule.

93. Due to the delay to the delivery and the changes made to the original offer, the Department informed the company on the 16 April 2020 that they would not proceed with the contract and requested a refund of the deposit. Despite follow-on offers from the company, the Department reiterated its demand for a refund on the 21 April 2020. The Department's finance team confirmed the receipt of the refund on the 24 April 2020, however, due to exchange rate fluctuations, a financial loss to the Department was recorded **(MS4/134 - INQ000514182; MS4/135 - INQ000514157)**.

94. The Department also discussed purchasing refurbished ventilators if these devices met the required quality standards **(MS4/ 136 - INQ000514164)**. The Department subsequently ordered 35 refurbished Flight 60 ventilators from Taiwan on 06 April 2020 **(MS4/137 - INQ000514165)**.

**The Distribution of Ventilators Across the UK**

95. I am asked if there were any regional variations across the UK in demand for and hospital stock of ventilators. The table below provides an overview of the number of critical care ventilators that were distributed to the nations of the UK other than England, as well as the Crown Dependencies and Overseas Territories by July 2020.

| Ventilator type | Scotland | Wales | Northern Ireland | CD/OTs | Total |
|---|---|---|---|---|---|
| Mechanical Ventilator - ICU | 283 | 177 | 96 | 26 | 582 |
| Mechanical Ventilator - Transport | 264 | 133 | 90 | 7 | 494 |
| Mechanical Ventilator - Anaesthetic | 8 | 3 | 3 | 1 | 15 |
| Mechanical Ventilator - Emergency | 1,063 | 614 | 367 | 2 | 2,046 |
| NIV (BiPaP) | 942 | 541 | 324 | 39 | 1,846 |
| NIV (CPAP only) | 493 | 283 | 168 | 28 | 972 |

***Table 1:*** *Distribution of ventilators across the nations of the UK, Crown Dependencies and Overseas Territories as of 17/07/2020* **(MS4/138 - INQ000514201)**

96. A clinically driven National Ventilator Allocation Panel (NVAP) was established to provide strategic direction and oversight of the allocation of ventilators and ICU equipment within England's regions. The NVAP was chaired by Emily Lawson and the membership of the group can be seen in the following exhibit **(MS4/18 - INQ000514158)**. Regional representatives varied per region but typically included regional medical directors and / or their delegates.

97. The process of allocation was informed by a daily review of data on ventilator supply and demand within England, alongside regional intelligence, and enabled clinically informed decisions about ventilator allocation across the country.

98. The fundamental approach of the NVAP allocation process was that Trusts would 'bid' on a clinical basis for equipment. Regional teams would then review these bids and, if supportive, submit these bids onto the online information platform. Bids in this platform would be reviewed and clinically prioritised at the NVAP meetings. The online system also contained information about the current situation within each Trust and hospital obtained through the daily sitrep process. This was vital in considering how to appropriately respond to requests. The level of spare capacity in the Trust, together with the patient trend was regularly used to

inform decision making about allocation of scarce equipment. The system operated across a range of scarce equipment products including ventilators, patient monitors, syringe drivers and other equipment **(MS4/16 - INQ000514204)**.

**Working with Devolved Administrations**

99. I am asked about how the Department engaged with the Devolved Administrations (DAs). Health is a devolved function and therefore the Department supported, where requested (but did not take responsibility for, or prevent separate action by), DAs, Crown Dependencies and British Overseas Territories provision by:

a. Sourcing ventilators, oxygen therapy devices and other ICU equipment; and
b. Establishing contingency arrangements with gas providing organisations working across the UK and Crown Dependencies **[page 5 of] (MS4/139 - INQ000494411)**.

100. By working with the DAs, the Department established what proportion of national ventilator stock should be allocated to the DAs. The allocation formula was designed to allocate ventilators proportional to population, based on 2018 Office for National Statistics (ONS) data **(MS4/140 - INQ000514161; MS4/16 – INQ000514204)**. The daily allocation and distribution process was established on 1 April 2020, overseen by the NVAP, consisting of representatives from the national incident team, national critical and respiratory care leads, and regional medical directors/colleagues **(MS4/141 - INQ000514210)**.

**Safety and Technical Standards of Ventilators**

101. This sub-section will provide an overview of the regulations and technical specifications and standards set for ventilators that were intended for use within the NHS as a response to the COVID-19 pandemic. The Department was not directly responsible for setting the medical or technical standards for ventilators either before, during or after the COVID-19 pandemic. For existing ventilator designs these standards are determined at a national level by a committee of industry experts set up by the British Standards Institute (BSI) and internationally by the International Standards Organisation (ISO).

*Ventilator Specification Guidance and Standards*

102. The specifications were updated on four different occasions between 19 March and 28 April 2020. The guidance covered the specifications for the ventilators to be used on patients

requiring oxygen. The guidance also included testing protocols for final validation of safety and performance of these devices, as well as the correct labelling of these devices **(MS4/142 - INQ000494394)**.

103. On the 20 March 2020, the MHRA published regulatory specifications for Rapidly Manufactured Ventilator Systems, outlining the legal minimum specifications for use in the UK; the NHS set the minimum acceptable clinical performance specifications for ventilators, procured through the Ventilator Challenge, to be used in UK hospitals during the COVID-19 pandemic **(MS4/142 - INQ000494394)**. It set out the clinical requirements based on the consensus of what is 'minimally acceptable' performance in the opinion of the anaesthesia and intensive care medicine professionals and medical device regulators in a pandemic environment. As referred to in paragraph 14 the MHRA regulates medicines, medical devices, and blood components for transfusion in the UK **(MS4/142 - INQ000494394)**.

104. Pre-pandemic, the manufacturing site and device were inspected by a qualified inspection organisation, using the methods detailed in the medical device regulations, and approved for sale in the UK. Devices bearing a CE mark are expected to meet the requirements detailed in The Medical Devices Regulations 2002, as well as the most up to date standards from when the device was placed on the market.

105. On 15 April 2020, the Cabinet Office provided an overview of the technical specifications of ventilators being considered for the Ventilator Challenge as covered above in paragraph 100. These technical specifications included minimum standards for the average oxygen consumption, and other specific functions that any models under consideration needed to fulfil **(MSx/143 - INQ000494404)**. This information was provided to the Cabinet Office on 15 April 2020, together with recommendations for the setting of targets for the number of ventilators to be procured through the Ventilator Challenge **(MS4/ 144 - INQ000514171; MS4/ 145 - INQ000514172; MS4/ 146 - INQ000514173; MS4/ 147 - INQ000494403; MS4/ 148 - INQ000514174; MS4/143 - INQ000494404; MS4/ 149 - INQ000514175)**.

106. On the same day (15 April 2020), in a Ministerial Trilateral Briefing, it was noted that the clinical experience of COVID-19 had grown rapidly over the last month and that there were certain technical requirements for mechanical ventilators for the effective critical care treatment of COVID-19 patients, relating to 'suction', 'stiff lung' and 'supported breathing' **(MS4/149 - INQ000514175)**. A recommendation was made to prioritise the manufacture and purchase of five device models - Penlon Prima ES02, OES Medical Genesis, Breas Nippy4+,

Breas Vivo65, Vyaire LTV2 - in order to meet demand. A recommendation was also made, pending final feedback, that the CO would no longer progress domestic production of Helix Plexus, Sagentia Mosquito, OxVent models.

107. On the 15 April 2020, the World Health Organisation issued Interim Guidance on Technical Specifications for Invasive and Non-Invasive Ventilators for COVID-19, which set out the minimum requirements that invasive and non-invasive ventilators must comply with to ensure quality, safety and effectiveness when used for the management of COVID-19 **(MS4/150 - INQ000514181)**.

*Clinical and Technical Due Diligence*

108. Additional due diligence was required for ventilators procured by the Department from overseas and donated ventilators, to ensure these devices met UK specific standards **(MS4/151 - INQ000514180)**. The Ventilator Due Diligence Team comprised two parts: a Clinical Due Diligence Team who inspected the equipment and reviewed in scope devices at MOD Donnington and a Technical Due Diligence Team who tested and classified devices at Queen's Medical Centre, Nottingham University Hospitals NHS Trust (NUH). The Clinical Due Diligence team was made up of clinicians who were temporarily assigned to inspect the completeness and functionality of delivered devices at MOD Donnington. The Technical Due Diligence team was led by Prof Thomas Clutton-Brock, Director of Medical Devices Testing and Evaluation Centre at the University of Birmingham and Prof Dan Clark, Head of Clinical Engineering at Nottingham University Hospital NHS Trust.

109. The Ventilator Due Diligence Team submitted a consolidated report for sign-off by the National Ventilator Allocation Panel (NVAP) allowing for in scope ventilators to be allocated by clinical leads **(MS4/152 - INQ000514192)**.

110. When due diligence took place, two devices from that shipment were reviewed (one by the Clinical Due Diligence Team and one by the Technical Due Diligence Team). This process happened concurrently rather than sequentially. Devices going through the due diligence process were placed in 'quarantine' at MOD Donnington and not released for allocation at the National Ventilator Allocation Panel (NVAP) until they had been signed off by NVAP Clinical Leads. Additional guidance on how to use new or unfamiliar machines or enable technical workarounds to get a machine operational was sometimes required for sign off **(MS4/151 - INQ000514180; MS4/153 - INQ000514221; MS4/154 - INQ000514213; MS4/155 - INQ000514183)**.

111. When the Clinical Due Diligence Team had reviewed the device, they would send their findings to the Technical Due Diligence Team. When the Technical Due Diligence Team had reviewed the device, they would produce a short report, which would be sent to NVAP Clinical Leads. The report would make one of the following recommendations:

a. Outcome 1 - De-quarantine the devices and release them into the NVAP process;
b. Outcome 2 - De-quarantine the devices and release them into the NVAP process accompanied by a guidance note about necessary workarounds to make the machine operational. This guidance note would be drafted where required by the Ventilator Due Diligence Team;
c. Outcome 3 - Hold the device in quarantine pending supply of additional components or consumables and a communication sent to NHS Supply Chain with specific reference to components and consumables to be ordered and received at MOD Donnington before the devices are released into the NVAP process;
d. Outcome 4 - The device cannot be used and should not be released into the NVAP process **(MS4/151 - INQ000514180)**.

112. The reviews of the clinical due diligence team resulted in twenty-nine devices being placed into Outcome 1, twelve devices into Outcome 2, three devices into Outcome 3, and ten devices were placed into Outcome 4. The Technical Due Diligence Team only reviewed mechanical ventilators, which required higher standards for patient safety and clinical use. Of those devices that were inspected by the Technical Due Diligence Team, four were placed into Outcome 1, five into Outcome 2, five into Outcome 3 and one into Outcome 4 **(MS4/100 - INQ000514224)**.

**Public Sector Equality Duty**

113. The O2VMD&CC Programme was subject to the public law duties of rationality, fairness, and compatibly with the human rights of those affected by the actions taken by this Programme, as set out in: The Human Rights Act 1998, National Health Service Act 2006, the Health and Social Care Act 2012, the NHS Mandate 2020-21 and NHS Constitution for England 2021 **(MS4/ 156 – INQ000184066; MS4/ 157 – INQ000184066; MS4/ 158 - INQ000409898)**.

114. This Programme was mindful of the need for equality. The programme had due regard to the Equality Impact Assessment and sought to ensure there was no shortage of oxygen, and ICU equipment and consumables required during the COVID-19 pandemic.

## SECTION 5: SECURING LONG-TERM SUPPLY OF VENTILATORS

115. After setting out the early stages of the O2VMD&CC Programme, this section will cover the next phase, which followed after the initial rapid procurement of ventilators and related medical equipment and focused on increasing the long-term resilience of the UK in the face of future waves of COVID-19. It will also cover the rationale for and examples of overseas donations of ventilators and the challenges faced by the Department in relation to fraud.

### Achieving a Surplus of Ventilators

116. On the 13 March 2020 the Department set a target of having 18,000 mechanical ventilators by the end of April and 30,000 mechanical ventilators by the end of June; these targets were set for the whole of the UK, not just England. On 15 April 2020, the Department shared with the Cabinet Office information which discussed the clinical evidence on the use of ventilators, updated demand projections and the targets to be set for the procurement of ventilators through the Ventilator Challenge **(MS4/149 - INQ000514175; MS4/147 - INQ000494403).**

117. It was now formally recommended that the Department and Cabinet Office adopt the targets of 18,000 mechanical ventilators by the end of April 2020 and 30,000 mechanical ventilators by the end of June for the whole UK. This was deemed sufficient to cover the latest demand curve outlined by the NHS projections. It was also expected that this would:

a. Provide surplus over requirements sufficient to cover regional variations in demand and hospital stock;
b. Provide sufficient margin of safety over current demand estimates, to be confident that the UK had enough ventilators to cover the NHS's needs; and
c. Meet additional demand from Devolved Administrations.

118. A programme summary paper from 19 April 2020 pointed out that demand in England for mechanical ventilators peaked at just under 4,000 ventilators (for COVID and non-COVID patients) between 12 and 18 April 2020. At the same time NHS England reported that just under 7,000 beds were capable of supporting mechanical ventilation, resulting in a surplus of

3,000 ventilated beds. As a result of having achieved this surplus in ventilation capacity, the Department began returning the 1,200 ventilators that had been loaned from the private sector, in advance of the deadline of end of June 2020 **(MS4/159 - INQ000514190)**.

119. I am asked if the Department at any point during the pandemic knew if any patient who needed a ventilator was unable to access one. The Department and NHSE/I received daily updates from Trusts regarding their ventilator requirements and are not on the basis of this data aware of a UK patient being unable to access a ventilator when they needed one. The Department held information about the oxygen supply, delivered capacity, medical gas pipeline system capacity, and ventilation equipment capacity of each trust, as well as the respective patient demand **(MS4/ 160 - INQ000514154)**. This information was used to determine the best allocation of procured ventilator units to different Trusts as covered above.

120. From June 2020, the next phase of the O2VMD&CC Programme began to be implemented, which built on the achievements of the initial response to the COVID-19 pandemic. This phase aimed to:

a. Improve the quality and availability of devices;
b. Solidify consumables system and stockpiles;
c. Establish a 'new normal'; and
d. Reduce reliance on complex supply chain systems.

121. The obligations of this phase of the programme were set out at the time in the following terms:

a. "Manage the deployment of assets to maximise quality, strategic fit and create a strategic reserve of devices for use as part of any future response;
b. Provide an equipment Operations capability to handle ongoing allocations, asset management, and distribution issues;
c. Handle purchasing and contract management to ensure receipt of remaining devices and appropriate ongoing contract management and transfer of assets to NHS trusts; and
d. Receive and manage devices created as part of the Ventilator Challenge." **(MS4/161 - INQ000514205)**.

122. This phase of the programme had a target of achieving a surplus of 30% of ventilators above the actual and projected demand. The metric used was the total number of patients on

ventilators (COVID and non-COVID) in England as a percentage of total availability in England. By late July 2020, the actual available surplus was 46%, of which 2% was for COVID-19 patients **(MS4/161 - INQ000514205)**.

123. As available stocks of ventilators increased, the National Ventilator Allocation Panel (NVAP) evolved to a more 'business as usual' format. For products where significant stocks were held, the criteria for 'immediate clinical need' were relaxed in line with stock availability and perceived demand. The frequency with which the allocation panel met was also reduced from daily to weekly **(MS4/16 - INQ000514204)**.

124. Due to the large-scale procurement of ventilators from domestic and international suppliers, as well as national lockdowns to reduce transmission rates and other efforts to reduce demand caused by serious infection, the UK had established a surplus of ventilators by September 2020 **(MS4/162 - INQ000514230)**.

125. Based on our records, by 30 May 2022, the stockpile held over 30,000 ventilators, with over half of these specifically being ventilator challenge machines **(MS4/163 - INQ000339321**). The Department also built-up supplies of non-invasive ventilators over this period.

126. From mid-2021 through to early 2023, a reserve stockpile was maintained to support 3,000 ICU beds for a period of six weeks. This represented levels sufficient to meet the needs like those seen in January 2021, when demand was at its peak.

**Donations of Ventilators to other Countries**

127. This sub-section provides some examples of the Department facilitating the donation and/or export of ventilators to other countries in the second half of 2020 and early 2021 and the reasoning behind such decisions.

128. By the second half of 2020, the UK had exceeded its target of having 30,000 ventilators available, with further deliveries expected. The Department was therefore in a position to consider donations of ventilators to other countries in need of such devices. By September 2020, the RWCS at the time predicted a demand of 6,500 ventilators across the NHS, meaning donating ventilators would have little impact and leave the UK with enough contingent capacity **(MS4/162 - INQ000514230)**.

129. At that time, FCDO posts overseas received requests for help with equipment such as ventilators. Upon FCDO approval, the request would then be sent to the Department, whereupon it would be considered if it fell within the scope of the O2VMD&CC programme.

130. Following these assessments, if the Programme Oversight Board recommended the approval of the donation request, final decisions were put to ministers for approval. Following ministerial approval, respective workstream leads would begin the process of delivering the ventilators agreed **(MS4/139 - INQ000494411**; **MS4/164 - INQ000514281)**.

131. The Department's priority when they received requests to donate equipment was to ensure the UK's domestic equipment needs were fully met. The Department anticipated that there was likely to be further requests for some further small donations, but all decisions would come to Ministers **(MS4/165 - INQ000514229)**.

132. One example for such a request submitted to the Department was for a donation of ventilators to Peru, following a call between the President of Peru and the Prime Minister on 5 August 2020. Peru had experienced one of the highest numbers of COVID-19 cases and the highest mortality rate globally and it was considered that the donation would demonstrate the UK's leadership in health, as well as supporting the wider UK bilateral relationship with Peru, and would also ensure surplus equipment not otherwise being used could help save lives. The proposed donation consisted of 20 mechanical ventilators and 40 non-invasive ventilators as well as associated monitors. The total value of this donation was approximately £520,000. The agreement to donate ventilators to Peru was signed by both parties by the 28 January 2021 **(MS4/166 - INQ000514280)**.

133. Similar agreements for donations of ventilators were reached with other countries, including India on the 25 April and 2 May 2021 **(MS4/167 - INQ000514263),** and Nepal on the 27 May 2021 **(MS4/168 - INQ000514265)**.

**Navigating Procurement Challenges, including Tackling Fraud**

134. This section of the statement provides an overview of the Department's view in relation to any fraud, challenges or issues relating to the fulfilment of contracts in the procurement of ventilators.

135. The majority of instances of potential fraud were instances where companies or individuals that genuinely believed that they could access stock but were being over-optimistic

about their capabilities given the unprecedented market conditions. There were some instances where there was a clear case of attempted fraud, such as suppliers claiming to have stock in a foreign country and, upon further questioning, would be unable to provide address details, or where suppliers would make claims that were not credible.

136. In order to assess the validity of offers, the Department requested documentation from potential suppliers, this included CE certificates and letters of authorisation from manufacturers. There were a very small number of cases where clearly fraudulent documents were supplied, and these were not taken forward.

137. Only one sophisticated suspected case of fraud was experienced by the Department in relation to the procurement of ventilators. However, this was flagged to the Department by the UK reseller involved and the deal was abandoned and the already paid deposit returned **(MS4/169 - INQ000514235)**.

138. During the pandemic, the Department's Anti-Fraud Unit (AFU) and the NHS Counter Fraud Authority (NHSCFA) actively engaged with the Cabinet Office on the COVID-19 counter fraud response **(MS4/ 170 - INQ000514187; MS4/ 171 - INQ000514188; MS4/ 172 - INQ000514189)**.

139. The Department's Anti-Fraud Unit (AFU) took steps to review and support controls around procurement and help ensure that teams had the correct audit trails in place for the transactions that had taken, and were taking, place as part of the COVID-19 response **(MS4/173 - INQ000514177)**.

140. Furthermore, in an effort to manage the potential fraud risks faced during the pandemic, the Department AFU reflected on risks identified and compiled a Fraud Risk Assessment document, which pulled together data they had gathered from departmental officials. This Fraud Risk Assessment document identified a range of potential fraud risks, compared them against the controls in place, and assessed the effectiveness of those controls at managing those risks **(MS4/174 - INQ000514170)**.

141. The Department's finance functions were also prepared for increased fraud risks associated with a divergence from usual protocol **(MS4/175 - INQ000514146)**.

142. By way of example, one risk faced across the various workstreams was one of bogus suppliers, where the Department might place an order and pay in advance for medical

equipment with an overseas supplier that does not exist, resulting in a loss of advance payment and shortfall in supply. The controls in place to respond to such a scenario were described and assessed within the Risk Fraud Assessment, as it was noted that there could be FCO checks that the supplier is bona fide, a requirement that all payments in such circumstances be authorised by 1 of 3 senior managers, a watchlist of bogus suppliers, and for there to be a number of checks undertaken through law enforcement partners. However, it was noted that credit rating checks were not available in such circumstances, and that controls were reduced due to the emergency circumstances. The control measures were therefore scored as 3 out of 5 on a scale of effectiveness. Similar assessments were conducted within the Fraud Risk Assessment in relation to a range of potential risks identified from the across the workstreams.

143. The NHSCFA has the role of submitting an annual Strategic Intelligence Assessment (SIA), a report which sets out an annual estimate of the level of potential fraud vulnerability and a description of the nature of the fraud threats in the NHS in England. In a report published on the 13 September 2023 the NHSCFA outlined that the intelligence collated in 2022-2023 and financial vulnerability estimates based on activity in 2021 – 2022 were included.

144. In January 2021, the Department's AFU worked with NHSE/I to sample a number of contracts for ventilator procurement to assure CO and the COVID-19 Fraud Ministerial Board that the money had been well spent, the goods that the Department paid for were actually the items received and that these items had been delivered within the agreed timeframes, and where issues had been identified, plans could be put together for recovery and that any conflict of interest had been declared **(MS4/176 - INQ000514252)**.

## SECTION 6: THE COST OF THE O2VMD&CC PROGRAMME

### Strategic Imperative & HMT Delegation

145. The total budget allocated to the Department by HMT was £600m, dedicated to the purchase of a stockpile of capital equipment. The development of the capital stockpile was undertaken alongside the Cabinet Office through their work with industry to develop new ventilators **(MS4/128 - INQ000514282)**.

**Price Rises**

146. On the 30 March 2020, the Department anticipated a shortfall of 8,000 ventilators for April of that year, lending weight to the argument that the procurement of these ventilators was necessary, despite the unit price being 2-3 times above the average price range typical outside of the pandemic.

147. On the 5 April 2020, the Department was made aware that the price to be paid for 100 ventilators from a supplier had increased substantially by over a third of the original price. The Department held internal discussions about how best to react to such a price rise, the main concern being the signal sent to other suppliers if such a price rise was accepted. The options for consideration in this case included cancelling the original contract and replacing it with a new one, or alternatively, sending a follow-on contract for the additionally requested funds. To secure the ventilator stock the Department went ahead with the deal **(MS4/ 177 - INQ000514159; MS4/178 - INQ000514160)**.

**Total Spend**

148. The Department, alongside the FCO and NHS Supply Chain, received a total of **I&S** mechanical and BiLevel ventilators by the 20 July 2020. At this point, the delivery of 5,288 mechanical ventilators was still outstanding. The final contract led by the Department was concluded on the 12 May 2020 **(MS4/179 - INQ000514202)**. The total cost of procuring these ventilators was just over £254m **(MS4/180 - INQ000514203)**.

149. The Department, NHS Supply Chain, and Cabinet Office spent a combined total of approximately £425m on ventilators of all types during the COVID-19 pandemic.

150. Including the cost of associated medical supplies, as well logistical arrangements and storage, the total programme cost was just under £700m **(MS4/181 - INQ000514267)**.

**SECTION 7: LESSONS LEARNED**

151. While the pandemic required the Department to respond at pace to unprecedented demand for ventilators, it also provided an opportunity to learn some valuable lessons. This final section of the statement reflects on the lessons that have been learned from the performance of the O2VMD&CC Programme and what lessons could be learned from the procurement of ventilators and other activities during that time.

152. The Department continues to affirm that the single most important source of its reflections on lessons learned is set out in the "Technical report on the COVID-19 pandemic in the UK, A technical report for future UK CMOs, Government Chief Scientific Advisers, National Medical Directors and public health leaders in a pandemic", ("the technical report") published on 1 December 2022 **(MS4/182 - INQ000203933).** The report includes a chapter on improvements in care of COVID-19, including 'Clinical Practice Evolution' and 'Measures to manage surging clinical needs', including the use of oxygen and ventilators and the changes to clinical practice at pages 346-353 and 353-359.

153. Having said that, this section provides some further specific context to lessons learned relating to procurement of ventilators, drawing in particular on reviews that took place in 2021 for both the Programme and the donation of ventilators to Peru **(MS4/183 - INQ000514278; MS4/184 - INQ000514279)**. The Department continues to believe that five lessons articulated in the Module 1 closing statement summarise the Department's key lessons, and our reflections below are set out under these headings below.

**A Toolkit of Capabilities is More Important than Plans**

154. As with other aspects of the Department's response, there were lessons learned about the value of being flexible and having a range of options available to support the response. Mindful of the need to include a range of views and expert insight, the programme sought close working relationships with stakeholders. Strong relationships were formed with clinicians, valuing their clinical input to quickly establish required consumables for COVID-19 treatment, and continually review and refine the scope and size of the stockpile to ensure it remained appropriate **(MS4/183 - INQ000514278)**.

155. Given clinicians can have strong preferences for particular equipment models and brands, greater account could perhaps have been taken of these preferences in determining the appropriate balance between stimulating the production of existing designs and developing novel designs.

156. When the programme began in March 2020 there was insufficient information available as to what products were interchangeable, nor which had dependencies and compatibility requirements. Throughout the programme this improved significantly.

157. Challenges experienced in procurement of ventilators, such as being fit for purpose, tackling expected shortfalls in capacity and overseas procurement are discussed in paragraphs 67, 69 and 82-91 respectively **(MS4/183 - INQ000514278)**.

**The Underlying Resilience of the System Matters**

158. The programme put in place robust demand management processes very quickly, whereby over-ordering by NHS trusts was limited to a proportion of national stock. This, combined with daily demand watch, enabled quick decisions on product areas that were 'surging' allowing the programme to regulate demand. Although supply and demand reporting enabled enhanced oversight and foresight of potential supply issues, the NHS Supply Chain did not provide reporting on open orders. Therefore, there was limited visibility of inflight orders, orders where excess consumables had been ordered and not delivered or orders which could not be cancelled were not reported and the cost to the stockpile was larger than anticipated when orders arrived very late and unexpectedly **(MS4/183 - INQ000514278)**.

159. Although having a large physical stockpile increases short term resilience of the system there are several considerations to be made:

a. Storage, maintenance and administration costs;
b. Depreciation of product value and Warranty Expiry;
c. Recall and logistical movement cost;
d. Disposal and/or replacement of products.

160. Due to these factors, in a future similar situation alternative stockpile models should be considered, such as stock held on hand by manufactures for call forward as part of an ongoing contract, or having preferred bidders and activatable prepared contracts should purchases need to be made rapidly. However, contracts to supply stock in an emergency do not give direct control of the holding and in some extreme cases, might be abandoned by contractors when it is financially expedient to do so, or subject to export restrictions preventing movement to the UK. This highlights that neither owning a physical stockpile, nor contracting out for a supplier to hold stock on our behalf is a perfect solution. A layered approach, building resilience at first, second and third line to arrive in waves would potentially save storage, management and disposal costs. This would focus only on physically holding items of high risk in sufficient numbers to bridge the gap to contract delivery in an emergency **(MS4/183 - INQ000514278)**.

**The Ability to Scale up in the First Few Months is Essential**

161. As with other aspects of the Department's response to the pandemic, it is clear that our ability to scale up procurement efforts at pace is really important. As mentioned in paragraph 115 by the second half of 2020, the UK had exceeded its ventilator target and therefore the Department was able to consider donations of ventilators to other countries in need of such devices.

162. There are many factors we can draw on to ensure that this ability to scale up is maintained or surpassed in future pandemics. The close working relationship between NHSEI and Departmental colleagues within the programme added immense value, enabling the team to respond efficiently in different situations and enabled decisions to be made quickly and effectively.

163. We also learned that scaling up at pace is facilitated by having the right people involved from the start. Bringing people into the programme who understood the system was also critical in increasing the speed and efficiency of delivery.

**Diagnostics and Data are Crucial in a Pandemic Response**

164. Data are an essential capability to help enable appropriate procurement, distribution and stockpiling of equipment. Forecasts enabled the programme to 'get ahead of the curve' in front line equipment distribution, for example **(MS4/183 - INQ000514278),** and as referred to in paragraph 33 modelling data was also considered when deciding further procurement was no longer required.

165. Our reviews on our performance have also demonstrated the role that data plays in maintaining careful monitoring and management of stocks. Maintaining key data assets and processes within a central repository is important to support responses to future surges and transition to BAU activities **(MS4/183 - INQ000514278)**.

**Prepare for Future Threats, not just for COVID-19**

166. The Department is committed to preparing for future health threats, including other pathogens and not just any potential further COVID-19 threat.

167. The operation and structure of the programme, for example, can be used to support learning for future pandemics. This includes the policies, data collection requirements, including stock levels, operating process and documentation which should reduce the need for re-learning **(MS4/183 - INQ000514278)**.

168. A further lesson learned relates to the need for specialist expertise to support and oversee processes relating to the possible donation of any equipment.

**STATEMENT OF TRUTH**

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

**Personal Data**