Witness Name: Chris Stirling

Statement No.: 1

Exhibits: CS/01 – CS/35

Dated: 29 January 2025

UK COVID-19 INQUIRY

FIRST WITNESS STATEMENT OF

CHRIS STIRLING

A - INTRODUCTION

I, Chris Stirling, will say as follows:

1. I make this statement in response to a request from the UK Covid-19 Public Inquiry ("the Inquiry") dated 8 November 2024, made under Rule 9 of The Inquiry Rules 2006 ("the Request") asking me to provide a witness statement setting out the key aspects of my involvement in respect of my role. The Inquiry wishes to understand the role I played from 1 January 2020 until 28 June 2022 ("the Relevant Period").

2. I am no longer working for the Department of Health and Social Care (DHSC) and therefore do not have direct access to the documents and records from the time. I would like to thank both members of the DHSC inquiry team for assisting me with locating key records, and members of the original programme team for keeping what appear to me in retrospect to be strong records of events.

3. Notwithstanding the access to these records, the majority of this statement is made primarily from my memory of events nearly 5 years ago.

4. This statement focuses predominantly on procurement (the scope of the module) extending beyond that where necessary to respond to the Inquiry's questions.

B - ROLES AND RESPONSIBILITIES

5. By profession I am a project / programme manager: over the last 15 years I have led government major programmes. Whilst I have worked extensively within health, my technical background is in computer science and I am not a medical or healthcare practitioner of any kind.

6. You have asked about my roles immediately prior to the pandemic:

    a. through 2017 and 2018 I was the Delivery Director supporting the turnaround of the Ministry of Justice's Technology Transformation Programme. I reported to the Programme Director, and was selected by interview; and

    b. through 2019 until immediately prior to the pandemic, I was the Programme Director for DHSC's Community Pharmacy Post Budget Supply Chain Review. I reported to DHSC's Chief Commercial Officer, and was selected by interview.

7. In late February 2020, as part of a reprioritisation of resources, work on many activities within DHSC, including the Community Pharmacy Review, was paused to enable

resources to be diverted to the Covid-19 response. During the pandemic period I played two related, and overlapping, roles:

a. March 2020 – September 2021: Programme Director of the Joint DHSC and NHS England & Improvement (NHSE/I) Covid Oxygen, Ventilation, Device and Clinical Consumable Response; and

b. April 2021 – October 2022: Interim Director of Medical Technology for DHSC.

8. In both of these roles I perceive I had a high degree of autonomy to shape activities and make decisions, as well a high of degree of scrutiny and assurance.

9. I have subsequently worked on a large infrastructure programme for a Ministry of Defence (MoD) Arms Length Body (ALB).

10. I have not previously had any direct responsibility for pandemic planning or preparedness. However, two of my previous roles have had connections to the broader preparedness agenda:

a. In 2015/6 I led the design of the future (now current) operating model for NHS Supply Chain. Supply Chain resilience, and inventory management, were important topics as part of this work however there was never any proposal, or suggestion, that NHS Supply Chain should be established to act as a provider of last resort; and

b. In 2014 I supported Public Health England on a part time basis to resolve technical delivery issues they were experiencing in the National Pandemic Flu Service they received from NHS Digital.

C – PROGRAMME OVERVIEW

Procurement landscape prior to the pandemic

11. At the time, the Medicines and Healthcare Regulatory Agency (MHRA) had approximately 2 million pieces of medical technology licenced for use in the UK market. Of these it was crudely estimated that ~100k are in regular use within the NHS each year. Within the products in regular use, many are variations on a theme: some of these variations are 'good' (containing valuable innovation or catering for different patients' needs etc) and others are 'bad' (sales / marketing differentiation or defensive adaptions to drive reuse).

12. Clinical choice is a key, structural, element of the UK health system. Hospitals could choose to run on significantly smaller ranges of products (~10-20k) but to do so would significantly constrain clinical choice. For comparison purposes, a main line supermarket may stock 50k different items, a budget supermarket will stock 1-2k different items: less choice, but higher volumes so better prices.

13. In this environment, it is the role of NHS Supply Chain to support trusts to source these items effectively. NHS Supply Chain's key services are centralised product evaluation, procurement, and consolidated ward level delivery. By consolidating volumes of products, it aims to secure more competitive prices in the market and reduce operational overheads for the NHS.

14. Usage of NHS Supply Chain is entirely voluntary: it acts as one of a number of approaches Trusts may take to meet their procurement and logistics needs. It was never designed to act as a supplier of last resort. NHS Supply Chain has a mission to increase its market share and had approximately 45% pre-pandemic but was, in no way, 'the' sole supplier to the NHS.

Programme intent and rationale

15. At the start of the pandemic, issues started to be experienced with suppliers being unable to fulfil demand and Trusts being unable to source required volumes through the usual channels. This led to early, small scale, examples of Trusts panic buying, hoarding, and competition between Trusts driving up prices. Whilst these issues were initially small, there was an expectation that things would get worse as stock positions and the global trade landscape deteriorated.

16. It appeared clear that the existing NHS structures both locally and nationally would not be able to cope effectively and that an enhanced national level intervention was required.

17. The inception of what became the Oxygen, Ventilation, Medical Devices and Clinical Consumables (O2VMD&CC) programme was on 3 March 2020. The underlying aims of the programme were to:

    a. **make sure we don't run out**: noting that the clinical requirements of what we needed were not clear and continued to change;

    b. **make sure we've got it in the right place:** in line with clinical need rather than strength of voice or procurement capability;

c. **get the best value for money we can:** in a fiercely competitive global procurement landscape; and

d. **to create confidence in the NHS, industry, and the public:** to avoid unhelpful or counterproductive actions.

18. The programme was intended to be one of a number of supply chain responses sitting alongside other 'pillars' of activity focusing on Medicines, Non-Clinical Items, Personal Protective Equipment (PPE) and Vaccines to provide a comprehensive supply response.

Programme Device Scope

19. The initial scope request focused on a specific subset of ventilation capability (mechanical / Intermittent Positive Pressure Ventilation - IPPV). In response to increasing clinical and situational awareness, the programme scope evolved rapidly over the first few weeks of the programme before stabilising.

20. The key products in scope of the programme were:

a. **Ventilators and associated capital equipment**: including various types of ventilators, patient monitors, syringe drivers and other necessary capital items to support patients on ventilation;

b. **Clinical consumables**: to support oxygen therapy and intensive care more broadly, covering a wide range of consumables, including various sensors, tubes and filters;

c. **Oxygen**: including associated regulators, cylinders and enhancements to capital infrastructure within Trusts to ensure oxygen could reach the patient bedside; and

d. **Special items:** items that needed to be treated differently to the categories above, predominantly focusing on renal and enteral feeding fluids.

21. There were a number of interactions and relationships between this programme and other supply pillars, notably that:

a. Oxygen, whilst being regulated as a medicine was managed by this programme, and not by the medicines response;

b. Generic PPE was handled by the PPE response, whilst specialist PPE (e.g. gloves specifically designed for use with chemotherapy drugs) were handled as part of the consumables response;

c. the Vaccine Taskforce was responsible for vaccination needle supply, however there was overlap with broader consumable needle usage and supply arrangements; and

d. whilst the programme had no responsibility for covid testing supply arrangements, in my later role as Director of Medical Technology, I supported the UK Health Security Agency (UKHSA) as DHSC's policy lead for lateral flow testing technology.

Phases

22. In order to respond to the changing environment and phases of the pandemic, the programme went through four distinct phases of operation as shown in page 3 of the MedTech Narrative Document [**CS/01 - INQ000535034**] and set out below:

a. Phase 1: **Initial Surge** (March – May 2020);

b. Phase 2: **Winter Preparation** (June – November 2020);

c. Phase 3: **Second Surge** (December 2020 – February 2021); and

d. Phase 4: **Transition and Closure** (April – September 2021).

23. Phase 1 comprised a rapid mobilisation and response to the initial surge in demand. During this phase there were significant activities to understand, and procure against, the changing clinical requirement as well as activities to establish data gathering, logistics, allocation, and distribution processes.

24. In contrast, Phase 2 represented a structured preparation for Winter 2020/21. Procurement of new capital equipment (including ventilators) had largely stopped at this point, significant volumes of equipment remained in transit, and the focus was on receiving, assessing, and deploying ventilators to build capacity. The consumables supply chain was replenished (depleted in Phase 1) and work to build a stockpile for surge 2 undertaken. In parallel, a structured programme of oxygen improvement works, alongside initiatives to improve Oxygen utilisation were undertaken.

25. Phase 3 enacted the contingency measures planned in Phase 2. The additional capacity built over the summer period placed significant extra pressure on Oxygen infrastructure

which became the primary constraint. In line with expectations, there was significant usage of the consumable stockpiles, and limited use of residual capital capacity (excepting oxygen infrastructure). Despite daily oxygen management process and resources being severely tested, at a system level, Oxygen capacity plans held.

26. Phase 4 focused on the transition of enduring activities to long term homes, and the mothballing of high intensity intervention processes. There was also an increased focus on donating surplus assets to support international development efforts.

D – GOVERNANCE

Key roles and programme operations

27. The Programme was a collaboration between DHSC and NHSE/I, with the aim of forming a single joint team across both parties, reporting activities together with accountability for specific roles held within respective organisations. Simplistically:

    a. NHSE/I: had responsibility for clinical decisions, NHS operational decisions, and NHS communications; and

    b. DHSC: had responsibility for strategic / policy direction, funding and commercial decisions, cross HMG interfaces (including communications) and interaction with Devolved Administrations.

28. The key programme governance individuals were:

    a. Dame Emily Lawson, Chief Commercial Officer NHSE/I, as NHSE/I lead and SRO;

    b. Steve Oldfield, Chief Commercial Officer DHSC as DHSC lead;

    c. Professor Sir Keith Willett as Covid-19 Strategic Incident Director for NHSE/I and our senior customer; and

    d. Edward Argar as Minister of State for Health and the DHSC ministerial portfolio holder.

29. Whilst the programme structure evolved in the first months of the programme, for the majority of its life, it operated a three-tier structure, as described in the programme induction pack [**CS/02 - INQ000494410**]:

a. a monthly **Programme Oversight Board**, chaired by Emily Lawson (as SRO) and containing key programme stakeholders was the ultimate decision-making body for the programme [**CS/03 - INQ000471091**; **CS/04 - INQ000514219**; **CS/05 - INQ000514251**; **CS/06 - INQ000514264**];

b. a fortnightly **Programme Delivery Board,** which I chaired (as Programme Director), managed the delivery process, resolved cross cutting issues and provided an opportunity to check alignment with programme priorities [**CS/07 - INQ000471090**; **CS/08 - INQ000514199**; **CS/09 - INQ000514250**; **CS/10 - INQ000514260**]; and

c. weekly **checkpoint meetings,** which I also chaired, were also normally held with each workstream focusing on reviewing progress and approaches to address key risks and challenges [**CS/11 - INQ000471089; CS/12 - INQ000514207; CS/13 - INQ000514228; CS/14 - INQ000514238**].

30. The terms of reference and key decisions made by the each of the above governance structures were captured in meeting minutes which have been previously disclosed to the inquiry, examples are referenced above.

31. Examples of key processes including due diligence, allocation and donation (covered in further detail in subsequent sections) are provided at [**CS/15 - INQ000514180**; **CS/16 - INQ000514158**; **CS/17 - INQ000535043** and **CS/18 - INQ000494411**].

32. In addition to the internal programme governance arrangements described above, the programme was subject to broader external scrutiny and assurance activities including reporting to:

a. the DHSC 'Battle Plan' rhythm and oversight structures;

b. the NHSEI National Incident Response Board (NIRB) rhythm and oversight structures;

c. HMT through the programme's Finance Business partner;

d. DHSC's Fraud Prevention team (who both provided support and sought assurance); and

e. the National Audit Office and Public Account Committee to support their publication focused on ventilators.

Procurement governance

33. Contracts to purchase items were either:

    a. entered into directly by the DHSC;

    b. entered into on DHSC's behalf on the Foreign, Commonwealth and Development Office (FCDO); or

    c. entered into on DHSC's behalf by NHS Supply Chain.

34. For contracts entered into directly by the DHSC, depending on scale and risk these would either be:

    a. approved by the Chief Commercial Officer (Steve Oldfield) on the basis of a standard pack of information / proforma recommendation; or

    b. escalated to Second Permanent Secretary (David Williams) if they were either outside of Steve's delegated authority or had aspects that were perceived contentious or risky.

35. For contracts entered into on DHSC's behalf by FCDO, a similar process applied. DHSC and HMT set out a series of expectation of the contracts and documentation. FCDO would complete this and DHSC would then take the decision as to whether to proceed.

36. However, the majority of contractual spend went through NHS Supply Chain, placing orders with existing framework agreement suppliers, predominantly for products with prices that had already been competitively tendered. For these items, the programme was effectively the 'customer' placing orders on behalf of the NHS and the normal supply chain rules and regulations were in place.

Target setting / scale of the requirement

37. It was not the responsibility of the programme to estimate likely covid inpatient numbers. It was, however, the responsibility of the programme to receive an inpatient estimate (our demand signal), translate that into estimates of the items required and then source and distribute those items.

38. In the early weeks of the pandemic, there was significant uncertainty of the inpatient requirement. Between 12 February and 17 March, requirements estimates varied between 59,000, 90,000 and 138,000 ventilator beds.

39. Whilst they have been subsequently published, distribution of official estimates at the time was highly restricted even within the health system. Whilst the conclusions of these analyses were shared, typically verbally, the supporting information and analysis was not. This coupled with the uncertainties surrounding speed of pandemic progression and efficacy of potential interventions created a highly uncertain target-setting environment.

40. In order to increase programme confidence in the scale of the response required, the programme organised a rapid modelling session with leading professional modellers on 6 March to independently create an alternative demand signal. Our intention was to sanity check the scale of the requirements; our expectation was that our alternative signal would be significantly lower. To our shock our alternative signal closely mirrored the official one: confirming the scale of the Covid impact and activities required.

41. I was subsequently involved in discussions leading to the setting of the 30,000 ventilator target. This target was informed by, but did not adopt, the output from various mathematical models available at the time. Instead, it sought to provide a clear direction for the programme whilst striking a balance between setting a small enough target not to create unnecessary panic, and setting a large enough target that:

    a. we would be able to materially pursue all options, leaving 'no stone unturned';

    b. we could clearly demonstrate to industry partners our intent to buy ventilators if they could supply / manufacture them; and

    c. we could clearly communicate to the public that we were responding at appropriate scale.

    The expectation at the time was that once achieved, this target would be increased.

Programme relationships, support and linkages

42. Programme delivery required collaboration and partnership working across a wide range of public and private sector partners. This section summarises the key relationships outside of the programme team, and governance structures described above. Further details on many of these interactions can be found in subsequent sections.

43. Within the DHSC, we worked with a broad range of teams including:

    a. **Commercial and finance**: establishing contracts, processing payments, tracking spend and reporting to HMT working on financial matters through Carl Wiggins (Finance Business Partner);

b. **Clinical leadership:** our primary interactions were with NHS clinical leadership although on occasions we engaged with Chris Whitty (Chief Medical Officer), and Jonathan Van-Tam (Deputy Chief Medical Officer); and

c. **Ministers**: predominantly with Edward Argar, Minister of State for Health, as the portfolio holding Minister.

44. Within the NHSE national structure, we worked particularly closely (i.e. daily contact) with:

a. **Clinical leadership teams**: with the National Clinical Directors for Critical Care (Ramani Moonesinghe) and Respiratory (Andrew Menzies-Gow);

b. **Estates teams:** on Oxygen-related issues with the National Estates Operational Lead (Adrian Eggleton) and Director of Estates (Simon Corben); and

c. **Incident response teams:** working with the Covid incident director (Professor Sir Keith Willett) and his two deputies (Mike Prentice and Chris Moran).

45. We were also supported by, but were less intrinsically entwined (i.e. weekly contact) with other teams within the NHSE national structure, specifically:

a. **Scientific teams**: primarily through the Deputy Chief Scientific Officer (Angela Douglas) and accessing the network of national clinical engineers;

b. **Digital teams**: primarily regarding access and usage of the various national data capture and reporting systems led by the National Director of Data & Analytics (Ming Tang); and

c. **Pharmacy teams**: including the Director of Hospital Pharmacy (Andrew Davies) and the Home Oxygen Service.

46. At the regional NHS level, we had representation from each region (typically medical directors) attending our daily allocation panels (discussed in more detail subsequently).

47. Whilst the regional tier handled most of our engagement with NHS Trusts, we engaged directly with NHS Trusts on issues as and when they occurred. Our predominant Trust level engagement being through the Consumable Shortage Management (SMOG) and Oxygen Hot List processes (again, both discussed subsequently).

48. We also worked very closely (i.e. multiple daily interactions) with the **NHS Supply Chain** and with **MHRA** on regulatory approval matters.

49. Our interactions with broader HMG stakeholders are summarised below:

    a. **HMT**: who provided funding with associated conditions;

    b. **Cabinet Office (CO)**: who both led the Ventilation Challenge, input into ministerial oversight (through the Minister for State for Cabinet Office – Lord Agnew) and who provided a number of key resources;

    c. **MoD**: who provided warehousing, and warehouse operations, UK and international logistics support as well as key resources;

    d. **FCDO:** who, through their network of embassies, supported the identification of, and contracted with, new sources of supply;

    e. **Business, Energy & Industrial Strategy (BEIS)**: who provided a triage service in response to the high volume of contacts offering assistance to the programme;

    f. **Department for Transport (DfT):** who supported plans to maintain NHS supplies transport should travel networks be disrupted;

    g. **Home Office:** who assisted with expedited clearances of key stocks through customs;

    h. **Government Legal Department (GLD):** who supported rapid negotiations and review of contracts placed; and

    i. Various other government departments, notably **Department for Work and Pensions (DWP)**, who contributed resource to the programme.

50. The programme also established working relationships with officers within the respective Devolved Administrations.

51. Programme testing activities were undertaken primarily at Medical Device Testing and Evaluation (MDTec) (Birmingham) and Queen's (Nottingham) with additional material support from individuals at Addenbrooks and Southampton.

52. The programme also worked closely with suppliers and importers: oxygen providers, home oxygen service, device manufacturers and importers.

53. The programme employed external consulting support from both PA Consulting and Deloitte. At peak, this was ~20 FTE of the ~150 FTE peak programme team (~13%).

E – VENTILATORS AND ASSOCIATED CAPITAL EQUIPMENT

Understanding device types

54. A wide range of different oxygen therapy treatments are available to support covid patients, each requiring different equipment to administer. Crudely, in order of increasing complexity and intervention, oxygen therapies can be simplistically grouped as summarised at page 6 of the programme induction pack [**CS/02 - INQ000494410**] and as set out below:

    a. **Breathing oxygen through a mask / nasal canula:** in which the patient breathes normally but rather than breathing air, they are breathing oxygen enriched air. As well as the oxygen supply itself, this typically requires a mask and tubes to deliver.

    b. **Forms of non-invasive ventilation:** in which the mask over the patient's face is sealed and an additional machine generates pressure to 'push' the oxygen into the patient's airway. This pressure is typically either Constant, or Bilevel (higher when the patient breathes in, and lower when the patient breathes out) and devices are normally called CPAP (Constant Positive Airway Pressure) or BiPAP (BiLevel Positive Airway Pressure) devices as a result.

    c. **Invasive ventilation:** is an intensive care treatment in which the patient is sedated and a breathing tube inserted into the patient's lungs. A more complicated machine typically provides Intermittent Positive Pressure Ventilation (IPPV) and is capable of providing life support. As well as the ventilator itself, a significant array of other technology is required to maintain the patient; this includes patient monitors, multiple syringe drivers (for necessary medicines) and pumps for infusion and feeding purposes.

    d. **ECMO:** standing for ExtraCorporeal Membrane Oxygenation is an even more advanced and complicated form of treatment in which a machine pumps blood out of the patient's body, removes carbon dioxide and adds oxygen before pumping it back into the patient. This requires a different set of technology, and is available at relatively few centres in the UK (currently ~8) at small patient volumes.

55. Within each of these categories, there are further complexities: some devices can fulfil multiple functions, there are significant differences in efficiencies (e.g. amount of oxygen used) and, at the more complicated end of the spectrum, differences in features and training requirements.

56. The term 'ventilator' can be used as a catch-all for all of the above: as part of the covid response, capacity in all of the above categories was purchased. However, the term "ventilator" was most often, and sometimes inappropriately, used as a shorthand for intensive care, invasive ventilators providing IPPV.

57. Within intensive care environments, clinicians generally have strong preferences about the ventilators they use, and a reluctance to change. These preferences typically arise from the impact that familiarity and consistency have on reducing patient risk.

Purchasing environment

58. Prior to the pandemic, purchasing a new intensive care ventilator normally occurred as part of a periodic asset replacement programme, or the establishment of a new ICU facility / ward. Pre-pandemic, the process typically involved:

    a. selecting a device as part of an extended procurement process often involving physically testing sample machines provided by suppliers for evaluation purposes;

    b. contracting with the supplier including provision for any non-generic consumables and long-term support and maintenance agreements;

    c. training and familiarisation processes both for staff using the devices and for clinical engineering teams providing support within Trusts;

    d. waiting for devices which, depending on configuration, often have reasonably long lead times;

    e. receiving and commissioning the devices, including checking components such as batteries and sensors have not been damaged in transit and incorporating devices into Trust asset management / tracking systems and maintenance regimes; and

    f. deploying them, and associated consumables, into the ward environment.

59. During the pandemic, the UK sought to secure significant increased volumes within a compressed timescale, amid a global stampede of demand. This necessitated a number of changes to the above, pre-pandemic standard process, specifically:

    a. considering a broader range of machines beyond those that had previously been used in the NHS;

b. purchasing at a distance, on the basis of a written specification, not on the basis of a machine the programme had directly tested;

c. dealing with a range of intermediaries, rather than with suppliers directly;

d. paying cash up front to secure devices; and

e. making decisions at speed (hours, not weeks).

60. As clinical understanding of covid increased, both specifications and volumes of products required changed. Examples include features such as ventilator capability to support 'weaning' which rose in importance and volumes of filters increased in response to frontline experience of them needing to be changed more often.

NHS Supply Chain Procurement

61. NHS Supply Chain held a number of standard framework agreements for the provision of ventilators. From programme inception on 3 March, requests for availability went to suppliers on 4 March, first contracts were placed on 9 March, and this route was largely exhausted by 12 March.

62. In order to secure a place on Supply Chain frameworks, these devices would have previously been assessed to have met NHS quality standards. Value for money would have been assured through previous competitive processes. These purchases were made in advance of any covid premium, although I recall agreeing to pay surcharges for air, rather than sea shipping to expedite delivery.

63. This combination of existing arrangements, proven suppliers, previously assessed quality and competed value for money made this NHS Supply Chain route the most successful route to securing devices.

64. A summary of the procurement spend on each category of item can be found on pages 24 and 25 of [**CS/01 - INQ000535034**].

65. The only issue with this route was that it was unable to achieve the volume required: we simply didn't have enough.

The 'Call to Arms'

66. Whilst I did not attend the COBR(O) meeting on 12 March, I recall articulating to Steve Oldfield (in attendance) that I saw no reasonable prospect of achieving the demand

projection using standard procurement / NHS Supply Chain means, and that to materially improve our current projection, we would need significant additional support from across government.

67. My understanding was that as an outcome of that meeting:

    a. a public 'call to arms' was agreed, supported and facilitated by BEIS and formally articulated by the PM on 16 March;

    b. FCDO was mobilised to support the purchase of ventilators from overseas manufacturers and distributors;

    c. Cabinet Office would lead a 'Make' drive which would become the Ventilator Challenge; and

    d. MoD would offer additional support on procurement, logistics and transportation.

68. In addition to the existing planned procurement activities, these actions created three distinct sourcing channels, each of which is described in further detail below:

    a. Offers received from the 'call to arms' from UK suppliers (triaged by BEIS);

    b. Offers received from overseas suppliers (facilitated by FCDO); and

    c. Devices sourced through the Ventilator Challenge (driven by CO).

69. On 25 March 2020, NHSE and DHSC issued guidance to Trusts setting out the scope of the national procurement effort and, in effect, instructing Trusts not to seek to buy ventilators directly. This clarified and formalised what had been the practical position for the last weeks [**CS/19 - INQ000535036**].

Offers from the 'call to arms' from UK based suppliers / legal entities

70. As a result of the public 'call to arms', thousands of inbound enquiries were received with hundreds of distinct offers of ventilators and other support. These calls were triaged by BEIS who would ask a standard set of questions of all enquiries, which included:

    a. Supplier information: of the organisation / individual making the offer;

    b. Device information: make and model details;

    c. Availability information: volume, location, and delivery details;

d. Commercial information: price sought; and

e. Validation information: we often asked for timestamped photos of stock.

71. BEIS also provided a triage service for suppliers offering components or other assistance to the ventilator challenge programme.

72. Some requests were received directly by DHSC, either through existing relationships, suppliers or through contacts with senior executive / ministers. The same information was collected for these inquiries as was collected by BEIS and all enquiries, regardless of source, went through the same assessment process.

73. Broadly, the process for assessing offers received was as follows:

a. models offered were compared against a list of known devices that had already been considered as acceptable, or unacceptable, by clinicians. If the device offered wasn't on either list, the spec would be sent for clinician review and then added to the appropriate list;

b. the credibility of the offer was assessed, considering factors such as the nature of the supplier, the volumes, and proposed lead times given current locations; and

c. the commercial offer was considered, primarily in light of what premium was being sought for the devices over and above normal market value.

74. On the basis of these considerations, a risk vs benefit decision on whether to proceed was then made. The primary risks considered were:

a. in a predominantly 'cash up front' environment, the risks of not receiving ventilators or being able to recover monies paid;

b. the risk of new or novel ventilators, purchased on the basis of specification, not being acceptable to NHS clinicians;

c. the risk of overpaying for ventilators should we subsequently be able to identify cheaper sources of supply; and

d. the risk of ventilators arriving after peak UK demand – i.e. too late.

75. These were weighed up against the benefits of increased UK capacity and resilience. The programme was given a clear steer from ministers, in line with agreement from HMT, that the primary consideration was ensuring capacity to save lives over value for money.

In this context, decision-making was dominated by confidence and delivery risk, rather than price considerations.

76. The majority of decisions were relatively straightforward: many offers couldn't supply the basic information sought, whilst others could. An example of the recommendation proforma can be seen in [**CS/20 - INQ000535033**]. The programme team would make recommendations and then the order would be placed under Steve Oldfield's delegated authority.

77. The more complex decisions were typically discussed with Steve Oldfield and / or Emily Lawson directly and in a few particularly challenging circumstances (e.g. high spend levels or higher risk levels) discussed with David Williams for input / additional sign off.

78. DHSC contracting teams would then process the necessary paperwork, generally utilising standard terms, and in parallel inbound logistics teams make the necessary arrangements to receive goods.

Offers from overseas suppliers / legal entities facilitated by FCDO

79. The process for overseas suppliers was operated in a similar manner to the one operated for UK suppliers with a number of key differences:

    a. the BEIS triage service was not in operation, instead country-based teams within FCDO were asked to actively search for, investigate, and engage with potential sources of available ventilators in their country of operation;

    b. supplier due diligence activities were primarily undertaken by FCDO in country; and

    c. contracting arrangements were undertaken by FCDO on behalf of DHSC in country.

80. FCDO teams were asked to focus on ventilators and other 'hard to source' items. We worked closely with FCDO teams to provide product specifications and review potential responses.

81. In addition, FCDO teams provided in country assurance services to the programme (for example, visiting supplier warehouses to check stock etc.) and at times logistical support with local customs / shipping clearance arrangements.

Ventilator Challenge

82. I have set out my role and relationship with the Ventilator Challenge below. However, questions on this subject would be best answered by representatives of Cabinet Office.

83. Whilst the programmes worked closely alongside each other (e.g. daily interaction), the Ventilator Challenge was an independent programme, run by CO, in support of the overall goal of increasing ventilator capacity.

84. My overarching role within the Ventilator Challenge programme was to make sure that the interests of the health system (DHSC and NHSE) were appropriately reflected within the programme. Specific activities that I undertook included:

    a. commissioning the initial specification and driving some of the very first industry engagements (prior to CO mobilisation);

    b. ensuring appropriate linkages and support from NHS clinical colleagues and the MHRA assurance process;

    c. supporting ministerial sponsors to review, and adjust, programme targets as necessary;

    d. arranging for devices to be received (both physically and legally) from CO into the health system; and

    e. providing an administrative umbrella that enabled 'buy' and 'make' projections to be combined into a single coherent report / forecast.

85. I was not involved in individual device selection or costing decisions.

Procurement process, fraud and regulatory considerations

86. All procurements undertaken, outside of existing framework agreements, were undertaken under the 'extreme urgency' exemption (Regulation 32) of the Public Contracts Regulation 2015. Whilst this exemption was used, efforts were made to ensure quality, and value for money, complying with regulations where possible.

87. Contract award notices for all DHSC contracts (whether UK or overseas) were published. The majority of these were published in bulk on 25 September 2020, which represented a delay in publication of up to 4 months beyond the normal 30 days target period. This delay reflected the prioritisation of activities supporting patient care during a period of intensive activity.

88. Public Sector Equality Duty (PSED) was primarily considered within the allocation and distribution of these devices, as part of our intent to fairly and equitably distribute capacity across the UK (see section on allocation and distribution below).

89. Regulatory compliance with MHRA obligations was achieved through ensuring that all devices either had a CE mark (in line with normal practice) or had received specific 'exceptional use authorisation' from MHRA.

90. The programme chose to pursue few of the offers that it received, believing that the majority of the offers received were unlikely to result in the NHS receiving ventilators. That is not to say that those offers were fraudulent: many offers were received from intermediaries who were often credible, well intentioned, individuals who wanted and believed that they could help, but may have either overestimated their ability to source ventilators through their professional contacts, or themselves had been offered ventilators from fraudsters.

91. The most common issue was simply misrepresenting the availability of ventilators: the programme being offered ventilators that simply did not exist. In country FCDO staff, being able to physically travel to warehouses to verify stock existence, were indispensable in countering this fraud.

92. I do not believe that any attempted frauds were successful.

Device testing and quality assurance

93. As part of the initial surge response, Trusts were requesting us to send them ventilators as quickly as possible. Speed of arrival was, at that point, their overwhelming priority in order to build capacity ahead of expected demand.

94. In line with this priority, the programme's initial operating process was to deliver devices to Trusts without undertaking any additional testing or checking process steps.

95. For devices that Trusts were familiar with, this approach generally worked well: staff and clinical engineering teams knew and understood devices, had previous experience of any unique features / challenges, and knew how to resolve / work around them.

96. For devices that were new to Trusts, or new to the NHS, this approach created a variety of issues. These issues ranged from the relatively straightforward, but time-consuming, issues of inappropriate connectors / plugs through to deeper concerns about device quality and safety.

97. Regardless of issue severity, it was clear that all issues with new devices were better managed once, centrally, rather than distributing devices to each Trust for them to work through issues individually.

98. A combination of this experience, in parallel with increasing confidence in capacity to meet the initial surge of demand, enabled the programme to agree with the NHS to move from a 'deliver it now' to a 'test it then deliver it' model. I recall this happening incrementally and organically over March and early April 2020.

99. On receipt at MoD Donnington, devices would be quarantined, and a team of clinicians would carry out a '**Clinical Due Diligence'** process. Tests were primarily aimed at resolving any immediate / obvious issues so that when they were received by the Technical Due Diligence teams they would be able to be tested appropriately.

100. Examples of the sorts of issues sought, and resolved, included:

    a. Identifying obvious transit related damage;

    b. identifying and obtaining any missing or additional components required (e.g. oxygen sensors);

    c. checking connectors are compatible with UK standards and sourcing adaptors;

    d. checking devices have UK mains plugs; and

    e. finding English language versions of relevant user manuals and training materials.

101. Examples of the checklist completed and supporting material produced can be found at [**CS/21 - INQ000535035** and **CS/22 - INQ000535037**]. Once this process had been completed, devices were passed to one of two specialist centres for technical testing.

102. Intensive care ventilators were sent to the Medical Device Testing and Evaluation Centre (MDTec), a specialist device test facility, led by Professor Thomas Clutton-Brock, and affiliated with Birmingham University and University Hospitals Birmingham NHS Trust.

103. All other devices were sent for testing at the Queen's Medical Centre, Nottingham University Hospitals Trust under the leadership of Professor Dan Clark.

104. As explained on page 3 of [**CS/15 - INQ000514180**], on completion of testing, the Technical Due Diligence teams would produce a short report making one of the following recommendations:

a. **Outcome 1**: de-quarantine the devices and release them into the allocation process without any further guidance;

b. **Outcome 2**: de-quarantine the devices and release them into the allocation process accompanied by a guidance note about necessary workarounds to assist in safe operations;

c. **Outcome 3**: hold the device in quarantine pending supply of additional components, communications, or resolutions to issues identified; and

d. **Outcome 4**: do not release the device into the allocation process.

Of new ventilators purchased and assessed, four were placed into Outcome 1, four into Outcome 2, six into Outcome 3, and two into Outcome 4 [**CS/23 - INQ000514224**]. By spend in this category of devices 92.5% of devices were Outcomes 1 and 2, 3.7% Outcome 3 and 3.4% Outcome 4.

105. The process deliberately avoided the language of 'go' / 'no-go' recommendations: noting that as circumstances changed, the NHS could have been forced to, by necessity, use devices that it would not, pre-pandemic, have chosen to use.

106. Some devices achieving lower outcomes were often in widespread, successful, use in other health economies. These outcomes, therefore, reflected both device quality and appropriateness for use in a UK, NHS pandemic, environment.

107. Once devices were in operation, post any period of initial monitoring, existing UK channels for reporting issues with products applied. The core reporting system being the MHRA's 'yellow card' system typically augmented by local processes within Trusts and supplier specific processes. In addition, the programme and clinical teams also sought feedback from device users either directly or via regional networks.

Logistics, allocation and distribution model

108. NHS Supply Chain logistics and warehousing facilities were unable to accommodate the increase in volume experienced as a result of covid activities across multiple fronts. There was, therefore, a need for alternative facilities, to augment NHS Supply Chain, to be established by the programme.

109. Facilities at MoD Donnington were rapidly (within a week) converted, and together with programme resources provided a service which:

a. tracked incoming goods: which proved unusually challenging given global transport disruptions;

b. supported goods through customs: both export and import;

c. physically received goods: including usual receipting checks;

d. housed onsite due-diligence activities: including Clinical Due Diligence Team;

e. packaged and prepared orders: including providing starter packs of relevant consumables; and

f. delivered good to Trusts on receipt of an approved allocation decision (see below).

110. In parallel, an allocation process was developed to ensure that devices were appropriately and fairly distributed [**CS/16 - INQ000514158; CS/17 - INQ000535043**]. Central to this was the concept of differentiating between:

a. **capacity building**: where Trusts would request devices to bolster future capacity and increase resilience; and

b. **immediate clinical need**: where Trusts were asking for devices which they believed they would be able to immediately (within the next few days) utilise on patients.

111. During surge periods, the focus was on providing devices to meet immediate clinical need. Between surges, the focus was on distribution to support capacity building. I perceived that this approach worked well: a clear process was quickly developed, stakeholders understood, and were engaged in what we were doing, and decision-making was informed by regularly updated data.

112. The process involved Trusts making requests for devices to their regional teams, and regional team representatives, having discussed and reviewed those requests, bringing them to the National Ventilation Allocation Panel (NVAP) for prioritisation and decision.

113. The panel was chaired by Professor Sir Keith Willett (NHSE Covid Incident Director) or one of his deputies, attended by senior representatives from each NHS region (e.g. Medical Directors) and supported by representatives of the programme.

114. The NVAP relied heavily on daily capacity and covid trajectory data to enable it to make decisions. The standard approach to considering requests for immediate clinical need was to review:

a. **trust reported capacity against bed occupancy:** how much spare ventilation capacity did a Trust have; and

b. **patient demand trajectory against residual capacity:** how quickly might any spare capacity be used.

115. Capacity building requests involved consideration of a broader range of factors, including alignment with Trust capacity building plans and the relative levels of ventilation capacity in regions. In capacity building allocations, the programme had an explicit objective to attempt to level up, rather than exacerbate, differentials in regional ventilation capacity.

116. In determining what makes and models of devices to provide, attempts would be made to provide consistent device types, reducing variation and complexity for clinicians.

117. The logistics services operated a 24-hour service level agreement (SLA) from NVAP decision. During surge and pre-surge periods, the NVAP panel would typically meet daily at 3pm. Decisions were communicated to MoD Donnington immediately (normally before 4pm), packed and shipped that evening, typically being received late that evening / early morning.

118. The process covered all capital items including patient monitors, syringe drivers and oxygen concentrators but did not cover consumables which operated a similar, but parallel, process.

119. As well as supporting device allocation, the NVAP panel also became a useful communication channel for engaging with regional leads on a variety of related topics especially regarding oxygen provision.

120. A key strength of the NVAP process was that it enabled us to create a relatively unemotional, data-driven system that helped reduce the pressure in a highly charged and emotional environment. It also helped provide transparency and levelling of different regional and trusts approaches.

Concerning specific devices

121. The Inquiry has asked me questions about a number of specific devices.

122. It is important to emphasise that ventilators are highly complicated technology devices requiring regular support and maintenance. As such, it is not unusual for devices to encounter problems and there were, and continue to be, a regular stream of upgrades,

safety notices and refinements to instructions etc. regardless of product quality. Similarly, product recalls are not uncommon and typically reflect clinicians' and suppliers' desire to reduce potential risks, however small they may be.

Concerning specific devices – GE R860

123. GE (General Electric) Healthcare is a large international US-based healthcare organisation creating a range of products including the R860 ventilator. This ventilator was in use within the NHS prior to Covid and additional capacity was purchased through the programme. In May 2022, MHRA issued a Field Safety Notice (FSN) [**CS/24 INQ000535045**] relating to the backup batteries (the battery that kicks in should the mains power fail) failing in advance of their expected life. Actions were provided, including testing / replacing batteries. Whilst important, this appeared a 'business as usual' issue of the sort regularly experienced and successfully managed between suppliers and NHS teams.

Concerning specific devices – UCL-Ventura

124. University College London, working with Mercedes and Oxford Optronix, developed a CPAP machine known as the UCL-Ventura. Early work was carried out as part of the Ventilator Challenge, but as the device was not intended to be an invasive ventilator, it dropped out of the Cabinet Office process.

125. A key feature of the Ventura was that it used less oxygen than traditional CPAP machines. However, this needs to be understood in the context that all CPAP machines are relatively 'high oxygen' usage.

126. Whilst there were differences in clinical opinion as to the value and utility of CPAP machines, it was clear that CPAP had some role to play and that these devices could contribute to meeting that need. A decision was therefore taken to proceed with the purchase of these devices [**CS/25 - INQ000514162**].

127. The devices were relatively low cost (under £2k per device), based on optimising a proven technology which already had MHRA approval and available quickly from a reputable UK source: as such, their procurement was considered a low risk.

128. Subsequent clinical trials (principally the Recovery trial) increased the evidence base for CPAP use, and the devices were widely deployed, including replacing higher oxygen

usage devices. The design, and devices themselves, were also exported to a wide range of countries.

129. In relation to the device usage within the NHS, I am aware of the following issues:

    a. **Use in inappropriate environments:** all CPAP devices consume considerable quantities of oxygen, and whilst the Ventura optimised this, there were still environments where these devices could not be deployed successfully;

    b. **Labelling issues:** normal procedure as devices progress from test, through emergency use, to full authorisation would have been to recall all devices, change the labels, and send them back out. To avoid withdrawing devices from active service, updated labels were instead sent out to Trusts for them to stick on top of the previous labels. In a pressured clinical environment, it was understandable that re-labelling was not always considered the clinical priority and in some cases did not happen, leading to the wrong labels on devices; and

    c. **Oxygen Monitors:** early users reported that oxygen monitors would be helpful to assist them in setting appropriate oxygen flow levels. These were subsequently bundled with devices.

Concerning specific devices – Shangrila 510s

130. AeonMed is a large Chinese ventilator manufacturer which produces the Shangrila 510s transport ventilator. Whilst not previously used within the NHS, the device is used extensively within China. Whilst designed as a 'transport' ventilator, rather than an 'intensive care' ventilator, the specification looked acceptable, the devices were relatively low cost, met the regulatory standards, and were available quickly from reputable suppliers. Given the perceived gap between demand and supply orders were placed.

131. These devices arrived before the due diligence process was established. Devices were sent to a small number of hospitals, aiming supply at hospitals that were believed to have capacity to test devices and not yet under peak surge pressure.

132. Feedback on devices from clinicians was disappointing. The devices worked very differently to those NHS staff were used to dealing with, there was insufficient time for training / familiarisation and there were concerns about quality. In light of this feedback, and alternative capacity, the devices were immediately taken out of service.

133. The remaining orders for devices not yet received were cancelled and either refunds obtained or exchanged for other preferred devices [**CS/26 - INQ000514215**].

134. The devices received were subsequently put through the Technical Due Diligence Process. This report was also disappointing, echoing clinicians' concerns, however it also did not identify a clear breach or failure of the devices on which to base any argument that the devices were not what we ordered or were not in line with the provided specification [**CS/27 - INQ000514240**].

135. At this point two options were negotiated with the supplier: a 70% refund or an exchange for alternative devices. Given the supply position at the time the refund appeared preferable. Given the absence of a clear breach of the specification and the difficulty of taking further against a Chinese company, and the broader supply position, the refund appeared preferable. [**CS/26 - INQ000514215**]. . The partial refund position resulting in a loss of ~£1.2 Million associated with writing off around 750 devices.

Other points

136. The programme also received large requests for devices and consumables to support the Nightingale hospital drive. Devices were allocated to Nightingales as part of the prioritisation process described above, viewing Nightingale hospitals as another facility in the region which regional teams could choose to prioritise or not. Our experience was that teams generally prioritised building capacity in existing facilities over diverting resources to new facilities.

137. A variety of statements have previously been made by senior figures along the lines of 'everybody who needed a ventilator got one'. I am not certain who said this first or the exact formulation of the original words; however, noting that such statements focus on ventilators, as opposed to availability of staff, beds, or other essential assets to treat patients which I am not well placed to comment on, I believe such statements to be true on the basis that:

    a. the data on availability of ventilators compared to the volume of ventilated patients shows that ventilators should not have been a factor constraining clinical care at any point in the pandemic response;

    b. there were processes and procedures in place to distribute both capacity and demand to where it was most appropriate; and

c. there were channels in place for escalating and resolving potential ventilator capacity issues which were regularly used but show no evidence to counter this statement.

F – CONSUMABLES

Understanding consumables pre-pandemic

138. The programme sourced a wide range of consumables covering both oxygen therapy and intensive care provision.

139. Given the range and diversity of products, issues within the supply chain are an inevitable part of the system. Prior to the pandemic these were generally dealt with either by using existing stock until the supply chain had recovered, or by substitution for a comparable product. This represented 'business as usual' for the NHS.

140. Periodically more significant issues would emerge, typically when issues were experienced with products without substitutes or where substitution was difficult or challenging. Prior to the pandemic the system would experience, on average, one major supply disruption per year requiring a small national incident response team to be mobilised.

Phase 1 Early / Surge 1 Consumable activities (March / April 2020)

141. The consumable supply chain entered the initial surge in a strong position at all levels: ward cupboards and trust storage facilities were generally well stocked, NHS Supply Chain held stock for a number of weeks and suppliers themselves also held stock. Separate stock had also been held as part of EU Exit preparedness activities.

142. In this context, our primary concern was less that we would be able to meet immediate demand, but more our ability to sustain supply should the surge protract and / or meet projected future larger surges, which at that time were projected for May.

143. The consumables programme response started in earnest on 9 March with two key activities over this early period:

a. working with lead clinicians to identify consumable requirements and volumes to support the emerging patient pathways; and

b. placing large volume orders to substantially increase stock availability.

144. Whilst ideally we would have undertaken these activities in sequence, planning then ordering, due to time pressure we did them in parallel. This resulted in a series of corrections to orders (mainly in April), predominantly increasing and decreasing volumes in line with emerging requirements.

145. At an operational level, orders were placed with existing NHS Supply Chain frameworks and suppliers where they could meet demand.

146. Throughout March as NHS Supply Chain tried to place orders, some were rejected by suppliers and others were accepted but subsequently not fulfilled due to insufficient capacity. In some product areas these gaps could be filled by alternative provision from existing suppliers, but in other areas this left a gap which NHS Supply Chain processes were unable to fulfil.

147. In order to address this gap, the programme stood up the Hard to Source Items (HTSI) capability. The intention of this team was to focus on a relatively small number of challenging items that could not be sourced through traditional means and ensure that NHS Supply Chain capacity could remain focused in productive areas.

148. This team was mobilised on 1 April 2020 and was largely composed of individuals redeployed from the Ministry of Defence's Procurement and Sourcing capabilities, augmented by NHS and private sector expertise. Amongst other approaches, the team worked closely with FCDO representatives exploring novel sources of supply for the NHS. The team investigated both consumable and capital equipment products, but was not directly involved in sourcing ventilators.

Phase 2 - Preparing for Surge 2 (May to October 2020)

149. The expected second surge in May 2020 did not appear. Over May and June, focus shifted to preparations for an expected autumn / winter surge against a September planning horizon. There were three main aspects of this preparation:

    a. structured stock build activities to increase NHS Supply Chain stock levels;

    b. the adoption of a system to classify products by level of perceived risk; and

    c. the establishment of a revised set of operational governance structures to manage consumable allocation and stock issues.

150. Using clinical input and projections available at the time, options for potential stockpile sizes were developed and assessed. Simplistically, the larger the stockpile, the greater

the cost but the lower the risk. The programme made a recommendation for a 110 product category, £405 M stockpile which was accepted by ministers in June [**CS/28 - INQ000535038**].

151. The target stock levels were achieved by phased overordering from suppliers over the June to September period. Examples of progress monitoring against the stock build can be found in [**CS/29 - INQ000535039**; **CS/30 - INQ000535040; CS/31 - INQ000535041;** and **CS/32 - INQ000535042**]. At the end of September, in advance of the expected winter surge we had broad coverage across all categories.

152. In parallel with this stock build we established a risk classification framework for consumables (same exhibits as the previous point). All consumables were placed in one of a number of categories:

    a. **Sustain:** the lowest level of risk, where products are freely available through NHS Supply Chain with minimal restrictions;

    b. **Monitor:** where products have no immediate supply issues, but there are some concerns about the strength of future supply. These concerns could arise from late / reduced stock arrivals, external factors such as border disruptions, market intelligence, or simply an inability to increase supply;

    c. **Protect:** where Trusts can still place orders for products in the usual manner but we are taking active steps to 'protect' stock levels, typically by intervening in large or unusual orders to manage supply.

    d. **Control:** the highest level of risk / intervention where products are removed from the normal NHS Supply Chain process and instead Trusts request items which are then allocated (or not) to them on the basis of clinical need.

153. This system enabled us to monitor and clearly communicate the overall supply risk level as well as respond to risk in a proportionate and consistent manner [**CS/29 - INQ000535039; CS/30 - INQ000535040; CS/31 - INQ000535041** and **CS/32 - INQ000535042**].

154. Supporting the stock build and classification framework, operational structures were established which formalised, and improved, the processes established in the initial surge. This included:

    a. **Shortage Management Oversight Group (SMOG):** whose key role was to review the allocation of products to risk categories and move products between categories as appropriate;

b. **Clinical Advisory Group:** whose key role was to review products in the sustain, monitor and control categories, determine where potential alternatives could be used and if so what additional clinical guidance or support might be needed to transition users to those alternative products; and

c. **Consumables Group:** whose key role was to manage allocation of products in 'control' on the basis of clinical need.

155. The groups were supported by teams from the programme and NHS Supply Chain both in terms of making sure that they had the appropriate data to make decisions and, once those decisions had been made, implementing them.

156. For products in protect and control we arranged a weekly stock level data return in conjunction with the NHSE Digital team.

157. A stock rotation policy was established, particularly for shorter shelf-life items, to minimise the amount of stock write-offs.

Phase 3 - Surge 2 operations (November 2020 - January 2021)

158. As expected covid cases, and demand, surged over the winter period. Over this period, the stockpile, and consumables supply chain performed as expected. There were material drawdowns against the stockpile to support both NHS demand and cover shortages in other programmes (e.g. vaccination needles).

Global supply chain resilience failures

159. Covid had two different impacts on the consumable supply chain:

a. it increased demand for consumables to support covid patients; and

b. it also decreased supply chain performance as businesses producing products were disrupted by covid, unable to obtain components, borders were closed and transport arrangements impacted etc.

160. At inception, the programme was very focused on the first, however over time it became clear that the second was in fact a more significant and enduring issue.

161. Prior to the pandemic, as would be expected in any highly diverse supply base, supply issues regularly occurred and crudely the system would expect to see a major / critical resilience issue requiring a co-ordinated national incident response in one product

category each year. In 2021, and through early 2022, the system experienced approximately one of these per month. When I left the department in late 2022, the global supply chain was far from returning to its pre-pandemic normal.

162. Examples of these included blood tube shortages (triggered by a plant maintenance shutdown) and sleep apnea machines (triggered by a product recall).

163. The covid stockpile helped insulate the system from these problems, but handling them still required significant effort and specific targeted procurement activities during a period (post January 2021 surge) where the general perception was that covid response activities should be winding down.

G – OXYGEN

Pre pandemic infrastructure and oxygen basics

164. Oxygen is produced either in large quantities in factories called Air Separation Units (ASUs), or at smaller scale in Oxygen Concentrators which can range from the size of a suitcase to large shipping containers. Air Separation Units produce oxygen for both industrial and healthcare purposes, the primary difference in product being the regulatory / assurance processes rather than the technical production process.

165. Oxygen is delivered to Trusts either as a gas contained within a cylinder, or in liquid form via a tanker. Cylinders are easy to use, but require manual handling and, even under pressure, hold relatively small quantities of oxygen. Liquid systems are more complex and capital intensive, but offer far greater capacity, partly because of greater physical volumes, but predominantly as liquid oxygen is significantly denser than gas.

166. Liquid oxygen is stored at hospitals in a device called a Vacuum Insulated Evaporator (VIE), a large storage cylinder which stores liquid at very low temperatures. These are connected to an evaporator which converts the liquid to a gas, and control panels with regulators to control the flow of oxygen into the hospital. The evaporators and regulators have a rated capacity, and if the flow of oxygen exceeds that capacity there is a risk of 'icing' and losing positive control of the system.

167. Most hospitals operate a Medical Gas Pipeline System (MGPS) which typically comprises one or two VIE's together with a network of piping to enable gas to flow to the patient bedside.

168. Commercially there are very few oxygen producers in the UK, the British Oxygen Company (BOC) and Air Products together comprising the UK market. Given

transportation challenges and volumes, there are no practical cost effective mechanisms for importing, or exporting, oxygen at scale.

Phase 1 Early / Surge 1 Oxygen activities (March / April 2020)

169. A key challenge on programme mobilisation was that there was no central, system wide, understanding of how healthcare Oxygen infrastructure worked. There was no clear national owner, or centre of expertise, and within Trusts systems had often been configured and set up a long time ago and subsequently expertise and understanding of system capacities had declined over time.

170. We quickly learnt that, as a legacy of historic UK steel production (which requires large volumes of oxygen), the UK was relatively well endowed with ASU capacity and that, at a macro level, the country was very unlikely to run out of Oxygen production capacity. However, the programme worked with oxygen producers to ensure contingency plans to maximise oxygen production were available should they be required.

171. The programme identified risks to the Oxygen distribution processes and took steps to mitigate these risks. Working with oxygen producers, the programme undertook a range of risk mitigation activities including:

    a. training additional drivers (from MoD) in the specific hazards and processes associated with driving and delivering oxygen so that they could provide contingency should the normal workforce be incapacitated through covid;

    b. converting nitrogen tankers to oxygen tankers to create additional capacity within the UK oxygen distribution fleet;

    c. working with DfT to ensure that Oxygen tankers could continue to move in the event of road travel restrictions; and

    d. increasing the redelivery thresholds so that Trust tanks were refilled more often (trading efficiency for confidence).

172. Further risks were identified within Trust local Oxygen infrastructure. The primary risk was not that Trusts VIE tanks would run out of Oxygen, but that either:

    a. Trust VIE evaporators and regulators would not have capacity to convert liquid oxygen to gaseous oxygen at required speed; or that

    b. Trusts would not have sufficient pipework / infrastructure to get oxygen to the bedside at pressure.

173. In this phase of response the programme focus was on:

    a. short term system optimisation (i.e. tuning of regulators / control panels); and

    b. supporting Trusts to understand, and plan for, both VIE capacity and associated pipework constraints.

174. Trusts continued to purchase Oxygen directly from suppliers in line with their pre-existing agreements. In no phase of the response did the programme purchase any Oxygen directly.

Phase 2 - Preparing for Surge 2 (May to October 2020)

175. At the end of the initial surge focus shifted to longer term preparations for winter. This enabled a broader set of medium term activities to be undertaken in three main areas:

    a. **oxygen improvement works:** physically upgrading Trust VIE and pipework capacities;

    b. **procuring and making additional capacity:** typically of supportive devices including regulators and oxygen concentrators;

    c. **promoting oxygen efficiency:** which, prior to covid, had simply not been a consideration.

176. NHSE Estates team led the development of a phased programme of Oxygen improvement works across Trusts. Examples of works undertaken, including replacing and upgrading VIEs and expanding Trust pipework infrastructure. Works were procured directly by Trusts but supported by funding from NHSE.

177. The programme procured a range of oxygen capacity supportive interventions including:

    a. sourcing additional oxygen concentrators, which had proved invaluable to enable rapid setup of additional oxygen capacity within Trusts;

    b. strengthening the cylinder supply chain through procurement of additional regulators and accelerating the testing and recertification of cylinders in the backlog awaiting revalidation; and

    c. supporting initiatives to create trolley and manifold systems for large cylinders.

178. The programme also established a series of oxygen efficiency materials, interventions and processes. These proved highly effective at enabling Trusts to reduce oxygen usage without impacting patient care, often in excess of 20%. These interventions included:

    a. establishing Oxygen Best Practice guides including housekeeping approaches;

    b. making transparent the relative oxygen efficiency levels of devices and encouraging / supporting the switch out of devices for more efficient ones;

    c. greater monitoring and intervention in the cylinder supply chain, including full for empty processes and additional support for Ambulance services struggling with the oxygen requirements of delayed discharges; and

    d. the daily 'hot list' process by which oxygen usage levels within Trusts would be nationally monitored and, as usage levels increased part of the national team would provide supportive assistance to ensure supply and usage were optimised.

179. The programme also liaised with the home oxygen service to ensure their requirements were considered as part of the country's broader oxygen needs.

180. Regular oxygen reporting including national oxygen thermometer and sample cylinder and hot list examples can be found in [**CS/29 - INQ000535039**; **CS/30 - INQ000535040**; **CS/31 - INQ000535041** and **CS/32 - INQ000535042**].

Phase 3 - Surge 2 operations (November 2020 - January 2021)

181. The programme expected the Winter 2020/21 surge's primary challenge to be about managing oxygen capacity and infrastructure effectively. Prior to the surge, cohorts of programme staff were re-trained in oxygen processes to provide hot-list style support to trusts should it be required.

182. As evidenced on page 23 of [**CS/01 - INQ000535034**], between June and October 2020 on average there was ~1 Trust over 60% oxygen capacity at any given time. In November and December this rose to ~5 Trusts. In January 2021 this peaked at ~55 Trusts of which ~10 Trusts were over 80% and ~5 Trusts were over 100%. This period represented peak healthcare oxygen usage, for comparative purposes the subsequent year this figure was ~10 (rather than 55) Trusts.

183. The oxygen infrastructure and processes established by the programme enabled the system to hold these levels. However, it would have been challenging to sustain these levels, and increasingly risky to attempt to operate above them.

H – SPECIAL ITEMS

184. Patients on ventilation require enteral feeding (where nutrition is delivered by a tube directly to the stomach) and often require Renal Replacement Therapy (RRT) to support kidney function. Both these treatments required specialist feed / products at volumes significantly in excess of the pre-covid norm.

185. These products are typically bulky bags of fluid which often need to be changed every few hours and are therefore required at high volumes. They are also short shelf-life products, only produced by a few different manufacturers.

186. In order to manage stock rotation issues appropriately, the Programme entered into specifically negotiated agreements with all active UK suppliers on a 'fair shares' basis. Suppliers committed to build stock levels within the UK to agreed targets and, as per pre-covid arrangements, were to directly manage the delivery / supply process to Trusts.

187. The programme also supported the purchase of additional ECMO capacity for some existing ECMO centres. However, given the complexity, this was not expected to make a material capacity impact. The programme also worked with FCDO to ensure adequate supplies of associated specialist ECMO consumables continued to be received from their manufacturer in Germany.

I – OTHER TOPICS

Programme closure

188. The programme was always intended as a temporary structure to support the pandemic response. However, in the post pandemic environment there was a realisation that a stronger national medical technology capability was required. It was agreed to set up an enduring DHSC function, similar to the longstanding medicines function, to fulfil this role.

189. Plans were made to close down programme activities and transition residual and enduring activities to appropriate long term homes: typically either NHS Supply Chain or

the new DHSC Medical Technology capability. In addition, a number of new activities, for example, the development of a new Medical Technology Strategy, were planned.

190. The submission of 2 September 2021 [**CS/33 - INQ000535044**] reflects this strategic intent. My role transitioned from acting as Programme Director to Interim Director of Medical Technology over the period April 2021 – September 2021. I supported recruitment of, and then handover to, a permanent successor who took responsibility in October 2022.

Devolved Administrations

191. The programme worked closely with Devolved Administrations, undertaking some activities (e.g. procurement of additional ventilation capacity and activities to boost UK oxygen production) at a UK-wide level, and other activities (e.g. sub-regional allocation of ventilation capacity) specifically for England.

192. The strategic intent was to do as much together as practical and beneficial whilst respecting the devolution of authority. A typical discussion with Devolved Administration representatives would involve the programme outlining our plans, adjusting it on the basis of feedback, and offering Devolved Administrations the decision as to whether to participate in that aspect, or not.

193. Devices procured by the programme on behalf of the UK were offered to administrations on a crude, but widely recognised, per capita basis. Given differing administration needs and equipment profiles, the actual devices delivered would often change: delivering more of some items and less of others whilst remaining broadly within the intent of the per capita distribution.

194. The programme also distributed equipment to Crown Dependencies and Overseas Territories. Given the relatively small population, this was done in response to specific requests, rather than on a per capita basis. An example of the allocation for mechanical ventilation can be seen at slide 18 of [**CS/32 - INQ000535042**].

International Donations

195. By the second half of 2020, the UK had exceeded its ventilation capacity target and future projections of demand were decreasing. The Department was therefore able to

consider donations of ventilators to other countries in need without impacting UK capacity or resilience [**CS/18 - INQ000494411**].

196. FCDO posts overseas were receiving requests for help which, upon FCDO approval, were then sent to the DHSC International Team. The role of the Programme was to:

    a. determine whether we had capacity of the appropriate device types to enable donation;

    b. support the creation of appropriate donation paperwork; and

    c. facilitate physical transfer of devices to destination countries.

197. The Programme team was not responsible for decisions as to whether, or where, to donate devices.

Communications

198. A key aspect of the programme was communicating positions to Trusts both directly and through regional networks. The patient safety notice on 31 March 2020 [**CS/34 - INQ000443868**] which the Inquiry has cited is an example of this relating to the use of high flow devices. The programme worked very closely with the authors of these notices, and at times the programme would variously request, help draft, provide input and support the dissemination of these notices.

199. This particular notice appears to be part of the broad drive to promote effective device usage and oxygen efficiency. I cannot recall the circumstances surrounding this specific note, but I expect that the programme would have, at a minimum, had sight of, and potentially supported the drafting of, or even requested, this notice being sent.

200. The programme also observed that there was significant diversity of clinical opinion in response to devices procured, including on devices that were previously in mainstream use within the NHS. The programme managed all clinical feedback through the national clinical directors and incident leadership teams.

J – LESSONS LEARNED

201. The programme undertook its own lessons learned processes at various points of its life, and individuals also contributed to both the DHSC and NHSE/I lessons learned

processes. I have prioritised my personal key lessons learned in three areas below covering:

a. programmatic / operational lessons and successes;

b. strategic MedTech issues for the future; and

c. specific tactical lessons for future implementation.

202. I believe the key factors below were central to the programme's successful delivery:

a. **Genuinely combined DHSC / NHSE team:** with strong senior sponsorship and connections into both organisations. Whilst this doubled reporting burden, this was more than offset by the programme's ability to act appropriately and decisively.

b. **Existing knowledge and relationships**: the majority of key senior programme staff already had a strong understanding of the subject area and strong relationships with key stakeholders. This enabled us to operate with a smaller, more coherent programme team.

c. **Reacting quickly to changes:** the different phases of the pandemic required substantially different focus, approaches and team configuration. Individuals were flexed across response areas, and team members were proud to have capacity to support other areas, as necessary.

d. **Daily data was transformative**: at the beginning the programme lacked clear data, but this was quickly addressed, enabling the programme to make better, faster and importantly less emotive decisions.

203. With regard to the key strategic issues facing Medical Technology, my key lessons learned are that:

a. **Medical Technology needs clear ownership:** it is now too big, and impactful to patient outcomes to not have clear direction and leadership. The new Directorate of Medical Technology is designed to play this role.

b. **The 'supplier of last resort' role:** NHS Supply Chain needs to either be given a clear mandate (and associated funding) to act as 'supplier of last resort' or not. At present, it is not commissioned to do this, but should issues arise, is expected to do this.

c. **The pandemic has highlighted the cost of choice:** the importance, advantages, and disadvantages of choice have long been debated. The

pandemic experience has shown that clinicians can, even under pressure, successfully switch products. It has also highlighted the significant cost and complexity of operating the current 'choice max' environment. Clearly, clinical choice needs to remain central to both clinical practice and innovation, but overall the pandemic has materially weakened the case for choice.

d. **Interoperability should be mandated:** too many times issues arose because companies had chosen to use bespoke connectors or approaches. Aside from the obvious commercial advantages, suppliers would typically justify these approaches on the basis of patient safety benefits. However, familiarity, training consistency and resilience also provide significant patient safety benefits, and there appears no clear basis for devices that cannot, in an emergency, be used in an interoperable manner.

204. There are also a number of very specific, tactical issues I believe merit specific consideration:

a. **The MGPS HTM needs updating:** the national specification that applies to oxygen infrastructure is now nearly 20 years old. Whilst noting the November 2021 'Performance of healthcare cryogenic liquid oxygen systems' guidance [**CS/35 - INQ000469763**], the main specification needs updating both in line with technical advances over the periods and pandemic experience. In particular, a revised set of diversity assumptions should be adopted for inclusion in the next generation of hospital estate developments.

b. **Mental health wellbeing support should be 'push' rather than 'pull'**: both DHSC and NHSE have created offerings for programme staff whose mental health has been impacted. However, these offerings require impacted individuals to 'pull' support and, with hindsight, the individuals most in need have not actively chosen to seek help but might have taken it had it been 'pushed' to them.

c. **UK Oxygen production will naturally decline over time**: the programme benefited from the legacy of the UK steel industry. Over time, UK oxygen production capacity will decrease as plants reach end of life and there is no commercial rationale for replacing them. Contingency planners should consider the case for ensuring that the UK retains an appropriate minimum level of Oxygen production capacity.

STATEMENT OF TRUTH

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

Name: Chris Stirling

Date: 29th January 2025

Signature:

PD