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BRIEFING PAPER

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Coronavirus: Ventilator availability in the UK

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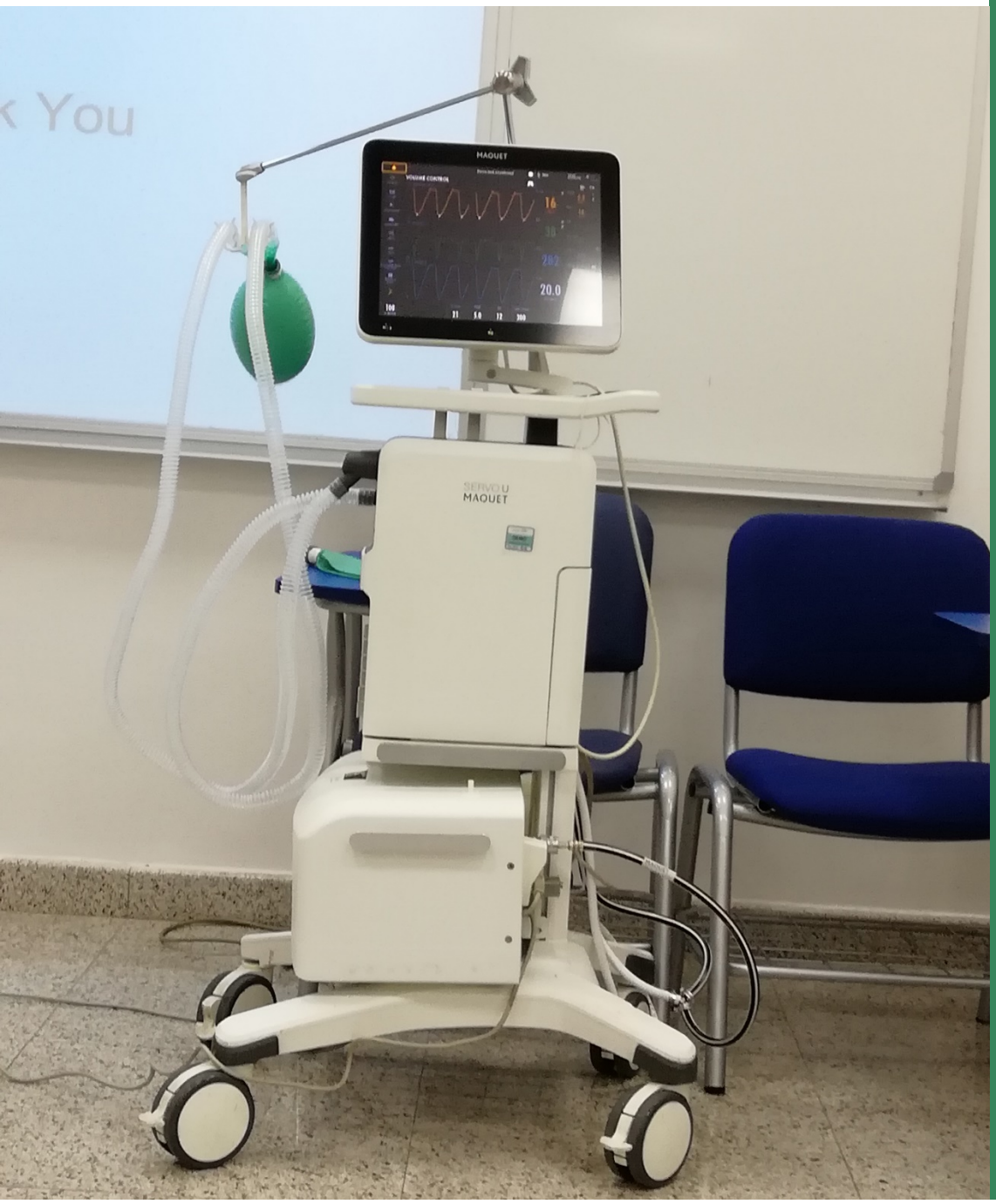

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Summary

The ongoing Covid-19 pandemic has resulted in a new and growing demand for ventilators across the world. These life-saving machines are being used to treat patients with more severe Covid-19 symptoms, which can include difficulty breathing.

In response to a predicted shortage of ventilators, the UK government issued a call for business to help make ventilators to supply to the NHS.[1]

The Government made an initial estimate of 30,000 ventilators to meet demand,[2] before Health Secretary Matt Hancock later revised this figure to 18,000.[3] Estimates made at the start of the Covid-19 outbreak suggested that the NHS had just over 8,000 ventilators available.[4]

Industry responded to the government's call, with a number of high-profile companies expressing an interest in manufacturing ventilators.

This included a consortium of engineering and manufacturing companies, Ventilator Challenge UK, of which companies such as Rolls Royce, Ford, Microsoft and Airbus, and ventilator manufacturer Penlon, are members.

Ventilator Challenge recently obtained regulatory approval for one of its new ventilator models and the government has since confirmed an order for 15,000 devices.[5]

This briefing paper provides an account of ventilator availability and procurement in the UK, a summary of government action, and a discussion of some other issues associated with ventilator use.

1 Call for businesses to help make NHS ventilators, Gov.uk, updated 30 March 2020
2 Coronavirus: Government orders 10,000 ventilators from Dyson, BBC News, 26 March 2020
3 Matt Hancock: 'Outdoor exercise could be banned if people flout rules', The Andrew Marr Show, BBC, 5 April 2020
4 Coronavirus: Government orders 10,000 ventilators from Dyson, BBC News, 26 March 2020
5 Regulator approves first Ventilator Challenge device, Gov.uk, 16 April 2020

1. Background

On 31 December 2019 a number of severe cases of pneumonia of unknown cause were reported in Wuhan, China.

Testing ruled out the known Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV) viruses,[6] but sequencing of the virus showed that it belonged to this same family of viruses, known as coronaviruses.

Coronaviruses are a large family of viruses that cause illness ranging from the common cold, to more severe diseases such as MERS-CoV and SARS-CoV.

On 7 January 2020, the Chinese authorities identified a new type of coronavirus,[7] that had not been previously identified in humans.[8] The virus, was named severe acute respiratory syndrome 2 (SARS-CoV-2) and the resulting disease was named Covid-19.

The main symptoms of Covid-19 include a high temperature, a new continuous cough and a loss or change to sense of smell or taste,[9] whilst severe cases may require intensive care treatment and ventilation.

On 11 March 2020 the World Health Organisation (WHO) declared a pandemic.[10]

6 Novel Coronavirus- China, WHO, 12 January 2020
7 Ibid.
8 Coronavirus, WHO, [accessed 31 March 2020]
9 Check if you have coronavirus symptoms, NHS, [accessed 1 June 2020]
10 WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020, WHO, 11 March 2020

2. Why are ventilators needed?

Most people infected with the Covid-19 virus will experience mild to moderate respiratory illness and recover without requiring special treatment.[11] Some patients go on to experience more severe Covid-19 symptoms requiring intensive care and ventilation.

Covid-19 causes a range of clinical syndromes, one of which is acute respiratory distress syndrome (ARDS).[12] An NHS webpage about ARDS explains that it is a life threatening condition where the lungs cannot provide the body's vital organs with enough oxygen.[13] The webpage states that individuals who develop ARDS will "probably be admitted to an intensive care unit (ICU) and use a breathing machine (ventilator) to help [their] breathing".

2.1 Respiratory treatment guidance for Covid-19

Covid-19 is a new disease and there is limited evidence available to inform guidance and best practice. Scientists and clinicians are relying on findings from early studies, anecdotal observations and previous experience with similar influenza-like illness to inform scientific discussion and clinical responses. Recent NHS guidance advised that alongside published evidence and clinical guidelines, the guidance had also been informed by "personal communications with colleagues in China and Italy".[14] The guidance also advised "that all guidance issued around best practice in the management of patients with Covid-19 is based on low levels of evidence".

On 13 March 2020, the World Health Organisation (WHO) issued guidance for the clinical management of severe acute respiratory infection (SARI) when Covid-19 disease is suspected. The guidance, intended for clinicians, advises on the use of oxygen therapy and ventilatory support in severe and critical Covid-19.

On 19 March 2020, NHS England and NHS Innovation published guidance on the clinical management of persons admitted to hospital with suspected Covid-19 infection intended for clinicians. The guidance advises on oxygen therapy and the use of non-invasive ventilation, which is discussed in more detail in section 2.3 of this briefing.

The use of non-invasive ventilation is also discussed in NHS guidance for the role and use of non-invasive respiratory support in adult patients with Covid-19 (confirmed or suspected) issued on the 6 April 2020.

11 Coronavirus, WHO, [accessed 31 March 2020]
12 Clinical management of severe acute respiratory infection (SARI) when Covid-19 disease is suspected, WHO, 13 March 2020
13 Acute respiratory distress syndrome, NHS, 12 March 2020
14 Guidance for the role and use of non-invasive respiratory support in adult patients with coronavirus (confirmed or suspected), NHS, updated 6 April 2020

2.2 Oxygen therapy

Oxygen therapy is used to treat low oxygen levels and is often the "first step" in treating hospitalised Covid-19 patients. On 13 March 2020, the WHO issued interim guidance for the Clinical management of severe acute respiratory infection when Covid-19 is suspected.[15] The guidance recommends the provision of supplemental oxygen therapy to patients with severe acute respiratory infection and respiratory distress, low blood oxygen or shock. The guidance also recommends that advanced oxygen therapy or ventilatory support should be provided when a patient with respiratory distress is failing standard oxygen therapy. NHS guidance on the Clinical management of persons admitted to hospital with suspected COVID-19 infection advises that clinicians should assess the need for oxygen supplementation in line with guidelines from the British Thoracic Society.

2.3 Ventilators

Ventilators are machines which move pressurised air containing a high concentration of oxygen in and out of the lungs and are used when someone has severe difficulty breathing on their own.

There are two types of ventilation; invasive or non-invasive. A Cochrane review,[16] Invasive versus non-invasive ventilation for acute respiratory failure, provides the following distinction:

> Invasive and non-invasive ventilation differ in how the air is delivered to the person. In invasive ventilation, air is delivered via a tube that is inserted into the windpipe through the mouth or sometimes the nose. In NIV [non-invasive ventilation], air is delivered through a sealed mask that can be placed over the mouth, nose or the whole face.[17]

NHS guidance, clinical management of persons admitted to hospital with suspected Covid-19 infection, advises that if invasive mechanical ventilation is appropriate, its use is preferred over non-invasive ventilation for infection prevention and control reasons.[18]

In invasive mechanical ventilation, the ventilator takes over the body's breathing process via a process called intubation where a tube is inserted into a person's airway and connected through connectors, filters and tubing to the ventilator machine.

Patients are heavily sedated before undertaking invasive mechanical ventilation.[19] Medicines are also used to help relax the respiratory muscles so a person's breathing can be fully regulated by the machine.

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15 Clinical management of severe acute respiratory infection when Covid-19 is suspected, WHO, 13 March 2020

16 Cochrane is an academic research network that provides systematic reviews of health research

17 Invasive versus non-invasive ventilation for acute respiratory failure in neuromuscular disease and chest wall disorders, Cochrane, [accessed 29 March 2020]

18 Clinical management of persons admitted to hospital with suspected COVID-19 infection, NHS England and NHS Improvement, 19 March 2020

19 BTS/ICS Guidelines for the Ventilatory Management of Acute Hypercapnic Respiratory Failure in Adults, Thorax, Volume 71, Supplement 2, April 2016

NHS guidance, clinical management of persons admitted to hospital with suspected Covid-19 infection, provides information on the use of non-invasive and invasive ventilation, and consideration clinicians will make when using them and/ or moving patients between them.[20]

2.4 Continuous positive airway pressure therapy

Continuous positive airway pressure (CPAP) machines provide a form of non-invasive ventilation. During treatment with a CPAP device, pressurised air containing a high concentration of oxygen is delivered via a tightly secured face mask, "hood" or "helmet" device.

Medicines such as opioids or benzodiazepines may be administered with CPAP therapy to reduce a patient's anxiety or feelings of breathlessness.[21]

CPAP therapy is usually administered to patients who are fully conscious or have been minimally sedated.

NHS Guidance for the role and use of non-invasive respiratory support in adult patients with COVID19 (confirmed or suspected) advises that CPAP is the preferred form of non-invasive ventilatory support in the management of Covid-19 patients with low blood oxygen levels.[22]

The same guidance advises that whilst CPAP does not replace the use of invasive mechanical ventilation, early application may provide a bridge to invasive mechanical ventilation.[23] It is reported that CPAP use in Lombardy, northern Italy, may have reduced the number of patients needing to use invasive mechanical ventilation by 50%.[24]

A BBC article refers to the use of "hoods" which can be used to deliver CPAP ventilation.[25] There is some thought that the use of hoods may reduce the risk of airborne transmission of the virus, although there is little evidence available to support this. Hoods are not routinely used in the UK.

20 Clinical management of persons admitted to hospital with suspected Covid-19 infection, NHS England and NHS Improvement, 19 March 2020
21 Guidance for the role and use of non-invasive respiratory support in adult patients with coronavirus (confirmed or suspected), NHS, updated 6 April 2020
22 Ibid.
23 Ibid.
24 Coronavirus: What are ventilators and why are they important?, BBC News, 7 April 2020
25 Coronavirus: What are ventilators and why are they important?, BBC News, 16 April 2020

3. How many ventilators?

In response to an 18 May 2020 Parliamentary Question, Minister of State at the Department of Health and Social Care (DHSC) Edward Argar provided an account of ventilator numbers:

> At the start of the COVID-19 outbreak in March there were more than 8,000 mechanical ventilators in hospitals across the United Kingdom. Today, we have around 11,900 mechanical ventilators available to National Health Service patients. As of 6 May, 344 of these have been provided by new UK suppliers responding to the Prime Minister's ventilator challenge and 118 by established UK suppliers.
>
> This figure will continue to rise as we procure further equipment and more products from the Prime Minister's ventilator challenge become available.[26]

In response to another Parliamentary Question, Mr Argar said that almost 900 ventilators had arrived from overseas and had been bought or donated from China, the US, Germany and Taiwan.[27]

During an appearance on the BBC's Andrew Marr Show on 5 April 2020, Health Secretary Matt Hancock responded to a question about whether the UK would be below the number of ventilators needed at the expected peak of Covid-19 cases.[28] He also adjusted an initial target of needing 30,000 ventilators to 18,000:

> No, because thankfully we've got the demand down because the vast majority of people are following the social distancing guidelines.
>
> If we manage to get this to peak within a week to 10 days then the [ventilator] demand will be even lower than the 18,000.
>
> But the 18,000 is our current goal because we want to be ready with belt and braces for a worst-case scenario rather than that central scenario.[29]

It has been difficult to identify reliable and useful information about the proportion of Covid-19 patients that require a ventilator.

An 18 May 2020 Parliamentary Question asked how many patients, who are being treated in hospital for Covid-19, have been attached to a ventilator.[30] Responding to the question, Minister for Innovation Lord Bethell said that this information was not currently being published.

The number of available critical care beds has also been used as a means of estimating ventilator availability across different countries, on the premise that critical care beds are usually equipped with ventilators.[31] However, consideration should be given to the difference in the structure of critical care across different countries, and the fact

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26 PQ 40494, 18 May 2020
27 PQ 37400, 11 May 2020
28 Matt Hancock: 'Outdoor exercise could be banned if people flout rules', The Andrew Marr Show, BBC, 5 April 2020
29 Ibid.
30 HL2959, 18 May 2020
31 European countries search for ventilators as virus cases surge, Financial Times, 15 March 2020

that not all patients admitted to intensive care go on to receive ventilatory treatment. The wider issue of differing testing strategies further makes it difficult for data on the proportion of patients who undergo ventilation to be applicable across different countries which are identifying Covid-19 cases at different rates.

The government have not stated the basis for their estimates of ventilator need, but these are likely to be based on a wide range of variables such as transmission rates, the experience of other countries, availability of medical facilities, population size and the number of individuals with existing conditions that make them more likely to experience severe Covid-19 symptoms.

4. Increasing the availability of ventilators

A 15 March 2020 article by the Guardian quoted the Health Secretary as having said "anyone who can" should "turn their engineering minds and production lines to making [ventilators]", and that the government were holding discussions with car manufacturers and military engineers as to the possibility of them manufacturing ventilators.[32]

On 16 March 2020, the Department for Business, Energy & Industrial Strategy (BEIS) issued a call for businesses to help make NHS ventilators.[33] BEIS said it was also looking for businesses with the following skills:

- design/specification
- rapid prototyping
- contract/product assembly
- certification/regulation/testing
- logistics
- medical training[34]

On 20 March 2020, the government published the Rapidly manufactured ventilator specification for a "minimally … clinically acceptable" ventilator to be used during the Covid-19 outbreak.[35]

On 15 April 2020, the *Financial Times* reported on comments from Dean of the Faculty of Intensive Care Medicine, Alison Pittard, who said that the specification for the UK ventilator programme would not produce machines suitable for treating Covid-19 patients.[36] Specifically, she said that the government's request for ventilators that would, at a minimum, stabilise patients for "a few hours", was not in line with what was requested by medical experts.

The article also reported on comments from the Cabinet Office, who said that the specifications had been "drawn up and agreed by expert medical clinicians from the MHRA [Medicines and Healthcare products Regulatory Agency] and the NHS". The Cabinet Office further said that the specifications were reviewed regularly in light of Covid-19 developments, and that they would continue to be led by the best available scientific and clinical evidence. A Gov.uk webpage provides details of a number of updates that have been made to the specification since its initial publication.[37]

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32 Coronavirus: UK manufacturers urged to consider switching to making ventilators, The Guardian, 15 March 2020
33 Call for businesses to help make NHS ventilators, BEIS, 16 March 2020
34 Ibid.
35 Rapidly manufactured ventilator system specification, DHSC, 20 March 2020
36 Ventilator standards set out for UK makers 'of no use' to Covid patients, Financial Times, 15 April 2020
37 Specification for ventilators to be used in UK hospitals during the coronavirus (COVID-19) outbreak, Gov.uk, 28 April 2020

4.1 Industry and other response

A number of companies responded to the government's call to produce ventilators. The response included updates to existing designs, the development of new designs, providing support to increase existing production and donations.

The Government has since said that it is not currently able to proceed with any new applications to provide ventilators that have not already started, and that the UK has fulfilled the clinical need for ventilators through existing CE marked ventilators and existing applications to the Ventilator Challenge.[38]

The overall budget for the Ventilator Challenge project is £454million.[39] In May 2020 it was reported that around £200million of this had been spent to date.[40]

Below is a summary of the major industry responses to the call to production, provided by industry collaboration Ventilator Challenge and a number of other companies and parties.

Ventilator Challenge

Ventilator Challenge UK Consortium is a collaboration of UK industrial, technology and engineering businesses from the aerospace, automotive and medical sectors, which has launched a joint initiative to produce ventilators for the UK. Airbus, Ford, Microsoft, Penlon, Rolls Royce and UK based Formula 1 teams are amongst the consortium members. The companies are reportedly expected to waive any profits, and the supply chain will come entirely from the UK, in case of any disruption to cross-border trade.[41]

On 16 April 2020 the government announced that Penlon's Prima ES02 model had received authorisation from the MHRA, and confirmed an order for 15,000 devices.[42] It was also confirmed that production of Smith's paraPAC plus would be increased as part of the challenge.

An 8 May 2020 Cabinet Office news story said that Breas Medical of Ventilator Challenge had supplied 150 devices to the NHS.[43] The batch consisted of the Vivo65 and Nippy4+ models, which were made from existing designs and had already been approved by regulators. The Government has ordered 2,000 of the devices.

38 Specification for ventilators to be used in UK hospitals during the coronavirus (COVID-19) outbreak, Gov.uk, 28 April 2020
39 Overview of the UK government's response to the COVID-19 pandemic, National Audit Office, 21 May 2020
40 Ventilator challenge to cost government £450m despite cancellations, Financial Times, 21 May 2020
41 How the UK plans to source 30,000 ventilators for the NHS, The Guardian, 26 March 2020
42 Regulator approves first Ventilator Challenge device, Gov.uk, 16 April 2020
43 New Ventilator Challenge devices arrive in UK, Cabinet Office, 8 May 2020

A 20 May 2020 Financial Times article reported on comments from a Cabinet Office Spokesperson who said that Ventilator Challenge had supplied over 2,000 ventilators to the NHS.[44]

CPAP Device

University College London engineers, Mercedes Formula One and Oxford Optronix worked jointly to adapt an existing off-patent design for a CPAP device.[45] The Formula One website advises that the device obtained regulatory approval, and that an order for "up to 10,000" has been placed by the NHS.[46]

4.2 Other industry and government efforts

A number of other companies have worked to support the government's call for ventilator production.

Manufacturers such as Honda, car parts firm Unipart and digger maker JCB were reported to be looking into the feasibility of switching production to ventilator manufacture.[47]

Defence firm Babcock were awarded a government contract to manufacture 10,000 Zephyr Plus ventilators.[48] A 13 April 2020 Guardian article reports that German medical device specialist Drägerwerk is working with Babcock.[49] In a 19 May 2020 update, Babcock advised that the first Zephyr Plus units are "currently being tested and remain subject to MHRA regulatory approval by Government".[50]

On 8 May 2020, the Cabinet Office said that OES Medical's model, Gemini, remained subject to ongoing review.[51]

In addition to working with industry, the government has taken a range of other action to increase ventilator procurement.

Though an arrangement with the private sector, the NHS secured nearly 1,200 ventilators, 8,000 hospital beds and almost 20,000 fully qualified staff.[52]

The Foreign Office reportedly asked British embassies around the world to source ventilators and personal protective equipment.[53] The NHS had reportedly asked vets to provide animal ventilators.[54]

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44 Ventilator challenge to cost government £450m despite cancellations, Financial Times, 20 May 2020
45 Coronavirus: Mercedes F1 to make breathing aid, BBC News, 30 March 2020
46 Design of new breathing aid developed by Mercedes to be made freely available, Formula One, [accessed 14 April 2020]
47 Coronavirus: Plan to ramp up ventilator production 'unrealistic', BBC News, 16 March 2020
48 Coronavirus: Defence firm Babcock to make 10,000 ventilators, BBC News, 6 April 2020
49 UK scraps plans to buy thousands of BlueSky ventilators, The Guardian, 13 April 2020
50 From Zero to Zephyr Plus – Babcock Ventilator Team Update, Babcock, 19 May 2020
51 New Ventilator Challenge devices arrive in UK, Cabinet Office, 8 May 2020
52 Coronavirus: Thousands of extra hospital beds and staff, BBC News, 21 March 2020
53 UK calls on embassies to source ventilators for coronavirus fight, Financial Times. 27 March 2020
54 Coronavirus: NHS asks vets to donate animal ventilators, BBC News, 25 March 2020

On 31 March 2020 the government announced that it would waive import duty on medical equipment, supplies and protective garments brought into the UK from non-EU countries during the Covid-19 outbreak. [55]

Designs not taken forward

The government reportedly cancelled a provisional request for thousands of BlueSky ventilators from a collaboration formed by Renault, Red Bull Formula One and specialist firm Darwood IP.[56] This was reportedly due to concerns that the BlueSky ventilator was not able to facilitate frequent changes in the device setting needed to manage lung fluid build-up in Covid-19 patients. A Cabinet Office spokesperson said that the decision had been taken "following a reassessment of the product's viability in light of the ever-developing picture around what is needed to most effectively treat Covid-19".[57]

On 8 May 2020, the Cabinet Office said, that following re-assessment from a panel of expert clinicians, it was ending support for the following devices:[58]

- Piran Vent, made by Swagelok
- Veloci-Vent, made by Cambridge Consultants Ltd and MetLase
- CoVent, made by TTP [The Technology Partnership] and Dyson
- Sagentia Ventilator, made by Sagentia
- AirCare, made by BAE Systems

Additionally, the Cabinet Office had previously said that it was ceasing support for the following ventilator designs:[59]

- • EVA, made by TEAM and Cogent Technology
- • Helix, made by Diamedica and Plexus
- • OxVent, made by KCL [Kings College London], Oxford University and Smith+Nephew
- • InVicto, made by JFD [James Fisher and Sons plc]

4.3 Regulatory considerations

The Medicines and Healthcare products Regulatory Agency (MHRA) is the designated competent authority that administers and enforces the law on medical devices in the UK. It has a range of investigatory and enforcement powers to ensure their safety and quality.

Manufacturers based in the UK wishing to supply medical devices in the UK or Europe are subject to The Medical Devices Regulations 2002,

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55 Pay no import duty and VAT on medical supplies, equipment and protective garments (COVID-19), HM Revenue & Customs, 31 March 2020
56 UK scraps plans to buy thousands of ventilators from Formula One group, The Guardian, 14 April 2020
57 UK scraps plans to buy thousands of BlueSky ventilators, The Guardian, 14 April 2020
58 New Ventilator Challenge devices arrive in UK, Cabinet Office, 8 May 2020
59 Update on the Ventilator Challenge, Gov.uk, last updated 30 April 2020

which transposed various EU Directives into UK law. The Regulations provide a definition of a medical device:

> "medical device" means an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which—
>
> - (a)is intended by the manufacturer to be used for human beings for the purpose of-
>   - (i)diagnosis, prevention, monitoring, treatment or alleviation of disease,
>   - (ii)diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
>   - (iii)investigation, replacement or modification of the anatomy or of a physiological process, or
>   - (iv)control of conception; and
> - (b)does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means,
>
> and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device.[60]

An MHRA webpage explains that medical device manufacturers must register with a competent authority in order to place their medical devices on the EU market:

> If you place certain medical devices on the EU market you or your designated authorised representative must register with the competent authority (national health regulator) in the EU state where you have an office or place of business. In the UK, Medicines and Healthcare products Regulatory Agency (MHRA) is the competent authority for the registration of medical devices. MHRA will only register manufacturers or authorised representatives that have a place of business in the UK.[61]

Changes to these arrangements may take place after the end of the current transition period.

Manufacturers must also demonstrate that their medical device meets the requirements in the Medical Devices Directive by carrying out a conformity assessment. If a product passes the conformity assessment, manufacturers may place a "CE mark" on their device to indicate this. An MHRA webpage provides more information on conformity assessments and the CE mark.

On 24 April 2020, the MHRA issued updated guidance for exemptions from devices regulations during the Covid-19 outbreak, which advised

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60 The Medical Devices Regulations 2002, as amended, section 2
61 Register as a manufacturer to sell medical devices, MHRA, 1 April 2020

that manufacturers may be able to obtain exemptions from certain medical devices regulations due to the Covid-19 outbreak.[62]

Specific guidance for ventilators advised manufacturers to first check the specifications needed, and then contact the DHSC for their approval. Following approval, manufacturers were asked to send their application for exemption to the MHRA.

4.4 Government protections for ventilator manufacturers

A 16 April 2020 article by the Financial Times reported that the government would provide manufacturers of new ventilators with protection from the financial burden of potential legal claims arising over intellectual property infringements, or personal injury caused by defective machines.[63] On 29 April 2020, the Cabinet Office published a Departmental Minute outlining the contingent liability for the Rapidly Manufactured Ventilator System Project.[64]

This outlines that the Cabinet Office had concluded six design contracts that give indemnity against intellectual property rights infringements.

As at 27 April 2020, five contracts for the manufacture of the rapidly manufactured ventilator system gave indemnities in respect of both IPR infringement, and for claims arising out of defects in the products.

The government noted that two of the products may not proceed to manufacture, which would reduce the scope of this liability.

The government set out that they had provided indemnity in two areas: to cover potential infringements if intellectual property as well as all forms of claims arising from product liability, such as death/ personal injury to a patient, patient loss of earnings and legal costs.

The government cited "unprecedented circumstances" caused by the pandemic and said that whilst the precise commercial terms negotiated with each supplier would remain commercially confidential.

The government estimated that the potential liability exposure could exceed £300,000, the reason for which it had to inform Parliament.

The government also said that manufacturers would have contractual obligations "to manufacture the products according to specification with due skill and care".

4.5 Concerns about government's approach to increasing ventilator production

When the UK Government announced the Ventilator Challenge, some in the industry raised concerns about how new manufacturers would

62 Exemptions from Devices regulations during the coronavirus (COVID-19) outbreak, MHRA, last updated 24 April 2020
63 UK ventilator manufacturers protected from injury claims, Financial Times, 16 April 2020
64 Notification of contingent liability: Rapidly Manufactured Ventilator System Project, Cabinet Office, 29 April 2020

achieve regulatory compliance. Craig Thompson, the head of products at Penlon, manufacturers of anaesthesia machines which include a ventilator, said:

> The idea that an engineering company can quickly manufacturer medical devices, and comply with the rules, is unrealistic because of the heavy burden of standards and regulations that need to be complied with.[65]

Mr Thompson said that "the focus should be on existing medical device companies increasing supply of ventilators".[66]

Make UK is an organisation that represents UK manufacturers. Its Chief Executive Stephen Phipson echoed the above concerns, commenting:

> Rather than a particular company trying in their own factory to make thousands and thousands of ventilators - which they would struggle to do - you have around them other manufacturers with capacity.[67]

Mick Farrell, chief executive of ResMed, a large ventilator maker suggested that rather than companies that were not already manufacturing ventilators undertaking this as a new role, they could instead provide support to existing ventilator manufacturers.[68]

A 17 April 2020 Financial Times article discussed similar concerns, and reported on comments from senior government officials who said that the scale of the crisis in Italy meant that it was determined that it was "better to have a basic machine which had a chance of being manufactured in a short timeframe , than no machine and thousands of deaths."[69]

Other concerns were raised about logistical challenges, such as sourcing electrical components from China, and testing the units which some considered to be a time-consuming process.[70]

A 20 May 2020 Financial Times article highlighted the cost of the Ventilator Challenge programme (£454 million),[71] also noting that some manufacturers had already purchased "millions of pounds' worth of components" after being told to prepare to produce ventilators in projects that were eventually not taken forward by the Government.

4.6 Wider concerns about ventilator provision

There were also concerns from clinical staff who said that efforts to increase ventilator production were "pointless" without the additional staff and supplementary equipment needed". The Nursing Times

65 Coronavirus: Plan to ramp up ventilator production 'unrealistic', BBC News, 16 March 2020
66 Ibid.
67 Ibid.
68 The ventilator challenge will test ingenuity to the limit, Financial Times, 29 March 2020
69 Muddled thinking punctures plan for British ventilator, Financial Times, 17 April 2020
70 Coronavirus: Plan to ramp up ventilator production 'unrealistic', BBC News, 16 March 2020
71 Ventilator challenge to cost government £450m despite cancellations, Financial Times, 20 May 2020

reported on comments made by chair of the British Association of Critical Care Nurses, Nicki Credland:

> We do not have enough fully qualified intensive care staff to look after an increased demand for ventilated patients. That's an absolute guarantee – we simply do not have them. We will need to look at diluting our workforce to be able to manage the situation.[72]

Health Secretary Matt Hancock reportedly said that the government would ask doctors who normally work in other specialties to retrain in ventilator use.[73]

On 17 March 2020, NHS Chief Executive Sir Simon Stevens and NHS Chief Operating Officer Amanda Pritchard wrote to a range of NHS bodies. The letter stated that refresher training for respiratory needs must be provided to all clinical and patient-facing staff within a fortnight.[74]

The government's specification for rapidly manufactured ventilator systems appears to give due consideration to the competence of staff operating the ventilator, stipulating that it:

a) Must not require more than 30 minutes training for a doctor with some experience of ventilator use

b) Must include instructions for use

c) Instructions for use should be built into the labelling of the ventilator, e.g. with 'connect this to wall' etc

d) Must include clear labelling of all critical functions and controls using standard terms, pictograms and colours that will be readily recognised by UK healthcare staff[75]

The BBC reported on concerns from doctors about the availability of medicines used during and after ventilation, such as muscle relaxants, anaesthetics and blood pressure medications.[76] The BBC included comment from the DHSC, who said:

> We are aware there is an increase in demand for a number of intensive care drugs and we are working with the pharmaceutical industry to make additional supplies available.
>
> We are working closely with industry, the NHS and the relevant national expert groups to ensure precautions are in place to reduce the likelihood of shortages.[77]

The Independent reported on similar concerns about medicine availability in the US.[78]

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72 Covid-19 ventilator appeal 'pointless' without staff and other kit, Nursing Times, 16 March 2020
73 Matt Hancock: 'We will retrain doctors to operate ventilators', Pulse, 16 March 2020
74 Next steps on NHS response to COVID-19: Letter from Sir Simon Stevens and Amanda Pritchard, 17 March 2020
75 Specification for rapidly manufactured ventilator system (RMVS), DHSC, updated 28 April 2020
76 Coronavirus: 'Local shortages' of intensive care drugs, BBC News, 14 April 2020
77 Coronavirus: 'Local shortages' of intensive care drugs, BBC News, 14 April 2020
78 Revealed: Hospitals fear shortage of essential pain relief and sedation drugs will make ventilators useless for worst-hit coronavirus patients, The Independent, 9 April 2020

5. International approaches to ventilator procurement

A number of other countries have taken a similar approach to that of the UK to work with industry to increase the production of ventilators.

The Australian government was reported to have asked carmaker Ford to manufacture ventilators, and is investigating whether veterinary equipment and sleep apnoea machines can be converted for use.[79] Similarly, US and Italian governments have reportedly received offers from car manufacturers to increase ventilator production.[80]

5.1 EU procurement scheme

The Joint Procurement Agreement is an EU framework which enables EU Member States to obtain a range of medical supplies needed to respond to cross-border pandemics and threats to health.[81] Procurement under the JPA is complementary to members' national efforts to obtain medical supplies. A European Commission explanatory note provides further background to the framework.[82]

The Prime Minister faced calls for the government to join an EU procurement scheme organised by the European Commission aiming to secure the supply of ventilators and protective equipment.[83]

The government was reported to initially have said that the UK would not be taking part in the scheme as "We are no longer members of the EU", and that the UK was "making [its] own efforts" in this area.[84]

Later, Downing Street officials were reported to have said that the government did not receive emails inviting the UK to participate in the procurement schemes, and that the UK would be able to join future schemes.[85] A 30 March 2020 article by The Times reported on comments from Cabinet Minister Michael Gove who said there had been some confusion regarding email communication.[86] He also said "there's nothing that participating in that scheme would have allowed us to do that we have not been able to do ourselves".

On 21 April 2020, Sir Simon McDonald, Permanent Under Secretary and Head of the Diplomatic Service at the Foreign and Commonwealth

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79 Coronavirus ventilators: Australian government asks carmaker Ford for help in boosting production, The Guardian, 26 March 2020
80 Ibid.
81 Coronavirus: 'Mix-up' over EU ventilator scheme, BBC News, 26 March 2020; European Commission website, Joint procurement and countermeasures, accessed on 24 April 2020
82 Explanatory note on the Joint Procurement Mechanism, European Commission, December 2015
83 Coronavirus: Boris Johnson urged to join EU procurement scheme to secure ventilators, The Independent, 19 March 2020
84 No 10 claims it missed deadline for EU ventilator scheme, The Guardian, 26 March 2020
85 Coronavirus: 'Mix-up' over EU ventilator scheme, BBC News, 26 March 2020
86 Michael Gove rejects ventilator criticism after failure to join EU partnership, The Times, 30 March 2020

Office, gave oral evidence to the Foreign Affairs Committee in a session looking at the effectiveness of the Foreign Office's response to Covid-19.

A BBC article reported on comments from Sir Simon in response to a question on why a decision was taken not to join the EU scheme.[87]

Sir Simon said, "We left the European Union on 31 January", and stated that the decision not to participate in the scheme was "a political decision".

Later that day, Sir Simon sent a letter to the Chair of the Committee Tom Tugendhat to "clarify a point" he made regarding the Joint Procurement Agreement. In the letter, which was posted on Tom Tugendhat's personal Twitter account, Sir Simon said:

> Unfortunately, due to a misunderstanding, I inadvertently and wrongly told the Committee, that Ministers were briefed by UKMIS on the EU's Joint Procurement Agreement scheme and took a political decision not to participate in it. This is incorrect. Ministers were not briefed by our mission in Brussels about the scheme and a political decision was not taken on whether or not to participate.
>
> The facts of the situation are as previously set out. Owing to an initial communication problem, the UK did not receive an invitation in time to join in four joint COVID EU procurement schemes. As those four initial schemes had already gone out to tender we were unable to take part.[88]

The Guardian reported on comments from Health Secretary Matt Hancock and Minister of State for Care Helen Whately who said on 21 and 22 April 2020 that the EU scheme was yet to deliver any medical supplies.[89]

A recent 15 April 2020 European Commission summary report from the Health Security Committee reported on updates to the ongoing joint procurement process, but did not provide information on whether medical supplies had been delivered to participating Member states.[90]

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87 Coronavirus: Top civil servant says he was wrong about EU medical equipment claim, BBC News, 21 April 2020

88 Letter to Tom Tugendhat, Chair of the Foreign Affairs Select Committee on the EU ventilator procurement scheme, from Sir Simon McDonald, 21 April 2020

89 What is the EU medical equipment scheme and why did UK opt out?, The Guardian, 22 April 2020

90 Health Security Committee, Audio meeting on the outbreak of Covid-19, Summary Report, European Commission, 15 April 2020

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