

Report by the Comptroller and Auditor General

Cabinet Office and Department of Health & Social Care

Investigation into how government increased the number of ventilators available to the NHS in response to COVID-19

What this investigation is about

1 Ventilators are medical devices that assist or replace a patient's breathing. Patients with COVID-19 who are admitted to hospital often have problems breathing. On arrival in hospital a patient's blood oxygen level is measured. If it is low, then the patient may be given: standard oxygen therapy using a mask; non-invasive ventilation where oxygen is delivered under pressure via a mask or helmet; or invasive mechanical treatment using a mechanical ventilator, which takes over a patient's breathing. Treatment is a judgement for clinicians and patients may undergo more than one treatment during a stay in hospital.

2 Our investigation covers how government increased the number of ventilators available to the NHS from March 2020, in response to the COVID-19 pandemic through:

- Department of Health & Social Care (DHSC) purchasing of ventilators on the global market, as part of a wider DHSC and NHS England and NHS Improvement (NHSE&I) oxygen and ventilation programme; and
- Cabinet Office's 'ventilator challenge' to encourage UK businesses to design and manufacture more mechanical ventilators.
- **3** We explain:
- what ventilators are and how they are used in treating COVID-19 (Part One);
- government's objectives and performance in increasing the number of ventilators available to the NHS (Part Two);
- how DHSC purchased ventilators (Part Three); and
- Cabinet Office's ventilator challenge (Part Four).

4 This report mainly covers the period March 2020 to September 2020. We conducted our fieldwork in the period June 2020 to August 2020. We focus on the Cabinet Office and DHSC and NHSE&I programmes but also explain other public bodies' roles, including the Medicines and Healthcare products Regulatory Authority. We consulted ventilator designers and manufacturers, doctors and other experts. Appendix One sets out our methodology in more detail. **5** This investigation is part of a programme of work the National Audit Office is undertaking to support Parliament in its scrutiny of government's response to COVID-19. It focuses on how government used public money to increase the number of ventilators available to the NHS, in response to COVID-19. We do not look at how ventilators are used by the NHS. As such, we do not express any medical or technical opinion on the role of ventilators in treating COVID-19, or on the safety, effectiveness, functionality or any other aspect of ventilators' performance. Furthermore, a ventilator is only part of the resources required to treat COVID-19 patients. Hospitals also need: skilled staff; power; bed space; an oxygen supply; drugs; and additional equipment such as monitors and feeding pumps. A wide variety of consumable products such as filters are also required. We do not cover these wider factors in this report.

6 This investigation examines the departments' approach to deciding which ventilators to purchase, but we did not audit in detail each of the individual contracts and transactions entered into and we do not express any legal opinion on the use of public procurement regulations or indemnities granted by the departments involved. We are currently investigating government procurement during the COVID-19 pandemic, including the use of emergency procurement regulations more generally. We will publish a report on this later this year.

Summary

Key findings

The delivery of ventilators against estimated need

1 In the early stages of the pandemic the NHS believed it could need far more mechanical ventilators than were available. By the beginning of March 2020, NHS England and NHS Improvement (NHSE&I) modelling, based on reasonable worst-case planning assumptions assured by the Scientific Advisory Group for Emergencies (SAGE), indicated that the NHS could need up to 90,000 beds with ventilators to care for COVID-19 patients. Meanwhile, NHSE&I's survey of NHS trusts in England, conducted in late February and early March, indicated that the NHS only had access to an absolute maximum of around 7,400 mechanical ventilators, including some that would not normally be used to treat adult patients in a hospital bed, such as ventilators from ambulances and paediatric departments (paragraphs 2.4 and 2.7 and Figure 2).

2 Government decided from 13 March to pursue all available options to acquire as many ventilators as possible, as quickly as possible. This followed DHSC's initial efforts from 3 March to secure as many ventilators as possible through existing routes. The government's strategy was to:

- buy as many ventilators as possible from both UK and global suppliers as part of a wider 'oxygen, ventilation, medical devices and clinical consumables' programme (with contracts let by DHSC as part of this wider joint programme with NHSE&I); and
- encourage UK manufacturers to scale up production of mechanical ventilators (the ventilator challenge, led by Cabinet Office).

The two departments ran their programmes separately but worked towards the same overall targets and exchanged data on their progress in acquiring ventilators daily. On 16 March, government announced a "call to arms" to industry bodies to provide as many ventilators as they could (paragraphs 2.8, 3.2, 3.3, 3.7, 3.8 and 4.7).

3 Government acquired 1,800 new ventilators before the mid-April peak of the pandemic. By 24 March, NHSE&I had revised down its estimate of the number of ventilated beds that could be needed in England on 13 April to 17,500, based on the latest SAGE-assured reasonable worst-case planning assumptions. However, in the week commencing 13 April, only around 10,900 mechanical ventilator machines were available to the NHS across the whole UK. This comprised around 9,100 existing units the NHS had by then found it already had access to across the UK, around 1,200 on loan from the private sector, around 400 newly purchased by DHSC and around 200 manufactured through the Cabinet Office ventilator challenge (paragraphs 2.9 and 2.10, and Figure 3).

4 In the event, the new ventilators were not needed at the April peak because demand was considerably lower than the reasonable worst-case scenario. NHSE&I data indicate that in total, around the peak of COVID-19 hospital admissions on 14 April, NHS providers in England had 6,818 ventilator beds operational, of which: 2,849 were occupied by COVID-19 patients; 1,031 were occupied by other patients; and 2,938 were unoccupied.¹ DHSC and NHSE&I are not aware of any point when a patient who needed a ventilator was unable to get one. They allocated new ventilators to NHS trusts in England to meet local demand based on trusts' individual requests, and analysis of trusts' current ventilator usage and patterns of demand (paragraphs 2.10, 2.12 and 2.18).

5 On 15 April government adopted formal targets to aim for 18,000 mechanical ventilators by the end of April and 30,000 by the end of June. Government deliberately set targets that were substantially higher than demand at that point, in order to build a surplus that:

- covered potential regional variations in demand and hospital stock; and
- provided a sufficient safety margin to be confident that the UK had enough ventilators, including in the event of a possible second peak.

Government did not consider it necessary to set targets for non-invasive ventilators (paragraph 2.14 and Figure 2).

6 Government missed its target for the end of April. By the end of April government had increased the total number of mechanical ventilators to around 11,500, meaning it missed its target by 6,500. However, the NHS still had more than the actual demand for ventilators (paragraph 2.15 and Figure 3).

¹ The 6,818 operational beds total is lower than the 7,400 ventilators available set out in paragraph 1 as at any given time some ventilators would be unavailable due to cleaning and servicing.

7 Government was closer to meeting its end of June target of 30,000 ventilators, surpassing this number in early August. By 30 June government had acquired around 24,000 mechanical ventilators against its target of 30,000. This comprised around: 9,100 already available to the NHS; 2,600 units purchased by DHSC and 12,300 built through Cabinet Office's ventilator challenge. At this point devices borrowed from the private sector had been returned. The departments met the 30,000 target around 3 August. In addition, by 9 July, the NHS had 27,700 non-invasive ventilators and continuous positive airway pressure (CPAP) machines, including up to 17,800 purchased by DHSC since March (paragraph 2.16 and Figure 3).

8 Most of the new ventilators are being held in reserve. As at 16 September only around 2,150 mechanical ventilator units acquired through the programmes had been dispatched to the NHS. This is because the anticipated demand did not materialise. The remaining units, which were largely purchased in case of increased demand in future waves of COVID-19, are stored in warehouses, including the Ministry of Defence's facility at Donnington, as a central reserve. DHSC and NHSE&I told us that they are distributing some of these devices to NHS trusts to prepare for potential future waves of COVID-19 (paragraphs 2.17 and 2.20).

The purchase of ventilators on the world market

9 DHSC had purchased all the stock of mechanical ventilators it could from established NHS suppliers by 13 March. In early March, DHSC contacted established ventilator suppliers operating in the UK and placed orders for as many ventilators and other oxygen therapy devices as suppliers could provide at the time. This increased the number of non-invasive ventilators and oxygen concentrators available to the NHS but was less successful in securing mechanical ventilators. DHSC explained that this was largely because mechanical ventilators are more complex devices which take longer to build so suppliers do not have large amounts of stock (paragraphs 3.3 to 3.4 and Figure 4).

10 From 17 March DHSC placed significant orders directly with overseas manufacturers and their agents. Following government's "call to arms" on 16 March, Cabinet Office and DHSC both received a large number of offers from intermediary bodies who said they had access to ventilators built overseas. DHSC found that these offers took a long time to review and that many offers were not backed up with firm commitments of stock. Only one such offer led to a purchase of ventilators (paragraphs 3.7 and 3.8, and Figure 4).

11 As the programme progressed, DHSC decided to only deal directly with overseas manufacturers and their accredited distributors. It focused particularly on China as a large market with less coverage from the UK distributors on its existing frameworks. It worked with the China offices of the Foreign & Commonwealth Office and the Department for International Trade, which provided personnel and expertise to assess potential purchases and place orders as quickly as possible. It placed the vast majority of its orders for mechanical ventilators before government set its longer-term targets on 15 April (paragraphs 3.7 to 3.10 and Figures 4 and 9).

12 DHSC experienced increasing global competition to buy ventilators and made purchases primarily on the credibility of the offer, not price. It did not set a maximum price it was willing to pay but weighed up a number of factors in each case including: speed of delivery; the credibility of the supplier; and the clinical suitability of the devices. It found global competition for buying the ventilators intensified over time and that prices rose steadily as stock became harder to obtain. Suppliers usually insisted on payment upfront to secure prices and manufacturing slots. This meant DHSC accepted the risks both on the quality of devices, and that clinicians may not deem it appropriate to use devices for purposes other than their intended use. DHSC told us it only knows of one such issue, where 750 transport ventilators were bought, at a cost of around $\pounds 2.2$ million, that clinicians were not comfortable to use in an intensive care unit environment (paragraphs 3.10, 3.11 and 3.13).

Cabinet Office's ventilator challenge

13 Cabinet Office needed to find mechanical ventilator designs that both worked and could be produced at scale. From 13 March it worked with industry to:

- develop new, or modify existing, ventilator or anaesthesia machine designs to meet standards that the Medicines and Healthcare products Regulatory Agency (MHRA) developed for rapidly manufactured ventilators; and
- increase manufacturing capacity to build each design at a much greater scale than usual. This meant securing new factory capacity for each design, managing global supply chains and ensuring regulatory approvals were in place. Each manufacturer taking legal responsibility for the ventilator needed to be subject to MHRA scrutiny, to consider whether an "exceptional use" authorisation could be considered for devices that did not already have 'CE' marking.

MHRA told us that regulatory approval in normal circumstances could take 18 to 24 months, so achieving approval for new or even modified designs, their production facilities and supply chains in a few weeks was a significant challenge (paragraphs 4.1 to 4.6). **14 MHRA updated the ventilator specification several times, reflecting growing clinical experience of treating COVID-19 in the UK.** DHSC told us that its initial specification for the rapidly manufactured ventilator was created on the assumption that a large number of machines would be required within a very short timeframe. The specification was therefore very basic and focused on key life-saving features. After DHSC published this specification on 14 March, MHRA produced an updated version on 18 March calling for a range of devices from very simple to more sophisticated designs. It updated the specification further during April, reflecting increased clinical understanding of treating COVID-19, issuing the fourth and final version on 10 April. Later iterations of the specification emphasised more sophisticated features such as suction and assisted breathing (paragraph 4.5 and Figure 6).

15 Cabinet Office pursued multiple options and shortlisted them using expert advice. Following the Prime Minister's "call to arms" to UK manufacturers on 16 March and a sift of more than 5,000 initial responses, Cabinet Office convened a 'technical design authority' (the TDA) to assess ventilators and inform decisions. The TDA included experts and representatives from the NHS national clinical team, critical care specialists, MHRA and government departments, and drew on data from device-testing experts. The TDA met 12 times between 18 March and 21 May. Following its initial meetings at which it rejected some devices, the TDA supported 17 participants and gradually reduced this number as each device proceeded through the regulatory testing process, taking into account the developing picture of demand and government's targets at the time (paragraphs 4.7 to 4.11 and Figure 6).

16 Cabinet Office's approach was in effect a competition that prioritised speed and maximising the chances of success, before considering cost.

The ventilator challenge was not a traditional procurement competition on "most economically advantageous tender" grounds. Instead, the TDA process was a way of continuously assessing multiple options against requirements. Cabinet Office eliminated devices only after it decided they were either: not likely to meet the regulatory standard in time; or, in the end, were not needed. Eventually, Cabinet Office ordered those that met the regulatory standard first. There was no direct competition between participants on cost, although Cabinet Office considered the cost of designs in deciding, for example, the volume and mix of devices (paragraphs 4.9, 4.12 to 4.14, and Figure 6).

Cabinet Office accepted higher levels of risk than normal and accepted 17 that few designs would meet the regulatory standard in the time available. Cabinet Office did not wait to identify which ventilators were most likely to work before entering into contracts. Instead, it sought contracts with all the participants that remained in the process as if they had been successful, issuing conditional letters of intent and agreeing to cover reasonable costs where required, until devices were removed via the TDA process. Under these agreements, it supported providers to undertake design work, pre-order components, develop factory capacity and secure supply chains to ensure the ventilators could be built. Cabinet Office committed to covering participants' reasonable direct costs and indemnified them against legal actions from inadvertently breaching intellectual property rights, competition and procurement law, and some aspects of product failure. It estimates it will spend £113 million (excluding VAT) on design costs, components and factory capacity for ventilators it did not buy because the design was not viable or not needed to meet the government's targets (paragraphs 4.11, 4.15 to 4.19, 4.21 and Figure 7).

18 Given its overall approach, Cabinet Office took reasonable steps to control the programme's costs where it could. The Cabinet Office sought assurance over suppliers' costs with input from the Ministry of Defence's Cost Assurance and Analysis Service. It also worked with suppliers to cancel unnecessary orders early and, where possible, recover costs of components brought in preparation for manufacture, selling them back into the wider supply chain. It estimates it has recovered about \pounds 36.3 million to date in this way. Cabinet Office is also working with participants to explore commercial opportunities overseas but told us it expects the overall impact of this to be modest in the context of the programme's costs (paragraph 4.20 and Figure 10).

19 The four ventilator designs Cabinet Office eventually ordered were based on existing designs. It ordered the first devices to successfully meet the MHRA's requirements. The devices were:

- the Penlon ESO2 from the Ventilator Challenge UK consortium. This is a modification of an existing anaesthesia machine, designed by Penlon but built at much greater scale by a group of large UK automotive, aerospace and other manufacturers;
- variants of the Parapac transport ventilator, an existing design from Smiths Medical, manufactured at scale by a consortium including Rolls-Royce plc and GKN Aerospace; and
- two designs from Breas Medical, for which manufacturing was accelerated and scaled up.

Cabinet Office believes that five other new products could have achieved the required regulatory standards given further time. However, during May and June, Cabinet Office decided that it could not justify the cost of further work to support the development of these products as by this time it was clear that the four devices from the three participants above, plus the devices purchased by DHSC, would be sufficient to meet government's target of 30,000 ventilators (paragraphs 4.12 to 4.14 and Figure 6).

The programmes' costs

20 DHSC has spent around £292 million excluding VAT on its ventilation programme. This comprised:

- £244 million for around 11,100 mechanical ventilators, including £221 million for around 8,100 intensive care unit (ICU) ventilators and £23 million for around 3,000 transport ventilators;
- £45 million on other oxygen therapy devices; and
- an estimated £3.4 million on programme costs.

These costs may understate the actual total because DHSC cannot easily separate out the costs of delivering and distributing the ventilators from overseas because shipping was often combined with other items, such as personal protective equipment (paragraphs 3.14, 3.15 and 3.17, and Figures 5 and 9).

21 Cabinet Office has spent around £277 million excluding VAT on the ventilator challenge. This comprises:

- £116 million for around 11,700 Penlon ESO2 ventilators;
- £26 million for around 1,500 Smiths Parapac ventilators;
- £8 million for 2,000 Breas Nippy 4+ and Vivo 65 ventilators;
- £113 million on design costs, components and factory capacity for ventilators it did not buy (including around £11 million for an order for 15,000 additional Penlon devices that was later cancelled); and
- £14 million on programme costs, which includes around £12 million earmarked for PA Consulting who acted as programme manager, providing specialist knowledge on manufacturing and supply-chain management.

The final cost of the programme may be lower if Cabinet Office is able to recover further costs in the ways described in paragraph 18. It could also be higher if any of the participants claim under indemnities Cabinet Office granted to protect participants against the risk of product failure and infringement of intellectual property rights, although Cabinet Office considers there is a low risk of government incurring significant costs in this way (paragraphs 4.19, 4.21 and 4.23, and Figures 7 and 10).

22 The cost of the mechanical ventilators acquired varied significantly.

It is difficult to compare the costs of different machines within or across the programmes. All designs have been certified as meeting standards for use in the COVID-19 emergency, but they vary widely in their type, functionality and clinical utility.

- The average total cost of a mechanical ventilator purchased through the ventilator challenge was around £18,300, including programme costs and all the costs of designs that did not proceed to manufacture.
- The average cost of mechanical ventilators purchased by DHSC was around £22,300. This included different types of ventilators:
 - intensive care ventilators purchased from new suppliers cost an average of around £30,100, compared with an average cost from existing suppliers of around £20,000.
 - transport ventilators purchased from new suppliers (including those withdrawn from use), which had an average cost of around £5,300 compared with an average cost from existing suppliers of around £8,800 (paragraphs 3.16 and 4.22, and Figures 5, 9 and 10).

Concluding remarks

23 Both Cabinet Office and DHSC started their ventilator programmes on the basis that securing as many mechanical ventilators as possible, as quickly as possible, was necessary to safeguard public health. This urgency was reflected in their approach of: getting the programmes up and running very quickly; protecting their private-sector partners from financial risk; making early commitments to contracts; paying cash upfront for ventilators before they could be inspected; showing a willingness to accept that prices were higher than the normal market rate; deliberately supporting multiple ventilator challenge options; and drawing significantly on technical expertise and capacity from the private sector. In total, the departments spent a total of £569 million across both programmes.

24 Ultimately, the anticipated urgent demand for ventilators in mid-April did not materialise. Instead, on 15 April Ministers decided to adopt new targets to provide additional resilience in the system and prepare for a potential second wave. By this point, the departments' earlier urgency meant that the majority of purchase contracts had been entered into, and the task turned into one of identifying the best mix of devices, ensuring they were delivered, identifying which options were no longer required to meet government's targets and managing the programmes' overall cost. While the two departments were not able to meet the initial target of 18,000 mechanical ventilators by the end of April, they made substantial progress towards the later target of 30,000 by the end of June. While the number of ventilators now significantly exceeds demand, this means there is more spare capacity should it ever be needed.

25 Inevitably, given the approach the departments took, the overall costs of both programmes are higher than we, or the departments, would expect to see in normal times. However, both departments maintained sufficient record of their programmes' rationale, the key spending decisions they took and the information they had to base those on. They also put in place effective programme management, controlled costs where they could and recovered some of their committed spending once it became apparent that fewer ventilators were needed than they had originally believed.