

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 We are the UK's independent public spending watchdog.

We support Parliament in holding government to account and we help improve public services through our high-quality audits.

The National Audit Office (NAO) scrutinises public spending for Parliament and is independent of government and the civil service. We help Parliament hold government to account and we use our insights to help people who manage and govern public bodies improve public services. The Comptroller and Auditor General (C&AG), Gareth Davies, is an Officer of the House of Commons and leads the NAO. We audit the financial accounts of departments and other public bodies. We also examine and report on the value for money of how public money has been spent. In 2019, the NAO's work led to a positive financial impact through reduced costs, improved service delivery, or other benefits to citizens, of £1.1 billion.



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

Report by the Comptroller and Auditor General

Ordered by the House of Commons to be printed on 28 September 2020

This report has been prepared under Section 6 of the National Audit Act 1983 for presentation to the House of Commons in accordance with Section 9 of the Act

Gareth Davies Comptroller and Auditor General National Audit Office

25 September 2020

This investigation provides an account of how government used public money to increase the number of ventilators available to the NHS. The 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.

Investigations

We conduct investigations to establish the underlying facts in circumstances where concerns have been raised with us, or in response to intelligence that we have gathered through our wider work.

© National Audit Office 2020

The material featured in this document is subject to National Audit Office (NAO) copyright. The material may be copied or reproduced for non-commercial purposes only, namely reproduction for research, private study or for limited internal circulation within an organisation for the purpose of review.

Copying for non-commercial purposes is subject to the material being accompanied by a sufficient acknowledgement, reproduced accurately, and not being used in a misleading context. To reproduce NAO copyright material for any other use, you must contact copyright@nao.org.uk. Please tell us who you are, the organisation you represent (if any) and how and why you wish to use our material. Please include your full contact details: name, address, telephone number and email.

Please note that the material featured in this document may not be reproduced for commercial gain without the NAO's express and direct permission and that the NAO reserves its right to pursue copyright infringement proceedings against individuals or companies who reproduce material for commercial gain without our permission.

Links to external websites were valid at the time of publication of this report. The National Audit Office is not responsible for the future validity of the links.

009204 09/20 NAO

Contents

What this investigation is about 4

Summary 6

Part One

Ventilators and their role in treating COVID-19 15

Part Two

Delivery of ventilators against estimated demand 19

Part Three

Department of Health & Social Care's purchase of ventilators on the global market 27

Part Four

Cabinet Office's management of the ventilator challenge 34

Appendix One

Our investigative approach 44

Appendix Two

Ventilator challenge case study 46

Appendix Three 48

The National Audit Office study team consisted of:

Kemi Duroshola, Paul Herbertson, Andy Nichols, Sarah Perryman, with assistance from Jonathan Hyde and Jack Bower, under the direction of Joshua Reddaway.

This report can be found on the National Audit Office website at www.nao.org.uk

For further information about the National Audit Office please contact:

National Audit Office Press Office 157–197 Buckingham Palace Road Victoria London SW1W 9SP

Tel: 020 7798 7400

Enquiries: www.nao.org.uk/contact-us

Website: www.nao.org.uk

Twitter: @NAOorguk

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.

Part One

Ventilators and their role in treating COVID-19

Use of ventilation and oxygen therapy in treating COVID-19

1.1 Ventilators are machines that assist or replace a patient's breathing by moving pressurised air with adjustable concentrations of oxygen in and out of the lungs. Ventilators are used to support the treatment of a range of diseases and illnesses. Patients with COVID-19 who are admitted to hospital often have problems breathing. If their blood oxygen level is low, the hospital may give them (**Figure 1** on pages 16 and 17):

- standard oxygen therapy using a loose-fitting mask;
- non-invasive positive pressure ventilation where the patient is given oxygen under pressure, through a sealed mask over their mouth, nose or whole face; or
- invasive intermittent positive pressure ventilation which takes over the patient's breathing. This is sometimes called mechanical ventilation. A tube is placed in the mouth or nose, or through a small cut in the throat (tracheostomy).

1.2 Patients may need more than one of these treatments during a stay in hospital (Figure 1). A ventilator machine is only part of the resources needed to treat patients using a ventilator. 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. This report does not look at these wider factors.

1.3 Clinical understanding of how best to treat COVID-19 (including the role of ventilators) has evolved rapidly since the pandemic began. The NHS has published guidance for clinicians about the use of different therapies but specific treatment decisions are ultimately made by each patient's clinicians. Clinicians told us that at present some clinicians prefer to use non-invasive techniques for longer and that others prefer to put patients onto a mechanical ventilator sooner.

	pital
	hos
	S
	ient
	pat
	6-1
	\leq
	8
	eat
	to tr
	ed.
	s us
	pie
	lera
	or th
	ilato
	/ent
	nd /
	ŝПа
	yge
_	fox
, e	O Sé
-igu	_yp€
علا	

COVID-19 reduces the amount of oxygen a patient is able to get into their bloodstream. Hospitals use three main ways to help COVID-19 patients who are having trouble breathing

Therapy	Machine	Who needs it?	What does it involve for the patient?	How does it work?	How often is it used?
Oxygen therapy with a standard face mask	Standard hospital bed with oxygen supply	Most patients admitted to hospital will require this for at least some of their stay. These patients are the least unwell but need some additional oxygen to support them.	The patient is awake, breathing on their own, wearing a loose-fitting face mask.	It increases the amount of oxygen in the air the patient breathes.	60% to 70% of COVID-19 hospital beds
	Specialist Continuous Positive Airway Pressure (CPAP) machine	Patients with low oxygen levels in their blood, but who can breathe on their own.	The patient is awake, breathing on their own, wearing a tight-fitting face mask, hood or helmet.	It increases the amount of oxygen in the air the patient breathes, and the ventilator helps keeps their lungs inflated even when the patient breathes out.	
Non-invasive - ventilation	Bilevel Positive Airway Pressure (BiPAP) non-invasive ventilator	Patients with low oxygen and higher carbon dioxide levels in their blood, but who can breathe on their own. Sometimes also used for patients with underlying lung or neuromuscular problems.	The patient is awake, breathing on their own, wearing a tight-fitting face mask, hood or helmet attached to a more sophisticated ventilator than a CPAP device allowing for different air pressures when breathing in and out.	It increases the amount of oxygen in the air the patient breathes, and the ventilator helps keeps their lungs inflated even when the patient breathes out.	- 7% to 15% of COVID-19 hospital beds
	Intermittent Positive Pressure Ventilator (IPPV) using a mask	Same groups as CPAP and BiPAP.	The patient is awake, breathing on their own, wearing a tight-fitting face mask, hood or helmet attached to an IPPV device that normally has both a CPAP and BiPAP function.	The mask is attached to an invasive positive pressure ventilator (IPPV) that pushes oxygen and air into the patient at a pressure set by clinicians. Used in a similar manner to CPAP and BiPAP devices.	
Mechanical ventilation	Intermittent Positive Pressure Ventilator (IPPV) using a tube	The most unwell. Patients who are largely unable to breathe properly on their own. Their oxygen levels are very low.	The patient is anaesthetised, a breathing tube inserted into their windpipe and their own efforts to breathe are supported. However, their own breathing effort is usually stopped using drugs and the mechanical ventilator provides the breath for them.	The breathing tube is attached to an IPPV ventilator that pushes oxygen and air into the patient at a pressure set by clinicians.	20% to 25% of COVID-19 hospital beds





Source: Information supplied by the Department of Health & Social Care

1.4 The length of time COVID-19 patients spend on oxygen or ventilation support varies. Intensive care national audit and research (ICNARC) data from July 2020 reported that patients needing a mechanical ventilator at some stage in their treatment will have oxygen and/or ventilation for a median average of 15 days. Overall, half of patients needing mechanical ventilation have help breathing for eight to 26 days (the inter-quartile range). Patients' stay in hospital may be longer still. Some patients need a mechanical ventilator for more than a month, followed by a long period of rehabilitation that might require oxygen or non-invasive ventilatory support. Unfortunately, some patients who require ventilation treatment for COVID-19 do not recover.

Part Two

Delivery of ventilators against estimated demand

2.1 This part of the report sets out the changing government estimates of how many ventilators could be needed and how many ventilators government managed to acquire. **Figure 2** overleaf sets out the key events leading up to government formally adopting firm targets on 15 April 2020.

Ventilators available to the NHS before the pandemic

2.2 Over the past decade, the NHS, the Department of Health & Social Care (DHSC) and Public Health England have run pandemic planning exercises. These exercises aimed to help the UK prepare for, and improve its response to, pandemic influenza. They did not highlight any specific need for more ventilators or contain plans to increase ventilator numbers rapidly.

2.3 NHS England and NHS Improvement (NHSE&I) did not have clear data on how many ventilators were available to the NHS before the pandemic. Each NHS trust has its own policy on how it records and accounts for assets such as ventilators. There is not a central, combined asset register. There is also no single taxonomy or classification system for ventilators.

2.4 At the end of February 2020, NHSE&I asked NHS acute trusts across England for a quick audit of how many ventilators they had. By 6 March, 143 out of 148 acute trusts had answered. The trusts said that they had a maximum of around 7,400 mechanical ventilators in total:

- 4,954 adult and 878 paediatric ventilators available immediately; and
- a potential extra 1,362 adult and 163 paediatric ventilators that could be brought into use.

This includes ventilators that would not normally be used in hospital settings, such as transport ventilators from ambulances and anaesthetic machines (normally used in operating theatres), which could be repurposed for COVID-19 use.



Key estimates presented to government about the potential supply of and demand for ventilators in response to COVID-19, and government's targets Government initially estimated that demand for ventilators could far outstrip supply before estimates of potential demand reduced during early April

12 February - NHS England and NHS Improvement (NHSE&I) estimated peak demand could be up to 59,000 ventilator beds Influenza Group on Modelling (SPI-M) should work with NHSE&I and others to model the impact of the pandemic influenza This was based on the Scientific Advisory Group for Emergencies (SAGE) recommendation that the Scientific Pandemic reasonable worst case on the NHS, including the number of people requiring respiratory support.

29 28 27 26 25 24 23 22 ы 20 10 <u>8</u> 4 10 5 4 **Ω** R February



8 April - To support local NHS planning, NHSE&I provided NHS regions

reasonable worst-case scenario from 31 March. This gave a planning figure set of models and plans that were able to draw on a reasonable time-series for the NHS overall of 6,200 ventilator beds in early May. This was the first with the output from updated modelling based on the SAGE assured of data based on what was happening in hospitals

contributed around 1,800 mechanical ventilators 14 April – First peak. 6,818 ventilator beds were 2,849, non-COVID patients occupied 1,031 and 2,938 were unoccupied. The programmes had to a UK-wide estimated total of around 10,900. available of which: COVID patients occupied

15 April – Ministers formally adopted a target of 18,000 mechanical ventilators by the end allow for a margin over demand and to build resilience ahead of a possible second wave. of April and 30,000 by the end of June to

Note

This figure summarises the key events, it does not provide details of every iteration of modelling or range of scenarios considered or presented

Source: National Audit Office analysis of information provided by Cabinet Office, Department of Health & Social Care and NHS England and NHS Improvement

2.5 Later data indicates that 9,139 mechanical ventilators may have been available to NHS trusts across all of the UK at the start of the pandemic, including 1,655 mechanical ventilators in the devolved administrations, in addition to an updated estimate of 7,484 available to the NHS in England. In addition, the NHS had access to 1,156 mechanical ventilators that it borrowed from the private sector during the peak of the COVID-19 pandemic.

2.6 A stocktake of July 2020 also estimated that, at the start of the pandemic in March, the NHS in England had approximately 9,200 non-invasive bi level positive airway pressure (BiPAP) and continuous positive airway pressure (CPAP) machines (see Figure 1).

Demand for ventilators in the pandemic

Initial estimates and goals

2.7 In the early stages of the COVID-19 pandemic, DHSC and NHSE&I believed the NHS might need far more ventilators than it had available:

- NHSE&I's modelling on 12 February indicated that a reasonable worst-case scenario demand for beds with mechanical ventilators in England could be as high as 59,000. This was based on the latest planning assumptions from the Scientific Pandemic Influenza Group on Modelling (SPI-M) that had been assured by the Scientific Advisory Group for Emergencies (SAGE), both of which provide scientific and technical advice to support government decision-makers during emergencies.
- By 1 March, NHSE&I modelling, based on the latest SAGE-assured reasonable worst-case planning assumptions, indicated a potential demand for up to 90,000 mechanical ventilator beds. This compared to the estimates available at that time that a maximum of around 7,400 mechanical ventilators could be made available in England (paragraph 2.4).

2.8 Government decided in this context to pursue all options to acquire as many ventilators as possible.

- Starting from the beginning of March it set out to buy as many ventilators as possible, initially focusing on UK distributors but increasingly buying directly from overseas suppliers. DHSC led on the contracting on the basis of specifications set out by NHSE&I (see Part Three).
- From 13 March, it started to encourage UK manufacturers to help scale up production of existing ventilator designs and develop new designs (Cabinet Office's ventilator challenge, covered in Part Four), setting an initial ambition to secure an extra 30,000 ventilators this way within two weeks. A later ministerial submission on 11 April noted that this target was not meant to be achievable but was intended to "wake up the industry".

On 16 March the Prime Minister announced a "call to arms" to British industry to help build and acquire ventilators for the NHS.

Reducing estimates of demand until the April peak

2.9 The estimate of the number of ventilators needed fell as understanding of how quickly the virus was spreading and the impact of mitigations such as social distancing increased:

- On 24 March, NHSE&I again updated its modelling using the latest SAGE-assured reasonable worst-case planning assumptions to estimate that it could now need up to 17,500 invasive mechanical ventilators in England by 13 April. This took into account the impact of new mitigations such as social distancing. Its modelling around that time indicated a further potential peak need of around 72,000 mechanical ventilators by the end of November.
- On 8 April, based on the new SAGE-assured government reasonable worst-case scenario, NHSE&I again revised its modelling and estimated that it could need up to 5,100 mechanical ventilators by 13 April, and a peak of 6,200 in early May.² This was less than the estimated 7,400 of mechanical ventilators machines available to the NHS in England before the start of the pandemic, although this does not take into account the suitability or location of the machines, or other factors such as breakdowns.

² SAGE documentation explains that the reasonable worst-case planning scenarios were not predictions and that the precise timings of peaks in infection and demand on healthcare were subject to significant uncertainty.

Actual demand at the peak

2.10 By the week commencing 13 April, the NHS had acquired 1,800 new ventilators, giving it access to around 10,900 mechanical ventilator machines across the UK. This comprised: around 9,100 existing ventilators it had now found were already available; around 1,200 on loan from the private sector; around 400 purchased by DHSC; and around 200 manufactured through the ventilator challenge (**Figure 3** on pages 24 and 25). This means that the NHS would not have had enough devices for the first wave had demand been as high as worst-case planning in February and March indicated it could be.

2.11 Not all the 10,900 ventilators deployed in hospitals were available for use in treating COVID-19. DHSC explained that this is because at any given time some ventilators would be unavailable due to necessary cleaning and servicing and some would be used for other purposes such as transport. Some ventilators will also have been deployed at intensive care beds in devolved administrations.

2.12 DHSC and NHSE&I are not aware of any point when a patient who needed a ventilator was not able to get one. On 14 April, around the peak of COVID-19 hospital cases, of the 10,900 ventilators available, 6,818 ventilators were deployed at NHS intensive care beds in England, of which:

- 2,849 (42%) were occupied by COVID-19 patients;
- 1,031 (15%) were occupied by other patients; and
- 2,938 (43%) were unoccupied.

2.13 However, patients may have had to be treated using ventilators that clinicians would not have chosen, such as operating theatre anaesthetic machines or transport ventilators. These can be used as intensive care ventilators, but critical care clinicians may not have been familiar with them, and they are normally used for short-term (hours) ventilation of relatively well patients having surgery rather than the long-term (days or weeks) ventilation of critically ill patients.

Government's delivery of ventilators against its targets

Setting targets

2.14 On 15 April, ministers set formal targets to aim for a total of 18,000 mechanical ventilators by the end of April and 30,000 by the end of June. They chose these figures to: allow a margin over estimated demand; build resilience for a possible second peak; and allow for additional demand from devolved administrations, which was not included in initial estimates. They did not consider it necessary to set specific targets for non-invasive ventilators.

Figure 3

Mechanical ventilators available to the NHS (UK) over time against Reasonable Worst-Case estimated COVID-19 demand (England only) as of 24 March 2020 and actual mechanical ventilator beds occupied (England only)

By 3 August over 30,000 mechanical ventilators were available to the NHS. Had the first peak in mid-April, been as high as expected, the devices would not have been ready in time

Volume



Ventilator challenge ventilators available to the NHS (UK)

Week commencing

- DHSC procured ventilators available to the NHS (UK)
- Loan from private sector (UK)
- Existing ventilators (including surge) avaliable to the NHS (UK)
- NHSE&I's (24 March 20) worst-case estimate of COVID-19 mechanical ventilation bed demand England only I
- Actual mechanical ventilation beds occupied England only

Mechanical ventilators available to the NHS over time against Reasonable Worst-Case estimated COVID-19 demand (England only) as of 24 March 2020 and actual mechanical ventilator beds occupied (England only)

Notes

- 1 Supply estimates are at the UK level whereas demand figures are for England only.
- 2 Supply estimates present the number of ventilators whereas demand estimates present the number of ventilator beds.
- 3 Baseline supply figures include 7,484 mechanical ventilators in England and 1.655 in the devolved administrations.
- 4 Supply estimates from week commencing 16 March to week commencing 25 May include 1,156 mechanical ventilators on loan from the private sector. Figures from week commencing 1 June onwards exclude these machines as they began to be returned. However, the programme has an ongoing arrangement in place to have access to some private sector capacity if needed in future.
- 5 Actual mechanical ventilation beds occupied includes both COVID-19 and non-COVID-19 patients. Data is for England only and takes the maximum figure for each week.
- 6 Reasonable worst-case estimates of potential COVID-19 mechanical ventilator bed demand estimate data are for England only and take the maximum figure for each week.

Source: National Audit Office analysis of data from the Department of Health & Social Care and NHS England and NHS Improvement

April's target

2.15 The departments missed their target of securing 18,000 mechanical ventilators by the end of April. By the end of April, the total number of machines had increased only slightly from the mid-April peak, to around 11,500 ventilators, which meant government's target of 18,000 at this stage was not met. However, this was still more than the actual demand for ventilators at this point (see Figure 3).

June's target

2.16 By the end of June, around 24,000 mechanical ventilators were available against a target of 30,000. By 3 August, the 30,000 target had been met. This comprised:

- around 9,100 units already available to the NHS;
- 5,900 units purchased by DHSC; and
- 15,100 built through Cabinet Office's ventilator challenge at that date.

By 9 July, 27,700 non-invasive ventilators were available to the NHS, including up to 17,800 that had been newly purchased by DHSC since March.³

³ The approximate 24,000 mechanical ventilators available at 30 June 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. The 17,800 non-invasive ventilators purchased by 9 July is likely to be an overestimate as DHSC's figures did not include estimates for existing non-invasive ventilators available to devolved administrations.

Allocating ventilators

2.17 At 16 September, around 2,150 mechanical ventilator units bought or built through the programmes had been distributed to NHS trusts. The remainder were not distributed because anticipated demand for more machines did not materialise.

2.18 NHSE&I allocated and arranged the delivery of ventilators to hospitals in England based on NHS trusts' requests, its own assessment of current usage and need, and patterns of increasing demand. It developed a National Ventilator Allocations Process which allowed NHS trusts to request equipment through their regional teams via daily calls during March and early April, as demand was increasing. NHSE&I assessed requests for additional machines using management information, such as data on the number of beds with mechanical ventilation available and the number occupied by patients with COVID-19 or other illnesses.

2.19 DHSC also allocated ventilators to the NHS in Scotland, Wales and Northern Ireland, based on their population relative to England, and to overseas territories on an ad-hoc basis, for the relevant administration to arrange allocation and delivery to local hospitals.

2.20 The remainder of the ventilator units are stored in warehouses, including the Ministry of Defence's facility at Donnington, as reserve against possible increased demand in the future. DHSC and NHSE&I are currently distributing these devices to NHS trusts to help with planning for potential future demand including further waves of COVID-19. However, if demand for ventilators does not increase, it is possible that many of the ventilators purchased or built during the pandemic will never be used.

Part Three

Department of Health & Social Care's purchase of ventilators on the global market

The oxygen and ventilation programme

3.1 This part sets out how the Department of Health & Social Care (DHSC) sought to buy ventilators from suppliers and manufacturers as part of a wider joint programme with NHS England and NHS Improvement (NHSE&I).**Figure 4** overleaf sets out a timeline of the key events.

3.2 On 3 March, DHSC formed its oxygen, ventilation, medical devices and clinical consumables programme in partnership with NHSE&I. The programme was overseen by NHSE&I's chief commercial officer and aimed to maximise the availability and effectiveness of oxygen to support patient care during a coronavirus surge. This involved assessing a range of factors including whether the UK:

- could produce enough oxygen and get it to hospitals where it was needed;
- could deliver this oxygen effectively to patients;
- had sufficient infrastructure and equipment to provide the oxygen to patients; and
- had all the necessary consumable items to enable their continued use.

DHSC and NHSE&I identified the availability of equipment such as oxygen concentrators and ventilators as one of the main constraints in providing oxygen to patients.



The Department of Health & Social Care's (DHSC's) procurement of ventilators in response to the COVID-19 pandemic

In response to the risk of a ventilator shortage, DHSC began the process of purchasing as many ventilators as possible from early March



Source: National Audit Office analysis of Department of Health & Social Care documents

3.3 DHSC contacted established suppliers of ventilators to the NHS and placed orders for as many oxygen concentrators and ventilators as they could provide. They placed their first set of orders on 9 March, using existing NHS supply chain framework agreements, which are designed to ensure competitive pricing. By 12 March, DHSC had ordered around 5,600 oxygen concentrators, 1,600 non-invasive ventilators and 2,400 mechanical ventilators. In total, it spent £62.3 million on around 4,300 mechanical ventilators purchased via the NHS framework, at an average cost of around £14,600 per unit. This comprised:

- around 2,200 intensive care unit ventilators at an average cost of £20,000 per unit; and
- around 2,100 transport ventilators at an average cost of £8,800 per unit.

3.4 These initial efforts did not, however, secure the significant number of mechanical ventilators required to meet the then anticipated demand. DHSC told us that it found that securing mechanical ventilators was particularly difficult as these machines are usually made to order and take a long time to manufacture.

The European Union's Joint Procurement Agreement

3.5 On 17 March 2020, the European Commission launched its tender for ventilators under the Joint Procurement Agreement for medical countermeasures. The European Commission told us that it signed 13 framework contracts with six companies (from the UK, EU and China) allowing member states to order invasive and non-invasive with ventilators since 15 April. It said the frameworks would run for a period of 12 months and that the first orders from member states were placed in May and delivered in July.

3.6 The UK did not join the EU scheme due to a communication problem: evidence provided by DHSC indicates that the European Commission sent its notification of the opportunity to participate to the old email addresses of the UK officials who were the UK's nominated representatives for the scheme in 2016, but these were no longer valid. This meant that ministers were not briefed and that the schemes had already gone to tender before DHSC could have decided whether to take part. However, it is not clear whether being part of the EU scheme would have provided additional benefits to the UK because it did not deliver ventilators as fast as the DHSC and Cabinet Office programmes.

Purchasing ventilators directly from overseas

3.7 From 13 March, DHSC stepped up its purchasing of ventilators directly from overseas manufacturers and distributors, with support from the Foreign & Commonwealth Office and the Department for International Trade, and began to purchase ventilators directly from overseas manufacturers and their accredited distributors.

The impact of the initial "call to arms"

3.8 Following the Prime Minister's "call to arms" on 16 March, DHSC and Cabinet Office received hundreds of offers, mainly from third parties or intermediaries who claimed to have connections to suppliers overseas. At its peak, DHSC told us that its staff and those from other departments such as the Foreign & Commonwealth Office and the Department for International Trade were triaging and responding to more than 1,000 emails a week. However, it found that offers took a long time to review and that many were not backed up with firm commitments of stock. Only one of these leads led to the purchase of ventilators (see paragraphs 3.10 and 3.11 for an explanation of a large purchase where Excalibur Healthcare Services was an intermediary).

3.9 On 24 March, DHSC changed its approach to only deal with intermediaries where it did not have established relationships with factories. On 1 April, it switched to solely dealing with the manufacturers of ventilators directly, as this was proving to be more successful at leading to confirmed orders.

Rising costs in the face of increased global demand

3.10 DHSC focused its efforts on China, which it considered to be the largest untapped manufacturing source for approved devices. The Foreign & Commonwealth Office and the Department for International Trade in Beijing played a substantial role in assessing offers and, as a result, DHSC was able to secure initial orders relatively quickly and at similar levels to normal market prices. It told us that this was because it started purchasing devices before international competition for devices had escalated. Global competition to buy ventilators grew sharply over the course of March. As a result, DHSC found that the price of some ventilators increased significantly. For example:

 between 18 and 24 March, DHSC secured an additional 1,600 devices from new suppliers. This included an order of 1,000 VG-70 intensive care unit (ICU) ventilators from Aeonmed at an average cost of around £9,000 per unit. This was below the £19,000 price for these devices on the existing NHS framework. DHSC told us that these costs are not directly comparable as the purchase did not include delivery, UK modifications or support arrangements; and • between 29 March and 4 April, DHSC ordered around 3,300 devices, including its largest overseas order of a further 2,700 VG-70 ventilators from Excalibur Healthcare Services. It paid around £50,000 per VG-70 unit. These latter figures include transport from China but are nevertheless much higher than the earlier prices for the same machine.

3.11 DHSC told us that, in the face of growing global demand for ventilators, most overseas suppliers would not accept payment on delivery and that it needed to pay cash upfront to secure orders. This meant it accepted the risks of non-delivery and limited government's leverage in the event of, for example, product failure. Excalibur Healthcare Services told us that the prices it charged enabled it to fulfil all its orders at a time when many other suppliers were not able to, and reflected the price it had to pay to secure stock from China against the threat of being gazumped by buyers from other countries and the difficulties it had to overcome in transporting ventilators from China at the height of global demand for ventilators.

Quality assurance

3.12 DHSC and NHSE&I put in place quality assurance processes for purchases of ventilators from outside the UK. DHSC sought only to purchase devices which carried CE marking (see paragraph 4.4). It also introduced additional processes to quality assure products once they arrived in the UK, which included:

- an initial clinical review of the device on receipt at the distribution centre;
- a subsequent technical review of devices within a specialist NHS facility; and
- reviews of devices by engineers once they were delivered to NHS trusts.

3.13 DHSC told us that, during the most critical period for ventilator demand, some devices were released without a review at a specialist NHS facility, so they could get the ventilators to hospitals quickly, where NHS engineering teams would have had to check the ventilators themselves. DHSC told us that this would be normal practice outside of the COVID-19 response. One such device was the Aeonmed Shangrila 510s transport ventilator, of which DHSC purchased 750 at a cost of around £2.2 million. Although this device was designed to be used in ambulances, DHSC and NHSE&I judged that it could be useful in an intensive care environment. It withdrew the device, however, in response to concerns raised by some clinicians who, after testing the devices, did not consider them appropriate for use within an intensive care setting. The DHSC and NHSE&I clinical due diligence team later completed a report confirming this. DHSC cancelled the purchase of a further 1,250 units, which had not yet shipped.

The cost of the programme

3.14 DHSC has spent around $\pounds 292$ million (excluding VAT) on a wide range of different ventilators and similar equipment. This is under the $\pounds 600$ million (excluding VAT) approved by HM Treasury (Figure 9).

3.15 The majority of expenditure, \pounds 244 million (excluding VAT), was on mechanical ventilators. This included:

- £221 million for around 8,100 intensive care unit (ICU) ventilators; and
- £23 million for around 3,000 transport ventilators.

3.16 The average cost of the mechanical ventilators bought by DHSC was around $\pounds 22,300$ ($\pounds 21,900$ excluding programme costs).⁴ Figure 5 sets out the costs of the different types of mechanical ventilators purchased from both existing and new suppliers. The average cost of intensive care ventilators purchased from new suppliers (around $\pounds 30,100$ per unit) was around 1.5 times that of ventilators purchased through the existing NHS supply chain ($\pounds 20,000$). This was primarily due to the largest order of 2,700 VG70 ventilators from Excalibur Healthcare Services, which also had the highest unit cost. Conversely, transport ventilators purchased from new suppliers had a lower average cost than those purchased via conventional routes, although this includes those withdrawn from use as set out in paragraph 3.13.

3.17 These costs are likely to underestimate the actual total because DHSC cannot easily separate out the costs of delivering and distributing the ventilators from overseas (predominantly from China) as shipping was often combined with other items, such as personal protective equipment. DHSC also spent around £45 million on other oxygen therapy devices and around £3.4 million on programme costs.

3.18 DHSC and NHSE&I told us that they are currently focused on distributing the purchased devices into the NHS. Once this is complete, they plan to reassess stocks against future demand projections and determine whether they should seek to sell or dispose of any surplus items.

3.19 Figure 9 (Appendix Three) sets out the costs of the ventilators ordered in more detail.

⁴ If all programme costs are attributed to the cost of mechanical ventilators, the average cost of the mechanical ventilators is £22,300. However, the total cost of the programme also included the costs of buying other types of ventilator.

Figure 5

The Department of Health & Social Care's expenditure on mechanical ventilators by ventilator type and purchase route

DHSC purchased a range of different types of mechanical ventilators for a total of around £244 million

Ventilator type and purchase route	Minimum cost per unit	Maximum cost per unit	Average cost per unit (weighted by volume of devices ordered)	Total spend
	(£)	(£)	(£)	(£)
All mechanical ventilators	2,900	50,200	21,900	244,500,000
Intensive care unit (ICU) ventilator: new supplier	7,200	50,200	30,100	176,800,000
ICU ventilator: existing supply chain	8,100	32,900	20,000	44,300,000
Transport ventilator: new supplier	2,900	32,000	5,300	5,300,000
Transport ventilator: existing supplier	6,300	16,700	8,800	18,000,000

Notes

1 Totals do not sum due to rounding. Actual total is £244,466,008 (see Figure 9).

2 Average costs exclude programme costs. If all programme costs are attributed to the cost of mechanical ventilators, the average cost of the mechanical ventilators is £22,300. However, the total cost of the programme also included the costs of buying other types of ventilator.

Source: National Audit Office analysis of Department of Health & Social Care's data

Part Four

Cabinet Office's management of the ventilator challenge

Establishing the ventilator challenge

- **4.1** This part sets out how Cabinet Office managed the 'ventilator challenge' to:
- engage with UK businesses to develop new ventilator designs from scratch and build as many as possible; and
- explore opportunities to increase production of existing products, or products that could be modified to be suitable, in the UK.

4.2 Government's chief commercial officer established the programme on 13 March and headed a team of officials from the Government Commercial Function in the Cabinet Office. Cabinet Office engaged PA Consulting to act as programme manager and to help select designs and manage supply chains and commercial operations.

Selecting which ventilators to support

4.3 Cabinet Office decided from the outset to pursue both new designs and existing designs because it was likely that:

- some new designs would not meet the required regulatory standards or would not be clinically useful in treating COVID-19; and
- it would face global competition for parts and components that were also used in existing designs, whose supply chains were predominantly not UK-based.

Regulatory approval of devices

4.4 All ventilators to be built through the challenge, whether based on new or existing designs, had to meet regulatory standards to ensure they were safe, effective and relatively easy to use. This included an assessment by the Medicines and Healthcare products Regulatory Agency (MHRA) of manufacturers' technical documentation and their production facilities, to consider whether an 'exceptional use authorisation' could be issued. MHRA regulates medical devices in the UK and can issue exceptional use authorisation allowing the use of non-CE marked medical devices (including ventilators) where there is an immediate clinical need and there are no alternative CE-marked devices available.⁵

4.5 For new devices that did not already have approval, this meant meeting the specification for 'rapidly manufactured' ventilators. This specification evolved through several iterations between 14 March and 10 April:

- On 14 March, the Department of Health & Social Care (DHSC) published an initial specification with input from its clinicians. This was before MHRA was consulted. 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.
- On 18 March, MHRA published a revised specification that in its view would meet the requirements for 'exceptional use authorisation', making clear that this would be updated. It also made it clear that while emergency ventilators would be needed for stabilisation, the requirement was ideally also to have machines capable of functioning as a broader-function ventilator which could support a patient through a number of days. This set the initial bar against which ventilator challenge devices were measured.
- On 19 and 25 March, second and third versions of the MHRA specification added further detail on safety, the testing devices would undergo and the features they needed.
- On 10 April, the fourth and final version clarified that, in light of greater clinical experience in treating COVID-19, more weight was being put on how ventilators managed: suctioning (to manage the amount of secretions in patients' lungs); and spontaneous breathing (to help 'wean' patients off ventilators after long periods).

⁵ CE marking means that a product has been through a conformity assessment and meets all essential requirements under the Medical Devices Directive. MHRA told us that, for medium-high-risk medical devices such as ventilators, this would involve an assessment of the manufacturer's production facility and technical documentation by an EU-based Notified Body. Notified Bodies are independent certification bodies designated to assess medical devices. MHRA is the UK Designating Authority.

4.6 MHRA told us that it estimated regulatory approval in normal circumstances could take 18 to 24 months, so in its view achieving approval for new products or production facilities in a few weeks was a significant challenge.⁶ Similarly, representatives of Draeger, a large company in the medical and safety technology sector, told us that a ventilation device with multiple modes of ventilation would typically take five to seven years from design concept to market release and that even a simpler product such as a continuous positive airway pressure (CPAP) machine or non-invasive ventilator could take three to five years to progress from design concept to final approved device.

Shortlisting, developing and reviewing devices

4.7 On 16 March, the Prime Minister joined a telephone call with a range of government and industry representatives to encourage as many as possible to participate in the challenge as a "call to arms" to UK industry. Following a sift of more than 5,000 initial offers of help, Cabinet Office held initial talks with potential suppliers and began a process to assess and develop shortlisted designs (**Figure 6** on pages 38 and 39).

4.8 Cabinet Office then convened a 'technical design authority' (TDA) to support decision-making on the programme and develop recommendations on which products to support. The TDA included clinicians from the NHS national clinical team, MHRA, Cabinet Office, PA Consulting (acting as programme manager) and other government departments including the Ministry of Defence and the Department for Business, Energy & Industrial Strategy.

4.9 The TDA selection process was not a traditional procurement competition on "most economically advantageous tender" grounds and was not designed to quickly pick winners and discard other options. Instead, it was a structured process through which Cabinet Office continuously assessed multiple options against changing requirements for the volume and mix of ventilators required:

- Each participant started in a different position and had a different amount of work to do to develop its device to meet the regulatory standard. Some were brand new designs, some were existing products and some were based on existing products but had to undergo extensive modification to make them easier to build at scale.
- Key selection criteria, such as the target number of ventilators and regulatory standards, evolved over time (see paragraph 4.5).

⁶ MHRA told us it based this view on its professional assessment and discussion with industry and Notified Bodies. MHRA does not have data on the normal average times to certify a product from product inception because it is not directly involved in conformity assessment.

• Cabinet Office was open to supporting multiple devices, if needed, and removed devices from the process only after the TDA recommended that they were not viable, would not meet required standards in time or were no longer required to meet government's targets. Some products that showed early promise against the specification did not ultimately pass all the tests. Others showed progress against the requirements but not quickly enough to be useful as demand fell (Figure 6).

4.10 The TDA met 12 times to assess products' progress between 18 March and 21 May (Figure 6). The TDA considered a range of information, such as reports from the Medical Devices Testing and Evaluation Centre (MD-TEC) as medical device testing experts, and devices' relative performance against the MHRA specification, using this to rank devices according to their clinical utility. It also considered the wider context at each point, including the number and mix of machines required and the likelihood of manufacturing each device.

4.11 In line with its approach of progressing multiple options, Cabinet Office worked actively with participants to progress their designs while they remained in the process. It sought contracts with participants that remained in the process, 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, if they went on to meet regulatory standards and were required.

4.12 During April, as clinical and regulatory requirements developed, demand fell and government set firm targets for ventilators, the process effectively became a competition to be one of the first participants to develop a product that met regulatory standards and could be built at scale. Around 22 April the TDA had identified that three participants' products could be sufficient to help meet clinical need and ministers' targets for 30,000 mechanical ventilators by the end of June:

- **The Penion ESO2.** This was a new product based on an existing anaesthesia machine produced by Penion, with new manufacturing facilities and supply chains supported by the Ford Motor Company, McLaren F1, Siemens, Airbus and others. Figure 8 in Appendix Two provides more detail on the Penion ESO2.
- Variants of the Parapac transport ventilator. This was an existing design produced by Smiths Medical, with new manufacturing facilities and supply chain supported by Rolls-Royce plc, GKN Aerospace and others.
- The Nippy 4+ and Vivo 65 models. These were recently launched machines produced by Breas Medical with new manufacturing facilities that the Cabinet Office supported to allow increased production.

Figure 6

Cabinet Office's selection of devices in the ventilator challenge

Cabinet Office convened a technical design authority (TDA) of experts to develop recommendations on which devices to support



Category	Reference	Device Reference	Designer	Manufacturer	New or existing	Support ceased (closedown letter sent)
Devices purchased	A	Prima ESO2	Penlon	High Value Manufacturing Catapult, Ford, Siemens, McLaren F1, Meggitt, Airbus, STI	Modification of existing anaesthesia machine product	n/a
	В	Nippy 4 and Vivo 65	Breas Medical	Breas Medical	Recently-launched existing product	n/a
	С	Parapac	Smiths	GKN Aerospace, Rolls-Royce plc	Existing product	n/a
Devices supported but later removed from challenge	D	Zephyr+	Draeger	Babcock	New product based on existing product	10 June
_	E	Gemini	OES Medical	BMW Group	Hybrid of existing designs	2 June
_	F	3CPAP (SOG)	Vobster Marine Systems	n/a	New design (non- invasive ventilator)	11 May
	G	Piran Vent	Swagelok	n/a	New design	8 May
_	Н	VelociVent	Cambridge Consultants Limited	Metlase	New design	8 May
	I	Mosquito	Sagentia	Sagentia	New design	8 May
	J	CoVent	TTP	Dyson	New design	8 May
	К	AirCare	BAE systems	Intersurgical	Modified version of existing product	8 May
	L	EVA	TEAM Consulting (based on Diamedica design)	Cogent	Modified version of existing product	28 April
	М	Helix	Diamedica	Plexus	Based on existing product	28 April
	Ν	OxVent	King's College London, Oxford University	Smith and Nephew	New design	28 April
	0	InVicto	JFD	n/a	New design (non- invasive ventilator)	28 April
	Р	BlueSky	Darwood/F1	Olympus medical	New design	12 April
	Q	UCL CPAP	Oxford Optronix	Mercedes	New design (non- invasive ventilator)	30 March (transferred to Department of Health & Social Care)

4.13 At this stage, officials recommended that three other designs be retained in the challenge to keep options open, and that the rest be removed on the basis that they were unlikely to meet regulatory standards in time to deliver significant volumes to meet government's 30 June target. However, ministers decided to retain a further five devices for two weeks to keep options open and give the devices more time to progress toward regulatory approval, at a cost of up to $\pounds 250,000$ each (Figure 6). All five were removed from the process on 8 May after a further TDA meeting on 5 May.

4.14 Cabinet Office continued to reduce the number of ventilators in the challenge over time and eventually placed orders for the Penlon, Parapac, Nippy 4+ and Vivo 65 devices. Of those that were eventually removed, the Cabinet Office believes that five could also have gone on to meet regulatory requirements had they been required but removed them following further review of the numbers and mix of ventilators required and the cost of the programme. These were:

- the CoVent by TTP and Dyson (one of the five removed on 8 May);
- the Metlase Veloci-Vent by Cambridge Consultants Limited (removed on 8 May);
- the Piranvent by Swagelok (removed on 8 May);
- the Gemini by OES Medical Ltd and BMW (removed 2 June); and
- the Zephyr Plus by Draeger and Babcock (removed 10 June).

Contracting with suppliers

4.15 Cabinet Office's contracting approach reflected the priority it had placed on the delivery of ventilators, and its approach of keeping options open and actively progressing them until it was clear that they were not viable, or not required. It told contractors that it would meet reasonable costs such as the cost of developing designs and component parts.

4.16 On its largest contract, with Penlon, Cabinet Office allowed a mark-up of 15% on eligible direct costs.⁷ This mark-up was based on an analysis of suppliers' current operating profit and included a 2% increment because of the 'novelty' of the situation. Cabinet Office sought advice from the Ministry of Defence's Cost Assurance and Analysis Service and acknowledged at the time that the mark-up was relatively high but that it considered it reasonable in the circumstances. By comparison, defence single source contracts where there is limited financial risk to the contractor are normally let with a mark-up of 8% to 10%.

⁷ This did not include 'pass through' costs from another firm within the project consortium or a third party that applied a margin within its price.

4.17 The requirements, scale and terms of each contract varied depending on whether Cabinet Office was contracting for a design, manufacture of a device or the purchase of devices. Manufacturing contracts included authorisations for participants to set up manufacturing facilities and purchase parts if required, which essentially meant that Cabinet Office was pre-ordering a large number of ventilators at its risk before it knew whether they would be viable or needed.

4.18 Cabinet Office awarded contracts directly to participants without competition on the basis that Regulation 32 of the 2015 Public Contracts Regulations applied. Regulation 32 states that a public authority may award public contracts by a negotiated procedure without prior publication "insofar as is strictly necessary where, for reasons of extreme urgency brought about by events unforeseeable by the contracting authority, the time limits for the open or restricted procedures or competitive procedures with negotiation cannot be complied with."⁸

4.19 Cabinet Office also granted indemnities to participants, assuming liability for key risks that participants might usually be expected to bear. Cabinet Office told us it granted these indemnities because government was asking manufacturers and designers to work much more quickly than they usually would and to use component manufacturers that were not always part of the medical device industry. **Figure 7** on pages 42 and 43 provides more detail on the indemnities.

Assuring and controlling expenditure

4.20 Cabinet Office took a number of steps to gain assurance that the programme's costs were reasonable, and to control and reduce costs where possible, including:

- working on an open-book basis with participants, for example by auditing claims for costs incurred at the point participants submitted them;
- seeking advice and challenge on suppliers' costs from the Ministry of Defence's Cost Assurance and Analysis Service; and
- a significant programme of 'wind down' activity, which involved working actively with participants to cancel orders for parts that were not needed, or sell or dispose of parts on the open market. Cabinet Office estimates that these activities reduced the cost of the programme by around £36.3 million. 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.

⁸ The Public Contracts Regulations 2015, regulation 32(2)(c) accessed at www.legislation.gov.uk/uksi/2015/102/ regulation/32/made on 5 August 2020.

\sim	
Ø	
'n	
ົວ	
ΪĒ.	(

Summary of the indemnities granted to ventilator challenge participants

	ഗ
	-
	≍
	2
- 1	Ē
	=
	σ
	2
	≂
	Υ.
	o
	_
	0
	2
	m
	•••
	ŝ
	÷.
	╘
	Ξ.
	đ٦.
	۳.
	-
	σ
	Ξ.
	m
	~
	o
	2
	ī
	22
	~
	5
	ŝ
	ت
- 2	=
	~
	5
	Ψ
	σ
	ē.
	=
	_
	-
	~
	Ψ
	Ξ.
	5
	U
	~
	_
	-
	σ
	_
	<u> </u>
	╘
	Ē
	ž
	nor
	norm
	tnorm
	ot norm
•	10t norm
•	not norm
	s not norm
	es not norm
•	es not norm
	oes not norm
	does not norm
•	does not norm
•	it does not norm
	It does not norm
	s it does not norm
	es it does not norm
	les it does not norm
	ities it does not norm
	nities it does not norm
	inities it does not norm
	mnities it does not norm
	emnities it does not norm
	emnities it does not norm
	demnities it does not norm
	ndemnities it does not norm
	indemnities it does not norm
	Indemnities it does not norm
	d indemnities it does not norm
	ed indemnities it does not norm
	led indemnities it does not norm
	ued indemnities it does not norm
	sued indemnities it does not norm
	ssued indemnities it does not norm
	issued indemnities it does not norm
	s issued indemnities it does not norm
	is issued indemnities it does not norm
	as issued indemnities it does not norm
	has issued indemnities it does not norm
	has issued indemnities it does not norm
	It has issued indemnities it does not norm
	nt has issued indemnities it does not norm
	ent has issued indemnities it does not norm
	nent has issued indemnities it does not norm
	ment has issued indemnities it does not norm
	Iment has issued indemnities it does not norm
	rnment has issued indemnities it does not norm
	ernment has issued indemnities it does not norm
	rernment has issued indemnities it does not norm
	vernment has issued indemnities it does not norm
	overnment has issued indemnities it does not norm
	covernment has issued indemnities it does not norm

	Intellectual property indemnity	Product indemnity	Competition and procurement law
Nature of the risk	That mechanical ventilators inadvertently use a third party's intellectual property without permission, due to the limited time available to undertake normal due diligence.	It was not possible for the machines to pass the normal testing for a CE mark in the time available. There is thus a greater risk of the machines not working as intended and causing physical harm, injury or death.	The ventilators were not procured using a normal competitive process.
Cabinet Office assessment of risk	Low	Low	Low
Who is covered?	The Smiths and Penlon consortia.	The Smiths and Penlon consortia.	The Smiths and Penlon consortia.
What warranties does the manufacturer give?	The manufacturer owns or is entitled to use all intellectual property rights incorporated in the design and specification of the products.	 That the products meet the specification and have been produced with reasonable skill and care (capped liability at 15% of revenue for lead supplier and 10% of contract value for other suppliers). Failure to comply with manufacturing specification (liability capped as above). 	
What indemnities does the manufacturer give?	Penlon only: that receipt and use of the products will not infringe third party intellectual property rights (unlimited liability)	Penlon only: death or personal injury caused by negligence (unlimited liability).	
What has government indemnified?	Losses resulting from third-party claims for infringement of intellectual property rights.	 Losses resulting from third party claims relating to: products that are defective or not fit for purpose (except where covered above); use of the products; and product failure where the product was produced in line with an approval from the Medicines and Healthcare products Regulatory Agency (MHRA). 	 Breach of procurement law and competition law. Delay in the supply of products due to exceptional circumstances.
What mitigations and controls are in place	Government may be able to claim "crown use" which has lower compensation than intellectual property infringement.	 NHS trusts told to use CE marked products first. All products passed MHRA emergency product testing. All products are subject to regulator quality control as part of manufacturing process. Products are used in controlled clinical settings with the potential for a rapid product recall if problems are detected. 	

Summary of the indemnities granted to ventilator challenge participants

Notes

- 1 Breas Medical has not been given an intellectual property or product indemnity as its products have been purchased under its existing NHS supply contract with standard terms and conditions.
- 2 This table provides a summary of the key indemnities granted by government and does not include all warranties given by suppliers under their supply agreements.
- 3 This table is based on information provided by the Cabinet Office. The National Audit Office does not express any legal view on the indemnities or warranties granted.
- 4 All government liabilities are uncapped.
- 5 CE marking means that a product has been through a conformity assessment and meets all essential requirements under the Medical Devices Directive.

Source: National Audit Office analysis of Cabinet Office documents

The cost of the programme

4.21 Cabinet Office sought and obtained approval from HM Treasury to cover the maximum cost of the programme, up to $\pounds454$ million. Of this, Cabinet Office expects to spend around $\pounds277$ million excluding VAT. This includes:

- £116 million for around 11,700 Penlon ESO2 ventilators;
- £26 million for around 1,500 Smiths Parapac ventilators;
- £8 million for 2,000 Breas ventilators;
- £113 million 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. This includes 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.

4.22 The costs of the ventilators purchased varied from £3,558 for the Parapac 310, to £9,952 for the Penlon ESO2 and £24,352 for the Parapac 300. This is in large part because they vary in sophistication and functionality, and in some cases include the costs of setting up new manufacturing facilities. The average total cost of a ventilator purchased through the ventilator challenge was around £18,300, including all the costs spent on designs that did not proceed to manufacture and programme costs. This is slightly less than the £22,300 average cost of mechanical ventilators bought from new and existing suppliers (paragraph 3.16).

4.23 The final cost of the programme and the average cost per ventilator may be lower than set out above if Cabinet Office is able to recover further costs in the ways described above. It could also be higher if any of the participants claim under the indemnities Cabinet Office granted (Figure 7).

4.24 Figure 10 (Appendix Three) provides more detail on the cost of the programme.

Appendix One

Our investigative approach

Scope

1 We conducted an investigation into how government used public money to increase the number of ventilators available to the NHS, in response to COVID-19. 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. We focused on:

- The Department of Health & Social Care's (DHSC's) 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.

Methods

- 2 In examining these issues, we drew on a variety of evidence sources.
- We interviewed key individuals from:
 - Cabinet Office and DHSC to establish their: objectives in setting up programmes; governance arrangements; processes that supported decisions on which ventilators to build and buy; and approach to contract and cost assurance.
 - NHSE&I to understand their role, particularly in regard to planning scenarios;
 - the Medicines and Healthcare products Regulatory Agency to understand their regulatory role.
- We engaged with members of the NHS national clinical team to understand their role and to understand the role of ventilators in treating COVID-19. We based our explanation of how ventilators work and their role in treating COVID-19 on information provided by DHSC and members of the NHS national clinical team.

- We invited comments from other stakeholders via our website.
- We reviewed a range of data and documentation relating to the management of the two programmes. These included:
 - documents setting out each programme's strategy, objectives and governance arrangements;
 - records of discussions and analysis concerning which ventilators to support;
 - management information and presentations and other submissions to senior officials and ministers;
 - contracts and contract assurance documentation; and
 - data on payments made to suppliers based on DHSC's and Cabinet Offices' management information. We reviewed the ways in which the data were collated and checked a sample of transactions to other sources including contracts and underlying financial records. We did not conduct a full audit of each transaction or payment, nor did we audit the underlying systems from which this information was drawn as part of this investigation. We were not able to verify the data with every supplier due to time and logistical constraints.

3 We also spoke to a range of other organisations involved in both programmes to understand their role in and perspective on the process, including private sector organisations. We spoke to:

- the Ministry of Defence's Cost Assurance and Analysis Service;
- PA Consulting;
- the Ventilator Challenge UK consortium;
- TTP;
- Swagelok;
- Cambridge Consultants Limited;
- Excalibur Healthcare Services; and
- the Medical Devices Testing and Evaluation Centre (MD-TEC), an independent medical device testing facility engaged in the ventilator challenge as device testing experts.

Appendix Two

Ventilator challenge case study

Figure 8

The Penlon ESO2 ventilator

A consortium of industrial, technology and engineering businesses worked together to produce around 11,700 Penlon ESO2 ventilators as part of the ventilator challenge

What is it?

The Penlon ESO2 is an emergency ventilator developed by Penlon. Its purpose is to "save lives by ventilating the sickest patients until they are strong enough to be transferred to one of the limited number of ICU (Intensive Care Unit) ventilators available for recovery".

Forming the consortium

Following the Prime Minister's 'call to arms' on 16 March, Penlon contacted the Cabinet Office with a proposal to manufacture a simplified version of its existing Prima anaesthesia ventilator.

Penlon is a small specialist firm which usually manufactures around 40-50 machines across its product range per month and it did not have capacity to manufacture enough ventilators itself.

Cabinet Office linked it up with Ventilator Challenge UK, a consortium of industrial, technology and engineering businesses put together by the High Value Manufacturing Catapult, including:

- Ford of Great Britain;
- McLaren F1;
- Airbus;
- STI;
- Siemens Healthineers;
- Ultra;
- Renishaw; and
- Meggitt.

Penlon engaged Deloitte to create and operate an accounting & finance capability for the programme.



The Penlon ESO2 ventilator

Orders and targets

Cabinet Office's technical design authority (TDA, a panel of experts used to assess and shortlist designs) first considered the ESO2 on 20 March 2020.

Cabinet Office placed an initial order for 5,000 ESO2 units on 26 March and a further order for 10,000 units on 29 March. These were contingent on the devices being manufactured to an agreed timescale (no later than week commencing 4 May for the first 5,000 and no later than week commencing 1 June for the remaining 10,000).

On 14 May, in the context of revised government targets for mechanical ventilators introduced in mid-April, Cabinet Office revised its 15,000 order to a minimum of 7,350 and a maximum of 12,696 devices, to be delivered by the end of June.

Manufacturing

The consortium extended production to sites across the consortia, creating various sub-assemblies for different parts of the device. Full assembly was completed by STI and devices were then sent to Penlon for final compliance testing, quality control, packing and shipment.

Securing enough components to manufacture the devices was a major challenge. In its first order on 26 March, Cabinet Office committed to covering the cost of parts for up to 30,000 devices, in case additional devices were needed. Each device needed 582 different components, which equated to around 17.5 million parts. The consortium identified components that were likely to be in critical demand or had long lead times at an early stage, which allowed it to place large orders for components. The consortium told us this helped to get it to the front of the queue with suppliers. The consortium also monitored the supply of components daily to resolve issues.

Delivery

The first Penlon ESO2 devices were dispatched on 13 April following approval from the Medicines and Healthcare products Regulatory Agency (MHRA), with production picking up pace at the beginning of May as more sites were approved for manufacturing. Penlon produced around 11,700 ventilators in total by the end of its last week of production (week commencing 29 June). This equates to over three-quarters (77%) of all machines manufactured as part of the ventilator challenge.

Cost and value recovery

In total Cabinet Office spent around \pounds 116 million excluding VAT on the Penlon ESO2s that were delivered, which equates to \pounds 9,952 per ventilator. This included initial set-up costs, labour and the costs of components that it covered for the consortium.

On 14 May, when Cabinet Office wrote to Penlon revising down its orders, it asked Penlon to cancel orders for the components of the additional 15,000 devices that were no longer needed. Penlon manged to recover around \pounds 11.6 million of the \pounds 23 million spent, which meant Cabinet Office spent an additional \pounds 11.4 million on the cost of components for additional devices that were not manufactured.

Lessons learned and successes

The Penlon Consortium attributes its ability to produce a large number of devices in a short space of time to a number of factors, including: a clear and compelling objective; an expert team with a flat structure; open data and information; process and product in parallel; an efficient system for issue/constraint resolution; a 'will-do' attitude; and a clear reporting structure.

Source: National Audit Office analysis of Cabinet Office documentation and interviews with Medicines and Healthcare products Regulatory Agency, Penlon and the Ventilator Challenge UK consortium

Appendix Three

1 Figures 9 and **10** set out the costs of DHSC's purchase of ventilators and Cabinet Office's ventilator challenge in detail. The tables show payments made to suppliers for ventilators and other products and services, such as logistics. They also show the administration costs of the programmes. At the time of publishing this report the Cabinet Office and DHSC programmes were still in the process of financial close. The final numbers of ventilators and costs may therefore vary slightly from those presented here.

Figure 9

Cost of the Department of Health & Social Care's (DHSC's) programme to buy ventilators

This table shows the cost of ventilators and oxygen therapy devices purchased as part of its 'oxygen, ventilation, medical devices and clinical consumables' programme

Product (type, supplier and product name)		Date of order	Units	Price per ventilator (£)	Payment in advance?	Value (excluding VAT) (£)
Total Spend						292,426,696
Mechanical ventilators (total):			11,141	21,943		244,466,008
Mechanical ventilators from existing NHS suppliers, of which:			4,266	14,603		62,297,308
Intensive care unit ventilators			2,216	19,994		44,306,535
Ortus Medical	VG70	18 March	500	18,990	no	9,495,000
GE Healthcare	R860	12 March	300	22,639	no	6,791,796
Draeger ICU	V800	12 March	300	18,021	no	5,406,348
Hamilton Medical	G5	12 March	200	19,788	no	3,957,682
SLE	Jenny Vent	25 March	100	32,900	no	3,290,000
MaquetGetinge	Servo-i	12 March	115	24,619	no	2,831,164
Braun	Bellavista 1000	12 March	150	17,309	no	2,596,302
MaquetGetinge	Servo-air	12 March	80	17,538	no	1,403,044
Hamilton Medical	C3	30 March	86	15,538	no	1,336,230
Penlon	Prima 465	25 & 26 March	60	18,567	no	1,114,000
Lowenstein Medical	Elisa 600	12 March	50	19,615	no	980,769
Inspiration Healthcare	Flight 60	17 March	50	19,036	no	951,800
Penlon	Prima 465 (with AM)	25 March & 9 April	44	20,755	no	913,200
Braun	Bellavista 1000e	12 March	25	24,906	no	622,661
Hamilton Medical	C6	30 March	25	22,528	no	563,194
MaquetGetinge	Servo-u	12 March	20	25,648	no	512,960
OES Medical	Astra 3 i (with Cygnus vent)	31 March & 8 April	33	15,509	50%	511,785
Aquilant	PB980	12 March & 24 April	22	23,000	no	506,000
Penlon	Prima 320	25 March	26	8,100	no	210,600
Penlon	Prima 450	25 March	15	11,000	no	165,000
Penlon	Prima 320 (Advance)	25 March	15	9,800	no	147,000

Cost of the Department of Health & Social Care's (DHSC's) programme to buy ventilators

Product (type, supplier and product name)		Date of order	Units	Price per ventilator (£)	Payment in advance?	Value (excluding VAT) (£)
Transport ventilators			2,050	8,776		17,990,773
Zoll	Z-Vent	12 March	600	7,967	no	4,780,308
Inspiration Healthcare	Ventway	18 March	350	9,772	no	3,420,200
Philips Respironics	Trilogy 202/EVO	17 & 24 March	500	6,333	no	3,166,725
Ortus Medical	Medumat 2	12 March	150	11,123	no	1,668,450
Draeger	Oxylog 3000 Plus	12 March	150	9,839	no	1,475,809
Medacx	EVE-IN2	12 March	125	11,262	no	1,407,781
Inspiration Healthcare	TV100	12 March	75	16,704	no	1,252,800
Ortus Medical	Meduvent	18 March	100	8,187	no	818,700
Mechanical ventilators from new suppliers, of which:			6,875	26,497		182,168,700
Intensive care unit ventilators			5,879	30,081		176,846,500
Excalibur Healthcare	VG70	4 April	2,700	50,176	yes	135,475,000
Agile Medical (via Guys' and St Thomas' Hospital)	e700		1,000	14,500		14,500,000
Beijing Aeonmed	VG70	18 to 24 March	1,000	8,800	yes	8,800,000
Nanjing Chenwei	CWH3010	29 March	300	17,600	yes	5,280,000
NINHAO International	SH300	3 April	100	48,000	yes	4,800,000
Northern Meditec	Crius V6	21 & 24 March	400	8,820	yes	3,528,000
Beijing Siriusmed	R50 with Compressor	27 March & 9 April	185	12,919	yes	2,390,000
Nanjing SuperStar	S1100A	21 & 24 March	140	7,943	yes	1,112,000
Medic Co	PB760	24 March	30	13,500	yes	405,000
Sinopharm	SV600	14 April & 12 May	15	24,520	yes	367,800
Meheco	SV600	8 April	5	32,000	yes	160,000
Draeger	Evita XL (refurb)	9 March	4	7,175	no	28,700

Cost of the Department of Health & Social Care's (DHSC's) programme to buy ventilators

Product (type, supplier and product name)		Date of order	Units	Price per ventilator (£)	Payment in advance?	Value (excluding VAT) (£)
Transport ventilators			996	5,344		5,322,200
Beijing Aeonmed	Shangrila 510s	17 March	750	2,880	yes	2,160,000
Jointown (Distributer)	Τ7	31 March	100	15,622	yes	1,562,200
Shenzhen Ambulance	Ambulanc T7	29 March	100	8,000	yes	800,000
BioSino	Trilogy 202	1 April	16	32,000	yes	512,000
Meheco	510s Workstation	4 April	30	9,600	yes	288,000
Bilevel ventilators (total):			11,643	1,835		21,368,234
Bilevel ventilators from existing NHS suppliers			11,613	1,720		19,976,234
ResMed	Lumis 150 ST-A	24 March	2,800	2,100	no	5,880,000
Philips/Respironics	Bipap S/T System One	20 March	5,000	1,112	no	5,557,500
ResMed	Lumis 150 ST-A (including iVAPS & AutoEPAP)	17 & 25 March	1,500	2,100	no	3,150,000
Lowenstein Medical	Prismavent50-C	12 March	500	5,400	no	2,700,000
ResMed	Lumis 100 ST	17 March	700	1,400	no	980,000
Breas Medical	Vivo 2	9 March	783	1,250	no	978,750
Breas Medical	Vivo 3	9 March	195	2,300	no	448,500
Philips/Respironics	BiPAP A40 International	9 March	100	2,427	no	242,746
Breas Medical	Vivo 1	9 March	25	1,050	no	26,250
Philips/Respironics	DreamStation S/T	9 March	10	1,249	no	12,488
Bilevel ventilators from new suppliers			30	46,400		1,392,000
Salamanca/U-Safe	Philips Trilogy 100	9 April	30	46,400	50%	1,392,000
CPAP devices			10,000	2,030		20,300,000
University College London	Ventura		10,000	2,030		20,300,000

Cost of the Department of Health & Social Care's (DHSC's) programme to buy ventilators

Product (type, supplier and product name)		Date of order	Units	Price per ventilator (£)	Payment in advance?	Value (excluding VAT) (£)
Oxygen concentrators from existing NHS suppliers			5,588	513		2,866,503
Baywater Healthcare	VisionAire 5	9 March	3,000	505	no	1,515,000
Air Liquide	VisionAire 5	11 March	1,600	453	no	724,800
Baywater Healthcare	Devilbiss 525	9 March	468	505	no	236,340
Baywater Healthcare	Nidek Mark 5 Nuvo	9 March	220	505	no	111,100
Baywater Healthcare	Everflow	9 March	180	505	no	90,900
Philips/Respironics	SimplyGo	11 March	50	1,694	no	84,713
Philips/Respironics	SimplGo Mini	11 March	50	1,593	no	79,650
Baywater Healthcare	Devilbiss 1025	9 March	20	1,200	no	24,000
Programme costs						3,425,952
Resources, of which:						848,917
External						633,932
Deloitte	Support for programme procurement activities					160,000
PA Consulting	Data management, modelling and analysis					195,458
NHS CSU Recharges	Spend across three different CSUs (Commissioning Support Units)					158,793
Other organisations	Spend across a further eight organisations					119,681
Government bodies						214,986
Opportunity cost of staff	Cost of resources from five different government bodies (not actually paid for)					214,986

Cost of the Department of Health & Social Care's (DHSC's) programme to buy ventilators

Product (type, supplier and product name)		Date of order	Units	Price per ventilator (£)	Payment in advance?	Value (excluding VAT) (£)
Operational costs, of which:						2,577,035
Storage and logistical costs						1,877,719
Ministry of Defence	Primary storage and logistics provider, including operational distribution					600,000
CEVA	Storage and logistics					629,943
DHL	Storage and logistics					261,799
Other organisations	Spend across 3 further organisations					385,978
Other						699,316
Exchange rate	Costs to the programme of adverse exchange rate movements between currency transfers					649,097
Dedicated logistical costs	Cost to the programme of product specific logistical activities outside of broader government logistics provisions					16,000
Other	Includes specific due diligence activities					34,220

Notes

- 1 Unit costs for separate purchases of VG70 devices prices are not directly comparable as DHSC told us that: some devices are standard UK specification while some required modification to UK specification after purchase; some devices included delivery and others did not; support and warranty arrangements vary between devices. However, DHSC considers that the most significant impact on price was the date of order with prices rising significant over March and April due to limited availability (see Part 3).
- 2 DHSC considers that the Philips Trilogy 100 is not directly comparable to other bi level devices as it has some capabilities normally associated with mechanical ventilation devices.
- 3 £20,300,000 is the maximum cost of Ventura devices under the contract; at the time of writing the final cost was not confirmed.
- 4 Data are based on DHSC management information as at the end of August. We have not checked the details of the information provided with suppliers or manufacturers.
- 5 In some cases the final numbers of ventilators delivered may vary slightly, depending on revisions to the numbers acquired though the various contracts. At the time of writing the programme is still in the process of financial close.

Source: National Audit Office analysis of Department of Health & Social Care's financial data

Figure 10

Costs of Cabinet Office's ventilator challenge

This table shows the cost of ventilators purchased by Cabinet Office under the ventilator challenge

Product (type, supplier and product name)		Units	Estimated Cost per unit (£)	Estimated cost at point of cessation (£)	Estimated value recovered (£)	Current estimated total exposure exc VAT* (£)
Total costs						277,048,526
Manufactured devices						149,992,331
Penlon	ES02	11,662	9,952			116,062,377
Smiths	Parapac 300	988	24,352			24,059,541
Breas Medical	Nippy 4+ and Vivo 65	2,000	4,039			8,077,039
Smiths	Parapac 310	504	3,558			1,793,373
Ceased devices				122,974,594	36,178,896	86,795,698
Babcock	Zephyr+			30,000,000	0	30,000,000
Penlon	Additional ES02s			22,966,550	11,580,462	11,386,088
Cogent	Eva			26,088,840	13,181,782	12,907,058
Plexus	Helix			16,549,724	5,364,291	11,185,433
Smith & Nephew	Oxvent			7,935,242	1,326,591	6,608,651
BAE Systems	AirCare			5,861,745	507,881	5,353,864
Olympus	BlueSky			8,238,652	3,649,304	4,589,348
Sagentia	Mosquito			3,152,607	187,805	2,964,802
OES Medical Ltd	Gemini			1,089,109	380,781	708,328
Swagelok	PiranVent			677,382	0	677,382
JFD	InVicto			237,135	0	237,135
Plexus	Veloci-Vent			137,109	0	137,109
Vobster Marine Systems Ltd	SOG			40,499	0	40,499

Figure 10 *continued* Costs of Cabinet Office's ventilator challenge

Product (type, supplier and product name)		Units	Estimated Cost per unit (£)	Estimated cost at point of cessation (£)	Estimated value recovered (£)	Current estimated total exposure exc VAT* (£)
Product designers						23,187,853
Cambridge Consultants Ltd	Veloci-Vent					9,291,491
TTP	CoVent					6,552,600
Sagentia	Mosquito					3,518,282
TEAM Consulting	Eva					2,594,592
Formula One Research Engineering & Development Ltd	BlueSky					1,099,663
Darwood IP Ltd	BlueSky					66,224
Marshall Airway Products Ltd	BlueSky					65,000
Early design work						2,766,221
Unipart						715,097
PA Consulting						480,122
Ford Motor Company Ltd						342,172
Mercedes AMG High Performance Powertrains Ltd						206,837
GKN Aerospace Services Ltd						185,605
McLaren Racing Ltd						148,694
Oxford Optronix Ltd						137,100
Meggitt Aerospace Ltd						130,868
Thales UK Ltd						73,472
Penlon						65,982
Siemens						61,877

Figure 10 *continued* Costs of Cabinet Office's ventilator challenge

Product (type, supplier and product name)		Units	Estimated Cost per unit (£)	Estimated cost at point of cessation (£)	Estimated value recovered (£)	Current estimated total exposure exc VAT* (£)
Airbus Operations Ltd						46,290
Diamedica UK Ltd						44,640
Ultramedic Ltd						44,450
Renishaw UK Sales Ltd						38,027
Norvap International Ltd						31,200
Narked at Ninety Ltd						13,788
Programme costs						14,306,424
PA Consulting	Programme management including project management, supply chain management and manufacturing support					11,850,000
Guardian Services	Resale and disposal of surplus components					1,280,000
Various	Legal support					575,000
n/a	Contingency costs to cover uncertainties including the transfer of the programme to DHSC					250,000
Inspiration Healthcare Ltd	24/7 ventilator helpline					201,000
Olivers Transport Ltd	Storage					12,000
British Standards Institution	Quality control					66,547
Medical Devices Testing and Evaluation Centre (MD-TEC)	Ventilator Testing					61,418

Figure 10 *continued* Costs of Cabinet Office's ventilator challenge

Product (type, supplier and product name)		Units	Estimated Cost per unit (£)	Estimated cost at point of cessation (£)	Estimated value recovered (£)	Current estimated total exposure exc VAT* (£)
Complex Transactions Team	Programme resources					120,000
An individual contractor	Programme resources					29,585
Government Actuary's Department (GAD)	Indemnities review					3,486
Resale income	Income from parts sold after programmes were closed down					(142,612)

Notes

1 Estimated costs are based on Cabinet Office management information as at 21 September. Current total costs are estimates based on underlying assumptions and are subject to change as Cabinet Office continues its 'wind down' activity with participants to sell or dispose of components on the open market. Cabinet Office also notes a risk that there may be some additional suppliers not currently captured in the estimates, for example, those involved in early design work.

2 Estimated costs per unit are based on Cabinet Office management information and include all costs we could clearly attribute to each device. As such they may not match contracted costs per unit. We have not checked the details of the information provided with manufacturers or suppliers.

Source: National Audit Office analysis of Cabinet Office management and financial data

This report has been printed on Pro Digital Silk and contains material sourced from responsibly managed and sustainable forests certified in accordance with the FSC (Forest Stewardship Council).

The wood pulp is totally recyclable and acid-free. Our printers also have full ISO 14001 environmental accreditation, which ensures that they have effective procedures in place to manage waste and practices that may affect the environment.



Design and Production by NAO External Relations DP Ref: 009204-001



£10.00