



National Audit Office

Report

by the Comptroller
and Auditor General

**Department for Business, Energy & Industrial Strategy,
Department of Health & Social Care, NHS England and
NHS Improvement, and Public Health England**

Investigation into preparations for potential COVID-19 vaccines

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NHS Improvement, and Public Health England

Investigation into preparations for potential COVID-19 vaccines

Report by the Comptroller and Auditor General

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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

14 December 2020

This is our first report on the preparations for COVID-19 vaccines and covers the period from April to 8 December 2020. It examines government's progress in securing potential vaccines and determining how they will be deployed to the public.

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.

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This report can be found on the
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Key facts

£2.9bn

total expected cost of contracts signed to date for potential COVID-19 vaccines

267m

number of potential COVID-19 vaccine doses secured by the UK government's signed contracts

25m

NHS England and NHS Improvement's (NHSE&I) estimate of the number of people in England who could be vaccinated in 2021 if, and when, sufficient vaccine becomes available

£11.7 billion

total expected investment required from government to purchase and manufacture COVID-19 vaccines for the UK, deploy them in England and support global efforts to find vaccines

£6.2 billion

total expected investment by the Department for Business, Energy & Industrial Strategy up to 2022-23

£4.9 billion

total expected investment by the Department of Health & Social Care up to April 2021

£619 million

total expected investment by government in global efforts to find a vaccine

Five

number of different vaccines secured by government

46,000

number of staff that may be needed to support the deployment of the vaccines based on NHSE&I's understanding in September 2020

Three

number of new delivery models NHS England and NHS Improvement are working on to deploy different COVID-19 vaccines in England

Summary

Introduction

1 Since the first cases of COVID-19 in the UK in January 2020, the impact on society and the economy has been significant. Government’s overall objective since May has been “to return to life as close to normal as possible, for as many people as possible, as fast and fairly as possible”.¹ A vaccination programme plays a central role in achieving this objective. The UK government, like those in many other countries, has worked to support the development of, and to secure access to, any potential vaccine against COVID-19. On 2 December 2020, the first vaccine for use in the UK was approved by the regulator and deployment began on 8 December.

2 The Department for Business, Energy & Industrial Strategy (BEIS) is responsible for securing the supply of vaccine for the UK, which includes: supporting the research and development of potential vaccines; selecting which vaccines to purchase; securing UK access to sufficient quantities of vaccines; and developing manufacturing capacity to ensure supply. A Vaccine Taskforce (the Taskforce) was created in April 2020 to deliver these responsibilities on behalf of BEIS. BEIS must also work closely with pharmaceutical companies, upon whom it is reliant to develop potential vaccines.

3 The Department of Health & Social Care (DHSC) is responsible for planning how to deploy the vaccine to the public in England. NHS England and NHS Improvement (NHSE&I) and Public Health England are leading on the operational delivery of the vaccination programme including designing and implementing delivery models and making storage and distribution arrangements respectively. Vaccines will be bought for the UK, Crown Dependencies and Overseas Territories. Northern Ireland, Scotland, Wales, Crown Dependencies and Overseas Territories are each responsible for deploying the vaccine to their own populations.

4 Government recognises that it “must compress the time taken to develop, test, manufacture and distribute a reliable vaccine or treatments as far as possible”.² Extremely high global demand, coupled with the scarcity of vaccine resources, has put added pressures on government to make fast-paced decisions to secure access to potential vaccines, and to build the capacity to manufacture and deploy them in a timely manner.

¹ Our plan to rebuild: The UK Government’s COVID-19 recovery strategy; May 2020. The guidance was updated in July 2020.

² See footnote 1.

5 At the outset of this programme, government could not know for certain if or when a vaccine against COVID-19 would be developed. The approval of the first COVID-19 vaccine for use in the UK on 2 December has given government more certainty and confidence. New potential vaccines continue to be developed, and the effectiveness of these continue to be tested, meaning government is still working with uncertainty across its programme. As a result, it remains likely that changes to plans will be needed, particularly for NHSE&I who must continually review its deployment plans to ensure it can respond to the latest information about which vaccines have been approved, which groups in society need to be vaccinated, how many doses of vaccines will be available and when and how those vaccines need to be deployed.

Scope of this report

6 This is our first report on the preparations for COVID-19 vaccines and covers the period from April to 8 December 2020. It examines government's progress in securing potential vaccines and determining how they will be deployed to the public. We undertook this review in real-time while government has been making decisions and responding to various challenges. Our aim is to provide Parliament and the public with an independent account of the challenges facing government at this stage and how they are being addressed. This report covers:

- government's approach to identifying potential vaccines (Part One);
- government's progress to date (Part Two);
- how government is organising itself to work at pace (Part Three); and
- challenges government needs to manage as it deploys the vaccine (Part Four).

7 BEIS's work to purchase vaccines and secure manufacturing capability is ongoing as potential vaccines continue to go through clinical trials and it understands more about the vaccines it has already purchased and other potential vaccines in development. As a result, BEIS is continuing to negotiate with pharmaceutical companies on a range of contracts. This report does not set out the individual price of contracts that have been agreed to date as we accept BEIS's view that this would have a detrimental impact on its ongoing negotiations. In the interests of public transparency, the report does set out the overall value of vaccine contract commitments and examines the different terms and conditions that have been agreed to help readers understand the risks associated with taxpayers' investment.

8 The report sets out the range of actions taken by government to date to secure and manufacture vaccines in the UK and deploy vaccines in England, and the associated costs, but not the value for money of these decisions. It does not examine deployment activities in Northern Ireland, Scotland, Wales, the Crown Dependencies or Overseas Territories. It does not examine the safety or clinical efficacy of any of the vaccines approved or in development. Details on our audit approach, our evidence base and its limitations are available in Appendix One.

Key findings

9 Government has had to work at pace and, until recently, without any certainty that an effective vaccine would be found. Vaccine development typically takes a minimum of 10 years. BEIS has been working to an accelerated timetable to make a vaccine available within 12-18 months. To make progress at the speed required, BEIS is necessarily making funding decisions based on information that is constantly changing. BEIS and DHSC have committed taxpayers' money to: secure access to potential vaccines; develop manufacturing capability; and to develop plans to administer a vaccine. In June, BEIS estimated the likelihood of a successful vaccine being developed, delivered on schedule, and successfully being deployed within the UK to be between 26% and 77%. On 2 December 2020 a vaccine produced by Pfizer Inc and BioNTech SE was approved as safe and effective. Deployment of this vaccine in England subsequently began on 8 December (paragraph 1.4).

10 BEIS has chosen to purchase several different types of vaccines recognising the uncertainty over which ones will be approved as safe and effective. BEIS decided to purchase different types of vaccines from different pharmaceutical companies to create a diverse set of options. In April 2020, BEIS identified there were around 190 vaccines in development globally. A short-list of 23 potential vaccines was created based on whether: the potential vaccine would begin clinical trials in 2020; the type of immune response the vaccine may provide; and the likelihood the pharmaceutical company could deliver what it was promising. Of these 23 potential vaccines, the Taskforce prioritised starting due diligence checks on 12. Due diligence reports assessed data on clinical trials and plans for manufacturing at scale. The reports did not use a common quantitative scoring mechanism, making it more difficult to compare how each vaccine was selected. Officials have told us that this was because ministers took decisions on a rolling basis as information became available, and it was not possible to compare different vaccine types against each other in real time. Based on the due diligence checks, BEIS started commercial negotiations with six companies and continued discussions with others (paragraphs 1.5 and 1.6).

11 The total cost to the taxpayer of purchasing and deploying the vaccines is uncertain. Based on its current understanding, government expects the total cost of its plans to secure and manufacture vaccines for the UK, deploy vaccines in England and contribute to global efforts to find vaccines to be up to £11.7 billion. These costs are likely to change as BEIS and DHSC obtain a clearer understanding through clinical trials as to how the vaccines are developing, what is required to manufacture them and how the vaccines need to be administered. This does not cover the costs of any future potential multi-year vaccination programmes. Total expected investments currently include:

- £6.2 billion to support BEIS's procurement and manufacturing activities;
- £4.9 billion to support DHSC's deployment activities in England; and
- up to £0.6 billion to support global efforts to find a vaccine (paragraph 1.7)

12 BEIS and DHSC have made several iterative funding requests to HM Treasury as their understanding of what is required has developed.

As part of the Spending Review in November 2020, BEIS revised the amount of funding required for the Taskforce's activities to £6.1 billion. BEIS also allocated £99 million to support manufacturing capability, which is separate from the Spending Review approval, meaning BEIS's total expected investment is £6.2 billion. This represents an increase from the £5.2 billion set out in its June 2020 business case. This increase reflects BEIS's improved understanding of the likely costs, requirements and benefits of finding a safe and effective vaccine. DHSC requested £4.8 billion as part of its revised business case in late November 2020. It also allocated £51 million for early clinical trials, bringing its expected total to £4.9 billion. This represents a decrease in the estimated costs from the £5.1 billion DHSC requested in September 2020. DHSC funding has not been fully approved by HM Treasury yet. DHSC requested some funding to be expedited to enable it to develop the technology and communications needed to deploy the vaccine and to support the seasonal flu vaccination programme. HM Treasury approved £180 million for technology and public communications in September and approved a further £476 million in November to cover the expected costs of deployment in 2020 (paragraphs 1.8, 1.11 and 1.12).

13 Government has invested up to £619 million in global efforts to find a vaccine, for both UK and international supply. The government has joined COVAX, which acts as an international platform to accelerate the global development, manufacture and equitable distribution of COVID-19 vaccines. In addition, it enables the UK to access other potential vaccines it has chosen not to purchase directly should it need them. The UK has invested £71 million to secure its access to the nine vaccines in the proposed COVAX portfolio. It has also provided up to £548 million of its international development aid budget to provide access to the vaccines for low- to middle-income countries. COVAX has committed to providing all participating countries, regardless of income, sufficient doses to vaccinate up to 20% of their populations (paragraph 1.13).

Government's progress to date

14 BEIS has had to pay more than originally anticipated to purchase potential vaccines. BEIS originally estimated that it would spend up to £294 million on each vaccine, including contingency and VAT, but recognised that costs would vary case by case. BEIS originally expected to pursue up to 12 different vaccines (with the option to pursue two more if required) but reduced this to up to nine different vaccines in early November based on its improved understanding of how well different vaccines are developing (paragraph 1.10).

15 BEIS has signed contracts with five pharmaceutical companies, providing access to 267 million potential doses at an expected cost of £2.9 billion.

Contracts are in place for the vaccines being developed by:

- Astra Zeneca UK Limited and the University of Oxford for 100 million doses, signed in August 2020;
- Valneva SE for 60 million doses, signed in September 2020;
- Pfizer Inc and BioNTech SE for 40 million doses, signed in October 2020;
- Novavax Inc for 60 million doses, signed in October 2020; and
- Moderna Inc for 7 million doses, signed in November 2020 (**Figure 1**).

Non-binding agreements that form the basis of formal contracts are also in place with the Sanofi S.A. and GlaxoSmithKline Biologicals S.A. partnership and Janssen Pharmaceutica NV, which BEIS expects to advance to agreed contracts. Like the contracts already in place, these two contracts are expected to be agreed with different terms and conditions. In total, these seven deals could provide 357 million doses of different vaccines to the UK at an anticipated cost of £3.7 billion (paragraphs 2.2 and 2.3, and Figure 1).

Figure 1

Potential vaccines secured as at 8 December 2020

The government has signed five contracts for potential COVID-19 vaccines

Vaccine developed by	Number of doses purchased (m)	Date contract signed
Astra Zeneca UK Limited and the University of Oxford	100	Contract signed in August 2020.
Valneva SE	60	Contract signed in September 2020.
Pfizer Inc and BioNTech SE	40	Contract signed in October 2020.
Novavax Inc	60	Contract signed in October 2020.
Moderna Inc	7	Contract signed in November 2020.
Total	267	

Source: National Audit Office analysis of Department for Business, Energy & Industrial Strategy data

16 Given the context that BEIS was negotiating contracts in, it has had to invest some money that may have to be written off if some of the vaccines purchased are not approved by the regulator. BEIS has agreed upfront payments of £914 million in the five contracts it signed up to 8 December 2020, prior to any vaccine being approved by the regulator. These payments have been used to start manufacturing and to support clinical trials. In all contracts, the payment will be used against future purchases of the vaccine if it is approved by the regulator. Only one of the contracts BEIS has signed provides for the full upfront payment to be refunded should the vaccine fail to achieve regulatory approval. Two other contracts contain provisions for BEIS to recover some of the upfront payments if the contract is terminated, but for the remaining two contracts the upfront payments are non-refundable (paragraphs 2.4 to 2.6).

17 The taxpayer may incur additional costs in future because the contracts each contain some form of indemnity protection for the pharmaceutical companies in the event of liabilities or legal action arising from any adverse effects that might result from the vaccines. In four out of the five contracts agreed so far, no cap has been applied to the amount that government could pay in the event of a successful claim against the pharmaceutical companies (paragraphs 2.8 and 2.9).

18 In November 2020, BEIS calculated it needed £519 million to provide manufacturing capacity for vaccines within the UK. The value of its commitments changed as it continued to learn more about what was likely to be required. BEIS had committed £302 million by 8 December 2020 including:

- £127 million to purchase, convert and run a Cell and Gene Therapy Catapult Manufacturing Innovation Centre to start vaccine production in June 2021;
- £93 million to accelerate the completion and expand the role of the Vaccine Manufacturing Innovation Centre (VMIC) where two vaccines against COVID-19 could be mass produced. This project was originally due to be completed in summer 2022 but BEIS now expects VMIC to start operating by the end of 2021 and be fully operational in the first quarter of 2022;
- £42 million to put up to two different vaccines into vials so they can be delivered to vaccination sites from August 2020 for 18 months. This process is referred to as 'fill and finish';
- £31 million to support skills development and early manufacturing of the vaccines developed by the University of Oxford and Imperial College London; and
- £9 million which BEIS told us is being used to train staff from VMIC and to purchase manufacturing equipment (paragraphs 2.10 to 2.14).

How government is organising itself to work at pace

19 Government set up the Taskforce to drive forward, expedite and co-ordinate its efforts to research and then produce vaccines as it was concerned that the civil service did not have all the necessary knowledge to secure access to vaccines quickly.

The chair of the Taskforce was appointed in May 2020 and reports directly to the Prime Minister. The chair of the Taskforce sets the overall direction and strategy for how vaccines and manufacturing capability will be secured. The chair of the Taskforce is not accountable to BEIS or DHSC. The senior responsible owner for the Taskforce is responsible for the Taskforce's performance and reports to the BEIS accounting officer. The specifics of the senior responsible owner's responsibilities were agreed in November 2020. The Taskforce has an expected running cost of £91 million up to 2022-23. Recruitment to the Taskforce has been carried out from a number of sources and includes civil servants, contractors and industry specialists. The Taskforce currently consists of 201.7 full-time equivalent staff, of which 79.9 full-time equivalent staff were recruited into the Taskforce from outside the civil service (paragraphs 3.1, 3.3, 3.4, 3.5, 3.11 and 3.12).

20 BEIS, HM Treasury and Cabinet Office have made changes to how investments are approved to make faster decisions and increase the chances of purchasing vaccines.

Investment proposals are still required to be supported by a full business case with a full accounting officer assessment. To speed up the process, HM Treasury increased BEIS's spending limit from £70 million to £150 million per individual investment and Cabinet Office increased BEIS's delegation level on commercial purchases from £10 million to £50 million. To support the pace of investment decisions that the Taskforce wanted to make, BEIS reduced the time investment decisions would normally take, something BEIS also introduced for EU Exit projects. Investment decisions valued at more than £150 million are still required to go through the existing BEIS approvals group, the Projects and Investments Committee, but the time taken to make investment decisions has been reduced from four weeks to seven to nine days for the Taskforce's proposals (paragraphs 3.8, 3.9 and Figure 5).

21 New structures to bring together ministers to approve expenditure have been created to speed up the process.

Investments valued at more than £150 million, including the vaccine contracts, are reviewed by a new Ministerial Panel consisting of the Secretaries of State for Business, Energy and Industrial Strategy, Health and Social Care, the Chief Secretary to the Treasury and the Minister of State for Efficiency and Transformation for the Cabinet Office. By 8 December the Ministerial Panel had met six times and approved all contracts for potential vaccines. The Ministerial Panel does not replace the BEIS Projects and Investments Committee. All investment decisions valued at less than £150 million are now considered by a new Investment Panel, instead of the Projects and Investments Committee, made up of senior officials from across the centre of government (paragraphs 3.9, 3.10 and Figure 5).

22 The Taskforce's decisions influence how vaccines are deployed but prior to September 2020 the organisations with the most operational experience were not always directly involved in the Taskforce's decision-making groups. Following changes made within the Taskforce in June 2020, Public Health England raised concerns that operational experience of vaccine deployment was not always represented on the senior boards and groups of the Taskforce. Although NHSE&I has told us that it was regularly consulted and provided input to the Taskforce, it was not until September 2020 that Public Health England and NHSE&I had regular senior representation at the Programme Board (paragraph 3.14).

23 In September 2020, the Secretary of State for Health and Social Care revised the governance for deployment activities and appointed a single senior responsible officer for deployment from within NHSE&I. The aim was to create a unified programme with streamlined responsibilities and greater cross-departmental working to reduce duplication and provide greater clarity of accountabilities and transparency. By August 2020, DHSC, NHSE&I and Public Health England had each set up its own deployment board. In September a new Deployment Programme Board was established to assure delivery and provide cross-government oversight. It is jointly chaired by the senior responsible officer for deployment in NHSE&I and the deployment workstream lead within BEIS. NHSE&I is responsible for the operational delivery of the deployment programme in England. From September 2020 onwards, NHSE&I and Public Health England have been represented by the senior responsible officer for deployment at Taskforce meetings. In November 2020 a Minister for COVID-19 Vaccine Deployment was appointed to oversee the deployment of the vaccine in England (paragraphs 3.15 to 3.17 and Figure 7).

Challenges government needs to manage as it deploys the vaccine

24 NHSE&I is currently planning on the assumption that 75% of people who are offered the vaccine will take it. Public trust in the vaccine will ultimately determine the number of people who choose to have the vaccine. DHSC is responsible for developing communications with the public around the vaccination programme. In 2019-20 the long-established seasonal flu vaccination programme had a take-up rate of 72% among those aged 65 years and older, and up to 45% for those aged 64 years or younger. In June 2020, Public Health England emphasised the need for attitudinal research to inform the communications strategy, but in August 2020 it reported that this research would not be completed in time for the first vaccinations, which at that time were expected in September 2020. DHSC has told us it is continuing to work on the public perception of COVID-19 vaccines including understanding changes in people's intentions to receive the vaccine, but it is not clear how this is being used to inform its communications strategy and assumptions on take-up rates among all parts of society (paragraphs 4.2 and 4.3).

25 Each potential vaccine will require different plans for deploying it to the public because each vaccine has different characteristics that NHSE&I has had to plan for. These characteristics include: the storage temperature; shelf-life once open; and any preparatory work needed before administration. BEIS has shared the information it has about the characteristics of each potential vaccine with NHSE&I, but characteristics are still uncertain and subject to change as clinical trials continue for some vaccines. NHSE&I needs to plan for all possible options of those vaccines purchased, until it has certainty. The current understanding of the characteristics of the approved vaccine developed by Pfizer Inc and BioNTech SE includes: the need for the vaccine to be stored in ultra-low cold storage conditions (between -80°C and -60°C); very large quantities (975 doses per pack) with each pack viable for five days once thawed provided it is stored between 2°C to 8°C; and a need to dilute the vaccine before it can be administered (paragraphs 4.4 to 4.7).

26 NHSE&I has developed three new delivery models that take account of different groups and different regional needs. NHSE&I has concluded that it is not possible to deliver both the COVID-19 and seasonal flu vaccination programmes solely through existing arrangements such as GP practices and community pharmacies. It has developed models which include offering vaccinations at large sites such as sports stadiums; mobile sites similar to polling stations; and roving units to take the vaccine to particular locations such as care homes. Each region must choose the delivery models that best suit its local conditions. NHSE&I is inviting individuals for a vaccination through a combination of letters, emails, texts and phone calls. NHSE&I and Public Health England will keep a record of their vaccinations to support on-going monitoring of vaccine safety (paragraphs 4.8, 4.11 and Figure 8).

27 The COVID-19 vaccination programme is one of several significant demands on NHSE&I and Public Health England's resources. Government has had to plan the deployment of a vaccine in advance of any being approved by the regulator. Deployment began on 8 December 2020. In addition to 17 existing vaccination programmes delivered with support from Public Health England, the challenges posed by a second wave of COVID-19, and expected winter pressures (increased demand for services due to cold weather and the onset of flu), NHSE&I is also delivering an expanded flu vaccination programme to up to 29.5 million people in 2020-21. This almost doubles the number of people vaccinated against the flu in 2019-20 (15.4 million). DHSC does not consider this additional workload to have increased the risk to deployment activities but recognises that staffing concerns could create a "bottleneck" (paragraphs 4.1, 4.8 and 4.10).

28 NHSE&I is planning deployment activities with high levels of uncertainty because information about the COVID-19 vaccines is constantly changing.

This means NHSE&I has to continually keep its deployment plans under review to ensure it can respond to the latest information about which vaccines have been approved, how many doses will be available and when, which groups in society can be vaccinated, and how those vaccines need to be deployed. In September 2020, NHSE&I calculated that the volume of vaccinations being planned for across the COVID-19 and flu programmes could increase its vaccination workload by 740%. This was based on the number of people expected to be vaccinated as part of the expanded seasonal flu programme in 2020-21 and the assumption that every adult in England will require two doses of a COVID-19 vaccine. At that time NHSE&I calculated that it may need up to 46,000 staff consisting of 26,000 vaccinators and 20,000 administrative staff to deliver the COVID-19 vaccination programme based on a 75% take-up rate. NHSE&I is continuing to review and update its assumptions about how many staff will be needed to support COVID-19 vaccinations in 2021. The recruitment of staff is taking place at a time when there are already workforce shortages and concerns about the well-being of existing staff due to their efforts responding to the pandemic (paragraph 4.13).

29 NHSE&I is currently planning on the assumption that up to 25 million people could be vaccinated against COVID-19 in England throughout 2021 provided sufficient doses of vaccine are available. Current understanding of the majority of vaccines is that each person will require two doses approximately four weeks apart for it to be effective. This equates to up to 50 million vaccinations for COVID-19 alone. When combined with the expanded flu programme this increases to up to 79.5 million vaccinations in 2020 and 2021 based on current assumptions as at 8 December, an increase of 64.1 million compared with 2019-20 (paragraph 4.14).

Part One

Government's approach to identifying potential vaccines

1.1 The Department for Business, Energy & Industrial Strategy (BEIS) is accountable to Parliament for securing COVID-19 vaccine supply for the UK, including selecting and buying potential vaccines and developing manufacturing capability.³ A Vaccine Taskforce (the Taskforce) was created in April 2020 to deliver these responsibilities on behalf of BEIS. The Taskforce includes individuals from the pharmaceutical industry, academics and civil servants who are working together to achieve government's aim to "compress the time taken to develop, test, manufacture and distribute a reliable vaccine or treatments as far as possible".⁴

1.2 The Department of Health & Social Care (DHSC) is accountable to Parliament for the deployment of the vaccine to the public in England. DHSC is responsible for setting the policy for deployment activities, which has had to be done in advance of a vaccine being approved, including developing legislation that sets out which clinical staff can administer the vaccine. The decision about who will be vaccinated was taken by the Secretary of State for Health and Social Care, as is the case with all vaccination programmes. This decision was based on advice from the Joint Committee on Vaccination and Immunisation, an independent group of experts who look at a range of factors including a vaccine's effectiveness and safety among different ages and ethnicities.

1.3 NHS England and NHS Improvement (NHSE&I) is responsible for the operational delivery of deployment activities, supported by Public Health England. NHSE&I is responsible for developing delivery models, readying vaccination sites, ensuring there are sufficient clinical and support staff available, developing an IT system to identify those who are eligible for a vaccine and inviting them to attend an appointment. Public Health England is responsible for taking delivery of the vaccine from manufacturers, storing it safely and distributing it, along with related materials such as gloves and aprons, to vaccination sites. It is also responsible for training clinical staff to administer the vaccine and future monitoring and surveillance of those who are vaccinated. NHSE&I and Public Health England have significant experience in this area as they are responsible for procurement and deployment activities for the 17 other vaccine programmes currently operating in England.

³ Throughout this report references to the purchase of vaccines for the UK includes the Crown Dependencies and Overseas Territories.

⁴ Our plan to rebuild: The UK Government's COVID-19 recovery strategy; May 2020. The guidance was updated in July 2020.

1.4 Government has had to work at pace and, until recently, without any certainty that an effective vaccine would be found. In June 2020, BEIS estimated the likelihood of a successful vaccine being developed, delivered on schedule, and successfully deployed within the UK at between 26% and 77%. On 2 December 2020 a vaccine produced by Pfizer Inc and BioNTech SE was approved by the regulator. Deployment of this vaccine subsequently began on 8 December. Developing any vaccine and delivering it to the public typically takes at least 10 years and involves several steps from research and development through to mass-manufacturing. BEIS has been working to an accelerated timetable to make a vaccine available within 12-18 months. The various steps involve multiple organisations, such as academics and pharmaceutical companies, who conduct research into potential vaccines; regulators who assess a vaccine to ensure it is safe and effective for the public; private sector manufacturers who produce vaccines and related items such as glass vials; logistical firms who provide storage and transportation; and organisations such as NHS regional teams who administer the vaccine (**Figure 2**). To make progress at the speed required, BEIS has necessarily made funding decisions based on information that is constantly changing. BEIS and DHSC have committed taxpayers' money to: secure access to potential vaccines; develop manufacturing processes; and to develop plans to deploy a vaccine.

1.5 To mitigate against the risk that one or more of the vaccines in development is not approved as safe and effective, BEIS has decided to purchase different types of vaccines from different pharmaceutical companies to give itself a diverse set of options. In June 2020, BEIS's business case for funding set out that it intended to purchase 12 vaccines with the option to add two more if required. In April 2020, BEIS identified that there were around 190 potential vaccines in development globally. In order to focus its efforts, BEIS discounted any vaccine that would not be able to start clinical trials in 2020 to help achieve its objective of delivering a vaccine as quickly as possible. This reduced its list of potential candidates to around 50. It then reviewed this list to understand the likely impact of each potential vaccine on a person's immune system based on the clinical evidence available, for example whether it would offer immunity or reduce symptoms; the type of immune response required; and an assessment of whether the pharmaceutical company could deliver what it had promised. This reduced its short-list to 23 potential vaccines.

Figure 2

The vaccine development process

Vaccine development involves multiple stages and organisations**Typical vaccine development process**

Pharmaceutical companies, academics, governments and non-governmental organisations research and develop potential vaccines.

The regulator assesses the safety, efficacy and quality of the new vaccine.

Public Health England conduct procurement activities after a vaccine has received regulatory approval.

Pharmaceutical companies and other private sector organisations manufacture approved vaccines.

NHS England and NHS Improvement (NHSE&I) make decisions about delivery models. It also makes provision for an IT system to record who has been vaccinated, and when, to ensure repeat doses are actioned if necessary.

Public Health England plans how it will accept delivery of vaccines from manufacturers, distribute onwards to administration sites, or store any excess after vaccines have been approved.

NHSE&I commissions vaccination services from a range of groups licensed to offer vaccinations including GP practices, schools and occupational health providers amongst others.

COVID-19 vaccine development process

Pharmaceutical companies, academics, governments and non-governmental organisations research and develop potential vaccines.

On 2 December 2020 the Medicines and Healthcare Products Regulatory Agency (MHRA) approved a new COVID-19 vaccine for temporary supply.

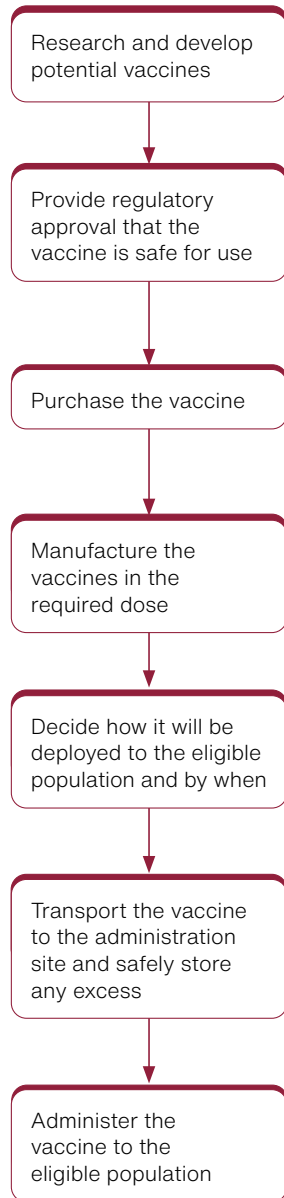
The Department for Business, Energy & Industrial Strategy (BEIS) signed contracts for five potential vaccines ahead of any receiving regulatory approval.

Pharmaceutical companies and other private sector organisations have been manufacturing vaccines at risk with the support of government.

NHSE&I has put in place several delivery models to deploy COVID-19 vaccines. It has also developed an IT system to invite people for vaccination and monitor vaccine safety.

Public Health England has accepted delivery of the vaccines from manufacturers and distributed the vaccine onwards for administration.

The Department of Health & Social Care (DHSC) has expanded the list of people that can offer vaccinations. NHSE&I continues to develop workforce plans that include existing NHS staff, retired staff and occupational health providers.

**Note**

- 1 In the typical vaccine development process these stages usually occur sequentially. However, for COVID-19 vaccines, given the pace at which many are being developed, some of these processes run simultaneously or overlap.

Source: National Audit Office analysis of Department for Business, Energy & Industrial Strategy and Department of Health & Social Care data

1.6 BEIS prioritised due diligence assessments on 12 of these 23 potential vaccines. The due diligence reports assessed data from pre-clinical and clinical trials and proposals for manufacturing the potential vaccine at scale. BEIS conducted a qualitative assessment of each vaccine, but did not use a common quantitative scoring mechanism, making it more difficult to compare how each vaccine was selected. Officials have told us that this was because ministers took decisions on a rolling basis as information became available, and it was not possible to compare different vaccine types against each other in real-time. The due diligence process also required BEIS to request pharmaceutical company data, which some companies responded to more quickly than others and in a minority of cases no response was received. Based on the due diligence checks, BEIS started commercial negotiations with six companies and continued discussions with others.

Estimated costs of the COVID-19 vaccine programme

1.7 The total cost to the taxpayer of purchasing vaccines, manufacturing and deploying them to the public is uncertain and costs are changing as BEIS and DHSC obtain a clearer understanding of how the vaccines are developing, what is required to manufacture them and how the vaccines need to be deployed. Based on current planning, the total cost to the taxpayer is expected to be up to £11.7 billion. This does not cover the costs of any future potential multi-year vaccination programmes. The £11.7 billion is made up of:

- £6.2 billion to support BEIS's activities to purchase vaccines and develop manufacturing capability for the UK;
- £4.9 billion to support DHSC's activities to deploy vaccines in England; and
- up to £0.6 billion to support global efforts to find a vaccine (**Figure 3** on page 20 to 21).⁵

⁵ Totals may not sum due to rounding.

1.8 BEIS's funding requests to HM Treasury have been iterative to reflect its ongoing learning and improved understanding of the vaccines, the costs of purchasing them and the manufacturing capability required. In September 2020, BEIS's business case for up to £5.2 billion in funding was approved by HM Treasury. HM Treasury has been clear that the approved funding can only be used to support activities up to 2022-23. Funding for activities that fall outside this timeframe, for example those that may support BEIS's wider objectives around developing manufacturing capacity could not be included. The approved business case funding was to:

- purchase up to 12 different vaccines, with the option to add two more if required;
- develop manufacturing capability and capacity in the UK to secure the supply chain for vaccines and increase commercial bargaining power;
- support the rapid delivery of clinical trials to make it more attractive for pharmaceutical companies to work in the UK; and
- pay for staff within the Taskforce.

1.9 BEIS estimated the potential benefits of its work to be between £11 billion and £231 billion. This estimate excludes wider health and social benefits. It is inherently difficult to accurately estimate the benefits of this work because of its unprecedented nature.

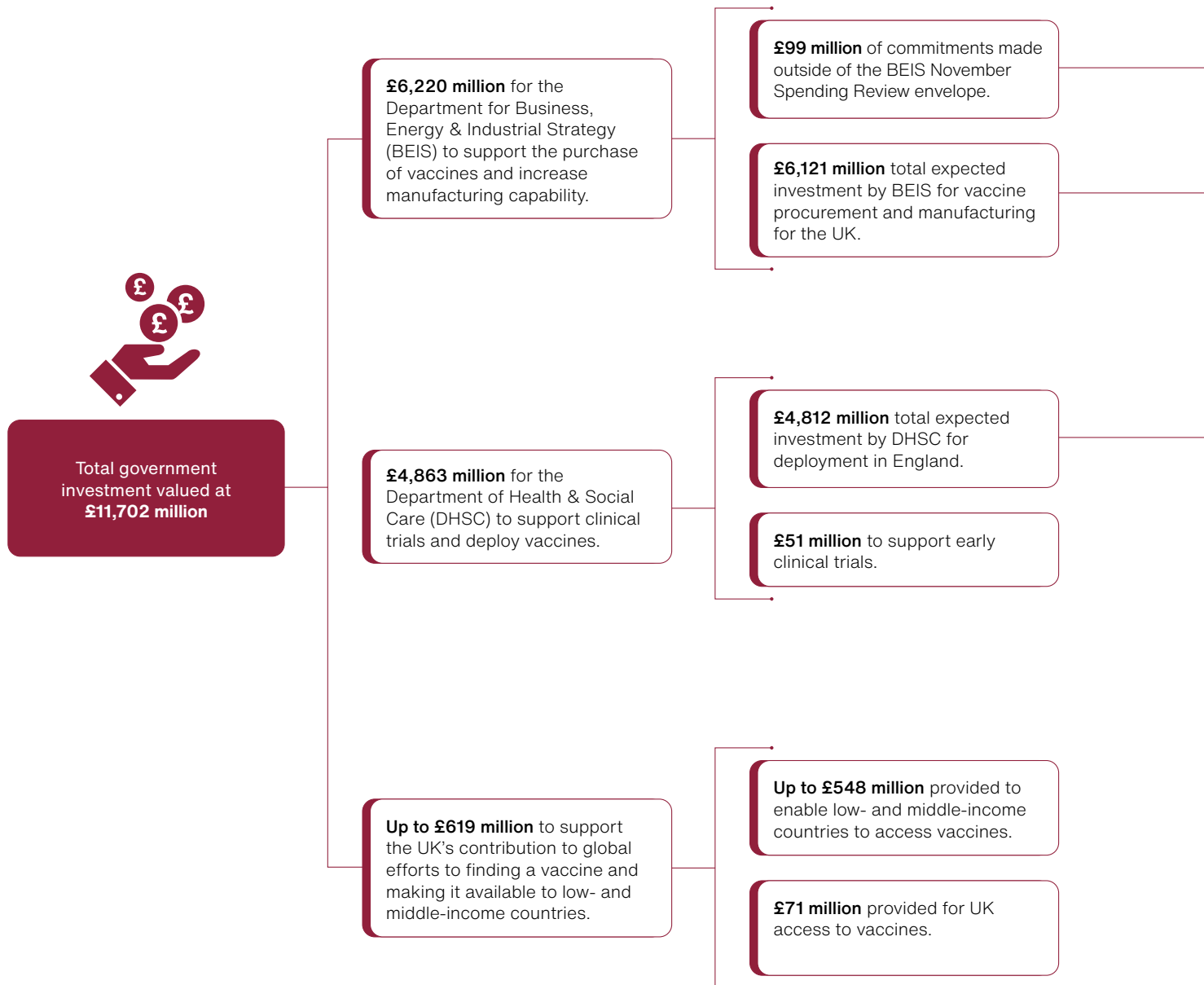
1.10 In its request for funding in June, BEIS estimated that each vaccine would cost on average £294 million (including contingency and VAT), but recognised costs would vary case by case. BEIS has ultimately had to pay more than it originally estimated for each potential vaccine. BEIS also originally expected to pursue up to 12 different vaccines (with the option to pursue two more if required) but reduced this to up to nine in early November based on its improved understanding of how well different vaccines are developing.

1.11 In September 2020, BEIS reported cost pressures meaning it may exceed its approved budget if all vaccines were approved as safe and effective. As part of the Spending Review in November 2020, BEIS increased the amount of funding required for the Taskforce's activities from £5.2 billion to £6.1 billion, reflecting its improved understanding of the likely costs, requirements and benefits of finding a safe and effective vaccine. BEIS also allocated £99 million to support manufacturing capability outside of the Spending Review bringing the total expected investment to £6.2 billion.

Figure 3

Total expected investment required to deliver planned COVID-19 vaccine activities as at 8 December 2020

Government's total expected investment required to purchase and manufacture COVID-19 vaccines for the UK, deploy them in England and support global efforts to find vaccines is **£11,702 million**



Notes

- 1 Antibody treatments are outside of the scope of this report.
- 2 Expected costs of deployment are for England only and do not include the cost of deploying vaccines in Northern Ireland, Scotland, Wales, the Crown Dependencies or Overseas Territories.
- 3 Up to £548 million provided to support global efforts has been allocated from the development aid budget.
- 4 Totals may not sum due to rounding.

£25 million for manufacturing commitments outside the Spending Review period.

£74 million for the Vaccine Manufacturing and Innovation Centre.

£4,826 million to purchase vaccines.

£91 million for operational costs.

£420 million for manufacturing.

£566 million for antibody work.¹

£217 million for clinical trials.

£2,402 million for staff costs.

£801 million for VAT.

£809 million for estates.

£366 million for technology and data.

£178 million for logistics.

£204 million for operational costs.

£44 million for equipment.

£8 million for communications.

1.12 DHSC has revised its required funding as it has understood more about deployment challenges. In late November 2020, DHSC submitted a revised business case to HM Treasury as it estimated it will require up to £4.8 billion to cover the cost of deployment activities in England. This represents a decrease from DHSC's original business case for up to £5.1 billion which was submitted to HM Treasury in September 2020. Funding has not yet been approved. DHSC also allocated £51 million to early clinical trials, which is not included in its business case, bringing the total expected investment to £4.9 billion. DHSC's funding request is required to: cover staff costs, arrange vaccination sites, purchase storage and equipment and develop specialised communications for the public for use in both this vaccination programme and the seasonal flu vaccination programme. DHSC requested some funding to be expedited to enable it to develop the technology and communications needed for the COVID-19 and seasonal flu vaccination programmes. HM Treasury approved £180 million for technology and public communications in September, and approved a further £476 million in November to cover the expected costs of deployment in 2020.

1.13 Government has also invested up to £619 million in global efforts to find a vaccine. This aims to help low- and middle-income countries gain access to vaccines, as well as to allow the UK to access other potential vaccines it has chosen not to purchase directly should it need them. COVAX acts as an international platform to accelerate the global development, manufacture and equitable distribution of COVID-19 vaccines. It is a group of 87 higher-income countries that have so far committed funding for vaccines for themselves and on behalf of 92 low- and middle-income countries. The UK has invested £71 million to secure its access to the nine vaccines in the proposed COVAX portfolio, plus up to £548 million from the international development aid budget to provide access for low- and middle-income countries. The group is coordinated by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations, and the World Health Organization. COVAX has committed to providing all participating countries, regardless of income, sufficient doses to vaccinate up to 20% of their populations.

1.14 The remainder of this report sets out the progress BEIS has made in securing access to vaccines and the different conditions in the contracts that BEIS has negotiated with pharmaceutical companies across its vaccine and manufacturing investments; how government has organised itself to make decisions and oversee progress; and the challenges faced by DHSC, NHSE&I and Public Health England in deploying vaccines.

Part Two

Government's progress to date

2.1 This part of the report examines in more detail the investments that have been made to date by the Department for Business, Energy & Industrial Strategy (BEIS) to purchase vaccines, support early clinical trials and develop manufacturing capability. BEIS is continuing to negotiate with pharmaceutical companies on a range of contracts. This report does not set out the individual price of contracts because we agree with BEIS's assessment that putting this commercially sensitive information into the public domain at a time when contract discussions are ongoing could have a detrimental impact on the UK's negotiating position. This does not preclude us from including this detail in future reports. In the interests of transparency, the report sets out the overall value of contract commitments and examines the different terms and conditions that have been agreed to help readers understand the risks associated with BEIS's investments.

2.2 By November 2020, BEIS had signed contracts with five pharmaceutical companies providing access to 267 million doses at an expected cost of £2.9 billion (Figure 1, see page 9).⁶ Contracts are currently in place for the vaccines being developed by:

- Astra Zeneca UK Limited and the University of Oxford for 100 million doses, signed in August 2020;
- Valneva SE for 60 million doses, signed in September 2020;
- Pfizer Inc and BioNTech SE for 40 million doses, signed in October 2020;
- Novavax Inc for 60 million doses, signed in October 2020; and
- Moderna Inc for 7 million doses, signed in November 2020.

⁶ The actual amount approved by ministers is higher and provides for additional contingency costs which vary by contract.

2.3 BEIS also has two non-binding agreements in place, that form the basis of formal contracts for a further 90 million doses, with:

- Sanofi S.A. and GlaxoSmithKline Biologicals S.A. for 60 million doses, signed in July 2020; and
- Janssen Pharmaceutica NV for 30 million doses, signed in August 2020.

Like the contracts already in place, these two contracts are expected to be agreed with different terms and conditions. In total these seven agreements could provide 357 million doses of different vaccines for the UK at an anticipated cost of £3.7 billion.⁷ The cost of deploying the vaccine is not included in these costs as it is DHSC's responsibility. In addition to the seven vaccines BEIS has focused on, it has continued to monitor clinical trial data for other potential vaccines and has ongoing discussions with these pharmaceutical companies.

Agreeing contract terms

2.4 When negotiating with pharmaceutical companies BEIS has had to consider a range of different factors, all of which have had an impact on the individual contract prices and terms agreed. Factors such as when the vaccine will be delivered to the UK, whether upfront payments are required, the potential for future costs from any indemnity claims that arise and termination rights have all influenced the commercial deals agreed. This means there is a wide range of costs and contract terms across the five contracts.

Value of upfront payments

2.5 In order to purchase vaccines for the UK, BEIS has accepted some money it is spending now may have to be written off if any of the vaccines are not approved by the regulator or if plans change. BEIS has agreed upfront payments of £914 million in the five contracts it signed up to 8 December 2020, prior to any vaccine being approved by the regulator.

⁷ The total cost of the vaccine contracts is subject to change according to the terms and conditions agreed with individual pharmaceutical companies.

2.6 These payments have been used to start manufacturing and to support clinical trials. In all contracts, the payments will be used against future purchases of the vaccine if it is approved by regulators. Only one of the contracts BEIS has signed provides for the full upfront payment to be refunded should the vaccine fail to achieve regulatory approval. Two other contracts contain provisions for BEIS to recover some of the upfront payments if the contract is terminated because the vaccine fails to achieve regulatory approval, but for the remaining two contracts the upfront payments are non-refundable. None of the contracts signed to date provide the UK with any rights to the intellectual property associated with the vaccines.

Securing early access

2.7 BEIS has negotiated priority access in four out of the five contracts to address the risk that global demand may outstrip supply initially. The terms of this priority access differ between contracts. For example, in one contract the priority supply is capped at the initial number of doses ordered, with any doses required over that amount not provided on a priority basis. Another contract states that the UK has priority access to doses manufactured within the UK, but if the UK supply chain cannot meet demand, the shortfall will be made up from outside the UK, but not on a priority basis.

Indemnities

2.8 The taxpayer may incur additional costs in future because the contracts negotiated by BEIS contain indemnity protections. Many pharmaceutical companies requested protection against all liabilities and legal action that could arise from any adverse events that might result from their vaccines.

2.9 Although the request for complete immunity was rejected, ministers took the decision that government should provide an indemnity to cover pharmaceutical companies for a range of specific circumstances. Our *Investigation into how government increased access to ventilators* found similarly that indemnities were provided against risks that companies might usually be expected to bear on the basis companies were working much quicker than they usually would.⁸ In four out of the five contracts agreed so far, no cap has been applied to the amount that government could pay in the event of a successful claim against the pharmaceutical companies.

⁸ Comptroller and Auditor General, *Investigation into how government increased the number of ventilators available to the NHS in response to COVID-19, 2019–2021*, HC 731, National Audit Office, September 2020

Managing risks to the supply of vaccines to the UK

2.10 BEIS has made a number of investments to develop manufacturing capability within the UK with the aim to establish and protect the supply chain for COVID-19 vaccines. This has been an iterative process as BEIS's understanding of what will be required to manufacture the vaccines has developed. In November 2020 as part of the Spending Review process, BEIS agreed with HM Treasury that it could spend up to £6.1 billion to support the work of the Vaccine Taskforce (the Taskforce) up to 2022-23 of which £420 million was expected to be allocated to manufacturing. BEIS also expected to commit a further £99 million to support manufacturing capability outside of the Spending Review, bringing the total expected investment in manufacturing to £519 million. By December, BEIS had committed £302 million to a range of manufacturing projects (**Figure 4**).

Figure 4

Manufacturing investments made as at 8 December 2020

Several investments have been approved to secure manufacturing capability within the UK

Manufacturing investment	Aim of investment	Actual commitments as at December 2020 (£m)
Cell and Gene Therapy Catapult Manufacturing Innovation Centre	To purchase the centre and support its conversion and running costs from June 2021.	127
Vaccine Manufacturing and Innovation Centre	To bring forward the centre's completion date from summer 2022 to summer 2021 and expand its scope. The site is currently not expected to become fully operational until the first quarter of 2022.	93
Fill and finish capacity for vaccines	Reserving the facility to undertake fill and finish activities for 18 months from August 2020.	42
Other manufacturing projects	Includes funding to support early manufacturing of the University of Oxford and Imperial College London vaccines within the UK and to develop manufacturing skills.	31
Rapid deployment facility	Originally to reserve the facilities to provide short-term capability between August and December 2020. Later revised to provide staff training and purchase manufacturing equipment.	9
Total		302

Note

1 'Fill and finish' is the process of putting a vaccine into sterile glass vials once it has been manufactured.

Source: National Audit Office analysis of Department for Business, Energy & Industrial Strategy data

2.11 As a result of the uncertainty around the vaccines and the manufacturing requirements, the amount of funding BEIS expected to invest in manufacturing projects has changed over time. In advance of the Taskforce being established, BEIS planned to invest up to £328 million to support: early manufacturing efforts with the University of Oxford and Imperial College London; expand the scope and accelerate the completion of the Vaccine Manufacturing and Innovation Centre (VMIC) and to reserve short-term manufacturing capability in the period before VMIC was operational.

2.12 In June 2020, BEIS submitted a business case to HM Treasury for funding to support the work of the Taskforce. This requested up to £5.2 billion of funding, of which £280 million was for investments to support the manufacturing of COVID-19 vaccines.⁹ This included a Cell and Gene Therapy Catapult Manufacturing Innovation Centre, investment in skills and securing 'fill and finish' facilities. Fill and finish facilities are required when a vaccine needs to be transferred from large single quantities into small containers such as sterile glass vials in preparation for delivery to vaccination sites.

2.13 The expected investments before the Taskforce was established and the business case funding brought BEIS's planned manufacturing investments to £608 million by June 2020. BEIS has told us that due to the uncertainty around the vaccines at this time, some of its planned investments were not needed or they required a different funding amount. As a result, some of the funding was re-allocated to other purposes, including the contracts to purchase vaccines. For example, the planned funding of the University of Oxford's early manufacturing was overtaken by its partnership with Astra Zeneca UK Limited, which led to more of the manufacturing costs being absorbed within the agreed contract. BEIS has told us that HM Treasury provided it with the flexibility to re-allocate this money as required.

2.14 The Spending Review in November 2020 has superseded all prior manufacturing commitments. This means they must now be funded from within the approved £6.1 billion or from underspends elsewhere in BEIS. By November, BEIS expected to invest £519 million in a range of manufacturing projects. By 8 December 2020, BEIS had committed £302 million to manufacturing projects, including:

- **Cell and Gene Therapy Catapult Manufacturing Innovation Centre:** This investment has purchased the centre and supports its conversion and running costs. The centre provides manufacturing capacity for COVID-19 vaccines from June 2021. By December 2020, BEIS had committed £127 million to this project;

⁹ A further £300 million was also requested to support the manufacturing of antibody treatments. This was subsequently not approved as part of the business case.

- **Vaccine Manufacturing and Innovation Centre (VMIC):** In May 2020, BEIS announced a £93 million investment to accelerate the completion of and expand the role of VMIC to support the manufacturing of COVID-19 vaccines. By December, BEIS had committed £93 million.
 - As a result of the investment, VMIC was expected to be ready in summer 2021, brought forward from summer 2022. In August 2020, it was confirmed that VMIC would not be fully operational until the first quarter of 2022, thereby only bringing forward its completion by two or three months. BEIS expects VMIC to start operating by the end of 2021 and when completed to have the capacity to produce 70 million vaccine doses in four months to support the manufacturing of two different vaccines.
 - BEIS told us that there is no demand from vaccine suppliers for manufacturing capacity in the UK between the rapid deployment facility contract ending in December 2020 and the Cell and Gene Therapy Catapult Manufacturing Innovation Centre being ready in June 2021;
- **Fill and finish facilities:** These facilities have the capacity to prepare doses up to two different vaccines for 18 months from August 2020. BEIS has told us that fill and finish activity started in September 2020. By December 2020, BEIS had committed £42 million;
- **Other investment:** This includes developing skills and supporting early manufacturing of the University of Oxford and Imperial College London's vaccines. By December 2020, BEIS had committed £31 million; and
- **Rapid deployment facility:** In May 2020 BEIS announced a £38 million investment in the rapid deployment facility to provide short-term manufacturing capacity for 40 million vaccine doses between August and December 2020. This decision was revised because it was no longer needed. By December 2020, BEIS had committed £9 million of this funding. BEIS told us this is being used to train staff from VMIC and purchase manufacturing equipment.

2.15 By increasing the UK's vaccine manufacturing capacity, BEIS is aiming to ensure that vaccines can be provided quickly to the UK and to reduce the risks to its supplies of the vaccines posed by a range of different factors, including 'vaccine nationalism'. This is where a country secures vaccines exclusively for itself or uses legislation to prevent the export of vaccines or associated materials, such as glass vials, that are in high demand until there is enough for its population.

2.16 BEIS has been monitoring the risks associated with the impact of the UK leaving the EU on potential vaccines. It is considering issues such as the time period when disruption might occur; what other government departments are doing to prepare; plans to enable vaccines to enter the country and the impact of World Trade Organization tariffs on its contracts. In our 2019 report on *Supplying the health and social care sector after exiting the EU*, we found that capacity for flow of goods across short Channel crossings could be reduced to 40% to 60% of current levels on day one of the UK's departure from the EU, returning to 50% to 70% of current flow after three months and return to close to current levels within 12 months.¹⁰ Any delays importing vaccines could create higher wastage as some vaccines are expected to have a short shelf-life and could result in lower than expected overall supply.

¹⁰ Comptroller and Auditor General, *Supplying the health and social care sector after exiting the EU*, Session 2017-2019, HC 2654, National Audit Office, September 2019.

Part Three

How government is organising itself to work at pace

3.1 In April 2020, government set up a Vaccine Taskforce (the Taskforce) to drive forward, expedite and co-ordinate efforts to research and then produce a COVID-19 vaccine as it was concerned that the civil service did not have all the necessary knowledge on its own to secure access to a vaccine quickly. The Taskforce consists of pharmaceutical industry experts, academics and civil servants from across government and sits within the Department for Business, Energy & Industrial Strategy (BEIS). This part of the report examines the structures put in place across government to enable it to do its work in securing vaccines and deploying them as quickly as possible.

Roles and responsibilities

3.2 The Taskforce's objective is to vaccinate the appropriate UK population against COVID-19 as soon as practicable. To do this the Taskforce has the following goals:

- Secure access to promising vaccine(s) for the UK population.
- Make provision for international distribution of vaccines.
- Support the industrial strategy by helping build a permanent vaccine capability sufficient to support a future pandemic response.

3.3 The chair of the Taskforce sets the overall direction and strategy for how vaccines and manufacturing capability will be secured. Supporting delivery of the Taskforce's objectives are:

- **the Taskforce Steering Group:** Chaired by the chair of the Taskforce, to steer and set the strategic direction for the Taskforce, oversee delivery of the Taskforce, and provide oversight of policies and strategies;
- **an Expert Advisory Board:** Chaired by the Chief Scientific Adviser to act as a sounding board and provide expert advice on the development and implementation of the actions of the Taskforce, and to champion and guide activities taking place across government, academia and industry to accelerate the development and manufacture of a COVID-19 vaccine; and
- **a Programme Board:** Chaired by the Taskforce's senior responsible owner, this is a cross-government group to develop and deliver the Taskforce's programme, and to act as the principal decision-making body which provides government with oversight of the Taskforce's activities.

3.4 The Taskforce currently has 201.7 full-time equivalent staff members which includes 79.9 full-time equivalent staff who were recruited from outside the civil service. The Taskforce has an expected running cost of £91 million up to 2022-23. Each year £13 million of its budget is ring-fenced for legal and professional services. The remainder of its budget is expected to cover staff, contingent labour and consultant costs.

3.5 Recruits into the Taskforce include civil servants, contractors and industry specialists. The Taskforce sought staff from a variety of sources including asking industry advisers to introduce people to the Taskforce and through the Crown Commercial Service consultancy frameworks, where consultants with experience in the health sector were offered secondments or short-term placements.

3.6 The Taskforce has drawn on the skills of programme delivery officials from across the civil service. Public Health England, as the responsible organisation for other vaccination programmes holds the necessary licence and qualified staff to legally purchase vaccines. As it was BEIS rather than Public Health England purchasing COVID-19 vaccines, Public Health England had to work with the Taskforce to support it in securing the necessary licence.

3.7 BEIS recognised that the involvement of a range of different people being brought in to support government's decisions created the potential for conflicts of interest. BEIS already had in place checks to prevent such conflicts from occurring. BEIS has told us that a register of conflicts of interest is shared weekly between its HR department and the Taskforce's Programme Management Office. By December 2020, 38 individuals within the Taskforce had registered at least one conflict of interest.

Changes made to facilitate quicker investment decisions

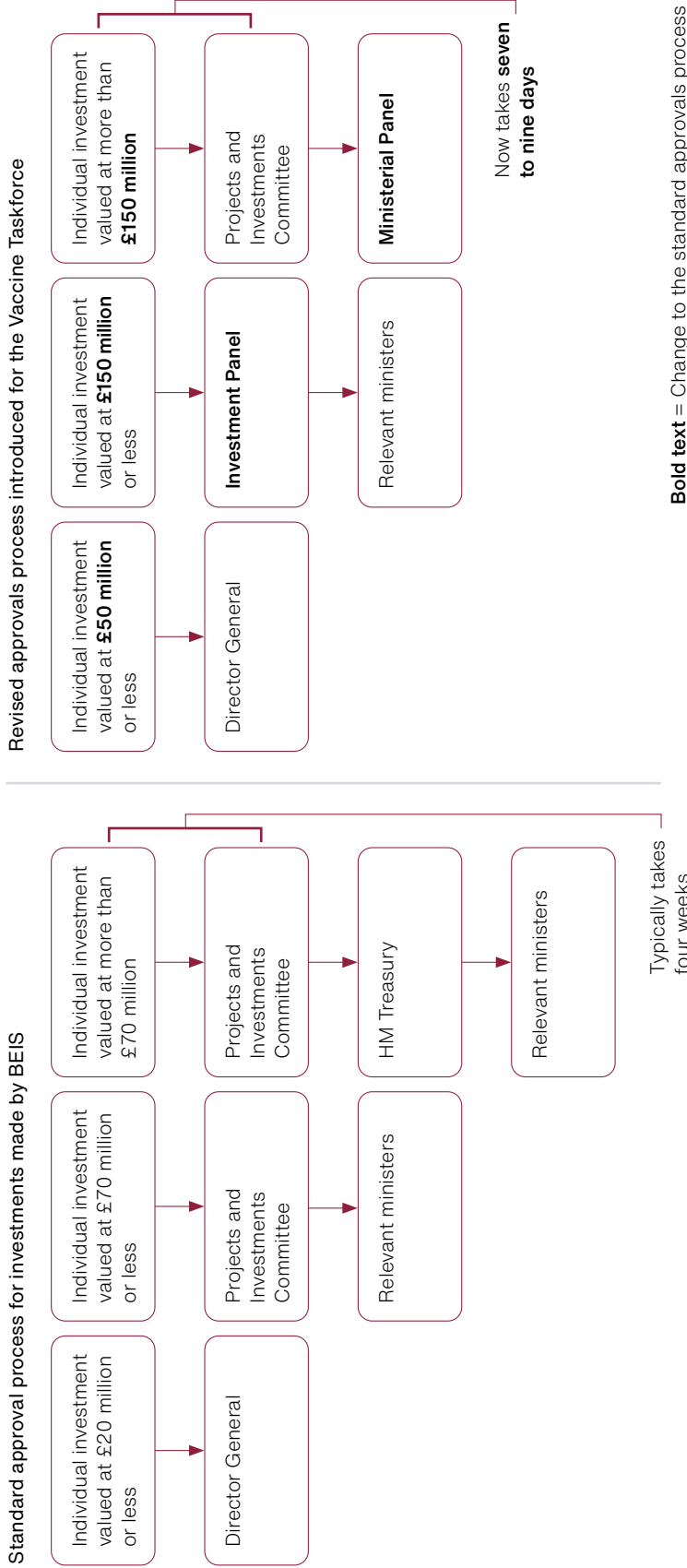
3.8 To support the pace of investment decisions that the Taskforce wanted to make to increase the chances of purchasing vaccines, BEIS has reduced the time investment decisions would normally take, something BEIS also introduced for EU Exit projects. Investment decisions valued at more than £150 million are still required to go through BEIS's existing Projects and Investments Committee, but the time taken for this committee to make investment decisions has been reduced from four weeks down to seven to nine days for Taskforce proposals. Investment proposals still need to be supported by a full business case with a full accounting officer assessment.

3.9 Changes have also been made by HM Treasury to support faster consideration of the Taskforce's proposals. In September 2020, HM Treasury increased BEIS's delegated spending limit from £70 million to £150 million per investment. Cabinet Office also increased BEIS's delegation level for commercial decisions from £10 million to £50 million. With the increased delegations, BEIS established an Investment Panel to consider investment decisions valued up to £150 million instead of the Projects and Investments Committee. The panel consists of senior officials from across the centre of government, including Cabinet Office and HM Treasury. As at 8 December, the Investment Panel had met three times and considered proposals worth £165 million.

3.10 Investments valued at more than £150 million are considered by the BEIS Projects and Investments Committee and then a new Ministerial Panel consisting of the Secretaries of State for Business, Energy and Industrial Strategy, Health and Social Care, the Chief Secretary to the Treasury and the Minister of State for Efficiency and Transformation for Cabinet Office. As at 8 December 2020, the Ministerial Panel had met six times and had approved all contracts for potential vaccines. The purpose of the Ministerial Panel is to speed-up decision-making by bringing together ministers in a single group. The Ministerial Panel does not replace the Projects and Investments Committee (**Figure 5**).

Figure 5
How investment decisions for COVID-19 vaccines are reviewed and approved within the Department for Business, Energy & Industrial Strategy (BEIS)

Approvals processes within BEIS have been amended to facilitate quicker decisions



Notes

- 1 The Projects and Investments Committee makes recommendations to the accounting officer. It makes four recommendations: full approval to proceed; approval with caveats; reapproval at a later date and within an agreed timescale; and recommended cancellation.
- 2 Any investment that is considered novel or contentious must also be approved by HM Treasury, regardless of value.
- 3 In the standard approval process, any commercial investment valued at more than £10 million must also be approved by the Cabinet Office. This limit has been increased to £50 million in the revised Vaccine Taskforce process.
- 4 The Investment Panel consists of senior officials from across the centre of government, including Cabinet Office and HM Treasury. Cabinet Office and HM Treasury officials have delegated authority to approve investments on behalf of their departments.
- 5 The Ministerial Panel consists of the Secretaries of State for Business, Energy and Industrial Strategy, Health and Social Care, the Chief Secretary to the Treasury and the Minister of State for Efficiency and Transformation for Cabinet Office.

Governance and accountability

3.11 The chair of the Taskforce was appointed in May 2020 and reports directly to the Prime Minister. The chair of the Taskforce is not accountable to BEIS or the Department of Health & Social Care (DHSC). The term of the current chair will expire at the end of 2020 and discussions between ministers are currently underway regarding a replacement.

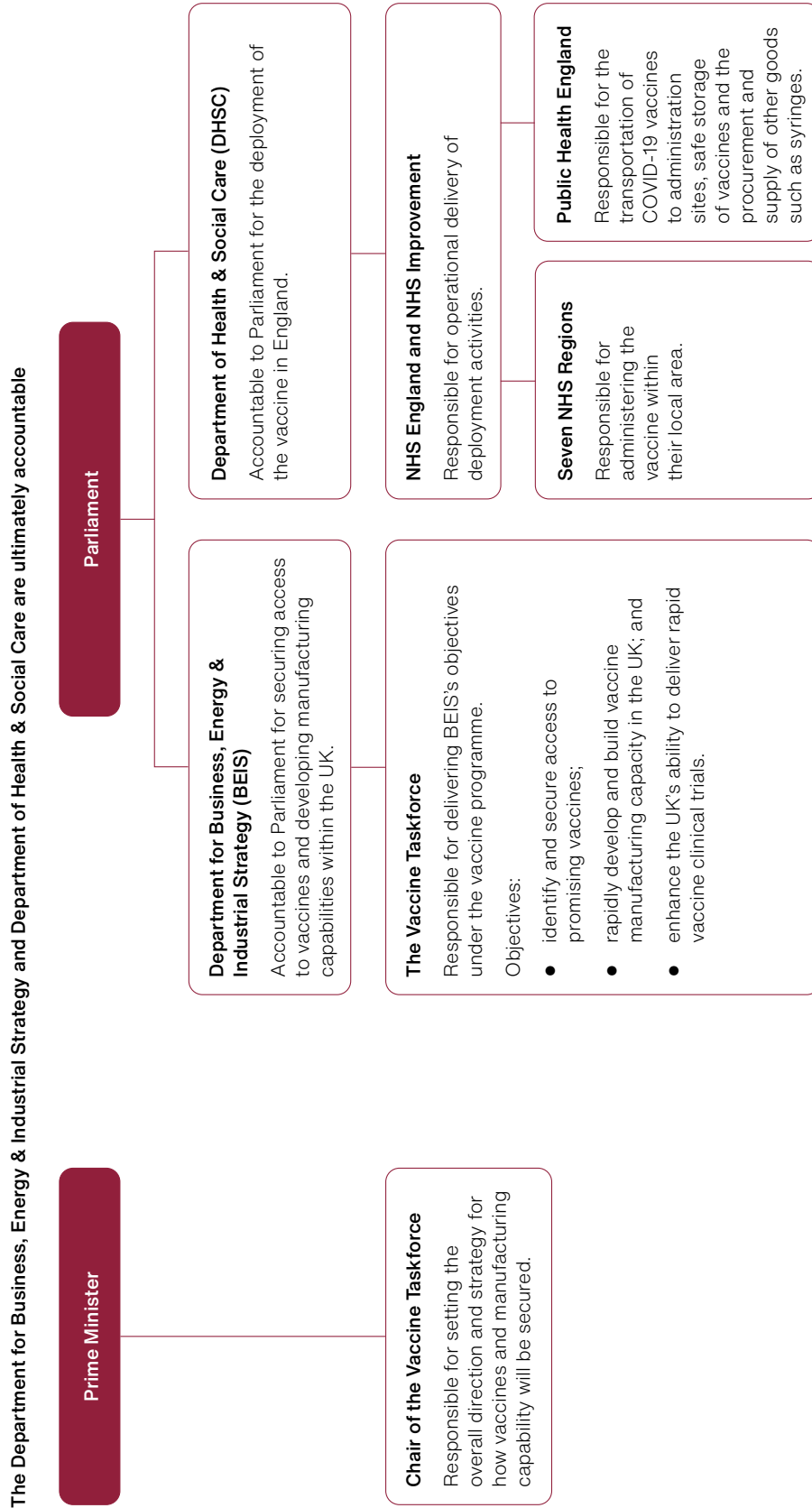
3.12 The senior responsible owner for the Taskforce was appointed in June 2020 and is responsible for the Taskforce's performance and reports to the BEIS accounting officer. The specifics of the senior responsible owner's responsibilities were agreed in November 2020. A separate senior responsible officer for deployment activities was appointed from NHS England and NHS Improvement (NHSE&I) in September 2020 (**Figure 6**).

3.13 The Taskforce has six workstreams to help guide its work: Vaccine Discovery; Clinical Trials; Manufacturing and Supply; Deployment; International; and Legacy. Each workstream has its own lead director who also sits on the Programme Board.¹¹ In August the BEIS accounting officer wrote to the DHSC accounting officer setting out the responsibilities of each department, including that funding of all deployment activities is the responsibility of DHSC.

3.14 Plans for deployment are largely dependent on and shaped by the decisions made by the Taskforce through its workstreams, for example the types of vaccines being procured. In May 2020, Public Health England set up a COVID-19 Vaccination Programme Board as DHSC considered it to be the expert in the planning and implementation of national immunisation programmes due to its key role in other vaccination programmes. Following changes made within the Taskforce in June 2020, Public Health England raised concerns that operational experience of vaccine deployment was not represented within the senior boards and groups of the Taskforce. Although NHSE&I has told us that it was regularly consulted and provided input to the Taskforce, it was not until September 2020 that both Public Health England and NHSE&I, the organisations with the most operational experience, had regular senior representation through NHSE&I becoming a member of the Programme Board.

¹¹ Some directors lead more than one workstream.

Figure 6
Current accountabilities for purchasing and manufacturing COVID-19 vaccines for the UK and deploying them in England



Notes

- 1 Northern Ireland, Scotland, Wales, the Crown Dependencies and Overseas Territories are responsible for making decisions about how to administer the vaccine to their own populations.
- 2 Public Health England is an executive agency of DHSC. For its role in all other vaccination programmes, Public Health England reports directly to DHSC under the arrangements set out in the Section 7A Agreement.

Source: National Audit Office analysis of Department for Business, Energy & Industrial Strategy and Department of Health & Social Care data

3.15 In September 2020, the Secretary of State for Health and Social Care revised the governance for deployment activities and directed that a single senior responsible officer, appointed from NHSE&I, should lead on deployment. The aim of this change was to create a unified deployment programme which spanned all organisations with clear streamlined responsibilities and accountabilities to reduce current duplication, enable greater cross-departmental working and provide greater clarity of accountability and transparency to deployment activities. From September 2020 onwards, NHSE&I and Public Health England have been represented by the senior responsible officer for deployment at Taskforce meetings. In November 2020 a Minister for COVID-19 Vaccine Deployment was appointed to oversee the deployment of the vaccine in England.

3.16 By August 2020 DHSC, NHSE&I and Public Health England had each set up its own deployment board. In September a new Deployment Programme Board was established to assure delivery and provide cross-government oversight. It is jointly chaired by the senior responsible officer for deployment and the deployment workstream lead within BEIS. NHSE&I is responsible for the operational delivery of the deployment programme in England. A COVID-19 Vaccine Deployment and Flu Delivery Group was also created as a forum for organisations involved in deployment including NHSE&I, DHSC and Public Health England to find practical solutions to deployment challenges.

3.17 These groups replaced the different deployment governance arrangements that had emerged since the start of efforts to secure a vaccine. A single Programme Management Office for deployment activities was also established to bring together the various programme management functions that existed across DHSC, NHSE&I and Public Health England. The devolved authorities make their own decisions about how to deploy the vaccine (**Figure 7** on pages 37 and 38).

Figure 7

Timeline of governance changes within the vaccine programme, April 2020 – November 2020

The governance arrangements supporting COVID-19 vaccine work have evolved over time

Date	Change that occurred	Description of change
April 2020	Vaccine Taskforce (the Taskforce) is created.	The Taskforce is set up to help deliver the Department for Business, Energy & Industrial Strategy's (BEIS's) responsibilities for securing access to vaccines and manufacturing capability.
	BEIS set up a Programme Board.	The purpose of the Board is to set direction and oversee the Taskforce, including the development and implementation of actions set out in the Taskforce specification.
May 2020	BEIS sets up six workstreams to oversee progress.	The workstreams are: vaccine procurement; trials, testing and regulation; manufacturing and supply; deployment; cooperation; and legacy.
	BEIS sets up a Steering Group.	The Steering Group sets the programme direction and strategy and makes recommendations to the Programme Board. Its members include BEIS and the Deputy Chief Medical Officer. The Department of Health & Social Care (DHSC), NHS England and NHS Improvement (NHSE&I) and Public Health England are not members of the Steering Group.
	Public Health England sets up a COVID-19 Programme Board.	The COVID-19 Programme Board is planning for the implementation of a safe and effective COVID-19 vaccination programme. Its members include Public Health England, DHSC, NHSE&I, BEIS and a range of government departments and agencies.
July 2020	BEIS sets up a revised Programme Board.	The Programme Board takes decisions about potential changes to the vaccine programme, manages cross-cutting risks, issues and dependencies and approves the recommendations of the Steering Group. Its members include BEIS, DHSC, the Deputy Chief Medical Officer and a range of government departments.
	BEIS sets up a Delivery Group.	The Delivery Group is responsible for managing the delivery of the Taskforce programme and is chaired by the programme director.
	DHSC sets up the DHSC led Deployment Programme Board.	The Deployment Programme Board reviews reporting of ongoing work and oversees and manages ongoing risks and issues. Its members include DHSC, Public Health England and a range of other health agencies.
	NHSE&I sets up a Steering Group.	The Steering Group aims to provide oversight of progress, receive reports from other operational groups and identify and manage interdependencies between organisations. Its members include NHSE&I national staff, regional programme senior responsible officers and regional programme leads.

Figure 7 *continued*

Timeline of governance changes within the vaccine programme, April 2020 – November 2020

Date	Change that occurred	Description of change
August 2020	BEIS accounting officer writes to DHSC accounting officer.	Letter clarifies the delivery and funding responsibilities of each department.
September 2020	Senior responsible officer for deployment activities appointed.	Secretary of State for Health and Social Care directs the appointment of a senior responsible officer for deployment from NHSE&I.
	NHSE&I sets up the Vaccine Deployment Programme Board to replace the existing Public Health England and NHSE&I boards.	Vaccine Deployment Programme Board provides assurance to the Secretary of State for Health and Social Care and BEIS on deployment activities. It is co-chaired by NHSE&I and BEIS. Its members include NHSE&I, DHSC, BEIS, Public Health England and a range of other government agencies and bodies.
November 2020	Minister for COVID-19 Vaccine Deployment appointed	The minister oversees the deployment of COVID-19 vaccines in England.

Source: National Audit Office analysis of Department for Business, Energy & Industrial Strategy, Department of Health & Social Care and Public Health England data

Part Four

Challenges government needs to manage as it deploys the vaccine

4.1 Government had to begin planning for deployment of a potential vaccine in advance of one becoming available. This part of the report sets out the steps that government has taken to allow it to start administering the vaccine on 8 December, some six days after it was approved by the regulator; and the challenges it will still need to manage. The Department of Health & Social Care (DHSC) is accountable to Parliament for deployment activities in England. The devolved authorities make their own decisions about how to deploy the vaccine.

4.2 NHS England and NHS Improvement (NHSE&I) has planned on the assumption that 75% of people who are offered the vaccine will take it.¹²

4.3 Public trust in the vaccine will ultimately determine the number of people who choose to have the vaccine. DHSC is responsible for developing communications with the public around the vaccination programme. In June 2020, Public Health England emphasised the need for attitudinal research to inform the communications strategy, but in August 2020 it reported that this research would not be completed in time for the first vaccinations, which at that time were expected in September 2020. DHSC has told us it is continuing to work on the public perception of COVID-19 vaccines, including understanding changes in people's intentions to receive the vaccine, but it is not clear how this is being used to inform its communications strategy and assumptions on take-up rates among all parts of society.

4.4 When planning deployment activities NHSE&I needs to understand:

- the conditions required for each vaccine;
- how the vaccine is expected to be administered; and
- who needs to be vaccinated and when.

¹² Public Health England has reported that the take-up rates among those aged under 65 years old was 45% for patients aged six months to under 65 years old in one or more clinical risk group(s); 44% in all pregnant women; and 44% for patients aged two and three years old.

4.5 There are critical interdependencies between these assumptions meaning that changes in one area will affect assumptions made elsewhere. For example, the efficacy of each vaccine could change across different groups in society. This will influence who is vaccinated first, which may impact on how deployment activities are planned.

Vaccine conditions

4.6 Each potential vaccine has specific characteristics that need to be carefully considered when planning deployment activities. Vaccine characteristics include key conditions such as the temperature it should be stored at, its shelf-life once opened and any preparatory work that needs to be done by staff before it can be administered. The characteristics of the approved vaccine developed by Pfizer Inc and BioNTech SE include:

- the vaccine needs to be stored in ultra-low cold storage conditions (between -80°C and -60°C). This creates challenges for Public Health England in planning how to store and transport the vaccine around the country to minimise the risk that the vaccine warms up and therefore leads to wastage;
- the vaccine is packaged in very large quantities with 975 doses per pack. This is provided as 195 multidose vials. Once thawed, each pack is viable for five days provided it is stored between 2°C and 8°C. NHSE&I must therefore understand and plan according to how many people can be vaccinated on a particular day in a particular location to reduce the potential for wastage; and
- the vaccine needs to be diluted before it can be administered. This increases the training required by clinical staff and potentially limits who can administer it, putting additional pressure on an already strained workforce.¹³

4.7 The Department for Business, Energy & Industrial Strategy (BEIS) has shared with NHSE&I the information it has received from pharmaceutical companies about the characteristics of the vaccines, but characteristics are still uncertain for some vaccines and are subject to change as clinical trials continue. NHSE&I has started deployment activities based on what it knows now but it needs to plan for all possible options of those vaccines purchased until it has certainty. NHSE&I will therefore need to change its plans as new information becomes available. DHSC reported to the Secretary of State for Health and Social Care in September 2020 that some of the vaccines contain a number of constraints that could affect deployment and ultimately could have implications for the safe and effective delivery of the programme.

¹³ Further details on the vaccine characteristics can be found in The Green Book published by Public Health England: <https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a>

How the vaccine will be administered to the population

4.8 NHSE&I has developed three new delivery models that take account of different groups and different regional needs (**Figure 8** overleaf). NHSE&I concluded that it is not possible to deliver both the COVID-19 and seasonal flu vaccination programmes solely through existing arrangements such as GP practices and community pharmacies. It has therefore developed models which include offering vaccinations at large sites such as sports stadiums; mobile sites similar to polling stations and COVID-19 testing centres; and roving units that will take the vaccine to particular locations such as care homes. Regional NHS deployment teams are responsible for choosing the combination of delivery models that best suit their local needs. Each delivery model is based on ‘vaccination pods’ that include everything needed for a day of vaccination activity, such as staff, equipment, and the vaccine. The ‘vaccination pod’ concept was developed to allow plans to be scaled up or down depending on local need or limitations imposed by particular locations.

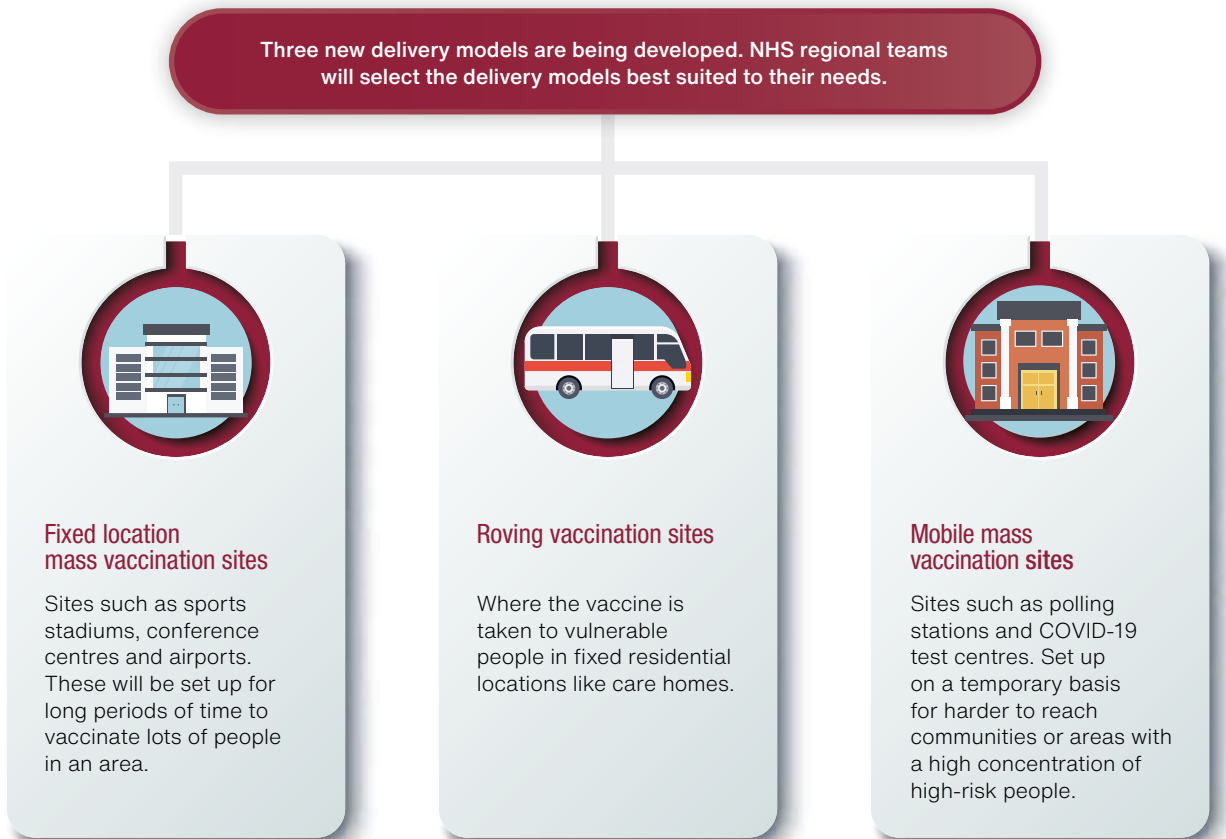
4.9 Planning and implementing the COVID-19 vaccination deployment programme is currently one of several significant demands on NHSE&I. The start of deployment activities on 8 December has coincided with a second wave of COVID-19 plus annual winter pressures (created by colder weather and flu), alongside NHSE&I’s existing workload that includes 17 other vaccination programmes delivered with support from Public Health England.

4.10 NHSE&I is delivering an expanded seasonal flu vaccination programme in England in 2020-21. NHSE&I vaccinated 15.4 million people against the flu in 2019-20 and is aiming to almost double this to up to 29.5 million in 2020-21. DHSC does not consider that the expanded flu programme has increased the risk to its COVID-19 deployment activities but recognises that a lack of staff to administer the vaccine could create a “bottleneck”.

4.11 In order to identify those eligible for a vaccination and invite them, NHSE&I needs to have accurate data on individuals in order to call and recall them and monitor them for any adverse reactions to the vaccine. The call and recall system for COVID-19 is managed nationally using the National Immunisation Management System, which is already used by NHSE&I to manage the call and recall service for other vaccination programmes including seasonal flu. The National Immunisation Management System is used to identify individuals eligible for the COVID-19 vaccine and the best way to contact them. The National Immunisation Management System is also expected to keep a record of vaccinations to support ongoing monitoring of vaccine safety by NHSE&I and Public Health England. NHSE&I is inviting individuals for a vaccination through a combination of letters, emails, text messages and phone calls. NHS Digital is responsible for the effectiveness of the COVID-19 vaccination information systems and technology.

Figure 8
Delivery models for administering COVID-19 vaccines

NHS England and NHS Improvement has developed three new delivery models to help deploy COVID-19 vaccines



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

Who will receive the vaccine?

4.12 DHSC’s policy objective is to vaccinate the entire adult population of England against COVID-19. Advice from the Joint Committee on Vaccination and Immunisation (JCVI) published in December 2020 stated certain groups should receive the vaccine before others, including health and social care workers and older adults living in care homes (**Figure 9**). JCVI is an independent group of clinical experts who make recommendations to the Secretary of State for Health and Social Care about which groups should be eligible for a vaccine based on its review of scientific evidence. These recommendations are provided for every vaccination programme.

Figure 9

Advice from the Joint Committee on Vaccination and Immunisation

The advice recommends older adults and health and social care workers should be prioritised**Priority recommendations for Phase 1**

Direct prevention of mortality and supporting the NHS and social care system

- 1 Residents living in care homes for older adults and their carers
- 2 All those 80 years of age and over
Frontline health and social care workers
- 3 All those 75 years of age and over
- 4 Those aged 70 years or over
Clinically extremely vulnerable individuals¹
- 5 All those 65 years of age and over
- 6 All individuals aged 16 years to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality
- 7 All those 60 years of age and over
- 8 All those 55 years of age and over
- 9 All those 50 years of age and over

Note

¹ Does not include pregnant women or the clinically vulnerable under the age of 16.

Source: Joint Committee on Vaccination and Immunisation: advice on priority groups for COVID-19 vaccination, 2 December 2020.

4.13 The scale of the vaccinations needed will require a significant additional workforce at a time when shortages exist and there are concerns about staff well-being due to their ongoing efforts responding to the pandemic. Our report, *The NHS nursing workforce*, reported that between July and September 2019, there were 43,590 unfilled nursing vacancies.¹⁴ Based on its understanding in September 2020, before any vaccine was approved by the regulator, NHSE&I calculated that it may need up to 46,000 staff consisting of 26,000 vaccinators and 20,000 administrative staff to deliver the COVID-19 vaccination programme based on a 75% take-up rate. NHSE&I is aiming to obtain these staff from a combination of existing primary care staff and targeted local recruitment campaigns. In September 2020, based on the expected increase in vaccination workload, the number of people expected to be vaccinated as part of the expanded seasonal flu programme in 2020-21 and the assumption that every adult in England will require two doses of a COVID-19 vaccine, NHSE&I calculated that delivering both the COVID-19 and expanded seasonal flu vaccination programmes could increase its vaccination workload by 740%. It is continuing to update its staffing calculations to reflect information about the approval of vaccines, how many doses will be available and how they need to be deployed. It remains uncertain whether the COVID-19 vaccination programme will need to take place more regularly, for example becoming an annual programme which would have long-term implications for NHSE&I's staffing and budgets.

4.14 NHSE&I is currently planning on the assumption that it could vaccinate up to 25 million people against COVID-19 in England throughout 2021 based on the advice from the JCVI. This assumption is dependent on sufficient doses of vaccine being available. Based on the current understanding of the majority of vaccines, each person will require two doses approximately four weeks apart for it to be effective. This equates to up to 50 million vaccinations for the COVID-19 programme alone. When combined with the expanded flu programme, based on assumptions as at 8 December 2020, this increases the total number of vaccinations required to up to 79.5 million in 2021. This represents an increase of 64.1 million vaccinations compared to those completed in the seasonal flu programme in 2019-20. NHSE&I is planning deployment activities with high levels of uncertainty because information about the COVID-19 vaccines is still changing. This means NHSE&I must continually review its deployment plans to ensure it can respond to the latest information about which vaccines have been approved, which groups in society need to be vaccinated, how many doses of vaccines will be available and when and how those vaccines need to be deployed.

14 Comptroller and Auditor General, *The NHS nursing workforce, 2019-2021*, HC 109, National Audit Office, March 2020.

4.15 DHSC began a consultation in August 2020 around changes to human medicines regulations to support the administration of COVID-19 vaccines. Among the suggested changes were:

- the extension of patient group directions to unlicensed medicines to protect against the risk that the vaccine will be unlicensed initially. Patient group directions allow groups such as pharmacists to supply or administer medicines without a doctor being present;
- the introduction of a new national protocol to allow registered healthcare professionals who do not normally vaccinate, and people who are not registered healthcare professionals, to safely administer the vaccine; and
- expanding who is allowed to administer a vaccine to include occupational health professionals.

4.16 Legislative changes in response to the consultation came into effect in October 2020, which has allowed NHSE&I since November to look for the workforce required for the COVID-19 programme from a range of sources including NHS professionals, doctors and nurses that have left the profession and first aid charities.

Appendix One

Our investigative approach

Scope

1 We conducted an investigation into government's preparations for potential COVID-19 vaccines. 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:

- government's approach to identifying potential vaccines;
- government's progress to date;
- how government is organising itself to work at pace; and
- challenges government needs to manage as it deploys the vaccine.

Methods

2 In examining these issues, we drew on a variety of evidence sources.

We interviewed key individuals from:

- the Department of Business, Energy & Industrial Strategy (BEIS), Department of Health & Social Care, NHS England and NHS Improvement, and Public Health England to establish their objectives, the work undertaken to date, governance arrangements and the contracts that have been entered into; and
- HM Treasury and Cabinet Office to understand their role in approving expenditure.

We reviewed a range of data and documentation. This included:

- documents setting out the governance arrangements, including papers presented to various boards and the minutes of those meetings;
- papers related to commercial activities including due diligence exercises and contracts; and
- risk registers.

3 BEIS is continuing to negotiate with pharmaceutical companies on a range of contracts. This report does not set out the individual price of contracts because we agree with BEIS's assessment that putting this commercially sensitive information into the public domain at a time when contract discussions are ongoing could have a detrimental impact on the UK's negotiating position. This does not preclude us from including this detail in future reports. In the interests of transparency, the report sets out the overall value of contract commitments and examines the different terms and conditions that have been agreed to help readers understand the risks associated with BEIS's investments.

4 We invited four pharmaceutical companies to provide their views on working with government. One company shared their experience with us.

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