



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

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).