**Top Lines and Q&A for stakeholders - COVID vaccine**

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# Top lines

* An effective vaccine will be the best way to protect the most vulnerable from coronavirus and the biggest breakthrough since the pandemic began. It is a huge step forward in our fight against coronavirus, potentially saving tens of thousands of lives. Once vaccinations begin, the UK Government will closely monitor the impact on individuals, on NHS pressures and on the spread of the virus.
* The Joint Committee on Vaccination and Immunisation (JCVI) are the independent experts who advise the Government on which vaccine/s the UK should use and provide advice on who should be offered the vaccination first. They advise that the vaccine first be given to care home residents and staff, followed by people over 80 and health and social care workers, then to the rest of the population in order of age and risk.
* The full impact on infection rates will not become clear until large numbers of people have been vaccinated, but as larger numbers do get vaccinated, we will hopefully move further along the path back to a more normal way of life. As large numbers of people from at risk groups are given a vaccine, the Government will be able to examine the impact on infection rates, hospitalisation and reduced deaths; if successful this should in time lead to a substantial reassessment of current restrictions.
* The UK government has secured early access to 355 million vaccine doses through agreements with seven separate vaccine developers, giving the UK the best chance of securing a safe and effective vaccine at the quickest speed. Should a vaccine be approved it will be available from the NHS – for free – to everyone who would benefit, starting with those most at risk.
* The NHS is ready to deliver a Covid-19 vaccination programme as soon as a vaccine is approved for use by the medicines regulator, the Medicines and Healthcare products Regulatory Agency (MHRA). Detailed planning is underway building on the NHS’s expertise delivering immunisation programmes including the flu vaccination programme.
* Countermeasures such as medicines and vaccines could eventually make Covid-19 a more manageable disease, reducing its impact on society and the NHS so we can all begin to get back to normal. Until then, we must all continue to take necessary actions to keep ourselves and our loved ones safe including by following the Hands, Face, Space guidance and other public health advice.
* It is over simplistic to imply that any vaccines are “superior” or “inferior”. A vaccine with slightly lower headline efficacy than another may prove to be the one that offers more durable protection or a greater effect on transmission. If the choice is between the eligible public accessing a safe vaccine with a lower interim efficacy or having no vaccine at all, you would always choose the former as some protection is absolutely better than no protection. Vaccines against Covid-19 will not all come at once, or in large quantities in all cases. Nor will they be delivered in volumes or over timeframes we can fully predict currently, and their storage characteristics may differ.
* The UK has secured early access to over 355 million vaccines doses through agreements with several separate vaccine developers at various stages of trials, including:

• 100 million doses of University of Oxford/AstraZeneca vaccine – phase 3 clinical trials

• 40 million doses of BioNTech/Pfizer vaccine – phase 3 clinical trials

• 5 million doses of Moderna vaccine – phase 3 clinical trials

• 60 million doses of Novavax vaccine – phase 3 clinical trials

• 60 million doses of Valneva vaccine – pre-clinical trials

• 60 million doses of GSK/Sanofi Pasteur vaccine – phase 1 clinical trials

• 30 million doses of Janssen vaccine – phase 3 clinical trials

# Q&A

# Government welcome the MHRA review into Pfizer/BioNtech vaccine.

The Government welcomes the Medicines and Healthcare products Regulatory Agency’s (MHRA) review of data from Pfizer/BioNTech to determine whether its vaccine meets robust standards of quality, safety, and effectiveness.

The companies have reported data that indicates their vaccine is 94% effective in protecting people over 65 years old from Covid-19, with trials suggesting it works equally well in people of all ages, races and ethnicities.

As the first country to pre-order the vaccine from Pfizer/BioNTech, the UK is expected to receive a total of 40 million doses by the end of 2021, enough to vaccinate up to a third of the population, with the majority of doses anticipated in the first half of next year.

# Oxford and AstraZeneca have announced that their vaccine is ~70% effective – what next?

* The results from the University of Oxford/AstraZeneca are very encouraging. The Government has already secured early access to 100 million doses of their vaccine for use across the UK if approved – on top of 255 million doses from other vaccine developers.
* The MHRA will carry out their crucial work to assess whether the vaccine meets robust standards of safety, effectiveness and quality once it receives the full data from Oxford/AstraZeneca.
* If authorised, the NHS will begin to roll out more widely, starting with those most at risk, in line with JCVI advice and taking into account logistics and practicality.
* This is terrific news and we should pay tribute to the volunteers who took part in these clinical trials. Without volunteers, we wouldn’t have the results we got today.
* This is the third vaccine to have received a positive readout. This makes it highly likely in the months that follow, we’re going to make Covid-19 a vaccine-preventable disease.
* The results today are interim. If you put all the studies around the world together, we have 70% effectiveness. But for a dose that involves a half dose, followed by interval then full dose, readout is 92%.
* There were no hospital admissions due to Covid at all in the patients who received either of the vaccine regimens. That is very good news indeed.

# Response to Pfizer submitting data to FDA first

* The MHRA has already started a rolling review to determine whether the Pfizer/BioNtech vaccine meets strict standards of safety, effectiveness and quality.
* Once the MHRA receives the full data from the company, the MHRA’s renowned team of scientists and clinicians stand ready to progress its assessment of the vaccine.

## **Pfizer has announced that its vaccine is 95% effective. What comes next?**

* The announcement from Pfizer/BioNtech is more welcome news. Thanks to the work of the UK’s Vaccine Taskforce, the Government has pre-ordered 40 million doses of this vaccine for the UK.
* The independent MHRA will carry out their crucial work to assess whether the vaccine meets robust standards of safety, effectiveness and quality once it receives the full data from the company. The MHRA will only approve a vaccine if it has met strict safety, effectiveness and quality standards.
* The NHS stands ready to roll out an approved vaccine to high risk groups identified by the JCVI once the MHRA has completed its work. The UK Government has put in place regulations so that if a vaccine is found before the end of the year, vaccinations can begin without needing to wait for approval from the European Medicines Agency.
* The NHS has vast experience delivering widespread vaccination programmes and an enormous amount of planning has taken place to ensure our health service stands ready to roll out a Covid-19 vaccine. This includes putting in place logistical expertise, transport, PPE and an expanded workforce to ensure we can deploy vaccines rapidly once they have met robust standards of safety and effectiveness and been approved by MHRA.

## **Moderna has announced that its vaccine is 94.5% effective. What comes next?**

* The news from Moderna appears to be good and represents another significant step towards finding an effective COVID19 vaccine.
* The UK government has completed negotiations with biotech Moderna to secure access to 5 million doses of its promising vaccine, enough for around 2.5 million people.
* Moderna is currently scaling up their European supply chain which means these doses would become available in spring 2021 in the UK at the earliest.
* To date, the UK government has secured early access to 355 million vaccines doses through agreements with seven separate vaccine developers. This includes 40m doses of Pfizer/BioNTech’s vaccine, which is based on the same platform as Moderna’s vaccine and if approved by the medicines regulator, is expected to begin delivery as early as December 2020.

## **Once we get a vaccine, can we end restrictions and lockdowns?**

* An effective vaccine will be the best way to protect the most vulnerable from coronavirus and the biggest breakthrough since the pandemic began. A huge step forward in the fight against coronavirus, potentially saving tens of thousands of lives. Once vaccinations begin, the Government will closely monitor the impact on individuals, on NHS pressures and on the spread of the virus.
* The full impact on infection rates will not become clear until a large number of people have been vaccinated, but as larger numbers do get vaccinated, we will hopefully move further along the path back to a more normal way of life.
* As large numbers of people from at risk groups are given a vaccine, the Government will be able to examine the impact on infection rates, hospitalisation and reduced deaths; if successful this should in time lead to a substantial reassessment of current restrictions.

## **How are vaccines regulated and approved for use?**

* The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK’s independent regulator, their role is to ensure medicines, devices and vaccines work and are safe for use. The safety of the public will always come first.
* Covid-19 vaccine will only be approved once it has met robust standards of effectiveness, safety and quality. Right through the tests and the trials. Teams of scientists and clinicians carefully, methodically, scientifically rigorously review all data on safety, effectiveness and quality as soon as they become available.
* The data looked at includes all the results from lab studies, clinical trials, manufacturing and quality controls and testing the product. The public can be very confident that all those tests are done to the very highest standards, and only then will a Covid-19 vaccine be made available.

## **COVID-19 vaccine development**

* All vaccines go through robust clinical trials, safety checks and quality controls. All vaccines are tested through three phases of clinical trials to ensure they meet strict standards.
* Phase one trials are to test initial safety, phase two is to test the immune response (production of antibodies) to different doses; and phase three is to test very large numbers of human volunteers for safety and effectiveness in preventing disease.
* There are extensive checks and balances required by law at every stage of the development of a vaccine.
* Independent regulators ensure that all the necessary safety checks are carried out. These decisions will be based on the evidence of vaccine trials involving very large numbers of people.
* As with any medicine, vaccines are highly regulated products. There are checks at every stage in the development and manufacturing process.
* The UK has some of the highest safety standards in the world and the MHRA is globally recognised for requiring the highest standards for quality, safety and medicines regulation.
* The NIHR (National Institute of Health Research) and UKRI (UK Research and Innovation) have invested heavily in the Research & Development of a COVID-19 vaccine; the NIHR has provided priority support through its Clinical Research Network to recruit to and facilitate the studies at pace.

## **COVID-19 Vaccine deployment**

* The NHS is ready to deliver a Covid-19 vaccination programme as soon as it is approved for use by the medicines regulator, the MHRA.
* Detailed planning is underway building on the NHS’s expertise delivering immunisation programmes including the flu vaccination programme.
* The NHS has a tried and tested track record for delivering vaccination programmes and will work with existing partners across the healthcare system to ensure a Covid-19 vaccine can be deployed safely and effectively.
* All plans recognise that there are numerous potential vaccines, meaning that the approach will need to remain flexible. Extensive preparations will ensure people across the country can access a vaccine, regardless of where they live, once it has undergone strict clinical trials and approved for use by the MHRA.
* As clinical trials progress and we understand more about the requirements of the vaccine – such as storage, transportation and how it is administered – we will continue to refine our plans to ensure we have the right resources in the right place.
* Planning considerations include the size and make-up of the workforce needed to deliver a potentially extensive vaccination programme, training requirements, guidance and equipment, as well as the supporting infrastructure required, including warehousing, transport, logistics and storage.
* Depending on the amount of vaccine which becomes available, it is likely that the NHS need to mobilise special delivery arrangements in addition to the usual routes via primary care and the workforce required to manage the volume of vaccinations. This will need to be done alongside maintaining routine programmes.
* The government is working closely with the devolved administrations to ensure successful delivery across the whole of the UK.

## **General vaccines messages**

* Vaccines are the most effective way to prevent infectious diseases.
* Vaccines save lives. After clean water, vaccination is the most effective public health intervention in the world.
* Vaccination is the most important thing we can do to protect ourselves and our children against ill health. Vaccines prevent up to 3 million deaths worldwide every year.
* Vaccines are the only way to eradicate disease. We have eradicated smallpox and are near to eradicating polio, both through using vaccines.
* Measles vaccination alone has prevented 20 million measles cases and 4,500 deaths in the UK.
* Vaccines teach your immune system how to create antibodies that protect you from diseases. It's much safer for your immune system to learn this through vaccination than by catching the diseases and treating them. Once a vaccine has trained your immune system to know how to fight a disease, it can often protect you for many years.
* Neither HIV nor malaria have vaccines, which shows just how challenging the process of developing a vaccine can be.
* To create a vaccine for a disease, the germ which causes it is weakened, or completely inactivated so that it cannot cause the disease in question.
* When this weakened or ‘dead’ germ is introduced to the immune system, it trains the immune system to recognise the disease and fight it off if you come into contact with it in the future.

## **When will the COVID-19 vaccine be available?**

* Whilst there are no certainties in the development and production of new vaccines, it is possible that a COVID-19 vaccine could be available in the first part of 2021.

## **Will you make the vaccine compulsory?**

* There are currently no plans in place to make the Covid-19 vaccine compulsory. The UK operates a system of informed consent for vaccinations.

**What vaccines will we have?**

* The UK has secured access to seven different possible vaccines, across four different vaccine types, reflecting the government’s strategy to ensure the UK has a supply of vaccines should they prove safe and effective in clinical trials. These are at separate stages of development.
* The UK has secured early access to over 355 million vaccines doses through agreements with several separate vaccine developers at various stages of trials, including:

• 100 million doses of University of Oxford/AstraZeneca vaccine – phase 3 clinical trials

• 40 million doses of BioNTech/Pfizer vaccine – phase 3 clinical trials

• 5 million doses of Moderna vaccine – phase 3 clinical trials

• 60 million doses of Novavax vaccine – phase 3 clinical trials

• 60 million doses of Valneva vaccine – pre-clinical trials

• 60 million doses of GSK/Sanofi Pasteur vaccine – phase 1 clinical trials

• 30 million doses of Janssen vaccine – phase 3 clinical trials

* The UK has invested over £230m into manufacturing any successful vaccine and an enormous amount of planning and preparation has taken place across Government to be able to quickly roll out the vaccine, including ensuring we have adequate provision, transport, PPE and logistical expertise to do so.

**Speed of development**

* It can take 10-15 years to develop a vaccine, but scientists recognised years ago the threat of a pandemic such as Covid-19 so had already researched how the right vaccine could be used. Because the scientists knew how to make a vaccine that should work, they could begin trials to find a vaccine that would work and more quickly than usual.
* They have spent the last year working on what the right vaccines will be and trialling with human volunteers all over the world.
* This science has been backed by considerable resources including investment by the UK government and commercial partnerships to fast track production.
* The final step is for the independent regulator to confirm that the vaccines are safe as well as an effective way for people to protect themselves and their families.

**Who decides who gets the COVID-19 vaccine first?**

* The Joint Committee on Vaccination and Immunisation (JCVI) are the independent experts who advise the Government on which vaccine/s the UK should use and provide advice on who should be offered the vaccination first.
* JCVI will consider each vaccine and provide their advice to the Government once detailed information on the characteristics and clinical properties of the approved vaccine becomes available.
* The current phase they recommend is a phase where the most vulnerable individuals in society are prioritised, particularly those who are most likely to die from severe Covid infection.
* The UK has focused on vaccines that are expected to generate an immune response among the over 65’s. Currently, over three-quarters of deaths caused by SARS-CoV-2 infection are in this older population, so it is essential that any vaccine is able to protect this group. The reason for this is because age is by far the strongest risk factor associated with severe Covid disease.
* The JCVI has advised that the vaccine first be given to care home residents and staff, followed by people over 80 and health and social workers, then to the rest of the population in order of age and risk. The prioritisation could change substantially if the first available vaccines were not considered suitable for, or effective in, older adults.

## **When will you publish vaccine ingredients?**

* If and when a vaccine candidate is successful and ready to deploy to the population, the MHRA will publish information on the ingredients in a summary of product characteristics (SPC) or equivalent.

**Government investment in vaccine research and manufacturing**

* The government has invested significantly to scale up manufacturing capabilities to ensure we are in a position to manufacture a successful vaccine in large quantities. The government has funded several UK vaccine manufacturing sites.
* The government is working closely with the devolved administrations to ensure successful delivery across the whole of the UK. We have also announced an additional £100 million investment to fund a state-of-the-art Manufacturing Innovation Centre in collaboration with the Cell and Gene Therapy Catapult, to accelerate the mass production of a successful COVID-19 vaccine in the UK.
* The government has invested £93 million additional funding to ensure the UK’s first dedicated Manufacturing and Innovation Centre will open 12 months earlier than planned, in summer 2021. While this centre is being built, the government has established a ‘rapid deployment facility’ thanks to a further investment of £38 million to begin manufacturing at scale from this summer.
* Collaboration between government, academia and industry is essential to manufacturing vaccine candidates at pace and scale. The UK’s leading life sciences industry knows how to develop, manufacture and distribute vaccines to global markets. The fact that the University of Oxford has signed a global licencing deal with UK-based AstraZeneca is testament to this.

## **Is our vaccine supply for all of the UK?**

* The UK government will make vaccinations available for all of the UK, plus the Crown Dependencies and Overseas Territories.

## **Is the deployment of vaccines UK wide?**

* Vaccination will be managed by the health services in each nation: NHS England and NHS Improvement, NHS Wales, NHS Scotland, and Health and Social Care Northern Ireland. The UK government is working closely with the Devolved Administrations to ensure an aligned approach to COVID-19 vaccine deployment across the UK.

## **Who is paying?**

* The UK government has agreed to buy these vaccines on behalf of the Devolved Administrations, Crown Dependencies and Overseas Territories at no charge.

## **Are British nationals who live overseas eligible to receive a Covid-19 vaccine?**

* We will be setting out more details on who is eligible for the NHS Covid-19 vaccine in due course [and if pressed] We expect the normal rules on access to the NHS to apply.

## **What is the government doing about the spread of disinformation?**

* Letting vaccine disinformation spread unchecked could cost British lives. We take this issue extremely seriously and have secured a major commitment from Facebook, Twitter and Google to tackle it by not profiting from such material, and by responding to flagged content more swiftly.
* We continue to work closely with social media firms to promote authoritative sources of information so people have access to vaccine facts not fiction.
* At a [virtual roundtable](https://www.gov.uk/government/news/social-media-giants-agree-package-of-measures-with-uk-government-to-tackle-vaccine-disinformation) to address the growth of vaccine disinformation, Facebook, Twitter and Google committed to the principle that no company should profit from or promote COVID-19 anti-vaccine disinformation, to respond to flagged content more swiftly, and to work with authorities to promote scientifically accurate messages.
* The Government will soon be publishing a full response to the Online Harms White Paper consultation, which will set out final details on the scope of planned legislation and other measures to tackle online harms.
* Throughout the pandemic the Government’s Counter Disinformation Unit has been developing a picture of the extent, scope and reach of disinformation and working with online platforms to ensure appropriate action is taken.

## **Vaccine trials importance**

* The encouraging news about vaccines is thanks to clinical study participants volunteering to take part and shows the importance of this vaccine research.
* Clinical trials into the vaccines against COVID continue at pace, and it is essential that these do so. We will need data about a number of vaccines and their safety and effectiveness, in order to protect the population. No one vaccine is likely to be suitable for everyone, the first vaccine may not be the most effective and easiest to use, and we must make sure that the other studies continue to allow us to have a selection of vaccines to protect the whole population. We are likely to need several vaccines to provide enough doses for everyone at risk, as early as possible.
* Once a vaccine is available, there will be a process in place so people on vaccine studies are not disadvantaged. People taking part in the vaccine research will still be able to have an approved vaccine when this is available. Taking part in a study is the best way to help effective vaccines to be identified and made available to everyone earlier and may even give you early access to a vaccine later found to be effective.

# How many people have taken part in clinical trials and what about ages, ethnic backgrounds and medical conditions?

* All the vaccines will be tested on between 15,000 to 50,000 people across the world. They are tested on both men and women, on people from different ethnic backgrounds, and of all ages between 18-84.
* The studies have also looked at if the vaccines work on people with certain medical conditions and in older people, as their immune responses can work less effectively and therefore give them less protection through vaccines. As a result of this testing on a representative sample of the population, we can be confident that an approved vaccine will be effective for the wider population in the UK.
* Research and vaccine development will not end with the first approved vaccine, there will be a process of continuous improvement.

# Will people on vaccine trials be able to have a Covid-19 vaccine when it is available?

* Once a vaccine is available, we will have a process in place so people on vaccine studies are not disadvantaged. People taking part in the vaccine research will still be able to have an approved vaccine when this is available. Taking part in a study is the best way to help effective vaccines to be identified and made available to everyone earlier and may even give you early access to a vaccine later found to be effective.