

**Top Lines and Q&A for stakeholders – Covid-19 vaccine**

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## **Quotes and statements**

### **NHS begins vaccinating the first UK patients (08/12/2020)**

#### **Health and Social Care Secretary Matt Hancock said 08/12/20:**

“We will look back on today, V-day, as a key moment in our fight back against this terrible disease, and I am proud our health services across the United Kingdom are about to embark on our largest ever vaccination programme.

“With over-80s and frontline health and care staff receiving their vaccinations from today, the whole country will breathe a collective sigh of relief as our most vulnerable loved ones start to be given protection from the virus. Now’s the time to sit tight and remain patient until you get notified by the NHS that it’s time for your vaccination. Until then, protect yourselves and the NHS by continuing to follow local restrictions. We can see light at the end of the tunnel but still have a long way to go.

“As a UK government, we have ensured the four nations will have enough doses of the vaccine to protect those across Scotland, Wales and Northern Ireland too. I want to congratulate each health service for their contribution to this momentous occasion.”

#### **Sir Simon Stevens, NHS chief executive, said (08/12/20):**

“Coronavirus is the greatest health challenge in NHS history, taking loved ones from us and disrupting every part of our lives.

“Hospitals have now cared for more than 190,000 seriously ill Covid-19 patients and have seen beds fill up again in recent weeks.

“The deployment of this vaccine marks a decisive turning point in the battle with the pandemic. NHS vaccination programmes which have successfully helped overcome tuberculosis, polio, and smallpox, now turn their focus to coronavirus.

“NHS staff are proud to be leading the way as the first health service in the world to begin vaccination with this Covid jab.”

### **Announcement on Oxford/AstraZeneca vaccine safety and efficacy data – 08/12/20**

#### **A Government spokesperson said:**

“Further evidence showing the Oxford/AstraZeneca vaccine is highly effective against Covid-19 is another piece of great news on the day we started to roll out vaccinations across the UK.

“Today’s publication is an important step forward in our efforts to develop a variety of effective vaccines for Covid-19. The UK was the first country to sign a deal with Oxford/AstraZeneca and, with 100 million doses already ordered, the UK will be one of the first countries in the world to the vaccine, but only if the independent medicines regulator, the MHRA finds it passes their strict standards of safety and effectiveness”

### **Government welcomes the MHRA’s approval of the Pfizer/BioNtech vaccine (02/12/20).**

**DHSC Statement (02/12/20):**

“The Government has today accepted the recommendation from the independent Medicines and Healthcare products Regulatory Agency (MHRA) to authorise Pfizer/BioNTech’s Covid-19 vaccine for use. This follows months of rigorous clinical trials and a thorough analysis of the data by experts at the MHRA who have concluded that the vaccine has met its strict standards of safety, quality and effectiveness.

“The Joint Committee on Vaccinations and Immunisations (JCVI) have also published its latest advice for the priority groups to receive the vaccine, including care home residents, health and care staff, the elderly and the clinically extremely vulnerable.

“The vaccine will be made available across the UK in the weeks and months ahead. The NHS has extensive experience in delivering large scale vaccination programmes and will begin putting their preparations into action to provide care and support to all those eligible for vaccination.

“To aid the success of the vaccination programme it is vital everyone continues to play their part and abide by the necessary restrictions in their area so we can further suppress the virus and allow the NHS to do its work without being overwhelmed.”

**Health and Social Care Secretary Matt Hancock said (02/12/20):**

“This is a momentous occasion and provides fresh hope that we can beat this pandemic, with the UK at the forefront of this revolutionary breakthrough.

“I can’t thank enough every single person who has contributed to this triumph - from the thousands of volunteers who took part in clinical trials, to the teams of expert scientists and clinicians at the MHRA who carefully analysed reams of data.

“This vaccine, when combined with effective treatments, will form a vital part in making Covid-19 a manageable disease, hopefully allowing us to return to normality in the future.

“This work will take time so for now we must all play our part and abide by the local restrictions to suppress the virus and protect the NHS as they start this vital work.”

**MHRA Chief Executive, Dr June Raine said (02/12/2020):**

“We have carried out a rigorous scientific assessment of all the available evidence of quality, safety and effectiveness. The public’s safety has always been at the forefront of our minds – safety is our watchword.

“I’m really pleased to say that the UK is now one step closer to providing a safe and effective vaccine to help in the fight against COVID-19 – a virus that has affected each and every one of us in some way - and in helping to save lives.

“We are globally recognised for requiring high standards of safety, quality and effectiveness for any vaccine. Our expert scientists and clinicians worked tirelessly, around the clock, carefully, scientifically, robustly and rigorously poring over hundreds of pages and tables of data, methodically reviewing the data.

“Vaccines are the most effective way to prevent infectious diseases. They save millions of lives worldwide.”

**Professor Wei Shen Lim, COVID-19 Chair for JCVI, said (02/12/20):**

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“The JCVI has considered the safety and efficacy data on the Pfizer/BioNTech vaccine and we’re pleased to say that it supports vaccinating those most at-risk of death from COVID-19 – starting with older people in care homes and those aged 80 years and above.

“This priority reflects the available data on those most at-risk of serious disease and death from COVID-19 infection. Our advice will be updated depending on the safety and characteristics of other vaccines, once available.”

### **Deputy Chief Medical Officer for England Professor Jonathan Van-Tam:**

“This is a remarkable day - congratulations to Pfizer/BioNTech and their researchers, and to all my colleagues in the Vaccine Taskforce for their tremendous work to get us to this point, and I want to thank the MHRA experts, including the experts at the Commission on Human Medicines, who have tirelessly and rigorously assessed the safety, effectiveness and quality of the vaccine.

“This vaccine has now passed all of the extensive checks needed for authorisation to supply and will soon be ready to be delivered to the NHS.

“To all those who are eligible – this is the start of vaccine supply for the UK. In time, you will be invited to book your appointments to get your vaccinations. I urge you to be ready, and to help make the process as smooth as possible. For now, stay patient, and keep yourselves safe by continuing to follow the rules and maintaining social distancing.”

### **General points**

- This is a huge step forward in our fight against coronavirus. Having an effective vaccine is the best way to protect the most vulnerable, saving tens of thousands of lives.
- The independent medicines regulator, the MHRA’s renowned teams of scientists and clinicians have advised that the Pfizer/BioNTech vaccine has passed their strict quality, safety, and effectiveness tests and can be given to people in the UK.
- The vaccination programme will build up steadily in the weeks and months ahead and will gradually be extended to more and more people.
- The UK was the first country to pre-order supplies of the vaccine from Pfizer/BioNTech, with 40 million doses ordered for delivery over the coming months, enough to vaccinate up to a third of the population, and the majority of doses anticipated in the first half of next year.
- An effective vaccine will be the best way to protect the most vulnerable from coronavirus and the biggest breakthrough since the pandemic began.
- Thanks to an incredible amount of hard work and planning, dozens of hospitals across the country will be giving the first vaccines to those aged 80 and over, and care home staff, with more to follow over the coming days and weeks.
- The public have an important part to play to help the NHS deliver the vaccine programme:
  - Please do not contact the NHS to seek a vaccine, the NHS will contact you;
  - When you are contacted, please attend your booked appointments;

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- The vaccination programme will build up steadily in the weeks and months ahead and will gradually be extended to more and more people. The vaccine will be given in hospitals, before being carefully rolled out to local vaccination services run by GPs, pharmacists and practice nurses, and in people's homes and care homes. More than 70 hospitals across the UK began vaccinating patients from Tuesday 8<sup>th</sup> December.
- 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.
- The UK government has secured early access to 357 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.

### **The different vaccines and regulation**

#### **Pfizer has announced that its vaccine is 95% effective and the MHRA have approved the vaccine. What comes next?**

The announcement from Pfizer/BioNtech and the MHRA approval is 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 NHS stands ready to roll out the approved vaccine to high risk groups identified by the JCVI. The UK Government put in place regulations so that if a vaccine was found before the end of the year, vaccinations could 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.

#### **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.

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.

We should pay tribute to the volunteers who took part in these clinical trials. Without volunteers, we wouldn't have the results we have.

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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 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.

### **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 7 million doses of its promising vaccine.

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 357 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 is expected to begin delivery as early as December 2020.

## **Q&A**

### **Top vaccine questions**

#### **Is one vaccine candidate superior to another? Is the Oxford vaccine worse than the Pfizer one?**

- A vaccine that is proven to be effective is one that will save lives and reduce hospitalisations.
- We don't yet know how long people who are vaccinated will be protected from coronavirus or if it prevents transmission.
- It's likely the T-cell response, which is responsible for this longer-term protection, will vary between the different vaccines.
- Therefore, a vaccine which has a lower effectiveness might actually prove to offer more protection in the long-term.
- Once we have more data, we will begin to have a more concrete idea of exactly how these vaccines perform, and how best to use them to save the most lives.

#### **How many doses of the Pfizer Covid-19 vaccine will need to be administered?**

- The vaccine is given in two doses - three weeks apart - and data from clinical trials showed the vaccine is 94 percent effective in protecting people over the age of 65 from coronavirus, with trials suggesting it works equally well in people of all ages,

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ances and ethnicities. There were also no serious safety concerns reported in the trials.

### **How quickly is the Pfizer vaccine effective after doses.**

- Full protection should begin 7-10 days after the second injection.

### **Where/how are vaccines going to be administered?**

- Vaccination to at-risk groups will take place at the most appropriate settings to encourage uptake. This includes administering vaccination to at risk individuals in their usual place of residence. The three models of delivery are:
  - Hospital Hubs - NHS providers vaccinating staff onsite.
  - Local Vaccination Services – Community and primary care-led service based on local and logistical considerations but is likely to include GP practices, local authority sourced buildings or other local facilities, and potentially roving teams if vaccines are transportable in this way.
  - Vaccination Centres - Large scale centres such as sports and conference venues set up for high volumes of people.

### **Who is going to be administering these vaccines?**

- Recruitment of workforce has focused on those who already have experience in handling vaccinations but may currently work outside of NHS settings, for example, independent nurses or allied health care professionals.

### **Should people who have already had Covid get vaccinated?**

- Yes, if they are in a priority group identified by JCVI. The MHRA have looked at this and decided that getting vaccinated is just as important for those who have already had Covid-19 as it is for those who haven't.

### **Is one easier to deliver?**

- All vaccines will present different logistical requirements, but the NHS has been planning for all eventualities, and people should be assured that the vaccine they will be offered is available because it has been assessed and approved by experts as being safe and effective.

### **Can people choose what vaccine they have? It has been suggested that vaccines could be mixed and matched?**

- Any vaccines that are available will have been approved because they pass the MHRA's tests on safety and efficacy, so people should be assured that whatever vaccine they get, it is worth their while.
- The Pfizer/BioNTech vaccine is being rolled out as fast as possible by the NHS across the UK. If authorised, the AstraZeneca/Oxford vaccine and other candidates will be deployed alongside the Pfizer/BioNTech vaccine to increase the pace and volume of the UK programme. There are no current plans to mix these vaccines.
- The Government's Vaccine Taskforce keeps its approach under review, ensuring the UK is in the strongest position to protect people. The science is uncertain about how mixing vaccines could produce a better immune response, so trials and testing will continue to assess and test vaccine responses.

### **Will vaccinations be available across the UK?**



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- 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.
- The vaccine will be available for free across the UK. We have procured vaccines on behalf of all parts of the country. And the Government is working with the devolved administrations to ensure it is deployed fairly across the UK.

### **Now that we have 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 our fight against coronavirus, potentially saving tens of thousands of lives.
- Once vaccinations begin, we will closely monitor the impact on individuals, on NHS pressures and on the spread of the virus.
- As large numbers of people from at risk groups are given an effective vaccine, we will be able to gather the evidence to prove the impact on infection rates, hospitalisation and reduced deaths; if successful this should in time lead to a substantial reassessment of current restrictions
- The full impact on infection rates will not become clear until a large number of people have been vaccinated with two doses, but as larger numbers do get vaccinated, we will hopefully move further along the path back to a more normal way of life.

### **Vaccine record cards**

#### **Why are some patients receiving Covid-19 vaccination record cards?**

- When patients are vaccinated, they are likely to receive a vaccine record card that notes the date of their vaccination, the suggested date for their second dose and details of the vaccine type and batch.

#### **Is this a vaccine ID card showing proof of vaccination?**

- This is a vaccine record card, similar to those given to patients for other NHS vaccinations as a note of when they received their vaccine.
- It is not intended to be used for any other purpose, or as an immunity certificate.
- All vaccinations are recorded on the patient's record with their GP.

#### **Where else will the vaccination be recorded?**

- All vaccinations are recorded on the patients record with their GP.

#### **Are you introducing vaccine passports?**

- We have no plans to introduce immunity passports following this vaccination programme.

### **Operational delivery (NHS)**

#### **If two vaccines are proved safe and effective, will the NHS have capacity to deliver both vaccines or will one have to be prioritised?**

- We have been planning extensively for this and a range of different scenarios, so if we get stocks of more than one at the same time this will potentially allow us to go further and faster. But we are not there yet.

#### **What type of sites will give it out? Are they all large sites and what if I can't get there?**



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- No, the NHS has been working together with local partners to ensure that people are not disadvantaged because of where they live, whether they own a car or if they are able to get about. This is why the NHS has developed three different models of delivery.

### **How is the vaccine going to be stored? Do you have enough freezers?**

- It's well-documented that the Pfizer vaccines needs to be stored at ultra-low temperatures. Special freezers are required for this and each of the hospital hubs has one in place.

### **How will patients be invited for a vaccination?**

- When it is the right time people will receive an invitation to come forward. For most people this will be in the form of a letter either from their GP or the national booking system; this will include all the information they need, including their NHS number.
- We know lots of people will be eager to get protected but we are asking people not to contact the NHS to get an appointment until they get their letter.

### **How will GPs be told who to vaccinate?**

- The JCVI will set criteria on an ongoing basis for who should get the vaccine when. GPs will be able to call in or go out to patients based on this, using their patient records. A national invite and recall system, drawn from GP patient records, may also be used.

### **Will you be running vaccine clinics over Christmas?**

- The NHS will be working hard to ensure the vaccine gets to those who need it, including on weekends and bank holidays – just as other vital services run 365 days a year.

### **Speed and safety**

#### **Can the government be sure that safety won't be compromised due to the speed of development of a Covid-19 vaccine?**

- There are extensive checks and balances required at every stage of the development of a vaccine, and this is no different for a Covid-19 vaccine. No stages in the vaccine development process are bypassed.
- All vaccines are tested through three phases of clinical trials to ensure they meet the gold standard. Phase 1 trials are with a small group of people to make sure there are no safety concerns and determines the appropriate dosage for the best immune response. Phase 2 trials are conducted on a larger group of people to check the vaccine works consistently and that the immune response is sufficient. Phase 3 trials test the vaccines on thousands of people for scientists to assess if the vaccine is producing immunity that will prevent disease.
- Usually, these phases are run in sequence, but in an effort to find a safe and effective Covid-19 vaccine as quickly as possible, once safety has been ascertained through Phase 1, Phases 2 and 3 are being run in parallel.

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- The data from each phase then goes to the regulator in a “rolling” review rather than once the trials have completed, which means the regulator can start looking at the results earlier than normal.
- Companies have made decisions to begin large scale production of vaccines which are still in trials. This means that if the vaccines are not shown to be safe and effective and are not approved for use the companies will have to destroy what they have manufactured. If, however the vaccines are successful, that means the vaccines are ready to be distributed.

### **How was the Covid-19 vaccine developed so fast?**

- Vaccine technology and the technological approaches to making vaccines are getting better and better and we couldn't have done it in this timeframe if we went back to the 2009 pandemic and we had a new virus about which we knew very little. We're in a different place today because of the technology.
- It was very clear that it was a global public health emergency from the word go and governments were prepared to put in lots of funding to manufacturers, without any guarantee of success, but hoping that they would find a solution
- Manufacturers knew this had to be a straight run through, they didn't have time for investment decisions and pausing or thinking about a commercial market at the end of it. It had to happen with real urgency.
- But the vaccine trials have been just the same as normal vaccine trials. Phase one, phase two and phase three. Where time has been saved is by recruiting participants in advance, so at the moment the study protocol is in place, the Ethics Committee is in place, so are the vaccine trial participants – which speeds up the process. And that happened at phase one, phase two and phase three and therefore things ran very fast.

### **How can a vaccine be developed in nine months?**

- These vaccines have been through phase 1, phase 2 and phase 3 clinical trials just like ordinary vaccines. The Pfizer vaccine clinical trial size was around 45,000 people. These are very, very big studies.
- Time has been gained is instead of getting an investment decision then going to ethics committee then starting to recruit volunteers, all of the recruiting volunteers was done in advance so that the people were completely ready to go and the ethics committees moved very fast to approve the trials.
- Organisations like the National Institute for Health Research made this their top priority and plans were made for the next phase by the companies without having to wait for things like investor decisions.
- But the numbers of people in the trials were the same as you would expect for any other vaccine, and on top of that the safety assessments and the assessments of effectiveness at the end are the same – it's the same regulators doing the same job.
- Companies have made decisions to begin large scale production of vaccines which are still in trials. This means that if the vaccines are not shown to be safe and effective and are not authorised for use the companies will have to destroy what they have manufactured. If, however the vaccines are successful, that means the vaccines are ready to be distributed.

### **How can people be confident there won't be long term side effects?**

- Every single vaccine authorised for use in the UK has been authorised by the MHRA and the three components of authorisation are a safety assessment, an effectiveness assessment and a manufacturing quality assessment.

## Regulation and Authorisation

### How are vaccines regulated and authorised 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 effectively and are safe for use.
- Each COVID-19 vaccine candidate is assessed on a case by case basis and will only be authorised once it has met robust standards of effectiveness, safety and quality.
- Teams of scientists and clinicians carefully, methodically, scientifically rigorously review all data on safety, effectiveness and quality as soon as they become available, and have done so throughout all tests and trials
- The data looked at includes all the results from laboratory studies, clinical trials, manufacturing and quality controls and testing the product. The public on that basis should be very confident that all tests are done to the very highest standards, and only then will a COVID-19 vaccine be made available

### Why haven't other regulators authorised this (Pfizer/BioNTech) vaccine yet?

- We cannot speak for other regulators on the details or timings of their review.
- The MHRA will evaluate the data rigorously for quality, safety and effectiveness to reach an independent, scientifically robust opinion.
- Any vaccine must undergo robust clinical trials in line with international standards, with oversight provided by the Medicines and Healthcare products Regulatory Agency (MHRA).
- This includes scientists and clinicians who will carefully and scientifically review the safety, quality and effectiveness data – how it protects people from COVID-19 and the level of protection it provides. The data includes results from the lab and clinical trials in humans; manufacturing and quality controls, product sampling, and testing of the final product. This process is designed to make sure that any vaccine authorised meets the expected high standards of safety, quality and effectiveness.

## Prioritisation

The full prioritisation list can be found [here](#) and is as follows (in order of priority):

- Residents in a care home for older adults and their carers
- All those 80 years of age and over and frontline health and social care workers
- All those 75 years of age and over
- All those 70 years of age and over and clinically extremely vulnerable individuals
- All those 65 years of age and over. All individuals aged 16 years to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality
- All those 60 years of age and over
- All those 55 years of age and over
- All those 50 years of age and over

### Why aren't BAME groups being prioritised?

- There is clear evidence that certain Black, Asian and minority ethnic (BAME) groups have higher rates of infection, and higher rates of serious disease and mortality. The reasons are multiple and complex.
- There is no strong evidence that ethnicity by itself (or genetics) is the sole explanation for observed differences in rates of severe illness and deaths. What is clear is that certain health conditions are associated with increased risk of serious

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disease, and these health conditions are often overrepresented in certain Black, Asian and minority ethnic groups.

- Prioritisation of people with underlying health conditions will also provide for greater vaccination of BAME communities who are disproportionately affected by such health conditions.
- Tailored local implementation to promote good vaccine coverage in Black, Asian and minority ethnic groups will be the most important factor within a vaccine programme in reducing health inequalities in these groups.

### **Why aren't you vaccinating economically active people? Surely that would be a good approach to get the economy back up and running again?**

- The full impact of vaccination on infection and transmission of the virus will not become clear until a large number of people have been vaccinated.
- The Joint Committee on Vaccination and Immunisation (JCVI) are the independent experts who advise Government on which vaccine/s the United Kingdom should use and provide advice on prioritisation at a population level.
- The Committee have advised that the first priorities for any COVID-19 vaccination programme should be the prevention COVID-19 mortality and protection of health and social care staff and systems. Secondary priorities could include vaccination of those at increased risk of hospitalisation and at increased risk of exposure, and to maintain resilience in essential public services.
- Given the current epidemiological situation in the UK, all evidence indicates that the best option for preventing morbidity and mortality in the initial phase of the programme is to directly protect persons most at risk of morbidity and mortality.

### **What about people who are immunocompromised who can't benefit from a vaccine?**

- The Government is exploring all avenues available to us, to ensure that a treatment for COVID-19 is found.
- Treatments containing COVID-19 neutralising antibodies have been secured from AstraZeneca to support immunocompromised people who will not be able to benefit from a COVID-19 vaccine.
- The antibody treatment currently being developed by AstraZeneca is a combination of two monoclonal antibodies and has the potential to be given as a preventative option for people exposed to the virus, and to treat and prevent disease progression in patients already infected by the virus if successful.

### **Why are care home workers prioritised over NHS staff?**

- There is evidence that infection rates are higher in residential care home staff, than in those providing home care or in healthcare workers. Care home workers are therefore considered a very high priority for vaccination.

### **Who is vaccinating care home residents and staff?**

- This group are a high priority and so as soon as it is possible for them to do so, GPs and local primary care networks will begin vaccinating care home residents. This is likely to begin before Christmas.
- In the first instance we will be working to vaccinate as many care home staff as safely as possible in hospital hubs in the immediate days and weeks, including bringing in staff.
- Taking the vaccine into the community and into care homes will come over the following weeks.

### **Has the MHRA approved care home jobs?**

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- The MHRA has now given the approval in principle for the vaccine to be moved and the trays of vaccines to be split in very specific and controlled circumstances.
- This is a new vaccine and has never been used before, and the scale we're all working at means there is only a small number of providers who can do this right now.
- The MHRA has set out how this can be expanded to GP-led vaccination channels.

### **Why do the JCVI's recommendations focus on reducing people's individual risk and not stopping transmission?**

- The most important thing is that we protect those who are most at risk of dying. At the start of any vaccination programme, we won't know the impact of the vaccine on transmission and so we will vaccinate those who are at highest risk of serious illness and death. This includes older people and care home residents.
- As vaccination programmes roll out globally, our understanding of the safety and effectiveness of each vaccine will increase, and these data will be used to develop advice on the next phase of the programme.

### **Why is vaccination not recommended for children?**

- Almost all children with COVID-19 have no symptoms or mild disease and the vaccines not yet been tested in younger children. The Committee advises that only children at very high risk of catching the virus and serious illness, such as older children with severe neuro-disabilities in residential care, should be offered vaccination.

### **Is the vaccine safe for people with pre-existing conditions?**

- The trials have involved people with chronic underlying conditions deliberately, and they have involved people from very broad age ranges and quite a lot of people in the elderly bracket. The JCVI have looked at this, there's no indication that there should be any difficulty in giving it to people with chronic underlying conditions.
- The JCVI has picked out, not just by age, but people 18 to 65 with at-risk conditions. And, and the reason for that is that they are at extremely high risk from coronavirus compared with the general population.

### **Why is vaccination not recommended for pregnant women?**

- These vaccines have not yet been tested in pregnant women and so we are taking a highly precautionary approach. Women should not be vaccinated if they may be pregnant or are planning a pregnancy within three months of the first dose.
- Data are anticipated which will inform discussions on vaccination in pregnancy. JCVI will review these as soon as they become available.

### **What about if a woman becomes pregnant between her first and second dose – what happens then?**

- Although the available data do not indicate any safety concern or harm to pregnancy, there is insufficient evidence to recommend routine use of COVID-19 vaccines during pregnancy. Vaccination should be postponed until completion of pregnancy. If a woman finds out she is pregnant after she has started a course of vaccine, she should complete her pregnancy before finishing the recommended schedule.

### **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.

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- We have secured early access to over 357 million vaccine 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
  - 7 million doses of Moderna vaccine
  - 60 million doses of Novavax vaccine
  - 60 million doses of Valneva vaccine
  - 60 million doses of GSK/Sanofi Pasteur vaccine
  - 30 million doses of Janssen vaccine
- We have 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. We are also working at pace to prepare for the delivery of any potential COVID-19 vaccination programme as quickly as possible.

### **Why doesn't JCVI's advice include anything about the other vaccine candidates?**

- After JCVI has been given the opportunity to review Phase III data on the vaccines, the statement will be updated. JCVI will continually monitor data on vaccines in development. As more Phase III data become available on candidate COVID-19 vaccines, the Committee will be able to prepare further advice for policy makers in the UK.

### **Vigilance, surveillance and adverse incidents**

#### **How will you monitor for problems, such as injuries or allergic reactions?**

- Each COVID-19 vaccine candidate is assessed on a case-by-case basis and will only be approved by the independent regulator, the MHRA, 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 independent expert working group have supported MHRA proposals for a proactive safety monitoring strategy. This comprises the Yellow Card scheme and a special active monitoring programme which we are inviting people to join.
- Approved COVID-19 vaccines will be monitored continuously after roll out by the MHRA and PHE to ensure that the benefit of the vaccines continues to outweigh any risk.
- You can report suspected side effects to COVID-19 vaccines through the Coronavirus Yellow Card reporting portal <https://coronavirus-yellowcard.mhra.gov.uk/>
- The MHRA will work in collaboration with partners in the health system to rapidly assess all available safety data in real time and communicate any emerging issues, as necessary.

#### **Are there any side effects?**

- Like all medicines, vaccines can cause side effects. Most of these are mild and short-term, and not everyone gets them.
- These are important details which the MHRA always consider when assessing candidate vaccines for use.



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- For this vaccine, like lots of others, they have identified that some people might feel slightly unwell, but they report that no significant side effects have been observed in the over 43,000 people involved in trials.
- All patients will be provided with information on the vaccine they have received, how to look out for any side effects, and what to do if they do occur, including reporting them to the MHRA.

### **If there are any significant medical incidents, could rollout be halted?**

- Each COVID-19 vaccine candidate is assessed on a case-by-case basis and 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.
- Once a vaccine has been rolled out, PHE will continue to closely monitor safety data. In the rare instance of a medical incident, DHSC will review the available data.
- The government are clear that all vaccines being rolled out must continue to meet high standards of safety and efficacy.

### **Allergic reaction with two people who received the vaccine yesterday (08/12/20)?**

#### **NHSE**

#### **Professor Stephen Powis, national Medical Director for the NHS, said:**

“As is common with new vaccines the MHRA have advised on a precautionary basis that people with a significant history of allergic reactions do not receive this vaccination after two people with a history of significant allergic reactions responded adversely yesterday. Both are recovering well.”

#### **Background**

- Both those affected were NHS staff members.

#### **MHRA**

#### **An MHRA spokesperson said:**

“We are fully investigating the two reports that have been reported to us as a matter of priority. Once all the information has been reviewed, we will communicate updated advice.

“In line with existing advice we advise anyone with a history of a significant allergic reaction due to receive the Pfizer COVID vaccine to speak to your healthcare professional who is administering the vaccine.”

#### **MHRA communication which has been issued to trusts:**

#### **Risk of allergic reactions - Advice to Healthcare professionals**

This precautionary advice is being issued following two case reports of anaphylactoid reactions associated with administration of Pfizer BioNtech COVID-19 vaccine.

#### **New advice:**

1. Any person with a history of a significant allergic reaction to a vaccine, medicine or food (such as previous history of anaphylactoid reaction or those who have been advised to carry an adrenaline autoinjector) should not receive the Pfizer BioNtech vaccine.
2. Resuscitation facilities should be available at all times for all vaccinations. Vaccination should only be carried out in facilities where resuscitation measures are available.

#### **Background**



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There have been two cases of anaphylactoid reactions in individuals with a strong past history of allergic reactions both of whom carried an adrenaline auto injector. These individuals developed symptoms of anaphylactoid reaction shortly after receiving the vaccine. Both recovered after appropriate treatment. We are seeking further information and will issue further advice following investigation.

Please report any suspected adverse reactions via the Yellow Card scheme. To make a report or find out more about the Yellow Card COVID-19 reporting site please visit: [Coronavirus Yellow Card reporting site](#)

### **Pfizer**

We have been advised by MHRA of two yellow card reports that may be associated with allergic reaction due to administration of the COVID-19 BNT162b2 vaccine.

As a precautionary measure, the MHRA has issued temporary guidance to the NHS while it conducts an investigation in order to fully understand each case and its causes. Pfizer and BioNTech are supporting the MHRA in the investigation.

In the pivotal phase 3 clinical trial, this vaccine was generally well tolerated with no serious safety concerns reported by the independent Data Monitoring Committee. The trial has enrolled over 44,000 participants to date, over 42,000 of whom have received a second dose of the vaccine.

### **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-19 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.

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

- All of 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 as to whether 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.
- There will be further studies to look at how best to use the different vaccines, for example, which vaccine is most effective in which individuals and what sized dose is most effective. A number of vaccines remain in development, and these may offer benefits over the first approved vaccine/s.

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- All this ongoing research will be vitally important to ensure we get the best protection from the vaccine. 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.

## **Communications and Campaigns**

### **Are you launching a campaign with celebrities to promote vaccinations?**

- An effective vaccine will be the best way to protect the most vulnerable from coronavirus and the biggest breakthrough since the pandemic began, potentially saving thousands of lives.
- We will provide advice and information at every possible opportunity to support those who have been prioritised to receive a vaccine and anyone who has questions about the vaccination process.

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

- Letting vaccine disinformation spread unchecked could cost 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.