### Coronavirus (SARS-CoV-2) Vaccines – Questions & Answers



10 ml / Injection or

#### How have the vaccines been produced so quickly?

Vaccines have been used safely for decades and must be fully tested before they can be used. There are normally 3 stages that must be undertaken before it can be deemed safe and effective. To speed up development phases were overlapped to shorten development time. Furthermore, higher level of investment to develop a COVID-19 vaccine meant that usual delays associated with securing funding for development and progressing through trial phases were removed. Another hurdle which aided rapid development was the significant interest among citizens to take part in trials, with high numbers of volunteers that were willing to participate. In addition, whilst COVID-19 was new virus, researchers were able to make use of learning from previous work exploring potential vaccines for other coronaviruses, such as MERS-CoV. Use of mRNA technology for vaccines is also built upon over a decade of research into using such approaches for cancer treatments which meant the technology could be swiftly adapted and applied

to vaccine development, it's potential for use in vaccine had been recognised prior to the start of the pandemic. All the factors discussed led to the quick development of this vaccine.

## 2. Are there safety concerns given the speed of development?

As with any medicine, vaccines are highly regulated products. There are checks at every stage in the development and manufacturing process. The vaccine will be continually monitored throughout delivery to the wider population. Safety has not been compromised, The Medicines and Healthcare products Regulatory Agency (MHRA) the official UK regulator of vaccines, have said this vaccine is very safe and highly effective, and we have full confidence in their expert judgement and processes.

During the development of the vaccine safety was a top priority. It is not unusual for a clinical trial to be temporarily paused when a possible side effect (called an adverse event) is detected. Clinical





trials are designed to pause when an unexpected health event (called a safety signal) is detected so scientists and physicians can investigate potential safety concerns. The approval process for COVID-19 vaccines was no different, safety is always the focus.

# 3. The first vaccines licensed use genetic technology, will it interfere with my own DNA?

No. The Pfizer vaccine is an RNA vaccine. These don't alter your DNA, they comprise of mRNA that gives the body instructions on how to make the spike protein on the surface of the Coronavirus. The mRNA strand gets used up so cells don't continue to produce the protein. The Oxford/AstraZeneca vaccine uses a strand of DNA, this enters cells but does not interfere with the body's own DNA. It gives instructions to the cell to make the mRNA and subsequent production of the spike protein. The immune system then responds to these spike proteins.

# 4. How do the mRNA vaccines (Pfizer / BioNTech and Moderna) work? - is this completely new technology?

The mRNA technology has had plenty of research before for other illnesses and diseases for over 10 years, but nothing so far has proven this successful. It uses small fragments from the genetic code of Covid-19 which would start making the virus inside a human body.

This would allow the immune system to recognise the virus as foreign and can therefore attack it with antibodies. In terms of the coronavirus vaccine, the patient would be injected with an initial dose, helping the immune system learn to produce antibodies to fight Covid-19. The second dose will strengthen the immune response. After the vaccination, if the person encounters the virus, antibodies and T-cells are then quickly triggered in order to fight it off.

### 5. How does the Oxford vaccine work?

It is made from a weakened version of a common cold virus (known as an adenovirus) from chimpanzees. It has been modified to look more like coronavirus - although it can't cause illness. When the vaccine is injected into a patient, it prompts the immune system to start making antibodies and primes it to attack any coronavirus infection. Unlike Pfizer's jab - which has to be kept at an extremely cold temperature (-70C) - the Oxford vaccine can be stored in a normal fridge. This makes it much easier to distribute.

### 6. The Oxford/AstraZeneca vaccine is less effective, should I bother?

Yes, research has shown both vaccines are highly effective. Both vaccines have been thoroughly assessed by The Medicines and Healthcare products Regulatory Agency (MHRA), the official UK regulator authorising licensed use of medicines and vaccines by healthcare professionals. They make this decision for each potential vaccine, and we have full confidence in their expert judgement and processes.



# 7. I don't have underlying health conditions and so I'm not at high risk of serious illness from coronavirus, should I bother getting a vaccine?

Yes, you will not only be protecting yourself but will be protecting others around you too. Vaccinating a large proportion of the population will have an important role to stop the virus from spreading.

# 8. I'm concerned that we don't know what the longer term side effects are, should I wait to be vaccinated until more is known?

These are important details which the MHRA will consider when assessing candidate vaccines for use. The NHS are monitoring patients immediately after their dose is given, and 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 the MHRA. Safety monitoring continues after a vaccine has been approved, in the UK this is through the Yellow Card Scheme.

Most side effects are mild and should not last longer than a week, such as:

- · a sore arm where the needle went in
- feeling tired
- a headache
- feeling achy
- You can take painkillers, such as paracetamol, if you need to.

It's very rare for anyone to have a serious reaction to the vaccine (anaphylaxis). If this does happen, it usually happens within minutes. Staff giving the vaccine are trained to deal with allergic reactions and treat them immediately.

The British Society for Allergy & Clinical Immunology (BSACI) BSACI COVID-19
Resources - BSACI

Coronavirus and Allergy - FAQs Coronavirus and Allergy - FAQs (allergyuk.org)

### 9. How long does immunity from the vaccines last?

Experts won't definitively know the length of immunity until they have followed vaccine recipients for a longer period. One study in The Lancet speculated that the duration of COVID vaccine-induced protection might last for less than a year, meaning this could end up being like the flu vaccine you get every fall. It depends on many factors, like how well the vaccine works and how long the human body maintains antibodies to fight COVID-19.

Oxford-AstraZeneca COVID-19 vaccine efficacy - The Lancet

### 10. Will I be able to go to my local GP Practice for my vaccination?

Across Warwickshire vaccines are being provided through GP Surgeries and community settings. The NHS will let you know when it's your turn to have the vaccine and where you will need to go. It's important not to contact the NHS for a vaccination before then.



### 11. Is the vaccine suitable for vegans?

There are no animal products listed in the ingredients.

#### 12. Does the vaccine contain the 'live' virus? Can it give me or anyone around me COVID-19?

No. The vaccines are designed to produce an immune response to just a small part of the virus, the spike protein. This is the part of the virus that allows it to enter into human cells and cause infection. No whole COVID-19 virus or live virus is used in the vaccines. This means the vaccine cannot give you COVID-19 and does not make you infectious after you have had the vaccine. This means it is also safe for people with a suppressed immune system

# 13. Which groups did PM pledge to vaccinate by 15 February – is this still the plan?

The PM set a target to offer vaccines to everyone in the top four priority groups, as outlined by the Joint Committee of Vaccination and Immunisation (JCVI), by 15 February 2021.

The plan also reiterates the commitment to offer the first vaccine dose to all those in the top four priority groups recommended by the JCVI by 15 February 2021:

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

With these groups accounting for 88 per cent of COVID-19 fatalities, the move will prevent thousands of deaths once their immunity develops in 14 days.

## 14. Who will be vaccinated after the four priority groups?

Phase 2 will look at the best tactics for achieving protection for the whole UK population, and may include vaccination of those at high risk of catching COVID-19 or delivering key public services. The JCVI will consider all available evidence for phase 2 recommendations of the vaccination programme.

### 15. Who can use the new vaccination centres?

As well as offering additional options for the over-80s, the NHS Vaccine Centres will also help in the NHS's drive to protect its own frontline staff as well as social care workers providing vital support in communities.



### 16. How can people use the new vaccination centres?

The NHS will contact you via letter. Please don't contact the NHS to seek a vaccine. When the NHS contact you, please attend your booked appointments.

The letters will explain how people can book a slot over the phone or online through the national booking service.

The centres are an additional option for people, who can book an appointment at one of the seven centres through the national booking service online or over the phone. If it is not convenient for them, they can instead be vaccinated at one of their local vaccination centres in the coming weeks.

People should wait until they are invited and should not call their GP but use the booking line.

# 17. What has changed to make 12 weeks safe for the dose interval when it wasn't last week?

The four UK Chief Medical Officers agree with JCVI that at this stage of the pandemic prioritising the first doses of vaccine for as many people as possible on the priority list will protect the greatest number of at risk people overall in the shortest possible time and will have the greatest impact on reducing mortality, severe disease and hospitalisations and in protecting the NHS and equivalent health services

This is because the evidence shows that one dose of either vaccine provides a good level of protection from serious illness, while the second dose will give ultimate longer term protection.

### 18. New variant of COVID-19

A variant of SARS-COV-2 is a version of the virus that has undergone some genetic changes (mutations). Some mutations may change the characteristics of the virus and how it interacts with humans. We have named this VUI – 202012/01 (the first Variant Under Investigation in December 2020). We are concerned that one of the mutations found in VUI-202012/01, called N501Y, has a potential impact on the characteristics of the SARS-CoV-2 virus

### 19. Is this strain resistant to the vaccine?

There is currently no evidence to suggest that the Pfizer/BioNTech or Astra/Oxford vaccine would not protect people against the new strain. Further laboratory work is currently being undertaken as a priority to understand this.

### 20. 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 disease, and these health conditions are often over represented 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.

All of the vaccines are 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

These test 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.

#### **Additional information**

9.6% of participants in the Phase 2 and 3 Pfizer/BioNnTech clinical trials were Black and 4.6% were Asian.

The phase 2/3 study was considered sufficiently representative of the UK population as a pre-authorisation study. Further effectiveness studies in representative populations are planned post-approval. In addition, MHRA have now published the Public Assessment Report on their website which has more information on demographics:

www.gov.uk/government/ publications/regulatory-approval-ofpfizer-biontech-vaccine-for-covid-19

### 20. 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. The reason for this is that they are at extremely high risk from coronavirus compared with the general population.

## 21. Can pregnant women have the Pfizer/ BioNTech or Oxford/ AstraZeneca vaccines?

The JCVI has amended its previous precautionary advice on Covid-19 vaccines and pregnancy or breastfeeding.

The new advice sets out that vaccination with either vaccine in pregnancy should be considered where the risk of exposure SARS-CoV2 infection is high and cannot be avoided, or where the woman has underlying conditions that place her at very high risk of serious complications of Covid-19, and the risks and benefits of vaccination should be discussed.

The Pfizer/BioNTech vaccine should only be considered for use in pregnancy when the potential benefits outweigh any potential risks for the mother



and baby. Women should discuss the benefits and risks of having the vaccine with their healthcare professional and reach a joint decision based on individual circumstances. Women who are breastfeeding can also be given the vaccine.

Those who are trying to become pregnant do not need to avoid pregnancy after vaccination, and breastfeeding women may be offered vaccination with either vaccine following consideration of the woman's clinical need for immunisation against COVID-19. The UK Chief Medical Officers agree with this advice.

### 22. Do I still need to follow the guidance if I've had the vaccine?

Whether you have had a vaccine or not, It is imperative that you continue to follow all the guidance to control the virus and save lives – that means staying at home as much as you can, and following the 'hands, face, space' guidance when you can't.