

A guide to vaccinations for COVID-19



Contents

| | | |
|---|---|-----------|
|  | How vaccines work and why they're important | 4 |
| | What is a vaccination? | 5 |
| | How does the immune system fight infections? | 5 |
| | How does vaccination work? | 6 |
| | Is it better to get COVID-19 naturally? | 6 |
| | Types of vaccines for COVID-19 | 7 |
| | What is 'herd immunity'? | 7 |
|  | Common questions about vaccines for COVID-19 | 9 |
| | What are COVID-19 vaccines made of? | 9 |
| | Are there animal products in vaccines for COVID-19? | 11 |
| | Can some people still get the disease even after they have been vaccinated? | 11 |
| | Can I get COVID-19 from the vaccines? | 12 |
| | How long does immunity to COVID-19 last following vaccination? | 12 |
| | After COVID-19 vaccination, can I still pass the SARS-CoV-2 virus on to others? | 12 |
| | I'm not at risk from COVID-19, why do I need a vaccine? | 13 |
| | I've already had COVID-19, why do I need a vaccine? | 13 |
| | Who should receive the vaccine against COVID-19? | 13 |
| | Is there a situation when I shouldn't be vaccinated? | 15 |
| | Do I need two doses of the vaccine and when should I receive them? | 15 |
| | Why are there multiple types of vaccines available for COVID-19? | 15 |
|  | Common concerns about vaccines for COVID-19 | 17 |
| | How do I know vaccines for COVID-19 are safe? | 17 |
| | Has the speed of developing vaccines for COVID-19 compromised safety? | 17 |
| | How are long-term side effects known when a vaccine is new? | 20 |
|  | Common questions about the Pfizer/BioNTech vaccine for COVID-19 | 21 |
| | How does the Pfizer/BioNTech COVID-19 vaccine work? | 22 |
| | Can mRNA vaccines alter my DNA? | 22 |
| | This is a new technology; how do I know it is safe? | 22 |
| | How effective is the Pfizer/BioNTech vaccine and what does that mean? | 23 |
| | Who should not receive this vaccine for COVID-19? | 23 |
|  | Common questions about the AstraZeneca/Oxford vaccine for COVID-19 | 25 |
| | How does the AstraZeneca/Oxford COVID-19 vaccine work? | 26 |
| | This is a new technology; how do I know it is safe? | 26 |
| | How effective is the AstraZeneca/Oxford vaccine and what does that mean? | 27 |
| | Who should not receive this vaccine for COVID-19? | 27 |
|  | Common questions about the Moderna vaccine for COVID-19 | 29 |
| | How does the Moderna COVID-19 vaccine work? | 30 |
| | Can mRNA vaccines alter my DNA? | 30 |
| | This is a new technology; how do I know it is safe? | 30 |
| | How effective is the Moderna vaccine and what does that mean? | 31 |
| | Who should not receive this vaccine for COVID-19? | 31 |
|  | Additional resources | 33 |

This guide has been written in January 2021, specifically about COVID-19 vaccinations and is accurate at the time of publishing. This guide explains how vaccines work and answers your common questions, as well as providing up-to-date information on the current approved COVID-19 vaccinations in the UK. Information will be updated as it becomes available.

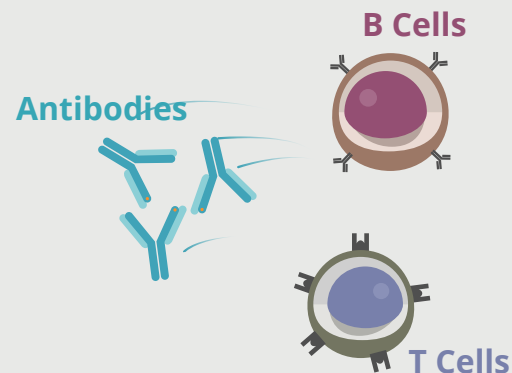
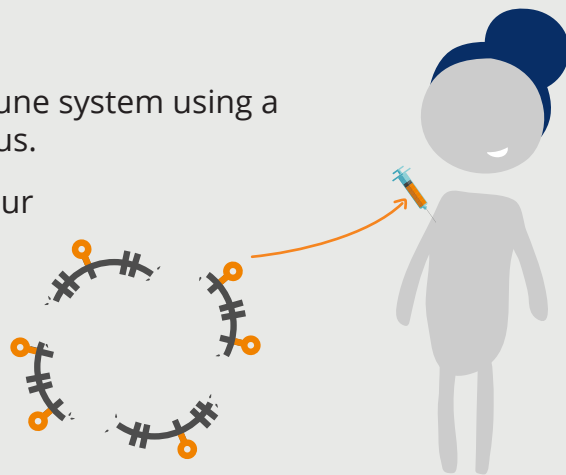
1

How vaccines work & why they're important

How do vaccines work?

Vaccines train your immune system using a harmless form of the virus.

The **vaccine** activates your immune response.



B cells that make highly specific **antibodies** to stop the virus getting into your cells.

T cells that can help stimulate the B cells and kill any infected cells.



These cells remember the virus and remain in the body. This is **immune memory**.

If you encounter the real virus in the future, your immune system responds faster and more effectively to prevent infection.

What is vaccination?

Vaccination is the safest way to protect against an infectious disease. Once you have been vaccinated, you should have the ability to fight off the infection if you come into contact with it. You will have a level of protection, or **immunity**, against the disease.

How does the immune system fight infections?

The immune system is a network of cells, tissues and organs that work together to help you fight off infection from harmful bacteria or viruses. Such disease-causing agents, including bacteria or viruses, are known as **pathogens**. When a pathogen invades your body, your immune system recognises it as harmful. Your immune system recognises unique features of the pathogen, called **antigens**, which will trigger an immune response.

Your immune system has many ways to fight off an infection. One of the ways is for specialised immune cells called **B cells** to create proteins called **antibodies**. These antibodies act as scouts, hunting down the pathogen, sticking to its antigens and marking it for destruction by the immune system or preventing it from entering your cells. Each antibody is specific to the pathogen that it has detected, matching precisely the shape of the antigen and triggering a specific immune response. Another way the immune system fights off infection is by activating other specialised immune cells called **T cells**, which can attack and kill any cells that are infected with the pathogen.

If your immune system wins the fight against the harmful pathogen, then these specific B cells and their antibodies and T cells will remain in the body after the infection has gone as memory cells. This means that if the same pathogen is encountered again, your immune system has a '**memory**' of the pathogen and is ready to quickly destroy it before you get sick and any symptoms can develop. Sometimes, however, the immune system doesn't always

Continues on page 6...

win this initial battle and you can become very ill with serious complications or in extreme cases die.

The virus which causes COVID-19 is called SARS-CoV-2. The immune response to infection with SARS-CoV-2 virus varies between individuals. In some cases, the person has no symptoms and feels well but in others, they get very sick and it can lead to admission to hospital, intensive care and in some cases death. The disease caused by SARS-CoV-2, COVID-19, can affect multiple organs across the body and is not limited to only the lungs and respiratory system. Some people can also suffer long-term effects from COVID-19 and take many months to feel well again – this is called 'long COVID'. We still have lots to learn about why this happens.

Vaccines have been developed to train your immune system and protect against infectious diseases and their serious complications.

How does vaccination work?

Vaccination is the safest way to gain immunity against a pathogen that your body has yet to encounter. Vaccines contain a harmless form of the bacteria or virus that causes the disease you are being immunised against. Your immune system will still recognise the harmless form of the bacteria or virus in the vaccine without making you sick and will produce a specific immune response to fight it off. The immune system then maintains a memory of the bacteria or virus, so if a vaccinated person encounters the bacteria or virus later, their immune system is already prepared to fight it off quickly and prevent an infection from developing.

Is it better to get COVID-19 naturally?

No. The only way to get COVID-19 naturally would be through infection with the SARS-CoV-2 virus that causes the disease. When infected, you become infectious to other

people around you and can spread the disease. Infection poses a serious risk to your health, potentially making you very ill and causing long-term health effects. As previously mentioned, we are still understanding the long-term health consequences of COVID-19 that may be serious for a long time. Vaccination allows you to build up immunity in a safe and controlled way without becoming ill with COVID-19 and passing it to others.

Types of vaccines for COVID-19

There are a wide range of approaches being used to develop vaccines against the SARS-CoV-2 virus, which causes COVID-19.

There are three COVID-19 vaccines currently approved for use in the UK. The Pfizer/BioNTech vaccine and the Moderna vaccine, which are both mRNA vaccines, and the AstraZeneca/Oxford vaccine, which is a viral vector vaccine. More information about these vaccines can be found in later sections of this guide.

What is 'herd immunity'?

Infectious diseases are often easily passed from person to person and entire communities can rapidly become infected. If a high enough proportion of a community is protected by vaccination, it makes it difficult for the disease to spread because the number of people who can be infected is so small.² This type of protection is known as '**herd immunity**'. Herd immunity is particularly crucial for protecting some individuals who are unable to receive vaccines, such as those that are too young, or undergoing certain medical treatment (such as for cancer). By getting vaccinated, you're not only protecting yourself, but you are also protecting the most vulnerable in your community.

For vaccines that prevent transmission of infectious diseases, a high percentage of the community needs to

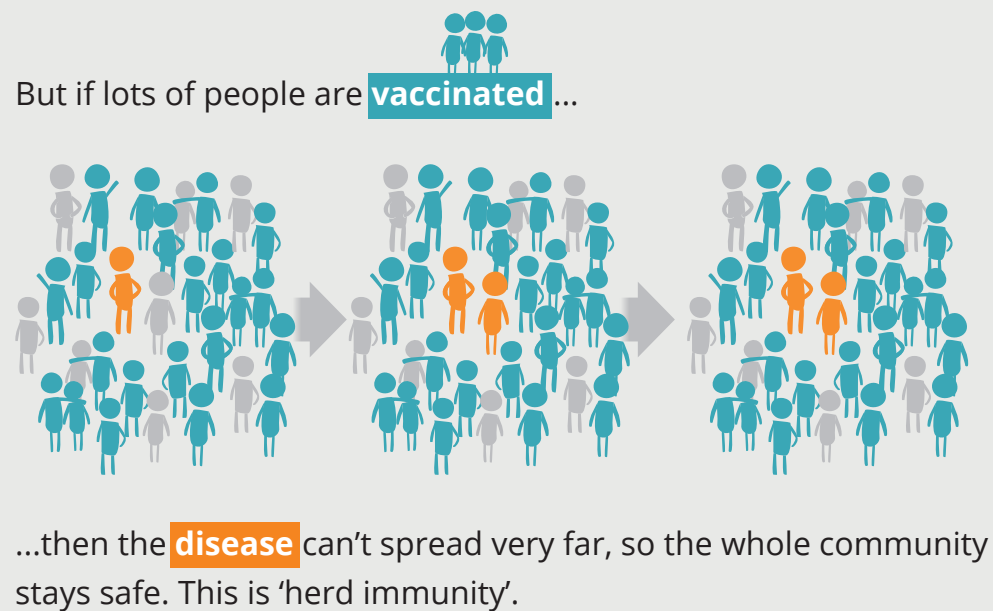
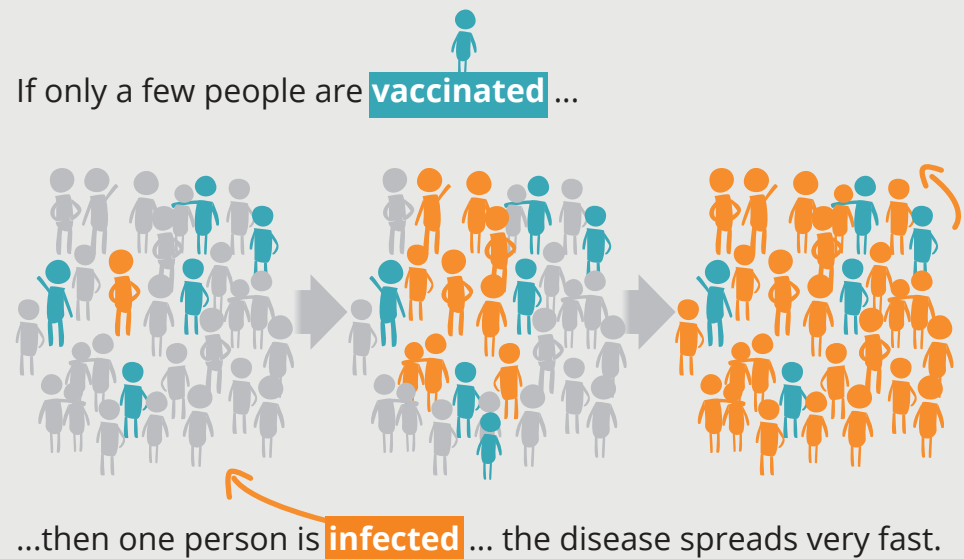
Continues on page 8...

be vaccinated. It is not yet known if vaccines for COVID-19 provide this type of protection through herd immunity. Research is underway to find out.

2

Common questions about vaccines for COVID-19

What is 'herd immunity'?



What are COVID-19 vaccines made of?

Each vaccine will be made up of slightly different ingredients depending on how the vaccine has been developed. The active ingredient in a vaccine is a very small amount of a harmless form of the bacteria or virus you are vaccinating against, which cannot cause disease. The role of the active ingredient is to deliver antigens to your immune system to generate a specific immune response. Vaccines for COVID-19 introduce SARS-CoV-2 antigens to your body in different ways.

The most abundant ingredient in a vaccine is water. The other ingredients in a vaccine are present in very small amounts and there is no evidence that they cause harm in these quantities (with the rare exception of people with severe allergies to some specific ingredients).

Vaccines contain very small amounts of preservatives and stabilisers, such as sorbitol and citric acid, to maintain quality and ensure the vaccine is safe to be transported and stored. These ingredients are often naturally found in the body or in food at much higher levels than in a vaccine. Preservatives are added to vaccines to prevent unwanted contamination, much like they're used in food products to stop them from spoiling. Stabilisers are also used in vaccines to stop the components separating or sticking to the vial during transportation and storage.

Continues on page 11...

What's in a vaccine?



Active ingredient

A very small amount of a harmless form of the bacteria or virus you are immunising against.



Adjuvants (only found in some vaccines)

Create a stronger immune response to the vaccine. Pose no significant risk to health in the very small quantities used. COVID-19 vaccines currently approved in the UK do not contain adjuvants.



Preservatives and stabilisers

Maintain vaccine quality, safe storage and prevent contamination.



Residual traces of substances that have been used during vaccine manufacture, measured as parts per million or billion in the final vaccine.



Water

The main ingredient.

Some vaccines have a very small amount of a substance added to them to help create a stronger immune response to that vaccine. These are called adjuvants. Adjuvants boost the immune response, which is particularly useful in vaccines given to older people, who have lower immune responses to vaccines. Adjuvants pose no significant risk to health in the very small quantities used in a vaccine and are often found in foods and other medicines at much larger quantities. **None of the COVID-19 vaccines currently used in the UK contain adjuvants.**

For a more extensive list of ingredients in each individual vaccine, you can refer to the Patient Information Leaflet (PIL) or Summary of Product Characteristics (SPC) sheet that comes with each vaccine. Both can also be found online.

Are there animal products in vaccines for COVID-19?

No. No animal products have been used in the manufacture of the current COVID-19 vaccines approved for use in the UK.

Can some people still get the disease even after they have been vaccinated?

Vaccines are the most effective medical intervention we have for preventing disease. However, no medicine can ever be 100% effective and the effectiveness of the vaccine will differ depending on how it is made and the disease it is protecting you from.¹

Variations in individual immune systems mean that the protective capacity of any vaccine will vary between different people, and in a very small number of cases, immunity against the disease will not fully develop. However, vaccination is extremely effective for the majority of the population.

Continues on page 12...

Some people may become ill with COVID-19 after vaccination before the vaccine has had time to take effect. Your immune system needs time to respond to the vaccine and immunity may take up to fourteen days to develop after vaccination.

Can I get COVID-19 from the vaccines?

No. The current vaccines approved for use in the UK do not contain any active SARS-CoV-2 virus and therefore cannot give you COVID-19 disease. If you have what you think is COVID-19 after vaccination it may be that you caught COVID-19 before the vaccine had taken effect and your body had time to develop immunity. Alternatively, you may have caught another virus that is not COVID-19 but has given you similar symptoms.

How long does immunity to COVID-19 last following vaccination?

It is not yet known how long immunity to COVID-19 from vaccines will last. Clinical trials for COVID-19 vaccines have been ongoing for many months and so far, results show that immunity is present in vaccinated individuals for the duration of these trials. Research into how long immunity lasts after COVID-19 vaccination is ongoing.

After COVID-19 vaccination, can I still pass the SARS-CoV-2 virus on to others?

There is strong evidence that vaccines for COVID-19 stop you from getting sick with the disease but there is no evidence whether they prevent you from spreading the virus. Continued monitoring of clinical trial participants and those who have received the vaccines will reveal this in the future, but it is currently unknown. Therefore, other measures are still needed to prevent the spread of the virus such as mask wearing, social distancing and hand hygiene.

I'm not at risk from COVID-19, why do I need a vaccine?

Even if you believe that you're not at risk of falling ill with COVID-19, it's important to remember how easily it can spread and the potential fatality. There is a huge variability in the symptoms and severity of COVID-19 between different people and while you may be in a less at-risk group this does not mean that the infection will not be harmful to your health. Vaccines decrease your chance of developing COVID-19 and reduce how unwell you become if infected.

I've already had COVID-19, why do I need a vaccine?

We do not yet know how long natural immunity to an infection with SARS-CoV-2 lasts and there seems to be a lot of individual variation. There have been rare reported cases of people re-infected with SARS-CoV-2, but we don't know how common this is.










Vaccines are capable of stimulating a better immune response than the natural infection. It is hoped that vaccines for COVID-19 will provide protective immunity for at least as long as natural immunity or longer, which is why you will still be offered the vaccine even if you've had COVID-19 in the past. It is likely that, in a significant proportion of the population, the vaccine will induce more effective and longer lasting immunity than that induced by natural infection. Hence it is recommended that everyone take the vaccine so that if your immunity after disease is absent or low, it can be boosted.

Who should receive the vaccine against COVID-19?

The Joint Committee on Vaccination and Immunisation (JCVI) has prioritised people for vaccination based on their risk of serious COVID-19 disease after SARS-CoV-2 infection. The priority order, confirmed in December 2020, is as shown on the following page.³

Continues on page 14...

Priority order for vaccines against COVID-19

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

The priorities are based on reducing risk of harm and the biggest risk of mortality from COVID-19 comes with age, even more so than underlying conditions such as cardiovascular disease or diabetes or being male or being in BAME backgrounds. Each older generation has approximately 10 times the risk of dying from COVID-19 than the generation below it. Because the vaccine has been shown to be effective in preventing disease in older people, they should be the first to receive it as they are most at risk.

People with a weakened immune system, such as those on certain medical treatments for cancer, are at high risk so will be offered the vaccine early.⁴ However, because their immune systems may not be able to make a response

to the vaccine, or a response that is not as effective, they should still take other precautions against the disease.

Is there a situation when I shouldn't be vaccinated?

Each COVID-19 vaccine will be recommended for use in defined groups of people depending on who was included in the clinical trials and found to safely tolerate it. It is rare that someone is unable to be vaccinated. People with an allergy to any ingredients of the vaccine should not receive it.⁴ Please speak to your GP if you are offered the COVID-19 vaccine and are concerned about whether you're able to receive it. These vaccines will not be routinely offered to children and young people under 16 years of age.

Do I need two doses of the vaccine and when should I receive them?

Yes, two doses of the Pfizer/BioNTech, Moderna and AstraZeneca/Oxford vaccines are needed to provide the best, longest-lasting protection against COVID-19.

It is recommended by the UK Government's Joint Committee on Vaccination and Immunisation (JCVI) that the second dose of the Pfizer/BioNTech and AstraZeneca/Oxford vaccines should be given a maximum of 12 weeks after the first dose. For the Pfizer/BioNTech vaccine, the second dose can be offered between 3 to 12 weeks after the first dose. For the AstraZeneca/Oxford vaccine, the second dose can be offered 4 to 12 weeks after the first dose.⁴

Why are there multiple types of vaccines available for COVID-19?

Multiple vaccines for COVID-19 will be essential to control the pandemic. We need a range of vaccines that can work for a diverse range of people, such as of different ages and ethnicities, because one type of vaccine might

Continues on page 16...

not be as effective for everyone. To vaccinate high-risk populations around the world we'll need to produce billions of vaccine doses and this will be more likely achieved through developing multiple COVID-19 vaccines. Technical and logistical challenges can be addressed with multiple vaccines. For example, the Pfizer/BioNTech vaccine needs to be stored at -70°C , which will prove difficult in many locations and settings, whereas the AstraZeneca/Oxford vaccine can be stored in a domestic fridge. Importantly, the vaccines need to be equally accessible and fairly distributed to people all around the world.

3

Common concerns about vaccines for COVID-19

Concerns over vaccine safety have allowed misconceptions and misinformation about vaccination to spread, despite there being little, if any, evidence to back them up. However, the large amount of unverified information available on the internet about vaccination can make it difficult to distinguish the facts from the myths. Here are answers to some of the most common questions and concerns about vaccines.

How do I know vaccines for COVID-19 are safe?

Before any vaccine can be given to the population it must go through rigorous testing. Like all medicines, vaccines undergo extensive clinical trials, where they are administered and monitored in groups of volunteers. In the UK, the results of the trials are then assessed by the Medicines and Healthcare products Regulatory Agency (MHRA).

No medicine can ever be completely risk free or 100% effective. However, strong licencing processes and safety tests ensure that the health benefits of medicines being given through the NHS greatly outweigh any risks. As vaccines are given to healthy people, these regulatory measures are even stricter, meaning that the level of 'acceptable risk' for vaccines is much lower than it would be for other medicines.⁶

Has the speed of developing vaccines for COVID-19 compromised safety?

No. All the standard safety procedures have been followed during clinical trials on vaccines for COVID-19 and the rigorous regulatory processes have been fully completed as for any other vaccine or medicine.

Vaccines for COVID-19 have been developed at a much

Continues on page 18...

faster pace due to several reasons. Vaccine development is normally a long and expensive process because of delays caused by applying for funding, obtaining ethical approval, recruiting trial volunteers, negotiating with manufacturers and scaling up production. In the emergency state of the COVID-19 pandemic the scientists, doctors, ethics approval boards, manufacturers and regulatory agencies have all come together to work harder and faster. Clinical trial phases and manufacture have been able to run in parallel to speed up the process.

Scientists have been sharing knowledge openly and promptly during the pandemic, with the SARS-CoV-2 genetic sequence being made public very quickly by Chinese scientists. Working together across many different countries has allowed researchers to work more efficiently.

The greatest barrier to vaccine development is funding. Normally it takes years to raise money to develop a vaccine and at each stage you would have to stop and apply for more funding to carry out the next stage. In the current emergency, many governments and funding bodies have joined forces to remove those financial obstacles. This has allowed large-scale manufacturing of the vaccines to occur in parallel with the clinical trials, which would normally only happen after clinical trials are completed.

The pandemic environment has meant acceleration of clinical trials and faster results because high case rates are needed to test a vaccine's effectiveness. Additionally, tens of thousands of keen volunteers have put themselves forward for the clinical trials so recruiting enough volunteers has not been an issue as it may be under normal circumstances.

Finally, scientific advances in vaccine technology have greatly aided the speed of development. Many of the approaches are built on the back of many years of research and could be rapidly deployed once the genetic sequence of SARS-CoV-2 became known.

Why have vaccines for COVID-19 been developed so fast?



How are long-term side effects known when a vaccine is new?

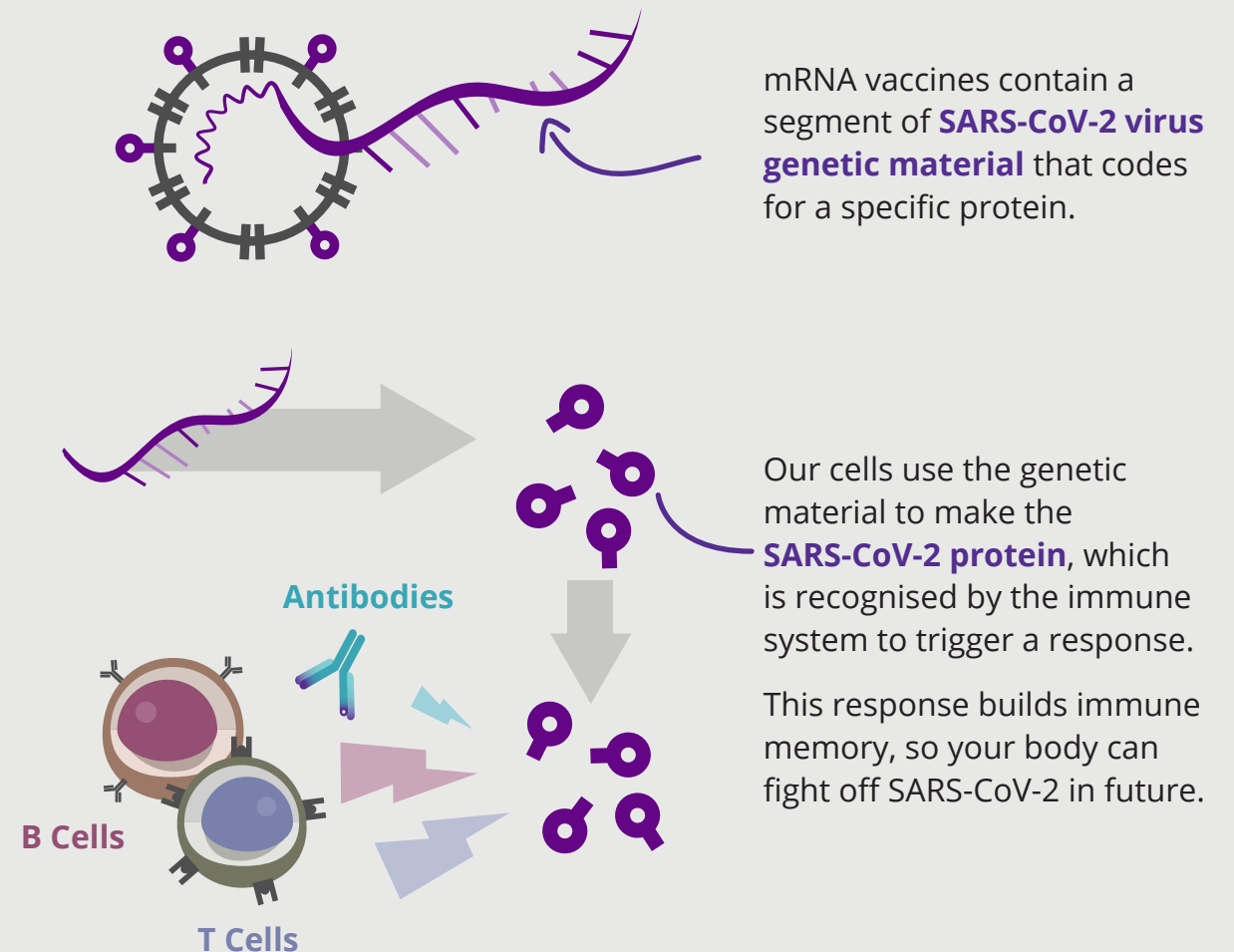
When any vaccine or medicine is approved, it is continuously and closely monitored for safety and effectiveness by the MHRA. Any suspected side effects are reported by medical providers or patients to the MHRA using the yellow card scheme. Cases of suspected side effects are investigated promptly, while precautionary advice is given and if necessary, advice is modified. You can find the yellow card scheme website at the end of this booklet.

Vaccines for COVID-19 have been monitored in large numbers of people for many months in clinical trials and no major safety concerns have arisen. Most side effects of vaccines appear at the time of vaccination or very soon after, within days or weeks, and are minor and temporary. The vaccines for COVID-19 have been monitored for long enough in clinical trials for the MHRA to find the vaccines safe. Short-term side effects include soreness and swelling at the site of injection, tiredness or a slight fever, but these are not long-lasting. These side effects are in fact evidence that the immune system is responding to the vaccine as it should be. Long-term side effects appear to be very rare but to be ultra-cautious, the MHRA will continue to monitor for them.

4

Common questions about the Pfizer/BioNTech vaccine for COVID-19

How do mRNA vaccines work?



How does the Pfizer/BioNTech COVID-19 vaccine work?

This vaccine is an mRNA vaccine. The virus itself is not used in this type of vaccine.

The vaccine contains a segment of the SARS-CoV-2 virus genetic material that codes for a specific protein from the virus, which is the spike protein on the surface of the virus. The genetic material in the vaccine is mRNA, which is used as instructions for the cell to make proteins.

When the vaccine is given, our cells at the site of injection take up the mRNA and make the SARS-CoV-2 protein. The mRNA from the vaccine is subsequently destroyed by the body. The protein produced is then recognised by the immune system and triggers a specific response. This response builds immune memory so that your immune system is ready to quickly fight off SARS-CoV-2 in the future and prevent you from getting sick with COVID-19. This immune memory builds up in your body after receiving two doses of the vaccine.

Can mRNA vaccines alter my DNA?

No. The mRNA delivered by the vaccine cannot enter the nucleus of your cells, where your DNA is stored, and will degrade naturally within hours. At no point is your DNA interfered with.

This is a new technology; how do I know it is safe?

This technology seems new but is built on the back of many years of research. mRNA vaccines for some cancers and rabies have been in clinical trials in humans for years with promising results and no major safety concerns.⁷ Once the genetic sequence of SARS-CoV-2 became known, this vaccine technology was adapted quickly to target the new virus.

The MHRA has thoroughly assessed the clinical trial data

and deemed it safe for use. The clinical trial data was published in the peer-reviewed and reputable journal called *The New England Journal of Medicine*.⁸ The most common side effects experienced by COVID-19 vaccine recipients was mild-to-moderate pain at the injection site, fatigue and headache which resolved within a few days. The published data followed participants for two months after vaccination with no safety concerns and safety monitoring of all trial participants will continue for two years after administration of the second dose of the vaccine. The MHRA will also carry out independent safety monitoring after the vaccine is released.

How effective is the Pfizer/BioNTech vaccine and what does that mean?

Over 43,000 people participated in the clinical trials which found that, seven days after the second dose, the vaccine was 95% effective in preventing people getting sick with COVID-19.⁸ Importantly, no one who received the vaccine suffered severe disease; the vaccine prevents the most severe cases of COVID-19.

Similar vaccine efficacy (generally 90 to 100%) was found across different groups of people. Age, sex, race, ethnicity, baseline body-mass index, and the presence of other health conditions did not affect the vaccine's effectiveness.

Who should not receive this vaccine for COVID-19?

The vaccine has not been tested on pregnant women or children under 16. There is no evidence that the vaccine will be unsafe in these groups but more data from clinical trials is needed before they can be offered the vaccine routinely.

The NHS advice states that pregnant or breastfeeding women will not be routinely offered the vaccine but it may be considered on an individual basis if the risk of exposure to SARS-CoV-2 is high and cannot be avoided or if the

Continues on page 24...

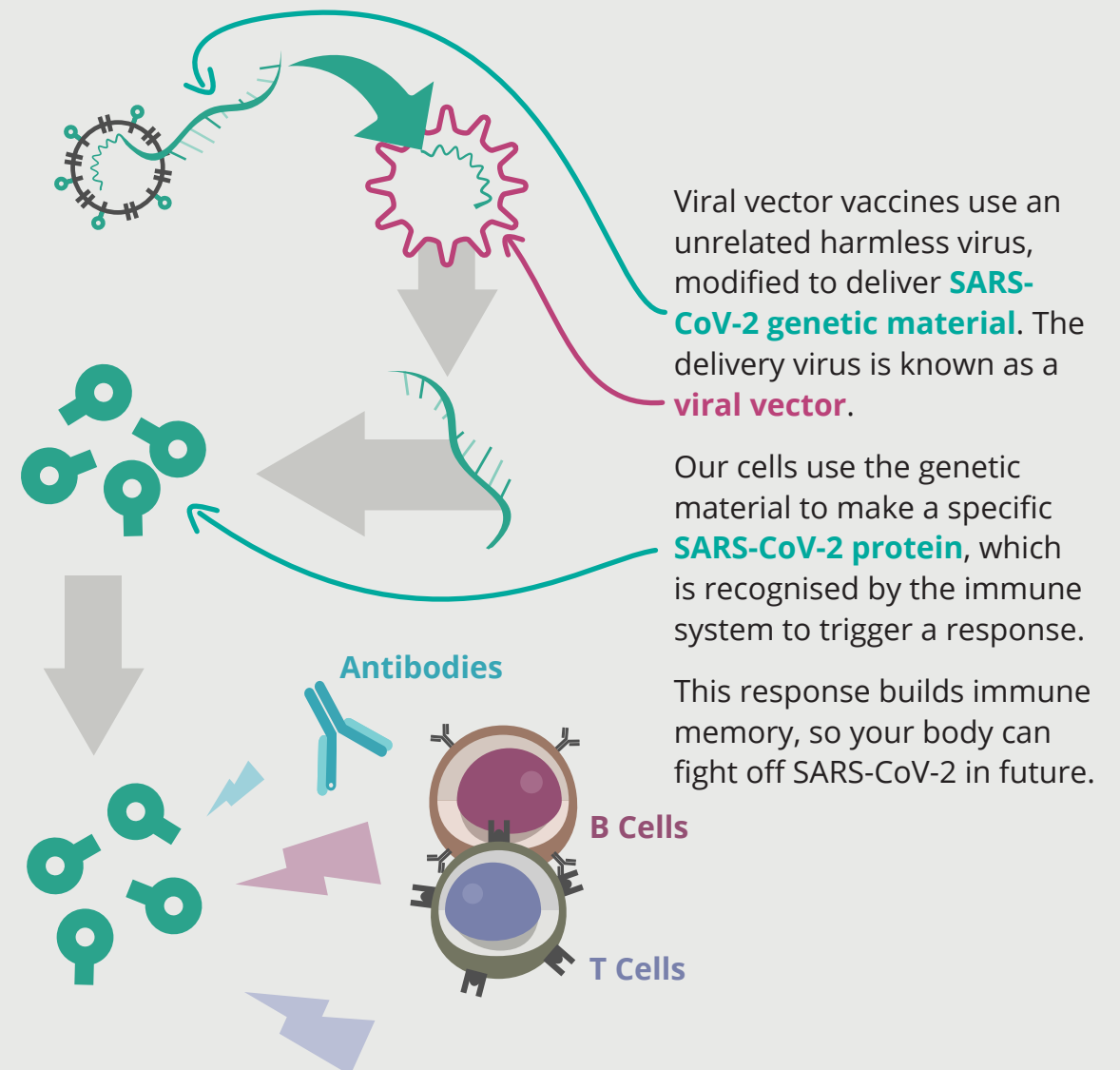
woman has an underlying health condition that puts them at very high risk of serious complications of COVID-19.⁹ If you have the vaccine, you do not need to avoid pregnancy because the vaccine cannot give you or your baby COVID-19.

The vaccine should not be given to people who have a history of immediate-onset anaphylaxis (serious allergic reaction) to any ingredients of the vaccine, multiple classes of drugs or an unexplained anaphylaxis.⁴ Some other mild allergies, such as hay fever or food allergies, do not pose a risk to a dangerous response to the vaccine. All people who are vaccinated are asked not to leave immediately so that the healthcare professionals can check there is no anaphylaxis, which usually happens within minutes.

5

Common questions about the AstraZeneca/Oxford vaccine for COVID-19

How do viral vector vaccines work?



How does the AstraZeneca/Oxford COVID-19 vaccine work?

This vaccine is a viral vector vaccine. The virus itself is not used in this type of vaccine.

The vaccine uses an unrelated and harmless virus which has been modified to act as a delivery system to carry the SARS-CoV-2 virus genetic material. The genetic material is a segment of SARS-CoV-2 DNA that codes for the specific spike protein from the SARS-CoV-2 virus. The delivery virus is known as a viral vector. In this vaccine, the viral vector is a weakened chimpanzee adenovirus, which normally causes the common cold in chimpanzees and has been changed so it cannot grow in humans.

When the vaccine is given, our cells at the site of injection take up the viral vector and the SARS-CoV-2 genetic material is delivered so the cell can make the SARS-CoV-2 protein. The viral vector from the vaccine is subsequently destroyed by the body. The protein produced is then recognised by the immune system and triggers a specific response. This response builds immune memory so that your immune system is ready to quickly fight off SARS-CoV-2 in the future and prevent you from getting sick with COVID-19. This immune memory builds up in your body after receiving two doses of the vaccine.

This is a new technology; how do I know it is safe?

This technology seems new but is built on the back of many years of research. Viral vector vaccines have been developed and approved for the prevention of Ebola after years of clinical trials in humans with successful results and no safety concerns.^{10,11} The research team at Oxford University were already working on pandemic preparedness, using this vaccine technology to fight emerging diseases. Once the genetic sequence of SARS-CoV-2 became known, the technology was adapted quickly to target the new virus.

The MHRA has thoroughly assessed the clinical trial data and deemed it safe for use. The clinical trial data was published in the peer-reviewed and reputable journal called *The Lancet*.¹² The most common side effects experienced by COVID-19 vaccine recipients was pain at the injection site, fatigue, muscle aches, feeling feverish and headache which resolved within a few days. The published data followed participants for between two to six months after vaccination with no safety concerns and safety monitoring of all trial participants will continue for 12 months. The MHRA will also carry out independent safety monitoring after the vaccine is released.

How effective is the AstraZeneca/Oxford vaccine and what does that mean?

Almost 11,700 people took part in the reported clinical trials.¹² Of the people in the trial who received the COVID-19 vaccine, 88% were aged between 18 and 55, 12% were aged over 55, 17% were BAME, 39% were male. The trial found that, fourteen days after the second dose, the vaccine was 62% effective in preventing people getting sick with COVID-19. Importantly, no one who received the vaccine suffered from severe COVID-19 disease; the vaccine prevents the most severe cases of COVID-19.

Who should not receive this vaccine for COVID-19?

The vaccine has not been tested on pregnant women or children under 18. There is no evidence that the vaccine will be unsafe in these groups but more data from clinical trials is needed before they can be offered the vaccine routinely.

The NHS advice states that pregnant or breastfeeding women will not be routinely offered the vaccine but it may be considered on an individual basis if the risk of exposure to SARS-CoV-2 is high and cannot be avoided or if the woman has an underlying health condition that puts them

Continues on page 28...

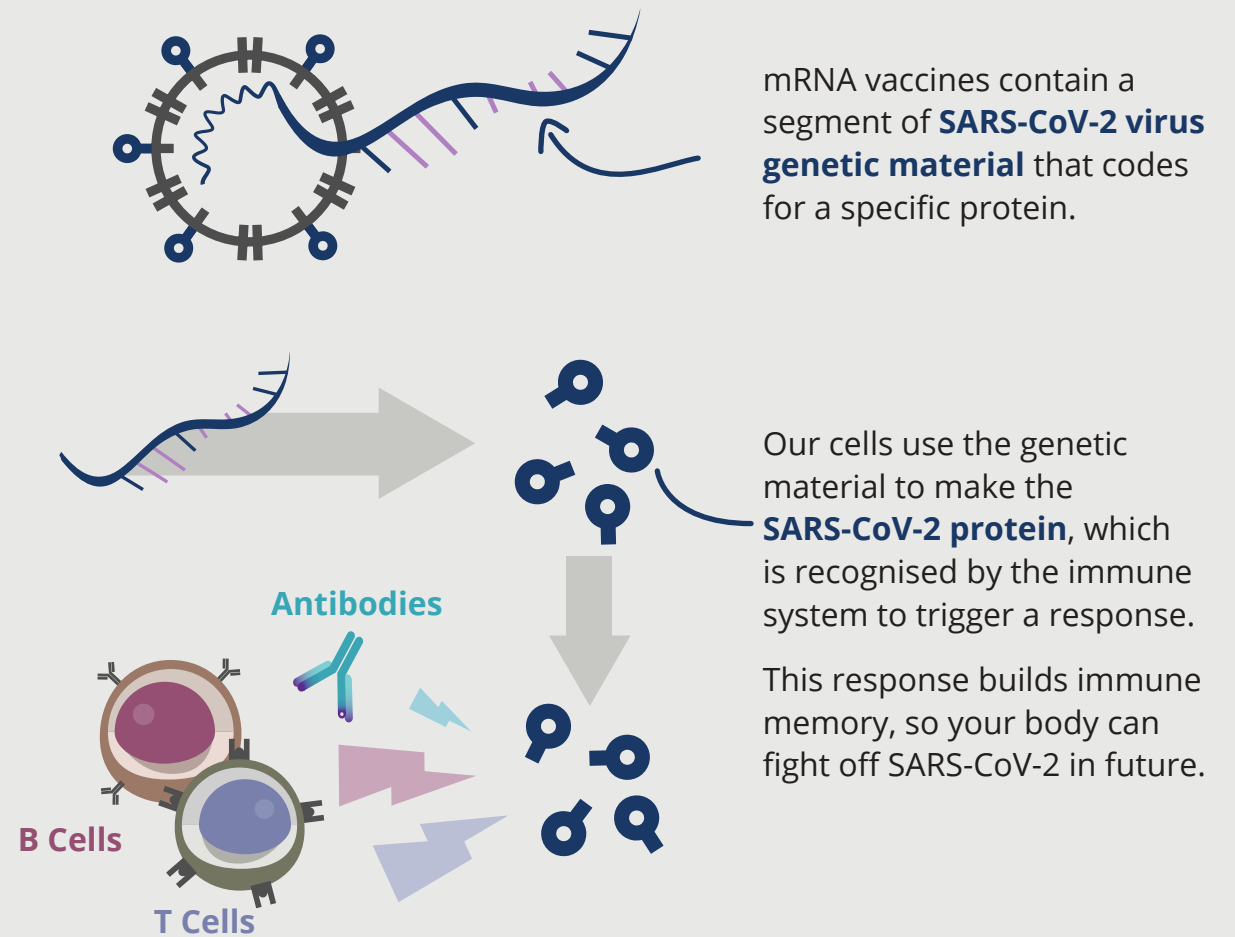
at very high risk of serious complications of COVID-19.⁹ If you have the vaccine, you do not need to avoid pregnancy because the vaccine cannot give you or your baby COVID-19.

The vaccine should not be given to people who have a history of immediate-onset anaphylaxis (serious allergic reaction) to any ingredients in the vaccine.⁴

5

Common questions about the Moderna vaccine for COVID-19

How do mRNA vaccines work?



How does the Moderna COVID-19 vaccine work?

This vaccine is an mRNA vaccine. The virus itself is not used in this type of vaccine.

The vaccine contains a segment of the SARS-CoV-2 virus genetic material that codes for a specific protein from the virus, which is the spike protein on the surface of the virus. The genetic material in the vaccine is mRNA, which is used as instructions for the cell to make proteins.

When the vaccine is given, our cells at the site of injection take up the mRNA and make the SARS-CoV-2 protein. The mRNA from the vaccine is subsequently destroyed by the body. The protein produced is then recognised by the immune system and triggers a specific response. This response builds immune memory so that your immune system is ready to quickly fight off SARS-CoV-2 in the future and prevent you from getting sick with COVID-19. This immune memory builds up in your body after receiving two doses of the vaccine.

Can mRNA vaccines alter my DNA?

No. The mRNA delivered by the vaccine cannot enter the nucleus of your cells, where your DNA is stored, and will degrade naturally within hours. At no point is your DNA interfered with.

This is a new technology; how do I know it is safe?

This technology seems new but is built on the back of many years of research. mRNA vaccines for some cancers and rabies have been in clinical trials in humans for years with promising results and no major safety concerns.⁷ Once the genetic sequence of SARS-CoV-2 became known, this vaccine technology was adapted quickly to target the new virus.

The MHRA has thoroughly assessed the clinical trial data

and deemed it safe for use. The preliminary clinical trial data was published in the peer-reviewed and reputable journal called *The New England Journal of Medicine*.¹³ The most common side effects experienced by COVID-19 vaccine recipients was pain at the injection site, fatigue, muscle aches, joint pain and headache which resolved within a few days. The published preliminary data followed participants for two months after vaccination with no safety concerns and safety monitoring of all trial participants will continue. The MHRA will also carry out independent safety monitoring after the vaccine is released.

How effective is the Moderna vaccine and what does that mean?

Over 30,000 people participated in the clinical trials which found that, at least fourteen days after the second dose, the vaccine was 94% effective in preventing people getting sick with COVID-19.¹³ Importantly, no one who received the vaccine suffered from severe disease; the vaccine prevents the most severe cases of COVID-19.

Similar vaccine efficacy was found across different groups of people with age, sex, presence of other health conditions that increase risk of severe COVID-19, race and ethnicity, not affecting the vaccine's effectiveness.

Who should not receive this vaccine for COVID-19?

The vaccine has not been tested on pregnant women or children under 18. There is no evidence that the vaccine will be unsafe in these groups but more data from clinical trials is needed before they can be offered the vaccine routinely.

The NHS advice states that pregnant or breastfeeding women will not be routinely offered the vaccine but it may be considered on an individual basis if the risk of exposure to SARS-CoV-2 is high and cannot be avoided or if the woman has an underlying health condition that puts them

Continues on page 32...

at very high risk of serious complications of COVID-19.⁹ If you have the vaccine, you do not need to avoid pregnancy because the vaccine cannot give you or your baby COVID-19.

The vaccine should not be given to people who have a history of immediate-onset anaphylaxis (serious allergic reaction) to any ingredients in the vaccine.⁵

Additional resources

The full reference list for this leaflet can be found online
www.immunology.org/guide-covid-vaccines/references

British Society for Immunology
<https://www.immunology.org>

WHO website – COVID-19 vaccines
<http://bit.ly/WHOcovidvaccine>

NHS website – COVID-19 vaccines
<http://bit.ly/NHScovidvaccine>

NHS website – why vaccination is safe and important
<http://bit.ly/NHSSafe>


MHRA yellow card scheme
<https://yellowcard.mhra.gov.uk>

If you have any questions about vaccines, ask your GP, nurse or other healthcare professionals.



The British Society for Immunology's mission is to promote excellence in immunological research, scholarship and clinical practice in order to improve human and animal health.

We are grateful to all our members who contributed to this booklet.

British Society for Immunology
34 Red Lion Square
London
WC1R 4SG
www.immunology.org
 @britsocimm

Registered charity: 1043255 in England and Wales; SC047367 in Scotland
Registered in England and Wales as a company: 3005933

© British Society for Immunology, first published January 2021.
Design: Anthony Lewis – www.anthony-lewis.com