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COVID-19 Vaccine Research

Frequently Asked Questions

1. Why is COVID-19 vaccine research moving so quickly? Are the checks, guarantees and ethical processes that are in place for research still being followed?

COVID-19 vaccine research is being reviewed and regulated in exactly the same way as any other piece of research that takes place in the UK. For COVID-19 research (including vaccine development), the set-up process has been streamlined by establishing a single, collective UK system-wide approach involving all the appropriate bodies, meaning that it can move through the process much quicker.

Before the research can begin, it will need to go through the following approval processes:

- 'Peer review' or 'Independent scientific review' - conducted by a group of people including healthcare professionals and lay people who are not involved in the research. This ensures the quality, validity and originality of the research and the plan for it (protocol) is suitable. They will raise any areas of consideration that the research team may not have thought of.
- Health Research Authority (HRA) approval - The HRA is accountable to the Department of Health and Social Care, and their core purpose is to protect and promote the interests of patients and the public in health and social care research. They make sure that research complies with relevant legislation and guidelines (such as Clinical Trials Regulations, the Human Tissue Act and the Data Protection Act).
- Research Ethics Committee (REC) approval - an independent group of people Including healthcare professions, lay members and other researchers who are brought together by the HRA to assess whether the research is ethical. They exist to protect the rights, safety, dignity and well-being of people who take part in research. No-one who is directly related to the research being reviewed will sit on the REC.

- Local site approval or Confirmation of Capacity and Capability: Each NHS site will assess if they have the capacity to undertake the research, including support departments like radiology and pharmacy. They also check if the research team has the right people with the right skills in place to successfully and safely conduct the research at that hospital/site.

2. How are vaccines developed? Can I catch or pass on COVID-19 from taking part in the COVID-19 vaccine research?

Vaccines are developed to train the body to recognise the virus as an invader and produce antibodies. This is called an immune response.

The vaccines being developed contain the spike protein from the COVID-19 virus. The spike protein is on the surface of the virus which is used by the virus to infect cells. When the virus enters the body and starts to infect cells, the body reacts by creating T-cells which cause an immune response and B-cells which make antibodies to block the virus from infecting cells. The B and T cells have a memory which identifies the virus if it enters the body in the future, and creates the same immune response and antibodies to block or kill the virus.

There are two different types of vaccine, and the information you receive about the research will clearly state which type of vaccine it is. They all work in the same way in terms of the immune response they create, but the virus used in them is created in different ways.

Live attenuated vaccines - these contain the virus itself, but in a weakened form. The vaccine causes a strong and long lasting immune response but not the disease or illness itself when given to healthy people. If it was given to a person whose immune system didn't work properly they could become ill. Examples of this type of vaccine include MMR, Shingles and Rotavirus vaccines.

Inactivated vaccines - There are several types of inactivated vaccines. These vaccines contain either the dead virus or uses specific pieces of the virus like a protein, sugar or casing. The immune response is then targeted to a key part of the virus. As there is no live virus in the vaccine it cannot cause infection. These types of vaccines can be given to people with weakened immune systems but they often do not provide long lasting protection and booster doses are usually needed. To strengthen the immune response, inactive vaccines are often combined with ingredients known as adjuvants (e.g. aluminium, egg protein) and these will be listed in the ingredients.

The types of inactivated vaccines are described below

- **Whole Killed vaccines:** These contain the killed virus; in the UK the vaccine for Rabies is a whole killed virus.
- **Subunit or acellular vaccines:** These vaccines contain sugars or proteins found on the surface of the virus and do not contain any whole cells (acellular). Most of the vaccines in the UK are this type and can be split into the following categories:

- Toxoid vaccines: These use a small amount of toxin made by bacteria/virus. The immune response is to the toxin for example the vaccines for Tetanus, Whooping Cough and Diphtheria are all toxoids.
- Conjuate vaccines: These vaccines contain sugars found on the surface of bacteria, which on their own don't produce a strong immune response. When the vaccine is joined (conjugate) with another protein that the body can recognise a strong immune response is created. Examples include Hib and MenC vaccines
- Recombinant vaccines: These vaccines are made by injecting genetic information (DNA) into a bacterial or yeast cell to manufacture the virus surface sugar or protein (vaccine active ingredient) used to create an immune response. Examples include MenB, Hepatitis B and the HPV vaccine. New types of recombinant vaccines are being developed which involve self-amplifying RNA. This method uses synthetic strands of genetic code (called RNA) based on the virus protein. The genetic information is put inside a fat droplet which is injected into the muscle. Once injected the RNA copies itself and instructs the body to make copies of the virus protein to trigger an immune response and antibodies.

3. What testing has the COVID-19 research vaccine been through to get where it is now? How will it become licensed?

There are four phases in clinical research trials. The stage or 'phase' of the research will depend on the vaccine research that you are taking part in. This will be explained to you in the written and verbal information given to you when you are deciding to take part or not. Each piece of research needs to move through the phases, which each have a different purpose and the number of people taking part in the research will increase with each phase to understand how well the vaccine works (how effective it is). If at any point during the phases, someone taking part in the research develops serious side effects, the research will be stopped and externally investigated by a medically qualified panel. It will only be allowed to continue once a review of the safety of those taking part has been made and any suggested changes carried out.

Phase one - this will be a small group of healthy volunteers. The purpose is to test the safety, watch out for potential side effects and decide the dose needed.

Phase two - the number of people will increase, and the focus moves to how well the vaccine works. At this point a 'placebo' will be introduced, which doesn't contain any vaccine. The placebo will be given to half of the people taking part in the research at random (known as randomisation) so the vaccine and placebo can be compared to measure how well the vaccine works. Whether you receive the vaccine or the placebo will not be known to yourself or the research team to make sure the findings can't be altered in any way, this is known as a double-blind trial. Potential side effects are still closely watched.

Phase three - this is the same as phase 2, but with even more people. How well the vaccine works and the side effects are still being closely watched.

As with any other piece of research, once the first three phases have been safely cleared and the vaccine is shown to work well, the vaccine can apply for licensing. As it is a vaccine it will be reviewed and licensed by the Medicines and Healthcare products Regulatory Agency (MHRA), which regulates medicines for the Department of Health and Social Care in the UK to ensure they work and are acceptably safe.

Phase four - the number of people will increase further as once the vaccine has been approved and licensed by the MHRA it can be made publically available. Like any new medicine; safety, side effects and how well the vaccine works will be watched by the research team for many years to come.

4. I am interested in taking part in COVID-19 vaccine research, but want to know more before I make a decision. What information will be shared with me and how will my consent be taken?

Each piece of research has a Participant Information Sheet or Leaflet. This outlines all the information you need to know about taking part in the research so you can make an informed decision about whether you would like to take part in the research or not. It is approved by the Research Ethics Committee and Health Research Authority to ensure that the details included in it are clear, transparent and accurate. If the research team wants to make any changes to it, it cannot do so without approval.

Before you can take part in research, you must give your 'informed consent'. This will be taken by a qualified member of the research team, and the process for doing this will have been ethically approved before the research is allowed to start. Informed consent confirms that everything to do with the research process has been clearly explained to you, that you have had a copy of the Participant Information Sheet or Leaflet explained to you and a copy to keep in an accessible format and that you are informed in your decision to take part in the research. At each research appointment you will be asked if you still want to take part in the research, and have the option and process explained to you if you no longer want to take part. If you decide that you don't want to take part anymore, you will not be expected to give a reason.

The Participant Information Sheet or Leaflet will cover why the research is happening, the purpose of it, how long it will last for and what is involved in the research. Possible side effects and risks will be outlined based upon what is already known. The practicalities of taking part in the research will be covered, including the detail of any follow-up visits and record keeping you may need to do e.g. keeping a diary. Processes outlining how your information will be kept confidential will be explained, and who to contact if you no longer want to take part in the research. Contact details for the research team will be provided, alongside information about what to do if you develop any serious side effects.

5. I'm worried about the side effects of the COVID-19 vaccine I take as part of research, what are they?

There has already been a lot of work done to establish the possible side-effects, so you can be assured they are quite well understood and will be shared with you.

Much like any other medicine or vaccine, there is a chance that you may develop side effects. The side effects may vary depending on the research that you are taking part in. So far the side effects reported have been mild and include soreness in the arm, fever and aches. Soreness in the arm is a common response to any vaccine or injection delivered into the arm, you may experience this when you have the flu vaccination. Fever and aches are a common response from your immune system as it responds to the threat of infection. The side effects have been reported as lasting only a couple of days.

If the research you are taking part in needs to be stopped for investigation due to someone developing a serious and/or unexpected side effect (known as a serious adverse event) you will be told about this and given advice about what to do. The research will be independently investigated (not by any member/s of the research team) and the findings will be presented to the Medicines and Healthcare products Regulatory Agency (MHRA) who will make a decision about whether any changes need to be made to the research plan (protocol) and if it is safe to continue. The safety of people taking part in research is the most important part of this process, and the MHRA won't allow the research to continue until they are confident about this. As someone taking part in the research, you will be notified of this decision and the planned steps.

The Participant Information Sheet or Leaflet will contain information about the types of side effects, the chances of developing them and what has been seen so far. You will also have the procedure explained to you about what to do if you develop any side effects, including how to report them and who to report them to.

It is important for researchers to know what side effects people taking part in the research experience, so they can understand what they are, the likelihood of them happening and if the research needs to be stopped to investigate further. This is an important part of the research process when reporting on safety.

6. What are the ingredients in the COVID-19 vaccine being used for research?

The ingredients will vary depending on which piece of COVID-19 vaccine research you are taking part in. It is important that the research team makes you aware of the ingredients, so you can make a decision about if you want to take part based upon your cultural and religious beliefs, and dietary requirements and preferences. This will be clearly explained to you in the Patient Information Sheet or Leaflet, and a member of the research team will also go through this with you. If you wish to stop taking part in the research because of the ingredients, you can do so. You will not be asked to or expected to explain your reasons as to why you no longer want to take part.

7. If I take part in COVID-19 vaccine research, how will I be monitored after? Will I need to attend any more appointments?

The monitoring process will vary depending on which piece of research you are taking part in. The Participant Information Sheet or Leaflet will contain all of the information regarding any follow up visits and will detail the follow-up process including what will be done, how it'll be done, when it'll be done and how often it will be done. This could include:

- A booster injection, to 'boost' the vaccine
- A blood test to check for antibodies (immune response)

Due to the current situation, you may be asked to take part in follow-up appointments over the phone or online. This will be agreed with you before you take part in the research, giving you a chance to discuss any access needs you may have.

You may also be asked to complete a diary detailing how you're feeling following the vaccination and a record of your temperature. Each piece of research will have a clear process and contact details for who to contact and what to do if you start to develop any side effects and you wish to discuss with a member of the research team and/or a healthcare professional.

8. How do I sign-up to take part in COVID-19 vaccine research?

You can express you interest in taking part in COVID-19 vaccine research by signing-up to the NHS Vaccine Registry

You will be asked to answer some questions about yourself, and then asked to give your permission for COVID-19 vaccine researchers to contact you. They will only contact you if you have given your permission and if there is research taking place in your area that you are suitable for. The researcher will tell you more about the research, and answer any questions you have.

If a researcher does make contact with you and you have changed your mind, you will not have to take part in the research or speak to the researcher. If after having the research explained to you, you decide that you don't want to take part it is your choice, and you will not be expected to take part or asked for your reasons as to why you don't want to take part.

If you sign up, your details will be kept secure. They'll only be shared with researchers who think you might be suitable for a study they're working on. You can withdraw your permission at any time.

9. I'm nervous about going into a crowded place or a health setting, where will the vaccination take place?

The location of the COVID-19 vaccine research will vary depending on which city you are in and which piece of research you are taking part in but they will all be COVID-secure. Some will take place in health care settings, others will take place in sports halls and other large venues.

The most important thing is the safety of those who are taking part and the staff who are supporting the research. Following Government guidelines, staff will be wearing facial coverings and floor markings will be used to make sure social distancing can be followed with clearly marked sections for each part of the process. People taking part in the research will also be asked to wear a face covering.

Upon arrival people taking part in the research will have a temperature check and a COVID-19 test. If anyone's temperature is a concern or their COVID-19 test comes back positive, they will not be able to continue with the research and advised to go home and follow Government guidelines around self-isolation.

If either someone taking part in the research or a staff member supporting the research is contacted through the Government's Track and Trace App and told to isolate due to a COVID-19 contact, they must contact the research team and will have to self-isolate for 14 days. The same applies if they have any known contact with someone who has tested positive for COVID-19 or show COVID-19 symptoms until the self-isolation time has come to an end or they receive a negative test result.

10. Why is the representation in COVID-19 vaccine research important?

Researchers want to produce COVID-19 vaccines that are suitable for everyone and offer the best protection possible, this will mean that research will continue after the first COVID-19 vaccine has been made available and there may be more than one vaccine available. Representation is important in developing the vaccine so researchers know how well the vaccine works for different groups of people, and if there are any differences in how they react to the vaccine.

Throughout the country different teams supporting COVID-19 vaccine research are engaging with their local communities to understand any hesitancies people may have about taking part in COVID-19 vaccine research. They are also looking to understand any misinformation that may have been circulating. This understanding is very important in making sure that the public has correct and transparent information about what taking part in COVID-19 vaccine research involves so they can make an informed decision about whether they want to take part or not. Like any other piece of research, no-one will be pressured into taking part in it if they don't want to.

11. I have a long-term health condition, can I still participate in COVID-19 vaccine research?

It depends; every piece of research has an inclusion/exclusion criteria. A member of the research team will go through this with you before you agree to take part in the research to make sure that you are able to take part. This will vary depending on the research you are taking part in, but exclusions may include age, long-term health condition/s and pregnancy.

12. Can you take part in COVID-19 vaccine research and still have the flu jab?

Yes you can, but the time in which you can have your flu jab around taking part in the research will depend on the research you are taking part in. The research team will let you know about the timings, as it is important that no-one is stopped from having their flu jab.

13. Will taking part in COVID-19 vaccine research stop me from getting the actual COVID-19 vaccine once it becomes available?

No it won't, but if you receive an established vaccine you will no longer be able to take part in the COVID-19 vaccine research.

14. I need help with reading and understanding the information that is given to me, will this be available?

Yes, a member of the research team will provide assistance and can arrange for the information to be presented to you in a way that meets your access needs (please let the team know when you are booking your appointment).

15. I need the information in a different language and/or format, will this be available?

Yes, translation services and interpreters can be made available (please let the team know when you are booking your appointment).

16. I don't use technology very often, will this stop me from taking part?

No, a member of the research team will teach you to use any special apps or online diaries required as part of taking part in the research.

17. I have a disability which limits my mobility, will the venue be accessible?

Yes, there are support assistants available at the venue. There are also recorded guides for the venue and details are available of the venue layout.

18. How many people are needed for COVID-19 vaccine research?

Thousands, most Phase 3 studies would be expecting to recruit 10,000 - 15,000 people to take part.

19. Is COVID-19 vaccine research only open to people who have had COVID-19, or currently have COVID-19?

Research is not open to those who have had COVID-19. To take part in the vaccine research you should not have been diagnosed with COVID-19 previously or have detectable antibodies in your screening test. If you do, you won't be able to continue with the research.