Can we trust the Covid-19 vaccines?

After the devastation of the coronavirus pandemic, a ray of light appeared at the end of 2020 when the first vaccine was announced, swiftly followed by news of at least two more. Yet many people say they will not take the vaccine. *Sorted* asked an expert in immunology, Denis Alexander, to answer some of the common questions asked about vaccinations in general, and the Covid-19 vaccines in particular.

BY DENIS ALEXANDER

How are vaccines tested?

All three vaccines against the coronavirus that have been approved for use in the UK have been very thoroughly tested. Since all medicines and drugs of any kind used by the NHS have to be tested in the same kind of way, let me summarise the process.

First, they are tested in animals, in this case animals such as rats and ferrets which have immune systems similar to our own. Very useful ideas about the actions of potential therapies can be gained from the immune responses of animals. Any toxic consequences can also be detected very easily.

Second, there are three essential phases of testing in humans, and every reagent has to go through all three before approval is possible. Details of the trials involved have to be approved by the government before starting and then published on a public website. In Phase 1, just a few dozen people are injected with the vaccine, to ensure there are no immediate safety concerns.

In Phase 2, the vaccine is then tested on a relatively small number of people. In the case of the Oxford-AstraZeneca vaccine now being rolled out, 1077 healthy adults were tested in the UK during April/May 2020. Testing is carried out by injecting half the group with the vaccine, and half with a very

similar reagent that acts as a 'vaccine mimic', without containing the vaccine reagent itself. In this phase, the immune responses are measured in some detail. Questions such as the best dose to use and the need for one or two jabs can also begin to be addressed, and the levels of neutralizing antibodies assessed. These antibodies bind to the virus and prevent it infecting the cells of our bodies. The Phase 2 trial was published in the top medical journal the *Lancet* in August 2020.

The really big trial comes with Phase 3. Here the test numbers shift up into the tens of thousands. The group as a whole are divided into the Test group who are jabbed with the actual vaccine and the Placebo group who are jabbed with the mimic reagent. No one involved in the trial knows who is in which group – neither those giving the jab, nor those being jabbed. This is because sometimes just the knowledge that one is being injected with a life-saving medication is enough to give a positive result. Nice as that may be, placebo responses vary a lot between people, which messes up the results. So this 'double-blind' method is the only reliable approach. Everyone is coded, so only well after the jabbing and measuring of responses is over are the codes matched to the people. And the codes are the crown jewels – heavily guarded until the eagerly awaited revelation day.

Taking the Oxford-AstraZeneca vaccine again as our example, the Phase 3 trial started with 23,848 participants and took place between April and November in three countries: the UK, Brazil and South Africa. The trial happened in different countries to check whether the responses differed in people from different parts of the world. These areas were chosen because they had high infection rates – the faster the rates, the quicker the results arrive. This trial also deliberately included those with underlying health conditions that might make them more susceptible to Covid disease. An older age range was also included and the male-female ratio between the Test and Placebo groups was kept in balance. Different dose levels and different times between the first and second jabs were also tested. The initial Phase 3 results were published, again by the *Lancet*, on 8 December 2020, and showed 62-90% protection against the coronavirus, depending on the precise protocol used for the group being tested. There was also 100% protection against hospitalization in vaccinated patients who did suffer viral infection. The Phase 3 trial continues to grow as more and more testing is carried out on ever larger groups, and those jabbed will be followed up for at least a year to assess longer-term results.

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How can vaccines be approved so quickly?

Previously it has taken around 8-10 years to develop a human vaccine. So how come that three vaccines (Pfizer, Oxford and Moderna) have already been created and approved for use in the UK in less than 12 months, with more on the way? The simple answer is that this is the first worldwide pandemic to devastate the world since the flu epidemic of 1918. Governments and research funding agencies have thrown huge sums of money at the enterprise. Research groups have been working night and day to make it happen and the results have been truly remarkable.

But there has been no cutting of corners in terms of testing or assessment. All the normal stringent procedures have been followed. The Medicines and Healthcare Products Regulatory Agency (MHPRA) is the key UK government agency that had to give the approval. As a government agency, their job is to assess all the data provided and make sure any medical reagent is safe to use. They were able to move fast on vaccine approvals by using a 'rolling review' process whereby they reviewed the data as it was sent during the months of the Phase 3 trial. But of course no final decision could be made until the trial is completed.

Now that the MHPRA has given its approval, each batch of vaccine that gets released for use has to go through both the manufacturer's own testing regime plus independent external testing from an agency such as the National Institute for Biological Standards and Control. This does slow down somewhat the release of the vaccine for use, but provides an important extra set of checks to ensure that the particular batch being used is absolutely safe. →

← How safe are the vaccines?

All vaccines used in the UK have to be approved by the MHPRA after going through the same rigorous testing programme as outlined above. All vaccine jabs can give some mild discomfort to some people, as anyone knows who has had the flu jab. Some of those who received the Oxford vaccine had a sore arm or mild fever after their jab, readily relieved using paracetamol. Some people may have an allergic reaction to the chemicals used to preserve the active reagent in the vaccine. These are treatable and vaccinations usually take place in or near medical centres where treatment for any rare cases of unexpected allergy are quickly available.

Compared to the dangers of suffering or actually dying from Covid-19, the risks involved in having the vaccine are tiny. Life is never 100% risk-free. We risk our lives crossing the road, but we still do it. Compared to such daily activities, the risks involved in having the vaccine are barely measurable.

Does it contain a microchip?

No, such claims belong to fantasy fake news websites. If you seriously think that you have a microchip in your brain that is controlling your thoughts (rather than just seeing it as a social media 'joke'), then you need to see a psychiatrist. As far as the safety of vaccines are concerned, it's also worth remembering that every batch of vaccine is tested by multiple people. Hundreds of people are involved in the production and testing of vaccines. And each separate batch is tested for purity before use.

Is the whole thing a conspiracy?

Again, pretty much everything in life is a conspiracy for some people who have a certain mind-set. Living in a social media bubble provides a good way to spread conspiracies, but they have to start somewhere with one disturbed mind. If you close your mind to the great mass of evidence that points in a certain direction, then you can believe in a flat earth or that our planet is only 10,000 years old – or pretty much anything.

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In this particular case, conspiracy theorists might want to ask why a government would want to foist a fake pandemic on a population which causes a financial crisis, mass unemployment and over 100,000 deaths of voters. Most governments want to get re-elected in due course!

Anti-vax campaigns have a long history. The Jenner Institute, where the Oxford-AstraZeneca vaccine was developed, is named after Edward Jenner who first started vaccination in the late eighteenth century [see our separate article for what he did and how it worked]. At that time, on average 400,000 people died from smallpox every year, and of those who survived, one third went blind, and many were disfigured. Today the disease has been eradicated from the world population. But even in 1797, people opposed what Jenner was doing.

Can it cause infertility?

Whether any medical reagent has any effect on fertility would clearly not be known with complete certainty until after many thousands of women have received it over a period of years. But in the case of Covid vaccines there is absolutely no reason

SUCCESSFUL VACCINES IN COMMON USE

- Smallpox (1796)
- Cholera (1885)
- Rabies (1885)
- Typhoid (1896)
- Tuberculosis (1921)
- Diphtheria (1923)
- Seasonal flu (1930s)
- Whooping Cough (Pertussis) (1950s)
- Polio (1956)
- Tetanus (1961)
- Measles (1963)
- Rubella (German measles) (1970)
- Anthrax (1970)
- Meningococcal Infections (1970s)
- Mumps (1970s)
- Chickenpox (Varicella) (1984)
- Hepatitis B (1986)
- Pneumococcal Infections (1980s)
- Hepatitis A (1993)
- Rotavirus (2006)
- Shingles (2006)
- Papillomavirus (2006)
- Ebola (2019)
- Covid-19 (2020)

The list shows only vaccines in common use. The dates show when a successful vaccine started to be used – it often takes decades to achieve widespread vaccination. In some cases vaccination has eliminated the disease e.g. Smallpox was eradicated worldwide by 1979. Polio vaccination has reduced worldwide cases by 99% since 1988, preventing thousands of deaths and cases of paralysis. Diphtheria was the third leading cause of death in children in England and Wales in the 1930s – now it is very rare. Chickenpox infection in pregnancy can be risky to the mother, to the pregnancy, and to the new-born. During 2019/20, flu vaccinations in the USA prevented 105,000 hospitalisations and 6,300 deaths.

to think that it would have any negative effect on fertility. Vaccines against similar types of virus, such as those that cause flu, have been given to many millions of people without any evidence that they cause infertility. There are false internet and social media claims being made about Covid vaccines causing infertility which are pure fantasy and based on no evidence at all. During the Pfizer-BioNTech vaccine study, there were 23 study participants who became pregnant during their vaccine trial. There was one pregnancy loss, but this was in a participant who received the placebo, not the vaccine.

So far around two million people worldwide have died from Covid-19, with millions more suffering from the lingering effects of Long Covid. The viral infection is known to have negative effects on both male and female reproductive organs. Furthermore, many pregnant women who have been infected with the virus during pregnancy have faced significant medical difficulties and some have died. Given these known facts – and comparing these facts with an unknown and very speculative possible risk that remains unexpected – for most people, the choice to be vaccinated is an easy one.

What about mutations – how likely is it that the vaccine will not work against the South African variant, for instance?

All viruses mutate with time, which is why we need to have a different flu vaccine every year just to keep up with the latest version. But compared with many viruses, the Covid virus doesn't mutate particularly fast. At present there is no evidence that any reported variants will escape the currently approved set of vaccines, but that remains a possibility for the future. The good news is that it's very easy to sequence variants and, if necessary, generate a new vaccine that will work against the new variant. That could be done in 4-6 weeks and the new vaccine would be so similar to the one already approved that it could be in use very quickly.

What would you say to those who refuse to be vaccinated?

There is one important command that Jesus gave that applies in a very direct and practical way to everyone in the present pandemic. Jesus said, 'Love your neighbour as you love yourself' and by 'neighbour' it's clear he meant 'everybody'. Anti-vaxxers may not realise that they have blood on their hands. If someone refuses to be vaccinated, it's the whole community that is affected, because if we don't get so-called herd immunity up to around the 80% level (based on data from the infectivity of the new Kent variant that has recently swept the UK), then the virus will not be defeated, and more people will die. No one is safe until everyone is safe – which means that the world population really needs to achieve such herd immunity, through vaccination. The virus needs people in whom to multiply just to keep going – so every person who refuses vaccination is giving the virus permission to take up a home in their bodies, multiply, and so infect others. Those who love their neighbour as they love themselves will care for their family, friends and wider community by being vaccinated. S.

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