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# Are we any closer to a coronavirus vaccine?

As the coronavirus pandemic continues, we're all waiting for a vaccine to help get life back to normal - but are we any closer to one?

Medical experts around the globe are working overtime studying the virus to develop a vaccine and there are some promising results coming out of these studies.

Dr William Bird, GP and co-author of the government's Better Health campaign, explains when we can expect to see a COVID-19 vaccine.

## The vaccines and the evidence

According to the World Health Organization there are around 29 potential vaccines in clinical trials, but none of them have yet gone through all the research stages needed to confirm they have the right combination of effectiveness and safety.

This includes one from the University of Oxford with pharmaceutical company AstraZeneca, a Chinese one called CanSino Biologics and another from the Russian Defence Ministry. The US government is also working with a number of pharmaceutical companies.

A COVID-19 vaccine from pharmaceutical company Novavax is already in phase three clinical trials as is a vaccine from Johnson & Johnson's Janssen pharmaceuticals.

"However, it looks like just about 20 are in advance stages and many of these are likely to fail to get to market," he explains. "Despite making astonishing progress, all of these trials are at relatively early stages. The Oxford trial seems to be a front-runner at this stage, although we must always note caution with vaccines, as more than 90% fail, even if they look promising to start with."

## How does the vaccine work?

These are being developed using the COVID-19 strain of coronavirus as an antigen. Scientists use a weakened or inactive version of the virus, or part of the virus, to trigger an immune response in the body.

The body's immune system remembers this antigen and triggers the same response next time it comes into contact with the virus, therefore creating an immunity.

"The Oxford trial saw 1,077 adult volunteers injected with a common cold virus with parts of coronavirus inserted, to trigger an immune response," Dr Bird says.

"Results demonstrated that the vaccine was safe - and also that two doses provided a better response than one. The results show theoretical benefit (in this case a response from the immune system) but now they will need to test the vaccine in real life to see if the antibody response is good enough to prevent an infection."

A paper from the Oxford study, published in The Lancet medical journal, suggests the vaccine 'stimulates antibody and T-cell response'.

Dr Bird says this means "the trial vaccine stimulates the production of Yshaped proteins known as 'neutralised antibodies' that should latch on to the coronavirus and prevent infection".

"It also stimulates the production of T cells, another key part of the immune system which destroy any cells that have become infected," he adds.

# When will we see a vaccine?

Unfortunately, the production of a vaccine isn't a quick process. It has to undergo rigorous testing, including human trials, to ensure it's safe to use before it can be approved for use. Some estimates have suggested it will be at least a 12- to 18-month wait for a vaccine to be ready.

"Under normal circumstances, most vaccine development programmes take more than five years, so this is still a considerably accelerated timescale," Dr Tonia Thomas of the Oxford Vaccine Group wrote in a blog post.

This timescale includes the manufacturing process to produce the vaccine on a large scale, testing in animals and evaluation in human clinical trials.

Thomas explains many of these can be undertaken more quickly if there are no "unexpected roadblocks".

"Firstly, the use of a platform technology approach, ie a vaccine delivery system that has been used before and can be adapted for a new pathogen, can shorten the initial vaccine development time," she says.

"Also, in an emergency situation, large-scale manufacturing could be carried out concurrently while the clinical trial is ongoing, which can shorten the overall timescale for vaccine development. This would mean that if the clinical trial is successful, the vaccine would be ready in larger quantities, to be deployed immediately.

"Finally, regulatory review of promising candidates is also undertaken faster in an epidemic, because more staff and resources are dedicated to the review process."

It is hugely important to stress that this does not mean any shortcuts in the rigorous process of assessing all the evidence; simply that more people are working to evaluate the evidence at the same time.

Because of the large amount of medical research being done at any one time, new drug proposals can sit for months with a regulator before they're considered. Currently, all COVID-19 vaccine proposals will be put to the front of the queue.

In addition, work has already been done globally to deliver large-scale vaccination programmes from pandemics - for example, Ebola - so the COVID vaccine programme will build on that.

That ensures we can get a vaccine as fast as possible without compromising safety.

#### How are vaccines tested?

Most vaccines follow the same principles when it comes to testing.

- Phase one: the vaccine is given to a small group of volunteers to learn more about the response it creates and test whether it's safe.
- Phase two: the vaccine is then given to hundreds of people to futher test safety and efficiency.
- Phase three: it is given to many thousands of people to confirm safety and effectiveness in a wider group of the population, including older people. Some volunteers are given a placebo (or an existing, non-COVID vaccine) as a control group to measure how the other vaccinated volunteers do.

In the case of the Oxford vaccine, plans for the clinical trials are:

- Phase one: vaccinate 510 volunteers aged between 18-25 years, half with a COVID vaccine and half with a control vaccine.
- Phase two: extend the maximum age of trial participants to 55-70 years, then over 70. Preliminary reports of the phase one and two trials have been published.
- Phase three: vaccinate 50,000 volunteers aged over 18 years, half to receive the COVID-19 vaccine. Clear efficacy endpoints will be used to assess the effectiveness of the vaccine, and volunteers from phase I and II will be included in the follow-up.

This vaccine is already in phase two/three development in the UK and has gone into phase three in Brazil and South America, with expansion into the USA from September 2020.

# Safety first

Headlines were generated when the Oxford vaccine trial was paused because of a possible adverse reaction in a study participant. Far from being concerning, we should be relieved to hear about this investigation, which is standard in clinical trials. This sort of pause to carry out an indepth analysis of any possible safety concerns is a reflection of the fact that regardless of the time imperative, there will be no corners cut in terms of establishing safety before any vaccine is licensed.

During the course of any study, people will become unwell: sometimes it's coincidence; sometimes the person concerned was actually in the placebo arm. But it should always be investigated. It has now been deemed safe for the trial to restart.

# Which vaccine will we get?

There are several potential treatments that could be rolled out in the UK.

Pharmaceutical company AstraZeneca, the same one working with the University of Oxford, has signed a £135 million deal to develop and manufacture the vaccine hoped to be delivered in Britain.

This vaccine is based on an adenovirus that causes common cold symptoms in chimpanzees: this is called the vaccine vector. This contains genetic protein spikes found on the coronavirus and triggers an immune response within the body.

On 29th July the government signed a deal with 60 million doses of an experimental treatment currently being developed by drug giants GSK and Sanofi.

In early August it was announced that the UK is to buy 60 million doses of a COVID-19 vaccine from Novavax, which is already in phase three trials.

Novavax's vaccine is engineered from the genetic sequence of SARS-CoV-2, the virus that causes COVID-19. It was created using nanoparticle technology to generate an antibody from coronavirus protein, which causes an immune response in the body, including high levels of neutralising antibodies to fight off the virus. The government also signed a deal with Johnson & Johnson's Janssen pharmaceuticals for 30 million doses of its vaccine. The company will be working with the UK on the global phase three clinical programme for its planned COVID-19 vaccine.

This vaccine utilises the same technologies Johnson & Johnson uses to develop and manufacture its Ebola vaccine. It uses a chemically weakened version of the virus to stimulate an immune response in the body.

Alongside these vaccines, an alliance between pharmaceutical companies BioNtech and Pfizer, as well as the firm Valneva, hope to supply 100 million doses of a vaccine by the end of 2020, with the aim of increasing that to 1.3 billion by the end of 2021.

As mentioned earlier, however, the delivery of these treatments is dependent on them passing rigorous testing and human trials.

## What will a vaccine programme look like?

When a vaccine is available it will be up to the parliament's Joint Committee on Vaccination and Immunisation to determine how the programme will work, and who will be eligible first.

A COVID-19 vaccine programme will likely look like any other vaccine programme, Dr Bird explains.

"It's likely to be similar to the flu vaccine - availability of which is going to be expanded this winter 2020," he adds.

"It would first be offered to those over the age of 70, followed by those with long-term conditions and underlying health issues, before being made more widely available."

# A jab for life?

Once a vaccine is made it doesn't necessarily protect you for life; it's highly dependent on what the disease you've been immunised against is.

As viruses mutate regularly, a vaccine you had for one strain won't protect you from another. The flu, for example, mutates every winter. To account for this, the World Health Organization identifies the strains likely to be an issue every flu season and new vaccines are developed accordingly.

In the case of coronavirus, when a vaccine is developed it will protect against the strain currently spreading but will likely be ineffective against other strains.

How often vaccines are updated depends entirely on the virus and the type of vaccine.

In the meantime, while we wait for a vaccine, the best thing you can do to protect yourself is follow the latest guidelines from Public Health England:

- Stay home as much as possible and avoid people outside of your support bubble (if applicable).
- Stay socially distanced, at least 2 m from people outside your household or 1 m+ where that isn't possible.
- Wear a mask on public transport, in shops and in other crowded public spaces.
- Make sure to regularly wash your hands or use hand sanitiser containing at least 60% alcohol if you can't get to a sink.

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