Internews

How to report accurately on COVID-19 vaccines

The global toll of the COVID-19 pandemic is enormous. As at 27 October 2020 more than one million lives have been lost, more than 43 million people infected with the coronavirus, hundreds of millions out of work, and trillions of dollars of wealth gone – and the numbers keep growing. With evidence in many countries of new surges in infections the virus has by no means run its course, and hundreds of thousands more people are likely to be infected and could die. While developing a safe, effective and affordable vaccine is a key step to ending the pandemic, prevention behaviour such as social distancing and wearing of masks remains of critical importance to stemming the tide of the SARS-CoV-2 virus.

According to the London School of Hygiene and Tropical Medicine's vaccine pipeline tracker https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/ there are, as of 14 September, 243 COVID-19 vaccine candidates, in various stages of development.

What do you need to know?

Speeded up trials

A notable feature of current vaccine research is the rapid rate at which vaccine candidates are moving through the phases of development. Several vaccine candidates have reached Phase III trials in just a few months which health researchers say is unprecedented. Historically vaccines have taken from 5 years (e.g. mumps vaccine) to more than 30 years (chicken pox) to be distributed to the general population.

Scientists say it's possible for a vaccine to be approved by the end 2020, but it will only be available for targeted groups such as health care workers, the elderly or those with co-morbidities. Health researchers are clear, that despite what politicians (in Russia, United States and China) are claiming, it's unlikely that the billions of doses necessary to be distributed among the broader population would be available before the second half of 2021.

The urgent need for a vaccine to address the global coronavirus crisis has seen nations competing to be the first to get a vaccine to market. This has raised concerns that some countries are taking short cuts in Russian scientists announced successful trials of a vaccine without completing the requisite clinical trial protocols causing some controversy.

They have pre-approved a vaccine in their country before completing a Phase III clinical trial, which is regarded as essential for proving the efficacy and safety of a vaccine. Ordinary people in several countries have since expressed concern about the safety of COVID -19 vaccines in general and feel hesitant about getting a vaccine when it becomes available.

A Phase III trial of a UK developed vaccine made by AstraZeneca was stalled recently after it was announced that a volunteer had developed neurological problems. The trial has since resumed after it was found that the problem was not related to the vaccine. Completing the phases (see below) of vaccine development is crucial in assuring that the vaccine is safe and accepted as broadly as possible once it becomes available.

Vaccine nationalism

While multiple groups of scientists began working on developing vaccines, governments began working on behind-the-scene deals with pharmaceutical manufacturers to secure access to these vaccines for their own people before any other country. This is called vaccine nationalism and is of great concern because it can cause supply problems that could leave poorer countries without access to life-saving vaccines.

Operation Warp Speed

The United States has several candidates in the race for a vaccine and President Donald Trump established a public private partnership called Operation Warp Speed which according to the US Health and Human Services, aims to deliver 300 million doses of a vaccine by January 2021. Under the initiative, the US government will speed up the development of various vaccine candidates and buy them – so that the medication can be in hand and quickly distributed once the US Food and Drug Administration (US FDA) approves or authorizes emergency use after clinical trials. It is reported that Americans will receive the vaccine for free.

The vaccine makers are already producing doses in anticipation that clinical trials might prove that they work and are safe for humans. The idea is that if a vaccine is shown to be protective, use of it can start immediately. Contracts with six vaccine manufacturers have been announced. The US has ignited a vaccine nationalism wildfire by locking down bilateral deals with vaccine manufacturers to be provided first with 800 million doses and options to buy a further 1.6 billion doses.

The World Health Organization (WHO) and other global health agencies have argued that early access to vaccines should be shared across the nations of the world to help protect health workers, but the US position has been that it will vaccinate Americans first, and share second.

The COVAX Facility

To address strong global concerns about vaccine access, three organizations: GAVI – the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI), and the World Health Organization have formed COVID-19 Vaccine Global Access (COVAX). Its creators propose that any effective vaccine that emerges should be treated as a global public good, to be distributed equally around the world, regardless of where it was invented or of a country's ability to pay for it. COVAX is designed to discourage national governments from hoarding a COVID-19 vaccine and to focus on first vaccinating the most high-risk people in every country.

COVAX proposes that all participating countries, regardless of income levels, will have equal access to these vaccines once they are developed. The initial aim is to have 2 billion doses available by the end of 2021, which should be enough to protect high risk and vulnerable people, as well as frontline healthcare workers. Wealthy countries that join COVAX will finance the vaccine purchases from their national budgets and will partner with 92 poorer nations supported through voluntary donations to the plan to ensure vaccines are delivered equitably.

To date, 76 upper middle-income and high-income countries have signed up, agreeing in principle to procure COVID-19 vaccines through COVAX for their populations. For lower-income funded nations, who would otherwise be unable to afford these vaccines, as well as a number of higher-income self-financing countries that have no bilateral deals with manufacturers, COVAX is a lifeline and the only viable way in which their citizens will get access to COVID-19 vaccines.

The issue of vaccine safety and access has become a source of rumours on social media around the world. Posts range from concerns about the potential availability of a vaccine for poorer nations to conspiracy theories about people being forced to be vaccinated with an unsafe vaccine.

As with many elements of this crisis, it is important to fully understand the complex issues so that you, as journalists, can present the facts in the context that your audience will understand. The extent of scientific uncertainty on COVID-19 poses challenges to journalists on how to report fairly, accurately, and comprehensively.

Questions that need to be addressed that relate to vaccine access

- Who should receive the first dose and subsequent doses of a vaccine?
- Who decides who is allowed into the queue to receive the vaccine and in what order?
- What special advantages are given to the country where a vaccine is developed, if any?
- Will countries where clinical trials are being conducted be given access to vaccines that have been developed elsewhere? The Oxford vaccine, for example was developed in the United Kingdom but is undergoing trials in Brazil and South Africa.
- To what extent will wealthier countries crowd out poorer ones?
- Will countries let geopolitics intrude, sharing the vaccine with allies while forcing vulnerable populations in adversary countries to the back of the line?

How can I report on this issue?

- Explain clearly what is known and what is still unknown about vaccines. Don't draw your own conclusions for a catchier headline.
- Don't base your reporting on pressers from vaccine developers. Ask to read the original research paper and consult with impartial experts not involved in the study.
- Keep up to date with the latest information. Trials are moving quickly - check the progress of the vaccine clinical trials at this database at https://clinicaltrials.gov/ct2/results?cond=COVID-19 developed by the US National Library of Medicine.
- Explain the vaccine production process and give examples that your audience can relate to. For example, the flu vaccine or other routine vaccines used to immunize people in your country, such as measles or polio.
- Ensure your reporting responds to the questions and concerns your audience has. Develop and support channels that allow them to easily ask more questions. This should be an-ongoing cycle of listening, responding and listening again.
- Explain that strong health systems, adequate testing capacity, implementing protective measures and accessing a safe and effective, universally available vaccine will be key to protecting societies from COVID-19.
- In the interest of public-service journalism, journalists must pressure health authorities to ensure that conditions for global, equitable, and affordable access to COVID-19 vaccines be built into any vaccine-development programme from the start.
- Advocate for poorer countries to be included in immunizations. There are already signs of "vaccine nationalism" where powerful countries like the US and UK are providing support to big pharmaceutical companies and research institutions in exchange for preferential treatment for their citizens. This will disadvantage people in low-income countries.
- Do profiles to showcase and humanize the work of virologists, immunologists, vaccinologists, geneticists, microbiologists and other researchers. Science and medical innovation, especially in vaccine development, thrives and progresses when researchers exchange and share knowledge openly, enabling them to build upon each other's successes and failures. Showcasing scientific research helps to improve science literacy in communities and to prevent rumours and pseudoscience from spreading.

Tell the participants' story, if possible. Good Participatory Practice in clinical trials includes the protection of participants' privacy, so unless you know of an individual who specifically wants to publicly talk about their experiences, it may be difficult to arrange stories about participants' experiences. However, great human interest stories can often be found by talking to participants from past trials. Most volunteers for clinical trials are motivated by a desire to contribute to the well-being of society and to advancing science.

Q&A about COVID-19 vaccines

How many vaccine candidates are at the stage of human testing?

As of 21 September 2020, there are 36 candidate vaccines in clinical evaluation in humans and 146 candidate vaccines in preclinical studies in animals. The landscape of COVID-19 vaccines is updated on a regular basis by WHO at the following link: https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

Only a portion of candidate vaccines will be successful. A study about vaccines targeting human infectious diseases showed that only 7% of candidate vaccines pass the safety test in preclinical evaluation. Of these 7%, only 17% of the number will pass stringent clinical evaluations in humans.

What are the different phases a vaccine must go through to be approved?

The evaluation of a vaccine candidate undergoes different phases (preclinical and clinical) before it can get regulatory approval from the national regulatory authority in a country. The regulator in the United States is called the Food and Drug Administration (FDA). In Africa, regulators from 29 countries are members of the African Vaccine Regulatory Forum for the regulation of clinical trials. WHO's Emergency Use Listing (EUL), launched in 2014 in response to the West Africa Ebola virus epidemic, makes safe and effective, still to be licensed, medical products available quickly in global public health emergencies to support United Nations procurement agencies and its member states. This includes COVID-19 vaccines.

Why must vaccines enter trial phases?

The objective of evidenced -based research is to ensure a vaccine is safe and effective. It also aims to determine the vaccine dosage, the target groups (e.g. adults or children), the time schedule for administration and to determine those who may not get the vaccine (contraindications).

Preclinical phase: focuses on testing the vaccine in animals to see if it is safe and non-toxic and to see if it produces an immune response in animals before moving to human trials.

The clinical evaluation of the vaccine in **humans** requires that the vaccine moves from one phase to the next before it is approved.

Phase I: These trials test the candidate vaccine on a small number of people – usually under 100 adults – to evaluate if it is safe and if it generates an immune response (immunogenicity). This phase could include studies to determine the number of doses needed, the method of administering the vaccine and vaccine schedule. If the vaccine proves to be safe during Phase I, it will advance to Phase II.

Phase II: At this stage the number of volunteers increases to usually between 200 to 2,000. These studies assess the impact of multiple variables on immune response such as age, ethnicity, gender and even pregnancy. During this phase, scientists will continue assessing safety, optimal dosage, and immunogenicity. Researchers may also try to identify measurable signs (correlates of protection) that a person is immune from becoming infected or developing disease. Additionally, different populations can be enrolled in different countries to reduce costs, save time, and still collect meaningful data to be able to proceed to the next phase of development. It is at this phase that it's a make or break for many trials with only the most promising moving onto Phase III trials.

Phase III: The candidate vaccine is tested on several thousand people and also looks at safety and variations in ethnicity, sex, age, weight, and those with chronic diseases. However, it is at this stage that efficacy is assessed, which tells the researcher whether or not the vaccine works. The FDA is willing to accept an efficacy rate of 50%. This means that any vaccine will need to prevent or decrease the severity of the disease by at least 50%. In these trials participants are randomly assigned to receive either the vaccine or the placebo (not the vaccine but a dummy which is usually salt water). The trials are double blinded meaning that neither the participants nor the researchers know which participants get the real vaccine. This is to eliminate bias. These trials are multi-centre and across several countries. This phase is usually the last step before the vaccine receives the regulatory approval for vaccination of the broader population.

Additionally, after approval vaccines mostly undergo a **Phase IV** or post marketing surveillance to assess effectiveness and to monitor for any unexpected, rare adverse events that may occur.

What types of COVID-19 vaccines are being developed?

Several approaches to COVID-19 vaccines are currently being tested. They include both traditional and novel approaches. Here is a brief summary of these different strategies as outlined by the Children's Hospital of Philadelphia:

- **Inactivated or killed vaccine** — The whole virus is killed in the laboratory with a chemical that is used to make the vaccine. This is the same approach that is used to make the inactivated poliovirus vaccine (IPV), hepatitis A virus vaccine, whole cell pertussis (whooping cough) vaccine and rabies vaccines.

- **Subunit vaccine** — A piece of the virus that is important for immunity, like the spike protein of COVID-19, is used to make the vaccine. This is the same approach that is used to make the influenzae type b, hepatitis B and human papillomavirus vaccines.

- **Weakened, live viral vaccine** — The virus is grown in the lab in cells different from those infects in people. As the virus gets better at growing in the lab, it becomes less capable of reproducing in people. The weakened virus is then used to make the vaccine. When the weakened virus is given to people, it can reproduce enough to generate an immune response, but not enough to make the person sick. This is the same approach that is used to make the measles, mumps, rubella, chickenpox, and one of the rotavirus vaccines.

- **Replicating viral vector vaccine** — Scientists take a virus that does not cause disease in people (called a vector virus) and add a gene that codes for, in this case, the coronavirus spike protein. Genes are blueprints that tell cells how to make proteins. The spike protein of COVID-19 is important because it attaches the virus to cells. When the vaccine is given, the vector virus reproduces in cells and the immune system makes antibodies against its proteins, which now includes the COVID-19 spike protein. As a result, the antibodies directed against the spike protein will prevent COVID-19 from binding to cells, and, therefore, prevent infection. This is the same approach that was used to make the Ebola virus vaccine.

- **Non-replicating viral vector vaccine** — Similar to replicating viral vector vaccines, a gene is inserted into a vector virus, but the vector virus does not reproduce in the vaccine recipient. Although the virus cannot make all of the proteins it needs to reproduce itself, it can make some proteins, including the COVID-19 spike protein.

- **DNA vaccine** — The gene that codes for the COVID-19 spike protein is inserted into a small, circular piece of DNA, called a plasmid. The plasmids are then injected as the vaccine.

- **mRNA vaccine** — In this approach, the vaccine contains messenger ribonucleic acid (RNA), called mRNA. mRNA is processed in cells to make proteins. Once the proteins are produced, the immune system will make a response against them to create immunity. In this case, the protein produced is the COVID-19 spike protein.

Which type of COVID-19 vaccine is most likely to work?

It is likely that more than one of these approaches will work, but until large clinical trials are completed, we will not know for sure. Likewise, the different approaches may have different strengths and weaknesses.

For example, mRNA or DNA vaccines are much faster to produce, but neither has yet resulted in a successful vaccine being produced. On the other hand, traditional vaccines such as the killed or inactivated viral vaccines and live, weakened viral vaccines have been used in people safely and effectively for many years, but they take longer to produce. In addition to differences in how long it takes to make different types of vaccines, each type may also cause the immune system to respond differently.

Understanding the immune responses that are generated will be important for determining whether additional (booster) doses will be needed, how long vaccine recipients will be protected, and if one type offers benefits over another.

If you had the virus and recovered will you still be able or need to get the vaccine?

Scientists do not know how long antibodies last after infection or whether they will protect against reinfection. New studies are showing that antibodies may last for up to three to four months in the body.

So, while vaccine trials are being completed, it will be important for scientists to continue learning about COVID-19, particularly whether people who got sick with COVID-19 can be reinfected. The current vaccine trials will include immunizing people who have never been infected with SARS-CoV-2 and those who have been previously infected.

We will soon know whether vaccination of those who have been previously infected affords more complete or longer lasting protection than those who were previously infected but haven't been vaccinated.