

# Market and profits impede COVID-19 vaccine effort

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Scientists around the world are in a desperate scramble to develop an effective COVID-19 vaccine. According to the science journal *Nature*, more than 115 vaccines are in various stages of development.

On December 31, the World Health Organisation (WHO) was informed of a cluster of pneumonia cases of unknown origin from Wuhan in China. By January 7, Chinese scientists identified the source of the infection as the SARS-CoV-2 virus. A few days later, on January 11, the Chinese National Health Commission published the genetic structure of the virus on the internet for the international scientific community.

The discovery of the genetic structure of the virus was the first step in the development of a vaccine to deal with the virus outbreak that has ravaged the world. It was also the starting gun for a wild free-for-all by private companies bidding to win the bonanza that will fall to the successful candidate vaccine.

“With the genomic sequence, we were off to the races,” said the head of the US National Institute of Allergy and Infectious Diseases, Dr. Anthony Fauci.

Scientists were able to identify that the virus is a type of coronavirus like those causing the common cold, Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS), which caused epidemics in 2003 and 2012, respectively.

The human coronavirus was first identified in the 1960s and is distinguished by club-like structures that cover its entire surface, giving the appearance of the sun’s corona in electron micrographs. Its genetic structure is made up of a single strand of ribonucleic acid (RNA) surrounded by a shell made of a protein membrane from which the spike proteins, club-like structures, protrude.

The COVID-19 virus invades cells in the human upper-respiratory tracts by first using its spike proteins to attach to and then fuse with the membrane of a host cell, in this case the respiratory tract of the infected individual. At this point, the virus can release its RNA, its genetic codes, into the cell, thereby commandeering the host’s genetic apparatus to reproduce the virus in massive numbers.

These new virions are released back into the extracellular spaces, spreading further into the host. They are also expectorated into the environment, where they can infect other people and spread the disease. The life cycle of the virion in the host cell ultimately destroys the host cell, but it also leads to an intense host immune response.

The lethal nature of the COVID-19 virus is due to the host’s immune system responding by going into overdrive, in a little understood process that overproduces chemicals known as cytokines in what is known as a cytokine storm.

The production of cytokines is part of the body’s natural immune response, aimed at destroying the invading virus. For an unknown reason, in response to the COVID-19 virus, the cytokines are produced in such vast amounts that they can cause dangerous levels of inflammation in the lungs and the respiratory system that lead to respiratory failure.

Influenza and other viral infections have been known to elicit such

heightened immune responses. Additional clinical manifestations include severe cardiovascular, gastrointestinal and neurological damage as a by-product of multi-organ failure, or a disseminated viral infection that can kill the host.

It has also recently come to light that the virus can cause severe inflammation in blood vessels, leading to an increased propensity to develop blood clots. That, in turn, can lead to strokes, pulmonary embolisms, kidney failure and other manifestations such as Kawasaki-like disease in young children. There is still much about SARS-CoV-2 that remains unknown.

In producing a vaccine, scientists try to stimulate the body’s immune system to generate antibodies to the SARS-CoV-2 virus and prevent or limit the scope of the infection. The scope of this work is quite multiplex, requiring careful study of the virus for vaccine targets, the design of the vaccine and protocols to determine the safety and efficacy of the vaccine. These are usually initiated in animal trials, also called preclinical trials, where suitable models such as mice are initially given the vaccine and exposed to the virus.

Success in these initial investigations is followed by the designing of phase 1 human trials, in which healthy volunteers are given the vaccine in escalating doses to determine if the drug is safe to check for efficacy. Phase 2 and phase 3 trials are larger trials that check efficacy and safety. If a candidate vaccine proves successful, it is licensed for production and distribution, entering a long-term phase 4 post-marketing surveillance to evaluate the drug’s long-term effects. The process is extraordinarily complex and very few vaccines are ever approved.

Although politicians and several scientists have optimistically speculated that a vaccine can be produced within 12 to 18 months, this has never been done and remains in the realm of the theoretical. Such statements, however, facilitate specious arguments like that made by President Donald Trump on Fox News: “We think we are going to have a vaccine by the end of this year.”

These statements completely ignore the objective difficulties in producing a respiratory vaccine, even in the era of modern science with its powerful investigative tools. Many candidate vaccines never reach the licensing and production stage. The mumps vaccine was the quickest ever produced so far. It was developed in the 1960s in a process that took four years.

Considerable time is necessary for the proper testing of candidate vaccines, as the human body is an incredibly complex system and problems may take some time to emerge. During the SARS outbreak in 2003, a vaccine candidate resulted in the dangerous enhancement of the disease in human subjects, necessitating the abandonment of its development.

According to Dean Peter Hotez of Baylor University’s National School of Tropical Medicine in Houston, Texas: “A year to 18 months would be unprecedented... Maybe with the new technology, maybe with throwing enough money on it, that will happen. But we have to be really careful

about those time estimates.”

The chair of the Translational Research Institute (TRI), Professor Ian Frazer from the University of Queensland, told the Australian Broadcasting Commission (ABC) said that there has never been an effective vaccine produced for any coronavirus, making it a “tricky” endeavour. The institute co-invented the Human Papilloma Vaccine that prevents cervical cancer.

The coronavirus attacks the upper-respiratory tract, where the immune system is relatively weak. It is a particularly difficult place to target a vaccine.

“It’s a separate immune system, if you like, which isn’t easily accessible by vaccine technology... it’s a bit like trying to get a vaccine to kill a virus on the surface of your skin,” Frazer said.

To achieve this difficult goal, several strategies are being adopted by the various research laboratories. Overall, 115 research teams are in the hunt for a vaccine, using several different techniques. Seventy two percent of the laboratories are working with private pharmacological companies, with only a minority controlled by university or hospital laboratories. Major pharmaceutical companies such as Janssen, Sanofi, Pfizer and GlaxoSmithKline are funding research.

This is a completely inefficient and wasteful process, with the various laboratories competing against one another when they should be working collaboratively. It is the result of a market approach to science, which prevents investigators from working in unison to share their findings with one another.

The essential issue is that in the effort to save lives, the profit motive is leading to loss of life, as delays in finding a successful vaccine lead to continued devastation from the pandemic. The resulting competitive pressures on scientists are so great that they will be compelled to take shortcuts that may lead to failures or compromise safety.

The pressure is so intense that Moderna Therapeutics, a Cambridge, Massachusetts-based biotech company, started phase 1 human trials on March 16, before animal testing had been completed. “I don’t think proving this in an animal model is on the critical path to getting this to a clinical trial,” said chief medical officer at Moderna, Tal Zaks.

Several other laboratories have commenced phase 1 trials, including three in China and another based in the US. Various strategies are being pursued internationally. Many of these techniques are very speculative and scientists have never successfully produced a vaccine using these techniques.

All vaccines in one way or another are based on getting the body’s immune system to mount an attack on the invader. In one of the oldest techniques, the virus is injected into the body after it has been made inactive. The immune system reacts to proteins made by the infecting microbe, stimulating the production of antibodies. The Chinese firm Sinopharm based in Shanghai has used this technique and has been licensed to advance to phase 2 trials.

Scientists more recently realised that instead of using the whole virus, they could use a single protein to get an immune response. Vaccines using this technique are the easiest to produce and the method has been used to produce many existing vaccines. The Chinese firm CanSino, based in Tianjin in northern China, has started a phase 1 trial and uses a spike protein, Ad5-nCoV, which the virus uses to penetrate the host cell. The company has used this technique to produce an effective vaccine for Ebola.

A research group based at Oxford University in the UK is using a spike protein and is in phase 1 testing.

Companies such as Moderna inject DNA or RNA to stimulate the body’s immune response. The candidate vaccine gives positive responses in animals, but has proven ineffective in humans. Scientists continue to pursue this technique, as such vaccines would be relatively easy to produce.

Maria Elena Bottazzi, the associate dean of medicine at Baylor University’s National School of Tropical Medicine, said, “If you look at all the attempts people have done for HIV vaccines using the DNA platform, they haven’t found the exact formula of how these DNA molecules should go into the right cell... It’s a little bit of dark science. That is why they are still experimental.”

Inovio Pharmaceuticals in Plymouth Meeting, Pennsylvania is working on a vaccine based on a similar method and is in phase 1 trials.

Queensland University, in conjunction with the Dutch group Viroclinics Xplore, has used a technique known as a “molecular clamp.” This was developed in conjunction with the Commonwealth Scientific and Industrial Research Organisation (CSIRO). The molecular clamp technique uses a synthetic version of the virus to stimulate an immune response.

The molecular clamp technique has been patented, highlighting the commercialisation of scientific discoveries.

In contrast, the great scientist Jonas Salk, who developed the polio vaccine in the 1960s, was asked, “Who owns the patent?” Salk replied, “The people, I would say. There is no patent. Could you patent the sun?”

Even though Queensland University is a governmental institution, it has been so starved of funds that it must resort to patenting scientific discoveries that should be for the benefit of humanity, not profit. Commercial arrangements such as patents have the effect of blocking scientific research.

If, and nobody really knows when, a successful vaccine is produced, it must be manufactured for release internationally. This may not be a straightforward process.

There is no guarantee the vaccine will be made available to the impoverished masses across the planet who are disproportionately affected by the pandemic. It is estimated that billions of doses will have to be produced to inoculate the world’s population. Arguably, political quid pro quos resulting in the vaccine being denied will be a factor in such geopolitical considerations.

Moreover, with nations armed with vaccines, biological weapons will no longer be restricted to the domain of science fiction writers.

For the newer vaccine technologies, mass production methods may have to be developed, making treatment expensive and out of reach of poorer people.

Geopolitical rivalry will come into play over who gets the vaccine. Most of the facilities researching a vaccine are in the US. In March, reports emerged that US authorities attempted to buy the German pharmaceutical company CureVac in order to gain exclusive access to any vaccine it might develop.

“It is a little naive to think because the US is doing a lot of the vaccine development, they are going to put us (Australia) right at the front of the queue... They are going to look after their own first,” said Dr. Craig Rayner, a former executive at pharmacological companies Roche and CSL, and now president of integrated drug development at Certara.

The existence of 115 research laboratories in competition with each other does not guarantee the development of an effective vaccine. In fact, it is extremely wasteful, as scientists are using various methods for arriving at the same end.

There must be a rational plan and division of labour in regard to how the research is approached.

Workers must demand that the research institutions be taken out of the control of the pharmacological giants and the market and brought under public ownership, so that the results of scientific research and any resulting vaccines will be freely available to the world’s population.





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