Rushing a coronavirus vaccine might undermine proven vaccines

By Maryanne Demasi, PhD

24 August 2020

Disclosure: I have no financial or other relevant conflicts of interest.

In an interview with the Financial Times about the economic pain caused by the coronavirus pandemic, Bill Gates said, "For the world at large, normalcy only returns when we've largely vaccinated the entire global population."

With that in mind, pharmaceutical companies are in a race to be the first to produce a successful coronavirus (SARS-CoV-2) vaccine.

Warp Speed

Under normal circumstances, it would take years to research and develop an effective candidate, but in these unprecedented times, companies are accelerating their operations. Governments are looking to fast-track a solution out of this economic disaster.

US President Trump has launched Operation Warp Speed in an effort to deliver vaccines and therapeutics in record time, applying public pressure on the US drug regulator (FDA) to "focus on speed".

Last week the Australian Government announced it struck a deal with pharmaceutical giant AstraZeneca to obtain 25 million shots of a coronavirus vaccine that is being trialled, although the details of that agreement are still unclear.

Even Russian President Vladimir Putin recently announced that his country had become the first in the world to approve a coronavirus vaccine for widespread use, despite Phase III (large safety) trials not yet completed. Trials involving 40,000 people will commence this week.

It has raised concerns that with such ambitious timeframes, it might be tempting to cut corners, but which corners are being cut? No one will know in a timely manner.

Author of the new book 'Vaccines: Truth, lies and controversy' Danish Professor Peter Gøtzsche says rushing safety trials could mean that rare but serious harms may not be detected. "The influenza vaccine developed for the 2009 swine flu pandemic called Pandemrix caused narcolepsy in over 1300 people - a life-long, seriously debilitating condition - with onset from about two months after vaccination and up to at least two years later", says Prof Gøtzsche.

The vaccine has now been abandoned in many countries, but it teaches us important lessons about vigilance in monitoring harms, especially if vaccines are being fast-tracked.

Vaccines are regarded as safe interventions, but as with most medical therapies when administered to millions, or billions of people, there will inevitably be some adverse reactions in the population.

Anecdotal reports of harms might run rampant on social media, escalating uncertainty and adding fuel to conspiracy theories. It will erode public confidence in vaccines and is likely to negatively impact the vaccination rates for other proven vaccine-preventable diseases, like measles.

Managing expectations

This month, the WHO said that a number of vaccines were still undergoing Phase III trials but warned that there was no 'silver bullet' for COVID-19 – and there might *never* be.

"There are concerns that we may not have a vaccine that may work, or its protection could be for just a few months, not more. But until we finish the clinical trials, we will not know," said WHO director-general Tedros Adhanom Ghebreyesus.

Prof Gøtzsche agrees saying, "They have tried to make coronavirus vaccines for decades with no success. A vaccine was developed against another coronavirus 30 years ago, but when tested in cats, they fared worse than cats that were not vaccinated".

Early in the pandemic, even immunologist Ian Frazer expressed doubts about whether an effective vaccine was possible since upper respiratory viruses are notoriously difficult to target with vaccines.

Virology professor Shibo Jiang has worked on developing vaccines and treatments for coronaviruses since the 2003 SARS outbreak. In a recent Nature publication, he said another factor that should be considered is the potential for emerging and re-emerging coronaviruses to cause future outbreaks.

"The virus behind COVID-19 might well mutate in ways that would make previously effective vaccines and antivirals useless. Therefore, any regulatory agency considering ways to accelerate treatments into testing should also weigh up how likely these drugs are to work beyond this particular coronavirus", said Prof Jiang.

Further, many of the potential vaccine candidates are being tested for safety and effectiveness in young volunteers with robust immune systems – an 'experimental model' that is most likely to succeed. But these vaccines will also need to work for the elderly with weakened immune systems and underlying illnesses.

Losing the nuance

It becomes difficult to have a considered conversation about vaccination in the media because it is inherently geared to polarise debate. People raising legitimate concerns about the transparency of safety data might fear being lynched by the 'fundamentalists' and want to avoid being typecast as anti-vaxxers or conspiracy theorists. Finding nuance in such a polarised debate is limited.

Assoc Prof Peter Doshi from the University of Maryland, who has spent years researching vaccines and communicating the science, wrote about these challenges in the BMJ.

"Labelling people concerned about the safety of vaccines as "anti-vaccine" risks entrenching positions," cautioned Prof Doshi. "It stigmatizes the mere act of even asking an open question about what is known and unknown about the safety of vaccines."

Who will be accountable if there are harms?

Against this background, pharmaceutical companies have acquired waivers for liability in case of vaccine-induced harms.

Recently, a senior executive of AstraZeneca, the same company charged with developing the Australian vaccine, told Reuters, "In the contracts we have in place, we are asking for

indemnification. This is a unique situation where we, as a company, simply cannot take the risk if in four years the vaccine is showing side effects."

It is not known if liability waivers were discussed in relation to Australia's agreement with AstraZeneca.

In the US, there is already a law, the National Childhood Vaccine Injury Act of 1986, which was created as a no-fault compensation program. The purpose of the Act was to eliminate the potential financial liability of vaccine manufacturers in the event of vaccine injury claims.

There is also the 2005 Public Readiness and Emergency Preparedness, or PREP Act, which is a controversial tort liability shield which offers immunity to drug companies from potential financial liability for any new vaccines that need to be rushed to market in the event of a declared public health emergency.

"Given the dire track records of drug companies, it is a very bad idea to make laws that do not hold them liable for the harms they may cause", says Prof Gøtzsche.

Mandatory vaccination

The Australia government hopes that 95% of the population will take up the vaccine despite many expressing concerns about the safety of an 'expedited' vaccine. Some are now left wondering whether the government will make them 'mandatory'.

"I would expect it to be as mandatory as you can possibly make it," said the Prime Minister on 3AW last week, but he soon walked back those comments in a subsequent radio interview.

Currently, no Australian can be subjected to a medical intervention without consent, although there are some exemptions that can compel someone to undergo a medical examination for an infectious disease, for example. The legalities around forced vaccination are complex.

The government has eluded to incentives to encourage vaccination. As we've seen in Australia already, compliance with childhood immunisation schedules has been linked to pre-school admission (No jab, no play) and to family assistance payments (No jab, no pay). Now, the "No jab, no JobSeeker" threat of losing welfare payments is set to further inflame the conversation against the backdrop of financial hardship and a crippled economy.

Already, Australian health authorities in some states are suggesting that the new vaccine could be associated with sanctions such as "things like not being able to go into restaurants, not being able to travel internationally, not being able to catch public transport".

As the science emerges, people's attitudes towards a new vaccine will become clearer but some are warning that linking vaccination to access to services will only invigorate the anti-vaccination movement. Already, 20% of Americans say they will refuse a coronavirus vaccine and 31% are undecided.

Instituting a mandatory vaccine might backfire and make people more likely to rebuff the idea of a government asserting its power to inject their body with a substance against their will.

It sets a precedent that is too frightening for many to even contemplate.