We may have to accept a 'good enough' COVID-19 vaccine, at least in 2021

November 18 2020, by Paul Komesaroff, Ian Kerridge and Ross Upshur

Credit: Nataliya Vaitkevich from Pexels

Australian health minister Greg Hunt said recently the government is on track to deliver COVID-19 vaccines from March 2021.

US biotech firm Moderna has just announced its COVID-19 vaccine has 95% efficacy, following on the heels of Pfizer's claimed 90% efficacy and the Russian Sputnik V vaccine's 92% efficacy, albeit based on limited data and yet to be peer-reviewed.

We'll likely see more preliminary results from other vaccine trials reported in the media in coming weeks and months.

While an effective vaccine will provide the best chance of controlling the disease, it is sadly not so simple. No vaccine will be perfect or end the pandemic instantly. The first vaccines are also likely to have significant limitations.

The issue is how good a vaccine is good enough? We also need to think about what imperfections we—as individuals, regulators or governments—will be prepared to accept.

How safe is safe enough?

Safety is obviously the major concern. Vaccines are designed to be given to very large numbers of healthy people. This means even an extremely rare, serious adverse event, when applied to a population of millions, can produce major harm.

Short-term trials on small population samples relative to the numbers expected to receive the vaccine may also not be able to pick up relatively rare but important risks. This is a problem we may not be able to avoid because the only way to find out is to give the vaccine to large numbers of people and then allow long periods of time to elapse, for any long-term adverse events to become evident.

> 'It seems too early' - in Europe, safety concerns dampen excitement over COVID-19 vaccine https://t.co/Kp6Shh1ODe

pic.twitter.com/msyGRq8Z6A

— Reuters (@Reuters) November 10, 2020

Obviously, all therapeutic agents carry the possibility of adverse effects and in individual cases decisions have to be made about whether the potential benefits justify taking the risks. It is arguable that the extreme dangers associated with COVID-19 justify accepting a higher level of risk for the vaccine. However, while the US and Australian regulatory authorities have broad guidelines relating to vaccine safety, neither has issued guidelines regarding the levels of risk that are considered justified for a coronavirus vaccine, and there has been only limited public debate on this subject.

How effective is good enough?

Efficacy—the vaccine's ability to produce clinical and public health benefits—is also uncertain.

Ideally, a vaccine should prevent any person who receives it from catching the disease. However, at least with the first vaccines, it is likely the benefits will be more limited. For example, they may slightly reduce the severity of the illness, or they may only benefit a small subset of the population. No current trials are looking at purely whether the vaccine will reduce the chance of dying from COVID-19 of individuals in specific risk groups.

In fact, different clinical trials have different "efficacy end points", including (among others) effects on susceptibility to infection, severity of disease, time to recovery and mortality, in different age and population groups.

There is no guarantee vaccines under development will provide

significant protection for those in most need, such as people in older age groups or those with existing medical conditions. Not all trials are specifically recruiting such participants and there is a real possibility benefits will not extend to them. In other words, a clinical trial might show "efficacy" in a formal sense but might not solve the key problems we are facing in the real world.

Earlier this year, the US Food and Drug Administration said it would only consider approving vaccines that "prevent disease or decrease its severity in at least 50% of people who are vaccinated". Australia's equivalent, the Therapeutic Goods Administration, has not issued any similarly precise guidance.

How equitable is good enough?

Access and distribution of any vaccine pose major problems. Some of these are built into the nature of the product itself.

For example, vaccines like the mRNA vaccine developed by Pfizer that need to be transported and stored at around -70°C, will have limited utility in low and middle income countries with limited health infrastructure and in rural and remote communities all over the world—meaning other vaccines may need to be found for these populations.

The role of minorities in relation to clinical studies of therapeutic products in the US is very uneven, in terms of participation, exposure to risk and access to benefits. There is a serious chance that in the search for a COVID-19 vaccine those least likely ultimately to receive the final product will be the ones who carry the greatest risk. This creates a possibility the social divisions already exposed by the COVID crisis will be further exacerbated.

Further, while there has been widespread acknowledgement of the need for access and supply of COVID vaccines to poorer nations there is no legal structure to ensure this and no guarantee it will actually happen.

Where to next?

A number of COVID-19 vaccines will likely become available during 2021 that offer either limited protection from infection or lower the risk somewhat of severe disease. However, these benefits may not necessarily be for those most at risk.

Robust regulatory systems, and independent scrutiny of clinical trial results, mean COVID-19 vaccines will likely be safe in the short-term. However, no-one will know about long-term risks and distribution may be limited, for logistic, economic and cultural reasons.

Even if we develop a "good enough" vaccine, there are no guarantees. Although many will be prepared to chance the first vaccines, many others will refuse them, despite government attempts at persuasion.

So herd immunity via vaccination, which for the coronavirus requires effective immunisation of at least two-thirds of the population, will remain a long way away.

This means strategies to reduce the spread, such as physical distancing, use of face masks and hand hygiene and, where necessary, rigorous quarantine measures, will be with us for some time.

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