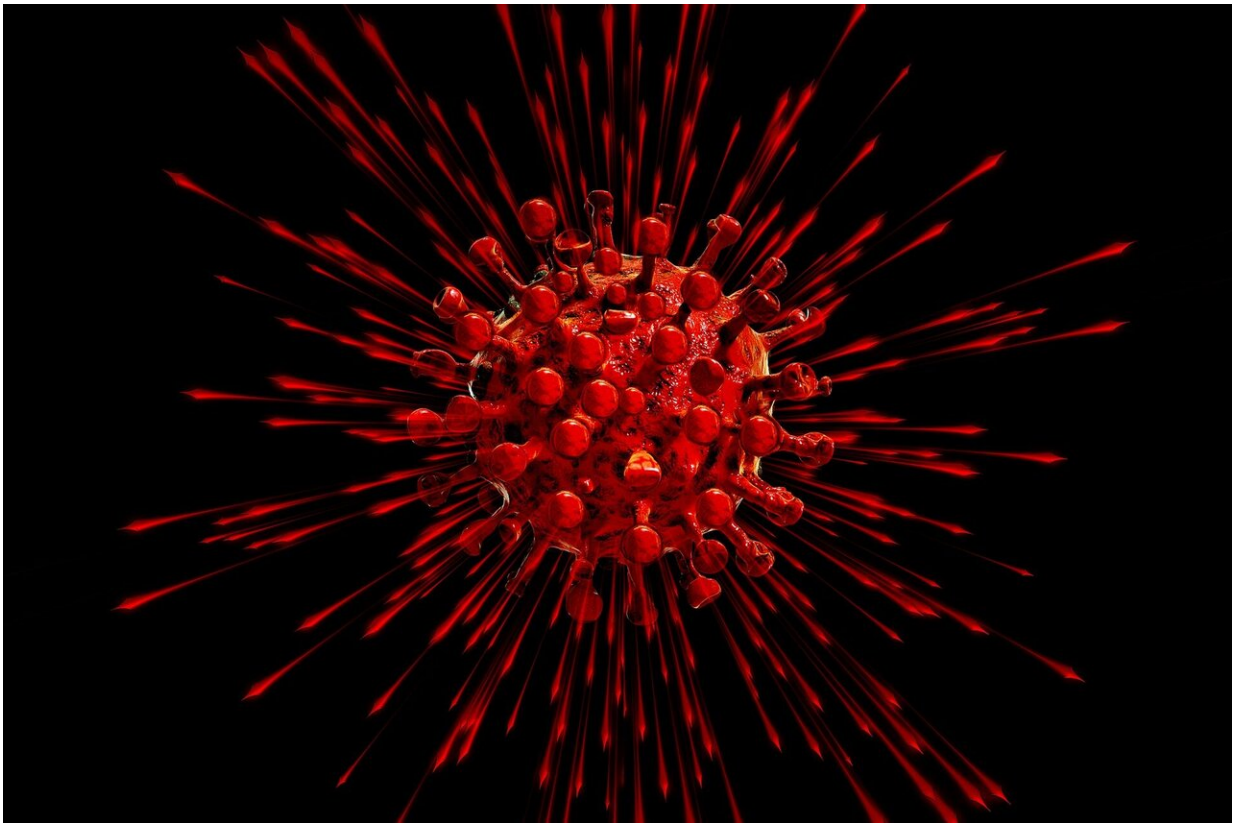
Why we'll get COVID booster vaccines quickly and how we know they're safe

March 5 2021, by Jamie Triccas and Anthony (Tony) Cunningham



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The United States' drug regulator, the Food and Drug Administration (FDA), said last week COVID vaccines updated for variants won't need to go through full randomized controlled clinical trials.

The booster shots will only be required to undergo initial testing to check they are safe and produce an immune response. They won't need to go through lengthy "phase 3" efficacy trials which would normally enroll tens of thousands of participants.

The European Medicines Agency hasn't published formal guidelines, but has taken the same position. Chair of the agency's vaccine evaluation team, Marco Cavaleri, told Reuters: "We will ask for much smaller trials, with a few hundred participants, rather than 30,000 to 40,000." The focus would be primarily on safety and immune response data.

This is encouraging news, because it means we could get access to booster shots much more quickly than if they went through full trials. And because drug companies will have to prove they're using the same technology and manufacturing process as the original vaccines, we can still be assured they'll also be safe.

Australia's Therapeutic Goods Administration (TGA) has not yet confirmed whether it'll do the same, but history tells us we can probably expect it to follow suit.

> The FDA said that companies would not need to conduct lengthy clinical trials to evaluate vaccines adapted for new virus variants. https://t.co/0tlbWmAyS0
>
> — The New York Times (@nytimes) February 22, 2021

Why do we need boosters?

Variant strains of the virus have been detected around the world, including those originating in the UK, South Africa and Brazil. People infected with these variants have been found in Australian hotel quarantine, and the B.1.1.7 strain, first found in the UK, has escaped the

quarantine system several times.

For those tested, the current crop of vaccines still perform relatively well against the B.1.1.7 strain.

And data suggest most COVID vaccines will still be somewhat useful in preventing hospitalization and death from these variants.

However, efficacy against mild to moderate illness, and against transmission of the virus, has likely dropped off sharply against some of these variants.

For example, preliminary data suggest vaccine efficacy for AstraZeneca's vaccine dropped to just 10% against mild-moderate illness from the B.1.351 variant which originated in South Africa. Efficacy of Novavax's shot slid from 89% to 60% against this variant. These data were from small trials and more studies are needed, but it's still very concerning.

We don't have solid real world data yet about the performance of the Pfizer vaccine against the B.1.351 variant.

Why don't we need full trials again?

Drug companies have flagged the need to develop updated booster shots to cover these new variants, which would involve tweaking their sequences.

Some scientists were worried this would mean drug companies would have to go through full randomized controlled clinical trials, including large phase 3 efficacy trials, to get these booster shots to market. These phase 3 clinical trials include many thousands of volunteers and the primary aim is to determine if the vaccine can prevent people from

getting the disease.

By the time these trials were completed, it may be too late to control outbreaks caused by variants, and new variants may emerge that we'd need coverage for. In a pandemic, we don't have the luxury of time.

But the FDA has dispelled this fear. The drug regulator seems most interested in ensuring any booster shots are safe and the manufacturing process hasn't been modified from the original vaccines it approved.

The boosters will still require smaller trials to show they're safe and generate an immune response. The trials typically involve a few hundred people and would examine the percentage of vaccinated volunteers who make antibodies to the variants, as well as the strength of the immune response.

This would be similar to what's done for annual flu shots, although not exactly the same. We get very different flu strains circulating every few years, but current COVID-19 vaccines and variant "boosters" could be sufficient to use for several years—we don't know yet.

The FDA also indicated boosters won't necessarily need to undergo animal testing before progressing to human testing, which will also save time. But this may be encouraged if results from human trials are ambiguous.

> Exclusive: EU drugs regulator plans to fast track variant-modified COVID vaccines https://t.co/gKZ0QHVQKS pic.twitter.com/8SO3ZB3hD0
>
> — Reuters (@Reuters) February 12, 2021

How do we know they'll be safe and effective?

Any potential side effects from a vaccine are mostly based on how the vaccine is made, the technology and how it's delivered.

If drug companies keep all these factors the same, and only make minor sequence changes to cover variants, then we can expect the boosters to still be very safe vaccines.

The US and EU drug regulators would like to see data where the booster is given to people who've already had an original COVID vaccine, given this will be the likely scenario for most people receiving a booster shot by the time they're approved.

The boosters will probably also be tested in people who haven't had any COVID disease or vaccine. This is to ensure the boosters can induce strong immune responses like the original vaccine.

When required, the TGA will independently review all of this data. It will also likely seek advice from internal and external experts.

It's also unclear when booster shots will be available or if they will be necessary in the short term. Melbourne-based biotech company CSL, which is producing the AstraZeneca vaccine onshore, said this week booster shots to cover coronavirus variants probably won't be available until the end of the year.

US pharmaceutical company Moderna has already sent a new COVID vaccine booster shot for phase 1 testing, to target the B.1.351 variant. Pfizer is also planning to develop a booster to cover this variant, either as a third dose or a reformulated vaccine.

New variants will continue to arise, but the best chance we have of stopping or slowing this process is by continuing public health measures to ensure as few people as possible become infected.

This includes vaccinating as many people as possible globally with the currently approved vaccines, which underscores Australia's responsibility to assist countries in our region in getting vaccinated.

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