

How we test the safety of rapidly developed COVID vaccines

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With the rollout of COVID-19 vaccines about to begin in Australia, people [may be wondering](#) if they're safe (and effective) in the long term. What might be the health consequences a year after vaccination, or further into the future?

While it's true COVID-19 vaccines have been developed in record time, the importance of tracking [vaccine safety](#) is not new. We [routinely monitor](#) the safety of all vaccinations, years after they've been used in millions of people.

And in [guidance](#) from the Therapeutic Goods Administration (TGA) this week, we have a clearer picture of how we'll know about any unexpected, rare or long-term side-effects of the COVID-19 vaccines. In fact, we'll use and build on many existing systems to look out for these.

Vaccine trials only tell us so much

Late-stage vaccine trials in tens of thousands of people only last for a defined period of time, typically 12 months. Vaccine manufacturers present data on vaccine safety (and efficacy) for that time-frame to regulatory bodies. Safety data is rigorously assessed before a vaccine is approved for use.

But when approved vaccines are then given to the general public, we can monitor for any new events that may occur unexpectedly in both the short and longer term. Tracking potential side-effects in the real world in all people who have a vaccine, and outside the tightly controlled conditions of a trial, means we can ensure the vaccine is safe when given to millions—or billions—of people.

So how might this work for COVID-19 vaccines? The Pfizer/BioNTech vaccine phase 3 trial reported safety data until [about 14 weeks](#) after the second dose. The Oxford/AstraZeneca trial [reported safety data](#) after about three months after the first dose, and two months after the second dose.

However, participants in both these large trials will continue to be followed up for both efficacy and safety until the end of the study from around 12 months after the first dose of vaccine.

COVID vaccine safety is also being monitored in several other ways, by [individual countries](#), including Australia. Countries also share their vaccine safety monitoring data via a [global database](#).

Here's how we'll monitor COVID vaccine safety in Australia

The TGA has overall responsibility for monitoring the safety of medicines and vaccines in Australia. Just this week, the TGA [released its plans](#) for monitoring the safety of COVID-19 vaccines.

This includes the timely collection and management of reports of COVID-19 vaccine adverse events, an ability to urgently detect any safety concerns and to communicate safety issues to the public.

"Passive' surveillance

A cornerstone of the system Australia has had in place for decades to capture any possible vaccine

reactions is "passive" surveillance. In practice, this means anyone can report a reaction to the TGA, the public included.

If your GP or nurse thinks you may have had a reaction they should report this to their state or territory health department, which then informs the TGA. This is mandatory in some jurisdictions but not in others.

The TGA is encouraging health professionals and consumers to report suspected side-effects to COVID-19 vaccines and there is a [guide on its website](#) on how to do this.

The TGA has a [database](#) that records any reported possible reactions. If there are any suspected safety issues, these are immediately investigated and necessary action is taken. For example, if necessary an immunization program can be stopped or special precautions implemented. TGA can also issue safety [alerts](#).

"Active' surveillance

Since 2014, Australia has also been actively looking for any safety concerns via the [AusVaxSafety](#) surveillance system, led by the [National Centre for Immunization Research and Surveillance](#), which we are affiliated with.

We send texts or emails to people asking them to fill out a survey on their health after being vaccinated. This system enables us to detect any suspected safety issues in near real time. Last year, AusVaxSafety [surveyed](#) nearly 290,000 people after they had the 2020 influenza vaccine and found more than 94% felt completely well. Others had mild and expected short-term side effects.

This system [will be used](#) to pick up any safety concerns when the COVID-19 vaccines roll out in the next few weeks. If you are vaccinated at selected sites, including GP practices and COVID-19 vaccine hubs, you will be told about this automated system. You don't have to register or enroll but will be sent an SMS on day three and day eight after each vaccine dose (you can decide whether to fill out the survey). Your anonymised

results will be reported to your state or territory health department and the TGA.

This system will probably be in place to monitor safety of the COVID-19 vaccines for a few years. And as new vaccine brands come on board, we will continue to monitor those too.

We can also learn from other countries

The United States has recently developed an equivalent system, [V-safe](#). Safety data from this system from about two million people who have had a COVID-19 [vaccine indicates](#) the vaccines are safe. The short-term side-effects are very similar to those reported in the [vaccine trials](#). The most common reactions include injection site pain, headache, tiredness and muscle aches, usually in the first two days and then resolving within a week after vaccination.

And worldwide, more than [150 million COVID-19 vaccine doses](#) have already been given, with no unexpected safety concerns.

In a nutshell

The potential benefits to us all from a mass vaccination program against COVID-19 far outweigh the potential side-effects, based on data from millions of people who have already been vaccinated around the world. Yet, we know all medicines, vaccines included, have the potential for side-effects.

However, by using, and building on, our already established safety surveillance system, we will be "on top" of rapidly identifying any possible [safety](#) concerns. That's immediately after vaccination and into the longer term.

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