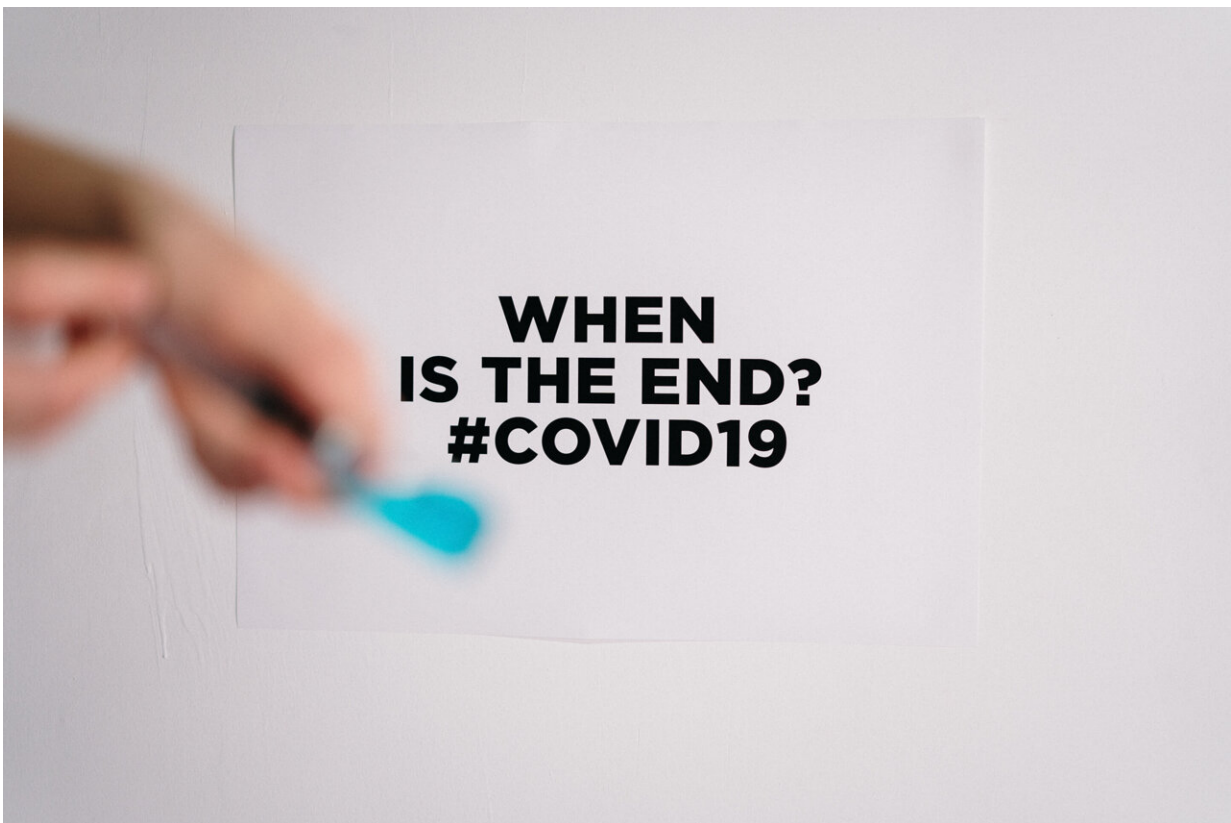


# Vaccine rollouts and safety scares: Give the public the facts and let them decide

March 25 2021, by Julian Savulescu, Dominic Wilkinson, Jonathan Pugh and Margie Danchin

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Credit: cottonbro studio from Pexels

When someone gets sick after receiving a vaccine, this might be a complication or coincidence. As the recent rollout out of the

AstraZeneca vaccine in Europe shows, it can be very difficult to know how to respond.

For instance, reports of blood clots associated with the AstraZeneca vaccine led to several European countries suspending their vaccination programs recently, only [to resume them](#) once these clots were judged to be a coincidence. However, authorities [couldn't rule out](#) increased rates of a rare brain blood clot associated with low levels of blood platelets.

There are also problems with the Pfizer and Moderna vaccines. By early February 2021, among the over 20 million people vaccinated in the United States, there have been 20 reported cases of [immune thrombocytopenia](#), a blood disorder featuring a reduced number of platelets in the blood. Experts suspect this is probably a rare vaccine side-effect but [argue vaccination should continue](#).

So what happens with the next safety scare, for these or other vaccines? We argue it's best to give people the facts so they have the autonomy to make their own decisions. When governments pause vaccine rollouts while investigating apparent safety issues, this is paternalism, and can do more harm than good.

## **The 'precautionary principle' can backfire**

Like any medicine, vaccines have risks associated with their benefits. And no one wants to recommend or use a vaccine with serious side-effects.

So when faced with recent unconfirmed serious side-effects following vaccination, European countries were tempted by the "[precautionary principle](#)", or "better safe than sorry." They opted to pause and gather more evidence.

Some might argue a precautionary approach could help protect the public's confidence in vaccination in the long term. However, suspending or withdrawing a vaccine [could also undermine confidence](#). Once a vaccine program is stopped due to safety concerns, it may not recover. This happened with the HPV (human papillomavirus) vaccine [in Japan](#).

The precautionary approach can also be lethal. In a pandemic, suspending or withdrawing an effective vaccine leads to preventable deaths. The number of preventable deaths depends on three factors.

## 1. Delay

The first is how many people will be delayed in receiving a vaccine. Fortunately, the AstraZeneca vaccine is not the only approved vaccine in Europe, so its suspension or withdrawal would not wholly prevent vaccination; however, some people's vaccinations could be delayed.

## 2. Deaths

The second factor is the [risk of people dying](#) if vaccines are delayed. For example, in England (a country that did not suspend the AstraZeneca vaccine), [people aged 56-59](#) are currently being invited to book appointments for vaccination. [A study in 2020 suggests](#) roughly 0.3% of unvaccinated 55-59 year-olds infected with coronavirus die. But in countries that have not yet vaccinated older people, the risks of a suspension will be higher. The same study suggests the risk of dying for (unvaccinated) 70-74 year-olds infected with the coronavirus is roughly 1.7%. For those infected over 80, the risk is 8.3%.

## 3. How widespread is the virus?

A third factor is how common infections are at the time of suspension.

When rates of infection are higher, we expect more deaths.

According to the [European Centre for Disease Prevention and Control](#), as low as 8 or as many as 1,518 out of 100,000 people are infected with the virus. The rate varies between countries. Australia could afford to be precautionary because testing figures currently suggest a low incidence of COVID-19 ([only 0.2%](#) of COVID-19 tests conducted in the past week have returned positive results). Indeed, its slow vaccine rollout is consistent with a precautionary approach, as evidence is gathered from other countries.

## **Paternalism or autonomy?**

Safety regulation involves value judgements around evidence and weighing risks and benefits. It also involves judgements about who we allow to make decisions about that balance.

[Paternalism](#) is the practice of making judgements for other people about what is best for them. And the strongest form of paternalism ("[hard paternalism](#)") fails to respect the autonomy of competent adults, and breaches their right to make decisions about their own lives.

Suspension or withdrawal of vaccines is hard paternalism. Preventing someone from accessing an effective life-saving vaccine to protect them from low risks of rare side-effects is a severe restriction of their autonomy.

There are limits to autonomy. Where an intervention will clearly do more harm than good, it is the government's responsibility to prevent it. And when there are limited public resources, it is necessary to distribute benefits and burdens fairly.

But what matters ethically is not only vaccine confidence and public

health, but whether people can make their own autonomous decisions about the risks they want to take: the risks of COVID-19 or the risks of vaccination.

## **So how would this work?**

Autonomous decision-making here requires:

- disclosure of even small risks if the outcomes are significant
- admission of limits to confidence (for instance, how much we know about the risks and what we don't know)
- disclosing this information in ways appropriate and comprehensible to all sections of the community
- helping people to think for themselves about the inevitable uncertainties of life.

Safeguarding autonomy here also requires putting safeguards in place to protect those who do not have the capacity to provide valid consent.

When looking at the background rates of blood clots, anaphylaxis or any other rare adverse events, it seems pretty clear vaccines are safe and the associated risks are small.

We must investigate all [vaccine](#) safety signals thoroughly. But the process also needs to maintain the public's confidence in vaccines through effective and transparent communication of risk.

Communicating risk in terms people understand is challenging but it is essential to ensure informed decision-making.

For most people, the benefits of being vaccinated will outweigh the risks. But we should treat people as adults and allow them to make up their own minds.

Governments should not be nannies, nor nervous ninnies. Suspending vaccination fails to respect people's right to make their own choices. It also threatens to cause much more harm overall.

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