

# Infecting healthy people in vaccine research can be ethical and necessary

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Credit: AI-generated image ([disclaimer](#))

Medical experiments involving intentionally infecting people with bacteria, viruses, and parasites are surprisingly common. And they are becoming more common worldwide, particularly in developing countries.

The ultimate aim of these "human [challenge](#) studies" is usually to test potential new vaccines.

However, because of the risks involved, this kind of research raises difficult ethical questions. For example, who should be infected? And which pathogens would be too dangerous to use?

In many challenge studies, people are first vaccinated with an [experimental vaccine](#), then deliberately exposed to a pathogen and monitored to see if the [vaccine](#) protected them against infection.

These studies can be especially valuable from a scientific perspective. They can be significantly [faster and less expensive](#) than other kinds of vaccine research. They are also usually much smaller, because [fewer people](#) need to be given experimental vaccines (that might not turn out to be safe or effective).

These studies sometimes involve infecting people with [deadly diseases](#) such as [malaria](#). In such cases, however, researchers are especially careful to minimise risks by ensuring [study participants](#) are provided with treatment.

## **How can this be ethical?**

The very idea of intentionally infecting humans with diseases will likely strike many people as unethical.

The history of human challenge studies is [tarnished](#). Some of the most blatantly unethical medical research ever conducted involved intentional infection. During world war two, for example, German and Japanese researchers infected prisoners with diseases such as tuberculosis and plague, killing them in the process.

According to most bioethicists who have discussed this topic, however, intentionally infecting people in a clinical trials isn't necessarily unethical, [at least under certain conditions](#).

Rather than intentional infection, the problem with the infamous historical cases is they involved cruel and brutal treatment of people against their will.

But human challenge studies can be ethically acceptable so long as we meet [basic research ethics requirements](#).

Among other things, this should involve proper informed consent and minimising risks. There should also be legitimate scientific reasons for performing the study.

Modern human challenge studies are regularly approved by research ethics committees. They have been [safely conducted](#) with no deaths or severe lasting harms.

Other types of research with healthy volunteers are sometimes more dangerous. One UK trial of an [experimental drug](#) had life-threatening consequences for six volunteers. One reportedly remained in hospital for four months, and all his toes had to be amputated. By comparison, infections in challenge studies are usually much more predictable and easier to treat.

## **Should this occur in developing countries?**

Most recent human challenges studies have taken place in wealthy, developed nations. This might partly reflect the aim of scientists to avoid conducting experiments on especially vulnerable people in developing countries.

But a recent development is the expansion of human challenge studies into low- and middle-income countries—such as Thailand, Colombia, Kenya (and other African countries) – where diseases of interest are more common.

One motivation for this shift is to obtain results more relevant to the populations in these countries. For instance, the diseases and/or vaccines might affect these populations differently to people in developed nations due to variation in immunity, genetics or nutrition.

Beyond being merely permissible, there may be an ethical imperative to [conduct more challenge studies in countries where the target disease is endemic](#) or widespread.

The fact that participants from endemic countries are more likely to be partially immune to diseases being studied means that conducting local challenge studies might involve less risk to them.

Studies can also sometimes directly benefit trial participants. That's because infection during a study can lead to immunity against a disease to which they otherwise would have been at risk, or because they receive a vaccine that protects them.

Such benefits do not usually result when challenge studies are conducted in rich countries where the disease does not normally occur.

## **What ethical issues remain?**

Though human challenge studies can be ethical—even in low- and middle-income countries—there are numerous unresolved issues about the conditions under which this kind of research should be conducted.

## Who should take part in these studies?

Some studies have aimed to [recruit university students](#) because, being more educated, they may be better able to provide adequate informed consent. But students might not provide a good representative sample of the general population, or they might feel pressure to participate in research being conducted at their institutions or by their academic superiors.

## How much should participants be paid?

It is generally agreed that subjects should [be paid for the costs they incur](#) while taking part in a study. This might include the costs of travel or loss of usual income.

Whether, or the extent to which, they should receive further payments reflecting the risks or other burdens endured, is more controversial.

Some say [higher levels of payment](#) reflecting burdens or risks endured would be appropriate, just as some workers receive higher pay for doing dangerous jobs.

Others [worry](#) that high levels of payment might be an irresistible lure, especially for poor people. It appears that [payment has been a major motivation](#) for people to participate in challenge studies in both [high-income](#) and [low-income](#) countries.

## Should children be involved?

Would it ever be acceptable to involve children in challenge studies?

Because diseases and/or vaccines might affect children differently,

conducting research with adults might not always provide reliable enough information about the safety and efficacy of vaccines for children.

But children are widely considered especially vulnerable because, among other reasons, they cannot provide informed consent.

## **Are there some pathogens that should never be tested?**

In general, challenge studies involving high risks that cannot be easily controlled should presumably not be permitted. The use of pathogens [like HIV](#), for example, should be off limits.

### **In a nutshell**

Human challenge studies are sometimes ethically acceptable. And it may be important to conduct them, especially in low- and [middle-income countries](#) where neglected diseases are most common.

Yet we still need bioethicists, policymakers and the general public to discuss unresolved ethical questions about where, when and how they should be conducted.

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