

Human Challenge Trials

PHIL 334: Pandemic Ethics

Review: Conspiracy Theories

What is a
conspiracy theory?

What are some
examples of
conspiracy theories?

Why Do People Believe Conspiracy Theories?

Why Do People Believe in Conspiracy Theories?

- (1) Cognitive Biases
[Evolutionarily Advantageous?]
- (2) Politically Motivated Cognition
- (3) Epistemic FOMO

FOMO:
Fear of Missing Out

People believe in conspiracy theories because they'd rather believe falsely than miss out on having true beliefs.

What Can Be Done?

Human Challenge Trials



Human Challenge Trials

What are they?

In a human challenge trial, healthy people are intentionally exposed to a disease.

This helps scientists to rapidly discover things... like whether, for example, trial participants who are given a potential vaccine are protected against the disease, when that protection kicks in, and to what extent it works (does the vaccine prevent infection, all symptomatic illness, serious illness and/or death?)



Current Human Challenge Programs

- We already conduct **human challenge trials** for seasonal flu, typhoid, and malaria.
- These are justified on the grounds that risks can be controlled in a clinical setting, especially where the disease is mild and therapies exist.



The Ethics of Human Challenge Trials

Pro:

Human-challenge trials could potentially reduce the wait time for an efficacious vaccine by several months, which would have tremendous social value.

It would save potentially millions of lives, allow a faster economic recovery, and so forth.

Con:

It is wrong, some think, to ask the few to bear the risk of severe illness or death in order to secure the collective good.

But human-challenge studies appear to do just that.

Can these ethical worries be assuaged?



COVID-19 is:

1. Deadly,
2. Not fully understood - we don't fully understand to whom it is the most dangerous or why,
3. Not currently treatable.

Nir Eyal on Human Challenge Trials



Fairness & Beneficence

Nir Eyal places importance on two different values: *fairness* and *beneficence*.

Fairness:

Persons who are equals (on medically relevant grounds) should qualify for equal treatment.

Beneficence:

The duty that health care providers have to bring benefit to the patient (care that is in the best interest of the patient), as well as to prevent and to remove harm from the patient.

Doctors Should Balance Trial Risks Against Benefits

Research ethics should not just attend to the **risks** of study participation.

It also needs to consider **benefits** from participation.

And then consider the **balance of the two**.

After all, this is what doctors do when prescribing a surgery or potentially toxic treatments...

Doctors Should Balance Trial Risks Against Benefits

“What matters in assessing the offer that researchers make to candidate participants is not simply the so-called absolute risk, better described as the raw or contributing risk, that comes with the challenge—whether viral exposure poses only minor or controllable risks or, alternatively, more serious ones—but **the net risk**: the risk from participating in that trial minus the risk that the same person would face otherwise.” - Nir Eyal

Are Challenge Trials Unethical?

Three Possible Scenarios:

1. The person declines to participate in any COVID-19 study.
2. The person participated in a standard community-based trial.
3. The person participates in a challenge trial.

Are Challenge Trials Unethical?

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1. **The person declines to participate in any COVID-19 study.**
2. The person participated in a standard community-based trial.
3. The person participates in a challenge trial.

They still have a significant risk of catching COVID-19 in the community.

They don't have access to the experimental vaccine (which may or may not protect her).

They don't have immediate access to the monitoring and top-level healthcare enjoyed by trial participants.

Are Challenge Trials Unethical?

Three Possible Scenarios:

1. The person declines to participate in any COVID-19 study.
They still have a significant risk of catching COVID-19 in the community.
2. **The person participated in a standard community-based trial.**
They have access to the experimental vaccine (which may or may not protect her).
They have some access to the monitoring and top-level healthcare enjoyed by trial participants.
3. The person participates in a challenge trial.

Are Challenge Trials Unethical?

Three Possible Scenarios:

1. The person declines to participate in any COVID-19 study.
They are certain to get COVID-19.
They have access to the experimental vaccine (which may or may not protect her).
2. The person participated in a standard community-based trial.
They are already at the hospital, so have immediate access to the monitoring and top-level healthcare enjoyed by trial participants.
3. **The person participates in a challenge trial.**
Probability of serious harm is much lower.

Other Issues:
Unfairly distributed benefits
Possibility of Exploitation
Informed consent

Conclusion

The right ethical question to ask about human challenge trials for COVID-19 vaccines is: "whether challenge trials would increase study participants' likelihood of bad outcomes, compared to two alternative scenarios: nonparticipation in any trial, and participation in standard efficacy trials for the same vaccines?"

It's not obvious that a COVID-19 challenge trial would increase study participants' likelihood of bad outcomes.

