Researchers outline need for new approach to COVID-19 vaccine testing

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Some of Rutgers' top health researchers are calling for a change in our approach to developing COVID-19 vaccines, and vaccines to fight future pandemics, to incorporate both conventional and challenge trails. Conventional randomized controlled trials are where participants receive a vaccine or placebo and then may or may not be exposed as they

continue with their lives over the course of the months that follow. Human challenge vaccine trials are where participants receive a vaccine or placebo and are then artificially exposed to the virus.

The commentary by bioethicist Nir Eyal and epidemiologists Tobias Gerhard and Brian Strom (the latter is chancellor of Rutgers Biomedical and Health Sciences)—published in *Pharmacoepidemiology and Drug Safety*—examines how this parallel approach to vaccine trials can lead to faster and more accurate vaccine assessment and more effective pandemic response.

The researchers say that further vaccine testing could help settle remaining questions about how effective the shots are at blocking infection against old and new virus strains. It could also reveal the most effective dosing and timing between shots, the level of protection compared to natural immunity and how well vaccines work in groups that were underrepresented in initial trials.

While some researchers proposed at the beginning of the COVID-19 pandemic that challenge trials take place, others argued that too little was known about the virus and that conducting the trials would be too dangerous. They were not used for the studies that led to approval of the major COVID-19 vaccines but are now being used in testing.

"The vigorous discussions about vaccine trial designs in the early months of the COVID-19 pandemic unfortunately played out as a mostly adversarial debate between pro-challenge trial and pro-conventional trial supporters. We felt that there was an overlooked third approach that involved combining strengths from both designs and could facilitate better outcomes throughout the remainder of the COVID-19 pandemic and in future pandemics," says Gerhard, Director, Center for Pharmacoepidemiology and Treatment Science at Rutgers Institute for Health, Health Care Policy and Aging Research (IFH) and Professor,

Rutgers Ernest Mario School of Pharmacy.

The Rutgers researchers' parallel approach, called "Combining Conventional and Challenge trials (CCC)," would involve trials of both types, conducted either simultaneously or at different times.

"In a pandemic, the value of obtaining information as early as possible is so vast that 'CCC' is ethically preferable to any single trial, and preparations for a future pandemic should include laying the groundwork for a CCC'," said Eyal, Henry Rutgers Professor of Bioethics and Director, Center for Population-Level Bioethics at Rutgers IFH.

Eyal and his colleagues say that researchers will be able to collect more information and increase confidence in the efficacy of vaccines.

"When either human challenge- or conventional trials are permitted, it may be even more advisable to combine conventional and challenge testing for surer, faster, and more comprehensive vaccine assessments and a fuller understanding of the infection and the disease," said Gerhard.

Two trials instead of one would conserve resources, answer more questions, and increase the chance that at least one trial would be successful, they said.

"The added value of faster, more informative completion of testing of the central weapon against a pandemic that threatens an exceptional number of people globally tends to be very high," Strom said.

More information: Tobias Gerhard et al, Pandemic vaccine testing: Combining conventional and challenge studies, *Pharmacoepidemiology and Drug Safety* (2022). DOI: 10.1002/pds.5429

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