

Strategies to Study Future SARS-CoV-2 Vaccines

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Abstract

The impact of COVID-19 vaccines on the pandemic will depend upon several factors. These include factors like the effectiveness of the vaccines; how quickly they're approved, manufactured, and delivered; and the way many of us get vaccinated.

Most scientists anticipate that, like most other vaccines, COVID-19 vaccines won't be 100% effective. WHO is functioning to assist make sure that any approved vaccines are as effective as possible, in order that they can have the best impact on the pandemic. Nevertheless, critical lessons are often learned for the event of vaccines against rapidly emerging viruses. Importantly, SARS-CoV-2 vaccines are going to be essential to reducing morbidity and mortality if the virus establishes itself within the population.

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Introduction

Potential Strategies to Study Future SARS-CoV-2 Vaccines

The most scientifically rigorous thanks to study vaccines that haven't yet entered clinical trials is to conduct randomized, blinded clinical trials that compare the vaccines with placebo controls. Influential groups have involved the utilization of such trials to gauge novel candidates also on still gather data on early vaccines, even after they receive authorization or licensing approval. This strategy may be tenable for a brief period, while access to emergency-authorized vaccines is limited and only selected subpopulations such as front-line health care workers and residents of nursing homes are often vaccinated. However, once authorized vaccines become available in sufficient quantities to start immunizing broader groups at high risk of severe disease, such as community-dwelling older people and persons with comorbidities, it's going to not be feasible or ethical to incorporate such individuals in placebo-controlled trials. Given the importance of evaluating vaccine efficacy and safety in high-risk subgroups, excluding them from placebo-controlled trials will substantially diminish the worth of these trials.

A second strategy, which the FDA contemplates in its guidance once immunologic correlates of efficacy such as levels of antibodies to vaccine antigens are established, is to administer experimental vaccines to groups of participants and to then base

decisions to authorize or approve those vaccines on surrogate measures. However, adequate evidence isn't yet available to define what constitutes a validated surrogate marker of vaccine efficacy. In addition, evaluating efficacy alone won't suffice; determining safety, which needs comparative trials involving large numbers of participants, is equally critical. Thus, a minimum of within the near term, trials supported surrogate measures of efficacy aren't a viable approach.

A third strategy is to conduct head-to-head randomized trials comparing a novel vaccine candidate with a vaccine that has previously received emergency authorization or full licensure. Such trials could use noninferiority designs that would declare the novel vaccine effective if the incidence of symptomatic COVID-19 infection or other primary end point isn't higher by some specified margin than incidence in the comparator group. These trials also could facilitate direct comparisons of safety between the novel vaccine and its established comparator; such comparisons are of particular importance given widespread public concerns about safety. Interpretation of such trials would require confidence that historical efficacy estimates of the comparator vaccine from prior trials also hold true within the present trial. The high reported efficacy of the vaccines from Pfizer/BioNTech and Moderna provide reassurance that, if the infection rate within the novel vaccine group was shown to be noninferior to the rate in the comparator group, it would be possible to conclude that the novel vaccine was effective even without a placebo control group to allow direct inferences (in other words, that the trial

had assay sensitivity). Conducting such a trial would hinge on cooperation between the manufacturer of the novel vaccine and the manufacturer of the established vaccine, a requirement that poses both logistical and financial challenges.

The fourth strategy, and therefore the one that might be most precious from a scientific and public health point of view, would be to initiate a multigroup platform trial that tests authorized or approved vaccines alongside novel, as-yet-unauthorized vaccine candidates. Such an attempt, which might be conducted under the auspices of Operation Warp Speed, would leave direct comparisons of efficacy and safety among established also as investigational vaccines. Investigational vaccine groups would be added to the platform as soon because the candidate vaccines met safety and immunogenicity benchmarks in smaller, earlier-phase trials. Based on interim safety and efficacy analyses, candidate vaccines would be dropped from the platform and their development discontinued using an adaptive design if they proved to possess inferior efficacy or significant safety concerns as measured against benchmark comparators. Conversely,

once reassuring initial safety and efficacy data were available, enrolment in novel vaccine groups could be extended to children and other populations that have largely been excluded from current phase 3 trials. Adaptive designs are utilized in other COVID-19–related settings, like the evaluation of therapeutic agents for patients hospitalized with serious disease [1].

It's too early to know if COVID-19 vaccines will provide long-term protection. Additional research is needed to answer this question. However, it's encouraging that available data suggest that the majority people that get over COVID-19 develop an immune reaction that gives a minimum of some period of protection against reinfection – although we're still learning how strong this protection is, and how long it lasts [2].

References

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