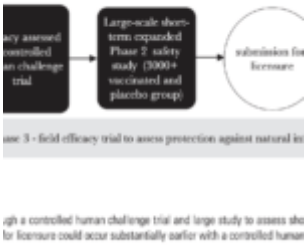
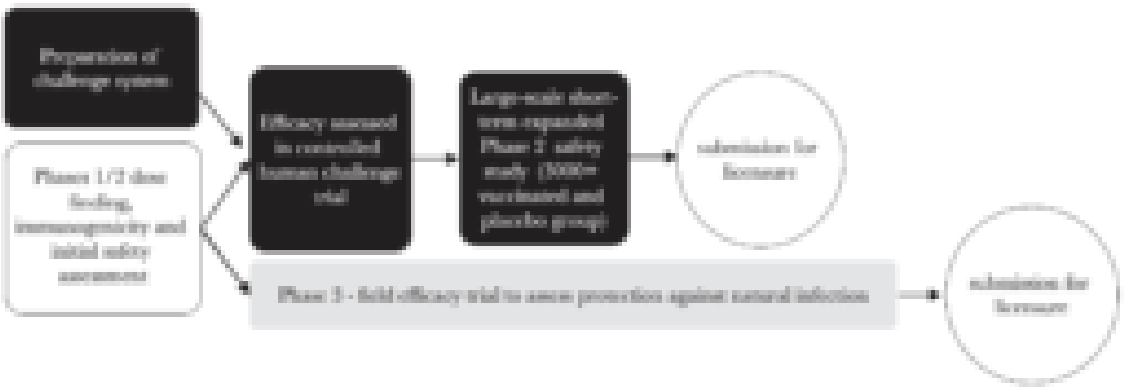
Should we consider SARS-CoV-2 human challenge models for vaccine testing ?



Vaccine clinical trials can be broadly classified into 3 phases: Phase I (safety); Phase II (immunogenicity) and Phase III (efficacy). This pipeline is very rigorous, lengthy and can be modified depending on the context (read Overview of Vaccinology for more details). One way of shortening this pipeline is the use of controlled human challenge models (CHCM). Where individuals are vaccinated with a vaccine candidate, followed by controlled infection with a pathogen* to determine if the vaccine can confer "protection". This enables researchers to directly assess the potential protective efficacy of the vaccine, before a large scale phase 3 trial. This strategy has been very valuable for accelerating Malaria Vaccinology

A recent article by Eyal and colleagues suggest using "Human Challenge Studies to Accelerate Coronavirus (SARS-CoV-2) Vaccine Licensure". *"The proposed trial method would potentially cut the wait time for the rollout of an efficacious vaccine. Challenge studies (which always directly expose all participants to a pathogen to assess efficacy) generally require fewer participants, followed over a shorter period than do standard efficacy studies (in which many participants are never exposed)."* This strategy would rule out any potential vaccines that would show no sign of potential "protection", and ensure that only candidate vaccines that

show signs of “protection” would proceed to phase 3 clinical testing.



Eyal et al., JID

One caveat to this proposed model is the lack of an attenuated form of SARS-Cov-2. Therefore, individuals would be at high risk of developing COVID-19. Eyal et al., acknowledge this and suggest, selectively choosing potential volunteers and exposing individuals to the virus in a very controlled and well-monitored manner, containing risks as much as possible.

Pathogens used in CHCM are usually attenuated and confer mild disease which is easily treatable.

Journal Artilce: Eyal et al., 2020. Human Challenge Studies to Accelerate Coronavirus Vaccine Licensure. Journal of Infectious Diseases

Also Read : **Should scientists infect healthy people with the coronavirus to test vaccines?** (Nature News)

Listen to NEJM podcast episode that interviewed the Editor and Deputy Editor on approaches to both passive and active vaccination strategies. How conserved is the virus? What is the viral mutation rate? what kind of immune responses might be required?

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