

Human Challenge Trials

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In News

As laboratories around the world race to develop a vaccine for the novel coronavirus, many people have volunteered to take part in a controversial testing method called human challenge trials. The method, which involves **intentionally infecting volunteers with the novel coronavirus**, is being promoted in order to **speed up the process of preparing a vaccine**.

More About Human Challenge Trials

- In most regulatory regimes, vaccines take several years to develop, and their development typically proceeds through three phases of clinical trials.
- . In **Phase 1, small groups of people receive the trial vaccine**.
- . During **Phase 2, the clinical study is expanded and the vaccine is given to people who have characteristics (such as age and physical health) similar to those for whom the new vaccine is intended**.
- . In **Phase 3, the vaccine is given to several thousand people and tested for efficacy and safety**. During this phase, participants either receive the vaccine or a placebo.
 - The efficacy of the vaccine is determined by comparing the prevalence of infection in the group that was administered the vaccine with the one which received a placebo.
 - Under human challenge trials, participants of both the vaccine group and placebo group upon consent are **deliberately exposed to the infection**, thus are challenged by the disease organism.
 - Proponents of the method believe that such trials could

save valuable time in developing a Covid-19 vaccine, as researchers **would not have to wait for participants to contract the infection under real-world conditions.**

- According to experts, such testing would also **require significantly less number of people than regular Phase 3 trials**, which require thousands of volunteers.

Ethics of Human Challenge Trial

- While human challenge trials are not new, they are usually carried out in developing medications for diseases which are considered **less lethal and have been better understood by scientists over the years, such as malaria.**
- Critics have questioned undertaking such trials for Covid-19, a potentially deadly disease for even those who are less at risk, and which researchers are still in the early stages of studying.
- In a 2016 document titled **'Human Challenge Trials for Vaccine Development: regulatory considerations'**, the WHO stated: Human challenge studies have contributed vital scientific knowledge that has led to advances in the development of drugs and vaccines. Nevertheless, such research can appear to be in conflict with the **guiding principle in medicine to do no harm.** Well documented historical examples of human exposure studies would be **considered unethical by current standards.** It is essential that challenge studies be conducted within an ethical framework in which truly informed consent is given.