



Human Challenge Trials

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Why in News

In the race to **develop a vaccine for the novel coronavirus**, many people have volunteered to take part in the **Human Challenge Trials (HCTs)**.

It involves **intentionally infecting volunteers** with the novel coronavirus, in order to **speed up the vaccination development**.

Key Points

- **Vaccine Development**

- In most of the regulatory regimes, vaccines take several **years to develop** and their development typically proceeds through **three phases of clinical trials**.
 - **Phase 1:** Small groups of people receive the trial vaccine.
 - **Phase 2:** 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.
 - **Phase 3:** Vaccine is given to several thousand people and tested for efficacy and safety. During this phase, participants either receive the vaccine or a placebo.
 - **Placebo** is anything which **looks like real treatment but it is actually not**. For example- sugar pills and saline injections.
- The vaccine's **efficacy is determined by comparing the prevalence of infection** in the **group that was administered the vaccine** with the **one which received a placebo**.
- The **hypothesis** that those in the vaccine group will be infected significantly less is thus tested.

- **Human Challenge Trials**

- Under HCTs, participants of both the vaccine group and placebo group are **deliberately exposed to the infection** after their **consent** and thus are **challenged by the disease organism**.
- HCTs are **not new** and 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 like **malaria**.
- Few scientists have suggested **replacing the conventional Phase 3 testing** of vaccines **by controlled HCTs** of **Covid-19 (SARS-CoV-2)** vaccine which can **accelerate the testing** and potential rollout of efficacious vaccines.

Such trials may reduce **many months from the licensure process**, making efficacious vaccines available **more quickly** and will also **require significantly less number of people** than regular Phase 3 trials.

- **Ethical Concerns**

- HCTs for Covid-19 have been questioned by critics because it is a **potentially deadly disease for even those who are less at risk**, and has **not been studied fully yet**.
- In 2016, the **World Health Organisation** (WHO) emphasised on the **ethical framework of the challenge studies** and also highlighted the **importance of informed consent**.
- Human challenge studies should be **conducted with abundant forethought, caution, and oversight**. The **value of the information** to be gained should clearly **justify the risks to human subjects**.

Source: IE