Human Challenge Studies

Why in news?

The World Health Organization (WHO) has permitted “Covid-19 Human Challenge Studies”, subject to a set of preconditions being met.

What is the objective?

- More than 20,000 people from 102 countries have enrolled on a US website to infect themselves voluntarily with the Covid-19 virus.
- 1daySooner is the US-based vaccine advocacy group, which has started registration of volunteers for the “Covid-19 human challenge”.
- The objective of this human challenge is to go on to **test whether a given vaccine works** on any of these infected persons.

What is a human challenge?

- **WHO definition** - The WHO has recently released the WHO Working Group for Guidance on Human Challenge Studies in Covid-19.
- In this guidance, it has said that the Controlled human infection studies (or ‘human challenge studies’) involve the deliberate infection of healthy volunteers.
- They can be substantially faster to conduct than vaccine field trials, because fewer participants need to be exposed to experimental vaccines in order to provide estimates of efficacy and safety.
- Such studies can compare the efficacy of multiple vaccine candidates and thus select the most promising vaccines for larger studies.
- **Speeds up** - Human challenges speed up trials because a lot of time may be lost waiting for a trial subject to contract the disease naturally.
- Until such time that happens, whether the vaccine works or not cannot be tested.
- Then again, if infection does not happen normally, there is little way of finding out whether it is because of the vaccine or whether it is because the person was never exposed at all.

Has ‘human challenge’ measure been used on previous occasions?

- Human challenge trials are routinely done for diseases such as **malaria, dengue, influenza** and **cholera**.

- These diseases extract a heavy public health toll but are not otherwise deadly.
- In 1796, Edward Jenner (Father of the **smallpox** vaccine) infected his gardener's son with the smallpox virus after having used his newly developed vaccine on the eight-year-old. The child did not get smallpox.
- Later, Jenner used the deliberate infection strategy on 6,000 people to test the efficacy of his vaccine, which eventually eradicated smallpox.
- The first well-described influenza challenge study was published in 1937 and involved the inhalation of a **human influenza virus**.
- Because only a small number of volunteers (20%) developed mild disease, this model was used across studies for many decades.

Why challenge studies are significant?

- These challenge studies allowed us to understand more about the human immune response to diseases.
- They test the preventative and therapeutic measures.
- In the last 50 years, challenge studies have been performed safely in consenting adult volunteers under the oversight of research ethics committees.
- These studies have recently helped to accelerate the development of vaccines against typhoid and cholera among others.

How necessary is this programme for Covid-19?

- There is currently no approved treatment against Covid.
- This means that there are only two ways of stopping the global march of SARS-CoV-2: Herd Immunity and Vaccines.
- **Herd immunity** - When the virus infects a critical mass of people in a given population, people develop some immunity against it.
- Thus, people stop being the vessels for further transmission of the disease. But, this method involves a lot of death and suffering.
- There is also an element of uncertainty because nobody knows how long immunity against Covid lasts in a person who has already had it.
- **Vaccine** - This is a feasible way to stop the spread of the virus.
- That is why there is so much work going on a Covid vaccine globally.
- Even a vaccine that clears all trials in a breeze could have a waiting period of 12-18 months before it is available at a global scale.

Is the 'Human Challenge' ethical?

- There is no easy answer to this. So, it is important to choose volunteers with care, with full disclosure given and informed consent sought from them,

before going ahead with the actual act of infection.

- WHO says that the challenge studies are nonetheless ethically sensitive.
- It says that they must be carefully conducted in order to minimize harm to volunteers and preserve public trust in research.
- It also adds that investigators, in particular, must adhere to standard research ethics requirements.
- Research should be conducted to especially high standards where
    1. Studies involve exposing healthy participants to high risks;
    2. Studies involve first-in-human interventions (including challenge) or high levels of uncertainty (about infection, disease, etc); or
    3. Public trust in research is particularly crucial, such as during public health emergencies.
- Based on the data available, WHO estimates that participation in Covid-19 challenge studies would be the least risky for young healthy adults.
- In ages 18-30 years, hospitalisation rates for Covid-19 are currently estimated to be around 1% and fatal infection rates around 0.03%

Source: The Indian Express

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