Can a COVID-19 vaccine be developed soon?

**Purpose of a vaccine**

à The great hope in the control of infectious diseases is always a vaccine.

à A vaccine could be a **weakened biological or synthetic agent** administered to humans that will protect them from contracting infectious diseases by **supplying specific antibodies** to **neutralise the disease-causing pathogen**, while not making a person actually sick from it.

à Vaccines have always sounded the bugle of **relief from morbidity and mortality** for societies.

à They have played an **important role** in the **reduction of communicable diseases** from the second half of the 20th century.

à In the last two decades with new infectious diseases emerging, particularly post the H1N1 influenza, global vaccine development activity has been rather frenetic.

à The World Health Organisation (WHO) site lists **10 vaccine candidates** in clinical evaluation and 126 candidate vaccines in preclinical evaluation, as on June 9.

**What is the process of vaccine development?**

à **Vaccine technology** has **significantly evolved** in the last decade, including the development of **several RNA (ribonucleic acid) and DNA vaccine candidates**, licensed vectored vaccines, recombinant protein vaccines and cell-culture-based vaccines.

à However, despite the many advances, including using **artificial intelligence** to determine **potential vaccine candidates**, the core principles of ensuring safety and efficacy of the vaccine for use in humans remain unchanged.

à While technology might have quickened some of the processes, the **trials for the vaccine** need to stick by these principles that are **time consuming** for a reason.

à According to the **Centers for Disease Control and Prevention (CDC)** website, the general **stages of the development cycle** of a vaccine are:

1. exploratory stage,
2. pre-clinical stage,
3. clinical development,
4. regulatory review and approval,
5. manufacturing and quality control.

à If vaccine candidates do make it to the **third stage, clinical development** is a three-phase process.

à It says:

1. During **Phase I**, **small groups of people receive the trial vaccine**.
2. In **Phase II**, the clinical study is expanded and vaccine is given to people who have
characteristics (such as age and physical health) similar to those for whom the new vaccine is intended.

3. In Phase III, the vaccine is given to thousands of people and tested for efficacy and safety.

à If a vaccine is approved by a licensing agency, then it can move into the manufacturing stage, but constant monitoring of the process and quality control measures must be put in place.

à Vaccine production should comply with the current Good Manufacturing Practice standards to ensure constant quality and safety of vaccine.

What is the status of a SARS-CoV-2 vaccine?

à To start with, the primary advantage with SARS-CoV-2 was that it was identified in record time, and its genomic sequence was made globally available by January.

à Amanat and Krammer say: “In addition, we know from studies on SARS-CoV-1 and the related MERS-CoV vaccines that the S protein on the surface of the virus is an ideal target for a vaccine... The structure of the S protein of SARS-CoV-2 was solved in record time at high resolution, contributing to our understanding of this vaccine target. Therefore, we have a target antigen that can be incorporated into advanced vaccine platforms.”

à Two important steps that are typically needed before bringing a vaccine into clinical trials.

- First, the vaccine is tested in appropriate animal models to see whether it is protective. However, animal models for SARS-CoV-2 might be difficult to develop...
- Even in the absence of an animal model that replicates human disease, it is possible to evaluate the vaccine because serum from vaccinated animals can be tested in in vitro neutralisation assays
- Second, vaccines need to be tested for toxicity in animals, e.g., in rabbits. Usually, viral challenge is not part of this process, because only the safety of the vaccine will be evaluated. This testing, which has to be performed in a manner compliant with GLP (Good Laboratory Practice), typically takes 3–6 months to complete.”

à The 10 candidates in clinical evaluation, as per WHO’s list, are based on five platforms — non-replicating coral vector, RNA, inactivated, protein sub unit, and DNA.

à The Johns Hopkins Bloomberg School of Public Health in a paper, defined platform thus: “The process under which a vaccine is manufactured qualifies it as platform-based. If it has the capacity to form the basis of myriad other vaccines using some conserved structure, it can be classified as a platform. The spectrum of different platforms ranges from viral vectored vaccines to nucleic acid vaccines.”

à In all, 126 candidate vaccines are in various stages of pre-clinical evaluation, including some in India. In mid-May, K. VijayRaghavan, Principal Scientific Adviser to the Union government, said there were nearly 30 ‘attempts’ from India to develop vaccines.

à The leading attempts among them are: the Pune-based Serum Institute of India tie-up with Oxford University operating with a weakened adenovirus; the Indian Council of Medical
Research’s collaboration with the Hyderabad-based Bharat Biotech to develop a vaccine based on a SARS-CoV-2 strain isolated at the National Institute of Virology, Pune.

Bharat Biotech is also involved in two other vaccine development projects with different groups, according to officials.

The New York Times, meanwhile, has an updated status report on vaccines, as of June 12: 125-plus are in the pre-clinical stage (not yet in human trial phase, seven in the first phase (vaccines testing safety and dosage), another seven in the second phase (vaccines in expanded safety trials) and two in phase three trials (vaccines in large-scale efficacy tests). Some coronavirus vaccines are now in phase I/II trials, for example, in which they are tested for the first time on hundreds of people.

**What about current projections and what happens next?**

The development of vaccines for human use takes years normally. Many additional steps are needed before these vaccine candidates that have shown promise can be used in the population, and this process might take months.

Experts say, some of the other concerns for the development of an effective vaccine are the prospect of the virus mutating, and a waning of the antibody response.

It is known that infection with human coronaviruses does not always produce long-lived antibody responses, and re-infection, likely to be mild [symptoms] in a fraction of individuals, is possible after an extended period of time.

Any effective vaccine must overcome all these issues in order to ensure protection against a virus that seems to have taken the world by surprise.

However, current projections indicate that the virus is likely to become endemic and cause recurrent seasonal epidemics. In such a scenario, a vaccine will be the most effective tool to battle a virus the world is yet to fully understand.