A Covid Vaccine around the corner

Syllabus: Prelims GS Paper I : Current events of national and international importance.

Mains GS Paper III : Science and Technology- developments and their applications and effects in everyday life; Awareness in the fields of IT, Space, Computers, robotics, nano-technology, bio-technology

Context

Researchers around the world are trying to find the best solution to the Covid-19 pandemic, but developing a COVID-19 Vaccine is the first and last hope of humanity.

Background

The World Health Organization (WHO) declared Covid-19 a pandemic, triggering unprecedented national lockdowns, badly impacted the economies and stretching healthcare systems to their limits. Developing a vaccine against Covid-19 is currently the most pressing challenge the world is facing. According to WHO chief scientist Dr Soumya Swaminathan such an enterprise may require funding of up to $18.1 billion to deliver two billion doses by the end of 2021.

What are the Stages in Development of a Vaccine?

Firstly, a new vaccine candidate has to pass testing in animals, following which clinical trials kick in. Then, over three phases, the vaccine candidate's safety and efficacy are tested as per protocols. A fourth stage involves collection and analysis of post-marketing data.

During a pandemic, a vaccine may receive emergency use authorisation before a formal green signal.

Pre-clinical tests: In this primary stage, scientists test the vaccine on animals such as mice or monkeys to see if it produces an immune response.

Phase I trials: This is the first step where the experimental vaccine is given to humans, usually between 20-80 subjects, to test safety and dosage and check whether it stimulates the immune system.

Phase II trials: In this stage, a larger group of several hundred individuals are enrolled for testing and they are split into groups age-wise such as children and elderly. The Phase II testing studies the candidate vaccine's safety, immunogenicity, proposed doses, schedule of immunisations and method of delivery.

Phase III trials: Since certain side effects may not surface in the smaller groups of humans tested in earlier phases, the vaccine candidate is given to thousands of people in this stage. Here, the scientists check how many become infected compared with volunteers who receive a placebo. These trials can determine if the vaccine protects against the coronavirus.

Approval: After Phase III trials, the vaccine developer submits a license application to the regulatory authority in their respective country. The regulator then inspects the factory where the vaccine will be made and approves its labelling.

What are the Primary Goals of Researchers?

Researchers are looking for signs of protection against SARS-CoV-2 — or of enhanced disease, when the animals encounter the virus. They will also study how earlier exposure to other viruses might affect the response to a COVID-19 infection. Previous studies found that some animals that were infected with severe acute respiratory syndrome (SARS) after being vaccinated fared worse than those that had not been vaccinated.

One of the research priorities is to determine whether previous viral exposure plays a part in the development of a more severe case of COVID-19. Epidemiological reports show that older people who develop COVID-19 are more likely to die than younger people are. It is possibly because of weak immune system compare to younger ones. Researchers are also look into reports that people who have recovered from COVID-19 can be re-infected with the virus.

Types of Vaccines and how they work

Traditional Vaccines:

Vaccines induce their protective effect against pathogens by artificially exposing a person to a modified version of the pathogen, a part of the pathogen, or some toxin that it produces. The intent of this exposure is to provoke an adaptive, or memory-

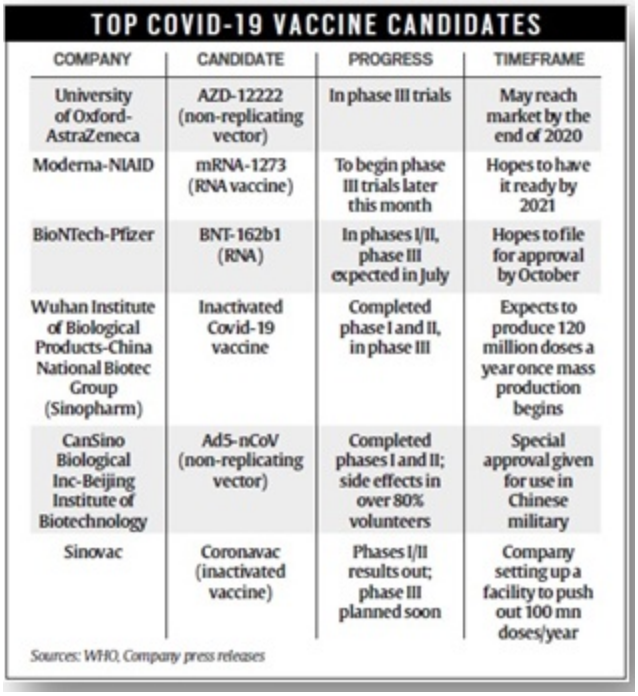
based, immune response that prevents future infection. This immune response relies heavily on B-lymphocytes, a type of immune cell that produces antibodies. Antibodies are produced in response to viruses, bacteria, or other foreign “invaders” and specifically bind to and neutralize antigens (i.e., surface molecules or structures) associated with them.

Some Traditional Vaccines Order:

- **Live, attenuated (e.g., chickenpox, MMR) –** comprised of a whole virus that has been neutralized or weakened to prevent it from causing disease.
- **Inactivated, killed (e.g., polio)–**made from dead viruses that are incapable of causing illness. Covaxin being developed by India is such type of vaccine for COVID-19.
- **Toxoid (e.g., tetanus) –** composed of inactivated bacterial toxins.
- **Subunit/ Conjugate/ Non-replicating Viral Vector (e.g., current influenza vaccines, Hepatitis B) –** made from a specific part of the virus, usually a key protein, either extracted from a live virus or manufactured using Recombinant DNA technology. . Oxford-AstraZeneca vaccine is of this type.

Modern Vaccines:

DNA Vaccines: As vaccine technology has advanced in recent years, new vaccine types have been developed. DNA vaccines have emerged as particularly promising alternatives to traditional vaccines. Mechanisms differ, but most of these work by introducing the genetic sequence of a viral antigen into a host’s cells and relying on the body to then transform (via transcription into mRNA and translation into protein) this genetic material into a viral subunit, which the body’s B-lymphocytes can target for adaptive immunity.



TOP COVID-19 VACCINE CANDIDATES

COMPANY	CANDIDATE	PROGRESS	TIMEFRAME
University of Oxford-AstraZeneca	AZD-12222 (non-replicating vector)	In phase III trials	May reach market by the end of 2020
Moderna-NIAID	mRNA-1273 (RNA vaccine)	To begin phase III trials later this month	Hopes to have it ready by 2021
BioNTech-Pfizer	BNT-162b1 (RNA)	In phases I/II, phase III expected in July	Hopes to file for approval by October
Wuhan Institute of Biological Products-China National Biotec Group (Sinopharm)	Inactivated Covid-19 vaccine	Completed phase I and II, in phase III	Expects to produce 120 million doses a year once mass production begins
CanSino Biological Inc-Beijing Institute of Biotechnology	Ad5-nCoV (non-replicating vector)	Completed phases I and II; side effects in over 80% volunteers	Special approval given for use in Chinese military
Sinovac	Coronavac (inactivated vaccine)	Phases I/II results out; phase III planned soon	Company setting up a facility to push out 100 mn doses/year

Sources: WHO, Company press releases

RNA Vaccines: RNA vaccines are similar, but they only need to undergo translation to produce the requisite viral subunits for a memory-based immune response. In the past, RNA was regarded as difficult to work with because of its instability and tendency to degrade rapidly. Furthermore, many early RNA vaccines were ineffective at producing a robust immune response because they failed to properly integrate with the body's cells. Recent innovations, however, have sufficiently improved the "packaging" of mRNA such that it can be used in a vaccine. Advantages of this new technology are numerous, including the ability to be rapidly scaled up, something that may prove exceptionally important in light of the COVID-19 pandemic.

India's First Covid-19 Vaccine - Covaxin

India is among the largest manufacturer of generic drugs and vaccines in the world. It is home to half a dozen major vaccine makers and a host of smaller ones, making doses against polio, meningitis, pneumonia, rotavirus, BCG, measles, mumps and rubella, among other diseases.

With the corona virus case tally crossing 11.5 lakh mark which is a very distressing figure, the scramble for Covid-19 vaccine has accelerated in India. A light of hope is appeared in the India's first indigenous Covid-19 vaccine Covaxin has started human trials. In phase I, the vaccine would be tested on 375 volunteers. India is one of the largest vaccine producers in the world and scientists are hoping to develop a corona virus vaccine within months because of the pandemic.

Covaxin, which has been developed by Bharat Biotech in collaboration with ICMR and NIV, Pune, will be tested on more than 1,100 people in phase 1 and 2 clinical trials.

The Drugs Controller General of India (DCGI) had permitted two vaccines -- one developed by the Bharat Biotech International Limited and another one by Zydus Cadila Healthcare Ltd to go in for the first and second phase of human clinical trials.

Drug Controller General of India:

The Central Drugs Standard Control Organisation(CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India.

The Drugs & Cosmetics Act, 1940 and rules 1945 have entrusted various responsibilities to central & state regulators for regulation of drugs & cosmetics. It envisages uniform implementation of the provisions of the Act & Rules made there under for ensuring the safety, rights and well being of the patients by regulating the drugs and cosmetics.

Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of New Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

Further CDSCO along with state regulators, is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products.

Conclusion

There are lots of different technologies being used, which is great, because that means that we have more chances of a vaccine being able to control the virus if one or more of those work. In the end, many of them are using the same approach, of making trying to make immune responses against the spike protein. The great news there is that if one of the vaccines that take this approach works, it is likely we will have multiple hits on target. Worldwide, we will need a lot of vaccines, so having multiple developers successful is extremely good news.

Connecting the Dots:

Question for Prelims

With reference to the Central Drugs Standard Control Organisation, consider the following statements:

1. It functions under the Department of Pharmaceuticals.
2. It is responsible for approval of New Drugs, Conduct of Clinical Trials.

Which of the statements given above is/ are correct ?

(a) 1 only
(b) 2 only
(c) Both 1 and 2
(d) Neither 1 nor 2

Question for Mains

Comment on the challenges for the development and trials of COVID-19 vaccine in India. Suggest measures to be taken for facing these challenges.