

MORE THAN A VACCINE, IT IS ABOUT VACCINATION

Relevant for: Developmental Issues | Topic: Health & Sanitation and related issues

Everyone eagerly asks: will we get a COVID-19 vaccine this year or only next year? During a pandemic, expecting vaccines the same year or the next, illustrates the power of technology, human hope, media hype — all at unprecedented frenzy.

Globally, innumerable vaccine trials are progressing; in India, two candidates have advanced considerably. An inactivated coronavirus vaccine was created by [Hyderabad's Bharat Biotech](#). It is safe and immunogenic (stimulates anti-coronavirus antibody) in laboratory animals and humans, to be re-confirmed in a phase 2 trial; phase 3 will assess the vaccine's safety and protective efficacy against COVID-19.

Coronavirus | Vaccine panel mulls early access

[Pune's Serum Institute of India](#) (SII) is testing Oxford University-AstraZeneca's vaccine using a Trojan horse approach — spiking chimpanzee adenovirus type 5 with coronavirus spike glycoprotein genes. When injected, adenoviruses are detected and devoured by immune system cells patrolling for invading microbes. The smuggled genes force these cells to synthesise and spew out spike protein that is immunogenic. This adenovirus is harmless in humans. The SII is ready to upscale production after regulatory clearances in the United Kingdom and India.

Both company-owners have invested heavily, without extramural research support, or advance purchase contract by the government. Both seem to have the best interests of fellow Indians first in their hearts; profit comes second. Risks are a part of the game. Neither company has all its eggs in one basket — confidence in their flagship antigens is not absolute, both are pursuing alternate vaccine candidates also.

Some wealthy nations made bilateral financial agreements with manufacturers in order to hog vaccines. Such vaccine nationalism is 'measles of the world', borrowing the phrase from Einstein. Global public good should not be hijacked by wealthy nations. Gavi, the global vaccine alliance, created COVAX — a funding facility to ensure up-scaling vaccine production and its access to low income countries as soon as regulatory approvals emerge. COVAX will support the SII with funds to bring down selling-price to \$3 per dose.

Coronavirus | WHO chief scientist warns against 'vaccine nationalism'

With good news on supply side, what about the delivery side? India's Universal Immunisation Programme is a vaccine-delivery platform for children and pregnant women, funded by the central government but implemented by State governments. However, the COVID-19 vaccine is for all age groups, necessitating an innovative platform, prioritised on the basis of need.

The first step is policy definition leading to a plan of action blueprint. The time to create them is now — it costs nothing, but will save time when a vaccine becomes available.

Policy emerges from objective(s) for vaccine use in individuals and community. Priority for individual need is to protect those at high risk of death (senior citizens and those with medical co-morbidities) and front-line workers who expose themselves to infection while providing health care. Children may be vaccinated before schools reopen to protect them and prevent infection from being carried home.

Coronavirus | India will have to deliver vaccine on a scale never seen before: Oxford scientist Andrew Pollard

Vaccine availability will be limited at first, when we must ensure that those on the priority list receive it. Those who already had COVID-19 or novel coronavirus infection require no vaccination; but how can we ascertain that? Past COVID-19 or infection cannot be readily identified unless we track archival information of all laboratory tests and medical records. Information should be made available to the individual and the health management system, for which computerised data are critical. A nationwide database with unique identification details already exists, a valuable resource to identify those who need not be vaccinated.

Identifying past asymptomatic infections requires systematic screening for IgG antibody. Antibody positives need not be vaccinated (no harm if vaccinated). All data should be saved permanently. Area-wise estimates of the numbers who need vaccination on a priority basis are necessary. Now is the time for State governments to capture all such data.

A community's need for vaccination is two-fold. All those who must rebuild essential activities, i.e. economic, educational, trade, transport, sociocultural and religious, must be protected. A more ambitious aim is to break the novel coronavirus transmission and eradicate the disease altogether. With India's notable representation in decision-making bodies of the World Health Organization, India is uniquely positioned to play a crucial role in advocating global eradication of COVID-19.

Without proper data Russian COVID-19 vaccine's efficacy, safety unknown: CCMB Chief

We need a vaccine-delivery platform to fulfil all such needs. A practical method is vaccination camps, supervised by a medical officer, staffed by health management and local government, and having the list of people who need vaccination. Information should be updated regularly, deleting those who got infected recently. Enumeration and registration of eligible persons can be started now. Vaccination by appointments will ensure that vaccination is without overcrowding and with minimum waiting time. Post-injection, vaccinated subjects should wait for half-an-hour in case of immediate side effects; emergency drugs to tackle side effects should be readily available.

Vaccine trials document the absence of serious side effects. Minor and inconsequential reactions are self-limiting fever, pain and swelling at the injection site. As it would be a new vaccine, all side effects must be documented for first and second doses; medical events during the month following each dose must be captured through phone calls, and analysed to check full safety of the vaccine.

Coronavirus | Imported vaccines may be fast-tracked

Phase 3 trial is usually in healthy volunteers, hence efficacy and safety profile in others will not be available when a vaccine is rolled out. However, senior citizens and those with co-morbidities must be vaccinated by/on priority. Some countries require that a proportion of volunteers should be the elderly and the vulnerable. In India, careful documentation of all side effects in all individuals, senior citizens, those with co-morbidities, and children must supplement trial data on vaccine safety. This 'post-marketing surveillance' must be built into the vaccine roll-out.

The vaccine regulatory agency should take a call on the special question of vaccine safety during pregnancy. One vaccine is an inactivated virus and the second is a live virus but non-infectious. Both may be assumed to be safe; yet safety in pregnancy must be ascertained in bridge studies that must be conducted as soon as possible.

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