Clear the fog, draw up a clear vaccination policy.

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India's COVID-19 control plan of actions can be the nucleus for building a much-needed public health infrastructure

Vaccines play a major role in human mastery over infectious diseases. Vaccine can induce immunity only in the vaccinated individual. So, vaccination is 'preventive medicine'. When a vaccine is rolled out as a national or global programme and increasing proportions of people are vaccinated, 'herd immunity' level increases and disease frequency decreases in the vaccinated population. That decelerates transmission of the microbe in the whole community, resulting in decreasing disease frequency even in the unvaccinated segment of population — a phenomenon called the 'herd effect' of vaccination.

DISEASE BURDEN AND CONTROL

Herd immunity plus herd effect reduce the overall disease burden in the community; in other words, the disease is controlled. In epidemiology, the common word control has a specific meaning: 'deliberate reduction of disease frequency to a desired level, validated with evidence'. For evidence, disease frequencies must be documented both at baseline and on an ongoing basis, through systematic surveillance. So, control interventions include a vaccination programme and disease surveillance.

The extreme form of control is 'elimination' of transmission of the microbe in a whole country. For example, measles and rubella have been eliminated in Sri Lanka through sustained vaccination achieving high coverage. Eradication is global elimination of an infectious disease.

In summary, the hierarchy of human mastery over infectious microbes using vaccines ranges from individual protection and community control, to elimination and eradication.

So far, smallpox and cattle plague have been eradicated using their respective vaccines. Severe Acute Respiratory Syndrome (SARS) was eradicated in 2003 without a vaccine, using 'non pharmacological interventions', or NPI, systematic case detection, contact tracing and quarantine. Success was possible because virus transmission occurred only after individuals developed fever. History of travel from affected countries and fever screening identified potentially infectious persons who were quarantined for breaking transmission chains. COVID19 novel coronavirus transmission occurs from infected persons before the onset of fever and from infected but totally a symptomatic individuals. So, we cannot stop transmission; but with NPI (face masks, hand hygiene and avoiding crowds), we can retard transmission.

VACCINE CANDIDATES AND INDIA

Three COVID19 vaccines have claims of about 90%-95% protective efficacy — BNT162b2 (Pfizer BioNTech), mRNA1273(Moderna) and Sputnik-V (Gamaleya Institute). Hopefully they will soon get registration for general use in their respective countries of origin. Sputnik-V is under phase 2phase 3 vaccine trials in India, by Dr. Reddy's Laboratories. Another vaccine, ChAdOx1 nCoV19 (Oxford Astra Zeneca), manufactured under license by Serum Institute of India as Covishield, is undergoing phase 2- phase 3 trials in India. The likelihood of Sputnik-V getting registration in India is probably high, possibly before end 2020. An indigenous vaccine candidate, Covaxin (Bharat Biotech), found safe and immunogenic in phase 1 and phase 2 trials, is now under phase 3 trial. If found safe and effective, it will, hopefully, get registration in the first or second quarter of 2021.

Should vaccination be used in India as preventive medicine for individual protection, community control or elimination? This is India's call — what is in the best interests of the country? In India's national Universal Immunization Programme (UIP), policy is defined, vaccines procured and supplied by the Union government and vaccination implemented by State governments. So, policy development is the function of the central government — States must implement the action plan emerging from policy. States have the freedom to surpass policy limits if no fund is sought. There are precedents: Delhi used the Measles Mumps Rubella vaccine when the central government policy was only for Measles vaccine and Sikkim unilaterally used human papillomavirus vaccine to prevent cervical cancer in women.

MIXED SIGNALS

A comprehensive vaccination policy is yet to emerge as evidenced by the divergent views expressed by different dignitaries. On October 22, Union Finance Minister announced NDA's Bihar election manifesto: "The NDA government in Bihar has set an example before the country in the fight against corona. It is our resolve that once the vaccine…has been cleared by the ICMR [Indian Council of Medical Research], we will make it available to the people of Bihar free of cost." Note the faux pas — the Drugs Controller General of India is the clearing agency, not the ICMR.

On November 3, the Union Health Secretary said in a press conference: "Union Health Ministry has asked State governments to refrain from making isolated plans for vaccine distribution. The Union government has set up an expert citizens are protected from exposure to infection by cocooning within homes. How will they be reached at home? If COVID-19 control is the policy objective, there will be additional questions. Experts must determine the age groups to be covered for disease control. Where will vaccination be conducted? If at fixed stations, will they be at healthcare clinics or elsewhere? Will vaccination be with or without user fee? In case of any adverse reaction, how and where will that be diagnosed and treated? India does not practise public health surveillance. How then can India monitor the control trajectory of COVID-19 over time? The COVID19 control plan of actions can be the nucleus for building a much needed public health infrastructure in India. The vaccination stations should be staffed with trained personnel and supervised by medical doctors.

The site must have a waiting area and a post vaccination staying area to manage any untoward reaction during the first hour. A computerised master list with details and mobile numbers of all vaccinated subjects needs to be maintained for the purpose of post vaccination follow up to document rare side effects. Data management has to be meticulously planned and executed. The central and State governments in general and Health Departments in particular have a mammoth task ahead of them. It is a big challenge to protect the life and the health of citizens, and also a huge opportunity to eliminate the novel corona virus from India, setting an example to the rest of the world. With will and wisdom we can, and should, accomplish this. T. Jacob John is former Professor and HOD, Clinical Virology Department, CMC Hospital, Vellore, and former President, Indian Academy of Pediatrics. M.S. Seshadri is former Professor and HOD, Clinical Endocrinology Department, CMC Hospital, Vellore, and is currently Medical Director, Thirumalai Mission Hospital, Ranipet, Tamil Nadu ert committee on vaccine administration. States were asked to set up committees under Chief Secretaries of each State to ensure time bound implementation of the Union government's direction". On November 19, the Puducherry Chief Minister announced that COVID19 vaccination will be provided free under the State Budget.

On November 20, the Union Health Minister identified the priority sequence for vaccination: healthcare workers and 'corona warriors'; citizens above 65 years; those between 50 and 65; those below 50 who have co-morbidities; and finally general public; workers in essential services are missed out. This represents a preventive medicine approach. Obviously, the government has not considered a public health goal of control or elimination.

UNANSWERED POLICY ISSUES

Fortunately, the three front running vaccines for India — Sputnik- V, Covishield, Covaxin — need only the standard cold chain available to the UIP, except that any new vaccine will require significant additional cold chain space. All vaccines in the UIP are available in the private sector too. Under the UIP, vaccines attract no user fee, but the private sector bills the beneficiary. Will this style be maintained for COVID19 vaccines also? Will insurance companies reimburse the recipients of a vaccine in the private sector?

An important policy issue is whether vaccination should be confined to only uninfected individuals. Or should it be for all people? In the first case, how should uninfected individuals be identified? All test results of infected subjects are available on a computer data base and that is one way to identify those who were already infected. For others, should COVID19 antibody or T cell immunity be tested for reserving vaccination for non immune persons?

What will be the policy for vaccinating children? Will not vaccinating teachers and students make school reopening safe? Many senior citizens are protected from exposure to infection by cocooning within homes. How will they be reached at home?

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