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A COVID-19 Vaccine Deployment Strategy for India

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Abstract

Deploying COVID-19 vaccines once they are available is going to be an unprecedented administrative and logistical challenge. This paper proposes a plan to vaccinate 80% of India's population by December 2021. We envision this process to be divided into four main stages viz., estimating the need, securing vaccine supply, distributing the vaccines, and post-market surveillance. Broadly, we suggest that essential workers be prioritised for vaccination in the first phase followed by everyone else. We recommend that the government issue a model contract to build manufacturer trust and incentivise ramping up manufacturing capacity. Vaccines can be priced as per market rates with the government subsidising the cost to necessary recipients to ensure equitable access. Along with public private partnerships and open markets, the government must leverage administrative capacities of Election Commission of India to roll out a nationwide vaccination drive for maximising vaccine coverage. Finally, we recommend post-market vaccine surveillance strategies to obtain data on adverse events and tweak vaccine deployments, when necessary.

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Introduction

Vaccination is only rivalled by clean water in reducing the infectious disease burden (Plotkin an Plotkin 2018, 1-15). For COVID-19, there seems to be no feasible alternative to a vaccine for mitigating the economic and social impact. The disease has afflicted over 6 million and taken over 102,000 lives in India as of October 5, 2020 (Worldometer, 2020). A slew of lockdowns and social distancing measures imposed by union and state governments have been ineffective in stemming the spread of the disease. With no known treatment option, a massive vaccination drive to confer herd immunity is a promising path to return to normalcy.

The alternative to mass vaccination is to build herd immunity via natural spread of the disease. However, to achieve herd immunity, about 70% of India's population would have to be infected by COVID-19 (WHO, 2020). With a presumed mortality rate of 1.5%, the death toll to reach herd immunity would be about an unacceptably high loss of 15 million lives (Mint, 2020). Early planning for a smooth rollout of vaccination is therefore essential.

Across the world, over 180 COVID-19 vaccine candidates are currently in various phases of clinical trials (Krammer 2020, 1-12). The urgency of the situation has accelerated vaccine research and shortened the development process from over a decade to a matter of few months (Hanney et al, 2020, 61). A number of vaccines are expected to be approved for commercial use in the coming months.

In preparation, several countries are currently finalising and communicating their vaccine deployment plans. The European Commission has released a strategy that centres around advance purchase agreements to secure supply (European Commission, 2020). Australia's vaccine strategy banks on multilateral and bilateral collaborations to boost indigenous manufacturing capacities (Department of Health, Australian Government, 2020). United States has been funding development of various vaccine candidates under Operation Warp Speed and has released plans of rapidly deploying the vaccine with the logistical support of Department of Defense and guidance of the CDC (US Department of Health and Human Services, 2020).

Procuring adequate vaccine quantities and safely deploying the vaccine to India's population of over 1.3 billion people is an unprecedented administrative and logistical challenge. On the demand-side, assuming that vaccinating 80 per cent of India's population will achieve herd immunity, a billion people need to be vaccinated. Most of the current vaccine candidates require two doses per individual adding layer of complexity, the need to track the interval between two doses and communicate it to the recipients (Bonifield 2020). For reference, India's current Universal Immunisation Programme (UIP) caters to nearly 27 million infants and 30 million pregnant women annually free of cost (World Health Organisation, 2013). Thus, the COVID-19 vaccine needs to reach one billion people — nearly 16 times the annual recipients under UIP. Even India's well-oiled and successful UIP machinery, in its current state, will be inadequate to carry out the COVID-19 vaccination exercise within a short time period. Innovative administrative mechanisms are needed to ensure timely and efficient delivery of the vaccine.

On the supply-side, it is unlikely that the two billion doses India needs will be available immediately upon approval of (a single or even a combination) of vaccine(s). Thus, vaccine distribution will have to be phased to match the available supply.

Additionally, vaccine deployment will need to account for several challenges such as transport and storage capacities, need for trained people to take recipient consent, a way to monitor who has received the vaccine, which vaccine has been administered, and track adverse reactions, if any.

Hence, an all-India rollout needs advanced planning to ensure infrastructure is set up, capacities are built, and recipients are prepared, even as we await approval of the vaccine after clinical trials.

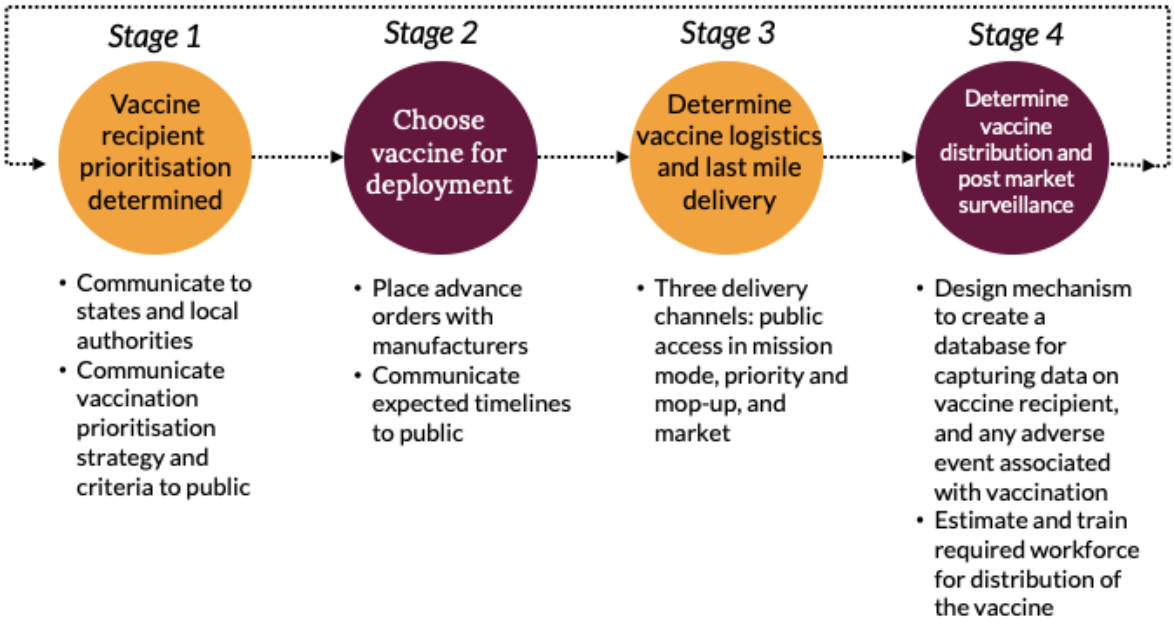
Our Proposal

Given the scale and the stakes involved, India needs to take some decisive steps now to ensure its people are vaccinated in a timely manner. We recommend that India should vaccinate eighty percent of its population by December 2021, at an estimated cost of ₹50,000 crores - ₹2,50,000 crores.

Hitting the ambitious target of eighty percent within the short time can ensure that herd immunity is achieved through the vaccination exercise, with far lower mortality than otherwise. Much is still unknown about the duration of the vaccine conferred immunity. Herd immunity works only when a large subset of the population is concurrently immune to the disease. As an example, if the vaccine-conferred immunity lasts one year but vaccine distribution takes three years, the objective of achieving herd immunity cannot be met. Therefore, it is critical that vaccination be implemented in as short a time frame as possible.

We split the design of vaccination exercise into a four-stage process: estimating vaccine demand, securing supply, choosing delivery channels and conducting post-market surveillance (Figure 1). The following sections of the paper detail each of these steps.

Figure 1: A 4-stage strategy for deploying COVID-19 vaccine in India



For each stage, we provide frameworks for decision making. As more information about the vaccines cleared by clinical trials surfaces, these steps might undergo changes. In any case, we envision the eventual deployment to be a continuous process, accounting for real-time information and finetuning the strategy in response.

Stage 1: Estimate Need

Assuming a two-dose regimen, we estimate that India would need two billion doses to vaccinate 80% of its population. Currently, India does not have domestic capacity to manufacture such a large requirement. Further, manufacture of COVID-19 vaccine cannot come at the expense of already existing vaccines, due to the public health impact of disruption in supply of such vaccines. Additionally, as a major contributor to global vaccine supply, Indian vaccine manufacturers have global COVID-19 vaccine commitments to balance along with domestic vaccine demand. These factors combined will put a heavy burden on India's vaccine manufacturers.

In the face of a supply crunch, we recommend that India prioritise vaccine recipients in the initial stages to ensure that critical sub-populations are covered first. However, prioritisation strategy cannot be a substitute for poor capacity. It is a temporary arrangement till increased production capacity meets vaccine demand. As more vaccine candidates get regulatory approvals, the supply-demand gap will shrink. Once critical sub-populations are vaccinated, we recommend no further prioritisation. In our view, randomisation is the best way to achieve an equitable distribution of the vaccine.

Identifying critical sub-populations

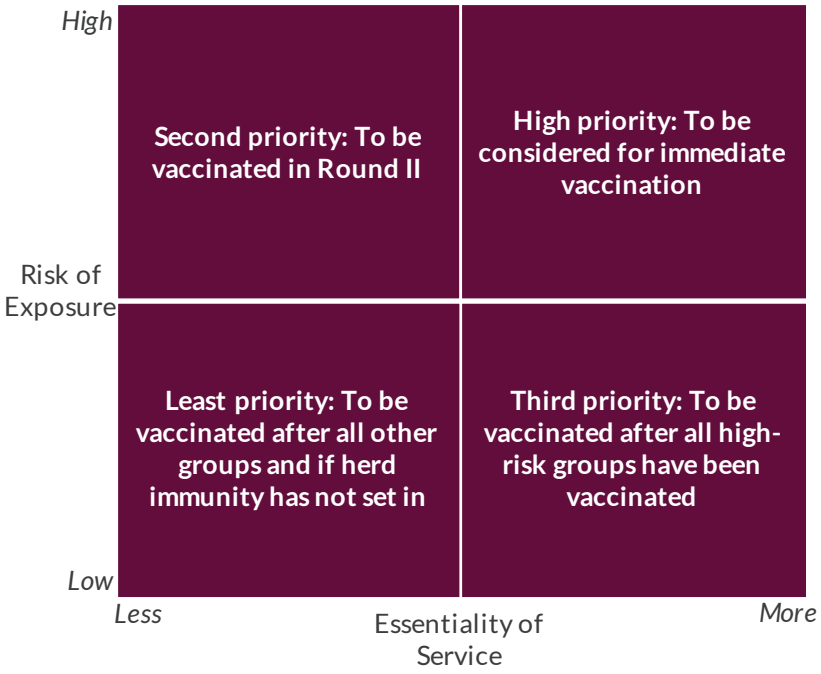
The limited supply raises concerns on how vaccines can be allocated in an equitable manner. A decision on prioritisation can be guided by principles of respect, equity and reciprocity (World Health Organisation, 2020). *Respect* involves recognising all individuals as having equal status and that individuals not be denied vaccine for any reason, e.g., due to lack of monetary capacity or documentation. The principle of *equity* suggests that vaccine distribution be based on disease risk, and those with highest risk should receive it first. The principle of *reciprocity* dictates that those groups whose occupations expose them to significant risks but are necessary for the benefit of society receive the vaccine first.

Prioritisation can be done through two broad approaches: essential-first and demography-first. We believe that an essential-first approach is well-suited for India. This section first describes both approaches, compares them, and reasons out the need for an essential-first approach.

1. Essential-first Approach

The essential-first approach categorises individuals based on the essentiality of their occupation in the functioning of the society and the risk of exposure to COVID-19. Based on this approach, individuals engaged in occupations of utmost importance to society and who have a high degree of exposure to COVID-19 as a result of their occupation are accorded highest priority for vaccination (top right quadrant in Figure 2).

Figure 2: Essential-first prioritisation strategy



This will include those who are at the forefront of managing the pandemic (healthcare workers, sanitation workers, etc.) and those who work to ensure business continuity of routine services (utility workers, logistics workers, police, etc.) These workers have been the backbone of India's response to COVID-19 and will be responsible for sustained running of services essential to the economy and society through the pandemic. This group consists of an estimated 30-50 million people[1].

This group will be followed by those services which are not essential for society but provide high risk of exposure to COVID-19 (top-left quadrant). This could include barbers, mall workers, etc.

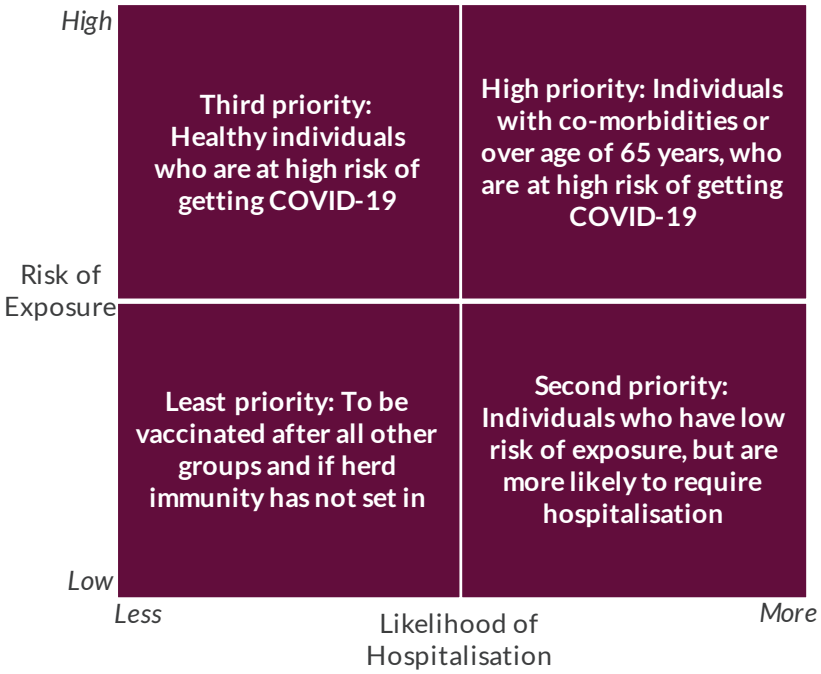
After these groups, workers in other services sectors can be vaccinated through a mass government programme which will take the vaccine to the people regardless of their ability to pay, occupation or location.

This approach minimises COVID-19 infection risk for service professionals and maintain business continuity of services essential to the economy and society.

2. Demography-first approach

This strategy categorises individuals based on their risk of exposure to COVID-19 and the probability of requiring hospitalisation. This approach prioritises individuals over 65 years or with co-morbidities to get the vaccine first, followed by randomisation (Figure 3). Data shows that this demography is particularly vulnerable (higher proportion of severe symptoms and higher mortality) and therefore, this approach is likely to reduce mortality rate in the near-term. Use of this approach is subject to availability of vaccine(s) that have been approved for use in this age group.

Figure 3: Demography-first prioritisation strategy



Comparing the two strategies

Both the prioritisation strategies have their merits and disadvantages (summarised in Table 1). The essential-first strategy enables the management of the pandemic and continuity of essential societal functions. However, it leaves at risk individuals that are most susceptible to severe disease.

Table 1: Comparison for the two prioritisation strategies

Strategy	Advantages	Disadvantages
Essential-First	Easy to identify individuals through existing occupational IDs Keep essential economic and health functions running Smaller population target group to begin vaccine roll out with	Unlikely to cause immediate reduction in mortality rates Those over 65 years of age may not be covered Those in the unorganised sector might be difficult to cover
Demography-First	Reduction in mortality rate Likely reduction in hospitalisation rate	Huge population to target in first phase Uncertainty of whether the vaccine will work in target population

The demography-first strategy is aimed at reducing mortality rate. However, there are two issues with this approach. First, the immune system weakens with age and hence, vaccination programs historically include individuals in a younger age group where the effectiveness of the vaccine has been satisfactorily demonstrated. Second, prioritising based on demography would require the vaccination of a 120-200 million people in the first phase[2]. Moreover, mortality rate in the highest-priority population in the demography-first strategy can be addressed by other means, including extra public awareness campaigns

for such individuals to follow masks, social distancing, recommended/ mandatory isolation, and so on. Further, as a large proportion of individuals in this group are unlikely to be in professions that require frequent interaction with others, their risk of catching the disease, which is already lower, can be further reduced by such means.

Out of the two approaches, the essential-first strategy is most aligned with the three principles of respect, equity and reciprocity. Frontline workers, whose jobs are essential for society's daily functions but expose them to COVID-19 should be the first recipients of the vaccine. Therefore, we recommend using the essential-first strategy for prioritising vaccine recipients to identify individuals for immediate vaccination.

Stage 2: Secure Supply

There are three different locally developed vaccines under clinical trials in India – COVAXIN (Bharat Biotech- ICMR), CoviShield (Serum Institute- ICMR) and ZyCov-D(Zydus Cadilla (ICMR 2020). However, other vaccines such as those from Oxford University and Moderna Inc. are in advanced stages of trials in other countries and may be approved for commercial use sooner. Therefore, it is imperative that the Indian government and companies strike licensing partnerships with such firms to manufacture the vaccine for use in India.

India currently produces nearly 120 million doses of vaccines per month (Business Today 2020, Panacea Biote 2020, Newsbytes 2020, Mint 2020). This capacity is being used for manufacturing a variety of vaccines targeting different diseases for domestic use as well global supply. This capacity cannot be entirely converted to producing COVID-19 vaccines, as the drop in availability of other vaccines would eventually result in increased burden of those diseases. A vaccine for COVID-19 cannot come at the expense of another disease outbreak in the future. Hence an increase in vaccine manufacturing capacity is imperative to meet the vaccine demand.

Securing vaccine supply would include regulatory approval of vaccines for use in India, tying up with vaccine research institutions and increasing manufacturing capacities to align with demand requirements.

Choosing a Vaccine

The first step would be to choose one (or more) vaccines for use in India. The choice can be based on several criteria:

One, the cost. Current reports suggest that the Moderna vaccine (Mason 2020) may cost about INR 1,125 per dose, while the Oxford vaccine may be available at a cheaper cost of INR 225. A possible trade-off to make is to wait longer for a cheaper vaccine, but the social and economic costs of waiting may be too high.

Two, reliability of clinical trial data. If clinical trial data from India is not available, it will be important to assess the quality control mechanisms used in creating the clinical trial data. India should accelerate domestic regulatory approvals for vaccine candidates that have reliable data and have received such approvals in other parts of the world.

Three, dosage requirement. Single dose vaccines are preferable and would make tracking of vaccine recipients easier.

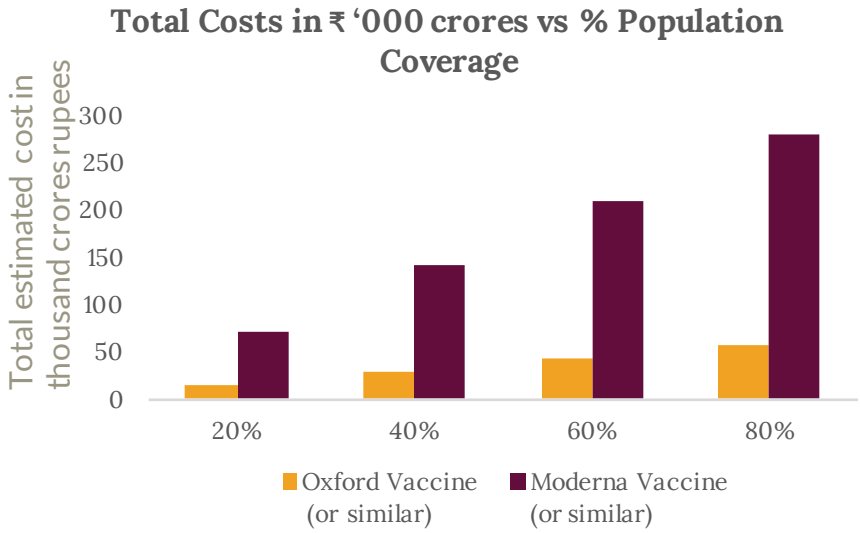
Four, supply chain requirements. For example, nucleic acid-based vaccines would require cold chains of extremely low temperatures and deploying them across the country would not be feasible.

Finally, delivery method – injectable or nasal. Delivering injectable vaccines would require development of a trained workforce.

Estimating Supply Costs

We expect the cost of the vaccine to immunise 80% of India's population would be between ₹50,000 crores (assuming Oxford or similar vaccine) to ₹2,50,000 crores (assuming Moderna or similar vaccine), depending on the vaccine chosen[3].

Figure 4: Estimated costs for vaccine deployment



Making it easy for vaccine manufacturers to access technology and ramp up capacity

India needs to invest rapidly in creating additional manufacturing capacity to cater to domestic and global demand for COVID-19 vaccine. We suggest the following actions to incentivise a rapid ramp-up of manufacturing capacity:

One, strike vaccine technology agreements and attract foreign vaccine companies. As of now, a limited set of private players have entered into manufacturing and/or distribution agreements with firms that are engaged in COVID-19 vaccine clinical trials. These include Serum Institute of India (partnering with AstraZeneca) and Dr Reddy's Laboratories (for Russia's Sputnik V vaccine). We recommend more such private party agreements as well as agreement directly between the Government of India and R&D firms developing vaccine candidates. This can help increase the volume as well as variety of COVID-19 vaccines being produced in India and the likelihood that a viable vaccine is available at the earliest. Additionally, the Government of India can also incentivise foreign companies to set up manufacturing facilities locally. India certainly has the expertise to set up low-cost, high-quality manufacturing facilities and we can leverage this capability to attract foreign companies.

Two, incentivise Indian vaccine research. Vaccine research is an expensive and risky endeavour. Vaccines developed within India, using viral strains found in India and trialled on Indian population are likely to be better suited for our need. Hence, India should set up measures to incentivise indigenous vaccine research. These measures could include investing in building more Biosafety Level 2/3 facilities, facilitating partnerships between research institutions/start-ups, clinical trial units, and vaccine manufacturers.

Three, facilitate vaccine manufacturing. Setting up vaccine manufacturing unit is also a cost-intensive and heavily regulated activity. We recommend that the government speed up regulatory processes for new manufacturing set ups and aid in procurement of imported machinery and raw materials. To offset the cost burden on the manufacturer, the government should defer utility payments and clear tax refunds and reimbursements immediately. Further, the government should refrain from price caps on COVID-19 vaccines to attract investment in the vaccine manufacturing business.

We recommend the Government of India release a transparent, model contract for vaccine procurement at the earliest opportunity to build manufacturer and public trust. The model contract should include guarantee of certain market access (e.g., minimum revenue or order size) to the manufacturer. It should also put in place mechanisms for dispute resolution, such as compulsory arbitration and address access rights to vaccine outcome data. The model contract should set terms for manufacturing partnerships with Indian vaccine manufacturers and for technology transfer (e.g., limited term IP license of the vaccine for India, to expire at end of pandemic; terms for follow-on IP) We envisage these to be tripartite contracts that involve domestic or R&D firms , with the Government of India playing the role of either buyer or guarantor on behalf of the Indian manufacturer. A transparent contract with advanced purchase guarantee will de-risk Indian manufacturers forging license partnerships with vaccine research institutions.

Pricing the Vaccine

There are various ways for the government to intervene in the vaccine pricing. One way is to do nothing and let market forces determine the price. The advantage of this approach is that more vaccines would be incentivised to be brought into the market leading to competitive pricing. Households would bear the entire cost of the vaccine, which would lead to inequitable distribution and exclusion. Without any government intervention, it would be difficult to achieve herd immunity at practical prices.

Another way is for government to bear all costs of the vaccine, effectively making it zero price for Indian residents. Vaccination is a public good and therefore, it would seem appropriate that the government pays for it. However, this approach can distort the market and increase chances of pilferage and corruption. Moreover, there is a significant opportunity cost for the money the government will spend on vaccinating everyone, including those who can afford the vaccine.

Therefore, we recommend the approach of allowing market price for the vaccine plus a direct benefit transfer for those who are unable to afford the vaccine. This approach will lower the immediate cost of roll out, target subsidy to the needy and well-off households pay fair share. This will lower the burden on government funding while ensuring those who cannot afford the vaccine, can get access to it.

Stage 3: Distributing the Vaccine

This stage involves distributing the secured vaccine supplies (as discussed in *Stage 2*) to the recipients (as designed in *Stage 1*). Distribution at India's scale is a non-trivial planning and management challenge. Solving it requires the ability to quickly mobilise a nation-wide decentralised administrative machinery in a phased manner.

Given the scale, several countries are exploring innovative solutions to tackle this challenge. A UK newspaper claims that the armed forces could be rallied in to distribute the vaccine (Birmingham Live 2020). A US think-tank has proposed that governments should establish nearly 7,300 community

vaccination clinics and recruit medical experts, celebrities, and community leaders for a vaccination campaign (Spiro 2020).

Learning from these solutions, there are five important considerations that are relevant for the Indian context.

One, multiplicity of incoming vaccines. It is likely that there will be multiple vaccine candidates that might receive final approvals from the regulatory agencies for distribution. These vaccines will differ in terms of effectiveness, production costs, and logistics requirements. These differences mean that it might not be possible for a government-run distribution channel to procure and distribute all approved vaccines. Distribution of vaccines that are approved but not procured by the government can be permitted to be distributed by private players to meet the overall vaccination target of 80% population by 2021.

Two, scarcity of available doses in the initial stages. The number of doses available initially is likely to be far less than the 80% population target. Postponing distribution until the nearly 2 billion doses are secured will be counterproductive. The utility of the vaccine will diminish over time. Thus, the distribution process needs to happen in several phases instead of a one-time mega campaign.

Three, equity. The recipients should not be denied access to a vaccine due to their inability to pay for it or their place of residence. This calls for a government-run distribution channel that brings vaccines close to where people are.

Four, positive externalities. Vaccination benefits even those who are not vaccinated. Hence, it is important to vaccinate as many people as possible as early as possible. This calls for a mission-mode nation-wide distribution channel.

Five, multiple dosage. Most vaccines will require administration of multiple doses after a specific time interval. This means that the distribution channels will require activation at least twice or thrice after a specified time interval.

Based on these considerations, we propose that distributing vaccines in India be done using three distribution channels, each addressing a specific need.

Channel 1: Public Access in Mission Mode

This is a government-owned, government-run distribution channel deployed in bursts in different geographies to cover a large section of India's population in a short period of time. The vaccine chosen to be distributed through this channel is likely to be cost effective, easy to transport and administer. After placing a large order, the government will need to plan and execute deployment as vaccine doses are delivered.

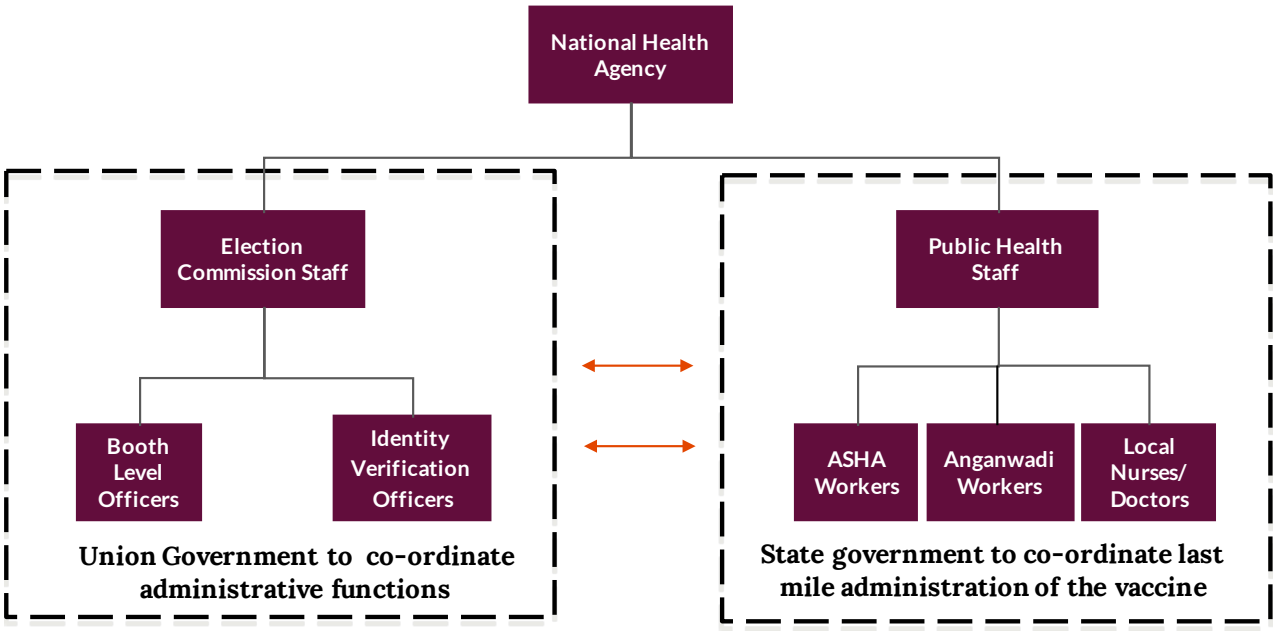
This channel demands extensive planning, logistics, and human power. Given the time and capacity constraints, we believe it is better to utilise an existing government mechanism instead of relying on building an entirely new one. With the UIP used to administering only one-sixteenth of the population per year, we explored solutions outside state health departments.

India routinely carries out one task of the same scale and similar complexity fairly regularly — the general election(Pai 2020). We propose that this channel run like a general election utilising the Election Commission of India's (ECI) tried and tested administrative setup to reach all corners of India in a mission-mode programme.

To manage the planning and execution under this channel, we propose an organisation structure (Figure 5) that draws upon the administrative expertise of the ECI, combined with the public health delivery expertise of state public health departments. This structure would be co-ordinated by the

National Health Agency (NHA), housed within the Ministry of Health and Family Welfare, Government of India.

Figure 5: Organisation structure to oversee and deliver COVID-19 vaccine



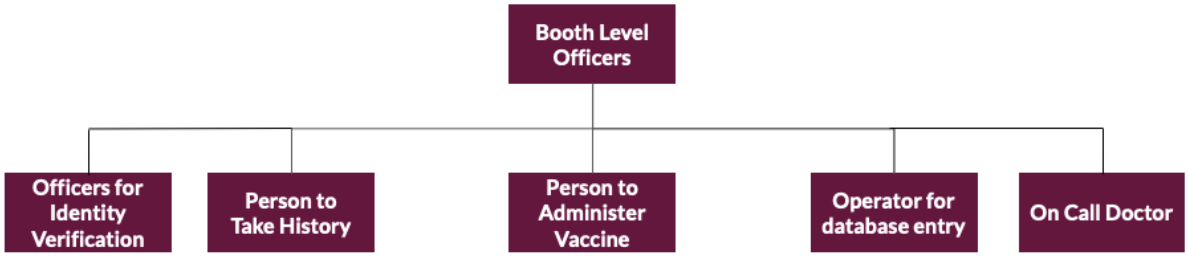
The use of ECI for overseeing administrative functions of a vaccine campaign will likely require legal action to amend the scope of the ECI beyond its current mandate. We recommend urgent examination of the legal pathways for such repurposing, including for example, promulgating an ordinance that enables ECI to be repurposed for vaccination and subsequent passing of a law as per parliamentary procedure.

The ECI conducted the last general election in 2019 over seven phases, covering constituencies across states in every phase. Similarly, depending on the available supply of vaccine doses and the administrative capacity required, the ECI can plan to cover all districts of India in multiple phases.

Staffing a Vaccination Booth

We recommend setting up vaccination booths within each target geography with a well-documented set of procedures and appropriate personnel. Within each vaccination booth', we envision that at least six officers be stationed as shown in the figure below.

Figure 6: Staffing vaccine booths



Minimum Personnel Requirement at Vaccination Booths

In our view, the process of vaccination should include identity verification of each individual, vaccinating the individual, and generating a proof of vaccination (one for each dose) for the individual.

Identity verification and generating the proof can be carried out by, an ECI appointed officer (ECI routinely does this during elections) will be responsible for verifying the identity of each vaccine recipient and marking their fingernail with election ink (thus generating the proof) once the individual has been vaccinated.

Vaccine delivery will be done by trained personnel appointed by state health departments. Vaccine providers should be adequately trained to ensure they can discuss any issues with recipients and take informed consent. We recommend the booth staff involved in the consent process receive Good Clinical Practice Training.

Successful deployment of the vaccine will depend on gaining informed consent of the vaccine recipients. This will involve educating the intended recipients of the risks and benefits of taking the vaccine, as well as risks and benefits of having their data entered in a database.

Additionally, the booth also needs an on-call doctor, in case of medical emergencies. Outside the booth, security personnel would be required to ensure smooth functioning.

The process flow for every recipient will be as follows: obtaining recipient consent (including verifying eligibility, in case there are negative indicators for a vaccine), the actual vaccination protocol, and safe disposal of used injections and/or other biohazardous material.

We recommend pilot studies to validate the protocol above (and tweak as necessary), and a training for the staff for each booth. We anticipate that trained staff at a booth can implement this protocol at the rate of 15-20 minutes per recipient. In running the booths, social distancing measures would be enforced.

Channel 2: Priority and Mop-up

This channel is imagined as a hub-spoke distribution model where the government procures the vaccines and distribution is done by a variety of private and public agencies such as private hospitals, primary health centres, and the armed forces medical corps. The government can contract out distribution district-wise to these agencies. The terms of the contract can include the coverage goals, standard specifications, and cost reimbursement conditions.

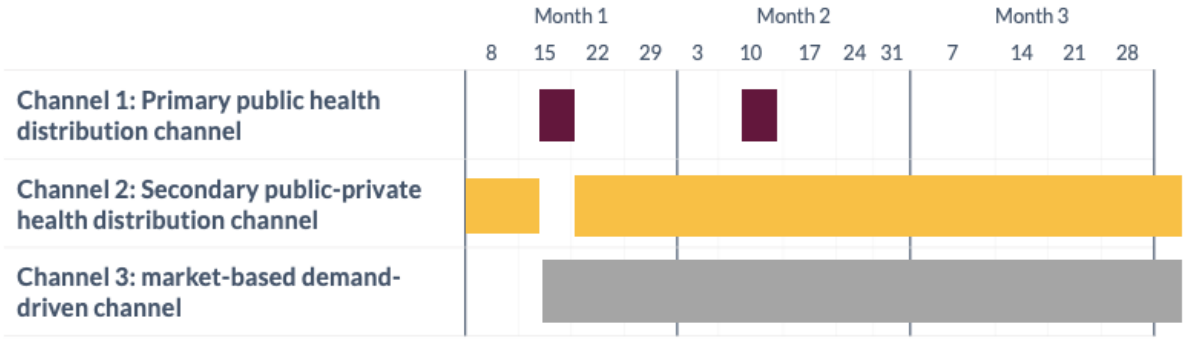
This channel can be deployed for two purposes. One, it can be used to administer vaccines only to the prioritised group identified through the *essential-first* framework as described in *Stage 1* once the initial supply of vaccines is secured. Two, it can be deployed district-wise to cover the population that may be left uncovered under Channel 1 after the booth in a district has been dismantled.

Channel 3: A market-based demand-driven distribution channel

The third channel is a demand-driven channel run by private hospitals, pharmacies and medical practitioners. This channel is useful for supplementing Channels 1 and 2. As the secured supply increases, the government can allow people the choice to get vaccinated at private medical centres. This is similar to vaccinating children at private clinics and hospitals outside the government-run UIP.

The Gantt chart below illustrates how these three channels will operate in tandem.

Figure 7: A representative timeline showing vaccine delivery options in a district



As soon as vaccine supplies are secured for all high priority groups, distribution to the essential-first group should be carried out using *Channel 2*. Once additional vaccine doses become available, *Channel 1* is pressed into action to run a vaccination campaign that covers many residents of a district in a short time period. If a second dose is needed, this channel can be reactivated for another short burst. *Channel 3* can be allowed to function as soon as the essential-first group has been vaccinated. Once *Channel 1* completes its initial campaign, *Channel 2* can cover those missed by *Channel 1.*

Stage 4: Post-market surveillance

The vaccine roll-out will need to be monitored to ensure correct number of doses are given to each individual, detect any adverse events and assess efficiency of the vaccine. If the vaccine recipient status of an individual is not tracked, it is possible that individuals are inadvertently administered excess doses. The health risks of taking higher than recommended (and clinically trialled) dose of the vaccine are unknown. If the vaccine is found to ineffective or faulty after it has been administered, a need can arise to reach the correct vaccine recipients and take corrective action. Aggregated, anonymised data based can also contribute to determining vaccine performance for each type of vaccine. This necessitates the formation of a database to document vaccine recipients, vaccine dose and adverse events.

We propose this database be housed in the NHA and be used for the specific purpose of post-market surveillance for this particular vaccine. The database can be seeded to use Aadhaar or any other national identifier as an enabler to establish individual identity but is isolated and independent of other databases. Aadhaar may be the preferred identifier because of its penetration. However, the use of Aadhaar must meet the three-point test of necessity, legality, and proportionality.

We envisage that the database would store data, for each individual, that includes vaccine dose received (name of vaccine and lot number), date of vaccination, recipient id, any co-morbid conditions and information regarding any adverse events that occur.

The database implementation should be in compliance with "privacy by design" principles and with a built-in purpose limitation that limits the use of the database to reach pre-defined objectives of assessing vaccine efficiency and adverse events. We suggest that the database establish mechanisms of anonymisation using Aadhaar's tokenisation method. Finally, the database should have a defined sunset period with guaranteed data destruction at the earliest one of the following end points: end of the public health emergency in India, end of post-market surveillance as warranted by the vaccine or five years from start date.

Public engagement beginning immediately would be a key determinant for educating the Indian public. We recommend that the chosen vaccine deployment strategy, including timelines for deployment and prioritisation criteria be communicated beforehand. The benefits and possible risks of the vaccine should also be communicated through mass media and published at vaccination booths. Simplified vaccine trial data along with the regulatory approvals the vaccine has received should also be published.

Determining a vaccine deployment strategy will not be a linear process. With uncertainties in many aspects such as vaccine availability, vaccine types, cooperation by the population, etc., we anticipate that one or more of the 4 stages as described would need tweaking. For example, a lower number of actual vaccinations may be acceptable for reaching herd immunity if the vaccine is delayed and a larger share of the population has experienced an infection prior to vaccination. Additionally, cold-chain considerations might restrict vaccination booth locations; manufacturing and logistical constraints may introduce delays; and so on. It is therefore anticipated and recommended that the framework described herein be tweaked during the rollout. As deployment progresses, data from vaccine performance, approval of new vaccines, changes in vaccine storage conditions, etc. should be used to alter the deployment strategy.

Conclusion

Rapid and wide scale deployment of a COVID-19 vaccine is a challenging task of unprecedented proportion. However, with a clear strategy and phased, decentralised delivery, it should be possible to vaccinate 80% of India's population by December 2021. This would require investment and urgent action from the Indian government, participation of the private sector and clear engagement with the public. India's capabilities of producing low-cost, reliable vaccines should be leveraged. Further, India should use its already set processes in overseeing the administrative functions, invest in training health workers, and set up a robust and transparent post-market surveillance capability for monitoring vaccine performance.

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Notes

[1] This is a rough estimate based on available figures for health workers (roughly 2 million - 1.2 million in urban areas and 0.8 million in rural areas including doctors, dentists and nurses. (Data from 2016 - https://www.who.int/hrh/resources/16058health_workforce_India.pdf), sanitation workers (5 million workers, data from 2018 - https://qz.com/india/1254258/sanitation-workers-a-five-million-people-large-blind-spot-in-india/), logistics workers (nearly 17 million in 2015; https://timesofindia.indiatimes.com/india/28-4-million-skilled-workforce-needed-in-Logistics-sector-by-2022/articleshow/47513316.cms), state police force (0.2 million, https://bprd.nic.in/WriteReadData/userfiles/file/202001301028101694907BPRDData2019-19forweb-2.pdf). We thus estimate there will be at least 30 million recipients in the high priority list and up to 50 million accounting for increase in number of people working in these jobs over the past few years.

[2] About 6% of India's population is estimated to be above 65 years of age. This accounts for 80 million individuals. Co-morbidities such as diabetes (estimated 77 million afflicted individuals) and hypertension (estimated 207 million afflicted individuals; https://www.nature.com/articles/s41371-018-0117-3). Given that diabetes and hypertension are also age-related, there is bound to be some overlap with elderly individuals and those with co-morbidities. Hence, we take the conservative estimate that if we want to target elderly and those with co-morbidities, we will have to target about 20% of the intended population.

[3] This cost has been calculated assuming India's population is 130 crores and every individual would require 2 doses of the vaccine. The price of the oxford vaccine is assumed to be INR 225 per dose and Moderna vaccines is priced at INR 1125 per dose. The costs include distribution costs, assumed to be ~20% of the price of the vaccine. However, these costs do not account for expenditure on building new vaccine manufacturing capacity. This is essential, since at our current production capacity manufacturing 2 billion doses will take 20 months and diversion of capacity from production of other vaccines.