A COVID-19 Vaccine Deployment Strategy for India

A strategy to vaccinate 80% of India’s population by December 2021

Takshashila Discussion SlideDoc
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India should vaccinate 80% of the population by 31st December 2021 at a cost of Rs 50K crore – 250K crore*

**Follow an Essential-First Approach for estimating need**
Prioritise vaccine recipients based on how essential the occupation is for managing the pandemic. This group is easy to identify, reach and vaccinate.

**National Manufacturing of the Vaccine**
Obtain vaccine in adequate quantities, with local manufacturing, through government action to ensure technology access and guaranteed demand.

**Delivery channel should not become the bottleneck**
Large-scale logistics and decentralised delivery necessitate a combination of Election Commission machinery and State government’s Public Health administration.

**Post-market Surveillance**
Use an Aadhaar-enabled, separate database to track vaccine recipients and adverse events.

* The cost range is based on options for the Oxford candidate (INR 50,000 cr) or the Moderna candidate (INR 2,50,000 cr)
Estimate Need
Considerations

Randomisation is the best way to achieve equity.

However, randomisation is not possible in the initial phases of vaccine deployment as the demand for COVID-19 vaccine is going to be significantly higher than the initial production capacity. The ultimate goal would be to vaccinate the proportion of people required to confer herd immunity. In the first few phases of vaccine deployment, production capacities will act as a bottleneck. Hence, there is a need to devise a prioritisation strategy, that will be perceived as fair.

Creating priority lists of vaccine recipients will also help in choosing a vaccine best suited for India’s demand, design a deployment strategy, and estimate costs of vaccine deployment. The next three slides present a prioritisation framework.
Strategy 1: Essential-First

<table>
<thead>
<tr>
<th>Risk of Exposure</th>
<th>Less</th>
<th>More</th>
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<tbody>
<tr>
<td>Low</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Second priority: To be vaccinated in Round II</td>
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<tr>
<td>High priority: To be considered for immediate vaccination</td>
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<td></td>
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<tr>
<td>Least priority: To be vaccinated after all other groups and if herd immunity has not set in</td>
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<tr>
<td>Third priority: To be vaccinated after all high-risk groups have been vaccinated</td>
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<td></td>
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<tr>
<td>High priority: To be considered for immediate vaccination</td>
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</tbody>
</table>

Takshashila recommends this strategy

This strategy categorises individuals based on **the essentiality of their occupation** and **the risk of that occupation exposing them to COVID-19**.

**Considerations:**
It will be easier to identify and target individuals using this approach.

**Expected Outcomes:**
Minimise COVID-19 infection risk for service professionals and maintain business continuity of services essential to the economy and society.
### Strategy 2: Demography-First

<table>
<thead>
<tr>
<th>Risk of Exposure</th>
<th>Likelihood of Hospitalisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Third priority: Healthy individuals who are at high risk of getting COVID-19</td>
</tr>
<tr>
<td></td>
<td>High priority: Individuals with co-morbidities or over age of 65 years, who are at high risk of getting COVID-19</td>
</tr>
<tr>
<td>Low</td>
<td>Least priority: To be vaccinated after all other groups and if herd immunity has not set in</td>
</tr>
<tr>
<td></td>
<td>Second priority: Individuals who have low risk of exposure, but are more likely to require hospitalisation</td>
</tr>
</tbody>
</table>

This strategy categorises individuals based on the probability of requiring hospitalisation and risk of exposure to COVID-19.

**Considerations:**
1. It is not yet clear if the vaccine would work effectively in those over 65 years or with co-morbidities
2. Identification of individuals for vaccination will be difficult, and thus complicate demand forecasting.
3. WHO determines the population over 65 years + co-morbidities is roughly 20%, which corresponds to 260 million people.

**Expected Outcomes:**
Reduce mortality rate and burden of COVID-19 on health services.
## Comparison of the two strategies

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essential-First</td>
<td>• Easy to identify individuals through existing occupational IDs</td>
<td>• Unlikely to cause immediate reduction in mortality rates</td>
</tr>
<tr>
<td></td>
<td>• Keep essential economic and health functions running</td>
<td>• Those over 65 years of age may not be covered</td>
</tr>
<tr>
<td></td>
<td>• Smaller population target group to begin vaccine roll out with</td>
<td>• Those in the unorganised sector might be difficult to cover</td>
</tr>
<tr>
<td>Demography-First</td>
<td>• Reduction in mortality rate</td>
<td>• Huge population to target in first phase</td>
</tr>
<tr>
<td></td>
<td>• Likely reduction in hospitalisation rate</td>
<td>• Uncertainty of whether the vaccine will work in target population</td>
</tr>
</tbody>
</table>
Using either of the above two strategies will still require vaccinating a minimum of 30-50 million people in the first phase.

It would not be recommended to delay vaccine roll out if required number of doses are unavailable.

Therefore, we would recommend a tiered funnel that can help prioritise people, based on the available vaccine doses.

For the second level of filtering, parameters such as population density of the area or age/co-morbidity status of the individual may be considered.
Secure Vaccine Supply
Considerations

Supply chain constraints
For example, nucleic acid based vaccines would require cold chains of extremely low temperatures.

Validity of Clinical trial data
If clinical trial data is not from India, it will be important to assess the quality control mechanisms used in the clinical trial.

Dose requirements – single or multiple doses
Single dose vaccines are preferable and would make tracking of vaccine recipients easier.

Vaccine delivery method – Injectable or oral
Delivering injectable vaccines would require development of a trained workforce.

Vaccine variants
We will likely have to deploy 2 or more vaccines depending on production, cost and effectiveness of the vaccine.

Once the demand for the initial phases of vaccine deployment are determined, the next step would be choose the vaccine best suited for Indian demand.

Apart from cost of the vaccine, we envision the following criteria to be important in the decision to choose a vaccine.
**Cost of Vaccine Deployment**

Takshashila recommends that 80% of India’s population be vaccinated

Oxford (or a similar vaccine) will cost ₹50,000cr. Moderna (or similar vaccine) will cost ₹250,000 cr.

Following assumptions have been made for calculating the cost:
1. 2 doses per individual
2. India’s population is 130 crores
3. Oxford vaccine price = $3/dose and Moderna vaccine price = $15/dose
4. $1 = Rs. 75
5. Distribution cost ~ 20% of vaccine price
6. This cost estimate does not account for costs required to ramp up vaccine manufacturing in India. The cost of vaccine deployment would include the cost of procuring a combination of approved vaccines, distributing them (cold chain logistics and administrative costs) and any costs associated with incentivising increased vaccine manufacture in India.
Relative production capacities for vaccines

At 80% target coverage, 2 doses for 104 crore population = 208 crore doses. Adding 15% wastage that occurs during usual vaccination drives = 240 crore doses

Current Local Production Capacity = 12.3 crores per month

Total deployment period = ~20 months

To scale up deployment, we need to source vaccines from other companies/countries and incentivise increased manufacturing in India.
Ramping up vaccine supply

Takshashila recommends ramping up vaccine supply to vaccinate ~80% of Indian population in 12 months

<table>
<thead>
<tr>
<th>Attract foreign vaccine companies</th>
<th>Incentivise Indian vaccine research</th>
<th>Facilitate vaccine manufacturing</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Enter into agreements (using model contract) with additional pharmaceutical entities developing vaccine candidates</td>
<td>• Fast track vaccine applications *</td>
<td>• Speed up government processes for vaccine manufacturers (import of equipment and ingredients, certification of manufacturing facilities, access to capital)</td>
</tr>
<tr>
<td>• Incentivise foreign companies to set up manufacturing in India</td>
<td>• Build incubator with BSL2/3 facilities for startups</td>
<td>• Defer utility payments</td>
</tr>
<tr>
<td></td>
<td>• Facilitate partnerships between research institutions/small to mid-size startups and clinical trial units/manufacturers</td>
<td>• Do not recommend price ceiling</td>
</tr>
<tr>
<td></td>
<td>• Create a safe clinical trials framework</td>
<td>• Clear tax refunds and reimbursements immediately</td>
</tr>
<tr>
<td></td>
<td>• Incentivise R and D through double tax deduction</td>
<td></td>
</tr>
</tbody>
</table>

These recommendations were first made in Takshashila Institution’s Proposal: Biotech 2025 – From lifesaver to economic engine.
Vaccine Procurement

Publish the main terms of a "model contract" for vaccine procurement that covers:

1. Guarantee of certain market access (e.g., minimum revenue or order size)
2. Dispute resolution guarantees (e.g., compulsory arbitration)
3. Control over and access to outcome data
4. Terms for manufacturing partnerships with Indian vaccine manufacturers
5. Terms 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)

Once a vaccine (or a combination of vaccines) has been chosen, the next step would be to set up a procurement pathway.

We recommend a transparent model contract that will build manufacturer and public confidence.
Choose the Delivery Channel
## Financing Models

Either a priced at zero or market priced with DBT approach can be used to finance the vaccine deployment. Takshashila prefers the second approach.

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Priced at Zero Approach</td>
<td>• Vaccination is a public good</td>
<td>• Distorts the market</td>
</tr>
<tr>
<td></td>
<td>• High Coverage</td>
<td>• Chances of pilferage and corruption</td>
</tr>
<tr>
<td></td>
<td>• Low transaction costs</td>
<td>• Government bears the entire cost</td>
</tr>
<tr>
<td>2. Market Priced with Direct Benefit Transfer Approach</td>
<td>• Lower immediate cost of roll out</td>
<td>• DBT database/mechanism needed</td>
</tr>
<tr>
<td></td>
<td>• Targeted subsidy to the needy</td>
<td>• Coverage is affected for those who cannot make initial payment</td>
</tr>
<tr>
<td></td>
<td>• Well-off households pay fair share</td>
<td></td>
</tr>
<tr>
<td>3. Market Price Only Approach</td>
<td>• Competitive pricing as more vaccines are approved.</td>
<td>• Inequitable distribution</td>
</tr>
<tr>
<td></td>
<td>• Households bear the entire cost</td>
<td>• Cannot achieve herd immunity at practical prices</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• May exclude many</td>
</tr>
</tbody>
</table>
Current mechanism of vaccine distribution

Vaccine distribution currently occurs through the Universal Immunisation Programme (UIP). UIP has evolved to target children and mothers with a select repertoire of vaccine and depends on trained ASHA workers and voluntary organisations for its execution.

However, this programme needs to be strengthened to achieve COVID-19 vaccination because:

• Target Population is larger
• Roll out needs to be quick
• Supply will be constrained and not uniform.
• Overcrowding at vaccination points needs to be avoided.

COVID-19 vaccine distribution will require a nation-wide decentralised machinery capable of quick deployment when necessary taking vaccines to people.
Organisational Structure

Takshashila proposes the below organisation structure to execute vaccine deployment in a mission-mode model.

Union Government to co-ordinate administrative functions

- Election Commission Staff
  - Booth Level Officers
  - Identity Verification Officers

State government to co-ordinate last mile administration of the vaccine

- Public Health Staff
  - ASHA Workers
  - Anganwadi Workers
  - Local Nurses/Doctors

The use of Election Commission for overseeing administrative functions will require a law to change scope. This law can be first passed as an ordinance and later converted into law as per Parliamentary procedures.
Points to Consider:
At least 20 min would be required per person to be vaccinated.
Social distancing will have to be maintained at all booths.
Security may need to be deployed to maintain law and order at the booth.
Emergency equipment will have to be maintained in case of medical emergency.
Conduct Post-market surveillance
A separate database, enabled by Aadhaar as an identifier, would need to be created to track vaccine distribution and adverse events.

A programme of this scale will need an independent and robust database to document vaccine recipients as well adverse events.

**Features of the Vaccination Database:**

1. A separate database housed in the NHA and allows Aadhaar or any national ID to be used as identifier

2. Track details of vaccination used along with Lot # and post vaccination telemedicine follow up

3. Be encrypted and used on user request to authenticate vaccination

4. Takshashila also recommends the use of election ink to mark individuals who have received the vaccine.
Considerations for usage of Aadhaar-enabled database

1. If the vaccine recipient status of an individual is not tracked, they might get extra doses accidentally administered. The health risks of taking higher than recommended (and clinically trialled) dose of the vaccine are unknown.

2. If the vaccine is found to ineffective or faulty after it has been administered, it will be easier to reach the recipient and take corrective action.

3. Aggregated, anonymised data based on identifiers can help determine vaccine performance.

4. The usage of Aadhaar should meet the three-point test of necessity, legality, and proportionality.

5. The National Health Authority (NHA) should be the owner of this database.
Features of the Vaccine Database

| Define objectives for data collection | Ensuring delivery of vaccine as per prioritisation  
|                                       | Ensuring correct dosage as per vaccination protocol  
|                                       | Determining vaccine efficacy and any negative impacts |
| Establish mechanisms for anonymisation | Use Aadhaar’s tokenisation method  
|                                       | Use of secure multi-party computation for privacy-preserving determination of outcomes. |
| Define sunset period for data storage  | Whichever of the three is earlier:  
|                                       | • End of public health emergency in India  
|                                       | • End of post-market surveillance as warranted by the vaccine  
|                                       | • Five years from the start date |
Implied versus Informed Consent

<table>
<thead>
<tr>
<th>Announce for public consumption</th>
<th>Prioritisation Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Age groups to be vaccinated</td>
</tr>
<tr>
<td></td>
<td>Strategy and timeline of delivery</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Publish at vaccination booths</th>
<th>Rejection Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>List of Possible adverse reactions and display at each site</td>
</tr>
<tr>
<td></td>
<td>Vaccine Trial Data prior to/alongside regulatory approvals</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Train staff at booth</th>
<th>Make vaccine recipients aware of vaccine risks and the addition to personal data to the vaccine database and its purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Staff to have GCP (Good Clinical Practice) training</td>
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COVID-19 vaccination programme needs informed consent of the public.
## Timeline

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</thead>
<tbody>
<tr>
<td>Stage 2: Set up vaccination organisation structure</td>
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<tr>
<td>Stage 3: Preparation for Distribution</td>
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<tr>
<td>Stage 4: Prepare vaccine priority lists</td>
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<tr>
<td>Stage 5: Collect post-market intelligence</td>
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<tr>
<td>Stage 6: Public Engagement</td>
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</table>
Overall Workflow

- Communicate to states and local authorities
- Communicate vaccination prioritisation strategy and criteria to public

Choose vaccine for deployment

- Place advance orders with manufacturers
- Communicate expected timelines to public

Determine vaccine logistics and last mile delivery

- Tie-up with local private and public sector players to manage delivery

Determine vaccine distribution and post market surveillance

- Design mechanism to create a database for capturing data on vaccine recipient, vaccine received and any adverse event associated with vaccination
- Estimate and train required workforce for distribution of the vaccine
Conclusion
Follow an Essential-First Approach for estimating need
Prioritise vaccine recipients based on how essential the occupation is for managing the pandemic.

National Manufacturing of the Vaccine
Obtain vaccine in adequate quantities, with local manufacturing.

Financing the Vaccine
A cost-free or market-priced with a DBT model can be used to finance the vaccine. Takshashila prefers the market-priced with DBT model.

Delivery channel should not become the bottleneck
Large-scale logistics and decentralised delivery necessitate a combination of Election Commission machinery and State government’s Public Health administration.

Post-market Surveillance
Use an Aadhaar-enabled, separate database to track vaccine recipients and adverse events.
End