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Latest News Scenario of COVID 19 Vaccine Development in India

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ABSTRACT: Officially affirming that no vaccines in history have been developed as rapidly as covid-19 vaccine, there is now a real risk that the poorest and most vulnerable will be trampled in the stampede for vaccines, the World Health Organization (WHO) has warned. In India also a few vaccine candidates are under different phases of clinical trials. Pune-based Serum Institute of India (SII) is in a process to manufacture Covishield which is being developed by Oxford University and pharma giant AstraZeneca which is undergoing phase 3stage of the clinical trials. Hyderabad-based pharmaceutical company Dr Reddy's Laboratories has partnered with the Russian Direct Investment Fund (RDIF) for conducting clinical trials of the Sputnik V vaccine and its distribution in India. Further, Covaxin is being developed by Bharat Biotech in association with the country's apex biomedical research body Indian Council of Medical Research (ICMR). Gujarat-based pharma giant Zydus Cadila Ltd is also developing another indigenous vaccine which is in the second phase of the clinical trials.

The National Expert Group on Vaccine Administration for covid-19 (NEGVAC) in consultation with state governments and all relevant stakeholders has prepared and presented a detailed blueprint of vaccine storage, distribution, and administration, officials in the Union health ministry said. The expert group in consultation with the states is also working actively on vaccine prioritization and its distribution. Prime Minister Narendra Modi has been saying that the government will ensure that the covid-19 vaccine, whenever available, reaches each and every Indian as soon as possible. The measles-mumps-rubella (MMR) vaccine may provide protection against Covid-19, according to a study that could also explain why children have a much lower case rate and death rate of the disease than adults. The private pharmaceutical company based in the southern city of Hyderabad is developing a whole-virion inactivated vaccine called Covaxin that could be licensed by the second quarter of 2021.

I. INTRODUCTION

PM Modi's visit to vaccine development centres will include Pune's Serum Institute of India (SII), Hyderabad's Bharat Biotech International Limited and Ahmedabad's Zydus Cadila. While SII will manufacture the AstraZeneca-Oxford University vaccine, Bharat Biotech is working on the country's first indigenous vaccine-COVAXIN. Zydus Cadila, meanwhile, is developing its vaccine candidate, ZyCoV-D. The Indian side also wants to understand President Ramkalanwan's development priorities to strengthen bilateral cooperation. India has tried to broad-base its relationship through assistance in the form of grants and concessional loans. India is a major supplier of vaccines globally, and its manufacturing capacity could be useful for the world for potential Covid-19 vaccines. Several MNCs are talking to Indian manufacturers to see if their vaccines can be made here, Gagandeep Kang, vice-chair, Coalition for Epidemic Preparedness Innovations (Cepi) said, adding that there's reason to be optimistic as "data emerging from clinical trials says a vaccine is feasible". Globally, there are 230-odd programmes looking to create Covid-19 vaccines, with 130 companies being in a reasonably advanced stage. Of this, around 10 have already started clinical trials. In India, over a dozen companies are working on vaccines.[1]

India is one of the few developing countries with production capacity, and this is important. Most governments and countries should be vocal about being local in manufacturing vaccines and also regional cooperation

Prime Minister Narendra Modi recently held a high level meeting to review planning for a vaccine against COVID-19, as and when one becomes available. Many researchers around the world are currently focused on developing a vaccine, so preparing for effective distribution and utilisation in advance is welcome. There are five particular ways in which India needs to prepare itself – and right away.[2]

1. We must develop an accurate directory of all available healthcare providers, in both the public and private sectors, and of health facilities, payers, geographic/administrative areas, and administrators. The directory will be required to plan and monitor vaccine distribution and delivery. A line list of all health providers in each health facility and geography on day one of the vaccination campaign will also help with prioritisation.



2. Along with the directory, a complete population enumeration will help identify vaccine requirements, draft geographical targets, develop vaccination schedules and monitor coverage. This will obviously be a huge effort, so the pandemic may justify the Indian government’s use of the 2011 census database, and we must debate and finalise the policies that will guide their use. A population enumeration will also help identify high-risk groups that in turn will help with prioritisation.
3. We need a single system to track vaccines from factories to health facilities to, ultimately, those who receive the vaccination. Such an end-to-end system is critical to ensure actual vaccination and prevent fudging of data. There are two ways to track the progress of the existing routine childhood vaccination programme, and they don’t talk to each other. So there is always an information discrepancy that results in an incomplete understanding of vaccination efforts. We should learn from our experience of these programs and create a unified system.
4. India needs to digitise all the data pertaining to (1), (2) and (3) or the scale of efforts could quickly get out of hand. We should fully develop and test digital systems before the first vial becomes available for public use.[3]
5. We must procure the requisite resources – including human, hardware and infrastructural – on a timely basis, including those required to maintain cold chains, plus mobile phones and data plans for all frontline vaccinators to provide real-time data. We will also need to train providers to manage vaccine-related side effects at the primary level, provide educational and awareness materials for receivers in different languages, develop a citizen grievance mechanism and hire independent agencies for quality audits. As vaccination for COVID-19 will be technically be additional work for vaccinators, the state has to finalise an incentive system to motivate them. A coordinator could be identified from the existing cadre of public health officers at every district whose only responsibility could be to prepare the district for vaccination en masse.

II. DISCUSSION

India is likely to start vaccination drive around January 2021 and is now preparing the road map for what will be perhaps the world’s largest vaccination drive next year. Data shows that India has ample manufacturing capacity (about 2.5 bn doses) that would be sufficient to meet both domestic and export demand, however, analysts point out that cold chain infrastructure is a key bottleneck.

According to Credit Suisse analysts India would need about 1.7 bn Covid-19 vaccine doses to vaccinate a majority of its adult population. The target is to administer 500 mn doses (or 250 mn people) by July next year. The key vaccines the country is banking on are from AstraZeneca, Novavax and Bharat Biotech and the earliest efficacy data is not expected before November-December 2020. As for the cold chain infrastructure, India’s current immunisation programme handles around 600 mn doses and the private sector has a capacity of about 250-300 mn doses. With this, the potential vaccinations reach 550-600 mn doses annually, claims Credit Suisse. Add to this manpower required to give the jab would be around 100,000 people. Mass inoculation of India’s population is likely to be achieved only by end of 2023, analysts feel.[4,5]

The government has already started preparing database of priority beneficiaries and has issued advisory at district and state levels to prepare database and upload to Covid-19 Vaccine Beneficiary Management System. The database of healthcare workers is expected to be ready soon, database of people above 50-years and frontline workers is ready. Challenge is in preparing the database of people with co-morbidities where data is currently limited to screening of people at 48,000 health centers.

Syringe and vial makers are already in ramp up mode and India is unlikely to face any supply constraint at least in the first half of 2021. In the cold chain, analysts feel the storage is not the issue, but transportation is. The organised sector does not have reach into the hinterlands and the government is likely to use existing fruit and vegetable cold storage and the Universal Immunisation Program network to serve these areas.[10]

India needs 1.7 bn doses for its population	
Total Population (mn)	1380
Population above 14 yrs	80%
Population with antibodies by March 2021 (estimates)	25%
Number of Indians to be vaccinated (mn)	828
Dose per person	2
Total Doses (mn)	1656



Priority groups identified for first phase of CoViD-19 vaccination in India				
Priority Population Segment	No. of Beneficiaries (mn)			
Healthcare Workers	7			
MBBS doctors	1.1			
Nurses	1.5			
Frontline workers	21			
Municipal workers, public transport drivers etc	15			
Police and Armed forces	6			
People above 50 yrs	260			
People less than 50 yrs but with co-morbidities (estimates)	12			
Total	300			
Vaccine production and Clinical Trial timelines				
Players candidates	with Capacity (mn doses)	Clinical Trial update	Temperature Requirements	
Serum - AstraZeneca	1000	Phase 3 by December 2020	2-8 degree celsius	
Serum - Novavax	500	Phase 2/3 to start by Dec 2020	2-8 degree celsius	
Cadila - DNA vaccine	100	Phase 3 by March 2021	2-8 degree celsius	
Aurobindo- Viral vector facility	300			
Russian vaccine	100	Phase 2/3 India trials to end by March 2021	2-8 degree celsius ***	
Biological E-J&J **	400	J&J global data expected in Q1CY21	2-8 degree celsius	
Bharat Biotech *	150	Phase 3 started in October	2-8 degree celsius	
Total (estimates)	2550			

* Bharat Biotech is trying to take capacity up to 500 mn doses/yr

** Biological E has capacity to make 1 bn doses for Texas based Baylor College of Medicine (BCM)'s recombinant protein vaccine candidate[9]

*** one variant may need -20 degree celsius

Key domestic logistics players offering cold chain storage and transportation across the country				
Company	Capacity	Remarks		
Snowman Logistics	1 lakh pallets, 289 vehicles, 33 warehouses	Largest organized player, can ramp up storage capacity to 650mn doses if it can repurpose all the food storage warehouses		
Gati Kausar	5500 pallets, 160 vehicles	Primary/Secondary distribution, dedicated reefer fleet, customized cold chain solutions for multiple industries, including healthcare		
Future Supply	8400 Pallets, 4	Storage temperature ranges from -25°C to +25°C		



Chain Solutions	Distribution Centers	
Transport Corporation of India	7000 pallets	Stores and transports agricultural products, processed foods, FMCG, healthcare products, etc
Mahindra Logistics	NA	State-of-the-art temperature controlled warehouse for pharmaceuticals opened recently
Current Cold Storage - electric and non-electric - in use in India		
ELECTRIC		
Equipment	Temperature (degree celsius)	
Cold Rooms	2 to 8	
Walk in cooler	2 to 8	
Walk in Freezers	-15 to -25	
Ice Lined Refrigerators	2 to 8	
Deep Freezer	-15 to -25	
NON-ELECTRIC		
Cold Box	2 to 8	
Vaccine carrier	2 to 8	

III. CONCLUSION

With Coronavirus vaccine likely to be ready by early next year, the government has started preparing its plan for immunisation. In its latest advisory issued to district and state-level nodal, the Union Health Ministry instructed them to prepare a database of both public and private healthcare workers and upload it on the COVID Vaccine Beneficiary Management System which is still getting ready. It must be noted that the first shot of COVID-19 vaccine will be received by frontline health workers who are estimated to be around 20 Lakh across the country. These frontline healthcare workers include ANM (auxiliary nurse midwife) and ASHA (accredited social health activist) workers, medical officers, allopathic doctors, including MBBS and post-graduates amongst others. Further, the government has also kept workers in biomedical waste management, sanitation workers, ambulance drivers, security staff, outsource agency employees and other support staff, clerical staff in its priority list of who gets the vaccine first, the report added.[6,7]

Prime Minister Narendra Modi called for full preparedness to ensure speedy access to COVID-19 vaccines for every citizen. He had also suggested developing a vaccine delivery system on the lines of conduct of polls and disaster management while involving all levels of government and citizen groups.[8]

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