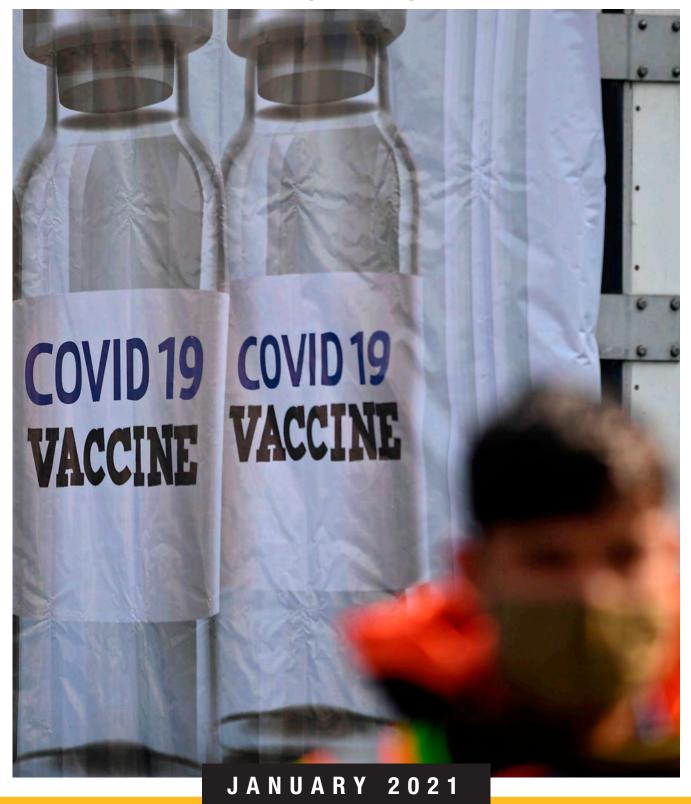
SPECIAL

REPORT

No. 126





INDIA'S HISTORIC VACCINATION DRIVE: EVALUATING THE STAKES, HURDLES AND OPPORTUNITIES

Kriti Kapur and Oommen C Kurian

ABSTRACT

arious vaccine trials across the world are showing highly promising efficacy, and multiple vaccines are getting approved across continents. The global vaccine race has now entered its second phase, where countries try and procure as many doses of Covid-19 vaccines as possible. India has put its faith primarily in the vaccines of Oxford-AstraZeneca

and Bharat Biotech-ICMR. It has also secured future stockpiles of Gamaleya and Novavax vaccines through Advance Market Commitments (AMC). However, India's crucial challenge is the vaccine rollout—a massive exercise that it will have to execute using a health sector delivery system that is in dire need of an upgrade. This special report weighs India's options.

Attribution: Kriti Kapur and Oommen C Kurian, "India's Historic Vaccination Drive: Evaluating the Stakes, Hurdles and Opportunities," *ORF Special Report No. 126*, January 2021, Observer Research Foundation.



INTRO DUCTION

accination is one of the most successful public health interventions in contemporary human history. It has aided the world in eradicating multiple diseases and brought many others to the brink of elimination. According to the World Health Organization (WHO), vaccination saves 2 to 3 million lives each year from diseases such as tetanus, influenza, measles and diphtheria.1 Vaccines are critical not only for the prevention of infectious diseases, but also to control the severity and spread of such diseases. Today the world finds itself in a race against time to develop and deliver vaccination against Covid-19, a disease that has claimed 1.8 million lives as 2021 began. As of 31 December 2020, more than 6 million doses of the Covid-19 vaccines have been administered across 26 countries, half of them in the United States (US) alone.² In India, the government has indicated emergency-use authorisation of Covid-19 vaccines beginning January 2021; this has brought widespread hope that the pandemic will soon be under control.

As globally recorded Covid-19 cases near 85 million, the world is getting ready for the biggest vaccination campaign in global history. It will not be easy. Despite steady progress in increasing universal access to important vaccines, each year nearly 20 million infants across the world suffer from inadequate access to vaccines.³ Ensuring widespread access to effective Covid-19 vaccines is a challenge that the world needs to overcome quickly, through collective measures like COVAX, the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator jointly coordinated by WHO, the Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi, the Vaccine Alliance.⁴

However, vaccine delivery is a necessary but not a sufficient condition for achieving immunity at the community level. Once effective vaccines are available, it is the effectiveness of the entire vaccination process that will be key to how countries can rebuild post-pandemic.

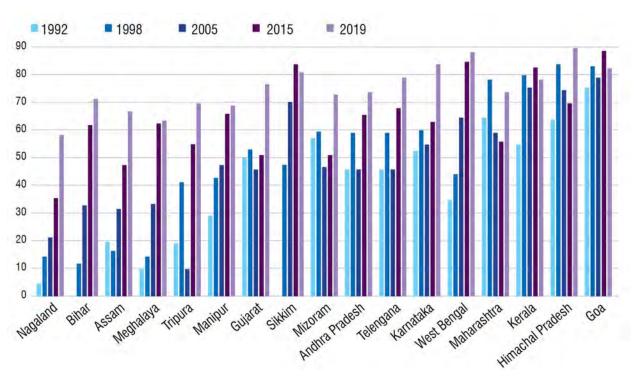
India, with one of the largest immunisation programmes in the world, has an annual estimated number of 26.7 million newborns and 29 million pregnant women. While the country's vaccination coverage has improved consistently (See Figure 1), progress has been slow. In 2016, 38 percent of infants in India failed to receive all basic vaccines within the first year of their birth. Analysts attribute the non-universality of vaccination coverage to various factors, including the remoteness of large populations in distant towns or villages, lack of physical infrastructure, and the prevalence of misinformation surrounding vaccination.

Compounding India's difficulties is that Covid-19 itself—and the subsequent lockdowns that the government imposed to attempt to arrest its spread—have led to the disruption of many important non-Covid health services, especially vaccination drives. To be sure, preparations have begun for the Covid-19 vaccine rollout, and Operational Guidelines and training programmes are already in place. However, the challenges and bottlenecks within the system are overwhelming. To ensure equitable distribution of the vaccine when it arrives, Indian policymakers must address key resource and logistical challenges.

Indian officials have gone on record that India is discussing procurement options with multiple manufacturers, including Pfizer.⁹ With WHO issuing its first emergency-use validation to Pfizer's Comirnaty vaccine on 31 December 2020, an approval in India may also be closer.¹⁰ However, along with timely availability and efficacy, other equally important factors will drive India's selection of Covid-19 vaccine(s) for its unprecedented vaccination drive: ease of storage, possibility of mass manufacturing, and



Figure 1: Proportion of Fully Vaccinated Children aged 12-23 Months



Source: NFHS-5 Fact Sheets.7

availability of logistics. A dry run of India's Covid-19 vaccination drive was conducted successfully in the states of Punjab, Assam, Andhra Pradesh and Gujarat on December 28 and 29, followed by a countrywide dry run, where 1.1 lakh vaccinators were trained on Day 1 alone.¹¹

This report explores the global progress in the development of a Covid-19 vaccine. It then outlines the most crucial administrative and logistical challenges that India must overcome once the vaccine is available. The aim will be to ensure a fair, yet strategic distribution of vaccines for its population of 1.38 billion. ¹²



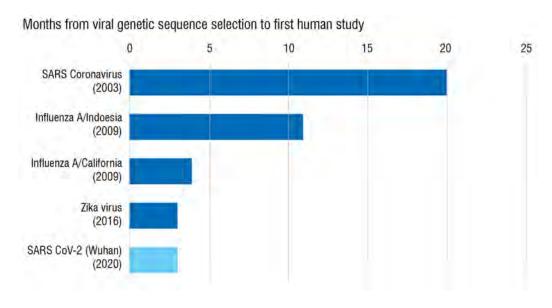
THE GLOBAL RACE FOR COVID-19 C

he world has seen from earlier pandemics and medical breakthroughs that it is rare for a vaccine to be developed in less than five years. Effective anti-viral drugs generally take longer. As the novel coronavirus (or SARS-CoV-2) threatens the lives of millions of people across socio-economic barriers, the global community is

hopeful that a vaccine will emerge. The targeted timeline for creating a vaccine for Covid-19 has often been pegged at 12 to 18 months. However, within 11 months of beginning research, more than half a dozen vaccines have been approved, or nearing approvals for mass use.

Over the years, advancement in medical technology has aided in the acceleration of efforts to develop vaccines for emerging infectious diseases. Figure 1 indicates the decreasing trend in time taken to determine the genetic sequence of a virus—a prerequisite to vaccine development. In January 2020, the world witnessed the discovery of the Covid-19 genome sequence in record time: within two months of the first reported cases in Wuhan, China in November 2019.¹⁴

Figure 2: Time taken from Viral-genetic sequence selection to human study for different diseases (in months)



Source: Wall Street Journal¹⁵



The development of a vaccine is resource-intensive and time-consuming. (See Figure 3)

As of 28 December 2020, there are 64 vaccine candidates in the three different stages of clinical trials, while another 162 vaccine candidates are in the pre-clinical evaluation stage. 18

Out of the 64 vaccines in the clinical trials, 19 are in the phase 3 of development. In India, three vaccines have applied for emergency approvals – Pfizer, Oxford- AstraZeneca and Bharat Biotech – and a few other including Zydus, Gamaleya and Novavax are in advanced levels of trials.¹⁹

Figure 3: Global Stages for Vaccine Development

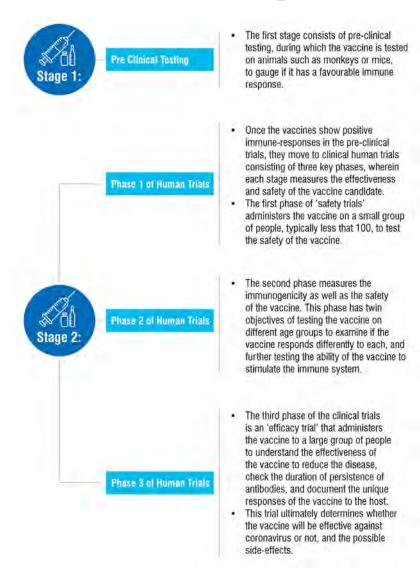
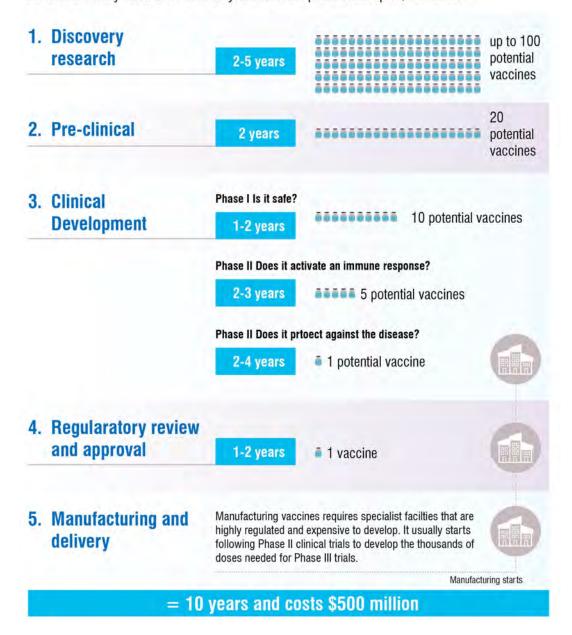




Figure 4: Time Taken under each Vaccine Development Stage

The 5 Stages of vaccine development

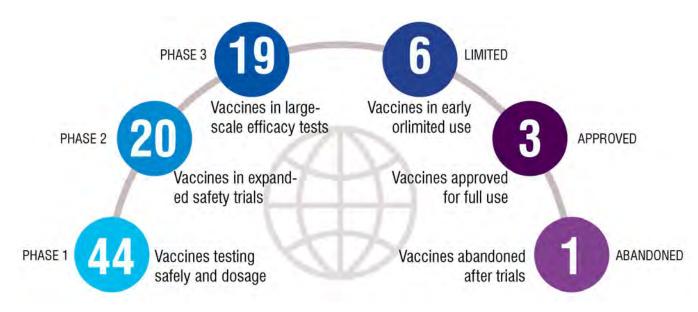
A vaccine usually takes more than 10 years to develop and costs upto \$500 million



Source: World Economic Forum¹⁶



Figure 5: Status of Global Covid-19 Vaccine Efforts



Source:NY Times Coronavirus Vaccine Tracker¹⁷



INDIA'S COVID-19 VACCINE DISTRIBUTION STRATEGY In a country as populated as Ir priority groups becomes the forest to the Ministry of Health and Fam

hile international organisations like WHO have outlined a framework for decision-making for the administration of the Covid-19 vaccine, the peculiarities of each country require unique implementation strategies.

In a country as populated as India, strategic vaccination of priority groups becomes the foremost imperative. According to the Ministry of Health and Family Welfare, only 10 percent of India's population (above 60 years old) have comprised 50 percent of all Covid-19 deaths so far, while 73 percent of the deaths are attributed to people suffering from co-morbidities, such as diabetes, hypertension, and cardiovascular and respiratory diseases.²⁰

As the government of India prepares for the deployment of the vaccine, a list of priority groups has been created, with inputs from the states.

Figure 6:

Phase 1 of Vaccine Rollout in India



Source: Covid-19 Operational Guidelines, Ministry of Health and Family Welfare²¹ (2020)



Those with higher risk of exposure to the virusincluding healthcare providers and other essential service providers such as transporters of essential goods, police, school teachers, armed forces, airline pilots and crewwill be part of the initial group selected for vaccines.²² The initial phase of the vaccine will include about 300 million individuals, starting with some 30 million healthcare workers and frontline workers, followed by another 270 million prioritised Indians: the relatively older population (above 50 years of age)a and those below the age of 50 suffering from comorbid conditions such as hypertension and diabetes. The priority group of above 50 years will be further divided into two categories: those above 60 years of age and those between 50 to 60 years. This ensures the phased rollout of the vaccine based on the evolving nature of the pandemic and availability of vaccines.²³

While the identification of these groups is based on risk of exposure and comorbidities, the selection process itself can be challenging. The country will have to make difficult decisions regarding its priorities for vaccine administration— those who are most vulnerable and constitute a higher number of potential causalities, or those who may be less likely to succumb to the disease, but could be super-spreaders owing to their particularly carefree lifestyle—the youth.

Indeed, as the pandemic is threatening to be a long-term disruption, it is necessary to prepare a strategic allocation framework to decide which populations fit which phase of the vaccination process, to avoid confusion during the latter stages. A key factor that needs to be taken into account while making this decision is the lack of medical records, which may hinder the selection process. Since the educated and the well-off sections of society have presumably better records, locating those who specifically may be in need of help can become skewed.

INDIA'S LOGISTICAL PREPAREDNESS

ne of the most complicated tasks associated with this pandemic will be the efficient deployment of the vaccine, which requires smooth coordination and collaboration at multiple levels. India knows this only too well, given its experience with its various immunisation programmes. India has seen a relatively successful national immunisation programme, especially with its Polio drive. However, it is important to note that these initiatives were meant specifically for children and pregnant women, and therefore a life-cycle

immunisaton programme will require a proper structure and larger-scale operations.

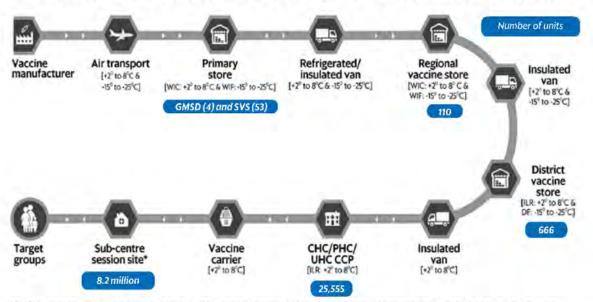
It is likely that a substantial proportion of the Indian population will get the vaccine for free as part of the national programme. Even for the rest, the prices are likely to be kept at affordable rates, either voluntarily by the manufacturers themselves, or through subsidies.

a The Indian Government intends to utilise the data from the latest electoral poll for the Lok Sabha and Legislative Assembly election to identify the population aged 50 years or more.



Figure 7: Vaccine Distribution Network in India

Vaccine cold chain distribution network in India



GMSD = Government medical store depot; SVS = State vaccine store; WIC = Walk-in cooler; WIF = Walk-in freezer; CHC = Community health centre; PHC = Primary health centre; UHC = Urban health centre; CCP = Cold chain point; ILR = Ice lined refrigerator; DF = Deep freezer; *in some of the states, selected sub-centres also function as CCP

Source: 'National EVM Assessment 2018' by NCCVMRC-NIHFW & UNICEF; 'Comprehensive Multi-Year Plan 2018-22: Universal Immunization Programme' by MoHFW

Source: Live Mint²⁴Covid-19 Vaccine manufacturing in India



Covid-19 Vaccine manufacturing in India

India is estimating that the first phase of distribution will cover 300 million individuals.²⁵ This proportion of about 20 percent of the population as high-priority is in contrast to that in other countries like the US, where a higher two-thirds of the population are prioritised for vaccine administration.²⁶ Since the vaccines being produced in India require different dosages each, planning for the future remains ambiguous awaiting finalisation of the vaccine basket.

As most global vaccines require a double dosage per person, the first phase of the vaccine process alone will require up to 600 million dosages in India. The Serum Institute of India (SII) holds the capacity for producing 1.5 billion doses, followed by Biological E. and Bharat Biotech, with half a billion doses each.²⁷ However, as the vaccine maker of the world, India exports about 74 percent of the 2.3 billion doses of vaccines it produces each year.²⁸ Serum Institute itself is planning to manufacture five different Covid-19 vaccine candidates, including Oxford-Astrazeneca and Novavax.²⁹

A partnership between SII, Gavi^b—the Vaccine alliance, and the Bill and Melinda Gates Foundation, has announced plans to accelerate manufacturing and aims to deliver an additional 100 million doses of its Covid-19 vaccine to India and other low- and middle-income countries as part of COVAX by 2021.³⁰ This has taken the total dosages committed to COVAX up to 200 million.³¹ To be sure, this provides some respite—assuming the safety and efficacy of the vaccine. Yet the situation remains uncertain. In addition to the health and essential workers, a total of 77 million people suffer from diabetes in India, of whom around 12 percent are older than 65.³² Once these population categories are covered, any vaccine or vaccines will be available for the general Indian population at a later stage.

Even as there is optimism about the Indian vaccine candidates from companies like Bharat Biotech and Zydus

Cadilla, it is likely that they will be delayed by some months in publishing their Phase 3 data and, consequently, their emergency-use authorisation by Indian authorities—well behind the timeline of international leaders like Pfizer, Moderna and Oxford-AstraZeneca. This will require exploring the feasibility of procuring a global vaccine for the Indian population at a reasonable rate. While India is a key producer of vaccines for the world, it is important that the country ensure a safety net for its citizens, while also supporting the global community.

At this stage, the priority is to ensure availability of Covid-19 vaccine for use by governments across the world. One of the FDA-approved vaccines, Comirnaty by Pfizer, will only be supplied through contracts based on agreements with respective government authorities and following regulatory authorisation or approval. Such a scenario would mean that for many months, Comirnaty and most other vaccines will be available only through the government, with minimal role for the private sector, if at all. As of 31 December 2020, India has managed to procure 2200 million doses—namely AstraZeneca/Oxford (1000 million doses), Novavax (1000 million doses), and Gamaleya (200 million doses).³³

Manufacturing of accompanying non-vaccine components

While vaccinating at a large scale, ancillary items such as syringes, glass vials, and medical devices are a prerequisite. Assuming a double dosage for about 300 million people, there is a requirement of more than 600 million syringes in the first phase alone.

b GAVI, officially Gavi, the Vaccine Alliance is a public–private global health partnership with the goal of increasing access to immunisation in poor countries.



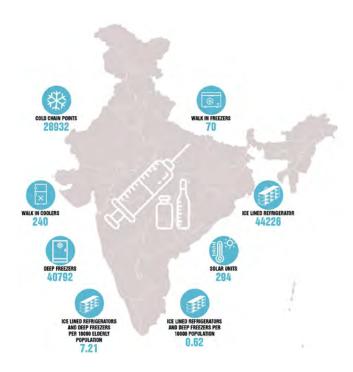
India is the biggest exporter of syringes in the world, with a capability of producing over 1 billion syringes for vaccination on a yearly basis.³⁴ With adequate incentive and assurance from the government, the syringe makers in India will be able to expand production to up to 1.4 billion; however, over 50 percent of this is being earmarked for exports. Till late December 2020, the Indian government had not taken any steps towards procurement of syringes or vials for the Covid-19 vaccine.³⁵ On 31 December, GoI ordered 83 crore syringes for the Covid-19 vaccination drive, and invited bids for 35 crore more.³⁶

It is equally important for the Indian government and the international community to work together to facilitate access to the necessary and irreplaceable components that will play a significant role in vaccine production and delivery. Primary of these is the 'adjuvant', 'which is required in the production of protein-based vaccines. The Novavax vaccine is a protein sub-unit vaccine, currently one of the frontrunners, and is in the third phase of trials that require an adjuvant, to generate effective immune response. However, this substance is available in the world in limited quantities, thus vaccines like Novavax may have limited usefulness in the future. When the substance is available in the world in limited usefulness in the future.

Supply Chain of Vaccines

A critical component of vaccine deployment is the temperature-controlled equipment and procedures that are used to maintain the integrity of vaccines. These include the storage facility at the manufacturing hub, the transportation facility, and the storage facility at the point of vaccine administration.

Figure 8: India's Cold Chain Network



According to the National Health Mission, India's Universal Immunisation Programme (UIP) currently consists of 28,932 running cold chain points.³⁹ Of these, approximately 97 percent are located at below district levels, such as primary healthcare centres, urban health centres, and sub-centres; the remaining 3 percent are located at district levels and above.⁴⁰ As of December 2020, these further consisted of approximately 85,634⁴¹ cold chain storage equipment that are managed by some 55,000 specialised technicians and handlers.⁴² These centres are responsible for the provision of 390 million doses of vaccines to newborns, infants and pregnant women on a yearly basis. However, as the map shows, the availability of freezers and refrigerators vary widely across states.

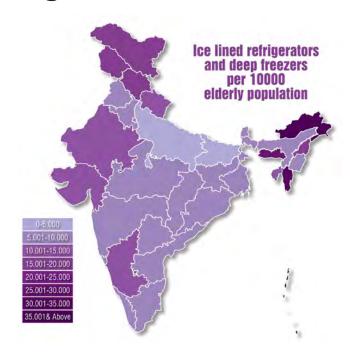
c An adjuvant is an ingredient used in some vaccines that helps create a stronger immune response in people receiving the vaccine.



Figure 9



Figure 10



While these units run a vast and successful immunisation programme, administering vaccines to an additional 300 million people in the first phase of the Covid-19 vaccine project, with time-bound multiple dosages per person, seems a difficult task. According to industry estimates, in order to conduct an efficient and effective vaccination drive for Covid-19 over and above the current UIP, the country would require at least 10 times the number of facilities operating currently—i.e., almost 800,000 cold chain units.⁴³ Not only will this require increasing the number of facilities in highly populated districts to reach more people, but also setting up cold chain units at smaller towns and villages that are now

Vaccines require to be stored at specific temperature ranges to maintain their efficacy. Most vaccines that make up India's UIP typically require a temperature range of 2 to 8 degrees Celsius, with the exception of the polio vaccine

emerging as Covid-19 hotspots.

which requires -20 degree Celsius.⁴⁴ While some Covid-19 vaccine candidates such as Oxford-AstraZeneca, Janssen or Novavax can be stored at these temperatures, other candidates such as Pfizer, require different temperatures. If India were to select a strategic combination of different vaccine candidates for its vast population, it will require the optimal temperature facilities to store these particular vaccines, in addition to all the vaccines under the current UIP programmes.

There is also a requirement for reliable temperature monitoring equipment to ensure that people do not receive a compromised vaccine. This will ensure savings in terms of cost of re-vaccination or loss of expensive vaccines. The problem for India is that the swift progress in various vaccine trials shows that the government may not have much time to improve infrastructure and logistical arrangements for the rollout.



Table 1: Covid-19 Vaccine Temperature Storage Requirement

Vaccine candidate	Storage temperature required
Oxford AstraZeneca	2-8°C
Moderna	-25°C to 15°C (can be refrigerated at 2-8°C for one month)
Pfizer	-80°C to -60°C
Sputnik V	-18°C (A freeze-dried form of Sputnik vaccine being explored)
Covaxin	2-8°C
Novavax	2-8°C

Transportation of the Vaccine to the people

Once the vaccine is manufactured and ready, it needs to reach the people, especially those living in India's remote villages; the task is massive. It requires, for one, adequate vaccine transportation facilities that will have the appropriate temperature-controlled storage units.

Based on estimates given by logistics company DHL, global coverage of vaccines over the next two years alone will require 200,000 movements by pallet shippers across 15,000 flights. The task will entail 15 million deliveries to be shipped in appropriate cooling boxes. Furthermore, reaching distant locations within the rural areas of India, at some stage, would require approximately 11,500 refrigerated trucks. Not only is this a logistical challenge, but also a financial one, and India will have to ramp up capacity at a steady and rapid pace, while maintaining quality checks.

The logistic leaders in India—Snowman Logistics, Blue Dart Express, Allcargo Logistics, DHL Express and Mahindra Logistics—have been gearing up to take on the mammoth task of transporting Covid-19 vaccines across the country. Snowman Logistics runs 31 temperature-controlled warehousing facilities across 15 locations in the country, along with a fleet of 300 trucks, for a combined capacity of 108,375 pallets. In order to aid delivery of vaccines to small towns and villages, the company intends to dedicate 200 trucks and 10,000 pellets, which will be able to hold 70 million doses of vaccines. Blue Dart, for its part, is constructing AC rooms in at least eight metro locations to store vaccines. Other logistical companies are gearing up and partnering with global and local cohorts, as well as pharmaceutical companies, to ensure successful delivery of vaccines.⁴⁸



Medical personnel infrastructure

If and when vaccines are approved, and assuming the distribution capabilities are resolved, comes the question of who will administer the vaccine. Across the world it is acceptable for pharmacists to administer vaccines; such is not the case for India, where only doctors and trained nurses are permitted.

India has 3.07 million nursing personnel, translating to a ratio of 1.7 nurses per 1000 population—this is far below WHO norms of 3 per 1000.⁴⁹ Moreover, as of September 2019, India's registered allopathic doctors were a meagre 1.2 million.⁵⁰ Given that the health personnel in the country are already overburdened by the pandemic, conducting a door-to-door vaccine drive for the 1.38 billion population seems an impossible feat. The government is opting for a site-based drive, where vaccination sessions will be conducted from 9 am to 5 pm.⁵¹

In 2011, 172 million children under the age of 5 received the polio vaccination within a span of five days. ⁵² While this certainly represents an ideal scenario, the width of exposure of Covid-19 and its challenges make it impossible to replicate such a campaign. Innovative responses like using the voting network or connecting the vaccine drive to schools may need to be introduced. India's voting rules mandate that no voter should have to travel 1.24 miles to vote, with a team of more than 5 million election workers travelling across the country to reach more than 900 million voters. ^{53,54}

Another approach could be the proper use of the newly constituted Health and Wellness Centres as well as Primary healthcare Centres (PHCs). At present, PHCs in India are supposed to cover a population of 30,000 per PHC.⁵⁵ However, PHCs do not function as expected uniformly across the country; in certain rural areas, they do not run at all. The pandemic and the subsequent vaccination process requires the upgrade of these centres.

Lastly, India consists of a comprehensive network of over one million Accredited Social Health Activists (ASHAs) and 2.5 million anganwadi workers who help provide medical assistance to women and children in villages and towns. Utilisation of this infrastructure can aid with reaching the priority population in the distant regions of the country. The Ministry of Health and Family Welfare is providing trainings to an additional 239,000 Auxiliary Nurse Midwifes (ANMs) who can provide vaccination under the UIP.⁵⁶ Out of these, only 65 percent (154,000) will be deployed for the Covid-19 vaccination, while others will ensure the smooth running of the current immunisation programmes.

d The Electronic Vaccine Intelligence Network (eVIN) digitises the vaccine programme, monitoring aspects from vaccine stocks to temperature in cold chains.



Monitoring of the Immunisation Process

Monitoring and evaluation is an indispensable aspect of any programme of this scale and complexity. Efficient tracking is required at the distribution and logistical level to ensure that vaccines are transported and stored based on internationally recognised safety norms. It is also necessary to document those who have received the vaccine to avoid duplication. In case of multiple dosages or booster shots, it is even more critical to monitor the process promptly.

In view of the current requirements, a Co-WIN (COVID-19 Vaccine Intelligence Network) has been developed on the existing platform of electronic Vaccine Intelligence Network (eVIN) module for planning, implementation, monitoring, and evaluation of Covid-19 vaccination. The Co-WIN system is aimed to be an end-to-end solution that covers different layers of the health delivery system up to the vaccinator level.⁵⁷

An exercise of this magnitude requires the use to digital platforms to enable quick and accurate flow of information across the country. The Indian government has been working to expand the existing digital platform—the eVIN network^d through a smartphone application.⁵⁸ eVIN provides a databased architecture that can instantaneously provide figures to support data-driven decision-making. It aids in real-time data visibility and monitoring to strenghen the vaccine delivery and maintenance system in India. The system has led to the increase in vaccine availability to 99 percent in most health centres in India.

The eVIN network is present in 32 states and being rolled out to the rest. Some 23,507 cold chain facilities across 585 districts utilise this system for efficient vaccine logistics management.⁵⁹ To prepare for the Covid-19 vaccination drive, approximately 23,900 electronic temperature loggers have been installed on vaccine cold chain equipment for accurate temperature review of vaccines in storage.⁶⁰

Figure 11: Electronic Vaccine Intelligence Network



- View real time stock & temp
- Vaccine requirement
- Emergency management
- Consumption patterns
- Route planning
- Stock reallocation

Source: Electronic Vaccine Intelligence Network (e-VIN), SMARTNET, Government of India⁶¹

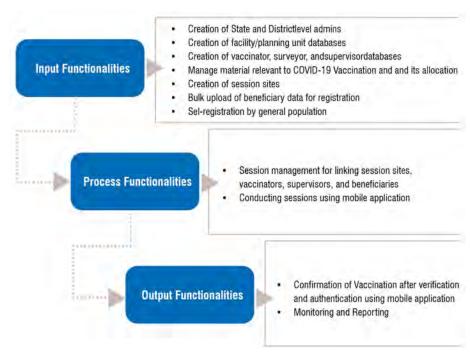


The eVIN network will additionally aid in geo-tagging the health centres and maintaining service quality in health facilities to ensure that the vaccine reaches the correct place, at the correct time and in the correct condition. Aadhaar could prove to be a useful platform to complement the digital backbone of the supply side of the vaccine rollout, with tracking population coverage. The Co-WIN network has put up a national website and a companion application.

Another pillar of the Covid-19 vaccination campaign is the quality of health personnel. The Covid-19 vaccine programme will not just require a large number of health workers, but suitably skilled ones. The digital infrastructure must also provide a comprehensive online training programme to the health personnel for storing, transporting and administering the vaccination. Since the vaccine will possibly be the fastest ever made, the health teams should be equipped with the basic knowledge of how vaccines work, in order to immediately report any side effects or adverse events faced while vaccinating the larger population.

India's initial dry run in four states will be followed by a brief countrywide one, to identify and mitigate the challenges associated with the immunisation process.⁶³ The key distinction between the general immunisation processes and that for Covid-19 is the vaccination of a pre-identified priority group using the Co-WIN application, rather than an age-wide vaccination campaign. This process will also allow cross-functioning of various government and non-government agencies to run the Covid-19 vaccination drive smoothly. The countrywide dry run, which will be conducted in all state capitals, will test the major steps of the vaccination process. It aims to assess the operational feasibility of using Co-WIN application in a field environment; test the linkages between planning, implementation and reporting mechanisms; identify the challenges and decide the way forward prior to actual implementation; and provide confidence to programme managers at various levels.⁶⁴ Due to the fast-tracked approval processes, there may only be a short gap between the dry run and the actual initiation of delivery.

Figure 12: Process flow of Co-WIN



Source: Covid-19 Operational Guidelines, Ministry of Health and Family Welfare (2020)⁶²



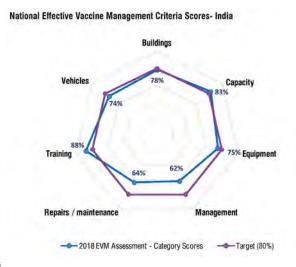
POTENTIAL ROADBLOCKS TO THE COVID-19 VACCINATION DRIVE

iven the size of the country and the scale of the Covid-19 vaccine rollout, the Indian government has initiated preparation measures for when the vaccine becomes available. A committee of experts^c has been formed to look into key aspects, ranging from capital generation and prioritisation to logistics and distribution of the vaccine.⁶⁵ Ma

Over the last few years, India has made progress in the advancement of the vaccination supply chain. Gaps persist, however. The 2018 report of the National Cold Chain Vaccine Management Resource Center, National Institute of Health and Family Welfare and UNICEF shows the development of key infrastructural and distributional aspects of vaccine deployment in the country. India's performance remains low in comparison to the global target of 80 percent.

Figure 13:

National Effective Vaccine Management Criteria



Source: National EVM Assessment 2018⁶⁶

e The committee is led by Niti Aayog's Dr VK Paul and co-chaired by health secretary Rajesh Bhushan.



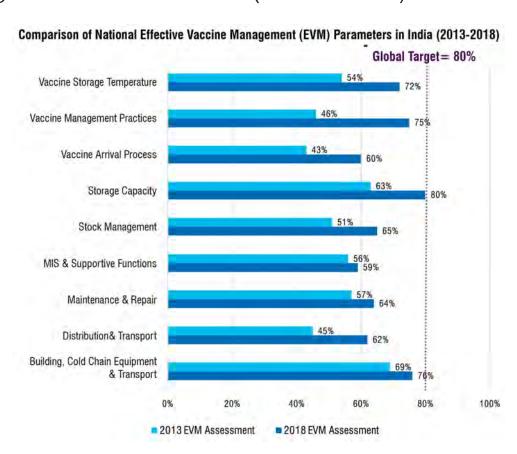
India ranked between the 51st and 75th percentile range among 89 countries on effective vaccine management according to a global analysis by WHO-UNICEF in 2018.⁶⁷ While immunisation capacity and training are at par with global targets, management of vaccines is low (62 percent) as does the maintenance of key logistical components (64 percent).

Figure 14 shows India's inadequate performance in utilising MIS/tech-based support systems, vaccine arrival processes, distribution and maintenance/repairs system. Authorities will need to give immediate attention to these

parameters for the successful implementation of the Covid-19 vaccine drive.

A fundamental challenge associated with the vaccination campaign is the yet-ambiguous nature of SARS-CoV-2. It is reasonably assumed that India will be able to roll out a vaccine (or vaccines) within the next few weeks given the promise shown by many advanced trials. While the primary concern is logistics, there has been little discussion about the challenges that will be posed by the possible mutation of SARS-CoV-2.

Figure 14: India's Progress in National Effective Vaccine Management Parameters (2013 – 2018)



Source: National EVM Assessment 2018⁶⁸



Studies have shown that viruses are constantly evolving as a result of genetic selection.⁶⁹ The same has been seen in the case of HIV, wherein the mutating nature of the virus means it forms newer variants when infecting one. Such viruses are quick to form resistance to any drugs, and producing effective vaccines becomes increasingly difficult. While there have been multiple HIV vaccines, none have performed well enough to be used.⁷⁰

The global community must be prepared for the possibility that a highly mutated variant of the virus making vaccines—even temporarily—ineffective. The current trio—social distancing, wearing masks, handwashing—will remain the most important aspect of the future unless a vaccine proves successful not just in preventing Covid-19 in infected persons, but also in limiting virus transmission, to begin with. As of now the UK, South Africa or Nigerian variants have not rendered any vaccine ineffective.

Another area of concern for India is the proper flow and continuity of current general immunisation and nutrition programmes. The past few years have seen rapid development in terms of both immunisation and nutrition programmes. However, the kind of attention given to Covid-19 has been rarely seen in other important areas of health and nutrition.

According to data from the Health Management Information System, immunisation suffered a significant disruption during the lockdown, with levels falling substantially from January to June 2020.⁷¹ Nutrition programmes throughout the country have suffered, too.

It is imperative that the Indian government ensure that other programmes not be sidelined. The current immunisation drive for children and pregnant women must be properly carried out, and newer systems and infrastructure be put in place to manage the pandemic. India has a long road to prepare for the Covid-19 vaccine, which includes the development of the vaccine and the subsequent systems which will be necessary to administer it.

The final aspect that warrants consideration is the people and the community. At present, the discourse surrounding the vaccine trials has been closely watched and interpreted by media and individuals. This has led to a plethora of misinformation, especially on social media platforms, causing fear of the vaccine. This may lead to many members of the community to disregard the vaccine altogether, even if developed, due to the anxiety and stigma surrounding it. The Indian government must organise community sensitisation drives to educate people and eliminate challenges pertaining to vaccine hesitancy. On 30 December, India published its Covid-19 Vaccine Communication Strategy, which aims to support such efforts systematically.⁷² These programmes are especially important in areas with higher populations with low levels of literacy and socio-economic status.

With multiple vaccine candidates in advanced phases of trials, and with more than 20 countries starting their vaccine rollout, the dilemma facing Indian policymakers is regarding fast approvals. At the time of writing this report, the Central Drugs Standard Control Organisation (CDSCO) is looking at three sets of vaccine candidates: these are Indian companies conducting trials in India, Indian companies conducting bridging studies in India for vaccines developed with international partners, and global pharmaceutical companies that seek approvals on the basis on international trials. The latest Indian regulation, from the New Drugs and Clinical Trials Rules of 2019⁷³ allows CDSCO to approve a vaccine without Indian trials or bridging studies. However, there is widespread apprehension that if global players like Pfizer get their vaccines approved in India without trials or bridging studies, it will put Indian manufacturers at a disadvantage. This may tilt the balance towards domestic vaccines, or vaccines manufactured in partnerships with Indian companies.



ENDNOTES

- 1 World Health Organisation, "Vaccines and Immunization", accessed October 17, 2020, https:// www.who.int/health-topics/vaccines-and-immunizati on?gclid=CjwKCAjwlID8BRAFEiwAnUoK1SJTCBJ xO_OpiU5JJgMeySrcFphkc5K_dBkGRXUvqIt2_rvPJNbGRoClrAQAvD_BwE.
- 2 "More Than 10.8 Million Shots Given: Covid-19 Vaccine Tracker", Bloomberg, https://www. bloomberg.com/graphics/covid-vaccine-tracker-globaldistribution/?srnd=storythread-QKT7T1T0G1L501
- 3 World Health Organisation, "Vaccines and Immunization"
- 4 "COVAX: Working for global equitable access to COVID-19 vaccines", World Health Organisation, https://www.who.int/initiatives/act-accelerator/covax
- 5 "Immunisation", National Health Mission, Government of India, https://nhm.gov.in/index1. php?lang=1&level=2&sublinkid=824&lid=220
- 6 Vandana Gurnani et al., "Improving Vaccination Coverage in India: Lessons from Intensified Mission Indradhanush, a Cross-Sectoral Systems Strengthening Strategy," The BMJ (British Medical Journal Publishing Group), December 7, 2018, https://www.bmj.com/ content/363/bmj.k4782
- 7 National Family Health Survey -5, India, "State/UTs Fact Sheets", International Institute of Population Studies, Government of India, http://rchiips.org/nfhs/NFHS-4Report.shtml
- 8 "Covid-19 Vaccine Operational Guidelines", Ministry of Health and Family Welfare, Government of India, December 28 2020, https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf
- 9 Hindu Business Line, "Govt bets big on India-made Covid vaccines", 17th November 2020, https://www. thehindubusinessline.com/news/govt-bets-big-on-india-made-covid-vaccines/article33119273.ece

- 10 World Health Organisation, "WHO issues its first emergency use validation for a COVID-19 vaccine and emphasizes need for equitable global access", December 31, 2020, https://www.who.int/news/item/31-12-2020-who-issues-its-first-emergency-use-validation-for-acovid-19-vaccine-and-emphasizes-need-for-equitable-global-access
- 11 "Covid-19 vaccine: Dry run in Punjab, Assam, Andhra Pradesh and Gujarat on December 28, 29", Hindustan Times, December 27, 2020, https://www.hindustantimes.com/india-news/covid-19-vaccine-dry-run-in-punjab-assam-andhra-pradesh-and-gujarat-on-december-28-29/story-5UE7d1iZVbWAPUNjxpa7kJ.html and Live Mint, 2nd January 2021, "India's Covid-19 vaccination dry run in numbers: 286 sessions, 1.1 lakh vaccinators trained on Day 1" https://www.livemint.com/news/india/indias-covid-19-vaccination-dry-run-in-numbers-286-sessions-1-1-lakh-vaccinators-trained-11609604272088. html
- 12 "India Population", Worldometer, October 15, 2020, https://www.worldometers.info/world-population/india-population/#:~:text=The%20current%20 population%20of%20India,of%20the%20total%20 world%20population.
- 13 "Can a Vaccine for Covid-19 Be Developed in Record Time?," *The New York Times*, June 9, 2020, https://www.nytimes.com/interactive/2020/06/09/magazine/covid-vaccine.html
- 14 Kriti Kapur, Dr. WHO and Mr. Hyde, Observer Research Foundation, https://www.orfonline.org/ research/dr-who-and-mr-hyde-64151/
- 15 "Drugmaker Moderna Delivers First Experimental Coronavirus Vaccine for Human Testing", Wall Street Journal, February 24, 2020, https://www.wsj.com/ articles/drugmaker-moderna-delivers-first-coronavirusvaccine-for-human-testing-11582579099
- 16 Douglas Broom, "5 charts that tell the story of vaccines today", World Economic Forum, June 2 2020, https://www.weforum.org/agenda/2020/06/vaccinedevelopment-barriers-coronavirus/
- 17 NY Times Coronavirus Vaccine Tracker, December 31, 2020, https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html



- 18 World health organisation, Draft Landscape of Covid-19 candidate vaccines", 10 December 2020
- 19 Central Drugs Standard Control Organization, Ministry of Health & Family Welfare Government of India, https:// cdsco.gov.in/opencms/opencms/en/Committees/SEC/
- 20 "UPDATES ON COVID-19" Ministry of Health and Family Welfare, June 2020 https://pib.gov.in/ PressReleasePage.aspx?PRID=1628696
- 21 Ministry of Health and Family Welfare, Covid-19 Vaccine Operational Guidelines, Ministry of Health and Family Welfare, Government of India, December 28 2020, https://www.mohfw.gov.in/pdf/ COVID19VaccineOG111Chapter16.pdf
- 22 Leroy Leo and Goutam Das, "Is India Ready to Deliver a Vaccine to a Billion People?," LiveMint, October 12, 2020, https://www.livemint.com/science/health/the-morningafter-the-coronavirus-vaccine-is-ready-11602512728712. html
- 23 "Covid-19 Vaccine Operational Guidelines, December 2020"
- 24 Tauseef Shahidi, Nikhil Rampal, "India's vaccine distribution challenge, explained in five charts", Live Mint, December 7, https://www.livemint.com/news/india/ india-s-vaccine-distribution-challenge-explained-in-fivecharts-11607106132744.html
- 25 Ministry of Health and Family Welfare, Government of India, Press briefing, December 8 2020
- 26 Helen Branswell, "Adults over 75, frontline essential workers should be in second Covid-19 vaccine priority group, says CDC advisory panel", STAT News, https://www.statnews.com/2020/12/20/adults-over-75-frontline-essential-workers-should-be-in-second-covid-19-vaccine-priority-group-says-cdc-advisory-panel/

- 27 Anoo Bhuyan, "India's COVID-19 Dilemma: Adults Need Vaccines, Supply Chains Geared For Children," IndiaSpend, October 13, 2020, https://www.indiaspend. com/indias-covid-19-dilemma-adults-need-vaccinessupply-chains-geared-for-children/
- 28 Anoo Bhuyan, "India's COVID-19 Dilemma: Adults Need Vaccines, Supply Chains Geared For Children".
- 29 Anulekha Ray, "COVID-19 vaccine: Serum Institute ties-up with 5 candidates; Poonawalla says 'it will be affordable'", Live Mint, November 5 2020, https://www.livemint.com/science/health/covid-19-vaccine-serum-institute-working-on-5-candidates-poonawalla-says-they-will-be-affordable-11604573043803.html
- 30 "Serum Institute of India to Produce up to an Additional 100 Million COVID-19 Vaccine Doses for India and Low-Middle Income Countries in 2021," Serum Institute Of India., accessed October 17, 2020, https://www.seruminstitute.com/news_sii_gavi_bmgf. php
- 31 "Serum Institute of India to Produce up to an Additional 100 Million COVID-19 Vaccine Doses for India and Low-Middle Income Countries in 2021"
- 32 "IDF Diabetes Atlas, Ninth Edition 2019", International Diabetes Federation, https://www. diabetesatlas.org/upload/resources/material/20200302_133351_IDFATLAS9e-final-web.pdf
- 33 Bloomberg, "More Than 6 Million Shots Given: Covid-19 Vaccine Tracker"
- 34 Leroy Leo and Goutam Das, "Is India Ready to Deliver a Vaccine to a Billion People?".
- 35 Anoo Bhuyan, "India's COVID-19 Dilemma: Adults Need Vaccines, Supply Chains Geared For Children".
- 36 "COVID-19 vaccination in India: Centre orders 83 crore syringes, releases guidelines for usage", Live Mint, December 31, 2020, https://www.livemint.com/science/news/covid19-vaccination-in-india-centre-orders-83-crore-syringes-releases-guidelines-for-usage-11609408089720.html



- 37 "Adjuvants and Vaccines," Centers for Disease Control and Prevention, August 14, 2020, https://www.cdc.gov/vaccinesafety/concerns/adjuvants.html
- 38 Brendan Borrell, "The Tree That Could Help Stop the Pandemic", The Atlantic, October 21, 2020, https:// www.theatlantic.com/science/archive/2020/10/single-treespecies-may-hold-key-coronavirus-vaccine/616792/
- 39 Ministry of Health and Family Welfare, Government of India, Press briefing, December 8 2020
- 40 Ministry of Health and Family Welfare, "Universal Immunization Programme, Comprehensive Multi-Year Plan, 2018-22,"https://nhm.gov.in/New_Updates_2018/NHM_Components/Immunization/Guildelines_for_immunization/cMYP_2018-22_final_pdf#:~:text=The%20aim%20of%20cMYP%20 2018,immunization%20coverage%20of%2090%20 percent.&text=Immunization%20has%20been%20 one%20of%20India's%20greatest%20public%20health%20 success%20stories
- 41 Ministry of Health and Family Welfare, Government of India, Press briefing, December 8 2020
- 42 "Universal Immunization Programme, Comprehensive Multi-Year Plan, 2018-22,"
- 43 Leroy Leo and Goutam Das, "Is India Ready to Deliver a Vaccine to a Billion People?".
- 44 Manoj V Murhekar et al., "Frequent exposure to suboptimal temperatures in vaccine cold-chain system in India: results of temperature monitoring in 10 states", World Health Organization, September 2013, https:// www.who.int/bulletin/volumes/91/12/13-119974/en/
- 45 Leroy Leo and Goutam Das, "Is India Ready to Deliver a Vaccine to a Billion People?".
- 46 Leroy Leo and Goutam Das, "Is India Ready to Deliver a Vaccine to a Billion People?".

- 47 Taslima Khan, "India's Vaccine Drive Will Need 100,000 Fridges, 11,500 Refrigerated Trucks, a Cold-Chain Evolution," The Economic Times, October 13, 2020, https://economictimes.indiatimes.com/prime/economy-and-policy/indias-vaccine-drive-will-need-100000-fridges-11500-refrigerated-trucks-a-cold-chain-evolution/primearticleshow/78625967.cms.
- 48 "Snowman, Blue Dart, DHL and others gear up for the 'Mission of The Century'", Logistics Insider, https://www.logisticsinsider.in/snowman-blue-dart-dhl-and-others-gear-up-for-the-mission-of-the-century/
- 49 "India's Shortage of Doctors, Nurses May Hamper COVID19 Response," IndiaSpend, March 30, 2020, https://www.indiaspend.com/indias-shortage-of-doctorsnurses-may-hamper-covid19-response/
- 50 "India's Shortage of Doctors, Nurses May Hamper COVID19 Response," IndiaSpend
- 51 "Covid-19 Vaccine Operational Guidelines, December 2020"
- 52 Sahil Deo, Shardul Manurkar, Sanjana Krishnan and Christian Franz, "COVID-19 Vaccine: Development, Access and Distribution in the Indian Context," ORF Issue Brief No. 378, July 2020, Observer Research Foundation. https://www.orfonline.org/wp-content/ uploads/2020/07/ORF-IssueBrief-378-Covid-Vaccine.pdf
- 53 Niha Masih, "Election Workers in India Traveled 300 Miles over 4 Days to Set up a Polling Booth for One Voter," The Washington Post, April 17, 2019, https://www.washingtonpost.com/world/asia_pacific/election-workers-in-india-traveled-300-miles-over-4-days-to-set-up-a-polling-booth--for-one-voter/2019/04/17/44b4eb46-5bb1-11e9-98d4-844088d135f2_story.html
- 54 Shreya Roy Chowdhury, "The Silent Army: Behind India's Election Are 5 Million Workers. This Series Brings You Their Stories," Scroll.in, April 9, 2019, https://scroll.in/article/918524/behind-indias-election-are-five-million-workers-this-series-brings-you-their-stories

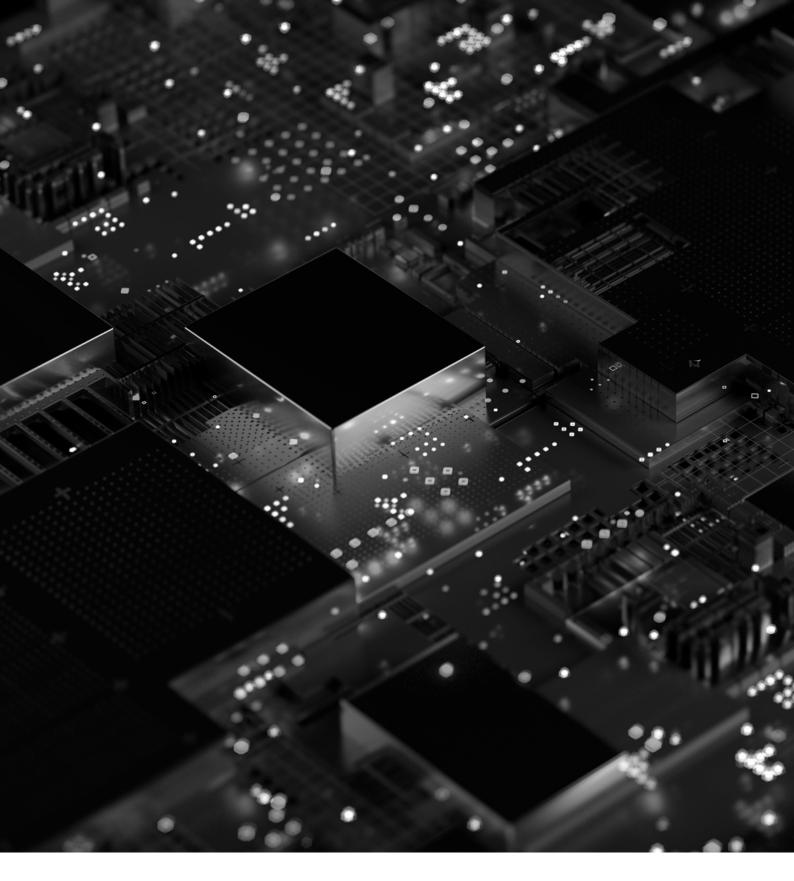


- 55 Leroy Leo and Goutam Das, "Is India Ready to Deliver a Vaccine to a Billion People?".
- 56 Ministry of Health and Family Welfare, Government of India, Press briefing, December 8 2020
- 57 "Covid-19 Vaccine Operational Guidelines, December 2020"
- 58 National Health Mission, "electronic Vaccine Intelligence Network (eVIN)" Ministry of Health and Family Welfare, Government of India, 2016. https://smartnet.niua.org/ content/d9b14fcf-c907-4260-bfd7-3ee9fa94c8d4
- 59 Ministry of Health and Family Welfare, Aug 2020, https://pib.gov.in/PressReleasePage.aspx?PRID=1643172
- 60 Ministry of Health and Family Welfare, Aug 2020, https://pib.gov.in/PressReleasePage.aspx?PRID=1643172
- 61 National Health Mission, "electronic Vaccine Intelligence Network (eVIN)"
- 62 "Covid-19 Vaccine Operational Guidelines, December 2020"
- 63 "Covid-19 vaccine: All states, UTs to conduct dry run on January 2", Hindustan Times, Dec 31 2020, https://www.hindustantimes.com/india-news/covid-19-vaccine-all-states-uts-to-conduct-dry-run-on-january-2/story-e5zi7kk9CZhPzQpOkCXSSP.html
- 64 "Covid-19 Vaccine Operational Guidelines, December 2020"
- 65 "Govt sets up committee for coronavirus vaccine distribution", Business Today, August 8, 2020, https://www.businesstoday.in/current/economy-politics/govt-sets-up-committee-for-coronavirus-vaccine-distribution/story/412426.html

- 66 "National EVM Assessment 2018", NCCVMRC-NIHFW & UNICEF, 2018, https://nhm.gov.in/New_ Updates_2018/NHM_Components/Immunization/ Guildelines_for_immunization/National_EVM_ Assessment_Report_2018.pdf
- 67 Shahidi "India's vaccine distribution challenge, explained in five charts"
- 68 "National EVM Assessment 2018"
- 69 W. Robert Fleischmann, Jr., "Medical Microbiology", chapter 43 Viral Genetics, University of Texas Medical Branch at Galveston, 1996, https://www.ncbi.nlm.nih. gov/books/NBK8439/
- 70 "Viruses and Evolution", The college of Physicians of Philadelphia, January 2018, https://ftp. historyofvaccines.org/content/articles/viruses-andevolution
- 71 Rukmini S, "COVID-19 Disrupted India's Routine Health Services", IndiaSpend, August 2020, https:// www.indiaspend.com/covid-19-disrupted-indiasroutine-health-services/
- 72 Ministry of Health and Family Welfare, "Covid-19 Vaccine Communication strategy", Ministry of Health and Family Welfare, Government of India, https://www.mohfw.gov.in/pdf/Covid19CommunicationStrategy2020.pdf
- 73 Ministry of Health and Family Welfare, "New Drugs and Clinical Trials Rules, 2019", Ministry of Health and Family Welfare, Government of India, March 19 2019, https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

Kriti Kapur is a Junior Fellow with ORF's Health Initiative. Oommen C Kurian is Senior Fellow and Head of Health Initiative at ORF.

Images used in this report are from Getty Images/Sajjad Hussain (front) and Getty Images/Andriy Onufriyenko (back).





 ${\bf Ideas. Forums. Leadership. Impact}$

20, Rouse Avenue Institutional Area,

New Delhi - 110 002, INDIA

Ph.: +91-11-35332000. **Fax**: +91-11-35332005

E-mail: contactus@orfonline.org **Website:** www.orfonline.org