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India's COVID-19 Vaccination Campaign: A Marathon, Not a Sprint

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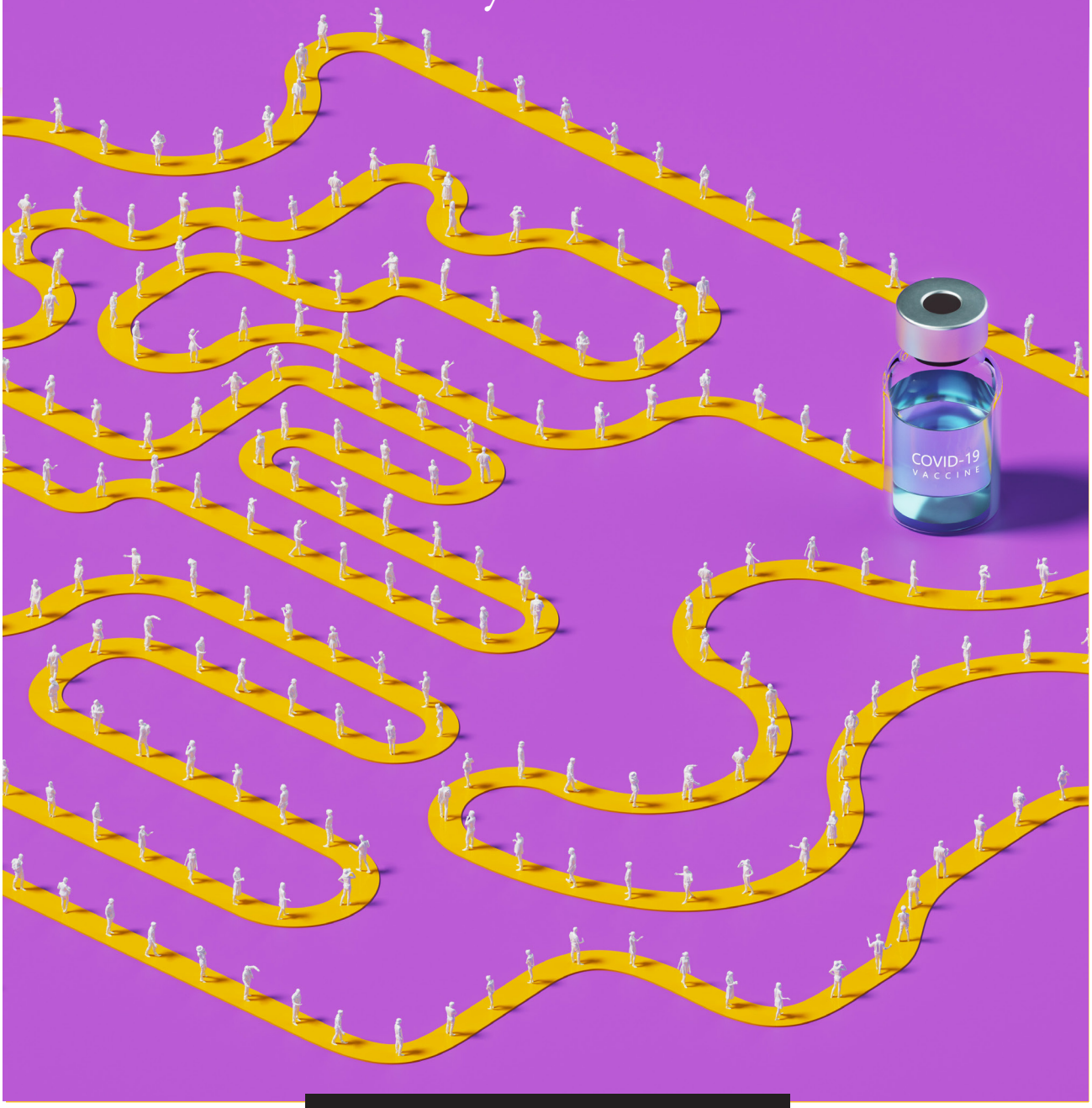

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Abstract

The year 2021 began with hope that the development, manufacture, and deployment of vaccines will soon bring the COVID-19 pandemic to an end. Halfway through the year, vaccination is underway across the world, albeit at a much slower pace for the mostly poorer nations. There is promising news from countries like the United States and Israel – where the vaccination drive has proven to be successful, and where health experts are considering the lifting of certain rules, such as that on wearing masks. India is still far from reaching its own targets. This special report examines the obstacles to India's vaccination campaign, other than the question of supply.

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Introduction

The first confirmed case of COVID-19 in India[1] was reported in the southern state of Kerala on 30 January 2020, of a 20-year-old female returning from Wuhan. Sixteen months later, the reported cumulative case count stands at 28.3 million.[2] Globally, India stands second only to the United States (US) in absolute numbers of cases. In proportion to India's entire population, the cases comprise two percent. As of 3 June 2021, India has had over 300,000 deaths due to COVID-19,[3] the highest number in the world after the US and Brazil. In terms of deaths per million population, India's number is 234.[4]

India officially launched its COVID-19 vaccination drive on 16 January 2021, with two approved vaccines – Covishield and Covaxin. As of 3 June 2021, as per reports from the Ministry of Health and Family Welfare (MoHFW),[5] India has administered just over 221 million vaccine doses. Of India's 1.38 billion population, only 45.1 million have been fully vaccinated at the time of writing – about 3.26 percent of the total population. The US, for instance, has fully vaccinated 41 percent of its population.[6]

Analysts agree that a quick vaccine rollout is India's only way through the pandemic.[7] On 30 May, the government informed the public that while a little more than 79 million doses of COVID-19 vaccine were available with the states in May, nearly 120 million doses will be made available in June.[8]

Other than the question of supply, however, there are issues that are critical to whether or not India will succeed in its vaccination campaign.

Obstacles to India's Vaccination Campaign

Myths and misinformation around vaccines circulating on both traditional and social media have had a significant impact on the global vaccination drive. Probably the greatest fears towards vaccination stem from the fact that the vaccines have been developed at a rapid pace and the mechanism of how these vaccines work is almost completely unknown to the general population.[9,10]

The US is one example of how a specific policy and mechanism has been put in place for the rapid development of vaccines—called Operation Warp Speed,[11] which it launched in May 2020. Vaccines usually take years to be developed and undergo trials, and Operation Warp Speed aimed to reduce that length of time, without compromising on the due scientific process. Other countries soon also started accelerating their vaccine development and approval process. (See Table 1) As a result, today there are over 300 vaccines in development across the world, with some already having received approval for emergency use.[12]

Table 1:
COVID-19 Accelerated Vaccine Development

	PRE-CLINICAL DEVELOPMENT	CLINICAL TRIALS	LOGISTICS	REGULATORY APPROVAL
TYPICAL PROCESS	1-2 years Laboratory Research and Animal studies	4-6 years Sequential human clinical trials in 3 Phases	2-4 years Infrastructure, manufacturing and distribution channels set-up after Phase 3 trials or after Regulatory Approval	1 year After completion and analysis of data from all phases of Clinical Trials
ACCELERATED PROCESS	6 months Fast-tracked research and use of existing vaccine platforms	1 year Human Clinical Trials in 3 Phases – conducted in parallel with continuous analysis	1 year Infrastructure and Manufacturing set-up even before Approval to enable faster distribution	1 year Analysis of data and procedure of approval in parallel with the Clinical Trials

Source: World Health Organization[13]

For India, the sheer magnitude of its 1.38-billion population makes it difficult to execute a swift rollout. Recognising the need for more vaccines to match the demand and the rising case count, the Drugs Controller General of India (DCGI)[14] made the decision to approve for use in the country all the vaccines being administered to different populations globally—as listed in the World Health Organization's (WHO) Emergency Use Listing, or approved by organisations like the United States Food and Drug Administration (USFDA), the European Medicines Agency (EMA), the United Kingdom Medicines and Healthcare products Regulatory Agency (UK MHRA), and the Pharmaceuticals and Medical Devices Agency, Japan (PMDA Japan).

Table 2:
Development and Manufacture of Vaccines in India

NAME	TYPE OF VACCINE	DEVELOPMENT & MANUFACTURING	STATUS
COVAXIN	Inactivated Whole Virion	Bharat Biotech / ICMR	EUA
COVISHIELD	Non-replicating Simian Adenoviral Vector	Oxford-AstraZeneca / Serum Institute of India	EUA
SPUTNIK-V	Non-replicating Human Adenoviral Vector	Gamaleya Institute, Russia /Dr. Reddy's Lab	EUA
NVX-CoV2373	Protein Subunit (Recombinant Nanoparticle)	Novavax / Serum Institute of India	EUA (Phase 2/3 Bridging Trials ongoing)
BNT162b2	mRNA	Pfizer/BioNTech	EUA
mRNA-1273	mRNA	Moderna/NIAID	EUA
Ad26.CoV2.S	Non-replicating Human Adenoviral Vector	Johnson & Johnson / Biological E	EUA
ZyCoV-D	Plasmid DNA	Zydus Cadila	Phase 3
BECOV	Protein Subunit	Baylor College of Medicine / Biological E	Phase 3
HDT-301 (HGCO19)	mRNA	HDT Bio Corp, USA / Gennova Biopharmaceuticals	Phase 1/2
BBV154	Non-replicating Simian Adenoviral Vector (Intranasal)	Bharat Biotech	Phase 1
COVI-VAC	Live Attenuated (Intranasal)	Codagenix / Serum Institute of India	Phase 1
VesiculoVax Platform	VesiculoVax™ VSV Vector	Aurovaccine, USA / Aurobindo Pharma Ltd	Pre-clinical
UB-612	Multitope Peptide Based Vaccine	Covaxx, USA / Aurobindo Pharma	Pre-clinical
-	Live Attenuated	Griffith University, Australia / Indian Immunologicals	Pre-clinical
-	Protein Subunit	Mynvax / Indian Institute of Science	Pre-clinical

Sources: WHO, "Draft Landscape and Tracker of COVID-19 Vaccine Candidates"[15]; Jeff Craven, "COVID-19 Vaccine Tracker"[16]; Sharun and Dhama, "India's role in COVID-19 vaccine diplomacy"[17]

Sputnik-V—manufactured and distributed in India by Dr. Reddy's Lab—is the third vaccine after Covishield and Covaxin to receive Emergency Use Approval in India. Meanwhile, the MatrixM™ protein subunit vaccine platform[a] from Novavax has shown promising results[18] against the variants and is undergoing Phase II/III bridging trials[b] in the country, in collaboration with the Serum Institute of India. For their part, the mRNA vaccines[c] from Pfizer and Moderna are expected to receive emergency use approval in the near future as negotiations are ongoing between the companies and the Government of India. They are expected to be important vaccines in the Indian context as they have shown some measure of efficacy against the B.1617,[19, 20, 21] B.1.1.7, and the B1.135[22] variants. Gennova Biopharmaceuticals is also developing a vaccine, HGCO19, based on a similar mRNA platform.

The BBV154 intranasal vaccine from Bharat Biotech is another vaccine candidate in development. Being intranasal, it is expected to induce mucosal immunity which should prevent infection and transmission of the virus as well. COVI-VAC, another intranasal vaccine from Codagenix, should also be crucial in reducing the transmission.

While India has reached a notable number of individuals for its vaccine rollout in a short time of five months, it is nowhere near enough to have an impact on the overall targets for herd immunity. India's primary healthcare setup has the capacity to vaccinate five to 10 million people per day. However, there has been a palpable degree of vaccine hesitancy, coupled with difficulties in using the online Co-WIN portal for securing slots for appointment, a shortage in doses, and wastage.

Vaccine Hesitancy

Across the globe, there are sections of people who have historically denied the need for vaccines. These people—referred to as "vaccine denialists"—launch vocal, active public campaigns against the use of any vaccine, including the ones for COVID-19. Their protests against the use of vaccines find space in both mainstream and new media, and reach significant numbers of people.

a Protein Subunit Vaccine - The antigenic proteins of the virus – the Spike Protein in this case – are developed outside the human body, in a lab, and then delivered to the human body as a vaccine.

b Bridging trials are small-scale clinical trials conducted in a new region/population to extrapolate the efficacy, safety and immunogenicity data from the large-scale clinical trials conducted in a foreign population.

c mRNA is a piece of genetic code responsible for protein synthesis in the human body. The genes coding for the Spike protein are encoded onto an mRNA segment. This mRNA vaccine delivers the code to the human cells that eventually express the Spike protein on their surface.

Another aspect of vaccine hesitancy is related fundamentally to fear. As vaccines are biological agents, they are bound to have side effects, differing in form and degree between individuals. The perception of the side effects of the COVID-19 vaccines has become exaggerated. Rarely, adverse events, allergies, anaphylactic reactions, or some other life-threatening events may occur post-vaccination, owing to multiple factors other than the vaccines themselves. But even rare events, like the post-vaccination clotting incidents in Europe,[23] are enough to create massive doubt in the minds of the potential recipients.

India must engage in proactive measures to address and dispel hesitancy and gain trust for vaccination.

A successful story comes from the remote village of Janefal,[24] in Aurangabad, Maharashtra, where the authorities have managed to vaccinate 100 percent of the eligible population through constant health messaging, awareness campaigns, and confidence-building measures. Indeed, effective vaccination coverage and uptake in rural areas requires a bottom-up approach: developing infrastructure at the ground level and mobilising human resources like grassroots health workers and volunteers to disseminate proper and adequate information to rural families who might be initially hesitant to get themselves vaccinated.

Digital Gaps

To streamline the process of vaccination, the Indian government developed a digital platform —called Co-WIN—where one could book an appointment for vaccination, check the status of vaccination, and later download their vaccination certificate. The same portal allows the government to keep track of the country's vaccination statistics. The idea was simple enough: digitise the process, avoid the hassles of analog record-keeping, and allow for easy data management. However, Co-WIN has had its fair share of problems.

As India opened up Phase 2 of its vaccination campaign in March for the elderly and those with comorbidities, the portal was flooded with millions of users trying to book a slot. The surge resulted in glitches in the mobile application or the website, with servers going down and users unable to find and block an appointment. Even as medical staff are required to undergo training in using the web portal, errors have been reported in data entry—either from the recipients or the authorities—that has led to duplication or erasure of many details. The flaws were heightened as vaccination opened up, first, for everyone above 45 including those without comorbidities, and later for those above the age of 18. The portal was overloaded, and there was a shortage of slots available for those who logged in.

> India must engage in proactive measures to address and dispel hesitancy and gain trust for vaccination.

While Co-WIN was meant to facilitate the vaccination drive, it needs more logistical support in terms of ease of access and use. The past few weeks have revealed the system's weaknesses, especially for use in the rural regions, as pointed out by the Supreme Court of India in a recent directive.[25]

Vaccine Wastage

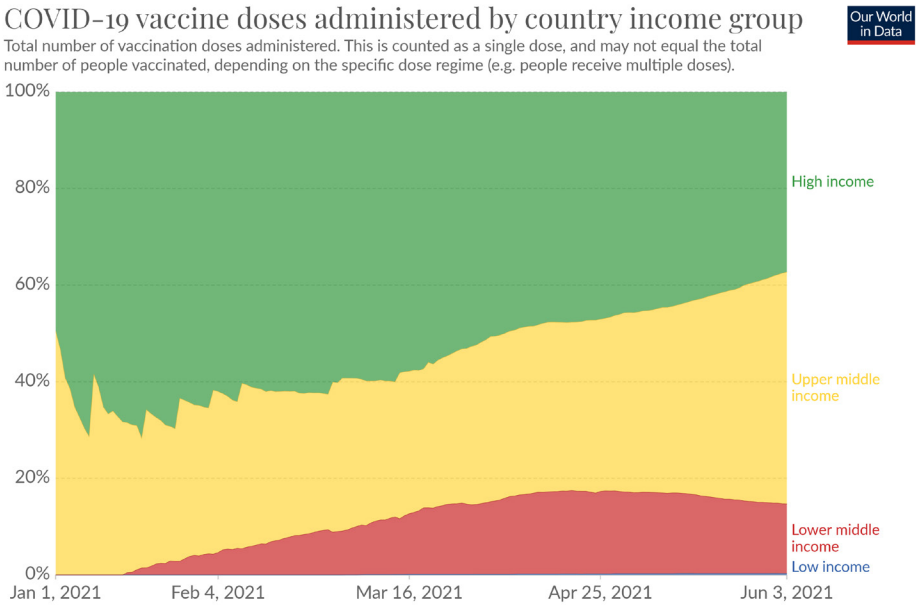
Wastage is a common enough issue for any vaccination drive of a similar scale as what India is attempting. There are various reasons,[26] primary of which are improper cold-chain maintenance and poor vaccine administration practices like inability to draw the stipulated number of doses from a vial. The concern with COVID-19 vaccines, however, is the amount of wastage occurring in India. Wastage creates an unnecessarily high demand for vaccines, while also slowing down the entire campaign.

Wastage of both Covishield and Covaxin has been brought down drastically over the past two months to under five percent as of 22 May 2021. The national average, as of 25 May 2021,[27] is 6.5 percent, with many states reporting wastage levels of over 30 percent. Consistent efforts are needed to keep this wastage to a minimum.

Towards Vaccine Equity

The key to curbing the COVID-19 pandemic is widespread vaccination, at a rapid pace, among the populations in rich and poor countries alike. The aim is vaccine equity. The Lower Middle Income Countries (LMIC), with their limited technology and resources, are dependent on the global vaccine alliances of WHO, the United Nations, The Gates Foundation, as well as GAVI and COVAX—where the wealthy regions have pledged to supply vaccines to the poorer nations. As seen in Figure 1, while the large economies have vaccinated a majority of their populations, the pace in the poorer nations has been painfully slow.

Figure 1: COVID-19 Vaccination by Country Income Group



Source: Our World in Data[28]

At the same time, India, as part of its 'Vaccine Maitri' initiative, has sent vaccines to many poor nations across the globe. As of 28 May, India has sent over 66.37 million doses[29] of both Covishield and Covaxin, to 95 countries. Amidst growing concerns that the effort is resulting in domestic shortages, the government and the Ministry of External Affairs[30] have maintained that the vaccine diplomacy has not compromised the country's own need.

In October 2020, India and South Africa moved the World Trade Organization (WTO) to waive certain provisions of the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[31] The aim of this plea was to encourage data-sharing and the necessary technology transfer, thus enabling the low-income nations to manufacture the mRNA vaccines and drugs for wider distribution and faster treatment/vaccination of their populations.

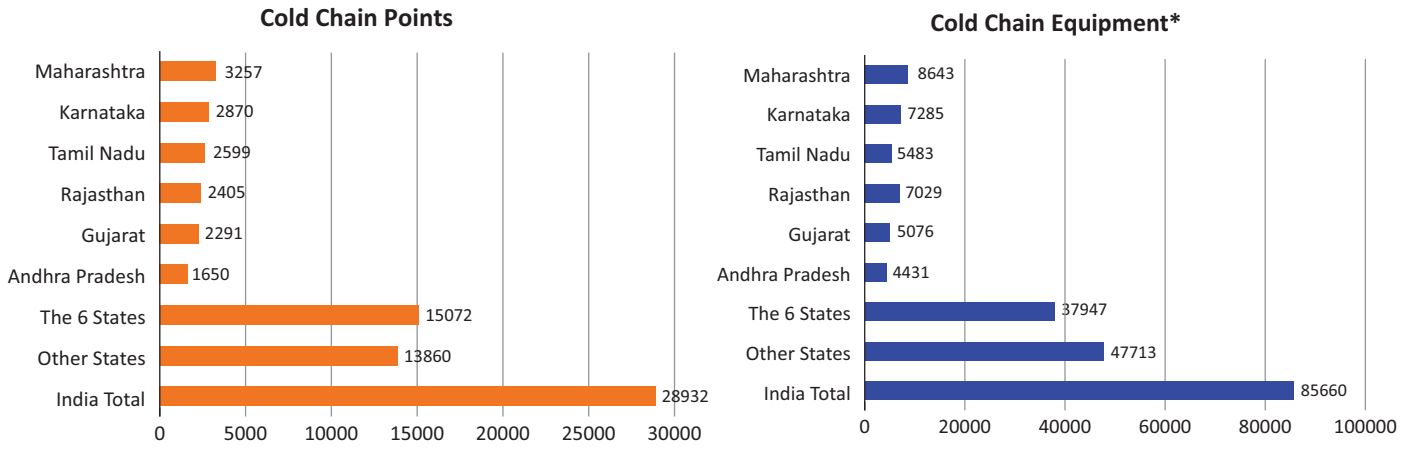
While the plea received a largely negative response initially, seven months later, the US has given its conditional approval[32] of the proposal. Following this, even the European Union,[33] New Zealand,[34] and France[35] have shown willingness to negotiate the terms and conditions of the TRIPS waiver.

The Rural Challenge

As large and diverse India is, vaccine equity is a challenge within the country as well. During the first wave of the pandemic, the rural areas were relatively less affected compared to the urban regions. Eventually, the rural regions saw a significant surge in cases, especially in the second wave. An analysis conducted by the State Bank of India[36] states that the share of rural districts in COVID-19 cases is 52.9 percent as of May 2021. Even in the first wave, the peak was at 53.7 percent of cases. It is a worrying trend, as rural areas also see lower rates of testing and poor reporting.[37]

The primary reason for this urban-rural divide is logistical constraints—infrastructure, supply chain, and skilled personnel, especially in the poorer states.[38] For the vaccination drive to be effective, the poorer states need resources and capacity building to improve the health infrastructure, which includes a very important component— i.e., Cold Chain.[d] While the vaccines in use currently do not have extreme cold chain requirements, the nationwide distribution of cold chain points in India is uneven. As of December 2020, India has 29,000 cold chain points across the country.[39] A detailed analysis by the IDFC Institute[40] in March 2021 reveals that six states with 34 percent of India's population have 52 percent of the entire country's cold chain points (See Figure 2).

Figure 2: No. of Cold Chain Points and Equipment across India, by State



*Source: IDFC (The Indian COVID-19 Alliance). *Cold Chain equipment includes walk-in coolers, freezers, and vaccine carriers.*

d Cold Chain is a temperature-controlled supply chain network of cold-chain points comprising of cold rooms, walk-in coolers, ice-lined refrigerators, deep freezers, vaccine carriers and solar units. This cold-chain is necessary to maintain the viability of the vaccine during transportation and storage - as per the given temperature requirements.

Recommendations and Conclusion

The vaccination of an individual may seem like a straightforward process—like a 100m sprint. Mass inoculation, however, is more of a 10,000m marathon and obstacle run, with hurdles erected in various points and manifesting in myriad forms. India will need a multipronged approach to tackle these hurdles. At the time of writing this report, the second wave was on the downward trend; the third wave is expected around November—this interval must be used as a buffer to launch the vaccination campaign into overdrive.

This report offers the following recommendations.

1. Manufacture and procurement. The Indian government must proactively negotiate deals for bulk procurement of vaccines and raw materials. With ongoing negotiations for the TRIPS waiver, rapid technology transfer and the import of raw materials should be initiated. At the same time, local manufacturing capacity needs a boost. Until the time that India can stock up or set up production lines for foreign-made vaccines – the locally made Covishield and Covaxin remain the best bets. Periodic assessments must be done with a viable plan for expansion by the end of 2021.

2. Infrastructure and Capacity Building. The existing supply chain and cold chain infrastructure need reinforcements, including public-private partnerships to ensure transportation and storage of vaccines even in remote areas. While the storage requirements for the mRNA vaccines have been relaxed, a robust setup must be in place to ensure quality control. With an influx of vaccine stocks expected in the coming months, all states must have adequate resources for storage and distribution.

3. Equitable distribution. High-risk areas and high-risk populations must be identified and targeted distribution of vaccines launched accordingly. Periodic assessments with respect to burden of cases, positivity rates, and mobility trends should be conducted to guide the effective disbursement of vaccine supplies. Supply chain logistics also need to be adequately upgraded for equitable distribution in rural India.

4. Reducing waste and Increasing vaccine uptake. Evaluation of the vaccination process is required —from manufacturing, transport, storage and administration—to identify the areas of vaccine wastage. Efforts must be made to reduce the wastage—this requires stringent documentation of wastage, training of healthcare staff, following the open-vial policy and/or WHO's multi-vial policy, which dictate that any vial of vaccines opened/used in a vaccination session can be stored for 28 days and used for another immunisation session provided they meet certain criteria.[41] A marker for wastage is reduced uptake, which is primarily observed at smaller centres or outreach sites. Such vaccination sessions must be carefully planned, with prior communication and mobilisation of human resources like Accredited Social Health Activist (ASHA) workers and Auxiliary Nurse Midwives (ANM).

5. Improving accessibility. Deploy mobile vaccination units with trained personnel and equipment to manage immediate adverse events, especially for the elderly and infirm. Outreach sessions should be initiated in rural and remote areas with proper planning and prior announcements. Some cities have started drive-through vaccination[42,43,44]—a practice that can be replicated nationwide. For mandatory registration in rural areas, district- or panchayat-level personnel can be deployed at the Covid Vaccination Centres. Both government and private CVCs should have the facility for walk-in registrations.

6. Vaccine advocacy. Hesitancy or denialism must be countered proactively, especially in rural areas where there is generally lower penetration of adequate and proper information. Behaviour change communication, with community-level engagement, must be done immediately.

> "The top imperatives are in vaccine manufacture and procurement; ensuring equitable distribution; reducing wastage; and battling hesitancy."

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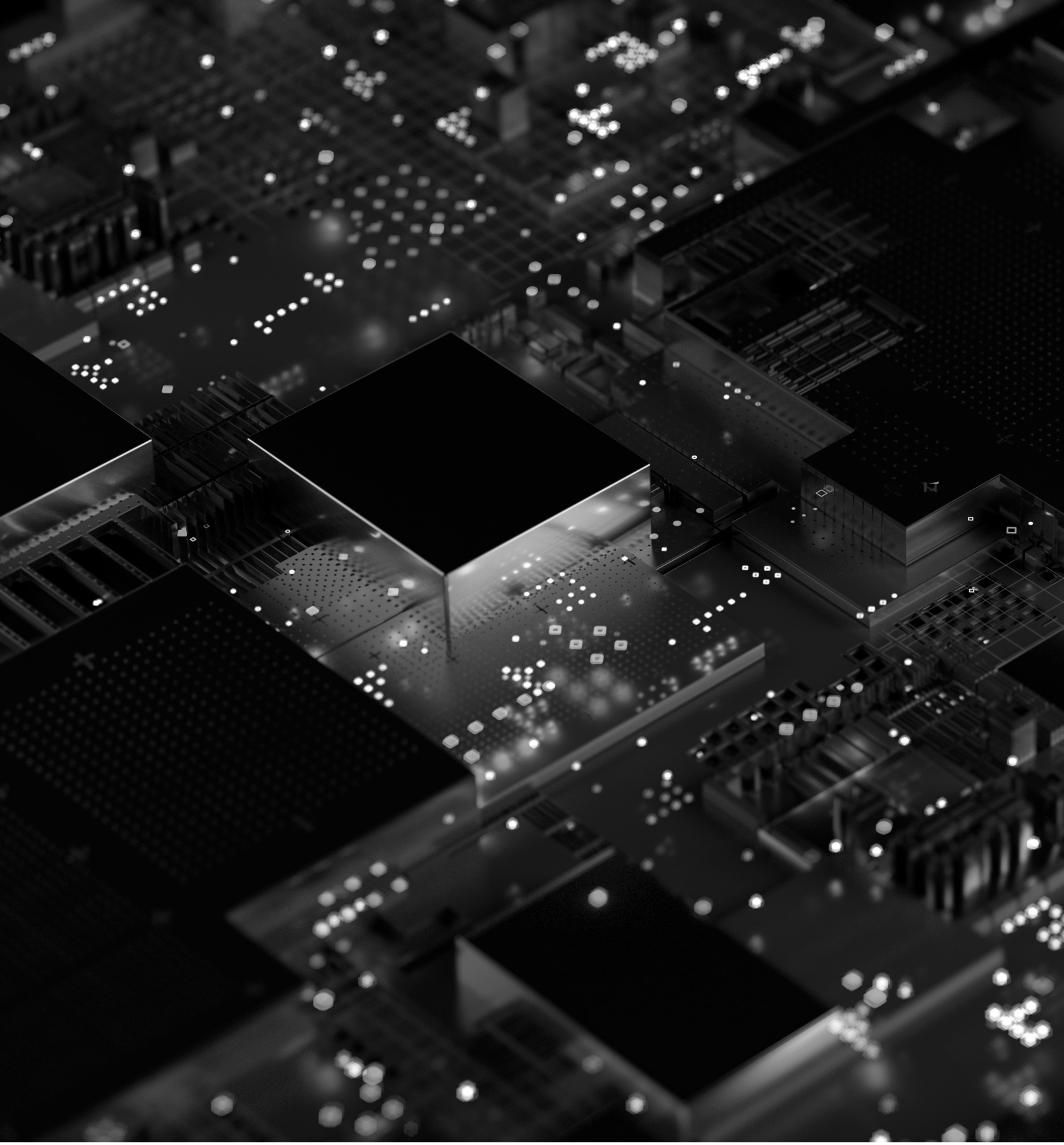

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