COVID-19 Vaccine Service Delivery Challenges: A Rapid Assessment of Private Health Facilities Providing COVID-19 Vaccination in Maharashtra, India, 2021

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ABSTRACT

Background: The private health sector has a significant role in the delivery of health services in India. However, given fast changing COVID-19 pandemic, it is critical to understand the role of the private health sector in delivery of services going forward. The supply of COVID-19 vaccines is firmly regulated by the Government of India and the private sector received unrestricted access to vaccine supply directly from manufacturers from June 2021 onwards. Materials and Methods: PATH carried out a rapid assessment of private health facilities in the state of Maharashtra to understand the challenges faced by private facilities in providing COVID-19 vaccination. Results: During the assessment it was found that 100% of the private health facilities have a robust cold chain system which is essential for safe storage of COVID-19 vaccines and delivery of immunization services. The in-charges of the health facilities reported difficulty in estimating requirement of COVID-19 vaccines doses, as 67% of the beneficiaries in Mumbai and Nashik were direct walk-ins. During the assessment 93.3% of the facilities were observed to have adequate availability of COVID-19 vaccines doses, based on the beneficiary registration data for the day. Ministry of Health, Government of India, recommends a trained 5-member vaccination team for providing services at each vaccination site. Conclusion: The key challenges faced by private health facilities during delivery of COVID-19 immunization were associated with differential vaccine pricing, time taken to receive supply of vaccines, difficulties in accurately estimating vaccine demand, multiple record keeping at the facility level and declining vaccine demand. Keywords: Vaccination, Service delivery, COVID-19 pandemic, Private health sector.

INTRODUCTION

The World Health Organization (WHO) declared COVID-19 a Public Health Emergency of International Concern on January 30, 2020,1 which coincided with the first laboratory-confirmed COVID-19 case in India. This first reported case in Kerala, India led to the activation of the Strategic Health Operation Centre (SHOC) by the National Centre for Disease Control (NCDC) and was followed by Nation Wide lockdown starting March 25, 2020. During the first wave of COVID-19, cases peaked in September 2020 with 90,000 cases reported daily. The reported cases fell to an all-time low by end of January 2021(10,064 cases being reported on 19th January)², which was followed by an exponential rise from mid-February 2021 marking the start of the devastating second wave of COVID-19 in India. The second wave peaked in May 2021 when the daily case count reached 400,000.3-4

India began its vaccination program against COVID-19 on January 16, 2021, with AstraZeneca Covishield, manufactured by Serum Institute of India. A few weeks later, Covaxin, developed by Bharat Biotech, was added. On April 12, 2021, the Drugs Controller General of India (DGCI) gave the emergency use approval for the third vaccine, Sputnik V (developed by the Gamaleya Research Institute of Epidemiology and Microbiology, in Russia). Vaccination efforts initially focused on health care workers, frontline workers, and those 45 years of age and older. The individuals in age group 18-<45 years were added once additional doses of COVID-19 vaccines were available. The Ministry of Health and Family Welfare, Government of India also released the guidance documents for immunization of pregnant women, lactating mothers, and those with comorbidities, working to ensure that no eligible beneficiary was denied COVID-19 vaccination. To schedule a vaccination, individuals were required to register on a digital platform called the COVID-19 Vaccine Intelligence Network (Co-WIN). The beneficiary could choose whether to take the vaccine at a government public health facility or a private facility. Upon successful registration, the

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date, time and venue for vaccination was shared as a text message on the registered mobile phone number.⁵ Starting 24th May 2021 Government of India, allowed onsite registration of walk-in beneficiaries at COVID-19 vaccination centers.

Maharashtra has the third highest annual per capita income of \$2,732 in India. The state has a large private health sector according to the estimates of Government of India. In 2015, there were 1.04 million private health enterprises in the country and in Maharashtra alone there were 95,684 private health enterprises.⁶⁻⁷ The private health sector has been steadily growing in Maharashtra, with the contribution of private health facilities increasing from 68% in 1981 to 83.4% in 2005. The private health sector accounts for almost two-thirds of all hospital beds in the state. Despite this, the immunization coverage for the children in the age group 12-23 month is at 56.3%.⁸

Recognizing the importance of private sector health facilities in providing health care services, the Ministry of Health invited willing private health facilities to be part of the COVID-19 vaccine roll out. A total of 7,935 private health facilities were empaneled with Ayushman Bharat-Pradhan Mantri Jan Arogya Yojana, which is the insurance scheme that provides financial protection for secondary and tertiary care to about 40% of the lower income group of Indian households based on the deprivation and occupational criteria of Socio-economic Caste Census 2011.9 To begin with, 687 private health facilities empaneled with Central Government Health Scheme started to administer COVID-19 vaccines, supplied by district health authorities, to those individuals willing to pay a user fee of INR 250 per dose is still required to expedite the coverage among adults, children and those requiring booster doses. This assessment of private health facilities focused on exploring the challenges faced by private facilities in providing services for COVID-19 vaccination in state of Maharashtra, India.

MATERIALS AND METHODS

This is a mixed methods assessment conducted in 30 selected private facilities across Maharashtra state using a convenience sampling approach. The list of empaneled private health facilities providing COVID-19 vaccination available in public domain was used to identify the health facilities in Mumbai and Nashik districts of Maharashtra.

During the process of reaching out to the listed private facilities in both districts it was observed that many facilities, although listed, were not participating in COVID-19 vaccine rollout as either they were not aware they were part of the COVID-19 vaccination center list, or they had voluntarily discontinued providing COVID-19 vaccine services. A total of 42 private COVID-19 vaccination centers were identified, which were not providing vaccination services and majority (37) of such facilities were from Mumbai. A total of 13 facilities in Mumbai and 15 in Nashik agreed to participate in the assessment. To overcome the sampling shortfall, 2 private facilities from sub-urban Thane district were selected.

Data Collection

An observation checklist was adopted from the monitoring templates available in the Operational Guidelines for COVID-19 vaccines developed by Ministry of Health and Family Welfare, Government of India. The checklist covered the information about the physical infrastructure, availability of IEC materials and human resources, and the practices followed to observe Adverse Events Following Immunization (AEFI) at the vaccination sites. The observation checklist was developed in English and pilot tested before use. On an average, the observation of the vaccination sites took between 90 and 120 min to be completed. Data from the paper-based observation checklist filled by the data collectors was entered in real time on to an Excel based data compilation tool and simultaneously screened for inconsistencies by matching the entries on the Excel based tool with the scanned copies of the observation checklist.

The in-charges of the private health facilities were interviewed using a semi-structured interview guide. The interview explored challenges faced by private health facilities in rollout of COVID-19 vaccines along the themes of: (1) Vaccine demand, supply chain and storage; (2) Trained human resources for COVID-19 vaccines rollout; (3) Co-WIN application; (4) Biomedical waste management; (5) Adverse Events Following Immunization (AEFIs); (6) Documentation and reporting requirements; and (7) Incentives.

The interviews with the facility in-charges were conducted in a private office setting. All interviews were audio recorded and verbal consent from participants was taken at the beginning of the interview. The interviewer followed up when necessary to clarify questions and to get a better understanding of the circumstances experienced by the participant. The participants were encouraged to share thoughts and information beyond the interview questions. All interviews were transcribed verbatim, with the personal information redacted from the transcripts to ensure participant confidentiality and data anonymity. The interviews were conducted by researchers with social science background and with five-year experience in research data collection. On average, it took between 60 and 90 min to complete one in depth interview.

All quantitative and qualitative data from the observations and in-depth interviews was collected between September 27th – October 24th, 2021, and stored on a password protected and encrypted Box folder on PATH's private server.

Data Analysis

Data from the vaccination site observations was analyzed and findings reported using descriptive statistics and frequency distribution of the core thematic areas. Data from in-depth interviews were coded and analyzed using a thematic content analysis technique which comprised a mix of inductive and deductive coding. Using an iterative process, a team of 2 researchers read through the transcripts and identified emerging themes. To ensure inter-rater reliability the researchers independently coded two transcripts and discussed to arrive at consensus on coding.

Ethical Considerations

Ethical guidelines were adhered to throughout the process of health facility assessment. The study was reviewed by Research Determination Committee (RDC) at PATH and was classified as Non-human Subject Research (HSR), RDC approval number: RDC – 00183, and did not require IRB oversight. The aim and scope of health facility assessment was explained in detail to the health facility in-charge and all the participants. Participation in the assessment was voluntary and all participants were free to withdraw consent at any stage of health facility assessment. To ensure confidentiality of participants no personal identifiers were collected. Prior to the observation of the vaccination sites verbal consent was taken from the facility in-charges, and it was ensured that no beneficiaries were getting vaccinated when vaccine storage and handling was observed. The researchers involved in data collection were trained in COVID – 19 appropriate behaviour to avoid getting infected during the data collection process.

RESULTS

Findings from Vaccination Site Observations

Observation of the COVID-19 vaccination sites at the private health facilities gave critical insights on infrastructure available at the sites, availability of vaccines and logistics, and human resources to administer COVID-19 vaccination.

Available infrastructure and facilities	Mumbai (13) and Thane (2) = 15	Nashik (15)				
Easy to access	15 (100%)	14 (93.33%)				
Differently abled friendly vaccination site	15 (100%)	15 (100%)				
vailability of designated waiting room, vaccination room and post-vaccination waiting area	15 (100%)	14 (93.33%)				
Hand washing facility available	15 (100%)	15 (100%)				
Drinking water facility available	15 (100%)	13 (86.67%)				
Availability of IEC materials on (a) spread of COVID-19 and its symptoms, (b) COVID appropriate behaviors and (c) COVID-19 vaccine	15 (100%)	9 (60%)				
Availability of vaccines and logistics						
Adequate doses of vaccines	13 (86.67%)	15 (100%)				
Availability of ice packs for maintaining temperature for opened vaccine vial	15 (100%)	15 (100%)				
Vaccine vial opener	15 (100%)	14 (93.33%)				
Needle hub cutter	15 (100%)	14 (93.33%)				
AEFI management kit	15 (100%)	15 (100%)				
Characteristics of vaccination teams						
Teams with all members trained	15 (100%)	15 (100%)				
At least one female member in team	15 (100%)	15 (100%)				
Teams with recommended 5-persons	8 (53.3%)	5 (33.3%)				
Vaccine storage and handling						
Vaccination sites with an Ice Lined Refrigerator or Refrigerator for storing vaccines	15 (100%)	15 (100%)				
Vaccination sites where opened vaccine vials were not kept in direct contact with ice packs	11 (73.3%)	8 (53.3%)				

Among the 30 facilities which were assessed, 15 were small standalone facilities with fewer than 100 beds, 4 were standalone large facilities with more than 100 beds, and 11 facilities were part of chain of corporate hospitals where the beds ranged between 50-250.

The findings from the observation of the COVID-19 vaccination sites are presented in Table 1.

Among the 30 private health facilities providing COVID-19 vaccines that participated in this rapid assessment, all facilities were easily accessible by the general population and those differently abled. In 29 facilities, (except for 1 facility in Nashik), it was observed that there were designated pre-vaccination waiting rooms, vaccination rooms, and post vaccination waiting areas.

Hand washing facilities were available at all sites. Drinking water was available in 28 facilities, while two facilities in Nashik did not have drinking water. IEC materials pertaining to (a) Symptoms of COVID-19 and how it spreads; (b) COVID-19 appropriate behavior to prevent transmission; and (c) Information on COVID-19 vaccines, was available in the 13 facilities of Mumbai and 2 facilities in Thane. IEC materials were only available at 9 (60%) out of 15 facilities in Nashik.

The adequate availability of the vaccine doses was assessed by comparing the available vaccine doses at the vaccination session site with the due list of beneficiaries expected to arrive on the day. The availability of adequate doses of COVID-19 vaccines ranged from 86.7% for Mumbai and Thane, to 100% in Nashik. The conditioned ice pack necessary to maintain cold chain of the opened vaccine vial was observed to be available at all 30 vaccination sites. The needle hub cutter used to destroy used syringes was available in all 30 vaccination sites. The kit for management of Adverse Events Following Immunization (AEFI) was available at 100% of the observed facilities, and the adrenaline in the AEFI kit was found to be within date of expiry.

Vaccination teams at all sites were trained and had at least one female member. As per the guidelines for COVID-19 vaccination by Ministry

of Health and Family Welfare, Government of India, each COVID-19 vaccination team should comprise of 5 people. At the observed vaccination sites, only 13 out of 30 sites had required 5 member COVID-19 vaccination team.

All sites used an Ice Line Refrigerator (ILR) or a domestic refrigerator for storing vaccines. The opened COVID-19 vaccine vials are required not to be kept in direct contact with the icepacks. Among the 30 observed facilities, 19 (63.3%) facilities followed the practice of not keeping the opened vial of COVID-19 vaccine in direct contact with the icepack.

Findings from the in – Depth Interviews

In-depth interview with the in-charges of private facilities who were engaged in providing COVID-19 vaccination helped to illuminate the provider level challenges. During the in-depth interviews, issues pertaining to vaccine supply, documentation requirements, reasons for variation in vaccine demand, and difficulties encountered with beneficiary management were discussed.

The facility in-charges felt that there are multiple factors pertaining to vaccine demand and supply which influenced the uptake of COVID-19 vaccination services at the private health facilities. The key factors are detailed in Table 2.

The prevailing differential vaccine prices for public and private health facilities and the cost of receiving a dose of COVID-19 vaccine at a private health facility is shared in Table 3.

Administrators and facility in-charges of more than 50% facilities reported that since the vaccines were available for free at public health facilities many individuals preferred to access the vaccine at public health facilities. This was even more so the case after the increase in the price of vaccines.

During the initial period of vaccine roll-out the vaccine supply was strictly regulated by the Government and vaccines could only be procured from

Table 2: Vaccine demand and supply factors influencing the uptake of COVID-19 vaccine services at private health facilities.

Factors	Mumbai (13) and Thane (2)	Nashik (15)
Decline in demand at private facilities as COVID-19 vaccine became available at greater number of public health facilities.	13 (86.7%)	12 (80%)
Increase in the market price of vaccines have created disincentive for individuals who earlier preferred taking vaccine at private health facility.	9 (60%)	8 (53.3%)
The cap on minimum order quantity (3000 doses if procured from manufacturers and 500 doses if procured from districts) was observed by facilities to be detrimental.	7 (46.7%)	5(33.3%)
Delay in supply of vaccines by the district authorities.	2 (13.3%)	4 (26.7%)

Table 3: Vaccine prices (INR) at public and private facilities in India (as of June 8, 2021).

Vaccine	Price per dose charged by manufacturer to the public facilities	Price per dose charged by manufacturer to the private facilities	Tax paid by private facilities for administering vaccines	Maximum service charge per dose charged by the private facilities	Maximum Cost per dose charged by private facilities
Covishield	400	600	30	150	780
Covaxin	600	1200	60	150	1410
Sputnik V	948	948	47	150	1145

Note: At the public facilities, COVID-19 vaccines are available free of cost

the district health authorities. The district health authorities supplied vaccines to the private health facilities within 15 days after the order being placed, and the volume of vaccine supplied varied with the stock available at the district.

In the month of June 2021, the revised guidelines for implementation of National COVID Vaccination program were launched, which allowed private health facilities to procure vaccines directly from the manufactures. This reduced the time taken for supply of vaccines to the private health facilities to 3 days.

Although the supply of vaccine could be expedited, it required health facilities to procure at least three thousand doses from the manufacturers. The private facilities that maintained a requirement of at least five hundred doses could still procure vaccines from the district health authorities, which was usually supplied within 6-8 days of placing the order.

All the facility in-charges reported to have deployed trained human resources for COVID-19 vaccinations sites. In-charges from more than 50 percent facilities (17) reported having vaccination teams with less than 5 members. The facility in-charges did not report any difficulty in providing immunization services with a smaller vaccination team.

Most facilities reported a positive user experience with the Co-WIN app which was observed to help streamline the process of registration

Table 4: Co-WIN app user experience and beneficiary trends.					
Use of Co-WIN app and user experience	Mumbai (13) and Thane (2)		Nashik (15)		
Number of sites utilizing Co-WIN app for registration.	15 (100%)		15 (100%)		
Number of sites with internet connectivity for using Co-WIN app.	15 (100%)		15 (100%)		
Reported Co-WIN app crashing in last 24 hr.	1 (6.7%)		5 (33.3%)		
Distribution of beneficiaries who are walk-ins versus pre-registered through Co-WIN app	Mumbai (13)	Thane (2)	Nashik (15)		
Direct Walk-ins.	1065 (67.4%)	120 (30%)	263 (64.3%)		
Numbers registered through CO-WIN App.	515 (32.6%)	280 (70%)	146 (35.7%)		
TOTAL	1,580	400	409		

and issuing of vaccination certificates. At the time of site visit, 80% of the assessed facilities reported no instances of Co-WIN app crashing in the preceding 24 hr. Facilities in Mumbai and Nashik reported higher numbers of direct walk-ins compared to those who preregistered on Co-WIN app. Two facilities from Thane reported a higher proportion of beneficiaries registering on Co-WIN application for availing immunization services. However, our study design didn't include capturing beneficiary perspectives and therefore reasons or this difference remain unknown. The district specific details of Co-WIN app user experience and beneficiary trends are detailed in Table 4.

All facilities had appointed a specific staff for ensuring the required documentation for COVID-19 vaccination services. Among 30 facilities, forty three percent of the facilities (Mumbai-6, Thane-1 and Nashik-6) reported record keeping and documentation for COVID-19 vaccine services to be time – consuming as apart from the electronic records, physical records were also required to be maintained. The reporting and recording of AEFI was done on standardized reporting formats shared by the district administration. None of the facility in-charges perceived any challenge in reporting AEFIs.

All the facilities reported having a robust bio-medical waste management and disposal system, and there were no perceived challenges in management of bio-medical waste generated at the COVID-19 vaccination sites.

DISCUSSION

Although numerous research articles described challenges faced during the roll-out of COVID-19 vaccines, there are no articles that explored the challenges faced by the private health facilities while providing COVID-19 vaccination services in India. This assessment has attempted to highlight the challenges faced by the private providers while providing COVID-19 vaccination services in Maharashtra.

During our assessment the major challenges faced by the facilities were related to vaccine supply, difficulties in estimating the vaccine demand, decline in the vaccine demand, and documentation requirements.

Immunization is a public good and its role in reducing mortality is evident from the fact that during 2010-17 immunization alone contributed to 24% reduction in mortality rates for children less than 5 years of age.¹⁰ Availability of immunization services is crucial for achieving the Sustainable Development Goal number 3, which envisages to "Ensure healthy lives and promote well-being for all at all ages".¹¹ In India, the government continues to be the main provider of immunization services, with limited involvement of the private sector. It is estimated that private sector contributes to the 19.2% coverage for BCG, 11.0% for pentavalent, and 5.7% for hepatitis B vaccines provided under the Universal Immunization Programme (UIP) in India.¹² The private sector is known to play a critical role for early adoption of vaccines. In India, private sector has facilitated early introduction of the newer vaccines such as the Human Papilloma Virus (HPV), Typhoid and Influenza that are yet to be included in the routine vaccination available under the UIP.¹³

In India, the COVID-19 vaccines were rolled out with involvement of the private health care providers. The uptake of COVID-19 vaccines through the private health care providers continues to be low in comparison to the Government public health facilities. The poor uptake of the COVID-19 vaccines through the private health care providers can be attributed to issue of (a) vaccine pricing (b) demand management and (c) documentation requirements.

Vaccine pricing - With the introduction of the liberalized COVID-19 vaccine policy, Government empowered the private vaccine manufacturers to fix the rate at which they would supply the vaccines to the private hospitals, a move meant to incentivize the vaccine manufacturers. This led to differential pricing of COVID-19 vaccines for public health and private health facilities, which was one of the factors that contributed to decline in vaccine demand at private facilities. The declined demand for vaccination was attributed to the differential pricing by the facility in-charges during interviews. With the recent reduction in price of the vaccination dose, it can be expected that the uptake may increase.

Demand management – The private health facilities do not have a demarcated geographical area like primary public health facilities because of which majority of assessed private health facilities found it difficult to estimate the demand for COVID-19 vaccines. The additional factors like (1) two-thirds of the actual vaccinees at the private facilities being direct walk-ins (2) minimum order cap of 3000 and 500 vaccine doses when ordered from manufacturers or district respectively and (3) free of cost availability of COVID-19 vaccines at public health facilities leading to vaccine procurement ambivalence at the private health facilities. With the recent introduction of booster dose for all double dose vaccinated beneficiaries above 18 years of age, it can be expected that there would be an increase in the demand for the vaccines at private health facilities. Development of a demand forecasting tool for the private health facilities and necessary orientation and training by the government would be helpful in future vaccination campaigns.

Documentation requirement - The Co-WIN application is helpful for beneficiary registration and in issuing vaccination certificates. However, private health care providers found reporting the utilization of COVID-19 vaccine doses to be tedious as it required multiple attempts to upload the data, and the facilities were required to maintain physical record of data being uploaded on to the server.

The private health sector can play a crucial role in delivery of COVID-19 vaccine services by (1) expediting the availability of vaccines (2) ensuring round the clock availability of the vaccination services and (3) providing vaccines on priority to those willing to pay.

CONCLUSION

During the COVID-19 pandemic, the private health facilities played a crucial role in augmenting the capacity for testing and management of COVID-19 cases. It was envisaged that the private health facilities will play a pivotal part in immunization of the population, however the potential of private health sector could not be utilized to its capacity.

To utilize the full potential of private health sector for improving coverage of COVID-19 vaccines it is imperative that (1) the COVID-19 vaccines are made available to the private health sector at affordable price(2) the minimum order quantity for procuring vaccines directly from manufacturers is reduced; and (3) mechanism for reporting the vaccine utilization and coverage is simplified. With substantial reduction in prices of Covaxin and Covishield and with both being available at INR 225 per dose, it may be expected that beneficiaries will now be willing to pay to get vaccinated at private health facilities. Since the perspective of the beneficiaries was not part of the assessment, the dimension of vaccine hesitancy was not explored. This may have an impact on the vaccine uptake as it has been reported by other assessments.¹⁴

Systematic research is needed to understand the contribution of private sector in augmenting immunization coverage for COVID-19 vaccines. The future research agenda should also explore potential strategies for engaging with private health sectors for (1) revision of national vaccine policy and (2) improving immunization coverage in focus areas.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

AEFI: Adverse Events Following Immunization; Co-WIN: COVID-19 Vaccine Intelligence Network; DCGI: Drugs Controller General of India; HPV: Human Papilloma Virus; HSR: Human Subject Research; ILR: Ice Line Refrigerator; NCDC: National Centre for Disease Control; RDC: Research Determination Committee; SHOC: Strategic Health Operation Centre; UIP: Universal Immunization Programme; WHO: World Health Organization.

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