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Special Report



Development of the India COVID-19 vaccine tracker

Harpreet Singh¹, Rohan Lohia⁴, Leyanna Susan George², Nivedita Gupta³, Jeromie Winsley Thangaraj¹³, Salaj Rana¹, Shweta Rana¹, Jasmine Kaur¹, Shashwat Shivam⁴, Narendra Kumar Arora¹², Jai Prakash Muliyil¹⁴, Manoj V. Murhekar¹³, Rakesh Lodha⁵, R.M. Pandey⁶, Vishnu Vardhan Rao⁷, Suhas Dhandore⁸, Akash Malik¹¹, Vijay Kumar⁹, Ankit Tripathi¹⁰, Samiran Panda⁸ & Balram Bhargava[†]

¹Division of Bio-Medical Informatics, ²Clinical Studies, Trials & Projections Unit, ³Virology Unit, ⁶Division of Epidemiology & Communicable Diseases, [†]Indian Council of Medical Research, ⁴Clinton Health Access Initiative, India Office, Departments of ⁵Paediatrics, ⁶Biostatistics, All India Institute of Medical Sciences, ⁷ICMR-National Institute of Medical Statistics, Divisions of ⁸Immunization, ⁹eHealth, ¹⁰Centre for Health Informatics, Ministry of Health & Family Welfare, ¹¹United Nations Development Programme, New Delhi, ¹²The INCLEN Trust International, Delhi, ¹³ICMR-National Institute of Epidemiology, Chennai, ¹⁴Department of Community Medicine, Christian Medical College, Vellore, Tamil Nadu, India

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COVID-19 was declared a pandemic by the World Health Organization (WHO) on March 11, 2020. Since then, efforts were initiated to develop safe and effective vaccines. Till date, 11 vaccines have been included in the WHO's emergency use list. The emergence and spread of variant strains of SARS-CoV-2 has altered the disease transmission dynamics, thus creating a need for continuously monitoring the real-world effectiveness of various vaccines and assessing their overall impact on disease control. To achieve this goal, the Indian Council of Medical Research (ICMR) along with the Ministry of Health and Family Welfare, Government of India, took the lead to develop the India COVID-19 Vaccination Tracker by synergizing three different public health databases: National COVID-19 testing database, CoWIN vaccination database and the COVID-19 India portal. A Vaccine Data Analytics Committee (VDAC) was constituted to advise on various modalities of the proposed tracker. The VDAC reviewed the data related to COVID-19 testing, vaccination and patient outcomes available in the three databases and selected relevant data points for inclusion in the tracker, following which databases were integrated, using common identifiers, wherever feasible. Multiple data filters were applied to retrieve information of all individuals ≥18 yr who died after the acquisition of COVID-19 infection with or without vaccination, irrespective of the time between vaccination and test positivity. Vaccine effectiveness (VE) against the reduction of mortality and hospitalizations was initially assessed. As compared to the hospitalization data, mortality reporting was found to be much better in terms of correctness and completeness. Therefore, hospitalization data were not considered for analysis and presentation in the vaccine tracker. The vaccine tracker thus depicts VE against mortality, calculated by a cohort approach using persontime analysis. Incidence of COVID-19 deaths among one- and two-dose vaccine recipients was compared with that among unvaccinated groups, to estimate the rate ratios (RRs). VE was estimated as 96.6 and 97.5 per cent, with one and two doses of the vaccines, respectively, during the period of reporting. The India COVID-19 Vaccination Tracker was officially launched on September 9, 2021. The high VE against mortality, as demonstrated by the tracker, has helped aid in allaying vaccine hesitancy, augmenting and maintaining the momentum of India's COVID-19 vaccination drive.

Key words COVID-19 - CoWIN - India - vaccine effectiveness - vaccine tracker

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COVID-19 was declared a pandemic by the World Health Organization (WHO) on March 11, 2020¹. Since then, intense efforts have been undertaken by global stakeholders to develop safe and effective vaccines for disease prevention and control. Several vaccines based on viral vector, subunit, nucleic acid and inactivated whole virion have been developed and used for immunizing people across the world². Till date, 11 vaccines have been included in the WHO's emergency use list³. Vaccine development under this unprecedented public health emergency has been undertaken in an expedited mode, curtailing the conventional pathways of 10-15 yr to less than a year⁴. Once convincing data on safety, immunogenicity and interim efficacy were available, vaccines were introduced into the public health programmes⁵. However, their ability to reduce or stop COVID-19 transmission is still unknown. Moreover, emergence and spread of variant strains of SARS-CoV-2 has altered the disease transmission dynamics, thus creating a need for continuously monitoring the realworld effectiveness of various vaccines and assessing their overall impact on disease control. The currently deployed vaccines are disease modifying in nature, where mild post-vaccination breakthrough infections are expected, but overall disease severity is reduced⁶. In view of this, many countries across the world started capturing data related to the number of hospitalizations and deaths due to post-vaccination breakthrough infections. The 'World Vaccination Tracker' reports COVID-19 vaccination coverage and uptake across the world, based on government reports⁷. The Centers for Disease Control and Prevention (CDC), USA, and the UK Health Security Agency also maintain a vaccination coverage tracker^{8,9}.

India launched concerted efforts to develop and manufacture safe and effective COVID-19 vaccines at the inception of the pandemic. Covishield (ChAl Ox1), the viral vector vaccine, and Covaxin (BBV154), an inactivated whole virion vaccine, were accorded restricted emergency use authorization in India and deployed in the public health programme on January 16, 2021. Starting from healthcare and frontline workers, the vaccination programme was extended in a phased manner¹⁰. For a country like India, it was important to collect and interpret the programmatic data meaningfully to get useful insights about vaccine effectiveness (VE). To realize this goal, the India COVID-19 Vaccination Tracker was developed and launched¹¹. Three major national databases were harmonized to elicit reliable information related to the

proportion of post-vaccination breakthrough infections and their association with the number of doses received and age-specific mortality trends. Here, we describe the efforts of establishing data synergies to develop the India COVID-19 Vaccination Tracker for the public and policymakers.

Description of available databases

COVID-19 data were captured from three major databases in India:

- (i) CoWIN vaccination database is hosted by the National Health Authority and Ministry of Health and Family Welfare (MoHFW), Government of India (GoI) with other partners. Beneficiaries need to mandatorily register on CoWIN prior to and at the time of vaccination^{12,13}. Data related to the approved vaccines (Covishield, Covaxin, Sputnik V and Corbevax) in India were captured.
- (ii) National COVID-19 testing database: Information related to the socio-demographic details, date and place of sample collection/testing, indication for testing, clinical symptoms and signs, hospitalization details and COVID-19 vaccination status was captured from the ICMR Specimen Referral Form for COVID-19¹⁴. This information was essentially filled up all across the country in the reverse transcription (RT)-PCR web-based application at the time of sample collection from all individuals¹⁵.
- (iii) COVID-19 India portal is maintained by the MoHFW, GoI and captures outcomes related to hospitalization and death of laboratory confirmed COVID-19 patients¹⁶. This centrally hosted database receives information from each State government after due verification of the reported outcomes by the State-level committees.

Constitution of Vaccine Data Analytics Committee

A Vaccine Data Analytics Committee (VDAC) consisting of a multidisciplinary team of independent experts was constituted to advise on the various modalities of the proposed tracker. VDAC reviewed the data related to COVID-19 testing, vaccination and patient outcomes available in the three different databases; assessed the feasibility of integration of different databases and advised on the various data points and projection of the proposed vaccination tracker.

Integration of databases

The COVID-19 India portal and the National COVID-19 testing database were synchronized since

inception, through a common ICMR identification number (ID). However, due to the lack of a common unique identifier between the National COVID-19 testing database and CoWIN, establishing data synergy proved to be challenging. Therefore, single and combination keys were explored using identifiers including names, place of residence, telephone numbers and unique citizen identification or Aadhar number¹⁷. With uniform consensus, the use of mobile phone numbers was considered the most common identifier for linking data between the national testing and CoWIN databases. Since both these databases allow registration of multiple individuals using a single mobile number, for each matched mobile number, name of the individual was compared using string (Levenshtein distance)¹⁸ and phonetic comparison (Soundex and Metaphone)¹⁹. Once these two databases were linked, the data were tracked in the COVID-19 India portal with the help of the ICMR ID. Vaccination status of all patients was recorded at the time of testing, and data were then retrieved and validated from CoWIN.

Data retrieval, validation and analysis

Following integration of the three databases, individuals vaccinated with any of the three approved vaccines (Covishield, Covaxin and Sputnik V) were included in the overall analysis in three different age groups: 18-44, 45-59 and ≥60 yr. Data filters were applied to retrieve information of all individuals \geq 18 yr who died of COVID-19 after vaccination, irrespective of the time between vaccination and test positivity. Information related to COVID-19 deaths in unvaccinated individuals was also retrieved. Data retrieved from all the three sources were analyzed to calculate VE against mortality. Reliable estimates of VE against hospitalization could not be made due to issues related to data quality. VE was calculated using a cohort approach and person-time analysis. The weekly aggregated number of vaccinated and unvaccinated COVID-19 deaths was estimated during the 23 wk period ranging from April 12 to August 15, 2021, using the three databases.

The total Indian adult population eligible for vaccination for the above-mentioned time period was 944,709,598 (data shared by MoHFW on August 8, 2021). The population was divided into three categories – unvaccinated, vaccinated with one dose only and those who were fully vaccinated. The change in population size of the group was calculated for every

week ending after the date of inception of the study, *i.e.* April 12, 2021. This change in population size of each week was multiplied by the number of weeks since the date of the inception. The sum of this multiplication for the entire category was the person-week-time for that specific category. Hence, the person-week-time was calculated to be 11,814,967,229 for the unvaccinated category, 3,003,281,183 for people vaccinated with only one dose and 944,415,859 for the fully vaccinated population at the end of 18 wk since the date of inception till August 15, 2021. The incidence rate for each category was calculated by dividing the number of deaths in each category by the total person-weektime of that category. The VE [95% confidence interval (CI)] was calculated as one-rate ratio (RR). The RR for one dose is the ratio of incidence rate of the population vaccinated with one dose divided by the incidence rate of the unvaccinated population and was equal to 3.4 per cent and subsequently, the VE for one dose was calculated to be 96.6 per cent. Similarly, for fully vaccinated category, the RR is the incidence rate of population vaccinated with two doses divided by the incidence rate of the unvaccinated population and was calculated to be 2.5 per cent and subsequently, the VE for two doses was calculated to be 97.5 per cent. To validate the data, cross-verification of 50 per cent of the entries was randomly done between the National COVID-19 testing database and CoWIN vaccination database. Matching for name, age, sex and phone numbers was undertaken.

Challenges in data retrieval and measures taken to overcome

The COVID-19 testing database and COVID-19 India portal were completely synchronized due to the use of ICMR ID as the common identifier in both these databases. However, linking CoWIN vaccination database with the other two databases posed challenges due to the lack of a single common identifier. CoWIN database captures information of the vaccination site, while the national testing database captures location of the testing site. Therefore, linking this information was difficult. Unique citizen identification or Aadhar numbers were explored but were available only for 10 per cent of the patients. Despite these limitations, the use of mobile numbers was considered the most feasible option for linking CoWIN and testing databases. The challenges involved people providing different phone numbers at the time of testing and vaccination, both databases permitting registration of multiple beneficiaries using a single mobile number

and people getting tested multiple times and providing different mobile numbers each time. Information retrieved through mobile numbers was supplemented by using a composite key comprising other identifiers such as place of residence, names and Aadhar number. Further, using 'Deterministic' alignment of mobile/ Aadhar numbers and 'Probabilistic alignment' of names of States/districts with a probability cut-off point 0.8, data were linked and these challenges were overcome.

Another challenge faced was to ensure the acceptable quality of data for making meaningful interpretation since data entry was carried out at the field level across thousands of vaccination and testing sites. Timeliness of data, completeness and uniformity also varied across States. To overcome these issues, a huge volume of data were filtered, edited and merged by inserting appropriate data filters. Even after cleaning and loss of erroneous data, a substantial amount of validated data were retrieved for informed decision-making. All these measures led to nearly 90 per cent data synchronization between the CoWIN and the other two databases and complete linkage of the testing and the outcome databases.

Even though several attempts were made to retrieve reliable information regarding COVID-19related hospitalization, the inadequacies in data, lack of completeness and timely entry of data by States affected its quality making it difficult to be analyzed. Therefore, the vaccine tracker focussed on VE in terms of reduction of mortality and not on hospitalizations.

Comparison with other vaccine trackers across the globe

The India COVID-19 Vaccination Tracker was officially launched on September 9, 2021 and displayed on the website of the Ministry of Health and Family Welfare¹¹. The tracker displays data related to age-specific mortality reduction in partially and fully vaccinated individuals in three different age groups: 18-44, 45-59 and ≥ 60 yr and overall VE against mortality for all the three licensed vaccines in the country. The tracker is updated monthly due to the time taken for data verification and reporting from States.

The UK tracker reports the COVID-19 vaccination coverage with the first, second and booster doses; number of COVID-19 tests conducted; hospitalizations; deaths and geographic distribution of cases. VE or breakthrough infections are not captured⁹. The CDC tracker also depicts vaccination coverage, demographic profile, overall disease trends, vaccination equity measured by social vulnerability index, effectiveness against infection, hospitalization and death. Outcomes are measured in different populations such as longterm care facility residents, healthcare providers, first responders, frontline workers and veterans⁸. Both UK and CDC trackers do not depict the VE. The India vaccine tracker depicts the overall VE in preventing COVID-19 deaths. It also gives an age-wise COVID-19 mortality based on vaccination status and proportion of people vaccinated with one and two doses. Other details regarding COVID-19 vaccination trends as per dose, age, gender, vaccine type, State- and district-wise distribution, rural versus urban trends, coverage, *etc.* are provided on the CoWIN dashboard¹².

Conclusion

Monitoring real-world safety and effectiveness of COVID-19 vaccines is critical to maintain public trust and allay vaccine hesitancy to improve uptake. India COVID-19 vaccine tracker will display periodically updated information on these aspects thereby ensuring data transparency. The tracker is expected to augment and maintain the momentum of one of the world's largest COVID-19 vaccination drives.

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For correspondence: Dr Nivedita Gupta, Virology Unit, Division of Epidemiology & Communicable Diseases, Indian Council of Medical Research, New Delhi 110 029, India e-mail: guptanivedita.hq@icmr.gov.in