RESEARCH ARTICLE

Real-time monitoring of the rollout of pneumococcal conjugate vaccines in rural India using a digital tracking platform [version 1; peer review: 2 approved with reservations]

Ruchit Nagar ^{1,2}, Mohammad Sarparajul Ambiya², Saachi Dalal², Pawan Singh Bhadauriya ², Hamid Abdullah², Mohammed Shahnawaz², Daniel M. Weinberger ³

¹Harvard Medical School, Boston, Massachusetts, USA

²Khushi Baby, Udaipur, Rajasthan, India

³Department of Epidemiology of Microbial Diseases and the Public Health Modeling Unit, Yale School of Public Health, New Haven, Connecticut, USA

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Abstract

Background: In 2017, the pneumococcal conjugate vaccine (PCV) was introduced into the Indian immunization program as a priority. However, monitoring the implementation of this program has been a major challenge in rural India. Novel digital health platforms, used to track vaccine delivery, can address this issue.

Methods: We analyzed data collected in a rural part of the Udaipur District of India, which recently introduced PCV13 into the routine immunization program. The data were collected by Khushi Baby, a novel technology platform which facilitates tracking the vaccination status of individual children. We assessed the percent of children receiving 1, 2, or 3 doses of the vaccine at different ages and time points, as well as geographic variations in uptake. Only doses received before 12 months of age were considered for this analysis.

Results: More than 96% of children captured by the database received the first dose of PCV13. Uptake of the second dose ranged from 69% to 90% across the five regions, and 44% to 76% of children received the third (booster) dose within 3 months of the recommended date.

Conclusions: These data provide early evidence that the primary doses of PCV13 are being administered at a high level in rural India; however, there is considerable variability between regions. Additionally, the receipt of the booster dose may be lower than desired. Given the importance of the booster dose in reducing pneumococcal transmission, its delivery is essential to ensure maximal benefit of the vaccine program.

Open Peer Review

Approval Status ? ?

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1. **Lorine P. Pelly** , University of Manitoba, Winnipeg, Canada

2. **Brian Wahl** , Johns Hopkins Bloomberg School of Public Health, Baltimore, USA

Any reports and responses or comments on the article can be found at the end of the article.

Keywords

pneumococcal vaccine, immunization, digital health, mHealth,

Corresponding author: Daniel M. Weinberger (daniel.weinberger@yale.edu)

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Introduction

Pneumococcal conjugate vaccines (PCVs) have been introduced in many parts of the world. PCVs prevent infection by pneumococcus, a major cause of severe bacterial pneumonia globally. The introduction of PCVs into lower and middle income countries has been a major priority for national governments and international health organizations. Globally, India has the highest number of under 5 deaths caused by pneumococcus. Given the high burden of pneumococcal disease in India and the size of the population¹, the introduction of PCVs has the potential to have a major impact^{2,3}. Starting in May 2017, several states and high-risk districts in India introduced PCVs into the routine childhood immunization schedule with two primary doses and a booster dose (2+1 schedule).

As PCVs are incorporated into the immunization schedule in India, it is critical to ensure that they are being used optimally. Key performance indicators for PCV include: the percentage of the eligible population receiving 1, 2 and 3 doses of the vaccine respectively (coverage), the percentage of children completing their vaccination series (completion), and the percentage of children receiving these doses according to the vaccine schedule (timeliness)⁴. However, monitoring this information on a paper-based system has limitations. Prior research has shown that paper-based tracking is often incomplete and lacks accountable, timely, and actionable data⁵. Digital community health platforms have the potential to fill this gap, even in hard-to-reach rural populations⁴.

In this study, we use data from Khushi Baby⁶, a novel digital health platform that captures individual-level data on maternal and child health care encounters at government-run Village Health and Nutrition Day (VHND) camps in five predominantly rural administrative blocks in the Udaipur district. The analysis of these data provides village-level resolution of the roll-out of PCVs in a high-priority rural district in northern India.

Methods

Database

At the monthly health camps, caregivers of infants are registered with the Khushi Baby mobile application. The medical history (including age, location, vaccination history, weight-for-age, and breastfeeding status) and biometric template are stored in a Near Field Communication (NFC) chip, embedded in a culturally-relevant amulet or health card. When the caregiver and child return to the follow-up VHND camp, the NFC chip is scanned by the health worker's mobile device. To authenticate the beneficiary, the primary caregiver's live thumbprint is compared against the biometric template stored at the time of registration. Now, the health worker can instantly view the beneficiary's comprehensive medical history. The health worker's mobile device also captures the timestamp and GPS location of the health camp. Together, these mechanisms help ensure that the health worker attended the camp and met the reported child, especially in rural areas where internet connectivity, data quality, and supervision are inconsistent. The NFC chip further provides a digitally auditable trail of the health interaction. Children residing in five administrative

blocks in the district of Udaipur, serviced by government outreach camps, are present in the database. For the study analyses, we used individual-level data detailing the date of birth, administrative region of residence, whether the beneficiaries were offered and accepted vaccination with PCV, and the date of administration of the first, second, and booster doses.

Analysis

Data on vaccine uptake by age were analyzed, using software package R 3.6.3, as a survival function, where the 'time' was the number of days since birth, and an event was the receipt of the vaccine. A child was censored if they did not receive the vaccine as of October 20, 2020 or when they turned 12 months of age. The system did not record receipt of PCVs received after 12 months of age. Separate analyses were conducted looking at receipt of the 1st dose, the 2nd dose, or the booster dose. Data were also disaggregated by block to evaluate geographic variations in uptake.

In separate analyses, data were also aggregated by month of birth to evaluate the percentage of children in each birth cohort that had received 1, 2 or 3 doses as of October 20, 2020. Aggregating by birth month can help to identify seasonal variations as well as to track uptake based on eligibility. Additionally, we also aggregated by gender to look for an effect of gender bias on vaccine uptake.

Vaccine timeliness was evaluated as the proportion of vaccinated children who received their dose within 1 month or 2 months of the recommended age.

As a comparison, we analyzed receipt of pentavalent vaccine (scheduled for 6, 10, and 14 weeks) and the first dose of measles vaccine (scheduled for 9 months). The pentavalent vaccine can be compared with the receipt of the primary doses of PCVs, while the measles vaccine can be compared with the booster dose of PCV.

Ethical considerations

Ethical approval for this study was obtained from the Yale Institutional Review Board (Protocol: 2000026892) under a secondary data analysis provision. As anonymized data was used, consent from participants was waived by the committee.

Results

Study population

The Khushi Baby platform captured data on 18,122 children born between February 9, 2017 and October 11, 2020 in Udaipur District, India (Figure 1). Of these, there were 10,202 children born on or after March 1, 2018, which includes the first group of children who received PCVs at a high rate. The children in the database reside in 5 administrative regions, with 1239–4965 children per region (Table 1), with Gogunda performing the best and Jhadol performing the poorest with respect to PCV completion. The Khushi Baby platform is deployed in villages where government camps service approximately 25% of the children born in the catchment area. The rate of reporting through the Khushi Baby platform varies

Figure 1. Spatial Distribution of PCV Uptake at VHND camps from 2018 to 2020 in Udaipur, Rajasthan, India. Visualization made using Tableau Software 2019.4.

Table 1. Number of children in the Khushi Baby database, through October 2020.

Admin. Region	All Children	Children born after Mar 2018
Gogunda	4207	2264
Jhadol	3868	2164
Lasadia	1239	823
Salumbar	3843	2102
Sarada	4965	2867
Total	18122	10202

between different Auxiliary Nurse Midwives (ANMs). We can assume each ANM on average reports half of the patients who turn up to a given maternal child health camp.

Uptake of primary and booster doses

Initiation of vaccination increased for children born in late 2017 and early 2018 and stabilized for children born on or after March 2018 (*Extended data: Figure S1⁷*). Almost all of the children (99%) captured by the system and born after March 1, 2018 received the first dose of PCV13 (*Figure 2*). 80% of the children received the 2nd dose of the vaccine. 56% of children received the booster dose by 12 months of age (*Figure 2*). There was considerable variability in vaccine uptake between the five blocks. (*Figure 3*). All five of the blocks had similarly high levels of uptake of the first dose of PCV, with >96% uptake. However, uptake of the 2nd dose ranged from 69% to 90%, and uptake of the booster dose

Figure 2. Percent of children receiving 1, 2, or 3 doses of PCV, by age in months. Only children born after March 1, 2018 are included.

Figure 3. Variation in uptake by administrative regions for the first 3 doses of PCV. Gogunda (red), Salumbar (purple), Lasadia (Green), Jhadol (blue), Sarada (orange). Children born after March 1, 2018 were included. For all doses, Gogunda performed best.

ranged from 44% to 76%. Children born more recently had lower uptake of the 2nd and 3rd dose, leading to lower apparent PCV completion rates (*Extended data: Figure S17*). Finally, there was no significant gender effect on vaccine uptake. Although uptake in the winter months was lower for PCV2

and 3 doses in 2018, a clear seasonal trend was not clearly discernible over multiple years.

These uptake values were comparable with pentavalent vaccines (scheduled for 6, 10, and 14 weeks) and the first dose of

measles vaccine (9 months). By 12 months of age, 99%, 89%, 79% received the first, second, or third doses of pentavalent vaccine, respectively. 60% received the measles dose, recommended at 9 months of age. By 2 years of age, the uptake of the measles dose increased to 69% (*Extended data: Figures S2, S3*⁷).

Timeliness of the doses

Vaccine timeliness can be evaluated with these data as well. Of those children vaccinated, 64% received their first dose of PCV13 within a month of the recommended age (6 weeks), and 85% of the children received it within 2 months of the recommended age (*Figure 4*). The timeliness of the 2nd dose was lower, with 40% and 64% receiving the dose within 1 or 2 months, of the recommended date, respectively. The timeliness of the booster dose can't be fully evaluated because data were only available for 3 months after the recommended date, but most children who were vaccinated by age 12 months were vaccinated within 1–2 months of the recommended age (*Figure 4*).

Discussion

These analyses provide important information on the extent to which PCV is reaching infants in rural India. A large proportion of the children captured in the database received their two primary doses of the vaccine. However, receipt of the booster dose within 3 months of the recommended date was suboptimal in most of the regions, and this trend mirrors findings seen for the measles vaccine with the same scheduled due date. Potential demand-side reasons for this dropoff might include a lack of health awareness among primary caregivers and a deviation in the monthly pattern of vaccinations within the first four months.

The majority of the benefit of PCVs is attributed to reductions in transmission (indirect protection)⁸. The booster dose is particularly important in reducing the prevalence of vaccine-targeted serotypes among the healthy children who carry pneumococcus and in maintaining long-lasting memory

responses^{9,10}. Therefore, improving uptake and timeliness of the booster dose in this population should be a priority.

The ability to evaluate variations in uptake at a local scale is enabled by the Khushi Baby system. We found substantial variations between the regions in the receipt of the 2nd and 3rd doses, and this information could be used to prioritize efforts to increase uptake in target populations. A possible decline in uptake during the winter months may be attributed to the overlap with the kharif harvest and festive season. Future work will explore how automated, targeted voice call reminders in the local dialect, already in place for other vaccines within the Khushi Baby system, could be used to decrease the drop out in PCV in combination with boots-on-the-ground campaigns.

Disruptions related to the COVID-19 pandemic influenced vaccination rates in the first two quarters of 2020. This is evident from the decline in children born near June 2019 receiving the booster dose of PCV (*Extended data: Figure S1*⁷). There was a nationwide lockdown from March 19, 2020 to June 30 2020, which resulted in suspension of vaccination camps. Normal activity of VHND camps resumed by July 2020. If children ultimately received their booster dose but received it after 12 months of age, we would not have captured it in our database.

There are important limitations to these data. First, we only capture 30% of the children in this region, who might not reflect the vaccination coverage in the broader population. The actual immunization rates could be lower if our sample is biased towards people who are seeking healthcare. Likewise, the uptake of the first dose is likely biased upwards because these are children who have initiated contact with the health-care system at a vaccination camp. Second, when there is no record of a child receiving subsequent doses, it is not clear if this child truly missed their vaccine, received the vaccine elsewhere and was not recorded, or moved out of the area (lost

Figure 4. Timeliness of the 3 doses of PCV received by 12 months of age. The red line denotes the target age for receiving the dose. Only children receiving the vaccine in 2019 and 2020 are shown.

to follow up). Nonetheless, these data are of a higher quality and reliability, and are more complete than alternative data sources for this population⁵.

In conclusion, we have demonstrated the ability of a digital health platform to track the introduction of a high-priority vaccine into a rural area of India. These data and analyses highlight areas where public health practitioners could target interventions to improve the implementation of the vaccine program.

Data availability

Underlying data

These data are comprised of individual health records, including dates of medical visits and birth date. Therefore, only aggregate data can be shared. Data can be requested from the Khushi Baby data committee via email to admin@khushibaby.org

Analysis code is available from: <https://github.com/weinbergerlab/kb-pcv>

Archived analysis code as at time of publication: <http://doi.org/10.5281/zenodo.4265328>¹¹

License: Apache-2.0 License

Extended data

Figshare: PCV Vaccine Uptake in Rajasthan Extended Data, <https://doi.org/10.6084/m9.figshare.13573877.v1>⁷

This project contains the following extended data:

- Supplementary Figure 1. Percent of children who have received 1 dose (black), 2 doses (blue) or 3 doses (red) of PCV by 12 months of age as of October 20, 2020, by month of birth.
- Supplementary Figure 2. Percent of children receiving 1, 2, or 3 doses of pentavalent vaccine (dose=1,2,3), or the first measles dose (dose=4) by age in months.
- Supplementary Figure 3. Percent of children who have received 1 dose (black), 2 doses (blue) or 3 doses (red) of pentavalent vaccine; or 1 dose of measles vaccine (gray) as of October 20, 2020, by month of birth.

License: Apache-2.0 License

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Open Peer Review

Current Peer Review Status: ? ?

Version 1

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Brian Wahl

Department of International Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA

The authors provide estimates of PCV coverage in a rural area of Rajasthan using a new mobile health tool that tracks immunization coverage. This is important since reliable vaccine coverage data from rural India are often not available. The authors suggest that the strength of this analysis lies in access to higher quality, more complete data on vaccine coverage. I commend the authors for this analysis and this difficult undertaking. However, I maintain some concerns around the conclusions that are inferred from this analysis; largely attributable to the completeness of data and the possible biases introduced. All together though, it provides helpful descriptive data for PCV rollout in India. I have included some comments below.

Major points:

- In the results, the authors state that the “rate of reporting varies between different Auxiliary Nurse Midwives”. They note that they assume each ANM on average reports half of the patients who turn up to a given maternal health camp. I find this a bit confusing and should be clarified further. First, I would not characterize children as patients. It might be more appropriate to call them beneficiaries. However, the more important point relates to whether the researchers are aware of what proportion of children are indeed captured in their system. If they are aware that they differ by ANMs, it would be good to present these data disaggregated by administrative region. If not, the authors need to provide a justification for their assumption regarding the proportion of ANMs that report beneficiaries. To me, this could be a significant source of bias within this study and therefore needs further contextualization. And given that it could differ by administrative region for a multitude of reasons, the bias could be differential by stratification thereby complicating comparisons between regions, as is done in Figure 3.
- The authors note in the conclusion that their data is of higher quality and reliability than alternative data sources for this population. The reference provided is a report authored by the same researchers. I do not doubt that their data is of higher quality. However, it would

be important to provide additional details here rather than just link to the report.

Minor points:

- In the results section, the authors state: “there were 10,202 children born on or after March 1, 2018, which includes the first group of children who received PCVs at a high rate.” This is unclear. Is this the first time the vaccine was available? Or just the first coverage reached a certain level? What is “high rate”? As a small side note, coverage is not technically a “rate”.
- Table 1 could be made clearer by including the proportion of children residing in each of the administrative regions.
- In the first paragraph of “uptake of primary and booster doses”, it is unclear how many children received the first dose of PCV. Was it 99%? Or >96% as stated toward the end of the page. Shouldn't the latter just be a weighted average of each region and therefore the same as the overall average? This is confusing.
- The lockdown began on 25 March, not on 19 March. There was a national curfew on 22 March.

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?

Yes

If applicable, is the statistical analysis and its interpretation appropriate?

Not applicable

Are all the source data underlying the results available to ensure full reproducibility?

No

Are the conclusions drawn adequately supported by the results?

Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Infectious disease epidemiology, immunization

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 11 February 2021

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Lorine P. Pelly

University of Manitoba, Winnipeg, MB, Canada

The article looks at the roll-out of PCV13 in 5 blocks of Udaipur district. It uses data from a digital health platform that allows tracking of health data for individual children to understand components of uptake. Overall this is a methodologically sound manuscript that emphasizes the important role for individual digital health records in identifying where the gaps in immunization are and improving coverage. The major limitations were addressed by the authors in the paper.

I have a few suggestions for the authors to consider that I've grouped under major and minor issues.

Major:

- Discussion
 - The paper that is cited about indirect transmission being the major benefit is from an analysis looking at the addition of PCV13 to a long-standing PCV7 program. The scenario in Udaipur is different in that PCV is being introduced to a vaccine-naïve population.
 - I suspect that it is unlikely that the Government of India or large states would take up a stand-alone digital platform such as Khushi baby. However, there is clear movement towards integrated digital health solutions as outlined in the National Digital Health Blueprint and several state-specific documents including individual level medical records. This means that there is the opportunity to understand the features of Khushi baby that make this kind of analysis (coverage – including geographic, completion and timeliness) possible in routine monitoring.

Minor:

- Background
 - I would suggest using *Streptococcus pneumoniae* at least one before using pneumococcus.
 - I would mention the PCV being implemented in India is the 13-valent vaccine and the schedule used is 6 weeks, 14 weeks and 9 months.
 - PCV13 prevents pneumococcal disease by serotypes covered by the vaccine which is the majority of those causing invasive disease but a little less so for pneumonia (especially when looking at more than just severe pneumonia).
- Data availability
 - Raw data is not available but the reasons are clear and valid. Strong efforts were made to share the analytic coding so that these types of data could be reanalysed in the same way.

Is the work clearly and accurately presented and does it cite the current literature?

Partly

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?

Yes

If applicable, is the statistical analysis and its interpretation appropriate?

Yes

Are all the source data underlying the results available to ensure full reproducibility?

Partly

Are the conclusions drawn adequately supported by the results?

Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Clinical pediatric infectious diseases, child health public health programming, implementation science

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.