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Optical scanning of the 'Mother and Child Protection Card' to improve routine immunization in India: the Tika Vaani platform

Submission date 22/07/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/07/2019	**Overall study status** Completed	
Last Edited 06/01/2022	**Condition category** Other	

Plain English summary of protocol

Current plain English summary as of 17/11/2020:

Background and study aims
Immunization is one of the most successful and cost-effective health interventions and is estimated to prevent between 2 and 3 million deaths annually worldwide. Immunization coverage in India has improved in recent years but an estimated 1 in 7 children in India do not receive immunization. Reaching these populations requires more effective immunization systems, and these in turn require improved immunization data. Immunization data in India is currently not available in high quality, at the right time and in the right place to support system decision making. Currently, the Mother and Child Protection (MCP) card immunization record is filled out by the ANMs at the point of service (usually, the local Village Health and Nutrition Day (VHND)), but entry of immunization data occurs offline, at the Primary Health Centre (PHC), with delays. New systems for data collection involving tablet computers are planned, but manual data entry poses important challenges for these health workers. Without timely and accurate data, vaccine supply and demand prediction suffer, leading to poorer coverage and follow-up of immunization.

Who can participate?
This study will take place in Uttar Pradesh, a north Indian state with poor health and development indicators. Two administrative blocks from a lagging district were identified for the study based on low immunization performance, inputs from local government authorities and sample size requirements (reflecting the number of health workers and immunization microplanning areas). A sample of immunization microplanning areas will be identified in each block. In these areas, we will recruit all frontline workers (ANM, ASHA, AWW) involved in delivery of immunization services. In the pre-intervention phase, we also recruited all families and primary caregivers (usually mothers) of children 0 to 23 months of age.

What does the study involve?
We have developed an application to help frontline workers equipped with a mobile smartphone in their tasks, which will ultimately help to strengthen immunization planning and other services

for beneficiaries. This mobile phone application will change the way that immunization and health data collected by the health workers are recorded and used. The new mobile phone application will collect immunization data in real time at point-of-service using image-recognition technology ("optical scanning"). The new system will also enable direct communication with beneficiaries to offer information about immunisation services and appointment reminders. The new system is known as "Tika Vaani" ["vaccine voice" in Hindi].
We will conduct a controlled before-and-after (CBA) study in which one administrative block receives the optical scanning intervention and one administrative block serves as a control group and does not receive the intervention. Observations will be made before and after the implementation of the optical scanning intervention in intervention and control areas.
We will study outcomes related to routine immunization performance, including health worker time allocation, costs of intervention delivery, data quality, equity and timeliness of vaccination, and missed opportunities for vaccination. We will also conduct a process evaluation to identify any barriers to success and areas for improvement.

What are the possible benefits and risks of participating?
There are no disadvantages or risks to participating in the study beyond those encountered in everyday life. Participants will not gain any personal benefit from participating in this study. Through this research, we hope to learn more about how to improve the performance of immunisation services. This will contribute to improved coverage, timeliness and completeness of immunization -- and ultimately, to improved health and well-being -- for currently left out individuals and communities.

Where is the study run from?
This study is run by OnionDev Technologies Pvt Ltd (Gram Vaani), headquartered in Gurgaon, India.

When is the study starting and how long is it expected to run for?
The study is expected to start on August 15, 2019 and run for 12 months. The anticipated end date is September 1, 2020. The study was interrupted due to the COVID-19 pandemic and lockdown in India. The new anticipated end date is June 1, 2021.

Who is funding the study?
This study is funded by the Government of India via the Department of Biotechnology (DBT) Biotechnology Industry Research Assistance Council (BIRAC) and the Bill & Melinda Gates Foundation.

Who is the main contact?
Dr. Aaditeshwar Seth
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Previous plain English summary:

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systems, and these in turn require improved immunization data. Immunization data in India is currently not available in high quality, at the right time and in the right place to support system decision making. Currently, the Mother and Child Protection (MCP) card immunization record is filled out by the ANMs at the point of service (usually, the local Village Health and Nutrition Day (VHND)), but entry of immunization data occurs offline, at the Primary Health Centre (PHC), with delays. New systems for data collection involving tablet computers are planned, but manual data entry poses important challenges for these health workers. Without timely and accurate data, vaccine supply and demand prediction suffer, leading to poorer coverage and follow-up of immunization.

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Associate Professor of Computer Science, Indian Institute of Technology (IIT), Delhi
aseth@gramvaani.org

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Additional identifiers

Protocol serial number
20190718protocol

Study information

Scientific Title
Image recognition based data entry processes to ensure immunization completeness and auditing of reported data: the Tika Vaani platform

Study objectives
Current hypothesis as of 17/11/2020:

We will study the effects on India's routine immunization system of introducing a new technology platform (Tika Vaani) for health workers to collect immunization data in real time at point-of-service using image-recognition technology via mobile phone. The image-recognition technology is linked to an interactive voice-response system for direct communication with beneficiaries and will make data immediately available to facilitate system planning and tailored interventions.

We hypothesize that introduction of this new technology will contribute to improved performance of routine immunization (RI) services for children 0 to 23 months of age.

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Previous hypothesis:

We will study the effects on India's routine immunization system of introducing a new technology platform (Tika Vaani) for health workers to collect immunization data in real time at point-of-service using image-recognition technology via mobile phone. The image-recognition technology is linked to an interactive voice-response system for direct communication with beneficiaries and will make data immediately available to facilitate system planning and tailored interventions.

We hypothesize that introduction of this new technology will contribute to improved performance of routine immunization (RI) services and improved coverage, timeliness and completeness of immunization among children 0 to 23 months of age.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/08/2019, Institutional Committee for Ethics and Review of Research, OnionDev Technologies Pvt. Ltd. (Building No. 346, 1st Floor, Udyog Vihar Phase II, Near People Chowk, Gurgaon - 122016, India; contact@oniondev.com; +91 (0)124-4303248), ref: n/a

Primary study design
Interventional

Study design
A quasi-experimental intervention study using a controlled before-and-after (CBA) design

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Child immunization

Interventions
Current interventions as of 17/11/2020:

Frontline health workers (assistant nurse midwives, or “ANMs”) equipped with a mobile smart phone will collect immunization data in real time at immunization sessions. The easy-to-use Tika Vaani mobile phone application scans the Mother and Child Protection card immunization record using optical character recognition (OCR) methods. Its aim is to reduce burdensome paper-based documentation and increase the availability of actionable information at the point of care.

Observations will be made at multiple time points before and after the implementation of the optical scanning intervention, both in a group that receives the intervention and in a control group that does not. Data will be analyzed using the differences-in-differences (DiD) method.

The study will emulate a target trial in which the intervention group receives the multicomponent Tika Vaani optical scanning intervention. The intervention is designed to support the delivery of routine immunisation services in India. The control group will be defined as eligible to receive the intervention but not in receipt of it. Members of the control group will receive the usual services offered by the Government of India.

The study will take place in poor-performing administrative blocks (each of approximately 200,000 population) in a rural area of Uttar Pradesh. Study blocks will be assigned to either intervention or control group by government officials.

The Tika Vaani optical scanning intervention has three main components:
1. Functionalities for data collection, guidance on vaccination timing and session planning (directed to health workers (ANMs, ASHAs))
2. Beneficiary communication (directed to caregivers of children 0 to 23 months of age))
3. Availability of data for real-time planning & course correction (directed to health systems managers & planners – not a focus of this study phase)

Data collection and follow-up:
1. ANMs in the intervention group will use the new Tika Vaani mobile phone application for data collection and work planning at all immunization sessions during the 6-month intervention period (comprising the 2-month intervention introduction and the 4-month post-intervention periods). ANMs will be followed over the entire study period (encompassing the 4-month pre-intervention period, 2-month intervention introduction period, and the 4-month post-intervention period). ASHA (community health) workers present at each immunisation session will also provide data. Each ASHA workers is expected to be observed only once during the study.
2. Beneficiaries (caregivers of children 0-23 months of age) in the intervention group will be contacted via mobile phone during the 6-month intervention period for two purposes: (1) to remind families about vaccination appointments; (2) to provide additional information post-vaccination. Each pre-immunisation and post-immunisation contact will take less than 2 minutes.

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Previous interventions:

Frontline health workers (assistant nurse midwives, or “ANMs”) equipped with a mobile smart phone will collect immunization data in real time at immunization sessions. The easy-to-use Tika Vaani mobile phone application scans the Mother and Child Protection card immunization record using optical character recognition (OCR) methods. Its aim is to reduce burdensome paper-based documentation and increase the availability of actionable information at the point of care.

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2. Beneficiaries (caregivers of children 0-23 months of age) in the intervention group will be contacted via mobile phone during the 6-month intervention period for two purposes: (1) to remind families about vaccination appointments; (2) to provide additional information post-vaccination. Each pre-immunisation and post-immunisation contact will take less than 2 minutes.

Intervention Type
Device

Phase
Phase II

Primary outcome(s)

Current primary outcome measure as of 18/11/2020:

1. Average time to vaccinate per beneficiary (for health workers) defined as the total time spent by frontline workers in each vaccination-related activity for the Village Health and Nutrition Day (VHND) (including activities undertaken during the observed immunisation session and the non-observed activities pre- and post-session), divided by the number of beneficiaries (children 0-23 months of age vaccinated at that session). The total time spent by frontline workers will be the sum of the time spent by the ANM and the ASHA worker. The variable will be measured through non-participant observation of the immunisation session by field staff using a structured questionnaire. Each immunisation session takes place on a single day and lasts for approximately 6 hours. Each ANM will be observed 3 times in the 4-month pre-intervention period and 3 times in the 4-month post-intervention period
2. Immunization dropout from receipt of the first dose to the third dose of pentavalent vaccine (among children eligible for vaccination). Child vaccination status will be measured through a household survey questionnaire. During the household survey, vaccination data will be taken from the immunisation card, or, in the absence of the card, by caregiver report. Each household will be surveyed only once, either in the 4-month pre-intervention period, or the 4-month post-intervention period

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Previous primary outcome measure:

1. Average time to vaccinate per beneficiary (for health workers) defined as the total time spent by frontline workers in each vaccination-related activity for the Village Health and Nutrition Day (VHND) (including activities undertaken during the observed immunisation session and the non-observed activities pre- and post-session), divided by the number of beneficiaries (children 0-23 months of age vaccinated at that session). The total time spent by frontline workers will be the sum of the time spent by the ANM and the ASHA worker. The variable will be measured through non-participant observation of the immunisation session by field staff using a structured questionnaire. Each immunisation session takes place on a single day and lasts for approximately 6 hours. Each ANM will be observed 3 times in the 4-month pre-intervention period and 3 times in the 4-month post-intervention period.
2. Immunization dropout from receipt of the first dose to the third dose of pentavalent vaccine (among children eligible for vaccination). Child vaccination status will be measured through a household survey questionnaire. During the household survey, vaccination data will be taken from the immunisation card, or, in the absence of the card, by caregiver report. Each household will be surveyed only once, either in the 4-month pre-intervention period, or the 4-month post-intervention period.

Key secondary outcome(s)

Current secondary outcome measures as of 17/11/2020:

1. Process outcomes including intervention fidelity, health worker acceptability, uptake and satisfaction, beneficiary acceptability, uptake, satisfaction, trust , and quality of care will be collected using quantitative methods (non-participant observation, structured questionnaires, linkage to administrative data) and qualitative methods (key informant interviews and focus groups with government officials, health workers, beneficiaries, and field staff; community meetings). Quantitative measures will be collected continuously over the entire study period (encompassing the 4-month pre-intervention period, 2-month intervention introduction period, and the 4-month observation period). Qualitative interviews will be conducted at study end line
2. Missed opportunities for vaccination (MOV), defined as any contact with health services by an

individual (child or person of any age) who is eligible for vaccination (e.g. unvaccinated or partially vaccinated and free from any contraindications to vaccination), but does not result in the person receiving one or more of the vaccine doses for which he or she is eligible. Data will be collected continuously over the entire study period (encompassing the 4-month pre-intervention period, 2-month intervention introduction period, and the 4-month observation period)
3. Measures of data quality [including agreement (overall, PPA positive percent agreement; NPA negative percent agreement), sensitivity, specificity, positive and negative predictive value, and coverage percentage point difference when subtracting the MCP vaccination record from a source designated as the reference standard] will compare household survey and administrative data. Data will be collected continuously over the entire study period (encompassing the 4-month pre-intervention period, 2-month intervention introduction period, and the 4-month observation period)
4. Intervention costs from the health care payer and societal perspectives. Data will be collected continuously over the entire study period (encompassing the 4-month pre-intervention period, 2-month intervention introduction period, and the 4-month observation period)
5. Performance indicators for routine vaccination [Immunization coverage % for each individual vaccine in the routine schedule, % full immunization, % dropout (BCG to MCV1 and MCV2), equity of vaccination coverage (poverty, education), timely vaccination (cumulative days undervaccinated), breadth of protection, integrated health service delivery, missed opportunities for vaccination] will be constructed using household survey and administrative data. Data will be collected continuously over the entire study period (encompassing the 4-month pre-intervention period, 2-month intervention introduction period, and the 4-month observation period)

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Previous secondary outcome measures:

1. Process outcomes including intervention fidelity, health worker acceptability, uptake and satisfaction, beneficiary acceptability, uptake, satisfaction, and trust will be collected using quantitative methods (non-participant observation, structured questionnaires, linkage to administrative data) and qualitative methods (key informant interviews and focus groups with government officials, health workers, beneficiaries, and field staff; community meetings). Quantitative measures will be collected continuously over the entire study period (encompassing the 4-month pre-intervention period, 2-month intervention introduction period, and the 4-month post-intervention period). Qualitative interviews will be conducted in months 11 and 12 (study end line)
2. Measures of data quality [including agreement (overall, PPA positive percent agreement; NPA negative percent agreement), sensitivity, specificity, positive and negative predictive value, and coverage percentage point difference when subtracting the MCP vaccination record from a source designated as the reference standard] will compare household survey and administrative data. Data will be collected continuously over the entire study period (encompassing the 4-month pre-intervention period, 2-month intervention introduction period, and the 4-month post-intervention period)
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Completion date
25/04/2021

Eligibility

Key inclusion criteria
1. Study clusters are immunisation microplan areas located in a selected block of Hardoi district, UP. Immunisation microplan areas have defined geographic boundaries and a population of approximately 1000 inhabitants; these catchment areas constitute the basis for immunisation session planning (Village Health and Nutrition Days). A sample of immunization microplanning areas will be identified in each block.
2. In selected areas, we will recruit all frontline workers (ANM, ASHA, AWW) involved in delivery of Village Health and Nutrition Days and associated immunization services.
3.In selected areas, we will recruit all families and primary caregivers (usually mothers) of children 0 to 23 months of age

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
10183

Key exclusion criteria
1. The study will exclude villages of more than 4000 inhabitants.
2. There are no exclusion criteria for health workers
3. We will exclude caregivers of children not able to understand and speak Hindi or Urdu

Date of first enrolment
15/08/2019

Date of final enrolment
25/04/2021

Locations

Countries of recruitment
India

Study participating centre
OnionDev Technologies Pvt Ltd (Gram Vaani)
1st floor, Plot 346

Udyog Vihar II Rd
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Sector 20
Gurgaon
India
122016

Sponsor information

Organisation
OnionDev Technologies Pvt Ltd (Gram Vaani)

Funder(s)

Funder type
Government

Funder Name
Department of Biotechnology , Ministry of Science and Technology

Alternative Name(s)
Dept. of Biotechnology, Govt of India, , , Department of Biotechnology, Department of Biotechnology, Ministry of Science & Technology, India, Department of Biotechnology, GOI, Dept. of Biotechnology, Govt. of India, Department of Biotechnology, Ministry of Sc & Tech, Govt of India, DBT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
India

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes