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A cluster-randomised trial of a multifaceted intervention to promote child vaccination and linkage to social protection schemes

Submission date
26/06/2024

Recruitment status
Stopped

Registration date
26/06/2024

Overall study status
Stopped

Last Edited
28/10/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The Immunization Agenda 2030 (IA2030) is a flagship global immunisation strategy for the decade 2021-2030. Extending immunisation services to regularly reach children who are under-immunised (not fully vaccinated) and zero-dose (those who do not receive basic vaccines delivered through the routine immunisation system), with a focus on underserved subnational geographies, is a cornerstone of IA2030. This strategy is seen as a potential game-changer for child survival and flourishing because it offers a critical window for "first contact", which can be leveraged to extend the reach of immunisation systems to deliver full vaccination and other services to those who are currently excluded, with an emphasis on primary health care (PHC).
In a high-needs geography in Uttar Pradesh, India, we aim to study whether a multifaceted intervention operating in high-priority "missed" communities (home to clusters of zero-dose and under-immunised children) that promotes child vaccination and linkage to basic health and non-health services will increase child vaccination, as compared to usual services.

Who can participate?
In communities selected to receive the interventions, the interventions will be offered community-wide and all adult (18 or more years of age) residents (all genders) will be eligible to participate. Communities will be selected to receive the interventions if (1) they are located in a catchment area of a health sub-centre assigned to the intervention group, (2) they are designated as a possible "missed community" (low immunisation area), and (3) consent is received from community gatekeepers (local elected officials with territorial responsibility, such as the Pradhan (mayor)).
On the service delivery side, all frontline health workers (ANM, ASHA) in the intervention group with territorial responsibility for a community selected to receive the interventions will be included in the field interventions.

What does the study involve?
The VIKAS study interventions are designed to increase overall vaccination coverage through an equity-oriented strategy focussing on high-priority areas (local pockets of low immunisation, or "missed communities" with high proportions of under-vaccinated and zero-dose children).

To support the health system in reaching high-priority communities, households, and children, the multicomponent intervention will be delivered to (all and only) areas identified as low performing, located within the catchment areas of health sub-centres assigned to the intervention group. Intervention components include:
1. Situation analysis - a rapid data collection to assess local vaccination status, local causes of under-vaccination, and access to a range of services and entitlements for health and social welfare.
2. Delivery of core interventions for community-based promotion of child vaccination and linkage to basic health and non-health services: Delivered to all identified low-immunisation areas, elements include community information meetings to share information on social welfare entitlements and a wide range of health benefits, including vaccination, and guidance on how to access benefits through local agents with the mandate to help beneficiaries apply for services (ASHA, JSK, Panchayat Sahayak), and digital communications supports (interactive voice response (IVR), Whats app bot) via mobile phone.
3. Knowledge exchange - Data and insights will be used to improve the health system-community interface, promote locally tailored, context-specific interventions, and advocate for community needs. Insights and results from the interventions will be shared with the relevant government officials and frontline workers on a monthly basis.
4. Intervention tailoring - following delivery of core interventions, communities may receive additional interventions from the above components, tailored to their needs.

The control group will be defined as eligible to receive the intervention but not in receipt of it. The control group will receive the usual services offered by the Government of India and partners. These include standard vaccination services, including community mobilisation for vaccination and vaccination delivery, and standard access to social welfare and health rights and entitlements.

Parallel cross-sectional surveys measuring child vaccination and household awareness of and access to health and non-health services and entitlements will be used for pre-post evaluation.

What are the possible benefits and risks of participating?
There are no risks to participants' health or safety beyond those routinely encountered in daily life.

Where is the study run from?
The study is managed by Gram Vaani (OnionDev Pvt Ltd) (India)

When is the study starting and how long is it expected to run for?
July 2016 to December 2025

Who is funding the study?
The study is funded by the Canadian Institutes for Health Research and the Bill and Melinda Gates Foundation.

Who is the main contact?
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Contact information

Type(s)
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Version_20240801

Study information

Scientific Title

A cluster-randomised 12-month, parallel arm, superiority trial of a multifaceted intervention to promote child VaccInation and linKage to sociAl protection Schemes (VIKAS) versus usual services on vaccination uptake among children 12 - 23 months

Acronym
VIKAS

Study objectives
A multifaceted intervention operating in high-risk "missed" communities (those with a high prevalence of zero-dose and under-immunised children) that promotes child vaccination and linkage to basic health and non-health services will increase child vaccination, as compared to usual services.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 18/12/2022, The Institutional Committee for Ethics and Review of Research (ICER) OnionDev Technologies, New Delhi, India (Plot No 2, First Floor, 100 Feet Road, Ghitorni, MG Road, New Delhi, 110030, India; +91 9211761369; contact@gramvaani.org), ref: #OTPL/ ICER/006 /1

2. approved 11/01/2017, Comité d'éthique de la recherche du CHUM (Pavillon R, 900 rue St-Denis, 3e étage, Montreal, H2X 0A9, Canada; +1 514 890-8000 poste 14485; ethique.recherche.chum@ssss.gouv.qc.ca), ref: 16.084

Study design
Single-centre interventional pragmatic cluster-randomized parallel two-arm repeated pre and post cross-sections open superiority trial with blinding of outcomes assessors and data analysts

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of vaccine-preventable diseases in children

Interventions
Current interventions as of 14/10/2024:

The VIKAS study is a pragmatically oriented trial, designed to demonstrate the effectiveness of the interventions in real-world conditions. The interventions are designed to increase overall vaccination coverage through an equity-oriented strategy focussing on high priority areas (local pockets of low immunisation, equivalent to "missed communities" with high proportions of under-vaccinated and zero-dose children). In high priority areas (missed communities), the study interventions promote immunisation while also linking communities to other health and non-health services offered by the Government of India.

Eligible health sub-centres will be randomised in equal (1:1) proportions to the control (usual care) or intervention groups using a computer-generated random allocation sequence. The intervention group will receive the multicomponent VIKAS intervention designed to strengthen delivery of routine immunisation services with a focus on missed communities with high proportions of under-vaccinated and zero-dose children. The control group will be defined as eligible to receive the VIKAS intervention but not in receipt of it. The control group will receive the usual services offered by the Government of India and partners.These include standard vaccination services, including community mobilisation for vaccination and vaccination delivery, and standard access to social welfare and health rights and entitlements.To support the health system in reaching high-priority communities, households, and children, interventions will be delivered to (all and only) areas identified as low performing, located within the catchment areas of health sub-centres assigned to the intervention group.

The interventions will be delivered over 9 months and involve four major components:

1. Situation analysis: a rapid assessment of local vaccination status, local causes of under-vaccination, and access to a range of services and entitlements for health and social welfare. The data will be used to better understand local needs and to inform future intervention planning
2. Core interventions to promote child vaccination and linkage to basic health and non-health services: Delivered to all identified low-immunisation areas, components include:
- Community mobilisation activities to share information, create awareness and generate demand for vaccination, and other health and non-health rights and entitlements.
- Digital technologies for two-way communication on information and educational entertainment (edutainment) on vaccination and other services via any (simple or smart) mobile phone. Access to digital technologies is free of cost to the end users.
3. Knowledge Exchange: Data and insights will be used to improve the health system-community interface, promote locally tailored, context-specific interventions, and advocate for community needs. Insights and results from the interventions will be shared with the relevant government officials on a monthly basis. As required, the field team will engage with frontline health workers to discuss issues and possible solutions, and build capacity. Information sharing processes will be low-burden and designed to integrate with existing system channels.
4. Intervention tailoring: following delivery of core interventions, communities may receive additional interventions from the above components, tailored to their needs. Communities are allocated to one of four tracks: no further intervention, demand (additional component #2), supply (additional #3), or mixed (additional #2 & 3).

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Previous interventions:

The VIKAS study is a pragmatically oriented trial, designed to demonstrate the effectiveness of the interventions in real-world conditions. The interventions are designed to increase overall vaccination coverage through an equity-oriented strategy focussing on high priority areas (local pockets of low immunisation, equivalent to "missed communities" with high proportions of under-vaccinated and zero-dose children). In high priority areas (missed communities), the study interventions promote immunisation while also linking communities to other health and non-health services offered by the Government of India.

Eligible health sub-centres will be randomised in equal (1:1) proportions to the control (usual care) or intervention groups using a computer-generated random allocation sequence. The intervention group will receive the multicomponent VIKAS intervention designed to strengthen delivery of routine immunisation services with a focus on missed communities with high

proportions of under-vaccinated and zero-dose children. The control group will be defined as eligible to receive the VIKAS intervention but not in receipt of it. The control group will receive the usual services offered by the Government of India and partners.These include standard vaccination services, including community mobilisation for vaccination and vaccination delivery, and standard access to social welfare and health rights and entitlements.To support the health system in reaching high-priority communities, households, and children, interventions will be delivered to (all and only) areas identified as low performing, located within the catchment areas of health sub-centres assigned to the intervention group.

The interventions will be delivered over 12 months and involve four major components:

1. Situation analysis: a rapid assessment of local vaccination status, local causes of under-vaccination, and access to a range of services and entitlements for health and social welfare. The data will be used to better understand local needs and to inform future intervention planning
2. Core interventions to promote child vaccination and linkage to basic health and non-health services: Delivered to all identified low-immunisation areas, components include:
- Community mobilisation activities to share information, create awareness and generate demand for vaccination, and other health and non-health rights and entitlements.
- Service linkage camps: in which consenting community members are screened for eligibility for almost 60 social welfare entitlements and a wide range of health benefits, including vaccination, made aware of their rights and entitlements, and offered support in accessing benefits.
- Digital technologies for two-way communication on information and educational entertainment (edutainment) on vaccination and other services via any (simple or smart) mobile phone. Access to digital technologies is free of cost to the end users.
3. Knowledge Exchange: Data and insights will be used to improve the health system-community interface, promote locally tailored, context-specific interventions, and advocate for community needs. Insights and results from the interventions will be shared with the relevant government officials on a monthly basis. As required, the field team will engage with frontline health workers to discuss issues and possible solutions, and build capacity. Information sharing processes will be low-burden and designed to integrate with existing system channels.
4. Intervention tailoring: following delivery of core interventions, communities may receive additional interventions from the above components, tailored to their needs. Communities are allocated to one of four tracks: no further intervention, demand (additional component #2), supply (additional #3), or mixed (additional #2 & 3).

Intervention Type
Other

Primary outcome(s)
The mean number (count) of government-recommended first year of life vaccine doses received by children 12 to 23 months of age at study end line measured using patient records

Key secondary outcome(s))
1. The (binary) proportion of vaccine received at study end line for children 12 to 23 months measured using patient records
2. The (binary) proportion of age-appropriate vaccine received at study end line, for children 0 to 11 months measured using patient records

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Communities:
1.1. Located in a catchment area of a health sub-centre assigned to the intervention group,
1.2. Designated as possible "missed community" (low immunisation area), and
1.3. Consent is received from community gatekeepers (local elected officials with territorial responsibility, such as the Pradhan (mayor)).
2. All adult (>18 years of age) participants in communities selected to receive the intervention will be eligible to participate
3. All frontline health workers in the intervention group with territorial responsibility for a community selected to receive the interventions will be included in the field interventions.
4. Participants in the baseline and end line cross-sectional household surveys are primary caregivers (usually mothers) and other adult (over age 18 years) family members of immunisation-age (0 to 23 months) children. Participants are eligible for inclusion in the household surveys if they reside in a study cluster (rural health sub-centre) catchment area and in an immunisation microplan area designated as a possible low immunisation area, and provide written informed consent. We will exclude those not able to understand and speak Hindi or Urdu.

Participant type(s)
Health professional, Resident

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Participation in Interventions: None.
2. Participation in data collection: We will exclude those not able to understand and speak Hindi or Urdu. Based on our experience, in this district, this criterion would result in exclusion of less than 1% of respondents.

Date of first enrolment
15/07/2024

Date of final enrolment
15/12/2024

Locations

Countries of recruitment
India

Study participating centre
OnionDev Technologies Pvt Ltd (Gram Vaani)
Plot No 2, First Floor, 100 Feet Road, Ghitorni, MG Road
New Delhi
India
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Sponsor information

Organisation
Canadian Institutes of Health Research

ROR
https://ror.org/01gavpb45

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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 datasets generated during and/or analysed during the current study are not expected to be made available due to Government of India policies concerning data access. Specific requests for access will be considered on a case-by-case basis.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Information Consent Form Individual Interview Adult (in Hindi) version 1		28/06/2024	No	Yes
Participant information sheet	Information Consent Form Village representative_survey_(in Hindi) version 1		28/06/2024	No	Yes