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Improving immunization coverage in urban slums in Indonesia

Submission date
25/03/2019

Recruitment status
No longer recruiting

Registration date
30/04/2019

Overall study status
Completed

Last Edited
25/04/2019

Condition category
Infections and Infestations

[_] 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 Provincial Health Office of Jakarta and UNICEF have been jointly implementing the Reaching Every Community (REC) Program in select Jakarta slums since 2019. The program employs mobile technologies to connect urban slum communities to nearby public health services. The aim of this study is to assess the impact of the REC program by comparing the changes in immunization coverage in slum areas receiving the intervention compared to matched communities not receiving the intervention, over the course of about one year.

Who can participate?
Children living in the intervention communities and matched control communities, between 12 and 23 months of age, along with one caregiver of any/all demographic categories (age, sex, etc)

What does the study involve?
The intervention consists of the following elements:
1. Registration of newborns: Community Health Workers (CHWs) use SMS to register babies 0-11 months old, along with the mobile numbers of caregivers
2. Personalized reminders: personalized vaccination reminders are sent to caregivers according to the child's vaccine schedule with notifications of upcoming vaccination sessions
3. Rapid Card Checks: quarterly micro-surveys of 12-23 month olds in each local area are conducted to assess levels of immunization coverage
4. Feedback to managers: Health managers and providers receive quarterly feedback on all aspects program performance in their areas which supports local planning and system improvements.
Immunization coverage is compared between target communities and matched comparison communities before the intervention and about one year later. In addition, focus group discussions and interviews are carried out in the target communities towards the end of the intervention period.

What are the possible benefits and risks of participating?
Participants will benefit from receiving personalized vaccination schedule reminders via SMS.

Community Health Workers have been trained on how to mitigate the potential risk that a caregiver receives reminders for a deceased child, which will be done by reporting the child's death to the SMS system to stop the automated reminders.

Where is the study run from?
The study will take place in 46 slum communities (administrative unit called RW) in North, East and West Jakarta; 23 of which will receive the intervention and 23 of which will be the control sites to compare the intervention sites to.

When is the study starting and how long is it expected to run for?
August 2017 to May 2019

Who is funding the study?
This study was funded by UNICEF Indonesia through funding received directly from the Pfizer Foundation

Who is the main contact?
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Type(s)
Public

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Additional identifiers

Protocol serial number
001

Study information

Scientific Title
Assessing the impact of mobile phone based platform for immunization reminders and microplanning on vaccination coverage in urban slums: a cluster randomized trial

Study objectives
This study hypothesizes that caregiver newborn enrollment to an SMS based immunization reminder system to improve demand and enhance micro-planning will increase levels of immunization coverage among 12-23-month-old children in vulnerable urban slum communities relative to matched comparison communities not receiving the intervention over the course of approximately one year.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/08/2017, University of Indonesia Ethics Review Board (Komite Kaji Etik Fakultas Kesehatan Masyarakat Universitas Indonesia, Building A, 3rd floor, Rumpun Ilmu Kesehatan, Universitas Indonesia; Tel: +62 (0)21 786 4975; Email: humas.fkm@ui.ac.id)

Primary study design
Interventional

Study design
Cluster randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
DPT3 and full immunization coverage in 12-23-month-old children in slums

Interventions
Urban slum areas are randomly selected using the covariate constrained randomisation function in Stata/15. Cluster-level covariates for randomization were generated after the baseline assessment and employed a number of indicators for each urban slum unit - coverage of mother & child health book, BCG immunization and complete immunization.

The intervention employs mobile technologies to connect urban slum communities to nearby public health services. It contains the following elements:
1. Registration of newborns: Community Health Workers (CHWs) use SMS to register babies 0-11 months old, along with the mobile numbers of caregivers
2. Personalized reminders: personalized vaccination reminders are sent to caregivers according to the child's vaccine schedule with notifications of upcoming vaccination sessions
3. Rapid Card Checks: quarterly micro-surveys of 12-23-month-olds in each local area are conducted to assess levels of immunization coverage
4. Feedback to managers: Health managers and providers receive quarterly feedback on all aspects of program performance in their areas which supports local planning and system improvements

The trial will compare immunization coverage between target communities and matched comparison communities. Clusters will be matched based on coverage of mother and child handbook, coverage of BCG, DPT3 and full immunization and average distance to primary health care center (Puskesmas). A serial cross-section assessment of 12-23-month-olds will be conducted at baseline (before the intervention) and approximately one year later. Quantitative baseline and end line surveys will be implemented to compare coverage of BCG, DTP3, Measles,

fully immunized children (FIC) and other key MNCH interventions, among households with children 12-23 months old children. As standards for assessing immunization coverage are among this age-restricted age group (to assess the receipt of vaccinations during the first year of life) baseline and endline surveys will be cross-sectional and contain different sample populations. In addition, a qualitative assessment, including focus group discussions and key informant interviews with program recipients, health providers and managers regarding the implementation experience and receptiveness of households to the REC project/SMS reminders, will be implemented in the target communities, toward the end of the intervention period. This will assess the barriers and facilitators to implementation, acceptability and how mobile health information informs access and service delivery.

Intervention Type
Behavioural

Primary outcome(s)
DPT3 coverage and Full immunization coverage defined as infants who received vaccination of: Hepatitis B0; BCG; DPT-HB-Hib 1 to 3; and Polio 1 to 4, among children 12-23 months of age, based on immunization book and/or mother's recall, measured at baseline (before the intervention) and approximately 1 year after.

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
05/05/2019

Eligibility

Key inclusion criteria
Caregiver of a 12-23-month-old child living in the sample urban slum communities

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Caregiver-child pairs, where the child is <12 months of age or >23 months of age
2. Caregiver-child pairs not residing in any of the pre-identified list of slum communities in North, East and West Jakarta

Date of first enrolment
01/07/2018

Date of final enrolment
01/05/2019

Locations

Countries of recruitment
Indonesia

Study participating centre
Provincial Health Office of Jakarta
Jl. Kesehatan No. 10, Daerah Khusus Ibukota Jakarta
Indonesia
10160

Sponsor information

Organisation
UNICEF

ROR
https://ror.org/02dg0pv02

Funder(s)

Funder type
Industry

Funder Name
Pfizer Foundation

Alternative Name(s)
The Pfizer Foundation

Funding Body Type
Private sector organisation

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

Location
United States of America

Funder Name
Nokia

Alternative Name(s)

Funding Body Type
Private sector organisation

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

Location
Finland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Iwan Ariawan (iwan.ariawan@reconstra.com).
Type of data: raw data
Data availability and for how long: upon request
Access criteria and data sharing: via email with specific requests
Types of analyses: for analysis of immunization coverage and its determinants in urban slums in Jakarta
Comments on consent/data anonymization/ethical or legal restrictions: Consent form was obtained and no name and address were recorded in the data to assure anonymity.

IPD sharing plan summary
Available on request