

Improving immunization coverage in urban slums in Indonesia

Submission date 25/03/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/04/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/04/2019	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

Dr Paul Pronyk, Chief of Child Survival and Development Cluster, UNICEF Indonesia

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Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

Study design

Cluster randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

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 measure

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.

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/08/2017

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

Age group

Adult

Sex

Both

Target number of participants

46 communities (clusters) and 25-30 participants per cluster

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

Sponsor details

Kav. 29-31, Jl. Jend. Sudirman, RT.8/RW.3, Karet

Kecamatan Setiabudi

Kota Jakarta Selatan

Daerah Khusus Ibukota Jakarta

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+62 (0)21 29968000
ppronyk@unicef.org

Sponsor type

Other

Website

<http://unicef.org>

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

Publication and dissemination plan

The results of this study will be shared first with the District Health Offices of North, East and West Jakarta, the Provincial Health Office of Jakarta, and the central Ministry of Health of Indonesia. In addition, the researchers will work to share the findings of this study with the scientific community through publication in a peer-reviewed journal. The specific target journal will be selected upon completion of the study. Additional documents can be made available upon request.

Intention to publish date

01/10/2019

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