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Randomized evaluation of All Babies Are Equal - a conditional cash transfer for routine childhood immunization in north-west Nigeria

Submission date
19/11/2018

Recruitment status
No longer recruiting

Registration date
11/02/2019

Overall study status
Completed

Last Edited
26/07/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
North West Nigeria has one of the highest fertility rates (6.7 births per woman (Demographic and Health Survey 2013)) and lowest vaccination rates in the world (UNICEF 2017). The most recent National Immunization Coverage Survey in 2011 found that only about 1 in 20 12- to 23-month-olds in the North West states of Katsina and Zamfara, respectively, had received all recommended childhood vaccines. Low immunization rates contribute to Nigeria's high death rate in children aged under 5 years (104 deaths per 1,000 live births). Two in five of deaths in this age group in Nigeria are from diseases that are preventable through vaccination. The region of North West Nigeria has particularly low levels of vaccination and has had frequent measles outbreaks. It is also one of the world's last locations where polio has not been eliminated.
Aid organizations have improved the infrastructure for routine immunization, but vaccination rates remain low. The World Health Organization's global immunization coverage target is 9 out of 10 children. Over half of people who either never vaccinated their children or skipped certain vaccinations said 'lack of knowledge' or 'ambivalence' (not knowing whether it was positive or negative) was the main reason for not vaccinating their children. For those who skipped one or more routine vaccinations, access and service delivery issues were a barrier. People who did vaccinate their child at least once were likely to say that health concerns were the main reason for doing so. People who had their child fully immunized said it was because they wanted to prevent illness, disease or death, rather than because of influence from community leaders or family members.
Previous studies have shown that a small incentive can have a large impact on health behaviors like vaccinating children. New Incentives, an international non-governmental organization (NGO), aims to boost demand for immunization by offering cash incentives to caregivers who have their child vaccinated at a program clinic. In collaboration with New Incentives, IDinsight is conducting a study to whether this approach will increase immunization in North West Nigeria. This study aims to investigate whether giving cash to caregivers in North West Nigeria who bring their infants to receive vaccination against common infections (tuberculosis, diphtheria, tetanus, pertussis, hepatitis B virus (HBV) infection, Haemophilus influenzae Type B (Hib), pneumococcal

bacteria, measles, rotavirus, polio, yellow fever) increases the proportion of children who are immunized. The study is taking place in Jigawa, Katsina, and Zamfara States between August 2017 and January 2020.

Who can participate?
Children aged 0 to 16 months living in the catchment areas of the clinics taking part in the study.

What does the study involve?
Eligible caregivers who bring their infant(s) to the health facility for immunizations are first enrolled in the program by New Incentives staff, who record caregiver and infant details. To be eligible for the program, infants must have received one of the routine vaccinations at the clinic – this is checked against the child's health card. If the child has received the vaccination, the caregiver receives the cash incentive, and instructions on when to return for the next vaccination and incentive payment. From the perspective of the participant, taking part in the study involves receiving a researcher into their home, providing informed consent, and answering a 1-hour survey.

What are the possible benefits and risks of participating?
Those who participate in the trial and are in the New Incentives arm will benefit from the cash payments. All data is anonymized and stored securely. The children will benefit from being protected from common infectious diseases, but might experience soreness at the injection site. There is a risk that by paying carregivers to vaccinate children, there might be a reduction in their motivation to get the children vaccinated for health reasons. The study will investigate this by asking caregivers for their attitudes towards vaccination at the start and end of the trial. They will also be asked if they would still vaccinate children if there was no incentive.

Where is the study run from?
IDInsight West Africa (Senegal)

When is the study starting and how long is it expected to run for?
June 2017 to June 2020

Who is funding the study?
GiveWell (USA)

Who is the main contact?
1. Zack Devlin-Foltz (public contact)
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2. Alison Connor (public contact)
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03870061

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomized evaluation of All Babies Are Equal - a conditional cash transfer for routine childhood immunization in north-west Nigeria

Study objectives
Current study hypothesis as of 12/12/2019:
New Incentives' program has meaningfully increased the percentage of children immunized with BCG, any PENTA, or Measles 1 across all program clinics.

Previous study hypothesis:
New Incentives program will increase the percentage of children immunized with BCG, any PENTA, or Measles 1 by an average increase of at least 7-percentage points across all program clinics that share a similar profile to the clinics New Incentives will operate in at scale.

Ethics approval required

Old ethics approval format

Ethics approval(s)
1. National Health Research Ethics Committee of Nigeria, 07/08/2017, ref: NHREC/01/01/2007-07/08/2017
2. National Health Research Ethics Committee of Nigeria, 11/08/2018, ref: NHREC/01/01/2007-11/11/2018B (extension)
3. National Health Research Ethics Committee of Nigeria, 12/11/2019, ref: NHREC/01/01/2007-12/112019C

Study design
Cluster-randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
No participant information sheet available.

Health condition(s) or problem(s) studied
Prevention of tuberculosis (BCG vaccine); diphtheria, tetanus, pertussis, hepatitis B and Haemophilus influenzae Type B (Pentavalent Vaccine), pneumococcal bacteria (PCV vaccine), measles, rotavirus, polio, yellow fever

Interventions
The study will be structured as a two-arm cluster RCT. One arm (83 clinics) will serve as the control and will operate as the status quo, while the other arm (84 clinics) will receive New Incentives full program. This design will measure the causal effect of New Incentives program on the likelihood of an infant receiving a vaccine.
New Incentives, an international non-governmental organization (NGO), is addressing the apparent shortfall in demand for immunization by offering cash incentives to caregivers for bringing their child to clinics for the first five visits of the Nigerian Routine Immunization schedule. These small cash transfers can provide some material benefit to new caregivers from poor communities. At a minimum, they help offset time and transport costs. The cash incentives are offered to caregivers who bring their child for vaccination at a program clinic. To be eligible, the child must reside in the catchment area of the clinic and fall within the age range targeted for the vaccination in question. Infants do not need to have received the previous vaccine in the schedule to be eligible. New Incentives has a team of field officers responsible for disbursing incentives to caregivers. On each vaccination day, the field officers check vaccine quality and stock, and then prepare to disburse incentives. Incentives are paid in cash by a New Incentives staff member who also ensures the infant meets the eligibility criteria outlined above.
We plan to limit our interaction and follow-ups to the duration of the evaluation (scoping to

endline). Our (researchers' and implementers') interactions with participants (caregivers and infants) consist of census and immunization surveys and cash disbursements. The last of these interactions will be the endline immunization survey, which will be conducted between November 2019 and January 2020. New Incentives (the implementer) will continue to offer cash disbursements for some period after that (with exact duration dependent on whether the evaluation results justify scale-up). However, these disbursements will not be part of the study we wish to register with you as they will occur after final data is collected.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 12/12/2019:
1. The probability that a 12- to 16-month-old in a community served by a program clinic received BCG
2. The probability that a 12- to 16-month-old in a community served by a program clinic received at least one dose of PENTA
3. The probability that a 12- to 16-month-old in a community served by a program clinic received Measles 1

Previous primary outcome measures:
1. The odds that a 12- to 16-month-old in a community served by a program clinic received BCG
2. The odds that a 12- to 16-month-old in a community served by a program clinic received at least one dose of PENTA
3. The odds that a 12- to 16-month-old in a community served by a program clinic received Measles 1

Data collection takes place at three points (baseline, midline, and endline) using a series of self-reported surveys of caregivers, examination of the child's health card (where available) and reviewing clinic records. Baseline was completed between August and October 2017, midline is scheduled for March 2019, and endline is planned for November 2019 to January 2020.
Across all outcome measurements, sampled infants will be aged between 12 and 16 months (though baseline surveyed some infants aged up to 24 months to increase sample size). We sample these age groups as they are well beyond the age at which children should receive the program vaccinations. (The Nigerian Routine Immunization schedule aims to give the vaccinations we measure between birth and 9 months old.) We do not follow the same infants from baseline to midline to endline but, rather, compare coverage rates in the same age group at each point in time.

Secondary outcome measures
Current secondary outcome measures as of 12/12/2019:
1. The probability that a 12- to 16-month-old in a community served by a program clinic is fully immunized (loose and strict)
2. The timeliness of vaccination, particularly for Measles 1, among 12- to 16-month-olds in communities served by a program clinic
3. The average number of vaccines received per 12- to 16-month-old child in communities served by a program clinic
4. The percentage of 12- to 16-month-olds in communities served by a program clinic who received at least one injectable vaccine
5. The probability that a 12- to 16-month-old in a community served by a study clinic received at least one dose of PCV

6. The change over time in the volume of BCG, Penta 1, Penta 2, Penta 3, and Measles vaccinations recorded in clinic administrative records between treatment and control

Previous secondary outcome measures:
1. The odds that a 12- to 16-month-old in a community served by a program clinic is fully immunized (loose and strict)
2. The timeliness of vaccination, particularly for Measles 1, among 12- to 16-month-olds in communities served by a program clinic
3. The average number of vaccines received per 12- to 16-month-old child in communities served by a program clinic
4. The percentage of 12- to 16-month-olds in communities served by a program clinic who received at least one injectable vaccine

Data collection takes place at three points (baseline, midline, and endline) using a series of self-reported surveys of caregivers, examination of the child's health card (where available) and reviewing clinic records. Baseline was completed between August and October 2017, midline is scheduled for March 2019, and endline is planned for November 2019 to January 2020.
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Overall study start date
01/06/2017

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Children aged 0 to 16 months can be enrolled in the program and incentives paid to their caregivers
2. Children aged 12 to 16 months will have their data measured at endline
3. All participants must reside in study clinic catchment areas.
4. Vaccination status will be measured by caregiver survey. Caregivers must consent to the survey

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants

7500

Total final enrolment
5183

Key exclusion criteria
1. Residence outside the study area (self-reported)
2. Outside the age range (self-reported)

Date of first enrolment
01/07/2018

Date of final enrolment
20/02/2020

Locations

Countries of recruitment
Nigeria

Study participating centre
Primary Health Care facilities across the study area.
Zamfara, Katsina, Jigawa states
various
Nigeria
n/a

Sponsor information

Organisation
GiveWell

Sponsor details
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Sponsor type
Charity

Website
https://www.givewell.org/

Funder(s)

Funder type
Charity

Funder Name
GiveWell

Results and Publications

Publication and dissemination plan
Results to be published on the funder's website: https://www.givewell.org/

Intention to publish date
01/07/2020

Individual participant data (IPD) sharing plan
All participant-level data is anonymized through removing any information that could lead to back-tracking the identity of the respondent — each respondent is allocated a random identification number in place of their name. Anonymized data are currently stored in a password-protected repository on IDinsight's Dropbox site. Access is restricted to IDinsight staff that are on the project.
IDinsight and New Incentives collect various clinic-level data as well for use as covariates and to inform operational decisions. These data are stored in the same repositories and in New Incentives' own password-protected internal dashboard.
Requests for access to data can be made directly to IDinsight (Manager: Zack Devlin-Foltz (zack.devlinfoltz@idinsight.org) and Corresponding Investigator: Dr. Niklas Heusch (niklas.heusch@idinsight.org))

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan		16/11/2018	11/02/2019	No	No
Statistical Analysis Plan		29/11/2019	29/11/2019	No	No
Funder report results		12/11/2020	26/07/2021	No	No