Introduction

IDinsight is conducting a cluster randomized controlled trial (RCT) to assess the impact of delivering cash incentives to caregivers to bring their infants for routine immunization in North West Nigeria. The purpose of the evaluation is to determine the degree to which these incentives increase coverage rates for the vaccines included in Nigeria's routine immunization schedule.[1]

This pre-analysis plan documents the key research questions the evaluation seeks to answer and specifies the analysis that will be performed for each question. It is registered on 3ie's Registry for International Development Impact Evaluations (RIDIE), the World Health Organization's ISRCTN registry, and clinicaltrials.gov. This version updates the document based on changes to the evaluation design since first registration in November 2018.

The first registered version of the pre-analysis plan was written after baseline analysis, randomization, and comments from GiveWell (funder) and New Incentives (program implementer). We wrote the first version of this pre-analysis plan after baseline data collection due to uncertainty regarding the optimal way to measure vaccination coverage in the study context. We used baseline to test and evaluate options. The decision to write the pre-analysis plan after baseline carries minimal risk of choosing specifications solely to inflate the treatment effect since we will survey different individuals[2] at endline than we did at baseline.

Evaluation Background

North West Nigeria has one of the highest fertility ratios in the world with 6.7 births per woman of reproductive age (DHS 2013). It also has one of the world's lowest vaccination coverage estimates. Consequently, this region is vulnerable to frequent measles outbreaks (NCDC 2016) and is one of the world's last locations that still has new cases of wild polio virus (GPEI 2017). In recent years, the donor community has invested substantially in improving supply-side infrastructure for routine immunization (NRISP 2013), but coverage remains low.

The Intervention

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 for recommended childhood immunizations. This is based on evidence that small incentives can have a large impact on health behaviors like vaccinating children (Banerjee et al. 2010), and evidence that that this finding could apply to immunizations in Nigeria (Sato 2014). 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 in Table 1 are offered to caregivers who bring their child for vaccination at a program clinic.[3,4] 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. The incentive amount for the Measles 1 vaccination is higher for two reasons. First, New Incentives believes that caregivers will need more inducement to return for the Measles 1 vaccination after the longer time interval following the last PENTA vaccination. Second, evidence suggests that

[1] This includes Bacillus Calmette–Guérin (BCG) for Tuberculosis, pentavalent vaccine (PENTA) 1, PCV 1, PENTA 2, PCV 2, PENTA 3, PCV 3, and Measles 1. The PENTA schedule protects against diphtheria, tetanus, pertussis, Hepatitis B and Haemophilus Influenza Type B (HIB)

[2] Baseline data were collected on 12 to 24-month-old children in 2017 to generate clinic-level averages of variables of interest, such as coverage, for stratification and further analysis. By endline (2019), all of these children will be too old for our sample. We will require a new sample of children in our target age of 12 to 16-month-old children.

[3] More details on the Nigerian routine immunization system, especially the structure of an average immunization visit day, can be found in in Annex 1 and in IDinsight's February 2017 site visit report. (www.givewell.org/http://www.givewell.org/research/site-visits/february-2017)

[4] New Incentives also distributes incentives through clinics' outreach services in which nurses go to the villages to administer vaccines.

there is greater potential health impact from the Measles 1 vaccine.[5] Infants do not need to have received the previous vaccine in the schedule to be eligible.[6]

Table 1: Description & Timing of Vaccines

Immunization	Description	Doses	Timing (age) for doses	Incentive amount[1]
BCG	Vaccine against tuberculosis	1	At birth, or as close as possible	₦[2]500
PENTA	Five vaccines against: diphtheria, tetanus, pertussis, Hepatitis B and Haemophilus Influenza Type B (HIB)	3	At 6 weeks, 10 weeks and 14 weeks	₦500 for each dose of PENTA, when PCV is also received
PCV	Vaccine against pneumococcal bacteria	3	[as for PENTA]	[as for PENTA]
Measles 1	Vaccine against measles, mumps, rubella, and varicella	1	9 months	₦2000

[1] If an infant is eligible for multiple vaccines on a visit, the caregiver will only receive the incentive for the latest vaccine.
[2] Nigerian Naira

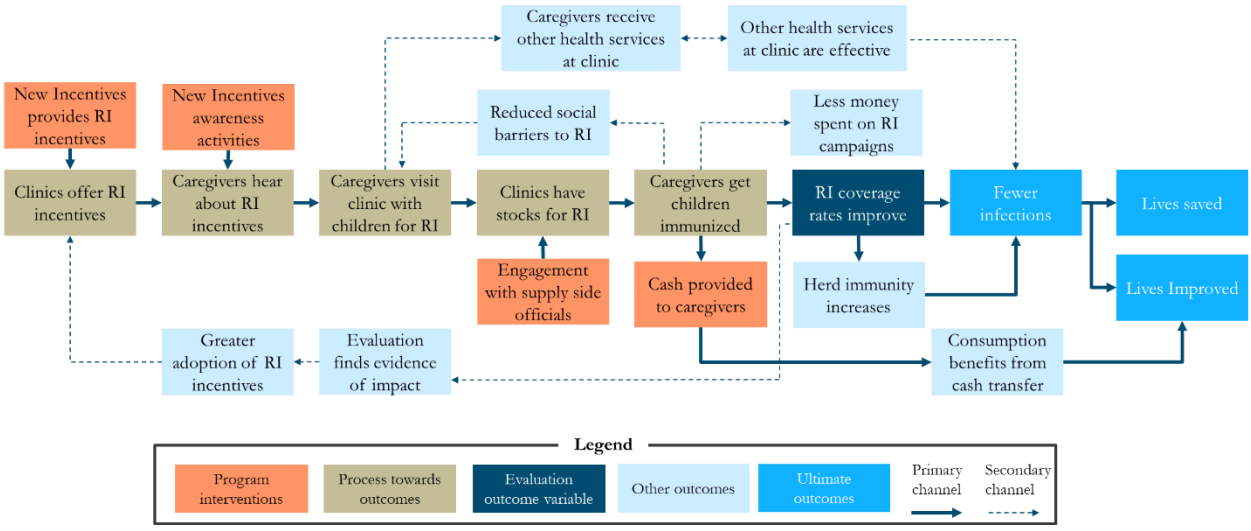
New Incentives has a team of field officers responsible for disbursing incentives to caregivers. On each vaccination day, the field officers check vaccine quality and stock,[7] and then prepare to disburse incentives. Incentives are paid in cash by a New Incentives staff member who also ensures the infant meets the eligibility criteria outlined above.[8]

Theory of Change and Outcome Variable

New Incentives anticipates that their incentive program will improve the health status of Nigerian children in a variety of ways. The primary focus of the study is the direct impact of the program on coverage rates for incentivized immunizations for eligible infants in the study area. The primary causal pathway is that cash changes the caregiver's assessment of the benefit of vaccination by minimizing barriers and providing a larger benefit. However, the theory of change includes other pathways that increase coverage such as New Incentives' supply side engagement, New Incentives' marketing and outreach to community leaders, and reduced social and informational barriers to vaccination as it becomes more common.[9] In addition, the theory of change includes secondary outcomes such as increased consumption (from cash transfers) and improvements in other health outcomes (from increased use of general health services).

[5] The WHO suggests that there is roughly a 30% chance a given child will be infected with measles in a given year in an area with low measles 1 coverage. GiveWell estimates the case fatality rate as 5% based on Simmons et al. 2012.
[6] Infants on a catch-up schedule - i.e. an unvaccinated infant comes to a clinic at twelve-months and receives BCG, PCV 1, and PENTA 1 - receive one incentive associated with the most recent vaccination visit. In this case, a caregiver would receive ₦500.
[7] If the stock is low, New Incentives' staff encourage the clinic staff to procure more vaccines, and work with Local Government Area (LGA) and State officials to ensure availability. However, New Incentives does not directly supply stock. If a vaccine runs out during the immunization day, New Incentives' staff give out number tags to indicate a caregiver's place in the vaccination queue and tell caregivers to come back on the next routine immunization day with their number tag to be vaccinated before other caregivers who arrive for the first time.
[8] Additionally, independent workers outside of Nigeria confirm these validity determinations by reviewing images of the documentation and transaction, itself.
[9] See Sato 2014 for details on vaccination peer effects.

Figure 1: New Incentives' Program Theory of Change



One secondary causal pathway warrants further mention: it is likely that New Incentives' program indirectly increases coverage rates for vaccinations beyond those for which it directly pays incentives. New Incentives aims to incentivize initiation and adherence to the Nigeria Routine Immunization Schedule. While technically New Incentives makes cash transfers for the vaccines listed in Table 1 above; in practice they have found that infants tend to receive all vaccines scheduled for a visit once they are at the clinic. New Incentives also works with clinic staff to improve their internal procedures and address supply-side issues, such as vaccine stockouts, through existing channels. These efforts apply equally to all routine immunizations. Accordingly, New Incentives chose to pay for *some* of each visit's immunizations with the expectation that this will encourage *all* of that visit's immunizations. During piloting, they found that this simplified payment schedule is easier for beneficiaries to understand.

Table 2 lists all the immunizations scheduled for each clinic visit and notes which are directly incentivized through cash transfers and which are indirectly incentivized by occurring at the same visit. IDinsight plans to measure coverage for all directly incentivized and at least some indirectly incentivized vaccinations at endline. Annex 5 discusses how GiveWell will incorporate each of these into its cost effectiveness estimates for the New Incentives program.

Table 2: New Incentives and the Routine Immunization Schedule

Timing (age) for visit	RI Schedule Vaccines for this visit	Directly Incentivized	Indirectly Incentivized
At birth, or as close as possible	BCG, Hepatitis B Vaccine, Oral Polio Vaccine (OPV) 0	BCG	Hepatitis B Vaccine, Oral Polio Vaccine (OPV) 0
6 weeks	PENTA 1, PCV 1, OPV 1, Rotavirus 1	PENTA 1, PCV 1	OPV 1, Rotavirus 1
10 weeks	PENTA 2, PCV 2, OPV 2, Rotavirus 2	PENTA 2, PCV 2	OPV 2, Rotavirus 2
14 weeks	PENTA 3, PCV3, OPV 3	PENTA 3, PCV 3	OPV 3
9 months	Measles, Yellow Fever	Measles	Yellow Fever

Evaluation Design

Decision to Inform

IDinsight designed this impact evaluation to inform GiveWell's decision on whether to recommend funding for the scale-up of New Incentives' program in North West Nigeria and/or designate New Inventives as a "Top Charity."[10] GiveWell bases this decision on a variety of factors, outlined in detail on their website.[11] One key input is the cost effectiveness of candidate charities: the cost of saving or improving a life via the charity's program. IDinsight's evaluation will inform GiveWell's cost effectiveness assessment of New Incentives by estimating the program's impact on immunization coverage rates.[12] GiveWell plans to translate the coverage increases for each vaccination into an estimate of lives saved and illness prevented in order to compare the cost-effectiveness of New Incentives' program to other programs GiveWell recommends. For more detail on GiveWell's methodology and decision making, please see Annex 5 and the GiveWell website.

Since coverage rates for each vaccination enter the GiveWell cost-effectiveness model separately, IDinsight will also estimate three separate outcome variables: the coverage rates for BCG, PENTA (any dose), and Measles 1.

Overall Design

The study will be structured as a two-arm cluster RCT. One arm will serve as the control and will operate as the status quo, while the other arm 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.[13]

[10] GiveWell "Top Charity" refers to the charities that GiveWell has evaluated to be robustly more cost-effective than GiveDirectly cash transfers. In some cases, this designation is associated with substantial funding in excess of 10 million United States Dollars."
[11] https://www.givewell.org/charities/top-charities
[12] Due to sample size constraints, IDinsight did not design the evaluation to directly measure New Incentives' impact on mortality. Further, an evaluation designed to measure mortality would have taken longer to deliver results, and substantial research on the medical benefits of routine immunization already exists.
[13] Care was taken throughout the evaluation design to ensure that New Incentives' implementation during the RCT reflects their anticipated implementation at scale. Thus, we expect findings from this study to predict the impact of New Incentives' program at scale.

Unit of Treatment and Randomization

The unit of treatment and randomization is the clinic catchment.[14]

Outcome Measurement

IDinsight will use caregivers' reports of their child's vaccination history to measure the coverage outcome variables. We will use various alternative sources, primarily administrative, to assess the accuracy of "self-reported" coverage. Administrative sources will be clinics' registers, child health cards, and.[15] Additionally, the BCG vaccination leaves a visible scar, for which enumerators will check, providing another opportunity to assess caregiver recall.[16] Additional outcomes of interest include timeliness based on vaccination dates recorded on child health cards or clinic registers.

Research Questions

The primary research questions are:

1. What is the effect of New Incentives' program on the probability that a 12 to 16-month old in a community served by a study clinic received BCG?
2. What is the effect of New Incentives' program on the probability that a 12 to 16-month old in a community served by a study clinic received at least one dose of PENTA?[17]
3. What is the effect of New Incentives' program on the probability that a 12 to 16-month old in a community served by a study clinic received Measles 1?

Secondary research questions include:

1. What is the effect of New Incentives' program on the probability that a 12 to 16-month old in a community served by a study clinic is fully immunized (loose and strict)?[18]
2. What is the effect of New Incentives' program on the timeliness of vaccinationamong 12 to 16-month olds in communities served by a study clinic?
3. What is the effect of New Incentives' program on the average number of vaccines[19] received per 12 to 16-month-old child in communities served by a study clinic?
4. What is the effect of New Incentives' program on the percentage of 12 to 16-month olds in communities served by a study clinic that received at least one injectable vaccine?
5. What is the effect of New Incentives' program on the probability that a 12 to 16-month old in a community served by a study clinic received at least one dose of PCV?

[14] Clinic catchment areas consist of the settlements for which a clinic is responsible for providing healthcare. Catchment areas do not necessarily correspond with other local political or administrative units, though they are closest in size to wards. In six cases, clinics that had catchments that were close to each other were randomized as pairs to reduce spillovers.

[15] We may also use New Incentives' internal records of cash transfers distributed to caregivers.

[16] IDinsight continues to evaluate risks from imperfect recall and options to mitigate those risks. Future versions of this document will include updates on our thinking and plans.

[17] We focus on at least one dose of PENTA and not all three doses, as caregivers are likely to find it difficult to recall whether their child received all doses.

[18] For this outcome, fully immunized (loose) is defined as receiving BCG, PENTA 1, and Measles 1. Fully immunized (strict) is defined as receiving BCG, PENTA 1 – 3, and Measles 1.

[19] The vaccines included in the average will be BCG, PENTA 1-3, PCV 1-3, and Measles 1.

6. What is the effect of New Incentives' program on 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?[20] [21]

Power

The study has an 80% chance (power) to detect a roughly 11-percentage-point increase[22] in measles coverage across 167 clusters using the following parameters:

- Conservative control group coverage rate of 40%.
- Conservative intracluster correlation coefficient of 0.2[23]
- An alpha (chance of false positive under a true null hypothesis) of 5%
- Sample size of just over 7,500 infants or 45 per catchment[24]
- The Free Step-Down Resampling (FSDR) method for multiple hypotheses[25]

Clinic Sample

New Incentives and IDinsight worked together to arrive at a representative sample of operational and secure clinics offering routine immunization services in Zamfara, Katsina, and Jigawa (details on clinic selection are in Annex 1). Allowing New Incentives to drive study clinic selection for operational reasons makes study results a reasonable forecast of results at scale. New Incentives selected clinics to operate in based on four criteria: security, availability of routine immunization (RI) services, remoteness[26], and staffing. New Incentives excluded clinics where there were no routine immunization services or that did not meet minimum security criteria.[27] New Incentives still chose to include a few clinics in the study that were remote and had few staff (more than 3 hours from an ATM and with only one RI staff member) in order to test whether they are viable. Clinics with stockouts of vaccines or child health cards, low patient volume, and clinics with designations such as Dispensaries or Health Posts were still included because these are clinics that New Incentives would include at

[20] IDinsight will collect either Tally Sheets or Monthly Immunization Summaries, depending on the workload of all clinic-enumerator tasks, as determined during field practice prior to data collection. Tally Sheets are – we think – a slightly more accurate source, though our Midline analysis showed them to be quite consistent with Monthly Immunization Summaries, which are much easier to collect.

[21] IDinsight collected these records as part of midline data collection in March/April 2019. We found a robust positive impact across vaccinations but these results were for a time period ending part-way through the RCT window so follow-on collection is necessary. These administrative records are imperfect, and we worry that the program itself may cause them to improve, leading to differential data quality in treatment and control. However, they remain an important alternative source that we expect to show results at least qualitatively similar to those found with self reports.

[22] Annex 5, written by GiveWell, describes how they expect to use this study for their funding and recommendation decisions. IDinsight used that document and conversations with GiveWell to determine mean detectable effect sizes used in power calculations. An 11 percentage point increase in coverage for Measles 1 was our planning factor for those calculations at time of sample size and budget finalization in July 2019. This represents a compromise accounting for the minimum effect likely to induce a Top Charity designation from GiveWell (estimated at 7 percentage points in summer 2017, increased to 10-15 percentage points at time of writing, subject to change prior to final results and decision) and on-the-ground factors – notably the desire to maintain a large buffer between clinics to limit spillovers.

[23] The baseline survey found an ICC of .12. We used conservative parameters for power calculations in case differential treatment effects across clusters have increased ICC since baseline.

[24] Calculations suggested that the increased power from adding more observations per cluster became minimal around 40 observations per cluster (catchment area). Accordingly, we plan to sample 45 x 167 = 7,515 at endline.

[25] IDinsight calculated power using both Bonferoni and FSDR corrections, which yielded similar results. FSDR is probably more appropriate in our setting given that we expect the program's effect across vaccinations to be highly correlated.

[26] It is also important to note that most clinics in which New Incentives operates are rural. The remoteness criteria applies to only those that are extremely difficult to reach relative to the norm for the region. See the clinic categorization section of Annex 1 for more detail.

[27] Please refer to Annex 1 which discusses further detail on New Incentives' clinic selection criteria.

scale. Lastly, we also sampled so as to maximize distance between selected clinics and thus minimize potential contamination between treatment and control clinics.[28]

Clinic selection occurred in roughly three phases. First, New Incentives selected 130 clinics in Katsina and Zamfara in preparation for the baseline. After the end of baseline data collection (but prior to random assignment), New Incentives reduced the Katsina and Zamfara clinic list based on security.[29] Finally, the study added clinics in Jigawa State to compensate for the reductions in the Katsina and Zamfara lists. The resulting sample comprises 167 clinics, primarily rural, basic Primary Health Care (PHC) facilities, which predominate throughout the region.

Randomization Procedure

The primary use of the baseline data was to facilitate randomizing clinics into balanced treatment and control groups. IDinsight grouped clinics based on coverage[30], security status, remoteness/staffing[31], and state, and then randomly allocated half of the clinics from each group, or stratum, to the treatment arm. To accommodate uncertainty around the security assessment for some clinics, IDinsight randomized the security-compromised stratum later than the secure clinics to allow more time for New Incentives to evaluate the situation.

There are three different security categories used for stratification:

Moderate

- Clinics that have reported robberies without deaths once over multiple data points.[32]

High

- Clinics that have reported robberies without deaths once over multiple data points but are situated in high-risk Local Government Areas (LGAs). High-risk LGAs are defined as having clinics where armed killings occur regularly and during daytime.[33]

Very High

- Clinics that have reported robberies without deaths repeatedly over multiple data points, or
- Clinics that have reported robberies with deaths.

IDinsight then randomly assigned 167 clinics across Katsina, Zamfara, and Jigawa to treatment and control groups. More details on the randomization process are in Annex 2.

[28] It is important to note that the requirement that the clinics be well-spaced means that clinics in clinic-dense areas were less likely to be selected. Future versions of this document will discuss options for correcting for this.
[29] Security concerns prompted the exclusion of four clinics from Katsina and 21 from Zamfara. New Incentives decided to replace one of these dropped clinics in Zamfara with a nearby clinic.
[30] Baseline coverage based on survey data is only available for Katsina and Zamfara. Jigawa was added as an additional state late in September. All stakeholders decided not to do a baseline there due to resource constraints and an upcoming measles campaign, which was conducted in October 2017.
[31] Remoteness and lack of staffing relate to New Incentives' screening categories, in particular screening category 4 and screening category 5. Category 4 clinics refer to those who are more than 3 hours by car from the next location with an ATM. Category 5 clinics refer to those with only one staff member.
[32] Multiple data points include New Incentives' staff interviews with RI focal points, communications with LIOs, community leader reports etc. The incident will only have occurred one time.
[33] The intent of these armed killings was not robbery.

Data Collection

IDinsight will collect the majority of data that will be used at endline. Some data collected by New Incentives during their standard clinic screening process will be used as clinic-level covariates and as a robustness check on self-reported outcomes in treatment clinics.

New Incentives Data Collection

New Incentives collected data during their clinic screening,[34] which took place prior to randomization. This data included security status, number of staff members, and travel time to hub towns. All data referencing clinic screening data was collected by New Incentives. During the study, New Incentives will track each vaccine and incentive that program participants receive on each treatment site's vaccination day as part of their standard operations.

IDinsight Data Collection

Baseline and endline data collection consist of three components:

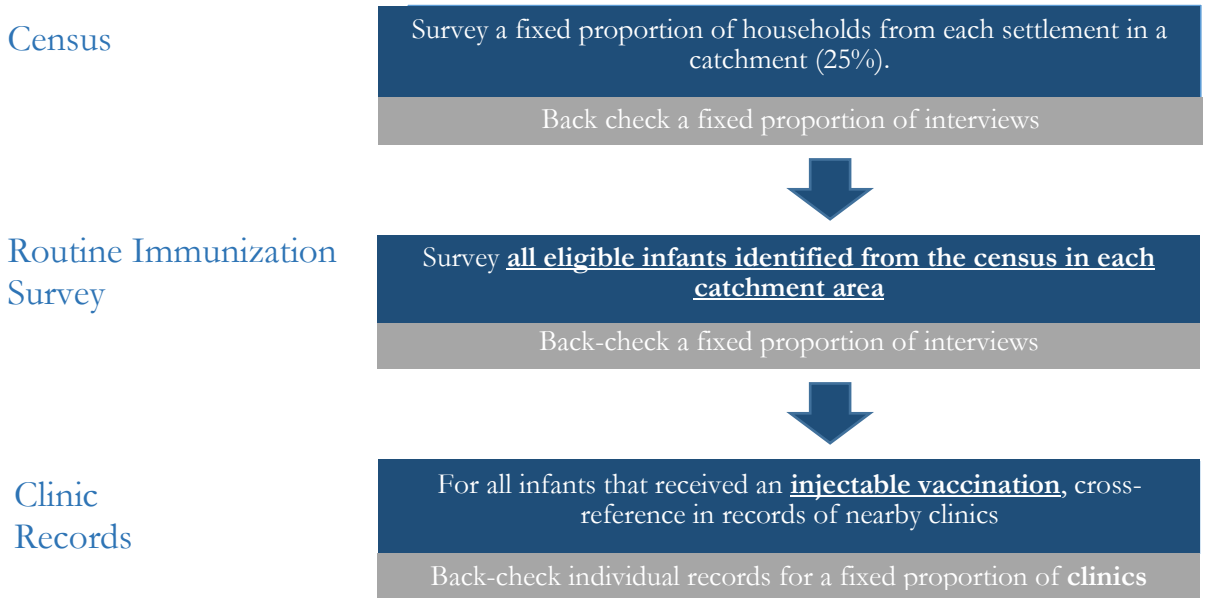
1. **Household census** - Identifies the population of eligible infants
2. **Routine immunization survey of eligible infants** – Collects information on immunization history of our sample and is the primary data source for analysis
3. **Administrative record[35] collection** - Provides an additional data source on vaccinations received to use for robustness checks and estimates of the accuracy of self reports

While IDinsight will collect data on vaccination coverage from multiple sources, the primary research outcomes will be defined by self-reported vaccination.[36]

Approximately 10% of interviews from each round of data collection are back-checked to ensure data quality.[37]

[34] New Incentives screened all potential study clinics to ensure that they met New Incentives' operational requirements and, therefore, reflected the types of clinics in which New Incentives would operate at scale.
[35] Includes child health cards kept by caregivers and child immunization registers and monthly immunization summaries kept at clinics
[36] Discrepancies between self-reported coverage and other coverage estimates will trigger further analysis aimed at identifying possible sources of the discrepancy. This analysis will inform our assessment of the robustness of our impact estimate as well as recommendations to New Incentives regarding the reliability of data sources that will be available to them when operating at scale.
[37] In practice, we shift some back-checker effort from the household listing portion of the survey to the routine immunization portion of the survey, which measures our key outcomes. This results in back-check targets of 9% for household listing surveys and 13% of routine immunization surveys. We also back-check clinic-record collection in 10% of clinics.

Figure 2: Data Collection Flow[38]



Measurement Steps

The study includes baseline,[39] midline, and endline measurement rounds.[40] The baseline and endline use a coverage survey and collect administrative data. Midline used only administrative data and was designed primarily as an in-stride monitoring activity to inform New Incentives and IDinsight rather than an impact estimate to inform GiveWell funding decisions. Endline will take place approximately 22 months after baseline. The timeline is meant to ensure the study cohort of 12 to 16-month olds at endline will have had the opportunity to fully complete the first four visits of the 9-month immunization schedule by midline and all five visits by endline. There is a three-month buffer at the start and end of the schedule to account for infants who are vaccinated late and for errors in age measurement as well as to allow New Incentives time to ramp up clinic operations before the study cohort was born.

Sampling within Clinic Catchments

The key geographical definitions used in the sampling approach are:

- **Catchment** – Each health clinic in Nigeria has a 'catchment' area which contains the population that the clinic is officially designated to serve.
    - Estimated catchment population sizes in the study area vary from fewer than 2200 people to over 40,000 people.
- **Settlement** – Within each catchment area, there are one or more 'settlements.' In many cases, settlements are defined through the local political process, typically corresponding to a natural community or geographical boundary. Baseline field work revealed that these boundaries are sometimes difficult to determine on the ground. IDinsight conducted field work prior to the endline survey to verify settlement boundaries.

[38] At baseline, IDinsight conducted separate household listing and routine immunization surveys. At endline, we will combine the surveys to increase efficiency and reduce the risk of attrition (i.e. not finding an infant identified by the listing when revisiting for the routine immunization survey)

[39] IDinsight did not collect baseline data in Jigawa as this state was added to the study after the point at which the baseline could be completed prior to the national measles campaign. An endline will be conducted in Jigawa.

[40] A separate proposal, to be drafted in November 2018, will outline the measurement and analysis plans for midline.

  - There is an average of roughly 10 settlements per catchment (in the study area), with substantial variance across clinics.
  - Settlements vary by population size and area.
- **Segment** – For the purposes of data collection and sampling for this study, we divide each settlement, into equal area 'segments.'
  - The process for determining segment size and number is set out in the sampling process section below.
  - Segment boundaries corresponded to physical infrastructure such as roads (to the extent possible) to make it easier for enumerators to follow them and supervisors to verify enumerators have surveyed the correct areas.

Background to the Compact Segment Sampling Approach

Our key sampling challenge is that there are no reliable population registers (including for the target population) for clinic catchment areas. A reliable population register would allow us to undertake simple random sampling, whereby each infant in each catchment would have been randomly selected from all infants in the catchment area (to be given the routine immunization survey). As a reliable population register is not available, and it is not financially feasible to create one (by conducting our own full census), we use compact segment sampling (CSS), which emerged as the method best supported by the literature to address this sampling challenge. CSS uses geographic area as a primary sampling unit: if we intend to randomly sample 25% of a settlement's population, we randomly sample 25% of its geographic area and survey the eligible population therein. Random sampling means that, in expectation, sampled geographic areas will be representative of associated settlements in population density and all demographics. Though any single segment may not be representative of its settlement (e.g. it may have greater population density than the settlement overall), it will tend to be offset by another segment (e.g. that has lower population density than its settlement overall) such that our study-wide estimates will be unbiased.

CSS using fixed land-area percentages across all settlements also results in a self-weighting sample: all eligible infants in the population have equal probability of being sampled regardless of how large or small their settlement is. The result is a sample representative of the average individual in our study area, which we and GiveWell determined to be the most decision-relevant. We will, however, also use population weights in our analysis to generate estimates of program effect on the average cluster (clinic catchment). The robustness checks section discusses this in more detail.

Steps in the compact segment sampling approach[41]

1. In February/March 2018 and July/August 2019, IDinsight conducted "map verification" across the study area. This activity provided us with the following information:
   a. Updated lists of settlements included in all clinic catchment areas according to clinic Microplans.[42] New Incentives collected this list at prior to baseline (Fall 2017) and IDinsight collected it at midline (March/April 2019). To account for changes in this list over time, we compared the summer 2019 lists to the past lists and attempted to determine when changes in the lists occurred. However, change records were not available in most clinics, making precise time-based list adjustment impossible. In conversations with GiveWell and New Incentives, we determined that the lists collected in August 2019 would be the most suitable for this study. This is because of three primary factors: 1. Most discrepancies between pre-baseline and August lists involved "new" settlements appearing on the July/August lists but

[41] The baseline CSS made multiple modifications to this approach to respond to time pressure. The baseline report describes these modifications in greater detail and explores their implications for its results. For endline, rigor and representativeness are the top priority, so IDinsight plans to follow this methodology closely and to only make modifications for methodological reasons (i.e. to improve rigor based on new information).

[42] A Microplan is a clinic's strategy for reaching the communities for which it is responsible and allocating resources among them.

not past lists, 2. New Incentives has been operating in the majority of these "new" settlements for the majority of the RCT window so including the "new" settlements is likely to be more representative of New Incentives' average impact,3. Map analysis showed that many of the "new" settlements actually correspond to land area that was considered part of the catchment during baseline – suggesting that many differences are more in naming or levels of aggregation than in the included population. However, it appears that some settlements may have been added around the geographic edges of catchment areas over time.

   b. Global positioning system (GPS) coordinates for all study settlements. This helps us locate the settlements on maps and satellite imagery and ensure that enumerators return to the correct settlements at endline.
   c. GPS coordinates for settlement boundaries in select cases. Some settlements are immediately adjacent to one another such that determining where one ends and another begins on overhead imagery is difficult. In such cases, we had enumerators visit the settlement, ask locals to identify the boundary, and record coordinates to the boundary and to nearby landmarks to make the boundary easier to identify on imagery.

2. Estimate the total target population in the study area.
   a. Start with data from the Bill and Melinda Gates Foundation's (BMGF) Vaccine Tracking System (VTS), which uses satellite imagery and micro-census validation data to estimate population.[43] This data provides a 'layer' that we apply in the open source Geographic Information System (GIS) program QGIS[44] to generate population estimates for a user-selected geographic area. We use settlement names and the GPS coordinates collected at map verification to ensure we have selected the correct settlements and correctly defined their boundaries.
   b. For each study-area settlement, we multiply the estimated population by the percentage of the population that falls between 12 and 16 months of age, as estimated at baseline. This gives us an estimate for the population of 12 to 16 month-olds in the settlements.
   c. We sum settlement-level estimates to estimate the target population for the entire study area.
3. Next, we used the total target population estimate and the results of the power calculations described above to determine what proportion of land area we need to sample.[45] This resulted in in approximately 25% of eligible infants in the study area, meaning that we will also randomly survey 25% of land area.

4. We divide each settlement into an even number of segments of equal area.[46] To do so, we hired Upwork freelancers to draw polygons on GoogleMaps images of the study settlements, identified using names and GPS coordinates. Upworkers were instructed to ensure segments each consisted of roughly the same propotion (usually 1/8) of the total area comprising the settlement and IDinsight reviewed their work to ensure this occurred.
5. Randomly select 25% of the segments in each settlement and conduct a full household census (HH) in those segments. At those households where we find eligible infants, we will also conduct a routine immunization survey (RI) to measure study outcomes. Wherever possible, these two surveys will take place during a single visit to the household in order to economize on travel time and reduce the likelihood of missing data (from not finding infants identified by the HH at the time of conducting the RI).

[43] More information and data files available at http://vts.eocng.org/
[44] https://qgis.org/en/site/
[45] Power calculations and discussions with GiveWell and New Incentives arrived at a target of 45 infants (on average) per catchment area in 167 catchment areas. The resulting 7,515 target number of eligible infants represents approximately 26% of the total eligible population we estimate to be in the study area. For ease of drawing segments, we chose 25% as our target proportion.
[46] In most cases, we use eight segments to allow us to adjust land area proportion in increments of 12.5% if fieldwork reveals population numbers to be substantially different from expectations. In some larger or smaller-than-average settlements, we use fewer segments.

Data Analysis

Unit of Analysis

The unit of analysis is the individual 12 to 16-month-old infant.

Sample Analyzed

Primary sample:

- Intention-to-treat (ITT) estimate for all clinics randomized. This is the study's primary analysis sample.

Alternative samples:

- Treatment on the Treated (TOT) estimate for all clinics where New Incentives operates for more than six months. This will only be estimated if many clinics suspend operations due to security reasons outside the security strata. This estimate would only be valid for vaccinations that could not have been received during the operational period as the TOT estimator requires no correlation between treatment assignment and the outcome of interest aside from being truly treated.
- Refined scaleup sample: This sample is intended to represent those clinics at which New Incentives will operate at scale, applying lessons-learned since randomization. Clinics with questionable operational viability due to lack of a nearby ATM, lack of staffing, or security risk were randomized as separate strata but still included in the RCT. Based on New Incentives' operational experience and, if necessary, raw coverage rates, GiveWell and New Incentives, with the advice of IDinsight, will decide on the refined screening criteria to be used at scale-up. We will then drop the strata that correspond to clinic types that would be screened out at scale. To ensure logical consistency, if a less severe security strata is dropped, all of the pre-identified higher risk categories will need to be dropped, as well. For example, if moderate risk clinics are dropped, high and very-high-risk clinics will also be dropped from the analysis even if they happen to experience no issues during the study. This is because the criteria used to define the strata included in the final analysis will need to correspond with the screening criteria New Incentives would use at scale, before deciding where to operate.

Data Analysis for Primary Research Questions

What is the effect of New Incentives' program on the probability that 12 to 16-month-old children receive:

1. BCG

2. any PENTA

3. Measles 1

Hypothesis

New Incentives' program has meaningfully increased the percentage of children immunized with BCG, any PENTA, or Measles 1 across all program clinics..

Construction of Outcome Indicator

The data source we will use for each of the three primary vaccines is self-reported immunization. This means the caregiver must report the child has received a) BCG, b) at least one dose of PENTA, or c) at least one dose of measles.

The source of the data is a survey questionnaire that asks caregivers to self-report if their infant has received injectable vaccinations. It identifies vaccinations primarily by location on the body, but also includes information on the name of the vaccine and disease it prevents. There is also a *don't know* option which we will

code as having not received a vaccine. In the baseline, these data sources proved to be reasonably reliable for the vaccines New Incentives incentivizes, with the exception of differentiating doses of PENTA and reporting PCV.[47] Consequently, PCV and the exact number of doses of PENTA received are not included as primary outcomes. There is a high degree of inaccuracy in caregivers' recall of the number of doses their infant received.[48] PCV is difficult to measure based on self-report since it is given in the same location as IPV.[49]

Details on the accuracy of self-reported immunization are in Annex 3. We do not expect meaningful differences in the accuracy of self-reported data between treatment and control groups. This is not true, however, for the accuracy of immunization reported by child health cards and in child immunization registers. As New Incentives' program checks child health cards and child immunization registers and encourages officials to supply them, we expect the program will improve the degree to which clinic staff record vaccinations on the cards and on the register, as well as the degree to which caregivers retain child health cards.

Specification

We will estimate the following regression specification:

$$\boldsymbol{Y_{ij}} = \beta_0 + \beta_1 * T_j + \beta_2 * B_j + \beta' * P_{ij} + \beta' * \alpha_j + \varepsilon_{ij}$$

- Y_{ij} is the endline vaccination status of eligible infant *i* in clinic cluster *j* based on caregivers' report. This is a binary for whether a child has received the vaccine associated with each primary outcome.
- T_j is the treatment status of clinic cluster j which includes infant *i*.
- B_j is the baseline coverage rate defined as the self-reported coverage among 12 to 16-month olds for clinic cluster *j*.[50] For Jigawa, this variable will take the value of 0 with the variation taken by the state dummy.[51]
- P_{ij} is a vector of individual and clinic level covariates.[52] These include:
    - Infant's gender
    - Whether the caregiver attended Islamic school
    - Caregiver's formal education (some primary, some secondary, some post-secondary)
    - Caregiver's age
    - Household Size (number of people who eat from the same pot or report the same household head)
    - Subjective Wealth (7-step ladder)
    - Objective Wealth (Latest Nigeria PPI index)

[47] See Annex 3 for a more detailed discussion of our assessment of self report data at baseline.
[48] For infants with PENTA 3 on child health cards, 90% of caregivers reported their infant received PENTA, but only 45% reported their infant had received three doses of PENTA. Conversely, 79% of those that reported receiving three doses of PENTA had PENTA 3 recorded on their cards, but if we restrict to those who reported three doses of PENTA at a health facility then 97% had PENTA 3 on their cards.
[49] While 92% of infants with PENTA marked on their cards had PCV marked, only 71% of infants that reported PENTA reported PCV.
[50] Segment or settlement level coverage rates are not used due to the small samples in many settlements and the likelihood that catchments in some clinics may change slightly.
[51] For the one clinic in Zamfara without baseline coverage survey data, (Kairu PHC), we will drop the clinic from the main specification. We will run a robustness check with the baseline coverage estimated as the average baseline coverage for Bukkuyum LGA.
[52] We expect these covariates to be largely available across the sample. If, however, they lead to dropping large numbers of observations due to missing covariate date we will a) run alternative specifications with dummy variables that absorb the variation associated with missing covariates and b) run robustness checks that drop the troublesome covariates.

- Whether the child was born at a clinic
- The catchment area in square kilometers
- Whether the UNICEF VCM[53] program was operating in the clinic at baseline
- Whether the UNICEF VCM program was operating at the clinic at endline
- Whether any other immunization programs were operating in the clinic catchment area during the study period

- α_j is a vector of dummies corresponding with randomization strata. These include:
  - State
  - Baseline coverage rate group[54]
  - Remoteness and limited staffing (as defined by New Incentives during clinic screening)
  - Baseline security category
- ε_{ij} is the error term for infant *i* in catchment *j* clustered at the clinic cluster-level.

P-values will be corrected using the Free Step-Down Resampling Method proposed by Westfall and Young (1993). Due to the highly correlated nature of the coverage outcomes, this method was chosen over simpler procedures as the power gains were potentially significant (Blakesley et al. 2009). Annex 4 describes the procedure in more detail.

Where appropriate for publication in medical/public health journals, we will also estimate a logistic regression specification, examining the impact of New Incentive on the odds that 12-16 months receive (1) BCG, (2) any Penta, or (3) Measles 1.

Secondary Research Questions

1. What is the effect of New Incentives' program on the percentage of 12 to 16-month olds that are fully immunized?
2. Does New Incentives' program improve the timeliness of vaccination, particularly for Measles 1 among 12 to 16-month olds?
3. What is the effect of New Incentives' program on the average number of vaccines received per 12 to 16-month-old child?
4. What is the effect of New Incentives' program on the percentage of 12 to 16-month olds that received at least one injectable vaccine?
5. What is the effect of New Incentives' program on the probability that a 12 to 16-month old in a community served by a study clinic received at least one dose of PCV?

[53] This is a widespread UNICEF program where community mobilizers encourage mothers to seek antenatal care and immunization services.
[54] Coverage strata were based on groups of five or six clinics based on a simulation suggesting given the sample size per clinic, strata of this size and smaller provide equivalent balance. For smaller strata, i.e. clinics with different screening or security status, we used coverage groups with as few as two clinics.

6. What is the effect of New Incentives' program on 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?[55] [56]

Analysis of Secondary Research Questions

The analysis of secondary research questions will follow the model specified above for the primary research question with different outcome variables.

Fully Immunized Child

The indicator we will use is self-reported full immunization. This means the caregiver must report the child has received BCG, PENTA 1-3, *and* Measles 1. These five vaccines are the key vaccines for Nigeria's five-visit routine childhood immunization schedule targeted by New Incentives.

We have loose and string definitions of full immunization due to the high degree of uncertainty in caregivers' recall, especially for different numbers of PENTA doses.[57]

Timeliness

The study defines timeliness as receipt of vaccination up until one month after the due date[58] because of concerns over birth date reliability. We measure timeliness from the demand-side, meaning we analyze to what extent caregivers bring their child for vaccination according to the prescribed due date. This is a binary indicator which will only include children whose cards or clinic register indicated they received the vaccine.[59] Gibson et al. 2016 used two weeks from the due date to define timeliness, but the study used demographic registry data and had exact birth dates. We will use this definition and a continuous outcome as robustness tests.

Average Number of Vaccines per Child

This outcome is a proxy for retention and will take the self-reported number of vaccinations corresponding with each visit in New Incentives' vaccination schedule from BCG, PENTA 1-3, Measles 1. The average number of vaccines received per child could range therefore, from zero to five vaccines. We use the number of vaccinations rather than individual visits as infants can receive multiple vaccines in the schedule during the same visit.

Children that received at least one injectable vaccine

While the primary outcomes are individual injectable vaccines, this outcome is based on the self-reported response to the question "Has your child ever received any injectable vaccinations to prevent him/her from

[55] IDinsight will collect either Tally Sheets or Monthly Immunization Summaries, depending on the workload of all clinic-enumerator tasks, as determined during field practice prior to data collection. Tally Sheets are – we think – a slightly more accurate source, though our Midline analysis showed them to be quite consistent with Monthly Immunization Summaries, which are much easier to collect.

[56] IDinsight collected these records as part of midline data collection in March/April 2019. We found a robust positive impact across vaccinations but these results were for a time period ending part-way through the RCT window so follow-on collection is necessary. These administrative records are imperfect, and we worry that the program itself may cause them to improve, leading to differential data quality in treatment and control. However, they remain an important alternative source that we expect to show results at least qualitatively similar to those found with self reports.

[57] The inaccuracy of dose recall is why the probability of receiving any dose of PENTA, rather than three doses of PENTA, define the primary outcome.

[58] We define an infant's due date for vaccination using the birth date written on their child health card or, if no card is available, their self-reported birth date. About 80% of infants had birth dates on cards within a month of the reported birth date.

[59] If card retention differs dramatically between treatment and control, it is unlikely we will be able to draw meaningful conclusions with respect to timeliness as the population with cards in the two groups would not be comparable.

getting a disease?" This question is accompanied by a visual aid clearly showing the difference between injectable vaccinations and oral vaccinations.

Robustness Tests

The following is a subset of the robustness tests we will also report:

- Regression controlling for a full range of covariates[60]
- Regression controlling for baseline coverage
- Alternative functional forms
    - Logistic regression model
- Alternative sources of vaccination coverage
    - Vaccination status based on child health card or clinic register match
    - Vaccination status treating "don't know" response as missing
    - Vaccination status using BCG scars as an alternative measure of BCG vaccination coverage (a check on self-reported data)
- Alternative measures of timeliness
    - Binary with two-week window (rather than one month)
    - Days since the due date
- BCG scars
    - This outcome is the percentage of infants that enumerators observe with BCG scars. Though not issue-free, BCG scars do avoid the recall problems that affect self reported data and the imperfect record keeping that affects administrative data.[61] Accordingly, we will use program impact on scars as a robustness test for impact on self-reported BCG vaccination. Large discrepancies will be cause for further investigation.

Limitations

In addition to the data quality and multiple hypothesis testing issues discussed in the primary outcome indicator and specification sections, the validity of the study may also be threatened by contamination and attrition.

Contamination

[60] The covariates we will control for will be

- The baseline coverage rate defined as the self-reported coverage among 12 to 16-month olds for clinic cluster j. For Jigawa, this variable will take the value of 0 with the variation taken by the state dummy.
- Individual and clinic level covariates. These include: infant's gender; whether the caregiver attended Islamic school; caregiver's formal education (some primary, some secondary, some post-secondary); caregiver's age; household Size (number of people who eat from the same pot); whether the caregiver ever received non-cash incentives for vaccinating; subjective Wealth (7-step ladder); objective wealth (latest Nigeria PPI index); whether the child was born at a clinic; whether the caregiver has heard positive messages about vaccination from local leaders; the catchment area in square kilometers; whether the UNICEF VCM program was operating in the clinic at baseline; whether the UNICEF VCM program was operating at the clinic at endline; whether any other immunization programs were operating in the clinic catchment area during the study period; dummies corresponding with randomization strata (these include state, baseline coverage rate group, remoteness and limited staffing as defined by New Incentives during clinic screening, baseline security category)

[61] During the baseline, around 29% of infants whose administrative records indicated BCG had no scar and 33% of infants who reported receiving BCG had no scar. The issue is more likely with the accuracy of the records than the enumerators. The opposite is not true for those with scars: 93% had BCG recorded on their card if they had a card, and 95% of these respondents reported BCG. In a study of 70 vaccinated infants at a hospital in India, Dhanawade (2015), found 91% of infants had scars indicating a scar failure rate of 9%.

New Incentives cannot ensure that all infants it serves are from program clinics' catchments. Even though New Incentives has systems in place to probe caregivers about their settlement of origin, it is certainly possible for caregivers to lie. This could lead to two issues: caregivers from control clinics receive incentives at treatment clinics or overcrowding occurs that could impact operations at treatment clinics in a way that would not exist at scale.[62] To combat the first issue, treatment and control sites were spaced such that the average control clinic is 22 km from the nearest treatment clinic. This was based on exit interviews at pilot sites in the North West and an analysis of settlements listed in clinic records for those clinics. More details can be found in the pre-RCT report.

In certain cases where clinics were relatively close to each other (15km as the crow flies), New Incentives confirmed that traveling between the two clinics was difficult. However, the main source of assurance that control caregivers will not travel to treatment clinics is the sheer number of non-study clinics between treatment and control sites. None of the study clinics' nearest neighbors are study clinics and only 2% of study clinics have a study clinic included among their five nearest neighbors. Thus, people from non-study neighboring clinic catchments would likely overcrowd a treatment clinic before substantial numbers of infants from control clinics would visit. During the baseline, we asked caregivers to identify other clinics attended. We did not identify any cases of caregivers listing a study clinic as an alternate clinic they visited to vaccinate their child.[63] However, 20.6% of infants reportedly received at least one vaccination at a non-study clinic (though they lived in the catchment area of a study clinic).[64]

Attrition

While attrition in terms of individual infants is only a minor issue[65] because a different cohort is surveyed for each round of data collection, attrition of clinics is possible. IDinsight may be unable to survey[66] some fraction of study clinic catchments at endline due to security threats. IDinsight and its survey partners will make every effort to survey all study catchment areas while ensuring personnel safety.

Migration

Infants who move into a treatment clinic after having started their vaccination schedule elsewhere are often ineligible for the program (to avoid fraud in the form of changing clinics to obtain incentives twice). These infants will be untreated but will be surveyed if they meet the age cutoffs. Infants who enroll in the program before moving out of the catchment area are partially treated but will not be surveyed. If rates at which both phenomena happen are large and different from what would occur at scale, this could reduce the extent to which we can extrapolate from the study's results to the scale-up context. Baseline and piloting suggest that this happens rarely and it is likely that both phenomena will occur at scale, though perhaps less often, since -

[62] At scale, overflow beneficiaries could go to nearby facilities, which would also provide the program.
[63] Our analyses focused on clinics where at least four caregivers reported going to another clinic so it is possible we missed a case. Further, sometimes caregivers used alternate names for facilities that we could not match to our database.
[64] New Incentives has taken additional steps to mitigate overcrowding at their program clinics, including adding additional immunization days. It is not possible to screen for overcrowding in all cases, and further strategies to mitigate this risk is an essential part of New Incentives' ramp up period.
[65] At baseline, we had very limited refusals and do not believe these will be different between treatment and control. We did have 18 infants that died between census and the routine immunization survey. While the treatment could affect the probability of this kind of attrition, there are likely to be only a handful of cases across the endline survey, especially since we plan to conduct RI at the same time as HH wherever possible. A broader concern is that enumerators would be more likely to be unable to find households that are on the physical or social margins of the community. However, this dynamic should affect treatment and control catchments equally. It is, therefore, a concern for generalizability rather than bias.
[66] IDinsight will make every reasonable effort to survey all clinics. In general, we will use New Incentives' security classification system, or similar criteria, to determine where it is safe to survey.

without control clinics - any enrolled infant who moves is much more likely to move to another program catchment and remain enrolled.

Annex 1: Clinic Selection

This annex explains how clinics were selected for the New Incentives Evaluation.

Summary

New Incentives and IDinsight's approach to clinic selection was to create a representative sample of well-spaced, operational, and secure clinics offering routine immunization services in the three North Western Nigerian States of Zamfara, Katsina and Jigawa. It is important to note that the requirement that the clinics were well-spaced does mean that clinics in clinic-dense areas were less likely to be selected. While clinic density is relatively uniform across North West Nigeria, we will analyze at endline the degree to which 27 semi-urban and urban clinics, across the three states, are different from clinics in less population dense areas to ensure the results are fully generalizable.

We optimized the selection of clinics across the three Nigerian states to maximize distance between selected clinics and thus minimize spillovers between treatment and control clinics. New Incentives screened out clinics at which New Incentive's scaled program would not normally operate. The four criteria set during pre-screening included: security, availability of routine immunization (RI) services, remoteness, and staffing. The latter two categories were used for prioritizing clinics rather than excluding clinics. To assess availability of RI services, minimum criteria were applied; specifically, records confirming ongoing RI services over the past six months and the clinic building was usable.

As New Incentives is uncertain of how one RI staff member and/or longer travel distance affect operations, especially longer-term sustainability, a few such clinics were included in the final sample so that New Incentives can learn how the program functions at these types of clinics. Clinics with stockouts of vaccines or child health cards, low-volume clinics,[67] and clinics with certain designations such as Dispensaries or Health Posts were *not* excluded because these are clinics that New Incentives would include at scale. This mix of criteria allowed for a diverse and representative sample of clinics.

Clinic selection occurred in roughly three phases. First, clinics in Katsina and Zamfara were selected in preparation for the baseline. After the end of data collection, the Katsina and Zamfara clinic list was reduced due to security issues. Finally, the Jigawa list was selected to compensate for the reductions in the Katsina and Zamfara lists.

Details of Selection Processes (Katsina & Zamfara)

Initial selection

IDinsight used an algorithm[68] to randomly select public clinics in each of the states, optimizing the distance between selected clinics. The program randomly selected a starting clinic and then dropped all clinics within 17km[69] before selecting the nearest neighbor. This process continued until all clinics were exhausted. The output of the best iteration of this program was then adjusted to increase the number of eligible clinics by selecting clinics slightly closer together than 17km but separated by natural gaps in the road network. There are only nine pairs of treatment and control clinics less than 17km apart, and New Incentives staff vetted these cases to ensure that travel times and costs would be greater than the value of the incentive.

[67] Low-volume is defined as less than an average of 20 injections per routine immunization day.
[68] IDinsight explored using maximum independent set algorithms but ultimately chose a Monte Carlo technique due to processing power limitations. The inputs into these algorithms were geocoded lists of clinics.
[69] 17km was chosen based on an analysis of distance caregivers traveled to clinics during the pre-RCT phase. That analysis found an average distance traveled of approximately 5km. The pre-RCT report contains a detailed discussion of distances traveled and travel costs recorded during June data collection.

To define the universe of possible clinic locations, we used two lists of health facilities in North West Nigeria. The first list is from eHealth Africa and is informed by Nigeria's national polio vaccination campaign microplanning. The second list is from the Nigeria Millennium Development Goals Information System (NMIS). The eHealth Africa data is continuously updated while NMIS data is from several snapshots (2010, 2012, and 2014). The eHealth Africa data had slightly more clinics than the NMIS data, and almost every NMIS data point overlapped or corresponded with a clinic in the eHealth Africa data. For Katsina and Zamfara, we used clinics present on either list. For Jigawa, however, we used only the NMIS list as we discovered that the eHealth list included many non-operational clinics.[70]

The next step was to determine which clinics were suitable for the New Incentives program and, therefore, representative of those in which it would operate at scale.

Pre-screening

Before visiting candidate clinics, New Incentives contacted state, LGA, and clinic-level officials to rule out clinics that were obvious non-options. Firstly, New Incentives consulted Local Immunization Officers at LGAs and RI Focal Points at clinics to identify clinics that were not operational or that did not offer RI services in July/August 2017. These were excluded from the study and not visited by New Incentives for a clinic screening. Similarly, Local Immunization Officers and State Immunization Officers identified clinics with such high security risk in July/August 2017 that it was not advisable to visit, even during the daytime. These areas were designated "no-go-zones," excluded from the study, and not visited by New Incentives for a clinic screening.

Clinic screening

New Incentives conducted clinic screening visits in all remaining selected clinics, as they would under typical program operations, to identify which clinics met four additional criteria for exclusion from the program: 1) clinic does not offer RI services; 2) clinic is in an insecure area ("no-go security zone")[71]; 3) clinic has only one staff member working on RI services (paid or unpaid); and 4) clinic located more than three hours' journey to a bank that provides cash transfer funds. New Incentives included some clinics that should have been excluded based on criteria 3 and 4 in order to learn more about implementation in those settings.

In addition, New Incentives used screening to gather information on indicators beyond the exclusion criteria such as clinic staff receptiveness to the program. These additional factors did not influence exclusion decisions but were meant to inform New Incentives' operational planning.

Clinic screenings included:

- Reviewing administrative vaccination records, staffing, and general clinic receptiveness to the program.
- Cross-referencing georeferenced settlement maps from eHealth Africa, often displayed in the clinics, with hand-drawn catchment maps and hand-written catchment lists. Listing the settlements in the catchment area was often the longest part of the screening.
- Estimating travel time for New Incentives' screening staff to reach the clinic from a nearby hub town with an ATM.

[70] It is possible these abandoned clinics are used during polio campaigns which explains their inclusion in the eHealth data, since the primary purpose of eHealth geodata is polio campaign microplanning.
[71] Based on new information not available during pre-screening.

Clinic categorization

Information from the clinic screening visits was used to categorize clinics according to a mix of security and operational considerations:

1 ("Yes"): These clinics were less than two hours away by public transport from hub-towns, had no security issues, and had more than one RI staff member. They also ranked well on a range of supply-side criteria like volume and stockouts (these criteria did ***not*** result in clinic exclusions and were only added for informational purposes).

2: These clinics were less than two hours from the nearest hub town, safe and had more than one RI staff member.

3: These clinics were two to three hours from the nearest hub town, safe and had more than one RI staff member.

4: These clinics were over three hours from the nearest hub town, safe and had more than one RI staff.

5: These clinics only had one staff member (paid or unpaid) working at the clinic on RI services.

"O": These clinics were not operational (abandoned/destroyed) or barely operational (e.g., routine immunization tools and records were not available or not used for months, building structure of clinic was severely damaged, no patients in past months).[72]

Added by IDinsight:

SC: Clinics with an estimated population of less than 1,500 in their official catchment.[73] This population is needed to ensure a sufficient sample of infants would be available to conduct the study.[74] This led to four clinics being excluded from the study (including baseline).

The clinic screening process identified clinics with additional security challenges, resulting in further categorization:

- **No-go Clinic (Category X) –** Clinics where staff members said it was unsafe to operate during the day, and the information was confirmed by a second official. All were excluded.
- **Serious Security Issues (Category 2x, 3x, 4x) –** Clinics where the staff flagged serious security concerns but clinic staff and other officials claimed the clinic was safe for daytime operations. The 2, 3, and 4 refers to how the clinic would be otherwise categorized i.e. less than two hours from the nearest town, over two hours but less than three hours, and over three hours respectively.
- **No security flag –** Clinics that had no or minimal security concerns. Clinics where staff noted some security issues but deemed it safe to work there in the daytime were not flagged if other officials reported it was safe. For example, the report, "There are a little security issues [sic] around the area, it is mere robbery and it has not affected the clinic in any way," did not result in a categorization flagging security issues.

New Incentives' security categorization was further refined after the baseline. These revised criteria are discussed in the section on clinics excluded prior to randomization.

New Incentives did ***not*** screen out clinics based on common supply-side indicators. This choice is meant to ensure the study results will generalize to a variety of clinics in the three states. Criteria that were not used to screen out clinics include:

[72] For example, one category O clinic operates out of a room in the village head's house, because a village member stole the roofing material from the clinic. There were no immunization records, and immunization only took place irregularly throughout the year.
[73] This assumption was based on initial New Incentives' clinic screening data collection.
[74] We assumed 10% of households would have a 12 to 16-month old and, based on our simulations, we estimated we needed twenty-five 12 to 16-month olds to use for stratification. However, during the pre-RCT phase we noted that sometimes infants are identified for RI that are ineligible, so we surveyed 300 households in every catchment instead of 250 in order to have a buffer.

- Vaccine stockouts
- Child Health Card stockouts
- Very low turnout in the past six months

Accordingly, we would expect to observe roughly equal rates of these factors in study clinics and in clinics to which New Incentives might scale up. Similarly, New Incentives included some clinics in remote and hard-to-reach areas despite the fact that initial clinic screening criteria would have excluded them. This is also meant to make the study sample more realistic and to give New Incentives experience in (and data on) this subset of clinics.

The following sections describe the precise exclusion categories and how they were applied to arrive at the final clinic list.

Clinic selection

The final list of clinics was selected first on minimum security and operational criteria. Some additional clinics that did not meet "strict" criteria were also included due to lack of alternate clinics. The criteria are outlined below.

Minimum Criteria

Operations

- Category 'O' clinics were excluded.

Security

- Clinics categorized as having "serious security issues", Categories X and 2-4x, were excluded as a precautionary measure. Since New Incentives' staff will be moving in these areas with cash, New Incentives prioritized staff safety when deciding at which clinics it would be reasonable to operate.
- Clinics with some security issues or no major security issues, i.e. no security flag, were included in the baseline.
- In general, the security situation in Zamfara, where all serious issues were flagged, is fluid and clinics deemed secure in the summer of 2017 may not remain so throughout the study. Changing circumstances could lead to additional exclusions.

After baseline, changing circumstances led to further exclusion of clinics from randomization for security reasons. The sample retained some Category 5 and category 4 clinics, that did not meet the "strict" criteria due to a lack of alternate clinics based on buffer zones. These considerations are discussed below.

Additional "Strict" Criteria (used for prioritization)

- Minimize the number of category 5 clinics since the ability of one staff member to handle the volume of infants produced by the program is unknown.
- Minimize the number of category 4 clinics since staff need to leave from hub-towns with ATMs on every immunization day. Car hire rather than public transportation can alleviate the problem, but may be too costly to sustain at scale. Some clinics will be served with car hire during the RCT phase, as previously discussed with GiveWell.

Replacement clinics

When New Incentives identified a clinic that should be excluded under the strict criteria (one staff and far-away clinics), IDinsight provided an alternate clinic that would continue to be well-spaced with respect to the other

clinics in the sample. For issues such as insecurity and remoteness, clinics may be clustered. For example, a category 4 clinic is likely surrounded by other category 4 clinics. Rescreening was still valuable for two reasons:

- Two clinics may be similar distances from the hub town, but because of bad roads or river crossings, transport time from the first clinic may be 2.5 hours while the second may be 3.5 hours. In this case, the first clinic would replace the second. Insecurity can similarly be concentrated in small pockets due to forests or other geographic features.
- As clinics were screened out, new areas with clinics that were well-spaced relative to other clinics but not immediately adjacent to the initially selected clinic sometimes emerged. For example, when two clinics were screened out, the area (and thus the clinics) between them became available for screening.

There were some far-away and one-staff (category 4 or 5) clinics that had no nearby replacements. In these cases, the initial clinic was kept so that all selected areas remained in the study.

Adjusting for Towns

As a final step, additional clinics were selected for New Incentives' operations in towns. Catchment areas in towns are more difficult to define and the official list of catchment neighborhoods often fails to correspond with who actually comes to the clinic. Consequently, if New Incentives operates at only one clinic in a town, it will either be flooded by beneficiaries or have a very high rate of caregivers who would be excluded from the incentives program because they are not from the catchment area. This high rate of turning caregivers away would be unlikely at scale when all neighboring clinics would also have the program. Thus, in certain towns, we recommended that New Incentives operate at multiple clinics to reduce this risk. These additional clinics would not add to the number of catchment areas in the study, so they do not increase power as catchments are the relevant unit for power.

Baseline Clusters and Clinics

After concluding this process, we identified the following catchments and associated clinics for the baseline:

- 73 clinics with 70 associated catchments in Katsina
- 66 clinics with 60 associated catchments in Zamfara

Clinics Excluded After Baseline and Prior to Randomization

After IDinsight completed baseline data collection, New Incentives conducted a detailed additional security screening on the clinics surveyed at baseline. This additional screening classified security incident reports into four categories:

- **No Go Zone**: Frequent armed violence with deaths on way to clinic or close to clinic during daytime (past two months)
- **Serious Security Issues**: Armed violence with deaths on way to or close to clinic, but not during daytime (past two months)
- **Some Security Issues**: Armed violence on way to or close to clinic but without deaths in the past two months
- **No Security Issues**: No security incidents were reported within these clinic catchments.

IDinsight randomly assigned clinics with no security issues to treatment and control in the first wave of randomization. New Incentives monitored clinics that had security issues across the month of November with screenings on the 3rd, 14th, and 21st of November. Based on the screening, clinics with three or more screening resulting in a "some security issues" flag or one screening with a more serious security flag were excluded from randomization. A qualitative risk assessment by New Incentives Zamfara staff also factored

into their decision to exclude clinics from randomization. The vast majority of these drops were in Zamfara, but New Incentives also excluded a few clinics in Katsina near the Zamfara border for security.[75]

Details of selection process (Jigawa)

The screening process for Jigawa simulated the screening process in Katsina and Zamfara. When the Jigawa screening started, IDinsight and New Incentives anticipated a requirement of 30-40 selected clinics based on the number of expected clinics in Katsina and Zamfara. The screening took place in two phases. First, IDinsight identified clinics that were spaced 24 kilometers rather than 17 kilometers apart. New Incentives then screened all clinics within a 4.5km radius of the identified clinics. This wider spacing allowed for replacements for category 4 and 5 clinics to be found without additional screening rounds by choosing clinics close to the initially screened clinics as replacements. In other words, we could select the nearest eligible neighbor and not worry about it being too close to other selected clinics.

After baseline data collection, and the first round of Jigawa clinic selection, it became evident that New Incentives would be unable to operate at a number of clinics in Katsina and Zamfara due to security issues. When the scope of security drops in Katsina and Zamfara became evident, IDinsight revised the screening process in Jigawa to instead focus on creating the longest possible list of clinics 17km apart in order to maintain the study's power. IDinsight tried to build this list from the initial screening, thus only 27 new clinic screenings were required for the new approach. Since security issues disproportionately affected category 4 and 5 clinics in Katsina and Zamfara, all category 4 and 5 clinics on the Jigawa list were included to ensure a sufficient number of these clinics were included in the overall study for New Incentives to learn about operating at these marginal clinic types.[76]

Table 3: Summary of Clinics in Katsina and Zamfara by Category

Exclusion Category	Clinics for Baseline			Randomized Clinics			
	Katsina	Zamfara	Total	Katsina	Zamfara	Jigawa	Total
Categories Yes and 2	34	35	69	33	29	32	94
Category 3	34	21	55	31	13	13	57
Category 4	2	7	9	2	1	7	10
Category 5	3	3	6	3	1	10	14
Total Clinics	73	66	139	69	44	62	175
Clinics Sharing Catchment	3	6	9	3	4[1]	1	8
Total Catchments	70	60	130	66	40	61	167

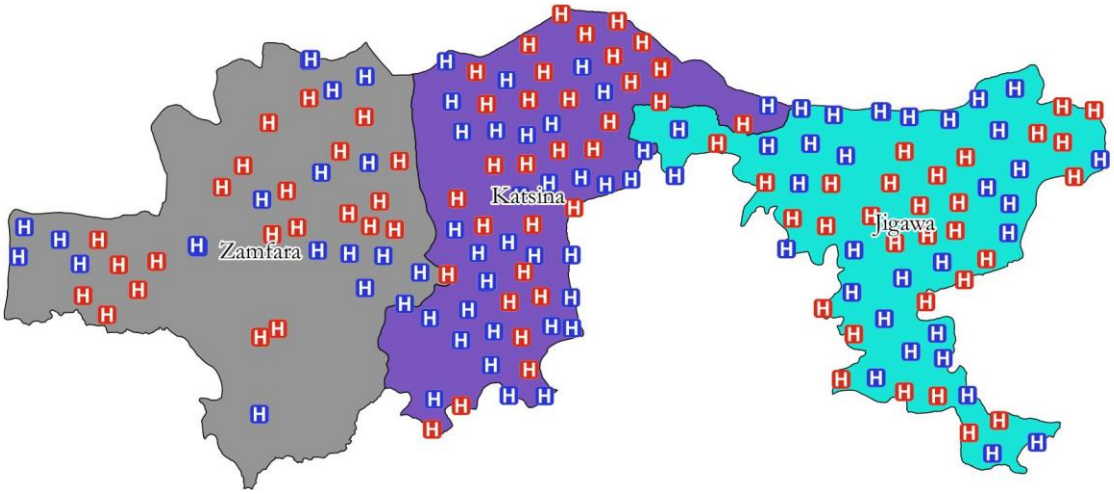
[1] Based on field verification, we determined two complementary clinics in Zamfara were not necessary.

[75] We dropped 21 clinics in Zamfara and four in Katsina. We replaced one dropped clinic in Zamfara with a nearby clinic.
[76] As previously discussed, New Incentives requested a sufficient number of category four and five treatment clinics so that they can benefit from operational learnings about these marginal clinic types.

Map of Randomized Clinics

Figure 3 is a map of randomized clinics in the New Incentives evaluation across Katsina, Zamfara and Jigawa. Clinics in red are treatment clinics while clinics in blue are control clinics. The area in southern Zamfara with no clinics is an area of high insecurity where many clinics dropped due to security concerns. There are a few cases where clinics are quite close to each other but are in the same treatment group. These clinics were randomized as pairs. More details on the randomization process, including paired clinics, are in Annex 2.

Figure 3: Map of Randomized Clinics in Katsina, Zamfara and Jigawa:



Annex 2: Randomization Procedure

This annex explains the strategy IDinsight used to randomize clinics in the New Incentives Evaluation.

Goals

IDinsight randomized among clinics that met New Incentives' criteria for operations, ensuring that our evaluation results are as representative as possible of those expected if New Incentives scales up throughout North West Nigeria. Recognizing the importance of ensuring balance between treatment and control clinics, GiveWell, New Incentives, and IDinsight agreed on a study design that included baseline survey activities. The objectives of randomization are highlighted below in order of importance:

1. Ensure balance on baseline routine immunization coverage between treatment and control clinics.
2. Facilitate sub-sample analyses to provide impact estimates for different scale-up scenarios.
3. Allow flexibility in the randomization and subsequent ramp-up timelines in response to changing security information.

Data Sources

- IDinsight baseline coverage survey in Katsina/Zamfara
- New Incentives' initial clinic screening
- New Incentives' security monitoring

Randomization Phases

Randomization was broken into two phases to balance the need to start operations while allowing time for New Incentives to re-asses the security situation in some clinics. The attributes of each wave were:

- **Secure Wave**: Initial randomization to allow New Incentives to start rolling out to secure study clinics (early November 2017)
    - Randomization of secure clinics in Katsina and Zamfara.
    - Randomization of 16 clinics in Jigawa without baseline coverage information. New Incentives chose these clinics - in a region where it already has trained staff - from the full list of clinics. These clinics did not have a higher probability of being selected for treatment, as the full list of clinics was randomized in later waves.
- **Security Compromised Wave[77]:** Randomization after all stakeholders reassessed security issues and IDinsight explored administrative data options for stratifying Jigawa clinics by coverage. Unfortunately, IDinsight determined administrative data was not reliable enough for this purpose, so Jigawa clinics were randomized using only the other stratification criteria.
    - Randomization of additional clinics in Katsina and Zamfara
    - Randomization of remaining clinics in Jigawa

Preparing for Randomization

Below is a high-level overview of the relationship between the clinic list and randomization units as well as the construction of the stratification variables:

Randomization Units

- Remove complementary clinics
    - There are some non-study clinics which share a catchment area with a study clinic or have a poorly defined catchment border with a study clinic within a town. We call these clinics 'complementary clinics.'
    - In general, we will survey the clinic catchment under analysis. We have suggested New Incentives operate at these complementary clinics to ensure the catchment areas we survey are fully treated. For example, if people in a particular neighborhood customarily go to two clinics, we want to ensure both are served by New Incentives.
- Define clinics to be randomized as a pair.
    - During the screening process, five pairs of clinics ended up closer than considered ideal to minimize contamination, (i.e. 10-14km rather than 17km apart). Further, these pairs have a limited number of clinics between them to prevent direct contamination between treatment and control.
    - While these clinic pairs will be analyzed as a cluster, the ICC we expect will be quite low as the clinics are far enough apart to have distinct catchments, unlike the complementary clinics.
    - These clinic pairs are randomized as one unit. The coverage stratum is based on the average coverage of the two clinics. For the two cases where one clinic in a pair was randomized in the first wave and the other was randomized in the second wave, the second clinic took the treatment status of the first. IDinsight did not reveal the pairs to New Incentives.

[77] During the security compromised wave, IDinsight and New Incentives agreed to drop 4 clinics from Katsina and 21 from Zamfara. New Incentives asked to replace one dropped Zamfara clinic with a nearby clinic.

Stratification Variables

- Coverage was defined as the percentage of children between the ages of 12 and 16 months who ever received an injectable vaccination.
    - Coverage for individual vaccinations, such as the measles coverage rate, was clustered around zero providing limited variation for stratification.
    - We were most confident in the self-reported data from caregiver on whether their children ever received an injectable vaccination. Locations and frequencies of vaccination, which are used to determine whether a child has received particular vaccines, can be more difficult to remember.
- Clinic randomization is also stratified on a number of variables related to operability and geography:
    - State
    - Category 4 screening status (very remote)
    - Category 5 screening status (only one staff member offering immunization services)[78]
    - Security (based on New Incentives' security assessments)
        - Categories
            - Very High: "Clinics that have reported robberies without deaths repeatedly over multiple data points"
            - High: "Clinics that have reported robberies without deaths once over multiple data points but are situated in high-risk LGAs (local government areas)[79]
            - Moderate: "Clinics that have reported robberies without deaths once over multiple data points"
        - Implications
            - If New Incentives decides to use stricter security screening criteria at scale the strata corresponding with less secure clinics will be dropped from the final analysis.
                - If only clinics classified as moderate and secure will be included at scale, the strata corresponding with high and very high-risk clinics will be dropped from the final analysis.
    - Timing of Jigawa randomization.
        - 15 clinics in Jigawa were selected by New Incentives for early randomization to expedite scale-up and were stratified separately.

Randomization Procedure

IDinsight followed the steps below to randomize the clinics into treatment and control groups:

- Group the clinics into strata based on the non-coverage variables.
- For each strata with more than four clinics in Katsina and Zamfara:
    - Generate a unique stable ranking of clinics by coverage rate for each stratum.
        - Replace the coverage of paired clinics with their average so they are ranked together.
    - Divide into roughly equally sized strata across the sample targeting sizes of 4-10 clinics per stratum

[78] Two clinics in Jigawa were accidently not stratified based on category 5 status. They were stratified as Jigawa clinics that were Category 1 (Yes), 2 or 3 clinics. We will still control for the fact that they are category 5 clinics in the regression analysis.
[79] High-risk LGAs are defined as having clinics where armed killings occur regularly and during daytime.

    - Choose strata sizes to minimize misfits. Simulations suggest strata with 4-10 clinics all perform similarly if we assume the coverage is measured with noise.[80]
  - If a stratum has an odd number of clinics, we randomly select one to send to a misfit stratum.[81]
- Randomize half of each stratum, including the misfit stratum, into treatment and control.
  - Given the limited number of misfits and strata, other approaches to misfits designed to limit imbalance at other levels of stratification were deemed unnecessary.

Annex 3: Details on Self-Reported Vaccination Data

The following section compares different sources of vaccination information collected during the baseline to provide further information on the potential accuracy of different data sources.

Around 75% of infants that reported getting Measles 1 had Measles 1 marked on their child health cards. For PENTA 3, this figure was 78%. If we look at whether the infant received any dose of PENTA, the agreement is 89%. That being said, there is a risk that some of the correspondence between self-report and cards is from enumerators simply using the cards to fill out the self-report section of the survey, despite being coached not to and being aware that their tablet may have been recording random audio audits.

One way to assess the accuracy of self-reported data for vaccines aside from measles, where register quality is low, is to compare self-reported vaccination status to the register for infants without cards. The agreement between these two sources is 79% for both BCG and receiving any PENTA vaccination among infants without child health cards. If we include all infants, the agreement increases to 83%.

We focused on receipt of any PENTA vaccination as there is a high degree of inaccuracy in caregivers' ability to remember doses. For infants with PENTA 3 on child health cards, 90% of caregivers reported their infant received PENTA, but only 45% reported their infant received three doses of PENTA. Conversely, 79% of caregivers that reported receiving three doses of PENTA had PENTA 3 recorded on their cards. When we restricted our analysis to those who reported three doses of PENTA at a health facility, then 97% had PENTA 3 on their cards.[82]

PCV is difficult to measure based on self-report since it is given at the same time as PENTA. While 92% of infants with PENTA marked on their cards had PCV also marked, only 71% of caregivers that reported PENTA reported PCV.

In a similar vein, nurses administer Measles 1 on the same arm as BCG but administer yellow fever on the other arm, usually on the same visit. While caregivers are generally better at differentiating BCG and Measles 1 since BCG leaves a scar and Measles 1 does not, there is still some evidence that mothers may over-report Measles 1. The yellow fever self-reported coverage estimate was 11% and the self-reported Measles 1 coverage estimate was 15%, while there was no difference in coverage among infants with cards for both vaccines. This discrepancy could be due to the fact that caregivers can remember receiving Measles 1 more clearly as it is a more salient disease in the community, or that nurses automatically mark Measles 1 and yellow fever together on child health cards even when there are yellow fever stock outs.

[80] The simulation simulated the noise of selection of 40 children and then looked at balance between treatment and control. The balance was constant between an average stratum size of 12.5 and an average stratum size of 5.7.
[81] If one clinic is a clear outlier in terms of coverage, it was sent non-randomly to the misfit strata.
[82] This may be due to inconsistencies in recording when caregivers receive vaccinations from multiple sources. New Incentives' own experience suggests this issue is often explained by poorer documentation during outreaches.

Annex 4 The Free Step Down Resampling Method (FSDRM):

This annex explains the Free Step Down Resampling Method in further detail.

Westfall and Young (1993) proposed this correction method for less conservative multiple testing procedures. Their method proves to be less conservative since it incorporates the dependence structure among test statistics (Ge Y, Dudoit S and Speed T.P. 2003). The FSDRM consists of the following steps:

- Step 1: Run the original regressions
- Step 2: Impose monotonicity in the p-values (increasing p-values)
- Step 3: Calculate a set of simulated p-values using a simulated treatment assignment variable
- Step 4: Enforce the original monotonicity of simulated p-values
- Step 5: Calculate the adjusted p-value = the ratio of the number of times that the simulated p-values are less than the original p-value divided by the total number of iterations.

Annex 5: GiveWell's Decision

The purpose of this Annex is to describe the process by which GiveWell plans to use the results of this study to inform its decision-making about recommending funding to the New Incentives program. GiveWell considers the following factors likely to influence its decision: magnitude of outcomes, significance and confidence intervals, likelihood and direction of bias in the results, and contextual validity. GiveWell drafted this section, and IDinsight and New Incentives have reviewed it.

Background

Funding for this study was provided by the U.S.-based philanthropic foundation Good Ventures (http://www.goodventures.org/) on GiveWell's recommendation. GiveWell (https://www.givewell.org/) is a U.S.-based nonprofit dedicated to finding outstanding philanthropic giving opportunities through in-depth analysis, and to the online publication of detailed reasoning behind its recommendations to donors.

This study will inform GiveWell's evaluation of the cost-effectiveness of the New Incentives program and will contribute to the body of evidence on the effectiveness of incentives for vaccination. Cost-effectiveness and quality of evidence, together with transparency and ability to use additional funds, are the criteria that GiveWell uses to identify outstanding philanthropic giving opportunities (https://www.givewell.org/how-we-work/criteria). GiveWell's list of top recommended charities includes all programs that have chosen to participate in GiveWell's evaluation process and met GiveWell's criteria. However, not all programs on GiveWell's list of top-recommended programs receive significant funding (in excess of an incentive grant for participating in our process, which in the past has been $2.5 million per year) from donors who use GiveWell's recommendations; GiveWell recommends to donors how to prioritize donations among top-recommended programs. GiveWell's evaluation of New Incentives will culminate in a decision of whether to include New Incentives on GiveWell's list of top-recommended charities (https://www.givewell.org/charities/top-charities). In addition, GiveWell's estimate of New Incentives' cost-effectiveness, based on impacts observed in this study, will inform GiveWell's recommendation of how to prioritize New Incentives' funding needs relative to the funding needs of other organizations evaluated by GiveWell, which may result in New Incentives receiving significant funding in the millions of U.S. dollars.

Relationship disclosure: GiveWell has recommended that Good Ventures provide funding to New Incentives since 2014. Descriptions of and explanations for the rationales behind these grants are available at https://www.givewell.org/charities/new-incentives/all-content. There are no personal relationships between GiveWell or Good Ventures staff and New Incentives staff.

Overview: How GiveWell will use the results of this study

GiveWell will use the results from this study to estimate the program's effect on vaccination rates for incentivized vaccines given at five vaccination visits (BCG; PENTA 1, 2, & 3; PCV 1, 2, & 3; and Measles), to inform its estimate of the program's effect on child mortality as part of a cost-effectiveness model comparing the program to other programs to which GiveWell recommends funding. More on GiveWell's cost-effectiveness modeling: https://www.givewell.org/how-we-work/our-criteria/cost-effectiveness/cost-effectiveness-models

GiveWell's cost-effectiveness estimates are uncertain and rely on many parameters about which GiveWell has little information. GiveWell makes cost-effectiveness estimates in order to identify large differences in expected cost-effectiveness of different programs. At the time of the design of this study, GiveWell's decision to recommend funding for this study, and the writing of this document, GiveWell and IDinsight relied on GiveWell's preliminary cost-effectiveness models of New Incentives' program in order to inform decisions about sample size and projections of likely decision-relevant outcomes of the study. GiveWell expects to substantively update its cost-effectiveness modeling of this intervention by the time the results of this study are available.

GiveWell will use its updated cost-effectiveness model and impact estimates based on this RCT to make two decisions:
(1) Is New Incentives robustly more cost-effective than providing cash transfers through GiveDirectly?
(2) Is New Incentives at least as cost-effective as the programs that GiveWell recommends that donors support in a given year with their donations?

If GiveWell concludes that New Incentives' program is robustly more cost-effective than providing cash transfers through GiveDirectly, and New Incentives fulfills GiveWell's other top charity criteria of transparency, ongoing evidence of effectiveness through high quality monitoring of its program, and ability to absorb additional funding for the program, GiveWell is likely to add New Incentives to its list of top-recommended charities. However, New Incentives is likely to receive substantial funding from GiveWell only if GiveWell concludes that additional funding to New Incentives is at least as cost-effective as additional funding to competing programs.

Because the main decision-relevant outcome of GiveWell's evaluation process is a rough ranking of the cost-effectiveness and priority of programs' funding gaps relative to each other, it is important that GiveWell try to be consistent across cost-effectiveness models. GiveWell's general approach to modeling may undergo changes by the time results from this study are available that necessitate making similar changes to our modeling for New Incentives for the sake of comparability. GiveWell will write publicly about differences between these plans and actual use of the study results.

Outcomes, magnitude and significance

As noted above, the primary outcomes of this study are the coverage estimates for 12- to 16-month-old children for three key vaccines: BCG, at least one dose of pentavalent vaccine, and Measles 1. In addition to these primary outcomes, GiveWell will likely use the secondary outcomes of: *coverage of a second dose of pentavalent vaccine*, *coverage with a third dose of pentavalent vaccine, and coverage with up to three doses of PCV vaccine* for 12- to 16-month-old children in its model of the cost-effectiveness of the New Incentives program. GiveWell understands that caretaker reporting of PCV vaccine(s) and the exact number of pentavalent vaccines received may be of lower quality than the primary outcomes.

The magnitude of the point estimate for each vaccination outcome is the degree to which New Incentives' program appears to affect vaccination coverage on average in the three Nigerian states in which New Incentives operates. Statistical significance refers to whether the point estimates pass the threshold for rejecting the null hypothesis that the program has no effect. Academia has conventionally used a p-value of 0.05 as the threshold for declaring a result statistically significantly different from zero. However, GiveWell's goal is to use the study results in its cost-effectiveness model to form a best-guess expectation of New Incentives' near-future impact on vaccine coverage, even if those results are not statistically significant at conventional levels.

In order to form a best guess of a program's impact based on a study result, GiveWell generally uses point estimate study results in its cost-effectiveness models, but it may also adjust these results to incorporate other factors such as its prior beliefs about potential impacts and its views about the accuracy, validity, or replicability of the final study results. As the study results for different vaccinations are likely to vary, GiveWell may apply different adjustments to each outcome used in its cost-effectiveness calculations for New Incentives. GiveWell discusses these adjustments publicly when publishing an evaluation of a program or explanation of its decision-making.

When using the results of this study on the vaccination outcomes named above, GiveWell does expect to take the variance and statistical significance of each result into account when considering its best guess of the program's impact. The farther away from the threshold for statistical significance a point estimate is, the more

likely GiveWell is to make an adjustment of some kind to reflect the fact that the point estimate is not precisely measured and could be consistent with qualitatively different outcomes. This approach is driven not by a threshold approach to significance, but by a principle of balancing accuracy with simplicity in modeling: prioritizing the incorporation of information or adjustments if they make a difference to the outcome of the model, but not if their effect on the model is small.

External validity to future program implementation

This program evaluation has been designed to be representative of New Incentives' average past impact in three states in Northwest Nigeria, but GiveWell understands that New Incentives may choose to operate in different areas in the future for which these study results may not be fully representative. Additional concerns such as program scale-up or the presence of other programs that seem likely to impact child vaccination rates may also affect GiveWell's estimate of the expected value of funding directed to the New Incentives program. GiveWell is likely to make an external validity adjustment to the study results to account for any major observable differences between past and planned future program context and operations.

GiveWell is aware that the World Bank is currently piloting a conditional cash transfer program in Nigeria, and that infant immunization is one possible condition for the transfer that could apply at the state level. If this program ever reaches a large scale in the future and incentivizes infant immunization, GiveWell will take this competing program into account in its external validity adjustment for New Incentives. However, because the World Bank program has been operating at a small scale to date during the pilot phase and has not yet begun to incentivize infant immunizations, GiveWell does not expect its presence to impact the RCT results. Future program scale-up after the pilot remains uncertain.

GiveWell may also consider subsample or secondary analyses from this RCT to inform its views about mechanisms behind program impact and external validity, if doing so allows for a model it believes is more representative of expected program impact at scale. However, GiveWell understands that this study is not necessarily designed or powered to detect representative program impacts in subsample analyses. As a result, GiveWell expects to take into account the main study outcomes and assess the sensitivity of its final decisions to use of results from subsample or secondary analyses. GiveWell will write publicly about its decision process and any adjustments made to the main study results.

Internal validity

When forming a best guess of the cost-effectiveness of a program based on results from a study, GiveWell generally takes into account its beliefs about the study's internal validity, which reflect any ways in which the results may be biased away from the true average effect of a program over the time period covered by the trial. Similarly, GiveWell expects to consider potential challenges to the internal validity of the New Incentives RCT, and may adjust its expected value of the program's results on this basis.

GiveWell's internal validity adjustments generally take into account aspects of study design, potential sources of bias, and GiveWell's prior beliefs about the magnitude of impact a program is likely to have. Some known potential internal validity challenges for this study include that caregiver report of vaccination may be biased by the social desirability of reporting vaccination to surveyors and/or imperfect recall, that the program's effects may spill over from treatment areas to control areas, that the boundaries of some clinic catchment areas have shifted somewhat since baseline such that the treatment areas surveyed at endline will include a small proportion of settlements that may not have had access to New Incentives' program for the full study period, and that security concerns have heightened in Northwest Nigeria during the course of the study, particularly in Zamfara state. GiveWell has participated in designing this RCT, and other sections of this pre-analysis plan have discussed strategies we plan to use to mitigate these challenges. GiveWell also believes that pre-registering the study's analysis plan increases confidence in the internal validity of the study's results.

GiveWell is particularly concerned with the potential for self-reporting bias in these study results and plans to consider several available backchecks to assess the importance of this factor. In addition to self-reports of vaccination, this study will collect data from child health cards (when available) and clinic immunization registers. Assuming that remaining biomarkers pilots pass predetermined thresholds for validation, this study will also collect biomarkers samples at endline to test for measles immunity from a subset of eligible children. GiveWell understands that simulations based on the Dawid-Skene model suggest that moderately informative biomarkers, combined with administrative records, can substantially improve bias in coverage estimates when self-reports are at least somewhat inaccurate. GiveWell may therefore prefer and choose to use these adjusted estimates for measles as primary inputs into the cost-effectiveness analysis, and may use differences between the adjusted and unadjusted measles results to inform its beliefs about the magnitude of self-report bias in other estimates. However, biomarkers failed to reach threshold sensitivity to measles immunity in an initial pilot, and GiveWell recognizes that any field challenges with biomarkers execution experienced at endline may reduce our ultimate confidence in the accuracy and contribution of biomarkers. When considering how much to rely on estimates adjusted using biomarkers, GiveWell expects to consider the degree of challenges reported by enumerators in collecting saliva samples, the proportion of samples that fall outside of the acceptable cold chain range or that are missing cold chain data points during transportation to the lab, IDinsight's impressions of lab competency, and whether the degree of biomarker agreement with additional backcheck data (clinic records and child health cards) seems credible.

In addition to or instead of modeling using biomarkers, GiveWell may consider simpler robustness checks on the accuracy of self-reports using child health cards, BCG scars, and administrative records as additional data sources. While GiveWell understands that not every BCG vaccination results in a scar, it expects that if a robustness check using presence of BCG scars as an alternative measure of BCG coverage is similar to results based on self-reports of BCG, this would increase GiveWell's confidence in self-reports of vaccination. *Unrecorded vaccinations* are vaccines reported by a caretaker but unable to be verified with the infant's child health card or clinic's administrative data. If there is a substantial difference between the proportion of self-reported vaccines that are unrecorded in treatment catchments compared to control catchments, this could indicate that caregivers are differentially inflating their reports of vaccination in treatment areas. If there is a significant difference in unrecorded reported vaccinations, GiveWell will test the sensitivity of its conclusions to an analysis that adjusts for reporting bias. Because New Incentives program staff are present at treatment clinics on vaccination days, the program may have an effect on improving recordkeeping at treatment clinics. A lower bound on the program's effect could be estimated by using caregiver report of vaccinations received in control catchments while only counting only counting administratively-confirmed vaccinations in treatment clinics.

Despite attempts to space treatment and control clinics during study design and to exclude out-of-catchment infants from program enrollment, spillover of the treatment's effect onto the control population could occur if caregivers living in control catchments learn about the program and this affects their uptake of vaccination, either within their catchment or by traveling to a treatment clinic. While the former is difficult to measure, the latter should be measurable by asking caregivers what clinic they traveled to and by observing whether caregivers in control catchments have a New Incentives "All Babies are Equal" stamp on their Child Health Card from visiting a treatment clinic. If there appears to be a significant degree of spillover onto some control clinic catchment areas, GiveWell is likely to test the sensitivity of its conclusions to exclusion of the affected clinics or to inclusion of a correction factor for the degree of program spillovers.

GiveWell has and will be more knowledgeable about this study's design, implementation, and analysis compared to other studies which GiveWell relies on in its evaluations. This increases GiveWell's confidence in the internal validity of this study.

Proxy vaccines

As of this writing, rotavirus vaccination is not available as a routine vaccination in the Nigerian states where New Incentives operates, but New Incentives has told us that Nigeria is planning nationwide rollout in 2020. If routine rotavirus vaccination becomes available on the same schedule as pentavalent vaccination by the time GiveWell is completing its evaluation based on the results of this study, or is expected in the near future, GiveWell is likely to add it to the cost-effectiveness analysis using the study's observed effect of the program on pentavalent vaccination as a proxy for the program's expected effect on rotavirus vaccination. GiveWell's prior is that inclusion of rotavirus could have a meaningful impact on program cost-effectiveness, because the rotavirus vaccine protects against severe diarrhea episodes caused by rotavirus and diarrhea accounts for a relatively large proportion of under-5 mortality. However, GiveWell has not yet formally modeled the program's potential impacts on diarrhea mortality.

New Incentives has also advised that the Meningitis A vaccine and a second dose of the measles vaccine (MCV2) are planned to be rolled out in Northern Nigeria in 2019-2020. GiveWell may also add these vaccines to the cost-effectiveness analysis in the future, again using the study results from the vaccine(s) it believes to be the most relevant as a proxy for expected program impact.

As mentioned in this document, PCV vaccination is difficult to measure based on self-report because it is given in the same location as IPV and administered at the same time as pentavalent vaccines. As a result, PCV has been named a secondary outcome of this study, and GiveWell expects that PCV is likely to be underreported by caregivers. IDinsight will evaluate the accuracy of reported PCV vaccination using the subset of respondents which can also provide a child health card. If PCV self-report appears to be less accurate than self-report of pentavalent vaccination, GiveWell may use the program's effect on pentavalent vaccination (which is given and incentivized at the same clinic visits as PCV, but is the only vaccine received on the left leg and thus easier to clearly identify) as a proxy for the program's effect on PCV vaccination. GiveWell will evaluate the sensitivity of its model's output to this decision.

Use of Additional Information in the Cost-effectiveness Analysis

GiveWell expects the results from this study to be critical to evaluating New Incentives' impact, but it does not expect this information to be sufficient for calculating program cost-effectiveness. GiveWell anticipates doing additional research and taking into account information from a variety of outside sources to translate any changes in vaccination coverage resulting from the program into the two main outcomes it considers, lives saved and lives improved. This translation of benefits may in some cases involve making uncertain assumptions. GiveWell will test the sensitivity of its conclusions to key modeling assumptions.

Possible Results and GiveWell's Decisions

Because GiveWell's current cost-effectiveness model for New Incentives is preliminary and likely to undergo major changes, it is difficult to specify an impact threshold above which New Incentives would be eligible for top charity status. GiveWell currently believes that if this study finds that the New Incentives' program has a 10-15 percentage point or greater effect on vaccination rates across all of the vaccination rate outcomes considered by GiveWell, GiveWell is likely to add New Incentives to its list of Top Charities, but this preliminary impression is subject to change as the cost-effectiveness model changes. This likelihood is somewhat diminished if the results are not significant or if other concerns about the validity of the results arise.

However, GiveWell is only likely to recommend large amounts of funding to New Incentives if GiveWell believes that the New Incentives program is at least as effective a use of funds as the other top contenders for funding. Because GiveWell's estimates of relative cost-effectiveness continue to evolve, and other organizations' funding needs change from year to year, it is difficult to estimate the likelihood that GiveWell will consider New Incentives' vaccination program to be among its best uses of funding in 2020 and beyond.

However, it is likely that if New Incentives has a very large impact on vaccination rates (>30 percentage points), GiveWell will recommend grants for a substantial amount of funding to New Incentives.

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