Pilot: CCTs for Immunizations - November 2016 to February 2017

Small incentives can have a substantial impact on health behaviors such as immunization rates (<u>Banerjee et al 2010</u>). We assume that this finding applies to immunizations in Nigeria as evidenced by <u>Sato 2014</u>. A relatively small incentive can provide a sufficient nudge to encourage women to overcome the financial and time costs of an infant vaccination visit to the clinic.

Program Design

New Incentives' goal is to incentivize uptake of all immunizations in the Nigerian Child Immunization Schedule. New Incentives will define the *minimum* conditions for each payout according to the vaccinations with the highest cost-effectiveness according to Disease Control Priorities, Third Edition (DCP3). This will ensure that payouts encourage all vaccines given during a visit but that absence of vaccines with lower cost-effectiveness (OPV) do not compromise those with higher cost-effectiveness.

Implementation Models

As vaccination visits are largely free (or a maximum of N100), we hypothesize that the cash amounts only need to cover transportation costs and provide a small additional incentive. Earlier vaccination visits in the Nigerian Child Immunization Schedule (see

AGE	ANTIGEN	DESCRIPTION
At Birth	BCG, OPVO, HEB BO,	BCG prevents Tuberculosis, OPV is Oral Polio Vaccine, HEB BO prevents Hepatitis B
6 weeks	OPV 1, PENTA 1, PCV1	PENTA is a combination of 5 vaccines which prevents Diphtheria, Tetanus, Whooping cough, Hepatitis B and <u>Haemophilus</u> influenza type B all through a single dose. PCV (Pneumococcal conjugate vaccine) prevents infection caused by <i>Streptococcus</i> <i>pneumonia</i> or <i>Pneumococcus</i>
10 weeks	OPV 2, PENTA 2, PCV 2	
14 weeks	OPV 3, PENTA 3, PCV 3, IPV	Inactivated Polio Vaccine (IPV)
9 months	MV , YF	Measles vaccine , Yellow fever vaccine

table) are incentivized with lower amounts given the higher baseline rates. The fifth and final visit in the schedule at 9 months (Measles and Yellow Fever) will be incentivized with a higher amount. This takes into consideration the low baseline rates around 30-50%, the lag to the 14-week vaccination visit, and the high impact of the Measles vaccine on mortality.

Two implementation models will be tested, all incentivizing each vaccination visit in the immunization schedule, thereby avoiding potential perverse effects. Both **Model 1** and **Model 2** pay mothers after completing each infant vaccination visit. While Model 1 tests the lowest amounts deemed effective (N4,000, \$13 in total), Model 2 includes higher amounts (N7,000, \$23).

The table below shows the two models, the payout structures, cash amounts and respective conditions. While New Incentives incentivizes all vaccination visits it does not require lower priority vaccines such as Hep B0, OPV1-3 and YV for conditionality. This is to focus transfer conditions on a few highly cost-effective vaccinations (BCG, Penta, PCV, and Measles). Furthermore, any mother/infant who gets the vaccination is eligible for the related cash transfer, even if the vaccination was delayed. Otherwise the program would miss out the most vulnerable that might not be able to always come back on time. In order to track the efficacy correctly, New

Incentives will, however, track the date of each vaccination. This will enable us to e.g. factor in a lower impact on mortality as a vaccine was given with delay or a higher seroconversion rate (e.g. Measles vaccine given at 12 instead of 9 months).

	Stage:	Birth	6 weeks	10 weeks	14 weeks	9 months			
Model	Amount:	₩500	₩500	₩500	₩500	№ 2,000			
1	Condition:	-BCG	-Penta1, PCV1*	-Penta2, PCV2*	-Penta3, PCV3*	-MV			
	Stage:	e: Birth 6 weeks 10 weeks 14 wee		14 weeks	9 months				
Model	Amount:	₩1,000	₩1,000	₩1,000	₩1,000	₩3,000			
2	Condition:	-BCG	-Penta1, PCV1*	-Penta2, PCV2*	-Penta3, PCV3*	-MV			
	* = if available at clinic. PCV rollout will be completed in most Nigerian states in 2016.								
	Hep B0, OPV1-3, IPV and YV are also part of the above vaccination visits, however, will not be enforced as part of transfer conditionality.								
	TT is not included for several reasons: vaccinations take place on a different day; some women only require one vaccination which is already given on the ANC registration day (=high baseline). New Incentives has found that incentives increase ANC registrations but does not believe this is a foremost priority to focus on and prove at this stage.								

The goal of the pilot stage from November 2016 to February 2017 is to get preliminary evidence on different cash amounts and payout structures. This will give us a sense of the impact and cost of each model. Thereby we can avoid conducting large-scale research at dozens of clinics on a model that might not be maximally cost-effective.

Disbursement Method

Based on its experience with electronic money in Nigeria and further exploration over the past months, New Incentives decided to test the CCTs for Immunizations program with a cash-based disbursement method. The current method for the facility delivery CCT, Firstmonie, has the associated cost of requiring women to travel to banks to receive their cash which means it is not feasible to use for implementing small cash amounts. Other electronic money platforms have not reached maturity or face similar issues. There is no M-Pesa equivalent in Nigeria at this time. Airtime payments, while administratively attractive, are deemed much less valuable by recipients (see e.g. <u>Wakadha et al 2013</u>). Finally, a prepaid debit card costs around \$2.50 per beneficiary and is less attractive for smaller incentives given the necessary trip to an ATM. Hence, the incentives will be paid out by New Incentives staff on vaccination days at public clinics. Staff will be closely supervised to prevent fraud (e.g. daily comparison of cash available, cash handed out, and records/pictures that prove receipt of payment). Cash disbursement is expected to build a solid basis for future scaling to remote but safe states in the North West of

Nigeria where banks are spread out widely and mobile phone network coverage is poor. In summary, physical cash disbursements as opposed to electronic disbursements enable New Incentives to 1) operate a CCT program with small amounts, 2) maximize retention since the payout will be immediate, and 3) design a program that can be operated in remote states where mortality is high and vaccination uptake low.

Timeline

The rollout of the vaccination program will be guided by a few core objectives. First, learn as fast as possible but without initiating a larger research project before a short pilot phase. Otherwise the implementation is not solid enough to be thoroughly tested (Karlan 2016). Second, test more than one implementation model. Third, prove the concept in different states with varying socio-economic contexts.

New Incentives aims to start testing each of the two models outlined above in four Nigerian states by mid-November (total of 12 clinics). Two of the states are North Central (FCT, either Benue or Nasarawa), one is in the South East (Anambra), one in South South (Akwa Ibom). The selection of these states has been made after collecting and reviewing clinic-level vaccination data at over 90 clinics in seven Nigerian states. Based on this, we selected clinics that have a reasonably high volume while selecting for median retention levels within a state. Though DHS shows high vaccination uptake in South South, clinic data indicates that retention is not as high and quite low at the stage of the Measles vaccine.

Phase	Activity	Nov 2016		Dec 2016		Jan 2017		Feb 2017	
		15	30	15	31	15	31	15	28
Pilots: Models 1, 2	Rollout 2 models: 12 clinics across 4 pilot states, reach 100 new infants per month per clinic								
	Start receiving BCG to Penta 1 retention data								
	Start receiving Penta 1 to Penta 2 retention data								
	Start receiving Penta 2 to Penta 3 retention data								
	Rollout Measles catch-up incentives across pilot clinics								
	Start receiving data for Measles catch-up incentives								

The success of each implementation model will be judged based on retention between the different vaccination visits. In all models, beneficiaries who have phone numbers will receive

SMS reminders for each vaccination visit and an automated phone call close to nine months for measles.

Based on the initial pilot phase from November to February 2017, New Incentives will activate more clinics early next year. By early January, we expect to get retention data for the two Models on at least 700 participants in each model for each stage, across the four states. Depending on initial program feedback, either Model 1 or Model 2 will be chosen for the subsequent scale-up and research phase.

Along with the decision on the best implementation model, New Incentives will submit a detailed research proposal in early January 2017. This will build on ongoing conversations with GiveWell and IDinsight over the coming months. The research phase will run from February or March to the end of July.

Budget

New Incentives seeks \$181,563 for the pilot of its CCTs for Immunizations program that runs from November 2016 to February 2017 (four months). The pilot includes 12 clinics in four states and approximately 4,800 beneficiaries. <u>See detailed budget</u>.

Questions from GiveWell

Q. When must a woman/infant receive a vaccination in order to be eligible for the cash incentive? We expect that vaccination schedules are not followed precisely. For example: measles vaccination is scheduled for 9 months. Is a woman whose infant is vaccinated against measles at 8 months or 10 months eligible for the cash transfer? What about 7 months or 11 months? What about a woman whose infant receives the first PENTA shot at 9 months (instead of 6 weeks) when she goes in for a measles vaccination? How wide is the window for each vaccine? (In monitoring of the effect of the program, what will count as 'proportion of infants who received timely vaccination'?) Depending on the design, we expect that the NI program could have an effect on the proportion of infants who are vaccinated at any age, or could have an effect on the rate at which infants are vaccinated in a timely manner according to the vaccination schedule.

- A. New Incentives' primary goal is to achieve an optimal balance between increasing the number of infants who have received at least one vaccine, increasing completion of the full vaccination schedule, and increasing completion of vaccines in a timely manner. Each objective conflicts with the others to some degree if focused on in isolation. New Incentives plans to solve this issue by:
 - Defining clear eligibility criteria for each vaccination payout. Vaccines with the highest cost-effectiveness according to Disease Control Priorities, Third Edition (DCP3) will define the minimum conditions for each payout. Other vaccines that are given based on Nigerian guidelines for vaccinations will be tracked, but not

be required as part of the condition of the CCT (see table on different models in proposal).

- a. Example: A woman who attends the six-week vaccination visit and receives Penta1 and PCV1 (the latter where available as the rollout in Nigeria is still ongoing) will be eligible for the cash transfer. Even though OPV1 is also supposed to be offered during the 6-week visit, a woman will receive the incentive if she only completes Penta1 and PCV1. This means that in case of a stockout of an essential vaccine such as Penta, the mother would not receive the respective cash transfer. However, in the case of a stockout or missed application of OPV1, the woman would still get the transfer as long as Penta1 and PCV1 were completed.
- 2. Restricting the transfers to only those who complete the vaccinations on time, misses a large opportunity to encourage unvaccinated children to return to the clinic. As a solution, any vaccines received within the respective vaccine's window of effectiveness will qualify for a payout. New Incentives expects that vaccinations given in a timely manner and those not given in a timely manner to have different cost-effectiveness estimates (e.g. the mortality impact of a vaccine given later might be lower. At the same time, a vaccine given at a later stage might have a higher seroconversion rate as is the case with the Measles vaccine). This is why New Incentives has decided to collect the specific date each vaccination was given so that this can be assessed.

Q. We expect that M&E for this program involves checking clinic vaccination records. Is the fact that a woman/infant is recorded as having received a vaccine good evidence that they indeed received the vaccine and have an immunization chance similar to clinical settings?

A. Two questions are being asked here: are clinic registers good evidence (likely yes, given a mother will not want to compromise her baby if she comes to the clinic, our incentives are very low, and we'll have a staff member in the clinic to verify this). Second question is efficacy in Nigerian setting. Based on preliminary data, temperature and storage conditions seem to be well maintained. New Incentives will conduct scaling assessments to get detailed information about these for every clinic it serves and continue to conduct clinic audits to assess the supply and storage of vaccinations twice a year (and on a weekly basis during normal clinic visits). The audits will also include knowledge-based questions for nurses about how to apply different types of vaccinations. In general, we believe that a health worker with years of training is able to correctly vaccinate a child (e.g. not inject it at the wrong spot). For clinics where refrigeration is available, vaccines are stored on site. For smaller clinics without registration, vaccines are brought from a central hub on the morning of every vaccination day.

Q. Some vaccines are not recommended for HIV+ infants due to high chance of adverse effects. How will New Incentives ensure that the program does not incentivize contraindicated vaccination of HIV+ infants? If the program requires that infants also have an HIV test, will this reduce uptake? Are HIV tests available? If women with HIV+ infants are not eligible for the program (or some of the transfers in the program), will this exclude a population that would benefit most from cash transfers and those vaccinations for which they are eligible?

- A. This issue is relevant for live vaccines (BCG, Polio, PCV, Measles and Yellow Fever). Initial recommendations can be found below (and in <u>this</u> table):
- 1. **BCG**: the vaccine most in guestion regarding this issue. Research shows that BCG should not be administered to infants who have been immunocompromised. WHO acknowledges the difficulty in assessing this for infants immediately after birth since early infant diagnosis (EID) tests can be carried out only six weeks after birth, with results only being available several weeks, often months later. Since the recommended timeline for administering BCG is immediately after birth, diagnosis before administration is not practical unless the mother comes forward and discloses that she is positive and severely immunocompromised (low CD4 count). According to the WHO, the risk of not giving BCG exceeds the risk of giving it to HIV-exposed infants. The main risk of BCG is that if given much later during the first year post birth, an infant might be immunocompromised by then (higher risk than if administered immediately after birth). New Incentives plans to do more research into how to address these issues if it pursues offering catch-up incentives for BCG whereby all infants under 1 who are not vaccinated for BCG could benefit from a CCT. For now we will follow the WHO guidelines and assume that an infant immediately after birth or even 1-2 weeks after birth cannot already be severely immunocompromised.
 - a. "The (WHO) Committee recognizes the difficulty in identifying infants infected with HIV at birth in settings where diagnostic and treatment services for mothers and infants are limited. In such situations, BCG vaccination should continue to be given at birth to all infants regardless of HIV exposure, especially considering the high endemicity of tuberculosis in populations with high HIV prevalence." <u>Source</u>.
- Polio: Inactivated polio vaccine (IPV) should be given instead of OPV (Oral). It is unclear how New Incentives can enforce this unless mothers disclose their HIV-positive status to nurses which is unlikely due to the high risk of stigma.
- 3. **PCV:** Evidence is inconsistent, but given the significantly higher risk of Pneumonia among HIV-positive children, PCV is recommended. There is no evidence regarding significant negative effects on HIV-positive children.
- 4. Measles: the measles vaccine has not shown any mortality effects on HIV-positive infants. Sometimes, there can be adverse effects but the effect of the vaccine seems to create immunity for most HIV-positive infants. However, it can be contraindicated in people who are severely immunocompromised. Extract from report of GACVS meeting of 17-18 June 2009, published in the WHO Weekly Epidemiological Record of 7 August 2009: <u>http://www.who.int/vaccine_safety/committee/topics/measles_hiv/Aug_2009/en/</u>
 - a. WHO guidelines are valid for HIV-positive infants and should not be modified. Further exploration should be done to determine efficacy and whether HIV-positive (and potentially HIV-exposed) infants require MCV2.
- 5. **Yellow Fever:** "Monitoring vaccination campaigns in countries where the prevalence of HIV is about 1–5% has identified only a few HIV-positive individuals among those with

any serious AEFI; no clear risk has been identified that precludes the use of yellow fever vaccine in people infected with HIV." Source: WHO Weekly Epidemiological Record, 2011, page 42: <u>http://www.who.int/vaccine_safety/committee/reports/wer8605.pdf</u>

Q. How will New Incentives verify whether beneficiaries received a vaccine, and whether they received it in a timely manner? Our understanding is that use of vaccination cards varies regionally. Even if clinics where New Incentives works use vaccination cards or records, it is possible that women and/or nurses have incentives to falsely record vaccination in order to access the cash transfer or avoid drawing attention to stockouts.

A. New Incentives staff will monitor vaccination days for visibility and accountability. It will cross-check vaccination cards with vaccination registers. Registers are the most reliable source of information because they are checked by different clinic staff and monitored by other health system partners. New Incentives will also look into a proper strategy for spot checks and/or stock audits (e.g., does the number of vaccinations documented in the clinic register match the number given on a specific vaccination day?). New Incentives believes that by making the verification of vaccines and cash payouts highly visible, the chance of fraud will be reduced.

Q. What is the vaccination rate in the population that already attends ANC? We make an educated guess at this, but we don't actually know. I worry that maybe women who attend ANC already get vaccinated at a high rate.

A. More women receive vaccinations than attend ANC based on Nigerian DHIS data for 2015. New Incentives will no longer focus on 'catching' women during ANC. Instead, we will focus on all infants who come in during vaccination days. By focusing on the vaccination days, we can increase the number of vaccinations each infant receives as well as attract unvaccinated infants.

Q. Are nurses properly trained to administer vaccines? We are uncertain about the level of skill or training needed to effectively administer vaccine.

A. Based on preliminary visits, yes. New Incentives will develop an assessment to study this in detail. In comparison to other medical procedures, administering vaccinations is relatively easy. The main task is to correctly verify the child's previous vaccination history and give the shot at the right spot on the child's body.

Q. Are vaccines available in clinics potent? i.e. are they transported and stored under appropriate conditions, are they unexpired?

- A. Based on preliminary visits, yes. New Incentives is drafting a detailed assessment to study the following regarding proper administration of vaccines (list is not complete):
 - 1. Questions to check expiration date and protocol if nurse receives an expired vaccine from the hub. Inquire at clinics and hubs.
 - 2. Are the vaccinations being given intramuscularly (IM)?
 - 3. Which (if any) vaccinations are being given subcutaneously (SC)?

- 4. How much separation do nurses leave between different vaccination sites on the body?
- 5. What does a nurse do when the needle is removed and there is blood?
- 6. Do nurses change gloves between patients if they wear them? [the recommendation is to not wear gloves but that if they are worn, they need to be changed in between each patient]
- 7. Which vaccines (if any) require the nurses to fill the syringe themselves? Depending on the response, do the nurses remove the air pockets before administering the vaccine?
- 8. Do nurses draw up vaccines at the beginning of the shift?
- 9. Are vaccines stored with the protective cap or only the seal? Are vaccines punctured?
- 10. Are separate alcohol swabs used to wipe vials and then the patient? What about separate swabs between patients?
- 11. Is the full vial of the vaccine always administered?
- 12. Does the nurse ever reuse a syringe or combine syringes when more than one vaccine is being administered?
- 13. What does the nurse do if a vaccine leaks out slightly during administration?
- 14. If a patient pulls away during administration of a vaccine and the needle comes out, does the nurse reintroduce the same needle and finish the injection? [important question since infants often wiggle or move away]
- 15. Which vaccinations should be given subcutaneously (SC) versus intramuscularly (IM)? Some like pneumococcal polysaccharide vaccines may be given either way but some must be given IM in order for the vaccine effectiveness to be maintained.
- 16. Non-live vaccines can be given the same day (or hour). For live vaccines, if they are not given the same day, they need to be separated by a period of 4 weeks. What if an infant comes in for Measles and Yellow Fever, but is only given one or the other, does the nurse ensure 4 weeks is maintained before the missing vaccine is administered?
- 17. Vaccines should always be administered while the patient is sitting. Is this going to be an issue when more women come?
- 18. If the nurses have to use diluents, can significantly complicate our assessment of proper administration. \rightarrow NI will inquire more

Outstanding Major Program Design Questions

- 1. How can we determine whether or not an older child received a given vaccination? (e.g., measles; relevant for catch-up incentives)
- 2. What do we do about outreach camps? Would children now refuse the camps because they then do not benefit from the incentives? Initial research shows that outreach activities only focus on certain vaccinations.
- 3. How can the program routinely assess the presence and frequency of vaccination camps; do they all use registers during community outreaches and camps? How do incentives conflict and/or collaborate with the camps?
- 4. If a child comes in for the first dose of Penta at 14 weeks, is this recorded as Penta 1 or Penta 3? So far, is recorded as Penta 3 but assess across all clinics.
- 5. How can we obtain mortality data by cause (e.g, Measles) broken down by age group?
- 6. How can we obtain mortality data by cause (e.g. Measles) broken down by state? If not available, by zone?

Pilot Proposal Questions for GiveWell

The following questions apply to the four-month pilot at 12 clinics from November 2016 to February 2017:

Q. There are costs to the level of M&E we adopt with our model. Our current inclination is to measure the increase in completion of PENTA by using the clinic registers to inform us of the percentage of women who came for BCG and finished the vaccinations through PENTA 3. Do you think this will be satisfactory?

Q. As part of our catch-up vaccination experiment, we plan on contacting mothers whose children have missed the 9 month Measles (and Yellow Fever) vaccine. For this, we will be contacting mothers whose phone number we can find in the immunization or delivery register and have children who are older than 10 months and younger than 5 years. Would it be satisfactory to use the names we find in the registers to match these women and include the additional uptake as part of New Incentives program contribution? Based on our research, we have found the efficacy of the Measles and YF vaccine is 90%+ after the age of 9 months. However, New Incentives does not have data regarding Measles mortality at different age levels. In other words, though Measles efficacy is strong at 3 years of age, if the bulk of mortality is for children under 3, the cost-effectiveness of vaccinating these children would be lower.

Q. We plan to use other methods to get the message out to women such as town criers, radio messages, referral bonuses, etc and we expect the message to travel widely via participating women. This is expected to attract infants who haven't previously had at least one vaccination in the past. How do we calculate the program's effect on attracting completely unvaccinated children?

CE Model Feedback

- Effect of facility delivery should not be included since we are not incentivizing it. Model assumes BCG, OPV0, HEP B0 is only given to children born in clinic, which is not the case since many women visit the clinic after giving birth. However, since not all do, BCG coverage is not 100% among this population so should reflect possibility to increase retention there too.
- 2. Why is there a facility delivery cap for BCG? BCG should be separated from facility delivery based on the feedback above.
- 3. Model would need to be updated based on weighted average of clinic baselines (ex: for Penta1 baseline is higher but for Measles, baseline is lower). New Incentives will share baseline data over the coming weeks.
- 4. MCV1 retention: model assumes an 8.3% increase. NI is aiming for a minimum of 20 percentage point increase.
- 5. DPT3 not an indicator that DPT1 and DPT2 have been given. Rather, means baby came in during that timeframe (14 weeks post birth) based on our initial conversations with health staff here.
 - a. Note by GiveWell in Pertussis tab states: "We assume that reported coverage rates for multi-part vaccines given as a series indicate the proportion of the population which have received some number of doses, not the proportion of the population which received a particular dose at a particular time. For example, if coverage for DPT 1, 2, and 3 is reported as 70%, 50%, and 40% respectively, our understanding is that this means that 70% of children have received DPT1 (and may have also received additional doses), and that 40% of children received all three doses of DTP. We do not believe these numbers mean that 70% of children have received DPT1, a vaccination given at or around week 6, and a (correlated, but not necessarily subset) 40% of children have received DPT3, a vaccination given at or around week 14. (For context: although measles vaccine is not a series, in some countries measles vaccine is given twice, at different ages. Our understanding is that coverage is reported separately for MCV1 which is given at 9 or 12 months, and MCV2, the same vaccine given at 15-18 months. For example, MCV1 coverage at 80% and MCV2 coverage at 50% indicates not that 50% of children received both MCV1 and MCV2, but simply that 50% of children received MCV2.)"
- 6. Question about a note in the draft CEA model: Supplementary Immunization Activities (SIA): Measles vaccination going down as more vaccinated at 9 months? → Can we interpret this as "the importance of the 9 month Measles vaccination decreases as more children are reached through SIA"?
- 7. There seems to be significant uncertainty about the case fatality rate for Measles. Would New Incentives need a mortality study in order to become a top charity with the CCTs for Immunizations program?
- 8. Mortality between 1-12 months (period of 11 months) is back-calculated from other data points (neonatal mortality, etc). Does this all pull from the same wealth quintile?

- 9. As currently structured, is it an issue in the CEA model that some children will only get Measles and not complete the full vaccination schedule? Could model instead be structured on the cost-effectiveness by vaccination stage instead of the total cost per woman?
- 10. Adding the PCV impact in the model would probably add the largest effect in addition to Pertussis and Measles. PCV rollout has been ongoing in Nigeria for a few years and is expected to be completed in 2016.