Improving Immunization Coverage in Rural India: A Clustered Randomized Controlled Evaluation of Immunization Campaigns with and without Incentives

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Abstract (278 words)

Context: Immunization rates in developing countries are low. The efficacy of incentive-based interventions designed to increase immunization rates has not been established.

Objective: We conducted a randomized, controlled study of immunization camps in rural India to assess the efficacy of modest, non-financial incentives on immunization rates of children aged 1-3, and compare it with the effect of improving the reliability of the supply of services.

Setting: Rural Rasthan, India.

Design: 134 villages were randomized to one of 3 groups: a once-monthly reliable immunization camp (intervention A; 30 villages); a once-monthly reliable immunization camp with small incentives (lentils and metal plates for completed immunization; intervention B; 30 villages), or control (no intervention, 74 villages). Surveys were undertaken in randomly selected households at baseline and approximately 18 months after the interventions started (at endline). The primary end point was the proportion of village children aged 1-3 at endline who were partially or fully immunized.

Participants: 1640 children aged 1-3 at endline.

Findings: Among children aged 1-3 in the endline survey, rates of full immunization were 38.3% for intervention B villages, compared to 16.6% for intervention A villages, and 6.2% for control villages. The relative risk of complete immunization for intervention B versus control was 6.19 (p<0.0005) and for intervention B versus intervention A was 2.30 (p< 0.0005). Children in areas neighboring intervention B villages were also more
likely to be fully immunized than were those from areas neighboring intervention A villages (RR 2, p<0.07).

Interpretation: Improving reliability of services improves immunization rates, and small, non-financial incentives have large positive impacts on the uptake of immunization services in resource-poor areas.

Trial Registration:

International Standard Randomized Controlled Trial Number Register (http://isrctn.org)

IRSCN87759937
Introduction

Immunization is a highly cost effective way of improving child survival in developing countries.\textsuperscript{1,2} However, it is estimated that every year, at least 27 million children and 40 million pregnant women worldwide do not receive the basic package of immunizations (as defined by the WHO and UNICEF), and 2 to 3 million people die from vaccine-preventable diseases.\textsuperscript{1,3} In India, immunization services are offered free in public health facilities, but the immunization rate remains low. According to the National Family Health survey (NFHS-3), only 44\% of 1- to 2 year-old children have received the basic package, That rate drops to 22\% in rural Rajasthan, the setting of the present study, and to less than 2\% in our study area (a disadvantage population in rural Udaipur district) at the time of our baseline (which used a more detailed survey instrument than the NFHS-3, less likely to over-estimate full immunization rates).\textsuperscript{4}

Both reliable supply of free immunization services and incentives to improve the demand for these services may improve immunization rates. Previous studies have assessed the effectiveness of financial and non financial incentives to encourage immunization and other preventive health behaviors. Non-randomized studies of the Measles Campaign carried out in Africa suggest that coupling the distribution of measles vaccines and bed nets increases bed net ownership by more than 40 percentage points,\textsuperscript{5,6} but the studies do not estimate the program’s impact on measles vaccination rates. Conditional Cash Transfer (CCT) programs, popular in Latin American countries, have been shown to be effective in promoting the utilization of certain preventive health care services, and have also demonstrated a positive impact on health outcomes for women and children.\textsuperscript{7,8,9}
However, these programs have not been found to have a large impact on immunization rates. The lack of impact may be due to high initial immunization rates in the areas where the programs were carried out. More generally, most CCT programs have been implemented in countries with existing adequate local health infrastructure, such that evaluations of their impact cannot shed light on the relative cost effectiveness of establishing incentive-based interventions (versus improving quality of health infrastructure) in more resource-poor settings.

Our study addresses these gaps by assessing the relative efficacy and cost effectiveness of only improving the supply of infrastructure for immunization, versus improving supply and simultaneously increasing demand through the use of incentives. Using a clustered randomized controlled trial, this study evaluated two interventions in rural Rajasthan, India. In one intervention, regular, well-publicized immunization camps were held, while in the second intervention, similar camps were held and parents were additionally offered small incentives to immunize their children. A third set of villages formed the control group. A clustered level was the only choice for intervention A, which was a village level intervention, and the only option that could be implemented in the field in intervention B. Individual level randomization would have generated resentment against the NGO. Therefore, our study examines the effect of supplying a reliable health service in a resource poor setting, and also tests the additional effect of coupling the supplied health service with an incentive.

**Methods**
This project was approved by the health ministry of the government of Rajasthan, the office on the use of human subjects at Massachusetts Institute of Technology, and the ethics committee of Vidhya Bhawan, the university which hosted the project in Udaipur. Informed consent was first obtained orally at the community level from the research hamlets through village meetings to which all adult members of the village were invited to attend. Individual level informed consent was then obtained orally from every family participating in the study.

*Selection and description of sample*

The main sample consists of 134 hamlets randomly selected from the partner NGO’s (Seva Mandir) catchment area in Udaipur, using the random sample generated in Stata and over sampling hamlets that are far away from a road (a hamlet is a well identified groups of houses, the equivalent of a village). In addition, to measure potential spillover of the interventions, one hamlet was randomly selected within 6 kilometers of each intervention hamlet.

Within each village, a household census was conducted, and 30 households were randomly selected using a random number generator to be part of the study. The criterion for inclusion in the study is to belong to a sample household, and to be a child aged 0 - 7 years at the end of the study.

Since Seva Mandir works in poorer and more tribal villages, the hamlets selected are not representative of Udaipur in general, but instead representative of Seva Mandir’s
catchment area, an impoverished area where health status is very poor.\textsuperscript{11} The public facilities serving these areas are characterized by very high absenteeism: weekly visits during the year preceding the intervention showed that 45 percent of the health staff in charge of immunizations (Auxiliary Nurse Midwives, or ANMs) were absent from their village-level health sub-center (and could not be found anywhere in the village) on any given workday, and there was no predictable pattern to their absence.\textsuperscript{11}

\textit{The interventions}

The vaccine package administered in this study is the WHO/UNICEF Extended Package of Immunization (EPI), which is the package provided by the Indian government. For children, the EPI includes one dose of BCG vaccine, three doses of DPT vaccine, three doses of oral polio vaccine (OPV), and one dose of measles vaccine.\textsuperscript{12} A child should be fully immunized (i.e. have received all the EPI vaccines) by age one year.

Given that a full immunization course requires at least five visits to a public health facility, the unreliability of the ANMs may deter families from taking their children to the sub-center to complete the full immunization schedule. Therefore, intervention A (“immunization camps”) focused on establishing regular availability of immunization services. It consisted of a mobile immunization team including a nurse and assistant (both hired by Seva Mandir) who conducted monthly immunization camps in the villages. The nurse and assistant held the camp on a fixed date every month at a fixed time (11 AM to
2 PM). The presence of the nurse and assistant was verified by the requirement of timed and dated pictures of them in the villages, and by regular monitoring. Review of records showed that of 1,336 planned camps, 95% (1,269) took place. In addition, in each village, a social worker was responsible for identifying children, informing mothers about the availability of the immunization camps, and educating them about the benefits of immunization.

Intervention B used the same immunization camp infrastructure as intervention A, but in addition offered parents one kilogram of lentils per immunization administered, and a set of thalis (metal plates used for meals) upon completion of a child’s full immunization. The value of the lentils was about Rs 40 (less than one dollar), equivalent to three quarters of one day’s wage.

At the first immunization, every child was given an official immunization card indicating his name, the name of his parent, and the date and type of each immunization performed. The nurse also kept a detailed logbook. Following standard guidelines, when a child arrived at a camp without an immunization card and it could not be ascertained whether he had received a given immunization, he was immunized.13

Study and evaluation design

The impact of the interventions was evaluated using a clustered randomized control trial. Figure 1 presents the flow chart. Using the random number generator in Stata, and after
stratification by geographical block (the administrative unit above the village), 30 out of the 134 study hamlets were randomly selected by professor Duflo to receive intervention A, and 30 were selected to receive intervention B. The 74 remaining villages were control villages, and received no intervention. When a camp was established in a hamlet, any non-immunized child younger than 5, from any hamlet, was eligible for immunization in the camp. All children younger than 2 were eligible for the lentils in intervention B camps. If a child began the immunization course before turning 2, she remained eligible for the incentives until the completion of the immunization course. Therefore, children included in the study sample are aged 1 to 3 at the endline survey.

Survey methodology and validation

The primary outcome is the immunization rate. Most households in the areas do not have immunization cards (unless they received one during the intervention). The immunization rate was therefore ascertained during interviews with the mother. Mothers were surveyed about the immunization status of all children under age 7 at endline, and about the mother’s immunization status during her pregnancy with each child.

The survey instrument used was developed to elicit accurate reporting of immunization status. Because a parent may confuse immunization with other injections (injection of antibiotics is a frequent treatment in India) and may not realize the difference between different vaccinations, the instrument asked in detail about each shot received by the
child, including whether it was administered to cure a sickness, by which facility it was administered, where on the body it was administered, and whether it left a mark.

To validate the survey instruments, we used a sample of 343 children who had valid immunization cards and 144 children for whom we had complete logbook records. Immunization status elicited from the survey instrument corresponded to within one injection of the status indicated on the card 80% of the time, and to within one injection of the status indicated in the logbook 75% of the time. This suggests that our measure of the number of immunizations received is accurate only to within +/- 1 shot. Therefore, we used two definitions of being “fully immunized”: (1) reporting that the child has received 5 or more vaccinations, and (2) reporting that the child has received 4 or more vaccinations. In contrast, the validation suggested a large level of over-reporting of immunization when using the basic data collection instrument used by the NFHS.

The baseline survey took place between June 2004 and February 2005, and covered all children aged 0-5 in the sample households. The intervention started in each geographical block after the baseline was completed. The endline survey took place between July 2006 and February 2007, about 18 months after the interventions started in a particular village. It used the same survey instruments, and covered all children age 0 - 7 in the same households. Both surveys were blind: interviewers did not know which villages belonged to which intervention (or control) group. Data entry, cleaning, and validation were completed in September 2007 and analysis and report write up took place between October 2007 and May 2008.
End points

The primary end point of the study was the proportion of children receiving part or all of the EPI. The main analysis reported in this study focuses on children aged 1-3 at endline (i.e. eligible and old enough to be fully immunized). Some of these children were not born at the time of the baseline survey. A complementary analysis examines a baseline cohort of children who were eligible to enroll in the program for at least 6 months after the program started in their village. These children are between 2 and 3.5 years of age by the time of the endline.

The outcomes include the probability of receiving at least one EPI immunization (excluding OPV, which almost all children have received, and therefore does not affect the statistics); the number of EPI immunizations received; and the probability of receiving the complete EPI, measured in two ways as described above.

Complementary analysis reports the impact of the interventions on neighboring villages. We report the probability of being immunized in hamlets neighboring intervention A and intervention B camps, differences between these two groups of neighboring hamlets and the control group, and relative risks.

Statistical analysis
Taking into account correlation of end point within village and clustering of the treatment at that level (a intra cluster correlation of 0.25 was assumed based on a preliminary survey), it was determined that a sample of 30 hamlets per treatment arm (with about 14 children ages 1-3 years surveyed in each household) was sufficient to obtain 80 percent power for a 5 percent level test of a difference of at least 5 percentage points in the probability to be fully immunized.

The analysis was performed using intention-to-treat analysis: i.e. all households were analyzed with the assumption that they remained in the treatment group to which they were initially assigned. The analysis is weighted to account for the oversampling of villages far away from the road, but the results are virtually identical using unweighted data (unweighted results available upon request). Robust (White) estimates of variance were used to allow for the clustered design at the hamlet level (using the “cluster” option in Stata). All confidence intervals are adjusted for clustering. For the binary variables, we report proportion in each group, difference in proportions across groups, and relative risks (with confidence intervals and p-value based on chi-square statistics). For the count variables (number of immunization), we report values in the treatment group, difference across groups, and relative risks. We present all the results both adjusted and unadjusted for basic covariates (age, gender, size of household, parental education, health behavior, geographical controls etc…).
Role of the funding source

Funding for the intervention came from the Dorabji Tata Trust. Funding for the research came from the Mac Arthur Foundation. Neither foundation participated in the design of the study (although they reviewed the design before making the funding decision), the data collection or analysis, or the decision to submit the paper for publication.

Results

The final sample includes 5279 children aged 0 - 7 years at endline, from 2898 households, in five groups of villages: 74 control, 30 intervention A, and 30 intervention B villages; and 27 villages neighboring an intervention A village and 26 villages neighboring an intervention B village. 2188 children were 1 - 3 years old at endline, with the following distribution: 860 from control hamlets; 379 from intervention A hamlets, 382 from intervention B hamlets, 265 from a hamlet neighboring an intervention A hamlet, and 302 from a hamlet neighboring an intervention B hamlet.

Baseline characteristics of children across the treatment arms were comparable (Table 1). There were no differences in proportions of children partially or fully immunized, or in the covariates. Immunization rates were less than 2 percent among 1-3 year olds. The intra-cluster correlation at baseline was 0.28.

Primary end point: impact on immunization in the treatment hamlet
Using the definition of 5 or more vaccines as the measure of being fully immunized, the highest rate of full immunization was observed for intervention B (Table 2, Figure 2). In intervention B hamlets, 148/382 (weighted mean: 38.3%; 95% CI: 29.0 - 47.7%) children were completely immunized, versus 68/379 (weighted mean: 16.6%; 95% CI adjusted for clustered design: 9.8 - 23.4%) in intervention A hamlets, and 50/860 (weighted mean: 6.2%; 95% CI: 3.1 - 9.2%) in control hamlets (Figure 2). The relative risks of being completely immunized are 2.69 for intervention A versus control (p = 0.002), 6.19 for intervention B versus control (p < 0.0005), and 2.30 for intervention B versus intervention A (p < 0.0005). Adjusted and unadjusted relative risks are similar (Table 2). Relative to the comparison group, immunization rates more than doubled in intervention A villages, and increased by more than 6 times in the intervention B villages. Similar results are obtained when “at least 4 shots” was used as the measure of being fully immunized (Table 2). The intracluster correlation at endline was 0.29 (all CI and p-value are adjusted for this intracluster correlation).

The difference between intervention B and intervention A is more marked for full immunization than for the number of immunizations received, and it disappears for the probability of receiving at least one shot (Figure 3). Specifically, 77% (95% CI: 69 - 85%) of children in intervention A hamlets received at least one shot, compared to 74% (95% CI: 67-82%) of children in intervention B hamlets. The impact of the incentive was mainly to reduce the number of children dropping out after 2-3 injections.
The results for a cohort of children covered by the baseline survey and eligible to enroll in the first 6 months of the program are shown in Table 2, panel B, and the results are very similar (in this case the adjusted risk controls for baseline immunization).

**Impact on neighboring hamlets**

Table 3 shows immunization rates in hamlets neighboring the intervention villages. In hamlets within a few kilometers of an intervention B camp, 61/302 children (weighted mean: 20.0%; 95% CI: 8.7-31.3%) were completely immunized, compared to 36/265 children (weighted mean: 10.0%; 95% CI: 4.2-15.8%) in hamlets bordering an intervention A camp. The relative risk of being completely immunized for hamlets neighboring intervention B camps versus control hamlets is 3.23 (p = 0.001), and that for hamlets neighboring intervention B camps versus those neighboring intervention A camps is 2.00 (p = 0.074) (Table 3).

Figure 4 shows a plot of the probability of being fully immunized as a function of the distance to the nearest intervention B hamlet. The probability of being immunized is a smoothly decreasing function of distance from the incentive hamlet, dropping to 10% after 2 kilometers.

**Discussion**
This randomized controlled study of immunization camps shows that offering families in resource-poor settings modest, non-financial incentives can significantly increase uptake of immunization services. In our study, reliable camps with incentives achieved significantly higher rates of full immunization for children aged 1-3 compared to control areas where no camps were made available and compared to reliable camps without incentives. While control hamlets had a full immunization rate of 6.2%, hamlets in which a reliable camp was held showed rates of 16.6%, and adding the incentive pushed rates to 38.3%, a statistically significant increase. Moreover, while a camp without incentives increased immunization rates only in the hamlet where it took place, camps with incentives also increased rates in neighboring villages.

A number of previous studies have shown that uptake of preventive behaviors is very sensitive to small incentives or small costs, suggesting that incentives can play a role in promoting preventive health services.\textsuperscript{14,15,16} However, other researchers have suggested that in resource poor settings, ensuring a reliable supply of health services and educating parents about the benefits of preventive care are more important than providing incentives.\textsuperscript{17,17} Previous studies on the effectiveness of incentives were conducted in environments where the delivery of care was already adequate. As a result, these studies did not address the question of the relative effectiveness of these two classes of interventions. In contrast, our study design allowed us to demonstrate that providing incentives \textit{in addition} to reliable services and education is more effective than providing services and education alone.
Limitations of our study include that the study was not blind from the point of view of the villagers, who may have been motivated to attend the camp to ensure that Seva Mandir would not cancel the program. The study was also conducted in an environment where initial immunization rates were extremely low. Similar interventions may not produce as dramatic an increase in areas where initial immunization rates are higher.

Nevertheless, the magnitude of our results shows that holding regular immunization camps combined with small incentives may greatly improve immunization rates in very poor areas. Moreover, in this context, providing incentives and improving the supply of services is also more cost effective than improving the supply of services alone. One implication of the increased immunization rates in the villages with incentivized camps (and in the surrounding villages) is that the camps with incentives were busier than those without incentives. Inspection of the logbook revealed that for any given camp, 2.8 more children were immunized in a camp with incentives than in a camp without. Because the camps had to be open from 11 am to 2 pm regardless of the number of children present, the cost per child immunized was lower in the camps which offered incentives than in those which did not, even considering the cost of the incentives. Specifically, the cost to Seva Mandir of fully immunizing a child was $27.94 (Rs. 1,102) in the reliable camp with incentives compared to $55.83 (Rs. 2,202) in the reliable camp without incentives. Moreover, while the lentils represented a cost to Seva Mandir, their distribution may have led to improved nutrition in an environment where malnutrition and anemia are endemic. These results thus nuance prior conclusions that achieving the Millennium Development Goals is strictly a function of addressing inadequate health infrastructure. We suggest
that simultaneously strengthening the supply and offering incentives to bolster demand for health service may be a more effective strategy.

Our results also suggest reasons that immunization has not been more widely embraced in developing countries. In intervention A, even when access is good and a social worker constantly reminds parents of the benefits of immunization, more than 80 percent do not get their children fully immunized. Nevertheless, more than 75 percent obtained the first shot without the incentive, and stopped attending the camps only after 2 or 3 shots. This shows that the parents do not have strong objections to immunization, but that they are not persuaded enough about its benefits to overcome the natural tendency to delay a slightly costly activity. This explains the tendency to not complete the whole course of immunization. Providing the lentils helps overcome this procrastination because the lentils make the occasion a (small) “plus” rather than a small “minus”. Thus, in the case of preventive care, small barriers may turn out to have large implications. Finding effective ways to overcome small barriers may hold the key to large improvements in immunization rates and uptake of other preventive health behaviors. In the case of immunization, small non-monetary incentives coupled with regular delivery of services appear to have the potential to play this role.
Author Contribution and Conflict of interest Statements

Esther Duflo (corresponding author). I declare that I participated in the study design, data collection, data analysis and interpretation, and drafting of the manuscript. I have seen and approved the final version. I had full access to all the data in the study and I take responsibility for the integrity of the data and the accuracy of the data analysis.

Abhijit Banerjee: I declare that I participated in the study design, data collection, data analysis and interpretation, and drafting of the manuscript. I have seen and approved the final version.

Rachel Glennerster: I declare that I participated in the study design, data collection, data analysis and interpretation, and drafting of the manuscript. I have seen and approved the final version.

Dhruva Kothari: I declare that I participated in the study design, data collection, data analysis and interpretation, and drafting of the manuscript. I have seen and approved the final version.

Conflict of interest statement

All authors declare that the answer to the questions on your competing interest form are all No and therefore have nothing to declare.

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Medical writer
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REFERENCES


### Table 1. Base-Line Characteristics of the Children

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Definitions: Treat A refers to the 30 villages randomly selected to receive reliable immunization camps. Treat B refers to the 30 villages randomly selected to receive reliable, incentivized immunization camps. The comparison group refers to the 74 villages randomly selected to receive no treatment. Clustered standard errors are reported in parentheses.
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Table 2. Treatment Effects: Immunization Status in Main Hamlets

Definitions: Treat A refers to the 30 villages randomly selected to receive reliable immunization camps. Treat B refers to the 30 villages randomly selected to receive reliable, incentivized immunization camps. The comparison group refers to the 74 villages randomly selected to receive no treatment. Clustered standard errors are reported in parentheses.

Note: Where noted, analyses are adjusted for the age and gender of the child, baseline immunization status, the size, income, land holdings, and caste of the child's household, the number of rooms in the child's house and whether it is electrified, and whether the child's household treats its water.
### Table 3. Treatment Effects: Immunization Status in Spillover Hamlets

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<td>vs. Treat B vs. Treat A</td>
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Definitions: Treat A refers to the 30 villages randomly selected to receive reliable immunization camps. Treat B refers to the 30 villages randomly selected to receive reliable, incentivized immunization camps. The comparison group refers to the 74 villages randomly selected to receive no treatment. Clustered standard errors are reported in parentheses.

Note: Where noted, analyses are adjusted for the age of the child and the baseline immunization status of the main hamlet.
Figure 1: Consort Flow Chart

Assessed for eligibility: 134 hamlets

Excluded: 0 hamlet
- Not meeting inclusion criteria
- Refused to participate
- Other reasons

Remarks: The randomization occurred at the hamlet level, and all hamlets assigned to receive the treatment did so.

Enrollment

Is it Randomized? Yes

Allocation

Allocated to intervention A
- (30 hamlets, 30 households per hamlet are surveyed)
- Received allocated intervention (30 hamlets)
- Did not receive allocated intervention (0 hamlet)
  - Give reasons

Allocated to intervention B
- (30 hamlets 30 households per hamlet are surveyed)
- Received allocated intervention (30 hamlets)
- Did not receive allocated intervention (0 hamlet)
  - Give reasons

Follow-Up

Found in follow up endline
- (n=871 children age 0 to 7 in 30 hamlets)
- (n=379 age 1 to 3 in 30 hamlets)
- Estimated lost to follow-up
  - (n=155 children aged 0 to 7), no hamlet was lost
- Give reasons: Household moved; unable to find child; child died.
- Discontinued intervention
  - (n=0 children)

Found in follow up endline (0-7yrs.)
- (n=886 children age 0 to 7 in 30 hamlets)
- (n=382 age 1 to 3 in 30 hamlet)
- Estimated lost to follow-up
  - (n=210 children aged 0 to 7) no hamlet was lost
- Give reasons: Household moved; unable to find child; child died.
- Discontinued intervention
  - (n=0 children)

Analysis

Analyzed
- (n=379 children aged 1 to 3 at endline): all children eligible for analysis
- Excluded from analysis
  - (n=492 children aged less than 1 or over 3)
- Give reasons:
  - Only children over 1 should be fully immunized, and only children under 3 were eligible for incentives in the camps.

Analyzed
- (n=382 children aged 1 to 3 at endline): all children eligible for analysis
- Excluded from analysis
  - (n=504 children aged less than 1 or over 3)
- Give reasons:
  - Only children over 1 should be fully immunized, and only children under 3 were eligible for incentives in the camps.
Allocated to Control
(n=74 hamlets 30 households per hamlet are surveyed)
Received control
(n=74 hamlets 30 households per hamlet are surveyed)
Did not receive control
(n=0 hamlet)

Found in follow up endline (0-7yrs.)
(n=2194 children in 30 hamlets ages 0-7 years
N=860 children aged 1 to 3 years)
Estimated lost to follow-up
(n=766 children aged 0 to 7)
Give reasons: Household moved; unable to find child; child died;
Discontinued intervention
(n=0 children)

Analyzed (n=860 children)
Excluded from analysis (n=1334 children aged less than 1 or more than 3)
Give reasons: Only children over 1 should be fully immunized, and only children under 3 were eligible for incentives in the camps.
Figure 2: Percentage of children 1-3 years fully immunized by intervention status

Note: Fully immunized is defined as reporting 5 or more immunizations. Weighted means are reported, and the bars reflect the 95% clustered confidence interval.

Figure 3: Number of immunizations received by children 1-3 years
Figure 4: Immunization status as a function of distance from Intervention B camps