Impacts of IRC's Fifth Child community engagement strategy to increase immunisation in northern Uganda

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Grantee Final Report

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Note to readers

This final impact evaluation grantee report has been submitted in partial fulfilment of the requirements of grant TW10.1018 awarded under Thematic Window 10. 3ie is making it available to the public in this final report version as it was received. The study has several major limitations, largely stemming from contamination between intervention and control groups. Some control sites implemented defaulter tracing systems that were similar to that provided by the mReach platform in intervention sites (albeit paper-based). In addition, some health workers were transferred from intervention to control sites during the course of the intervention. Thus, there is limited basis for drawing inferences about the causal impact of the intervention. Also, different measures of immunisation coverage showed different results: reported coverage based on administrative records (i.e. immunisation cards) showed marked improvement while coverage based on caregiver self-report showed no increase. It is therefore possible that the overall increase in recorded coverage resulted only from improvement in administrative tracking.

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Executive Summary

The 2011 Uganda Demographic and Health Survey (UDHS) reported that the national coverage of the third dose of the combined diphtheria, pertussis, tetanus vaccine (DPT3) among children 12-23 months of age was 73%, and only 52% were fully immunized.

Intervention overview

In search of innovative ways to increase immunization coverage, the IRC, in coordination with the Uganda Ministry of Health, piloted from August 2015-April 2016 an mReach application (mReach) and community engagement strategy (the 'Fifth Child' intervention), working with Village Health Teams (VHTs) to identify immunization defaulters and re-enter them into the vaccination schedule. Based on positive results of this pilot, the IRC received funding from 3ie to scale and evaluate the impact of this intervention. The goal of the 'Fifth Child' intervention was to increase immunization coverage through defaulter tracing and targeted service delivery, facilitated by the mReach data platform and community engagement strategies. The intervention was implemented from mid-September 2016 to mid-September 2017.

The underlying hypothesis of the intervention is that data-driven, targeted community engagement would facilitate more effective defaulter tracing and contribute to increased immunization coverage in hard-to-reach communities. The project has two main components. The first is supporting activities aimed at strengthening the health system (support for outreaches, transport of vaccines and supplies, financial support for VHTs to attend community engagement meetings with health care workers and community leaders, etc.). The second component, mReach with community engagement, included continuous newborn registration, quality VHT home visits for immunization due and defaulter tracking, and community leader involvement and co-management of outreaches based on defaulter data.

Evaluation overview

A cluster randomized controlled trial was conducted to evaluate whether the intervention increased coverage of DPT3 & measles-containing vaccine (MCV) in children 12 to 23 months old. The trial had 2 arms, intervention and control. A cluster was defined as a health facility catchment area (HFCA). 32 HFCAs were included, 16 control clusters had supporting activities only, 16 intervention clusters had the 'Fifth Child' intervention plus supporting activities. Cross-sectional household surveys were used at baseline (June-July 2016) and endline (September-October 2017) to measure the extent to which the data-informed, community-co-managed defaulter tracing approach worked to increase DPT3 coverage, reduce dropout rates, and improve timeliness of immunization uptake. 16 clusters per arm were required with 55 children aged 9 to 23 months per cluster giving a total of 1,760 children.

The process evaluation aimed to examine: 1) the implementation of the intervention; 2) the mechanisms of impact of the intervention; and 3) the context and how this interacts with the intervention. A combination of quantitative, qualitative and observational methods was used.

65 stakeholders including parents, VHTs, health care workers, IRC staff, district health officers and political, administrative and community leaders were interviewed, and six focus

groups conducted with VHTs and six with parents/caregivers. The focus of the observations was the monthly VHT meetings at Health Facilities, VHT home visits, and vaccination outreaches.

Findings to primary evaluation questions

Data from the endline survey showed no difference between intervention and control clusters for the DPT3 and MCV combined coverage (p=0.56). However, there was a significant increase in valid coverage (i.e. vaccination history verified from documentation e.g., child health card) compared to baseline estimates of DPT3 & MCV in both arms, control 64.0% (95% CI 57.1, 70.0) -77.2% (95% CI 72.1, 82.3) and intervention 63.1% (95% CI 58.3, 68.5 -76.2% (95% CI 71.4, 81.1). There was no change in the timeliness of vaccinations except for MCV which increased by approximately 10% overall. DPT3 age-appropriate valid coverage remains low at 35%. Of the estimated dropout rates, only DPT3-MCV dropout rate decreased over the study period.

Process evaluation findings indicated that the intervention was well received. However, use of the mReach application required additional manpower and the referral forms needed to be simplified. It was observed that defaulter-tracing activities were also conducted in some control areas partly due to health care worker transfers and possibly also an increased focus on immunization and a desire by health workers to perform well. This observation suggests some contamination of the intervention; however, this was not widespread and was limited to three sites in the control arm. Further, the process evaluation identified four main mechanisms of impact. These mechanisms were: 1) improved accessibility of immunization services; 2) increased VHT motivation (allowance and social pressure); 3) drawing on community resources (the VHT network and community leadership); and 4) facilitating interactions between health care workers and VHTs by supporting a monthly health facility meeting. These were not limited to intervention areas suggesting that the supporting activities played a significant role in increasing valid immunization coverage.

The unit cost of implementing the mReach application per 12-23-month old child reached $277. Comparatively, the total cost of implementing the supporting activities was $409,000 and the unit cost per child 12-23 months was $274. Investment in supportive activities for health facilities may be driving the change in immunization coverage rates, thus, pairing this hypothesis with cost data suggests that supporting health systems to deliver services could be a more cost efficient means to improving immunization coverage than mReach. However, the inconclusive nature of the evaluation findings limits our ability to draw causal inferences.

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List of Figures and Tables

Abbreviations and Acronyms

AL	Artemeter + Lumefantrine (an antimalarial)
CA	Catchment area
CE	Community engagement
CHC	Child health card
95% CI	Confidence interval
CI	Concentration index
cRCT	Cluster-randomized controlled trial
DALY	Disability-adjusted life year
DHT	District Health Team
DPT	Combined diphtheria-pertussis-tetanus vaccine
EPI	Expanded Program on Immunization
FGD	Focus group discussion
HC	Health center
HCW	Health care worker
HFCA	Health facility catchment area
HMIS	Health Management Information System
IPA	Innovations for Poverty Action
IRC	International Rescue Committee
LSHTM	London School of Hygiene & Tropical Medicine
MoH	Ministry of Health
MCV	Measles containing vaccine
PCA	Principal component analysis
PDA	Personal Digital Assistants
PE	Process Evaluation
SAs	Supporting Activities
SSI	Semi-structured interview
UDHS	Uganda Demographic and Health Survey
UNEPI	Ugandan Expanded Programme on Immunization
VHT	Village Health Team

1. Introduction

The 2011 Ugandan Demographic and Health Survey (UDHS) reported that the national coverage of the third dose of combined diphtheria, pertussis, tetanus vaccine (DPT3) among children 12-23 months of age was 73%, and only 52% of children in this age bracket were fully immunized (Uganda Bureau of Statistics (UBOS) 2012). Further, Uganda is among the 35/194 WHO Member States which did not succeed in reaching the Global Vaccine Action Plan's (GVAP) intermediate goal of reaching 90% national coverage with three doses of diphtheria-tetanus-pertussis containing vaccines by 2015 (WHO, 2015).

In the search for novel ways to address low and stagnating immunization coverage rates and improve access to and utilization of immunization services, there are calls to use community engagement (CE) strategies to leverage the roles of community health structures and community leaders (Sabarwal et al., 2015). Ideally, communities should not be passive consumers of immunization services but actively involved in shaping immunization programmes.

Contextual factors and the degree to which community members understand and trust the immunization process affect vaccination coverage rates (Rainey et al., 2011, Favin et al., 2012, Streefland et al., 1999). The effectiveness of CE strategies in addressing vaccine supply and demand factors and improving vaccine coverage is less well known. Evidence suggests that vaccine interventions that are designed and co-managed with community members are more likely to be successful, however more attention needs to be paid to evaluating and developing current CE practice (Sabarwal et al., 2015). Studies have focused on immunization activities that aim to raise awareness and promote behaviour change by running education programmes targeted at infant caregivers or community health workers, or using a variety of communication tools such as improved vaccination cards or community-based posters (Jain et al., 2015, Owais et al., 2011, Ryman et al., 2011, Usman et al., 2011). Fewer studies have evaluated integrated CE strategies that seek to involve community members and leaders in identifying new ways of reducing the childhood immunization gap and strengthening existing immunization programmes. In their work on identifying key drivers for immunization performance in Africa, LaFond *et al* stress the importance of co-operation between the health system and administrative and political leaders at district and community. They also highlight the value of community-based health workers who can promote and support vaccination activities in the places where they live, and emphasize the need to tailor immunization activities to community needs.

1.1 Factors influencing vaccine uptake in the study area

Health system factors affecting immunization service delivery and uptake in northern Uganda include interruptions in the vaccine cold chain due to poor management of equipment and supplies, limited supervision of health teams by the district health teams, low staffing levels, long distances to the health facilities especially in the hard-to-reach areas, and limited resources to support outreach services. There is also a lack of good quality data to support decision-making.

Localized immunization coverage data by health facility catchment area are rarely available, preventing a clear analysis and understanding of the low-coverage pockets most in need of immunization services. Vaccine due and defaulting children are identifiable from the child

health registers at health facilities. Each month, health workers calculate the number of children who have received DPT1 and they subtract those that received DPT3 to obtain the dropout rate. The children, who do not come for DPT3 should ideally be followed up in the communities by the facility-based and community-based health workers. Due to the limited resources at the health facility, follow-up visits rarely happen and districts tend to rely on the government national immunization days to provide catch up vaccinations to children in schools and communities, including vaccine defaulters. Community health volunteers known as Village Health Teams (VHTs) are not actively involved in the follow up of children for immunization as they lack tools and resources such as the due and defaulting children's list and bicycles to enable them reach especially remote areas. Neither is there a system in place to engage the wider community structures as local political leaders in vaccine due and defaulting children identification, tracing and referral for immunization services. The tracing of vaccine defaulting children is entirely reliant on the health facility staff who are limited in skills, tools, time and resources. Improvement in data availability and quality is necessary for a more robust analysis and for targeted community engagement activities to promote immunization uptake.

From April 2015 to April 2016, the IRC, in coordination with the Uganda Ministry of Health, piloted in Lamwo district, the mReach application and community engagement strategy (the 'Fifth Child' intervention), working with community health workers (CHWs) to identify immunization defaulters and re-enter them into the vaccination schedule. The pilot used a quasi-experimental study design to determine if the 'Fifth Child' intervention was associated with an increase in completely vaccinated children in the study area. The 'Fifth Child' intervention consisting of the phone-based mReach application for defaulter tracing and community engagement intervention was implemented in one sub-county, and one non-neighbouring sub-county, most similar to the intervention sub-county, was selected as the comparison arm. A post-implementation cross-sectional survey was conducted in the intervention and comparison sites to assess changes in immunization coverage. Children in the intervention area were significantly more likely to complete all scheduled vaccinations by age 23 months, than children in the comparison group (60.4% vs. 48.3%, $p<0.001$). Based on findings of this pilot, the IRC received funding from 3ie to scale and evaluate the impact of The 'Fifth Child' intervention in a cluster randomized controlled trial.

This study aimed to contribute to the emerging evidence base by conducting an impact and embedded process evaluation of an integrated CE strategy implemented by the International Rescue Committee (IRC) in northern Uganda.

1.2 Overarching evaluation questions and design

The purpose of the study was to evaluate IRC's 'Fifth Child' strategy on community engagement in defaulter-tracing (based on individualized data) and outreach planning, implementation and monitoring strategy as a potential solution to address stagnating immunization coverage in remote areas. The evaluation measured the extent to which the data-informed community co-managed defaulter-tracing approach worked in the context to increase DPT3 and measles containing vaccines (MCV) combined coverage, reduce drop-outs and improved timeliness of immunization uptake.

The study (an impact and embedded process evaluation) design measured the impact of the intervention (using a cluster randomized control trial (cRCT)) while also allowing for

triangulation and synthesis of findings from quantitative and qualitative data, thereby accounting for factors that could influence the intervention implementation and fidelity, the non-contamination of the control groups, the pathways to achieving outputs, primary impact outcome of a 10% increase in DPT3 and MCV combined coverage, and secondary outcomes.

The study was intended to provide evidence for both global decision-makers regarding the testing and scale-up of promising community engagement interventions to increase coverage and for local decisions-makers on the iteration of current policies for increased program feasibility and impact.

2. Intervention, theory of change and research hypotheses

The goal of the 'Fifth Child' intervention was to increase immunization coverage by 10% through defaulter tracing and targeted service delivery, facilitated by an mReach immunization data platform and community engagement strategies. The specific objectives of the intervention were:

1. To improve access to quality data on immunization status
2. To utilize community engagement to trace defaulters and optimize outreaches
3. To reduce missed opportunities for immunization by supporting the Ministry of Health District Health Teams (DHTs) and health facilities to provide Ugandan Expanded Programme on Immunization (UNEPI)-defined package of services.

The 'Fifth Child' project had two main components.

The 'Fifth Child' project hypothesized that data-driven, targeted community engagement would facilitate more effective defaulter tracing and contribute to increased immunization coverage in intervention sites.

The primary outcome was defined as DPT3 and MCV combined coverage. DPT3 is the final dose of DPT administered in the first year of life, and as such is an important measure of repeat use of immunization services. Further, the 'Fifth Child' intervention aimed to reduce dropout and vaccination defaulting and a vaccine administered later in the schedule would be more useful in this respect. DPT3 coverage is the standard measure used by UNICEF of how well countries are doing in providing immunization to their children. MCV given at 9 months is the EPI vaccine given at the oldest age group for children under 1 year old and therefore adds a further assessment of defaulting.

2.1 Component 1: the mReach application plus community engagement

This was implemented in only the intervention arm of the project. The mReach application aided in producing and integrating improved data on the number of infants in the catchment area and data from immunization services at both fixed and outreach sites to create a user-friendly data platform on immunization status for tracking children who were due for or had defaulted from their scheduled immunizations. The application was designed for use by facility-based health care workers who downloaded immunization due lists (children due for immunization within five days of an appointment) or defaulter lists (children who had missed scheduled immunizations by 14 days or more). These lists were shared with VHTs for follow up during home visits.

Specific community engagement activities included:

- Continuous newborn registration into list of eligible children on the data platform
- Quality VHT visits with household decision makers for immunization due reminders and defaulter tracking
- Community leader involvement and co-management of outreaches, based on defaulter data

2.2 Component 2: supporting activities

These were implemented across both the intervention and control arms of the trial. The 'Fifth Child' project design was mindful of how the term 'defaulter' may carry a negative connotation as it may be seen as placing the blame on caregivers rather than acknowledging that incomplete vaccination is also a failure of the system. It was for this reason that the 'Fifth Child' project also implemented the supporting activities (SAs), and vaccine delivery systems support, highlighting the shared responsibility necessary to help ensure all children in the catchment area were fully immunized. The supporting activities implemented included:

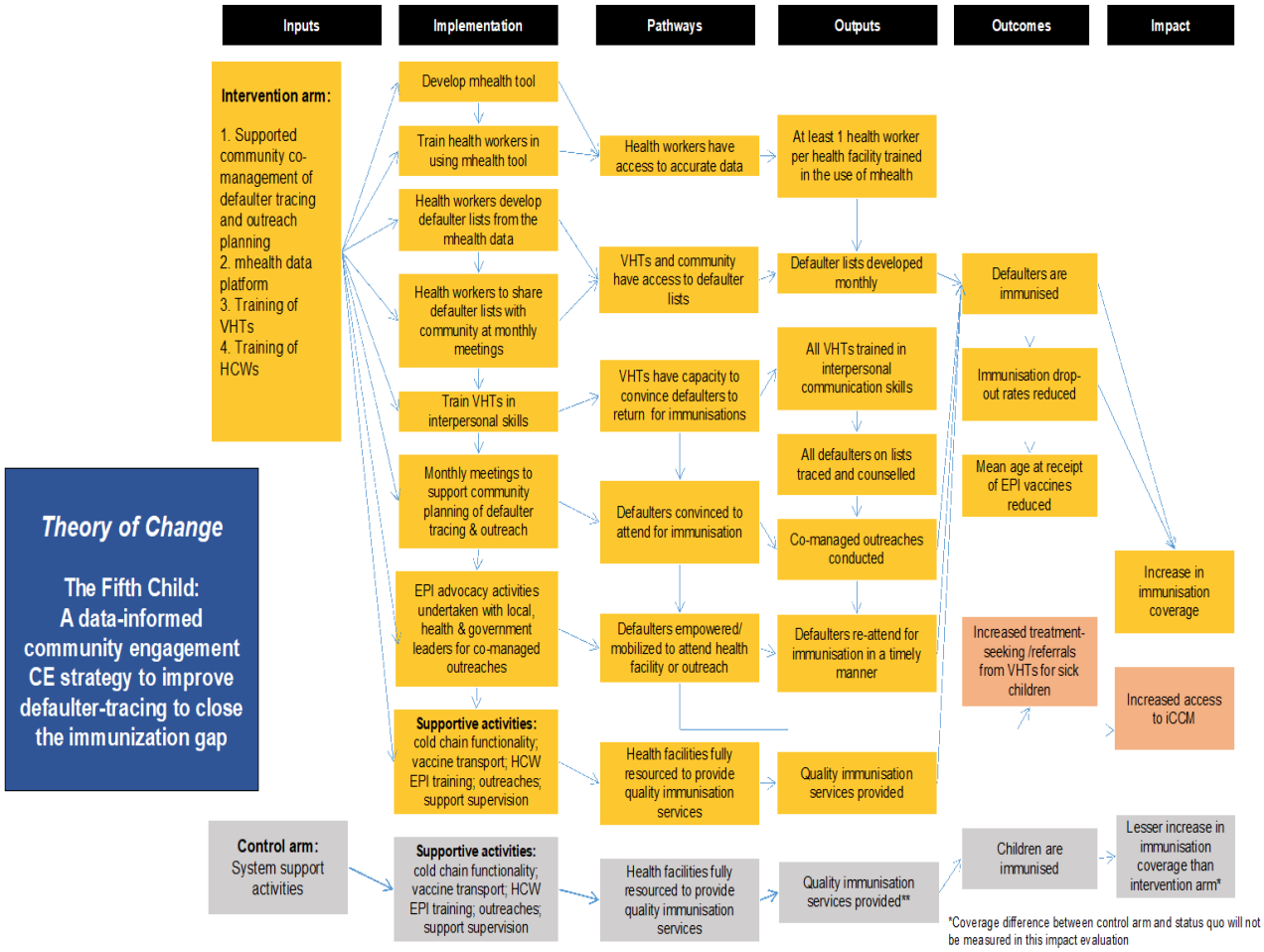
- Cold chain management
- Transport of vaccines and related supplies
- EPI training
- Support for outreaches
- Supportive supervision with DHT

2.3 Theory of change of the intervention

The 'Fifth Child' intervention was informed by a theory of change which hypothesized that data-driven, targeted CE will facilitate more effective defaulter-tracing, contributing to increased immunization coverage in underserved, vulnerable, and hard-to-reach communities. The theory of change integrates three co-dependent causal pathways leading to the intended intermediate and final outcome: reduced number of defaulting/under-immunized infants and increased DPT3 and MCV coverage.

The mReach activities specifically targeted caregivers of children, in the intervention arm, who had missed a vaccination in the national EPI schedule. Thus, the study expectation was that, after one year of implementing the 'Fifth Child' intervention, vaccination coverage (measured by DPT3 and MCV combined coverage) would increase in the intervention arm only, and not in the control arm.

Figure 1: Theory of change of the 'Fifth Child' intervention



3. Context

Two decades of conflict in northern Uganda resulted in the deaths of over 100,000 people and displaced 1,500,000, causing disruption and weakening of government-provided services. In this post-conflict context, gaps in the delivery of health services remain; the coverage rates of critical services, such as immunization, have stagnated.

3.1 Study areas

The Acholi sub-region of northern Uganda where all three study districts are located is inhabited by the Acholi Luo speaking people from the Nilotic ethnic group who originally migrated from the Bar el Ghazal region of Sudan and are also found in Western Kenya and South Sudan. The Acholi are primarily subsistence farmers with the women engaged in agricultural activities while the men were traditionally skilled hunters with a few people keeping cattle, goats and sheep. The main religious affiliation is Christianity of various denominations, followed by Islam. According the 2011 UDHS (Uganda Bureau of Statistics (UBOS) et al., 2012), more than 70% of households in Northern Uganda are in the lowest or second to lowest wealth quintile. Only 4.6% of female UDHS respondents from Northern Uganda had

completed the 7 years of primary school and 22.7% had no education at all. For male respondents this was 9.8% and 9.3% respectively.

3.2 Health systems considerations

Uganda has a decentralized governmental administration. Each district is autonomous and responsible for the health needs of the population in their jurisdiction. The health system is also decentralized and encompasses the following facilities: National Referral Hospitals, Regional Referral Hospitals, District General Hospitals and four different types of health centers (HC IV, HC III and HC II and HC I).

HC I is not a physical structure but a VHT, which includes at least two trained community health workers per village, who serve as a link between health facilities and villages. VHTs promote community coordination and collaboration to generate a healthy environment at the household and community level. They are non-political, chosen by their communities and receive a standard training package on communication, community mobilization, child growth and development, control of communicable diseases, sexual and reproductive health, environmental health, non-communicable disease, and monitoring. Other VHTs duties include community-based disease surveillance, mobilization, health promotion, water, sanitation and hygiene, and screening for malnutrition. VHTs have specific tasks relating to health promotion, service delivery, community participation and community empowerment in access to and utilization of health services. Immunization falls under VHT health promotion activities. Although community based, they have links with HC II or HC III for supervision purposes.

The HC IIs provide the first level of interaction between the formal health sector and the communities. HC IIs only provide outpatient and community outreach services (these include immunization activities). HC IIIs provide basic preventive (including immunization), promotive and curative care and provide support supervision of the community and HC IIs under its jurisdiction. There are provisions for laboratory services for diagnosis, maternity care and first referral for the sub-county. HC IVs act as referral centers for HC I-IIIs and supervise HC I-IIIs. In addition, HC IVs host the County's Administrative Unit (i.e., the Health Sub-District). HC IVs were not directly involved in the study, although caregivers could easily go from HC IIs or IIIs to some HC IVs for services.

The Ministry of Health, specifically the Uganda National Expanded Program on Immunization (UNEPI), is responsible for policy, standards and priority setting, capacity building, coordinating with other stakeholders and partners, resource mobilization, procurement of inputs such as vaccines and injection safety materials, monitoring and technical support supervision to the districts. The districts and health sub-districts are responsible for planning, management and delivery of EPI services through the implementation of the overall district health plan. The community is involved in mobilization and bringing the children for immunization. Immunization is part of the primary health care package and is integrated into the child survival activities at the district and health facility levels.

3.3 Factors influencing vaccination coverage

Given the coverage for the third dose of DPT3 in northern Uganda of 73% and the high national fertility rate (6.2 children per woman of reproductive age), Uganda is recognized as a

country with a high burden of under-immunized children (Uganda Bureau of Statistics (UBOS) et al., 2012). Barriers to increasing immunization in Uganda include cultural, social, and socioeconomic factors, and the weak health system.

Cultural, social and economic barriers include the agency of women/mothers, mistrust between health workers and communities, long distances to health facilities, and lack of money for travel to facilities or immunization outreach sites. These issues are not unique to the study sites. Global evidence promotes extending health services to hard-to-reach areas through the integration of and task shifting to lower level health workers and volunteers (Ryman et al., 2008, Glenton et al., 2011). Vaccine refusal does not appear to be an issue in the study area, although pockets of hesitancy, due to lack of convenient service times, lost confidence in services, and some complacency about adherence to the childhood immunization schedule exist.

Health system issues affecting immunization services in northern Uganda include interruptions in the cold chain due to poor management of vaccines, equipment and supplies, limited supervision by the district health teams, low staffing levels, long distances to the health facilities especially in the far hard to reach areas, and limited resources to support outreach services. There is also a lack of good quality data to support decision-making. Localized immunization coverage data by health facility catchment area are rarely available, preventing a clear analysis and understanding of the low-coverage pockets most in need. Vaccine defaulters are identified via the child health registers at health facilities. Each month health workers calculate the number of children who have received DPT1 and they subtract those that received DPT3 to obtain the dropout rate. The children, who do not come for DPT3 should then be followed up in the communities by the facility-based health workers. Due to the limited resources at the health facility, follow-up visits rarely happen and districts tend to rely on the government national immunization days to reach vaccine defaulters. VHTs are not actively involved in the follow up of the children for immunization as they lack resources such as bicycles to enable them reach especially remote areas. Neither is there a system in place to engage the wider community in defaulter tracing. The tracing of defaulters is entirely reliant on the health facility staff who are limited in skills and resources. Improvement in data availability and quality is necessary for a more robust analysis and for targeted community engagement activities to promote immunization uptake.

According to the results from the cross-sectional post-intervention survey (n=683 children) of the pilot conducted by IRC in April 2016 preceding the current ‘Fifth Child’ intervention, approximately one-third (34.3%) of caregivers cited at least one barrier to vaccinations.

Table 1: Caregiver barriers to vaccinations, ‘Fifth Child’ project pilot, April 2016

n (%)	Control	Pilot	Total	p value
Problems at clinic*	41 (26.1)	21 (27.3)	62 (26.5)	>.05
Family Problems	23 (14.6)	15 (19.5)	38 (16.2)	>.05
Thought child was fully vaccinated	30 (19.1)	7 (9.1)	37 (15.8)	.001
Distance	26 (16.6)	8 (10.4)	34 (14.5)	.01
Caretaker too busy	19 (12.1)	12 (15.6)	31 (13.2)	>.05
Other	4 (2.5)	9 (11.7)	13 (5.6)	>.05
Knowledge	9 (5.7)	3 (3.9)	12 (5.1)	>.05

Wait time too long	2 (1.3)	2 (2.6)	4 (1.7)	>.05
No belief in vaccines	3 (1.9)	0 (0)	3 (1.3)	>.05
Total	157	77	234	

*Examples include unavailable staff and stock-outs.

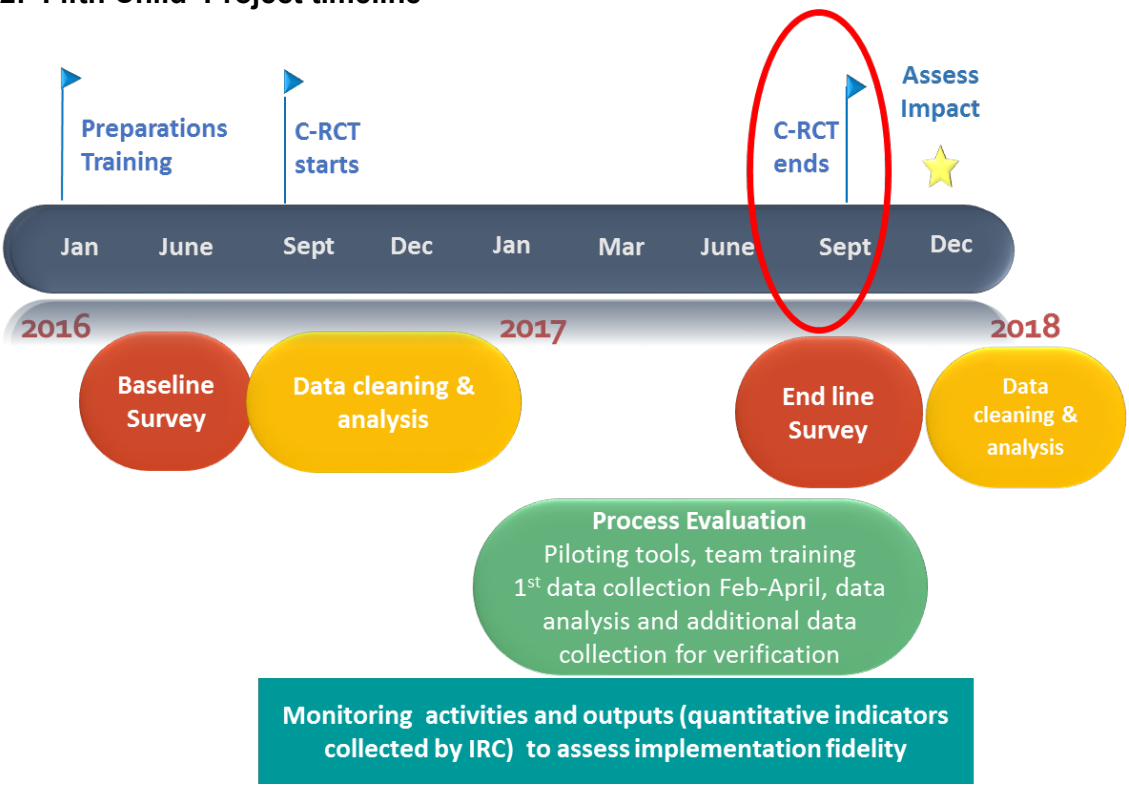
The data are drawn from internal IRC documents (reference: International Rescue Committee 2016) but cannot be verified.

4. Timeline

The baseline survey took place between mid-June and mid-July 2016. The intervention, which was due to begin by mid-August 2016, was slightly delayed and began in mid-September 2016 thus the endline survey took place from the mid-September 2017 until mid-October 2017.

The qualitative data was collected 5 months after the start of the trial during the first three weeks of March 2017, transcribed in April 2017 and subsequently analyzed. Figure 2 depicts the phased project timeline.

Figure 2: 'Fifth Child' Project timeline



5. Evaluation design and methods

A cluster randomized controlled trial was designed to evaluate the impact of the intervention as follows:

- A cluster randomized controlled trial with two arms
- Population: children 9 - 23 months
- Unit of randomization: health facility catchment areas
- Control arm: supporting activities
- Intervention arm: 'Fifth Child' intervention and supporting activities

The primary outcome measure was an increase in DPT3 and MCV combined immunization coverage in 12 to 23-month-old children. The secondary outcomes were:

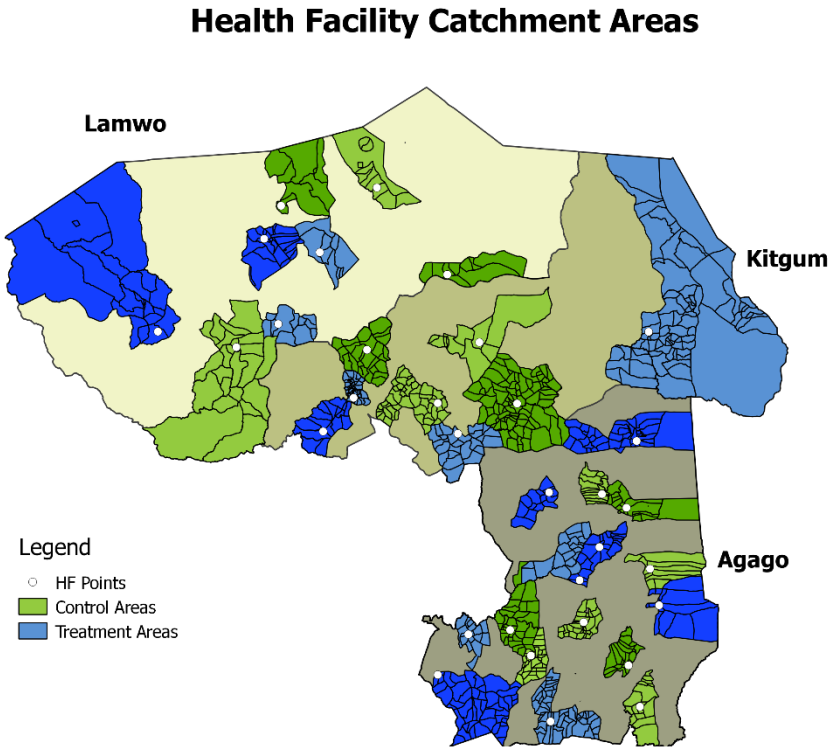
1. Reduction in vaccination drop-out rates for DPT 1, 2 & 3 and oral polio vaccine (OPV) 1, 2, 3
2. Improvements in the timely uptake of EPI immunizations[1]
3. Increased integrated community case management (iCCM) treatment of children aged 6-59 months.

5.1 Study site

The trial was implemented in 3 districts in Northern Uganda: Kitgum, Lamwo, and Agago. A map of the 3 districts and selected health facility catchment areas (HFCA) is shown in Figure 3. A list of potential trial clusters defined as the catchment area of a health facility was compiled using 2014 census boundaries as used by district health teams (DHTs) and Quantum Geographic Information System (QGIS) shape files provided by UBOS. Inclusion criteria for the health canters was level II or III, rural, funded by the Uganda Ministry of Health (MoH) and functional. A total of 64 health facilities met these criteria, and from these 64 corresponding HFCA, 32 were selected to be included in the trial. HFCAs that were non-neighbouring were visually selected to minimize instances in which villages in one or more HFCA were adjacent to one another. Half of the selected HFCAs were randomly assigned to the intervention group.

1 According to the UNEPI Immunization Schedule

Figure 3: Health facility catchment areas included in the evaluation



5.2 Household and health facility surveys

The evaluation method was a cross-sectional household survey linked to a health facility survey in all of the 32 trial clusters. The baseline survey took place a month before the start of the implementation, and the endline survey occurred immediately after the implementation had run for 1 complete year, namely September 2017.

5.2.1. Sample size

A sample size for proportions in an unmatched cRCT was used to calculate the number of required clusters and cluster size needed for the surveys. With 80% power to detect a significant difference at the 5% level between the two arms, if the intervention increased by 10%, i.e. from 73% to 83% and assuming an estimated baseline prevalence of 73%, between cluster coefficient of variation of 0.1% , 5% non-response rate and 5% non-differential misclassification bias (to address mothers' immunization recall where there is no child health card), 16 clusters per arm were required with 55 children aged 9 to 23 months per cluster giving a total of 1,760 children. This sample was sufficient to evaluate all the secondary objectives and impact variables.

5.2.2. Sampling process

A two-stage cluster random sample was used for the household surveys. At the first stage 7 villages within each of the 32 catchment areas were selected using probability proportional to size sampling based on village population sizes from the 2014 census data. For the second stage, 8 households with at least one child aged 9-23 months were randomly selected per

village. Household members are family members or friends who all live under the same roof and eat from the same pot and have lived at the household for three months or more or somebody who has come to stay with the family permanently. All children under 5 years within selected households were included for the child illness component, while all children of immunization age (9 – 23 months) were included in the immunization status component. Using the additional subset of 9 to 11 month children rather than the standard 12 to 23 months that is usually reported, ensures that at the endline we have some children who have the possibility of full exposure to the intervention from birth.

All 32 health facilities defining the trial clusters were included in the health facility survey.

5.2.3. Household survey tool

The survey tool collected information about household characteristics, interactions with VHTs, immunization practices and status for children aged 9 to 23 months and childhood diseases (diarrhoea, cough and fever) in all children under 5 years. The respondent for the interview was the primary caregiver, or the main guardian of the children who is the most knowledgeable about their health care. Immunization-related questions were asked whilst examining vaccination records where possible. The main documentation for immunization history was the Child Health Card (CHC); if this was not available then other sources of documentation that the caregiver may have at home included the UN blue book and the 'Mother's passport' both of which record child health related data. Appendix H-1 details the endline household survey instrument.

5.2.4. Health facility survey tool

The health center survey was administered to the most senior staff member at each health facility, preferably the In-Charge. The survey tool included questions about health center staff, interactions with VHTs, outreach services and costs associated with services. The survey also extracted secondary data from vaccine and drug stock-out forms and Health Management Information System (HMIS) monthly immunization summary forms. (Appendix H-2 details the endline health facility tool).

5.3 Process evaluation aim and objectives

5.3.1. Overall objective

The process evaluation aimed to examine: 1) the implementation of the intervention; 2) the mechanisms of impact of the intervention; and 3) the context and how this interacts with the intervention.

5.3.2. Specific objectives of the process evaluation

Implementation evaluation:

1. To assess the fidelity of implementation of each component of the intervention
2. To assess the dose (amount, frequency) of each component of the intervention delivered to intended target
3. To determine any adaptations made to the intervention, why these were made and the perceived benefits

4. To determine the reach (no. children served, areas covered) of the intervention components

Mechanisms of impact evaluation:

5. To assess participant (implementers, target group) experience with and interaction with the intervention components
6. To determine mediators of impact of the intervention components (for example staff who are familiar with digital technology)
7. To describe unintended consequences of the intervention

Context evaluation:

8. To develop a theory of the influence of contextual factors on how intervention components work
9. To assess the influence of contextual factors on the way in which the intervention works

5.4 Process evaluation design and methods

The process evaluation applied a combination of quantitative, qualitative and observational methods as follows:

5.4.1 Data from the evaluation cross sectional surveys

Selected indicators from the cross-sectional surveys were used in assessing implementation fidelity of implementation of the intervention in the intervention clusters, and to explain findings in both the intervention and control clusters.

5.4.2 IRC quarterly monitoring & implementation reports

As part of routine data monitoring the IRC Uganda Team collated data on a set of indicators relevant to the process evaluation; for example number of VHT meetings that took place in control and intervention areas, number of outreaches conducted in control and intervention areas as per the study protocol. This information was shared with LSHTM & IPA at intervals in the form of a quarterly report, which also provided a narrative report on the implementation of FCP and supportive activities at intervention and control sites.

5.4.3 Qualitative field work

In Feb-April 2017, five months after the start of the trial (Sept 2016), qualitative data were collected within the 3 districts where the trial was taking place, with a specific focus on 4 ‘intervention’ and 2 ‘control’ sites (sampling procedures explained below). These data were collected by a team of 8 Ugandan research assistants, including two experienced social science researchers who filled the roles of field manager and team lead. Prior to the data collection the LSHTM process evaluation lead (TC) ran a training workshop for the team which included pre-testing data collection tools in the field. The field manager and team lead coordinated the data collection and transcription process with support from the IPA research manager (LS).

5.5 Sampling approach for the qualitative field work

To achieve the study objectives, the sample included individuals who worked at district level (e.g. members of district health management teams), across the districts (e.g. IRC staff responsible for the implementation of the FCP) and in HCFA intervention and control sites. To be able to examine in depth processes at intervention and control sites 4 intervention sites and 2 control sites were included. The rationale for including more intervention sites was to be able to assess how the FCP and supporting activities were being implemented within those areas and identify any relevant mechanisms of impact. The control sites provided a counterfactual in terms of the supporting activities and additional contextual insights. Targeted participants at these sites included health workers, VHTs, infant parents/caregivers and community leaders.

The following sampling strategy was used to select the intervention and control sites. Firstly, we applied purposive maximum variation sampling to ensure that the 4 intervention sites differed in terms of: i) HFCA infrastructure & geography: Distance from furthest villages to the health facility, type of Health Facility (HCII or HC III), ii) Socio-demographics: Poverty index, rural, semi-urban, urban, any tribal/cultural differences iii) Immunization related factors: Data from the baseline survey. Secondly, we matched two clusters in the intervention arm with two clusters in the control arm based on the same criteria.

Table 2: HFCA intervention and control sites for process evaluation

HFCA	Palabek Ogili	Palabek Gem	Orom	Lagot*	Toroma	Omiya Pacwa
District	Lamwo	Lamwo	Kitgum	Kitgum	Agago	Agago
Intervention / Control	Intervention	Control	Intervention	Control	Intervention	Intervention
Matched / Unmatched	Matched		Matched		Unmatched	Unmatched
HFCA geography & infrastructure	Close to South Sudan border		Remote rural areas		Remote rural area	Rural area
	Health Center III		Health Center II		Health Center II	Health Center III
Socio-demographics	Influx of South Sudanese refugees Sept-Dec 2016[2]					
Baseline mean wealth quintile	2.93	3.34	2.72	2.45	2.84	2.15
Measles vaccine coverage	84.7%	77.5%	77.0%	78.0%	51.0%	87.5%

Note: * Lagot HCII – additional information form IRC implementation report: VHTs and community leaders said they have decided to focus and engage in extensive community mobilization for immunization services after hearing that their colleagues at intervention facilities are being helped with a mReach application to improve immunization coverage.

5.6 Qualitative fieldwork participants

The research team spent several days in each selected area. Activities included: visits to the community leaders and health facilities to inform them about the study; potential participants identified, provided with information about the study and invited to take part in an interview; participants were given time to decide and tentative appointments made where individuals expressed interest and willingness to take part in an individual or focus group interview; written

2 IRC Implementation report, Sept-Dec 2016

informed consent was obtained prior to interviews, which were conducted in places conducive to privacy and where interviewees felt at ease and comfortable.

5.6.1 District level & IRC

Interviews were conducted by the field manager and team leads in participants' places of work or preferred private spaces. Interviewees were contacted in advance to explain the purpose of the interviews and confirm willingness to participate. Interviewees were given a study information letter and written informed consent was obtained prior to all interviews and basis socio-demographic information was also collected from interviewees.

5.6.2 Control and intervention sites

The research team moved from one site to another to conduct observations, interviews and focus groups. Firstly, the team visited the health facilities, community leaders and VHTS and made contact with potential interviewees. The purpose of the study was described, study information letters left with potential interviewees and provisional interview arrangements made. Interviews took place within participants' homes, yards and or places of work. Informed consent was obtained from participants prior to interviews and focus groups and basic socio-demographic data was collected from semi-structured interview participants and numbers of focus group participants were counted.

A total of 12 focus group discussions (FGDs) and 76 semi-structured (SSIs) (Tables 15 & 16 and Appendix H-3) were conducted with parents/caregivers, VHTs, health care workers, community and district leaders and IRC staff. In addition some observations were conducted at control and at intervention sites. The foci of these observations were the monthly VHT meetings at Health Facilities, VHT home visits, and vaccination outreaches.

5.7 Process evaluation data analysis

5.7.1 IRC quarterly monitoring & implementation report

This involved reading these reports in detail, highlighting issues of importance in terms of implementation fidelity, mechanisms that may have hindered implementation or mechanisms of impact and context. Additional information was also sought where necessary and the reports were a useful source for seeking insights into end line survey results.

5.7.2 Qualitative fieldwork

Anonymized transcripts and observational field notes were sent to the LSHTM investigators in password protected zipped files, after being checked for accuracy of the transcription and translation. The LSHTM investigators downloaded this material into a qualitative data analysis software programme (NVivo), which facilitates the display, coding, and management of qualitative data.

The approach to data analysis was mainly thematic (Boyatizis, 1998). The field manager (JA) and LSHTM PE lead (TC) coded the same 5 transcripts to start with to agreed codes and help develop the coding framework. This framework also reflected pathways and other components of the intervention Theory of Change. An interim analysis was shared and discussed with the advisory committee and IRC implementer in November 2017.

In addition to this thematic inductive analysis the qualitative data helped to add explanatory detail to questions that arose from the end line survey. Transcripts and field notes were reviewed and reanalyzed to provide insights into specific issues.

5.8. Trial approval and registration

The trial protocol was reviewed and approved by the Institutional Review Board of the American Economic Association (AEARCTR-0001089).
https://www.socialscienceregistry.org/trials/1089

6. Implementation in practice

The IRC has been implementing activities in close collaboration with district health teams, facility-based health care workers (HCWs), Village Health Teams (VHTs) and local community leaders in the northern Uganda the study area since 1998. The study activities best fall into two categories namely supportive activities to strengthen systems for immunization service delivery and the mReach facilitated community engagement in immunization service delivery.

6.1 Supporting activities to strengthen systems for immunization service delivery

Supporting activities were designed based on Uganda Expanded Programme on Immunization (UNEPI) guidance and focused on the provision of supportive activities (SAs) that fill key gaps in immunization system and service delivery gaps such as: i) cold chain checks, maintenance and repairs, ii) supportive supervision, iii) basic training of HCWs, iv) immunization outreach services, and v) transportation and distribution of vaccines between district stores and health facilities. The SAs were aimed at ensuring a minimum basic package of inputs were provided to each supported health facility. The IRC team monitored the supportive activities monthly, recording what input/resource/funding was provided per facility. More detail about the IRC SAs is presented below:

Training:

- Basic training for HCWs on routine EPI package and interpersonal communication (IPC).
- Training of VHT on basic immunization based on existing package of VHT duties and IPC.

Materials:

- Reproduction and dissemination of MOH immunization materials to the facility level.
- Procurement and distribution of bicycles to each VHT from villages in the 32 catchments areas.

Supervision:

- Facilitation of DHTs to conduct health facility integrated supportive supervision (quarterly).

Meetings:

- Project (SA) inception meeting (one per district).
- Holding of VHT-health workers monthly meeting at the HCIII/sub-county level to facilitate reporting and supervision.
- Facilitation of (providing catering and participants transport reimbursement) and participation in bi-annual DHT-led immunization performance review meetings.

Resources:

- Financial support to cover fuel costs, per diem, vehicle rental if needed, to ensure that at least 3 immunization outreaches/per facility are conducted per month.
- Facilitation of district cold chain technician (DCCT) to conduct monthly checks, maintenance and or repairs at each of the 32 health facilities for vaccine gas/solar fridges (including replacement/refilling of gas cylinders/and transportation/distribution of vaccines from district stores to health facilities in case of stock outs). This is gap-filling support for UNEPI whereby IRC allows a fixed amount of spending to ensure that each health facility receives a monthly visit for cold chain functionality and vaccine stock assessment.
- Provision of a fridge maintenance toolkit to Agago, Lamwo and Kitgum districts.
- Facilitation of Child Health Days (DHT-led blanket activities, including catch up immunization of in-and out of school children) whereby IRC allowed a fixed amount of support (monetary allowance, supplies, transportation support) to each district (Lamwo, Kitgum, Agago).
- Facilitation of bi-annual health management information system (HMIS) data quality audits jointly with DHTs.

6.2 mReach-facilitated community engagement in immunization service delivery (the Intervention)

For the past 8 years, Uganda has routinely been included in the top ten priority countries for GAVI support – not only due to the stagnating immunization coverage rates – but also the large population and high fertility rate, due to the high number of children that default and thus have incomplete immunization status. Therefore, between January-May 2015, the IRC worked with *CommCare* software developers Dimagi Inc to design a mobile health (mReach) application to facilitate immunization status data collection, aggregation, analysis and monitoring of immunization data at community and facility levels to reduce defaulter rates. Input was solicited on an ongoing basis from HCWs, VHTs and the district EPI focal persons on tailoring the data platform to the specific needs of users, allowing implementers/users to gauge the feasibility and acceptability before roll-out.

In mid-2015, based on the foundation of supportive activities, the IRC established The 'Fifth Child': A data-informed community engagement strategy to improve defaulter-tracing to close the immunization gap intervention (**the 'Fifth Child' intervention**). The intervention aimed to improve immunization outcomes through integrating immunization activities to the existing cadre of health workers and VHT to reach the most remote areas. The strategy focused on enhancing community (VHTs and community leaders) engagement through the use of localized quality data for targeted vaccine due and defaulting children tracing and referral for immunization. The village list of vaccine due and defaulting children were generated using the innovative mReach data collection and aggregation tool. The mReach system creates

efficiencies and new capabilities for data collection, aggregation, analysis and visual monitoring of health data that can be easily shared with community leaders.

The ‘Fifth Child’ intervention starts in the community. Guided by IRC staff, VHTs work with village leaders (e.g. local councillors and religious leaders) to register all children, 0-12 months, and continually add newborns to the cohort. Villages included in the intervention arm health facility catchment areas are clearly delineated and all the community-generated data on individual infant immunization status is entered by the HCW into the mReach tool containing the following programmatic applications:

- Comprehensive immunization register: when an infant is immunized either at the facility or an outreach session, data on the updated status of that child is easily uploaded into the single CommCare platform, (rather than relying on facility-based registers and outreach tally sheets that are rarely consolidated). Healthcare workers are encouraged to routinely review child immunization cards at contact opportunities and update the mReach tool since some infants may receive immunizations outside of the catchment area.
- Facilitated vaccine reminder and defaulter identification: Infants are registered by birth date and health facility staff can easily open the ‘Vaccine Reminder’ tab in the application that flags those infants in their catchment area with immunizations due in the next 5 days. A separate tab, maintains an up-to-date list of defaulting children, defined as having missed an immunization by >14 days, (either based on their birth date or when the previous antigen was administered). This list can be easily sorted by parish, village, or VHTs responsible.

Screenshots of the mReach application can be found in Appendix F.

6.3 Intervention implementation

The ‘Fifth Child’ intervention utilized community engagement strategies to trace defaulters and optimize outreaches and thereby decrease the number of defaulters through systematic engagement with community leaders and other key community groups in outreach planning, mobilization, and implementation, based on coverage data, and performance monitoring of defaulter-tracing. The intervention aimed to equip VHTs with the tools and techniques necessary to encourage caregivers to seek immunization services. It was based on the hypothesis that data informed defaulter tracing, VHT home visits and active engagement of community leaders e.g. local councillors will promote linkages between community members and health facilities that organize immunization services and outreaches.

Community leaders, are most often local counsellors (LCs), but could also include religious leaders, women leaders, of villages where there were more than 5 defaulting children that month, were supported to review coverage data for their village and. actively participate in planning meetings and to help plan and schedule the outreaches in collaboration with VHTs and HCWs. This meeting for the planning of ‘smarter outreaches’ was held at the facility level and was conducted with the assumption that if outreaches were convenient, and based on the data showing where the most defaulters were, it would be more likely that infants would be brought. This pathway also postulates that community co-management leads to strengthened

linkages between the community and health facility and increased community ownership, and accountability of HCWs. An intended positive outcome in the short-term would be creation of community demand for other maternal and child health services and more referrals from community to facilities. Another possible intended outcome may be community participation in other last mile health services.

During monthly meetings, HCWs informed VHTs which infants in their villages were due for immunization and shared the list of defaulters. Based on the number of infants/village and estimated dropout rate, it was expected that each VHT would visit approximately 2-3 infants due for immunization and 1-2 defaulters per month.

VHTs were trained on communicating key immunization messages, addressing myths and misconceptions and improved interpersonal communication skills for counselling that focused on reasons why the child missed their immunizations. Home visits were intended to be interactive where VHTs facilitated caregivers and other household decision-makers to develop an action plan for catch-up immunization. They informed caregivers of the date, time, and location of the next outreaches in the catchment area and provided a referral ticket for immunization services either at health facilities or outreach sites. As defaulters presented referral tickets, the infants were vaccinated and updates were entered into the data platform, the HCW and the project team were then able to examine the timeliness and rates of catch-up vaccination post home visits. Of 10,495 defaulters registered via mReach, 5,395 (51%) were caught-up on the vaccinations they had missed.

6.4 Randomization and sampling

The sampling strategy occurred at the district, health center, health center catchment area, village and household level as described below.

District level: Three districts in Northern Uganda were included in the study. These districts were selected because of IRC's historical presence in this area, as well as the low immunization rates in this region compared to other areas of the country. These districts included Agago, Kitgum and Lamwo.

Health center level: Within these three districts, there were 64 Health Centers that met the study criteria. All health centers were a) government HCs funded by the Ministry of Health level b) functional and were c) HCII and HCIII level. Half, or 32 total HCs, were included in the study sample, 16 being treatment and 16 being control

Health center catchment area level: During the 2014 census, the Ministry of Health assigned each health center a list of villages to be included in their Catchment Area. For HCIIIs, this was divided at the sub-county level and for HCIIs at the parish level, with some exceptions. Each catchment area included a list of between 10 – 90 villages depending on the size and level of the HC. In order to promote sustainability and support the government structures, this definition of HC CA was used for the study.

Each of the health center catchment areas were mapped out using QGIS Mapping Software, village-level shape files provided by the Uganda Bureau of Statistics (UBOS), and HC GPS coordinates collected by another IPA Uganda health study. These HC CAs to be included in the study were then visually selected based upon a non-neighbouring rule that minimized instances in which villages in one or more HC catchment areas were adjacent to one another,

to prevent the likelihood of contamination. The randomization of health centers to the treatment and control groups was completed using Stata. See the full written sampling strategy in Appendix A.

Village level: While IRC implements the intervention in all of the villages defined in each HC CA, it was not financially or logistically feasible for IPA to collect surveys in such a large area. Thus, within each HC CA, seven villages where the baseline survey would take place were randomly selected using Stata.

Household level: In order to create a representative, random sub-sample of households in a catchment area, households were first mapped using a village-level administrative listing conducted in each of the seven villages selected for surveying within the HC CA. This involved recording an updated village household list with the support of the Local Chairperson 1 (LC1), Village Health Team members (VHTs), and other local leaders knowledgeable about child health. All households within each village with any children between 9-23 months of age were eligible for inclusion. Among the eligible households, eight were randomly selected using electronic PDAs (Personal Digital Assistants) where the interviews would be conducted. The listing protocol is included in Appendix H. Within each of the 7 villages included in the study, 8 households with children of immunization age (9-23 months) were selected for interviews.

6.5 Project monitoring system

Routine health data were used alongside the embedded process evaluation to monitor project implementation in both the intervention and control areas. Routine immunization records as well as supplementary records of implementation activities not usually collected routine. Some of the supplementary records included training logs, participant lists, agendas and minutes of VHT/HCW/CL meetings, and defaulter tracing data, etc. Additional logs were also created to track ongoing activities such as national immunization days, mop-up campaigns, communicable disease outbreaks, and activities by other partners that had the potential to affect project outcomes in the study areas. Implementation data were monitored on an ongoing basis through quarterly data quality audits in the both intervention and control arms.

6.5.1 Data collection and management

The research team developed strict quality monitoring guidelines and internal review processes to ensure that survey development and subsequent data collection processes met the highest standards of accuracy. This process began with designing and piloting all survey tools and extensively training the enumeration team. *Samsung Galaxy Tab 4* tablets were used as electronic PDAs to collect the survey data and to ease usability among surveyors. The Open Data Kit (ODK) based SurveyCTO platform was used to program, administer, and host the data collected from electronic surveys. Following data collection each day, all surveys were uploaded to the SurveyCTO's cloud server.

The surveys were then downloaded the following day onto the SRA computer into encrypted folders using *Boxcryptor* where a set of high-frequency, statistical checks (HFCs) were conducted to detect outliers, duplicate IDs and other logical inconsistencies in the survey data. The quality of the data was also verified through "back-checking," or performing an audit by resurveying of a random 10% of individuals who were surveyed to ensure that responses are

consistent. This was done by having a second, independent team of experienced surveyors re-visit these households.

6.5.2 Data collection challenges

Delays in Sampling: A number of issues were associated with the sampling. The health center village catchment area mapping and selection relied heavily on two data sources: (1) the QGIS village shape files shared by the Uganda Bureau of Statistics (UBOS) and (2) the district-level census data containing the sub-county, parish and village names alongside the population for each village.

- The district-level census data were obtained from district officials, however not all districts had a finalized list and so receiving this list after the initial request took longer than expected.
- After receiving these lists, IPA found gaps in the population numbers that required our teams to return to the district offices in person to obtain the missing data.
- Discrepancies were found between the village names in the UBOS shape files and the district-level census data, thus the merging of the two databases in order to visually map them out was difficult and took more time than anticipated.

Listing Challenges: During the listing, the enumerators gathered together the most knowledgeable local leaders, however not every village had an updated village roster and not all leaders were engaged in creating a more updated list. In this case, the most knowledgeable representatives were called together to reconstruct the list. If this was not possible, the traditional listing method of walking through the village and mapping out the households was employed.

Although the objective of the listing was to randomly select 8 households in the village with children of immunization age (between 9 – 23 months), in some cases there were less than 8 households in each village, thus the method of walking through the village from house to house was employed to confirm that there were absolutely no more children within this age range. These concerns were dealt with by having the tracking team return to villages to verify if the target number of children per village were available.

Reaching households in peri-urban areas: While the IRC study was designed to operate in "rural" areas, some villages considered peri-urban including small towns or trading centers posed several challenges. In particular, local officials and community members alike were less likely to know all village members in these areas due to being more highly populated and the higher level of transience of the residents than in smaller villages. Some respondents in these areas worked every day until the evening, and were unable to be reached aside from on evenings or weekends. If respondents were unable to be located during the first attempt, they would be tracked 2 times and if they were still unable to be found or interviewed, additional replacement households were randomly selected using the listing database.

Poor transportation infrastructure: Areas that were very rural also posed their own challenges. Randomly selected households were often far apart. Poor road infrastructure and occasional rain sometimes made collecting the target number of surveys challenging and time-consuming. In addition, the large team of 61 staff could only find accommodation in a large enough town, thus often increasing the distance from the more remote health center

catchment areas. Enumerators were given transport funds that allowed them to reach the villages on *boda bodas*, or motorcycles. This allowed them more autonomy in managing their schedules than a mini-bus taxi or bus, however, meant for long days in the field and sometimes greater expenditures.

Tracking missing surveys: In order to adhere to the baseline timeline, successfully collect the target number of 3-4 surveys per enumerator per day and stay within the envelope of projected expenditures, the baseline protocol stated that 2 tracking visits would be allowed for each of the households. If the respondent was not available after these tracking visits, the household was replaced with a household from a replacement list randomly generated during the listing. Overall, less than 10% of selected households were unable to be interviewed and had to be replaced.

7. Impact analysis and results of the key evaluation questions

7.1 Impact analysis

7.1.1 Data processing and recoding

Data processing and analyses were carried out using Stata 14.2 (College Station, TX). Initial data checks were followed by recoding of variables to produce re-categorized and newly generated variables as required. Principal Components Analysis (PCA) was used to generate a 5-category wealth index for each household from household assets (material of roof, walls and floor, water source, toilet facilities, fuel for cooking and household contents such as furniture and electrical equipment) and respondent characteristics (education achieved). All analyses were carried out for both baseline and endline surveys and where appropriate comparisons were made between surveys.

Immunization-related primary and secondary outcomes for each vaccination were generated with valid[3] coverage estimates based on documented data only while crude[4] estimates also included information from caregivers. An unvaccinated status was assumed for children with no documents for valid coverage estimates. Dropout rates were generated for DPT 2,3 & MCV compared to DPT1 and OPV1,2,3 compared to OPV0. Timely receipt of immunizations was measured as children who received a vaccination within 2 weeks of the proposed age for each specific vaccination.

After an initial description of the study population, baseline characteristics of households and individuals were summarized and compared across intervention and control clusters. Similarly, exposure to VHTs in the household, measured by reported visits and actions taken post VHT visit were summarized and compared.

Immunization coverage estimates were obtained for all children aged 12 to 23 months and children aged 9 to 23 months for comparison, 12 to 23 months is the standard for immunization coverage estimates, the additional 9 to 11 month children were included to allow for full exposure to VHT's. Coverage of the primary outcome DPT3 & MCV was also assessed across the 3 districts, stratified by 3-month age categories and by wealth index.

[3] Valid coverage, in this context, refers to immunization coverage information verified from a documented source, e.g. the Child Health Card

[4] Crude estimates here refer to coverage estimates from all sources of information, including caregiver recall

To assess for inequality of DPT3 & MCV coverage across socio economic groups a concentration index was obtained. This measure assesses whether there is equal distribution of coverage across wealth quintiles or if it is disproportionately concentrated in poorest or least poor groups. The concentration index measure is based on departure from the line of equity when the DPT3 & MCV coverage is plotted against increasing categories of the wealth quintile.

For all children 6 months to under 5 years in the household, cluster summary estimates for the prevalence of fever, respiratory symptoms, and diarrhoea were obtained, together with measures of appropriate treatment and its source.

All estimates are cluster summaries. Analysis of cluster summary residuals from logistic models assessed potential baseline covariates. A t-test was used to compare intervention and control estimates. All analyses were intention-to-treat (ITT).

7.2 Summary of impact evaluation results

The endline survey was carried out in a sample of 7 villages in the catchment area of each of the 32 health facilities (16 intervention and 16 control). At baseline, the household survey included 899 children 9-23 months old in the intervention arm and 943 children in the control arm. At endline, the household survey included 855 children 9-23 months old in the control arm and 879 children in the intervention arm. Table 3 summarizes the surveyed populations for both the baseline and endline surveys. Examination of the estimates and corresponding confidence intervals for each characteristic at baseline show no differences between the intervention and control clusters.

Impact evaluation results show no difference at the endline between intervention and control groups for the primary outcome DPT3 & MCV and all other outcome estimates. Coverage of DPT3 & MCV was lower in age 9 to 11 months old children and children from households in the poorest quintile. Analysis of cluster summary residuals from adjusted logistic models for DPT3 & MCV assessed the effect of baseline DPT3 & MCV, potential confounders and socio economic status on the effect of the intervention on DPT3 & MCV coverage. All models showed no significant adjustments to the cluster summary measures of DPT3 & MCV at endline, see Appendix G for summary results.

Whilst there was no difference between intervention and control clusters, overall there was an increase of approximately 10% in DPT3 & MCV coverage from baseline to endline. On examination of the valid coverage estimates this appeared to be due to the increase in MCV uptake more than uptake of DPT3. Potential reasons for this were explored in the process evaluation analysis.

Table 3: Sample description

	Baseline		**Endline**	
	Control group	**Intervention Group**	**Control group**	**Intervention group**
Health facilities	16	16	16	16
Villages	109	112	110	112
Households	885	924	832	857
Children 6 months to <5 years	1478	1539	1390	1393
Children 9 to 23 months	899	943	855	879
Children 12 to 23 months	715	785	685	719

Table 4 gives estimates of household and respondent characteristics for both intervention and control clusters. Similar to baseline, at the endline the majority of respondents were under 30 years, married, had not completed primary education and were almost all Acholi. This balance suggested there was no adjustment needed for baseline covariates when estimating the primary and secondary outcome summaries in the endline survey, however this was still formally assessed.

Table 4: Characteristics of household respondents

	Baseline				Endline			
Characteristic		**Control**		**Intervention**		**Control**		**Intervention**
	N	**% (95% CI)**	**N**	**% (95% CI)**	**N**	**% (95% CI)**	**N**	**% (95% CI)**
Total	885	100.0	924	100.0	832	100.0	857	100.0
Age of respondent								
Less than 25 years	356	40.2 (35.8, 44.8)	348	37.7 (34.8, 40.6)	353	42.4 (38.9, 46.3)	365	42.6 (38.9, 46.3)
25 to 29 years	171	19.3 (16.0, 23.1)	211	22.8 (20.0, 25.9)	170	20.4 (18.5,24.0)	181	21.1 (18.5, 24.0)
30 to 34 years	185	20.9 (17.7, 24.5)	202	21.9 (19.3, 23.7)	171	20.5 (17.8, 24.4)	179	20.9 (17.8, 24.4)
35 years or more	173	19.6 (17.0, 22.4)	163	17.6 (15.2, 20.3)	138	16.6 (13.4, 17.7)	132	15.4 (13.4, 17.7)
Education								
None	483	54.56 (50.6, 58.6)	476	51.5 (44.6, 58.3)	507	60.9 (56.0, 65.7)	520	60.7 (55.7, 65.4)
Nursery	132	14.9 (12.6, 17.6)	134	14.5 (11.8, 17.6)	91	10.9 (8.8, 13.5)	77	9.0 (6.4, 12.5)
Primary	233	26.4 (22.6, 30.5)	245	26.5 (23.7, 29.6)	182	21.9 (17.7, 26.7)	199	23.2 (19.8, 27.0)
Secondary or more	36	4.1 (3.2, 5.1)	69	7.5 (4.3, 12.6)	52	6.3 (4.5, 8.7)	61	7.1 (4.1, 12.1)
Ethnic group								
Acholi	811	91.8 (76.3, 97.5)	856	92.7 (80.2, 97.6)	772	92.8 (76.2, 98.1)	801	93.5 (83.0, 97.7)
Lango	57	6.5 (1.4, 25.2)	44	4.8 (0.9 20.8)	49	5.9 (1.2, 24.7)	42	4.9 (1.2, 17.7)
Other	16	1.8 (1.1, 3.0)	23	2.5 (1.5, 4.1)	9	1.1 (0.5, 2.2)	9	1.1 0.2, 1.5)
Marital status								
Married	490	55.4 (43.5, 66.6)	482	52.2 (42.4, 61.8)	438	52.6 (44.2,61.0)	488	57.0 (48.9, 64.8)
Unmarried	78	8.8 (6.4, 12.0)	95	10.3 (6.4, 16.1)	64	7.7 (5.6, 10.5)	67	7.8 (6.1, 10.0)
Divorced	43	4.9 (3.7, 6.3)	55	6.0 (4.5, 7.8)	57	6.9 (5.3, 8.8)	43	5.0 (3.4, 7.3)
Widowed	24	2.7 (1.9, 3.9)	17	1.8 (1.3, 2.7)	9	1.1 (0.6, 1.9)	13	1.5 (0.8, 2.9)
Cohabiting	250	28.3 (19.8, 38.5)	275	29.8 (23.8, 36.6)	264	31.7 (23.8, 40.9)	245	28.6 (22.5, 35.7)
Residential Status								
Reside at dwelling all year	852	96.4 (93.9, 98.0)	891	96.6 (95.3, 97.6)	769	92.9 (90.4, 94.8)	781	91.4 (87.5, 94.1)
Socio economic group								
Q1 Poorest	179	20.4 (15.9, 25.8)	165	18.1 (12.8, 25.0)	182	21.9 (16.2,28.9)	147	17.2 (13.1, 22.1)
Q2	169	19.3 (16.8, 22.1)	186	20.4 (16.0, 25.6)	154	18.5 (15.8, 21.6)	174	20.3 (17.2, 23.8)
Q3	194	21.2 (19.9, 24.6)	170	18.6 (15.5, 22.2)	175	21.0 (18.3, 24.1)	165	19.3 (16.3, 22.6)
Q4	184	21.0 (18.3, 24.0)	182	19.9 (16.6, 23.7)	163	19.6 (16.3, 23.3)	172	20.1 (16.4, 24.3)
Q5 Least poor	150	17.1	211	23.1	158	19.0	199	23.2

		(14.5, 20.1)		(14.6, 34.6)		(15.5, 23.1)		(16.2, 32.2)

Exposure to VHT household visits, a key component of the intervention in the trial, was examined by estimating the proportion of respondents who had a visit, reasons for the visit, and actions taken by the respondent post visit. Table 5 shows estimates for key measures related to exposure to VHT household visits. The results show there was no difference in exposure to VHT household visits or actions taken by the respondent post visit, between intervention and control clusters. The percentage of households who had a visit from a VHT decreased from baseline to endline, 64.8% and 53.9% respectively (p=0.001). Whereas the percentage of respondents who had a visit because they were due for an immunization increased from 6.3% at baseline to 12.8% at endline (p=0.0004), as did respondents who learned what their child needed post visit, 6.5% at baseline and 22.1% at endline (p<0.0001).

Table 5: Exposure to VHT household visit and actions taken by respondent post visit

	Baseline				**Endline**			
	Control		**Intervention**		**Control**		**Intervention**	
N	885		924		832		857	
	%	**95% CI**	**%**	**95% CI**		**95% CI**	**%**	**95% CI**
Had VHT visit	65.5	58.4, 73.2	64.2	55.7, 70.5	54.7	48.7, 60.6	53.0	49.3, 56.7
Reason for visit								
Due immunization	6.8	3.1, 9.4	6.0	1.8, 8.6	14.8	11.3, 18.3	10.8	6.0, 15.7
Defaulter	1.3	0.1, 2.2	0	-	3.7	1.7, 5.7	2.4	0.4, 4.4
Other immunization related	49.8	45.1, 54.0	57.5	51.0, 61.6	54.6	50.0, 59.2	54.6	44.9, 56.9
Number who had a VHT visit	456		492		369		316	
Took action post visit *	86.6	83.2, 91.0	83.9	79.6, 88.1	85.9	81.6, 90.2	83.2	77.5, 89.0
Took immunization related action*	55.8	48.4, 60.7	58.8	50.0, 67.0	63.3	57.8, 68.8	62.6	55.7, 69.4
Number who took immunization related action	220		243		199		197	
Had child immunized post visit **	96.4	92.6, 1.00	92.6	84.6, 98.9	79.9	70.8, 88.9	83.7	77.0, 90.4
Learned what child needed **	4.1	1.0, 6.7	8.6	2.8, 12.7	26.7	17.3, 36.1	17.5	7.9, 27.2
Saw health worker to update/ replace CHC**	5.5	1.3, 7.7	3.7	0.8, 6.9	2.1	0.3, 3.9	1.6	0, 3.5

Note: * Of those who had a VHT visit ** of those who took action post VHT visit

Table 6 shows the cluster summary valid coverage estimates for children aged 12 to 23 months immunized with each specific vaccine for both intervention and control clusters at baseline and endline. Coverage of vaccines given in the first 3 months of life were the same across intervention and control clusters and from baseline to endline. However, for the later vaccines there was a consistent increase from baseline to endline, from DPT3 onwards and still no difference between control and intervention groups at the endline. Despite there being no difference in intervention and control groups, overall there is an increase in the primary outcome, of approximately 10%, and the 2 component vaccines.

There was no change observed in coverage of DPT1 in the control group, 84.4% at baseline and 86.6% at endline DPT1 (p=0.32) however a significant increase was seen in the intervention group, 81.4% at baseline and 87.4% at endline (p=0.01). Coverage of DPT2 was similar, in the control group this was 83.7% at baseline and 85.5% at endline (p=0.37), while in the intervention group, baseline coverage was 79.5% compared to 85.7% at endline (p=0.01)

In the control group, valid coverage for children who had DPT3 at baseline was 79.7% and at endline 84.8% (p=0.05) while for MCV valid coverage was 68.6% at baseline and 77.5% at endline (p=0.02). In the intervention group valid coverage for children who had DPT3 at baseline was 76.4% and at endline 84.0% (p=0.003) while for MCV valid coverage was 66.5% at baseline and 76.7% at endline (p=0.004).

For DPT3 & MCV combined valid coverage increased from 67.5% to 77.2% in the control clusters (p=0.02) and 65.2% to 76.2% in the intervention clusters (p=0.003). This increase across surveys was higher in the intervention group.

Table 6: Valid immunization coverage in children 12 to 23 months old at baseline and endline

	Baseline				**Endline**			
	Control		**Intervention**		**Control**		**Intervention**	
N	714		778		685		719	
	%	**95% CI**	**%**	**95% CI**	**%**	**95% CI**	**%**	**95% CI**
BCG	85.9	82.19, 88,9	81.8	78.5, 85.3	86.3	83.7, 88.9	87.3	84.4, 90.3
OPV0	84.3	79.9, 87.8	81.4	78.2, 84.8	84.7	81.8, 87.5	84.8	82.5, 87.0
OPV1	82.0	75.9, 86.5	80.5	76.6, 84.3	84.1	81.5, 86.7	84.8	80.4, 89.1
OPV2	81.7	76.4, 86.2	78.3	74.0, 82.3	81.9	78.8, 84.9	83.0	78.6, 87.5
OPV3	77.6	70.8, 83.5	75.0	71.4, 79.0	82.4	79.8, 85.0	81.1	76.3, 85.8
DPT1	85.0	80.5, 88.3	81.4	78.2, 85.0	86.6	84.2, 89.0	87.4	84.2, 90.5
DPT2	83.9	79.7, 87.3	79.4	76.0, 82.7	85.5	82.4, 88.7	85.7	82.4, 88.9
DPT3	80.3	75.4, 84.1	76.2	72.7, 80.0	84.8	81.7, 87.9	84.0	80.6, 87.5
PCV1	75.1	69.7, 80.0	78.0	73.8, 82.3	81.7	78.3, 85,1	84.7	80.6, 88.8
PCV2	70.8	63.3, 77.8	74.9	70.0, 80.0	79.6	76.3, 82.9	81.1	76.9, 85.2
PCV3	67.8	61.0, 74.2	71.3	70.0, 76.0	78.5	74.3, 82.2	78.7	74.4, 83.1
MCV	69.2	63.0, 74.6	66.2	61.5, 71.5	77.5	72.3, 82.6	76.7	71.9, 81.4
DPT3 & MCV	64.0	57.1, 70.0	63.1	58.3, 68.5	77.2	72.1, 82.3	76.2	71.4, 81.1

Both valid and crude coverage for DPT3 & MCV overall and by district are shown Table 6. Comparing the overall crude coverage estimates across surveys, unlike for valid coverage shown above, there was no significant increase in control or intervention clusters (p = 0.15 and p = 0.26 respectively). For valid coverage at endline, estimates were similar across districts and intervention and control clusters with all estimates increasing from baseline to endline. However, the highest increase in valid coverage was in Agago which was 61.7% at baseline and 79.8% at endline in the control clusters (p= 0.002), and 62.8% at baseline and 74.8% in intervention clusters (p=0.03).

Examination. across all 3 districts, of the difference between crude and valid coverage between baseline and endline saw a stronger decrease in the difference in coverage estimates for intervention clusters, from 18.1% to 10.1% (p<0.005) and also a significant decrease in control clusters, 15.7% to 10.7%, (p=0.03). Focusing on Agago district, there was also a decrease in the difference between crude and valid estimates from baseline to endline, 19.3% to 11.6% in intervention clusters (p=0.04), and in the control clusters 17.0% at baseline and 9.0% at endline (p=0.03).

Table 7: Valid and crude coverage of DPT3 and Measles vaccines in children 12 to 23 months old overall and by district

	Baseline				Endline			
	Control		Intervention		Control		Intervention	
N	714		778		685		719	
	%	**95% CI**	**%**	**95% CI**	**%**	**95% CI**	**%**	**95% CI**
Valid coverage								
Had both DPT3 & MCV	68.1	61.7, 73.4	65.0	59.9, 70.6	77.2	72.1, 82.3	76.2	71.4, 81.1
Agago	62.0	54.0, 70.0	62.3	54.9, 70.7	79.8	72.4, 87.1	74.8	66.1, 83.4
Kitgum	71.35	48.3, 93.7	71.5	59.6, 82.7	77.8	57.1, 98.3	77.3	63.1, 91.5
Lamwo	75.5	63.5, 87.8	63.0	43.6, 84.3	71.4	60.3, 82.5	78.1	64.8, 91.3
Crude coverage								
Had both DPT3 & MCV	83.4	77.2, 88.4	83.3	79.4, 87.4	87.8	84.0, 91.7	86.3	82.5, 90.2
Agago	78.6	69.0, 88.4	82.0	78.3, 86.0	88.7	83.8, 93.7	86.4	78.9, 93.8
Kitgum	84.9	68.9, 100.0	88.3	76.5, 99.4	89.2	73.0, 100.0	86.1	72.9, 99.3
Lamwo	90.6	86.5, 95.0	80.5	62.5, 100.0	84.7	72.5, 97.0	86.5	81.0, 92.0

Table 8 shows the percentage of valid documentation and recall only used for immunization status. There was a significant increase in the percentage of valid documentation overall from baseline to endline ($p<0.0001$), in control clusters ($p=0.01$) and in intervention clusters ($p = 0.0008$). There was no change in the percentage of child health cards or blue books used as the source of documentation for vaccination status. However, the mothers passport increased significantly from baseline, 13.1%, to endline, 24.0% ($p=0.05$). This change was significant in intervention clusters from 11.2% to 26.3% ($p=0.04$) but not in control clusters, 14.9% to 21.7% ($p=0.44$).

Table 8: Source of information of vaccination status*

	Baseline				Endline			
	Control		Intervention		Control		Intervention	
N	686		742		674		702	
	%	**95% CI**	**%**	**95% CI**	**%**	**95% CI**	**%**	**95% CI**
Valid documented source **	76.1	72.1, 80.2	73.3	68.6, 78.1	82.9	78.9, 86.8	84.1	80.5, 87.7
Recall only	23.8	19.8, 27.9	26.7	21.9, 31.4	17.1	13.2, 21.1	15.9	12.3, 19.5

Note: * Measured via source of measles vaccination

** Valid documents include Child health cards (old and new version), Mothers passport and UN blue book

Table 9 shows the valid and crude coverage of DPT3 & MCV stratified by 3 months age groups. Within each category coverage increased overall from baseline to endline but there was no difference between intervention and control clusters. At both baseline and endline, coverage in the 9 to 11 month age group lags behind. Including the additional subset of 9 to 11 month children rather than just the standard 12 to 23 months that is usually reported allowed some children to be seen to have exposure to the intervention from birth. However, due to the wide range for timing of MCV it is clear from the data that in this age group, children have not yet had the opportunity to receive MCV at 11 months. In the 9 to 11 month children, valid coverage at endline was 86.7% and 90.0% for DPT3 in the intervention and control

clusters respectively, while only 67.6% had MCV in the intervention clusters and 59.0% had MCV in the control clusters.

Table 9: Valid and crude coverage of DPT3 & MCV in children 9 to 23 months stratified by 3 month age groups

	Baseline				**Endline**			
	Control		**Intervention**		**Control**		**Intervention**	
N	896		935		855		879	
	%	**95% CI**	**%**	**95% CI**		**95% CI**	**%**	**95% CI**
Valid DPT3&MCV								
9 to 11 months	48.4	35.2, 60.1	53.8	43.7, 63.0	67.6	57.3, 77.9	59.0	47.8, 70.2
12 to 14 months	61.0	53.4, 69.0	67.7	59.5, 75.0	80.7	73.9, 87.4	73.1	63.9, 83.5
15 to 17 months	70.5	59.0, 77.7	68.2	60.0 76.0	78.6	71.0, 86.2	78.5	73.9, 83.1
18 to 20 months	76.4	67.7, 84.2	63.4	54.6, 72.2	77.2	72.4, 82.0	77.1	67.4, 86.8
21 to 23 months	66.2	58.4, 73.0	59.1	50.3, 70.0	73.2	62.8, 83.6	76.1	68.5, 83.7
Crude DPT3&MCV								
9 to 11 months	54.9	44.6, 66.3	58.9	47.4, 70.0	74.7	64.4, 85.0	64.1	52.7, 75.5
12 to 14 months	74.4	68.5, 83.8	80.4	74.4, 86.3	87.3	81.9, 92.8	81.5	72.7, 90.4
15 to 17 months	85.0	76.9, 90.0	79.9	70.4, 88.6	86.3	80.2, 92.3	88.5	84.3, 92.7
18 to 20 months	87.9	79.7, 94.2	85.2	79.0, 91.0	89.0	84.4, 93.7	87.9	81.0, 94.8
21 to 23 months	89.6	83.6, 95.0	89.2	84.8, 95.9	89.4	83.8, 94.9	88.8	82.5, 95.0

Valid coverage of DPT3 & MCV across socioeconomic groups is shown below in Table 10. As with the baseline, at endline there was a higher vaccination coverage with increasing household wealth measured in quintiles. Children from households in the poorest quintile had a coverage of 65.7% and 67.8% in control and intervention groups respectively, while in the least poor group this was almost 20% higher at 83.1% and 84.2%. A concentration index was calculated to quantify the level of disparity in coverage of DPT3 & MCV across socio economic groups for control and intervention clusters in each survey. A value of zero shows equity across all groups, a value greater than zero shows coverage is biased towards the least poor while a value less than zero shows coverage is more pro poor. For valid coverage, the concentration index was higher at baseline for control clusters (CI=0.0657, p<0.0001) compared to endline (CI=0.0339, p=0.004) but higher at endline for intervention clusters, baseline (CI=0.0339, p=0.04), endline (CI=0.0365, p=0.002). Thus indicating a decrease in socio-economic disparity of vaccine coverage between poorest and least poor in the control clusters, but not in the intervention clusters. For crude coverage, the concentration index was higher at baseline for both control (CI= 0.0335, p=0.0004) and intervention (CI=0.0439, p<0.0001) clusters compared to endline for control (CI=0.0227, p=0.005) and intervention (CI=0.0255, p=0.002) indicating decreased inequity in coverage at endline. Note the concentration index is also higher in intervention clusters compared to control in both surveys indicating a socio-economic disparity to the advantage of less poor households.

Table 10: Valid coverage of DPT3 & MCV by socioeconomic group in children aged 12 to 23 months

	Baseline				Endline			
	Control		Intervention		Control		Intervention	
N	706		769		685		719	
	%	**95% CI**	**%**	**95% CI**		**95% CI**	**%**	**95% CI**
Had both DPT3 & MCV	67.9	61.7, 73.4	64.8	59.9, 70.6	77.2	72.1, 82.3	76.2	71.4, 81.1
Q1 poorest	47.8	39.5, 59.4	54.9	42.3, 72.5	65.7	53.5, 77.8	67.8	57.9, 77.8
Q2	68.3	58.1, 76.6	68.2	60.8, 78.7	79.2	70.4, 88.0	81.1	73.8, 88.4
Q3	75.0	64.1, 82.3	62.1	52.9, 74.3	79.9	71.6, 88.2	71.0	62.3, 79.2
Q4	72.6	60.5	67.3	58.4, 75.2	81.1	72.0, 90.2	73.8	63.8, 83.8
Q5 least poor	74.6	65.3, 85.9	69.8	51.7, 75.3	83.1	75.6, 90.6	84.2	75.5, 92.9

To assess the timeliness in uptake of immunizations, date of vaccination from a documented source was used to calculate the age (in days) when specific vaccines were received. Table 11 shows the proportion of children who were vaccinated and received their vaccine within 2 weeks of the scheduled time. Of those who stated they were immunized, only children with a recorded date of immunization were included, i.e. timing can only be assessed for validated coverage estimates. Children with a valid record of not being immunized were included in the analysis. These estimates show that there is more timely uptake of vaccines closer to birth. The timeliness of subsequent doses of polio, DPT and PCV was also similar across vaccines administered in the same immunization visit. For measles vaccine an interval of 9 to 12 months is an acceptable appropriate age. Again there is no difference between intervention and control cluster summary estimates of valid coverage, however it should be noted that age-appropriate MCV uptake is considerably higher than the other later doses which usually occur closer to birth. This may be influenced by the wider window of consideration of age appropriate, i.e., 3 months for this immunization compared with 2 weeks for the other vaccines.

Table 11: Timeliness of valid coverage of vaccinations in children aged 12 to 23 months

		Baseline				Endline			
		Control		Intervention		Control		Intervention	
	Proposed vaccine age (weeks)	Age appropriate vaccination		Age appropriate vaccination		Age appropriate vaccination		Age appropriate vaccination	
N		611		631		685		714	
		%	**95% CI**	**%**	**95% CI**		**95% CI**	**%**	**95% CI**
BCG	0	85.6	81.2, 90.8	85.6	80.4, 90.6	88.7	85.5, 92.0	89.2	85.6, 92.7
OPV0	0	89.8	86.5, 94.1	89.8	85.5, 93.7	89.6	86.2, 93.1	89.1	86.1, 92.1
OPV1	6	70.7	64.7, 75.5	73.0	65.5, 79.7	74.1	67.8, 80.3	72.8	66.4, 79.2
OPV2	10	49.3	41.0, 57.3	52.2	43.7, 59.6	52.0	44.5, 59.6	49.8	42.4, 57.1
OPV3	14	29.8	21.7, 38.0	32.2	23.5, 41.0	32.3	25.3, 39.3	32.1	23.8, 40.3
DPT1	6	88.3	79.5, 97.2	94.3	85.2, 100.0	83.7	76.2, 91.3	88.7	84.4, 92.9
DPT2	10	47.9	39.5, 55.8	52.3	44.2, 60.0	52.1	44.5, 59.6	49.0	42.0, 56.1
DPT3	14	32.6	24.3, 39.8	34.5	25.3, 43.7	34.4	27.5, 41.3	35.2	26.8, 43.6
PCV1	6	64.0	58.4, 69.1	71.7	64.3, 78.1	71.6	65.7, 77.4	73.4	67.4, 79.3
PCV2	10	42.2	34.8, 49.4	49.5	40.9, 57.6	49.6	41.8, 57.4	47.2	40.2, 54.2
PCV3	14	26.6	19.3, 33.5	30.2	21.8, 38.7	31.3	24.0, 38.8	32.1	24.1, 40.0
MCV	38 to 52	68.6	63.1, 74.1	69.2	63.4, 74.7	78.5	71.9, 85.1	77.7	72.4, 82.9
DPT3 & MCV *		25.7	19.3, 32.1	30.4	21.8, 39.0	30.1	22.7, 37.5	31.3	23.4, 39.2
DPT3 & MCV **	-	64.0	57.1, 70.0	63.1	58.3, 68.5	77.2	72.1, 82.3	76.2	71.4, 81.1

Note: * timely valid coverage ** valid coverage irrespective of timing

Dropout rates for key immunizations are shown in Table 12. Again, there was no difference between the intervention and control clusters. The most noticeable change in dropout at endline is the decrease in dropout rates from DPT3 to MCV 14.6% and 14.3% for intervention and control respectively at baseline compared to 9.8% and 9.1% at endline. This decrease in DPT3-MCV dropout was a significant decrease overall (p=0.002), in the control clusters (p=0.06) and in intervention clusters (p=0.01). There was no difference in this dropout between control and intervention clusters at endline (p=0.75).

Table 12: Dropout rates, valid coverage only in children aged 12 to 23 months

	Baseline				Endline			
	Control		Intervention		Control		Intervention	
N	776		719		771		685	
	%	**95% CI**	**%**	**95% CI**	**%**	**95% CI**		**95% CI**
DPT1 – DPT2	2.5	1.4, 3.6	2.4	0.8, 3.9	2.9	1.3, 4.5	3.9	1.8, 6.0
DPT1 - DPT3	6.2	3.7, 8.9	5.7	3.5, 7.9	3.6	1.4, 5.7	5.6	3.2, 8.0
DPT1 - MCV	17.9	13.1, 23.3	16.2	12.9, 19.3	11.1	7.2, 15.2	13.0	9.0, 16.9
DPT3 – MCV	14.6	10.6, 18.5	14.3	11.7, 16.5	9.8	6.4,13.2	9.1	6.0, 12.2
OPV0 – OPV1	7.1	3.3, 11.4	3.4	1.5, 5.5	6.8	3.6, 10.0	7.5	4.1, 10.9
OPV0 – OPV2	5.7	1.9, 9.6	4.8	2.8, 7.3	8.7	5.8, 11.6	9.1	5.2, 12.9
OPV0 – OPV3	9.79	4.4, 15.4	7.9	5.3, 10.3	8.2	4.4, 11.9	10.8	6.7, 14.9

Table 13 shows the prevalence and treatment of diarrhoea in children aged 6 months to under 5 years in the 2 weeks prior to the surveys. In all children, there was a significant decrease in diarrhoea from baseline to endline (p <0.0001), this was also seen within both control (p= 0.002) and intervention (p= 0.004) clusters. There was no difference in the prevalence of diarrhoea between control and intervention clusters at endline (p=0.45). The percentage of

children ill with diarrhoea who were treated with both ORS and zinc did not change from baseline to endline, in the control group (p= 0.87) and intervention (p= 0.35).

Table 13: Diarrhoea among children aged 6 months to 5 years in the previous 2 weeks

	Baseline				**Endline**			
	Control		**Intervention**		**Control**		**Intervention**	
N	1470		1535		1390		1393	
	%	**95% CI**	**%**	**95% CI**	**%**	**95% CI**		**95% CI**
Had diarrhoea in last 2 weeks	45.1	42.0, 48.3	42.8	39.6, 46.0	36.5	32.4, 40.9	34.0	30.5, 38.3
Level of drinking during diarrhoea illness*								
More	36.7	32.4, 41.2	37.4	30.5, 44.9	31.9	26.6, 37.7	30.2	25.6, 35.2
Less	48.3	43.6, 53.1	47.6	40.5, 54.9	36.9	31.5, 42.5	35.7	30.5, 41.2
Same	15.0	12.4, 17.9	15.0	12.6, 17.7	31.5	28.0, 34.7	34.0	28.1, 40.5
Level of eating during diarrhoea illness								
More	15.7	13.6, 18.0	13.2	9.9, 17.4	13.8	10.4, 18.0	13.9	10.9, 17.5
Less	69.5	66.0, 72.9	68.0	62.5	73.0	55.2, 61.1	57.9	53.3 ,62.4
Same	14.8	12.1, 17.9	18.8	15.6, 22.6	28.1	24.5, 32.0	28.2	24.9, 31.8
Seek advice or treatment*	89.4	85.9, 92.1	90.9	89.2, 92.3	87.3	83.42,90.3	86.7	83.7, 89.3
Took ORS *	63.4	57.0, 69.3	67.2	59.0, 74.4	58.6	51.7, 65.1	58.2	51.0, 65.0
Powder / sachet **	98.9	97.4, 99.6	98.3	96.5, 99.1	99.6	97.3, 99.9	98.7	96.2, 99.6
Pre packed liquid**	1.1	0.4, 2.7	1.3	0.6, 2.6	0		1.7	0.6, 4.1
Homemade solution **	0.5	0.1, 2.1	1.2	0.5, 3.3	0.7	0.2, 2.9	0.4	0.1, 3.1
Took zinc *	54.8	46.5, 62.9	58.6	50.1, 66.5	57.4	50.0 ,64.6	53.7	47.3, 60.0
Tablets **	96.0	91.6, 89.1	89.6	96.3, 99.5	99.6	97.1, 99.4	99.5	99.8, 99.9
Syrup **	4.6	2.1, 10.0	2.3	1.0, 5.2	1.6	0.5, 4.9	0.5	0.1, 3.2
Had both ORS and zinc *	44.4	36.6, 52.6	47.4	39.4, 55.5	43.7	36.3, 51.4	44.4	38.9, 50.0

Note: * Of children with diarrhoea in last 2 weeks ** of children who took ORS or zinc

Table 14 shows estimates of fever prevalence and treatment. Overall there was a significant decrease in fever for both control (p<0.0001) and intervention (p<0.0001) clusters. No difference in fever prevalence was seen between control and intervention clusters at endline (p=0.23). Of children who took treatment for fever, the overall percentage of children who took antimalarials decreased across surveys (p<0.0001), while there was an increase in children who took antibiotics (p=0.006). There was no change from baseline to endline in the prevalence of febrile children who were treated with the recommended antimalarial drug Artemether + Lumefantrine (AL) within one day of the start of fever (p=0.42) in control clusters (p=0.79) or intervention clusters (p=0.58).

Table 14: Fever in children aged 6 months to 5 years in the previous 2 weeks

	Baseline				**Endline**			
	Control		**Intervention**		**Control**		**Intervention**	
N	**1469**		**1535**		**1374**		**1385**	
	%	**95% CI**	**%**	**95% CI**	**%**	**95% CI**		**95% CI**
Had a cough in last 2 weeks	50.5	46.1, 52.9	47.4	43.9, 51.0	57.6	54.0, 61.1	56.8	53.8, 58.7
Had difficulty / fast breathing	26.8	23.1, 30.8	23.0	19.6, 26.8	31.4	27.8, 35.1	28.8	25.5, 32.4

Breathing problems due to blocked/runny nose	79.7	75.9, 83.1	76.9	69.4, 83.0	85.3	81.4, 88.6	84.3	78.3, 88.9
Had fever in last 2 weeks	76.9	73.5, 80.0	74.9	70.1, 79.1	53.9	49.8, 57.8	49.5	43.8, 55.3
Children with fever								
Seek treatment for fever *	94.8	93.1, 96.1	96.0	94.2, 97.3	90.1	87.8, 92.1	89.5	86.9, 91.6
Had blood test *	66.2	61.2, 70.9	65.6	59.9	70.9	62.4, 73.5	60.4	54.2, 66.2
Took medication **	98.8	98.0, 99.4	98.7	98.0, 99.2	96.4	94.5, 97.7	98.0	96.7, 98.8
Antimalarials	93.1	91.3, 94.6	91.7	89.8, 93.3	76.7	70.5, 81.9	78.4	70.6, 84.5
Antibiotics	7.0	5.3, 9.2	6.7	4.7, 9.5	12.6	9.5 , 16.6	14.8	11.6, 18.7
Other drugs	64.2	57.6, 70.3	60.5	53.1, 67.4	72.8	66.3, 78.4	68.7	60.0 , 76.3
Which antimalarials were taken ***								
Artemether	5.3	2.9, 9.5	4.1	2.1, 7.5	2.4	1.3, 4.6	3.0	1.4, 6.1
Artesunate	0.3	0.1, 0.9	0.6	0.2, 1.6	0.6	0.2, 1.8	1.3	0.6, 2.9
Artemether + Lumefantrine	88.6	84.1, 91.9	88.7	84.0, 92.1	92.5	90.2 ,94.3	94.1	90.6, 96.3
Chloroquine	0		0.2	0.1, 0.8	0.2	0.02, 1.4	0	
Quinine	5.5	4.1, 7.4	6.2	4.2, 9.0	5.9	4.0, 8.5	4.9	3.2, 7.4
Sulfadoxine + pyrimethamine	0.3	0.1, 1.3	0.3	0.1, 1.0	0.2	0.02, 1.4	0.2	0.03, 1.7
How long after onset of fever was antimalarial taken ***								
Same day	34.4	30.2, 38.9	37.9	33.9, 42.0	37.1	31.9, 42.7	36.7	32.0, 41.8
Next day	43.8	39.6, 48.2	41.5	37.5, 45.6	46.7	41.4, 52.0	46.3	40.9, 51.8
2 or more days later	21.8	17.8, 26.3	20.6	17.9, 23.6	16.2	13.6, 19.2	17.0	13.2, 21.6
Antimalarial form ***								
Injection	4.8	3.3, 6.8	6.1	3.7, 10.0	4.8	3.6, 6.2	4.5	2.5, 7.8
Tablet	93.4	91.1, 95.1	91.6	88.3, 93.9	95.3	93.8, 96.4	95.1	92.0, 97.0
Suppository	1.8	1.0, 3.4	2.3	1.2, 4.6	0		0.4	0.1, 1.7
Took AL the same or next day (all fever)	59.2	55.2 ,63.2	59.6	55.8,63.2	53.4	49.6, 57.1	54.2	48.4, 60.0
Which antibiotics were taken for fever								
Ampicillin	3.0	0.7, 12.2	1.6	0.2, 10.9	4.9	2.0, 11.3	7.7	3.8, 15.3
Benzylpenicillin	3.0	0.4, 20.5	0		1.2	0.2, 9.2	2.4	0.5, 9.2
Chloramphenicol	1.5	0.2, 10.9	1.6	0.2, 10.6	-		-	
Gentamicin	1.5	0.2, 9.1	1.6	0.2, 11.6	3.7	1.4, 9.5	0	
Amoxicillin	60.6	47.2, 72,6	77.1	68.6, 83.8	56.8	42.7, 69.9	60.7	50.2,70.2
Ciprofloxacin	1.5	0.2, 0.1	3.3	1.0, 11.2	7.4	3.2, 16.2	3.4	1.8, 9.2
Cotrimoxazole	25.8	15.2, 40.3	13.1	6.2, 25.7	9.9	4.5, 20.4	10.1	5.1, 19.1
Metronidazole	3.0	0.8, 10.7	1.6	0.2, 10.6	2.5	0.6, 9.5	2.2	0.6, 7.7

Note: *of children with fever ** of children who took medication *** of children who took antimalarials

The control and intervention health facilities were very similar in terms of cadres of staff, assessed as the numbers of the 16 facilities in each arm that had at least one of each cadre of staff mentioned (Table 15). All health facilities had VHTs attached and the median number was similar in control and intervention facilities, however the number of VHTs attached to each facility was very wide ranging, from 3 to 162 overall. At the time of the survey there were stock-outs in a few facilities of OPV, IPV, MCV and Child Health Cards. In both the control and intervention health facilities 7 each reported to have staff who had been trained in the use of mReach.

Table 15: Health facility endline survey

	Control		Intervention		
	N	**%**	**N**	**%**	**P value***
Staff at the facility (at least one)					
Clinical officer	5	31.3	6	37.5	0.71
Nurse	16	100.0	16	100.0	-
Mid wife 32	14	87.5	13	81.3	0.63
Health assistant	8	50.0	10	62.5	0.48
Record keeper	7	43.8	7	43.8	-
VHTs attached to facility	16	100.0	16	100.0	-
Number of VHT's attached to facility	Median: 35	Range: 3 to 162	Median: 42	Range: 4 to 124	0.48
Staff member who supervises VHTs					0.59
In charge	11	68.8	12	75.0	
Health assistant	4	25.0	4	25.0	
Midwife	1	6.3	0	-	
Frequency of VHT referrals					1.0
Very often	11	68.7	11	68.7	
Sometimes	5	31.3	5	31.3	
Provides immunization services	16	100.0	16	100.0	-
Birth doses					0.41
At the facility only	5	31.3	3	18.7	
At the facility and outreach	11	68.7	13	81.3	
Infant doses					1.0
At the facility only	0		0		
At the facility and outreach	16	100.0	16	100.0	
Frequency of immunization services					0.74
Daily	12	85.7	13	81.3	
>= Once a week	2	14.3	3	18.7	
Days since most recent outreach	Median:4	Range: 1 to 27	Median: 5	Range: 0 to 33	0.41
How long until the next outreach	Median: 4	Range: 0 to 25	Median: 2	Range: 0 to 8	0.48
Facilities where VHT's refer children who have missed or are due an immunization?	16	100.0	14	93.3	0.29
Frequency where parents bring referral forms given by a VHT?					0.22
Always	5	31.3	7	50.0	
Sometimes	9	56.2	3	21.4	
Rarely	0	0	1	7.1	
Never	2	12.5	3	21.4	
Paper referral forms recorded	12	75.0	10	71.4	0.83
Frequency of DPT and MCV supply					0.35
>=1 week	0	0	1	7.1	
>=1 month	9	60.0	11	78.6	
>= 3 months	2	13.3	1	7.1	
Upon request	4	26.7	1	7.1	
Main vaccine supplier					0.54
National medical stores	14	87.5	15	93.7	
Regional hospital	2	12.5	1	6.3	
Vaccines currently in stock					
BCG	13	81.3	16	100.0	0.07
OPV	16	100.0	14	87.5	0.14
IPV	14	87.5	13	81.3	0.63
PCV	16	100.0	16	100.0	-
DPT	16	100.0	16	100.0	-

	Control		Intervention		
	N	%	N	%	P value*
MCV	16	100.0	13	81.3	0.07
Equipment required for immunization available					
Sharps container	16	100.0	16	100.0	-
Cold box	16	100.0	16	100.0	-
Child health cards	12	75.0	13	81.3	0.52
Tally sheets	16	100.0	16	100.0	-
Immunization registers	16	100.0	16	100.0	-
Has a functioning refrigerator	16	100.0	16	100.0	
Temperature monitoring device					0.29
Thermometer	1	6.3	3	18.7	
Fridge tag	15	93.7	13	81.3	
Involved in MoH child immunization days	15	93.8	15	93.8	-
Other services offered					
Outpatient care	16	100.0	16	100.0	-
Inpatient care	6	37.5	6	37.5	1.0
Antenatal clinic	16	100.0	16	100.0	-
Delivery	16	100.0	14	87.5	0.14
Laboratory (exc RDT)	9	56.3	12	75.0	0.26
HIV services	15	93.8	15	93.8	1.0
Family planning	16	100.0	16	100.0	-
Staff had training in use of mReach / Commcare (only half the facilities responded to this)	7	43.8	7	43.8	0.6
Use of mReach					
Updating vaccination status					0.57
Daily	6	75.0	7	77.8	
At least once a week	1	12.5	2	11.1	
<Once a week	1	12.5	0	0.00	
Sharing list of defaulters					0.21
Daily	5	62.5	2	22.2	
At least once a week	2	25.0	5	55.6	
<Once a week	1	12.5	2	22.2	

Note: * chi square test for percentages; Kruskal Wallis test for medians

Table 16: Semi-structured interviews and focus group discussions in control and intervention sites

Respondent type	Control sites		Intervention sites	
	SSI	FGD	SSI	FGD
Health Care Worker	4	-	8	-
Community Leader	2	-	4	-
Village Health Team Member	4	2	8	4
Parents/care givers	6	2	12	4
Total	**16**	**4**	**32**	**8**

Table 17: Semi-structured interviews with district stakeholders and IRC staff

Respondent type	Kitgum	Lamwo	Agago	Cross district
District stakeholders				
District health officer	1	1	1	
Cold chain technician	1	1		
EPI focal person			1	

Secretary health / political leader	1	1		
District health secretary			1	
IRC staff				
Senior health officer	1	1	1	
Monitoring & evaluation officer				1
mHealth officer				1
Immunization specialist				1
Health co-ordinator				1
Total	4	4	4	4

7.3 Process evaluation findings

7.3.1 Implementation fidelity

The assessment of whether the intervention was implemented as expected was based upon a mix of IRC implementation reports, the cross-sectional surveys and stakeholder interviews to explain the findings.

mReach data platform

At least one health care worker (HCW) at each intervention facility was trained in the use of the mReach application prior to the trial and by the start of the trial health care workers had started to use the application to register and review the vaccination status of children under the age of 2. Several challenges were however noted and commented in the interviews. HCW workers were using the application but it was time consuming and not straightforward initially.

"This is good but hectic, needs your mind to be fresh and clear not to makes mistakes however, I prefer to use the mobile application over the register book." (HCW #35, intervention, Kitgum)

It quickly became apparent that one trained health worker per health facility was not enough to maintain use of the system hence other health care workers started to use the application. Some learnt to use the application by practice and others were trained during additional sessions run by IRC when they recognized that more than one HCW needed to manage the system.

An additional issue that arose was that a few HCWs downloaded large personal files on the phone, which hosted the application. This impeded the functioning of the application and required closer supervision by the IRC Senior Health Officers and the mHealth officer. The latter also provided additional mentoring support to the HCWs to help them use the application and associated defaulter tracing system more effectively.

Monthly VHT, Health Care Worker and Community Leader Meetings

These meetings happened at both control and intervention sites and were conceived of as a supporting activity. VHTs were provided with an allowance (10,000 Ugandan Shillings) for attending these meetings. These types of allowances are expected and required of NGOs who involve VHTs in their health activities. The amount was relatively standard and did not just provide compensation for attending the meeting but was also meant to support health related activities performed by VHTs.

The focus of the meetings at both control and intervention sites was immunization. HCWs provided updates on the status of immunization and any changes to vaccination policies, schedules of activities. The intervention meetings were mainly taken up in reviewing defaulter tracing forms and checking them against the health facility register and mReach application data. Observation data indicated that a lot of time was taken in reviewing forms and providing guidance on how to complete the forms. *'Each VHT brings his challenges and his report'* – this note from an observation captures what happened during intervention meetings, which were also learning opportunities for the VHTs and the HCWs. It was evident that some of the VHTs found it difficult to read, complete and interpret the form.

"…if you have failed to interpret the form that have been given to us [Hmmm], we learn among yourself, we can say that the person has not said it well or not, someone who understand the form well can interpret it" (VHT, FGD, Agago, intervention)

Outreaches were also planned during these meetings. The HCWs identified areas with a high level of immunization default in advance of the meeting s and invited the relevant community leaders to attend the meeting to help with planning. Appendix Table A3 indicates that community leaders did attend these meetings but that their engagement varied across sites.

In terms of organization, at one site there was some criticisms about the length of meetings and that IRC staff who mainly attended intervention meetings were sometimes forceful. Specifically, at this intervention site VHTs complained that IRC staff had become forceful in their language when VHTs had raised questions about the payment of their allowances if they (VHTs) were unable to attend the monthly data review meetings. It is worth noting that these allowances were provided to support the transportation costs of VHTs to attend review meetings. However we do not have direct evidence of any impact and no records of interactions between IRC and health workers and VHTs being difficult at other sites.

A larger question about these meetings is whether they constitute a 'supporting activity' (SA) within the framework of standard MoH immunization service provision. The purpose of the supporting activities in the trial design was to ensure that all sites were enabled to provide standard immunization services, for example that they could maintain the cold chain. The VHT/HCW monthly meeting sits outside this definition, in that although it is good practice it is not a regular feature of immunization services. Hence this 'supporting activity' could be viewed as an intervention in and of itself and this could have some explanatory power in terms of the lack of difference in outcomes between control and intervention sites.

Observation reports from two control VHT/HCW meetings indicate that as part of these meetings VHTs and HCWs had devised their own activities to support defaulter tracing; for example, creating a defaulter tracing register and undertaking more community mobilization to encourage parents to immunize their children. Another point of note is that IRC staff attended some of the control meetings as well as the intervention meetings. This was partly because they needed to disburse the money for the VHT allowances, but their presence also stimulated vaccine-related discussions. For example, at one meeting, IRC staff insisted that attendees needed to be vigilant in completing child health cards.

Attendance at control and intervention VHT/HCW meetings was generally higher in intervention clusters during the course of the trial but not markedly. IRC staff stated that attendance reduced slightly in Lamwo and Kitgum in the latter months since VHTs input was

sought by other organisations involved in the refugee response in those areas, who paid VHTs higher allowances.

Community engagement

The involvement of community leaders in supporting immunization services was viewed positively by caregivers. Leaders are entrusted with significant responsibility at community level and afforded a lot of respect.

"I think it is good because the community leaders talk on behalf of government, so at least they talk with authority and this makes people obey them." (VHT, FGD, Agago, intervention)

"The way that the community leaders are involved in immunization outreach, if information reaches them from the health center that immunization is on such a date, so at least the information can reach people from the church, so they will convey the message to the people who have gone to the church [Hmmm], at times, the Local councillor I [LCI] moves door to door informing people that immunization is on such a date, so the information reaches all the people. That is how I think the community leaders are involved in the immunization outreach event." (FGD, Male caregivers, Agago, intervention)

The importance of the involvement of community leaders in supporting immunization activities was stressed by district leaders, who also thought that leaders should be recompensed for their support. Caregivers also stated that they think community leaders' involvement should be recompensed or that they should be given a bicycle to support this work.

"For me, the way I see the community leaders are involved in promoting the immunization is good, because I see them mobilizing the community to come for immunization , at times there are some parents who do not want to take their children for immunization, therefore, they work together with the VHT to bring the parent and the child for immunization at the health center[Hmm], sometimes , they also come up to the health center to check the parents whose child has missed the immunization and they follow the parent up to their home making immunization program to work well[Hmmm] and I ask this organization to support them with at least some thing to move within the villages , they can give them like a bicycle to make their work better." (Male caregivers, FGD, Agago, intervention)

The engagement of religious leaders and traditional leaders was also viewed as facilitating the delivery of communication for childhood immunization in both intervention and control areas. All respondents indicated that such engagement was a major boost to immunization since these institutions were trusted by many in the communities.

"…if you want to achieve or maybe for any activity to work in the community you have to involve the religious leaders because they are the ones who talk a lot for us mostly in churches and people listen to politicians when they go to the church they have been respondent to so we have the religious leaders, the cultural leaders we have the village health team [mhm] we have the L.C 2, L.C1 and the L.C 3 at the sub county [okay] those are the people that we work with." (DHT member # 9, Agago)

Community leaders' involvement in immunization activities and the responsibilities they assumed and were variously described. Some instances were very collaborative and supportive other raised questions about the authority they assumed.

The former approach involved leaders 'walking with VHTs' as part of defaulter tracing activities and providing guidance to community members. Local leaders also maintain birth registers and district leaders are keen for them to encouraged people to assume responsibility for immunizing their children.

"As a community leader I give guidance to people when I see them going astray, I sit them down and we talk, I tell them that life is not lived the way they are living, and I correct them on what to do, so that is how I am working with the community." (Community leader, #4, Kitgum, control).

"The partnership and also the leadership, the orienting is focused at the community level (mmm) and making people take charge of the immunization (mmm), the feedback and others" (DHO, # 9, Agago)

A more authoritarian approach which was reported to be adopted by some community leaders involved leaders taking different degrees of action against caregivers who had not immunized their children. These included removing items of property, threatening police involvement and being authoritarian in dispensing reprimands.

"The leaders have resorted to moving around the community imposing that such mothers they will forcefully take their property when they fail to take children for immunizations because for them [meaning the mothers] were taken for immunizations by their parents so then why don't they want to take the children for them to be healthy.

I: So they take their belongings, what do they take?

R: They take things like jerry cans or the saucepans that they use for cooking; they take things that are good to her.

I: Do they get those things back when they complete immunization?"

R: They return them back and they also confirm that they will now take the child for immunization. And the VHT also work together with the health workers and fix a date then inform the mothers in the community that we will come to immunize on such a set date, so all mothers should bring their children [mhm] so they bring the vaccines in the community. (Female caregiver, #3, Kitgum, control area)

"More is like this, we unite with the LC1, if you find caregiver whom even though you talk and explain to them slowly and they still cannot listen or understand. The LC 1 can then use his authority as government representative and even tell the caregiver that if you do not take the child for immunization then I will tell the police to come and arrest you. In that case the stubborn caregiver ends up obeying." (VHT, FGD, Agago, intervention).

<u>Health facilities resourced to provide immunization services</u>

As stated above, as part of the trial design, IRC provided SAs to ensure that health facilities were equipped to provide quality immunization services. In terms of quality, the main measure taken was to conduct immunization update training for all HCWs at the start of the trail. An unintentional effect of this could have been to increase the productiveness and attention given to immunization services across all sites. District leaders were also involved in this training which may have raised district level interest in the delivery of immunization services. We

cannot draw any conclusions from this, but it is possible that this training and other SAs improved the performance of immunization services at intervention and control sites.

At the same time, it is noteworthy that despite these SAs, vaccine stock-outs were common across all sites (Table A5). The number of stock-outs between control and intervention sites also did not differ, probably because they were due to central delivery issues. These may also explain why SAs could not resolve these issues since this was a MoH responsibility. The IRC SAs mainly helped with transporting vaccines to health facilities. Where there was a slight difference in terms or vaccine related resources was in the functionality of the fridges where vaccines were stored. Fridges at intervention sites were dysfunctional 20 times in contrast to 16 times in control sites (Table A6).

The process of defaulter referral

The defaulter tracing system that complemented the mReach application and consisted of referral forms that were given to VHTs by HCWs and used by VHTs to follow up defaulters was introduced across all the intervention sites at the start of the trial. It was perceived as useful but also complicated to use and VHT literacy levels were a challenge.

The referral process was credited with having achieved change, making VHTs' work easier and improving the follow-up of unimmunized children. The forms gave VHTs credibility in homes, were evidence of their work and the whole process helped strengthen VHTs work in their local communities.

"There is change because those days when they were not using the phone, some of the children were hidden and could not be traced, the VHTs would not also go to check on the child health card that have missed immunization or completed but now the VHTs move to check the child health card of the children who have missed immunization or completed the immunization so it is helping people in the community" (Male caregiver, FGD, Agago, intervention).

However, VHTs and sometimes community leaders still had to cover long distances as part of the referral process. Another issue that arose was that some parents took their children for vaccination at health facilities that were not part of the trial. Also, when caregivers changed their location and moved to different places, addresses were not updated, which could mean that some names kept on reappearing as defaulters although they were no longer resident in the area.

VHTs stated that reminding and counselling caregivers required patience and persistence:

"You know these mothers in the local community sometimes need counselling. Some of them do not understand very well. So, you have to talk to them slowly. You may write to them referral form that they should take the child to the health center but if you do not talk to them well, she will not take the child. You may give the referral form and it takes some days or a week. If you do not go back to follow up to ask whether she went with the referral form to health center and the child got immunized. If you do not follow up she may just keep it and stay home. What we do is we go back and check again. I gave you a referral form; did you take your child for immunization? If they have got immunized, then I go back to the health center and ask whether child was immunized whether from health center or from outreach". (VHT, FGD, Agago, intervention).

Caregivers were mainly positive about VHT home follow-up although it was evident that there was less interaction in control areas. A few people also raised some concern about unannounced abrupt visits. Caregivers did however value the reminder form because it was a good reminder and a means of ensuring that parents and HCWs know that children are immunized.

"I think it is good because it reminds me about immunization date of my child and so helps to follow up on immunizations and I ensure that the child doesn't miss immunizations." (Female Caregiver, FGD, Agago, intervention)

"The referral form is very important [Hmmm], first, it will help me to have the information that I have missed immunization, so it is a reminder to me to complete the immunization, secondly, when I have completed the immunization of the child, the health workers will have the knowledge that I have completed the immunization." (Male caregiver, FGD, Agago, intervention)

The referral form also worked in other ways, it stimulated action by inducing shame and helped caregivers negotiate relationships with health workers.

"To inform you so that when you default a number of times the form [referral form] will just keep piling up for you so that you get a shamed and take your child for immunizations …" (Female caregiver, FGD, Agago, intervention)

"Giving referrals reduces mothers fear, she knows that if she goes to the health facility without a letter then maybe the health staff would quarrel with her…" (VHT, FGD, Agago, intervention).

Control areas introducing their own defaulter tracing charts

The intervention was not widely publicized, but it could also not be blinded due to the nature of the activities. Hence other facilities and areas had some knowledge of the activities that were taking place at the intervention sites. Some jealousy was noted by district leaders who stated that control areas were also keen to improve the performance of their immunization services. As a result they conducted more community mobilization to promote vaccine uptake in their areas. There were also some HCW transfers from intervention to control sites. In one instance this resulted in a HCW creating a system that would raise awareness about vaccine default. This HCW manually tallied defaulters from the child health register, wrote them on a chart which was displayed on the wall of the clinic so that mothers, VHTs and other community members who visited the clinic could see the burden of default and work to improve vaccine uptake. It is important to note that activities that mimicked the intervention in terms of defaulter tracing were only paper-based, the mReach application was not copied.

It is also important to note that the monthly HCW/VHT meetings, which have been described above, acted as a catalyst for immunization activities. These were mainly community-based mobilization activities but another control site also developed their own defaulter register to help them trace unimmunized children. Hence only two control sites developed paper-based system for recording default but all sites did try to promote immunization more at community level.

Outreaches

Most of the respondents in both intervention and control said that the outreaches brought immunization services closer to them and saved them from the long journeys to health facilities. Caregivers also felt less restrained when attending outreaches which made it easier for them to vaccinate their children.

"This is the only way we can take opportunity, even if you are lazy you can take your child and even from the garden, just take the child no need to put on smart clothes (Female caregiver, # 48, Lamwo, intervention).

This sentiment was confirmed in an outreach observation at Omiya Pacwa where caregivers were observed coming directly from the garden to bring their children for immunization. Furthermore, outreaches that provided weigh/height measurement and vitamin A administration in addition to immunization were a means of attracting parents who were vaccine hesitant, since they were keen to benefit from wider services.

Outreaches were supported as part of the SA implemented by IRC. This regular support was highly appreciated and helped reach a significant number of children, who attended outreach events. Health facilities are required to conduct outreaches as part of standard immunization service provision however insufficient funds can impede the implementation of the outreaches. The main difference between the control and intervention outreaches was the decision on where to conduct the outreaches. They were conducted in areas of high default, regardless of geography, as identified by the mReach application in intervention areas, and in hard to reach areas in control sites. The former, were not always highly populated or necessarily hard to reach areas which may explain why attendance at control was higher than at intervention outreaches. It is also possible that mobilization following control VHT/HCW meetings resulted in high attendance at control outreaches.

Community leaders were involved in organizing control and intervention outreaches and there was not much difference in their responsibilities. In intervention areas they were invited to take part in the VHT/HCW meetings for planning purposes but other than that community leaders at all sites were involved in mobilizing community members to attend outreaches. Some interviews suggested that community leaders were not as proactive as they could be and mainly acted following receipt of information from VHTs and HCWs.

7.3.2 Mechanisms of impact

These are processes that helped achieve the desired outcomes and impact of the intervention. Four main mechanisms were identified, the first was the improved accessibility of immunization services that was facilitated by supporting more vaccine outreaches. This mechanism was a supporting activity hence it was not just provided at intervention sites and it played a significant role in overcoming barriers to immunization. The second mechanism was also evident at intervention and control sites although the element of competition was more pronounced at intervention sites. This mechanism was VHT motivation which was augmented by the receipt of monthly allowances during the VHT/HCW meetings and social pressure manifest in VHTs trying to outperform each other in defaulter tracing activities.

The third mechanism related to how the intervention drew on community resources to achieve its intended outcomes. The VHT network was essential to conducting defaulter tracing and

they were supported by local councillors; groups which are well known, respected an entrusted with leadership at community level.

"The people we relate with and share information with very well are the VHTs. They come and talk to us from within the community. They also encourage us mothers to immunize children." (Caregiver, FGD, Lamwo Control)

This mechanism contributed to caregivers and communities assuming more responsibility for immunization.

The fourth mechanism was increased interaction between HCWs and VHTs which was facilitated by another supporting activity. The monthly VHT/HCW meetings provided a forum for discussing immunization and planning activities that would help increase vaccine uptake. The value of this dynamic should not be underestimated and could explain why control areas also saw vaccine coverage increase over the course of the trial.

Another mechanism was also observed but it was not straightforward since it both encouraged immunization and deterred health facility attendance. This mechanism was stigma and shame related to non-immunization. This stigma was partly triggered by the receipt of defaulter referral forms but also related to previous experience of HCWs treatment of vaccine defaulters. Caregivers usually sought to overcome the stigma by having the children vaccinated but a few were scared about how they would be treated by HCWs.

Excerpt from a caregivers' focus group discussion in an intervention area (Lamwo)

I: Okay, how does this form work?

R3: I don't know its work, they gave me yesterday that I should go with it to the health center that I missed immunization and I should go with it to the health center.

I: So what do you think will happen from the hospital when you go with it? How does this letter work?

R: [unknown] me I think the doctors will quarrel on me (mmm).

R8: I think some fine would be levied on me.

R9: Me I think this letter would call for a very serious questionings from the health workers, because like me I gave birth to boys, and I missed their immunization, when I took them for immunization later, they detained my card, and every one finished their immunization, then they called me and questioned me, saying do I love my child, then I told them yes I do, then why did you miss his immunization like this… I was there and every one left me there and it was already late in the evening and they wanted me to stay [was like a prison] yes that was like a cell now and they wanted me to first stay, but some doctor say I should be forgiven and that should sound warning to everyone, so I think this people are also treated the same way (mmm). (Female caregiver, FGD, Lamwo, intervention)

7.3.3 Context evaluation (control and intervention)

The distance between health facilities and communities was stressed repeatedly as an impediment to accessing immunization. Furthermore, vaccine stock-outs at health facilities discouraged caregivers from attending vaccination services.

"I moved for 3 weeks they kept on telling me from the health Center that the DPT vaccine was not available, yet I would walk 4 miles coming another 4 going back I decided to give up" (Female caregiver, # 2, Kitgum, control)

HCWs ability to serve communities was also limited by lack of transportation (e.g. bicycles), equipment, drugs and budgets for outreaches and shortages in staff. Caregivers reported that HCWs were very stretched which resulted in long waiting times or non-receipt of vaccines.

Most caregivers had a good understanding of the purpose of vaccination and were positive about immunization. However, some caregivers had problems interpreting and reading their child's health card which made it difficult for them to remember when to take back the child for immunization.

"I forgot the date when I took my child's card to my neighbor she told me the date for my child to received immunization has passed by 2 weeks" (Female caregiver, # 25, Agago, intervention)

Another pressure on health service provision was the renewed influx of refugees from Southern Sudan that commenced at the end of 2016. This mainly affected the northern district of Lamwo and to a certain extent Kitgum district. It resulted in some logistical challenges in those areas, but it was not a major issue.

<u>Reasons for non-vaccination</u>

Vaccine hesitancy was rare in these communities and mainly limited to some religious groups. Key reasons cited for non-immunization were related to lack of convenience; the aforementioned distance between homes and health facilities, moving to the fields during farming seasons, vaccines only being available on certain days at health facilities, shame about lack of clean clothes to wear to health facilities, lack of information and difficulties in deciphering child health cards. Others related to caregivers' fear of being reprimanded by HCWs, domestic arrangements, including domestic violence and fathers' opposition to vaccination.

"You see even from my case my husband did not like the idea of immunization like when I go for immunization like today it is like a real fight again he say that what is the use of immunization to you? For me say that immunization is good because the child will not fall sick so often the child can fall sick just because of unavoidable cases". (Female Caregiver, # 23, Agago, intervention)

<u>Community-imposed immunization regulations</u>

As indicated in the community leader involvement section some leaders would impose sanctions for non-immunization. Additional data also suggests that communities developed their own regulations with regards to non-immunization. However, the introduction of the

intervention resulted in changes to these laws and to the way defaulters used to be treated at health facilities.

I: How do you follow up the children who miss immunization?

R: I use the card, if you don't have the card, means you don't take your child for immunization and yet you have been informed and also there is a law for it.

I: Do you have an example of the law? (Yes), okay can you tell me one law that was set?

R: Sometimes you are fined at the health center, if you don't take your child for immunization (mmm).

I: So, do you people also have your own law in your village here?

R: Yes, we have, if you don't take your child for immunization, then you must face the consequences from the health workers, we send your names to the health workers, the name of the child and the care giver. (Community Leader, 26 x, Agago, intervention)

"There I answer for myself, the clan where I am married; it is their policy that you must have your children immunized whether you like it or not (eeh) uhm." (Female caregiver, FGD, Lamwo, control)

"What I have seen is also working well is that those days people do not like immunization, the way they would treat someone who has missed immunization was not good for example if Nighty [referring to an example of a fellow VHT] has missed immunization, her child health card should be withhold at the health center, and the person have to pay some money like about 5000/= so that the child can be also immunized, after payment of this money, your child is immunized and the child health card is then returned to the parent of the child[Hmm], now when the CommCare (term for describing the mReach application) begun there is now no withholding of the child health card, because of missing of the immunization even no fine at the health center [Hmmm], that is what I see is working well, therefore making the parents to bring their child for immunization[Hmmm]. (VHT, FGD, Agago, intervention).

7.3.4 Summary of process evaluation findings

The intervention was implemented at all intervention sites and SAs were rolled out at all control and intervention sites. No direct changes were made to the intervention however two rather than just one health care worker had to be trained and mentored in the use of the mReach application to facilitate implementation at intervention sites. VHTs also needed more support than envisioned to use the defaulter tracing system, particularly those who were less literate. The defaulter referral process was credited with having achieved change, making VHTs' work easier and improving the follow-up of unimmunized children. The forms gave VHTs credibility in homes, were evidence of their work and the whole process helped strengthen VHTs work in their local communities. The forms also stimulated action by inducing shame and encouraging caregivers to take their child to be immunized. Of interest, caregivers found it easier to approach HCW if they had a referral form. Community leaders were actively involved in planning vaccine outreaches in intervention areas and their involvement was viewed positively by caregivers and district leaders who thought they played a significant role in promoting immunization.

The SAs helped to ensure that health facilities were resourced to provide immunization services but could not mitigate for vaccine stock outs, which occurred as a result of central delivery issues. Outreaches increased access to immunization services three main ways several ways; i) reducing the distance caregivers had to travel, ii) reducing social barriers (caregivers less embarrassed about the state of their clothes) and iii) vaccine hesitant parents attended to access additional services, such as Vitamin A supplementation. The main difference between the control and intervention outreaches was where they were conducted. They occurred in areas of high default identified by the mReach application in intervention areas, and in hard to reach areas in control areas. The former, were not always highly populated or hard to reach areas, which may explain why attendance at control outreaches was higher than at intervention outreaches. One of the SAs had a significant impact on the profile of immunization in control and intervention areas. This was the monthly VHT/HCW meeting that provided a forum for discussing immunization and planning activities that would promote vaccine uptake. A larger question about this meeting is whether it constitute a SA within the framework of standard MoH immunization service provision. The purpose of SAs as part of the trial design was to ensure that all sites were enabled to provide standard immunization services, for example that they could maintain the cold chain. The VHT/HCW monthly meeting sits outside this definition, in that although it is good practice it is not a regular feature of immunization services. Hence, this SA could be viewed as an intervention in and of itself and this could have some explanatory power in terms of the lack of difference in outcomes between control and intervention sites.

Observation reports from two control VHT/HCW meetings indicated that as part of these meetings VHTs and HCWs had devised their own activities to support defaulter tracing (the creation of a defaulter tracing register and more community mobilization to encourage parents to immunize their children). The transfer of a HCW from an intervention site also resulted in a change of practice at a control site. The HCW created a chart which identified defaulters and encouraged caregivers to immunize their children. These activities indicate that some cross contamination occurred between control and intervention sites however the mReach application and the defaulter tracing system were not copied in their entirety.

Four main mechanisms of impact (processes that helped achieve the desired outcomes of the intervention were identified. Of note is that three of these mechanisms were associated with SAs that were provided at control and intervention sites. The first mechanism was the improved accessibility of immunization services facilitated by supporting more vaccine outreaches. The second mechanism was VHT motivation which was augmented by the receipt of monthly allowances during the VHT/HCW meetings. The third mechanism related to how the intervention drew on community resources to achieve its intended outcomes. The VHT network was essential to conducting defaulter tracing and they were supported by local councillors; groups which are well known, respected an entrusted with leadership at community level. The fourth mechanism was increased interaction between HCWs and VHTs which was facilitated by the monthly VHT/HCW meetings. The value of these meetings should not be underestimated and could explain why control areas also saw vaccine coverage increase over the course of the trial.

7.4 Cost of implementing mReach

The IRC spent approximately $215,000 dollars to implement mReach in the 16 catchment areas of Kitgum during the window of treatment[5]. Given results of the impact evaluation, we cannot assess the cost per increase in coverage rate, which would be a true cost effectiveness analysis. However, we can estimate the cost per unit served by mReach (based on sample at baseline).

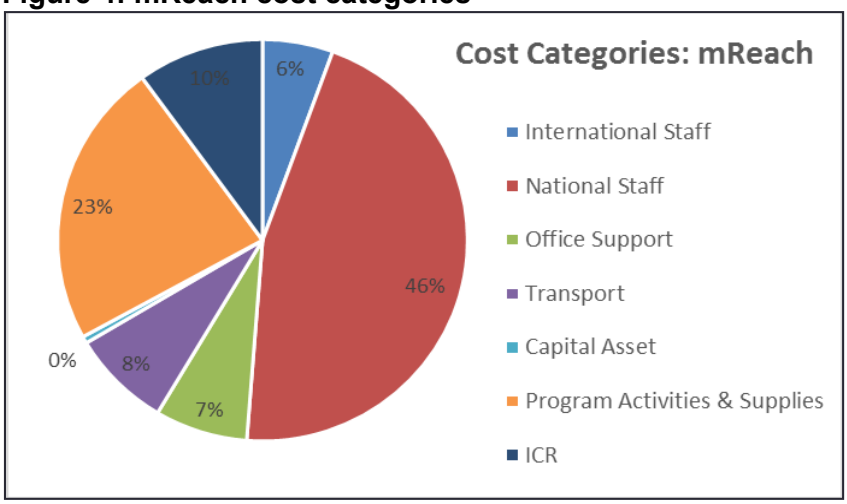
Table 18: Cost of implementing mReach

Unit	Count in Sample	Cost Efficiency
Health Facilities	16	$ 13,458
Villages	112	$ 1,923
Households	910	$ 237
Children 12-23 months	778	$ 277

7.4.1 Cost Drivers

The main cost of implementing mReach tool is staff time (46%). The Immunization Manager, Health manager and officer, and M&E officer all contributed substantial time to mReach implementation6. Program Materials & Supplies were the next biggest cost category (23%). Included in the cost categories presented (Figure 4) are costs for both programmatic and support functions. A significant portion of the grant funding (31%) covered a share of IRC operational fixed costs, such as office rent, vehicles, IRC Uganda management team, and ICR.

Figure 4: mReach cost categories



7.4.2 Ministry of Health Take-up of mReach

Should the Ministry of Health decide to implement mReach within the government health system, the ministry must budget for several projects costs on an annual basis. Allowances

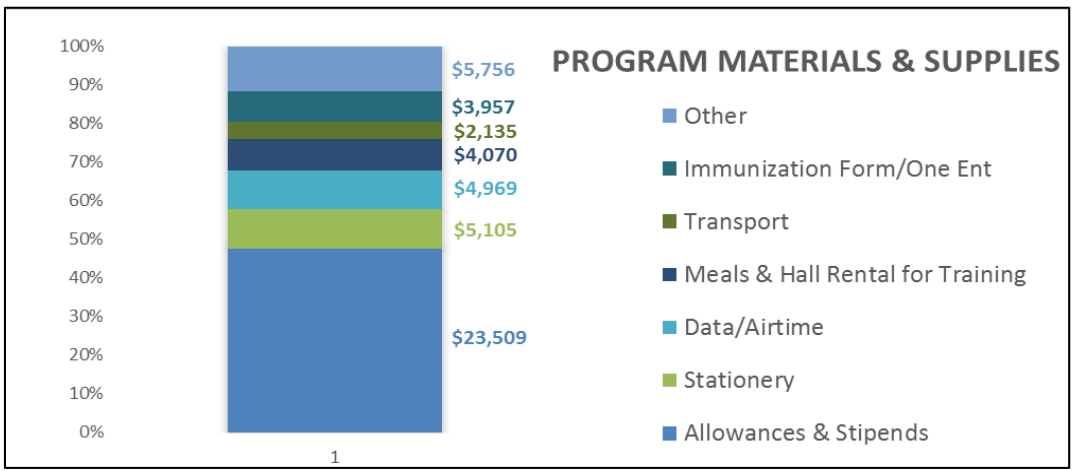
[5] Cost estimate includes IRC incurred costs from January 2016 through September 2017, when the endline survey began. See Appendix E for more detail on what items are/aren't included in this figure.

[6] Pfizer Costed Workplan provides details of what IRC staff were doing to execute mReach, which included training HCWs and VHTs, and follow up visits to each facility on a monthly basis.

and stipends for village health teams were 48% of the material & supplies costs when IRC implemented. These are a key ingredient to ensure community leaders and other groups are involved in tracking, outreach and mobilization of defaulters.

The IRC recommends that at least one full time ministry health staff be hired per district to train health facility workers on the tool and supervise implementation. Existing staff at health facilities would also need to take on additional responsibilities, most importantly meeting with village health teams to review defaulter data. IRC expects the additional health facility staff time to be no additional fiscal cost, as it would be part of the job for already salaried ministry staff, but the dedication of MoH staff time is a key resource for success of mReach. The same is true of transportation. A substantial cost (8%) for the IRC to deliver treatment was vehicle hires & fuel (Figure 5). Because the ministry of health system has transportation infrastructure in place for staff, vehicle costs should be far lower under ministry implementation, but at the least fuel budget is needed. A more detailed cost model for the MoH to use for scaling up mReach is available in Appendix E.

Figure 5: Breakdown of program materials and supplies



8. Discussion

The 'Fifth Child' project hypothesized that data-driven, targeted community engagement would facilitate more effective defaulter tracing and contribute to increased immunization coverage in hard-to-reach communities. The complex intervention included: the mReach defaulter tracing tool, training in the tool, health worker led monthly meetings with VHTs on defaulter tracing, planned outreaches based on coverage data and community engagement to trace defaulters. The intervention was layered on supporting activities (SAs) which were also complex and comprehensive including: basic training on routine EPI, immunization materials and bicycles, meetings to facilitate reporting and supervision, and support to resources – ensuring cold chain and transporting vaccines from districts to facilities.

A cluster randomized controlled trial was used to evaluate the intervention. A cluster was defined as a health facility catchment area (HFCA) where VHTs associated with each health facility worked. Thirty two HFCA's were selected from all potential catchment areas in the 3 districts. The intervention was implemented in 16 randomly selected clusters the remaining 16 clusters were defined as the controls. Supporting activities were implemented in both

control and intervention clusters. The intervention was evaluated through baseline and endline cross sectional surveys and an embedded process evaluation.

The primary outcome of the study was an increase in DPT3 and MCV combined immunization coverage in 9 to 23-month-old children. We measured this as an increase in valid coverage of DPT3 and MCV combined in children 12 to 23 months, not 9 to 23 months as originally planned. This was because age appropriate MCV vaccination has a 3 month window and therefore those who are only 9 months at the endline were unlikely to have had MCV. Hence the majority of coverage estimates presented were for the standard 12 to 23 month age group. There may be need for additional sensitivity analysis to examine coverage rates of the earlier vaccines administered from birth through 14 weeks among children 9-11 months. It is possible that due to ongoing exposure to the intervention, children 9-11 months may have higher age-appropriate vaccination rates, with the exception of MCV, than older children (12-23 months old).

There was no difference in valid coverage of DPT3 & MCV between the intervention and control clusters at endline, thus the impact analysis findings did not support our hypothesis that data-driven, targeted community engagement would facilitate more effective defaulter tracing and contribute to increased immunization coverage in hard-to-reach communities. However, there was a significant increase in this outcome from the baseline survey to endline survey in both the intervention and control clusters, with a greater increase in the intervention clusters. As a result of there being no difference between intervention and control clusters for the primary outcome, we were not able to attribute the increase in valid immunization coverage to the 'Fifth Child' intervention. Despite the increase in valid immunization coverage we did not find an increase in crude immunization coverage. This suggests the increase in coverage found between baseline and endline in valid coverage was due to an improvement in recording of immunizations. It appears that this was specifically an increase in Mothers Passports, for both intervention and control clusters, however the increase was only significant in the intervention group.

In addition, there was a significant increase in DPT1 coverage from baseline to endline in the intervention arm and a non-significant increase in the control arm. DPT1 coverage is an EPI access indicator. While we cannot attribute this improvement solely to the 'Fifth Child' intervention, it is possible that the registration of infants in the mReach platform, coupled with community engagement strategies may have facilitated the prompt identification of infants who were due for early vaccine series, which was not the case in the control arm.

Assessment of exposure to the intervention in this study was difficult. The proxy indicator for exposure to the intervention was household visits from VHTs where the reason for the visit was about immunization. Although the proportion of respondents reporting a home visit by a VHT decreased from baseline to endline in both control and intervention clusters the proportion of visits where immunization was the reason for the visit increased. The decrease in VHT home visits may be due in part to observations that in the latter months of the intervention, VHT services were sought by other organisations involved in the refugee response in some of the project areas, who paid VHTs higher allowances.

Although it was planned at the start of the study, in order to strengthen potential exposure, to link referral cards issued by a VHT during a household visit and referral cards of children who actually attended for immunization at the Health facility, this was not possible due to lack of

unique child identification numbers on the cards. This was a difficult task to achieve in the field setting. VHTs were observed to copy from other VHTs forms during meetings which raises concerns about their ability to use the forms correctly in the community. VHT peer supervisors had to provide significant support to help less literate VHTs use and complete the referral forms. The forms also had other minor problems, they did not contain a space for VHTs to explain reasons for default and they were also not translated into the main local language.

Secondary outcomes included 1) improvements in the timely uptake of EPI immunizations and 2) reduction in drop-out rates for DPT 1 & 2 and oral polio vaccine (OPV) 1, 2, 3. We found an increase in valid coverage of timely immunization for the vaccines due at 6 weeks of age from baseline to endline in both the control and intervention groups. This increase was not seen for vaccines due at 10 and 14 weeks but was for MCV due at 38 to 52 weeks. These data suggest that the increase in valid coverage of DPT3 was not timely and that therefore timeliness of the defaulter tracing intervention and resulting behaviours of caregivers may need to be explored further.

The significant decrease in drop-out rates between DPT3 & MCV between baseline and endline surveys for both control and intervention clusters was not seen with other immunizations. For OPV1, 2 & 3 there was an upward trend in dropout rate between the baseline and endline surveys in the intervention clusters, but this was not significant.

Based on the indicators captured, overall the health facilities in the control and intervention clusters were similar in terms of cadres of health workers. There were stock-outs of some vaccines but this was scattered and not likely to have been significant in terms of impact on the findings. The finding that 7 out of 16 health facilities in each of the control and intervention clusters reported having staff who had been trained in mReach was surprising as the expectation was 0 and 16 in control and intervention. However, this question was badly answered as there was no response from 9 health facilities in each of the arms of the study.

Coverage of immunizations by socio-economic quintile may be viewed as a proxy for reach of immunization services to hard-to-reach communities as such communities tend to be the most socio-economically disadvantaged. Assessment of the concentration index suggested that despite a decrease in socio-economic disparities as assessed by crude coverage, this did not translate to the same decrease in socio-economic disparity in valid coverage in the intervention clusters at endline compared to baseline, whilst it did in the control clusters.

The process evaluation assessed the implementation of the intervention, the mechanisms of impact of the intervention, and the context and how this interacts with the intervention. Intervention here refers to the package of activities that were implemented in the intervention clusters plus the supplementary activities delivered in both intervention and control clusters. The overall findings of the process evaluation were a lack of distinction between some of the activities in the intervention and control clusters, and the importance of the supplementary activities in bringing about change to the extent that they acted as the mechanisms of change, that is, an intervention.

The intervention and supplementary activities were popular and generally accepted by the health workers, VHTs and community. There was interest in the control health facilities and communities in the mReach intervention and in strengthening defaulter tracing. This was influenced by the community meetings that were implemented in the control as well as

implementation clusters. The VHT meetings motivated VHTs to be more active in follow-up and improve their immunization performance. VHTs were given monthly allowances at these meetings. These meetings are not part of MoH standard care, so were in fact an intervention. Additional immunization training was given to both intervention and control clusters. There was some contamination of control clusters, largely due to transfer of health workers from intervention to control sites. At two control sites it was evident that the health workers sought to set up a similar defaulter tracing approach. Albeit paper-based systems such as one wall chart created by a HCW transferred from an intervention to a control site, and a paper-based defaulter register started by the second HCW transferred from intervention to control site. However, the descriptions of these paper-based systems do not suggest that there was active follow-up of defaulters comparable to the intervention.

The main mechanisms of change identified were improved accessibility to immunization services through increased numbers of vaccination outreaches, increased VHT motivation through monthly allowances together with social motivation in outdoing each other in defaulter tracing, use of community resources to achieve outcomes that is the support of local community leadership; and increased interaction between health workers and HCWs and VHTs at monthly VHT/HCW meetings. These identified mechanisms of change were predominantly due to supplementary activities that were implemented in both intervention and control clusters.

The evaluation did not show an increase in DPT3 and MCV coverage, timeliness, or drop-out rates due to the 'Fifth Child' intervention. However, increases in DPT3 and MCV coverage were found between baseline and endline surveys in both the intervention and control clusters. Implementation fidelity was compromised in the control clusters and three out of four of the mechanisms of change identified were due to supplementary activities implemented in both the intervention and control clusters.

The mReach intervention was one objective of IRC activities in Kitgum during the window of treatment. However, the IRC also implemented a variety of immunization supportive activities during this window. The supportive activities (SAs) were aimed at filling in MoH systems and service delivery gaps to ensure a minimum basic package of inputs were provided to each supported health facility[7]. IRC spent approximately $403,000 dollars on supportive activities between January 2016 and September 2017. While the total spent on supportive activities was almost double the cost of mReach activities, when paired with output data, the cost per facility/village/ household/child for the supportive activities and mReach are similar.

Table 19: Unit cost of implementing supporting activities

Unit	Count in Sample	Cost Efficiency
Health Facilities	32	$ 12,603
Villages	221	$ 1,825
Households	1783	$ 226
Children 12-23 months	1492	$ 270

[7] These supportive activities (SAs) filled key gaps in immunization system and service delivery such as: i) cold chain checks, maintenance and repairs, ii) supportive supervision, iii) basic training of healthcare workers (HCWs), iv) immunization outreach services, and v) transportation and distribution of vaccines between district stores and health facilities.

This is in part due to the scale factor; supportive activities (SAs) were done in both treatment and control catchment areas, thus implemented at twice the scale.

But since investment in supportive activities for health facilities may be driving the change in coverage rates, pairing this hypothesis with cost data suggests that supportive activities could be a more cost effective means to improving immunizations coverage than mReach. In addition, the cost to replicate supportive activities strictly for immunization (excluding integrated FP) would be even lower cost per area/village/household.

The findings of this research were presented to the Advisory Panel and Ministry of Health and Uganda National Expanded Program on Immunization, as well as other stakeholders. Impact findings were contrary to the hypothesis and stakeholder expectations. The study team hypothesized that the mReach defaulter tracing system would increase DPT3 and MCV combined coverage rates above the levels of supporting activities in intervention areas only. Contrary to this hypothesis, the impact evaluation findings showed comparable increases in both intervention and control arms. As discussed above, there are possible reasons for these results; key among them being the investments in supporting the functioning of the health system in delivering immunization services. The trial was designed to have a pure control group, but there were observations of contamination in three control sites. Stakeholders and program managers at the three project districts and national level have reportedly seen an improvement in immunization uptake in project areas, as evidenced by routine data collected and reported through the District Health Information System (DHIS2). It is likely that the said improvements witnessed may be due to the supporting activities that were implemented in both intervention and control arms of the trial.

A notable area for further research is to understand the independent contributions of supporting activities to increases in immunization coverage. Such a study would warrant a three-arm design whereby supporting activities would be treated as an independent intervention which would be compared with mReach and standard MoH/UNEPI basic activities.

9. Policy implications and recommendations

From an intervention perspective, this study was intended to generate evidence for decision-makers regarding the promise of community engagement interventions as a strategy to increase immunization coverage. The mReach intervention was designed to equip VHTs with the tools and techniques necessary to encourage caregivers to seek immunization services. While the findings of the impact evaluation are inconclusive, the overall positive effect was positive in that there was a significant increase in coverage of the combined coverage of DPT3 and MCV, the primary outcome. The increase was observed across both the intervention and control arms of the study.

Nonetheless, there was an increased focus on immunization stimulated by the trial and supporting activities. Specifically, the facilitated VHT and HCW meetings focused on immunization and may have strengthened linkages between the VHTs and primary health care system. VHTs represent the community, so by creating a forum and paying for VHTs to

attend meetings with the formal health care system and valuing the contributions of their work stimulated more community involvement in immunization services. Continued engagement of VHTs in the health care system has promise in terms of increasing community members' feedback and engagement in the provision and use of other health services as well. In addition, the EPI training provided across all 32 sites at the start of the trial increased momentum and awareness of immunization services.

Other SAs may have contributed to the overall increase in immunization coverage. Outreach services are a key component of EPI service provision as this increases access to immunizations for children in hard-to-reach areas. This was acknowledged as an important activity by caregivers and other beneficiaries of EPI services. The trial enhanced outreach activities as a supporting activity by supporting HCWs to plan and conduct outreach sessions in coordination with community leaders. Thus interventions that make outreach sessions more efficient through planning and coordination with the community may be prioritized.

Whereas, some control facilities conducted outreaches at social gatherings and sites such as on market days, at churches or mosques etc. which are places well known to the community and thus more children may have been vaccinated at such sites. High defaulting villages may not necessarily be the venues for social gathering or convenient venues for the community to receive health services. Days of immunization outreaches to high defaulting villages may also not match with social events in the village like market or prayers or sports days. Outreaches in the intervention arm focused on where the mReach data indicated high numbers of children due for vaccinations or defaulters. These areas were not necessarily densely populated. Therefore, further research would benefit from expanding mobilization for immunization outreaches beyond the immediate communities where the data indicate large pockets of under-immunized or unimmunized children to maximize the reach and effectiveness of these services.

Another key component of the 'Fifth Child' intervention was the immunization due and defaulter tracking system. A weak link of this component of the intervention was that the referral forms were perceived as complex given the literacy levels of most VHTs. It was difficult for some VHTs to independently complete the forms. Also, the forms were translated into the local language. Simplifying the referral forms and possibly translating them into local languages may also be of benefit for further research. One other challenge with the tracking system was that it was not possible to update the information of families who had moved out of the trial area. Similarly, there was no system for tracking children who received vaccinations from health facilities outside the trial area, thus they were retained in the system as defaulters, while, in fact, they may have received their vaccinations. Modifications to the referral and tracking system may be warranted for further research.

The intervention required heavy investment in training stakeholders and incentivizing regular community meetings to track defaulters. The results do not prove that mReach is effective in increasing DTP3 and MCV combined coverage rates in this evaluation. Thus, we cannot claim that investing in our model of data-informed defaulter tracing, VHT home visits, and active engagement of community leaders are cost effective means to improving coverage for hard-to-reach communities. Strengthening the health system to provide EPI services through the investment in supporting activities may have contributed to the increased immunization rates observed across both intervention and control sites.

Getting the last quintile of children immunized is clearly a challenge for the Ugandan health system, and the global health community. The volume of community outreach currently done by government health facilities in Uganda is quite low; only 3% of District Health Office resources go to community outreach[8]. Unfortunately, the degree to which the Ministry of Health and other health providers from the NGO community should invest in community defaulter tracking programs (like mReach) as a strategy to improve immunization rates is unclear. But the Ministry of Health will certainly need to invest more than $44[9] per child to reach the "Fifth Child." Future research is needed to identify the effective strategies for getting defaulters to full immunization status, which very well could involve more community engagement activities or systems strengthening to improve defaulter tracking.

Even if mReach is not the most cost effective means to improving coverage rates, investing resources to increase coverage is cost savings for the government when weighted against how much it costs to treat the diseases and the DALY's averted by immunizations.[10] The social, economic and environmental benefits for every dollar spent on immunizations are magnitudes higher than most other health interventions[11], thus spending on interventions that increase coverage, even if it increases the cost per child immunized, is very (long term) cost effective.

[8] "Costing and Financing Analyses of Routine Immunization in Uganda" Technical Report by Health & Development Africa (Dr. Anthony Kinghorn), available here, page 42

[9] "Costing and Financing Analyses of Routine Immunization in Uganda" Technical Report by Health & Development Africa (Dr. Anthony Kinghorn), available here, page 37. On average, the cost per DTP3 child is $44 ($12 in delivery costs, $13 in vaccine costs, and $20 in salaries). The cost per child for DTP3 varies depending on the type of health facility, with HCII and HCIV being the most expensive, and HCIII being the least expensive.

[10] The savings from future health costs deferred depends on the disease. As an example, prior research estimates that pneumococcal and rotavirus vaccine programs can save the Ugandan government nearly $3 million in direct annual medical costs. Citation- Tate, Jacqueline, et al. "Projected health benefits and costs of pneumococcal and rotavirus vaccination in Uganda." Journal- Vaccine (2011). Figure pulled from abstract, available here .

[11] Copenhagen Consensus: http://www.copenhagenconsensus.com/sites/default/files/post2015brochure_m.pdf

Appendix A: The 'Fifth Child' Sampling Design

Sampling overview:

- Include health centers that meet study criteria
    - HC II or HC III (rural)
    - Funded only by Uganda MOH
    - Functional
- Identify 32 non-neighbouring catchment area surrounding each HC
- Randomly assign each HC catchment area a treatment arm (16 treatment/16 control)

Health Center Catchment Areas by District			
	HC CAs Eligible for Selection	HC CAs Included in Sample	HC CAs Included in Treatment
All districts	64	32	16
Lamwo	17	8	4
Kitgum	16	8	4
Agago	31	16	8

Data sources:

- Database 1: Health center village catchment area designations compiled by District Health Teams that use 2014 census jurisdiction boundaries, including health center, district, sub county, parish and village
- Database 2: QGIS shape file map data table including the shape file, district, sub county, parish and village, but not including corresponding health centers
- Database 3: Health center GPS points of all health center level II and level IIIs that are funded by the Uganda Ministry of Health and are fully functional

Operationalizing sampling:

1. Import Database 1 into Stata statistical analysis software. Export attribute tables from Database 2 and Database 3 and import Database 2 and Database 3 into Stata.
2. Clean databases to only contain information for 3 districts within the study (Lamwo, Kitgum and Agago) and relevant clearly named variables
3. Combine Database 1 and Database 2 by using command "reclink" or "fuzzy matching", as way to add the health center variable to Database 2. Use unique variable that combines parish and village to match each village to a health center
4. Export this new database that contains village lists each linked to a health center to a shape file on a QGIS map and join this file to the Database 2 on the map
5. Using QGIS software, select each of the 64 health centers eligible for inclusion and plot each of these health center catchment areas on the map
6. To select health center catchment areas that are non-neighbouring, visually select health centers that minimize instances in which villages in one or more HC catchment areas are adjacent to one another
7. In Stata, create a new variable to indicate which HC catchment areas were selected
8. Set random seed to ensure replicability, and run sampling command to randomly sample a total of 16 health center catchment areas

Appendix B: Statistical Pre-Analysis Plan

Primary outcomes

Increase in DPT3, MCV immunization coverage in 9 to 23 month old children

Secondary outcomes

1. Reduction in drop-out rates for DPT 1 & 2 and OPV 1, 2, 3
2. Improvements in the timely uptake of EPI immunizations
3. Increased integrated community case management (iCCM) treatment

Study site

Kitgum, Lamwo, Agago districts, Northern Uganda

Study design

- A cluster randomized, controlled trial with two arms
- Population: children 9 - 23 months
- Unit of randomization: health facility catchment areas
- Control arm: supporting activities
- Intervention arm: 'Fifth child' intervention and supporting activities

Sample size

16 clusters per arm with 55 children 9 to 23 months per cluster giving a total of 1,760 children.

Evaluation methods

Two cross-sectional cluster surveys, a baseline that will take place a month before the start of the trial, and an endline that will take place at the same time a year later.

Timeline

The baseline survey will take place in June 2016, the intervention will commence in July 2016 and the end line survey will take place in June 2017.

Proposed analysis

Initial data consistency checks will be one followed by recoding of data to generate appropriate indicator variables. Baseline characteristics of individuals and clusters will be summarized. Cluster-level analyses will be used to assess the overall effect of the intervention with respect to primary and secondary outcomes, as appropriate for a cluster-randomized trial with repeat cross-sectional surveys. This involves obtaining mean coverage estimates per cluster and using a 2-sample t-test to assess the null hypothesis of no intervention effect. A log transformation will be applied to the estimated proportions for each cluster if required, alternatively, a non-parametric test will be used. Analysis to adjust for covariates will use a two-stage approach. Logistic regression will first be used to adjust for baseline confounders at the individual and cluster level to obtain adjusted cluster level residuals. As individual level factors are also of interest this will be analyzed using individual records. A 2 sample t-test will then be used to compare these residuals across intervention and control arms. Similar

analyses will be used to assess change in coverage for all impact variables from baseline to follow up.

Potential exposure to intervention activities will be adjusted for age and a dose response effect.

Heterogeneity analyses of subgroups will include impact amongst children in households across socio-economic quintiles, by distance from a health facility, and by ethnic group. Principal components analysis will be used to generate a wealth index from household and respondent characteristics.

Data source

The table below shows the definition and source of data for main outcome variables.

Outcome definition and component source

Outcome	Definition	Source	Variables	Notes
Increase in DPT3, MCV immunization coverage in 9 to 23 month old children	Number of children aged 9 to 23 months receiving DPT3 & MCV divided by all children aged 9 to 23 months	Household survey [Validated at Health Facility survey]	Age of child DPT3, MCV (from child health card or reported by caregiver)	Can break down in 3 month age groups to as a measure of potential exposure
Reduction in drop-out rates for DPT 1 & 2 and OPV 1, 2, 3	Number of children aged 9 to 23 months receiving specific dose (of either DPT or OPV) divided by all children aged 9 to 23 months	Household survey [Validated at Health Facility survey]	Age of child DPT1, 2 ,3, OPV1, 2,3(from child health card or reported by caregiver)	Consider coverage from 1 immunization to the next, how many received 1st dose, then 2nd, then 3rd
Improvements in the timely uptake of EPI immunizations	(Date of DPV minus date of birth/30) divided by 9 months	Household survey [Validated at Health Facility survey]	Age of child Date of immunization (from child health card or reported by caregiver) DPT3, MCV (from child health card or reported by caregiver)	Use DPT3 and MCV as a marker for all EPI immunizations but can also look at timing for all. Any deviation from zero shows lag in timing

Increased integrated community case management (iCCM) treatment	Percentage of children receiving prompt and appropriate treatment for diarrhoea, malaria and pneumonia	Household survey	Fever Diarrhoea Cough Seek treatment Where treatment What treatment When treatment	Subgroup from VHT first source; from correct provider Provide separate estimates for each illness
Caregiver exposure to VHT / intervention	Percentage of caregivers that have been visited by a VHT specifically for immunization	Household survey	Visit by VHT Immunization related visit	Do we need to distinguish between defaulter and reminder of upcoming vaccination

Hypothesis

We hypothesize that after 1 year, a higher proportion of children aged 9 to 23 months will have been immunized with both DPT3 and MCV in the study clusters randomized to the intervention.

Main results

The table below summarizes the main results of the evaluation, focusing on the primary and secondary outcomes.

Proposed tables for main results by study arm and survey

Table 1	Characteristics of clusters and individuals in surveys
Table 2	Coverage for main immunization outcomes for children 9 months to 23 months
Table 3	Coverage of immunization by source (Child Health Cards, caregiver recall) for each vaccination
Table 4	Timing of immunization for DPT3 & MCV and specific vaccinations
	Effect of exposure on immunization coverage adjusted for covariates
Table 5	Effect of exposure using age as a proxy and validated exposure adjusted for age
Table 6	Percentage of children with diarrhoea, fever, malaria and pneumonia
Table 7	Percentage of children receiving timely and appropriate treatment for ICCM diseases.

Appendix C: Sample Size and Power Calculations

CRT sample size and power for unmatched proportions

1-type I	power	z_a	z_b		π_0	% reduction	π_1	Cluster size	k	**# clusters per arm***	***to be conservative, round up**	# in each arm	total in trial	* 10% non response
0.95	**0.8**	1.96	0.8416	7.8489	**73.00%**	**-14%**	83.04%	**50**	**0.1**	15.79	16	800	1600	1760
0.95	**0.8**	1.96	0.8416	7.8489	**80.00%**	**-13%**	90.00%	**50**	**0.1**	16.31	17	850	1700	1870
0.95	**0.8**	1.96	0.8416	7.8489	**75.00%**	**-21%**	90.38%	**50**	**0.1**	7.40	8	400	800	880
0.95	**0.8**	1.96	0.8416	7.8489	**70.00%**	**-14%**	79.80%	**50**	**0.1**	16.28	17	850	1700	1870
0.95	**0.8**	1.96	0.8416	7.8489	**70.00%**	**-22%**	85.05%	**50**	**0.1**	7.54	8	400	800	880
														0
0.95	**0.8**	1.96	0.8416	7.8489	**80.00%**	**-19%**	95.00%	**100**	**0.1**	7.10	8	800	1600	1760
0.95	**0.8**	1.96	0.8416	7.8489	**80.00%**	**-13%**	90.00%	**100**	**0.1**	14.34	15	1500	3000	3300
0.95	**0.8**	1.96	0.8416	7.8489	**75.00%**	**-21%**	90.38%	**100**	**0.1**	6.49	7	700	1400	1540
0.95	**0.8**	1.96	0.8416	7.8489	**75.00%**	**-13%**	84.75%	**100**	**0.1**	14.19	15	1500	3000	3300
0.95	**0.8**	1.96	0.8416	7.8489	**70.00%**	**-22%**	85.05%	**100**	**0.1**	6.37	7	700	1400	1540
														0
0.95	**0.8**	1.96	0.8416	7.8489	**80.00%**	**-19%**	95.00%	**75**	**0.15**	14.07	15	1125	2250	2475
0.95	**0.8**	1.96	0.8416	7.8489	**80.00%**	**-13%**	90.00%	**75**	**0.15**	29.22	30	2250	4500	4950
0.95	**0.8**	1.96	0.8416	7.8489	**75.00%**	**-21%**	90.38%	**75**	**0.15**	12.52	13	975	1950	2145
0.95	**0.8**	1.96	0.8416	7.8489	**75.00%**	**-13%**	84.75%	**75**	**0.15**	28.28	29	2175	4350	4785
0.95	**0.8**	1.96	0.8416	7.8489	**70.00%**	**-22%**	85.05%	**75**	**0.15**	12.02	13	975	1950	2145
														0
0.95	**0.8**	1.96	0.8416	7.8489	**75.00%**	**-27%**	95.06%	**75**	**0.15**	8.04	9	675	1350	1485
0.95	**0.8**	1.96	0.8416	7.8489	**75.00%**	**-27%**	95.25%	**75**	**0.15**	7.92	8	600	1200	1320
0.95	**0.8**	1.96	0.8416	7.8489	**75.00%**	**-21%**	90.38%	**75**	**0.15**	12.52	13	975	1950	2145
0.95	**0.8**	1.96	0.8416	7.8489	**75.00%**	**-13%**	84.75%	**75**	**0.15**	28.28	29	2175	4350	4785
0.95	**0.8**	1.96	0.8416	7.8489	**70.00%**	**-22%**	85.05%	**75**	**0.15**	12.02	13	975	1950	2145

Appendix D: Monitoring Plan

Monitoring indicators – Facility-level

Data source	Frequency	Indicator
Form 4 - Health Facility Monthly Summary Form	Monthly	# of children vaccinated in static clinic
		VHT-HCW facility-level meeting conducted in past month (Yes = 1, No = 0)
		# of VHTs in attendance at VHT-HCW facility-level meeting
		ONLY IN INTERVENTION GROUP: # of VHTs who submitted vaccine due/defaulter tracing report
		# of days with any vaccine stockout
		# of days without standby gas cylinders
		Cold chain technician visited the clinic (Yes = 1, No = 0)
		# of outreach activities conducted
		# of children vaccinated during outreach event
Form 7 - Cold Chain Technician Report	Monthly	# of HFs that received a cold chain maintenance visit (triangulation of another indicator)
		# of HFs with at least one functional fridge at time of visit
HMIS	Monthly	# of outreach events conducted
		DPT dropout rate %
		measles coverage %
		DPT 3 coverage %
		stockout of measles (triangulation of another indicator)
Form 8 - Quarterly supervisory visit summary	Quarterly	# of HFs that received quarterly supervisory visit (triangulation of another indicator)
		# of HCW at facility who is trained with national EPI policy and protocols in last 12 months
		# of HFs that have a standard package of EPI materials available in reporting quarter

Intervention only

CommCare output data	Monthly	# of new children registered this month
		# of defaulters on last day of month

		# of defaulters vaccinated during the month
		# of dues on last day of month
		# of dues vaccinated during the month
Form 5b - Monthly Supervisory Form	Monthly	# of high defaulter villages with at least one community leader in attendance at HCW-VHT meeting

Appendix E: Cost data for the programme implementation to provide the 'ingredients' into CEA, CBA or CUA

E-1: mReach programme implementation costs

Ingredient List	mReach Cost
IRC Support Costs	
National Staff	
Kitgum	$ 13,230
Kampala	$ 12,864
Travel	
Kitgum	$ 1,164
Kampala	$ 1,617
Capital Assets	
Kitgum	$ -
Kampala	$ 181
Office Support	
Kitgum	$ 10,478
Kampala	$ 5,271
Program Staffing Costs	
Health Coordinator (Kampala)	$ 3,675
Health Officer (Kitgum)	$ 8,777
Immunization Officer (Kitgum)	$ 32,228
Immunization Research Manager (Kitgum)	$ 24,300
M&E Officer (Kitgum)	$ 1,449
Mhealth Specialist (Kitgum)	$ 1,823
TA Time (HQ)	$ 11,983
TA Travel	$ 4,332
Program Materials for mReach Activities	
Laptop	$ 1,001
Vehicle Rental & Maintenance	$ 5,301
Staff per diem	$ 4,617
Allowances & Stipends	$ 23,509
Stationery	$ 5,105
Data/Airtime	$ 4,969
Meals & Hall Rental for Training	$ 4,070
Transport	$ 2,135

Immunization Forms	$	3,957
Other	$	5,756
ICR	$	21,530
TOTAL IRC SPENT ADDITIONAL ON MHEALH COMMCARE	$	215,321

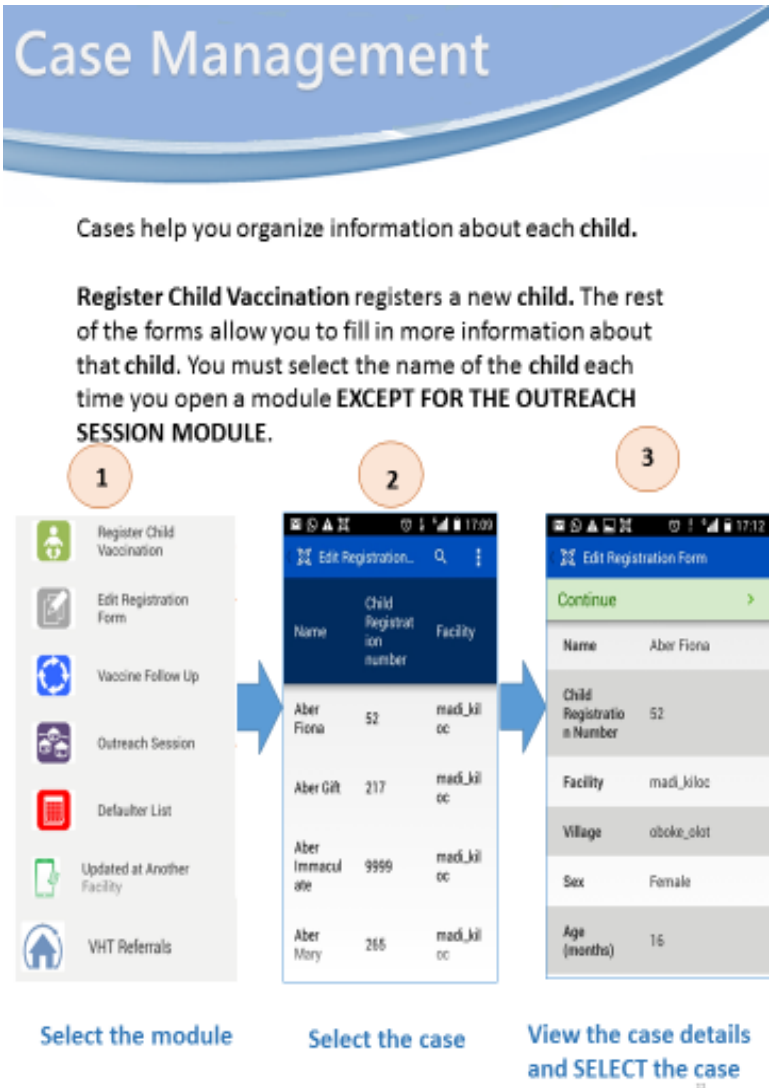
Appendix E2: Cost data for the programme implementation to provide the 'ingredients' into CEA, CBA or CUA

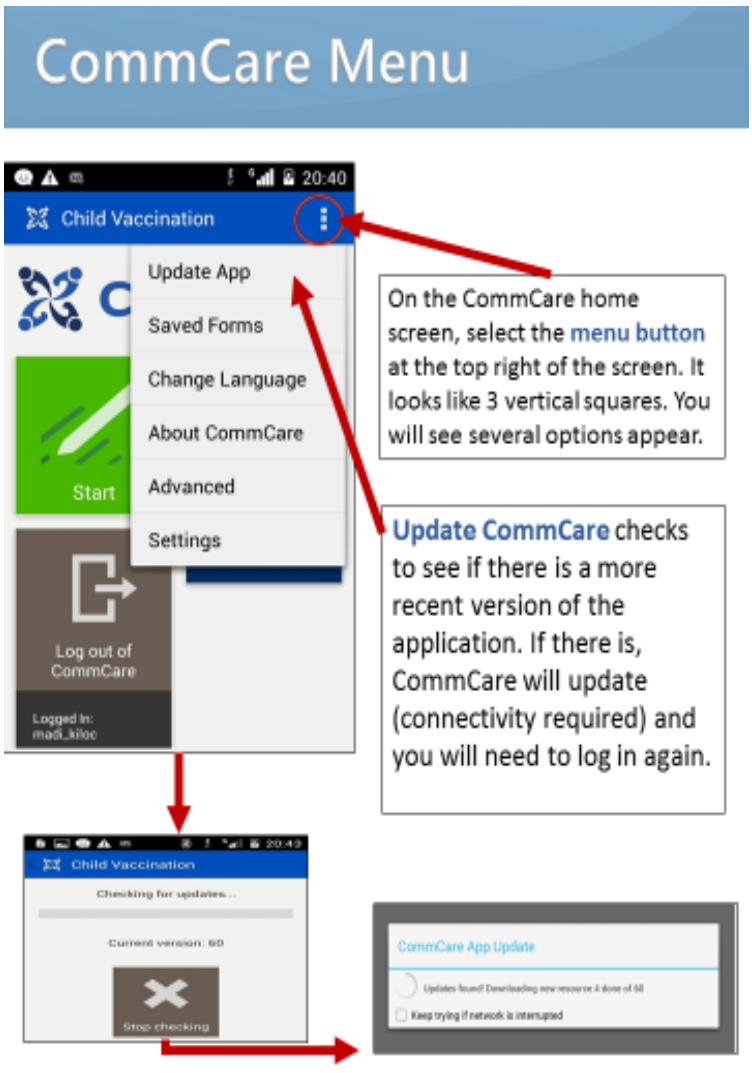
Model Inputs	
Number of Districts	125
Average Number of Facilities per District	32
Months	12
Days of CommCare Training for MoH Health Workers (HW)	3
Days of CommCare Refresher Training for MoH HWs	2
Number of mHealth Specialists that can be trained at once	50
Frequency of VHT meetings per year	12
Number of Village Health Workers (VHTs) Trained per villages	2
Average Number of Villages per Facility	20
Number of District Officials trained per District	2
Number of Health Facility Staff trained per facility	2
Number of Community Leaders in Monthly Meetings	2
Percent of Villages that have high default per month	10%
Average # Liters Fuel Needed per facility per month (for HW monitoring visit)	10
Average # Liters Fuel Needed per district per month (for mHealth Specialist)	160
Cost in UGX per liter of Fuel	3500
UGX to USD Conversion Rate	3500

Cost to run CommCare for 1 year per Inputs above	Unit Cost	Units	Total Cost
Incremental Staffing Costs for mHealth Specialists			
Staff Time at the Facilities	0	600	0
Full Time mHealth Specialists	124.3483429	125	15543.54286
Facility Rental for mHealth Specialists Training + Refresher	500	12.5	6250
Transport, Lodging for mHealth Specialists at Training	500	125	62500
Training Facility Health Workers in how to use the defaulter tracker			
Per Diem for Facility Health Workers	40	40000	1600000
Facility Health Workers Transport Stipend	14.28571429	8000	114285.7143
Per Diem for District Officials	20	1250	25000
Facility Rental for HW Trainings	500	275	137500
Food for Training	6.571428571	41250	271071.4286
Stationery for Training	5	8250	41250
Training VHTs in how to use the defaulter tracker			

None- this was in pilot, but would be cost prohibitive at scale	0	0	0
CommCare Tool			
Subscription Fee	1200	40	48000
Data Bundle for Internet- Use of Tool	428.0571429	4000	1712228.571
Phone with Internet Capability	142.8571429	4000	571428.5714
Monthly VHT & HW Meetings			
Stipend for VHTs to attend meetings	2.857142857	1920000	5485714.286
Stipends for community leaders in defaulter villages to attend	2.857142857	9600	27428.57143
Stipend for facility HW to lead meeting	4.857142857	48000	233142.8571
Monitoring Costs			
Fuel for facility Health Workers to do visits to villages	1	480000	480000
Monthly Airtime for facility Health Workers to communicate with VHTs	2.857142857	48000	137142.8571
Fuel for mHealth Specialists to visit facilities	1	7680000	7680000
Airtime for mHealth Specialists	14.28571429	1500	21428.57143

Appendix F: Screenshots of IRC's mReach application – submitted as attachment





Appendix G: Effect of intervention on DPT3 & MCV coverage adjusted for baseline coverage of DPT3 & MCV, and potential covariates at baseline and endline

Coverage estimates for DPT3 & MCV and their confidence intervals presented in the main text show no difference between the intervention and control groups. Therefore only cluster summaries for all outcomes are presented and corresponding significance tests reported. However, even though there was baseline balance between study arms for both study characteristics and outcomes, in order to assess potential confounding and also account for baseline estimates of the primary outcome, cluster summary residual analyses were carried out for the primary outcome.

The table below first shows analysis based on cluster summaries only. Using residuals from adjusted logistic models for DPT3 & MCV at endline, adjustment was made: for socio economic group only (at baseline and endline) this being the only characteristic that showed an association with DPT3 & MCV; with respondent characteristics (at baseline and endline), and finally baseline DPT3 & MCV. Results show there is no change to the effect on the primary outcome DPT3 & MCV in any of the models.

Effect of intervention on valid coverage of DPT3 & MCV in children aged 12 to 23 months, unadjusted and adjusted for respondent characteristics and baseline DPT3 & MCV coverage

	Intervention	Control	Risk ratio (95% CI)	P value
Number of clusters	16	16		
Analysis based on cluster summaries				
Mean coverage for DPT3 & MCV	0.762	0.772		
SD of cluster coverage	0.905	0.959		
			0.987 (0.420, 2.319)	0.78
Analysis based on residuals adjusted for socio economic group at endline				
Mean cluster residual	0.989	1.013		
SD of cluster residual	0.110	0.127		
			0.976 (0.895, 1.064)	0.64
Analysis based on residuals adjusted for socio economic group at baseline				
Mean cluster residual	0.990	1.013		
SD of cluster residual	0.108	0.126		
			0.977 (0.900, 1.061)	0.60
Analysis based on residuals adjusted for respondent characteristics* at endline				
Mean cluster residual	0.992	1.013		
SD of cluster residual	0 .111	0.126		
			0.979 (0.895, 1.063)	0.62
Analysis based on residuals adjusted for respondent characteristics* at baseline				
Mean cluster residual	0.993	1.011		
SD of cluster residual	0 .111	0.115		
			0.982 (0.903, 1.062)	0.64
Analysis based on residuals adjusted for baseline DPT3 & MCV				
Mean cluster residual	0.994	1.007		
SD of cluster residual	0.030	0.031		
			0.987 (0.966, 1.008)	0.77

* Respondent characteristics include socio-economic group, age of carer, religion, education and marital status

References

Favin, M., Steinglass, R., Fields, R., Banerjee, K. & Sawhney, M. 2012. Why children are not vaccinated: a review of the grey literature. *International Health,* 4**,** 229-238.

GLENTON, C., SCHEEL, I. B., LEWIN, S. & SWINGLER, G. H. 2011. Can lay health workers increase the uptake of childhood immunization? Systematic review and typology Pueden los trabajadores sanitarios legos aumentar la aceptación de la inmunización infantil? Revisión sistemática y tipología. *Tropical Medicine & International Health,* 16**,** 1044-1053.

INTERNATIONAL RESCUE COMMITTEE 2016. The Fifth Child – Endline Evaluation. A data-informed community engagement strategy to improve defaulter tracing on immunizations.

JAIN, M., TANEJA, G., AMIN, R., STEINGLASS, R. & FAVIN, M. 2015. Engaging Communities With a Simple Tool to Help Increase Immunization Coverage. *Global Health: Science and Practice,* 3**,** 117-125.

OWAIS, A., HANIF, B., SIDDIQUI, A., AGHA, A. & ZAIDI, A. 2011. Does improving maternal knowledge of vaccines impact infant immunization rates? A community-based randomized-controlled trial in Karachi, Pakistan. *BMC Public Health,* 11**,** 239.

RAINEY, J. J., WATKINS, M., RYMAN, T. K., SANDHU, P., BO, A. & BANERJEE, K. 2011. Reasons related to non-vaccination and under-vaccination of children in low and middle income countries: Findings from a systematic review of the published literature, 1999–2009. *Vaccine,* 29**,** 8215-8221.

RYMAN, T. K., DIETZ, V. & CAIRNS, K. L. 2008. Too little but not too late: Results of a literature review to improve routine immunization programs in developing countries. *BMC Health Services Research,* 8**,** 1-11.

RYMAN, T. K., TRAKROO, A., WALLACE, A., GUPTA, S. K., WILKINS, K., MEHTA, P. & DIETZ, V. 2011. Implementation and evaluation of the Reaching Every District (RED) strategy in Assam, India, 2005–2008. *Vaccine,* 29**,** 2555-2560.

SABARWAL, S., BHATIA, R., DHODY, B., PERUMAL, S., WHITE, H. & PURI, J. 2015. Engaging communities for increasing immunization coverage: what do we know? 3ie scoping paper 3. New Dehli: International Initiative for Impact Evaluation (3ie).

STREEFLAND, P., CHOWDHURY, A. M. R. & RAMOS-JIMENEZ, P. 1999. Patterns of vaccination acceptance. *Social Science and Medicine,* 49**,** 17051716.

UGANDA BUREAU OF STATISTICS (UBOS), ICF INTERNATIONAL INC & 2012. Uganda Demographic and Health Survey 2011. Kampala, Uganda: UBOS and Calverton, Maryland: ICF International Inc

USMAN, H. R., RAHBAR, M. H., KRISTENSEN, S., VERMUND, S. H., KIRBY, R. S., HABIB, F. & CHAMOT, E. 2011. Randomized controlled trial to improve childhood immunization adherence in rural Pakistan: redesigned immunization card and maternal education. *Tropical Medicine & International Health,* 16**,** 334-342.

WHO 2013. Global vaccine action plan 2011-2020. Geneva: World Health Organization.

WHO 2015. National Immunization Coverage Scorecards Estimates for 2014. Geneva: World Health Organization.