Impacts of engaging communities through traditional and religious leaders on vaccination coverage in Cross River State, Nigeria

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Note to readers

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Executive summary

Coverage for routine vaccines falls short of Gavi, the Vaccine Alliance, target globally. The coverage is particularly low in low-and-middle income countries. A recent survey shows that less than a quarter of children 12 to 23 months of age are fully vaccinated in Nigeria (NBS/UNICEF 2017). The reason for the low coverage is said to be multi-factorial. Among these are poor parental knowledge and attitude. A previous study made use of traditional and religious leaders in Northern Nigeria to tackle the challenge of poor attitude demonstrated by parents towards Polio vaccination and the study found a scale up of the coverage of Polio vaccination. The traditional and religious leaders are perceived as influencers and have been used by governments at various levels to intervene on matters of communal interest.

Our aim was to measure the impact of engaging the traditional and religious leaders in influencing vaccination uptake in Cross River State, Nigeria.

Some experts have suggested the adoption of a multi-faceted intervention to address gaps in vaccination based on local needs. Our study adopted such an intervention and included the training of traditional and religious leaders on vaccination, their leadership role, and community mobilization; training of health workers to share vaccination data, and revitalization of the Ward Development Committee. Eight Local Government Areas (LGAs) in Cross River State, Nigeria were selected for the study. The traditional and religious leaders had eight sessions of training within 18 months. Health workers had three sessions of training to summarize data and share vaccination data with the community leaders. The WDCs were reactivated. Evaluation was carried out before the intervention, in the middle, and at the end of the 18 months of the intervention among children aged 0 to 23 months of age. A total of 2598, 2570, and 2550 children were assessed at baseline, midterm, and endline respectively.

The results showed that the intervention had no evidence of impact on the proportion of children with up-to-date with vaccination ($p=0.69$). However, it was effective in reducing the number of unvaccinated children from 7% to 0.4% ($p=0.001$). It was also effective in improving timeliness of the later vaccines Penta 3 (OR 1.55; 95% CI: 1.14, 2.12; $p= 0.005$) and Measles (OR 2.81; 96% CI: 1.93-4.1; $p<0.001$). These impacts were already observed by the mid-term survey and were maintained at the time of the endline survey. In terms of cost-effectiveness, the marginal cost-effectiveness ratio, relevant for scaling up the intervention, was 34 USD per additional measles case averted.

The traditional and religious leaders are the untapped resources in the community that can be used to support vaccination uptake. Informal training to enhance their knowledge on vaccination and their leadership role can empower them to be good influencers for childhood vaccination. The impact has a good prospect to be sustainable as it drives demand: the leaders take the responsibility to support vaccination services in their respective communities. Vaccination program managers and health workers involved in providing vaccination services should, therefore, advocate for the active engagement of the traditional and religious leaders in the planning, implementation, and monitoring of vaccination services. Policy makers should incorporate this in vaccination delivery policies. There is, however, a need to explore further the reason behind the lack of impact of the intervention on the proportion of children up-to-date on vaccination.

Contents

List of figures and tables

Abbreviations

DHIS	District Health Information System
DTP	Diphtheria, Pertusis, Polio
EPI	Expanded Program on Immunization
FGD	Focus Group Discussion
LGA	Local Government Area
LMIC	Low and Middle-Income Countries
NBS	National Bureau of Statistics
PHC	Primary Health Care
RI	Routine Immunization
RL	Religious Leader
TL	Traditional Leader
TRL	Traditional and Religious Leaders
UNICEF	United Nations Children Fund
WDC	Ward Development Committee
WHO	World Health Organization

1. Introduction

Vaccines prevent 2 to 3 million childhood deaths globally (United Nations' Children Fund (UNICEF), 2018). It is the single most effective means of controlling childhood diseases for which vaccines have been found. Eradication of these diseases is also feasible if the herd immunity for each vaccine is achieved and sustained. Global Small Pox eradication was possible through vaccination. Currently, tetanus has been eradicated in all but 14 countries of the world. Similarly Polio is found in only three countries (Nigeria inclusive) having been eradicated in all other countries. It is, therefore, a public health concern to reach the 90% coverage of vaccination target set in the Global Vaccine Action Plan (2010 – 2020) (UNICEF/WHO, 2018) to reduce the morbidity and mortality of these diseases and subsequently eradicate them.

Six of the targeted childhood diseases (pneumococcal diseases, Rota virus diarrhoea, Hib, Measles, Pertusis, Tetanus) contribute more than a third of childhood deaths globally and in the African region (WHO, 2017). In the effort to reduce childhood morbidity and mortality the World Health Organisation (WHO) launched the Expanded Program on Immunization (EPI) in 1974 targeting six childhood killer diseases (Polio, tetanus, diphtheria, pertussis, measles, and tuberculosis. Only 5% of world children had received vaccination in the first year of life as at the launch of EPI (Trostle and Shen, 2014). Rainey et al (2011) have reported a global increase in vaccination rate in the past three decades; coverage of three doses of Diphtheria, Tetanus, Pertusis (DTP3) increased from 21% in 1981 to 85% in 2017 (UNICEF, 2018). Similarly the coverage of 3rd dose of polio and first dose of measles coverage are estimated between 84% and 86% (Feldstein et al, 2017).

These coverage levels, however, fall short of the Global Vaccine Alliance Program 90% target. The coverage is much lower in low- and middle- income countries, and Nigeria is one of the ten countries with coverage of DTP3 and first dose of measles below 50% (UNICEF/WHO, 2018). The 2016/2017 Multi-Indicators Cluster Survey in Nigeria reported 21% full vaccination coverage of children aged 12 – 23 months (National Bureau of Statistics (NBS) and UNICEF 2017). Full vaccination coverage rates vary across the country from 8.5% in North West to 50.2% in South West geopolitical zones (NBS) & UNICEF 2017). Full coverage in Cross River State located in the South South geopolitical zone was 49.9% as reported by the 2016/2017 Multi-Indicators Cluster Survey (NBS & UNICEF, 2017) and 51.5% by the 2013 Demographic Health Survey (National Population Commission & ICF, 2014).

The reasons for the low coverage of childhood vaccinations are multi-factorial. A review of grey literature on why children are not vaccinated in low-and-middle-income countries (LMIC) showed that reasons may include issues on immunization services and parental knowledge and attitude (Favin, 2012). In a report that reviewed the 2013 Nigeria Demographic Health Survey, children whose mothers found it difficult to reach the health facility, and who lived in socioeconomically disadvantaged settings were less likely to be fully immunized (Adedokun, 2017). Similarly a systematic review of peer-reviewed published literature between 1999 and 2009 reported that the reasons for non- and under-vaccination were related to immunization systems, family characteristics, parental knowledge and attitude, and limitations to immunization-related communication and information (Rainey et al, 2011). Stemming from the multi-factorial reasons behind non- and under-vaccination of children, Rainey et al (2011) suggested a multi-faceted approach to bridge the gap in vaccination. The authors also noted that while it may be easy to address some factors like access to vaccination service, such factors that keep a child completely unvaccinated may be more difficult to tackle and may require locally developed strategies (Rainey et al, 2011).

A Cochrane systematic review on interventions to improve vaccination coverage in LMIC had shown paucity of quality interventions targeting improvement of vaccination in this setting (Oyo-Ita et al, 2016) and globally (Ryman, et al, 2012). In this study, we developed a multi-faceted intervention centred on the use of TRLs in the Primary Health Care (PHC) system for evaluation. The engagement of TRLs in vaccination was reported to have contributed to the progress in Polio vaccination uptake in Nigeria (Nwaeze and Mohammed, 2013). The TRLS are influential and are respected in their communities as opinion formers and guides in religious, social and family life. They have been used as agents of change to get communities to use health services (SAfAIDS, 2011; Johns Hopkins, 2014 . The community members hold them in high esteem and depend on them, to a large extent, to make decisions. In an exploratory study in Ghana, the authors acknowledged the need to tap the indigenous knowledge embedded in the traditional leaders for sustainable development (Arthur & Nsiah, 2011).

In the study area communities are accessed through the traditional leaders. Their permission is sought for any intervention or development in the setting. For this reason, the traditional leaders lead the Ward Development Committee (WDC). The WDC was introduced into the PHC system in Nigeria following the Alma Ata declaration of 1978. It is a structure that was set to facilitate community participation in health and development (Abdulraheem, et al, 2012). Members of the Committee (which included a representative from the women, men, youths, occupational group, Non-Governmental Organizations, traditional birth attendants along with the TRLs) were to liaise with the Local Government Authority to monitor and support PHC services in their locality. The WDCs identify the health and social needs of their community and harness resources to meet those needs in collaboration with the government and Non Governmental Organizations (Ezinwa, 2017)

The WDCs' involvement in Routine Immunization (RI) was limited. They were involved in mobilisation for vaccination campaigns. Health teams approached the traditional leaders who head these committees to mobilise for the camapaigns. Their contribution in supporting the scale up of Polio campaigns in Northern Nigeria has been reported (Nwaeze and Mohammed, 2013). Similar influence has been reported in South Africa for HIV and AIDS prevention (SAfAIDS, 2011). John Hopkins University also observed that traditional leaders in Zambia were "an untapped resource and a key link needed to bring various stakeholders on the same path to better health" (JHU CCP, 2014). With the low performance of LMIC in vaccination coverage there is a dire need for evaluation of strategies to adopt to bridge the gap. This is particularly so as the Global Vaccination Action Plan has a target to extend the full benefit of vaccination to all people by 2020 irrespective where they are born, who they are, and where they live (WHO 2012). A strategy like the use of TRLs, therefore, needs to be evaluated to determine its impact on uptake of childhood vaccination.

This multi-component intervention was designed to train the TRLs as key community influencers that will influence the WDC and the communities to support RI and improve uptake of childhood vaccines.

This report is the evaluation of the effects of the intervention in the targeted communities. The research questions as provided in the pre-analysis plan were:

- What are the effects of a community-and health facility-based multicomponent intervention to improve vaccination coverage, especially among the most vulnerable and marginalised communities?
- What are the mechanisms by which this multicomponent intervention may have worked and for what reasons?

The evaluation process adopted a cluster-randomised design. Four Local Government Areas (LGAs) in Cross River State, Nigeria were randomly allocated to intervention and control arms each. The intervention, which involved training of TRLs, health worker, community engagements, strengthening of the WDC, was delivered in the intervention arm but not in the control. Assessment was carried out at baseline, mid-term, and final evaluation.

This report describes the theory of change of the intervention, delivery of the intervention, monitoring of the intervention, impact analysis and cost analysis of the intervention in Cross River State, southern Nigeria.

2 Intervention, theory of change and research hypotheses

2.1 Description of the intervention

The intervention had multiple components namely training of TRLs, training of health workers, community engagement, and strengthening of the WDCs. It was designed to impact the knowledge of TRLs on vaccination, strengthen their leadership role, and provide vaccination information to them and their communities to engender mutual decision-making with the health team on RIs. To facilitate data sharing with the TRLs, health workers were trained to produce user-friendly vaccination data from the RI activities in their respective facilities. Community engagements served as the platform for sharing information on vaccination with the community.

2.2 Outcomes

2.2.1 Primary Outcomes

The primary outcomes were:

1) Fully vaccinated rates among children 0 to 23 months of age
2) Pentavalent and measles timely vaccination
3) Pentavalent 1-3 drop-out rates

2.2.2 Secondary Outcomes

1) Degree of community engagement: community members attending different types of meetings; qualitative assessment of knowledge, beliefs and attitudes.
2) Satisfaction of TRLs, communities, health workers and WDC members with the intervention
3) Increase in the utilization of other health services: treatment of common sickness in under-fives and ANC.
4) Costs and cost-effectiveness

Expected long term impacts of the intervention were reduction in proportion of children with vaccine preventable diseases in the community and reduction in mortality from childhood vaccine preventable diseases

2.3 Theory of Change

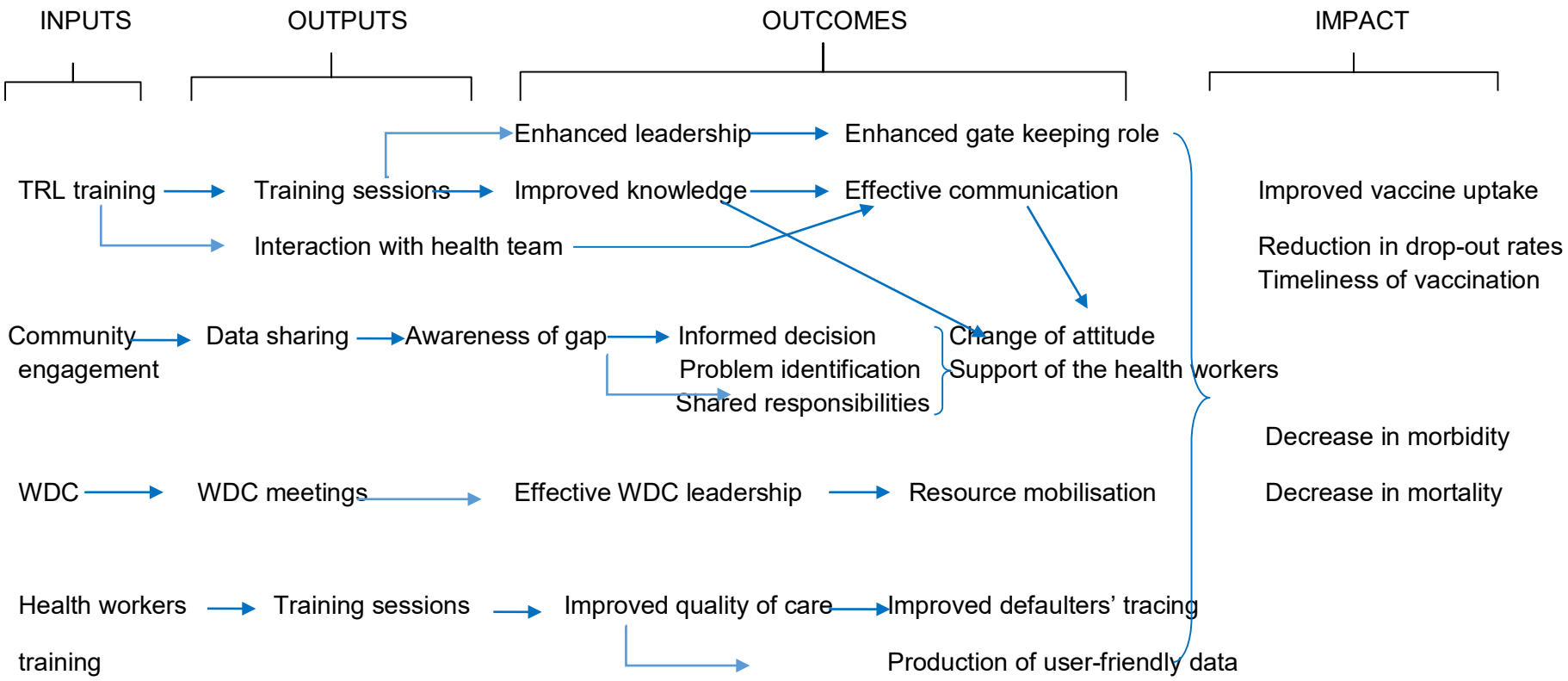
It has been reported that leaders do not understand their roles in enhancing the health of their communities, and so are less supportive of the health workers (JHU CCP, 2014). The TRL training was based on the assumption that making TRLs realise their roles in delivering health care to their

communities will stimulate them to support the health workers and create an avenue for a concerted effort between them to achieve their shared goals. This was to create a sense of ownership among the leaders and to promote the active participation of the communities in their health care. It was further assumed that since the TRLs are key community influencers training them on vaccination and communication will enhance their ability to effectively communicate vaccination messages with their community members and to impact positively on the community's attitude towards vaccination of their children with the intention of impacting on the indices of vaccination. Training was also expected to foster interaction between the TRLs and the health workers for ease of communication between them.

Community meetings served as platforms for sharing vaccination messages. Another assumption was that communities' knowledge of their RI performance will stimulate their interest to perform better and cause them to be the watchdog in their communities to ensure the unvaccinated among them get vaccinated. Health workers training on preparation of user-friendly data was expected to support the data shared at the community meetings. By sharing the data the communities could support the health workers in identifying the unvaccinated and defaulters in their midst.

The WDCs had the responsibility of providing oversight for the health facilities in their domains. The assumption in this component of the intervention was that since the TRL are heads of the WDCs, ensuring that they meet regularly and appreciate their role in RI would strengthen the committees as an avenue for improving RI. The intervention was expected to
empower the TRLs to perform their gate-keeping role and provide effective leadership in the WDC towards increasing utilisation of immunisation services. The overall assumption was that the composite units of the intervention will synergistically impact on vaccine uptake, reduction in drop-out rates, timeliness of vaccination, and reduction in morbidity by the end line, and eventually impact on childhood mortality in the long term.

Figure 1: THEORY OF CHANGE



3 Context

The study setting was Cross River State in Southern Nigeria. It is one of the 36 States in Nigeria with a population of approximately 3 million. The State is divided into three senatorial districts; the Northern, Central and Southern senatorial districts. The Northern senatorial district has 5 LGAs; the central has 6, while the South has 7 LGAs. Each LGA was further subdivided into wards which were the smallest political units. There were 196 wards in the study setting. Each ward comprised of villages. Every village was headed by a village leader. Every ward had a clan head. A Clan head was a traditional leader (village head) selected among the village heads within the ward. The village heads with their respective clan head constitute the Council of Chiefs in each ward.

3.1 Rationale for Selection of Study Sites

The unit of sampling was the LGA. The rationale for using the LGA was because the TRL activities were coordinated at the LGA level across the country. The LGAs were stratified into urban and rural LGAs within each senatorial district. Eight LGAs were randomly selected from the north (2 LGAs), central (3 LGAs) and south (3 LGAs) senatorial districts with even distribution of two urban LGAs in the intervention and control arms each. In each LGA, four wards were randomly selected and within each selected wards four villages were selected into the study.

A total of 24 participants were trained in each of the four intervention LGAs, except Obudu. This comprised all the village heads in the selected villages and the Clan head from the selected ward and two religious leaders from each Ward. The majority of the religious groups were Christians: only Obudu, an LGA in the Northern Senatorial District, had an Islamic religious group. Two religious leaders with the largest followers and the leader of the only Islamic group were invited to participate in the training in each ward. Obudu, therefore, had an additional participant. All the participants were literate and could be communicated with in Pidgin English.

4 Timeline

The preparatory stage of the intervention lasted from December 2016 to May 2017. Baseline data was collected in December 2015 while tools were developed and piloted. First phase of training was in May 2017. Five sessions were held within 9 months, half way through the period of intervention. Midterm data was collected at the 9th month and intervention continued for another 9 months. Three sessions of training were held in the second half of the intervention. Endline evaluation took place in February 2019. The timeline is presented in Figure 2.

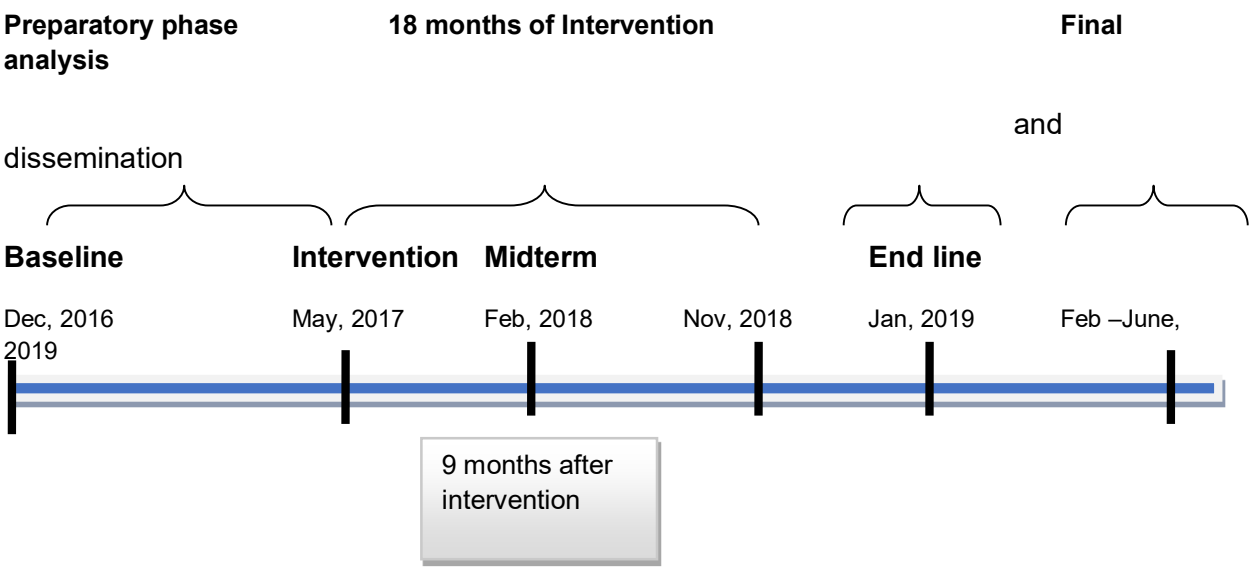


Figure 2: Evaluation timeline

5 Evaluation: Design, methods and implementation

5.1 Ethical Review and Approval

Ethical approval was obtained from the Cross River Ethics Committee. Advocacy visit was paid to each of the PHC Coordinators who are in-charge of PHC in each LGA. Clan heads were also visited and consent sought from them for the intervention. Consent was obtained from the traditional leaders for each round of the evaluation. In addition verbal consent was obtained from the respondents before applying the questionnaire. Those that declined consent were excluded. Signed inform consent was obtained from all the participants for the qualitative study.

5.2 Sample Size Determination

5.2.1 Quantitative study

The sample size calculation was based on the primary outcome, the proportion of fully vaccinated children aged 0 to 23 months.

For the calculation, the assumed pre-intervention proportion of fully vaccinated children was 53%. We would like to detect a change of 10% (to 63%) with at least 80% power and a 5% significance level. We based the sample size on the comparison between the pre-intervention survey and the final survey.

There were three levels of clustering, children within village, villages within wards and wards within LGA. For this situation, available formulae were lacking and so simulation was used. We simulated a range of combinations of numbers of LGA, wards and children. We simulated 100 trials for each scenario. We assumed a proportion of 53% fully vaccinated children before the intervention and in the control group at the final survey. We assumed a value of 63% in the intervention group following implementation of the intervention. The hierarchical clustering of LGA, wards and children was reproduced. We assumed that the

variation between LGA is equivalent to a value of k (SD/mean) of 0.18. This was based on data on the mean coverage of Pentavalent 3 and recommendations by Hayes and Bennett (1999).

We did not have information on the variation between wards or the variation between villages and so we assumed the same value (k=0.18). For each simulated trial, an effect of the intervention of 10% was assumed. Stochastic variation arises due to binomial variation in the proportion fully vaccinated within a ward, variation in the differences between village, wards and LGA. For each trial, we applied the regression analysis detailed below and the resulting p-value for the intervention recorded. The power was estimated using the proportion of trials which resulted in a significant p-value at the 5% level. The simulation code was written in R. We allowed for 15% non-response by inflating the number of children per ward. The simulations did not take into account potential contamination since this was not known.

For logistical and financial reasons, the number of LGA should be as small as possible to fulfil these requirements. The state has a large land mass and terrains that are difficult to access.

The smallest number of LGA which would reach 80% power at the 5% significance level would be four per arm. Four wards per LGA, 3 villages per ward and 25 children per village would give a total of 1200 children per survey per arm: these numbers provide at least 90% power and allow a margin of error.

5.2.2 Qualitative study

Key Informant Interviews and Focus Group Discussions (FGDs) were held at baseline and final evaluation phases of the intervention with key decision makers in the community on vaccination issues. The Key Informants were the members of the health team (PHC Coordinators the Social Mobilization Officer, and the Ward Focal Person in the eight selected LGAs. FGDs were held with traditional leaders and the religious leaders, the WDC members, and mothers that utilized vaccination services in the health facilities.

5.3 Sampling

5.3.1 Quantitative sampling

Of the 18 LGAs in the study location eight LGAs were selected from the north, central and south of the State. The eight LGAs were selected, in four strata. The strata were: north urban, central rural, south rural, mixed urban. Two LGAs were randomly selected per strata and one of each pair was randomised to control or intervention using random number generation in R..

Three wards were selected within each LGA using simple random sampling using random number generation in R. Each ward had between 2 and 16 villages, within the region of 500-2000 inhabitants. Wards adjacent to a ward in the opposite study arm were not eligible for selection. The list of the inhabitants per village was unavailable.

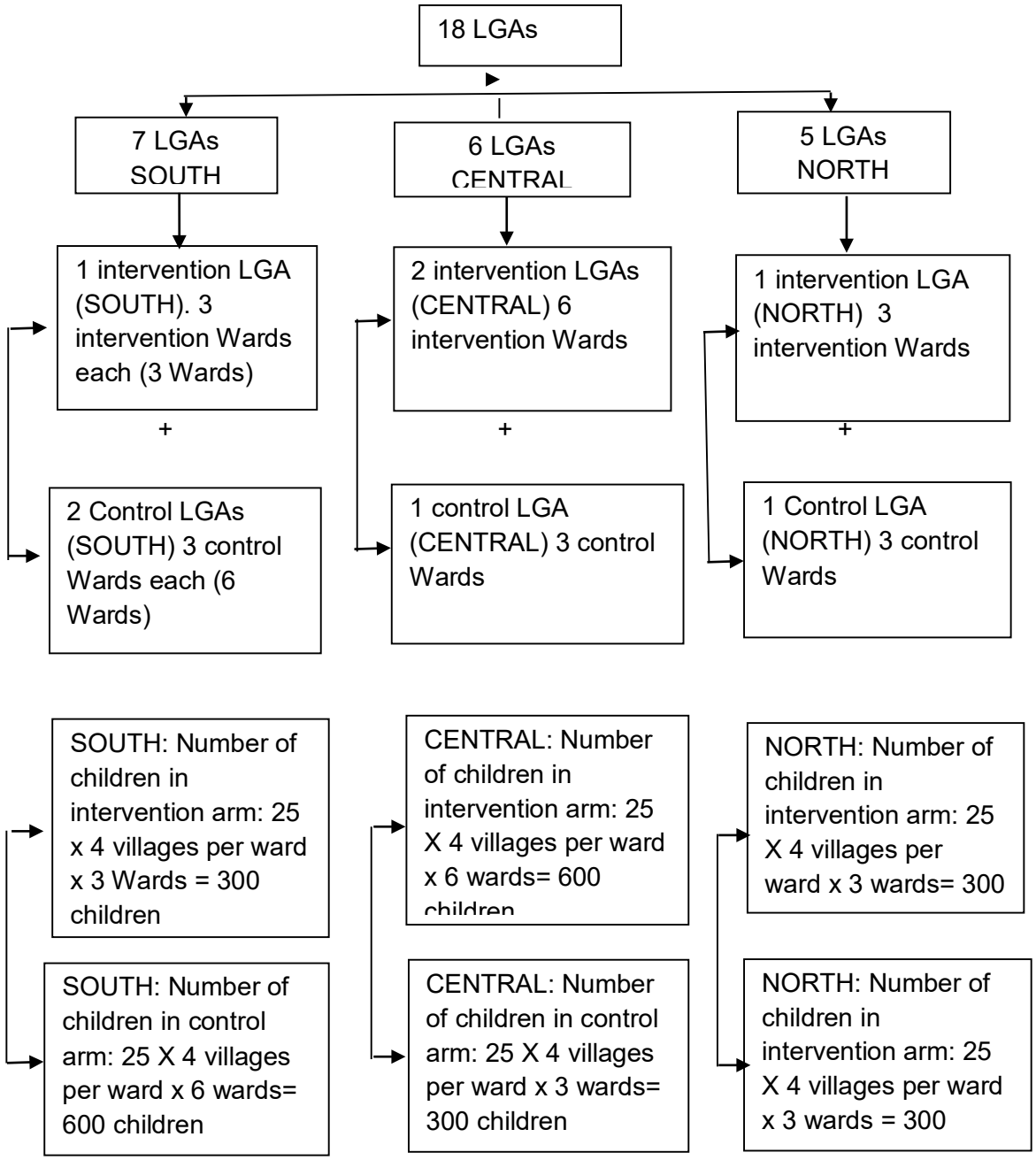
Within each ward, four villages were randomly selected. Where there were less than four villages in a ward all the villages were included in the study. One ward, Adadama in the control arm, had a communal clash when the team were on the ground and so was replaced with Itigidi after the baseline survey. The selection of Itigidi was based on its having the same

characteristics with Adadama and the results with Itigidi excluded were very similar to those including Itigidi.

Within each village, 25 children aged 0-23 months were selected (Figure 2). In the absence of aerial photographs the earlier WHO-recommended method of spinning the pen was used to sample the households. Because there was no list of all households in the village a team member dedicated to sampling of households went to the centre of the village and spun a bottle to choose a random direction. The “sampler” then walked in the direction indicated until the edge of the village was reached, sketching a map of all the households passed, and numbering them as they went. One of these houses was selected at random as the starting point, or “house 1” of the village. At this house, a bottle was spun to choose a random direction, and the sampler walked in that direction until they came to another household, which was the second house of the village, and so on. If there was a junction in the path, the bottle was spun again to select from the choices available. This procedure was repeated until 25 households with children were counted (WHO, 2019).

The sample size was achieved as planned (Annex A). In each arm at each survey, there were between 1268 and 1302 children, slightly higher than the target of 1200.

Figure 3: Diagrammatic presentation of sampling design



5.4 Study Design

The study was a cluster randomised-controlled trial. Randomization took place at the LGA level. LGAs were stratified by geographical zone and within each strata allocated to intervention and control arms by simple random sampling using R by the collaborating institution, Swiss Tropical and Public Health institute. Blinding the TRL to the intervention was not possible, but the respondents and the data collectors were blinded.

5.5 Data Instruments

A mixed method evaluation employing quantitative and qualitative data tools was employed. For the quantitative data a semi-structured interviewer-administered questionnaire was developed to assess immunization coverage. Sections included general information about the caregiver and the child, history of vaccination with dates, knowledge on vaccination, prevalence of selected childhood diseases, and mothers' health facility utilization. A web-based data platform was set up in the cloud.

The FGD guide was also developed to capture data on knowledge, attitude, and beliefs of TRLs on vaccination, degree of community engagements for vaccination services, challenges in getting a child vaccinated, satisfaction with intervention.

5.6 Data Collection

5.6.1 Quantitative Data

The field survey served as the basis for the evaluation of the impact of the intervention on vaccination coverage. This was carried out by independent data collectors and at the community level. Three cross-sectional surveys were conducted at baseline, mid-term, and endline respectively. Baseline survey was carried out in December 2016 prior to the intervention. The intervention was introduced in May 2017 in the intervention arm only. The mid-term and final surveys were carried out in February 2018 and January 2019 respectively. A three-day training of trainers was conducted for field supervisors on the use of the tool on android phone. Subsequently the supervisors trained the data collectors at site. Five data collectors were trained in each of the eight sites. Three best performing ones were selected to participate in the field survey after a 2-day training. Training was conducted for each phase of data collection for supervisors and data collectors.

Respondents were caregivers of children below the age of two years. They were interviewed after obtaining verbal consent. Less than 10 percent declined consent at each round of the evaluation. Data on child's immunization was extracted from the child's vaccination card. When this was not available parental recall was resorted to which accounted for a third of the response.

5.6.2 Qualitative data

FGDs and Key Informant Interviews were held with TRLs and the Local Government health team members respectively at baseline. The sessions sought information on community engagement for RI and knowledge, beliefs, and attitude of the communities towards immunization. Most of the sessions were held at the Local Government secretariat halls in the respective LGAs. Each session lasted for approximately 60 to 75 minutes. At endline, FGDs were held with the TRLs, the health team, and caregivers attending vaccination

service in each of the eight LGAs. Data from the FGDs and Key Informant Interviews were tape recorded and transcribed verbatim.

5.6.3 DHIS data

Routine data generated from the health facilities are captured using the Health Management Information System data tools, summarized and fed into the electronic data base called the District Health Information System (DHIS). Data is entered from each facility in a ward in every LGA on a monthly basis. The DHIS data is mostly generated from the Primary Health Care facilities. Data from the DHIS was extracted from the selected Wards on facility attendance, attendance at antenatal care, deliveries, measles, and neonatal tetanus for 2017 to monitor trend in uptake of services.

5.6.4. Data Quality Measures

Data collection and management was done using ODK (Open Data Kit) technology. This is a robust and reliable Android mobile application that enabled real-time as well as offline data collection and transmission to the cloud server running the ODKAggregate.

Coding of the paper tool into the mobile device included the creation of built-in data validation logic, constraints and loops. Logic was also built into the mobile device to allow data entry (interview) of only children that fall between 0 – 23 months during each survey. The mobile form was also designed to automatically calculate age of child at each immunization received from the date of birth and each date of immunization. This was to checkmate human error that could arise from manually calculating the age of child and the age at which the child received each vaccine. Other validation checks included validating the data type at point of entry (*e.g., the application will not allow non-date to be entered in a date field*), and reducing free-text typing to the barest minimum, by deploying select dropdown lists as much as possible. The skip logic ensured that only relevant questions were made available on the screen to the data collector at each interview session, based on previous inputs. This was to save time for the data collector, who would have had to read through all questions (relevant or otherwise). The skip logic also prevented the user from inadvertently entering data into a wrong field. These design measures invariably helped to reduce data entry errors and enhanced the data quality and integrity.

Prior to the commencement of the survey (fieldwork), the mobile tool was subjected to critical review by an information technology (IT) team, in conjunction with the team of health professionals working on the TRL Project, to confirm that both the logic of the paper questionnaire and that of the mobile tool are in sync, and further reviews were done, otherwise, until both teams were satisfied.

During the 2 days training of data collectors in the field, adequate time was allotted for hands-on practice and role play on the use of the mobile device for interviews, including various scenarios that could be thrown up during the actual data collection.

At the end of data collection each day, the Supervisors retrieved the mobile devices from the data collectors and the data was checked for correctness before uploading to the cloud-based ODKAggregate server. Data collectors (interviewers) took pictures of immunization cards of eligible and recruited children after every interview. During review of the data by the supervisors, these cards were transferred to a computer and the information compared with what was actually inputted by the data collector. The supervisors were able to spot and

correct errors through this approach. Questionable entries were usually reviewed together with the data collector involved. Any irreconcilable data were discarded and a new eligible household surveyed as replacement.

Before commencement of fieldwork each day, the mobile devices were charged overnight and checked to ensure it functioned correctly, including the date and time of the device and then assigned to the data collectors. Checking the date on the mobile device before handing over to the interviewers, was particularly important, because, a wrong date could include ineligible children and exclude eligible ones.

On the cloud server platform, the Data Manager took regular backups of the data, monitored data collection progress and performed quick checks. Observed errors and/or inconsistencies were communicated to the field team involved, for immediate resolution.

Additional data cleaning was performed at the end of data collection to enhance the quality of the data prior to analysis. This included, doing a further check to ensure that, for any reason, any data from a child older than 23 months was excluded, as well as identifying situations where an immunization card was seen but no immunization was recorded.

6 Programme or policy: Design, methods and implementation

6.1 Programme design

6.1.1 Recruitment Strategy

The participants for the TRL intervention included TRLs and health workers. Traditional leaders were recruited from the selected villages. An advocacy visit was paid to the Clan heads of the selected wards by the research team with the Ward Focal Person in attendance. The team explained the purpose of the visit and requested the Clan head to invite the village heads from the selected villages to the training. Similarly visits were paid to church leaders of the two largest churches in the Ward. The only Imam in the study location was also visited and invited to the training. The health workers from the Primary Health Centres in the study location were recruited for the health workers' training.

The beneficiaries were the intended target group. All the village heads in the 48 communities in the intervention sites were invited for the training. Two Pastors from the largest congregation in each ward were invited to participate in the training with the only Imam in one of the intervention sites. In two villages in Ehom ward, Biase LGA the village heads were indisposed and were represented by their WDC secretary. The Clan head in Nde did not attend the sessions but was represented by the WDC Secretary who was also a village head.

6.1.2 Training tools

Training tools were developed by the research team and reviewed by the training team. The tools were adapted from existing relevant national and international manuals. They addressed topics on the expected leadership role of the TRLs in the community and the health sector as influencers, providers of information and data, supporters of health workers, communicators, and identifiers of priority health problems in their areas. Graphic tools were used for the sessions to promote interactions and discussions among the trainees.

The tools for the training were piloted in Akpabuyo LGA that was not included in the study, with five traditional and three religious leaders in attendance. The aim was to test the skills of the trainers to

deliver the training and to assess the ability of the trainees and the effectiveness of the training tools in stimulating interaction with the trainees.

6.1.3 Trainers

A trainer was recruited for each intervention LGA. These were retired Community Health Officers with experience as health educators and community mobilizers. They had experience in health facility management and delivery of vaccination services in rural and urban settings. In addition they were trained nurse midwives with additional training in Community Health Officer's course. Trainers were trained for three days for each training session. Training included role plays. Training was prescriptive with a guide for each session.

6.2 Training Components

The intervention had multiple components which were designed to fit the structure of the PHC system that has the WDC headed by a traditional ruler executing its oversight function. The components of the intervention were:

- TRL training
- Community engagement
- Health services
- Strengthening of the WDC

Training of the TRLs aimed at improving their leadership role in the community and in the WDC. It also targeted improving their understanding of the purpose for vaccination, improving their communication skills, and community mobilization. Community engagement was to provide the forum for the leaders to share information on RI as a means of encouraging the community members to get their wards vaccinated. The health service component trained the health workers to prepare user-friendly data generated from RI to be shared with the leaders; while the WDC component aimed at ensuring that the WDC meetings were held routinely to facilitate the interaction of the members with the leaders.

Details of the intervention are provided below.

6.2.1 Intervention component 1: TRL training

Training was conducted at the LGA level with TRLs from the selected villages in attendance. The venue for training was the PHC facility in three LGAs and the town council hall in one LGA. The sessions were interactive and participatory. Methods of training adopted included brainstorming, large and small group discussions, role plays, problem solving case studies, and learning aids. Five sessions of training were held in the first 9 months and 3 sessions in the second 9 months. Training sessions included:

- Leadership styles – a 90 minutes interactive session with role plays demonstrating the different types of leadership styles and discussion on the merits and demerits of each style. Training objective was to guide the leaders to appreciate the different leadership styles and adopt the style of leadership that will make them good leaders of their communities.
- Characteristics of a good leader – 60 minutes brainstorming session on the characteristics of a good leader. Leaders identified the characteristics that will make them good leaders.
- How to influence people - session commenced with a 45 minutes group discussion and ended with a 15 minutes role play to reinforce the role of leaders as community influencers.
- Transformational leadership – Illustrative flash cards were used to stimulate discussion on how the leaders can be innovative in playing their leadership role particularly on vaccination services. The session lasted for 3 hours with intermittent breaks. Brainstorming and discussions were employed to demonstrate that a leader makes the impossible possible, and possibility a reality. It identified the barriers to vaccination within the localities. Having identified the barriers the training portrayed that they should not be victims of these barriers but the leaders should create "new realities" that will bridge the gap. They should not be

"reactive" pointing accusing fingers to others for the barriers but be "responsive" by breaking through the barriers.

- Vaccine preventable diseases – this session was presented with the aid of a graphic handbook. The aim was to improve the knowledge of the leaders on what the vaccine preventable diseases were, how they present, how they are transmitted, and how to prevent them. Local names of the diseases were used in the presentation and discussion. Discussions focused on what they knew about the disease and what the diseases are. This session lasted for 90 minutes with intermittent breaks.
- Vaccine uptake – a practical session that involved sharing vaccine uptake data from RI in the locality with the leaders. The aim was for the participants to appreciate the gaps in RI uptake. This was followed with discussion on the problems that caused the observed gaps. Using problem tree analysis solutions were proffered by the leaders. In a 45 minutes break out into small discussion groups the leaders developed a plan of action to address the gaps. This was shared during a feedback session.
- What to know about vaccination – To address dropout of immunization schedule a graphic animation of how vaccine works was shared with the leaders for an hour. The training tool also had information on when and where in the respective wards to receive immunization.
- Mapping of community resources – In small group brainstorming session the leaders identified the resources available in their respective wards that they could harness to support RI. This was followed by a feedback session.
- Composition and role of wards and village development committees – The session began with exploring the composition of the WDC committee and the roles they play. This lasted for an hour. The "ideal" composition of the WDC from the National PHC and Development Agency was presented and the roles expected of the Ward and Village Development Committees.
- Effective communication – the leaders were taken through a 3 hour interactive session on the process and characteristics of a good communicator. Each stage of the process was followed with a practical example.
- Identification and prioritization of problems through participatory learning action –to meet the objective of supporting the leaders to identify problems in their communities the leaders were taken through participatory learning action process in identifying problems. The training included how to set up a community discussion group that was representative of the community including the vulnerable groups like women, those residing in areas with difficult terrains. They were taken through the problem identification steps using problem tree analysis approach. Identified problems were prioritized and solutions proffered.
- Community mobilization – This training aimed at highlighting different ways of achieving community involvement with the aim of achieving sustainable community participation in RI. It lasted for 3 hours with demonstration of different types of mobilization illustrated with graphics. The trainer presented the graphic flashcard to the participants who discussed what they saw on the card. This was followed with further explanation by the trainer with the participants contributing to the reasons for each type of mobilization. This ended with a session on steps to community mobilization.

No training was conducted for the TRLs in the control sites.

6.2.2 Intervention component 2: Community engagement

The leaders educated their communities during their routine community meetings on vaccination. Vaccination data from RI services was presented on a dashboard and shared during the monthly WDC meetings. This was planned to be presented during the town hall meeting but such meetings were seldom. Council of Chiefs' meetings were held monthly at the ward level. The traditional leaders shared information on RI through the Council of chiefs

which were subsequently relayed to the community groups at the village level. The religious leaders' forum was the church and the mosque.

Similar community meetings were being held monthly in the control sites. However, the information on RI was not shared.

6.2.3 Intervention component 3: Health services

Training was conducted for the health workers in the intervention sites to improve their quality of summarization and communication of vaccination data with lay persons. The cadre of health workers in the study location at the PHC level were the Senior Community Health Extension Workers and Community Health Extension Workers. A one-day training session on data summarization and presentation using infographics was held in a Health Centre in each LGA. Participants were the health worker in charge of the Health Centre from the three Wards included in the study, the Ward Focal Person, the Local Immunization Officer, The Monitoring and Evaluation Officer, and the Cold Chain Officer. The training lasted for 3 hours. Data generated from RI services in health facilities in the respective wards were analysed from the immunisation registers and presented on a dashboard. The dashboard was a portable 60 by 70 cm plastic panel for ease of conveyance to meetings outside the health facility with stick-on plaques. The health workers used this to share data with the TRLs at Council of Chiefs' meeting and the WDC meetings. Data on the dashboard included RI monthly uptake and drop out on Pentavalent 3 vaccine. A hands-on training was conducted for the health workers on defaulters' register following a report from them that they did not have a means of identifying children that had dropped out of immunization. The training was delivered on the fifth month of the intervention. They were also trained on management of adverse effects of vaccination.

No training was conducted for health workers in the control sites.

6.2.4 Intervention component 4: leadership and coordination of the WDC

The WDC was to be strengthened to become decision-making bodies through re-drafting of its terms of reference with clear objectives and operations if necessary. Meetings were to be formalized to allow the organized presentation of health facility data and to monitor implementation. As at the time of commencement of the intervention, WDCs had become docile in most of the Wards in the intervention sites following non-support of the Committees' meetings by the government. Only 3 of the 12 were functioning as at the time of the commencement of the Project. Following the training, the nine non-active WDCs were reactivated. The WDCs did not operate by the terms of reference set by the national body for PHC. Interaction with the WDCs showed that every WDC was constituted by either the Ward Focal Person, or the Clan Head. Their composition was not unified.

The research team did not deem it necessary to draft another terms of reference for the WDC. Rather, the State PHC Agency will be informed of the state of the WDCs and suggestion made to standardise the appointment of community members into the committee in accordance with the existing terms of reference.

All the WDCs in the control arm were meeting regularly except the WDC in Odot, Odukpani LGA. The WDC in Odot did not sit all through the duration of the intervention. The reason for not holding meetings was lack of funding by the Government. Table 1 presents the number of sittings of the WDCs in the intervention arm.

Table 1: Frequency of WDC meetings in intervention arm

Name of Ward	Name of Ward	No of sitting
Biase	Aguwagune	18
	Akpet	18
	Ehom	18
Etung	Abijang	18
	Mkpot	18
	Nsofang	21
Ikom	Abayom	18
	Nde	10
	Ofutop 1	21
Obudu	Ipong	18
	Urban 1	21
	Utugwang 1	18

6.3 Monitoring System

Reports were received from the trainers on each training session held with pictures of the training session attached. Training sessions were also witnessed by co-researchers.

The Ward Focal Person monitored and reported on the meetings in the community. Reports of such meetings were corroborated with the TRLs during the training sessions. However, the details of the deliberations could not be ascertained as minutes of the meetings were not kept.

Information was also collected from the health workers during a monitoring visit of the researchers to the health facilities in the intervention and control sites. They reported on the frequency of visits of the TRLs in the facilities. Information on the use of the defaulter's register was obtained during the monitoring visit. The registers were sighted to confirm use.

Minutes of WDC meetings were retrieved and agendas and discussions reviewed for related RI and health facility activities. Town hall meetings were rarely held: only one town hall meeting was held in one of the intervention villages during the study period. Community engagement was achieved through extant community meetings (See details in Table 2). The Ward Focal Person supplied information on the various meetings in the community. This was further corroborated during the sessions of training of the TRLs. Information on the issues discussed during community meetings could not be tracked as minutes of these meetings were not kept.

Monitoring depended solely on the verbal reports by the TRLs and Ward Focal Persons. Reports on number of times vaccination was discussed at such meetings could not be verified.

Data from the DHIS was analysed for impact on facility utilization and prevalence of selected vaccine preventable diseases.

Table 2: Community meetings

Type of meeting	Meeting frequency	Who participates	Purpose

Women	Monthly	Married women	Issues concerning women in the community
Men	Monthly	Married men	Issues concerning men in the community
Youths	Monthly	Young unmarried men	Issues concerning youths in the community
Council of Chiefs	Monthly	Village and clan heads	Community interest including land issues
WDC	Monthly	Committee members	Community development

6.4 Implementation Fidelity

The intervention was carried out as planned for the TRL training. Eight sessions of training were held with 5 sessions held before the midterm evaluation and three held after the midterm evaluation. Three sessions of one-day training were held for the health workers instead of a 2 day training. This was to avoid keeping them out of their facilities for two continuous days due to poor staffing of the facilities.

During the intervention there was a rumour that the government was injecting children with Monkey Pox virus instead of vaccines. This stemmed from an epidemic of Monkey Pox in the country. Children were withdrawn from schools and vaccination exercises were resisted. This rumour was nationwide and impacted on both the intervention and control arms equally.

The government used the mass media at national and State levels through the Federal Ministry of Health, National and State PHC Agencies to refute the allegation and allay fears. Health workers were trained to counsel the caregivers.

The community engagement did not use the town hall meeting as planned. Only one town hall meeting was held. It was called for when there was an emergency. In its place, the data sharing was limited to the TRLs and the WDC members. Other community engagements utilised the existing community group meetings. Utilising these meetings for engagements was not in the original plan but was resorted to when the traditional leaders reported disseminating information through them.

WDC meetings exceeded the 7 meetings targeted in each ward. Almost all the WDCs held monthly meetings after their revitalisation except in Odot ward (Odukpani LGA in the control arm). The WDC in Odot ward did not hold all through the intervention period.

The defaulters' register was not put to use in two health facilities in Ehom, and Itu-Agwuagune (Biase LGA) respectively, and one in Abinti 2 ward (Ikom LGA). The staff complained of being short staffed. The dashboard was not used in one of four Health Centres in Akpet/Abini ward, two of four in Ehom (Biase LGA)

6.5 Weak Links in the Intervention

Community engagement could not be achieved directly with the community members because the town hall meetings were rarely held. It is not certain how much of the data generated from the facilities was shared with the community members. The essence of sharing the data was for the community members to appreciate how many of their children have failed to be immunized. This was expected to spur the community members to identify resistant and defaulting members of the community to support them to have a change in attitude and behaviour.

Low staffing of facilities constrained the health staff from deploying the defaulters' register. Some complained that they had many registers other than the defaulters' register to fill.

The intervention was delivered by retired health workers. The expected interaction between the health workers (trainers) and the TRLs was, therefore, with the retired health workers used as trainers. Using the in-service health workers will be preferable to foster the interaction between the health workers and the TRLs.

7.1 Descriptive statistics and balance table:

The characteristics of the respondents were similar for intervention and control arms (Table 3) except for whether they lived in hard-to-reach communities or not. Hard-to-reach were areas defined by the study team that have difficult terrains like riverine areas, hilly areas or bad roads. These vary greatly between LGA. Primary Health Care facilities are provided in some hard-to-reach communities.

Table 3: Characteristics of the respondents

	Control Baseline n=1301	Control Mid-term n=1268	Control Final n=1274	Intervention Baseline n=1297	Intervention Mid-term n=1302	Intervention Final n=1276
age in years						
13-19	107 (8%)	89 (7%)	89 (7%)	92 (7%)	107 (8%)	78 (6%)
20-29	702 (54%)	690 (54%)	727 (57%)	765 (59%)	782 (60%)	770 (60%)
30-39	434 (33%)	444 (35%)	413 (32%)	372 (29%)	374 (29%)	396 (31%)
40-49	48 (3.7%)	37 (3%)	40 (3%)	51 (3.9%)	29 (2%)	32 (3%)
50-59	7 (0.5%)	5 (0.4%)	3 (0.2%)	12 (0.9%)	9 (0.6%)	0
60+	2 (0.2%)	2 (0.2%)	2 (0.2%)	5 (0.4%)	1 (0.07%)	0
age not known**	1	1	0	0	0	0
Level of education of caregivers						
None	30 (2%)	30 (2%)	21 (2%)	14 (1%)	12 (0.9%)	8 (0.6%)
Primary	248 (19%)	223 (18%)	221 (17%)	168 (13%)	158 (12%)	107 (8%)
Secondary	818 (63%)	848 (67%)	857 (67%)	973 (75%)	932 (72%)	939 (74%)
Tertiary	205 (16%)	167 (13%)	175 (14%)	142 (11%)	200 (15%)	222 (17%)
Religious affiliation						
Orthodox	679 (52%)	707 (56%)	826 (65%)	726 (56%)	780 (60%)	757 (59%)
Pentecostal	590 (45%)	528 (42%)	410 (32%)	543 (42%)	496 (38%)	486 (38%)
White garment	18 (1%)	15 (1%)	14 (1%)	21 (2%)	20 (2%)	25 (2%)
Islam/Others/None	14 (1%)	18 (1%)	24 (2%)	7 (0.5%)	6 (0.4%)	8 (0.6%)
Where help was sought last for child's ill health						
Health facility	674 (58%)	649 (53%)	404 (38%)	568 (47%)	624 (53%)	554 (46%)
Medicine shop	318 (27%)	372 (31%)	500 (47%)	580 (48%)	430 (36%)	557 (46%)
Treated at home: drugs	146 (13%)	146 (12%)	120 (11%)	31 (3%)	85 (7%)	63 (5%)

Treated by a friend: drugs	19 (2%)	15 (1%)	10 (0.9%)	5 (0.4%)	15 (1%)	12 (1%)
Other***	10 (1%)	35 (3%)	26 (2%)	14 (1%)	28 (2%)	19 (2%)
Distance to health facility						
15min walk or less	452 (35%)	559 (44%)	618 (49%)	491 (38%)	513 (39%)	567 (44%)
15-<30min	458 (35%)	346 (27%)	364 (29%)	506 (39%)	580 (45%)	431 (34%)
30-<45m	136 (10%)	129 (10%)	115 (9%)	188 (14%)	118 (9%)	194 (15%)
45m-1h	107 (8%)	137 (11%)	104 (8%)	74 (6%)	53 (4%)	58 (5%)
>1h	148 (11%)	97 (8%)	73 (6%)	38 (3%)	38 (3%)	26 (3%)
Hard to reach						
Yes	131 (10%)	87 (7%)	83 (7%)	539 (42%)	602 (46%)	572 (45%)
No	1170 (90%)	1181 (93%)	1191 (93%)	758 (58%)	700 (54%)	704 (55%)

NOTE: ** percentages of known values (excluding missing values)
*** included only 'other' that had been ill (some of the answers to this question suggested that the child had not been ill).
A comparison of control vs intervention in the baseline survey used regression models with LGA as a random effect (ward and village omitted due to singularity): all variables have p>0.05 except for hard to reach p<0.01 (age: p=0.99, education p=0.99, religion p=0.99, where help sought p=0.99, distance to health facility p=0.99).

The characteristics of the children were also similar between the arms (Table 4).

Table 4: Characteristics of the children by survey

	Control baseline N=1301	Control Mid-term N=1268	Control final N=1274	Intervention baseline N=1297	Intervention mid-term N=1302	Intervention Final N=1276
Age of child in months						
0-5	460 (35%)	406 (32%)	410 (32%)	468 (36%)	507 (39%)	429 (34%)
6-11	321 (25%)	338 (27%)	377 (30%)	313 (24%)	382 (29%)	405 (32%)
12-17	302 (23%)	311 (25%)	294 (23%)	296 (23%)	238 (18%)	244 (19%)
18-23	218 (17%)	213 (17%)	193 (15%)	220 (17%)	175 (13%)	198 (16%)
Sex of child						
Female	651 (50%)	618 (49%)	629 (49%)	648 (50%)	649 (50%)	654 (51%)
Male	650 (50%)	650 (51%)	645 (51%)	649 (50%)	653 (50%)	622 (49%)
Birth order						
First	401 (31%)	378 (30%)	386 (30%)	416 (32%)	384 (30%)	369 (29%)
Second	356 (27%)	335 (26%)	329 (26%)	333 (26%)	340 (26%)	347 (27%)
Third	257 (20%)	248 (20%)	252 (20%)	245 (19%)	241 (19%)	285 (22%)
Fourth	142 (11%)	153 (12%)	139 (11%)	129 (10%)	154 (12%)	140 (11%)
Fifth	73 (6%)	76 (6%)	80 (6%)	97 (7%)	98 (8%)	77 (6%)
Sixth	39 (3%)	31 (2%)	46 (4%)	54 (4%)	54 (4%)	43 (3%)
other birth order	33 (3%)	47 (4%)	42 (3%)	23 (2%)	31 (2%)	15 (1%)

For the comparison control vs intervention in the baseline survey, all variables have p>0.05.

Overall, around two-thirds of the children had their immunisation cards seen. Younger children were more likely to have their cards available to be seen than older children (Table 5). The proportion of children who had their immunization cards seen was similar in the intervention and control group at baseline. However, a higher proportion of children had their immunization cards seen in the intervention arm at midterm and final evaluation compared to

the control arm. It may be that the intervention increased awareness of vaccination in general and so the cards were kept more carefully.

Table 5: Immunization cards seen by age group

Age group	Control			Intervention		
	baseline	mid-term	final	baseline	mid-term	final
0-5 months	322/460 (70%)	304/406 (75%)	281/410 (69%)	339/468 (72%)	465/507 (92%)	407/429 (95%)
6-11 months	246/321 (77%)	246/338 (73%)	263/377 (70%)	245/313 (78%)	372/382 (97%)	387/405 (96%)
12-17 months	191/302 (63%)	214/311 (69%)	178/294 (61%)	216/296 (73%)	224/238 (94%)	231/244 (95%)
18-23 months	133/218 (61%)	158/213 (74%)	120/193 (62%)	129/220 (59%)	156/175 (89%)	175/198 (88%)

*Recorded as having been seen (missings are counted as not seen).

7.2 Empirical analysis

The proportion of children who were fully up-to-date with vaccinations increased slightly in both the intervention and control groups (Table 6) and the proportion of children who had had no vaccinations decreased over time in the intervention arm.

Table 6: Vaccination status of children

	Control baseline	Control mid-term	Control Final	Intervention baseline	Intervention mid-term	Intervention final
Not vaccinated	125 (10%)	104 (8%)	128 (10%)	87 (7%)	25 (2%)	5 (0.4%)
Partial	551 (42%)	452 (36%)	449 (35%)	619 (48%)	574 (44%)	610 (48%)
Up-to-date	625 (48%)	712 (56%)	697 (55%)	591 (46%)	703 (54%)	661 (52%)

NOTE; There was no evidence of a difference at baseline between the control and intervention arms for the proportion at least partially vaccinated (p=0.52) or fully up to date (p=0.82).

There was no evidence of an effect of the intervention on the proportion of children fully up-to-date on vaccination (Table 7). However, there was a significant effect of the intervention on increasing the proportion of children with at least one vaccination.

Table 7: Estimated impact of the intervention

	Mid-survey vs baseline		Endline survey vs baseline	
	OR (95% CI)	p-value	OR (95% CI)	p-value
Up-to-date vs partial & not vaccinated	0.96 (0.76, 1.22)	0.74	0.95 (0.75, 1.21)	0.69
Up-to-date & partial vs not vaccinated	2.21 (1.37, 3.57)	0.001	12.13 (6.03, 24.41)	<0.001

NOTE: The analysis was carried out using logistic regression with random effects for LGA, ward and village to take account of clustering in the sample. The effect of the intervention was estimated as the difference in the change from baseline to the survey under consideration in the intervention arm compared to the change from baseline to the survey in the control arm. Adjusting for hard-to-reach produced very similar estimates: up-to-date or partial vs not vaccinated mid 2.31 (1.42, 3.74) and endline 12.63 (6.27, 25.43); up-to-date vs partial and not vaccinated mid: 0.97 (0.77, 1.24), final 0.95 (0.75, 1.21). Each vaccine had 1.5% to 2% respondents who said they did not know if the child had received the vaccine: for the purposes of calculating vaccine status we counted these as not having had the vaccine.

We examined the proportion of vaccinated children by the following sub-groups: age group, stratification zone, distance to health facility and whether classified as 'hard-to-reach'. These variables were chosen on the basis that they may potentially affect the impact of the intervention.

We used interaction tests to assess whether there was a difference in the effect of the intervention by each of these variables. We found no evidence of any interactions for age-group or distance to health facility (all p>0.05 for both fully alone compared to partial and not vaccinated and fully and partial compared to not vaccinated).
For stratification zone and hard to reach, and the sex of the child, there was no consistent pattern of evidence that the intervention worked better in some settings than others (Table 8). Although there were isolated significant results, the pattern of the direction of effect was

not consistent and we think that this is related to the sub-groups being compared rather than a real effect.

Table 8: Vaccination status by sub-group

	Control baseline	Control mid-term	Control Final	Interventio n baseline	Intervention mid-term	Intervention final
0-11 months only						
Not vaccinated	94 (12%)	80 (11%)	95 (12%)	60 (8%)	21 (2%)	5 (0.6%)
Partial	279 (36%)	250 (34%)	284 (36%)	359 (46%)	374 (42%)	435 (52%)
Up-to-date	408 (52%)	414 (56%)	408 (52%)	362 (46%)	494 (56%)	394 (47%)
12-23 months only						
Not vaccinated	31 (6%)	24 (5%)	33 (7%)	27 (5%)	4 (1%)	0 (0%)
Partial	272 (52%)	202 (38%)	165 (34%)	260 (50%)	200 (48%)	175 (40%)
Up-to-date	217 (42%)	298 (57%)	289 (59%)	229 (44%)	209 (51%)	267 (60%)
Stratification zone						
Central rural (Abi & Etung)						
Not vaccinated	10 (3%)	10 (3%)	9 (3%)	4 (1%)	2 (0.6%)	1 (0.3%)
Partial	130 (35%)	103 (30%)	137 (38%)	115 (37%)	47 (15%)	152 (49%)
Up to date	227 (62%)	234 (67%)	210 (59%)	190 (61%)	260 (84%)	156 (50%)
South rural (Odukpani & Biase)						
Not vaccinated	111 (35%)	91 (29%)	105 (35%)	26 (8%)	8 (2%)	1 (0.3%)
Partial	120 (37%)	121 (38%)	112 (38%)	222 (67%)	249 (70%)	206 (62%)
Up to date	90 (28%)	105 (33%)	79 (27%)	84 (25%)	98 (28%)	123 (37%)
North urban (Ogoja & Obudu)						
Not vaccinated	3 (1%)	3 (1%)	11 (4%)	47 (14%)	9 (3%)	1 (0.3%)
Partial	209 (66%)	170 (55%)	127 (41%)	151 (46%)	138 (42%)	115 (35%)
Up to date	103 (33%)	137 (44%)	172 (55%)	130 (40%)	180 (55%)	217 (65%)
Mixed urban (Calabar Municipality & Ikom)						
Not vaccinated	1 (0.3%)	0 (0%)	3 (1%)	10 (3%)	6 (2%)	2 (0.6%)
Partial	92 (31%)	58 (20%)	73 (23%)	131 (40%)	140 (45%)	137 (45%)
Up to date	205 (69%)	236 (80%)	236 (76%)	187 (57%)	165 (53%)	165 (54%)
Distance to health facility						
Less than 30min						
Not vaccinated	71 (8%)	63 (7%)	88 (9%)	63 (6%)	17 (2%)	5 (0.5%)
Partial	377 (41%)	323 (36%)	360 (37%)	467 (47%)	466 (43%)	486 (49%)
Up to date	462 (51%)	519 (57%)	534 (54%)	467 (47%)	610 (56%)	507 (51%)
30 minutes or more						
Not vaccinated	54 (14%)	41 (11%)	40 (14%)	24 (8%)	8 (4%)	0 (0%)
Partial	174 (45%)	129 (36%)	89 (30%)	152 (51%)	108 (52%)	124 (45%)
Up to date	163 (42%)	193 (53%)	163 (56%)	124 (41%)	93 (44%)	154 (55%)
Hard to reach						
Hard to reach						
Not vaccinated	47 (36%)	19 (22%)	32 (39%)	33 (6%)	10 (2%)	3 (0.5%)
Partial	37 (28%)	32 (37%)	27 (33%)	240 (45%)	215 (36%)	275 (48%)
Up to date	47 (36%)	36 (41%)	24 (29%)	266 (49%)	377 (63%)	294 (51%)
Not hard to reach						
Not vaccinated	78 (7%)	85 (7%)	96 (8%)	54 (7%)	15 (2%)	2 (0.3%)
Partial	514 (44%)	420 (36%)	422 (35%)	379 (50%)	359 (51%)	335 (48%)
Up to date	578 (49%)	676 (57%)	673 (57%)	325 (43%)	326 (47%)	367 (52%)

Sex of child						
male						
Not vaccinated	55 (10%)	54 (8%)	71 (11%)	40 (8%)	16 (4%)	4 (1%)
Partial	284 (42%)	239 (37%)	219 (34%)	323 (48%)	285 (42%)	315 (50%)
Up-to-date	311 (48%)	357 (55%)	355 (55%)	286 (44%)	352 (54%)	303 (49%)
female						
Not vaccinated	70 (12%)	50 (8%)	57 (10%)	47 (9%)	9 (2%)	1 (0.3%)
Partial	267 (39%)	213 (34%)	230 (36%)	296 (44%)	289 (44%)	295 (45%)
Up-to-date	314 (48%)	355 (58%)	342 (54%)	305 (47%)	351 (54%)	358 (55%)

The proportion of children receiving doses of individual vaccines by age is shown in Table 9. The median ages at vaccination were within the scheduled dates for each antigen in each arm of the study except for Penta 3 which was a week more than the scheduled age in the intervention arm and the end survey in the control arm. However, the ranges were fairly wide with both early and late vaccinations.

Table 9: Age at vaccination in weeks for those with date known (median, IQR, range)

Antigen (Scheduled age in weeks)	baseline	Mid-term	Final
Penta 1 (6 -8)			
Control	6.7 (6.1-8.6) (0.8-68.1)	7.0 (6.1-8.7) (1.0-65.3)	7.0 (6.1-8.7)(1.3-65.7)
Intervention	7.1 (6.3-8.9) (0.3-64.9)	7.0 (6.3-8.9) (1.4-58.9)	7.1 (6.4-8.7)(2.0-50.1)
Penta 2 (10-12)			
Control	11.3 (10.4-14.1)(5.6-69.3)	11.7 (10.4-14.1) (1.4-74.4)	11.9 (10.6-14.6)(5.0-88.7)
intervention	12.0 (10.6-14.6)(0.9-67.8)	11.7(10.6-14.3)(2.4-57.3)	12.1(10.9-13.9)(4.7-51.1)
Penta 3 (14-16)			
Control	16.0 (14.6-20.0) (3.1-91.0)	16.1 (14.9-19.7)(10-75)	16.6 (15.0-20.4) (9.4-76.0)
intervention	17.0 (14.7-20.6)(5.1-58.0)	16.9 (15.0-19.9)(11.0-52.7)	16.9 (15.3-19.3)(8.3-62.0)
Measles (39-41)			
Control	40.6 (39.6-43.1) (9.4-91.0)	40.9 (39.6-43.8) (27.1-93.4)	40.6 (39.6-43.4) (23.0-88.7)
intervention	39.7 (37.3-42.8) (2.3-82.4)	39.9 (38.4-42.3) (29.6-84.0)	40.1(39.0-42.7) (27.0-83.6)

The effect of the intervention on timeliness of vaccination was statistically significant for all vaccines at midterm and final evaluation (Table 10).

Table 10: Proportion of children who received vaccine on time of those old enough to have done so

	Control baseline	Control mid-term	Control final	Intervention baseline	Intervention mid-term	Intervention final	OR mid CI p-value	OR final CI p-value
Penta 1	531 (46%)	529 (46%)	496 (43%)	511 (46%)	632 (57%)	694 (60%)	1.63 (1.26,2.09) <0.001	1.96 (1.53,2.53) <0.001
Penta 2	375 (36%)	377 (35%)	341 (32%)	340 (33%)	450 (44%)	447 (41%)	1.69 (1.29, 2.22) <0.001	1.63 (1.25, 2.14) <0.001
Penta 3	273 (28%)	272 (27%)	243 (24%)	226 (24%)	311 (33%)	292 (29%)	1.72 (1.26,2.35) <0.001	1.55 (1.14,2.12) 0.005
measles	155 (24%)	158 (25%)	154 (24%)	124 (19%)	211 (37%)	240 (41%)	2.53 (1.73, 3.68) <0.001	2.81 (1.93, 4.10) <0.001
Penta 3 on time of those who had penta 1 on time	254 (59%)	258 (57%)	239 (57%)	214 (50%)	295(55%)	281 (48%)	1.15 (0.77, 1.74) 0.44	1.20 (0.80, 1.81) 0.37

NOTE: *Timeliness defined as within 2 weeks before or after target age

The proportion of children over 6 months who have had all three Penta doses was significantly increased by the intervention for the mid-term (OR= 1.49 (1.01,2.21), p=0.04) and final (OR=1.88 (1.24, 2.85) , p=0.003) surveys (Table 11).

Table 11: Number of Penta doses in children aged 6-23 months

	Control baseline	Control mid-term	Control final	Intervention baseline	Intervention mid-survey	Intervention final
0	86 (10%)	70 (8%)	88 (10%)	64 (8%)	15 (2%)	3 (0.2%)
1	29 (3%)	32 (4%)	23 (4%)	19 (2%)	34 (4%)	19 (2%)
2	49 (6%)	59 (7%)	34 (7%)	55 (7%)	47 (6%)	42 (5%)
3	677 (80%)	701 (81%)	719 (81%)	691 (83%)	699 (88%)	783 (92%)

The effect of the intervention on children aged at least 14 weeks having penta 3 given that they had had Penta 1 was estimated to be OR=1.21 (0.80, 1.84) p=0.36 for the mid-term survey and 1.66 (1.08, 2.55) p=0.02 for the end line survey (Table 12).

Table 12: Drop-out: number of children aged 14+2 weeks who received Penta doses

	Control baseline	Control mid-term	Control endline	Intervention baseline	Intervention mid	Intervention endline
0	109 (11%)	89 (9%)	102 (10%)	77 (8%)	24 (3%)	5 (0.1%)
1	43 (4%)	47 (5%)	42 (4%)	29 (3%)	54 (6%)	29 (3%)
2	71 (7%)	85 (8%)	68 (7%)	91 (9%)	78 (8%)	76 (8%)
3	756 (77%)	788 (78%)	797 (79%)	763 (79%)	791 (84%)	884 (89%)

Penta 3 of those who had penta1	556 (86%)	589 (85%)	559 (85%)	586 (84%)	744 (86%)	824 (89%)

The pattern of drop-out in the control arm was that the proportion of children having their vaccination doses on time decreased with age: roughly 45% had Penta 1 on time, 35% Penta 2, 25% penta3 and 20% measles. Nevertheless, in children aged 6 to 23 months, 80% had had all three Penta doses, suggesting that the drop-out tended to reflect increasing lateness rather than not having the doses at all. The effect of the intervention was to increase the proportion of children who had their doses on time, this effect was similar across all of the penta doses and slightly stronger for measles.

The intervention was significantly associated with the mother having two or more doses of tetanus toxoid, the mother attending ANC and the child being reported to have had measles at the final but not at the midterm survey (Table 13).

Table 13: Other outcomes: Health-care utilisation by the mother, and child illness

	Control Baseline n=1301	Control Mid-term n=1268	Control Final n=1274	Intervention Baseline n=1297	Intervention Mid-term n=1302	Intervention Final n=1276	p-value
Tetanus vaccination status of mother							
None	195 (15%)	189 (15%)	168 (13%)	131 (10%)	101 (8%)	60 (5%)	
One	117 (9%)	123 (10%)	136 (11%)	144 (11%)	148 (11%)	146 (11%)	
Two	717 (55%)	692 (55%)	770 (60%)	753 (58%)	771 (59%)	813 (64%)	0.28[ac]
Three	237 (18%)	229 (18%)	182 (14%)	256 (20%)	258 (20%)	240 (19%)	0.02[bc]
More than three	35 (3%)	35 (3%)	18 (1%)	13 (1%)	24 (2%)	17 (1%)	
Attendance at ANC							
Yes	1114 (86%)	1129 (89%)	1143 (90%)	1148 (89%)	1206 (93%)	1240 (97%)	0.95[a]
No	183 (14%)	137 (11%)	131 (10%)	134 (10%)	95 (7%)	36 (3%)	<0.001[b]
Don't know	4 (0.3%)	2 (0.1%)	0	15 (1%)	1 (0.08%)	0	
Has the child ever had measles?							
Yes	1229 (95%)	1238 (98%)	1227 (97%)	1178 (91%)	1259 (97%)	1252 (99%)	0.37[a]
No	71 (5%)	28 (2%)	43 (3%)	115 (9%)	35 (3%)	18 (1%)	<0.001[b]
Not known	1	2	4	4	8	6	

NOTE: Percentages are of known values (excluding missing values)
[a]effect of intervention on change between baseline and mid-term surveys
[b]effect of intervention on change between baseline and final survey
[c]comparing 0-1 vs 2 or more tetanus doses

The number of reported suspected measles cases was extracted from the DHIS. The numbers are small, and the trends similar in the two arms (Figure 4).

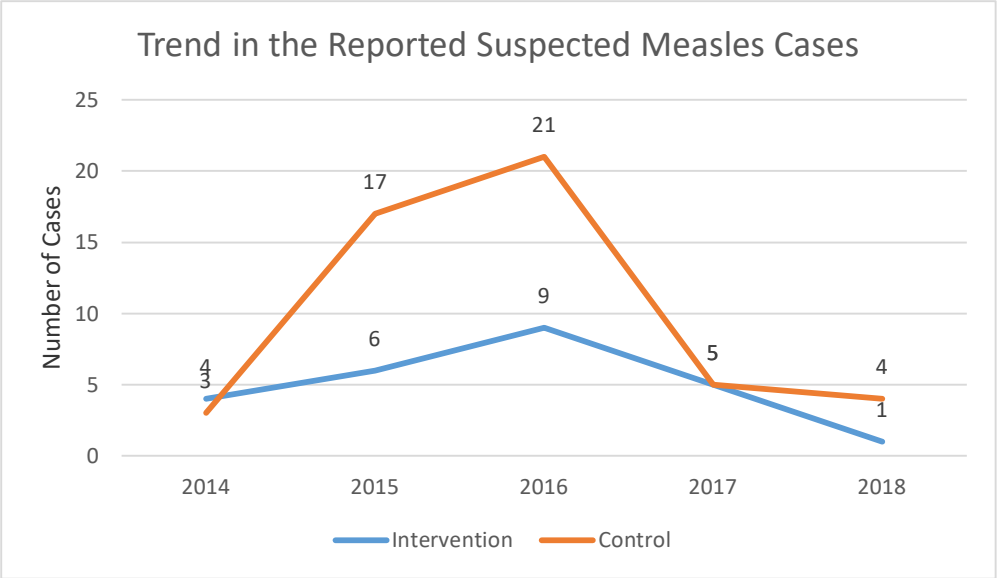


Figure 4: Trend in reported suspected cases of Measles

Comparison of the trend in facility attendance showed a similar trend between intervention and control arms of study (Figure 5 & Figure 6).

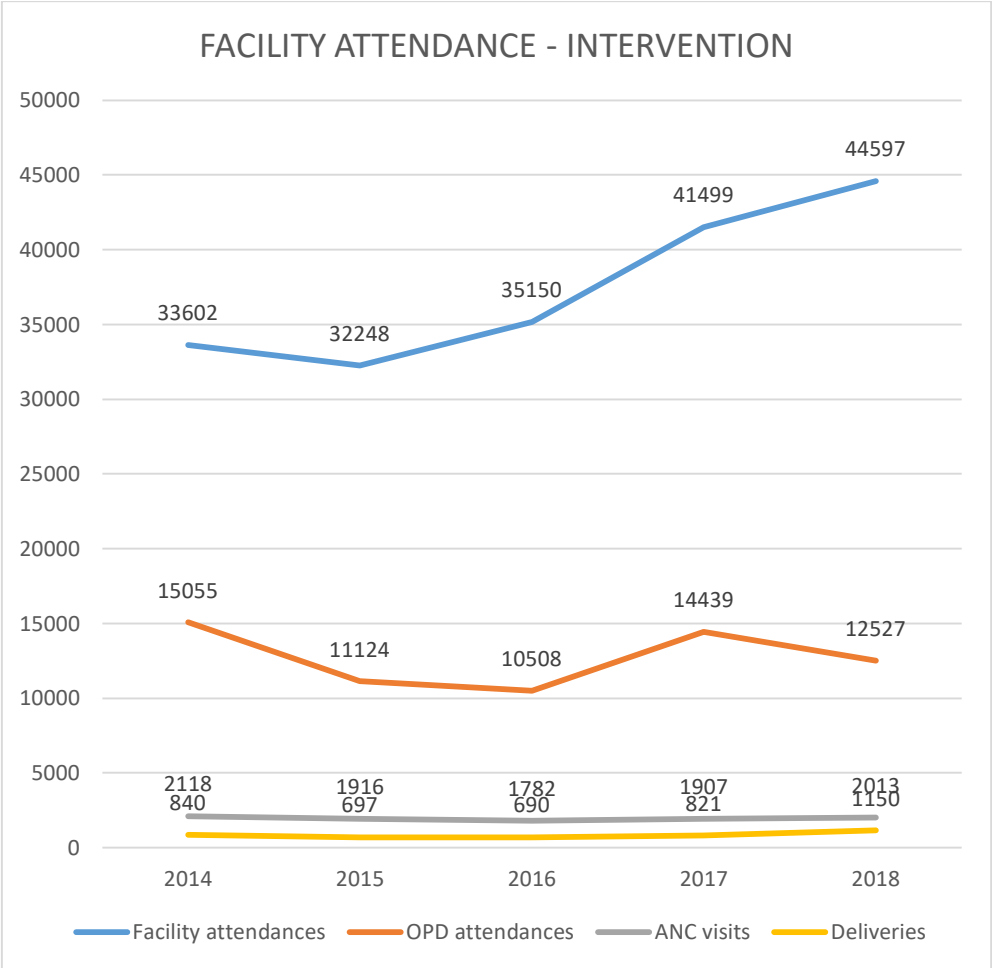


Figure 5: Trend in selected services from the DHIS, Intervention arm

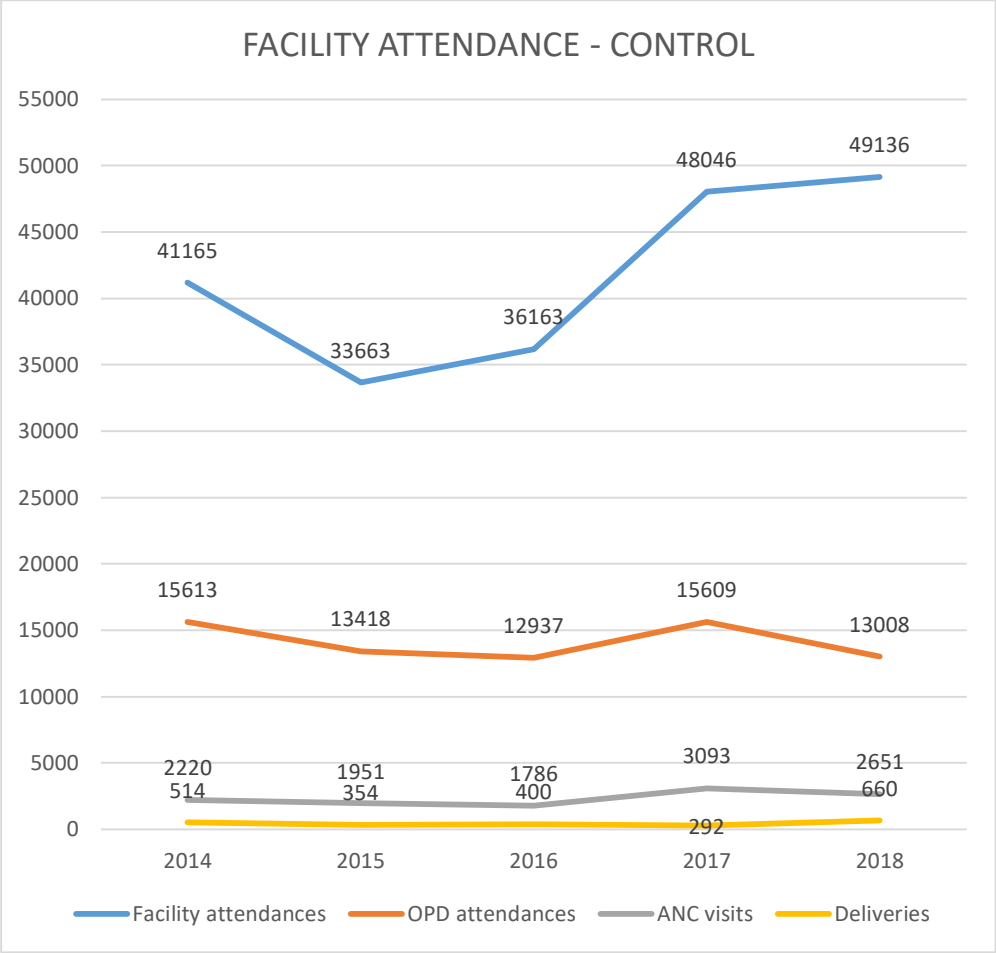


Figure 6: Trend in selected services from the DHIS, control arm

The estimated variance for each level of the cluster sampling indicates that the greatest variation was generally between LGAs (Table 14).

Table 14: Variance and ICC values for the cluster sampling

	Variance (logit)			ICClogit		
	LGA	ward	village	LGA	ward	village
Up-to-date	0.390	0.212	0.062	0.099	0.054	0.016
At least one vaccine	1.838	0.115	0.310	0.331	0.021	0.056
Penta 1 on time	0.477	0.116	0.121	0.119	0.029	0.030
Penta 2 on time	0.476	0.140	0.111	0.118	0.034	0.028
Penta 3 on time	0.649	0.257	0.063	0.152	0.060	0.015
3 penta doses in children 6-23months	0.615	0.224	0.119	0.145	0.053	0.028
Measles on time	0.396	0.158	0.039	0.010	0.041	0.010
Attend ANC[a]	0.352	0.455	0.181	0.082	0.106	0.042
Ever had measles[a]	0.482	0.093	0.034	0.124	0.024	0.009

NOTE: ICClogit – calculated assuming residual error is pi^2/3. Wu *et al*, 2012 Contemp Clin Trials, 33(5): 869-880. Comparison of methods for estimating the intraclass correlation coefficient for binary responses in cancer prevention cluster randomized trials.
[a]Small numbers of positive or negative values therefore variance and ICC are less precise

7.3 Degree of engagement

The WDCs were involved in the mobilization of the communities for specific immunization campaigns before the intervention. Information about the campaign was given to the WDC and TRLs to announce. This was not done for RI. According to some of the leaders: **"***Routine immunization … normally is for those that are working in the health facility. Our team don't interfere."(WDC member Obudu). "I am not sure we do anything in routine. It is only when they send letters for campaign immunization"* (Religious leader, Etung). It was generally assumed that the mothers were aware of the RI days. The PHC Coordinator in Biase said *"…women know about our routine immunization because it is what we have been carrying on for a long time …". It is only during campaigns that we now involve a larger group but for the routine immunization every community member knows that every Thursday or Wednesday." (Health worker, Ikom).*

Following the training there was more interest among the leaders on RI activities. In Etung LGA, the TRLs established a monthly contribution by the men to hire a boat and support the maintenance of the cold chain in their locality. They also provided petrol for motorcycles for the health workers during outreach. Similarly TRLs in Itu-Agwagune provided a boat to the health workers to convey vaccines to the riverine communities. In Abijang (Etung LGA) the Health Centre, which was located up a hill where the well-to-do members of the community lived, was relocated to the health post down the hill to facilitate access to the majority of the members who had complained about climbing the hill to access care. In Mkpot (Etung LGA) a foundation was laid for a house for the Ward Focal Person who was living outside the village. The community also provided accommodation for the health staff in Mkopt (Etung LGA) and Ukwop-Eyere (Biase LGA). Yet another community in Obudu LGA (Utugwang) built a bridge they called "monkey bridge" to facilitate access by the health workers to a hard-to-reach community.

7.4 Mechanism of interaction

The findings from the FGDs and key informant interviews at baseline showed that the Health Workers interacted with the WDC and the TRLs through formal and informal meetings to sensitize them to mobilize the community for immunization campaigns. The Health Workers also send letters to churches and schools to inform them of forthcoming campaigns. It could be deduced from the analysis of the post-intervention qualitative study that the TRLs in the intervention arm did not wait for the letters from the health workers; they actively shared information about RI in their domains. *"We do that every month based on our [RI] schedule" (RL, Biase). "Town criers will announce round the village about the immunization" (TL, Etung); "Time to time in the village when we have the village meeting I share this information to all the women." (TL, Ikom); "For the past year information use to go round for vaccination on the stipulated time that all nursing mothers and pregnant women should go to the facility at a stipulated time to take the necessary vaccines. So that use to take place almost every week …" (TL, Obubu).*

The WDC members visit health facilities as part of their routine supervision and monitoring of the health facility. However, at baseline, the TRLs reported that the level of communication

between them and the health workers was inadequate. This was reflected in the quotes below:

"Communication from the clinic to us is not sufficient enough."(TL Obudu). "There should be more contact between the religious leaders and the health staff to enlighten us more." (RL, Biase).

The training provided an opportunity to foster stronger and focused interactions between the health team and these community influencers. In response to a question on whether health workers share information on RI with the TRLs at post-intervention responses like *"no they hardly do"* (TL, Calabar) were obtained in the control arm while the intervention arm reported *"they use dashboard to share information …" (TL, Biase)*. This is an indication of better communication following the intervention.

7.5 Knowledge, attitude and beliefs towards vaccination

It was found from the baseline qualitative study that respondents were generally knowledgeable and had positive attitude towards vaccination. They believed vaccines prevent their children from acquiring deadly infections and attribute low deaths of children to vaccination. At post-intervention the TRLs in three of the four intervention sites (Biase, Etung and Ikom) and one of the control sites (Odukpani) displayed good knowledge on how vaccines work.

Qualitative data did not reveal changes in the attitude and belief of the respondents. At baseline there were responses like:

"*Some just stick to taking herbs. I met a lady who told me that ever since she got pregnant until she delivered she never visited the hospital; that she takes herbs. She said she doesn't want anybody to give her child injection so that the child will not become sick. (RL, Biase). "There is real irony in the belief of our people that immunization makes a child not to walk well. They belief that when they bring their children as healthy as they are that the injection used will further paralyse the child. So instead of taking a healthy child to the centre for immunization I should take the one that is sick." (WDC, Etung)*.

These responses are indications that the fear of side effects can hinder vaccine uptake. This may have contributed to non-impact on the proportion of fully vaccinated children in this study as the TRLs at the post-intervention qualitative study still mentioned these as a common reason for poor uptake of vaccines. Knowledge about the causes of fever was similar in the two arms of study at post-intervention. However, while in the control arm a respondent said the mothers did not know why their children had fever after vaccination [*"that is the most reason why someone fear to go and take immunization. That fear that when you immunize your child he will be sick. They don't know why" (TL, Biase)];* a respondent in an intervention arm provided support for the mothers [*"we feel that the mothers are always afraid of coming back to the health centres but we keep encouraging them and we advise them that it is normal …" (TL, Biase)].*

More communication, particularly by the TRLs, on this will be required to change this notion among the caregivers.

7.6 Heterogeneities

There was a difference in the starting proportions of children vaccinated by geographical zone and LGA. However, there was no evidence of any heterogeneities in the effect of the intervention using interaction tests by age-group or distance to health facility. There was no consistent evidence by geographical zone or whether the setting was classified as hard-to- reach.

7.8 Internal validity

There was no differential attrition since we used cross-sectional surveys with different children at each survey. LGA was used as the unit of randomization to prevent contamination, and the study design avoided adjacent wards for control and intervention arms to prevent spillover. It is possible that differential bias arose from the greater number of immunization cards being seen after the intervention, however it is not obvious in which direction the bias would go.

7.9 Cost of the intervention

The cost of the intervention was obtained from the accounting records for expenditures incurred in the course of implementing the intervention. The expenditures covered administrative cost, targeting cost, cost of developing and printing of the training tools, staff training, implementation, monitoring cost, and user cost based on the J-PAL costing guidelines (Jameel, 2019).

The perspective for the costs is that of the implementers of the interventions. Additionally, the opportunity cost of the TRLs for the time spent for the interventions was converted to the costs of the salary for these people for these days.

The costs reported covered the period from the inception of the project in April, 2016 to the final data collection in February, 2019. The exchange rate used was N306.30 to a US Dollar being the Central Bank of Nigeria's "Central Rate" exchange rate [6]. The costs and the outcomes were "discounted" to 2019 using the Nigerian Central Bank Treasury Bill rate at the end of each year as per the following sources. This is in accordance with Drummond (1997) [7].

	2016	2017	2018	2019
Treasury Bill Rate %	13.97	13.01	10.91	Present value = 2019

https://www.cbn.gov.ng/rates/mnymktind.asp?year=2016
https://www.cbn.gov.ng/rates/mnymktind.asp?year=2017
https://www.cbn.gov.ng/rates/mnymktind.asp?year=2018

The costs for the intervention are outlined in the **Table 15: Higher level costs** below and are listed according to the J-PAL Costing Guidelines (J-PAL, 2019). Please note that the costs have been calculated in terms of: 1. full costs including investments to get the TRL program running, but excluding the costs of managing the project, as well as 2. an estimate of the marginal costs of reproducing the intervention in adjacent additional wards building on the investments already made which need not be repeated. The high level total costs amounted to 4,738,395 NGN (15,470 USD). The average and marginal costs per ward were 394,866 NGN and 224,991 NGN, respectively.

The estimate for averting measles was estimated based on the estimated short term cost of measles illness (i.e. cost of treatment, transport, caretaker lost wages). This was estimated to be 7 USD per care-seeking case averted (Ozawa et al, 2017). The cost of care averted was estimated based on the number of cases of measles reported on the DHIS.

Table 15: Higher level costs

		NGN	USD	NGN	USD
1	**Base year: 2019**			**Discounted to 2019**	**Discounted to 2019**
2	**Total program cost[1]**	4'652'276	15'189	5'929'090	19'357
3a	**Number of beneficiaries (wards[2])**	12 wards	Wards	15 wards	Wards
3b	**Average cost per beneficiary (ward)[3]**	387'690	1'266	394'221	1'287
4a	**Number of beneficiaries (children who could benefit)**	1276	Eligible children	1599	Eligible children
4b	**Average cost per beneficiary(child who could benefit)[4]**	3'646	12	3'707	12
5	**Marginal cost to add a beneficiary (ward)[5]**	224'991	735	216'361	706
6	**Exchange rate information[6]**	306.3		306.3	

[1] This includes administrative cost, targeting cost, cost of developing and printing of the training tools, staff training, implementation, monitoring cost, and user cost.

[2] Number of wards the intervention was carried out.

[3] Average cost per ward.

[4] Average cost per eligible child.

[5] This the marginal cost of adding one ward. The cost of developing the training tools and advocacy visit to communities were removed because these were one off activities. Also removed is the monitoring of community meetings as this was done by the Ward Focal person.

[6] Bank rate: This was accessed on 23.05.2019 to establish the exchange rate at November 30th 2018 being the end of the month project interventions were completed, at the website: https://www.cbn.gov.ng/rates/ExchRateByCurrency.asp?CurrencyType=$USD

[7] Drummond M et al. Methods for the economic evaluation of health care programmes. 2nd ed. Oxford. Oxford University Press. 1997 accessed 10.12.2019 at websitehttps://www.nlm.nih.gov/nichsr/edu/healthecon/drummond_list.html

The following table details the actual costs as well as the intervention running (variable) costs excluding fixed costs of start-up investments. The latter are the pre-testing of the training tool,

the consultancy services to develop the training materials, and the development of the dashboard.

Table 15: Detail of costs under two scenarios: full costs and intervention running costs only.

		Scenario 1	Scenario 2
	Basic cost collection template	**Total costs NGN (Sub totals used for the ingredients)**	**Intervention running cost NGN (without investments**
1	**Programme administration and staff cost**		
	cost of full time staff		
	Administration		
	Stationary	39’850	39’850
	Printing & photocopies	14’500	14’500
2	**Targeting cost**	-	-
	Advocacy visits to 8 LGAs and government offices/agencies	224’000	224’000
3	**staff training**	-	-
	TOT meetings to review intervention messages/trainings	-	-
	Restoration/lunches during training	235’735	235’735
	Printing of training materials (cost above for printing and papers)	10’500	10’500
	Markers (1 packet of markers)	2’000	2’000
	flip chart	6’500	6’500
	Pre-testing of training tool	143’850	-
4	**Participants training**	-	-
	Participants tea break and lunch (TRL)	1’480’000	1’480’000
5	**Implementation and program material cost**	-	-
	consultancy services for development of training materials	1’500’000	-
	Production of handbook on vaccination (leaders with a heart for vaccination manual-development/printing), other graphics and flash cards	8’200	8’200
	Flash cards *	143’531	-
	folders, note pads and pens	35’330	35’330
	development of dash board	165’000	-
	Transportation for Trainers	183’100	183’100
	Communication for Trainers	36’000	36’000
	Health workers' training	-	-
	Defaulters' register	7’200	7’200
6	**User costs**	-	-
	Opportunity cost of TRLs time	579’600	579’600
7	**Averted cost**	-	-

	Cost of care for Measles	(186’620)	(186’620)
8	**monitoring costs**	-	-
	Costs incurred by field staff for monitoring WDC meetings	24’000	24’000
	Grand Total	**4’652’276**	**2’699’895**
	Discounted to 2019	**5’929’090**	**3’254’075**

* 4 year life annual costs

7.9.1 Cost-effectiveness analysis

The effect indicators, which were obtained through the study, are illustrated below including a calculation of the **counterfactual**, which would have resulted, based on the results of the control arm of the study. These were then used to calculate the **net effect** of the intervention arm. The counterfactual represents here the results, which would have been attained in any case, if no intervention had taken place.

The control percentage changes between baseline and end-line were applied to the end line ‘intervention’ population to derive the counterfactual effect in numbers. Then, the counterfactual effect in numbers was deducted from the effect actually derived in the intervention population to obtain ‘net’ effect. These in turn, according to procedures recommended in Drummond (1997) were discounted to 2019, as were the costs.

Table 16: Net effect of the intervention in selected outcomes.

	Control				Intervention				Population (as if intervention)	Control		Intervention		**Net effect**	**Discounted to 2019**
	Before		After		Before		After								
	N	%	N	%	N	%	N	%		Effect %	Effect	Effect %	Effect		
Not vaccinated	125	9.6%	128	10.0%	87	6.7%	5	0.4%	1,250	0%	0	-7%	-83	-83	-104
Partial	551	42.4%	449	35.2%	619	47.7%	610	478%	1,271	-7%	-89	0%	0	89	112
Penta 1	531	46.3%	496	43.0%	511	46.1%	694	59.5%	1,157	-3%	-35	14%	162	197	247
Penta 3	273	27.9%	243	24.1%	226	23.5%	292	29.4%	1,007	-4%	-40	5%	50	91	114
measles	155	23.9%	154	24.4%	124	19.1%	240	41.0%	585	0%	0	22%	129	129	162
2 TT vaccines in mothers	989	76.0%	970	76.1%	1022	78.8%	1070	83.9%	1,270	5%	64	6%	76	13	16
Attendance at ANC	1114	856%	1143	89.6%	1148	88.5%	1240	97.2%	1,278	4%	51	8%	102	51	64

For the actual calculation of the unit cost, the total intervention costs were divided by the net effect of the intervention on a series of outcomes. The incremental costs assume being compared to not doing anything (controls). As well, the estimated total marginal cost was divided by these same net effect values to estimate the additional cost per unit of effect obtained if the intervention were to be implemented in additional wards in the future.

In the table below, the incremental unit costs for full cost and for running cost are summarized:

Table 18: Incremental unit costs

	Costs (USD) per unit of outcome			Discounted Costs (USD) per discounted unit of outcome		
	Net effect (numbers)	**Full cost per unit**	**Running cost per unit**	**Net effect (numbers)**	**Full cost per unit**	**Running cost per unit**
Cost of intervention		**15'189**	**8'815**		**19'357**	**10'624**
Unit cost per ward	12	1'266	735	15	1'287	706
Unit cost per TRL trained	97	157	91	122	159	87
Absolute value for reduction of unvaccinated	83	183	106	104	186	102
Timely vaccination for Penta 1	197	77	45	247	78	43
Timely vaccination for Penta 3	91	167	97	114	170	93
Timely vaccination for measles	129	118	68	162	119	66
Number of Measles cases care averted	258	59	34	323	60	33
Number of mothers that attended ANC	51	298	173	64	302	166
Number of mothers that had at least 2 doses of TT	13	1'168	678	16	1'210	664
Number of children who could benefit	1276	12	7	1599	12	7

The first set of unit costs reflect the costs per unit of net effect to replicate the interventions in a fully new setting. The second set of unit costs reflect the estimated cost per unit of net expected benefit in a setting where the initial investments are not necessary, in this case an adjacent ward.

All outcomes showed net beneficial effects. The net effect also provides an approximate idea of 'how hard' is to achieve good outcomes; for example, the net effect of timely Penta 1 is more than twice the net effect of Penta 3; suggesting that the latter may be more difficult to achieve.

The costs of the intervention per ward is an average based on the random sample of wards. It is difficult to estimate any economies of scale for implementing in larger wards without further collection of data. The average cost per TRL (here about USD 160) trained for the intervention gives another indication for estimating the cost of implementation on a wider scale: number of TRLs x USD 160 for a ball park figure for the replication in a fully new setting.

Please note that it was not possible to separate out the costs per component as these were conducted concurrently and any separation would be a mere estimate. The full total costs as well as the full running costs used provide a most conservative unit cost calculation.

The unit costs are less advantageous for mother-related events, which seems consistent with the EPI children vaccination focus of the intervention.

It is appealing that, for example, the cost per measles case averted is only 60 USD. The Measles & Rubella Initiative[1] has estimated that:

- Measles is the leading cause of death among children despite the availability of a safe and effective vaccine for over 50 years
- More than 10 million people are affected by measles each year particularly in Africa and Asia
- In developing countries where children are often malnourished and have limited or no access to medical treatment, measles kills easily
- Outbreaks cost money, time and lives when public health authorities spend time tracing potential contacts, and spend money treating people in hospital. Sick children stay home from school and parents stay home to care for them.
- 75% of global measles deaths occur in just six countries - India, Indonesia, Nigeria, Pakistan, Democratic Republic of Congo, and Ethiopia.
- The measles vaccine will save more lives before 2020 than all other vaccines combined.
- Due to its effectiveness, low cost and impact, the rate of return for the measles vaccine is $58 for every $1 invested

8.1 Substantive and statistical significance of the findings

Generally, there was no difference in the proportion of children that were up-to-date on vaccination between the baseline and the end line (p=0.69). However, the intervention was effective in reducing the proportion of non-vaccinated children from 7% at baseline to 0.4% at the final evaluation (p = 0.001). The non-impact on up-to-date vaccination could have been accounted for by the weak link in the intervention caused by not sharing data directly with the community members as planned. The opportunity for the community to be part of spurring themselves to identify resistant and defaulting households was missed which could have ensured encouraging caregivers to complete their wards' vaccination schedule. It is also possible that the weak health system also accounted for the non- impact on up-to-date vaccination status. The theory of change was based on the assumption that the recommended vaccination schedule was adhered to by the health facilities. When vaccination services are spaced out and only available when the health system plans to provide them, caregivers are unable to vaccinate their children when they are due for the vaccination.

It is also worthy of note that though the WDCs in the control arm met regularly and those in the intervention arm did not before the intervention, vaccination coverage at baseline was similar in the two arms of study. This may imply that WDCs need to include RI in their agenda for there to be an improvement in immunization uptake. The frequency of vaccination services was rather few and with few or no outreaches in some settings because of inadequate number of staff.

There was a wide variability in the timing of vaccination. Most children had late vaccination; less than 50 percent of the children received Penta 1 on time in both arms of the study at baseline. While there was a 3 percent decrease in the control arm, the intervention arm had 14 percent increase at end line evaluation and the difference was statistically significant (OR 1.96; 95% CI

[1] https://www.cdc.gov/globalhealth/measles/pdf/measles-rubella-fact-sheet.pdf

1.53 – 2.53; p <0.001). Similarly there was a 4 percent decrease in timely uptake of Penta 3 in the control arm and a 5 percent increase in the intervention arm (OR 1.55; 95% CI: 1.14,2.12; p= 0.005). Measles vaccination timely vaccination remained the same in the control arm at the end of the intervention while there was almost a three-fold increase in the odds of receiving the measles vaccine on time in the intervention arm (OR 2.81; 96% CI: 1.93-4.1; p<0.001). All the observed differences were statistically significant. The variability in the timing of vaccination may be attributed to the differing frequencies in vaccination services per location. Some locations provided weekly service, others provided services twice a week and others once a month. There could also be errors in the recording of the date of vaccination by the health workers.

Drop-out was assessed between Penta 1 and Penta 3 vaccination among those 14 weeks and above. There was a 5% increase in the proportion of children that had received Penta 1 that also received Penta 3 at end line in the intervention arm. The difference between control and the intervention arm was statistically significant (OR=1.66: 95% CI: 1.08, 2.55; p=0.02).

The analysis of reported cases of suspected Measles on the DHIS platform showed a sharp reduction in the number of cases of Measles in 2017 in the two arms of the study. While the number of cases continued to drop in the intervention arm the control arm showed a rise at the endline. The survey result also showed a similar impact: the proportion of measles cases dropped from 5 percent to 3 percent and from 9 percent to one percent in the control and intervention arms respectively. The observed difference was statistically significant (p=0.001). This observation could be attributed to the Measles campaign that was carried out across all the LGAs in the State in March 2017. Children aged 9 months to 5 years were given the Measles vaccine during the campaign. The intervention was introduced in May 2017 and this may have sustained the gains of the Measles campaign in the intervention arm of the study.

Routine data from the DHIS on the pattern of attendance in the health facilities showed a trend in attendance which were similar in the intervention and control arms except for a spike in ANC attendance in the control arm. Data from the survey showed that the intervention may have impacted on the level of utilization of the health facilities by mothers. Mothers in the intervention arm were more likely to attend ANC (p <0.001) and received at least two doses of tetanus toxoid during pregnancy (p = 0.02). The observed difference in the routine data from the DHIS may be attributed to the Safe Mothers Giving Birth program that was reported in some facilities in the control arm. This Program targeted mothers to promote safe delivery and improve the number of births attended by trained personnel.

The perception of clients on care received did not change after the intervention as clients reported being satisfied with care at baseline and final evaluation. The major reason for satisfaction of the mothers was the fact that they were not asked to pay for vaccination. However, there was a difference in attitude of the TRLs on the sense of ownership of services in the facilities. In two control sites (Abi and Odukpani LGAs) the TRLs did not think it was their responsibility to know the frequency of vaccination but that of the health worker. According to one of them

> *"that is the civic responsibility of the health workers. Our own is to tell us (i.e. the health worker to tell the leader) on so so day we are going to do this and we inform our subjects, tell us the venue and we direct them to go there." (Traditional Leader, Odukpani)*

Such a passive stand does not enhance positive attitudes towards supporting the health workers. On the contrary the leaders in the intervention arm became the change agent and could communicate vaccination confidently.

8.2 Comparison of findings with existing literature

Several studies have assessed the impact of various interventions on full vaccination coverage among children less than 2 years. These range from monetary incentives to disincentives (Maluccio, 2004; Robertson et al 2013) to provision of monthly reliable vaccination service (Banerjee, 2013). Pooled data for the interventions on incentives showed that non-monetary incentives were more likely to improve full vaccination (OR 6.6; 95% CI3.93 -11.28); ensuring availability of vaccination service through outreach also had a positive impact on full vaccination (RR 3.09, 95% CI 1.69 to 5.67). Monetary incentives, on the other hand, had little or no effect (RR 1.03, 95% CI 0.83 to 1.28) in improving full coverage of vaccination in children (Oyo-Ita et al, 2016). Our study showed no difference in the proportion of children fully vaccinated by age. The observed difference in the impact of the interventions may be due to differences in the interventions themselves. While the monetary incentive studies examined conditional cash transfers targeting poverty reduction, our study targeted improving the knowledge of the community gate keepers to influence their communities. These two studies could be said to be interventions that support “pulling” (request for service) from the recipients. The non-monetary incentive on the other hand (a reward to caregivers for attending the health facility) and the outreach directly targeted vaccination services and supported “pushing” of the services to the recipients. It may be that interventions that directly target vaccination services are more likely to improve full vaccination coverage. Outreach, in particular has been reported to improve parents-health worker interactions thereby improving vaccine uptake. On the other hand, timeliness of vaccination in our study setting was poor and most children had late vaccination which may plausibly be due to the weak health system. It could, therefore, be inferred that if the health system is strengthened in our setting, there is high possibility of achieving timeliness and full coverage with the TRL intervention particularly as the non-vaccinated are reached. While the sustainability of the monetary incentive is questionable, our intervention has a good chance of being sustainable as it is embedded into an existing structure. This is more so as it drew support from the State PHC Agency, the body that is directly responsible for the delivery of vaccination in State.

The uptake of DTP is usually used as a proxy to assess the success of vaccination uptake globally (UNICEF, 2013). A meta-analysis of data from interventions that target educating caregivers at the community level showed 68% increase in the uptake of DTP3 by one year of age (RR 1.68, 95% CI 1.09 to 2.59), (Oyo-Ita et al, 2016). These studies included evidence-based discussions (Andersson et al, 2004) and use of pictorial messages in the community (Owais et al, 2011). In our study, which is also a community based health education intervention, there was more than two-fold increase in the odds of receiving Penta 3 among children aged 6 to 23 months in the intervention arm in the end line evaluation (OR=2.20; 95% CI:1.53, 3.16; p<0.001).

Drop-out in Penta 3 vaccination was estimated to have dropped from 16% to 11% in the intervention arm after the 18 months of intervention in our study. In a facility-based longitudinal study in South–East Nigeria, the use of telephone to recall caregivers who failed to keep their vaccination appointment was shown to reduce dropout rate from 20.8% to 14% within a month (Nwokeukwu, HI et al, 2015). Another study in Kenya targeting reduction in DTP3 dropout rate with text messages reported a reduction in the drop-out rate of DTP3 among children under 12 months of age (OR 0.2, 95% CI: 0.04–0.8), (Haji et al, 2016). Reasons for DTP3 dropout has been attributed to demand side factors rather than supply side factors (Gosh A and

Laxminarayan, R, 2017) in rural India. To reduce DTP3 dropout rate, therefore, interventions to drive the demand should be considered.

8.3 Limitations of the study

In light of more vaccination cards being seen in the intervention arm at midterm and end line evaluation it is possible that there was differential bias though the direction is difficult to ascertain. Caretakers of children without vaccination cards may be prone to recall bias, either forgetting vaccinations or saying that vaccinations had taken place when they had not. The evidence on the direction and degree of over- or under-estimation of vaccination status based on different sources is conflicting and embrace a large range of possibilities (Miles 2013). Since the proportion of vaccination cards tended to increase with the intervention but remained the same in the control arm, the estimated effect of the intervention may potentially have a bias.

Additionally, the cluster randomisation of allocation units may have posed challenges in terms of comparability. However, these have been taken into account in the statistical approaches used to report the findings. The analysis focuses on changes between surveys in the same locations by including village, ward and LGA in the model as random effects.

Finally, as in many other similar studies, we cannot be certain about the sustainability of the effects in both senses: whether with time TRL practices may get optimised and produce more benefits or TRL practices may somehow fade-out particularly when there is cabinet change and new stakeholders are appointed into office.

9. Specific findings for policy and practice

9.1 Policy makers

The TRL trial provides evidence of the effects of an intervention to improve vaccination rates. In the current context when vaccination coverage rates seem to experience a stagnation, the findings of this trial are even more crucial.

The TRL intervention is a demand-focused intervention. Policymakers need to consider interventions that drive demand for vaccination to ensure optimal uptake of vaccination even among the possible resistant groups in the community. This is critical in order to build holistic strategies that build upon the complexity of vaccination programmes (Oyo-Ita 2016). This can be seen on the impact on the non-vaccinated children, a critical outcome which targets the most vulnerable populations (Bosch-Capblanch 2012). It is expected that the shared ownership displayed by the TRLs can sustain the coverage of vaccination.

Inclusion of TRLs in the planning, implementation and evaluation is useful in ensuring support from the community. Based on the findings of this study it is recommended that the National and State P Agencies adapt the use of TRLs in their guidelines for improved vaccination coverage particularly as it has the prospect of reaching the unreached in the community. Focus needs to be put on using them to address fears about vaccination. As key influencers they may be able to persuade caregivers on the common discomforts associated with vaccination like fever and pain at the injection site. This may contribute to boosting the up-to-date vaccination rate among those who may be deterred from completing the schedule as a result of these side effects.

It is also recommended that the health system be strengthened to ensure that a demand-focused strategy like TRL achieves its full potential. For this, policy makers should ensure adequate personnel and logistics to support more frequent vaccination sessions. Else, this could deter the efforts of the influencers and cause a diminishing return in their inputs.

9.2 Programme and Implementation

The TRLs can be seen as the untapped resources in the community that the implementers and practitioners can take advantage of to boost and sustain vaccination coverage. It is, therefore, important that health workers involved in vaccination engage the TRLs actively for RI. However, this may not be said of up-to-date with vaccination. For a child to be up-to-date with vaccination the health system needs be strengthened to ensure regular access to vaccination services. The synergy between different strategies cannot be overemphasised.

The cost of averting one measles case is minimal when compared to the cost of the disease with its possible complications. This is a useful finding for policy influencers to adapt to advocate for the formal adoption of the strategy to boost vaccine coverage.

It has been observed that WDCs in the control communities held regular meetings before the intervention. However, the vaccine coverage in their localities were similar to that of the intervention arm at baseline. Programme implementers should note that WDC meeting may not translate to improved vaccination coverage if a targeted plan is not developed to utilize the forum to constructively include RI in their agenda and share vaccination information with the Committee regularly. By so doing the health team works with the community towards a defined target. Program implementers should, therefore, adopt means of including RI in the agenda of the WDC and follow up by updating the community on the progress made.

Programme implementers should also avail themselves of the resources at the community through the key influencers and harness such resources to reach the unreached.

9.3 Generalisability/ External validity

The TRL intervention is feasible in low-and-middle income countries where the T are key influencers in their communities. Several interventions target mothers or caregivers to boost vaccination coverage. The TRL targets the leaders to reach the caregivers who are mostly mothers. Similar settings (like what is obtainable in most low-and middle-income countries) may have similar impact of the intervention. It is more likely to be impactful where the traditional and religious leadership are embedded in one system. Furthermore, even if TRL in Cross River state are under the same social system, there are large differences between TRL in different wards. So we could expect to see similar results in areas that have different TRL setups.

From the midterm survey there is an indication that the training sessions need not be too frequent (which may cause fatigue) but frequent enough to keep the tempo and make the health worker accountable to the leader. How the effect will be in a long term may depend on the level of interaction of the leaders with the health care workers to some extent.

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Annex A: Sample size

The sample size was achieved as planned.

	LGA	wards	villages	Individuals
Required by s-s calculation per arm and survey	4	3 per LGA = 12	4 per ward = 48	25 per village = 1200
Baseline survey				
control	4	12	48	1301
intervention	4	12	46	1297
Mid-term survey				
control	4	12	48	1268
intervention	4	12	46	1302
Final survey				
Control	4	12	48	1274
intervention	4	12	46	1276

Annex B: Map showing LGAs in the study location