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

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Executive summary

Coverage for routine vaccines falls short of the global target of Gavi, the Vaccine Alliance. Coverage is particularly low in low- and middle-income countries. A recent survey shows that less than a quarter of children 12–23 months of age are fully vaccinated in Nigeria (NBS and UNICEF 2017). The reason for the low coverage is said to be multifactorial. Among these factors are poor parental knowledge and attitude.

A previous study used traditional and religious leaders (TRLs) in northern Nigeria to tackle the challenge of poor attitude demonstrated by parents towards polio vaccination. The study found that polio vaccination coverage had scaled up. The TRLs 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 TRLs in influencing vaccination uptake in Cross River State, Nigeria. Some experts have suggested the adoption of a multifaceted intervention to address gaps in vaccination based on local needs. Our study adopted such an intervention and included: training TRLs on vaccination, their leadership role and community mobilisation; training health workers to share vaccination data; and revitalising ward development committees.

Eight local government areas in Cross River State were selected for the study. The TRLs had eight training sessions during an 18-month intervention period. Health workers had three training sessions to summarise data and share vaccination data with the TRLs. Ward development committees were reactivated. A total of 2,598, 2,570 and 2,550 children aged 0–23 months of age were assessed through baseline, midterm and endline surveys, respectively.

The results showed that the intervention had no impact on the proportion of children with up-to-date vaccinations ($p = 0.69$). However, it was effective in reducing the number of unvaccinated children from 7 per cent to 0.4 per cent ($p = 0.001$). It was also effective in improving the timeliness of the later vaccinations in the schedule: pentavalent 3 (odds ratio (OR) 1.55; 95% confidence interval (CI): 1.14–2.12; $p = 0.005$) and measles (OR 2.81; 95% CI: 1.93–4.1; $p < 0.001$). These impacts had already been observed by the midterm 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 USD34 per additional measles case averted.

The TRLs are untapped community resources who 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. Their impact has a good prospect of being sustainable, as it drives demand and the TRLs take on responsibility for supporting vaccination services in their respective communities.

Vaccination programme managers and health workers involved in providing vaccination services should, therefore, advocate for the active engagement of TRLs in planning, implementing and monitoring vaccination services. Policymakers should incorporate the engagement of TRLs in vaccination delivery policies. There is, however, a need to explore the reason for the intervention's lack of impact on the proportion of children with up-to-date vaccinations.

Contents

List of figures and tables

Abbreviations

ANC	antenatal care
DHIS	district health information system
DTP3	three doses of diphtheria, tetanus, pertussis
FGD	focus group discussion
LGA	local government area
L&MIC	low- and middle-income country
PHC	primary healthcare
RI	routine immunisation
TRL	traditional and religious leader
WDC	ward development committee
WHO	World Health Organization

1. Introduction

Vaccination prevents 2–3 million childhood deaths globally (UNICEF 2018). It is the single most effective means of controlling those childhood diseases for which vaccines have been found. Eradication of these diseases is also feasible if herd immunity for each vaccine is achieved and sustained. Global smallpox eradication was possible through vaccination.

Currently, tetanus has been eradicated in all but 14 countries. Similarly, polio is found in only three countries (including Nigeria), having been eradicated in all other countries. It is, therefore, a public health concern to reach the 90 per cent vaccination coverage target set in the Global Vaccine Action Plan (2011–2020) (UNICEF and WHO 2018) to reduce the morbidity and mortality of these diseases and subsequently eradicate them.

Six of the targeted childhood diseases (pneumococcal diseases, rotavirus diarrhoea, Haemophilus influenzae type b, measles, pertussis and tetanus) cause more than a third of childhood deaths globally and in the Africa region (WHO 2017). In an effort to reduce childhood morbidity and mortality, the World Health Organization (WHO) launched the Expanded Programme on Immunization in 1974, targeting six childhood killer diseases (polio, tetanus, diphtheria, pertussis, measles and tuberculosis).

Only 5% cent of children worldwide had received a vaccination in their first year of life at the launch of the programme (Trostle and Shen 2014). Rainey and colleagues (2011) reported a global increase in vaccination rates from the 1980s. Global coverage of three doses of the diphtheria, tetanus and pertussis vaccine (DTP3) increased from 21% in 1981 to 85% in 2017 (UNICEF 2018). Similarly, global coverage of the third dose of the polio vaccine and the first dose of the measles vaccine is estimated to be between 84% and 86% since 2010 (Feldstein et al. 2017).

This coverage level, however, falls short of the 90% target of Gavi, the Vaccine Alliance. Coverage is much lower in low- and middle-income countries (L&MICs), and Nigeria is one of 10 countries with coverage below 50% for DTP3 and the first dose of the measles vaccine (UNICEF and WHO 2018). The Multiple Indicator Cluster Survey 2016–17 in Nigeria reported 21% full vaccination coverage of children aged 12–23 months (NBS and UNICEF 2017).

Full vaccination coverage rates vary across the country, from 8.5% in the North West geopolitical zone to 50.2% in the South West (NBS and UNICEF 2017). Full coverage in Cross River State, located in the South South geopolitical zone, was 49.9% as reported by the Multiple Indicator Cluster Survey 2016–17 (NBS and UNICEF 2017) and 51.5% in the Demographic and Health Survey 2013 (NPC and ICF International 2014).

The reasons for the low coverage of childhood vaccinations are multifactorial. A review of grey literature on why children are not vaccinated in L&MICs showed that reasons may include issues around immunisation services, and parental knowledge and attitude (Favin et al. 2012). In a report that reviewed the Demographic and Health Survey 2013, children whose mothers found it difficult to reach the health facility, and who lived in socioeconomically disadvantaged settings, were less likely to be fully immunised (Adedokun et al. 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 immunisation systems, family characteristics, parental knowledge and attitude, and limitations to immunisation-related communication and information (Rainey et al. 2011). Stemming from the multifactorial reasons behind non- and under-vaccination of children, Rainey and colleagues (2011) suggested a multifaceted approach to bridge the gap in vaccination. The authors also noted that while it may be easy to address some factors, such as access to vaccination service, the factors that keep a child completely unvaccinated may be more difficult to tackle and may require locally developed strategies.

A Cochrane Systematic Review of interventions to improve vaccination coverage in L&MICs showed a paucity of quality interventions targeting improvement of vaccinations in this setting (Oyo-Ita et al. 2016). A literature review by Ryman and colleagues (2008) comes to a similar conclusion. In this study, we developed a multifaceted intervention centred on the use of TRLs in the primary healthcare (PHC) system for evaluation. The engagement of traditional and religious leaders (TRLs) in vaccination was reported to have contributed to the progress in polio vaccination uptake in Nigeria (Nwaze and Mohammed 2013).

TRLs are influential and 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; JHU CCP 2014). 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 traditional leaders for sustainable development (Arthur and Nsiah 2011).

In the study area in Nigeria, TRLs act as gate-keepers for their communities. Their permission is sought for any intervention or development in the setting. For this reason, the TRLs lead ward development committees (WDCs). WDCs were introduced into the PHC system in Nigeria following the Declaration of Alma-Ata in 1978. It is a structure that was set up to facilitate community participation in health and development (Abdulraheem et al. 2012).

Committee members – including women, men, youth, representatives of occupational groups and non-governmental organisations, and traditional birth attendants, along with the TRLs – were to liaise with the local government authority (LGA) to monitor and support PHC services in their locality. The WDCs identify the health and social needs of their communities and harness resources to meet those needs in collaboration with government and non-governmental organisations (Ezinwa 2017).

The WDCs' involvement in routine immunisation (RI) was limited. They were involved in mobilisation for vaccination campaigns. Health teams approached the TRLs 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 (Nwaze and Mohammed 2013). Similar influence has been reported in South Africa for HIV and AIDS prevention (SAfAIDS 2011). A Johns Hopkins University study 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 L&MICs in vaccination coverage, there is a dire need for evaluation of strategies 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 of where they are born, who they are and where they live (WHO 2012). A strategy such as the use of TRLs, therefore, needs to be evaluated to determine its impact on uptake of childhood vaccination.

This multicomponent intervention was designed to train the TRLs as key community influencers who will influence the WDCs and communities to support RI and improve uptake of childhood vaccination. This report evaluates the effects of the intervention in the targeted communities. The research questions 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 LGAs in Cross River State were randomly allocated to both the intervention and control arms. The intervention, which involved training TRLs and health workers, community engagements and strengthening the WDC, was delivered in the intervention arm but not in the control. Assessment was carried out at baseline, midterm and endline.

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

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 WDCs. It was designed to increase TRLs' knowledge of vaccination, to strengthen their leadership role, and to 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 engagement served as the platform for sharing information on vaccination with the community.

2.2 Outcomes

2.2.1 Primary outcomes

The primary outcomes were:

- fully vaccinated rates among children 0–23 months of age
- timely pentavalent and measles vaccinations
- rates of drop-out between pentavalent 1 and pentavalent 3.

2.2.2 Secondary outcomes

The secondary outcomes were:

- degree of community engagement: community members attending different types of meetings; qualitative assessment of knowledge, attitude and beliefs
- satisfaction of TRLs, communities, health workers and WDC members with the intervention
- increase in the use of other health services: treatment of common sickness in under-fives and antenatal care (ANC)
- costs and cost-effectiveness.

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

2.3 Theory of change

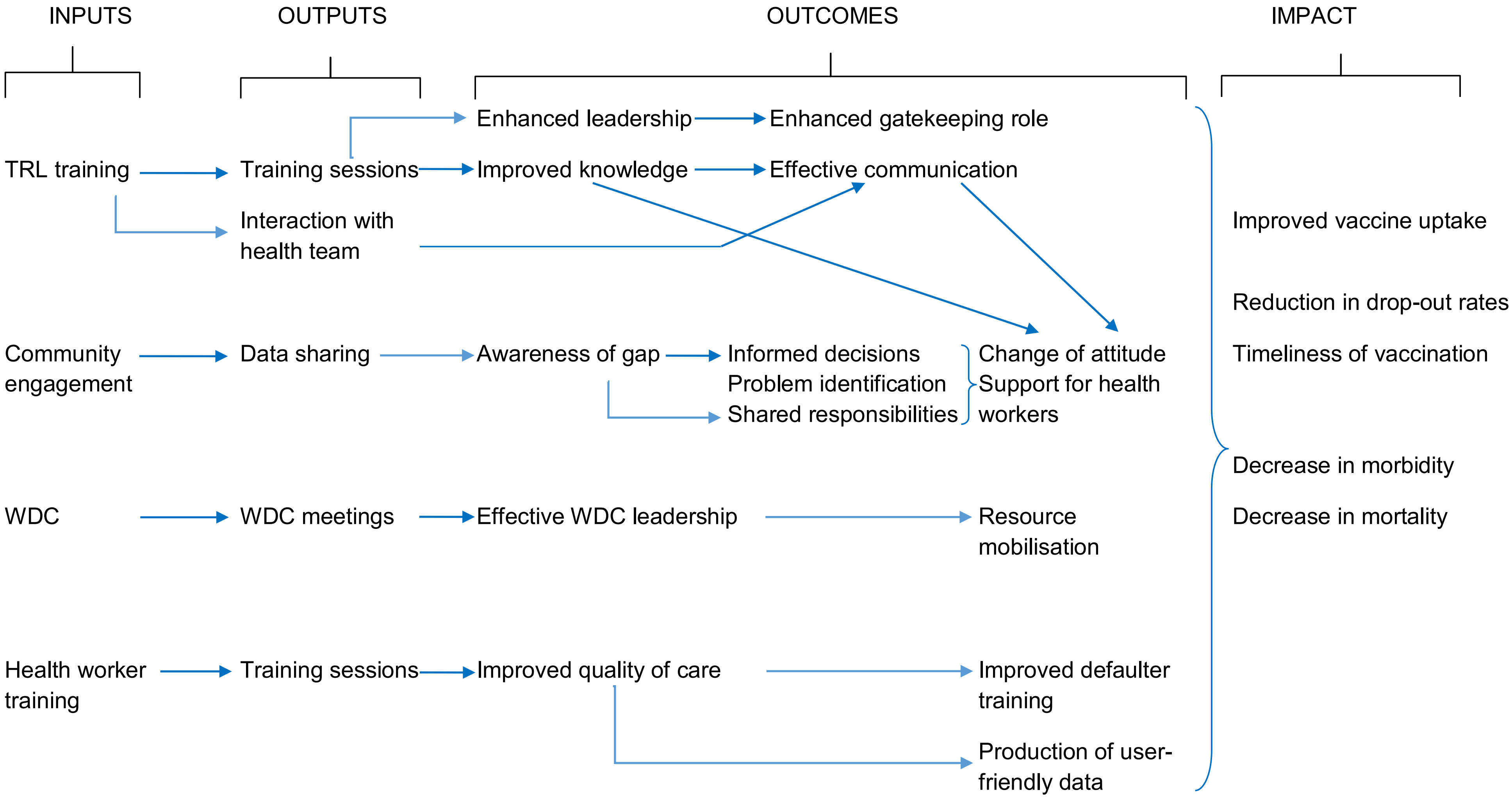
It has been reported that leaders do not understand their roles in enhancing the health of their communities, and so are less supportive of health workers (JHU CCP 2014). The TRL training was based on the assumption that making TRLs aware of their role in delivering healthcare to their communities would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

It was further assumed that since the TRLs are key community influencers, training them on vaccination and communication would enhance their ability to effectively communicate vaccination messages with their community members; and have a positive impact 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 would stimulate their interest to perform better and cause them to be the watchdog in their communities to ensure unvaccinated people got vaccinations. Health workers training on the preparation of user-friendly data were expected to support the data shared at the community meetings. By sharing the data, the communities could support the health workers in identifying unvaccinated people 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 TRLs 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 gatekeeping role and provide effective leadership in the WDCs towards increasing use of immunisation services. The overall assumption was that the components of the intervention would synergistically impact on vaccine uptake, reduction in drop-out rates, timeliness of vaccination, and reduction in morbidity by the endline, and eventually impact on childhood mortality in the long term. The theory of change is presented in Figure

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: Northern, Central and Southern districts. Northern district has 5 LGAs, Central has 6 and Southern has 7. Each LGA is further subdivided into wards, which are the smallest political unit.

There were 196 wards in the study setting. Each ward comprises villages, with every village headed by a village leader. Every ward has a clan head, a traditional leader (village head) selected from 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

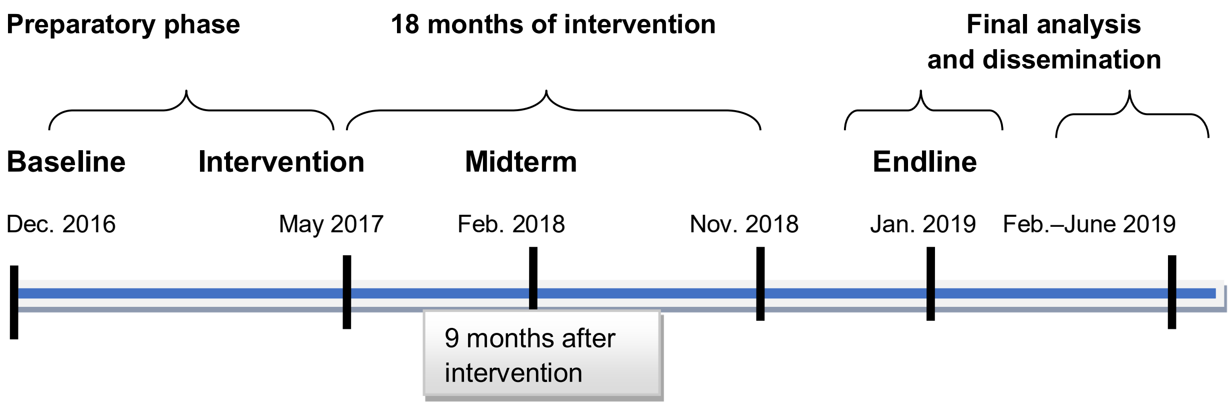
The unit of sampling was the LGA. The rationale for using LGAs was that TRL activities are coordinated at LGA level across the country. The LGAs are stratified into urban and rural LGAs within each senatorial district. Eight LGAs were randomly selected from Northern (2 LGAs), Central (3 LGAs) and Southern (3 LGAs) 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 ward, four villages were selected into the study.

A total of 24 participants were trained in each of the 4 intervention LGAs, except Obudu. This comprised all the village heads in the selected villages, the clan head from the selected ward and two religious leaders from each ward. The majority of the religious groups were Christian: only Obudu, an LGA in the Northern senatorial district, had an Islamic religious group. Two religious leaders with the largest numbers of 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 were collected in December 2016 while tools were developed and piloted. The first phase of training was in May 2017. Five sessions were held over nine months, halfway through the intervention period. Midterm data was collected during the ninth month and the intervention continued for another nine months. Three training sessions were held in the second half of the intervention. The endline evaluation took place in February 2019. The evaluation 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 visits were paid to each of the PHC coordinators in charge of the PHC in each LGA. Clan heads were also visited and consent sought from them for the intervention. Consent was obtained from the TRLs for each round of the evaluation. In addition, verbal consent was obtained from the respondents before applying the questionnaire. Those who declined to give consent were excluded. Signed informed 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 0–23 months.

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

There were three levels of clustering: children within villages, villages within wards and wards within the LGA. For this situation, available formulae were lacking and so simulation was used. We simulated a range of combinations of numbers of LGAs, wards and children. We simulated 100 trials for each scenario. We assumed a proportion of 53 per cent fully vaccinated children before the intervention and in the control group at the final survey. We assumed a value of 63 per cent in the intervention group following implementation of the intervention. The hierarchical clustering of LGAs, wards and children was reproduced. We assumed that the variation between LGA was 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% variation between treatment and control groups was assumed. Stochastic variation arises due to binomial variation in the proportion of children fully vaccinated within a ward, and variation in the differences between villages, wards and LGAs. For each trial, we applied the regression analysis detailed below and recorded the resulting p-value for the intervention. The power was estimated using the proportion of trials that 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 LGAs was 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 LGAs that would reach 80% power at the 5% significance level would be four per arm. Using 4 wards per LGA, 3 villages per ward and 25 children per village would give a total of 1,200 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) on vaccination issues were held with key decision makers in the community at the baseline and endline evaluation phases of the intervention. The key informants were the members of the health team (PHC coordinators, the social mobilisation officer, and the ward focal person in the eight selected LGAs). FGDs were held with the TRLs, WDC members and mothers who used vaccination services in the health facilities.

5.3 Sampling

5.3.1 Quantitative sampling

Of the 18 LGAs in the study location, 8 LGAs were selected from the Northern, Central and Southern senatorial districts. The eight LGAs were selected in four strata. The strata were: north urban, central rural, south rural and mixed urban. Two LGAs were randomly selected per strata and one of each pair was randomised to either the control or intervention using random number generation in R.

Three wards were selected within each LGA by simple random sampling using random number generation in R. Each ward had between 2 and 16 villages, with a population of 500–2,000 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.

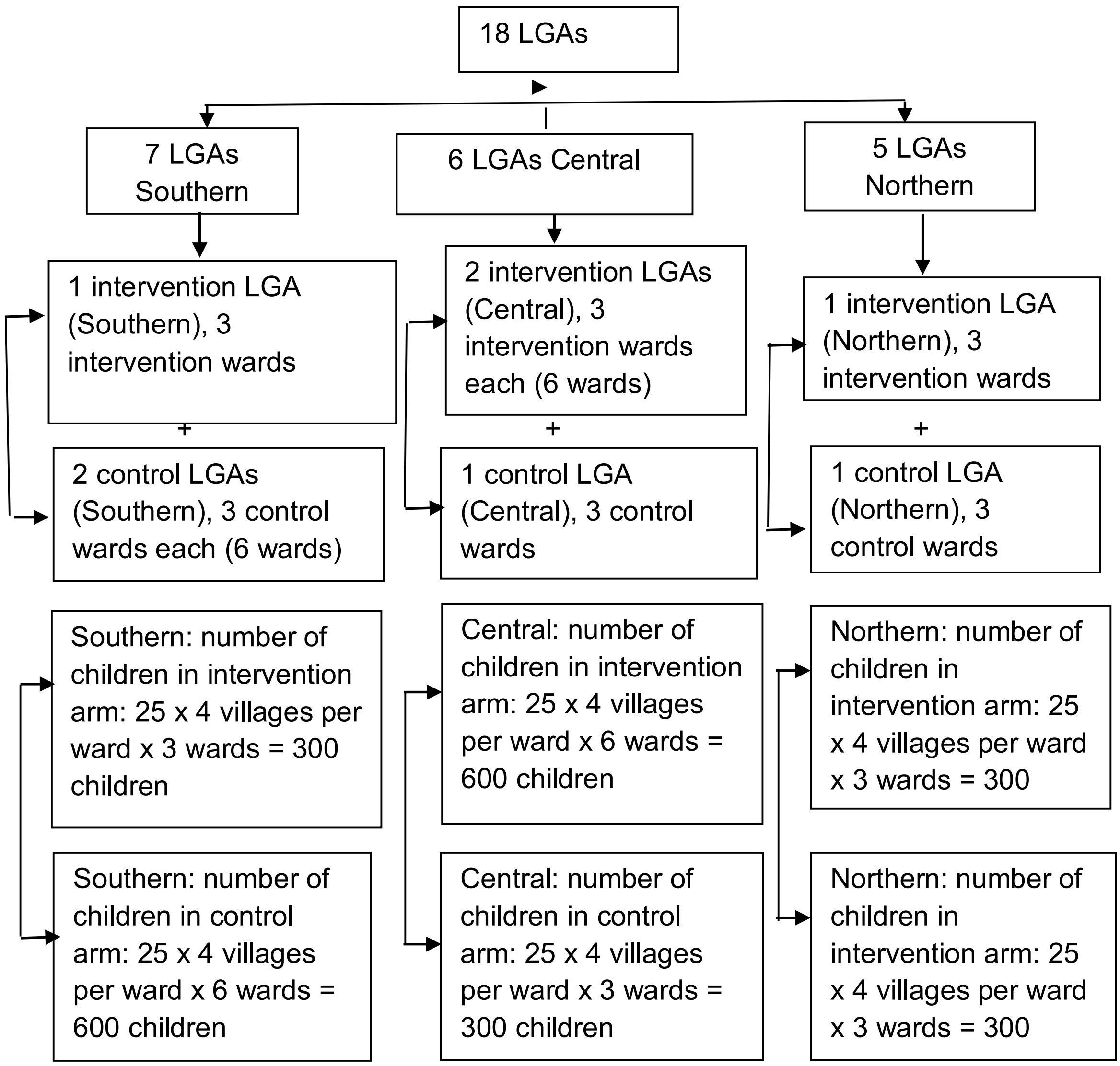
Within each ward, four villages were randomly selected. Where there were fewer than four villages in a ward, all the villages were included in the study. One ward, Adadama in the control arm, witnessed communal violence when the team was on the ground and so was replaced with Itigidi after the baseline survey. The selection of Itigidi was based on it having the same characteristics as Adadama. The results with Itigidi excluded were very similar to those including Itigidi.

Within each village, 25 children aged 0–23 months were selected (Figure 3). In the absence of aerial photographs, the earlier WHO-recommended method of spinning the pen was used to sample households. Because there was no list of all households in the village, a team member dedicated to sampling the 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 they reached the edge of the village, 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, the sampler spun a bottle to choose a random direction, then walked in that direction until they came to another household, which was 'house 2' of the village, and so on. If there was a junction in the path, they spun the bottle again to select from the choices available. This procedure was repeated until 25 households with children had been counted (WHO 2008).

The sample size was achieved as planned (Appendix A). In each arm at each survey, there were between 1,268 and 1,302 children, slightly higher than the target of 1,200.

Figure 3: Diagrammatic presentation of sampling design



5.4 Study design

The study was a cluster randomised-controlled trial. Randomisation 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, the Swiss Tropical and Public Health Institute. Blinding the TRLs to the intervention was not possible, but the respondents and data collectors were blinded.

5.5 Data instruments

A mixed methods evaluation employing quantitative and qualitative data tools was employed. For the quantitative data, a semi-structured interviewer-administered questionnaire was developed to assess immunisation 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 mother's health facility use. A web-based data platform was set up in the cloud.

An 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, and satisfaction with the intervention.

5.6 Data collection

5.6.1 Quantitative data

The field survey served as the basis for 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, midterm and endline. The 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 midterm 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 using the tool on Android phones. Subsequently the supervisors trained the data collectors on site. Five data collectors were trained at each of the eight sites. The three best-performing ones were selected to participate in the field survey after a two-day training. Training of supervisors and data collectors was conducted for each phase of data collection.

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

5.6.2 Qualitative data

FGDs and key informant interviews were held with TRLs and local government health team members, respectively, at baseline. The sessions sought information on community engagement in RI and knowledge, attitude and beliefs of the communities towards immunisation. Most of the sessions were held at local government secretariat halls in the respective LGAs. Each session lasted approximately 60–75 minutes. At endline, FGDs were held with the TRLs, the health team and caregivers attending vaccination services in each of the eight LGAs. Data from the FGDs and key informant interviews were tape-recorded and transcribed verbatim.

5.6.3 District health information system data

Routine data generated from the health facilities are captured using health management information system data tools, summarised and fed into the electronic database called the district health information system (DHIS). Data are entered from every facility in all wards in each LGA on a monthly basis. The DHIS data are mostly generated by PHC facilities. Data from the DHIS were extracted from the selected wards on facility attendance, attendance at ANC check-ups, deliveries, measles and neonatal tetanus for 2017 to monitor the 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 enables real-time (as well as offline) data collection and transmission to a cloud server running 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 children aged 0–23 months during each survey. The mobile form was also designed to automatically calculate children's age at each immunisation received since birth and each immunisation date. This was to prevent human error that could arise from manually calculating children's age and the age at which they received each vaccine.

Other validation checks included validating the data type at point of entry (e.g. the application would not allow a 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 the wrong field. These design measures invariably helped to reduce data entry errors and enhanced data quality and integrity.

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

During the two 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 arise 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 were checked for correctness before uploading them to the cloud-based ODKAggregate server. Data collectors (interviewers) took pictures of immunisation cards of eligible and recruited children after every interview. During the 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 a replacement.

Before commencement of fieldwork each day, the mobile devices were charged overnight and checked to ensure they functioned correctly, including the date and time on the device, and were then assigned to the data collectors. Checking the date on the mobile device before handing it over to the interviewers was particularly important, because the 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 children older than 23 months were excluded, as well as identifying situations where an immunisation card was seen but no immunisation was recorded.

6. Programme or policy: design, methods and implementation

6.1 Programme design

6.1.1 Recruitment strategy

The participants in the intervention included TRLs and health workers. TRLs 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 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. Health workers from the primary health centres in the study location were recruited for the health worker training.

The beneficiaries were the intended target group. All the village heads in the 48 communities in the intervention sites were invited to 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, which 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 mobilisers. They had experience in health facility management and delivery of vaccination services in rural and urban settings. In addition, the trainers included nurse midwives with additional training on community health officer's course. Trainers were trained for three days as part of each training session. Training was prescriptive, with a guide for each session, and included role plays.

6.2 Training components

The intervention had multiple components, which were designed to fit the structure of the PHC system that had 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 to improve their leadership role in the community and in the WDC. It also targeted improving their understanding of the purpose of vaccination, improving their communication skills, and community mobilisation. Community engagement was to provide a forum for the leaders to share information on RI, as a way 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 TRLs, while the WDC component aimed to ensure that the WDC meetings were held routinely to facilitate the interaction of the members with the TRLs.

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. There were 5 training sessions held in the first 9 months, and 3 sessions in the second 9 months. Training sessions included:

- Leadership styles – a 90-minute interactive session with role plays demonstrating the different types of leadership styles and discussion of the merits and demerits of each style. The training objective was to guide leaders to appreciate the different leadership styles and adopt the style of leadership that would make them good leaders of their communities.

- Characteristics of a good leader – a 60-minute brainstorming session on the characteristics of a good leader. TRLs identified the characteristics that would make them good leaders.
- How to influence people – the session commenced with a 45-minute group discussion and ended with a 15-minute role play to reinforce the role of TRLs as community influencers.
- Transformational leadership – illustrative flash cards were used to stimulate discussion on how the TRLs could be innovative in playing their leadership role, particularly in relation to vaccination services. The session lasted for three hours, with intermittent breaks. Brainstorming and discussions were employed to demonstrate that a leader makes the impossible possible, and possibilities reality. It identified barriers to vaccination within localities. Having identified the barriers, the training portrayed that they should not be victims of these barriers, but leaders should create 'new realities' that would bridge the gap. They should not be 'reactive', pointing accusing fingers at others for creating 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 TRLs on what the vaccine-preventable diseases are, 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 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 TRLs. The aim was for the participants to appreciate the gaps in RI uptake. This was followed by a discussion on the problems that caused the observed gaps. Using problem tree analysis, solutions were proffered by the leaders. In a 45-minute breakout into small discussion groups they developed a plan of action to address the gaps. This was shared during a feedback session.
- What to know about vaccination – to address drop-out from immunisation schedules, a graphic animation of how vaccines work was shared with the TRLs for an hour. The training tool also had information on when and where in the respective wards to receive immunisation.
- Mapping of community resources – in small group brainstorming sessions, the TRLs identified 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 committees and the roles they play. This lasted for an hour. The 'ideal' composition of the WDC from the perspective of the National Primary Health Care Development Agency was presented, and the roles expected of the ward and village development committees.
- Effective communication – the TRLs were taken through a three-hour interactive session on the characteristics of a good communicator and the process they could follow to communicate effectively on RI. Each stage of the process was followed with a practical example.

- Identification and prioritisation of problems through participatory learning action – to meet the objective of supporting leaders to identify problems in their communities, the TRLs were taken through a participatory learning action process in identifying problems. The training included how to set up a community discussion group that was representative of the community and included vulnerable groups such as women and those residing in areas with difficult terrains. They were taken through the steps of identifying problem identification using a problem tree analysis approach. Identified problems were prioritised and solutions proffered.
- Community mobilisation – this training aimed to highlight different ways of achieving community involvement, with the aim of achieving sustainable community participation in RI. It lasted three hours, with a demonstration of different types of mobilisation illustrated with graphics. The trainer presented a graphic flashcard to the participants who discussed what they saw on the card. This was followed with further explanation by the trainer, with participants contributing to the reasons for each type of mobilisation. It ended with a session on steps towards community mobilisation.

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

6.2.2 Intervention component 2: community engagement

The TRLs 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 town hall meetings, but such meetings were seldom held. Council of chiefs' meetings were held monthly at ward level. The TRLs 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 summarisation and communication of vaccination data with lay people. The cadre of health workers in the study location at PHC level were senior community health extension workers and community health extension workers. A one-day training session on data summarisation 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 immunisation officer, the monitoring and evaluation officer, and the cold chain officer. The training lasted for three 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 x 70-centimetre 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 meetings and WDC meetings. Data on the dashboard included monthly RI uptake and rates of drop-out from pentavalent 3 vaccination. A hands-on training was conducted for the health workers on a defaulters' register following a report from them that they did not have a means of identifying children that had dropped out of immunisation. The training was delivered in 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: WDC leadership and coordination

The WDCs were to be strengthened to become decision-making bodies through re-drafting their terms of reference, with clear objectives and operations if necessary. Meetings were to be formalised to allow the organised presentation of health facility data and to monitor implementation. At the time of commencement of the intervention, WDCs had become dormant 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 at the time of the commencement of the project. Following the training, the nine inactive WDCs were reactivated. The WDCs did not operate according to the terms of reference set by the national PHC body. 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 new terms of reference for the WDCs. Rather, they informed the State Primary Health Care Development Agency about the status of the WDCs and made suggestions to standardise the appointment of community members to committees in accordance with the existing terms of reference.

All the WDCs in the control arm met regularly, except the WDC in Odot, Odukpani LGA. The WDC in Odot did not sit at all during the intervention. The reason for not holding meetings was lack of government funding. 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 LGA	Name of ward	No. of sittings
Biase	Agwagune	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 to the facilities. Information on the use of the defaulters' register was obtained during the monitoring visit. The registers were examined 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 (Table 2). The ward focal person supplied information on the various meetings in the community. This was further corroborated during the TRL training sessions.

Information on the issues discussed during community meetings could not be tracked as minutes of these meetings were not kept. Monitoring depended solely on verbal reports by the TRLs and ward focal persons. Reports on the number of times vaccination was discussed at such meetings could not be verified. DHIS data were analysed for impact on facility use 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
Youth	Monthly	Young unmarried men	Issues concerning youth 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 TRL training intervention was carried out as planned. Eight training sessions were held, with five sessions held before the midterm evaluation and three after. Three one-day training sessions were held for the health workers instead of one two-day training session. 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 conspiracy theory 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 conspiracy theory spread nationwide and impacted both the intervention and control arms equally.

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

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

WDC meetings exceeded the target of seven meetings 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 meet at all during the intervention period.

The defaulters' register was not put to use in two health facilities in Ehom and Agwagune, Biase LGA; and one in Abinti 2 ward, Ikom LGA. Staff complained of being short-staffed. The dashboard was not used in one of four health centres in Akpet/Abini ward, and two of four in Ehom ward, both in Biase LGA.

6.5 Weak links in the intervention

Community engagement could not be achieved directly with community members because the town hall meetings were rarely held. It is not certain how much 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 had not been vaccinated. This was expected to spur the community members to identify resistant and defaulting community members to support them to change their attitude and behaviour.

Low staffing of facilities constrained 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 in-service health workers would be preferable, so as to foster interaction between health workers and TRLs.

7. Findings

7.1 Descriptive statistics and balance table

The characteristics of respondents were similar for the intervention and control arms (Table 3), except that more of the respondents in intervention areas lived in hard-to-reach areas. Hard-to-reach areas were defined by the study team as having difficult terrains, such as riverine and hilly areas, or bad roads. These vary greatly across LGAs. PHC facilities are provided in some hard-to-reach communities.

Table 3: Characteristics of the respondents

	Control baseline n = 1,301	Control midterm n = 1,268	Control final n = 1,274	Intervention baseline n = 1,297	Intervention midterm n = 1,302	Intervention final n = 1,276
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 (0.1%)	1 (0.1%)	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						
15mins walk or less	452 (35%)	559 (44%)	618 (49%)	491 (38%)	513 (39%)	567 (44%)
15–< 30mins	458 (35%)	346 (27%)	364 (29%)	506 (39%)	580 (45%)	431 (34%)
30–< 45mins	136 (10%)	129 (10%)	115 (9%)	188 (14%)	118 (9%)	194 (15%)
45mins–1hr	107 (8%)	137 (11%)	104 (8%)	74 (6%)	53 (4%)	58 (5%)
> 1hr	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	1,170 (90%)	1,181 (93%)	1,191 (93%)	758 (58%)	700 (54%)	704 (55%)

Note: * Percentages of known values (excluding missing values).
** Included only an 'other' who 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 arms (Table 4).

Table 4: Characteristics of the children by survey

	Control baseline n = 1,301	Control midterm n = 1,268	Control final n = 1,274	Intervention baseline n = 1,297	Intervention midterm n = 1,302	Intervention final n = 1,276
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 comparison of control vs intervention in the baseline survey, all variables have $p > 0.05$.

Overall, approximately 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 immunisation cards seen was similar in the intervention and control groups at baseline. However, a higher proportion of children had their immunisation cards seen in the intervention arm at midterm and endline evaluation compared with the control arm. It may be that the intervention increased awareness of vaccination in general, so the cards were kept more carefully.

Table 5: Immunisation cards seen* by age group

Age group	**Control**			**Intervention**		
	Baseline	**Midterm**	**Endline**	**Baseline**	**Midterm**	**Endline**
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 (any missing 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 group.

Table 6: Vaccination status of children

	Control baseline	Control midterm	Control endline	Intervention baseline	Intervention midterm	Intervention endline
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 with vaccinations (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

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

Notes: OR = odds ratio; CI = confidence interval. 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 with the change from baseline to the survey in the control arm. Adjusting for hard-to-reach areas produced very similar estimates: up to date or partial vs not vaccinated midterm 2.31 (1.42, 3.74) and endline 12.63 (6.27, 25.43); up to date vs partial and not vaccinated midterm: 0.97 (0.77, 1.24); endline 0.95 (0.75, 1.21). Each vaccine had 1.5–2% of 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 subgroups: 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 have affected 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 with partial and not vaccinated, and fully and partial compared with 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 subgroups being compared rather than a real effect.

Table 8: Vaccination status by subgroup

	Control baseline	**Control midterm**	**Control endline**	**Intervention baseline**	**Intervention midterm**	**Intervention endline**
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%)

	Control baseline	Control midterm	Control endline	Intervention baseline	Intervention midterm	Intervention endline
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 30mins						
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%)
30mins 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 pentavalent 3 which was a week more than the scheduled age in the intervention arm and the endline 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, inter-quartile range, range)

Antigen (scheduled age in weeks)	Baseline	Midterm	Endline
Pentavalent 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)
Pentavalent 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)
Pentavalent 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 endline evaluation (Table 10).

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

	Control baseline	Control midterm	Control endline	Intervention baseline	Intervention midterm	Intervention endline	OR mid CI p-value	OR final CI p-value
Pentavalent 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
Pentavalent 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
Pentavalent 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
Pentavalent 3 on time of those who had had pentavalent 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: OR = odds ratio; CI = confidence interval. * Timeliness defined as within 2 weeks before or after target age.

The proportion of children aged over six months who have had all three pentavalent doses had significantly increased by the midterm (odds ratio (OR) 1.49 (95% confidence interval (CI): 1.01–2.21), p = 0.04) and the endline (OR 1.88 (95% CI: 1.24–2.85), p = 0.003) surveys (Table 11).

Table 11: Number of pentavalent doses in children aged 6–23 months

	Control baseline	Control midterm	Control endline	Intervention baseline	Intervention midterm	Intervention endline
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 pentavalent 3 given that they had had pentavalent 1 was estimated to be OR 1.21 (95% CI: 0.80–1.84) p = 0.36 for the midterm survey, and OR 1.66 (95% CI: 1.08–2.55) p = 0.02 for the endline survey (Table 12).

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

	Control baseline	**Control midterm**	**Control endline**	**Intervention baseline**	**Intervention midterm**	**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%)
Pentavalent 3 of those who had had pentavalent 1	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 pentavalent 1 on time, 35% pentavalent 2, 25% pentavalent 3 and 20% measles. Nevertheless, in children aged 6–23 months, 80% had had all three pentavalent doses, suggesting that 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 pentavalent 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 check-ups and the child being reported to have had measles at the endline but not at the midterm survey (Table 13).

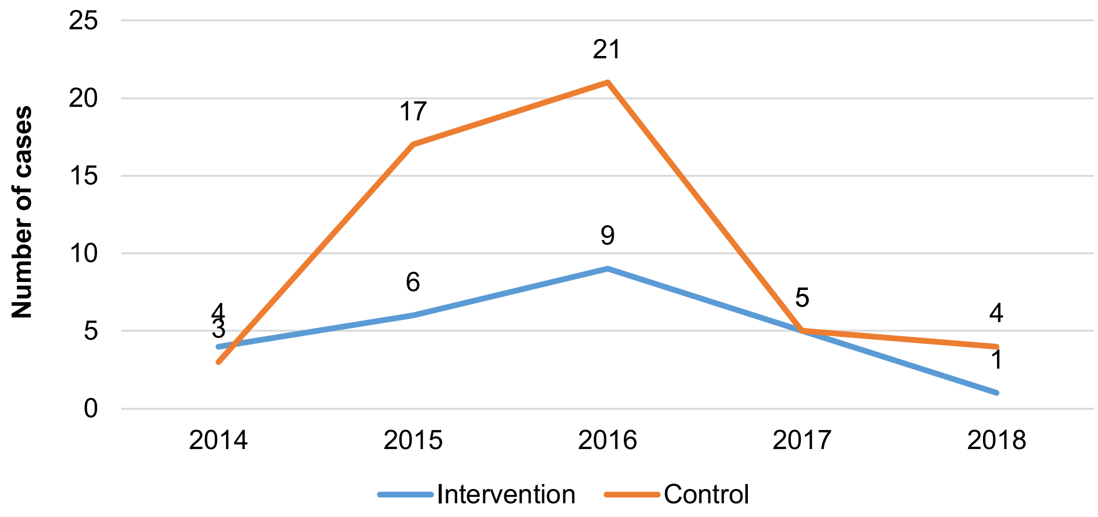
Table 13: Other outcomes: healthcare use by mother, and child illness

	Control baseline n = 1,301	Control midterm n = 1,268	Control endline n = 1,274	Intervention baseline n = 1,297	Intervention midterm n = 1,302	Intervention endline n = 1,276	p-value
Tetanus vaccination status of mother							
0	195 (15%)	189 (15%)	168 (13%)	131 (10%)	101 (8%)	60 (5%)	
1	117 (9%)	123 (10%)	136 (11%)	144 (11%)	148 (11%)	146 (11%)	
2	717 (55%)	692 (55%)	770 (60%)	753 (58%)	771 (59%)	813 (64%)	0.28[ac]
3	237 (18%)	229 (18%)	182 (14%)	256 (20%)	258 (20%)	240 (19%)	0.02[bc]
3+	35 (3%)	35 (3%)	18 (1%)	13 (1%)	24 (2%)	17 (1%)	
Attendance at ANC							
Yes	1,114 (86%)	1,129 (89%)	1,143 (90%)	1,148 (89%)	1,206 (93%)	1,240 (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	1,229 (95%)	1,238 (98%)	1,227 (97%)	1,178 (91%)	1,259 (97%)	1,252 (99%)	0.37[a]
No	71 (5%)	28 (2%)	43 (3%)	115 (9%)	35 (3%)	18 (1%)	< 0.001[b]
Don’t know	1	2	4	4	8	6	

Note: Percentages are of known values (excluding missing values).
[a] Effect of intervention on change between baseline and midterm surveys.
[b] Effect of intervention on change between baseline and endline 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 the intervention and control arms of study (Figure 5 and Figure 6).

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

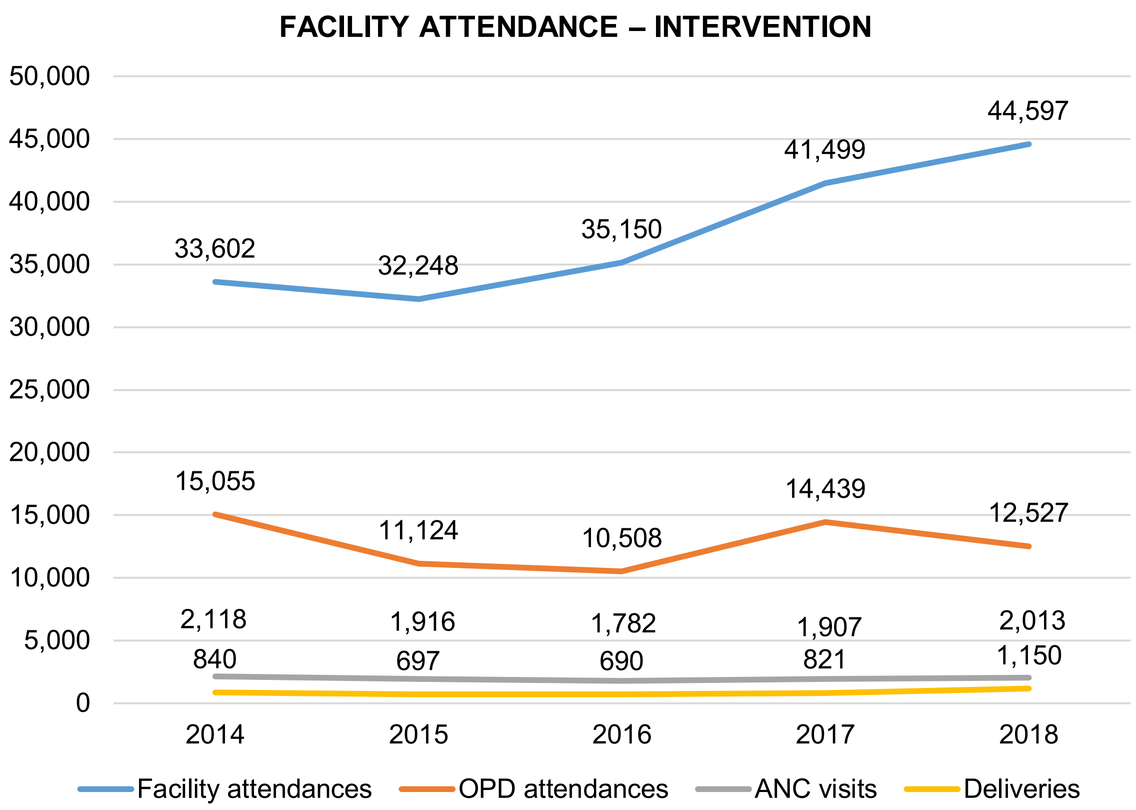
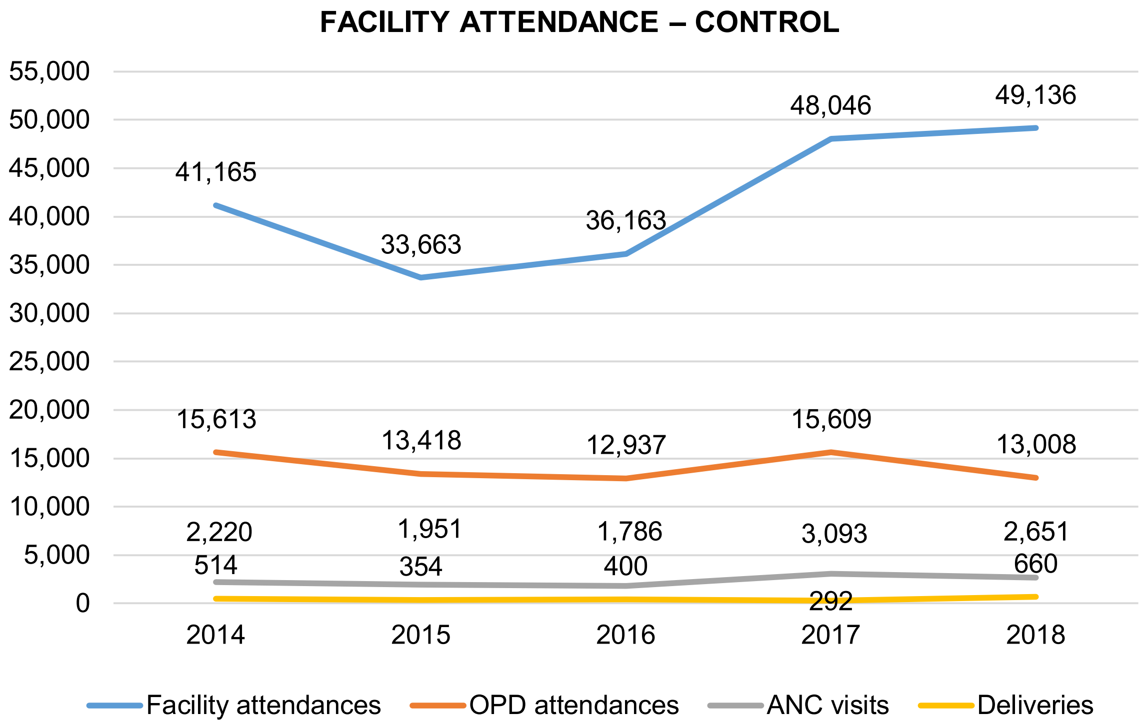


Figure 6: Trend in selected services from the DHIS, control arm



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 intra-cluster correlation 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 vaccination	1.838	0.115	0.310	0.331	0.021	0.056
Pentavalent 1 on time	0.477	0.116	0.121	0.119	0.029	0.030
Pentavalent 2 on time	0.476	0.140	0.111	0.118	0.034	0.028
Pentavalent 3 on time	0.649	0.257	0.063	0.152	0.060	0.015
3 pentavalent doses in children 6–23 months	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).
[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 mobilisation of the communities for specific immunisation campaigns before the intervention. Information about the campaign was given to the WDCs and TRLs to announce. This was not done for RI according to some of the leaders:

> Routine immunisation…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 immunisation. — Religious leader, Etung

It was generally assumed that the mothers were aware of the RI days:

> Women know about our routine immunisation because it is what we have been carrying on for a long time. — PHC coordinator, Biase

> It is only during campaigns that we now involve a larger group but for the routine immunisation every commu nity 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 Agwagune provided a boat for the health workers to convey vaccines to riverine communities.

In Abijang, Etung LGA, the health centre, which was located up a hill where the wealthier 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, the foundation was laid for a house for the ward focal person who was living outside the village. The community also provided accommodation for health staff in Mkpot, Etung LGA, and Ukwop-Eyere, Biase LGA. Yet another community in Utugwang, Obudu LGA, 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 WDCs and the TRLs through formal and informal meetings to sensitise them to mobilise the community for immunisation campaigns. The health workers also sent 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. — Religious leader, Biase

> Town criers will announce round the village about the immunisation. — Traditional leader, Etung

> Time to time in the village when we have the village meeting I share this information to all the women. — Traditional leader, Ikom

> For the past year information used 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 used to take place almost every week. — Traditional leader, Obubu

The WDC members visited 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 following quotes:

> Communication from the clinic to us is not sufficient enough. — Traditional leader, Obudu

> There should be more contact between the religious leaders and the health staff to enlighten us more. — Religious leader, Biase

The training provided an opportunity to foster stronger and more focused interactions between the health team and these community influencers. In response to a question on whether health workers shared information on RI with the TRLs at post-intervention, responses such as, 'No, they hardly do' (traditional leader, Calabar) were obtained in the control arm; whereas the intervention arm reported, 'They use dashboard to share information' (traditional leader, 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 about and had a positive attitude towards vaccination. They believed vaccines prevented their children from acquiring deadly infections and attributed low numbers of deaths of children to vaccination. Post-intervention, the TRLs in 3 of the 4 intervention sites (Biase, Etung and Ikom) and 1 of the control sites (Odukpani) displayed good knowledge on how vaccines work.

Qualitative data did not reveal changes in the attitude and beliefs of the respondents. At baseline, responses included:

> 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. — Religious leader, Biase LGA

> There is real irony in the belief of our people that immunisation 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 immunisation I should take the one that is sick. — WDC, Etung LGA

These responses are indications that 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 in the post-intervention qualitative study still mentioned this 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. In the control arm, a respondent said that the mothers did not know why their children had fever after vaccination:

> That is the most [common] reason why someone fear to go and take immunisation. That fear that when you immunise your child he will be sick. They don't know why. — Traditional leader, Biase LGA

However, 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. — Traditional leader, Biase

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

7.7 Internal validity

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

7.8 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 training tools, staff training cost, implementation and monitoring cost, and user cost based on J-PAL costing guidelines (J-PAL 2019).

The perspective for the cost calculations 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 salaries 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 NGN306.30 to USD1, the Central Bank of Nigeria's 'central rate' exchange rate (note 6 in Table 16). The costs and the outcomes were discounted to 2019 using the Nigerian Central Bank Treasury Bill rate at the end of each year (Table 15). This is in accordance with Drummond and colleagues (1997).

Table 15: Rate of discounting (present value = 2019)

	2016	2017	2018
Treasury bill rate (%)	13.97[1]	13.01[2]	10.91[3]

Notes: [1] https://www.cbn.gov.ng/rates/mnymktind.asp?year=2016
[2] https://www.cbn.gov.ng/rates/mnymktind.asp?year=2017
[3] https://www.cbn.gov.ng/rates/mnymktind.asp?year=2018

The intervention costs are outlined in Table 16 and are listed according to the J-PAL Costing Guidelines (J-PAL 2019). Note that the costs have been calculated in terms of: (1) full costs including investments to get the TRL programme running, but excluding the costs of managing the project; and (2) an estimate of the marginal costs of reproducing the intervention in adjacent additional wards, building on the investments already made that need not be repeated. The high-level total costs amounted to NGN4,738,395 (USD15,470). The average and marginal costs per ward were NGN394,866 (USD1,289) and NGN224,991 (USD735), respectively.

The estimate for averting measles was based on the estimated short-term cost of measles illness (i.e. cost of treatment, transport, caretaker's lost wages). This was estimated to be USD7 per care-seeking case averted (Ozawa et al. 2012). The cost of care averted was estimated based on the number of cases of measles reported on the DHIS.

Table 16: Higher-level costs

		NGN	USD	NGN	USD
1	Base year: 2019			**Discounted to 2019**	**Discounted to 2019**
2	Total programme cost[1]	4,652,276	15,189	5,929,090	19,357
3a	Number of beneficiaries (wards)[2]	12		15	
3b	Average cost per beneficiary (ward)[3]	387,690	1,266	394,221	1,287
4a	Number of beneficiaries (eligible children who could benefit)	1,276		1,599	
4b	Average cost per beneficiary (eligible child)[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	

Notes: [1] This includes the administrative cost, targeting cost, cost of developing and printing training tools, staff training cost, implementation and monitoring cost and user cost.
[2] Number of wards in which 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 costs of developing the training tools and the advocacy visit to communities were removed because these were one-off activities. The monitoring of community meetings was also removed as this was done by the ward focal person.

[6] Bank rate: this was accessed on 23 May 2019 to establish the exchange rate at 30 November 2018 being the end of the month project interventions were completed, at the website: https://www.cbn.gov.ng/rates/ExchRateByCurrency.asp?CurrencyType=$USD.

Table 17 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 17: Detail of costs under two scenarios: full costs and intervention running costs only

	Basic cost collection template	**Scenario 1: total costs, NGN (subtotals used for the ingredients)**	**Scenario 2: intervention running costs, NGN (without investments)**
1	*Programme administration and staff cost*		
	Cost of full-time staff		
	Administration		
	Stationery	39,850	39,850
	Printing and photocopies	14,500	14,500
2	*Targeting cost*	–	–
	Advocacy visits to 8 LGAs and government offices/agencies	224,000	224,000
3	*Staff training*	–	–
	Training of trainers 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 (TRLs)	1,480,000	1,480,000
5	*Implementation and programme materials cost*	–	–
	Consultancy services for development of training materials	1,500,000	–
	Production of handbook on vaccination (Leaders with a Heart for Vaccination, development/printing), other graphics	8,200	8,200
	Flash cards*	143,531	–
	Folders, notepads and pens	35,330	35,330
	Development of dashboard	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

	Basic cost collection template	Scenario 1: total costs, NGN (subtotals used for the ingredients)	Scenario 2: intervention running costs, NGN (without investments)
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** that would have resulted, based on the results of the control arm of the study (Table 18). These were then used to calculate the **net effect** of the intervention arm. The counterfactual represents here the results that would have been attained if no intervention had taken place.

The control percentage changes between baseline and endline were applied to the endline '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 the 'net' effect. The net effect in numbers, in turn, according to procedures recommended in Drummond and colleagues (1997) were discounted to 2019, as were the costs.

Table 18: Net effect of the intervention for 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
Pentavalent 1	531	46.3	496	43.0	511	46.1	694	59.5	1,157	-3	-35	14	162	197	247
Pentavalent 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	1,022	78.8	1,070	83.9	1,270	5	64	6	76	13	16
Attendance at ANC	1,114	856	1,143	89.6	1,148	88.5	1,240	97.2	1,278	4	51	8	102	51	64

Note: TT = tetanus toxoid.

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 assumed being compared with not doing anything (controls). Also, 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.

Table 19 summarises the incremental unit costs for full cost and for running cost.

Table 19: 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 pentavalent 1	197	77	45	247	78	43
Timely vaccination for pentavalent 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 who attended ANC	51	298	173	64	302	166
Number of mothers who had at least 2 doses of TT	13	1,168	678	16	1,210	664
Number of children who could benefit	1,276	12	7	1,599	12	7

Note: TT = tetanus toxoid.

The first set of unit costs reflect the cost per unit of the net effect to replicate the interventions in a fully new setting. The second set of unit costs reflect the estimated cost per unit of the 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’ it is to achieve good outcomes; for example, the net effect of timely pentavalent 1 is more than twice the net effect of pentavalent 3, suggesting that the latter may be more difficult to achieve.

The cost of the intervention per ward is an average based on a 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 trained for the intervention (about USD160) gives another indicator for estimating the cost of implementation on a wider scale: number of TRLs x USD160 for an approximate figure for the replication in a fully new setting.

It was not possible to separate out the costs per component, as these were conducted concurrently and any separation would be an unreliable estimate. The full total costs, as well as the full running costs used, provide a more conservative unit cost calculation. The unit costs are less advantageous for mother-related events, which seems consistent with the focus of the intervention on children's vaccination under the Expanded Programme on Immunization.

It is pertinent to note that, for example, the cost per measles case averted is only USD60. The Measles & Rubella Initiative (2017) 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 as 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.
- A total of 75 per cent of global measles deaths occur in just six countries: India, Indonesia, Nigeria, Pakistan, Democratic Republic of the Congo and Ethiopia.
- The measles vaccine was expected to save more lives until 2020 than all other vaccines combined.
- Due to its effectiveness, low cost and impact, the rate of return for the measles vaccine is USD58 for every USD1 invested.

8. Discussion

8.1 Substantive and statistical significance of the findings

Generally, there was no difference in the proportion of children who were up to date with vaccinations between the baseline and the endline ($p = 0.69$). However, the intervention was effective in reducing the proportion of non-vaccinated children from 7 per cent at baseline to 0.4 per cent at the endline survey ($p = 0.001$).

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 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 would be adhered to by the health facilities. When vaccination services are spaced out and only available when the health system plans to provide them, caregivers may be unable to vaccinate their children when they are due for vaccination.

It is also worthy of note that, although 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 the study. This may imply that WDCs need to include RI in their agenda for there to be an improvement in immunisation uptake. The frequency of vaccination services was irregular, with few or no outreaches in some settings because of the inadequate number of staff.

There was wide variability in the timing of vaccinations. Most children had late vaccinations; less than 50% of the children received pentavalent 1 on time in both arms of the study at baseline. While there was a 3% decrease in the control arm, the intervention arm had a 14% increase at endline evaluation and the difference was statistically significant (OR 1.96; 95% CI: 1.53–2.53; $p < 0.001$). Similarly, there was a 4% decrease in timely uptake of pentavalent 3 in the control arm and a 5% increase in the intervention arm (OR 1.55; 95% CI: 1.14–2.12; $p = 0.005$).

Timely measles 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; 95% 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 in each location. Some locations provided a weekly service, others provided services twice a week and others once a month. There could also be errors in the recording of the dates of vaccinations by health workers.

Drop-out between pentavalent 1 and pentavalent 3 vaccination among children aged 14 weeks and above was assessed. There was a 5 per cent increase in the proportion of children that had received pentavalent 1 who also received pentavalent 3 at endline in the intervention arm. The difference between the control and intervention arms 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% to 3% and from 9% to 1% 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 nine months to five 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 at health facilities showed a trend in attendance that was 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 mothers' use of health facilities. 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 programme that was reported to be functioning at some facilities in the control arm. This programme targeted mothers to promote safe delivery and improve the number of births attended by trained personnel.

The perception of mothers on care received did not change after the intervention, as they reported being satisfied with care at baseline and endline. The major reason for mothers' satisfaction was that they were not asked to pay for vaccinations. 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 about the frequency of vaccinations, but the health workers'. According to one of them:

> That is the civic responsibility of the health workers. Our own is to tell us [i.e. for the health workers to tell the leaders] 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 health workers. However, the leaders in the intervention arm became change agents and could communicate about 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 aged under 2 years. These range from monetary incentives to disincentives (Maluccio and Flores 2004; Robertson et al. 2013) to provision of monthly reliable vaccination services (Banerjee et al. 2010). Pooled data for the interventions on incentives showed that non-monetary incentives were more likely to improve full vaccination (risk ratio (RR): 6.6; 95% CI: 3.93–11.28); ensuring availability of vaccination services through outreach also had a positive impact on full vaccination (RR 3.09; 95% CI: 1.69–5.67). Monetary incentives, on the other hand, had little or no effect (RR 1.05; 95% CI: 0.90–1.23) on 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 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 community gatekeepers to influence their communities. These two studies could be said to be interventions that support 'pulling' (requests for services) from the recipients. The non-monetary incentive (a reward to caregivers for attending the health facility) and the outreach, on the other hand, directly targeted vaccination services and supported 'pushing' 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 parent–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 vaccinations, 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 a high possibility of achieving timeliness and full coverage with the TRL intervention, particularly because 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 draws support from the state PHC agency, the body that is directly responsible for the delivery of vaccination in the state.

The uptake of DTP3 is usually used as a proxy to assess the success of vaccination uptake globally (UNICEF 2018). A meta-analysis of data from interventions that target educating caregivers at the community level showed a 68 per cent increase in the uptake of DTP3 by one year of age (RR 1.68; 95% CI: 1.09–2.59) (Oyo-Ita et al. 2016). These studies included evidence-based discussions (Andersson et al. 2009) 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 a more than two-fold increase in the odds of receiving pentavalent 3 among children aged 6–23 months in the intervention arm by the endline evaluation (OR 2.20; 95% CI: 1.53–3.16; $p < 0.001$).

Drop-out in pentavalent 3 vaccination was estimated to have fallen from 16% to 11% in the intervention arm after the 18 months of our study. In a facility-based longitudinal study in Nigeria’s South East geopolitical zone, the use of telephone calls to caregivers who failed to keep their vaccination appointment was shown to reduce the drop-out rate from 20.8% to 14% within a month (Ijeoma et al. 2015).

Another study in Kenya targeted at reducing the DTP3 drop-out 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 drop-out in rural India have been attributed to demand-side rather than supply-side factors (Gosh and Laxminarayan 2017). To reduce the DTP3 drop-out rate, therefore, interventions that drive demand should be considered.

8.3 Limitations of the study

In light of more vaccination cards being seen in the intervention arm at the midterm and endline evaluation surveys, it is possible that there was a differential bias, although 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 embraces a wide range of possibilities (Miles et al. 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 be optimised and produce more benefits; or if they may somehow fade away, particularly when there is a change of government and new officeholders are appointed.

9. Specific findings for policy and practice

9.1 Policymakers

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 be stagnating, the findings of this trial are even more crucial.

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

Inclusion of TRLs in the planning, implementation and evaluation of an intervention is useful in ensuring support from the community. Based on the findings of this study, it is recommended that the national and state PHC 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, TRLs may be able to allay caregivers' fears about the common discomforts associated with vaccination, such as 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 such as using TRLs achieves its full potential. For this, policymakers should ensure adequate personnel and logistics to support more frequent vaccination sessions. Otherwise, this could undermine the efforts of the influencers and lead to a diminishing return on their inputs.

9.2 Programme and implementation

The TRLs can be seen as an untapped community resource that implementers and practitioners can take advantage of to boost and sustain vaccination coverage. Therefore, it is important that health workers involved in vaccination engage the TRLs actively for RI. However, this may not boost the timeliness of vaccinations. For a child to be up to date with their vaccinations, the health system needs to 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 with 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 was similar to that of the intervention arm at baseline. Programme implementers should note that WDC meetings may not translate to improved vaccination coverage if a targeted plan is not developed to use this forum to constructively include RI in their agenda and share vaccination information with the WDCs regularly. In so doing, the health team works with the community towards a defined target. Programme implementers should, therefore, adopt means of including RI in the WDCs' agendas and follow up by updating the community on the progress made. Programme implementers should also avail themselves of community resources through the key influencers and harness such resources to reach the unreached.

9.3 Generalisability and external validity

The TRL intervention is feasible in L&MICs where the TRLs are key influencers in their communities. Several interventions have targeted mothers or caregivers to boost vaccination coverage. The TRL intervention targets leaders to reach the caregivers who are mostly mothers. Similar settings, which exist in most L&MICs, may have a similar impact on the intervention. It is more likely to have an impact where the TRLs are embedded in one system. Furthermore, even if TRLs in Cross River State are part of the same social system, there are large differences between TRLs in different wards. Therefore, we could expect to see similar results in areas that have different TRL setups.

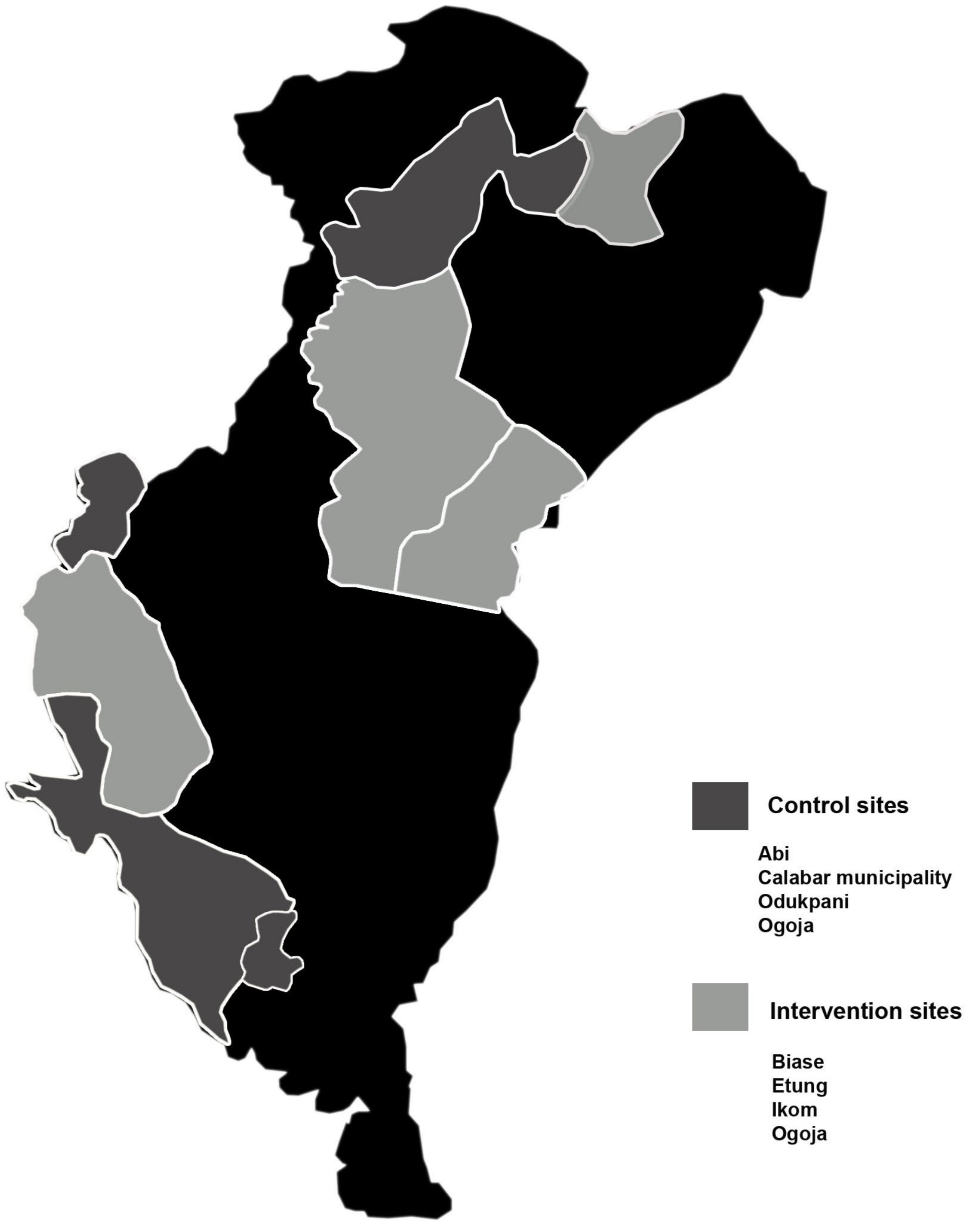
From the midterm survey, there is an indication that the training sessions need not be very frequent, which may cause fatigue, but frequent enough to keep the tempo going and make health workers accountable to TRLs. What the effect will be in the long term may depend, to some extent, on the level of interaction between the TRLs and the healthcare workers.

Appendix A: Sample size

The sample size was achieved as planned.

	LGAs	Wards	Villages	Individuals
Required by sample size calculation per arm and survey	4	3 per LGA = 12	4 per ward = 48	25 per village = 1,200
Baseline survey				
Control	4	12	48	1,301
Intervention	4	12	46	1,297
Midterm survey				
Control	4	12	48	1,268
Intervention	4	12	46	1,302
Endline survey				
Control	4	12	48	1,274
Intervention	4	12	46	1,276

Appendix B: Map showing LGAs in the study location



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