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Impacts of the Stimulate, Appreciate, Learn and Transfer community engagement approach to increase immunization coverage in Assam, India

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Executive summary

Background

Despite the operation of a long-standing national program for immunization in India since 1985, full immunization coverage has not reached the desired level. Completion of vaccine schedules that require multiple doses (e.g. diphtheria, pertussis and tetanus [DPT] or pentavalent) remains a major challenge impeding this goal.

Both demand- and supply-side bottlenecks contribute to suboptimal vaccination coverage rates in India. In the context of a universal immunization program in India, most existing interventions are geared toward addressing supply-side challenges. But there is a growing body of literature indicating that demand-side interventions could lead to significant improvement in childhood vaccination coverage in low- and middle-income countries.

Community engagement approaches can potentially address demand-side barriers while also mobilizing the community to advocate for better service delivery. Participatory engagement of communities could help to help identify barriers to vaccination at local level, and thus might lead to sustainable solutions that a top-down approach cannot achieve. Our proposed intervention engages with communities and strives toward increasing a sense of community 'ownership' of the issue(s).

Context

Assam state in the northeast region of India has historically faced challenges in addressing its high maternal and infant mortality indexes. According to the Rapid Survey of Children 2013–2014, full immunization coverage in Assam (55.3%) is lower than the national level (65.2%). Dropout rates of vaccines that require multiple doses were also higher in Assam than the national figures. According to the 2015 sample registration system bulletin, Assam had the second-highest infant mortality rate in the country, with 47 deaths among infants under one year of age per 1,000 live births, which exceeds the national average of 37 per 1,000.

Topographically, Assam comprises the fertile plains of the Brahmaputra river with some hilly regions inhabited by indigenous peoples or scheduled tribes (as they are referred to in India). Assam covers an area of 78,523 square kilometers (30,318 square miles); a narrow corridor running through the foothills of the Himalayas connects the state with the Indian 'mainland'. Assam shares borders with six states in the northeastern region of India. To the east are the states of Arunachal Pradesh, Nagaland, and Manipur, to the south are Mizoram and Meghalaya, and to the west is Tripura.

Assam shares international borders with Bhutan in the northwest and Bangladesh to its southwest. The capital was Shillong in the state of Meghalaya for more than one hundred years, until it was moved in 1972 to Dispur, a suburb of Guwahati, after Meghalaya became a separate state of India. As per the 2011 census, scheduled tribes form approximately 12 per cent of Assam's population of 31.2 million (Office of the Registrar General and Census Commissioner 2011). The main language is Assamese but a number of other languages are also spoken, such as Bodo, which is the language of Assam's hill tribes.

The intervention

Supporting this community-based intervention is The Constellation, a Belgium-based NGO. The intervention is complex and involves prolonged interactions at community level with multiple steps, referred to by the acronyms CLCP (community life competence process) and SALT (stimulate, appreciate, learn and transfer). In this report we have often referred to the entire process by the latter acronym, SALT. The intent of CLCP/SALT is for communities to take the initiative, identify challenges, take action to bring about change based on where they are and what they want to achieve, learn from their actions and share their experiences with other communities.

During implementation of the intervention, trained facilitators from local NGOs – the Voluntary Health Association of Assam and the Centre for North East Studies and Policy Research – interacted with the communities to enable them to leverage their own strengths to address their concerns, and accompanied them through a process of learning from action.

Study design and methods

We adopted a cluster randomized design with two groups to evaluate the intervention in Assam. The study included villages from three districts, namely, Bongaigaon, Kamrup Rural and Udalguri. Stratified purposeful sampling was used so that the selected districts would represent varied socio-demographic characteristics of Assam. The intervention group received the SALT intervention for about a year (March 2017–March 2018), along with routine immunization services. The control group received routine immunization services only.

The study used a repeated cross-sectional design wherein we tracked the same sampled villages but drew independent random samples of households at baseline and endline. Post intervention, the endline survey did not follow up with the same households (unlike most other randomized controlled trials), as estimating immunization coverage rates requires targeting a particular age group of children.

Process monitoring and evaluation were carried out during the baseline and endline surveys. Process monitoring was also undertaken during the course of the intervention, with some routine data collected by the implementation team. The evaluation team also made observations during various stages and steps of the CLCP/SALT implementation process, and conducted interviews with the villagers and other stakeholders.

This study used a mixed-methods approach, with a larger quantitative aspect and a smaller qualitative component. The quantitative component used structured questionnaires to collect data from 90 intervention and 90 control villages.

The required sample size used for the study is powered to detect an increase of at least 8 percentage points from an expected coverage of 84% and 79% for three doses of DPT or pentavalent and full immunization, respectively, in the control group, with 80% statistical power based on a two-sided test, having a 5% level of significance after accounting for an intracluster correlation of 0.17 for three doses of DPT or pentavalent and 0.18 for full immunization. We further assumed that a village would have a minimum of 15 children aged 6–23 months and 10 children aged 12–23 months. If there were more than 15 eligible children in a village, we randomly selected 15 children.

The qualitative methods were used for process monitoring and evaluation, as well as to help interpret evaluation outcomes. For qualitative data, focus group discussions were the primary method of data collection. At the end of the intervention phase, they were conducted in 28 villages, including 22 intervention and 6 control villages.

Outcomes measured and statistical analyses

Our study assessed the intervention's impact on two primary outcomes: full immunization in children 12–23 months old, and three doses of DPT or pentavalent in children 6–23 months old. We analyzed the effect of the intervention by comparing outcomes at endline between the intervention and control arms, after adjusting for village-level log odds of coverage at baseline. We used a random-effects logistic regression model to analyze the binary outcome variables clustered at village level.

The unadjusted model includes only two explanatory variables: the treatment assignment indicator and the baseline village-level log odds of the outcome. Explanatory variables in the adjusted model include (in addition to the variables in the unadjusted analysis) district, gender and birth order of the child, mother's age and education, spouse's education, household head's religion and caste, and household wealth quintile. Village-level variables included the proportion of households in the poorest wealth quintile, the proportion of mothers who cannot read and/or write, and the average travel time to the vaccination site.

Key findings

The adjusted analysis shows that the intervention has had no effect on full immunization in children 12–23 months old, as the odds ratio is close to 1 (OR = 0.97, 95% CI [0.70,1.34]). Also, the odds of receiving all three doses of DPT among children 6–23 months old is similar across the intervention and control arms. The results for the adjusted and unadjusted analyses are very similar.

None of the subgroup analyses based on various factors (such as district, gender of the child, birth order of the child and village-level baseline full immunization coverage) showed a significant effect of the intervention on either of the primary outcomes. However, some of the results were promising, though they were not statistically significant. For example, in villages with low full immunization coverage at baseline, children in the intervention arm were 1.4 times more likely to receive all three doses of DPT than children in the control arm. However, this finding was not statistically significant.

The qualitative data showed mixed results: while many mothers and grandmothers present in focus group discussions were aware of aspects of the CLCP/SALT process (but not the name or acronyms used), there were many members of the community who were not aware of the CLCP/SALT process. This perhaps suggests that within villages, dissemination of the process was not as efficient as anticipated at the start. Villagers who were aware of the SALT process reported benefits both in increasing immunization awareness and service utilization, and additional benefits outside the context of immunization.

Conclusions

Community engagement interventions such as SALT in theory have the potential to improve immunization coverage, as they can help to identify barriers to vaccination at the local level and thus might lead to customized and sustainable solutions. The findings from this evaluation study based on a cluster randomized controlled trial, however, showed no effect of the SALT intervention on children's immunization coverage in our study population after one year of implementation.

After our baseline assessment (June–August 2016), we found that all study districts had significantly higher immunization coverage compared to the earlier assessment by the National Family Health Survey-4 (November 2015–March 2016). We postulate that one reason for this improvement in both intervention and control villages could be due to the widespread implementation of Mission Indradhanush, the flagship program of the Indian government, across Assam during the study period.

Given the high vaccination coverage in study districts at baseline, the intervention could have been more targeted. The null results from this study suggests that a more targeted approach may be the way forward if SALT is to be effective across various contexts and issues. Qualitative data demonstrated that the CLCP/SALT intervention helped in improving awareness and utilization of services to some extent, and had additional benefits outside the context of immunization.

Contents

List of figures and tables

Abbreviations and acronyms

AER	After-experience reflection
ASHA	Accredited social health activist
CLCP	Community life competence process
C-NES	Centre for North East Studies and Policy Research
DPT3	Diphtheria, pertussis and tetanus vaccine (three doses)
FGD	Focus group discussion
FIC	Full immunization coverage
ICC	Intra-cluster correlation
IDI	In-depth interview
KII	Key informant interview
MCP	Mother and child protection
NFHS-4	National Family Health Survey 2015–2016
OPV	Oral polio vaccine
SALT	Stimulate, appreciate, learn and transfer
VHAA	Voluntary Health Association of Assam

1. Introduction

Immunization is a globally accepted public health intervention that helps to avert vaccine-preventable diseases. Incomplete or lack of immunization increases the risk of illness and death among children. The Global Vaccine Action Plan (2011–2020) sets a goal of 90 per cent coverage at national level, and 80 per cent in every district or equivalent administrative unit, for all vaccines in national programs by 2020 (WHO 2013).

India is one of the 194 member states of the World Health Assembly, which endorsed the global plan's framework in 2012. Despite the existence of India's long-standing national program for immunization implemented in 1985, only 65.2 per cent of children 12–23 months old are fully immunized (UNICEF 2015). Full immunization is defined as children receiving: one dose of the Bacillus Calmette-Guérin vaccine to prevent tuberculosis; three doses of the oral polio vaccine (OPV); three doses of the diphtheria-pertussis-tetanus vaccine (DPT3) or the more recently introduced pentavalent (DPT-hepatitis B-haemophilus influenzae type B) vaccine; and one dose of the measles vaccine.

Completion of the schedule of vaccines that require multiple doses (e.g. OPV and DPT or pentavalent) remains a major challenge toward achieving higher full immunization coverage (FIC). Both demand- and supply-side bottlenecks contribute to suboptimal vaccination coverage rates in India (Vashishtha 2012; UNICEF India 2010; Pramanik et al. 2015; Favin et al. 2012; Rainey et al. 2011; Ghosh and Laxminarayan 2017).

In the context of India's universal immunization program, most existing interventions are geared toward addressing supply-side challenges, such as: ensuring better immunization services and more focused implementation by deploying more health workers across health facilities; introducing alternate vaccine delivery systems; including new vaccines in the immunization schedule; organizing sessions in hard-to-reach areas; and initiating supplementary immunization activities for children who were missed in the routine immunization program (Pramanik et al. 2015; MoHFW 2009, 2015a).

However, there is a growing body of literature showing that demand-side interventions lead to significant improvement in childhood vaccination coverage in low- and middle-income countries (Oyo-Ita et al. 2012; Johri et al. 2015). Community engagement approaches can address demand-side barriers while also mobilizing communities to advocate for better service delivery (Hahn et al. 2005; Jain et al. 2015). With the growing realization that community-level factors influence vaccination uptake, more recent strategies to increase vaccination coverage have attempted to focus on community-based interventions (Sabarwal et al. 2015; Saeterdal et al. 2014; Oyo-Ita et al. 2016; Owais et al. 2011).

Existing community engagement programs, however, mostly focus on communication activities that do not actively involve communities in planning, monitoring and surveillance activities (Sabarwal et al. 2015). The participatory engagement of communities can help to identify barriers to vaccination at local level, and thus might lead to sustainable solutions in a manner that a top-down approach cannot achieve. Our proposed intervention goes a step beyond merely engaging with communities and strives toward increasing a sense of community 'ownership'.

In various steps of the proposed intervention – referred to by the acronym SALT (stimulate, appreciate, learn and transfer) – the communities lead the way, identifying challenges, taking actions based on where they are and what they want to achieve, learning from their actions and sharing their experiences with other communities. Trained facilitators stimulate the communities to leverage their own strengths to address their concerns and accompany them through a systematic process of learning through action.

This community-based approach has also been shown to be effective in generating behavioral change in other contexts. The WHO-UNICEF evaluation of the AIDS competence process in Papua New Guinea concludes that it is an effective approach to combating HIV/AIDS through local empowerment (WHO and UNICEF 2009). Economic evaluation of the process in Thailand shows that it is likely to be cost-effective when comparing its incremental cost-effectiveness ratio with other HIV prevention programs (Teerawattananon et al. 2011).

In the context of malaria, a retrospective study of SALT versus non-SALT districts in Togo shows a significant increase in impregnated bed net use and a decrease in malaria prevalence among children under five (Legastelois and Forth 2009). A recent study (unpublished) in the Democratic Republic of Congo found that SALT interventions can reduce resistance to vaccination and increase polio vaccination rates (Centers for Disease Control and Prevention, 2014). However, the evaluation design and method used in the study did not measure the attributable impact of SALT.

In the last 5–6 years, according to various health and demographic surveys, there has been no significant improvement in India's FIC rate (UNICEF India 2010; UNICEF 2015; IIPS 2017). It has been suggested that approaches in which communities play a prominent role may be effective for improving immunization coverage (Sabarwal et al. 2015). We aim to assess the impact of this novel community engagement approach (SALT) on increasing immunization coverage. The objective of this impact evaluation study is to generate high-quality evidence that will allow us to causally attribute changes in immunization coverage, if any, to the SALT intervention.

We adopted a cluster randomized design with two groups to evaluate the intervention in Assam, a state in the northeast region of India. Our study assessed the intervention's impact on two primary outcomes: full immunization in children aged 12–23 months and DPT3 or pentavalent in children aged 6–23 months. We considered the following secondary outcomes: dropout between doses 1 and 3 for the DPT or pentavalent vaccine; availability of vaccination cards; timeliness of the measles vaccination; mothers' exposure to immunization messages; and mothers' belief in the community's role in and ability to impact her child's health. The evaluation outcomes are aligned with the pre-analysis plan submitted to 3ie. Per the 3ie review committee's suggestion, we also examined the effect of the intervention on several water, sanitation and hygiene (handwashing) indicators.

The report is organized as follows. Following a brief introduction in section 1, section 2 describes the key components of the SALT intervention, including the community life competence process (CLCP). Section 3 provides context for the selection of study sites, and aims to help readers to assess the transferability of the program, as well as findings. Section 4 covers the timeline of implementation and evaluation. In Section 5, we describe details of the study design, including data gathering (both quantitative and qualitative),

the treatment-assignment and identification strategy, and measures taken to ensure data quality. Section 6 expands on the intervention, including how it was implemented in practice and the process-monitoring measures used to track implementation. Section 7 describes the mixed-methods analyses undertaken to estimate the intervention's effect on evaluation outcomes. Sections 8 and 9 describe the main findings. Sections 10 and 11 cover discussion and policy implications, respectively. Additional results and other relevant information are provided in a set of appendixes at the end.

2. Intervention basic principles and key activities

This community engagement intervention originated at The Constellation, an NGO registered in Belgium. The Constellation's experience over 12 years in more than 60 countries indicates that communities can and do respond to the challenges that they face when they take ownership. The Constellation seeks to accompany communities as they take ownership of their challenges. The Constellation refers to the methodology used by the community as the **Community Life Competence Process (CLCP)**. The Constellation accompanies the community as it applies CLCP with an approach or attitude referred to by the acronym SALT; Stimulate, Appreciate, Learn, and Transfer approach. In this report we have used the acronyms CLCP and SALT interchangeably, and often just the latter.

The foundation of the intervention is that *communities change themselves, we do not change communities.* The underlying belief is that when a community takes ownership of the challenge that it faces, it is on the road to sustainable change. The intervention uses the CLCP, a form of learning cycle wherein a community identifies a problem, makes an action plan, takes action and learns from the process. The CLCP is facilitated in communities by trained facilitators who use a mental attitudinal approach referred to as SALT. Through the CLCP, the community takes action and learns from its experience. That learning becomes the basis for another round of action and learning. The cycle can potentially go on indefinitely in a self-renewing loop, with the ultimate goal of promoting community ownership of its issues.

We considered villages in selected study districts as communities for administrative and implementation convenience (e.g. availability of a sampling frame for sample selection). In public health literature concerned with community-based interventions, the term 'community-based' often refers to community as the setting for interventions. As a setting, the community is primarily defined geographically and is the location in which interventions are implemented.

The steps of this learning cycle allow a community to divide an apparently insurmountable challenge into a set of specific and manageable steps. The intervention starts with trained facilitators conducting *home visits* in villages. Facilitators engage with people, listen to their hopes and concerns, appreciate their strengths, and eventually bring the community together to discuss the common values they share. SALT home visits are a crucial starting point, as they help to build trust between facilitators and the community, and to identify strengths available in the community.

The next step is collective *dream building*, which starts with individuals and small groups. and then involves the wider community. In our context, a dream of healthy children in the

community, with immunization as a component that can contribute to healthy children, was considered.

Once the community embraces its dream, a *self-assessment* exercise starts under the guidance of the facilitator in order to understand where the community currently stands with respect to practices linked to their shared dream. It is important to note that the practices must ideally come from the community. The facilitators stimulate the conversation so that with respect to healthy children, immunization-related practices emerge during self-assessment.

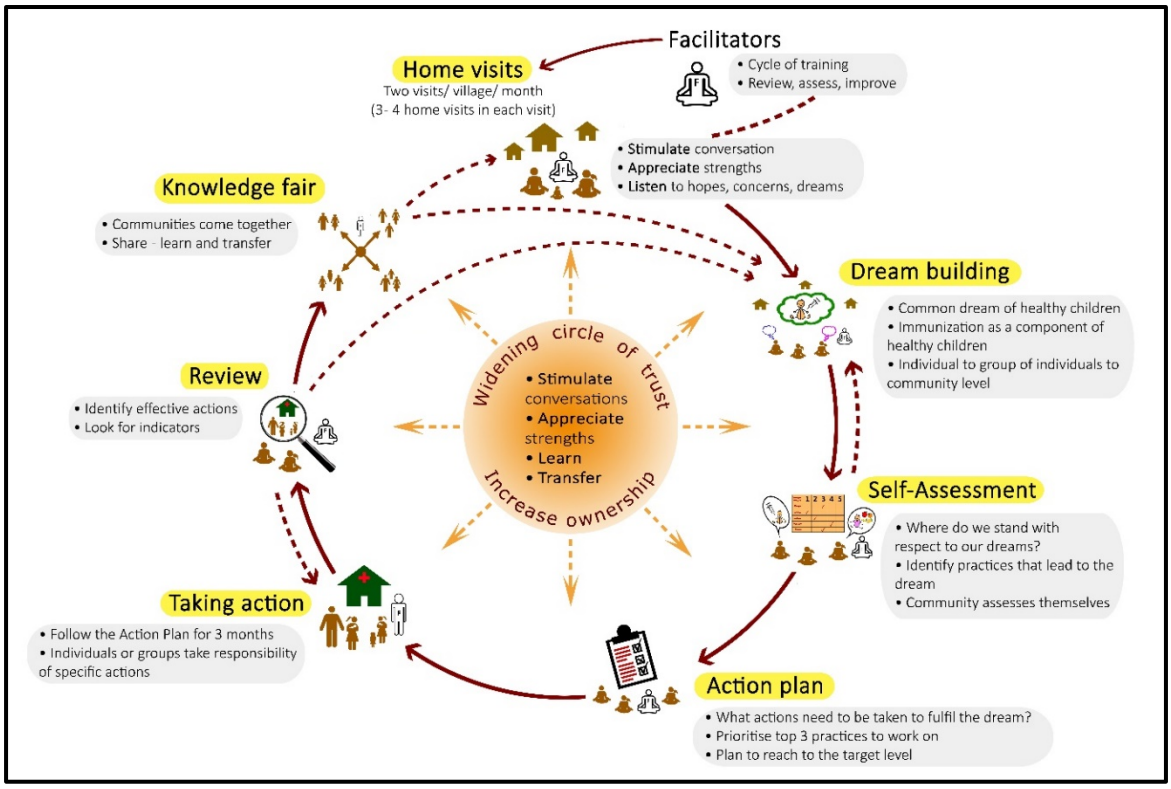
The self-assessment framework requires the community to assess itself on the set of practices defined by the community on a scale of 1 to 5, where 1 indicates a low level of competence and 5 indicates a high level of competence. The central idea behind the self-assessment exercise is that the community assesses itself, rather than the facilitator assessing it. Therefore, this is not about an ‘expert’ coming from outside to assess the community and advise it of its weaknesses or strengths.

In the next phase, the community chooses three priority practices, relevant to its shared dream, where it feels that it can make progress within a stated timeframe (e.g. 2–3 months). The discussion evolves around what actions need to be taken (*action plan*) in order to reach the next desired level from the current level agreed by the community during self-assessment. For each selected practice, the community itself comes up with a certain number of actions, based on its strengths and resources, which would help it to reach the target level within the specified period. Often, specific individuals or groups are identified from the community who take responsibility for each of the actions. To measure the effectiveness of an action plan, some indicators are defined by the community members.

This is followed by the *action phase* and the review process. The emphasis is that a plan is used to help take action, with actions taking precedence. Facilitators then bring communities together to share with and learn from each other in a ’knowledge fair’, wherein a transfer of knowledge and experience takes place between communities.

Throughout the intervention process the community takes action and learns from its experience. This learning becomes the basis for another round of action and learning. Ideally, the cycle goes on indefinitely: there is no end point. However, within the limited timeframe of one year some communities complete the cycle only once while others are able to revisit the dream (and the various steps in the process). A pictorial illustration of the SALT intervention and its processes is presented in Figure 1.

Figure 1: Pictorial illustration of the CLCP and SALT – a path to ownership



2.1 Primary outcomes and impacts of interest

The two primary outcomes are FIC in children 12–23 months old and coverage of DPT3 or pentavalent in children 6–23 months old. We defined full immunization as children receiving one dose of the Bacillus Calmette-Guérin vaccine to prevent tuberculosis; three doses of OPV, DPT or pentavalent vaccine; and one dose of the measles vaccine. We combined information from the vaccination card and mother's recall to define the vaccination status for each vaccine.

We considered the following secondary outcomes: dropout between doses 1 and 3 for the DPT or pentavalent vaccine; availability of a vaccination card; timeliness of measles vaccination; mother's exposure to immunization messages; and mother's belief in the community's role in and ability to have an impact on her child's health. Dropouts between doses 1 and 3 were defined as children who had failed to receive all three doses but had received at least one dose. The vaccination card was defined as available for the child if it was seen by the enumerator.

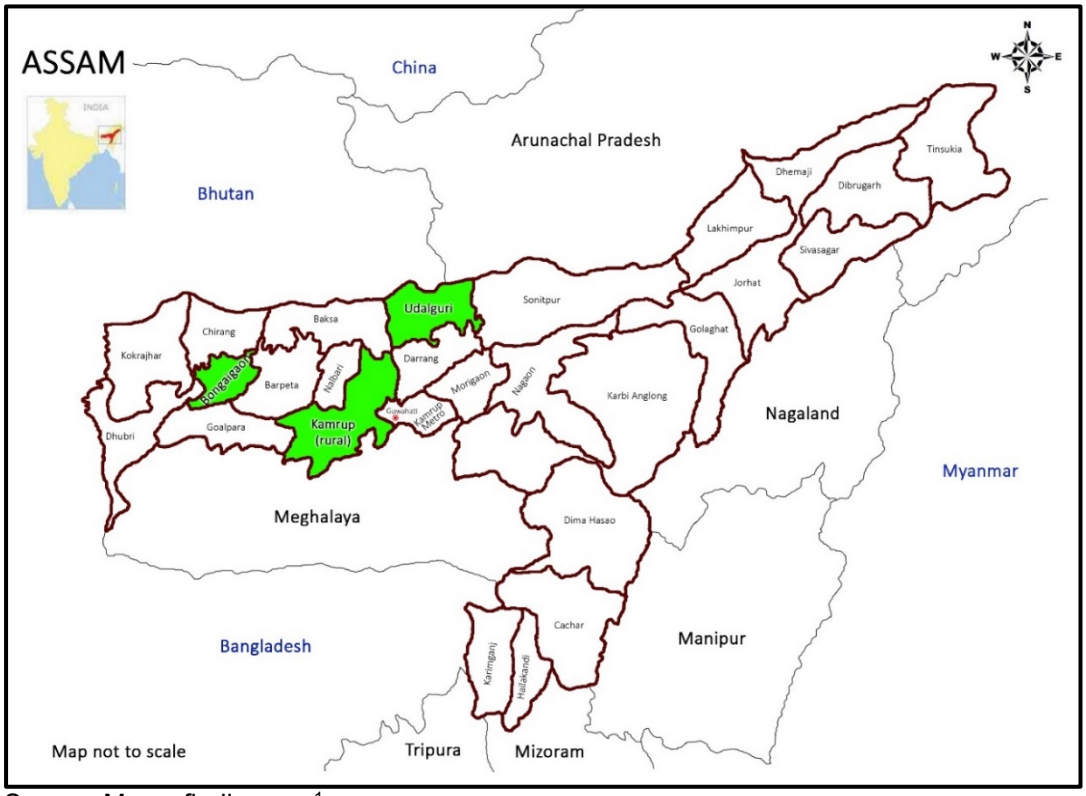
Of the children aged 12–23 months with a vaccination card, those who received a measles vaccination between 7–12 months were considered to be vaccinated in a timely manner. If the mother had heard, seen or read any immunization messages in the last six months, she was considered as being exposed to immunization messages. The mother was asked if she believed that the community had a role to play in improving the health of her child and whether the community was capable of taking actions to prevent her child from getting sick. If the mother replied 'yes' to both these questions, we considered her to believe in the community's role in and ability to have an impact on her child's health.

The water, sanitation and hygiene outcomes considered were the water source and handling of drinking water in the household, whether the household had a latrine, and handwashing practices of the mother. A household was defined as having safe drinking water if its source of drinking water was 'improve' according to the WHO definition; if it was treated to make it safe to drink; and if it was stored in closed containers. The mother was defined as having 'good handwashing practices' if she reported washing her hands with soap or ash after going to the toilet and after cleaning a patient or a person who had defecated; and if she reported washing her hands with either soap or ash or water before handling or preparing food, before eating food and before feeding a child.

3. Context

The study site is in Assam, a northeastern state of India. Historically, Assam is known to have poor public health indicators and weak health infrastructure (MoHFW 2015b). FIC in Assam (55.3%) is lower than the national level (65.2%). Dropout rates for vaccines that require multiple doses are higher in Assam than national figures (UNICEF 2015). According to the 2015 sample registration system bulletin (Office of the Registrar General 2016), Assam has the second-highest infant mortality rate in the country, with 47 deaths in infants less than a year old per 1,000 live births, which exceeds the national average of 37 per 1,000. We considered three districts from Assam: Bongaigaon, Kamrup Rural and Udalguri. Figure 2 shows the location of Assam and the three selected districts.

Figure 2: Location of Assam (inset India map) and three selected districts of Bongaigaon, Kamrup Rural and Udalguri (Assam map)



Source: Mapsofindia.com.[1]

[1] *https://www.mapsofindia.com/maps/assam/.*

Stratified purposeful sampling was used so that the selected districts represented varied socio-demographic characteristics of Assam. Although stratification was used to ensure representativeness, the districts were purposefully selected so that they were not too far away from the central location of Guwahati and were reachable within 3–4 hours by road. This precluded inclusion of districts in Upper Assam and Barak Valley. We excluded two districts from the sampling frame (Dima Hasao and Karbi Anglong) because of safety concerns. Table 1 illustrates the variation across the three districts in terms of selected indicators. We considered only rural areas of selected districts for this impact evaluation.

Table 1: Socio-demographic characteristics of three selected districts of Assam along with DPT3 coverage rate

District	Population	Urban (%)	Tribal (%)	Female literacy rate	Muslim (%)	DPT3 coverage
Bongaigaon	7,38,804	14.9	2.5	64.4	50.2	56.2
Kamrup (R)	15,17,542	9.4	12.0	69.5	39.7	67.2
Udalguri	8,31,668	4.5	32.1	58.0	12.7	62.0

Source: Census 2011 and 2007–2008 district-level household survey data (Office of the Registrar General and Census Commissioner 2011).

We considered an appropriately stratified sampling design of select districts from Assam. Based on a 2011 census sampling frame, Assam has 27 districts. We stratified these 27 districts into three strata and selected one district from each stratum. Strata were created based on the composite index constructed using the following district-level indicators: proportion of rural households, percentage of tribal population, female literacy rate, FIC rate and proportion of institutional deliveries.

The indicators were chosen in accordance with the study objective; they were either directly related to the primary outcome or determinants of the outcome. The first three demographic variables were available from the 2011 census and the other two indicators were obtained from the third round of the Annual Health Survey conducted in 2012–13 (Office of the Registrar General and Census Commissioner, n.d.). To construct the composite index, we applied a principal component analysis technique.

Stratification of districts can be loosely defined as dividing districts into three levels of development and selecting one district from each level. We believed this stratification strategy would lead to a representative sample of rural Assam, even though a limited number of districts were selected. Therefore, any inference regarding the impact of the intervention could be generalized for rural Assam.

4. Timeline

In this section, we provide a visualization of the unfolding of the implementation and evaluation in the context of this impact evaluation study. The timeline also includes some of the challenges which led to minor delays in the project timeline.

Table 2: Timeline of the project: evaluating the impact of the SALT intervention in Assam

	2016				2017				2018				'19
Activities	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
Project initiation formalities: contract signing, hiring new personnel, ethics clearance													
First stakeholder meeting in Guwahati to launch the project													
Preparation of baseline survey													
Hiring of survey agency (L-1) for baseline and contract termination[2]													
Hiring of L-2 agency for baseline													
Baseline quantitative survey													
Baseline data analysis, revising sample size, randomization post baseline, balance check													
Qualitative data collection (FGDs and KIIs) and analysis													
Selection of local NGOs in Assam for the implementation of the intervention in three districts													
Delay in the start of intervention implementation[3]													
Intervention implementation[4]													
Knowledge fair													
Process monitoring and collection of process indicators													
Publication of study protocol													
Endline survey in CAPI													
Qualitative data collection and analysis													
Endline data analysis and drafting the final report for 3ie													
Submission of final report and other deliverables to 3ie and manuscript writing													

Notes: FGD = focus group discussion; KII = key informant interview; CAPI = computer-assisted personal interviewing program.

[2] This occurred due to the survey agency's inability to deliver as per the expected quality and timeline.
[3] This occurred due to concerns regarding the Foreign Contribution Regulation Act status of SIAAP (the agency that was meant to oversee intervention implementation and fund management, as The Constellation does not have a registered office in India). Another agency, SAMRAKSHA, was hired for this purpose. Individual and institutional contracts were revised.
[4] The pace of the intervention slowed down for several months due to a lack of cash flow as a result of the cancellation of Foreign Contribution Regulation Act registration of the Public Health Foundation of India, particularly in Kamrup Rural and Udalguri.

5. Evaluation design and methods

5.1 Ethics approval

Institutional review board approval (TRC-IEC-285/16) for the intervention and evaluation component of the study was received through the Institutional Ethics Committee of the Public Health Foundation of India on 6 April 2016. Written informed consent was obtained from the participants. However, informed consent for randomization was not given, which does not seem to be a strict requirement for cluster randomized trials as the unit of randomization and the unit of observation are different (McRae et al. 2011). The trial was registered on 7 February 2017 under the Clinical Trials Registry of India, which is hosted at the India Council of Medical Research's National Institute of Medical Statistics, and was allotted registration number CTRI/2017/02/007792. A letter of support was also received from the Directorate of Health Services, Assam.

5.2 Evaluation design

We adopted a cluster randomized controlled trial design with two groups to evaluate the intervention. The intervention group received the SALT intervention for about a year (March 2017–March 2018) along with the routine immunization services. The control group received routine immunization services only. A cluster randomized design was appropriate here as opposed to individual- or household-level randomization, as the intervention was intended for implementation at the community (village) level, with the village being our unit of randomization.

The study used a repeated cross-sectional design, wherein we tracked the same sampled villages but drew independent random samples of households at baseline and endline. Post intervention, the endline survey did not follow up with the same households, unlike most other randomized controlled trials, since estimating immunization coverage rates requires targeting a particular age group of children. The children sampled at baseline had mostly grown beyond the desirable age limit by the time the endline survey was conducted.

5.3 Sampling design: recruitment of clusters and participants

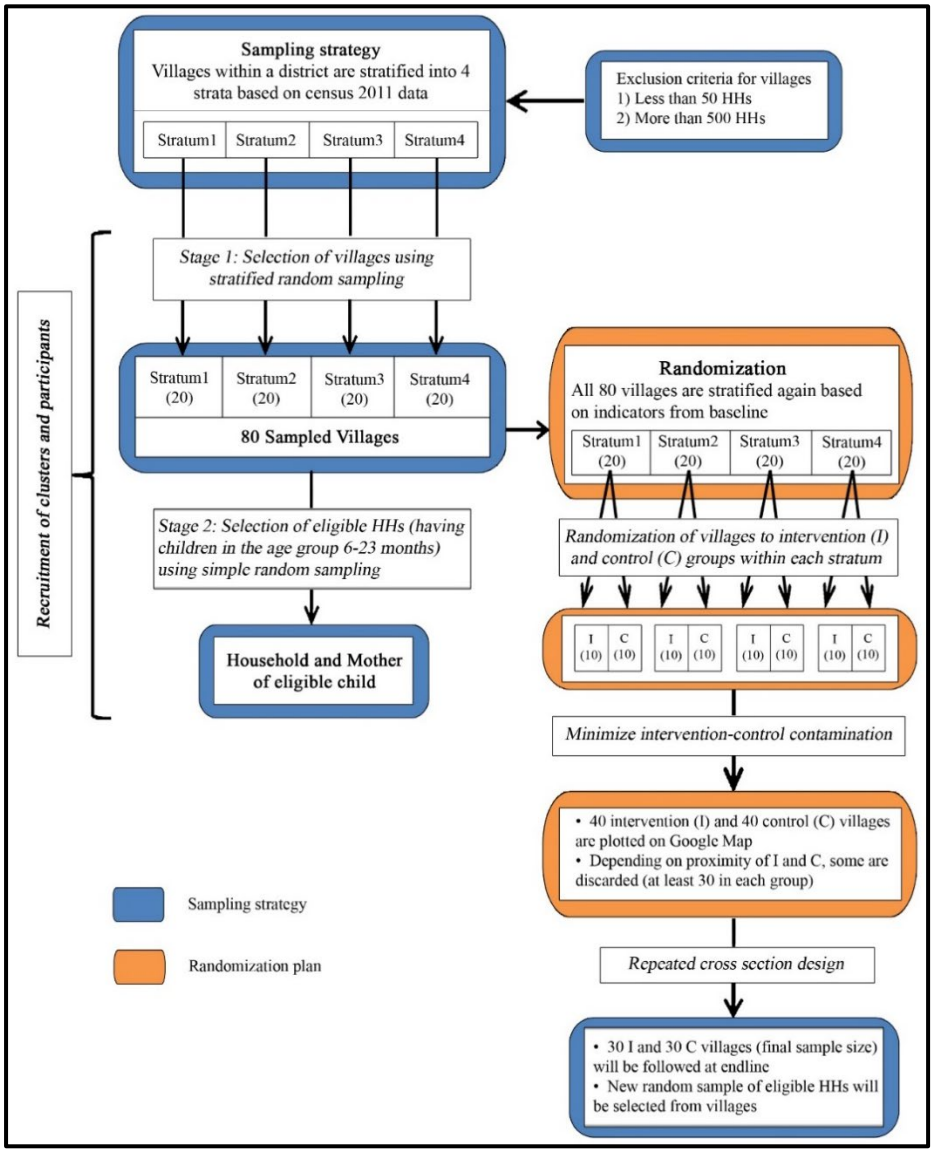
Within each district, we considered a two-stage cluster sampling design. In the *first stage*, we selected villages (clusters) using a stratified sampling technique. We stratified villages within a district into four strata and then randomly selected villages from each stratum. For the selection of villages, we used village-level data from the 2011 census as our sampling frame. The following villages were excluded from the census sampling frame: (1) villages with fewer than 50 households (as capturing enough households with children 6–23 months old would have been a challenge); and (2) villages with more than 500 households (as there would have been logistical challenges in pulling the community together for implementation within the timeframe and resources of the study).

To stratify the villages, we used the following village-level indicators: population size, percentage of scheduled caste residents, percentage of scheduled tribe residents and female literacy rate. Scheduled castes and scheduled tribes are officially designated groups recognized in the constitution of India, comprising historically disadvantaged people (NCST 2006).

Based on these indicators, we developed a composite index that was then used to construct the four strata based on the quartiles of the index. Twenty villages were selected from each of the four strata using a simple random sampling method. The choice of a stratified sampling design ensured a representative sample of villages with varied socio-demographic characteristics in each district. The requirement of 20 villages per stratum stemmed from the sample size calculation, as discussed in Section 5.4. This led to 80 villages (20 × 4) in each district, resulting in a total of 240 villages across 3 districts of Assam for the baseline survey.

In the *second stage*, a random sample of 15 eligible households was selected for the baseline survey in all sampled villages. In each selected household, mothers with children aged 6–23 months were eligible to participate and we collected information pertaining to the mother's youngest child in this age group. The flowchart in Figure 3 provides a visual display of the sampling strategy (in blue). In the endline survey, while the sampled villages remained the same, a new random sample of 15 eligible households was drawn from each village. The baseline survey in 240 villages was carried out from June–August 2016, and the endline survey was conducted in the same 240 villages after conclusion of the intervention, from June–September 2018.

Figure 3: Flowchart describing sampling strategy and randomization plan for the cluster randomized controlled trial within a district (applicable for all three districts)



Note: HH = household.

5.4 Sample size

Sample size calculation for this study evolved over time based on the availability of updated estimates of different parameters involved in sample size calculation. In this section we present sample size calculation at two different points in the study. Final sample size calculation (Section 5.4.2) suggests a requirement of a smaller sample size for evaluation than was initially anticipated.

5.4.1 Initial sample size calculation

To calculate the initial sample size, we considered the two primary outcomes: DPT3 coverage among children aged 6–23 months and FIC among children aged 12–23 months. Per our initial (pre-baseline) sample size calculation, we needed 120 villages per group (intervention and control, leading to a total of 240 villages) to detect a difference of

at least 10 percentage points in coverage between the two groups, with 80 per cent statistical power using a two-sided test at 5 per cent level of significance, after accounting for the correlation in immunization status among children from the same village.

We considered an equal allocation of 240 villages across 3 districts, resulting in 40 intervention and 40 control villages in each of the selected districts. Estimates of the coverage rate for DPT3 and FIC in the control group were obtained from the most recent data available at the time (UNICEF 2015). In Assam, the estimates were 65.9 per cent and 55.3 per cent for DPT3 and FIC, respectively. If the coverage rates for DPT3 and FIC in the intervention group are at least 10 percentage points higher (75.9% and 65.3%, respectively), our sample size would allow us to detect the difference in coverage rates between the two groups.

To calculate the intra-cluster correlation (ICC) for these outcomes, we extracted unit-level data for Assam from the 2007–2008 district-level household survey (IIPS 2010) and obtained the estimates as 0.21 and 0.25 for DPT3 and FIC, respectively. We further assumed that a village would have a minimum of 15 children aged 6–23 months and 10 children aged 12–23 months. If there were more than 15 eligible children in a village, we randomly selected 15 children. The baseline survey was conducted in all 240 villages, as per the requirement of the pre-baseline sample size calculation.

5.4.2 Up-to-date ICC and re-estimation of sample size

Sample size is sensitive to the ICC estimate used in the calculation. Often interpreted as the degree of homogeneity among units within a cluster with respect to the outcome variable, the ICC is defined as the ratio of between-cluster variability to total variability in the outcome. ICC estimates used in the pre-baseline sample size calculation were based on 2007–2008 district-level household survey data.

We expected the recent ICC estimates for DPT3 and FIC to be different – most likely smaller in magnitude because of the improved reach of maternal and child health services including immunization under the National Rural Health Mission (NRHM 2005). Immunization service delivery, the supply chain system, vaccine logistics and the process of linking the health system with communities through accredited social health activists (ASHAs) have all been standardized to a large extent in all rural areas. Moreover, we considered that estimates of the coverage rate for DPT3 and FIC might have also changed. These changes would affect the sample size needed to detect a difference in coverage rates between the control and intervention groups.

On another note, our intervention was complex in nature and involved sustained interaction with the community over several months. Owing to the intensity of the intervention, there were concerns that implementation might not happen optimally within the timeframe and budget if the sample size was unnecessarily large. The international panel of reviewers of this study also recommended that the sample size and ICC be recalibrated based on new data that would become available to us from the baseline survey. These considerations led us to recalculate the sample size based on estimates derived from baseline data.

Table 3: Final sample size requirement for two primary outcome variables calculated using SALT baseline survey (July–August 2016) data

Outcome of interest	Updated coverage rate (%)	Updated ICC	Updated sample size (villages in each group)
DPT3	84	0.17	57
FIC	79	0.18	90

Table 3 presents the revised estimates based on data from the baseline survey and the revised sample size. Note that the ICC estimates based on baseline data have decreased relative to earlier estimates from the 2007–2008 district-level household survey, as anticipated. On the other hand, vaccination coverage rates have increased substantially relative to data from UNICEF's 2013–2014 rapid survey on children (UNICEF 2015).

This sudden increase in vaccination coverage – which has also been observed in other historically poor-performing states such as Bihar, Rajasthan and Madhya Pradesh (Pramanik et al. 2016) – can perhaps be attributed to Mission Indradhanush, the flagship program of the Ministry of Health and Family Welfare. Two phases of the program had occurred before our baseline survey (phase one in April–July 2015 and phase two in November 2015–February 2016), and all three study districts received at least one round of the program's intervention.

However, it was possible that this high level of immunization coverage will not be sustained after the supplementary immunization activities under Mission Indradhanush are discontinued. In view of these high coverage rates, we reduced the minimum detectable difference from 10 to 8 percentage points in the revised calculation of sample size.

Per our revised sample size calculation, we needed 90 villages per group to detect a difference of at least 8 percentage points in coverage between the control and intervention groups, with 80 per cent statistical power based on a two-sided test having a 5 per cent level of significance, after accounting for the correlation in immunization status among children from the same village. The total number of villages required for the study was 180 (90 × 2). We considered an equal allocation of 180 villages across the 3 districts, resulting in 30 intervention and 30 control villages in each of the three selected districts. The intervention was implemented in 90 villages across 3 districts. However, endline data were collected from all 240 villages (120 intervention and 120 control) where the baseline survey was carried out before the launch of the intervention.

5.5 Randomization strategy

We adopted a restricted randomization strategy – specifically stratified randomization – to achieve better balance and leverage information available to us prior to allocation. As opposed to a completely randomized allocation, stratification has the potential to provide explicit balance of potentially important covariates known to be associated with coverage outcomes, as randomization happens within each stratum (Donner and Klar 2000).

All 240 villages sampled in the baseline survey were randomized to the intervention and control groups. For our stratified randomization strategy, the key advantage of randomization post baseline survey is that the stratification of villages, and subsequently randomization within a stratum, can be based on up-to-date indicators obtained from the baseline data.

Sampled villages from the baseline survey within a district were stratified into four strata based on a composite score constructed using the following village-level indicators: average number of children under 5 years; percentage of households living for more than 50 years in the village; percentage of scheduled caste households; percentage of scheduled tribe households; percentage of Muslim households; percentage of households belonging to the poorest wealth quintile; percentage of households belonging to the richest wealth quintile; percentage of mothers having no formal schooling; percentage of mothers with educational qualification of higher secondary or greater (12 years or more); percentage of mothers receiving full antenatal care[5] during pregnancy; and whether the village experienced a flood the previous year. These indicators were derived based on data from the baseline survey.

Not all indicators were used for stratification within a district; the choice of variables depended on the district-specific context. For example, in Kamrup Rural, all three socio-demographic indicators – percentage of scheduled caste, scheduled tribe and Muslim households – were considered, whereas in Bongaigaon the percentage of scheduled tribe households was not relevant and in Udalguri only the percentage of scheduled tribe households was relevant.

To define economic indicators, a wealth index was constructed for each household using baseline data. The wealth index is a widely accepted measure of households' long-term economic status (Rutstein et al. 2004; Filmer and Pritchett 2001). We considered variables related to housing characteristics, household sanitation facilities and asset possession. Each variable is assigned a weight generated through principal component analysis, and the standardized variables are multiplied by the weights and totaled to produce the wealth index. The first principal component, which explains 25 per cent of the total variation in the data, was considered as the wealth index. Based on this, households were divided into quintiles: poorest, poorer, middle, richer and richest.

Finally, within each stratum we randomized sampled villages to intervention and control groups. After stratification within a district, each stratum contained 20 villages, as the baseline sample covered 80 villages in each district. We randomly selected 10 villages to receive the intervention and the remaining 10 villages would continue to receive immunization services from the routine immunization program in place (as a control group). The flowchart in Figure 3 illustrates the randomization procedure (in orange). R statistical software was used to implement the randomization strategy through the use of random numbers (R Core Team 2018).

5.5.1 Minimizing intervention-control contamination

In each district, we randomized the 80 sampled villages to the intervention and control groups in equal proportion. However, according to our revised sample size calculation, we needed only 30 intervention and 30 control villages; that is, we had the liberty to exclude 10 villages from each of the two groups. We attempted to use this opportunity to minimize intervention-control contamination while excluding villages, as opposed to random exclusion.

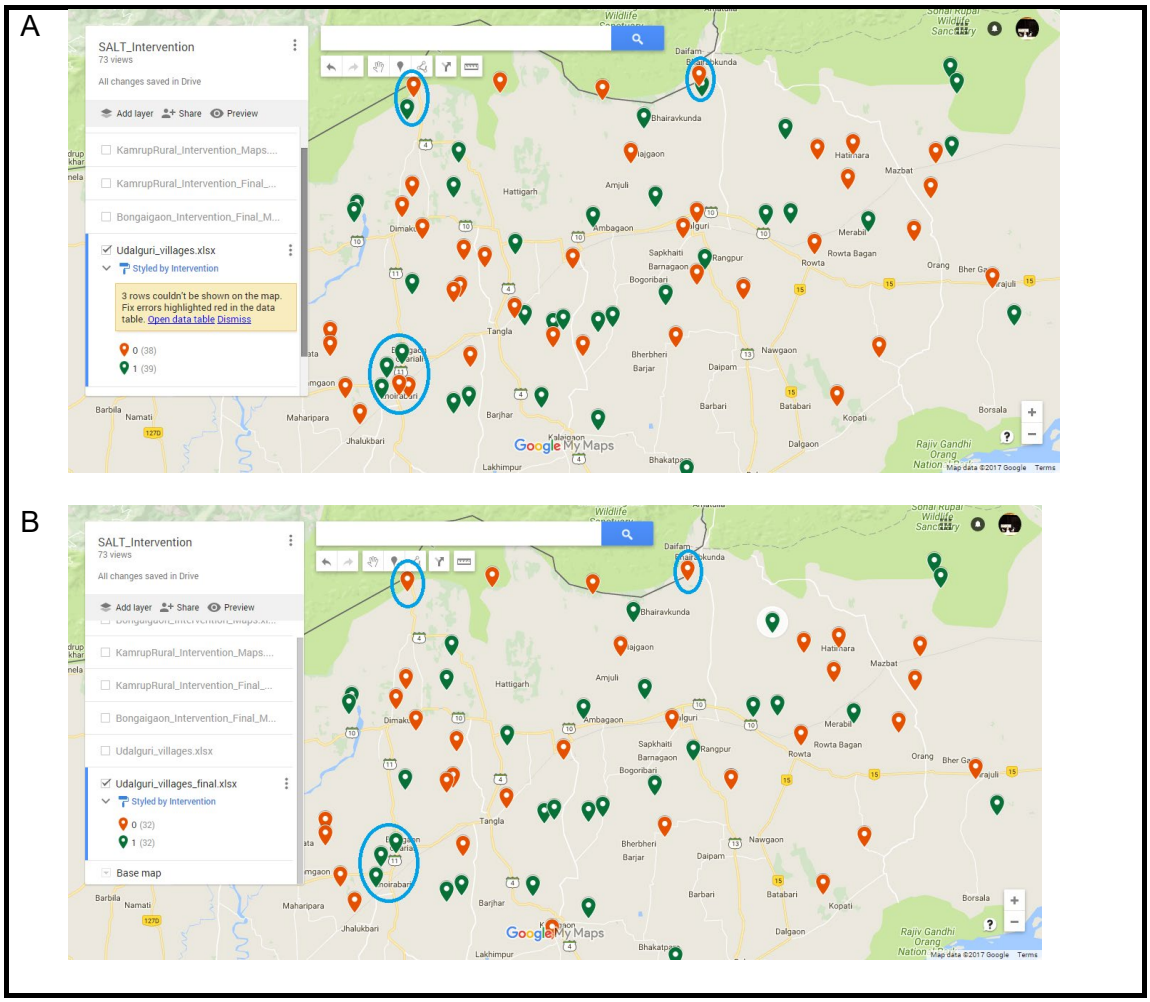
[5] Full antenatal care is defined as the consumption of iron and folic acid tablets or syrup for 100+ days, three or more antenatal checkups, and receipt of at least one tetanus injection.

Transfer of knowledge is an important component of the SALT intervention. Particularly during the knowledge fair, the community may have had an opportunity to meet peers from the control community and share their knowledge and experience when intervention and control villages were in close proximity. To mitigate potential contamination between intervention and control villages, we attempted to ensure that the intervention and control villages were sufficiently far apart from one another. By separating the intervention and control villages geographically, we sought to reduce the chances of interaction between community members belonging to the intervention and control groups. The following procedure was used to ensure a geographical buffer between them.

After randomization, we plotted the intervention and control villages on Google Maps by uploading an Excel file of villages using their locations (defined by ‘village name, district name, state name’) as a column. Differently colored place marks were used for intervention and control villages. Using features of Google Maps, we then calculated straight-line distances between intervention and control villages when they visibly appeared to be close. If the distance was less than 3 kilometers, we discarded one of the villages. While discarding villages, we were mindful about two things: (1) ensuring that an equal number of intervention and control villages were discarded; and (2) the distribution of intervention and control villages across strata did not change significantly, as this might have had an impact on balance between the two groups.

Figure 4 illustrates the procedure using two Google Maps screenshots. In Panel A, we plot all 80 villages from Udalguri district that were randomized to intervention (green) and control (red) groups. In Panel B, we present the same plot after discarding villages in instances where intervention and control villages are within 3 kilometers of each other. For example, in the bottom left corner, two control villages appeared to be located in close proximity to three intervention villages. Distance calculation confirmed that the straight-line distance is less than 3 kilometers and, hence, two control villages were discarded (circled in blue in Panels A and B). Using the same rationale, two intervention villages were also discarded, as seen in the top left and top middle part of the plot (circled in blue in Panels A and B).

Figure 4: Screenshot of intervention (green) and control (red) villages in Udalguri: potential scenarios of intervention-control contamination and subsequent use of geographical buffer to minimize it



Source: Google Maps

Notes: Panel A: Original randomization of baseline survey villages.
Panel B: After discarding villages when intervention and control villages are within three 3 kilometers of each other.

5.5.2 Balancing checks

Balance between intervention and control groups was examined with respect to potentially important covariates after randomization of the 240 villages using baseline data. Although randomization was undertaken at the village level, the unit of analysis was the child. Therefore, we performed balancing checks at the level of village, child, child's household and the mother. Balance was re-examined after excluding the villages discarded to minimize intervention-control contamination.

The results in Table 4 suggest that reasonably good balance has been achieved across indicators for villages, children, their households and mothers. This was expected as the randomization of villages to intervention and control groups happened within each stratum, after stratifying the villages based on several of the indicators presented in Table 4. The two groups remain balanced after excluding intervention and control villages discarded to minimize intervention-control contamination.

To check balance between intervention and control groups based on selected households, mother- and child-level characteristics have been adjusted for clustering, as responses from households (as well as mothers and children) within a village are correlated. However, when checking balance based on village-level indicators, this adjustment does not have any impact on standard errors and hypothesis testing. All analysis has been done using the 'survey' package (Lumley 2011) in R software (R Core Team 2018). The Wilcoxon rank sum test has been adjusted as per the survey design (Lumley and Scott 2011).

Table 4: Balancing checks based on selected village-, household-, mother- and child-level indicators: comparison between intervention and control groups

Characteristics	*After randomization of all 240 baseline survey villages*			*After discarding villages to minimize contamination (180)*		
	Control	Intervention	p-value	Control	Intervention	p-value
Village-level indicators						
Having subcenter	40.5	39.2	0.8334	39.8	41.7	0.7926
Having secondary school	31.0	25	0.3034	29.6	26	0.5833
Occurrence of flooding last year	30.2	37.5	0.2359	31.6	35.4	0.5787
% of HHs living more than 50 years in the village	75.9	76.5	0.6841	77.2	76.1	0.8800
% of tribal HHs	26.4	26.2	0.5359	25.6	27.3	0.6494
% of mothers with HS education or more	12.3	13.1	0.6777	12.6	13.6	0.6390
% of mothers receiving full antenatal care	41.9	42.1	0.936	42.5	43	0.8386
Household-level indicators						
Average HH size	5.33	5.28	0.4336	5.34	5.3	0.4867
HH head is Muslim	27.9	32.3	0.4104	27.7	30.2	0.6453
HH has (pour) flush toilet	35.9	33.6	0.5033	35.3	35.1	0.9965
HH belongs to poorest wealth quintile	19.7	19.7	0.9838	20.4	17.3	0.2405
Average time (in minutes) from HH to vaccination site	19.9	20.6	0.5764	19.9	19.9	0.6037
Mother- and child-level indicators						
Mothers received full antenatal care	41.9	41.9	0.9612	42.4	42.9	0.8787
Child was born in health facility	85.9	86.5	0.7941	84.9	88.4	0.2184
Child has vaccination card	92.7	92.4	0.7852	92.1	92.1	0.9731
Child (12–23 months old) is fully immunized	78.5	77.6	0.8244	77.6	77.6	0.8479

Note: HH = household; HS = higher secondary. Wilcoxon rank sum test of null hypothesis: location parameters of the distribution are the same in each group.

5.6 Data collection and data quality control measures

5.6.1 Quantitative data collection

The process of endline survey data collection started with selection of a data collection agency. Based on their performance during the baseline survey, Nielsen (India) Pvt. Ltd. was selected to conduct the endline survey. A computer-assisted personal interviewing mode of data collection was used. Nielsen was found to be experienced in managing large-scale studies through computer-assisted interviewing programs across India, including Assam.

The survey comprised two stages: a house listing exercise followed by a household survey of mothers. For the main survey, the program developed by the Nielsen team was tested multiple times and subsequently revised based on feedback from the evaluation team. The program was also field-tested in mid-July. Based on the feedback received from the field monitoring reports and a series of feedback sessions involving the evaluation team and the Nielsen team, the final version of the computer-assisted interviewing program was developed on 25 July 2018.

The quantitative survey started toward the end of July 2018 and continued until the second week of September 2018. Nielsen maintained an effective communication channel throughout the course of endline data collection, thereby ensuring that the feedback provided by the evaluation team – based on field monitoring reports and analysis of real-time data – was conveyed to the entire field team. Nielsen also shared the field plans with the evaluation team in advance on a regular basis, which helped the evaluation team to better plan the field monitoring.

Nielsen employed 21 interviewers and eight supervisors. Their work in the field was closely monitored by the Indian Institute of Public Health-Shillong monitoring and evaluation team. Each of the field interviewers and supervisors was monitored at least once. Interviewers and supervisors who required more handholding were monitored more (3–4 times) than the others. A monitoring plan and grading format for the interviewers and supervisors were developed to evaluate interviewing and supervising skills and attitude.

The monitoring and evaluation team accompanied the survey data collectors and their supervisors, and observed them closely in the field. Feedback reports were prepared on the same day and sent by the end of the day to the principal investigator and co-principal investigators, who in turn went through the reports before sharing feedback to the survey agency for continued improvement.

The evaluation team faced several difficult circumstances during the endline survey monitoring, such as lack of drivable roads, which resulted in both the survey and evaluation teams walking several kilometers and using country boats to reach the selected villages. Despite these challenges, the team monitored 23 villages across the three districts and ensured that the interviewers understood the content of the questionnaire and followed proper interviewing techniques to collect data.

We received the data sets from Nielsen twice per week in both SPSS Statistics and Stata formats. To check data quality and ensure internal consistencies in data, we developed 27 parameters covering both household and mother questionnaires. However, our main focus remained on the following four indicators related to our primary

evaluation outcomes:

1. Whether the images of the vaccination cards were captured or not by interviewers (for children having vaccination cards and cards being seen by interviewers);
2. A comparison of the vaccination dates entered by interviewers with the information captured in the images of the vaccination card;
3. The time taken to complete the household and mother questionnaires across interviewers (whether some interviewers were always rushing or unrealistically slow); and
4. Whether the order of different vital events in the mother questionnaire is reflected in the data. In other words, whether life events were laid out chronologically (mother's age is greater than their age at the birth of their first child, which is greater than their age at marriage, etc.).

These indicators were checked regularly, and feedback based on data analysis was shared with the survey agency. To ensure the quality of our primary outcome data, we matched the immunization data recorded from the card with the vaccination card image. We calculated the status of primary evaluation outcomes (full immunization and DPT3 doses) independently from the images of the vaccination card and the dates recorded by interviewers for 137 randomly selected children. Only one discrepancy was noted in the FIC status, and no discrepancy was noted for the coverage of DPT3.

5.6.2 Qualitative data collection

Qualitative data were collected to understand community perceptions regarding immunization and the SALT intervention from 28 villages (22 intervention and 6 control villages).

Methods of data collection adopted included: (1) focus group discussions (FGDs); (2) key informant interviews (KIIs); and (3) in-depth interviews (IDIs). A total of 39 FGDs were conducted across the three study districts with parents (mothers and fathers separately) and grandmothers of children in the age group of 6–23 months. Twelve IDIs were carried out with parents and grandmothers in Kamrup and Bongaigaon districts. IDIs were initially not a part of the qualitative data collection plan, but in certain instances where an adequate number of participants did not turn up for FGDs, the research team conducted IDIs.

In addition, 33 KIIs were carried out across the three study districts. The KIIs were conducted with the district program manager and block community mobilizer of the National Health Mission, auxiliary nurse midwives, ASHAs and their supervisors (Table 5). Other than a few KIIs (e.g. with the district program manager) wherein some of the conversation was conducted in English, all other qualitative data collection methods used the local language only.

Table 5: List of different qualitative data collection methods along with sample size across study districts

	IDIs				KIIs						FGDs			
Districts	GM	MO	FA	**Tot**	ASHA	ANM	ASHA Sup.	BCM	DPM	**Tot**	GM	MO	FA	**Tot**
Kamrup	7		1	**8**	8					**8**	3	9	1	**13**
Bongaigaon		4		**4**	9	1	5	1	1	**17**	4	8	3	**15**
Udalguri				**0**	8					**8**	2	8	1	**11**
Total	**7**	**4**	**1**	**12**	**25**	**1**	**5**	**1**	**1**	**33**	**9**	**25**	**5**	**39**

Note: GM = grandmother; MO = mother; FA = father; Tot = total; DPM = district program manager; BCM = block community mobilizer; ANM = auxiliary nurse midwife; Sup. = supervisor.

Interview topic guides were used to conduct FGDs, KIIs and IDIs. The topic guides included questions about perceptions of a healthy child, common childhood ailments and corresponding treatment-seeking behavior, knowledge and perception of vaccination, and any challenges faced in vaccinating children. In intervention villages, participants' opinions were probed with regard to the different steps of the SALT process (dream building, self-assessment, action plan and taking action) and whether any transfer of information within the community had taken place.

The FGDs, KIIs and IDIs were recorded with the prior consent of the respondents. The interviews with rich information were prioritized for in-house translation and transcription into English by the study team, while the remaining files were outsourced through Earth Lingua, a translation and transcription agency.

The field research team was well versed in Assamese as well as English. It cross-checked a randomly selected 15 per cent of the tapes and verified with the transcripts as a quality check.

6. Intervention implementation and process evaluation

6.1 Implementation of the intervention in practice

6.1.1 Selection of local NGOs for intervention implementation

The Constellation engaged two local NGOs – Voluntary Health Association of Assam (VHAA) and the Centre for North East Studies and Policy Research (C-NES) – to implement the intervention. C-NES was responsible for implementation in Bongaigaon district, while VHAA implemented the intervention in Kamrup Rural and Udalguri.

In order to select the local NGOs, The Constellation's team visited Assam in June 2016 to view the short-listed NGOs' experience of the activities at first hand. The evaluation team provided support in the selection process and shared insights based on their experience regarding the short-listed agencies. The Constellation used the following criteria to select the NGOs:

- Experience and willingness to work with the community;
- Interest in the SALT approach;
- Experience of working in different contexts and issues (particularly within the health sector);

- Infrastructure (how they execute their ongoing projects and the strength of their finance team, advocacy team and communication team);
- Their relationship with the government; and
- Whether the NGOs are registered under the Foreign Contribution Regulation Act.

Each of the selected NGOs engaged three SALT facilitators for a district, and each facilitator was responsible for implementing the intervention in 10 villages. A total of nine SALT facilitators were engaged in implementing the intervention. C-NES hired an additional district coordinator based in Bongaigaon to coordinate the intervention. The VHAA district coordinators were based out of Guwahati. The SALT facilitators and district coordinators were trained on the SALT approach during the course of the intervention (February 2017–April 2018).

6.1.2 First learning event

Implementation of the intervention began with the first learning event organized by The Constellation along with the local NGOs on 13–18 February 2017. The Constellation's coaches Ian Campbell, Rituu Nanda and Bobby Zachariah took the lead in conducting the learning event. A team of facilitators from VHAA and C-NES, along with the district coordinators, participated in the event. From the evaluation team the principal investigator, co-principal investigators, senior program assistants, research fellow and research assistant were also present.

The teams were introduced to the concept of the SALT intervention, its basic foundations and the process of home visits. 'SALT home visits' were described as a crucial starting point for building rapport between facilitators and the community, and to identify the strengths of the community. The event included interactive training sessions and hands-on experience through home visits made to the selected villages in the three study districts. The evaluation team members played an active role in translating (English to Assamese) the session proceedings and explaining the content to the facilitators. Four villages were selected for demonstration of home visits. These are Barkukuria village in Kamrup Rural, the riverine village Chatpara, Pachonia part 1 in Bongaigaon and Saikiapara village in Udalguri. The teams used a C-NES boat clinic to reach Chatpara village.

6.1.3 Subsequent learning events and support visits

After the first learning event in February 2017, The Constellation's team organized subsequent learning events and support visits to explain the different steps of the intervention to the facilitators. In March 2017, Jean-Louis Lamboray and Rituu Nanda visited Guwahati to meet the local implementation teams. Although the primary objective of this visit was to launch Jean-Louis's recent book '*What makes us human?*' in Guwahati, The Constellation coaches took this opportunity to expand on the concept of the CLCP and to understand the challenges faced by facilitators during home visits.

A five-day learning event was conducted again in June by Marlou De Rouw, Bobby Zachariah and Rituu Nanda. Three coaches from The Constellation leading three field teams in Bongaigaon worked well and acted as a morale booster for the teams. There was a noticeable improvement in facilitation skills among facilitators, especially those who had difficulties in communicating and facilitating during the first learning event.

The learning event on 8–9 July was conducted by Constellation coaches Philip Forth and Rituu Nanda. During the learning events in June and July, the concept of CLCP and the steps involved (e.g. dream building, self-assessment and action planning) were explained in detail. The visit by Philip Forth was particularly noteworthy, as during this visit a more comprehensive approach to outlining the CLCP/SALT approach was carried out, while a more incremental approach had been used in previous visits. Thus, in the latter visit, facilitators gained a clearer picture of the entire intervention. The local facilitators also gave valuable feedback to the lead facilitators on how their training could have been improved.

During 4–7 October 2017, Luc Barrière-Constantin and Rituu Nanda made another support visit to explain and illustrate the action plan step of the CLCP in detail. There were sessions dedicated to understanding the challenges faced by facilitators and what they were doing to overcome challenges in the field. During this support visit there were comprehensive inter-district discussions, which led to an exchange of learning and ideas, such as:

1. Including champions in facilitation work (e.g. for conducting dream building, self-assessment and action plans);
2. Including champions or any other interested person from the community in the after-experience reflection (AER) process, which is commonly performed by SALT facilitators;
3. Pasting a copy of dream-building, self-assessment and action plan charts in a common community space;
4. Conducting a district-level meeting with ASHAs and their supervisors for smooth implementation of the intervention;
5. Inviting block community mobilizers and other health officials to community meetings; and
6. Forming small groups (action implementation groups) during the action plan if desired by the community (as occurred in Boinashri Village of Udalguri). These groups would meet regularly with the person responsible for a specific activity and follow up on progress or problems.

The key points that were discussed for each of the steps involved in CLCP were as follows.

Dream building

1. Ask the question: What is your dream (as a community or individual) for the health of children in your community in 10 years?
2. Build and share the individual dream.
3. Divide people into small groups (men/women/children/youth).
4. Facilitate the development of the group dream.
5. Discuss all the group dreams to develop a common dream for the community.
6. Document the common dream pictorially and in writing.
7. Document the ideas of change that emerge.
8. Carry out AER to discuss what went well in the facilitation team, what could have been better and how they did as a team.

Self-assessment

1. Self-assessment is an exercise done by the community to assess where they are now in terms of achieving their dream to a desired level. It is the community that assesses themselves and not the facilitator.
2. The practices should begin with 'We… [followed by an active verb]'.
3. The self-assessment exercise is time-consuming and challenging for the community to understand, and so the facilitator should not rush the process. The community should be given enough time to understand the levels of self-assessment.
4. If the self-assessment exercise is carried out in two days, then on the second day summarize and explain what was done the previous day.
5. For ease of facilitation, the facilitator should carry the chart of the common dream of the community, a few charts of the home visits made in that village, a chart with the self-assessment framework drawn, and extra blank charts and pens.
6. The community can be divided into groups for listing the key practices but not for assessing the levels of self-assessment.
7. Apply the principles of SALT – stimulate, appreciate, learn and transfer – while facilitating the discussion with the community.
8. Carry out AER with yourself and fellow team members after completing the exercise for the day.

Action plan

1. The facilitators will assist in establishing a dialogue through which the community chooses three practices which are feasible and doable in a specified period of time (e.g. 2–3 months) from the practices selected by the community during their self-assessment. Following a desire for healthy children, the facilitator should facilitate such that the community picks up the practice of immunization as one of the three practices in their action plan. All the selected practices are to be listed on the action plan chart.
2. The facilitator should link the community with necessary individuals or organizations and not provide any immediate solutions to the community.
3. AER should be conducted after completing the action plan, and members of the community and health workers can be included in AER.

6.1.4 Knowledge fair

The knowledge fair is the last component of the CLCP process, wherein the communities share their experiences and learn from each other. Knowledge fairs were organized by The Constellation and its local partner organizations in the three districts in April 2018. These were followed by a combined knowledge fair in Guwahati, where communities from the three districts came together. The objectives of the fair were to bring together communities from the project districts to connect for cross-learning and inspiration and to gain new perspectives from shared experiences. The evaluation team members attended these sessions as observers.

6.2 Process evaluation of the intervention

In order to measure the extent of communities' exposure to the intervention, we collected process indicators throughout the intervention phase. Specifically, the aim was to gain understanding about intervention fidelity around the following aspects: (1) whether the intervention was implemented as intended; (2) whether the intervention incorporated the

primary objective of the study (that is, increasing immunization coverage); (3) consistency of intervention delivery across communities in terms of the process of administering the intervention; (4) the reach and coverage of the intervention across villages and districts; and (5) whether contextual factors influenced the implementation of the intervention.

The components of the process evaluation were developed based on the framework of Grant and colleagues (2013). Data on the indicators relevant for each step of the intervention were collected through a combination of methods, including a monthly reporting format developed by the evaluation team and duly filled in by the SALT facilitators; direct observation of different steps of the intervention by the evaluation team; and IDIs with SALT facilitators and district coordinators by the evaluation team. The evaluation team also interacted informally with community members during the dream-building, self-assessment and action plan sessions in the community.

6.2.1 Development of process evaluation indicators and monthly reporting format

It was agreed that some indicators would be documented by facilitators, compiled by the lead NGO and shared with the evaluation team. To develop the indicators for process evaluation, the evaluation team first reviewed existing literature and identified key indicators used for evaluation of complex interventions in a randomized evaluation setup. While developing the indicators, the various steps involved in the SALT intervention were kept in mind.

After multiple iterations, the final set of indicators was included in the monthly reporting format and shared with C-NES and VHAA. The idea was to keep the format simple so that it was not a burden for the facilitators to fill in on a regular basis. After a series of meetings by Skype, phone and in person, a simple monthly reporting format with the following indicators was developed in July 2017:

- Total number of households (as per house-listing data) in the village;
- Number of visits made to this village;
- Total number of households where SALT visits were conducted;
- Total number of community meetings that happened;
- Total number of meetings involving specific groups (e.g. community-based organizations/self-help groups/health workers/religious leaders/others);
- Whether the community dream building happened in this village (if yes, specify month);
- Whether immunization emerged as a topic during dream building;
- Whether the self-assessment exercise happened in this village (if yes, specify month);
- Whether practices around immunization were discussed during self-assessment;
- Whether the community developed an action plan based on three practices;
- Duration (in months) of the action phase in the village; and
- Number of follow-up visits made to the village for follow-up of the action plan.

Once the monthly reporting format was finalized, the process evaluation team conducted a two-hour training session during The Constellation's learning event in July 2017, explaining the indicators and how to fill them.

All nine SALT facilitators used to submit filled-in monthly reporting formats to the evaluation team at the end of each month more or less in a timely manner. Based on the monthly

reports from SALT facilitators, the evaluation team created consolidated reports at district level. District-wise, village-level process indicators are included in Appendix C.

6.2.2 Development of process evaluation data collection tools

Based on the concepts gained from the learning events and other support visits conducted by The Constellation, the evaluation team developed checklists for on-site process monitoring of home visits, dream building, self-assessment and the action plan. The checklists had indicators to understand and document the 'what, where, when and how' aspect of implementation of the intervention. Furthermore, to understand implementation through the lens of the facilitators, IDIs were conducted with SALT facilitators and district coordinators. IDI guides were developed for ease of conducting interviews (Appendix E). These guides had questions that not only helped to cross-check some of the indicators of the monthly reporting format, but also to get a better understanding of on-the-ground realities pertaining to the intervention.

6.2.3 Process evaluation data collection

After developing the tools for process evaluation data collection, the evaluation team began data collection from June 2017. Each facilitator and district coordinator was interviewed twice in person during the intervention phase. In addition, one-to-one follow-up was done over the phone and through WhatsApp in order to resolve confusion. The interviews were conducted in Assamese language and were audio-recorded. The audio recordings were transcribed into English and further analyzed. The team also conducted informal interactions with community members just after dream-building, self-assessment and action plan sessions.

6.2.4 Key observations based on process evaluation data

Some overall observations as well as specific observations related to SALT facilitators, trainers and community members are outlined below.

Overall observations

- **Progress and completeness:** In 88 of the 90 villages, the entire intervention was completed before the end of the intervention period (March 2018). Bongaigaon district largely followed the implementation plan as outlined within the timeline. Dream building and self-assessment were completed in 90 per cent of the villages by December 2017, and the full cycle of CLCP was completed by March 2018. In Kamrup Rural, dream building and self-assessment had been carried out in 23 of the 30 villages by December 2017, and the full intervention was completed in 28 of the 30 villages by March 2018. In two villages, the intervention was not completed within the stipulated time. In Udalguri district, dream building and self-assessment were completed in 23 of the 30 villages (76%) by December 2017. The whole intervention was done in all 30 villages by March 2018, with four villages moving through the different phases of CLCP within a period of one month (March 2018).
- **Who is exposed to the intervention?** Generally, 10–30 community members participated in the CLCP activities under the SALT intervention. It was observed that there was no mechanism in place for tracking whether the same participants participated in all the activities under SALT. For example, in many cases it was evident that people who were present during the dream-building exercise were not part of the subsequent sessions (self-assessment, action plan and follow-up) and

new members also joined in each subsequent activity. An assumption at the start was that intra-village transfer of SALT would take place, but this did not appear to be the case, as new members present during later steps and processes were often unaware of the previous activities (according to observations by the monitoring and evaluation team).

- **Duration of intervention:** Each of the key SALT activities was a time-consuming process; hence, the community had to be present at the venue for around 3–4 hours. If multiple steps were conducted in a single day due to paucity of time or other reasons, it could potentially hamper optimal outcomes. The SALT facilitators who started the intervention early had time to complete the dream-building, self-assessment and action plan exercises on separate dates. But facilitators who joined the intervention late *(UG_FL03– Udalguri and KM_FL03 – Kamrup Rural)* had less time to complete the intervention and had to carry out the dream-building, self-assessment and action plan exercises on the same day in a few villages (*29/01/2018, Chilabandha village, Udalguri, SALT Facilitator: UG_FL03, VHAA*).
- **Other issues relative to immunization:** In many facilitation sessions, particularly in Kamrup Rural, it was observed that concerns other than immunization were highlighted through the SALT process.

Observations related to trainers

- **Simple and easy sessions are crucial:** After initial difficulties (especially around language), lead facilitators were able to adapt and explain in a suitable manner to the field team. Facilitators also said that their understanding of the SALT approach had increased after the second learning event. The Constellation team members used pictures and/or drawings to explain key concepts of the SALT approach and this was helpful.
- **Bringing together the community through humor and games:** During the dream-building exercise held at a village in Bongaigaon district, Marlou (from The Constellation) requested that the community teach her a game so that she could play that game back in her country. The community obliged her by playing the ‘cow and tiger’ game. In this game, one person plays the part of a cow and another becomes the tiger. Other villagers try to protect the cow by forming a circle around the cow. The tiger tries to get hold of the cow by breaking the circle. Once the tiger is successful in entering the circle, the people who form the circle by holding hands, release the cow from inside the circle and do not allow the tiger to get out of the circle, thereby protecting the cow. This game went a long way in helping the team mix well with the community.

Observations related to facilitators

- **Motivation of the facilitators:** Implementing an unusual intervention like SALT requires internalization of the approach before its implementation. The facilitators were required to unlearn their earlier community engagement experience, which mostly entailed imparting knowledge and awareness among the community members, whereas SALT demanded the skills of listening and appreciating. It was initially observed that the facilitators had difficulties in communicating and facilitating during the first learning event, but we observed improvement and better motivation during the second learning event. Some of the common motivating factors that the facilitators shared lay in helping the community to find links that opened up solutions, mutual hope, trust and reciprocity.

- **Focus on introduction as 'human beings':** In the SALT approach, facilitators were encouraged to introduce themselves as 'human beings' rather than belonging to any organization, office or institution so that the community could identify with them better. This potentially helped the community members to open up to the facilitators and share their dreams, hopes and concerns.
- **Using SALT in their own lives:** Some of the facilitators shared that they 'have started using the SALT approach in their lives due to which there is a positive change' in themselves.
- **Good coordination among field team members:** Good team coordination was observed among the field teams during the dream-building and self-assessment exercise. The NGO leads understood the process well and were actively participating throughout the process.
- **Preparedness of SALT facilitators:** The facilitators were generally found to be well prepared while going into the field. Most of them carried copies of the home-visit, dream-building, self-assessment and action plan charts with them while going to the villages. However, in some instances the facilitators were not fully prepared. During one of the follow-ups of the action plan exercise in one of the villages, it was observed that the SALT facilitator did not carry any of the charts related to dream building, self-assessment or the action plan. The activity had to be cancelled due to a *Puja* (worship) in the village. But the SALT facilitator should ideally have had a copy of the charts for better follow-up on the actions, since the names and phone numbers of the persons responsible for the actions are mentioned in the action plan chart *(31/01/2018, Ischadagharia village, Kamrup Rural, SALT facilitator: KM_FL03, VHAA)*.
- **Recap of the CLCP process is important:** Since there are chances of new community members participating in various steps of the intervention, the CLCP process needs to be explained from scratch to new members. This was not found to have been done during one of the monitoring visits *(27/01/2018, Jalkubari FV Village, Kamrup Rural, SALT facilitator: KM_FL02, VHAA)*.

Observations related to the community

- **Trust-based relationship:** A good relationship of trust was developed between the community members and the SALT facilitators, which helped to continue the intervention for more than a year (and even beyond that in some villages).
- **Complex intervention to grasp:** It was observed that due to the novelty of the SALT intervention, some of the communities found it difficult to grasp the whole concept behind it. According to facilitators, it took around 4–6 months for the SALT facilitators to build rapport with the community and make them share their thoughts. In most of the cases, the community was not able to recall terms like CLCP or SALT. However, when the reference to the dreams for their children and village came up and charts were being drawn for the various activities under the SALT intervention, they could recall the name. As per their understanding, 'this is a process where the community comes together to work for their betterment'.
- **Taking initiative and ownership:** During follow-up in one of the villages, it was observed that although the community did not take any action until that time, the mothers had started calling the ASHA to ask about the due dates of immunization for their children *(01/02/2018, Mazgaon Village, Kamrup Rural, SALT facilitator: KM_FL01, VHAA)*.

During one of the monitoring visits, it was found that fathers had started taking ownership of the immunization program after the SALT intervention. Some of the fathers had themselves brought their children for the OPV during the polio immunization drive *(31/01/2018, Tarabari Village, Udalguri, SALT facilitator: UG_FL02, VHAA)*.

- **More time for relationship building:** From observations during monitoring and evaluation in a village in Bongaigaon during one of the activities of revisiting households post follow-up (one of the activities only seen in Bongaigaon district), a kind of appreciative inquiry could be seen developing in the community. This was likely due to the repeated visits of the SALT facilitator and the corresponding SALT exercises. The champions were found to be very active and supportive. The community seemed to hold the facilitators in high esteem. Each of the champions wanted the team to have tea and snacks in their individual houses, although the team could not oblige each one of them *(08/02/2018, Kanara Beel Village, Bongaigaon, SALT facilitator: BN_FL02, C-NES)*.
- **Expectation from SALT facilitators:** It was observed that the community often expected more from the SALT facilitators than just enabling linkage to various departments, experts and program personnel as envisaged in CLCP/SALT. In Bongaigaon, the community had requested that the facilitation team carry out an awareness program on immunization and other health issues. In one follow-up visit, the community asked the facilitators to explain in detail the immunization schedule. Even though the auxiliary nurse/midwife and community health officer were present at the discussion, they did not come forward to explain the immunization schedule to the community. One of the auxiliary nurses/midwives said she was new and had limited knowledge about immunization. Eventually, the SALT facilitator had to explain the immunization schedule to the community *(06/02/2018, Bashbari No.4 Village, Bongaigaon, SALT facilitator: BN_FL01, C-NES)*. In Udalguri, the ASHA requested that the facilitators talk to health officials regarding issues in the community.
- **Lack of awareness continued to be the case:** During one of the monitoring visits, it was observed that although the community took their children for immunization, they were not aware of the immunization schedule, the diseases prevented through immunization or the details given in the MCP (mother and child protection) card. After implementation of the SALT intervention, facilitators said there was improvement in understanding the details such as the immunization schedule and names of the vaccine-preventable diseases *(09/02/2018, Majgaon Pt II, Bongaigaon, SALT facilitator: BN_FL01, C-NES)*.

7. Analytical approach to the evaluation questions: methods

7.1 Primary hypothesis

Our primary hypothesis was that FIC among children 12–23 months old, and DPT3 or pentavalent coverage in children 6–23 months old, would be higher in the intervention group compared to the control group. Moreover, any improvement in vaccination coverage could be attributed to the SALT intervention. The two primary outcome variables – full immunization and DPT3 status of children (both binary) – are defined in Section 2.1.

In this report we do not attempt to differentiate between DPT and the pentavalent vaccine. Even though the pentavalent vaccine was launched in study districts long before the endline survey, the old vaccination cards are still used and available within the study population. There was much confusion with regard to vaccination card entries and mothers' understanding of the specific vaccine administered to the child (DPT or pentavalent). DPT status refers to whether the child received either DPT or pentavalent. Completion of a vaccine schedule for those requiring multiple doses (e.g. OPV, pentavalent) remains a major challenge toward achieving the optimal level of FIC. Therefore, DPT3 coverage is an important indicator in the context of childhood immunization.

7.2 Statistical analyses

We conducted the analysis of individuals as they were randomized (intention-to-treat analysis). Since we expected the outcomes to be correlated within villages, we accounted for clustering at the village level. We analyzed the effect of the intervention by comparing outcomes at endline between the intervention and control arms, after adjusting village-level log odds of coverage at baseline. We used a random effects logistic regression model to analyze the binary outcome variables clustered at the village level. Specifically, the model is:

$$logit\left(\pi_{ijk1}\right) = \alpha + \beta G_k + \gamma C_{jk0} + x'_{ijkt}\beta + z'_{jkt}\gamma + u_{jk}$$
$$u_{jk} \sim N(0, \sigma_u^2)$$

where $y_{ijkt} \sim Bin\left(\pi_{ijkt}, 1\right)$ denotes the binary response for the i^{th} child in the j^{th} cluster (village) in the k^{th} treatment arm ($k = 0$ for control, $k = 1$ for intervention) at time t ($t = 0$ for baseline, $t = 1$ endline) and where π_{ijkt} denotes the probability of the child being either fully immunized or having received three doses of DPT or pentavalent. In the regression model, let G_k denote the treatment arm (control $= 0$ and intervention $= 1$) and C_{jk0} denote the baseline log odds of the response for the j^{th} cluster in the k^{th} treatment arm, $C_{jk0} = \log\frac{\bar{Y}_{.jk0}}{1-\bar{Y}_{.jk0}}$, $\bar{Y}_{.jk0} = \frac{\sum_{i=1}^{n_{jk0}} Y_{ijk0}}{n_{jk0}}$. Let x'_{ijkt} and z'_{jkt} denote the individual- and village-level characteristics, respectively. Finally, let u_{jk} denote the village-level random effects that are independently and identically distributed as normal variables with mean 0 and variance σ_u^2. The intervention effect is the exponential of the treatment arm coefficient (β). The primary quantitative equation as mentioned above was discussed in the pre-analysis plan (0).

Several researchers (Vickers and Altman 2001; Ukoumunne and Thompson 2001; Lewsey 2004; Austin 2007, 2010) compared the relative power of different statistical methods for the analysis of cluster randomization trials with binary outcomes. In the context of analysis of repeated cross-sectional cluster randomized controlled trials with binary outcomes and using Monte Carlo simulation techniques, Austin (2010) found that the use of random effects models to estimate the effect of the intervention on the change in follow-up response from baseline response consistently had lower statistical power compared to the other competing methods across a wide range of scenarios.

In other words, modelling only the endline binary response adjusted for the baseline response (the analysis method used for the study) tended to have greater power than that of a difference-in-difference (actually, ratio-of-odds ratios for binary outcomes) method where the intervention effect is the interaction term between treatment arm and time.

We ran a sequence of models. Initially, in the unadjusted analysis, we controlled for the treatment assignment and the baseline log odds of the outcome. In the subsequent adjusted analysis, we controlled for key socio-demographic and economic characteristics at the individual and village levels. The individual-level variables considered were child's gender, birth order, mother's age during survey, mother's education, father's education, household head's caste and religion, and household wealth quintile. The village-level variables included in the adjusted analyses were the percentage of mothers who could not read and/or write, percentage of households in the poorest wealth quintile and average time to the vaccination site.

We used district, child gender and birth order to predefine subgroup analyses. In addition, we explored whether there was treatment heterogeneity by village baseline coverage. For each subgroup, we repeated the analysis with the addition of the subgroup variable along with its interaction with treatment, while adjusting for key background characteristics. Heterogeneity is assessed based on the significance of the interaction term.

We conducted a range of sensitivity analyses to examine the effect, if any, of dropping the villages from the intervention and control arms after randomization. We compared the baseline characteristics of the dropped villages with the villages that were retained in the trial. We also compared the characteristics of the dropped villages with the control villages at endline.

Lastly, we combined the dropped villages with the control villages and examined the effect of the intervention for the two primary immunization outcomes by comparing the intervention villages with the combined group of dropped and control villages. As per requests from the reviewer, we also applied difference-in-difference (actually, ratio-of-odds ratios for binary outcomes) method using data from the baseline and endline to estimate the intervention effect, which is defined as the interaction term between treatment arm and time.

7.3 Qualitative data analysis

Qualitative data analysis started with the first set of interviews. Each FGD and interview were followed by the drafting of short summaries to capture key issues that emerged from the interviews. Memos were written down and discussed within the team daily and during debriefing sessions conducted with principal investigator. NVivo 11 Pro was used to support analysis, especially for coding and categorizing data.

A thematic analysis approach was used; an *a priori* coding framework was prepared based on the topic guides used in the data collection process for each of the three methods (FGDs, KIIs and IDIs). The framework was applied to a set of five interviews to check for emerging codes, which were then added to the framework.

An *a priori* code list was developed to help in segregating the data under various themes. These codes were extracted to gain a preliminary understanding of the data. The extracts were manually analyzed to group comments related to specific categories for commonalities and contrasts, and to further develop overarching themes. The preliminary findings obtained from the data were further discussed within the team to improve the analysis.

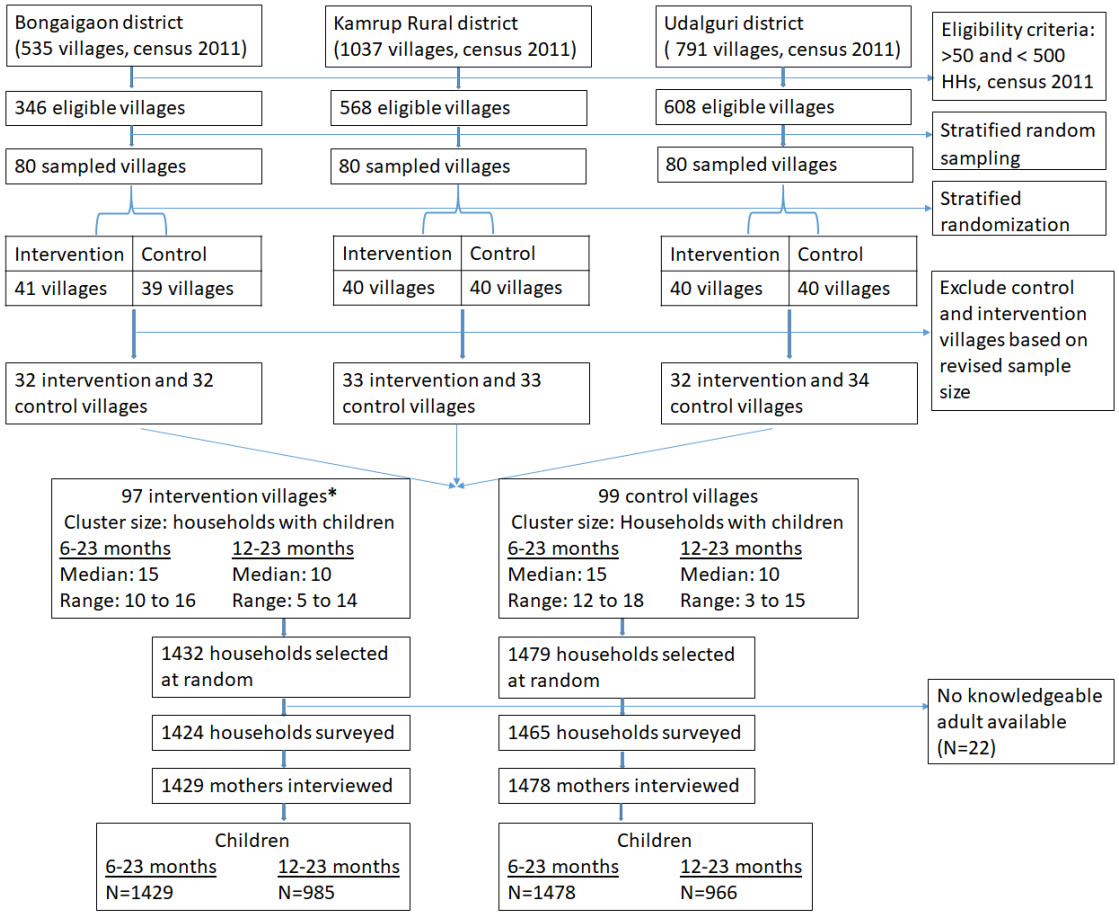
A final NVivo file was prepared thereafter, wherein the final codes were entered and a codebook for the final qualitative data analysis was also generated to check for discrepancies. A team of three researchers coded all interview transcripts, and various output files of the coded transcripts were retrieved to analyze various themes.

8. Results: quantitative data analysis

8.1 Trial profile

First, we present the profile of the randomized evaluation study along with sample size and data exclusions at various steps of sampling and randomization (Figure 5). Post randomization, after minimizing the chance of intervention-control contamination, we were left with 64 villages (32 intervention + 32 control) in Bongaigaon, 66 (33 intervention + 33 control) in Kamrup Rural and 66 (32 intervention + 34 control) in Udalguri. The intervention agency was given the liberty to drop two intervention villages, as our sample size requirement was 30 intervention villages per district. This was considered while keeping in mind perceived implementation-related challenges such as difficult terrain and transportation issues in reaching the village. However, for intention-to-treat analysis, we considered 97 intervention villages and 99 control villages.

Figure 5: Trial profile of the randomized evaluation of the SALT intervention in rural Assam



*Note: Although our sample size requirement was 90 villages in each treatment arm, for intention-to-treat analysis, we considered 97 intervention villages and 99 control villages.

8.2 Background characteristics of participants

In Table 6 we present the socio-demographic and economic characteristics of study participants based on endline data at the individual and household levels, as well as at the village level where the study participant lived at the time of the survey. As per our analytic dataset, a total of 2,907 mothers with children 6–23 months old at the time of the endline survey were interviewed: 1,429 in the intervention villages and 1,478 in the control villages.

Mothers in the intervention and control arms have similar characteristics: age at survey, education, age at marriage, receipt of full antenatal care during pregnancy and spouse's education. Small differences exist; for example, there are more mothers with no schooling or some primary education in the intervention arm as compared to the control arm (33% versus 27%). Children aged 6–23 months old in the two arms are very similar with respect to their background characteristics: gender, birth order, and whether they were born in a health facility and had a vaccination card. Households are also similar across the two arms.

The villages in the intervention arm, on average, have a higher proportion of households in the poorest wealth quintile (a median of 20% versus 13% in control villages) as compared to the control villages. The intervention villages also have a higher proportion of mothers who cannot read and/or write (a median of 12% versus 7% in control villages), and a higher proportion of households with the head of household belonging to a scheduled tribe (a median of 20% versus 13% in control villages) as compared to the control villages.

Even though small differences exist at the cluster (village) and individual levels, overall the participants in the two arms are quite similar, as is evident in figures provided in Table 6.

Table 6: Background characteristics of children 6–23 months old in the endline survey by intervention and control arm

Characteristics	Intervention (*N* = 1,429)	Control (*N* = 1,478)	Total (*N* = 2,907)
Child			
District			
Bongaigaon	466 (33%)	475 (32%)	941 (32%)
Kamrup Rural	479 (34%)	485 (33%)	964 (33%)
Udalguri	484 (34%)	518 (35%)	1,002 (34%)
Sex			
Boy	730 (51%)	744 (50%)	1,474 (51%)
Girl	699 (49%)	734 (50%)	1,433 (49%)
Age in months			
6–11	444 (31%)	512 (35%)	956 (33%)
12–23	985 (69%)	966 (65%)	1,951 (67%)
Birth order			
First	778 (55%)	823 (56%)	1,601 (55%)
Second	460 (32%)	473 (32%)	933 (32%)
Third or more	186 (13%)	180 (12%)	366 (13%)
Missing	5 (0%)	2 (0%)	7 (0%)
Born in a health facility			
No	134 (9%)	126 (9%)	260 (9%)
Yes	1,290 (91%)	1,350 (91%)	2,640 (91%)
Missing	5 (0%)	2 (0%)	7 (0%)
Has vaccination card			
No	51 (4%)	54 (4%)	105 (4%)
Yes	1,378 (96%)	1,424 (96%)	2,802 (96%)
Mother			
Age in years			
Under 20	97 (7%)	76 (5%)	173 (6%)
20–24	563 (39%)	605 (41%)	1,168 (40%)
25–34	693 (48%)	732 (50%)	1,425 (49%)
35+	76 (5%)	65 (4%)	141 (5%)
Age at marriage			
Under 18	410 (29%)	377 (26%)	787 (27%)
18–24	870 (61%)	964 (65%)	1,834 (63%)
25+	149 (10%)	137 (9%)	286 (10%)
Education			
No schooling	146 (10%)	121 (8%)	267 (9%)
Some primary	324 (23%)	279 (19%)	603 (21%)
Some secondary	742 (52%)	821 (56%)	1,563 (54%)
More than secondary	217 (15%)	257 (17%)	474 (16%)
Received full ANC during pregnancy			
No	780 (55%)	838 (57%)	1,618 (56%)
Yes	644 (45%)	638 (43%)	1,282 (44%)
Missing	5 (0%)	2 (0%)	7 (0%)
Spouse's education			
No schooling	160 (11%)	118 (8%)	278 (10%)
Some primary	342 (24%)	352 (24%)	694 (24%)
Some secondary	677 (47%)	730 (49%)	1,407 (48%)
More than secondary	250 (17%)	278 (19%)	528 (18%)

Characteristics	Intervention (*N* = 1,429)	Control (*N* = 1,478)	Total (*N* = 2,907)
Household			
Household head's caste			
Scheduled caste	109 (8%)	82 (6%)	191 (7%)
Scheduled tribe	309 (22%)	385 (26%)	694 (24%)
Other backward class	369 (26%)	422 (29%)	791 (27%)
General/don't know	642 (45%)	589 (40%)	1,231 (42%)
Household head's religion			
Hindu	931 (65%)	981 (66%)	1,912 (66%)
Muslim	425 (30%)	417 (28%)	842 (29%)
Other	73 (5%)	80 (5%)	153 (5%)
Household wealth quintile			
Poorest	296 (21%)	280 (19%)	576 (20%)
Poorer	279 (20%)	301 (20%)	580 (20%)
Middle	289 (20%)	291 (20%)	580 (20%)
Richer	288 (20%)	294 (20%)	582 (20%)
Richest	277 (19%)	312 (21%)	589 (20%)
Village (cluster)			
N[a]	99	97	196
Percentage of households in poorest wealth quintile[a], median (IQR)	20% (27%)	13% (20%)	13% (20%)
Percentage of mothers who cannot read and/or write[a], median (IQR)	12% (25%)	7% (20%)	7% (20%)
Percentage of households with Muslim head of household[a], median (IQR)	0% (60%)	0% (70%)	0% (64%)
Percentage of households with the head of household belonging to a scheduled tribe[a], median (IQR)	6% (33%)	0% (54%)	0% (64%)
Average time to vaccination site (in minutes)[a], median (IQR)	18 (9)	19 (9)	18 (9)

Note: ANC = antenatal care; IQR = interquartile range. Data are N (%) unless indicated otherwise. N indicates the number of children expected for variables measured at the village level (as indicated by [a]).

8.3 Results of primary and secondary outcomes and subgroup analysis

Tables 7 and 8 present the findings from the main analysis for primary and secondary outcomes, respectively. The unadjusted model includes only two explanatory variables: the treatment assignment indicator and the baseline village-level log odds of the outcome. Explanatory variables in the adjusted model include, in addition to the variables in the unadjusted analysis, district, gender and birth order of the child, mother's age, education, spouse's education, household head's religion and caste, household wealth quintile and village-level variables (the proportion of households in the poorest wealth quintile, the proportion of mothers who cannot read and/or write, and average travel time to the vaccination site).

The adjusted analysis shows that the intervention has had no effect on full immunization in children aged 12–23 months, as the odds ratio is close to 1 (OR = 0.97, 95% CI [0.70,1.34]). Also, the odds of receiving all three doses of DPT among children 6–23 months old is similar across the intervention and control arms. The results for the

adjusted and unadjusted analyses are very similar. The analyses suggest that the intervention also did not have any effect on the secondary outcomes (Table 8). Similarly, the intervention did not have any effect on water, sanitation and hygiene outcomes (Table 9).

Table 10 presents the findings of the subgroup analyses for the two primary immunization outcomes. None of the subgroups based on various factors (district, gender of the child, birth order of the child and village baseline FIC) show a significant effect of the intervention on either of the primary outcomes. However, some results were promising, though they were not statistically significant. For example, in villages that had a low FIC at baseline, children in the intervention arm were 1.4 times more likely to receive DPT3 than children in the control arm. However, this finding was not statistically significant.

Table 7: Analysis of primary evaluation outcomes based on endline survey data

Outcome	Intervention N (%)	Control N (%)	Total N (%)	Unadjusted[α]			Adjusted[β]		
				N	Odds ratio (95% CI)	p-value	N[γ]	Odds ratio (95% CI)	p-value
Full immunization (children 12–23 months old)									
Baseline									
No	211 (24%)	214 (24%)	425 (24%)						
Yes	660 (75%)	679 (76%)	1,339 (75%)						
Missing	8 (1%)	3 (0%)	11 (1%)						
Endline									
No	230 (23%)	223 (23%)	453 (23%)	1,948	0.98 (0.70, 1.36)	0.89	1,943	0.97 (0.70, 1.34)	0.85
Yes	753 (76%)	742 (77%)	1,495 (77%)						
Missing	2 (0%)	1 (0%)	3 (0%)						
DPT3 (children 6–23 months old)									
Baseline									
No	267 (18%)	265 (18%)	532 (18%)						
Yes	1,174 (81%)	1,210 (82%)	2,384 (81%)						
Missing	6 (0%)	7 (0%)	13 (0%)						
Endline									
No	253 (18%)	258 (17%)	511 (18%)	2,902	0.99 (0.73, 1.35)	0.95	2,895	1.01 (0.75, 1.36)	0.96
Yes	1,173 (82%)	1,218 (82%)	2,391 (82%)						
Missing	3 (0%)	2 (0%)	5 (0%)						

Note: [α] Explanatory variables in the unadjusted model include the treatment assignment and the baseline village-level log odds of the outcome.

Note: [β] Explanatory variables in the adjusted model include (in addition to the variables in the unadjusted analysis) district, gender and birth order of the child, mother's age, education, spouse's education, household head's religion and caste, household wealth quintile and village-level variables (proportion of households in the poorest wealth quintile, proportion of mothers who cannot read and/or write, and average travel time to the vaccination site).

Note: [γ] Because of missing adjustment variables data, the observations used in adjusted analysis are fewer than those used in unadjusted analysis.

Table 8: Analysis of secondary outcomes based on endline survey data

Outcome	Intervention N (%)	Control N (%)	Total N (%)	Unadjusted[α]			Adjusted[β]		
				N	Odds ratio (95% CI)	p-value	N[γ]	Odds ratio (95% CI)	p-value
Dropout between DPT doses 1 and 3									
Baseline									
No	1,174 (83%)	1,210 (83%)	2,384 (83%)						
Yes	247 (17%)	241 (17%)	488 (17%)						
Endline									
No	1,173 (84%)	1,218 (83%)	2,391 (83%)	2,869	0.97 (0.71, 1.33)	0.85	2,863	0.97 (0.72, 1.30)	0.82
Yes	230 (16%)	248 (17%)	478 (17%)						
Vaccination card available and seen by enumerator									
Baseline									
No	117 (8%)	125 (8%)	279 (8%)						
Yes	1,330 (92%)	1,357 (92%)	3,307 (92%)						
Endline									
No	225 (16%)	198 (13%)	423 (15%)	2,907	0.83 (0.62, 1.10)	0.18	2,900	0.76 (0.57, 1.01)	0.05
Yes	1,204 (84%)	1,280 (87%)	2,484 (85%)						
Timely measles vaccination[ƨ]									
Baseline									
No	175 (22%)	149 (19%)	324 (21%)						
Yes	618 (78%)	625 (81%)	1,243 (79%)						
Endline									
No	134 (17%)	126 (16%)	260 (16%)	1,581	0.83 (0.58, 1.20)	0.32	1,578	0.99 (0.68, 1.43)	0.94
Yes	653 (83%)	668 (84%)	1,321 (84%)						
Mother has seen/heard/read any immunization messages in the last 6 months									
Baseline									
No	727 (50%)	690 (47%)	1,417 (48%)						
Yes	720 (50%)	792 (53%)	1,512 (52%)						
Endline									

Outcome	Intervention N (%)	Control N (%)	Total N (%)	Unadjusted[α]			Adjusted[β]		
				N	Odds ratio (95% CI)	p-value	N[γ]	Odds ratio (95% CI)	p-value
No	517 (36%)	468 (32%)	985 (34%)	2,907	0.75	0.13	2,900	0.73	0.12
Yes	912 (64%)	1,010 (68%)	1,922 (66%)		(0.51, 1.10)			(0.48, 1.15)	
Mother believes that the community has a role to play in improving the health of her child and that the community is capable of taking actions to prevent her child from getting sick									
Baseline									
No	528 (36%)	449 (30%)	977 (33%)						
Yes	919 (64%)	1,033 (70%)	1,952 (67%)						
Endline									
No	299 (21%)	232(16%)	531 (18%)	2,907	0.68	0.07	2,900	0.73	0.06
Yes	1,130 (79%)	1,246 (84%)	2,376 (82%)		(0.45, 1.04)			(0.48, 1.01)	
Household attends village meetings and engages in community actions to tackle village issues									
Baseline									
No	723 (50%)	606 (41%)	1,329 (45%)						
Yes	724 (50%)	876 (59%)	1,600 (55%)						
Endline									
No	459 (32%)	423 (29%)	882 (30%)	2,907	0.75	0.06	2,900	0.75	0.05
Yes	970 (68%)	1,055 (71%)	2,025 (70%)		(0.55, 1.01)			(0.55, 1.01)	

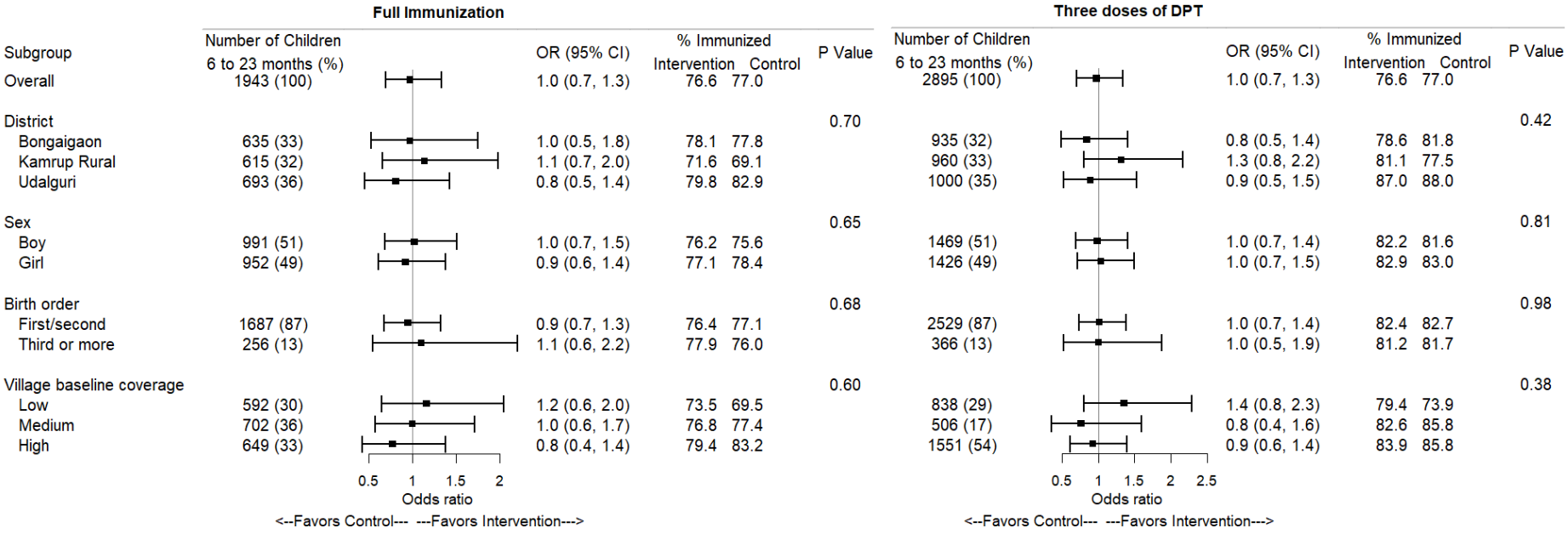
Note: [α] Explanatory variables in the unadjusted model include the treatment assignment and the baseline village-level log odds of the outcome.
Note: [β] Explanatory variables in the adjusted model include (in addition to the variables in the unadjusted analysis) district, gender and birth order of the child, mother's age, education, age at marriage, spouse's education, household head's religion and caste, household wealth quintile and village-level variables (proportion of households in the poorest wealth quintile, proportion of mothers who cannot read and/or write, proportion of households with a Muslim head of household, proportion of households where head of household belongs to a scheduled tribe and average travel time to the vaccination site).
Note: [γ] Because of missing adjustment variables data, the observations used in adjusted analysis are fewer than those used in unadjusted analysis.
Note: [ê] Assessed in children 12–23 months old who had a vaccination card.

Table 9: Analysis of water, sanitation and hygiene outcomes based on endline survey data

Outcome	Intervention N (%)	Control N (%)	Total N (%)	Adjusted[β]		
				N[γ]	Odds ratio (95% CI)	p-value
Safe drinking water						
Baseline						
No	788 (54%)	851 (57%)	1,639 (56%)			
Yes	659 (46%)	631 (43%)	1,290 (44%)			
Endline						
No	900 (63 %)	839 (57 %)	1,739 (60 %)	2,900	0.71	0.06
Yes	529 (37 %)	639 (43 %)	1,168 (40 %)		(0.50, 1.02)	
Household has latrine						
Baseline						
No	200 (14%)	251 (17%)	451 (15%)			
Yes	1,247 (86%)	1,231 (83%)	2,478 (85%)			
Endline						
No	189 (13%)	118 (8%)	307 (11%)	2,900	0.45	< 0.01
Yes	1,240 (87%)	1,360 (92%)	2,600 (89%)		(0.29, 0.70)	
Good handwashing practices						
Baseline						
No	276 (19%)	322 (22%)	598 (20%)			
Yes	1,171 (81%)	1,160 (78%)	2,331 (80%)			
Endline						
No	293 (21%)	270 (18%)	563 (19%)	2,900	0.90	0.52
Yes	1,136 (79%)	1,208 (82%)	2,344 (81%)		(0.65, 1.24)	

Note: [β] Explanatory variables in the adjusted model include (in addition to the variables in the unadjusted analysis) district, gender and birth order of the child, mother's age, education, age at marriage, spouse's education, household head's religion and caste, household wealth quintile and village-level variables (proportion of households in the poorest wealth quintile, proportion of mothers who cannot read and/or write, proportion of households with a Muslim head of household, proportion of households where head of household belongs to a scheduled tribe and average travel time to the vaccination site).
Note: [γ] Because of missing adjustment variables data, the observations used in adjusted analysis are fewer than those used in unadjusted analysis.

Table 10: Subgroup analyses for the primary immunization outcomes based on endline survey data



Note: OR = odds ratio.

8.4 The possible role of Mission Indradhanush in immunization coverage

One event that took place and that could have had a major effect on the findings is Mission Indradhanush, the flagship program of the Ministry of Health and Family Welfare for improving immunization coverage. All three study districts had received phase 2 (implemented November 2015–February 2016) before the baseline survey.

Table 11: Comparison of DPT3 coverage in the National Family Health Survey (2015–2016) and SALT surveys

District	NFHS-4 (rural)* Data collection period: Nov 2015–Mar 2016	SALT baseline (children 6–23 months old)** June–Aug 2016	SALT endline (children 6–23 months old)** July–Sep 2018
Bongaigaon	69.1	78.8 (1,180)	80.8 (1,181)
Kamrup Rural	54.8	85.3 (1,201)	80.4 (1,154)
Udalguri	80.5	88.2 (1,203)	88.2 (1,212)

Note: NFHS-4 = National Family Health Survey 2015–2016.
*Note: Sample includes children 12–23 months old. Sample size is not readily available from NFHS-4 district fact sheets. Coverage estimates are survey weighted.
**Note: The parenthesis includes sample size. The district-level estimates are unweighted estimates.

In Table 11, we compare DPT3 coverage across National Family Health Survey 2015–2016 (NFHS-4) data and two rounds of surveys conducted before and after the SALT intervention. Although the estimates are not strictly comparable, it is evident that the coverage has improved significantly between the NFHS-4 and the SALT baseline, and remained at a high level during the SALT endline.

This sudden increase in vaccination coverage can perhaps be attributed to Mission Indradhanush. The NFHS-4 data collection period in Assam coincides with the mission's second phase; therefore, the impact on coverage may not be seen during NFHS-4. The mission's third phase (April–July 2016) includes only Bongaigaon district, among the three study districts. In selected blocks of all three study districts, the mission's fourth phase (February–May 2017) was also implemented. None of our study districts were part of the intensified Mission Indradhanush, which was implemented during October 2017–January 2018.

Note that the estimates in Table 11 from NFHS-4 and SALT surveys are not strictly comparable due to several reasons: exclusion criteria (considering only villages with a total number of 50–500 households) used in our study; the way in which vaccination coverage is defined and sources of data are used (a combination of vaccination cards and mothers' recall); not using survey weights; and differences in data quality, among others. However, methods used to define the estimates from SALT surveys do not compromise the internal validity of the evaluation study.

8.5 Summary findings from the process evaluation

District summaries of village-level process indicators are presented in Appendix C. During the 13-month intervention period (March 2017–March 2018), all steps of the intervention were completed in 88 of the 90 villages where implementation happened.

The median number of visits to a village made by SALT facilitators during the intervention period varied from 14 in Kamrup Rural to 20 in Udalguri. The protocol suggested that the facilitators visit each village twice a month, implying a requirement of approximately 25 visits per village. During home visits, the facilitators were able to reach out to 19 per cent (median; the interquartile was 16–25%) of households in the village.

The intervention resulted in an average of eight (median; the interquartile range was 6–12) community meetings (including meetings with specific groups). During the intervention period, the dream-building activity took place at seven months, leaving six months for the remaining activities: self-assessment, action planning and the action phase. These activities are meant to be iterative; the number of villages in which self-assessment was repeated at least once varied between 23 (more than two thirds) in Bongaigaon to 14 (less than half) in Udalguri.

9. Results: qualitative data analysis

The results for this report are drawn from all FGDs, KIIs and IDIs representing different groups of respondents across the three study districts. The qualitative findings on community perceptions of child health, and the community and frontline workers' perceptions and experiences of immunization (including the latter's challenges and constrains in implementation of immunization services), are shared in Appendix D. Here we present only the opinions and experiences pertaining to the SALT intervention.

9.1 SALT intervention: opinions and experiences

This section outlines people's opinions about SALT and provides insights into the SALT approach's potential contribution to immunization. The ASHA generally provided open invitations for FGD participation to mothers, grandmothers and fathers. Not all had heard of or were aware of the elements on the CLCP/SALT process. A summary of awareness among those attending FGDs is outlined in Table 12.

Table 12: Analytical summary of awareness of CLCP/SALT as noted during FGDs

Districts	Total FGDs conducted	FGDs where none had heard about SALT	Villages where none had heard about SALT	FGDs where everyone present had heard about SALT	FGDs where at least some had heard about SALT
Bongaigaon	15	4	4 (2 control)	5	6
Udalguri	11	3	3 (2 control)	6	2
Kamrup Rural	13	9	8 (2 control)	1	3
Total	39	16	15 (6 control)	12	11

From Table 12 it is evident that there were a considerable number of villages (15 out of 28) in which none of the FGD participants could recall any aspect of the CLCP/SALT intervention, despite probing about specifics. When excluding control villages, this would still include 9 out of 22 villages (41%) sampled for qualitative work.

9.1.1 Did the SALT intervention bring about changes in immunization?

Those individuals and groups who had participated in the SALT process in some way tended to agree that the SALT intervention was useful to them. In an FGD with fathers in

Bongaigaon district, respondents claimed that after the SALT intervention their knowledge regarding vaccines had increased. Whereas earlier the health workers failed to address their queries even if they were curious to know why vaccines were given, immediately after the SALT intervention awareness had increased. People now reported being aware of the benefits and/or importance of immunization. It was said that they had started taking their children for vaccination without prodding from the health workers. Earlier, people had not welcomed the idea of vaccination, although health workers repeatedly spoke to them about its importance.

> Now, the people have started giving importance to vaccination schedules, and even before the ASHA informs, people come forward enquiring about matters relating to child's health or immunization. — Father in Bongaigaon district FGD

In a few villages – Tinkonia Pt. II and Nayapara Pt. I Bongaigaon and Uttar Bordol in Kamrup – positive responses were recorded regarding the SALT intervention, wherein people could recollect the meetings organized and process discussed, but often had poor recollection of the details of the SALT process.

A few respondents said that they had discussions in self-help groups related to their confusion regarding vaccination. One respondent (in an FGD with mothers in Kamrup Rural district) mentioned that progress in immunization had happened due to the ASHA's effort in carrying forward the vaccination procedure. A similar response was recorded in a control village (in Kamrup Rural) wherein the ASHA spoke about arranging meetings and discussions amongst people to spread awareness of the importance of immunization.

In the baseline qualitative data, it was found that mothers and mothers-in-law had lower levels of awareness regarding the importance of immunization. However, in the endline data set, it appeared that mothers and mothers-in-law were generally more aware about the importance of immunization.

Improvement in the coverage level of immunization after the SALT intervention was observed by FGD participants (mothers, fathers and grandmothers) across the three study districts. KIIs in Bongaigaon and Udalguri districts also indicated changes with regard to immunization. FGD and KII respondents mentioned a reduction in fear regarding side effects following vaccination, thereby leading to an increase in acceptance of vaccination. Awareness amongst mothers had increased regarding immunization dates, and several also mentioned going through the MCP cards. There were a few instances wherein people recalled issues discussed during the process but did not remember any specific terms, such as SALT.

The district program officer of Bongaigaon district talked about role reversal in an IDI, claiming that people were not previously serious about the immunization cards and did not have much knowledge about vaccination. He explained that people had realized the importance of the immunization card and their responsibility regarding this card. Now even a SALT champion or a villager could explain the immunization schedule clearly and they knew which vaccine was due and when. At times it happened that if an ASHA worker or the auxiliary nurse/midwife did not come, people would call them and remind them about the vaccine schedule. According to the district program officer, 'This role reversal is a real big achievement.'

One KII respondent also asserted that when the ASHA or auxiliary nurse/midwife did not come to inform people about immunization dates, people in the community reminded others about the dates. The KI considers this role reversal to be an achievement of the SALT intervention.

9.1.2 Was the SALT process useful?

Through the SALT dream-building process, community members in one village decided to put up signboards displaying the usefulness of vaccination. It was said that after the SALT intervention, many people initiated the practice of reading the MCP cards. Several people mentioned that although some did not turn up for any SALT meetings, a transfer of knowledge had taken place among them (non-participants) too. In one FGD with fathers in Bongaigaon district, participants mentioned that a transfer of knowledge regarding vaccination had taken place between participants in SALT meetings and among those unable to attend. Due to this knowledge sharing of the SALT intervention process, water supply facilities were introduced in some communities which solved their water crisis problem. The community started to identify its own issues and take collective community initiatives to tackle them.

Examples of initiatives taken on by communities themselves include the generation of funds (suggested by a woman from Kadamgudi Village in Udalguri) in order to purchase sports equipment for children, and willingness of mothers in communicating immunization information, which had moderately decreased the ASHA's workload. Some of the youth from Udalguri initiated planting trees at the community level. In villages like Saikiapara and Simalubari of Udalguri district, male involvement was reported to have improved, whereby the fathers had started taking their children for vaccination, as well as attending village health and nutrition day meetings.

Respondents not only highlighted the current changes, but also shared their thoughts for long-term outcomes. Some people said that apart from increasing their knowledge of the benefits of immunization, if the community came together and used the SALT process all the social problems and corruption prevailing in their community could be eliminated one day.

After the SALT intervention, communities noticed changes in drinking water practices, as people had come to know about the importance of 'pure' drinking water and had started using boiled water. They had also set up tube wells and made domestic filters.

> Earlier illnesses amongst children such as diarrhea [that were] prominent have decreased a lot due to information sharing. — FGD fathers-03, Bongaigaon

It was said that after the SALT intervention, there had been an **elimination of superstitious beliefs** and **promotion of institutional delivery** among community members. The response with regards to elimination of superstitious beliefs came up in an FGD with fathers in Bongaigaon district, where participants mentioned that after the SALT intervention, superstitions regarding institutional delivery had declined and people now came forward for institutional delivery:

> People used to have some blind beliefs that giving birth to a child in the hospital might ruin their health condition as in hospitals vaccinations are given to the child so giving home delivery was preferred. — FGD fathers-03, Bongaigaon

> After [the] SALT team arrived, lots of improvement occurred here, mainly about hygiene and family planning. They are coming forward regarding family planning too. Before, they gave least importance regarding family planning. But now they are coming forward. — KII ASHA worker-04, Bongaigaon

Promotion of hygiene sanitation and cleanliness also improved. Respondents explained that since the SALT intervention they had started using latrines and had also taken initiatives to keep the village and its surroundings clean and tidy. Respondents in one FGD collectively made the following comment:

> After [the] SALT process was initiated in our village, we have taken initiatives to clean the roads in and around our village. We clear the shrubs and other outgrowths around the roads on a regular basis. — FGD mothers-01, Udalguri

Respondents in one FGD reported that since the SALT intervention, children had the opportunity to play with proper sports equipment. They felt that they were able to find **solutions to community problems** locally through the SALT process. The respondents stated that water provision in their village was initiated by the Public Health Department, but in the last two to three years the water supply facility was dysfunctional, which was followed by a water crisis in their village. After initiation of the SALT intervention in their village, frequent meetings were held to discuss the issues concerning the community in which they brought forward the issue of water supply. Based on discussions in those meetings, the community collectively approached the village *panchayat* (council) and sought a solution to the water crisis:

> Earlier we did not have water supply facilities here but now after this project of almost 1.5 years the water crisis problem has been solved. With the help of [the] *panchayat* this water supply provision has been started. — FGD mothers-09, Kamrup Rural

Respondents also expressed that the SALT intervention had strengthened **unity and solidarity** among them. This response was seen across FGDs in the three study districts, and although unity and solidarity were said to have existed earlier, the SALT intervention had intensified them:

> We have developed a sense of unity among ourselves. Although it was there before, the SALT process has strengthened the sense of unity among the people of our village. — FGD mothers-01, Udalguri

Box 2: List of other benefits attributed to the SALT intervention

- Addressing social problems
- Information sharing among the community
- Elimination of superstitious beliefs
- Promotion of institutional delivery
- Changes in community perceptions about family planning
- Promotion of hygiene, sanitation and cleanliness
- Opportunities for games and sports for children
- Solution of community problems
- Strengthening of unity and solidarity in the community

9.1.3 Experience of using MCP cards

The practice of reading MCP cards was one area in which information was sought from respondents during the qualitative data collection process. Responses varied across discussions with fathers, mothers and grandmothers.

In the FGDs conducted with fathers, responses ranged from 'they have read the MCP cards' to 'there are a lot of things written in the MCP card and we have read only some of it', to 'cannot recall everything written on the MCP card'. Respondents asserted that the practice of reading MCP cards was a part of the SALT action plan in their village and some people had already adopted the practice of reading the MCP cards.

> Yes, we read the MCP to check the date of next vaccine. — FGD mothers-03, Kamrup Rural

Most respondents in the FGDs with grandmothers stated that they had not read the MCP card as they 'cannot read and write'. Some respondents said their daughters-in-law knew about the MCP cards. They also expressed that ASHAs retaining the MCP cards hampered their ability to read them:

> The ASHA keeps the card with her. She informs us about the dates of vaccines. We will be able to read the card only if we get it in our hand. The card is with the ASHA so we do not get a chance to read it. — FGD grandmother-02, Udalguri

One of the issues flagged in FGDs with mothers and grandmothers was that no meetings were held in their village to help them discuss, read and understand the MCP cards.

9.1.4 Dreams regarding the village

Dream building was an important step in the SALT intervention through which people were encouraged to discuss the dreams they cherish about the community. The respondents said that as a part of the dream-building exercise in their villages, they undertook discussions on issues concerning the community at large, such as provision of safe drinking water, improvement of child health and overall health status of the village. With regard to immunization, they said part of the dream-building exercise discussions concerned the importance of vaccines, their benefits and the need to vaccinate children on time.

However, in three FGDs conducted in Uttar Bordol, Hirajani and Khatkhati villages in Kamrup Rural, participants stated that they had not heard of or participated in any dream-building exercise in their village.

9.1.5 Action plans made and plans fulfilled

When FGD participants were asked about the action plans taken, they stated that they had initiated awareness meetings and camps regarding immunization and the practice of reading the MCP card. The SALT action plan reported as largely fulfilled was the attainment of full vaccination coverage in the village, and they stated that vaccination coverage had increased and been achieved to the level outlined in their action plans.

In Kamrup Rural district, respondents also decided to take action to promote purification of water for drinking. In Udalguri district, along with the awareness meetings regarding immunization to reduce dropouts, some of the actions reported included: organizing meetings to ensure that each household under the government scheme received toilet facilities; raising funds to provide playgrounds with necessary sports facilities for their children; raising funds to construct a clubhouse; and making provisions for safe drinking water. They also submitted one application explaining the need for construction of an *Anganwadi* (mother childcare center) in their village, and acted for renovation of their local school and cleanliness drives within their village.

Box 3: List of SALT action plans

- Awareness meetings and camps regarding immunization
- Practice of reading MCP cards
- Signboards describing the benefits of SALT
- Plan to recruit more teachers
- Plan to promote purification of water
- Plan to ensure availability of toilet facilities
- Raised funds to provide playgrounds with sports facilities
- Raised funds to construct the clubhouse
- Submitted application for construction of *Anganwadi* center
- Plans for renovation of local school
- Plans to promote cleanliness drives
- Planting trees

Another action plan that was discussed as fulfilled was the requirement of a teacher in a school, which in turn increased the number of students attending the school.

9.1.6 Self-assessment (level of grading)

FGD respondents were asked to discuss the grading levels outlined during the SALT process, from Level 1 to level 5 (level 1 indicated a low level of competence and level 5 indicated a high level of competence). The central idea behind the self-assessment exercise was that the community assessed itself, rather than the facilitator assessing it.

FGDs conducted with fathers from Bongaigaon district showed that before the SALT intervention they were at level 1 with regard to immunization; however, now they considered themselves to be at level 3. They felt that they could have achieved level 5 if there had been more ‘cooperation’ from the community. The response regarding lack of

cooperation in the community was found only in one FGD with fathers in Bongaigaon, but it did not mention any specific reason for this.

In another FGD conducted with fathers belonging to a different village, respondents stated that prior to the SALT intervention they were at level 3, and now they considered themselves to be at level 4 and to have achieved almost 99 per cent immunization coverage. Similarly, in one of the KIIs conducted in Bongaigaon district, the ASHA stated that they were initially at level 3 and post SALT they had reached level 4 and aspired to reach level 5. Another ASHA also stated they had reached level 4.

In an FGD with mothers in a village of Kamrup Rural district, respondents were initially unable to recall the levels of grading. However, upon further probing they remembered that they were previously at level 3 and after the SALT intervention they reached level 4 and were aspiring to reach level 5.

In one of the FGDs with grandmothers of Udalguri district, respondents said:

> When SALT intervention started in our village, we were in level 3. We feel that now we have reached level 5. — FGD grandmothers-02, Udalguri

9.1.7 Time and sustainability

The district program officer of C-NES was of the opinion that the capacity-building and ownership process of the community in the SALT approach was ‘very good’. He added that one year was not sufficient for SALT, as people now had started seeing change and were coming forward to be SALT champions; and that sustaining changes might require the process to continue for one or two more years or longer.

> Obviously, there is hope. I don’t want to claim that we have fulfilled everything. No doubt the SALT process is a beautiful one but not easy at all. Essentially it is an antithesis of the age-old tradition that people at large [have been] accustomed to for so long. For example, to appreciate, to arrange a meeting, get together, to discuss with the community, generally we lack these qualities. Those qualities are being developed to a great extent. Yes, obviously it will sustain, if we can increase the longevity of the SALT process by a few more years. It will take some time. Mere one or two years may not be enough. We cannot expect such a good thing within a short span of time. But we are sure that if the same pace continues then obviously the day will not be very far when [the] SALT process will be [one] hundred per cent successful. — IDI district program officer CNES-01, Bongaigaon

10. Discussion

Our study evaluated the impact of a novel community engagement intervention (SALT) in improving immunization uptake. The findings, based on a cluster randomized controlled trial, showed no effect of the SALT intervention on children’s immunization coverage in our study population after one year of implementation.

A meta-analysis of the effectiveness of community engagement in public health interventions has shown solid evidence that community engagement approaches have a positive impact on a range of health outcomes including health behaviors (e.g. diet, physical activity and smoking habits), health consequences (e.g. change in body mass

index and reduction in cholesterol) and participant self-efficacy pertaining to the health behaviors (O'Mara-Eves et al. 2015). However, studies evaluating the impact of community engagement interventions in improving immunization coverage are sparse (Habib et al. 2017; Schoeppe et al. 2017; Pandey et al. 2007; Andersson et al. 2009; Owais et al. 2011). Our study addresses this gap in the literature.

To identify the impact of SALT on increasing immunization coverage, we adopted an experimental design considered to be the gold standard for evaluation studies. Specifically, we used a cluster randomized controlled trial design. To recruit clusters and participants at baseline, we used a two-stage stratified random sampling method. Within a district, first we stratified clusters (villages) based on census data and randomly selected villages from each of the four strata.

In the second stage, we selected a random subsample of eligible households (with children aged 6–23 months) from each selected village. After the baseline survey, we used baseline data to stratify our sampled clusters again and, within each stratum, randomly allocated them to the intervention and control groups. Randomization after baseline allowed us to use an extensive set of socio-demographic and economic characteristics for stratification at the village level, which were not available from census data. Moreover, it provided us with a more accurate estimate of ICC and coverage rates leading to re-estimation of an appropriately justified sample size.

Note that the rationale to consider *stratification* for sampling design is different from the rationale to consider *stratification* for randomization. While the former ensures a representative sample of villages from Assam with varied socio-demographic characteristics, the latter guarantees balance between intervention and control groups with respect to potentially important covariates at baseline.

Since the control group forms the basis for a counterfactual theory of causation, it is important to ensure that intervention and control groups are similar, and our methodology does ensure this. The study uses a repeated cross-sectional design. Eligible households within a cluster were randomly sampled at baseline and were sampled again at endline following the same method. An appealing feature of repeated cross-sectional surveys is that concerns regarding attrition can be avoided (Donner and Klar 2000). These features of our evaluation design justify the internal validity of our study.

A cluster randomized controlled trial, by design, minimizes the risk of intervention-control contamination as compared to individual-level randomization, wherein sharing of information is more likely to happen if individuals living within the same cluster receive different interventions (Donner and Klar 2004). However, cluster randomization design does not guarantee that the threat of contamination will be entirely removed.

Contamination of control participants may lead to an underestimation of the intervention effect in the context of improving immunization coverage. This may result in rejection of an effective intervention as ineffective because the observed effect size may be neither statistically significant nor programmatically relevant. Our study attempts to minimize intervention-control contamination through introducing a distance buffer between intervention and control villages.

As per our revised sample size (90 villages per group), our study was powered to identify a difference of at least eight percentage points in immunization coverage between the intervention and control groups. Any effect size below that may not be detected and risks the intervention being declared as ineffective. With a larger sample size, the chance of detecting a difference is higher, even if it is smaller than the expected difference. We had to tally these methodological considerations against practical considerations, which also could affect the quality of evidence.

In order to avoid intervention-control contamination, after randomization we discarded some villages from both groups in case intervention and control villages were located in close proximity. It can be argued that this violates the principle of randomization. However, the process of discarding the villages was done in a blind manner, without considering the logistics of implementation.

We assumed that geographical separation of at least 3 kilometers between intervention and control villages would reduce the chance of interaction of community members between groups. A larger buffer would have further reduced the chances; however, enforcing a buffer over 3 kilometers was not feasible, since within a district we could discard only 10 villages from each of the two groups. Post evaluation, we do not believe that inter-village contamination was a problem, as even the intra-village transfer of information was potentially suboptimal.

To identify the impact of the intervention on childhood immunization, we use a random effects logistic regression model to analyze the binary outcome variables (FIC and DPT3) clustered at the village level. Since we expect the outcomes to be correlated within villages, we account for the clustering at the village level. We compare outcomes at endline between the intervention and control arms after adjusting village-level log odds of coverage at baseline.

Vickers and Altman (2001) recommend adjusting for baseline responses over analyzing change from baseline, as it generally has higher statistical power. The advantage of using an adjusted model is its ability to adjust for an imbalance of cluster- or subject-level characteristics between arms of the trial, in the unlikely scenario of imbalance in a cluster randomized controlled trial (Klar and Donner 2001).

The adjusted analysis shows that the intervention had no effect on full immunization in children aged 12–23 months, as the odds ratio is close to 1 (OR = 0.97, 95% CI [0.70,1.34]). Also, the odds of receiving DPT3 among children aged 6–23 months is similar across the intervention and control arms. The results for the adjusted and unadjusted analyses are very similar.

None of the subgroups – based on various factors including district, gender of the child, birth order of the child and village baseline FIC – show a significant effect of the intervention on either of the primary outcomes. However, some of the results were promising, but they were not statistically significant. For example, in villages that had a low FIC at baseline, children in the intervention arm were 1.4 times more likely to receive all DPT3 than children in the control arm. However, this finding was not statistically significant.

Randomized controlled trials of complex interventions like SALT are often criticized as being ‘black boxes’, as it can be difficult to determine why and how the intervention worked (or not) (Grant et al. 2013). The absence of an impact, as in our study, could be simply because SALT was ineffective in this particular context, or it could potentially be because of less-than-optimal implementation of the intervention. We attempted to collect relevant process indicators to share insights explaining the findings. The potential reasons behind evidence of the intervention’s lack of impact on improving immunization coverage are elaborated below.

Less-than-optimal reach of the intervention. To understand uptake of the intervention, it is pertinent to know what proportion of households or individuals in the community participated in the SALT intervention. The summary findings from the process data, as presented in the results section, suggest less-than-optimal reach and coverage of the intervention. On the other hand, we do not have specific information on whether the households selected for endline evaluation were exposed to the SALT community engagement intervention or not.

Our endline survey did not include questions regarding participation of selected households in SALT activities. Inclusion of direct questions would have made the identity of intervention villages evident to the field data collectors, based on positive responses from several households. This would have violated the principle of using blind outcome assessors in a randomized controlled trial, which could lead to substantial bias in the outcome variable (Guyatt et al. 2011; Moher et al. 2012; Higgins et al. 2019; Di Ruffano et al. 2017).

Moreover, it was not straightforward to define exposure of study participants to the intervention in a multi-step, complex intervention like SALT, as all steps were interrelated. However, findings from FGDs during the endline evaluation suggest that a considerable number of households in the intervention villages did not hear about the intervention or barely participated in it.

The intervention could potentially have been more targeted in order to reach the last mile. After our baseline assessment (June–August 2016), we found that all three study districts had significantly higher immunization coverage compared to the earlier assessment by NFHS-4 (November 2015–March 2016). We postulate that one reason for the sudden jump in immunization coverage could have been the widespread implementation of Mission Indradhanush, a supplementary immunization program of the Indian government, in the study districts prior to this study (November 2015–February 2016), and also in selected blocks during the study.

For example, in rural Bongaigaon, DPT3 coverage among children aged 12–23 months was 69 per cent according to NFHS-4. Our baseline survey found the DPT3 coverage in rural Bongaigaon to be significantly higher (79%) among children aged 6–23 months. Similar findings hold true for the other two districts. Given the already high level of coverage, to achieve further improvement through the SALT intervention, it would have been better if the intervention was adapted to engage with the marginalized and hard-to-reach population in a targeted manner.

A strategy of community mobilization and targeted community-based health and immunization camps during polio immunization campaigns in high-risk, conflict-affected areas of Pakistan was successful in increasing OPV coverage (Habib et al. 2017). While intra-village transfer and sharing of learning among households was one of the assumptions of the SALT intervention, this might not have happened as expected during implementation.

Limited time frame for a complex and ambitious intervention. Any behavioral change takes time and requires sustained effort until a critical mass is reached; more so if it requires identifying and reaching out to a population usually left out of the health system and its immunization service delivery. The limited time frame for the SALT intervention was perhaps inadequate for sustained interaction with the entire community to develop a sense of community ownership regarding children's immunization.

Although the specific steps of the intervention's learning cycle allow a community to divide a seemingly impossible challenge into a number of manageable steps, it was nonetheless a difficult concept to grasp both for the facilitators and the communities. Allowing more time for training and implementation of the intervention could have helped to improve uptake and achieve the desired level of community ownership. For example, a relatively longer-term intervention of three years showed promise by using parent advocates as part of a community-based approach to reduce vaccine hesitancy (Schoeppe et al. 2017).

Conflict between the idea of community ownership and some level of 'coercion' in implementation. Through the SALT intervention – ideally grounded in a democratic, sensitive and ethical approach – the community is supposed to set its own priorities during implementation. It is quite natural that some communities may not prioritize immunization if there are other pressing issues prevalent in the community. Our experience of process evaluation suggests that many communities initially did not perceive immunization as a major concern. However, child health was accepted by all villages as a shared dream, and it was through this dream that the facilitators stimulated discussion around immunization.

The objective of the study was to evaluate the impact of SALT on increasing immunization coverage. Therefore, the facilitators had to stimulate the discussion so that immunization-related issues 'emerged' as a topic during dream building, and that practices around immunization were taken up for developing action plans. In one sense, this is a conflict between the idea of community ownership and decision-making and external pressure (coercion) from the facilitator during implementation of the intervention. Appendix A provides reflections on this by the lead implementing agency, The Constellation.

In the context of evaluating community engagement interventions, our study raised some important concerns and dilemmas for the evaluators. First, what are the appropriate metrics to measure the success of a community engagement intervention? It is possible that an intervention with very limited reach and coverage (with respect to the whole community) might lead to improvement in outcomes of interest, if targeted properly.

For example, had we only recruited households with pregnant women before the start of the intervention, and implemented SALT only in selected households in the community, we could have possibly observed better immunization outcomes at endline among

children from intervention villages relative to control villages. This is because the implementation would have been more targeted and would have utilized the resources in an efficient manner. However, this may not have led to sustainable improvement in immunization outcomes or development of community ownership of the issue of immunization, as the majority of community members would have remained unexposed to the intervention.

Second, what is the most appropriate design choice in evaluating community engagement interventions? One commonly used method is the cohort design (i.e. recruit participants at baseline, implement the intervention on recruited participants, and use the same set of participants to evaluate outcomes at endline). If the extent of reach and coverage of the intervention is an important metric for measuring its success, this design choice may not be ideal, as it ignores the metrics in evaluation. It would perhaps be more appropriate to consider a repeated cross-sectional design, as we did in our study, where communities remain the same at baseline and endline, but a new random sample of eligible participants is recruited at endline for evaluation of outcomes.

This design choice can be considered as a conservative approach to evaluating community engagement interventions. If wider exposure in the community is expected from an intervention, then this particular design choice promotes evaluation after accounting for that metric. For example, the impact evaluation study of the Reaching Married Adolescents program in Niger follows up with 25 recruited couples every month and counsels them individually and in smaller groups (Challa et al. 2019). At the end of the intervention, the study assesses the same set of couples for evaluation outcomes based on their reported use of modern contraceptive methods.

Even if the evaluation finds improved uptake of modern contraceptive methods, the question remains whether there would be a sustainable change in the community among adolescent girls and their husbands once the intervention period is over. Moreover, since the 25 couples have been counselled regularly, conformity and social desirability considerations may lead to higher reporting of modern contraceptive use than the actual practice. So this particular evaluation study of a community-based program, by using a cohort design, may end up introducing a Hawthorne effect (McCambridge et al. 2014; McCarney et al. 2007) and inflating the estimate of treatment effect.

The strengths of our study include the use of a theoretically grounded community engagement intervention and the use of robust methods to assess it. The SALT community engagement intervention is participatory, interactive, prolonged and involves multiple inter-related steps. Based on the level of participation and involvement of the community, community engagement interventions can be classified into five graded categories ranging from inform to consult, involve, collaborate and empower (the last being the highest form of engagement) (Victorian Auditor-General 2017).

Most common intervention strategies in public health include providing education and advice, which can be considered a low level of community engagement (O'Mara-Eves et al. 2015). The next most common intervention strategies provide social support and skill development training through involvement with the community and can be classified as mid-level community engagement. The SALT intervention comes in the latter category of empowering the community.

The internal validity of our impact evaluation study is justified through: the identification of a comparable control group; selection of clusters and participants using probability sampling design; consideration of a sample size adequate to detect a programmatically significant effect size with recommended statistical power; random allocation of clusters to the intervention and control groups, ensuring treatment allocation being independent of outcome; and measurement of relevant covariates at the participant and cluster levels (Pramanik et al. 2018).

Our impact evaluation study includes two primary outcomes: full immunization in children aged 12–23 months and DPT3 in children aged 6–23 months. Having two primary outcomes may require adjustment for multiplicity of testing. However, the two age groups overlap, and the two outcomes are strongly correlated. It would be difficult to control the error rate without being overly conservative. We therefore make no adjustments for multiplicity of testing.

Moreover, the vaccination outcomes are constructed using information recorded from vaccination cards and elicited from mothers. Depending on the age of the child and complexity of the vaccination schedule, the accuracy of a mother's recall data is questionable. On the other hand, vaccination cards may be unavailable, or all vaccinations may not be recorded accurately on the card (Pramanik et al. 2016). Sensitivity analyses suggest that coverage rates are different depending on the data source used for defining a child's vaccination status (vaccination card only, mother's recall only and a combination of the two).

Qualitative data from intervention villages indicated that the SALT approach of community engagement has improved attitudes towards immunization in some target areas by addressing misconceptions about vaccines and initiating the practice of reading MCP cards; however, some of these changes were also reported in control villages. Health workers asserted that ownership of immunization by the community can play a pivotal role in increasing immunization coverage, and that the SALT approach supported community engagement.

While several villages acknowledged the contribution of frontline health workers in some instances, they expressed concerns about inadequate information from health workers, which acted somewhat as a barrier to the acceptance of vaccines. In addition, the SALT intervention reportedly strengthened unity and solidarity among people, bringing them together to address issues concerning their community at large. It provided them with a platform to discuss and chalk out a strategy to fulfil the dreams they agreed upon for their village and children.

Overall, the qualitative data showed mixed results: while many mothers and grandmothers present at FGDs were aware of aspects of the CLCP/SALT process (but not the name or acronyms used), there were many members of the community unaware of it. This perhaps suggests that intra-village dissemination of the information about the process was not as efficient as anticipated at the start. Villagers who were aware of the SALT process reported benefits in increasing immunization awareness and utilization, as well as additional benefits outside the context of immunization.

Although stratified sampling was used to ensure that selected districts were representative in terms of the socio-demographic diversity of Assam, the districts were purposefully selected so that they were reachable within 3–4 hours' drive from the central location of Guwahati. We should therefore exercise caution when generalizing the study findings to other parts of the state and the country.

11. Policy implications and recommendations

Community engagement interventions such as SALT in theory have the potential to improve immunization coverage, as they can help to identify barriers to vaccination at the local level and thus might lead to customized and sustainable solutions. The findings from this evaluation study based on a cluster randomized controlled trial, however, showed no effect of the SALT intervention on children's immunization coverage in our study population after one year of implementation. However, qualitative data showed some positive changes taking place in smaller pockets of villages. The fact that persons with little educational qualifications could participate and engage in a self-evaluation exercise after defining a self-evaluation rubric was noteworthy.

Because of the flexibility this approach gives the community to prioritize an issue, it is quite natural that some communities may not prioritize the issue of childhood immunization if there are other pressing issues prevalent in the community. This is particularly true when communities do not perceive immunization as a major problem, given the improved immunization service delivery provided by the National Health Mission.

Any behavioral change takes time and sustained effort until a critical mass is achieved. In the context of immunization, reaching out to the left-out population may require sustained interaction over a longer period of time within the community; this is potentially where the SALT approach could help. Although the intervention's learning cycle steps allow a community to divide an apparently insurmountable challenge into a set of specific and attainable steps, it is nonetheless a difficult concept to grasp both for facilitators as well communities. More intensive training of facilitators and supportive visits could help to improve uptake.

As observed from the national-level surveys on immunization, coverage in most areas (like the study districts) is not very low; neither is it at the optimum desired level. In order to achieve the desired level of coverage, it is important to engage with the marginalized and hard-to-reach population. During implementation of the intervention, an emphasis on reaching out to the community's target subgroups could be of additional benefit. Although intra-village dissemination of the process was assumed, this clearly did not happen at an optimal level. Therefore, more thought could be given to how a community is defined for operational purposes of an intervention.

The null results from our study suggest that a more targeted implementation strategy may be the way forward if the SALT community engagement intervention is to be effective across various contexts. Behavioral change in villages could take time and requires sustained effort. We believe that the SALT approach may be better suited in situations that target a smaller group of individuals, or where the issue is perceived as a priority by the community and emerges organically through discussions (e.g. villages with a high prevalence of vaccine hesitancy).

Online appendixes

Online appendix A: Reflections from The Constellation (lead implementing organization)

https://www.3ieimpact.org/sites/default/files/2020-11/TW10.1075-Online-appendix-A-Reflections-from-the-Constellation.pdf

Online appendix B: Definition of vaccination outcomes

https://www.3ieimpact.org/sites/default/files/2020-11/TW10.1075-Online-appendix-B-Definition-of-vaccination-outcomes.pdf

Online appendix C: District-wise village-level process indicators

https://www.3ieimpact.org/sites/default/files/2020-11/TW10.1075-Online-appendix-C-District-wise-village-level-process-indicators.pdf

Online appendix D: Qualitative data – additional material

https://www.3ieimpact.org/sites/default/files/2020-11/TW10.1075-Online-appendix-D-Qualitative-data%E2%80%93additional-material.pdf

Online appendix E: In-depth interview guides for facilitation teams

https://www.3ieimpact.org/sites/default/files/2020-11/TW10.1075-Online-appendix-E-In-depth-interview-guides-for-facilitation-teams.pdf

Online appendix F: Pre-analysis plan

https://www.3ieimpact.org/sites/default/files/2020-11/TW10.1075-Online-appendix-F-Pre-analysis-plan.pdf

Online appendix G: Additional results

https://www.3ieimpact.org/sites/default/files/2020-11/TW10.1075-Online-appendix-G-Additional-results.pdf

Online appendix H: Cost analysis for the intervention implementation

https://www.3ieimpact.org/sites/default/files/2020-11/TW10.1075-Online-appendix-H-Cost-analysis-for-the-intervention-implementation.pdf

Online appendix I: Checklists for onsite process monitoring

https://www.3ieimpact.org/sites/default/files/2020-11/TW10.1075-Online-appendix-I-Checklists-for-onsite-process-monitoring.pdf

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Full immunisation coverage in Assam is lower than the national level. The dropout rates of vaccines that require multiple doses are also higher in Assam than the national figures. Community engagement interventions can help identify barriers to vaccination at the local level, and have the potential to improve immunisation coverage in a sustainable way. Authors of this report evaluate the effectiveness of one such community engagement intervention that strives to promote community ownership to increase uptake of vaccinations in Assam, India.

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