



**Formative Evaluation of ‘The Fifth Child Project’: A new initiative to close the childhood immunization gap in Benishangul-Gumuz Regional State in Ethiopia
June 1st 2017**

Funded by: International Initiative for Impact Evaluation (3ie)



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Acknowledgements

The study team would like to thank the International Initiative for Impact Evaluation (3ie) for their funding, technical review and support throughout this formative evaluation, Pfizer for their support for the intervention components as well as the Benishangul-Gumuz Regional State Health Bureau and the Assosa and Bambasi Woreda Health Offices for their significant collaboration. In addition, we would like to acknowledge all research participants as well as the key members of the formative evaluation data collection team: Samuel Wodajo, Abdella Alhasen, Yinam Mengegsha, Atom Mohammed and Bersabeh Sile.

Executive summary

According to the 2011 Ethiopia Demographic Health Survey, 41.7% of children 12-23 months old in Benishangul Gumuz Regional State received the third dose of the pentavalent vaccine; approximately 13% were completely unimmunized, thus susceptible to vaccine-preventable diseases.

Intervention overview

To address low coverage and support Ethiopia's Health Extension Program, in 2013, the International Rescue Committee began implementing the 'Fifth Child Project' – a multi-pronged community engagement strategy to improve timely utilization of maternal and child health services, with emphasis on immunization, across Assosa and Bambasi woredas. The intervention focuses on promoting systematic use of quality immunization data for local level decision-making, particularly around defaulter follow-up through the introduction of a defaulter tracing tool. It also applies an overarching community engagement approach by equipping existing cadres of Health Extension Workers and Health Development Army members with improved interpersonal communication skills for effective and tailored counselling sessions and leveraging them to conduct timely home visits targeted at defaulters. At the household level, it integrates the use of a colour-coded calendar known as *Enat Mastawesha*. The calendar serves as a planning tool for caregivers to keep track of upcoming for peri-natal appointments and serves as a job-aide for health workers. Essential systems support is also provided to ensure that immunization services meet basic policy standards (e.g. cold chain functionality, support for outreach sessions).

The project is informed by a theory of change that incorporates three main inter-related causal pathways: i) enhanced engagement on immunisation at household and community levels, ii) improved defaulter tracing, and iii) underlying immunisation systems support, that, combined, will lead to increased immunization coverage.

Evaluation overview

The International Rescue Committee, in partnership with the London School of Hygiene & Tropical Medicine, conducted a formative evaluation to assess the integrated community engagement strategy as a potential solution to address the main outcome of interest; low and stagnating immunization coverage. Evaluation questions also examined project integration in the Health Extension Program, evaluated utilization and acceptability of project tools and assessed contribution to secondary outcomes of interest such as the uptake of post-partum family planning and antenatal care.

Qualitative data was collected from May-July 2016 in 3 kebeles. This consisted of: 46 semi-structured interviews, 6 focus group discussions and 16 semi-structured observations. Four research assistants with previous research experience were recruited and trained in evaluation.

Interviews were transcribed, translated and imported to NVIVO-11 for systematic coding. A thematic approach was used for analysis. Data was verified in November 2016 and involved 2 additional focus groups and 6 interviews. Coverage was examined using routine data.

Main findings of this formative evaluation

The 'Fifth Child Project' was well integrated into the local health system and enabled more systematic follow-up of unimmunised children. The project contributed to improved awareness about, and increased demand for, vaccination. The *Enat Mastawesha* served as a communication aide for health workers and a catalyst for health-related discussions between family members. It supported more personalised interactions between health workers and caregivers and played a significant role in ensuring the timely vaccination. Pre-existing administrative structures and related accountability mechanisms facilitated community co-management of the project although varied levels of engagement were observed. Engagement was influenced by the quality of working relationships between Health Extension Workers and kebele leaders, competing priorities and the frequency of meetings. The observed use of community agreed sanctions for defaulters raised questions about what levels of shared community responsibility for public health programmes is appropriate. Finally, whilst there was strong support for project continuation, the need to strengthen health system infrastructure was also highlighted.

During the intervention, there was an overall increase in infants immunized with the first and third dose of pentavalent vaccine and measles vaccine in both woredas. We observed statistically significant increases in quarterly coverage with all three scheduled vaccinations only during the project phase when both the *Enat Mastawesha* and defaulter tracing tool were implemented. Coverage increased by 13.3% (95% CI: 6.9-20.0%) for pentavalent 1, 18.4% (95% CI: 9.8-26.9%) for pentavalent 3, and 12.4% (95% CI: 3.6-21.1%) for measles.

The defaulter tracing tool provided quality data to identify and subsequently vaccinate defaulters. In 2016, of the 2,830 defaulting children identified, 2,363 (84%) were successfully immunised with the vaccine they had defaulted on. This proportion exceeds the 70% target selected in the performance monitoring plan. This intervention has the potential to improve the timeliness of vaccine uptake by promptly identifying defaulters and getting them caught up on missed vaccines. Immunisation dropout rates observed in the intervention woredas were lower than those reported for the region. The modest dropout rates observed may be potentially due to the defaulter tracing strategies introduced, however, the evaluation design does not allow such inference without further research.

The intervention appeared to have increased the utilization of other peri-natal services. Notably, there was a general increase in the proportion of women adopting a postpartum family planning method within six months of delivery in both woredas. Similarly, we observed a general increase in attendance at the first and fourth antenatal care visits.

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Abbreviations and Acronyms

ANC - Antenatal care

BGRS - Benishangul-Gumuz Regional State

CE - Community engagement

DTT - Defaulter tracing tool

EPI - Extended programme on immunisation

FGD - Focus group discussion

FP - Family planning

HDA - Health Development Army

HDAL - HDA leader

HEP - Health Extension Programme

HEW - Health Extension Worker

HMIS - Health Management Information System

IRC - International Rescue Committee

LSHTM - London School of Hygiene & Tropical Medicine

MoH - Ministry of Health

Penta - Pentavalent combined diphtheria, pertussis, tetanus, hepatitis B, and Haemophilus influenza type B vaccine

PHCU - Primary health care unit

RA - Research assistant

RHB - Regional Health Bureau

SSI - Semi-structured interview

WoHO - Woreda Health Officers

1. Introduction

Ethiopia's national coverage of the third dose of the pentavalent, combined diphtheria, pertussis, tetanus, hepatitis B, and Haemophilus influenzae type B, vaccine (penta) at 12-23 months of age is 37% and the dropout rate between the first and third doses of this vaccine was reported as 43% in 2013 (Central Statistical Agency [Ethiopia] and ICF International, 2012). The country is one of the 35 of the total 194 WHO Member States which has not succeeded in reaching the Global Vaccine Action Plan's intermediate goal of reaching 90% national coverage with three doses of penta by 2015 (WHO, 2015). Less than half of WHO African region states were able to meet this goal, and although some East African countries, like Eritrea, have surpassed the 90% threshold, rates in Ethiopia, Kenya, Uganda and South Sudan have stagnated and remained low (WHO, 2015).

In the search for novel ways to address low and stagnating vaccination rates and improve access to and utilisation of immunisation services, increased attention is being paid to the role of communities and community engagement (CE) strategies (Sabarwal et al., 2015). It is argued that communities should not be viewed as passive recipients of immunisation services but actively involved in shaping vaccination programmes. The Global Vaccine Action Plan places significant emphasis on shared individual, community, and governmental responsibility for immunisation against vaccine preventable diseases, and cites the following as one of its strategic objectives: "Ensuring that individuals and communities understand the value of vaccines and demand immunisation as both their right and responsibility". (WHO, 2013, p.30)

It is well established that contextual factors and the degree to which community members understand and trust the immunisation process affect vaccination coverage rates (Rainey et al., 2011, Favin et al., 2012, Streefland et al., 1999). Less well documented is the effectiveness of CE strategies in addressing vaccine supply and demand factors and improving vaccine coverage. Evidence suggests that vaccine interventions that are designed and co-managed with community members are more likely to be successful, however more attention needs to be paid to evaluating and developing current CE practice (Sabarwal et al., 2015). Existing evidence has tended to focus on immunisation activities that aim to raise awareness and promote behaviour change by running education programmes targeted at infant caregivers or community health workers, or using a variety of communication tools such as improved vaccination cards or community-based posters (Jain et al., 2015, Owais et al., 2011, Ryman et al., 2011, Usman et al., 2011). Less attention has been paid to integrated CE strategies that seek to involve community members and leaders in identifying new ways of reducing the childhood immunisation gap and strengthening existing immunisation programmes. In their work on identifying key drivers for immunisation performance in Africa, LaFond et al (2014) stress the importance of co-operation between administrative and political leaders at district and community level. They also highlight the value of community-based health workers who can promote and support vaccination activities in the places where they live, and emphasise the need to tailor immunisation activities to community needs.

This study aims to contribute to the emerging evidence base by conducting a formative evaluation of an integrated CE strategy that is being implemented by the International Rescue Committee (IRC) in two districts (Assosa and Bambasi) in Benishangul-Gumuz Regional State (BGRS) in north-west Ethiopia.

2. Context

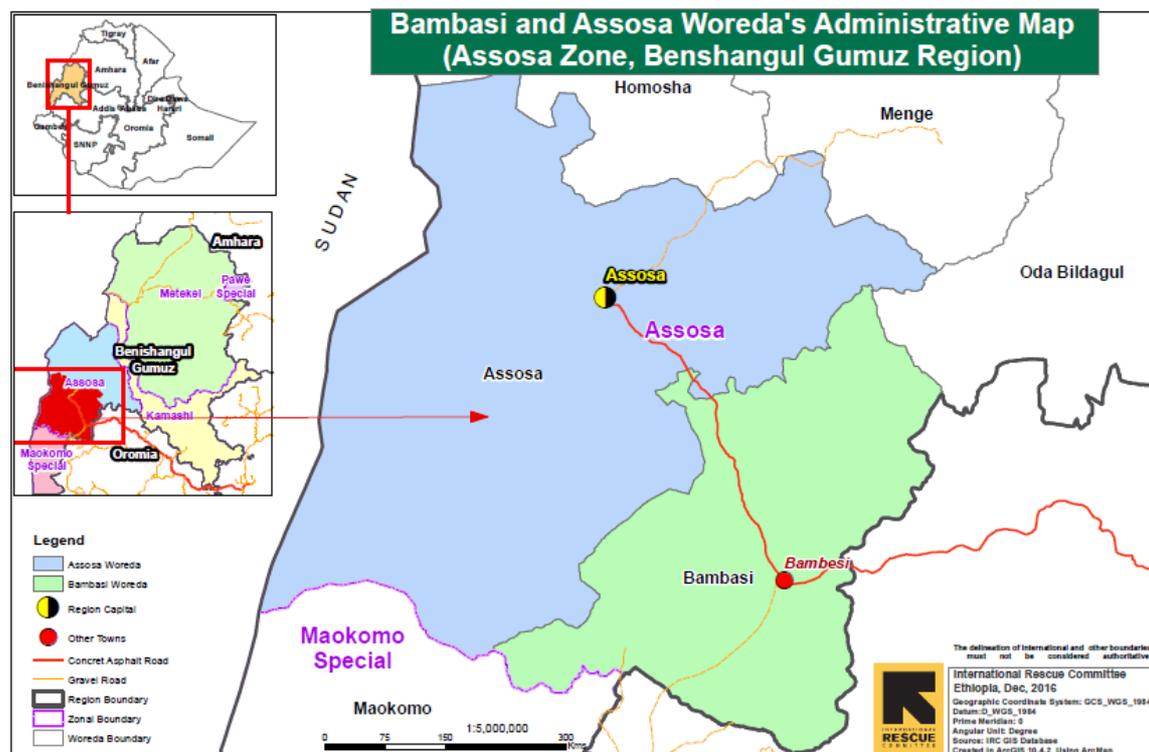
2.1 Geographic and socio-demographic profile

Ethiopia has an estimated population size of 96 million (USAID, 2015) of which 82% live in rural areas where they rely on farming and livestock production (Central Statistical Agency [Ethiopia] and ICF International, 2012). It is one of the least developed countries in the world and is currently ranked 173 out of 182 on the Human Development Index (UNDP, 2015), with an estimated 47% of the population living below the poverty line (Federal Ministry of Health, 2010, p. 11). Despite recent progress in addressing population health needs the infant and under-5 mortality rates are still high: 41 per 1,000 live births, 59 per 1000 live births respectively (The World Bank, 2015). Several factors inhibit further improvements in health status including malnutrition, failure to control vaccine-preventable disease, limited access to water and sanitation and low rates of health services utilisation.

BGRS in north-west Ethiopia is an underserved remote and rural region that rarely benefits from large multi-year maternal and child health programmes run by the government and international agencies. BGRS borders Sudan and South Sudan and has an estimated population of 784,345. Its transport infrastructure is weak and the majority of the population has poor access to health services. Consequently, with an infant mortality rate of 101 deaths per 1,000 live births and under-five mortality rate of 169 per 1,000 live births, child health indicators are worse in BGRS compared to the national indicators.

Bambasi and Assosa districts (referred to as woredas in Ethiopia) are lowland areas which are inhabited by predominantly Muslim agrarian communities. The average household size is 5 and the total population in both woredas in 2015 was 169,615 (105,430 and 64,185 respectively), of which 5,208 were children < 1 year (3,237 and 1,971 respectively).

Figure 1: Benishangul-Gumuz Regional State in Ethiopia



2.2 Factors influencing vaccine uptake in the study area

A total of 13% of children living in BGRS were reported to have received no vaccines at all in the 2011 Demographic Health Survey, and coverage for penta 3 was reported at 41.7%, which is only slightly above the national average of 37% (Central Statistical Agency [Ethiopia] and ICF International, 2012).

Based on IRC implementers' field visit observations, prior to the study period, and information obtained from woreda health officers (WoHO), the primary reasons for low immunisation coverage before the start of the intervention were:

- Low awareness and misunderstanding about vaccines, particularly around the vaccination schedule and series of doses;
- Poor health-seeking behaviour, often due to a lack of confidence in the system;
- Lack of access to services, particularly due to irregular and poorly targeted immunisation outreach services;
- Generally low capacity level among health workers, especially related to defaulter tracing and stock management; and
- Shortage of vaccines at health facilities, most often due to poor forecasting of vaccine needs and ruptures in the cold chain.

Vaccine refusal has not been observed to be an issue in the study area, although small pockets of hesitancy, due to lack of convenient service, lost confidence in services, and some complacency about adherence to the childhood immunisation schedule exist.

2.3 Health system considerations

Ethiopia has a decentralised health policy, which encourages the participation of communities. To create community ownership and empowerment in the health sector, the government introduced the Health Extension Programme (HEP) in 2002. The underlying vision is that as health knowledge is transferred to the community, households can take responsibility for protecting and maintaining their own health. The HEP serves as the primary vehicle for implementation of community-centred essential health care packages, and facilitates referral processes from grass-roots to secondary and tertiary levels. The lowest level of referral system in Ethiopia is the primary health care unit (PHCU), which is composed of five satellite health posts, one health centre and one primary hospital. Health extension workers (HEWs) run the health posts where they provide preventive and basic curative services, including immunisation, and conduct household visits and immunisation outreach services at the community level.

To extend the reach of the HEP and enhance community participation the Ethiopian government introduced a female led Health Development Army (HDA) in 2014. The aim of the HDA is to scale up and reinforce positive health practices at household level by organising and mobilising families. The HDA strategy involves creating a network of groups of five households, each linked to a model household led by a member of the HDA. HEWs based at health posts, HDA team leaders and civil service and political leaders support the HDA network. The decentralisation of the health system in Ethiopia has increased decision-making powers at woreda health system level, with the aim of improving health care delivery at community level.

At a woreda level, there is a WoHO with a responsibility of managing PHCUs. Where PHCUs are fully developed, health centres manage satellite health posts but where PHCUs are not functional such as in BGRS, the health posts directly report to the WoHOs. Each health post, usually one

health post per kebele, the smallest administrative unit in Ethiopia, is staffed with two governmental salaried female HEWs. The HEWs implement 16 health extension packages identified in the HEP. At community level, the HEWs select and train HDAs and HDA leaders (HDALs). HDAs report to HDALs and the HDALs in turn report to the HEWs. Immunisation services are usually offered at health centres and the health posts that have a functioning cold chain at least once or twice per week. Normally, once per month an immunisation outreach service is scheduled in communities farther than 5km from fixed immunisation services at the centre or post level. Due to resource constraints, outreach services are often conducted at the health post level, usually posts without functional cold chains, rather than deeper in the community.

Assosa woreda has 74 kebeles, 69 health posts and 3 health centres. In Bambasi woreda there are 43 kebeles, 42 health posts and 2 health centres. In terms of human resources, across the two woredas, there are 5,601 HDAs, 962 HDALs, 176 HEWs and 91 nurses.

3. Intervention description, intervention logic, theory of change and monitoring system

The ‘Fifth Child Project’ strategy, where HEWs and HDAs collaborate with community leaders to register, counsel and track all pregnant women and infants (0-12 months) for increased childhood immunisation uptake, comprises two integrated components and a cross-cutting CE approach.

3.1 Integrated component 1: household-level engagement for increased and timely immunisation uptake

The *Enat Mastawesha* calendar tool, distributed to all pregnant women during antenatal care or to households with newborn children during postnatal visits, is used by HEWs and HDAs during home visits and aims to address identified barriers of caregiver-understanding around the timing and purpose of the uptake of critical maternal and child health services. The calendar contains pictorial descriptions of five key health services, as well as warning signs of pregnancy-related dangers and is designed to reflect a continuum of care covering antenatal care, skilled delivery, postnatal care, immunization and postpartum family planning. During home visits, HEWs/HDAs describe the colour-coded images on the tool and place the same coloured stickers on appointment days to help remind families about important health post visits for critical services. The HDAs also use the calendar to initiate broader conversations with the family since it is known that women are often not the main or only decision-makers within the household with regards to the health of their children.

*Enat Mastawesha*ⁱⁱ aim to complement family health cardsⁱⁱⁱ and are used during the following periods:

ⁱFunding for this project is part of a multi-country grant focused on increasing immunization coverage through innovative strategies, including community engagement. The title of “Fifth Child” alludes to the approximately 20% gap in coverage of the third dose of diphtheria tetanus pertussis vaccine at the global level during the design of the project. The coverage gap is much higher in rural Ethiopia.

ⁱⁱ Please see Appendix G for a photo of the tool and additional project photos

ⁱⁱⁱ The Family Health Card is a slight misnomer as this tool is actually a large [multi-page folder](#) covering many aspects of maternal, newborn and child health services and is supposed to be used for health promotion and record keeping.

- 1) Pregnancy period: pregnant women in the village are visited and counselled by HEWs, using *Enat Mastawesha*, on antenatal care (ANC) and birth planning for skilled deliveries, alongside key decision-makers in the home;
- 2) Immediate post-delivery period: HEWs discuss and place appointment stickers for postnatal, immunisation and family planning (FP) services with new mothers and their families; specifically alerting them about date/time of the next outreach;
- 3) Immunisation drop-out: If an appointment is missed, HEWs include infants in the defaulter tracing tool (DTT) and HDAs are informed to visit and counsel the caregivers on catch-up immunisation and will place an additional sticker on the calendar to indicate the next outreach date. That HDA will visit the same household again a few days prior to the outreach to promote attendance.

Under this intervention, the IRC also aimed to increase the quality of home visits. They are intended to be interactive, motivational sessions where HDAs and HEWs engage caregivers, as well as other decision-makers in the household, to develop a plan for preventative healthcare-seeking, including catch-up vaccinations as neededⁱ. Therefore, IRC trained HEWs directly, and facilitated HEW-led training of HDAs, on immunisation key messages, addressing myths and misunderstandings, improving interpersonal communication skills for effective, tailored, counselling sessions. User feedback from informal key-informant exchanges, prior to this formative evaluation, suggested that the calendars play an important role in immunisation-seeking decision-making in the household, reminding and empowering families to better plan appointments.

3.2 Integrated component 2: improved access to quality data on defaulters

To facilitate individual defaulter tracing, IRC and the WoHOs co-designed the DTT, and trained HEWs and HDALs on how to use it. The DTT is a simple paper-based registration form with three built-in carbon copies used at the health post level to record infant/caregiver information and antigens missed for all defaulters/villageⁱⁱ. During pre-existing command postⁱⁱⁱ meetings, the carbon copy of the DTT with the number of defaulters is presented and discussed with HEWs, HDALs and community leaders. Corrective actions related to the Extended Programme on Immunisation (EPI) including defaulter tracing and improvement of data collection are collaboratively planned. Copies of the DTT are given to the HDALs by HEWs so that they, in turn, inform HDAs of which defaulters to visit that month. The HDAs then conduct home visits to counsel families whose children have defaulted or never been immunised to promote catch-up immunisation. Once visits are conducted, HDAs inform HDALs who note this on their carbon DTT copy and return this copy to the HEWs at the next meeting.

3.3 Integrated component 3: cross-cutting community engagement approach

This intervention aimed to introduce an ownership and feedback mechanism between communities and health posts related to immunisation services. Village leaders (who are often HDAs as well)

ⁱ In this intervention, caregivers also receive a certificate from HEWs upon completion of their child's immunisation schedule.

ⁱⁱ There are usually 2-3 villages/health post and 1 health post/kebele.

ⁱⁱⁱ In the monthly command post meetings, the IRC distributes monthly progress reports to feedback information on individual performance and motivate health workers.

are directly informed by the HDALs of any defaulter children in their community that month and actively participate in mobilising caregivers to attend immunisation outreach sessions. In the hardest-to-reach places, community leaders attend outreach sessions to monitor whether the sessions took place on time, HEWs were available, EPI supplies and vaccines were available and defaulting children attended. Participating leaders have suggested to the project team that HEWs have been more accountable to communities and adherent to plans for outreach services since they began attending the sessions.

Observations from community leader outreach monitoring are brought forward in the bi-monthly kebele meetingsⁱ, attended by village, HDA and politically appointed kebele leaders and HEWs. The HEWs present a performance overview of defaulter tracing trends (number of defaulters/month/kebele) and HDALs and village leaders advocate on the strengths and remaining barriers to address in order to increase immunisation coverage. Serious issues are also brought forward at quarterly woreda-level meetings attended by WoHOs and kebele leaders.

Implementation of the 'Fifth Child Project' intervention is feasible as it was designed to be integrated into the existing health system and is adapted to the context and structures of maternal and child health programming in the study sites. The approach is in line with the HEP and HDA strategies that aim to extend more services to the community level and task-shift health promotion activities to the recently trained cadre of HDAs.

Project implementers considered that any perceived additional responsibilities introduced under the intervention could theoretically contribute to HEW or HDA de-motivation possibly reducing performance in other areas of community work. Given that each HDA is responsible for only five households within their village, the HDAs note that under this project they conduct, on average, one defaulter counselling or outreach reminder home visit per month in their small catchment population. Neither the HDAs nor the HEWs have reported during routine IRC project monitoring and support visits that the intervention components have overburdened them. However, it is important to note that the responsibilities reinforced as part of this intervention are part of existing HEW/HDA roles under the HEP. The tools and approaches introduced by the IRC are meant to facilitate these responsibilities.

The contextual understanding and social and political capital established by the project team in 10 years of collaboration with key stakeholders in intervention areas, also contributes to the implementation feasibility of the programme. Nevertheless, this formative evaluation aims to identify any implementation challenges as well as potential intervention iterations in order to adapt activities for increased feasibility as needed.

3.4 Theory of change of the intervention

The theory of change, Figure 2, incorporates three main inter-related causal pathways: improved engagement on immunisation at the household and community levels, the defaulter tracing system, and underlying immunisation systems support.

3.4.1 Household and community engagement

The quality of home visits is critical. It has been shown that strong interpersonal communication between health providers and clients contribute to behaviour change and the increased uptake of

ⁱ These meetings existed before the intervention but since roll-out have included focus on immunisation

preventive servicesⁱ. The 'Fifth Child Project' intervention is built upon this principle. It anticipates that if HDAs/HEWs receive necessary training, tools (DTT and *Enat Mastawesha*) and support, they will be motivated by this principle and the connection to their communities in order to conduct effective home visits. In turn, this level of HEW/HDA dedication will encourage caregivers to bring infants for timely immunisations.

Based on the experience of 18 months of initial implementation, the evaluation team postulated that formative findings will demonstrate that the *Enat Mastawesha* tool simultaneously serves as an information, education and communication job aide during home visits (for HEWs and HDAs), as a reminder on fixed appointments for health services (for families) and stimulates dialogue between HEWs/HDA and their clients.

A critical component of this causal pathway is as follows: HDAs live in their communities and as such, are already trusted and familiar to their communities. However, they lack the technical tools for routine monitoring of vaccination status (i.e. the DTT) and for targeted counselling and reminders when necessary (i.e. the *Enat Mastawesha*). To facilitate these actions, CE approaches are needed from multiple levels. During the existing bi-weekly meetings, HEWs now present the numbers of defaulters, infants due for immunisation as evidence of actions needed, and mobilise community leaders to conduct outreach and find defaulters. This adds greater accountability at the community level and leads to improved targeting of service delivery.

3.4.2 *Defaulter tracing tool*

Before this intervention, the registration of pregnant women, allowing HEWs/HDAs to track mother/new-born pairs, was weak. To establish an accurate denominator of vaccine-eligible children, the intervention systematises this registration and improves the quality of data in the child immunization register. If immunisation status data for the infant is not reflected in the register, then the HEW will review the child's vaccination card at their next health post or home visitⁱⁱ.

The DTT causal pathway anticipates that if HEWs, HDAs and community leaders have individualised data on defaulters, they will become motivated and supportive co-managers of routine defaulter tracing/defaulters mobilisation for outreaches, aiming to protect their communities against vaccine-preventable disease.

3.4.3 *Immunisation systems support*

Sustained delivery of immunisation services by the Ministry of Health (MoH) and HEP (with some support from IRC) is a precondition for the formative evaluation of this intervention. To help ensure that EPI systems remain functional, the IRC fills identified gaps related to vaccine transport, basic EPI training for HEWs, financing of outreaches and supportive supervision by WoHOs as well as basic cold chain functionality.

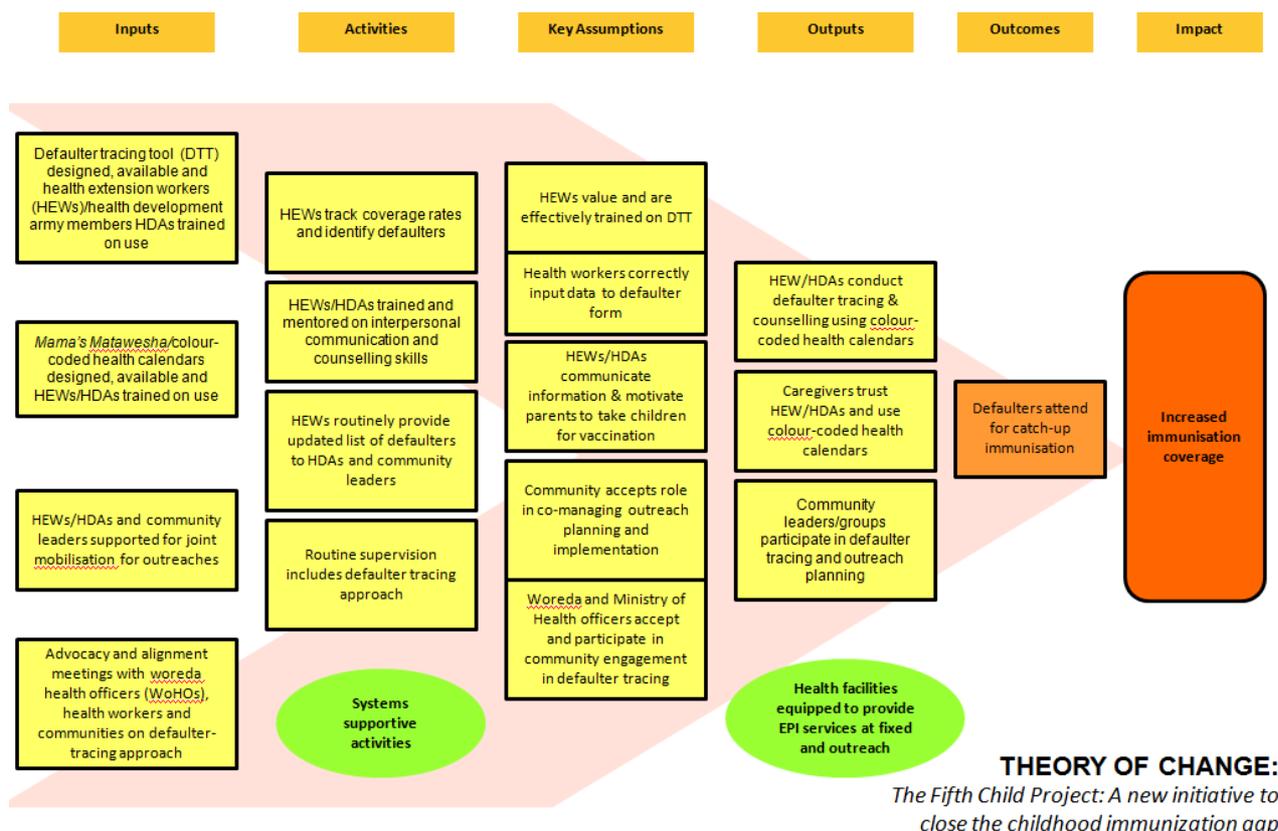
ⁱ S Waisbord, H Larson. Why Invest in Communication for Immunization? Evidence and Lessons Learned. A joint publication of the Health Communication Partnership based at John Hopkins Bloomberg School of Public Health/Center for Communication Programs (Baltimore) and the United Nations Children's Fund (New York). June 2005

ⁱⁱ HEWs encouraged to routinely review child immunisation cards at all contact opportunities and update the EPI register and DTT (as some infants may receive immunisations from other posts/outreaches). Card retention in the study areas is good; in case of lost cards, HEWs provide updated replacements.

3.4.4 Additional intended outcomes

An intended outcome of this intervention is that increasing demand for EPI services could lead to uptake of other maternal and child health services at the health posts or at the higher-level health centres. For example, home visits may identify and refer more sick children, sick new-borns in particular, for postnatal care services or integrated management of neonatal and childhood illnesses as well as women who should access ANC and postnatal FP services.

Figure 2: 'Fifth Child Project' theory of change



3.5 Project monitoring system

Routine health data were used to monitor project progress and for potential course correction, as needed. For most of the data, the IRC used health facility-based immunization registration books, integrated FP-Immunization registration book that the IRC introduced in consultation with WoHO, and the District Health Information System. The DTT carbon-copy pad was also used to monitor project performance in defaulter tracing. Other record books were used to monitor outreach sessions, *Enat Mastawesha* calendar distribution, and home visits. Details on how these monitoring tools were used is noted in the section below

3.5.1 Data collection procedures

Data collection by HEWs is ongoing throughout the month and is submitted to IRC health officers at the end of each month. The IRC health officers then submit the data from health facilities to the health manager who is based at the field office, and the manager enters the data into an excel database and shares it with the Addis Ababa based IRC health department who review the data and provide feedback. Monthly monitoring data stems from four sources, two existing MoH tools

and two tools introduced as part of the IRC intervention: the EPI immunization register (MoH), the family planning register (MoH), the integrated FP/immunization register (IRC) and the DTT (IRC).

Immunization register: There is an immunization registration book in each health post and the HEWs update this register each time they provide vaccines (usually monthly for health posts that act as outreach sites) and more frequently for health facilities that have a cold chain to store vaccine. Data from the immunization register is aggregated each month and feeds into HMIS reporting.

Family planning register: This data collection tool is found in each health post and is used to monitor FP service uptake. Health Extension Workers update this registration book each time they provide a family planning service and this data is compiled at the health post level month and feeds into HMIS reporting.

Integrated FP/Immunizaion register: This is an IRC-introduced tool to specifically monitor the proportion of mothers who sought immunization services for their children and were offered family services and accepted. This data is compiled monthly by HEWs and submitted to the IRC project team for the IRC database; it is neither part of the HMIS nor monitored by the WoHO.

Defaulter tracing tool: The list of defaulters is generated from immunization registration books. HEWs identify the list of defaulters following monthly immunization sessions and list them in the DTT by village. Copies of the DTT are given to the HDALs by HEWs so that they, in turn, verbally inform HDAs of which defaulters to visit that month. The HDAs then conduct home visits to counsel families whose children have defaulted or never been immunized to promote catch-up immunization. Once visits are conducted, HDAs inform HDALs who mark the visit on the space provided on the DTT and return the copy of the DTT page for their village to the HEWs at the next monthly meeting. The second copy is shared with the woreda Health Office and IRC Health Officers for monitoring purposes. The third copy remains on the DTT pad for the HEW to use for follow up. Health Extension Workers then compare their copy of the DTT (left on pad) to marked the copy returned to them by the HDALs, after HDA home visits, to compile the number of defaulter children identified and subsequently immunized with the vaccine(s) they had missed.

3.5.2 *Process monitoring indicators*

The following key indicators were tracked for 2016 project year: 1) proportion of postpartum women adopting a modern FP method, 2) number of monthly FP acceptors, 3) penta 3 coverage, 4) measles coverage, 5) number of infant defaulters who are identified and the number of these who are subsequently vaccinated (for penta 1, 2, & 3 and measles). Table 1 presents these indicators which, measured against their targets, was used to monitor project progress each month. In this formative evaluation, analysis was done for indicators 1), 3), 4) and 5), as well as on the proportion of pregnant women who attend ANC 1 and ANC 4 services, which was not one of the main indicators included at the start of the project. These indicators were selected for analysis as they are related to the use of the *Enat Mastawesha*, DTT and integrated community engagement activities.

Table 1: Key project indicators, targets and data sources

Indicator	Baseline	Target	Source of Verification
1 Increase mothers who bring their child for immunisation and accept a modern FP method	N/A	35%	IRC database

2	Increase the number of monthly FP acceptors from baseline to endline	N/A	80%	HMIS report, IRC database
3	Increase penta3 coverage in Assosa woreda	63%	85%	HMIS report, IRC database
	Increase penta3 coverage in Bambasi woreda	78%	85%	HMIS report, IRC database
4	Increase measles coverage in Assosa woreda	77%	85%	HMIS report, IRC database
	Increase measles coverage in Bambasi woreda	59%	85%	HMIS report, IRC database
5	Proportion of defaulter children who are identified and vaccinated	N/A	70%	IRC database (from monthly HEW analysis)

The data for two of the monitoring indicators stem solely from the IRC database which was developed to complement HMIS data. The IRC database is managed and maintained by IRC staff and contains multiple data elements that are not available on government HMIS, such as postpartum FP, defaulter tracing and subsequent vaccination as well as the distribution of the *Enat Mastawesha*. For indicators 2, 3 and 4, both the IRC database and the HMIS are listed under source of verification. This is because of the need for triangulation to support data quality and to mitigate potential over-reporting during data compilation at the WoHo level. Therefore, each month, IRC field officers collect the data for these indicators directly from the HEW reports at each health post and from the WoHOs after the WoHOs aggregate all HEW reports that ultimately feed into the HMIS. Since HMIS figures are officially recognized, HMIS data was used during the analysis for this evaluation.

Besides the four data collection tools, the project team also tracks, through routine monthly IRC field visit reports, any information pertaining to other key activities in the project area such as trainings, review meetings, supervision and community group meetings. In addition, HEWs maintain records for other associated activities such as monitoring outreach sessions conducted, number of *Enat Mastawesha* and DTT distributed, and number of home visits conducted. On a monthly basis, HEWs compile and share a report with the WoHO and IRC health officers.

In terms of targets, it is expected that: each health post has at least one immunization session per month, which is usually in the form of an outreach from a health centre since the majority of health posts do not have a cold chain; each household with a pregnant women or infant has an *Enat Mastawesha* displayed; and each health post has a copy of the DTT with sufficient pages for their catchment population. For home visits, HEWs/HDAs conduct visits every 15 days, not necessarily to the same homes each time, to orient caregivers and confirm that they understand the functions of the calendar, troubleshoot any misunderstandings, confirm attendance of health post for the previous appointments and encourage attendance of the upcoming appointments. In case of missed appointments, HDAs are expected to visit and counsel the caregivers on catch-up immunization and place an additional sticker on the calendar to indicate the next outreach date. That HDA visits the same household again a few days prior to the outreach to promote attendance.

Finally, regarding the training of health workers and community members, the IRC conducted multiple trainings relevant to the project targeting HEWs, HEWs supervisors, HMIS focal persons, religious and clan leaders, influential persons, and kebele mangers. The trainings were mostly facilitated by IRC health team jointly with WoHOs, Zonal Health Department or Region Health Bureau (RHB). For HDAs and HDA leaders, the IRC provided training of trainers

(ToT) training for HEWs who then train the HDAs and HDA leaders with supervision from IRC team and WoHOs. For specialized trainings such as implant insertion, the IRC provided trainings with specialized trainers from the regional hospital. Data on the key trainings conducted by the IRC are detailed in the table Appendix A2.

4. Formative study evaluation questions and primary outcomes

The purpose of this study is to evaluate the contribution of community co-managed caregiver counselling and defaulter tracing to improve immunisation rates. The 'Fifth Child Project' consists of an overarching CE approach and two complementary communication and defaulter tracing components, hence the evaluation will assess the overall effect of these activities without aiming to tease out their individual benefits. The CE approach and component activities are dependent on each other since they constitute a response to different factors, which contribute to low and stagnating immunisation coverage in Ethiopia. The calendar seeks to increase uptake by reminding caregivers of the dates on which they need to take their children for vaccination. The DTT helps identify children who need to be followed up by HEWs and HDAs. Finally, the CE approach seeks to engender community level shared responsibility for immunisation by involving community leaders in the management of project activities in their areas.

4.1 Study aim

This study aims to evaluate the 'Fifth Child Project' in terms of integration into the local health system, utilisation and acceptability by the community, implementation of the CE approach and project components, and the overall effect on immunisation performance.

4.2 Study objectives

The underlying rationale of objectives 1-6 is to obtain data that will allow us to determine whether the project is being implemented as planned, to evaluate the theory of change and consider what is working well or what needs or is being changed to improve practice.

1. To observe how the 'Fifth Child Project' is integrated within the local health system and document health workers/officials, community leaders and caregiver's perspectives and experiences of this project and its' contribution;
2. To explore community leaders and health workers' views and experiences of co-managing 'Fifth Child Project' activities;
3. To observe how the *Enat Mastawesha* tool and interpersonal communication skills training are used and applied in HDA and HEW interactions with caregivers, and document HDAs and HEWs perspectives and experiences of using the tool and applying new skills;
4. To explore caregiver perspectives and experiences of interactions with health workers and community leaders, who co-manage 'Fifth Child Project' activities;
5. To observe how the defaulter tracing system and tool is being applied and document health workers/officials', community leaders' and caregivers' perspectives and experiences of the system and tool;
6. To assess the performance of the 'Fifth Child Project' by reviewing defaulter statistics and monitoring trends in the uptake of routine immunisations, specifically pentavalent vaccine.

4.3 Primary outcomes

It is not common to have clearly specified primary outcomes in qualitative research; hence, none were included for the original formative evaluation protocol. For the purpose of this report, we have indicated key focal areas that correspond with the above objectives and the original 'theory of change'. We have also specified primary and secondary outcomes for the monitoring of routine and project immunisation data.

4.3.1 Qualitative

To collect data that will help assess the following:

- a) Integration of the 'Fifth Child Project' within the primary care HEP
- b) Acceptability of the project as a longer term strategy within the HEP
- c) Community ownership of the project
- d) Acceptability and usability of the calendar and defaulter tracing system and tool

4.3.2 Quantitative

Primary outcomes

- a) Increased vaccination uptake as measured by coverage
- b) Improved access to immunisation for underserved communities (outreaches functional at health posts and beyond)
- c) Defaulter tracing system identified un-immunised children and provides catch-up vaccinations

Secondary outcomesⁱ

- a) Increased uptake of maternal health services (ANC, skilled delivery, postnatal and FP)

5. Formative study evaluation design and methods

5.1 Mixed methods design

The formative evaluation consisted of primary qualitative research complemented by a quantitative analysis of routine immunisation and project data. A variety of data collection methods were used to assess the following:

1. Acceptability and utilisation of the integrated CE approach among health workers, community leaders, and caregivers: semi-structured interviews (SSI), focus group discussions (FGD), observations
2. Quality of health worker interactions with caregivers and use of the calendar: SSI, observations
3. Performance of the defaulter tracing system: review of immunisation data

ⁱ Please note that these were considered as particularly important and promising outcomes by stakeholders when we met to discuss the study evaluation findings in November 2016

4. Overall performance of the 'Fifth Child Project': examining trends in penta 1 & 3 coverage from the MoH information system

5.1.1 Research conduct and ethics approval

London School of Hygiene & Tropical Medicine (LSHTM) investigators provided leadership in terms of evaluation design, qualitative data analysis and write-up and IRC investigators monitored and analysed routine project immunisation data. The IRC investigators were also responsible for recruiting external research assistants (RAs) who conducted the interviews, FGDs, and observations.

The evaluation was approved by the LSHTM Observational and Interventions Research Ethics Committee on March 7 2016 (LSHTM Ethics Ref: 10542) and by the Regional Health Bureau of Benishangul Gumuz Regional State (Ref 674/ጢ.ሮ m-01).

5.2 Qualitative methods

The 'Fifth Child Project' was iteratively developed and implemented in 114 kebeles across Assosa and Bambasi woredas between 2013 and 2015. Although the same programming and geographic scope were covered for January to December 2016, the qualitative part of this formative evaluation focused on three of the 114 kebeles. These kebeles were chosen to represent areas that are situated at different distances from the woreda main town and that differ in terms of population size. Two of the kebeles were also mainly inhabited by indigenous Muslim populations, whereas the other was home to Christian settler groups, who moved to BGRS from other parts of Ethiopia (mainly Amhara Regional State). Religion was not identified in the initial discussions with local stakeholders as a barrier to vaccination, but kebeles were selected to be heterogeneous, including in terms of religion, and to learn more from different types of study settings. Agriculture was the main income generating activity across all 3 of these kebeles with gold mining supplementing this in Mugfude. Table 2 provides more details about these kebeles; please note that in addition to these numbers, we estimated that there were about 60 community leaders across these kebeles.

Table 2: Composition of selected study sites

Kebele (Woreda)	Distance from woreda main town	HEWs/ Health post	HDAs/ HDALs	Total population	Infants <1year
Mugfude (Assosa)	58km	2 / 1	42 / 14	2,011	62
Amba 17 (Assosa)	32km	2 / 1	18 / 15	1,035	32
Jematsa (Bambasi)	24km	2 / 1	43 / 11	1,432	46
Total		6 / 3	103 / 40	4,478	120

5.2.1 Data collection

Recruitment and training of research assistants

Four RAs (all males) with good knowledge of English and Amharic and previous research experience were recruited in April 2016 to conduct the qualitative interviews, FGDs, and observations. Two of the RAs were fluent in Rutana (a local Berta language spoken in two of the three kebeles). Although all of the RAs had previous quantitative research experience, none had qualitative research experience. Therefore, a two-week evaluation training workshop, facilitated by LSHTM investigators, took place at IRC facilities in BGRS in April- May 2016 to train the RAs on qualitative data collection and analysis. As part of this training, the LSHTM investigators observed a small number of interviews and observational activities to mentor the RAs and support high quality data collection. In addition to these RAs, a British/Ethiopian female translator, based in London, provided translation and comprehension support to the LSHTM investigators to further enhance the accuracy and quality of the data. She also accompanied one of the LSHTM investigators on the data verification exercise and findings dissemination activities that occurred in Ethiopia in November 2016.

The RAs received technical supervision from the LSHTM investigators and logistical support from the IRC Ethiopia investigators. One of the four RAs was selected as team supervisor.

Participant sampling

Five groups of participants from the three kebeles were selected to take part in evaluation interviews and FGDs: caregivers, healthcare workers, community health workers, community members, and WoHO. Sampling details for each of the groups is provided below:

- **Caregivers:** There are approximately 120 infants in all three kebeles. We aimed to interview 12 caregivers (four per kebele); and organise three FGDs with 8-10 participants each (two for mothers, one for fathers). Potential participants were selected purposively in a way that ensures maximum variation in terms of gender, age, religion, and villages. The interviews were conducted in caregiver's homes. Given the setting the caregiver interviews may have involved more than one person depending on who was present at the time of the interview. To be sensitive to any privacy concerns, the main interviewee was offered the option of seeking a more private place or rescheduling.

The FGDs were conducted in a community building, like a church or school, where participants felt free to speak openly about their views and experiences. Consideration was given to providing and supporting appropriate childcare arrangements during the FGDs.

- **Healthcare workers:** All of the six HEWs and three nurses working at the health posts of the selected kebeles were invited to participate in an individual SSI. They were approached at their respective health posts and the interviews took place at the health posts, or at their home outside of working hours. One HEW supervisor per kebele, based in the health centres, was also recruited to participate in the study.
- **Community health workers:** At the time of the evaluation there were 103 HDAs and 40 HDALs across the three study kebeles. The target was to interview three HDAs and one HDAL per kebele, aiming for a total of nine HDAs and three HDALs. The HDAs and HDALs were purposively selected in a way that ensures maximum variation in terms of age, villages, and previous health work experience (HDA members are all female). The

evaluation team obtained guidance from the HEWs to identify the HDAs and HDALs. We also conducted three FGDs with HDAs, one in each kebele. The interviews with HDAs and HDALs took place at their homes or a private place of their choosing.

- **Community members:** We aimed to interview three community members per kebele (one kebele leader, one kebele manager, and one teacher), aiming for a total of nine community members. Community members were selected purposively in a way that ensures maximum variation in terms of gender, age, religion, villages and level of involvement in the 'Fifth Child Project'. The RAs sought guidance from the HEWs in the identification and selection of community members. The interviews were conducted in community members' homes or private place of their choosing.
- **WoHO:** This group included two WoHO and two EPI coordinators (Assosa and Bambasi).

Participant recruitment

RAs travelled to the three kebeles to invite potential participants to take part in the study. Each potential participant received a study information letter in Amharic which was discussed with them in Amharic or Rutana. The information letter explained what the study is and what will happen with the results (confidentiality). Participants were assured that they could withdraw from the study at any point and were given the opportunity to ask questions and the RAs contact details. Care was taken to ensure that the consent process was conducted in a private and confidential manner and no record would be kept of individuals who chose not to participate.

Participants' willingness to take part in this research was documented by asking each participant to record a statement in which they were asked to cite their name, the date and their willingness to take part in the research. These recordings were stored securely on password protected computers at the IRC offices, separately from the recordings and transcripts of the actual interviews or FGDs. Verbal consent is the preferred practice for obtaining agreement for participating in this type of health research in this region as asking people to sign forms is generally viewed as a sensitive practice that can evoke fear about what participants are being asked to do or provide. Participants that agreed to take part in an interview had the option of being interviewed immediately or scheduling an appointment at a more convenient date.

Data collection for the interviews and focus groups

Data collection took place between May and July 2016. Weekly calls between the LSHTM investigators and the RAs occurred during this periods to support RAs during the data collection phase and respond to any challenges or queries. A semi-structured approach was chosen for the interviews and FGDs to allow RAs to cover predefined topics and provide the necessary flexibility for the interviews to be shaped by interviewees' interests, their roles and experiences. The topic guides for the interviews and FGDs were developed by the LSHTM investigators based on the evaluation questions described in the study protocol. Specific guides were designed for interviews with: 1) healthcare workers and community health workers, 2) WoHO, 3) caregivers, 4) community members; as well as for the FGDs with: 5) caregivers and 6) HDAs. Local contextualisation and cultural appropriateness was ensured by the IRC Ethiopia investigators and the RAs, who also translated the topic guides into Amharic (written) and Rutana (direct verbal since this is mainly a spoken language with no orthography). Two interviews with caregivers in

Amba 17 were conducted to pilot the topic guide (not included in the final analysis), in presence of an LSHTM investigator, and topic guides were revised based on feedback (Appendix B).

Interviews and FGDs, which lasted approximately 1-1.5 hours, were conducted by two RAs in Amharic or in Rutana. One RA facilitated the discussion while the other took notes and observed non-verbal communication. The interviews and FGDs were audio recorded using a digital recorder with participants' prior permission. Basic socio-demographic information (age, gender, occupation, address, place of work, relevant background experience in health and how long they have been doing current job for health workers, age of child, their immunisation status, other family members for caregivers) was collected at the start of the interview. At the end of each interview and FGDs, the RAs compiled field notes summarising the interaction paying particular attention to context, quality and feel of the exchange, content interviewees emphasised and content that needs specific follow up.

Participant observation of project activities

The purpose of the observations of the routine command post meetings was to learn about and record any challenges faced by healthcare workers in carrying out and managing immunisation activities, noting also how these were addressed. The RAs also sought to document how the 'Fifth Child Project' was integrated into routine events and how community leaders were involved.

Participant observation of project activities took place between May and July 2016, by two teams of two RAs. Approval from the relevant leaders and participants to be present during these activities was sought, and participants were informed why they are being observed and what will happen with the information collected. RAs took notes during the events and wrote up any of their recollections as soon as possible after the event took place to describe: the type of event observed, the type and number of people present, the content of the activity and discussions which took place. All notes were anonymised and codes were used to indicate where the activities took place.

Observations could only be organised for two types of project activities, as the timing of other activities did not fit with the timing of the evaluation: 1) routine monthly command post meetings with kebele managers, kebele leaders, HEWs, HDALs, and representatives of youth and women groups of the kebele and 2) HEW/HDA routine visit to caregivers' homes.

The home visits consisted of 5 visits in each of the three kebeles with the aim of visiting homes with newborn infants, defaulting infants, and regular home visits conducted by HDAs. The HEWs and HDAs/HDALs were informed about these planned home visits and were asked whether they would be willing to participate. They were advised that the main aim of these observations was to learn more about how health workers were applying the interpersonal skills training and using the colour-coded health calendars. It was not designed to be performance management exercise. The HEWs and HDALs/HDAs were given the opportunity to opt out from this observational exercise if they felt uncomfortable with the process. Their verbal consent was obtained in the same way as described for the interviews and FGDs. The RAs conducted home visit with all of the HEWs and a randomly selected sample of HDALs/HDAs. The HEWs and HDALs/HDAs informed the relevant households in advance that an additional person would join their visits to ensure that the caregiver and other family members provided their permission for the RA to join the home visit.

The home visit observation sheets were developed jointly by LSHTM and IRC investigators to allow the RAs to assess different aspects of HEW/HDA visits to caregivers based on pre-

determined measurement criteria which corresponded to what was covered in the interpersonal skills training provided by IRC: purpose of the visit, initial greeting, how rapport is established, who is involved in the visit, who is present, whether and how the colour-coded health calendar is used, what key immunisation messages or other health messages are imparted, what caregivers say or ask, the nature and quality of interactions between the caregiver and the HEWs/HDAs (behaviour, mannerisms, active listening), and actions agreed (Appendix B).

Transcription and translation

The RAs transcribed the interviews and FGDs from the audio recorders in Amharic by hand. Interviews in Rutana were directly translated into Amharic during transcription. Each transcript was verified by the RA supervisor and typed up with secretarial support. Electronic copies of these transcripts were sent to the IRC office in Addis who contracted a private firm to undertake translation from Amharic to English. These translations were verified by the RA supervisor and an IRC investigator based in Addis. In addition, a British/Ethiopian translator, based in London, provided translation and comprehension support to the LSHTM investigators to further enhance the accuracy and quality of the data.

Qualitative data management

Each participant was allocated a numerical identifier and only the Ethiopian principle investigator, the RAs and LSHTM investigators had access to the socio-demographic sheet that linked the location code and numerical identifier to particular interviewee. The electronic audio files and transcripts only referred to the code and numerical identifier and these documents were stored separately to the Excel spreadsheet listing participants' details. Interview transcripts, field notes, scanned copies of participant's socio-demographic information and routine immunisation and project data were sent to LSHTM investigators by email as password-protected zip file attachments. These files were stored on the secure LSHTM network and were only accessed by the LSHTM study investigators. The emails were destroyed as soon as the files were retrieved.

Qualitative data analysis

The analysis of the SSIs and the FGDs was performed by LSHTM investigators with inputs and support from the RA supervisor and the IRC Ethiopian team. The approach to data analysis was mainly thematic (Boyatzis, 1998). A coding framework was developed by two of the LSHTM investigators through a mixed deductive and inductive coding process. Parent codes were drawn from the topic guides deductively and sub-codes were developed using an inductive process. They both coded a first five transcripts individually in order to be able to compare findings, enhance consistency and start to develop a coding framework. Observational data and home visit review sheets were also reviewed and relevant descriptive content was included in this qualitative data analysis. Investigators coded the transcripts using the NVivo® qualitative data analysis software and achieved consensus on a final coding framework which was then used to code all transcripts and some of the observational data. The RA supervisor also wrote up a fieldwork and analysis report which he shared with the LSHTM investigators in October 2016. This report was very useful since it allowed us to compare and verify our analytical decision-making. By November 2016, the LSHTM investigators had identified preliminary themes as also highlighted areas which we need to follow up in additional interviews and FGDs. This data verification exercise is summarised below.

Verification of initial analysis exercise

The purpose of this exercise was to address questions that had arisen during our analysis and to collect additional data that would allow us to verify our analytical thinking. This exercise took place in BGRS between 14th-17th November 2016 leading up to and including part of the BGRS stakeholder dissemination activities. It involved conducting more fieldwork in Assosa woreda (Amba 17 and Mugfude kebeles): SSI with a WoHO, two FGDs with caregivers (all mothers) and HDAs, 2 SSIs with kebele leaders and 2 SSIs with HEWs. The LSHTM investigators developed key objectives (Appendix B) for these interviews and the RA supervisor and British/Ethiopian LSHTM translator (who travelled to Ethiopia for this purpose) developed relevant questions from these objectives. One of the LSHTM investigators was present during the interview with the WoHO but the other interviews and FGDs were conducted by the RA supervisor and LSHTM translator on their own. The data collected in these verification interviews were incorporated in the data analysis which is reported in the qualitative findings section.

To further support the verification process of our data analysis, stakeholders attending the dissemination meeting on the 17th November, were asked to respond to set of key questions. They were given these questions after the presentation of the evaluation findings and were split into groups that included diverse actors to encourage discussion across different groups of health staff, including representatives from non-governmental organisations. The list of questions given to the groups can be found in Appendix B and their responses are summarised in the qualitative findings section.

5.3 Quantitative methods

5.3.1 Data source

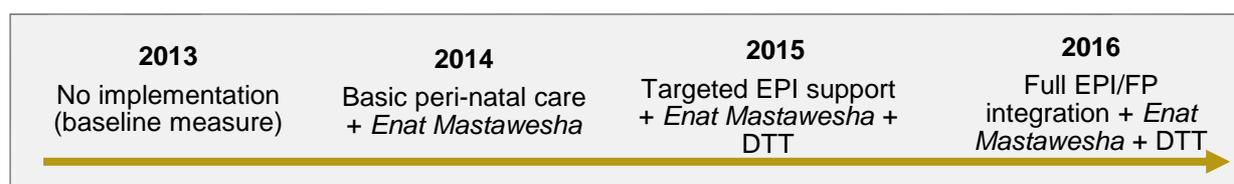
The routine immunisation data were collected from health management information system (HMIS) of each woreda and stored in an excel database on password-protected computer. The HMIS is the central platform used by Ethiopia's Ministry of Health for the reporting and management of all information related to health services at all levels, including immunization. The main limitation that the IRC faced was in relation to the data. The WoHO provided IRC with forecasted population data based on the most recent census conducted in 2007. Thus, population estimates may not be very accurate. Mindful of issues around population estimates, the WoHO conducted an actual count of infants during the polio supplemental immunization, and obtained lower numbers of infants than those forecasted. The current quantitative results are calculated based on the forecasted denominators provided by the WoHO, as these are the officially recognized figures.

Some project data that are not on government HMIS (e.g. defaulters by type of vaccine, post-partum FP, and calendars distributed) were collected using a different reporting template that the project team developed. The Excel database is updated by the IRC Health Manager in the field and sent to Data Management Officer and other IRC Health Technical Unit members for review, analysis and feedback.

5.3.2 Timeline of intervention data reviewed

Figure 3 illustrates how the intervention evolved over time, across different grants. Health management information system data from 2013 serves as a baseline prior to IRC implementation. In 2014, the *Enat Mastawesha* was introduced and activities for maternal and newborn health commenced, supporting peri-natal care, basic strengthening of routine immunization and family planning services. More intensive health system strengthening for immunization services started in 2015 and the DTT was rolled out as well as the integrated community engagement activities. In 2016, the period of this formative evaluation, the project included full implementation of the integrated immunization and FP strategy as well as the community engagement activities related to the *Enat Mastawesha* and the DTT, with minimal continued support for peri-natal care.

Figure 3: Timeline of IRC 'Fifth Child Project' interventions



5.3.3 Data analysis

The monthly data, ranging from January 2013 to September 2016, were transferred from Excel to Stata for analysis. Data for penta 1, penta 3, and measles vaccinations were aggregated into quarters (Jan-Mar, Apr-Jun, Jul-Sep, Oct-Dec) to derive more stable estimates, and coverage was calculated using the number of under-one children due for vaccination in each woreda. The estimates used for <1 year old children due for vaccination are reported in Table 3 according to the WoHOs.

Table 3: Estimated number of under-one infants due for vaccination in BGRS

Year	Assosa		Bambasi	
	Annual	Monthly	Annual	Monthly
2013	3,744	312	1,976	165
2014	3,738	312	2,036	170
2015	3,111	259	1,891	158
2016	3,237	270	2,052	171

In some quarters, the vaccine coverage was greater than 100% but not on the annual coverage. Quarterly number of vaccinations and coverage rates were plotted against calendar time.

Multi-level linear regression analysis was conducted. The main independent variable of interest was the intervention, coded as a categorical variable, with the reference category coded as prior to any intervention (year 2013), and other categories coded as 1) the IRC's general programme rollout (health workers trainings and mentorship, joint supportive supervision, quarterly review meetings and logistics assistance) (year 2014, quarters 1 and 2), 2) after the rollout of the *Enat Mastawesha* but before rollout of the DTT (year 2014, quarters 3 and 4, year 2015 quarters 1 and 2), and 3) after the rollout of both interventions (year 2015 quarters 3 and 4, year 2016 quarters 1, 2, and 3). The intervention was also coded separately as before full implementation as

reference and after full implementation (category 3 above) in a separate regression model. The dependent variable was quarterly vaccinations administered and coverage rates respectively. The regression model controlled for seasonality by including a variable distinguishing the rainy season (July-Sep) from the dry season (Oct-June) and accounted for clustering at the woreda level. Because of the high correlation between calendar time and intervention, we could not statistically control for secular trends. Stata version 13 was used for the analysis.

We also analysed the data on defaulter tracing, post-partum FP, and ANC to obtain frequencies for the following indicators: 1) proportion of defaulters identified and subsequently immunized, 2) proportions of women who adopted post-partum FP, and 3) proportion of pregnant women who had one ANC (ANC1) and four ANC (ANC4) visits, respectively.

6. Formative study timeline

Figure 4: Formative evaluation timeline

Timeline	A formative evaluation of the 'Fifth Child Project': A new initiative to close the childhood immunisation gap in BGRS, Ethiopia											
	01/16	02/16	03/16	04/16	05/16	06/16	07/16	08/16	09/16	10/16	11/16	12/16
Stakeholder meeting		Red										
Ethics approval obtained			Yellow									
Online journal updated for lessons learnt			Red				Red				Red	
Polio campaign in the area				Grey								
Recruitment of RAs				Purple								
Training of RAs on research methodology				Yellow								
Interpersonal skills and immunisation training for HEWs and HDAs					Purple	Purple	Purple					
Collection and analysis of routine data	Purple	Purple	Purple	Purple	Purple	Purple	Purple	Purple	Purple	Purple	Purple	Purple
Qualitative data collection & observations					Red	Red	Red					
Qualitative data transcription & translation						Purple	Purple	Purple	Purple			
Qualitative data & observations analysis								Yellow	Yellow	Yellow	Yellow	
Height of rainy season + Eid al Fatal/Ramadan						Grey	Grey	Grey	Grey			
National holidays 9/12, 9/24, 9/28									Grey			
Verification of qualitative data results with participants											Yellow	
Dissemination and reporting of results											Red	Red
Main partner responsible	Red	Both partners	Purple		IRC		Yellow	LSHTM		Grey	Notable event	

7. Analysis and findings from the formative evaluation

7.1 Qualitative findings

7.1.1 Participant characteristics

A total of 46 SSIs and 6 FGDs were conducted in the three kebeles as part of the main data collection period in May-July 2016. An additional 2 FGDs with caregivers and HDAs, a SSI with a WoHO, and 2 SSIs with kebele leaders and 2 with HEWs were conducted as part of the data verification exercise in November 2016. Participants were grouped as follows for the analysis: healthcare workers (HEWs, nurses, HEW supervisors), caregivers, community health workers (HDAs, HDALs), community members (kebele managers, kebele leaders, and teachers), and woreda officials (Health officials, EPI coordinators). Fifteen observations of routine visits by HEWs and HDAs to caregivers (five per kebele) and three command post meetings observations (one per kebele) were also conducted.

Table 4: Interview participants: role, age, gender and education level

Participant identifier	Role	Age	Gender	Education level
# 01	HDA	25	F	Grade 4
# 02	HDA	27	F	Grade 6
# 03	HDAL	50	F	None
# 04	Caregiver - Mother	40	F	None
# 05	Caregiver - Mother	39	F	Grade 4
# 06	Caregiver - Father	40	M	Grade 5
# 07	Caregiver-Father	40	M	Grade 5
# 08	Kebele manager	27	F	Grade 10+4
# 09	Kebele chairman	28	M	Grade 10+3
#10	HEW	27	F	Grade 10+1
#11	HEW	28	F	Grade 10
#12	HEW supervisor	28	M	Grade 10
#13	Nurse	26	M	Grade 10+4
#14	EPI officer	34	M	Grade 12+3
#15	HDA	42	M	BSc
#16	Teacher	29	F	Grade 12+3
#17	Caregiver – Mother	20	F	Grade 5
#18	Teacher	29	M	Grade 10
#19	Caregiver - Mother	20	F	Grade 5
#20	Caregiver - Father	30	M	Grade 7
#21	HDA	26	F	None
#22	HDA	22	F	Grade 5
#23	HDAL	40	F	None
#24	HEW	22	F	Grade 10
#25	HEW	21	F	Grade 10+3
#26	HEW supervisor	29	M	Grade 10+3
#27	Nurse	24	M	Grade 10+4
#28	WoHO	48	M	Grade 12+3
#29	Teacher	29	M	Grade 10+3

#30	EPI coordinator	42	M	Grade 12+3
#31	Kebele chairman	52	M	None
#32	Caregiver - Father	28	M	Grade 5
#33	Caregiver - Mother	29	F	Grade 5
#34	Caregiver - Mother	20	F	Grade 5
#35	Caregiver - Mother	30	F	None
#36	Caregiver - Father	32	M	None
#37	HDA	27	F	Grade 9
#38	HDA	28	F	Grade 2
#39	HDAL	24	F	Grade 8
#40	HEW	23	F	Grade 10+1
#41	HEW	28	F	Grade 10+1
#42	WoHO	32	M	Grade 12+BSC
#43	Nurse	23	F	Grade 10+3
#44	Kebele manager	25	F	Grade 10
#45	Kebele chairman	54	M	None
#46	Teacher	24	M	Grade 10+3

Note: Primary school in Ethiopia corresponds to Grades 1 to 8, while secondary school corresponds to Grades 9 to 12. Technical and vocational education can be started from Grade 10.

Table 5: Interview participants: socio-demographic details and geographic location

	Participants	Gender	Age
Amba 17	4 caregivers 4 healthcare workers 3 community health workers 3 community members	Females: 64.3% (9/14) Males: 35.7% (5/14)	18-24: 0% (0/14) 25-30: 64.3% (9/14) 31-40: 21.4% (3/14) 41+: 14.3% (2/14)
Jematsa	4 caregivers 4 healthcare workers 3 community health workers 3 community members	Females: 57.1% (8/14) Males: 42.9% (6/14)	18-24: 42.9% (6/14) 25-30: 42.9% (6/14) 31-40: 7.1% (1/14) 41+: 7.1% (1/14)
Mugfude	4 caregivers 4 healthcare workers 3 community health workers 3 community members	Females: 71.4% (10/14) Males: 28.6% (4/14)	18-24: 35.7% (5/14) 25-30: 42.9% (6/14) 31-40: 14.3% (2/14) 41+: 7.1% (1/14)
Assosa	2 WoHO	Females: 0% (0/2) Males: 100% (2/2)	18-24: 0% (0/2) 25-30: 0% (0/2) 31-40: 100% (2/2) 41+: 0% (0/2)
Bambasi	2 WoHO	Females: 0% (0/2) Males: 100% (2/2)	18-24: 0% (0/2) 25-30: 0% (0/2) 31-40: 0% (0/2) 41+: 100% (2/2)
Total	46 participants	Females: 58.7% (27/46) Males: 41.3% (19/46)	18-24: 23.9% (11/46) 25-30: 45.7% (21/46) 31-40: 17.4% (8/46)

			41+: 13.0% (6/46)
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Table 6: Focus group participants

FGD	Average Age (Range)	Total
Amba 17 - mothers	27 (24-35)	10
Amba 17 - HDAs	32 (22-40)	8
Jematsa - mothers	27 (23-40)	8
Jematsa - HDAs	28 (21-34)	8
Mugfude - fathers	33 (26-55)	8
Mugfude - HDAs	32 (25-40)	7
Total	30 (21-55)	49

Note: Verification FGDs were conducted in November 2016 with additional participants but no participant descriptive information was collected

The following sections feature the main themes identified as part of our qualitative data analysis.

7.1.2 Community acceptance of the project

“Had the community and the leaders not accepted Enat Mastawesha as a positive thing, it would not have been admitted into our houses. In the same way, a door is opened with keys, the calendar was introduced with the consensus of the community.” (Female caregivers, FGD).

Initially there was some hesitation about the ‘Fifth Child Project’, community members thought they were being forced to accept something that may not be to their advantage. A kebele chairman (45) explained: *“When these aid materials were delivered to our office for the first time the community was suspicious and they thought the government was forcing them to do something that was not in their interest. Things have changed completely these days. Women with the right knowledge on how to use the mother’s reminder tool are teaching others”*.

Other initial hesitations related to perceptions, mainly referred to in past tense, that vaccination is only for Christian communities (the role religion may still be playing in vaccine confidence merits further investigation in future evaluation), concerns that fathers not support the calendar, and that the project would be useless and even harmful. IRC staff sought to address concerns in orientation meetings with community leaders, including Imams and Pastors.

“The 5th vaccination project has included the education of religious leaders and elderly people who before had negative opinions about the vaccination. Currently they are giving support to the community to vaccinate their children. At the moment everyone in the community understands the benefit of the vaccination and is supporting each other.” (Woho. #15)

Project training provided to HEWs also helped to allay anxieties and increase understanding of the purpose of the project, especially when HEWS passed on information and skills acquired to HDAs working in their areas.

Over time the benefits of the project became more apparent. HEWs reported that the project tools decreased their workload, enabled them to reach remote areas, improved awareness of vaccination and increased vaccination demand uptake. At an individual level, mothers stated that the calendar helped them maintain better control over their child’s and their own health. Kebele managers and HEWs reported a change in attitudes towards vaccination and valued how the project had strengthened the performance of the HEP in their communities.

“We now have mothers who previously used to hide their children away arriving early at the health post to be first in line for the vaccinations. All this is due to the increased understanding they now have of the benefits of vaccination. I cannot overstate the positive impacts this project has had. The project has really strengthened the work of the HEWs and HDAs and we are seeing the results in the increased willingness of previously reluctant mothers.” (Kebele leader, #9)

“It is a big community and now it is seen in a better light by the District officials. Mothers bring their children for vaccination with own initiative.” (HEW, #24)

At the time of qualitative data collection, familiarisation with the project, had resulted in high levels of acceptance, attested by requests for the project to continue and expand to other areas from all groups of interviewees. One HEW demonstrated her sense of ownership and commitment to the project by placing additional emphasis on reaching the 5th child: “In my area our motto is: ‘If 1 child goes unvaccinated then we might as well not have vaccinated the other 4.’” (HEW, #11).

7.1.3 Enat Mastawesha: facilitating health communication in the home

The calendar was described by all types of interviewees as an excellent personalised reminder for mothers that has reduced health workers’ workload, increased demand for immunisation and facilitated timely uptake of vaccines. According to a female caregiver focus group interviewee, the *Enat Mastawesha* had “brought about extremely positive changes into our lives”. Not only had it had increased their understanding of immunisation but it had also encouraged them to attend ante and post-natal appointments, give birth in health facilities and consider FP options. The calendar, which was attached to walls in caregivers’ homes, served as a communication aide for health workers and a catalyst for health-related discussions between family members.

“Previously it was considered taboo for women to discuss obstetric/gynaecological issues with her husband. But since the training with the Enat Mastawesha we have learnt that everything can be discussed openly within the marriage, with health workers and even with friends. Due to these open discussions, women have been able to receive help as soon as their symptoms arise. (Male caregiver, #7).

“The Enat Mastawesha has made my work easier as it makes it easier to communicate with mothers, children and the community. It has allowed the community to understand the importance of giving birth at the health station.” (HEW, #11)

HEWs mentioned that using the calendar had not increased workload; on the contrary, it helped transfer responsibility (and therefore workload) from the health professionals to the caregivers themselves. A nurse explained that: “Prior to the introduction of the *Enat Mastawesha* we used to visit the mother many times because the mother would forget her appointments. (...) But now she only needs to come once and once we have explained the way it works to her, it is up to her to come in for all her appointments so the work load is easier on us.” (Nurse, #13). The project also allows HEWs to visit caregivers in their own time to distribute the calendar, since they live in the same community, freeing up consultation time.

Mothers liked the fact that the calendar included pictures and found the stickers useful, although a few reported that their primary school aged children had removed the stickers to play with them. Older children on the other hand helped their mothers with less education to read the calendar as did some of their husbands. Illiterate users could identify calendar dates but were unable to read the titles of the health education pictures. Despite this, they were mainly able to relay and to act on the key messages conveyed by the pictures. Conversely, HEWs reported that more literate users queried the choice of pictures with regards to the text headings. The application of the

colour coded stickers for different health service appointments made the tool more accessible for illiterate users.

“Even though I cannot read and write, I am still reading the Enat Mastawesha. I find it extremely useful.” (Female caregiver, #35)

7.1.4 The defaulter tracing system: Enabling systematic follow-up

HEWs stated that the defaulter tracing system and the related tool/defaulters tracing form had improved their access to vaccination data and enabled them to count and identify defaulters more effectively. They shared this information with the HDALs by giving them a copy of the form and sharing this information with them verbally as well since some of the HDALs were not able to read the form. HDALs coordinated the follow up of defaulters with the support of HDAs. However if they were unable to locate defaulters or encourage compliance they enlisted the support of kebele command post leaders and village leaders. Generally, kebele leaders only provided strategic assistance to solve problems. For example, if infants had missed vaccines because parents had to migrate in the short-term for work in the gold mines, kebele leaders would send local militia (who support the police) to ensure the child returned for immunisation. However, some of the interview data indicates there was a lack of clarity about how involved kebele leaders should be in terms of following up vaccine defaulters. The below quotes suggest that kebele leaders were directly involved in the follow-up of defaulters, and that they were well placed to do this due to the respect afforded to them.

“According to the plan and programme, we announce the date and place of the vaccination centre. We encourage the mothers in the community to take their children to vaccination. If there are defaulting children, we go and ask the reason and make sure they continue follow up.” (Kebele leader, #31)

“It’s very good. The chairman, who is heard by the community, order those who have interrupted the vaccination, if any, or those having it, all automatically comply.” (Female caregiver, 35)

Caregivers generally supported community leaders’ involvement in defaulter tracing but were also keen to highlight their role in promoting vaccination uptake as part of the 1 in 5 HDA model household health network. One mother also argued that vaccination seeking behaviours were the responsibility of the family unit: *“The kebele leaders do not do the work of searching children or infants who discontinued vaccination. The community brings children to vaccination centres by themselves. Except my husband no one orders me to take my child to get vaccinated”* (Female caregiver, #19).

7.1.5 Shared community responsibility for vaccination

“Local leaders will participate in tracing defaulters with HEW, religious leaders are always standing with us for example every Friday Muslim leaders announce to the people about immunisation in the mosque, and they order us to be on the side of the government, so immunisation in this kebele is coordinated by all.” (HDAL, #23)

Pre-existing kebele administrative structuresⁱ (command posts) and related accountability mechanisms facilitated the community co-management of the 'Fifth Child Project'. HEWs and HDAs were answerable to the kebele command post and expected to provide reports and work with kebele leaders to address service gaps. 'Fifth Child Project' activities, especially defaulter tracing, were reviewed at command post meetings and interviewees reported varying levels engagement and support from kebele leaders. Factors that influenced engagement were: 1) the frequency of command post meetings, 2) whether HEWs tabled activity reports at command post meetings, and, 3) kebele leaders' priorities and commitments.

The contribution of WoHOs (oversight and supervision) also varied depending on budgetary workload and time constraints. WoHOs were however very positive about the project and how it had supported their interactions with kebeles.

"The existence of this project has positive impact in our programmes, it strengthened our relationship with the community, we have quarterly meeting with community leaders to evaluate the activities so we are on good track, sometimes we faced transportation problem on EPI service except this all things are all right." (WoHO, #30)

Kebele leaders' specific project input included reviewing vaccination planning, highlighting service gaps, community mobilisation prior to vaccination outreaches, and supporting defaulter tracing. One HEW reported that the 'Fifth Child Project' had resulted in kebele leaders becoming more involved in promoting vaccination.

"Before the implementation of the IRC project, the awareness among kebele officials was not that good with regards to the importance of vaccinations. But, now, after having much training, they are working with us. For example, for children/infants who live in remote places or when access is impossible because of rivers' swell, we discuss with command posts and they command the parents to bring their children towards us (from those inaccessible areas)." HEW, #24

With regards to defaulter tracing we found evidence of community agreed sanctions (e.g. monetary fines, cautions by local court) in two kebeles. We were informed that the purpose of these sanctions was to ensure that pregnant mothers gave birth at health facilities and caregivers complied with the EPI infant vaccination schedule.

"The kebele leadership take measures when families interrupt childhood vaccinations. For instance, if a parent lets his child miss a vaccination or a husband hinders or does not help his wife give birth at a health facility, he can be detained for 24 hours. Such penalties are agreed by the consensus of the community. And so the people like it because they see it as a way of supporting their health post. The community thinks to pay a penalty of up to birr five hundred, for failing to attend for health services is a good thing. This shows their eagerness for the service, however, so far nobody has been penalised." (Focus group, male caregivers)

"...what I have observed in particular is mothers being reluctant to take the children on time, making excuses that they would take the children after finishing their household tasks. These women will be penalised even to the level of being charged in court." (Kebele leader, #45)

ⁱ Kebeles are led by an executive body of five to seven cabinet members including chairman (elected), three council members, a kebele manager, development agent, health extension officer and school director. The manager is reasonably educated, salaried and appointed by the woreda. Kebele command post meetings occur weekly or bi-monthly and as part of their agenda they review and evaluate the performance of different sectors (e.g. health, education) and subsequently the kebele managers submit reports to the relevant woreda offices.

In the data verification exercise, we sought to obtain more clarity about these types of sanctions. The WoHO we spoke to confirmed that monetary penalties could be applied if couples failed to present to health facilities for the birth of their baby but he did not think that sanctions were applied to failure to attend for vaccination. However, when we spoke to kebele leaders from the local areas which reported these sanctions, they confirmed they were part of their enforcement strategy. As indicated in Figure 5, these sanctions were rarely applied but could be used if there was evidence of time-wasting and complete disregard of guidance provided by HEWs and HDAs (see Figure 5).

Figure 5: Box - Excerpt from an interview with a Kebele Chairman in November 2016

I: What has the 5th Child Project contributed?

R: It has facilitated the systematic follow-up of all children that need to be vaccinated and that have not yet been vaccinated yet. Previously, it was not so systematic. It has also helped us keep proper documentation. It has also helped us enforce the timely vaccination of all children.

I: What do you mean by enforcement?

R: We have a penalty of anything between 50 birr to 500 birr. However, we first ask whether there is a valid reason why the mother was absent on the vaccination day, such as the having gone to a different kebele for work or for urgent family matters. If the reason is not valid, such as she was informed of the scheduled day but chose to stay at home with her child then it means that she simply did not want to listen to the advice of the HDA. I personally don't think this is a valid reason.

I: So mothers can be fined up to 500 birr, correct?

R: Potentially yes but the reasons are very rarely invalid. It is usually the case that the mother is absent because she was not aware of the vaccination day as she was temporarily in a different kebele for an urgent matter such as a family funeral or family illness. Also it would be up to the magistrate court to decide if the penalty should actually be issued.

I: Who decided on the fact that there should be a penalty and the amount this penalty should be?

R: This decision came from the community. To be honest this is more of warning but hasn't really been used in practice because mothers are really more than willing to come forward for the vaccination.

I: Let's say the penalty is issued, would the mother still be expected to vaccinate her child even after paying the penalty?

R: Theoretically yes. It would be because she has wasted our time unnecessarily. However, I can't really give you a recent example.

7.1.6 Demand for, and access to vaccination

In addition to scheduled monthly health post vaccination sessions, logistical support provided by the 'Fifth Child Project' enabled health workers to conduct vaccination outreaches in remote villages. This was important since demand for vaccines was reported to have increased gradually since the introduction of the HEP. *"Families feel like these vaccinations are their human right, and if vaccinations don't take place as scheduled, they come to us to ask when the vaccines will be given."* (WoHO, #28)

Some of the main reasons cited for default were infrastructural barriers; holding outreach sessions, at the hottest time of day because of the late arrival of vaccines from district centres

not being able to store vaccines at health posts due to a lack of fridges, not being able to open some multi-dose vaccine vials if less than 10 children attended vaccination sessions and intermittent shortages of vaccines. Other reasons for default included short-term migration of families for gold mining activities, long distances to health posts, and poor communication.

“What we consider a problem at present is that we have no constant refrigeration at the health clinic. If we had a fridge then we would be able to administer Polio 0 and BCG to the child as soon as mother gives birth.” (Nurse, #13)

“In my opinion one important problem is the business of traditional gold mining in the area. They travel long distance from their home to do mining because after all they have to earn some income. This causes 2-3 hours to reach to the vaccination spot. There is also a problem of commitment from professional to travel long distance to give the service.” (WoHO, #42)

In our first round of interviews it was evident that there had been a shift in opinion about vaccination over the past 5-8 years. From reluctance and hesitation to high levels of acceptance.

“At present the people within this community people have matured and have a wider understanding especially about vaccination it was very good. Especially vaccination is given to pregnant woman people know the benefit and they to come to be vaccinated. Nobody in this community wants the vaccination to stop.” (Male caregiver, #6)

Concurrent rollout of the HEP, which reached BGRS in 2009, and various NGO projects could be a reason for this. Over the past decade, key related interventions in the target woredas included: i) IRC's implementation of ICCM (2009-2013), that indirectly supported immunisation programming in terms of support for campaigns, logistics assistance (vaccine transport and motorbike maintenance for the WoHO) and immunization promotion messaging; ii) the Core Group Polio Project (2012-2017) led by World Vision, that supports the surveillance of measles, acute flaccid paralysis and neonatal tetanus as well as the implementation of polio campaigns; and the Clinton Health Access Initiative support for cold chain system transformation and effective vaccine management which was present during the formative evaluation period and still continues, mostly at the regional level and to some extent at the woreda level.

“People used to think vaccination causes death. But these days they are asking for it. Children run to vaccination centres and the community has made it its culture to bring children for vaccination since the past 2 years it is encouraging.” (Kebele leader, #9)

“Previously some had opposed this project; and still a small minority argue that the vaccination is only acceptable to Christians and not to the Muslims. However, after a lot of education, now most of the community has improved their awareness and accepted this as a good thing for them.” (HEW, #24)

Within the scope of this formative evaluation we were not able to find out more about the views of the small minority, cited in the last quote. The information we collected suggested that views about the acceptability of vaccination is changing in the Muslim community, however it would be useful to explore this further and tease out whether hesitations are generic to all immunisations or more specific and whether there is any perceived association between immunisation and family planning services since they are provided at the same health facilities and promoted as part of the *Enat Mastawesha*.

It was difficult to gauge the specific role the 'Fifth Child Project' had played in this change of opinion. Many participants thought it had played a key role, but in their elaborations about this they also referred to the importance of the establishment of health posts manned by HEWs, the introduction of the HDAs and the reduction in infectious diseases over the past decade. They did

not always distinguish between the 'Fifth Child Project' and these different components. In verification interviews, we probed further on this with HEWs and WoHOs. They stated that one of the core values of the project and related tools was the personalised caregiver/health worker interactions it facilitated. These interactions provided caregivers with the opportunity to express any concerns they had about vaccination (e.g. side effects, reactions) and helped health workers identify and make connections with hard-to-reach families.

7.1.7 Health system integration

WoHOs reported that the "Fifth Child Project" introduced new ways of working, which were described as valuable and integral to the existing HEP, specifically the Family Health Services packages: *"This project has introduced a new way of working. For example, previously there was no mechanism to remind mothers about delivery and their vaccination schedule. Having the Enat Mastawesha and the follow up form is useful for reminding the women of their check-up dates and vaccination dates. This all in one format has proved to be very useful."* (WoHO, #14). Kebele leaders and other health workers agreed that the project had created more systematic ways of encouraging uptake of immunisation in their areas.

Caregivers and HDAs tended to assume that the *Enat Mastawesha* was provided via the HEP or the government. This is an indication that the tools were well integrated within the health system, but it also made it difficult to tease out the specific effects of 'Fifth Child Project' tools on immunisation perceptions and behaviours. This is because the term 'project' was often associated with broader components of the HEP, such as the establishment of health posts in kebeles and associated access to primary care that is provided by HEWs (e.g. treatment of fevers, diarrhoea).

The 'Fifth Child Project' and related tools worked well within the context of the HEP infrastructure (health posts and HEWs) and HDA network. HDAs provided a trusted conduit for communication and follow-up at household level, and HEWs had the skills to explain the calendar, administer vaccinations, report to kebele managers and coordinate the follow-up of unimmunised children. Caregivers spoke very positively about interactions they had with HEWs and HDAs and the way they were treated during home visits and in clinics.

"Members of the health development army roam from house – to house in very good relationship with the community, because they respect them. Organise them peacefully, explain everything to them, assist them" (Male caregiver, #36).

HEW supervisors appreciated training support that the 'Fifth Child Project' provided to HEWs, not only immunisation training but also training on other maternal child health care subjects (e.g. ante/post-natal care and family planning). The training model used by the 'Fifth Child Project', followed the principle of 'training the trainers'. This model was already being used within the HEP, as HEWs are tasked with the responsibility of mentoring HDAs. However, some HEWs argued that it would be helpful if IRC assumed responsibility for providing 'Fifth Child Project' trainings for HDAs, and several HDAs also stated that they had not received formal training on the project from the HEWs.

"Currently the IRC gives the health extension workers training then it is up to the health extension workers to train the development group and the 1 for 5 group members. I think going forward it should be the IRC that train the development group and the 1 for 5 group members." (HEW, #11)

7.1.8 Need for infrastructural investment

As stated under the sub-section 'Acceptance of the project', interviewees were very keen for the project to expand but they also highlighted the need for infrastructural investment support to improve the performance of the immunisation programme. The following system weakness and service gaps were highlighted: shortages in trained health workers, availability of vaccines and other essential medicines, cold chain logistics specifically the lack of fridges in health posts, lack of fuel for transporting vaccines, shortages of delivery room equipment, shortages of beds, chairs, bedsheets and towels, and a lack of a latrine and cleaning materials to maintain high standards of cleanliness at health facilities. These infrastructural weaknesses will need to be considered in discussions on how to scale up the 'Fifth Child Project'. Discussions that will need to include the MoH, IRC and other NGOs and collaboration between and with NGOs, were viewed as very important to achieving lasting change.

7.2 Quantitative data analysis

7.2.1 Vaccine achievement and coverage

The quarterly summary of vaccine achievement and coverage in Assosa and Bambasi are presented in Table 7, and are plotted in Figures 6-7. The mean and median achievement and coverage levels were similar for all three vaccines in Assosa, but lower for measles in Bambasi. The denominator for the coverage indicator is presented in Table 3.

Table 7: Average quarterly vaccine achievement and coverage in BGRS from Jan 2013- Dec 2016 (16 quarters)

	Penta1		Penta3		Measles	
	Achievement	Coverage	Achievement	Coverage	Achievement	Coverage
Assosa						
Mean	611	71.1%	610	70.4%	612	70.8%
Median	597	73.5%	623	71.3%	600	69.6%
Range	462-753	49.4-91.7%	257-810	27.5-89.4%	446-810	57.3-88.5%
Bambasi						
Mean	437	86.7%	434	85.8%	360	72.3%
Median	434	87.4%	434	84.7%	361	72.4%
Range	352-531	71.1-97.7%	313-541	61.0-92.2%	215-474	42.2-92.0%

Figure 6: Quarterly vaccine achievement (number of vaccines administered), in Assosa and Bambasi, BGRS from Jan 2013-Dec 2016

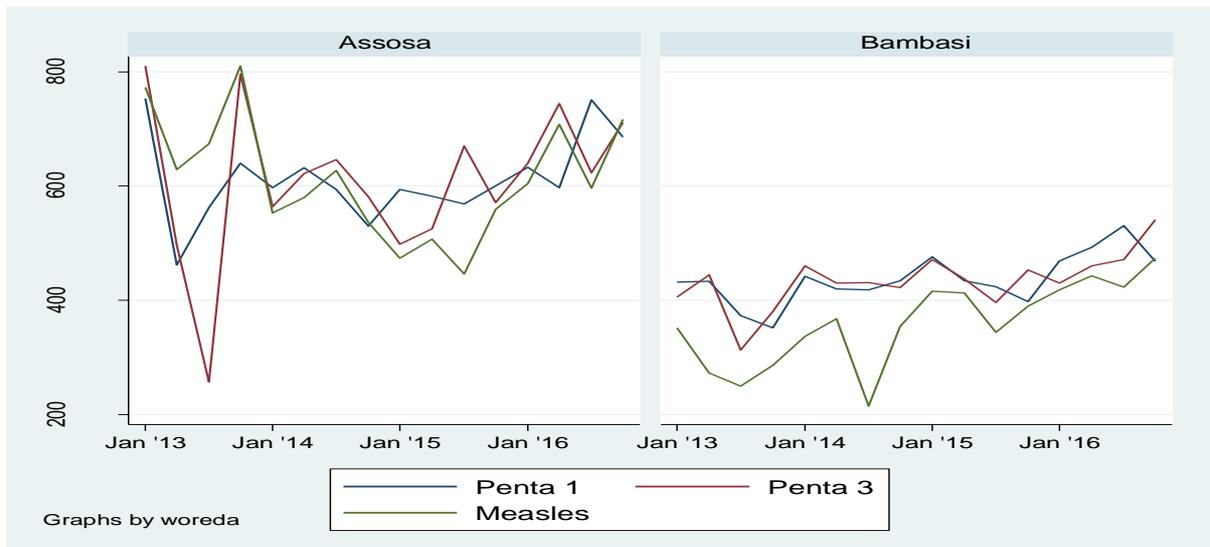
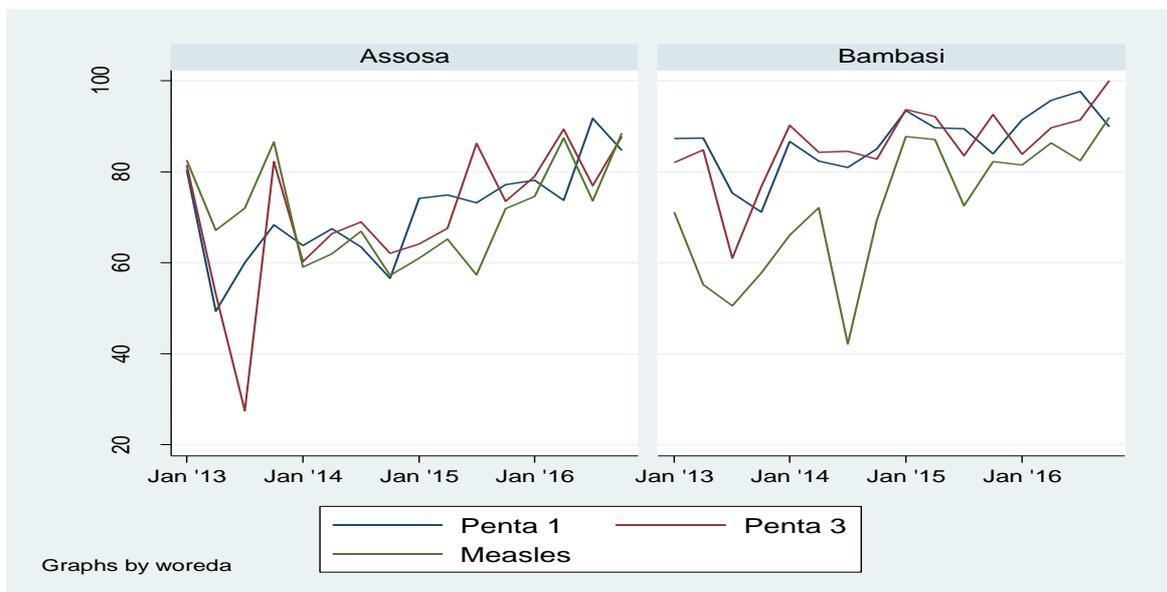


Figure 7: Quarterly vaccine coverage in Assosa and Bambasi, BGRS from Jan 2013-Dec 2016



7.2.2 Quarterly number of vaccination by intervention

The intervention did not statistically significantly increase the number of vaccines administered at the $p < 0.05$ level, but penta 1 and penta 3 had a marginally significant ($p < 0.10$) increasing trend with the implementation of both the colour-coded health calendar and DTT. Measles vaccination showed a decreasing trend, except in the case of the intervention phase involving the colour-coded health calendar and DTT.

Table 8: Change in quarterly number of vaccinations, by intervention

	Penta 1		Penta 3		Measles	
	Beta	p	Beta	p	Beta	p
No IRC programme	Ref					
IRC programme implementation	21.8 (-47.0, 90.6)	0.534	113.1 (-97.5, 123.8)	0.816	-62.4 (-159.5, 34.7)	0.208
+ colour-coded health calendar	6.9 (-48.5, 62.2)	0.808	13.5 (-75.6, 102.6)	0.766	-63.1 (-141.3, 15.0)	0.113
+ colour-coded health calendar, DTT and CE	50.7 (-0.5, 101.4)	0.050	77.3 (-4.2, 158.8)	0.063	9.6 (-61.9, 81.2)	0.792

Note: IRC programme refers to implementation of project activities, per the timeline in section 5.3.2.

When the numbers of vaccines provided were compared between the period before all intended programming was rolled out (no IRC programme, IRC programme, IRC programme + colour-coded health calendar) and after (IRC programme + colour-coded health calendar + DTT + integrated community engagement activities), there was a significant increase in vaccines provided per quarter by 44 penta 1 vaccine doses (95% CI: 2.8, 85.1) and 69 penta 3 vaccine doses (95% CI: 3.5, 135.3), and non-statistically significant, but positive trend in measles vaccine achievement.

Table 9: Change in quarterly number of vaccinations, by intervention

	Penta1		Penta3		Measles	
	Beta	p	Beta	p	Beta	p
Before full implementation	Ref					
After full implementation	44.0 (2.8, 85.1)	0.036	69.4 (3.5, 135.3)	0.039	46.8 (-13.7, 107.3)	0.130

7.2.3 Quarterly coverage of vaccination by intervention

The same analysis was conducted for coverage data. For coverage, we saw statistically significantly increased coverage for all three vaccines, only when both the *Enat Mastawesha* and the DTT were implemented. Coverage increased by 13.3% (95% CI: 6.9-20.0%) for penta 1, 18.4% (95% CI: 9.8-26.9%) for penta 3, and 12.4% (95% CI: 3.6-21.1%) for measles.

Table 10: Change in quarterly coverage (percentage points), by intervention

	Penta1		Penta3		Measles	
	Beta	p	Beta	p	Beta	p
No IRC programme	Ref					
+ IRC programme implementation	2.2 (-6.5, 10.9)	0.616	4.2 (-7.4, 15.9)	0.478	-6.1 (-17.9, 5.7)	0.313
+ <i>Enat Mastawesha</i>	4.9 (-2.1, 11.8)	0.172	8.4 (-1.0, 17.7)	0.081	-0.7 (-10.3, 8.8)	0.879
+ <i>Enat Mastawesha</i> & DTT	13.3 (6.9, 20.0)	<0.001	18.4 (9.8, 26.9)	<0.001	12.4 (3.6, 21.1)	0.005

Note: IRC programme refers to implementation of project activities.

Similar magnitude increases were seen when comparing the quarters before and after full implementation.

Table 11: Change in quarterly coverage (percentage points), by intervention

	Penta1		Penta3		Measles	
	Beta	p	Beta	p	Beta	p
Before full implementation	Ref					
After full implementation	10.9 (5.6, 16.2)	<0.001	14.2 (6.9, 21.4)	<0.001	13.8 (6.6, 20.9)	<0.001

The difference in statistical significance of the association between interventions and absolute number of vaccinations versus vaccine coverage is likely driven by the change in the denominator across the years, as displayed in Table 3. However, there are no major discrepancies in the interpretation of results for penta 1 and penta 3; both absolute number of vaccinations and coverage had increases that were statistically or marginally statistically significant. The greater difference in interpretation of the measles data may be driven by small sample size.

7.2.4 Defaulter tracing

Defaulter children identified and vaccinated

The IRC printed the DTT pads and distributed them to each health post at the start of the project. Distribution was designed such that each health post receives one pad which would be replenished based on needs. Health posts with larger catchment populations required new DTTs more quickly than posts with small catchment populations. Out of 5,289 children under one year in Assosa and Bambasi woredas in 2016, a total of 2,830 defaulted on one or more scheduled vaccination visits between January and December 2016 (default rate: 54%). Of the 2,830 defaulting children identified, 2,363 (84%) were successfully immunised with the vaccine they had defaulted on.

Table 12: Default on any scheduled vaccination visit by woreda, Jan to Dec 2016

	Assosa	Bambasi	Total
<1 year old children	3,237	2,052	5,289
# defaulter children	1,382	1,448	2,830
Default rate (any scheduled visit) (%)	43	70	54
# defaulters identified and vaccinated	1,216	1,147	2,363
% defaulter children identified and vaccinated	88	79	84

Immunisation dropout rates

Penta 1 – penta 3 and penta 1 – measles dropout rates were also examined by woreda. The analysis of 2016 immunisation data showed higher dropout rates in Bambasi woreda than those in Assosa woreda. Notably, at the end of 2016, Assosa recorded a negative penta 1 – penta 3 dropout rate (-1.9%) and a 3% penta 1 – measles dropout rate. On the contrary, in Bambasi woreda, the penta 1 – penta 3 dropout rate was minimal at 1.6%, and a high penta 1 – measles dropout rate of 10.4% was observed.

Table 13: Immunisation dropout rates by woreda, 2016

	# Penta1	# Penta3	Penta1 – penta3 dropout rate (%)	# Measles	Penta 1 – measles dropout rate (%)
Assosa	2,667	2,718	-1.9	2,625	1.6
Bambasi	1,961	1,902	3.0	1,758	10.4

7.2.5 Distribution of *Enat Mastawesha*

Ongoing distribution of the calendars was managed by the HEWs, once the IRC project team delivered them to the health posts. A total of 9,000 *Enat Mastawesha* calendars were printed since the start of the project in mid-2014, and, by the end of 2016, 8,448 were placed on the walls of homes with pregnant and/or infants. The study design did not allow evaluators to assess whether all 5,289 infants targeted in 2016 had *Enat Mastawesha* hanging in their homes.

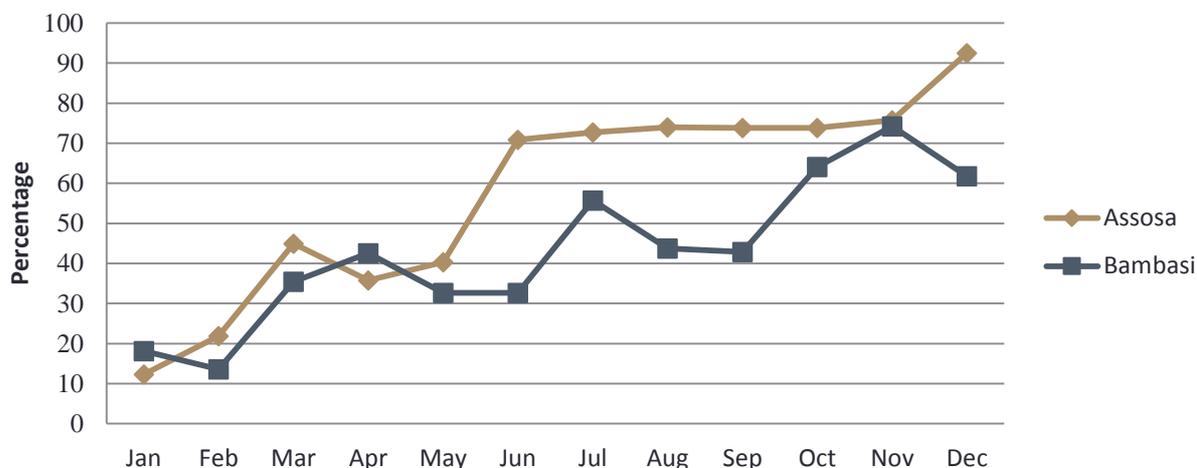
7.2.6 Home visits conducted

In 2016, the target for the number of home visits conducted by HDAs across Assosa and Bambasi woredas was 27,223. No baseline measure is available for reference. During the formative evaluation period, 24,442 home visits were conducted (90%), based on aggregation of HEW monthly reports. These visits were related to the distribution of, and the maternal, newborn and child health promotion discussions with household members prompted by, the *Enat Mastawesha*. Home visits related to defaulter tracing are not included in this figure. Based on these figures, and the total number of eligible infants, it can be estimated that, on average, each household was visited 4-5 times in 2016 in relation to the roll-out and continue health promotion use of the *Enat Mastawesha*.

7.2.7 Uptake of postpartum family planning

Increased uptake of postpartum FP was a secondary outcome of this intervention. The proportion of postpartum women adopting a modern FP method generally increased in both woredas throughout 2016, closing at 93% (of 1,752 deliveries) in Assosa and 62% (of 918 deliveries) in Bambasi (Figure 8).

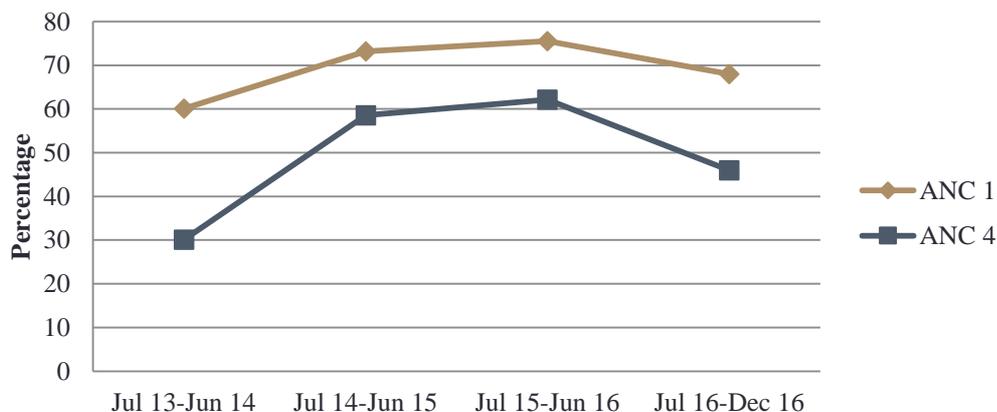
Figure 8: Proportion of women adopting postpartum family planning in 2016



7.2.8 Uptake of antenatal care

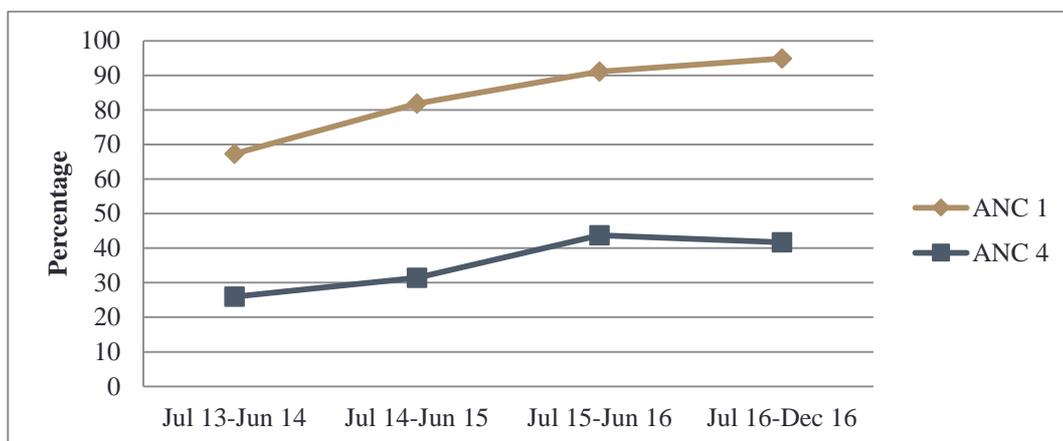
There was an overall increase in the uptake of antenatal care in both woredas. In Assosa, coverage of both the first antenatal care visits initially increased from a baseline of 60% in 2013 to 76% in June 2016, then declined to 68% by December 2016. Similarly, coverage of the fourth antenatal care visit increased from 30% in 2013 to 62% in June 2016, and then declined to 46% during by December 2016.

Figure 9: Antenatal care coverage – first and fourth visits, Assosa woreda, Jul 2013-Dec 2016



Attendance at one and four antenatal care visits generally increased in Bambasi woreda from 67% to 95% and 26% to 42%, respectively, from July 2013 to December 2016.

Figure 10: Antenatal care coverage – first and fourth visits, Bambasi woreda, Jul 2013- Dec 2016



7.2.9 Cost of the intervention

This formative evaluation did not include cost-effectiveness analysis; however, based on 2016 expenditure, basic retrospective analysis is possible. For reference, the cost to print one DTT is 95 Ethiopian birr (\$4.06) and the cost for one *Enat Mastawesha* is 82 birr (\$3.50). Table 14 breaks down the cost of the intervention across major categories and provides the total cost per household and beneficiary in terms of programming costs alone and programming plus support and indirect costs. Because this analysis was done retrospectively, allocation of shared costs was done based on recall rather than tracked time and effort, therefore cost estimates may be less precise. Further, the support cost allocations are calculated as a flat percentage of total support costs; we would expect support costs to fluctuate based on other factors in future implementation.

For this analysis, household is defined as a mother and child pair, since the intervention, particularly the *Enat Mastawesha*, is designed to benefit pregnant women, their infants and these same women post-delivery. Since the rate of multiple births is unknown, we have used the total number of eligible infants, 5,289, as a proxy for the number of households. For a rough estimate of the cost per individual beneficiary, we have simply divided the cost per household by two, yielding a cost of the intervention per beneficiary of \$7.00 and \$8.66 when support and indirect costs are included.

Table 14: Cost of intervention, per household and beneficiary

Cost of Intervention	Total Spend	Cost per household	Cost per beneficiary
Total Spend on Program Supplies & Activities	\$53,209.14		
Additional Spend on Programming (Staffing, Transport, Laptop)	\$20,782.42		
Support Cost Allocation	\$8,419.31		
Indirect Cost Rate (@ 11.11%)	\$9,155.85		
Total Spend on Intervention	\$91,566.71		

Program Costs	\$13.99	\$7.00
Total Cost	\$17.31	\$8.66

8. Implications of formative study findings

8.1 Implications for the intervention

The 'Fifth Child Project' was well integrated into the local health system and enabled more systematic follow-up of unimmunised children. The project contributed to improved awareness about, and increased demand for, vaccination. The *Enat Mastawesha* served as a communication aide for health workers and a catalyst for health-related discussions between family members. It supported more personalised interactions between health workers and caregivers and played a significant role in ensuring the timely vaccination.

Penta 3 coverage increased from 63% in 2013 to 84% by December 2016 in Assosa woreda, and from 78% in 2013 to 93% by December 2016 in Bambasi woreda. Similarly, measles vaccine coverage increased from 77% in 2013 to 81% by December 2016 in Assosa woreda, and from 59% in 2013 to 86% by December 2016 in Bambasi woreda. These immunisation coverage rates exceed the implementation performance monitoring indicators (Table 1), as well as the 80% district coverage recommended under the WHO Global Vaccine Action Plan (WHO, 2013). The project team finds this HMIS data to be fairly reliable, particularly for trend analysis, since project activities allowed for more frequent visits by IRC field staff who reviewed EPI data quality throughout the month. Please see section 9 regarding the challenges around the accuracy of the denominator; total number of eligible children.

Most relevant, nearly 54% of all eligible infants in both woredas defaulted at least once during the implementation period. It should be noted that the 54% default rate included multiple counts for each child depending on the number of scheduled immunisation visits they missed. Nonetheless, most of the defaulting infants (84%) were identified and subsequently caught up on the vaccinations they had missed. This proportion exceeds the 70% indicator target selected in the project performance monitoring plan (section 3.5.2). This intervention has the potential to improve the timeliness of vaccine uptake by promptly identifying defaulters and getting them caught up on missed vaccines. Immunisation dropout rates observed in the intervention woredas were lower than those reported for BGRS, according to the 2016 Demographic and Health Survey (Central Statistical Agency [Ethiopia] and ICF International, 2016). The modest dropout rates observed may be potentially due to the defaulter tracing strategies employed in the intervention. However, the evaluation design does not allow such inference without further research.

The implementation of the 'Fifth Child Project' intervention did not differ in significant ways from the intended plan in that the majority of HEWs and HDAs valued the tools and were able to use them effectively to motivate mothers and caregivers to seek the services highlighted in the *Enat Mastawesha*, such as ANC, immunization and postpartum FP, when needed. However, certain assumptions, included in the original theory of change, were challenged. For example, the implementation team hypothesised that the Woreda health offices, health centres, HEWs and community leaders would accept and be involved in monitoring defaulter tracing activities and performance. The WoHO officials were somewhat involved; however, the strongest involvement and effort came from the command post at the kebele level. Implementers now hold the view that effective community leader engagement for this project largely depends on the functionality of a health sector accountability mechanism, in this case, the role of the command post. Study findings

indicate that in some communities, the leaders were quite involved and had a sense of ownership of the activities, so much so that they took it upon themselves to introduce sanctions against caregivers who failed to comply, without consultation with the implementation team.

Regarding these penalties, the IRC will work closely with the WoHOs and key kebele leaders to look into whether the sanctions, or just the idea of the sanctions, may potentially negatively affect immunization uptake and other programming. The first step will be to organize a workshop with key stakeholders involved to jointly address it and discuss a way forward. This workshop is tentatively planned for the beginning of the third quarter, 2017.

In addition, evaluation findings and stakeholder feedback prompted implementers to slightly revise the *Enat Mastawesha* and DTT specifically in terms of what the images on the tools depict (i.e. male involvement, infant feeding best practices) and improving further on their acceptability for a low literacy audience. The comprehension of the health education tools should be further reviewed with reference to the text titles. The findings also informed implementers that using the *Enat Mastawesha* tool with the aim of an increase in immunisation coverage as the only primary outcome, was perhaps short-sighted. Respondents strongly indicated that community leaders, HEWs and caregivers see the *Enat Mastawesha* as a promising conversation starter for both the home and community level around uptake of the other key maternal and newborn health services that are integrated into the calendar tool as well.

Therefore, the implementation team believes that the 'Fifth Child Project' approach and tools should ideally be used in an integrated strategy to increase uptake of other targeted interventions (ANC, skilled delivery and FP), not only immunisation. Please see the descriptive statistics Appendix D for additional data on increasing ANC and postpartum FP, which coincided with the implementation of the 'Fifth Child Project' approach. The data suggest some positive outcomes in the uptake of these services and will benefit from further research. However, the drop in postpartum FP uptake in Assosa woreda during the fourth quarter of 2016 warrants further examination. The team has revised the theory of change and implementation design to better integrate, and emphasise immunisation and postpartum FP services since these interventions are commonly given at the same time and location and by the same health workers. Please see Appendix C for additional details.

Given that the purpose of *Enat Mastawesha* tool is to improve health seeking behaviour, the IRC will aim to continue working to support behaviour change activities with the intention that health seeking behaviour once improved would be sustained. The IRC has received suggestions for improvement of the *Enat Mastawesha* and the team is incorporating most of the feedback in the next version of the calendar. While the feedback provided by the stakeholders is very important, the project team is concerned about the following issues: a) the space on the calendar may not be sufficient to accommodate all of the topics indicated without changing the size of the calendar; b) the new proposed topics (malaria and nutrition) fall outside of the project focus under the current grant, although these topics are all relevant to the project area; c) the new topics will need time and some level of effort to develop, and including pictures alone on the calendar will not bring the desired effect unless that is complemented with other activities; d) there is high chance of diluting the project focus areas and affecting the simplicity of the tool. Nonetheless, the IRC will adapt the next iteration of the calendar, improving the images, enhancing male involvement and simplifying text as much as possible. Concerns regarding incorporating other feedback will be shared with stakeholders before revisions are made.

The IRC plans to work directly with the WoHOs, Zonal Health Department and RHB to adapt the DTT based on the formative findings and institutionalize its use in the targeted woredas meaning that the WoHOs will begin printing it themselves and will use it without IRC support. Also, since

the cost of DTT is very minimal it can be absorbed into the WoHOs budget. The WoHOs are also very interested in scaling up the use of the *Enat Mastawesha*, however, since the cost per household is at least \$3.50 for a calendar, the WoHOs maintain their request for partner support and moreover have asked for impact data. The IRC has been providing logistical assistance to the local health system through this project and this includes support for cold chain management and maintenance, provision of transportation assistance for vaccines and outreach services and maintenance of motorbikes and support to health workers and HEWs that work in the hard to reach areas. The IRC is able to continue this support for at least 12 months after the formative evaluation period (the current grant ends December 31st 2017).

Furthermore, the IRC will continue to support the continued integration of the project components and tools into the health system. Specifically, the IRC will work for sustainable integration of capacity building of HEWs, HDALs and WoHO to improve technical expertise in providing the continuum of care from pregnancy to institutional delivery, postnatal care, immunization and family planning. The IRC envisages achieving this through formal trainings and on-job mentoring of technical and support staff across health facilities in the targeted woredas. The project team found that the number, structure and content of the trainings during the project was fine, however, a key element for reinforcement in the remaining period is post-training follow-up. In collaboration with the trainees and WoHOs, the project team will develop HEW mentorship plans and assessment tools for WoHO supervisors to help evaluate knowledge and demonstrated skills. These tools may be in a form of checklist and can be utilized during supportive supervisions to help determine whether trainees apply the new skills in the right manner, and if not, these visits will provide opportunities for in-person mentoring or troubleshooting. The IRC health team works closely with the WoHO experts and these experts are encouraged to join IRC team in trainings serving as co-facilitators, and participating in joint supportive supervision of the HEWs allowing them to co-mentor the HEWs. This process would facilitate continued knowledge and skill-transfer between IRC project team and WoHO experts. For sustainability, the IRC will use a training-of-trainers model. The trainings will emphasize development of WoHO and health centre personnel technical expertise and facilitation skills to provide effective trainings to HEWs, nurses, midwives and other health cadres.

8.2 Implications for further research

Both the implementation and evaluation team feels that there is great value in conducting of full impact evaluation of the revised intervention. Moreover, research participants and policy stakeholders agree. Based on the findings, policy relevance and stakeholder feedback the key evaluations questions for further research include:

- Does the integrated *Enat Mastawesha*, DTT and community engagement approach, plus supportive EPI service delivery activities, increase immunisation coverage more than supportive EPI service delivery activities alone?
- Does the *Enat Mastawesha* tool and community engagement approach increase coverage of other services, namely: ANC, skilled delivery, postpartum FP?
- What other support is needed to improve the capacity of the health system to provide immunization services?
- How are men, and other gatekeepers, engaged most effectively in this approach?
- What is the impact of the intervention on HEW workload?
- Is this approach scalable across the region? Across the country?
- Is this approach cost-effective?

- Can the DTT be adapted for use in conjunction with community engagement strategies in different immunisation contexts, particularly those with very low coverage (below 50%), with reproducible results?
- How are community agreed sanctions for vaccination default determined and administered?

The research team envisions conducting a cluster randomised controlled trial with an embedded process evaluation to answer these key questions. This design will also enable us to measure the causal effects of the intervention more accurately, by being clear about how the intervention builds on the HEP. This will help disentangle some effects of the intervention from that of the HEP as a whole. It is anticipated that the implementation would follow the revised theory of change to achieve the primary and secondary outcomes and would use the same tools, currently being revised based on the findings of the formative evaluation.

The team anticipates that attempting to evaluate the ‘Fifth Child Project’ tools and community engagement approach in a context where supply side challenges are not actively addressed to a certain extent by either the implementing partner or the woreda health bureau would be misguided and impact would be diminished; this was also highlighted in the qualitative finding around infrastructural investment in section 7.1.8. Therefore, it is critical to maintain inclusion of basic EPI system supportive activities in any subsequent programming and evaluation since gaps in MoH service delivery, such as ruptures in the cold chain, missed outreaches or lack of trained or supervised personnel, may result in the community losing confidence in immunization services and/or HEWs.

The evaluation would be completed in a timeline of 24 months in areas that have not yet been exposed to the intervention. The implementation team is assessing whether the project could potentially take place in the Gambella region, an area with low immunisation, coverage of penta 3 was 54.8% in 2016, low percentage of deliveries in health facilities, 45%, and where only 34.9% of women of reproductive age are using a modern FP method (Central Statistical Agency [Ethiopia] and ICF International, 2016). If an impact evaluation were possible, after the end of the current project, the project team would reduce levels of support in BGRS, allowing the RHB and WoHOs to further integrate the Fifth Child approach, tools and costs into the HEP, while the IRC would roll out a new project in the targeted, still unexposed region.

Since the cost analysis was not in the evaluation design and was conducted retrospectively, the project team is hesitant to compare the \$7.00 cost per beneficiary figure with other studies. However, it is promising to think that further research, including an embedded cost effectiveness analysis, could examine how the fixed cost of the *Enat Mastawesha* is spread over multiple outcomes. For example, investing in calendar procurement and the trainings around its use, should the intervention be able to improve uptake of multiple services and health outcomes, would allow investment in the calendar as a fixed cost to achieve multiple outcomes for both infants and their mothers. This would improve the scale and efficiency in regard to the number of health outcomes addressed by one tool and strategy.

Regarding the policy relevance of this approach, the project strategies fall within the prevailing government policy of the integrated HEP and the IRC will promote the use of study findings to improve regional and national strategies for improving immunisation coverage in hard to reach areas, areas that are under-performing in terms of access and utilisation and areas with weak routine immunisation and health system. The formative study provides evidence relevant for policy makers and programme managers involved in determining the future directions of regional and national strategies for improving vaccination coverage in remote and vulnerable populations and in how to utilise community engagement approaches within the HEP. The implementation

team will continue to deepen the understanding of the use of project strategies and tools including the *Enat Mastawesha* and DTT among the key stakeholders. The IRC will also offer support for stakeholders (including government and civil society) if they decide to scale up project strategies and tools in terms of providing training materials and sharing lessons.

9. Major challenges and lessons learnt

Some overarching limitations and challenges were noted during the evaluation, and are reported here. Some bias might have been introduced by the fact that our participants and selected kebeles were aware of their participation in the evaluation (non-blinded). This may have led them to share more positive experiences with the project, avoiding discussing barriers or challenges. Participants might have particularly been prone to provide the information they believed researchers wanted to hear as the RAs collecting the data may have sometimes been perceived as members of IRC or the government. The RAs selected in this study were all males, which could have influenced some of the interviews and FGDs organised with females. This was taken into consideration when analysing the results of the evaluation as it was not possible to have a blinded participant group within the timeframe of this research.

Biases could have been introduced by the use of different languages in the study. Interview materials (topic guides, informed consent forms) were first developed in English, and translated to conduct the interviews and FGDs in Amharic or Rutana. An additional difficulty comes from the fact that Rutana is a spoken language only which means recordings had to be translated directly to Amharic during transcription. Transcripts then had to be translated to English for analysis, which could have led to additional misunderstandings. Amharic is a fairly different language from English, and some expressions might not have been possible to translate to English as they were originally meant. Although steps were taken to verify the translations at multiple stages during the evaluation, by multiple reviewers (including the RAs and some participants) as described in the methods, biases could have been introduced. Verification of translations also took longer than originally planned, which led to some delays in the analysis of the data.

The choice of the three kebeles might have impacted the results as these particular communities might have had better vaccination coverage rates than other kebeles in the region because they were relatively more accessible. This might have biased the evaluation of the impact of the programme on defaulting rates. Furthermore, due to time restrictions and the 3ie-request formative evaluation scope, the study design could only evaluate the project implementation in three kebeles, with a small number of children. Future evaluation of the project would be needed with a larger sample size to provide more reliable and robust data. This might also compensate for the difficulty in obtaining correct and up-to-date estimates of the target population for immunisation. The targets provided by the WoHO are incorrect. Estimates obtained using conversion factors overestimates target children while estimates obtained by counting children during polio campaign underestimates the target children. A larger sample size might compensate for these challenges.

Regarding challenges faced during implementation, the project team experienced a 2-3 month delay in project start up as it took a bit longer than expected to secure RHB approval for the combined project and evaluation protocol. In addition, project activities sometimes overlapped RHB or WoHO-planned activities, leading to the minor postponement of intervention rollout per the project timeline. For example, the IRC, with WoHos, often plan to conduct various trainings or review meetings for HEWs. However, given the number of campaigns, such as polio, onchocerciasis and the response to acute watery diarrhoea as well as urgent government tasks

and/or requests to the HEWs, 'Fifth Child Project' planning has to be shifted accordingly. Therefore, the IRC now discusses project activities well in advance to overcome this challenge as much as possible.

Occasional stock-out of Bacillus Calmette–Guérin (BCG), measles and pneumococcal vaccine was also an issue as was the way that the MoH multi-dose vial policy and vaccine wastage policies are locally interpreted. Health workers are trained that they should open multi-dose vials even if there is only one child present – so as to not miss the opportunity to vaccinate – however they are also being assessed on how much vaccine they waste; they have to discard unused vaccine 6 hours after a multi-dose vial is opened due to lost potency. Therefore, HEWs are hesitant to open multi-dose vaccine vials if there are not at least half the number of children present for the number of doses in the vial; most often 20 doses/vial for BCG and 10 doses/vial for measles. This is a particular problem during static immunisation sessions at health centres since there is less community mobilization conducted and thus fewer children attend. Community mobilization activities were particularly challenging in kebeles where mining activities are common, leading community leaders to send local militiasⁱ to alert families in the case that their child missed an appointment and/or to inform them of upcoming outreach sessions. Like the leader imposed sanctions, involvement of local militias was not discussed with the IRC project team in advance but does illustrate a sense of ownership over project activities and investment in the uptake of immunization services. This should also be examined through further research.

There were few challenges experienced in the provision of logistical support, except during the rainy season, where IRC field officers sometimes needed to hire animal transport to facilitate access to remote facilities for outreaches and supervision since vehicles and motorbikes were unable to pass. A further challenge regarding logistical support were the significant expectations by WoHOs compared to the limited service delivery gap-filling support provided by IRC. Soon after the start of the project, the IRC team ensured joint planning and prioritization with the WoHO to ensure transparency in decision-making around the provision of logistical support. Another challenge was the high turnover of HEWs, especially in hard to reach areas, leading to WoHO-recruitment of new HEWs, rather than devising and supporting an HEW retention plan. The new HEWs required intensive on job training and supervision by IRC field officers.

After the initial start of the project in 2014, the government shifted approaches from community health volunteers to HDAs. The new shift and the associated government policy restricted direct NGO engagement with HDAs. This restriction initially created some confusion, but later, the IRC team started to rely on HEWs to train and support the HDAs as per the policy. The IRC provides ToT and interpersonal communication skills training to HEWs for them to cascade trainings to HDAs. The IRC is not able to directly train the HDAs as this is contrary to government policy. However, the implementation team will strengthen monitoring mechanism to ensure that each HDA is trained on topics identified for them; it is unclear why some HDAs reported not being trained by HEWs.

Few challenges were identified with regards to the use and basic comprehension of the *Enat Mastawesha*. The calendar material is durable and dust and water resistant and can remain stuck on the wall for a long period, using nails through the metal-reinforced holes at the top and bottom. The project team is advising the households to hang the calendars little higher so younger children will not reach them and remove the stickers. The calendars were deemed to be readable in the local language; if not by the caregiver, then by another member of the household present, per

ⁱ A kind of local community policing force, most often unarmed, that work together with kebele leaders.

intervention design, during the HDA home visits. As noted in section 8.1, the IRC team is still working to simplify the text used as much as possible.

Similarly, concerning the DTT, HEWs reported no major challenges with regards to comprehension, record keeping or retention of DTT carbon copies by HDALs. The HDALs do not retain the whole DTT pad but rather mark their DDT carbon copy with an 'X' or a '✓' as needed next to each defaulter and submit the copy back to the HEWs once they or their HDAs trace the caregivers and subsequent vaccination is provided. Health extension workers then retain this copy, update their DTT pad, and use this information during command post discussions and for reporting to the IRC and the WoHO. The design of the intervention made it such that the HDAs, for literacy reasons, were in possession of the HDAL DDT carbon copy only in the very rare occasion that the HDALs shared it with them. The vast majority of the HDAs were informed verbally by their HDALs of the households to visit.

Finally, in October 2016, a state of emergency was declared in Ethiopia. Although the state of emergency had no impact on the project as issues occurred in other regions of the country, it led to disruptions in communication between the partners involved in the evaluation due to cuts in internet access and created some delays in the evaluation.

9.1 Specific limitations

9.1.1 Qualitative data and findings

The RAs were all male due to lack of female applicants for these posts. The addition of the British/Ethiopian female translator who assisted with data verification helped to rebalance this.

Home visit checklists provided limited descriptive data (needed more time to train RAs on the use of these, probably a better tool for internal quality checks).

9.1.2 Quantitative data analysis and results

The coverage results should be interpreted with caution for two reasons. One, by examining the programme in four distinct intervention periods, there are very few data points contributing to each period. Two, we observed a drop in the estimate of number of under-one children due for vaccinations in 2015-2016 compared to 2013-2014. We cannot assure the accuracy of these "children due" estimates, and this drop could be contributing to the increase in coverage rates.

In addition, the denominator data may not be same as the actual number of children. When counted children data that were provided by the WoHOs were used, the above coverages were 100% and above. When conversion factors, again provided by the WoHOs, were used, the number of <1 children was overestimated as compared to the counted children. The team chose to use the conversion factor for this analysis.

10. Appendixes

Appendix A: Process monitoring indicators

Indicators	Indicator Definition	Sources	Frequency	People Responsible	Information Use/Audience
Penta 1 coverage	Proportion of surviving infants who have received first dose of the combined diphtheria, tetanus toxoid, pertussis, hepatitis B and Haemophilus influenzae type B vaccine	Immunization register	Monthly	1. HEWs and IRC health officers 2. IRC health manager 3. IRC Health Technical Unit	1. Immunization performance monitoring 2. Input for quarterly joint supportive supervision by IRC and WoHOs 3. Input for quarterly project review meeting
Penta 3 coverage	Proportion of surviving infants who have received three doses of the combined diphtheria, tetanus toxoid, pertussis, hepatitis B and Haemophilus influenzae type B (pentavalent vaccine)	Immunization register	Monthly	1. HEWs, WoHOs and IRC health officers 2. IRC health manager 3. IRC Health Technical Unit	1. Immunization performance monitoring 2. Input for quarterly joint supportive supervision by IRC and WoHOs 3. Input for quarterly project review meeting
Measles coverage	Proportion of surviving infants who have received a dose of measles vaccine before their first birthday	Immunization register	Monthly	1. HEWs, WoHOs and IRC health officers 2. IRC health manager 3. IRC Health Technical Unit	1. Immunization performance monitoring 2. Input for quarterly Joint supportive supervision by IRC and WoHOs 3. Input for quarterly project review meeting
Proportion of postpartum women adopting a modern FP	Proportion of mothers who bring their child for immunization services and adopt a modern FP method	Integrated FP-Immunization registration book	Monthly	1. HEWs, WoHOs and IRC health officer s 2. IRC health manager 3. IRC Health Technical Unit	1. Post-partum FP performance monitoring 2. Input for quarterly Joint supportive supervision by IRC and WoHOs 3. Input for quarterly project review meeting
Defaulter infants identified and vaccinated	Proportion of defaulters identified and vaccinated (for penta 1, 2, & 3 and measles)	DTT Pad Immunization register	Monthly	1. HEWs, WoHOs and IRC health officers 2. IRC health manager 3. IRC Health Technical Unit	2. Defaulter tracing performance monitoring 3. Input for quarterly Joint supportive supervision by IRC and WoHOs 4. Input for quarterly project review meeting

Proportion of planned household visits completed	Proportions of houses visited compared to planned	Daily activity record book	Monthly	<ol style="list-style-type: none"> 1. HEWs, WoHOs and IRC health officers 2. IRC health manager 3. IRC Health Technical Unit 	Monitoring of services utilization, use of <i>Enat Mastawesha</i> , and to address any misunderstandings.
Number of outreach sessions conducted	Number of outreach sessions conducted	Outreach Immunization register	Monthly	<ol style="list-style-type: none"> 1. HEWs, WoHOs and IRC health officers 2. IRC health manager 3. IRC Health Technical Unit 	<ol style="list-style-type: none"> 1. Immunization performance monitoring 2. Input for quarterly Joint supportive supervision by IRC and WoHOs 3. Input for quarterly project review meeting

Appendix A2: Training topics and monitoring indicators

#	Training Title	No. of sessions	Duration	Content of training	Measure of training effectiveness
1	Topic - Interpersonal communication skills Target – HEWs Total no. - 214	8	3 days	Definition of communication, elements, types, characteristics of good communication, approaches and barriers to effective communication.	<ul style="list-style-type: none"> ✓ Pre and post test ✓ Post training on-job follow-up using checklists
2	Supervisory skill training Target – HEWs supervisors Total no. - 25	1	5 days	Training on basic supervisory skill and techniques.	<ul style="list-style-type: none"> ✓ Pre and post test
3	Orientation training for religious and clan leaders on immunization Target – Religious and clan leaders, or other gatekeepers in selected 41 kebeles Total no. - 247	7	1 day	Importance of vaccine, schedule, and common misconceptions; and support to HEWs for better coverage.	<ul style="list-style-type: none"> ✓ HEWs feedback on the level of involvement of religious and clan leaders following trainings on immunization and other health interventions

4	Orientation training for kebele Managers on immunization Target – kebele Managers from all kebeles Total no. - 148	3	1 day	Importance of immunization, immunization schedules, and common misconceptions and the role of the community leaders in mobilizing the community.	✓ HEWs feedback on the level of involvement of kebele managers following trainings on immunization and other health topics.
5	Better data for better decision (data quality and data use training) Target – HEWs supervisors and HMIS focal persons from WoHOs and HCs Total no. - 28	1	4 days	Introduction and terminology, Data collection, Data flow, 3 C's of data quality, data verification, data interpretation and data presentation	✓ Pre and post training tests ✓ Improvements in data quality (as observed through data review meetings)
6	Implant insertion training for HEWs Target – HEWs Total no. – 220	9	6 days	General overview of FP, and theoretical and practical session on insertion of implant.	✓ Pre and post test ✓ Post training follow-up using checklists
7	Training on male involvement immunization and FP Target – HEWs Total no. – 214	6	2 days	The role of male involvement on immunization and FP and the need to involve men actively and how to do that.	✓ Pre and post test

Appendix B: Survey instruments

Appendix B provided as attachment

Appendix C: Revised theory of change

Appendix C provided as attachment

Appendix D: Descriptive statistics

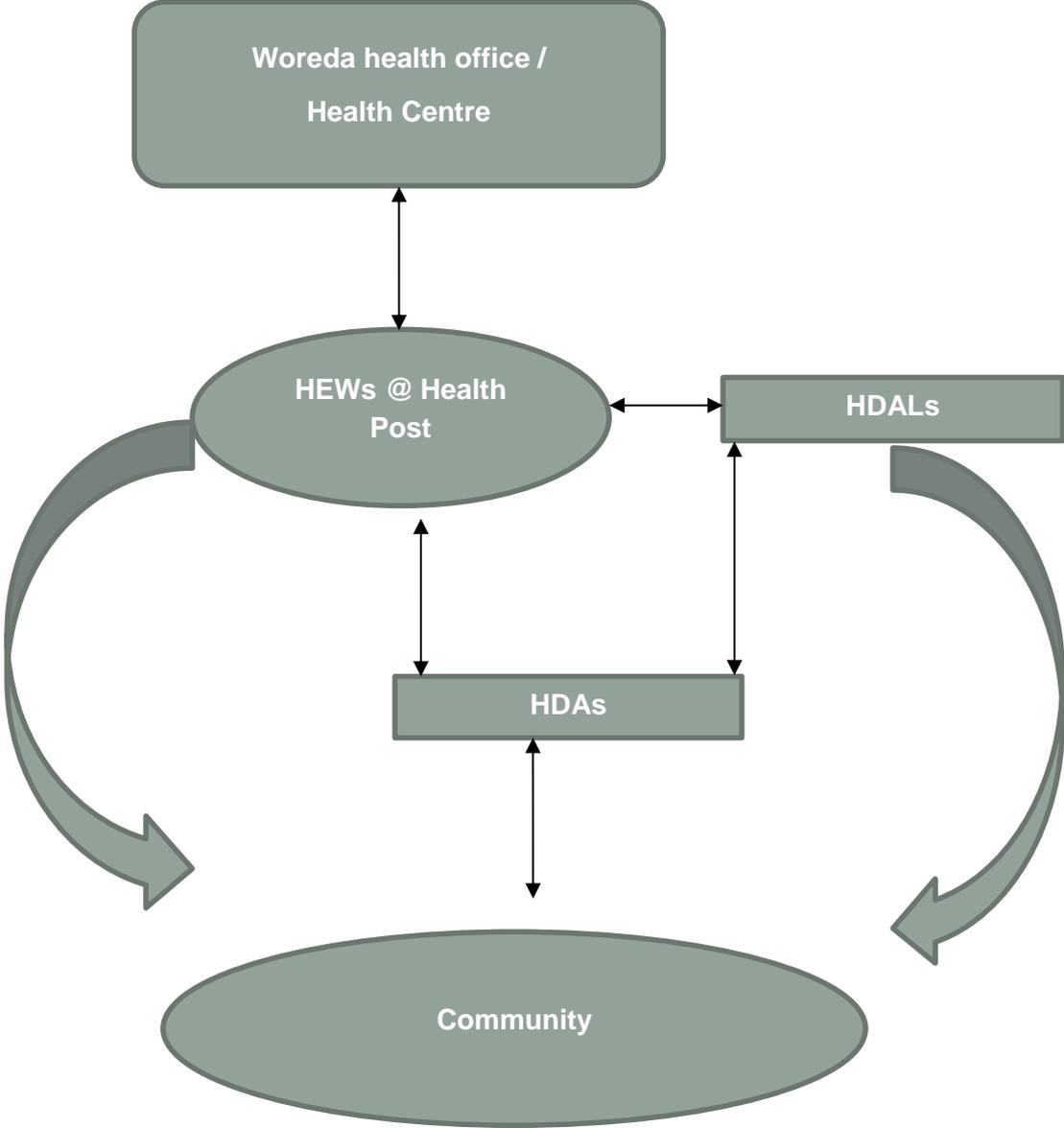
Appendix D provided as attachment

Appendix E: Roles and responsibilities of health personnel

Acronym	Full description	Employer	Position created by intervention	Specific additional task in intervention	Part time / Full Time	Remuneration
Health Centre/ Woreda Health Offices experts	Health Centre/ Woreda Health Office health extension supervisors, EPI Officers	Government	No	<ul style="list-style-type: none"> • Supervises the HEWs routine immunisation activities • Monitor and evaluate their performances on immunisation • Conduct joint supportive supervision with IRC staff members 	Full time	Government paid
HEW	Health Extension Workers	Government	No	<p>At Health post level</p> <ul style="list-style-type: none"> • Provide immunisation services to children and mothers • Conduct health education to care givers • Manage cold chain system for vaccines • Dispose used immunisation supplies safely • Integrate Immunisation in to other MCH services <p>At Community level</p> <ul style="list-style-type: none"> • Conduct awareness creation on immunisation and surveillance to the community through house to house visits and mass campaigns • Carryout defaulter tracing using DTT • Actively participate in Immunisation campaigns • Conduct new-born tracking • Integrate immunisation counselling and delivery with other RMNCH activities using <i>Enat Mastawesha</i> and other tools 	Full time	Government paid

				<p>Documentation and reporting</p> <ul style="list-style-type: none"> • Compile and Submit reports on immunisation and surveillance on a regular basis • Provide technical support (including training and supervision to HDAs) • Identify and deploy HDAs in consultation with the kebele leaders 		
HDAL	Health Development Army leader	Community	No	<ul style="list-style-type: none"> • Provide technical support to HDAs • Conduct home visits in order to create model households • Report to HEWs on a regular basis on issues related to HEP • Lead community sensitisation Campaigns • Lead defaulter tracing using DTT 	Part time	Volunteer
HDAs	Health Development Army	Community	No	<ul style="list-style-type: none"> • Conduct health education and promotion activities on immunisation to mothers and caregivers • Submit reports to HDAL regularly (mostly orally) • Mobilise the community in immunisations campaigns • Carryout defaulter tracing 	Part time	Volunteer

Appendix F: Reporting structure of intervention



Appendix G: Pictures of the intervention and project evaluation

Appendix G provided as attachments

11. References

- BOYATIZIS, R. E. 1998. Transforming qualitative information: Thematic analysis and code development, London, Sage.
- CENTRAL STATISTICAL AGENCY [ETHIOPIA] & ICF INTERNATIONAL 2012. Ethiopian Demographic and Health Survey 2011. Addis Ababa, Ethiopia and Calverton, Maryland, USA: Central Statistical Agency and ICF International.
- Central Statistical Agency (CSA) [Ethiopia] and ICF. 2016. Ethiopia Demographic and Health Survey 2016: Key Indicators Report. Addis Ababa, Ethiopia, and Rockville, Maryland, USA. CSA and ICF.
- FAVIN, M., STEINGLASS, R., FIELDS, R., BANERJEE, K. & SAWHNEY, M. 2012. Why children are not vaccinated: a review of the grey literature. *International Health*, 4, 229-238.
- FEDERAL MINISTRY OF HEALTH 2010. Ethiopia National Expanded Programme on Immunization: Comprehensive Multi-Year Plan 2011-2015. Addis Ababa
- JAIN, M., TANEJA, G., AMIN, R., STEINGLASS, R. & FAVIN, M. 2015. Engaging Communities With a Simple Tool to Help Increase Immunization Coverage. *Global Health: Science and Practice*, 3, 117-125.
- LAFOND, A., KANAGAT, N., STEINGLASS, R., FIELDS, R., SEQUEIRA, J. & MOOKHERJI, S. 2014. Drivers of routine immunization coverage improvement in Africa: findings from district-level case studies. *Health Policy and Planning*.
- OWAIS, A., HANIF, B., SIDDIQUI, A., AGHA, A. & ZAIDI, A. 2011. Does improving maternal knowledge of vaccines impact infant immunization rates? A community-based randomized-controlled trial in Karachi, Pakistan. *BMC Public Health*, 11, 239.
- RAINEY, J. J., WATKINS, M., RYMAN, T. K., SANDHU, P., BO, A. & BANERJEE, K. 2011. Reasons related to non-vaccination and under-vaccination of children in low and middle income countries: Findings from a systematic review of the published literature, 1999–2009. *Vaccine*, 29, 8215-8221.
- RYMAN, T. K., TRAKROO, A., WALLACE, A., GUPTA, S. K., WILKINS, K., MEHTA, P. & DIETZ, V. 2011. Implementation and evaluation of the Reaching Every District (RED) strategy in Assam, India, 2005–2008. *Vaccine*, 29, 2555-2560.
- SABARWAL, S., BHATIA, R., DHODY, B., PERUMAL, S., WHITE, H. & PURI, J. 2015. Engaging communities for increasing immunisation coverage: what do we know? 3ie scoping paper 3. New Delhi: International Initiative for Impact Evaluation (3ie).
- STREEFLAND, P., CHOWDHURY, A. M. R. & RAMOS-JIMENEZ, P. 1999. Patterns of vaccination acceptance. *Social Science and Medicine*, 49, 1705-1716.
- THE WORLD BANK. 2015. Mortality Rates (Accessed 2nd December 2015 at <http://data.worldbank.org/indicator/SH.DYN.MORT/countries>) [Online].
- UNDP 2015. Human Development Report 2013. The Rise of the South: Human Progress in a Diverse World, Ethiopia (Accessed 2nd Dec 2015 at <http://hdr.undp.org/sites/default/files/Country-Profiles/ETH.pdf>).
- USAID 2015. Ethiopia Factsheet (accessed 2nd Dec 2015 at https://eads.usaid.gov/esdb/analysis/fact_sheets/ethiopia.pdf).
- USMAN, H. R., RAHBAR, M. H., KRISTENSEN, S., VERMUND, S. H., KIRBY, R. S., HABIB, F. & CHAMOT, E. 2011. Randomized controlled trial to improve childhood immunization adherence in rural Pakistan: redesigned immunization card and maternal education. *Tropical Medicine & International Health*, 16, 334-342.
- WHO 2013. Global vaccine action plan 2011-2020. Geneva: World Health Organization.

