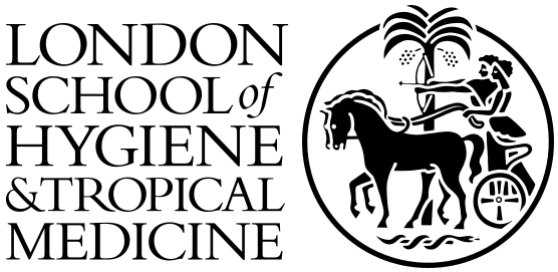

# Evaluation of the Mamás del Río Intervention in Rural Amazonian Peru

## Study Protocol

Version 2.0, 18th February 2019

| | |
|---|---|
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| **Conflict of interest** | We declare no conflicts of interest |
| **Compliance** | The study will be conducted in compliance with the protocol, ICH GCP Guidelines and other relevant regulatory requirements applying in the country in which the study will be conducted |

# Table of Contents

## List of Tables and Figures

# 1. LITERATURE REVIEW

## 1.1 CHW Home Visit Interventions to Improve Neonatal Mortality

Systematic reviews suggest that home-visits to women and families by Community-health workers (CHW) during pregnancy, birth, and postpartum periods are effective in reducing neonatal mortality (NM) among home and facility births [1, 2]. The meta-analysis by Gogia 2016 [1] included five large, cluster-randomized-controlled trials (cRCT) with low risk of bias from South-Asian low-middle income countries and found reductions in NM of 25% (pooled relative risk, RR:0.75;95%CI:0.61-0.92). Hanson 2017 [2] updated the previous meta-analysis on CHW home visits studies with three additional cRCT, including two studies with low risk of bias from sub-Saharan Africa, and found smaller NM reductions of 11% (pooled RR:0.89;95%:0.85-0.94). Subgroup analyses to explore effect of study setting on effect sizes were conducted for CHW home visits and women participatory groups interventions pooled together; and suggested that reduction in NM was stronger among settings with higher baseline NM, lower proportion of facility births, and lower density of health facilities [2]. Such settings typically have high proportion of deaths due to infections and prematurity [3] where improvement of essential newborn care (ENC) practices, a principal component of home-based interventions, is expected to have high impact since primarily targeting those causes [4]. This is supported by a series of meta-analyses and delphi panels that directly link improved ENC practices, including breastfeeding, clean birth practices, and thermal care, to NM reductions [4-7].

## 1.2 CHW Home Visit Interventions to Improve ENC Practices

The two meta-analysis did not assess the effect of CHW home visits on individual ENC practices [1, 2]. A meta-analysis by Lassi 2015 [8] did evaluate ENC outcomes but in addition to CHW home visit studies also included studies on participatory groups from low-and middle-income countries , limiting the generalizability to CHW home visit interventions alone. They found that use of clean delivery kits was increased by 82% (pooled RR:1.82;95%CI:1.10-3.02, n=1 CHW home visit cRCT with low risk of bias and n=3 women participatory groups cRCT with low to medium- risk of bias) and initiation of breastfeeding within 1 hour of birth was increased by 93% (pooled RR:1.93;95%CI:1.55-2.39, n=7 CHW home visit cRCT with low risk of bias; n=4 women participatory groups cRCT with low to medium risk of bias). Immediate wrapping of the baby, delayed bathing, and clean cord care were not improved [8]. A number of studies that were included in the systematic review of Lassi evaluated and reported relevant

ENC outcomes but were missing from their respective meta-analysis of ENC practices; the authors did not discuss reasons for this.

Given that no meta-analysis assessed ENC outcomes exclusively within CHW home visits studies, I conducted a review of the n=7 cRCT [9-15] included in the latest systematic review by Hanson 2017 [2] to summarize the effect of CHW home visits on ENC practices (Appendix A). Since RR were not consistently reported, I extracted absolute differences of ENC prevalence between intervention and control arms at endline and reported as median and range across all studies. Almost all studies showed improvements in ENC practices; however, there was large variation across studies (Appendix A): drying/wiping (median: 5% ;range: -1-11%; n=2 cRCT [13, 15]), clean cord cutting (median: 28%; range: 4-46%; n=3 cRCT [11, 13, 15]), skin-to-skin contact (median: 20%, range: 2-75%, n=3 cRCT [9, 12, 14]), breastfeeding (median: 24%; range: 6-55%, n=7 cRCT [9-15]), no pre-lacteal feed (median: 42%; range: 36-47%, n=3 cRCT [9, 12, 15]), nothing harmful applied to cord (median: 17%; range: 9-44% [12, 13, 15], and delayed bathing (median: 39%; range: 12-53%, n=7 cRCT [9-15]. Comparison of effect sizes with respect to study characteristics suggested that largest differences were seen in settings with low proportion of facility births and low baseline prevalence. Impact of supportive components (TBA training, women groups, community mobilization or sensitization), CHW characteristics, training, and supervision, or coverage of home visits on differences in effect sizes was not obvious when comparing purely descriptively (Appendix A).

The contribution of individual intervention components and characteristics on outcomes has not been evaluated and remains unknown. Gogia and Hanson [1, 2] conducted sensitivity analyses and found that coverage of home visits, the principal indicator for implementation strength in CHW home visit studies, was not associated with neonatal mortality. Authors concluded that the intervention effect is explained by a complex interaction of factors related to intervention components, strength of implementation, and study setting [1, 2] which are likely not captured by coverage of home visits alone.

## 1.3 Mechanisms of Change

Complex interventions contain a high number of interacting factors, involve multiple stakeholders, and are targeting difficult behaviours impacted through multiple pathways of change [16, 17]. Interventions where CHW home visit present the core fall into this category as the effectiveness to improve health outcomes in the target population depends on a complex interaction of factors related to the CHW who delivers the intervention, the client who receives the intervention, their interaction and relationship; as well as contextual factors at the community and health-system level [18-20].

A systematic review by Kok et al. 2015 [18] included quantitative and qualitative studies (n=140) describing CHW delivering promotional, preventive, or curative tasks in low- and middle-income countries in any health area to assess factors associated with CHW performance. In their conceptual framework, performance at the CHW-level was defined through the principal attitudes of motivation, job satisfaction, attitude, competencies, and adherence to standards and procedures, which then through mediating processes exert effect on client outcomes. Based on a qualitative synthesizes of the literature, they identified factors that were related with performance of CHW which can be actively addressed through intervention design: Selection of CHW and their characteristics (level of education, experience in the health area, and gender); working conditions (scope of tasks including balance of curative and promotive tasks, clarity of roles, workload and time available for service delivery to clients), financial and non-financial incentives; training, supervision, and performance appraisal, as well as resources and logistics (job aids, transport, and supplies). Links to the community (support, selection, monitoring, and expectations) and health system (embedment, communication, and coordination) were found to impact CHW motivation. Limitations of this study are the lack of quality appraisal of included studies and the broad focus of the review, limiting the ability to give out specific recommendations as dependent on the health area targeted and the country-context.

The same authors conducted another systematic review (Kok et al. 2015-2) using the same methodology to identify contextual factors affecting performance of CHW from studies (n=94) conducted in low-and-middle income countries [20]. Cultural norms, practices, and beliefs in the community were found to directly influence the acceptance of the CHW or the content of the intervention, particularly in MCH programs [20]. For interventions to improve ENC to be effective, context-specific prevailing newborn care practices, underlying beliefs in the population, and key influencers need to be understood to tailor behaviour-change interventions [21-23]. Other contextual factors affecting CHW performance identified by Kok et al. [20] were gender roles and norms that could hamper access to and uptake of CHW by clients, particularly in MCH related interventions [20]. Selection, retention, and coverage of services provided by male CHW, especially when volunteering, could be impacted as conflicting with the traditional male role of generating income. Lack of monetary compensation, especially in very poor settings, could present a further threat.

A systematic review by Glenton et al. [19] provided a synthesis of qualitative studies (n=53) describing chain of events related to greater success of CHW programs in low, middle, and high-income countries, with a specific focus on programs providing MCH services. Findings of moderate certainty, defined as if supported by moderate quality studies and seen across

several studies and settings, were included in the narrative. Authors identified that visible support from community leaders, members, and the health system were elemental for social recognition of CHW and to achieve credibility and confidence among recipients of the intervention, leading to improved motivation among CHW and trustful relationships with recipients. Similarly, CHW selected by the community that are socially similar and possess characteristics valued by clients, including trustworthiness, respect, kindness, and empathy, were identified as important for good client relationships, and ultimately long-term outcomes. Comparable to the findings of Kok et al. 2015, working conditions, training, and supervision were found to be related to the willingness and ability of CHW to deliver the services. Consistent and predictable incentives, career pathway, systems to voice complaints and share experiences; sufficient, relevant, and high-quality training that includes counselling and communication, adequate and skilled supervision, and reasonable workload and flexible working conditions.

## 1.4 Supportive Interventions

In addition to the core components enabling CHW home visit programs, including training and supervision of CHW, additional intervention components can help strengthen causal pathways for impact, improve CHW performance, and address influence of contextual factors on the intervention.

The systematic review by Glenton [19] et al. described above found that CHW credibility, acceptance, and utilization by the target group could be enhanced through close ties with the health system, visible community support, and participation of family decision makers and influencers [19]. Qualitative formative research conducted with pregnant women, mothers of newborns, family members, CHW, and TBA to inform development of a CHW home visit intervention targeting ENC practices in Ghana [22] concluded that to enhance behaviour-change, all relevant stakeholders need to be targeted to ensure consistency of promoted messages and support for the intervention. TBA were identified as important influencers for immediate newborn care practices but were unlikely to be captured in home visits and therefore best targeted in separate sensitization. Health facility sensitization was required to align ENC practices in facility births with those promoted in communities, and sensitization of community was required to raise awareness and garner general support.

An analysis of prospective data from four large community-based cRCT trials conducted in South Asia showed that ENC coverage gaps were not only limited to home births but also encountered in facilities [24]. Peruvian DHS data from 2016 supports this, suggesting suboptimal coverage of the two ENC signal indicators skin-to-skin contact (64%) and early

breastfeeding (68%) in facility births in Loreto [25]. Findings of a recent evaluation of a large scale CHW home visit program to improve ENC in Tanzania also found ENC coverage gaps in facilities; authors suggested simultaneous strengthening of care in facilities [26]. This is in line with recent efforts to prioritize quality of care in facilities, with ENC as a principal component [27, 28]; despite limited evidence on effective training strategies [29, 30].

A systematic review covering quantitative and qualitative studies (n=42) describing the use of mhealth devices by CHW and other health workers in low and middle income-countries was conducted to assess the feasibility and effectiveness for their use during delivery of care [31]. Qualitative synthesis of studies suggested that with adequate training, CHW were able to use mhealth devices as job aids to that provided support in key functions: increasing number and timing of visits through visit schedule and reminders, completeness of visit contents through checklists, and enhancement of behaviour-change communication through images and videos. Several studies described improved motivation through perceived self-improvement by using mhealth devices; which in return could impact retention, especially in implementation settings without direct CHW remuneration. A critical appraisal of studies was not performed; potentially limiting the validity of results. As found by other reviews, the direct effect of the use of mhealth devices on maternal and neonatal outcomes remains unknown [32, 33].

## 1.5 CHW Programs: Global and in Peru

Early CHW programs were developed after the Alma Ata Declaration by the World Health Organization (WHO) in 1979 in an attempt to address failure of existing health systems to reach rural and poor populations [34]. Following a period of decline in the 1990s, a human resource crises in health and low use of facility services have resulted in renewed political interest in CHW [35]. Building on evidence for the effectiveness of CHW programs to deliver essential health care to communities, including neonatal care [36], the WHO “Global Strategy on Human Resources for Health (HRH): Workforce 2030” [37] envisions a more diverse skill mix and manifests the national importance of CHW as community-level actors in primary care cadres.

There is consensus in literature on the importance of key factors for the success of CHW programs, which include continuous training, supervision, clearly defined tasks and roles, targeted incentives (monetary, non-monetary, or mixed), support by communities, and collaboration with health professionals [18, 19, 35]. A key problem identified when failing to account for those factors in the intervention design is attrition of CHW, which disrupts the continuity of care and threatens the success of programs, especially beyond small-scale initiatives [38]. Authors call for research to better understand the magnitude, determinants,

and ways to reduce attrition [38]. Tulenko et al. 2013 highlight further challenges for the scale-up and sustainability of CHW programs at the national level; including fragmented CHW cadres with unclear responsibilities and accountability, caused by multiple waves and parallel initiatives by public and private actors that lack coordination at the national level [39].

In Peru, the concept of CHW was introduced in the 60s and since then mainly promoted by NGOs, churches, and international agencies. CHW were only officially recognized by the Peruvian government as “Agentes Comunitarios de Salud” in 1995 [40]. Since then, several national guidelines and training manuals for CHW as health promoters “Promotores de Salud” in different health areas were developed; the latest was published in 2009 with a strong focus on MCH and newborn care [41]. In 2014, a national policy framework was released aiming to define the role, responsibilities, and integration of the CHW into the formal health system [40]. In 2015, national routine data on CHW suggested more than 35,000 largely female (64%) CHW existed across the country [42]. CHW are male or female volunteers and community residents, selected by their own community, in collaboration with local health facilities or organizations. Training, usually provided by regional health authorities, covers the entire continuum of care from pregnancy to children under 5 and is divided into five independent modules covering: organization of work, communication and structure of family visits, maternal health during pregnancy, birth, and after birth, newborn care, and child health). CHW are expected to provide home visits and hold community meetings to deliver health promotion; however, no specific schedule exists. Full training is expected to be completed within one year, involving a total of 15 days coursework, 10 months reflection and practical application, and final evaluation of one day [40, 43]. Trained CHW are expected to receive yearly refresher training and regular supervision from local health facilities [43]; however, no specific manuals exist for this. CHW do not receive monetary compensation; non-financial incentives include certificates for training and public acknowledgement by health authorities, preferential consideration for job openings in social or health programs, and provision of basic equipment to fulfil role [43].

Routine documentation of CHW on a national level only includes basic demographic data collected upon completion of training [44]; there is no monitoring and evaluation system in place; type and level of training, degree of supervision, coverage of services, attrition, and impact on health outcomes remain unknown. Unlike on a national level, descriptive studies from rural and indigenous regions and our own formative research in the study area in Loreto suggest that the majority of CHW are male, likely due to prevailing patriarchal norms [45, 46], potentially limiting the delivery of MCH intervention targeted at women. An evaluation of an integrated management of childhood illness (IMCI) program implemented in 1996 in Peru, also

consisting of a CHW training component, was hampered by lack of documentation to understand basic coverage and quality of care of CHW. Findings from the facility component evaluation however suggested strong regional variations in coverage of training; overall weaknesses of policy and programme support were identified as principal reasons for lack of impact [47, 48]. Impact and process evaluations of CHW programs targeting MCH outcomes are not available for Peru and Amazonian settings in Latin America [49].

## 2. STUDY SETTING

Peru has achieved substantial reductions in neonatal mortality (NM), with rates decreasing from 16.2 to 8.0 per 1,000 live births between 2000 and 2013 [50]. Although the equity gap in coverage of family planning, maternity care, and child immunization overall halved [50], not all of Peru's regions benefited equally from this progress [51]. Loreto, the largest department located in the Amazon rainforest in the North of the country (Figure 1) is one of the departments with the poorest maternal and child health (MCH) indicators in Peru. Based on 2010-2012 DHS birth cohorts, Loreto had a NM rate of 18.7 per 1,000 live births, second highest in Peru [51]. Under-registration of neonatal deaths was over 50% [52]. In 2010, Warrant et al. used verbal autopsies in a convenience sample of n=130 women from nine rural communities in the districts of Nauta and Parinari of Loreto and reported a NM rate of 31/1,000 live births (95%CI:16-62). Most common causes of death were infection (43%), asphyxia (29%), and prematurity (14%)[53].

The department of Loreto is divided into eight provinces and 53 districts [54, 55], the study area covers three districts: Parinari, Nauta, and Saquena, located on the rivers Maranon, Amazonas, and Ucayali, opportunistically selected due to logistic and political benefits (Figure 1). The intervention will be implemented in 76 rural river-bound communities in all three districts with a population of about 18,000 inhabitants (Table 1). Prevalence of facility births was 35% (95%CI: 25-45%), skin-to-skin contact 28% (95%CI: 21-37%), and early breastfeeding 35% (25-46%); as estimated by a systematic sampling survey in April 2018 conducted as part of formative research.

The definition of "rural river-bound communities", extends the threshold used in the national definition for rural settlements [56] from a clustering of 100 to 200 houses, since better fitting characteristics commonly associated with rural areas in the zone (i.e. lack of infrastructure and access to services).

**Table 1. Study population receiving intervention**

| Communities [a] | Houses [a] | Population [b] | Expected live births py [c] | Facilities [d] | Facility birth [e] | S2S contact [e] | Early BF [e] |
|---|---|---|---|---|---|---|---|
| 76 | 3,047 | 18,282 | 219 | 17 | 35% (25-45%) | 28% (21-37%) | 35% (25-46%) |

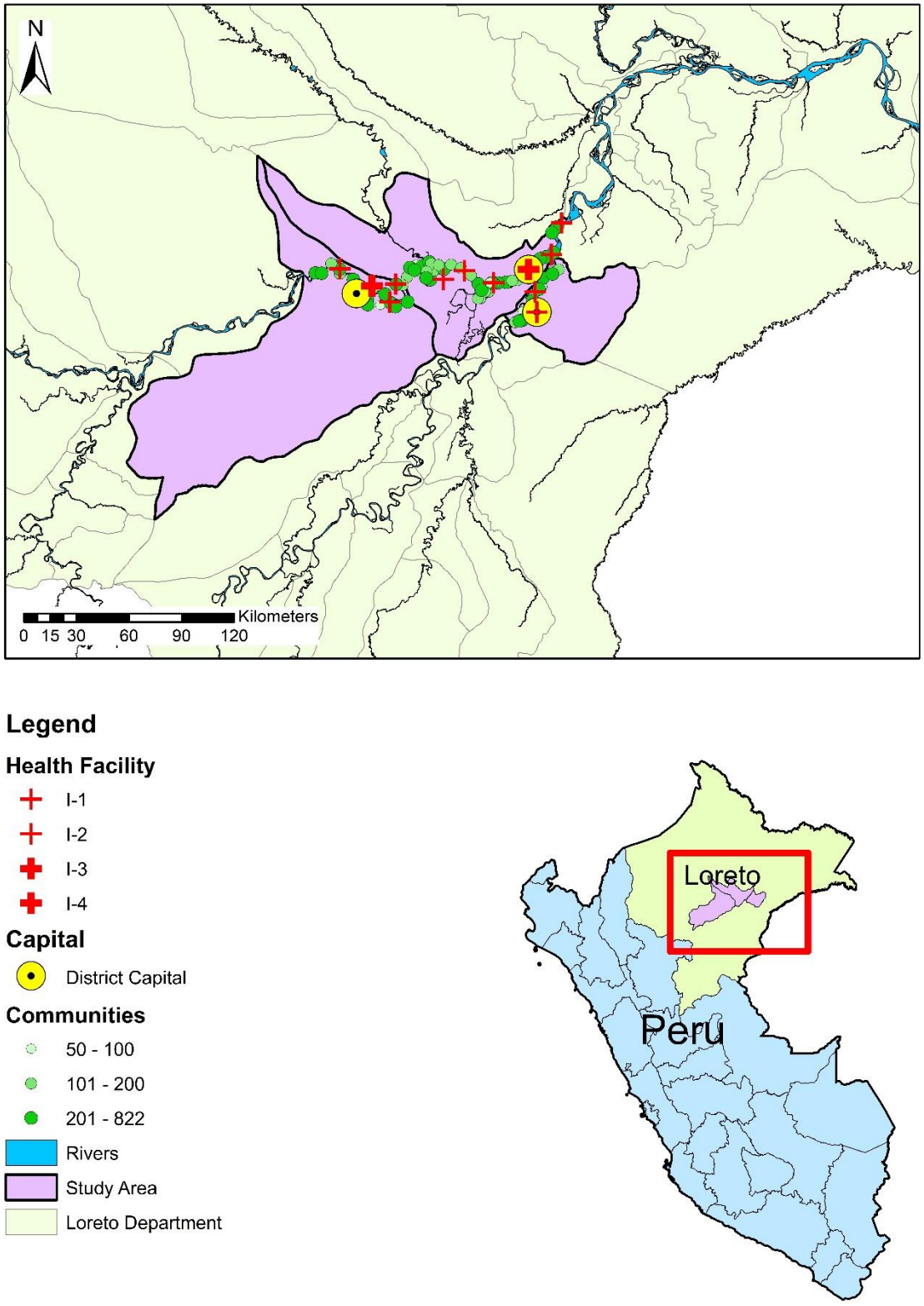
[a] From mapping exercise plus eight additional communities
[b] Based on average number of 6 inhabitants per house
[c] Based on a crude live birth rate in the study area of 12/1,000 inhabitants
[d] Facilities level-1 to 4
[e] Estimates for skin-to-skin contact and early breastfeeding from pilot survey, proportion and 95% confidence intervals

The study area lies within dense tropical rainforest with a warm, humid climate. The rural population is dispersed in small communities located alongside the rivers Ucayali, Marañon, and Amazon river, extending over a total distance of about 350km. People live in individual wooden huts with roofs made of palm trees. There is usually one household per hut, typically consisting of a couple and their children, sometimes relatives.

We explored birth and immediate newborn care practices in seven opportunistically selected communities in Nauta and Parinari. Semi-structured interviews (n=57) with mothers of recent newborns, their families and informal care providers showed that the home was the universally preferred place of birth as a comfortable and familiar environment. Traveling to facilities by canoe heavily pregnant was considered inconvenient, costly, and often considered only in emergencies. Giving birth in facilities was often considered being “physically and spiritually weak”. Most home births were attended by female family members; the presence of a renown “community” TBA was reported in about half of all births. Two home birth observations corroborated expected lack of essential hygienic measures. Drying and cutting of cord, usually with boiled or “cleaned” scissors, was often substantially delayed until the arrival of the godfather. Colostrum was often considered harmful for the baby and discarded. An 8-day rest-period after birth was common.

Due to outdated census data from 2007, we conducted an exhaustive mapping exercise in March and April 2018 to enumerate and describe all rural river-bound communities, defined as a clustering of ≥10 to 200 houses. Most communities were of indigenous heritage; Spanish was the universal language. Main occupation was subsistence farming and fishing. Infrastructure was poor, in only half of the communities ≥75% of houses had access to electricity and a private latrine; a communal treated water source was mostly not available.

**Figure 1. Map of the study area** *(own assembly)*




There are 17 governmental health facilities in the study area, median travel time to the nearest facility of any level with a motorized canoe is about 45 min. There are two health centres (level

3 and 4) with inpatient capacity and a designated delivery room; median travel time from any community is about 5h. Of all communities, 33% (95%CI: 18-53%) receive regular visits by a medical boat and coverage of at least one CHW is (87%, 95%CI: 76-93).

## 3. MAMAS DEL RIO INTERVENTION

Mamas del Rio (MDR) is a multi-component, maternal and neonatal health (MNH) program aiming to improve ENC practices in rural Amazonian Peru through educational home visits by CHW to pregnant women, mothers, and their families; as well as supportive sensitization of communities and strengthening of health facilities (Figure 2).

**Surveillance and Follow-up**

CHW conduct community surveillance to identify possible pregnancies through community engagement and by promoting self-referral if pregnancy is suspected, confirm pregnancies by administrating urine-based pregnancy tests, and register new pregnancies for home visits (Figure 3). Basic demographic and pregnancy related details (name of pregnant women, contact details, ID number, date of birth, date of last period, number of previous pregnancies, marital status, educational level) that are essential as informing the work of the CHW are collected at registration. Vital events (live births, miscarriages, stillbirths, maternal and newborn deaths) occurring from registration until end of neonatal period are recorded. During visits, information on family members attending, number of prenatal controls attended, place of birth, type of birth, and weight of baby are collected. Verbal permission for home visits and recording of data is obtained by the CHW from each pregnant woman.

**Home visits**

The CHW home visit schedule was adapted from WHO/UNICEF [57] and Peruvian materials [41]. Three visits during pregnancy and three visits during the first week postpartum are planned. Main target are pregnant women or mothers of newborns; in addition, the presence of a female family member attending the birth is solicited. During the first visit, planned between month 1 and 6, institutional care is promoted and a birth and pregnancy plan is created. Visit 2 and 3, planned for month 7 and 8, focus on home preparations in case facility birth is not possible, promotion and demonstration of immediate newborn care at home, supported by the distribution of clean delivery kits, and newborn care within the first week after birth. The first postnatal visit is planned within 24 hours of the birth in which the CHW weighs the newborn, promotes care practices for low birth weight babies and refers very low birth weight babies to health facilities; newborn care practices already covered in visit 3 are

reinforced. During visit 5 and 6, planned for day 3 and 7, messages from visit 4 are reinforced and implementation checked.

**Figure 2. Conceptual Framework of the Intervention**

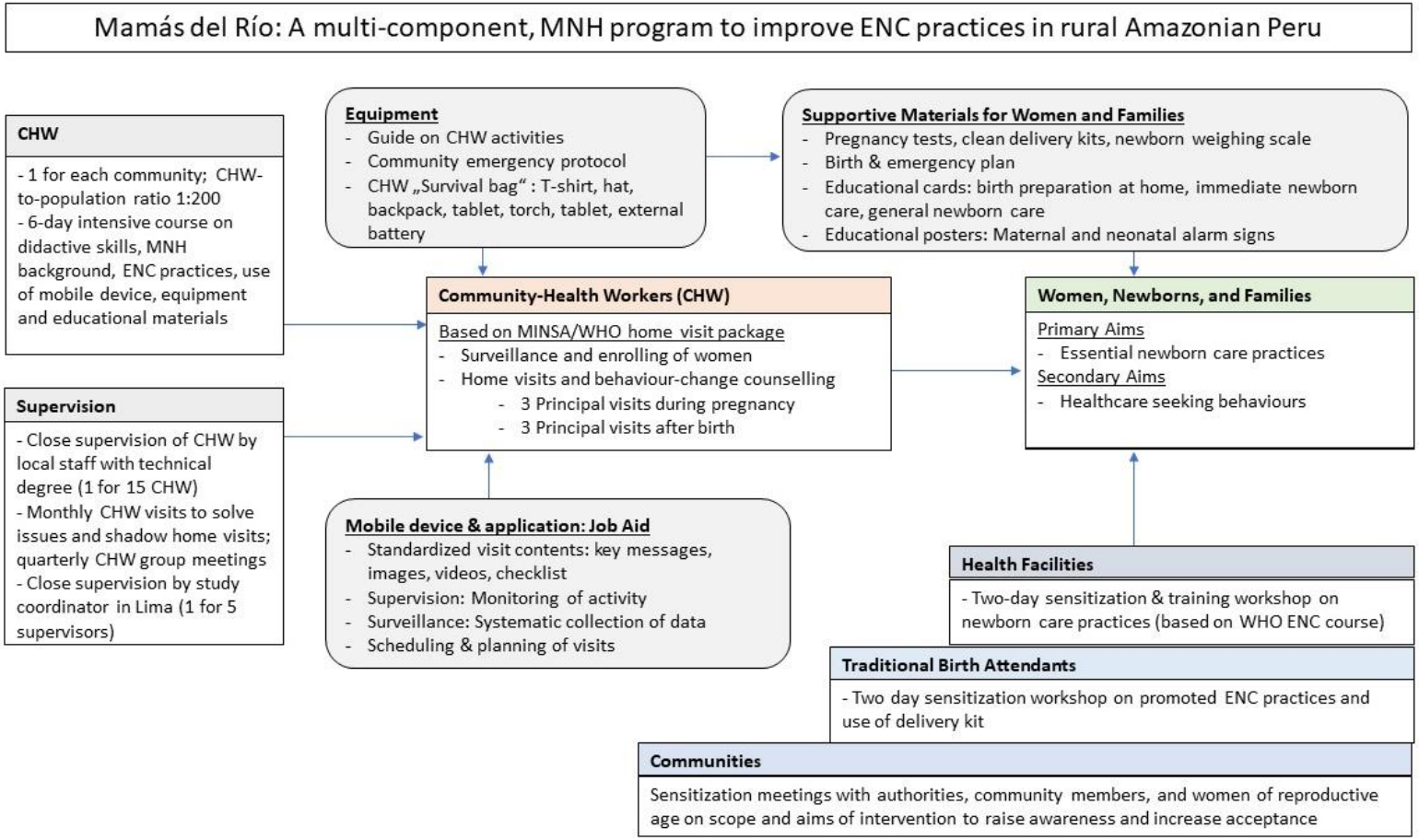


**Table 2. Home Visit Schedule and Content**

| Phase | Time | Home Visit, Key messages *(& Tools)* |
|---|---|---|
| Surveillance | Continuously | **Surveillance & Enrollment**<br>• Identification and enrollment of women with new pregnancies of any age group *(confirmed by pregnancy test)*<br>• Registration of basic demographic, contact, and pregnancy-related data as well as vital events within time span of planned home visit schedule |
| Prenatal | Month 1 to 6 | **Home Visit 1**<br>Key messages<br>• Promote health facility birth & antenatal care (ANC) attendance *(video)*<br>• Prepare birth and emergency plan: decide birth place, birth attendant, godmother, preparation supplies birth *(birth and emergency preparedness card)*<br>Supportive messages<br>• Recognize maternal alarm signs *(alarm signs home poster)*<br>• Promote maternal home care: diet, physical activity, no alcohol |
| | Month 7 | **Home Visit 2** *(presence of person attending birth solicited)*<br>Key messages<br>• Prepare for home birth if facility birth not feasible: clean room, clean water, clean perineum, clean delivery kit, availability godfather, clothes, and food *(home birth preparedness card)*<br>• Promote immediate newborn care at home: clean hands birth attendant, clean delivery surface, immediate drying, immediate skin to skin contact, sterile cord cutting, early breastfeeding, give colostrum *(immediate newborn care card, video)*<br>Supportive messages<br>• Reinforce importance health facility birth & ANC attendance<br>• Recognize maternal & labor alarm signs *(alarm signs home poster)* |
| | Month 8 | **Home Visit 3** *(presence of person attending birth solicited)*<br>Key messages & actions<br>• Promote and demonstrate immediate newborn care at home: clean hands birth attendant, clean delivery surface, immediate drying, immediate skin to skin contact, sterile cord cutting, early breastfeeding, give colostrum *(immediate newborn care card, delivery kit [1], video)*<br>• Promote newborn care practices: clean hands, give colostrum, exclusive breastfeeding, correct attachment, delay bathing, clean cord care, promote PNC attendance on first after *(newborn care card, video)*<br>Supportive messages<br>• Promote ANC attendance<br>• Recognize neonatal alarm signs *(alarm signs home poster)* |
| Postnatal | Day 1 (<24h) | **Home Visit 4**<br>Key messages & actions<br>• Weigh newborn, and refer very low weight babies to facilities when born at home *(checklist, scale)*<br>• Reinforce newborn care practices *(newborn care card)*<br>• Extra care for low weight babies: frequent & exclusive breastfeeding, extended skin to skin contact, delay bathing for at least 3d<br>Supportive messages<br>• Promote early PNC attendance |

| | | |
|---|---|---|
| | | • Recognize maternal and neonatal alarm signs *(alarm signs home poster poster)* |
| | Day 3 & 7 | **Home Visit 5 & 6**<br>• Reinforce messages from day 1 & check implementation |
| [1] Delivery kit contents: Plastic sheet, soap, razor blade, umbilical clamp. Delivery kit is supplied to the family in Visit 3 | | |

**Mobile application**

CHW are equipped with mobile internet devices (LenovoYogaTab38) running the CommCare application, chosen for its capability of longitudinal management of cases [58]. The application's content is tailored to the logical structure of the visit schedule and intended as the principal job aid supporting the CHW in four key areas: registration of new pregnancies and systematic follow-up by prompting the CHW to enter vital events; enhancement of behaviour-change communication and standardization of visit content through tailored forms for each visit containing key messages supported by images and videos; management of upcoming visits through built-in calendar function; and improved supervision through real-time monitoring of performance and activity of CHW (section 5.1). CHW will be allowed to use the tablet for private purposes and granted a limited amount of call and data allowance per month, intended as a principal non-monetary incentive. All forms and content can be accessed offline; data collected can be stored on the device and synced when mobile connection is available or collected by the supervisor during monthly visits (see section supervision).

**Materials & Equipment**

CHW are supplied with functional and educational materials to enhance and maximize impact on ENC during and after visit (Figure 3). Delivery kits are provided in month 8 if facility birth is not desired or feasible. CHW use a simple hanging scale to weigh newborns after home birth, refer or give out birth weight-specific recommendations. Three educational cards containing illustrations and text reinforce key ENC practices are left with the women, intended as a post-visit reminder and instructions during birth. Posters picturing maternal and neonatal danger signs are hung up on visible locations in the house intended to reduce delay to seek care for possible complications. In addition to the tablet, CHW are supplied with equipment containing logos of the Mamás del Río project, intended as a non-financial incentive and to support their credibility in the community.

**CHW Selection and Training**

Community authorities received written invitations to participate in the intervention and asked to select one CHW who is respected, established, and engaged in the community, keeps

confidentiality of visits, has own children, willing to volunteer to do home visits to pregnant women and mothers, and knowledgeable to attend the training workshop. It is expected that most communities will select existing CHW, who were during a recent mapping exercise identified as largely male and middle-aged. There will be one CHW per community, 76 CHW in total. CHW work on a voluntary basis as per national policy [40] but receive compensation for their 6-day intensive training (Figure 2). Written informed consent (IC) will be obtained from all CHW prior to the start of the training (Appendix D3). A maximum of 12 CHW will be trained at once by one member of the study team and two facilitators. Facilitators are hired nurses, midwives or educators with experience working with indigenous populations and competence-based teaching methods who will be trained by the study team using adapted “training of trainer” materials [57]. The core study team consists of the intervention director (a medical doctor), three medical doctors, a midwife, and a nurse with training in neonatal care, who have all participated in the development of the intervention and materials.

**Supervision**

Supervisors are paid staff with at least a technical degree in nursing, recruited from larger communities in the study area or cities adjacent to the study area, who are willing to spend time in the field. They will be selected during a 2-day workshop and then receive at least 5-day workshop and field-training by the study team covering the intervention goals and CHW activities, problem-solving skills, and tasks in communities. Supervisors are required to pay monthly community visits to CHW in their respective supervisory units (supervisor-to-CHW ratio 1:20) to provide support, on-the-job training; provide materials for the CHW, and collect data from the CHW’s tablets if needed. Each month, supervisors are expected to spend 3 weeks in the field and rest one week at home. In addition to their payment, they will receive allowances for food and transport. The supervisor maintain a Whatsapp group with the study coordinator in which they can raise problems and receive direct support. During visits to the communities, supervisors will also meet with community authorities, health facility staff, and traditional birth attendants to maintain ongoing dialogue and solve any problems if needed. Supervisors are asked to complete daily activity logs on their mobile devices which will be sent to and reviewed by the intervention coordinator.

**Community Sensitization**

Sensitization activities include a meeting with indigenous federations, community authorities, townhall meeting with community members as well as a meeting with women of reproductive age to explain the importance of their participation, the intervention components, and the activities of CHW to increase awareness and garner support by the community. The initial

sensitization will be led by facilitators; and thereafter, supervisors together with CHW conduct sensitization meetings every 6 months to collect feedback and maintain ongoing dialogue about the intervention with community stakeholders.

**TBA sensitization & training**

A two-day sensitization and training workshops with TBA, considered key influencers of ENC, is conducted to convey importance of key ENC and teach use of delivery kits. The initial sensitization is held together with the facilitators, the supervisor, and the CHW; refresher sensitization every 4 months thereafter is led by the supervisor and CHW.

**Facility sensitization & training**

A two-day sensitization and training workshop will be conducted with health facility staff in the intervention area. The sensitization is intended to raise awareness on the intervention's aims and scope, and to integrate work by CHW and services offered by facilities. CHW are introduced to the facility corresponding to their community and formal linkages are established through community-specific referral plans, detailing the nearest and most appropriate facilities to attend routine services including ANC, facility birth and PNC; as well as referral for maternal and neonatal emergencies. The training portion will be on routine newborn care [28], adapted based on the WHO ENC course [59] and national guidelines [60]. Sensitization and training are conducted by members of the study team together with the regional health authorities. This will be repeated half-yearly based on expected heavy staff rotation in facilities.

# 4. RATIONALE

Evidence from South Asia and South Africa suggests that CHW home visit programs are effective at reducing neonatal mortality [1, 2]. A review of individual studies [9-15] suggests that essential newborn care (ENC) practices can be improved; however, the magnitude of impact likely depends on a complex interaction of factors related to intervention components, strength of implementation, and study setting [1, 2].

Epidemiology of neonatal mortality, access and quality of care, cultural beliefs, and CHW cadre are unique in Amazonian Peru. In the absence of setting-specific evidence, a rigorous evaluation is needed to understand if and how the MDR intervention works in rural Amazon Peru. Learnings could help to improve intervention design, inform the Peruvian CHW program, and add to the international evidence base on how to optimize CHW in MCH.

# 5. STUDY OBJECTIVES

1) To conduct a before-and-after-study to assess changes in ENC practices and healthcare seeking over a 2-year period using repeated household censuses

2) To conduct a mixed-methods process evaluation to assess coverage and intensity of the intervention components, mechanisms of impact, and influence of contextual factors

# 6. BEFORE-AND-AFTER STUDY

## 6.1 Study Design

A before-and-after study will be conducted comparing outcomes before and after the implementation of the intervention over a 2-year period. This design was chosen after a cluster-randomized controlled trial was ruled out due to logistic and budget limitations and a quasi-experimental study was ruled out due to lack of comparability of the planned control group. The intervention was only piloted in a small number of communities previously. At this early programmatic stage, an uncontrolled design with a rigorous process evaluation providing evidence for the mechanisms of the intervention is therefore considered most appropriate before investing more resources into a study design with higher levels of causal inference [16, 61].

Three repeated, cross-sectional household censuses will be conducted at baseline, shortly before the implementation of the intervention, and at 1 and 2 years afterwards. The censuses at year 1 and 2 will be pooled to constitute endline data as it is expected that the intervention will exert a similar effect over the entire study period. Three censuses are needed to obtain a sufficient sample size since the study area is fixed and a census with a 2-year recall period was discarded to not compromise validity of outcomes relying on maternal self-report [62, 63]. A before-and-after analysis is undertaken to compare changes from baseline to endline of outcomes in the study area. The target population are women between the age of 15 and 49 years who had a live birth in the last 12 months prior to the census.

## 6.2 Outcome Measures

The principal aim of the intervention is to improve ENC practices, as such promotion of newborn care practices has received a substantial weight in the CHW home visit schedule (Table 2), is extensively supported by educational materials and delivery kits provided to

families, and supportive intervention components (facility staff and TBA sensitization) principally target ENC practices to assure consistent messages are provided through all levels of care (section 1.2). Although the intervention also includes facility staff training in ENC practices, greatest improvements are expected in home births since the core of the intervention presents CHW home visits, supported by TBA sensitization, which will mostly impact home births. During a pilot survey, greatest coverage gaps were detected in home births, resulting in greater room for improvement and therefore greater likelihood to detect statistical differences. Primary outcomes are therefore ENC practices restricted to home births (Table 3) since presenting the strongest theoretical link to intervention components.

Secondary outcomes are ENC practices examined among live births at facilities to evaluate the effect of the supportive facility training and other ENC practices (Appendix A- Table 1), healthcare seeking practices among all live births that are important but likely less impacted by the intervention (Appendix A- Table 2), as well as indicators related to birth preparedness that are targeted by the intervention but with an unclear link to neonatal mortality and/ or lower measurement validity (Appendix A- Table 3)

**Table 3. Primary outcomes: ENC practices among home births**

| Indicator | Numerator | Denominator |
|---|---|---|
| Proportion of newborns that were immediately dried after birth | Number of newborns that were placed immediately and naked on the mother's belly or chest touching her bare skin | Number of live births in the last 12 months prior to survey *(at home)* |
| Proportion of newborns with clean cord cut | Number of newborns who had cord cut with new or sterilized instrument | Number of live births in the last 12 months prior to survey *(at home)* |
| Proportion of newborns with immediate skin-to-skin contact | Number of newborns that were placed immediately and naked on the mother's belly or chest touching her bare skin | Number of live births in the last 12 months prior to survey *(at home)* |
| Proportion of newborns that received colostrum | Number of newborns that received colostrum | Number of live births in the last 12 months prior to survey *(at home)* |
| Proportion of newborns that received early breastfeeding | Number of newborns that were breastfed within 1 hour after birth | Number of live births in the last 12 months prior to survey *(at home)* |
| Proportion of newborns who were weighed on the day of birth | Number of newborns who were weighed on the day of birth | Number of live births in the last 12 months prior to survey *(at home)* |

| | | |
|---|---|---|
| Proportion of newborns who had noting harmful applied to cord | Number of newborns with nothing other applied to cord apart from alcohol/ gauze from the moment cord was cut until it fell off | Number of live births in the last 12 months prior to survey *(at home)* |
| Proportion of newborns who only received breastmilk in first 3 days | Number of newborns who have not received anything else than breastmilk in the first 3 days after birth | Number of live births in the last 12 months prior to survey *(at home)* |

## 6.3 Data Collection

The censuses conducted at baseline, year 1 and 2 will consist of a house-to-house enumeration to identify women with a recent newborn and administration of a questionnaire to evaluate the exposure and outcomes of the intervention. Census are independent; the same individuals can potentially be sampled twice, if given multiple births during the study period.

**Inclusion criteria** are:

- Woman in reproductive age between 15 and 49 years
- Singleton live birth in the last 12 months prior to census *(at home and facility)*
- Provision of written informed consent by an independent witness

The census will be conducted in all rural river-bound communities in the study area. Indigenous federations and community authorities are informed and asked to announce census activities with anticipation to ensure availability of population. Community maps created during the pilot survey will aid systematic visiting of households in clockwise direction from the landing point of the boat. Households are GPS-tagged to increase efficiency for subsequent censuses and revisits.

A household enumeration (Appendix C1) will be conducted, consisting of identification of the head of the household, if not available, the next person in charge; listing of all women usually residing in the household[1], and subsequent ascertainment of age, pregnancy status, and live birth in the last 12 months prior to census date, to determine eligibility for participation in the questionnaire for each woman. If eligible, the purpose of the questionnaire will be explained and if interested to participate, written informed consent, testified by an independent witness from the community (Appendix D1), will be obtained. A questionnaire (Appendix C2) will then be administered; containing study outcomes and questions on sociodemographic details, birth

[1] A resident is defined as 1) born or moved to community ≥6 months ago, AND 2) lived in the community ≥3 months in the last 6 months, AND 3) usually sleeps more than 4 nights a week in the household

history, and household characteristics, including known confounders for ENC [11, 15, 64-66]. Households will be revisited twice to maximize encounters and participation.

Logistics of the census are based on established processes and learnings from a previous pilot survey; complemented by new procedures for the household enumeration. The household enumeration and questionnaire will both administered electronically using mobile devices. Two interview teams will be deployed, each team consists of one supervisor, three interviewers, one local guide, and one boat driver. Interviewers will be female, with a nursing or other health-related degree, residents of the region, and if possible having participated in the prior survey or having prior data collection experience [67, 68]. A 2-day training workshop with a field exercise will be conducted by the evaluation coordinators (myself and a research nurse); best performing interviewers will be selected and prepared for the supervisor role separately.

## 6.4 Power Calculations

Power calculations for a before-and-after analysis for all primary outcomes were conducted using a standard comparison of two independent proportions allowing for survey design, using STATA 14.2. Since the exact design effect (DEFF) to be expected is unknown, two different scenarios with DEFF values ranging from 1.5 to 2 were tested.

An expected 142 live births at home constituting the “before” group (i.e. before the intervention was implemented, pilot survey plus baseline census) and an expected 285 live births at home constituting the “after” group (i.e. expected to occur during the two-year study period, census year 1 and 2), will provide 80% power to detect absolute increases between 10 to 20%, depending on prevalence levels of outcomes and DEFF scenarios (Table 7), at a significance level of 5%.

**Table 4. Absolute detectable increase from baseline to endline prevalence of primary outcomes among home births using different DEFF scenarios for fixed sample size**

| Outcome | Prevalence “Before” Group | Minimal absolute detectable increase | | |
|---|---|---|---|---|
| | | DEFF=1.0 | DEFF=1.5 | DEFF=2.0 |
| Immediate drying | 83% | 9% | 11% | 12% |
| Sterile cord cut | 79% | 10% | 12% | 14% |
| Immediate skin-to-skin contact | 14% | 12% | 15% | 17% |
| Colostrum fed | 37% | 14% | 18% | 20% |
| Early breastfeeding | 36% | 14% | 17% | 20% |

| | | | | |
|---|---|---|---|---|
| Weighed on day of birth | 34% | 14% | 17% | 20% |
| Nothing harmful applied to cord | 56% | 14% | 17% | 20% |
| Only received breastmilk in first 3 days | - | - | - | - |
| ICC from published literature (Pagel 2011[69] for exclusive breastfeeding (ICC range:0.01-0.09, DEFF 1.1-1.5) and own calculation for skin-to-skin contact from Peruvian DHS (ICC=0.19, DEFF 2.0). DEFF calculated based on ICC assuming average community (cluster) size of n=6 after 2 years, based on community mapping<br>Prevalence estimates among home births. Number of live births at home for before and after group calculated based on steady home birth rate of 65%. Size of the before group | | | | |

### 6.5 Analysis Plan

I will carry out a descriptive analysis to present the study participant's characteristics included in the before and after group using proportions. Household characteristics will be compared to DHS data for rural Loreto to assess generalizability.

Principal analysis will be a before-and-after analysis, using individual-level data and adjusting for clustering at the community level, to compare effect of intervention on outcomes before and after the introduction of the intervention. Data collected at year 1 and 2 is pooled for endline. Trends in home visit coverage and CHW activity will be calculated to describe intervention fidelity; if this assumption cannot be supported, differential effect will be accounted for in the analysis.

Prevalence ratios will be calculated using log-binomial generalized linear models testing the null hypothesis that the comparison of before and after groups equals zero. A priori known confounders [11, 15, 64-66] for ENC practices at the individual level, including maternal age, educational level, and household income are included as covariates in the model; other confounders identified in exploratory baseline analysis will be considered for inclusion. 95% confidence intervals (CI) will be corrected for clustering at the community level, which is also expected to capture facility-level clustering since women from same communities likely attend the same facilities.

## 7. Process Evaluation

A mixed-methods process evaluation will be conducted to assess the coverage and intensity of the intervention components, mechanisms of impact, and influence of contextual factors to understand how and why the intervention exerts effects as measured through study outcomes

[16, 17]. A Theory of Change Map has been prepared a priori (Appendix B) that was converted into a simpler Theory of Change model linking activities, mechanisms, outputs, and outcomes plus underlying assumptions.

**Table 5. Theory of Change model linking intervention activities, mechanisms, outputs, outcomes and underlying assumptions**

| Activity | Mechanism | Assumptions | Output | Assumptions | Outcomes |
|---|---|---|---|---|---|
| Training of CHW | CHW detects and registers new pregnancies early | **CHW**<br>• CHW of right profile gained theoretical knowledge & practical skills in surveillance<br>• Access to supportive materials (tests, app)<br>• Proficiency in device use* (see activity tablet)<br>• Remains motivated*<br>**Women, Partner, Family**<br>• Awareness of CHW services*<br>• See relevance of home visits, registration no hurdle<br>**Community**<br>• Trusts, respects, and acknowledges work of CHW* | Distribution of pregnancy tests and enrollment of pregnant women for home visits | - | - |
| | CHW conducts home visits during pregnancy | **CHW**<br>• Theoretical knowledge & practical skills to conduct visits 1 to 3<br>• Access to supportive (kit, app) & educational materials (cards, posters, B&E plan)<br>**Women and partner, family, planned BA**<br>• Women/ families perceive need for visits*<br>• Women and KI are present for visit | Women and KI receive supportive and educational materials and messages *during pregnancy* | **CHW**<br>• Builds trustful relationship<br>• Engages and negotiates ENC practices successfully<br>**Women and Key Influencers (KI) of ENC**<br>• Are aware of and see value in ENC practices<br>• Availability of understandable supportive / educational materials during birth<br>• Theoretical and practical knowledge to implement practice<br>• KI that received training present during birth<br>• No other barriers present | Improvement of immediate newborn care (drying, cord cutting, S2S contact, colostrum, early breastfeeding) *for home births* |
| | CHW conducts home visits after birth | **CHW**<br>• Theoretical knowledge, practical skills, and discipline (timeliness) to conduct visits 4 to 6<br>• Access to supportive (balance, app) & educational materials (cards, posters)<br>**Women and newborn**<br>• Women and newborn present for visit | Women and KI receive supportive and educational materials and messages *after pregnancy* | | Improvement of newborn care (weighing, cord care, exclusive breastfeeding 3d) *for home births* |
| Use of tablet by CHW as job aid | Longitudinal collection of CHW activity & visit data | **Device**<br>• High usability, functionality & design to improve workflow<br>• Minimal infrastructure available for use<br>**CHW**<br>• Proficiency in device use<br>• Use of device during tasks | Direct feedback cycle for supervision | - | - |
| | Collection of data from women | | Identification of risk cases and link with authorities | | |

| | | | | | |
|---|---|---|---|---|---|
| | Management of dates of upcoming visits | **Women/ families**<br>• No issues with presence of tablet and providing personal data | Timing of visits as per protocol | | |
| | Standardization of visit content | **CHW & Women / families**<br>• Reading from device does not impede rapport & engagement | Complete and correct coverage of visit content | | |
| | Education using images & videos | **Women/ families**<br>• Can relate to videos and engage<br>• Videos are understandable with clear message | Enhancement of behaviour change communication | | |
| Training of TBA | Increase in theoretical knowledge and practical skills in ENC | **TBA**<br>• TBAs who received training are those that attend births<br>• Persons who receive training are TBAs with experience, and not interested novices | Trained TBA attend births *at home* | **TBA**<br>• See value and purpose of promoted ENC practices over possibly conflicting traditional practices; flexibility for change<br>• Practical training with dolls translates to actual practice with newborn | Improvement of immediate newborn care (drying, cord cutting, S2S contact, colostrum, early breastfeeding) *for home births* |
| Training of supervisors | Supervision of CHW activities | **Supervisors**<br>• Supervisors of right profile gained theoretical knowledge and practical skills for problem solving *<br>• Retain motivation for exhausting field work<br>• No access barriers<br>• Trusted and respected by CHW / community* | Improvement of coverage & quality of CHW home visits | - | - |
| | Stock assessment of materials | | Availability of functioning materials | | |
| | Conduct community sensitizations | | Supportive community | | |
| Training of health staff | Increase in theoretical knowledge and practical skills in ENC | **Facility staff**<br>• High coverage of training among facilities & all staff | Trained facility staff attend births *at facility* | **Health staff**<br>• See value and purpose of promoted ENC practices over possibly conflicting established care routines<br>• Practical training with dolls translates to actual practice with newborn | Improvement of immediate and newborn care *for facility births* |
| * also applies to subsequent mechanisms related to same actor | | | | | |

## 7.1 Research questions

To conceptualize the process evaluation, I have reorganized the assumptions that need to be satisfied for the intervention to work, as set out in the Theory of Change Map (Links A to I, Appendix B), according to groups of stakeholders, and have derived key research questions that need to be investigated:

**Community health workers**

- What is the profile of the CHW cadre participating in the training? *(Link A)*
- Did the training result in knowledge gain and was it retained over time? *(Link B-D)*
- What are the activity and performance levels and were they maintained over time? *(Link C-D)*
- What is the quality of home visits? *(Link D)*
- What motivates CHW to volunteer and what are reasons for drop out? *(Link C-D)*
- Do CHW perceive the intervention relevant and materials useful? *(Link B-D)*

**Women and families**

- What is the exposure to the intervention among the target group across the study period? *(Link D)*
- Do women and families perceive the intervention as relevant and are CHW home visits acceptable?
- Were ENC practices adopted during last birth and if not, what were the barriers? *(Link C-E)*

**Traditional birth attendants**

- What is the response to promoted ENC practices? *(Link I)*

**Supervisor**

- What are the activity and performance levels and were they maintained over time? *(Link G)*
- What is the quality of tasks conducted during community visits? *(Link F-D)*
- Are supervisors satisfied with their work and perceive it as meaningful? *(Links A-I)*

**Study team**

- What level of implementation fidelity was achieved and what are reasons for not achieving? *(Links A-I)*

- Were implementation activities rolled out per protocol and if not, why? *(Links A-I)*

**Community authorities and members**

- Do community authorities and members perceive the intervention as relevant and are supportive of it? *(Contextual)*

**Facility staff**

- Did the training result in knowledge gain of ENC practices? *(Link H)*
- How does facility staff perceive the intervention, in communities and facilities?
- What are the barriers and facilitators to adopt ENC practices for facility births? *(Link H)*

## 7.2 Data collection

I will set up quantitative and qualitative data collection mechanisms to systematically address the stated research questions. The following section contains details on the study design, including type of data collection, sample size, target population, and analysis, organized by stakeholders.

### 7.2.1 Community health workers

Data collection mechanisms to address principal questions related to CHW include a cross-sectional survey to describe the profile of CHW, written tests to understand knowledge gains and retention, home visit observations to assess acquired competence levels, semi-structured interviews, observations and informal feedback from CHW supervisor meetings to explore motivation and relevance of intervention, as well as reasons for drop-out. Data obtained by mobile devices will be used to assess CHW activity and performance levels (Table 5).

**Table 5. Data Collection Mechanisms Related to CHW**

| Research Question and Topics to Explore | Data Collection Mechanism |
|---|---|
| **What is the profile of the CHW cadre participating in the training?**<br>• Sociodemographics, selection and previous experience/ training, workload and activities, technology use | Cross-sectional census of all CHW candidates participating in training (n≈76, administered before training |
| **Did the training result in knowledge gain and was it retained over time?**<br>• General role, surveillance, ENC, healthcare seeking, preparedness, device use | Written tests by all CHW candidates, undertaken pre- and post-training (baseline) and during study period (n≈76 at each time point) |

| | |
|---|---|
| **What are the activity and performance levels of CHW and were they maintained over time?**<br>• Surveillance: Pregnancies confirmed with test, women and newborns registered<br>• Home Visits: Number and duration of home visits, within expected time window, materials provided, newborn weight, family members attending home visits<br>• Device adoption: Intervention and other app usage | Data manually entered by CHW and automatic usage statistics from mobile devices, collected continuously throughout study period (n≈76) |
| **What is the quality of home visits conducted by CHW?**<br>• Content & dosage: Topics and materials covered, time taken<br>• Proficiency of app use<br>• Competence: Communication and attitude by CHW, engagement by participants, and overall relationship | Home visit observations using checklists and observation guide, opportunistic selection of CHW (n=16) |
| **What motivates CHW to volunteer and what are reasons for drop out?**<br>• General motivation for volunteering, satisfaction with working conditions, relevance of work & tasks, appropriateness of incentives, supervision, acknowledgement from community<br>• Concerns and problems leading to lack of motivation, cease of activity, and resignation<br>**Do CHW perceive intervention relevant and materials useful?**<br>• Relevance of promotional messages, especially ENC<br>• Usability of device, support in key functions including behaviour-change communication<br>• Usability of supportive materials | Semi-structured interviews (n=16), with same CHW selected for home visit observation<br><br>Semi-structured interviews (up to n=6) with CHW who dropped out (i.e. officially resigned)<br><br>Observations and informal conversations during community visits and CHW training sessions |

*Profile of CHW*

All CHW candidates who are participating in the training will be administered a questionnaire (Appendix C3) to understand their profile which will provide important contextual information helping to interpret data gathered from other sub-studies described in this section (e.g. knowledge gains, activity and performance levels, or quality of home visits). I have developed a questionnaire that covers the CHW's sociodemographics characteristics, their current dedication, workload, and income; experience as a CHW including how and when they were selected as CHW, number and type of trainings received, as well as type of activities conducted; previous experience with mobile devices and basic reading, writing, and math skills. An electronic version of the questionnaire will be administered by facilitators and/or members of the study team prior to the start of the training using mobile-devices. I will undertake a descriptive analysis and present proportions for each variable. Written informed consent (Appendix D3) obtained from CHW to participate in the training and become a volunteer for the program (section 1.2) will cover the questionnaire.

*Knowledge of CHW*

I have developed a written, paper-based test with close-ended multiple-choice questions (Appendix C4) to assess theoretical knowledge of key intervention domains and their principal learning objectives as specified in the intervention's training manual (i.e. intervention outline & communication, surveillance, ENC, healthcare seeking, preparedness, device use). Facilitators and/or members of the study team will ask all CHW to complete the test before start of the training (t0), after the training (t1), at year 1 (t2), and at the end of the study (t3). The test at t0 will only include questions related to the domains ENC and healthcare seeking as it is not expected that CHW have prior knowledge in the other areas as not covered in the Peruvian National CHW training guide [41]. The test covers 20 questions and each question yields 1 point if answered correctly and 0 points if not correct. Double-date entry of paper-based tests and scoring will be conducted by two independent research assistants. I will calculate an overall test score covering all questions and individual domain scores covering only questions assigned to the respective domain by dividing the achieved score by the total possible score. I will conduct before-and-after comparisons of means summary scores using the Wilcoxon signed-rank test paired sample, as a non-normal distribution is expected, to assess knowledge gain associated with the training (t0/t1 comparison) and knowledge retention (t1/t2 or t3 comparison). Written, paper-based tests will be handed out to CHW by facilitators and study team conducting the training. Absolving the knowledge test will be covered in the written informed consent (Appendix D3) obtained from the CHW as described in the previous paragraph.

*Activity and Performance of CHW*

The use of mobile devices as job aids by CHW presents an opportunity to explore monitoring of CHW activity and performance in near real-time which will be triangulated with intervention exposure obtained directly by women during household census (see section 5.2.4). CHW will be prompted to enter data related to provision of surveillance and home visits (Table 2). In addition, use of mobile device during the home visits will automatically generate user statistics pertaining to the home visits, including time, date, and duration needed to complete application forms associated with each visit. Data will be uploaded by CHW in real-time or at least monthly when travelling to larger communities with mobile internet connection. Principal indicators to assess performance for surveillance activities are coverage of registered pregnant women and live births out of all events identified during the census (see Appendix E). Key indicators to assess performance for home visits are coverage of home visits during and after pregnancy (proportion calculated as number conducted / number expected); coverage of visits with complete content displayed from mobile device (i.e. image and video context shown),

coverage of visits with recommended visit duration of 1h, and coverage of visits within the expected time window. Engagement and adoption of the mobile device will be assessed by describing activity levels through usage statistics on the total device usage time; as well as use of allowance for calls, text, and data usage. Activity and performance levels will be plotted continuously using graphs.

*Quality of home visits*

Drawing on approaches from implementation science and measures of fidelity, quality of home visits can be conceptualized through the content, dosage, and competence of the person implementing [70]. Content and dosage relate to the topics covered, materials provided, and time used for visits and can be measured quantitatively; whereas competence which is related to softer implementation skills in evaluation of CHW home visits, including technical abilities, communication, and interaction, is often more challenging to capture quantitatively [71, 72]. Direct observations of home visits using checklists will be conducted which allow for a thorough assessment of the context and non-verbal aspects of communication and interaction between CHW and participants [70].

Quality of home visits, defined by the dosage, content, and interaction between CHW and recipients of the visit, will be assessed through direct observation of CHW home visits using checklists (Appendix D3). Home visits 2 and 3, most critical for influencing the primary outcomes ENC practices, will be targeted. A total of n=16 home visit observations of CHW from all three districts will be undertaken which is considered sufficient to capture a snapshot of the quality of CHW home visits. CHW will be opportunistically selected and balanced target quota of gender and community size will be aimed for, allowing stratified analysis to explore impact of those factors hypothesized to influence acceptance and performance, respectively.

Observations will be performed by myself and a female Peruvian research assistant (RA). She will have experience in conducting interviews, observations and qualitative analysis, preferably with indigenous populations, who will be familiar with the intervention contents but independent to the study team. Support by a research assistant with this profile will foster trust in the local population, especially in interviews with women, and allow a distinct and unbiased perspective as not involved in design of intervention and evaluation during collection and analysis of qualitative data for all substudies.

The RA is expected to conduct about three quarter of all observations. Verbal consent will be obtained by the recipients of the home visits (pregnant women and her family) and the CHW to attend the visit. The checklist (Appendix D3) used during the observations was developed by myself and based on a review of existing tools to assess quality of CHW home visits [71,

72]. It consists of a section collecting contextual information on the visit and a quantitative section on content evaluating the completeness of covered topics and delivered materials as per protocol (with binary variables covered/ not covered) and dosage defined by the duration of individual topics discussed and the total visit duration, as measured in minutes. Observations regarding less tangible items including abilities in application use and content navigation, communication skills, and participants' engagement will be recorded as free text at the end of the checklist and after completion of the visit. The checklist however also contains empty fields to record any spontaneous observations for each topic.

Data analysis will be done by the RA and myself, which is explained in detail in the section on interviews with CHW.

*Motivation of CHW & relevance of intervention*

Motivation to work as volunteers and perception of relevance of intervention and materials will be explored through semi-structured interviews with the same CHW selected for home visit observation (n=16). Interview guides (Appendix C5) cover principal topics listed in Table 2 but will remain dynamics and allow spontaneous exploration of topics. Interviews will be conducted in Spanish by myself and the anthropologist and audio-recorded with the permission of the participants, after obtaining written informed consent (Appendix D4). Audio recordings will be professionally transcribed by a provider who understands the local dialect; sporadic quality checks will be performed. The anthropologist and I will analyse transcripts jointly using Atlas.TI in Spanish to maintain cultural nuances and integrity. The framework analysis approach [73], closely related to thematic or content analysis, will be employed as it provides a systematic procedure for generation of themes from qualitative data ideal for use in multi-disciplinary teams with different levels of qualitative research experience. The approach is largely based on deductive inference; however, also allows flexibility for consideration of new themes. Initial coding books will be developed based on topic guides which were informed based on hypothesized mechanisms and assumptions as set out in the theory of change for the intervention (Appendix B). New codes for emerging topics not covered in the guide will be added and applied in an iterative way to already coded transcripts, if necessary. A framework matrix will be used to summarize data from individual codes into categories for each interview, operationalized through a spreadsheet where columns represent categories, rows individual interviews, and cells the summarized data. Common themes are generated through comparison across categories, cases, and different interview phases.

Semi-structured interviews will be conducted with a maximum of twelve CHW who dropped out of the study to understand the underlying context, explore the reasons and possible factors related to motivation (Table 9). A maximum of twelve CHW who have either officially resigned or ceased their activity will be selected and interviewed by the anthropologist and myself. Written informed consent (Appendix D5) and permission to make audio-recording will be obtained. The topic guide (Appendix C6) will be dynamic and informed by contextual data (CHW characteristics, observations in community, and routine data collated by supervisors and coordinator). Analysis and interpretation done by the anthropologist and me following the same approach as described in the previous paragraph.

The anthropologist and I will attend a total of twelve 4-monthly meetings of supervisors with their group of CHW, at three time points covering each time all four supervisors. Participant observations and formal feedback sessions with CHW will be conducted which will allow capturing general concerns and problems encountered; as well as specifically related to their motivation and relevance of intervention and materials as described in Table 2. Three different time points across the study period were selected to capture greater variation since issues and feedback discussed might change with time; exact timing is coinciding with planned field visits. The anthropologist and I will ask for permission to attend the supervisor meetings and take written notes which will be later organized and analysed thematically.

*Relevance and usefulness of intervention and materials*

Relevance and usefulness of intervention and materials (Table 2) will be discussed as part of the same semi-structured interviews conducted with CHW to assess motivation, following the same methodology as for semi-structured interviews described earlier. Topic guides (Appendix D4) will be dynamic and further informed by other sub-studies conducted as part of the process evaluation.

The anthropologist and I will attend one 6-day CHW training session each to observe and conduct informal feedback rounds with the group at the end with the aim to capture first impressions related to the relevance and usefulness of the intervention and materials (Table 2). The staff conducting the training will also contribute their written observations and learnings from routine feedback rounds with CHW at the end of the training.

Attendance of twelve 4-monthly supervisor group meetings with CHW throughout the study period, as described in the previous section, will be used to gather general feedback on relevance and usefulness of materials (Table 2) and general strengths and limitations of the intervention and management. Insights gained from the three data collections mechanisms described will help to detect issues early and adapt intervention materials if needed, such as

refinement of the application run on the tablet to increase usability. Consideration of feedback is also expected to enhance uptake and compliance through a strengthened sense of ownership by CHW and supervisors.

### 7.2.2 Supervisors

Data collection mechanisms to address principal questions related to supervisors include monitoring of activity and performance levels, observations of community visits and group meetings with CHW, and repeated focus groups (Table 6).

**Table 6. Data Collection Mechanisms Related to Supervisors**

| Research Question and Topics to Explore | Data Collection Mechanism |
|---|---|
| **What are the activity and performance levels of supervisors and were they maintained over time?**<br>• Monthly community visits: Number of community visits, CHW meetings, CHW home visit observations, sensitization meetings, monthly report of CHW performance<br>• 4-monthly group meetings: number of meetings, CHW attending<br>• Device adoption: Usage time device, supervisor application, whatsapp, private use; call, text, and data use | Daily activity logs and automatic usage statistics from mobile devices of supervisors, collected continuously throughout study period |
| **What is the quality of community visits and 4-monthly CHW group meetings?**<br>• Competence in performing monthly community visits and 4-monthly supervision meetings: structure, content, duration as per protocol; appraisal of credibility, communication, and problem-solving skills | Observations of monthly community visits (n=12)<br>Observation of 4-monthly CHW supervisor group meetings (n=12) |
| **What are the strengths and limitations of the intervention?**<br>• Open feedback: strengths and limitations<br>• Work of the CHW: delivery of activities per protocol, response to work by different stakeholders<br>• Supervisor work: acceptance by stakeholders, satisfaction of working conditions, improvements | Repeated focus groups (n=3), each with all 4 supervisors<br>Observations and informal feedback session during 4-monthly CHW supervisor meeting (n=12) |

*Activity and Performance of Supervisors*

Activity and performance of supervisors will be monitored continuously by the intervention coordinator through self-report and automatically collected data from their mobile devices. Supervisors are asked to fill in daily activity reports which will allow to track whether activities have been performed according to protocol. I have created principal performance and activity indicators that relate to the conduct of monthly community visits, including meetings with CHW,

key stakeholders, and home visit observations; conduct of 4-monthly group meetings with CHW, and the device adoption (Appendix E). Mobile devices allow tracking the GPS position of supervisors which will allow independent confirmation whether supervisors were located at the geographical position where the community visits or 4-monthly CHW meeting was meant to take place.

*Quality of supervisor activities*

Quality of the two main activities conducted by supervisors, community visits and 4-monthly CHW group meetings, will be evaluated through direct observation using checklists. In total, twelve observations of community visits will be conducted by the anthropologist and I. Communities to be visited will be sampled opportunistically, each time covering a different community and CHW; with preference to those that have not been visited for the sub-study quality of home visits (section 7.1.1) to gain a broader picture. A checklist with quantitative and qualitative elements will be used (Appendix C7) to assess whether each component of the community visit (home visit observation and feedback meeting with CHW, dialogue with community authorities and members) was conducted per protocol (structure, content, and duration). The interaction between the CHW and supervisor, including communication, problem-solving skills, and credibility will also be assessed. Each community visit is expected to take half a day, during which there will be the opportunity to collect informal feedback from any stakeholder covered in the process evaluation.

4-monthly CHW group meetings of all four supervisors will be observed by the anthropologist and I and informal feedback will be collected from participants during n=12 meetings, at three time points throughout the study period, each time covering all four supervisors. A checklist (Appendix C8) evaluating the same domains, adapted to the content of the meeting, will be used to evaluate competence of the supervisor. The anthropologist and I visiting the community and the CHW group meetings will obtain verbal consent from the supervisor. Analyses that I will conduct for both type of observations will be similar as described previously for the CHW (section 7.1.1).

*Strength and limitations of the intervention*

The anthropologist and I will conduct repeated focus groups (n=3) with all four supervisors to evaluate the strengths and limitations of the intervention. Topic guides (Appendix C9) will be used to guide the discussions, which will remain dynamic as informed by insights gained from other sub-studies or earlier phases of the focus groups. The focus groups will be conducted at a central location to all four supervisors; written informed consent (Appendix D6) will be

obtained from each supervisor by the anthropologist and I prior to the start of the discussion. Methods for analysis will be similar to those described for the semi-structured interviews.

Informal feedback will be collected from all four supervisors after initial training to capture their first impressions on the intervention components and materials, as well as their expected tasks. Informal feedback from supervisors will also be collected after community visits and observations of 4-monthly CHW meeting described in the previous paragraph. Topics covered will be any problems related to the delivery and response to the intervention; as well as issues captured by the coordinator through the routine feedback mechanisms between supervisor and coordinator (see next section) and Whatsapp communication channel between CHW and supervisors. Written notes taken by investigators will be organized thematically.

### 7.2.3 Study Team

Data collection mechanisms related to the intervention director, investigators of the process evaluation (the anthropologist and I), as well as intervention coordinator and facilitators (section 1.2) include routine documentation maintained by the coordinator, informal discussion rounds with the program director, intervention coordinator, and facilitators, as well as any observations by the investigators of the process evaluation (Table 7).

**Table 7. Data Collection Mechanisms Related to Study Team**

| Research Question and Topics to Explore | Data Collection Mechanism |
|---|---|
| **What level of implementation fidelity was achieved?**<br>• Coverage and retention of trained CHW<br>• Coverage of stocked CHW<br>• Coverage of facility sensitization & training | Routine documentation (quantitative) by intervention coordinator, collected continuously from baseline to 24 months |
| **How and why was implementation fidelity (not) achieved?**<br>• Supervisor activity logs on issues raised during community visits and 4-monthly CHW supervisor meetings<br>• Interaction of supervisors with CHW and issues raised in whatsapp groups<br>• General adherence to implementation protocol<br>• Logistical, political, and cultural challenges<br>• Strengths and limitations of intervention | Routine documentation (qualitative) by intervention coordinator, collected continuously from baseline to 24 months<br><br>Informal feedback from intervention director, coordinator, and facilitators throughout study<br><br>Observations by investigators, continuous from implementation through evaluation until end of study |

*Levels of implementation fidelity*

The intervention coordinator will maintain a database containing routine documentation of the fidelity of implementation of the intervention collected throughout the study. In addition to

activity and performance indicators sourced from CHW mobile devices (section 7.1.1) and activity logs of supervisors (7.1.2), implementation fidelity will be assessed through coverage and retention of trained CHW, supply & stock of CHW supportive materials, as well as facility training (Appendix E). The intervention coordinator will monitor all quantitative indicators in real-time; coverage indicators will be expressed as proportions and summarized monthly using descriptive analysis.

*Factors explaining implementation fidelity*

To understand how and why implementation fidelity was or was not achieved, multiple source will be tapped to obtained qualitative data (Table 4). Routine documentation by the intervention coordinator includes monthly thematic summaries of issues raised by supervisors through their daily activity logs; as well as issues raised in whatsapp communication channels between CHW and their supervisors. I will further collect informal feedback from the intervention director, coordinators, and facilitators throughout the study. A non-standard source of information will be any observations by myself and the anthropologist working with me on the process evaluation, made throughout the study, starting from the implementation of the intervention.

### 7.2.4 Women and Families

Research questions related to women and families will be addressed through questions on intervention exposure embedded in the household census evaluating study outcomes and semi-structured interviews with women who had a live birth and have received home visits (Table 8).

**Table 8. Data Collection Mechanisms Related to Women and Families**

| Research Question and Topics to Explore | Data Collection Mechanism |
|---|---|
| **What is the exposure of the intervention among the target group across the study period?**<br>• Home visit coverage during pregnancy and after birth<br>• Coverage of received services and materials: pregnancy test, educational materials, clean delivery kit, newborn weighing | Self-report by eligible women captured by household census, at baseline before implementation, at 12 and 24 months |
| **What is the acceptability and relevance of the intervention and were there barriers for adopting ENC practices during last birth?**<br>• Acceptability of pregnancy testing and home visits by current largely male CHW cadre, frequency & timing of visits | Semi-structured interviews with women who had a live birth and have received home visits (n=12) |

| | |
|---|---|
| • Usefulness and relevance of intervention content and supportive materials, with focus on promotion of ENC<br>• Barriers and facilitators for adoption of ENC | |

*Intervention exposure*

The principal measures of intervention exposure (Table 5) among the target population, consenting women between 15 and 49 years with a singleton live birth in the last 12 months, will be assessed through questions embedded in the household census conducted in the study area as part of the outcome evaluation (section 3.3). Indicators are coverage of home visits and materials received by pregnant women and are presented as proportions (Appendix E). The 12-month recall period used in the census will be exploited to present intervention coverage indicators by quartal, allowing interpretation of the principal outcomes; as well as triangulation with activity and performance data of CHW collected through devices. An exploratory subgroup analysis will be conducted to explore whether home visit coverage or other indicators describing intervention exposure are associated with primary outcomes.

*Acceptability and relevance of intervention & barriers for ENC practices*

Semi-structured interviews with women who had a live birth and who have received CHW home visits will be conducted to assess the acceptability and relevance of the intervention as well as to understand barriers for adopting recommended ENC practices. Interviews will be conducted by the anthropologist after the first year to allow full exposure to the intervention (all home visits received). It is expected to achieve saturation with a planned sample size of n=12. Women will be selected opportunistically, with target quota based on parity and educational level to capture women from diverse backgrounds. If possible, women will be selected who were previously visited for the home visit observations of the CHW (see section 5.2.1), this allows availability of a context built through earlier observations. Availability of all interviewees will be assured through prior scheduling by supervisors and/or CHW. Interviews will be semi-structured, content of topic guides (Appendix C10) dynamic based on earlier findings from other sub-studies, and analysis approach as described in section 5.2.1. Family members, including the husband or person attending the birth, will be welcomed to join the interview. The anthropologist and I will seek written informed consent testified by an independent witness from women, including permission to audio-record the interviews (Appendix D2).

### 7.2.5 Traditional Birth Attendants

The anthropologist and I will attend and observe two opportunistically selected TBA training sessions and will conduct informal feedback rounds with TBA after completion of the training, with the aim to explore response to promoted ENC practices. We will obtain verbal consent for participation in the training; written notes will be taken which will be organized thematically afterwards.

**Table 9. Data Collection Mechanisms Related to TBA**

| Research Question and Topics to Explore | Data Collection Mechanism |
|---|---|
| **What is the response to the promoted ENC practices?**<br>• Acceptability of promoted ENC; focus on pre-identified harmful beliefs (e.g. throwing away colostrum) | Observation of training and informal feedback round with TBA after completion of initial training (n=2) |

### 7.2.6 Community Authorities and Members

To explore the response to the intervention within the communities, the anthropologist and I will document any observations and informal feedback received from community authorities and members during community visits as part of other sub studies, including visits for evaluation of quality of CHW home visits and interviews with CHW (section 7.1.1), visits to evaluate the quality of supervisor activities (section 7.1.2), visits for semi-structured interviews with women (section 7.1.4). We will take written notes which will be organized thematically; no audio recordings will be made and only verbal consent will be obtained.

**Table 10. Data Collection Mechanisms Related to Community Authorities and Members**

| Research Question and Topics to Explore | Data Collection Mechanism |
|---|---|
| **Is the intervention relevant and acceptable to communities?**<br>• Usefulness, support, and engagement with intervention and promoted messages<br>• Response to the intervention | Observations and informal feedback received from community authorities and other community members, members, during community visits for other sub-studies |

### 7.2.7 Facility Staff

*Knowledge of Facility Staff*

A written, paper-based test with close-ended multiple-choice questions will assess theoretical knowledge of ENC practices (Appendix C11) that will be taught as part of the 2-day training on routine newborn care provided to all facilities in the study area (n=17) with a cadre of approximately 55 health workers directly involved in maternal and newborn care. The test will be self-administered and distributed by the intervention coordinator or facilitators before and

after the initial training to assess knowledge gain. Thereafter, post-training tests will be administered after every refresher training, repeated in half-yearly intervals due to heavy staff rotation in the study area, to assess knowledge retention until the end of study at month 24. Written informed consent (Appendix D7) will be sought by intervention coordinator or facilitators conducting the training. I will calculate summary scores for ENC practices and will conduct a before/ after comparison to assess knowledge gain after initial training will be performed as described for the CHW test (section 5.2.1). Summary scores for subsequent post-training sessions will be plotted with 95%CI to assess retention over the study period.

*Adoption of ENC practices*

A comprehensive quality of care assessment is not intended given the small scope of the facility-based training. Focus groups with facility staff are substantially smaller in effort and are expected to generate valuable insights into barriers and facilitators for the adoption of ENC practices for facility births. Focus groups were chosen to capture the consensus and procedures of the entire organization unit. Focus groups will be conducted using topic guides (Appendix C12) by a physician with experience in qualitative data collection responsible for the development of the facility-based component. A total of four focus groups will be conducted throughout the study period which is considered sufficient to reach saturation. To achieve a broad diversity, different facilities will be opportunistically selected for each round; sampling will be proportional to district size and type of facility. Content of topic guides will be informed by further literature review and adapted after each round based on the findings of the previous round. A content analysis will be performed as described previously (section 5.2.1). Written informed consent (Appendix D8) will be obtained from each participant of the focus group and includes permission to audio record.

**Table 11. Data Collection Mechanisms Related to Facility Staff**

| Research Question and Topics to Explore | Data Collection Mechanism |
|---|---|
| **Did the training result in knowledge gain of ENC practices and was it retained over time?**<br>• Theoretical knowledge of ENC practices covered in routine newborn care training course | Written test self-administered by all facility staff undergoing training, conducted at pre- and post-training (baseline); and post-half-yearly training sessions (6, 12, 18, and 24 months) |
| **What are the barriers and facilitators to adopt ENC practices for facility births?**<br>• Relevance and acceptability of ENC practices among facility staff and the target group (women and family members) | Group interviews with facility staff (n=4) |

| | |
|---|---|
| • Organizational and logistical barriers/ facilitators for implementation of ENC practices in facilities | |

## 8. ETHICS

Ethical approval for the implementation and evaluation of the intervention was obtained from interventional committees of Cayetano Heredia University (Reference number: 100419) and LSHTM (Reference Number: 16071).

There is no physical risk involved in participating in the study, both in receiving the intervention and taking part in the census as well as in data collection instruments as part of the process evaluation. Institutional birth is promoted in the first visit; preparations for home birth, if facility birth is not feasible, and supply of delivery kits is only covered from the third trimester to not disincentivise facility births. Women who received CHW home visits may change ENC and healthcare-seeking practices; women who deliver in facilities might receive improved ENC by staff, intended to reduce NM. In consideration of a partly illiterate indigenous population in which requesting signatures provokes distrust due to a history of Western exploitation, seeking written informed consent testified by an independent witness is considered most appropriate for research activities involving ordinary members of the communities, including women. Written informed consent will be obtained for all other stakeholders that are part of the evaluation, including supervisors and facility staff, as well as CHW who will deliver the intervention. Verbal informed consent will be obtained for observations planned or informal feedback received from any stakeholder during the process evaluation to maintain natural interaction and avoid causing any distrust, which is considered appropriate given the minimum interference by investigators.

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# Appendix A – Secondary Outcomes

**Table 1. Secondary outcomes: ENC practices**

| Indicator | Nominator | Denominator |
|---|---|---|
| Proportion of newborns with immediate skin-to-skin contact | Number of newborns that were placed immediately and naked on the mother's belly or chest touching her bare skin | Number of live births in the last 12 months prior to survey *(at facilities)* |
| Proportion of newborns that received colostrum | Number of newborns that received colostrum | Number of live births in the last 12 months prior to survey *(at facilities)* |
| Proportion of newborns that received early breastfeeding | Number of newborns that were breastfed within 1 hour after birth | Number of live births in the last 12 months prior to survey *(at facilities)* |
| Proportion of newborns who had noting harmful applied to cord | Number of newborns with nothing other applied to cord apart from alcohol/ gauze from the moment cord was cut until it fell off | Number of live births in the last 12 months prior to survey *(all births)* |
| Proportion of newborns who only received breastmilk in first 3 days | Number of newborns who have not received anything else than breastmilk in the first 3 days after birth | Number of live births in the last 12 months prior to survey *(all births)* |
| Proportion of birth attendants who washed hands before birth | Number of birth attendants who washed hands before birth | Number of live births in the last 12 months prior to survey *(at home)* |
| Proportion of newborns who had cord tied or clamped with new instrument | Number of newborns who had cord tied or clamped with new instrument | Number of live births in the last 12 months prior to survey *(at home)* |
| Proportion of newborns who had first bath | Number of newborns who were not bathed during the first day | Number of live births in the last 12 months prior to survey *(at home)* |

| | | |
|---|---|---|
| delayed for at least 1 day | | |

**Table 2. Secondary outcomes – Health care seeking**

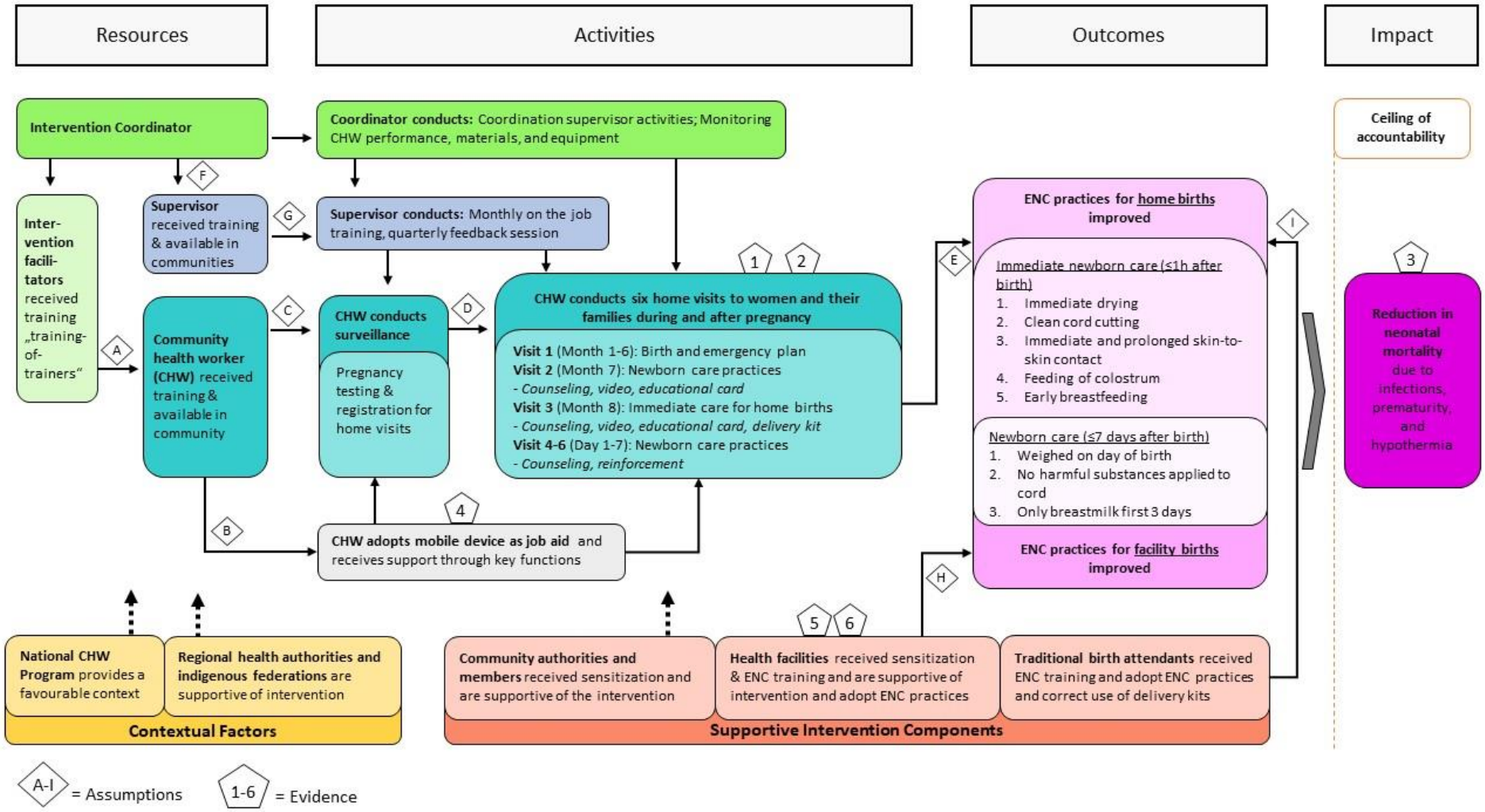
| Indicator | Nominator | Denominator |
|---|---|---|
| Proportion of pregnant women with ANC visit at health facility within the first trimester | Number of pregnant women with first ANC visit at any type of health facility within the first trimester *(ascertained by pregnancy card)* | Number of live births in the last 12 months prior to survey *(all births)* |
| Proportion of pregnant women who had ≥6 ANC visits at health facility | Number of pregnant women with a total number of more than 6 ANC visits at any health facility *(ascertained by pregnancy card)* | Number of live births in the last 12 months prior to survey *(all births)* |
| Proportion of women who delivered health facility | Number of pregnant women who delivered at any type of health facility | Number of live births in the last 12 months prior to survey *(all births)* |
| Proportion of newborns who had their first PNC at health facility ≤3 days after birth | Number of newborns who had their first PNC visit at any type of health facility within the first 3 days after birth *(ascertained by newborn/ vaccination card)* | Number of live births in the last 12 months prior to survey *(all births)* |
| Proportion of newborns who received BCG vaccination within first month | Number of newborns who received BCG vaccination within the first month after birth *(ascertained by newborn/ vaccination card)* | Number of live births in the last 12 months prior to survey *(all births)* |
| Proportion of newborns who received HvB vaccination within first month | Number of newborns who received HvB vaccination within the first month after birth *(ascertained by newborn/ vaccination card)* | Number of live births in the last 12 months prior to survey *(all births)* |

**Table 3. Secondary outcomes – Birth preparedness**

| Indicator | Nominator | Denominator |
|---|---|---|
| Proportion of newborns who received ID within first month | Number of newborns who received ID within first month | Number of live births in the last 12 months prior to survey *(all births)* |

| | | |
|---|---|---|
| Proportion of women who saved money for birth or emergencies | Number of women who reported to have saved money for birth or emergencies in advance | Number of live births in the last 12 months prior to survey *(all births)* |
| Proportion of women who notified godfather/ mother before birth | Number of women who reported to have notified godfather or godmother before birth | Number of live births *at home* in the last 12 months prior to survey |
| Knowledge of danger signs for maternal complications during pregnancy | Average number of danger signs for maternal complications during pregnancy mentioned spontaneously | Number of live births in the last 12 months prior to survey *(all births)* |
| Knowledge score for danger signs of maternal complications during labour | Average number of danger signs for maternal complications during labour mentioned spontaneously | Number of live births in the last 12 months prior to survey *(all births)* |
| Knowledge score for danger signs of maternal complications after birth | Average number of danger signs for maternal complications after birth mentioned spontaneously | Number of live births in the last 12 months prior to survey *(all births)* |
| Knowledge score for danger signs of neonatal complications | Average number of danger signs for neonatal complications mentioned spontaneously | Number of live births in the last 12 months prior to survey *(all births)* |

## Appendix B – Theory of Change Model



**Assumptions**

A. **CHW candidate** with favourable profile, accepted by community, willing to undergo and complete training, gain in competency (surveillance, home visits, device, communication), high coverage rate in communities
B. **CHW** retains proficiency in device use, device has high usability, key functions increase work & process efficiency, acts as an incentive and motivator, facilitates behaviour-change communication (videos, images), minimal infrastructure (electricity) available, routine use & high adoption rate
C. **CHW** retains good competence for surveillance activities (theoretical knowledge, practical skills testing & communication skills), remains motivated (high job satisfaction, satisfied with working conditions, appropriate incentives, regular supervision, acknowledgement from community), has access to functional supportive materials (pregnancy test, mobile device), achieves high performance (high testing & registration coverage)
   **Women** are aware, see value and relevance for testing, registration, and home visits; trust CHW, supportive of environment of intervention (husband, family, community)
D. **CHW** retains good competence for home visit activities (theoretical knowledge & practical skills ENC, counselling skills), ensures presence of **key influencers** during visits (women, female family birth attendant) and **decision makers** (husband), builds a trustful relationship to the family, remains actively engaged, access to functional supportive materials (device, educational materials, delivery kit, scale), achieves high performance (coverage of timely, complete, and high-quality home visits)
E. **Key influencers (women, female family birth attendants, traditional birth attendants, godfather/godmother)** of newborn care are aware of ENC practices, see value and purpose in practice, barriers are overcome, delivery kit and educational materials available, understandable & used, high coverage ENC practices
F. **Supervisor candidate** has desired profile, available locally in study area, willing to undergo training, gain in competency for supervisor tasks (intervention components, device mastery, problem identification and solving, credibility)
G. **Supervisor** retains good competence for supervisor activities, remains motivated, logistical feasibility for visits (funds, boat), achieves high performance (high rate of visits and group sessions)
H. **Health facility staff** gain competence (theoretical knowledge & practical skills in ENC), see value and purpose in practices, no barriers present, high coverage of ENC practices (at facility)
I. **TBA** gain competence (theoretical knowledge & practical skills in ENC and delivery kit use), see value and purpose in practices, no barriers present, high coverage of ENC practices (at home)

**Rationale**

1. Large, cluster-randomized controlled trials from South Asia and sub-Saharan Africa with low level of bias suggest that home visits during and after pregnancy by trained CHW can increase uptake of ENC practices *(Kumar 2008, Bhutta 2011, Baqui 2008, Bhandari 2008, Hanson 2015, Kirkwood 2013, Darmstadt 2010)*
2. Meta-analyses suggest that CHW home visits are effective in reducing neonatal mortality; however, effect is likely context-specific (study setting, supportive components, strength of implementation) *(Gogia 2016, Hanson 2017)*
3. Systematic reviews and delphi panels suggest improved ENC practices (breastfeeding, clean birth practices, and thermal care) can reduce mortality due to infections, prematurity, and hypothermia *(Smith 2017, NEOVITA Study Group 2016, Moore 2016, Blencowe 2011, Bhutta 2014)*
4. A systematic review covering qualitative studies suggests that it is feasible to train CHW to use mobile devices as job aids and CHW performance may be improved through providing key supportive functions; impact on ENC practices or neonatal outcomes remains unknown *(Agarwal 2015)*
5. A systematic review covering qualitative studies suggests that CHW performance as well as acceptance and utilization of their services by the target group may be improved through active support at the community-level and integration into the health system *(Glenton 2013)*
6. Formative research for a CHW home visit intervention to improve ENC practices in Ghana suggests that all relevant stakeholders (TBA, communities, facilities) need to be sensitized for the intervention to ensure consistent messages across the continuum of care to enhance behaviour-change communication *(Hill 2008)*

## Appendix C1 – Household Enumeration Form

ENG_Household_En
umeration_18Aug18

## Appendix C2 – Women Questionnaire

ENG_Women_Quest
ionnaire_29Aug18_v

## Appendix C3 – CHW Questionnaire

ENG_CHW
Questionnaire_v6_2

## Appendix C4 – CHW Knowledge Test

ENG_Knowledge
Test CHW_24Aug18_

## Appendix C5 – Quality of CHW home visits – Checklist

ENG_CHW Home
Visit Checklist_27Ag

## Appendix C5 – CHW Interview (Active)

ENG_Topic Guide_CHW_active_

## Appendix C6 – CHW Interview (Dropped)

ENG_Topic Guide_CHW_droppe

## Appendix C7 – Supervisor Checklist – Community

ENG_Checklist_Com munity_Supervisor_3

## Appendix C8 – Supervisor Checklist – Meeting

ENG_Checklist_CH W-Meeting_Supervi

## Appendix C9 – Supervisor Checklist – Focus Group

ENG_Topic Guide_Supervisors_2

## Appendix C10 – Women Interview

ENG_Topic Guide_women_ENG_

## Appendix C11 – Facility Staff Test

ENG_Staff Knowledge_Test_27J

## Appendix C12 – Facility Staff – Focus group

ENG_Topic Guide_Facility_FG_3(

## Appendix D1 – Informed Consent Women – Questionnaire

ENG_Written IC_Survey_Women 1

## Appendix D2 – Informed Consent Women – Interview

ENG_IC_Interview_ Women_28Aug18_v

## Appendix D3 – Informed Consent CHW – Training

ENG_IC_CHW_Traini ng_v3_31Ago18_Cle

## Appendix D4 – Informed Consent CHW – Interview (Active)

ENG_CI_CHW_Interv iew_Active_ENG_28A

## Appendix D5 – Informed Consent CHW – Interview (Dropped)

ENG_CI_CHW_Interv
iew_Dropped_ENG_

## Appendix D6 – Informed Consent Supervisor – Focus group

CI_Supervisors_FG_
ENG_28Ago18_v3.dc

## Appendix D7 – Informed Consent Staff – Test

CI_Facility_Test_ENG
_30Ago18_v2.docx

## Appendix D8 – Informed Consent Staff – Focus Group

CI_Facility_FG_ENG_
30Ago18_v2.docx

## Appendix E –Quantitative Process Indicators

| Indicator | Data Source |
|---|---|
| **CHW Activity and Performance**<br>*Surveillance*<br>• n / % of confirmed pregnancies with test, participants registered, out of all eligible women identified during census<br>• n / % of participants (women) dropped out (+reasons)<br>• n / % of live births registered<br>*Home visits*<br>• n / % of prenatal (1,2,&3) and postnatal (4,5,&6) visits<br>• % timely visits (within expected time window), % complete visits (image and video content shown), % minimum duration (≥1h) [1]<br>• n / % of educational cards, clean delivery kits provided, newborns weighed | CHW mobile device – self-reported and automatic usage statistics |

| | |
|---|---|
| • n of types of family members attending home visits<br>*Device adoption*<br>• Average usage time intervention application/ private use<br>• Call, text, and data usage | |
| **Supervisor Activity and Performance**<br>*Monthly community visits*<br>• n / % of community visits (confirmed by GPS tracking)<br>• n / % of CHW meetings<br>• n / % of CHW home visit observations<br>• n / % of sensitization meetings (authorities, TBA, health facility)<br>*4-monthly CHW group meetings*<br>• n / % of group meetings conducted (confirmed by GPS tracking)<br>• n / % of CHW attending<br>*Device adoption*<br>• Average usage time intervention application, whatsapp, private use<br>• Call, text, and data usage | Routine activity logs by supervisor |
| **Implementation**<br>*CHW coverage & retention*<br>• n of existing/ newly recruited CHW invited for training<br>• n / % of existing/ newly recruited CHW completed / not completed training<br>• n / % of existing/ newly recruited CHW actively working / dropped<br>*Supply & Stock*<br>• n / % of CHW with working tablet & supportive equipment<br>• n / % of CHW with available pregnancy tests<br>• n / % of CHW with available educational materials (pregnancy plans, cards, posters)<br>*Facility*<br>• n / % of health facilities with completed initial/ half-yearly refresher sensitization & training<br>• n / % of staff attending initial/ half-yearly refresher sensitization & training | Routine documentation by coordinator |
| **Intervention Exposure**<br>• n / % of CHW home visits received during pregnancy / after pregnancy<br>• n / % of pregnancy tests and educational materials received<br>• n / % of clean delivery kits received, newborns weighed *(home births only)* | Household census – self-report by women |
| [1] To be defined based on date/time of the initiation and completion of forms associated with each visit; and based on gestational age, which allows calculating whether the visit was performed within the expected time window, whether all standardized contents were covered, and whether it had a defined minimum duration. | |