



Ethiopia iCCM Implementation Snapshot & Quality of Care Assessment Study Protocol

Jimma and West Hararghe zones, Oromia, Ethiopia

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1. BACKGROUND

In recognition of the difficulties of reaching the majority rural population with health services, the Ethiopian government launched the Health Extension Program (HEP) in 2004. The program has trained over 30,000 Health Extension Workers (HEWs) to provide preventive and curative care in communities. While the HEP includes an urban program, the vast majority of HEWs work in rural areas.

The lowest level of the Ethiopian health system is the primary health care unit, which comprises one health center and five satellite health posts. Each health post is run by two HEWs and serves one kebele,* with a population of approximately 5,000 people. At the community level, HEWs are assisted by volunteer community health workers (VCHWs).

The HEP initially emphasized preventive activities, but was later expanded to include basic curative interventions as well. The program included treatment of children with diarrhea with oral rehydration salts (ORS), malaria with artemisinin-based combination therapy (ACT), and severe acute malnutrition (SAM) with ready-to-use therapeutic foods (RUTF). Pneumonia cases, on the other hand, were to be referred to health facilities for treatment.

Following the national policy change towards community treatment of childhood pneumonia in late 2009, Ethiopia is scaling-up integrated community case management (iCCM) within the pre-existing HEP in five regions of the country: Amhara, Oromia, SNNP, Tigray and Benishangul-Gumuz with support from CIDA, UNICEF, USAID and others. This initiative aims to accelerate reduction in under-five mortality in Ethiopia by strengthening the health system and increasing equity in access to high-impact, cost-effective preventive and curative interventions. In the focus regions, community case management (CCM) of childhood pneumonia with cotrimoxazole and zinc for treatment of diarrhea are being introduced in addition to the already existing CCM of malaria with ACTs, diarrhea with ORS and SAM

* Kebele is the lowest administrative unit, followed by woredas (districts), zones, and regions.

with RUTF.^{1†} The program is expected to strengthen the capacity of HEWs to assess, classify and treat malaria, diarrhea and SAM through refresher trainings, strengthened supervision, improved supply chain management for essential drugs and supplies and improved monitoring and evaluation.

To date, there are few examples of large-scale iCCM programs, especially in sub-Saharan Africa,²⁻³ and rigorous evaluations of the programs that exist are rare.⁴ The effectiveness of iCCM varies across specific country contexts and depends largely on the strength of program implementation.⁵⁻⁸ It is therefore essential to evaluate the effectiveness of the scale-up strategy to provide a basis for future program improvement in the country and to provide global evidence on effective strategies for scaling up high-impact child survival interventions to accelerate reductions in under-five mortality. To this end, the Institute for International Programs at the Johns Hopkins Bloomberg School of Public Health (IIP-JHU) has been commissioned by CIDA and UNICEF to conduct an independent prospective evaluation of the implementation of iCCM in Ethiopia. The independent evaluation will assess the impact of the rapid scale-up of iCCM on increases in coverage of child survival interventions, reductions in child mortality and improvement in nutritional status among children under five years of age.

The evaluation is being conducted in the Oromia region where iCCM implementation is being phased in, allowing the identification of comparison areas. Within the Oromia region, the evaluation is focused on Jimma and West Hararghe zones and uses a cluster-randomized design with stratification by zone. Within each zone, rural woredas were randomly assigned to intervention and comparison arms. Intervention woredas were fully implementing the iCCM program as of July, 2011 and the comparison woredas are planning to begin implementation of iCCM no sooner than 18 months later, in January, 2013. During the evaluation period, the comparison woredas will continue to offer services included in the routine HEP (including CCM of malaria, diarrhea and SAM).

With program implementation fully under way, the Ethiopian Federal Ministry of Health (FMOH), UNICEF and other implementing partners need measures of iCCM implementation strength and quality of care (QoC) to assess how widely and at what intensity the iCCM program is being scaled up to reach its intended populations. Furthermore, it is necessary to have measures of implementation strength in comparison areas to be able to document the strength of implementation of CCM services of the existing HEP.

The IIP-JHU evaluation team, in collaboration with UNICEF and the FMOH, is planning to conduct a “quality of care implementation snapshot” study in the two evaluation zones to assess the strength of the program and provide appropriate feedback to the FMOH and implementing partners.

There are two main rationales for measuring the strength of implementation. First, the FMOH, UNICEF and other implementing partners need measures of iCCM implementation strength to assess how widely and at what intensity the iCCM program is being scaled up to reach its intended populations. These data can be used by program managers to strengthen processes and intermediate outputs,

[†] Although treatment of diarrhea with zinc is part of the iCCM policy, the iCCM program is currently being implemented without zinc due to a lack of supply of zinc in Ethiopia. It is not clear whether zinc will be included during the evaluation period.

thereby improving outcomes. Second, program evaluators need measures of iCCM implementation strength to assess the relationship between the program and expected outcomes. For evaluators to be able to confidently make conclusions about the program’s impact, they must have information on program fidelity (were processes carried out as planned), as well as intermediate outputs and contextual factors.

Table 1: Definitions of key terms as applied in this study

Community case management	CCM is defined for this study as management, including assessment, classification and treatment, of childhood illnesses, carried out by a paraprofessional health worker in the community.
Integrated community case management	iCCM in this context is defined as integrated management of all of the following childhood illnesses: pneumonia, diarrhea, malaria and severe acute malnutrition.
Implementation strength	For this study, this term refers to key program processes that must be completed for the program to have the desired impact on under-five mortality. Indicators of essential program activities include 1) population coverage of HEWs providing iCCM services, 2) HEWs trained in iCCM, 3) HEW receiving supportive supervision for iCCM, 4) adequate and consistent stocks of essential iCCM commodities and supplies and 5) activities to generate demand for iCCM services.
Quality of care	Quality may be measured through indicators of outcomes (patient health outcomes), processes (healthcare provider actions) or structure (adequacy of facilities and equipment, qualifications of health workers, administrative structure). ⁹ For this assessment, we will measure quality based on processes. The term quality will refer to whether health workers correctly assess, classify and treat/refer iCCM illnesses and provide counseling to caretakers based on Ethiopia iCCM clinical algorithms. To measure quality of care provided to a patient, we must have gold standard assessment, classification and treatment that follows the iCCM algorithms with which to assess the health worker’s performance. We will also measure indicators of structure, or readiness to deliver services (drug supplies, trained health workers, supervision, etc.), but these will be considered as measures of implementation strength rather than quality of care.

The effectiveness of the iCCM program requires that each component of the program – coverage and availability of HEWs; whether HEWs are trained in iCCM; supportive supervision; continued availability of drugs and supplies; and demand-generating activities, such as community education and mobilization – is delivered at a high level of intensity that is sustained throughout the program in each of the intervention woredas. Likewise, improvements should be seen in the quality of services provided by HEWs and in utilization of services by the community. The adequacy of program inputs, processes and outputs needs to be assessed early after the inception of the program to ensure that necessary adjustments and corrections are made. Appendix 1 presents a conceptual model that illustrates the hypothesized relationship between the iCCM program and the desired impacts.

2. OBJECTIVES

The objectives of the survey are to:

- (1) Assess the strength of iCCM program implementation in intervention woredas;

- (2) Assess the quality of iCCM services provided by HEWs in intervention woredas; and
- (3) Document the strength of implementation for the routine HEP CCM program in comparison woredas.

3. METHODS

3.1. STUDY POPULATION

The intervention and comparison woredas in Jimma and West Hararghe zones of Oromia region defined for the iCCM evaluation will be used for the implementation snapshot. Table 2 presents the iCCM evaluation intervention and comparison woredas. The study will sample functional health posts[‡] as primary units. Study participants will include: 1) HEWs performing case management of childhood illnesses, 2) sick children 2-59 months of age presenting at health posts for consultations and their caretakers and 3) sick children 2-59 months in the communities surrounding health posts and their caretakers.

Table 2: iCCM evaluation interventions and comparison woredas

Jimma		West Hararghe	
Intervention Woredas	Comparison Woredas	Intervention Woredas	Comparison Woredas
Chora Botor	Dedo	Boke	Anchar
Gera	Gumay	Chiro	Burka dimtu
Goma	Limu Seka	Doba	Daro Labu
Kersa	Nono Benja	Gemechis	Habro
Limu Kosa	Seka Chokorsa	Guba Koricha	Mesela
Mana	Sokoru	Hawi Gudina	Mieso
Shebe Senbo	Tiro Afeta	Oda Bultum	Tulo
Omo Nada	Sigamo		
Setema			

3.2. Inclusion Criteria

- a. Health posts: All functional health posts in the study zones will be included in the sampling frame. In cases where an HEW is providing services, but an official health post structure has not been constructed, the HEW's primary location for providing case management services will be considered as the health post.
- b. HEWs: All HEWs providing case management services in selected health posts will be included.
- c. Patients presenting spontaneously at the health post must meet the following criteria:
 - i. Between 2 and 59 months of age;
 - ii. Described as sick by the caretaker. Sick children must have at least one of the following complaints: signs or symptoms of severe illness (change in consciousness/lethargy,

[‡] A functional health post is defined as a location where at least one HEW is currently assigned to provide services to the community. A health post will be considered functional even if the physical health post structure has not been constructed.

convulsions, vomiting everything, not eating or drinking); fever/malaria; cough, fast/difficulty breathing, pneumonia; diarrhea/vomiting; ear problem; measles; nutrition or feeding problems;

- i. Initial consultation: the first time the patient has been seen at the health post or by either of the HEWs (including in the home/community) for the current illness episode;
- d. Data collectors will ask caretakers the following screening questions about the children:
1. How old is this child?
 2. What is wrong with this child?
 3. Is this the first contact with these HEWs for this illness?
 4. What is the caretaker's relationship to the child?
 5. How old is the caretaker?
- Note: If a caretaker has more than one sick child, then each child is treated as a separate child and screened separately. A caretaker can have more than one child included in the survey.
- e. Recruited patient consultations: In cases where fewer than two eligible children spontaneously present at a health post for consultations on the day of data collection, data collectors will recruit up to two sick children in the surrounding community to receive consultations by the HEWs. Children recruited for consultations will have to meet the same eligibility criteria as children spontaneously presenting at the health post. Additionally, the child may not have already received a consultation from any appropriate health care provider (government health facility, HEW or private health clinic) for this illness episode.
- f. Data collectors will observe/re-examine a maximum of five consultations/patients per health post.

3.3. Sampling & Sample Size

The study will be a randomized cross-sectional survey, with stratification by intervention and comparison arms. The sampling frames will be made up of all functional health posts within both intervention and comparison woredas in the two zones and will be obtained from the zonal health bureaus. Selection of health posts within each stratum (intervention and comparison areas) will be made through systematic random sampling.

The study will not be powered to conduct hypothesis tests, such as testing for differences in levels of various indicators between intervention and comparison areas. With the proposed sample size, we will be able to provide reasonably precise estimates of the variables of interest for the intervention woredas. In the comparison woredas, a smaller sample will be chosen that will allow for less precise estimates of values of indicators of CCM implementation strength for assessment of the routine HEP CCM program as a contextual factor.

Some indicators, such as drug stock-outs, supervision, etc. will be calculated at the health post level. Other indicators, such as training of HEWs and the proportion of patients to receive correct assessment, classification and treatment, will be calculated at the HEW level and patient level, respectively. Since there are generally two HEWs per health post and there should be at least two patients observed/re-examined per health post, determining the sample size based on a sample of health posts will guarantee a large enough sample size for indicators at the health post, HEW and patient levels.

Most of the indicators of interest are proportions. We will assume that the proportions of the variables of interest (e.g. proportion of health posts with no stock-outs in the previous three months) are 50%, as this will give the most conservative sample size. Alpha will be set at 0.05. Since the sample size is based on health posts and all health posts in the sampling frame have an equal probability of selection, it is not necessary to include a design effect to account for clustering. Clustering of HEWs and patients within health posts will be present, but this effect is expected to be small (because of the expected small number of HEWs and consultations per health post) and will be accounted for by the fact that there should be two HEWs and at least two sick child consultations per health post. Finally, non-response of 5% will be factored in for the sample of health posts. Non-response is expected to be low, since we will need only one out of two HEWs to be present to carry out the survey and HEWs will be informed beforehand that they will need to be present at the health post on a given day. We will assume a design effect of 1.3 for HEW-level and patient-level indicators and non-response of 10%.

Table 3 below presents the sample sizes needed at varying levels of precision. Precision will be set at +/- 10%, which should be feasible in terms of budget and still provide meaningful estimates.

Table 3: Sample size required in the intervention woredas at varying levels of precision

Health Post-level Indicators (Proportions)			HEW or Patient-level Indicators (Proportions)		
Precision	Sample size (# of HPs)	Sample size (# of HEWs)	Precision	Sample size (# of HEWs/ patients)	Sample size (# of HPs)
.05	406	812	.05	557	279
.06	282	564	.06	386	193
.07	207	414	.07	284	142
.08	159	318	.08	219	110
.09	126	252	.09	172	86
.1	103	206	.1	141	71
.11	85	170	.11	116	58
.12	71	142	.12	97	49
.13	60	120	.13	83	42
.14	52	104	.14	71	36
.15	46	92	.15	63	32
Assumptions: - Confidence level = 0.95 - Proportion = 50% - Design effect = 1 - Non-response = 5%			Assumptions: - Confidence level = 0.95 - Proportion = 50% - Design effect = 1.3 (assuming four consultations per HP) - Non-response = 10%		

Given the decision to set precision at .1, a sample of 104 health posts will be selected in the intervention woredas. With a sample size of 104 health posts (208 HEWs), we will be able to make estimates of HEW-level indicators at a precision level of .09. Patient-level indicators will have even greater precision if the average number of patients per health post is greater than two.

A smaller sample of 46 health posts will be selected in the comparison woredas. This smaller sample will provide estimates of health post-level indicators for the comparison area with precision of +/-15%. This sample size should allow for relatively precise estimates of HEW-level indicators (e.g. proportion trained in iCCM). A total of 150 health posts will be surveyed.

3.4. Data & Indicators

The data collected will comprise core indicators of implementation strength, as well as indicators on demand-generation activities, utilization and the quality of services provided by HEWs. The specific elements to be assessed will be:

1. Access and availability of deployed HEWs
2. Training of HEWs in iCCM
3. Availability of essential iCCM commodities (drugs and essential equipment and supplies)
4. Supportive supervision of HEWs
5. Demand-generation activities
6. Utilization of health posts/HEWs
7. Quality of services provided by HEWs

Appendix 2 provides the full list of indicators to be assessed in the implementation snapshot.

3.5. Study Procedures

3.5.1. Development of Study Protocol and Tools

The study protocol and tools have been developed by the IIP-JHU study team, in collaboration with researchers from ABH Services, PLC (ABH), an Ethiopian research firm that has been contracted for data collection; UNICEF; iCCM program implementation partners; and the Oromia Regional Health Bureau (ORHB). This work is an iterative process and involves periodic field testing to ensure that the tools are accurate, complete and appropriate. ABH will be responsible for translation of the protocol, training guide and tools into Afan Oromo (the local language of Oromia). Back translation into English will be carried out to ensure accuracy of the translation. The survey questionnaire is available in Appendix 3.

3.5.2. Pre-testing

Once near-final versions of the protocol and tools are completed, a pre-test will be carried out in health posts in Oromia (near Addis Ababa). The field test will attempt to approximate actual data collection procedures. At least two survey teams will carry out the pre-test for three days. Following the pre-test, necessary changes will be made to the questionnaire, protocol and training materials.

3.5.3. Training Survey Personnel

Training will be held over six days. Instruction will be led by ABH and will be conducted mostly in Amharic and Oromifa. IIP-JHU researchers will participate in the training with translators. The training will cover the study procedures, the questionnaire, data collection techniques, iCCM clinical guidelines, quality assurance procedures and study ethics. The training will include simulations and practice of the data collection procedures. Training materials will be prepared by IIP-JHU and ABH. A greater number of data collectors will participate in the training than will be needed for data collection. This will allow us to

select the best-performing data collectors as well as leave some trained data collectors as reserves. Concordance testing will be conducted to assess observation/re-examination skills of data collectors and training will continue until there is at least 90% inter and intra-observer agreement.

3.5.4. Piloting the Survey

Following the in-class training, the survey will be piloted to test the survey procedures and tools and to further train the survey personnel under conditions that simulate the actual survey. The pilot will include all data collectors and supervisors that participated in the training. The pilot will follow the exact procedures of the study to replicate actual data collection to the extent possible.

3.5.5. Data Collection

Survey Personnel

Six survey teams will be deployed for data collection. Each team will be made up of one supervisor and two data collectors. The two data collectors will be separated into observers and re-examiners. Re-examiners will be clinicians (nurses or medical students) who are trained in IMCI and iCCM so they can carry out clinical re-examination of sick children for the assessment of quality of care. Data collectors will not carry out data collection in the same woreda in which they normally work to avoid bias. Two coordinators (one for each zone) will plan and oversee data collection and will be responsible for organizing the survey and monitoring the progress of survey teams. Finally, study researchers from IIP-JHU and ABH will provide supervision, quality control and support to data collection teams and the coordinators. ABH will be responsible for recruiting and hiring survey personnel and other human resources matters.

Data Collection Procedures

- a. Data collection is expected to last approximately 32 days. As health posts are generally closed on weekends, survey teams will collect data Monday through Friday and rest and travel during weekends. Each survey team must complete one health post per day (5 per week), including data collection and travel time.
- b. HEWs will be notified of upcoming study visits and will be told the exact date of the visit. Informing HEWs of a coming visit may introduce a bias, as they may make special preparations for the assessment. However, since HEWs are supposed to spend much of their time in the communities, there could be a large non-response due to absent HEWs if they are not informed and told to be present. Additionally, utilization of health posts for clinical services is low and it is highly unlikely that we would achieve a sufficient sample of sick children with unannounced visits. To overcome this limitation, HEWs will be instructed to mobilize caretakers of children in their catchment area to bring sick children to the health post on the day of the survey visit.
- c. With the exception of indicators of access and availability of HEWs, for which data will come from the zonal health bureaus, all data will be collected within the health posts.
- d. On the day of the survey visit, survey teams will arrive at each health post before regular working hours begin (e.g., arrive at 7:30am). Survey teams will carry a letter from the Oromia Regional Health Bureau and/or zonal health bureau specifying the purpose and nature of the assessment.
- e. All HEWs working in selected health posts will be included in the data collection. The survey team

will meet with the HEWs and introduce themselves and explain the purpose of the visit (emphasizing that results will be used to assess and improve health services—not to individually assess or punish HEWs). The supervisors will ask each HEW to give verbal consent to participate in the study. The survey team will explain that after patients are re-examined, the treatments prescribed to the patient and other care may be altered if the HEW's prescription was not consistent with the gold standard re-examination.

- f. *Enrolling children:* As patients arrive to the health post, the supervisor will screen the children. First, he/she will ask the age of the patient. If the patient is between 2 months and 59 months of age, the supervisor will ask what the child's complaints are and if this is the first consultation the patient has received from these HEWs for this illness episode. The supervisor will also ask the age of the caretaker and their relationship to the child. See enrollment cards in appendices 4-5. If the child is eligible and the caretaker can give consent, the supervisor will read the informed consent in Afan Oromo and request verbal consent. The supervisor will fill out an enrollment card for each eligible child and record whether the caretaker accepted to participate in the study. At the end of the day, the team will use the enrollment cards to confirm the total number of initial consultations performed at the health post that day and the number of refusals (and the supervisor will record these numbers).
- g. *Health post information:* Prior to the first consultation, the team will ask the HEWs to provide basic information about the health post and the HEWs. This information will be entered in the Health Post Questionnaire Panel. One Health Post Questionnaire Panel will be completed per health post.
- h. *Observation of the consultation:* The supervisor will randomly select (with a coin toss) one of the HEWs to provide the first consultation with an eligible patient. The observer will silently observe the consultation and use the Observation Checklist to record the HEW's assessment, classification, treatment and counseling of the patient. At the end of the consultation, if all information is not clear, the observer may ask the HEW: 1) what the patient's diagnoses are and 2) what treatments were given to the patient during the encounter. If the patient leaves the HEW at some point during the consultation (e.g. to receive treatment from the other HEW), the observer will follow the patient and continue to observe the consultation. One Observation Checklist will be completed per eligible patient.
- i. *Caretaker exit interview:* Once the HEW's consultation is completed, the observer will take the patient and caretaker to a separate location away from the HEW. The observer will ask the caretaker about the medicines that were prescribed for home treatment to assess the caretaker's understanding of the prescription. The caretaker will be asked to explain the dose, schedule and duration of the treatments, as well as when to return for follow-up.
- j. *Patient re-examination:* The re-examiner will perform a re-examination of the patient using the Re-examination Form and will closely follow the Ethiopia iCCM guidelines. The re-examination will be used to obtain gold standard classifications and treatment with which the HEW's classifications and treatment will be compared. One Re-examination Form will be completed per eligible patient.
- k. *Malaria testing:* If a rapid diagnostic test (RDT) is performed by the HEW, the observer will record the result of the test and whether the HEW performed the test correctly. During the re-examination, if an RDT is required according to the iCCM guidelines, the re-examiner will see if an RDT was

performed by the HEW. If the RDT was performed correctly, the re-examiner will use the result of the HEW's RDT in the re-examination. If the RDT was not performed by the HEW when it was indicated or if the RDT was performed incorrectly, the re-examiner will perform an RDT for the child and record the result for the gold standard classification.

- l. Before releasing the patient, the re-examiner must check the treatment prescribed by the HEW. If a patient received incorrect treatment or did not receive a needed treatment, the re-examiner should discuss the error with the HEW and ensure that the patient receives all needed treatments and only needed treatments. If any needed treatments are out of stock in the health post, the re-examiner will provide the treatments from a reserve supply that will be carried by the survey team.
- m. When the first patient has received a consultation by the HEW and a re-examination, the next eligible patient will receive a consultation by the HEW that did not perform the first consultation. The patient will then receive re-examination. This procedure will continue up to a maximum of five patients.
- n. Children observed with life-threatening illnesses will receive facilitated referral to a health facility.
- o. During periods when at least one of the HEWs and at least one of the data collectors are not occupied with patients, the free data collector can work with the free HEW to complete the Equipment, Supplies and Support Checklist and the HEW Questionnaire. When all patients waiting for consultations have been attended to, both data collectors will work with the HEWs to complete the Equipment, Supplies and Support Checklist and the HEW Questionnaire. If more patients arrive during this time, the HEWs and data collectors will attend to the patients (consultations and re-examinations) and then return to the other sections when there are no more patients.
- p. *Equipment, Supplies and Support Checklist:* The data collectors will ask the HEWs to show them all drug stocks and other iCCM supplies and equipment. The data collectors will complete the Drugs and Supplies Module by observing iCCM drugs, diagnostics, supplies, equipment and job aids. Since stock cards are unlikely to be available, stock-outs of drugs and diagnostics in the previous three months will have to be assessed based on the HEWs' recall. The Services and Support Module will be completed by the data collectors based on the HEWs' answers to questions about the functioning of the health post, VCHWs, supervision received and referral of severely ill children. One Equipment, Supplies and Support Checklist will be filled out per health post.
- q. *Register review:* Data collectors will complete the Health Post Records Module based on information recorded in the iCCM registration books. Details on sick child consultations in the previous month will be recorded. Then, data for the last 10 initial consultations of sick children 0-2 months of age and the last 10 consultations of sick children 2-59 months of age will be extracted from the patient registers.
- r. *HEW Questionnaire:* Data collectors will interview each HEW to complete the HEW Questionnaire. HEWs will provide information on their socio-demographic background, their history as an HEW and their time allocation. One HEW Questionnaire will be completed per HEW.
- s. After the initial period at the health post, the supervisor will try to estimate how many children are likely to show up at the health post for routine consultation during the morning session. If he/she expects fewer than two children, then the supervisor will recruit additional sick children from the

community so that the total number of observations/re-examinations, including both spontaneous and recruited consultations, is equal to two. The supervisor will recruit a representative from the community (e.g. a volunteer community health worker) to lead them to households that have children aged 2-59 months. The supervisor will ask the caretaker if any child in the household is currently ill. If a child is experiencing any of the signs/symptoms that satisfy the eligibility criteria, then the caretaker will be asked if the child has already received care for the illness. If the child has received care from these HEWs or another government health facility or from a private health clinic, the child will be excluded from the study. If he/she has not received care from one of these sources, the caretaker will be asked if he/she is willing to take the child to the health post to receive a consultation by the HEW and a re-examination. If the caretaker agrees, the consent script for recruited children will be read and the caretaker will be asked to give consent. The child will then be brought to the health post and will undergo consultation with observation and re-examination as detailed above. The caretaker will also be asked if the child has already received any treatments for the illness to avoid over-medication. Ineligible sick children visited by the supervisor will receive an examination by a clinician if the caretaker agrees. No data collection will occur during this examination. Children with life-threatening illnesses will receive facilitated referral to a health facility.

- t. Data will be entered by data collectors as it is collected using tablet computers.
- u. Once all data collection is finished in the health post, the team will thank the HEWs and provide feedback to the HEWs. Before leaving the health post, the supervisor will review all data collected in the health post to ensure completeness and consistency of the data. Any missing or inconsistent data will be rectified before leaving the health post. The team will then proceed to the next health post. The team should sleep close enough to the next health post that they can arrive at the health post before the opening time.
- v. The procedures above apply to health posts in the intervention woredas. For selected health posts in the comparison woredas, data collectors will **not** carry out observation of consultations, caretaker exit interviews or re-examination of sick children. All other procedures will be the same as in the intervention area.

3.5.6. Quality Assurance

Survey personnel at each level will be assigned with certain tasks and responsibilities to ensure data quality.

Data collectors:

- Review completed forms for accuracy, completeness and consistency immediately following data collection (e.g. after each consultation).

Supervisors:

- Edit each completed questionnaire for completeness and consistency before leaving the health post;
- Note missing data or potentially incorrect recording of key variables, and ensure that these omissions or errors are addressed, where possible;
- Observe data collection by surveyors to ensure that it is properly conducted, that the questions are

- asked correctly and that responses are recorded correctly;
- Provide help to surveyors to resolve problems that arise in the course of data collection, to understand key concepts contained in the tools or to resolve difficulties that may have arisen in the course of data collection;
- Meet with surveyors to review all forms completed that day and to discuss any problems, challenges or questions and solutions.

Study researchers/senior supervisors:

- Check randomly selected health posts to ensure that the data collectors have visited the correct health posts and correctly completed data collection;
- Observe data collection by data collectors to ensure that it is properly conducted, that the questions are asked correctly and that responses are recorded correctly;
- Provide help to data collectors to resolve problems that arise in the course of data collection, to understand key concepts contained in the tools or to resolve difficulties that may have arisen in the course of data collection;
- Meet with data collectors to review completed forms and to discuss any problems, challenges, questions and solutions.

The utilization of tablet computers for data collection allows for additional quality control measures. During observations of HEWs' consultations, the observer will record the audio of the consultation on the tablet. This will allow the observer to review the audio to ensure that answers were recorded correctly or to review questions that were missed during the initial observation. Likewise, re-examinations will be recorded and can be used to ensure correct answers. Supervisors will also review the audio recording for a sample of consultations and re-examinations to ensure that the questionnaire was filled out correctly.

The tablets are also equipped with a camera, which can be used to capture patient registers that are reviewed. Data collectors and supervisors can use this to ensure that the information extracted from the registers is correct.

The audio recordings and cameras will also allow study researchers to ensure that study teams have visited the correct health posts and have actually carried out the recorded number of consultations at each health post.

3.6. Data Management

Data entry will be conducted by the data collectors in the field using electronic tablets. The tablets will be password protected and data will only be stored on the tablet during data collection. Either at the end of each consultation or at the end of each day, the data collectors will review the survey data on the tablet and then the data will be transferred to the supervisor for their editing. Once reviewed, the supervisor will save the data to an encrypted folder on their password-protected laptop and back-up the data to an encrypted external hard drive. Survey data will be removed from the data collector's tablet once the supervisor has reviewed and secured the data. The data will be exported and sent to ABH via email. Data will also be stored on the supervisor's computer and on the encrypted hard drive for physical transfer to ABH.

3.7. Analysis

There will be four units of analysis for the indicators: health posts, HEWs, patients and health post catchment area population. These data will be aggregated for estimates at higher levels. A stratified analysis will be done to report results for all of the indicators for 1) the intervention woredas as a group and 2) the comparison woredas as a group.

Point estimates for each of the indicators will be calculated and compared to the targets for each indicator set by the program implementers. Binary measures, such as health post supervised in last three months (yes/no), will be calculated as proportions with 95% confidence intervals. Continuous variables, such as number of community activities carried out by HEWs in the last 3 months, will be reported as means and medians, with standard deviation and inter-quartile range. Population coverage indicators will be calculated per 1,000 children under five in each health post catchment area.

Bivariate and multivariate logistic regression analyses will be carried out to assess relationships between measures of quality of care of iCCM services and potential explanatory variables, adjusting for possible confounders. Planned outcome and potential explanatory variables for HEW quality of care are outlined in appendix 6. Likelihood ratios will be used to assess the fit of multivariate models. Point estimates and standard errors for HEW and patient-level variables will be calculated using the Taylor linearization method to account for clustering of HEWs and patients within health posts. This will adjust the standard errors to account for reduced independence due to clustering and provide more accurate confidence intervals. All analyses will be carried out in Stata 11.¹⁰

The study is not powered for hypothesis testing of a significant difference in implementation strength indicators between study areas. Estimates will also be calculated at the zonal and woreda levels to provide greater insight to implementers regarding which areas may be under-performing and require additional attention and resources. However, the small sample sizes for these areas will allow only for an imprecise estimate, so results should be interpreted with caution.

4. ETHICAL CONCERNS

4.1. Risks & Benefits to Subjects

Risks to study subjects for involvement in the surveys are minimal. Loss of time by HEWs and community respondents will be the main burden from participation. Clinical re-examination of sick children may involve additional discomfort to the child (e.g. weighing, MUAC, RDT). Undergoing clinical re-examination will require that children and caretakers spend additional time at the health post. The extra time for re-examination is likely to be around 15 to 30 minutes per child. The waiting time for consultations may also be increased as HEWs will be asked to wait until the data collector is available to observe the consultation. HEWs will have to spend extra time answering questions and therefore may lose time to carry out other tasks on the day of data collection.

No monetary benefit will be accrued by the respondents in the study. However, HEWs will receive feedback on their work, both immediately from the data collectors and when the survey results are

disseminated. Furthermore, the information obtained will be used to improve health service delivery in their communities. Sick children will receive a re-examination from a trained clinician that will closely follow the Ethiopia iCCM clinical guidelines, which should increase their chance of receiving appropriate care. Additionally, data collectors will ensure that drugs and RDTs are available for children, even if the health post is out of stock. Sick children recruited for consultations from the community will receive care from the HEW and a trained clinician, whereas otherwise they possibly would not have received any care at all. Children with life-threatening illness will receive facilitated referral to a health facility from the survey team.

4.2. Informed Consent

Informed consent will be obtained from all study respondents prior to any data collection. Data collectors will obtain verbal consent from HEWs in surveyed health posts, from caretakers of children who are observed receiving consultations in the health posts and from caretakers of children who are selected from communities to receive consultations from HEWs. To give consent, a caretaker must be a parent or legal guardian and at least 18 years of age. If the caretaker is under 18 years old, the supervisor will attempt to obtain permission from the caretaker's parents and assent from the caretaker.

Consent forms will be read in Afan Oromo. The consent forms will clearly explain that participants are free to refuse to participate in the study or to participate in specific portions or to answer specific questions. HEWs will also be informed that their confidentiality will be protected and there will be no negative consequences from refusing to participate or because of their individual performance during the assessment. See appendices 7-13 for the consent forms, parental permission forms and assent forms.

4.3. Costs & Compensation

There will be no monetary compensation for the respondents and the respondents will not incur any out-of-pocket costs.

4.4. Confidentiality Assurances

Sensitive and personal information on child health and illness may be collected from caretakers. Information about HEWs' work practices or other personal details that they may not want others to know will be collected. Confidentiality of every participant will be protected. Information on individual participants will only be available to the study team. All data will be stored on password-protected computers with access only to the investigators. The data set will be made available for public access two years after the major results are published.

4.5. Intervention in Case of Life-Threatening Action

If a data collector is observing sick child consultations and the data collector determines that the HEW's actions could threaten the life of the patient, the data collector will be trained to intervene and assist the HEW in giving correct treatment.

4.6. Ensuring Appropriate Care

Children that are observed and re-examined will receive the treatment recommended by the gold standard re-examination. If the treatment prescribed by the gold standard re-examination differs from that prescribed by the HEW, the gold standard treatment will supersede the HEW's prescription. Data collectors will carry a stock of iCCM drugs and RDTs in case the health post is out of stock.

4.7. Referring Participants for Care

If the study team encounters a life-threatening illness in a participant that cannot be managed appropriately in the setting where the observation takes place, study personnel will be instructed to do their utmost to assist in obtaining appropriate care for the child, including providing transportation to a higher-level health facility.

4.8. Data Security & Participant Confidentiality

Data will be collected electronically, so there will be no hard copies of the data. Tablet computers on which data will be entered will be password protected, as will the computers to which data is transferred. Personal identifiers will not be included in the database.

4.9. Conflict of Interest

There are no other gains from taking part in this study other than the normal scholarly gains.

4.10. Ethical Clearance

Ethical approval will be sought from the Institutional Review Boards of the Johns Hopkins Bloomberg School of Public Health and the Oromia Regional Health Bureau.

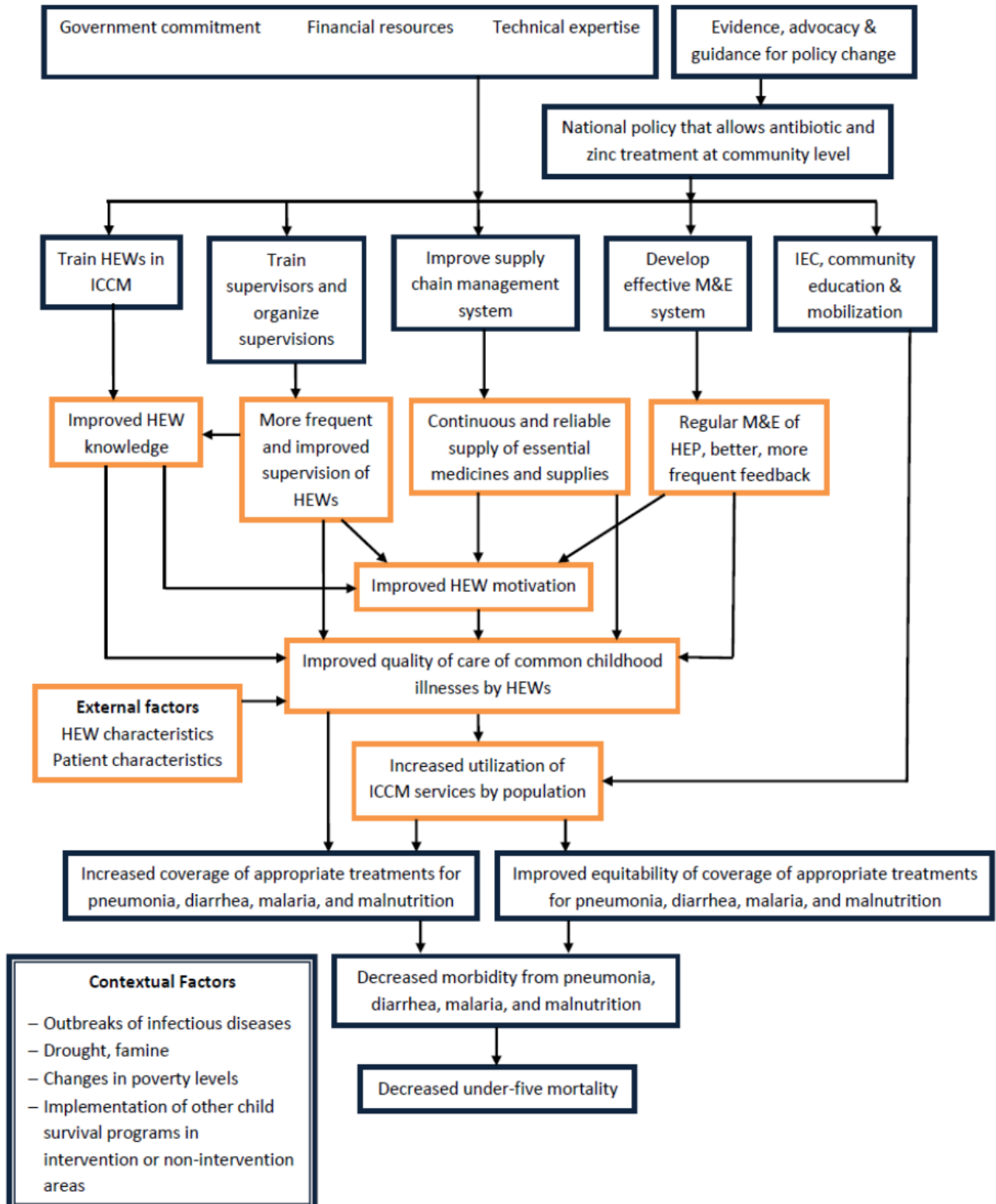
5. TIMELINE

Activity	Description	Deadline
Finalize draft survey protocol and tools	Work with IIP-JHU to produce survey protocol, tools and training manuals. The protocol, questionnaire and other materials will be provided by IIP-JHU. The firm will be asked to assist with final review and revisions only.	February 10, 2012
Obtain list of all HPs in survey zones	Obtain the list of health posts in the study areas in Jimma and West Hararghe zones to be used as the sampling frame for sampling of health posts.	February 17, 2012
Randomization of health posts	Randomly select health posts.	February 17, 2012
Translate survey tools and training manuals	Contract a translator and ensure quality translation (including back translation) of the survey questionnaire and other survey materials.	February 24, 2012
Recruit survey	Recruit data collectors and supervisors. Data collectors	March 2, 2012

personnel	performing clinical re-examination must be IMCI-trained clinicians (nurses, medical students, etc.). All survey field personnel must be fluent in Afan Oromo.	
Contracting and financial payments	Sign contracts with survey personnel, vehicle rental and training venue and ensure timely payments.	March 2, 2012
Manage and coordinate pre-test of survey tools	Manage and coordinate a three-day pre-test of the survey tools in non-study health posts in Oromia.	March 9, 2012
Finalize survey tools	Make revisions to questionnaire and protocol and other tools and finalize materials.	March 9, 2012
Finalize training materials	Work with IIP-JHU to finalize training manuals and other training materials.	March 9, 2012
Train survey personnel	Conduct a six-day training of survey personnel on the survey protocol, data collection procedures, supervision, and quality assurance.	March 16, 2012
Obtain local and JHSPH IRB approval	Obtain final ethical approval from the appropriate IRBs.	March 16, 2012
Manage and coordinate survey pilot	Manage and coordinate a three-day pilot of the survey in non-study health posts in Oromia. The pilot may be done in two three-day sessions, so that trainers can observe all of the data collectors during the pilot.	March 23, 2012
Manage and coordinate data collection	Manage and coordinate all aspects of data collection, including composition of survey teams, scheduling, logistics, and communications.	April 27, 2012
Supervision and quality assurance	Provide adequate supervision and quality control measures to ensure that survey procedures are adhered to and data is of high quality.	April 27, 2012
Data management	Data will be entered electronically in the field. The firm will have to ensure safe delivery of data to headquarters and carry out data cleaning and coding and prepare the data for analysis.	May 4, 2012
Data analysis	Carry out preliminary data analysis, including analysis of descriptive indicators.	May 11, 2012
Produce preliminary survey report	Produce a preliminary report describing the data collection process, limitations of the results, and results of the preliminary data analysis.	May 18, 2012
Feedback meetings	Present initial study results to stakeholders.	May 25, 2012
Produce final survey report	Revise comments on preliminary report and produce a final report.	June 1, 2012

6. APPENDICES

Appendix 1: ICCM impact model



7. BIBLIOGRAPHY

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