Quality of case management for common childhood illnesses provided by Health Surveillance Assistants (HSAs) in Malawi

Concept note and assessment plan

v. 8 July 2009

1. Rationale

Globally: Many countries are scaling-up high-impact child health interventions in order to accelerate progress toward the Millennium Development Goal (MDG) 4—to reduce under-five mortality by two-thirds by 2015. Community-based delivery of services and interventions through trained community health workers (CHWs) has received renewed global interest as a strategy to expand access to effective interventions, including treatment of childhood illnesses.[1]

Despite effective interventions to prevent and treat child illness, pneumonia, malaria and diarrhea account for over 50 percent of child deaths in sub-Saharan Africa.[2] Community case management (CCM) is a strategy in which trained CHWs assess symptoms, classify illness and treat common childhood illnesses, such as pneumonia, malaria and diarrhea with antibiotics, antimalarials, ORS and zinc. Studies have shown this approach can have large impacts on childhood morbidity and mortality.[3-9] A meta-analysis of community-based trials of case management of pneumonia in infants and preschool children showed a 24% reduction in mortality.[9] Recent studies in Bangladesh have also shown significant reductions in neonatal mortality with CHW home visits after birth.[10,11]

Evidence about integrated CCM (iCCM) for multiple illnesses, such as pneumonia, malaria and diarrhea, is relatively limited, especially in programmatic settings in sub-Saharan Africa.[12] In a small-scale project in Kenya, an evaluation demonstrated that CHWs adequately treated 90.5% of malaria cases but had difficulties in classifying and treating sick children with pneumonia and severe illness.[13] In Sudan, CHW classification rates were found to be similar to those in facilities.[14] Few documented experiences exist related to the implementation of iCCM programs at scale in sub-Saharan Africa. There is a recognized need for further evidence related to the quality of iCCM services delivered by CHWs, as well as documentation of operational strategies and processes related to the scale-up of iCCM programs.[1,12]

Malawi: National plans for scaling-up interventions to reduce mortality and improve health among mothers, newborns and children (MNCH) in Malawi have attracted international attention and support. A central strategy of the MNCH scale-up in Malawi is the provision of additional training and support to Health Surveillance Assistants (HSAs, a cadre of community-based workers) to provide high-quality iCCM services for children with pneumonia, malaria and/or diarrhea at the community level. The training of HSAs to provide iCCM services started in late 2008 and the full complement of processes to supervise and support HSAs are still in the early stages of development and deployment.

Canadian CIDA and the Bill and Melinda Gates Foundation have commissioned the Institute for International Programs at The Johns Hopkins University (IIP/JHU) to work with the MNCH Core Implementation team and research institutions in Malawi to design an evaluation of the MNCH scale-up. One key aspect of this broader evaluation will be an assessment of the quality of iCCM services provided by HSAs in the community. Standard protocols exist to evaluate the quality of services provided to sick children at first-level health facilities.[15-20] However, no equivalent set of standard evaluation methods exists for the community level that produces valid results across a variety of settings and contexts. IIP/JHU therefore proposes to work with its in-country counterparts, the Centre for Social Research (CSR) at the University of Malawi and the National Statistics Organization (NSO), and the MNCH Core Implementation team to develop and apply a set of standard assessment methods and tools to

determine the quality of iCCM services provided by HSAs. Assessing HSAs early in the implementation of iCCM in Malawi will also provide interim feedback to the Government of Malawi and the implementing partners about quality of iCCM services. The final methods and tools will serve as a basis for the development of generic tools that will be adapted for use in other countries scaling-up iCCM programs.

2. Objectives

IIP/JHU and CSR will work with the Core Implementation team to describe the quality of care for children ill with pneumonia, malaria and/or diarrhea as provided by HSAs. The specific objectives of this sub-study include:

Objective 1: To determine the quality of care provided to sick children for pneumonia, diarrhea and malaria by HSAs in Malawi;

Objective 2: To describe the processes in place to ensure the quality of iCCM services provided by HSAs, including training, drug supply, and supervision;

Objective 3: To estimate the cost of care for childhood illnesses provided by HSAs.

3. Methods

3.a. Guiding definitions and frameworks

Definition of Community Case Management: Integrated community case management (iCCM) is defined for the purposes of this study ***as management, including assessment, classification and treatment, of childhood illness, carried out by a paraprofessional worker in the community and not based at a fixed health facility.*** In Malawi, we will examine the quality of services delivered by HSAs in the management of pneumonia, malaria and diarrhea, as well as referral of children with danger signs. Pneumonia, malaria and diarrhea are leading causes of death in Malawi,[2,21] and thus we have chosen to focus on the management of these illnesses. Other aspects of the HSAs' responsibilities,[*] such as management of eye infections or promotion of hygiene practices, will be included only where appropriate.

Dimensions of quality of iCCM services: The Quality Assurance Project defines nine dimensions of quality (box 1),[22,23] which can also apply to services delivered in the community. The primary focus of our work will be ***technical performance*** of HSAs in delivering iCCM services, as measured in relation to WHO standards. We will also examine some aspects of ***continuity, comfort, choice and interpersonal relations***. Other components of the independent evaluation of the MNCH rapid scale-up will measure the ***access, effectiveness*** and ***efficiency*** of CCM services on a population level. The safety of CCM services is outside the scope of the evaluation, as CCM services are limited to simple, proven treatments shown to have limited side effects.

Processes necessary for quality CCM services: A number of processes need to be in place for HSAs or other community-based workers to be able to deliver quality iCCM services to sick children. Figure 1 presents a conceptual model showing the processes necessary, but not always sufficient, for delivery of quality iCCM services. This framework builds on the common evaluation framework for the scale-up for MDGs 4 and 5,[24] and was developed specifically to guide this and other similar assessments of quality of care in the community. The processes enabling quality of care can be classified into four broad categories: 1) Human resources; 2) Training; 3) Drug supply; and 4) Quality assurance activities, such as supervision. Community engagement and functioning health systems at the facility level often influence

[*] HSA roles and responsibilities in areas outside of CCM will be determined in a parallel study to be undertaken under the broader umbrella of the IIP/JHU PMNCH-CI evaluation in Malawi.

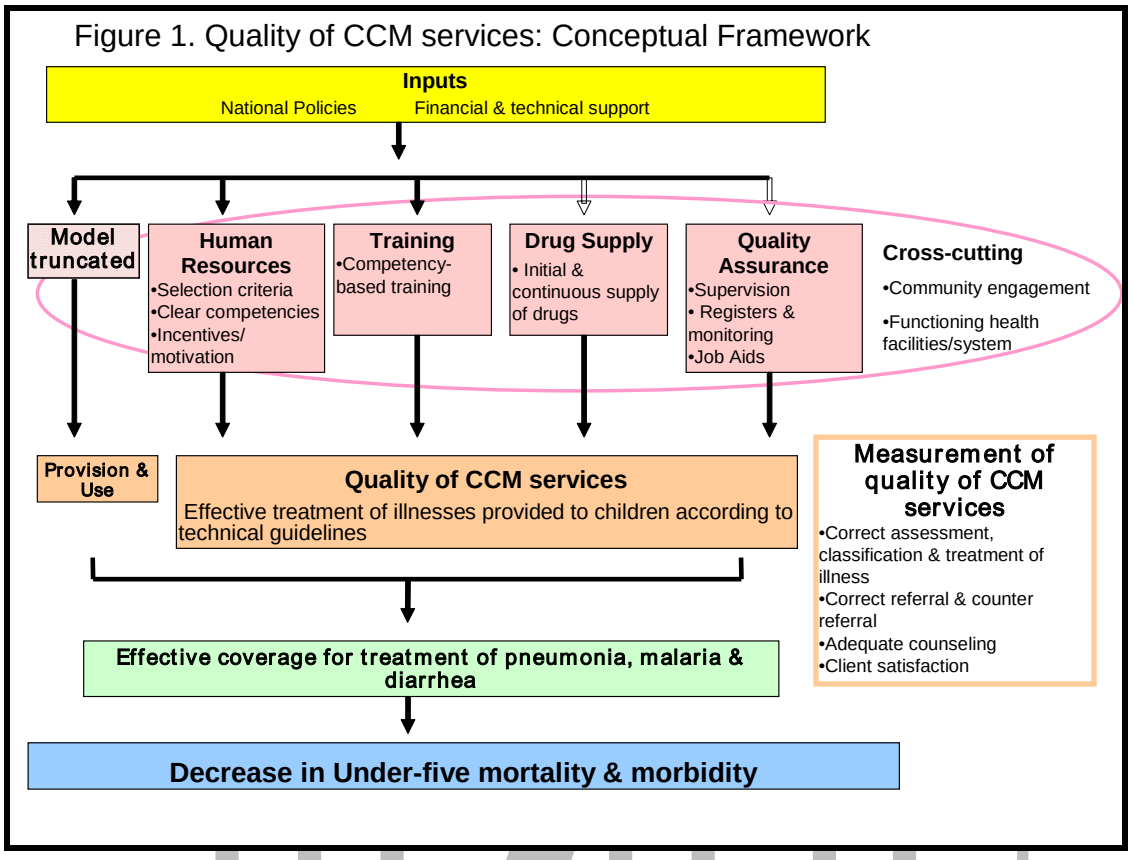
all these components in some way, and are thus shown as crosscutting issues and not in their own domain. Within this assessment, we will describe and quantify, where possible, the processes deployed to support high quality iCCM.

Box 1. Dimensions of quality*

1. **Technical performance**	Health workers follow technical standards
2. Access	Services are close, affordable, and in the right language
3. Effectiveness	Children using the services are getting better
4. Efficiency	Waste of time or materials is minimized
5. Safety	Risks of harmful side effects are minimized
6. Continuity	Delivery of care by the same healthcare provider throughout the course of care (when appropriate) and appropriate and timely referral and communication between providers
7. Comfort	The location of service is comfortable and private
8. Choice	As appropriate and feasible, client choice of provider, insurance plan, or treatment
9. Interpersonal relations	Effective listening and communication between provider and client; based on trust, respect, confidentiality, and responsiveness to client concerns

*As described by the Quality Assurance Project,[22,23] adapted for CCM programs by authors and CCM essentials (CITE)

Figure 1. Quality of CCM services: Conceptual Framework



3.b. Overall Design

The technical performance of HSAs in delivering iCCM services aggregated at the district and national levels will be assessed using a cross-sectional, observational design. We will use a stepwise design in which we first determine that the minimum requirements are in place in districts before initiating the assessment. The study will be carried out in six MNCH rapid scale-up districts included in the larger evaluation (Balaka, Chiradzulu, Phalombe, Kasungu, Ntcheu, Karonga).[†] This concept note limits its description to a cross-sectional assessment planned for 2009; however, we anticipate a similar, follow-up assessment later in iCCM program implementation (~2011) will be necessary to provide additional information to program managers and evaluators.

3c. Assessment of iCCM processes for entry of districts into quality of care study

Standard iCCM training for HSAs is on-going. Currently, many HSAs trained in iCCM have not yet received drug boxes with antibiotics for pneumonia, antimalarials and antipyretics to treat fever, and ORS and zinc for diarrhea. Other HSAs have incomplete drug boxes with only a few of the necessary drugs. To evaluate the quality of services provided to sick children in the community, HSAs must first be trained to provide iCCM services and equipped with an adequate drug supply.

Thus, as a first step we will determine the inputs and processes carried out to support iCCM services. This step will not involve any primary data collection, and will draw on the documentation at the

[†] The assessment may also be carried out among the six comparison districts (Mangochi, Chikwawa, Mwanza, Salima, Dowa, Rumphi) once CCM training and initial drug supply are adequate in those areas.

national and district levels carried out by the larger evaluation team in coordination with program managers. The assessment of quality of care provided by HSAs (described below), will only be undertaken in districts meeting minimum criteria. The criteria include:

➔ At least 15% of the target HSAs in the district trained in iCCM (e.g., a district of 400,000 population has a target of approximately 400 HSAs at one HSA per 1000 population. Thus, at least 60 HSAs trained in CCM fulfill the entry criteria.)

➔ At least 80% of iCCM-trained HSAs in the district have received initial drug stocks of antibiotics, antimalarials, antipyretics and ORS[‡]

The achievement of these criteria in each district will be assessed using information collected in the documentation activities, including review of training and program reports, supplemental questions included in a health facility survey and interviews with program managers. We anticipate that districts outside of the six MNCH scale-up districts (comparison areas) will not meet these criteria in the period of this assessment, but they may be included in a later assessment, tentatively planned for 2011.

3c. Measures of quality of care and selected processes

Quality of care measures: The quality of care assessment will focus on technical performance of HSAs in adhering to standard WHO guidelines in assessing, classifying and treating sick children (objective 1). We will also collect other complementary dimensions of quality, such as continuity, comfort and interpersonal relations. Table 1 presents the priority and supplementary indicators of quality of care. These indicators have been closely adapted from priority and supplemental indicators for IMCI at first-level facilities,[15] as well as vetted by the international CCM Operational Research Group (CCM.ORG) as part of a process to develop standard indicators and modules to assess iCCM programs globally.

[‡] Zinc is not currently available in Malawi, and the assessment may take place before extensive availability of zinc

Table 1. Indicators and measurement methods to assess quality of care

Domain	*Indicators*	*Measurement methods*
Technical Performance: Assessment	Proportion of children checked for three general danger signs (able to drink/BF, vomit everything, had convulsions)	Direct observation with re-examination
	Proportion of children checked for presence of cough, diarrhea and fever	
	Proportion of children assessed for presence of fast breathing through counting of respiratory rates	
	Proportion of sick children assessed for 4 physical danger signs+	
Technical Performance: Classification	Proportion of children whose respiratory rate was assessed by CHW with a discrepancy of + / - 3 versus the gold standard	Direct observation with re-examination
	Proportion of children whose classifications given by HSA match all the classifications given by IMCI-trained clinician/evaluator	
Technical Performance: Treatment	Proportion of children with cough and fast breathing who are prescribed an antibiotic correctly*‡	Direct observation with re-examination [Also register review where feasible]
	Proportion of children with fever who are prescribed an antimalarial (ACT) correctly*‡	
	Proportion of children with diarrhea who are prescribed zinc and ORS correctly*‡	
	Proportion of sick children treated and/or referred correctly for all illness classifications*‡	
	Proportion of children who need an antibiotic, ORS or zinc, and/or antimalarial who receive the correct first dose in presence of HSA	
	Proportion of children without cough and fast breathing who leave the HSA without having received an antibiotic*‡	
Continuity: Referral	Proportion of children with danger signs needing referral who receive correct pre-referral treatment and are referred	Direct observation with re-examination
Interpersonal relations: Counseling	Proportion of children who have had their vaccination status checked‡	
	Proportion of children with diarrhea whose caretakers are advised to give extra fluids and continue feeding‡	
	Proportion of children prescribed ORS and zinc, and/or oral antibiotic, and/or antimalarial who received at least dose and duration counseling messages about administering treatments‡	
	Proportion of children prescribed ORS and zinc, and/or oral antibiotic, and/or antimalarial whose caretaker can describe correctly how to give the treatment‡	Caretaker interviews
Comfort & choice: Client Satisfaction	Proportion of caretakers who report satisfaction ("services good as they are") with HSA services	Caretaker interviews

Notes:
+ Physical danger signs include chest indrawing; Palmar pallor; Red on MUAC tape; Swelling of both feet
* may also be assessed for consistency with illness assessment through register review
‡ among children not presenting with danger signs and requiring referral

Measures of processes to ensure quality of care: We will also collect information about essential processes that enable quality iCCM services (objective 2). These processes include iCCM training, adequate drug supply, and supervision of CCM activities. Table 2 presents the priority information and

indicators to be collected in this study. These will be complemented by qualitative and quantitative information on human resources, training, initial drug supply and quality assurance systems collected through documentation activities as part of the broader MNCH evaluation. Further information on documentation methods and indicators in Malawi is available upon request from Kate Gilroy (kgilroy@jhsph.edu) or Jennifer Callaghan (jcallagh@jhsph.edu).

Table 2. Indicators and measurement methods to assess processes to ensure quality of care

Domain	***Indicators***	***Measurement methods***
Human Resources	Socio-demographic profiles of CCM-trained HSAs sampled	HSA interview/ visit
	Proportion of time spent by CCM-trained HSAs in CCM activities	
	Average length of time since CCM training	
Drugs	Proportion of CCM-trained HSAs with ORS, zinc, antibiotics, antimalarial (ACT), and paracetamol present the day of visit	Observed during HSA visit
	Proportion of CCM-trained HSAs reporting a stock-out of ORS, zinc, antibiotics, antimalarial (ACT), or paracetamol in the previous 3 months	HSA interview/ visit
Quality assurance	Proportion of HSAs that received a CCM supervision visit within eight weeks of CCM training	HSA interview/ visit
	Proportion of CCM-trained HSAs that received at least one routine CCM supervisory visit in the previous three months	HSA interview/ visit
	Proportion of HSAs that have necessary materials (timers, sick child recording form, referral forms, counseling materials etc) on the day of the visit	Observed during HSA visit

Measures of the cost of care: We will also collect information about the cost of iCCM services (objective 3). Through direct observation, we will have data on the type and quantity of drugs provided; using price data we will estimate the cost of these drugs. We are also asking about the allocation of the HSAs time for treating childhood illnesses; this will enable us to apportion their salary accordingly. In addition, caretaker exit interviews will include questions about the costs borne by households seeking and receiving care from HSAs (and prior to the HSAs as well where that took place).

Data collection and tools: The quality of care assessment will include six components with distinct modules (forms): (1) Direct Observation with (2) Re-examination; (3) Caretaker Exit Interview; (4) Equipment and Supply Checklist; (5) HSA Socio-demographic and Background Information; and (6) Oral Case Scenarios. These forms are based on the WHO Health Facility Survey designed for evaluation of sick children in outpatient facilities according to IMCI.[15] They are adapted to follow the WHO training in iCCM for HSAs in Malawi. The purpose of each of these components and associated forms is described in table 3; the information they collect will be complementary to each other in evaluating HSA technical performance and other aspects of quality.

Table 3. Data collection instruments to assess quality of care and selected processes

Instrument	Description
Direct Observation and Re-examination (Form 1 & 2)	***Technical performance*** will be evaluated through a checklist that records correct assessment of danger signs, classification of illness, decision to refer or treat at home, treatment, and communication to the caretaker. The child will be re-examined by a trained clinician to provide a 'gold-standard' evaluation that will then be compared to the performance of the HSA. The first eligible sick children that present to the HSA for care on the day o f the evaluation team visit will be directly observed; therefore the type of cases will not be preselected.
Caretaker Exit Interview (Form 3)	***Interpersonal relations*** and ***comfort*** will be evaluated by interviewing caretakers on their satisfaction with the encounter. Correct caretaker understanding of child illness and treatment (including drugs dispensed, if any), as well as costs of seeking care for the child's illness and household information will also be assessed.
Equipment, Supply & Support Checklist (Form 4)	Data on ***processes*** that may directly affect the ability of the HSA to perform iCCM will be collected (e.g. drugs available, supplies, etc) through review of available equipment. ***Continuity*** and ***efficiency*** will also be assessed through questions posed to the HSA on supervision, referral process, and other ongoing services the HSA is required to provide to the community. The HSA's documentation in registers will also be reviewed. HSA ***technical performance*** of appropriate treatment will be evaluated based on written documentation of child age, illness classification, and treatment through record review, where feasible. The last 10 cases documented will be reviewed for correct treatment of illness, based on the documented classification.
HSA Background Information (Form 5)	Data on each HSA's background, education, training, roles and responsibilities, and work experience will be collected. This module includes questions on the time HSAs spend on iCCM and other activities.
Oral Case Scenarios (Form 6)	These scenarios will also evaluate ***technical performance*** through standardized cases, in order to complement those cases observed randomly during Direct Observation. They are designed to test the underlying knowledge each HSA must have, or be able to refer to, in order to manage a sick child correctly. These scenarios will focus on pneumonia, diarrhea, and malaria, and will range in severity of illness from commonly seen cases that can be treated in the community to more rare cases of severe illness requiring referral. The case scenarios will be read to the HSA by the evaluators and each HSA will be asked in an open-ended fashion how he or she would manage the child. In responding, the HSA will be allowed to use any information or reference that is normally available to him or her during consultations (such as Sick Child Recording Form).

<u>*Pilot test of study instruments:*</u> While iCCM training and drug distribution are in the start-up phase, we plan to conduct the pilot study described below as part of a post-iCCM training assessment. We will pilot test the study instruments in a post-training assessment in two districts, immediately following the six-day training of HSAs in iCCM. Each training is designed for 24 HSAs and all HSAs will be asked to stay an additional day for this assessment. HSAs who agree to participate will be provided with the same per diem as during the training. Training facilitators will also be asked to participate in the pilot study in order to serve as evaluators as well as clinical re-examiners for direct observation.

The pilot will be conducted at the local district hospital or outpatient health center utilized during the training. Four of the six evaluation methods will be utilized in the pilot—Direct Observation with Re-examination, Case Scenarios, and HSA Background Information. Information from the pilot will allow us to refine these evaluation instruments and to give feedback to the MOH on the quality of the training. We will then continue planning for the full-scale evaluation. The other assessment instruments (Caretaker Exit Interview, Equipment and Supply Checklist) will be pilot tested among approximately 10 HSAs in their communities before the full assessment takes place.

3.d. Sampling, sample size and enrolment

Sampling of HSAs for assessment: The sample of HSAs will be chosen using systematic random sampling, stratified by district. Districts meeting minimum criteria will be asked to provide a list of iCCM-trained HSAs to serve as the sampling frame for selection of HSAs. We may opt to sample using a probability of selection proportional to HSA utilization, if data describing the utilization of HSA services for sick child care are available at the time of sampling and HSA utilization rates vary widely.

Sample sizes of direct observations and HSAs: To calculate sample size and precision, we use the priority indicator of "Proportion of sick children treated and/or referred correctly for all illness classifications," which will include all cases directly observed. On average, we anticipate that each HSA will be directly observed managing three sick children.

A sample size of approximately 360 direct observations of sick children (among 120 HSAs) in the six MNCH intervention districts will provide adequate precision. Table 4 presents the precision for a range of point estimates and sample sizes. The estimates are centered on 75% adherence to guidelines, which was reported in a similar study conducted in Kenya.[25] The precision of these estimates is affected by the intra-class correlation coefficient at the HSA level.[26] An interclass coefficient of 0.25 (ρ), similar to found in other studies of health worker performance,[27,28] with a design effect of 1.5 given the cluster size of 3 consultations per HSA, was assumed to calculate the precision of point estimates. As shown in table 4, the precision of the point estimates will be relatively high if all consultations in the group of six districts are considered; however, district-level estimates or analyses of sub-groups of consultations, such as severe illness or sub-groups of HSAs, will have lower precision due to limited sample size.

Table 4. Precision for point estimates of the sensitivity of HSA classification of sick children, alpha=0.05

Point Estimate	n = 60 consultations among 20 HSAs	n = 360 consultations among 120 HSAs
	+/-	+/-
60%	15%	6%
70%	14%	6%
75%	13%	6%
80%	12%	5%
85%	11%	5%
90%	9%	4%

HSA enrolment: All sampled HSAs will be asked to give written consent to direct observation of their care of sick children (Form 1 and 2) and to an interview, including information about equipment and supplies (Form 4), background information (Form 5) and oral case scenarios (Form 6). Additionally, the HSA will be asked to show the interviewer specified drugs and supplies available the day of the visit. Evaluators (clinicians or interviewers) will ask HSAs to consent during a visit to their village, before any assessment activities would commence. We will work with MOH and district officials to ensure that HSA participation is voluntary and no punitive measures are taken against HSAs who decline participation.

Enrolment of sick children/caretakers: All caretakers of eligible sick children presenting to the HSA for care at the village clinic during the day of the evaluation team visit will be asked to consent to participate in the assessment (observation of sick child consultation, reexamination of sick child and caretaker exit interview). The following are necessary inclusion criteria for assessment of the consultation with a sick child:

a) the child must be sick;
b) the child must be at least 2 months and up to 5 years of age;
c) the child must be presenting with a new problem;
d) the child does not require urgent referral for a severe, life-threatening problem.

'Sick' is defined as having any of the following: cough, diarrhoea, fever, convulsions, feeding or nutritional problems, red eye, chest indrawing, fast breathing, sleepiness/unconscious, or other complaint. The first sick children meeting inclusion criteria and from whose caretaker gives consent will be included in direct observation with re-examination. Up to five children will be directly observed in one day per HSA. The evaluation team will be encouraged to observe as many sick children as time permits, up to five.

If a sick child meets inclusion criteria, the evaluators will ask for informed consent from the caretaker for direct observation of their sick child's consultation and the caretaker follow-up interview before the sick child consultation with the HSA in each village. The consent process will be verbal, with the consent form read in Chichewe to caretakers (usually mothers) of sick children. Sick children of caretakers who do not consent to participate in the assessment will be seen by HSAs as routine practice, but the consultation will not be observed by evaluators and no follow-up interview conducted. Sick children requiring urgent referral will not be enrolled in the study and the evaluation team will facilitate referral to the appropriate level of health care, in collaboration with district health authorities.

3.e. Carrying out the assessment

Evaluation Teams: Each team will consist of at least two evaluators. Evaluator #1 will have clinical training in at least IMCI and iCCM (such as a iCCM training facilitator). This clinical evaluator will serve as the 'gold-standard' for re-examination of the child. Evaluator #2 may have less clinical training, but must be trained in iCCM (such as a senior HSA). Both evaluators will be trained to carry out the remaining modules (Direct Observation, Caretaker Exit Interview, Oral Case Scenarios, and Register review). The evaluation team will carry out the assessment in a district separate from where they work on a daily basis in order to avoid bias. Each evaluation team will be dispatched to these districts during the evaluation period and will plan to spend one full day with each HSA in their typical place of work in order to carry out the assessment. We anticipate that six evaluation teams will be trained and deployed.

Training of evaluators: Training of evaluators will last approximately five days and include introductions to the survey instruments, role plays and practice observations and interviews. The specific conduct of the assessment (annex 2) will be discussed and agreed upon among the independent evaluation team, supervisors and assessment teams. The training content, timing and methods will closely follow the WHO health facility survey guidelines.[15]

Observer training will continue until the agreement of practice results of observers and trainers (Independent evaluation team) is greater than 90%. Likewise, clinical evaluators performing the gold

standard re-examination will be trained until the results of their practice re-examinations match the trainer's (CC) results.

Field work: The evaluation team will work with district and health center staff to obtain sampled HSAs' monthly workplans, and plan to visit each HSA for the assessment during a day planned for one of his or her "village clinics." HSAs normally conduct "village clinics" on certain days of the week in a public place in the village; they vaccinate and care for sick children during this dedicated time.

The evaluation team must determine how to most efficiently observe encounters with sick children (direct observation with re-examination) while also carrying out the other evaluation methods. A minimum of one direct observation with re-examination of a sick child per HSA is required, with a maximum of five direct observations. Therefore, upon arrival to the HSA's place of work[§], if a sick child is present immediately, the evaluation team should take advantage of this scenario and start with direct observation. However, if there are no readily available sick children, the evaluation team may choose to start with the oral case scenarios and register review while awaiting the arrival of a sick child (Appendix). Each evaluation team will be expected to visit one HSA per day, and will be dispatched to each district for one month's time. Therefore, each evaluation team will be expected to evaluate approximately 20 HSAs.

As the primary purpose of this study is to evaluate quality of iCCM services aggregated at the district and national levels, direct verbal feedback to the HSA will not be provided at the time of the assessment. This will ensure that poor-performing HSAs are not penalized for participation in the study and that the evaluators remain unbiased in their role as part of the study team.

Supervision of field work: Supervisors will participate in the training of the assessment evaluators and received an additional two days of training to ensure good and standard supervision practices. Supervisors will visit the evaluation teams at least once during their time in each district, or approximately every 10 days. Supervisors will conduct at least one "double" assessment—where the supervisor also observes the interaction using a separate checklist, and then compares with evaluator to see if there was consistency—in each district to check on the quality of observation and re-examination. Cell phone calls will be used for verbal supervision and checks every two days, as well as for problem solving.

In order to ensure the on-going standardization of observers and re-examiners, the assessment teams will receive an additional one to two days refresher training at a central location at the mid-point of the survey. Mid-point training and standardization will continue until inter and intra-observer agreement is greater than 90%.

3.f. Ethical considerations and informed consent

The consent process will consist of several stages. The evaluation team (JHU/IIP and CSR) will work in partnership with the Ministry of Health and health teams at the district levels. The objectives of the study and the data collection procedures will be explained in detail to the district medical officers and other members of the district health teams. At each participating health center and village, the study

[§] HSAs place of work is most often a village clinic; however, the location may be anywhere they treat sick children in the community, such as their home or public area in the village

and its objectives will be introduced in short meetings with health center staff, HSAs and community members. Opportunities will be given to ask questions or provide feedback on the assessment.

The evaluation team will explain the purpose of the study and ask for informed consent from the HSA at the start of the visit for direct observation, interviews and observation of the registers and supplies. The consent form will clearly explain to the HAS that his confidentially will be protected and no negative consequences will result from a refusal to consent. If a sick child meets inclusion criteria, the evaluation team will ask for informed consent from the caretaker for direct observation and the caretaker follow-up interview. Sick children requiring urgent referral will not be enrolled in the study and the evaluation team will facilitate referral to the appropriate level of health care. If a child with a severe illness needing referral is identified through the re-examination, and this child has not been referred by the HSA, the evaluators will be trained in procedures developed with the MOH to ensure that the child reaches the referral centre. In such cases, no further observations will be made of the care provided by the HSA.

3.g. Data entry and management

Assessment forms will be verified for completeness and consistency in the field by supervisors and the independent evaluation team. Assessment forms will be collected from evaluation teams on a regular basis, using the best strategy agreed upon during training. All assessment data forms will be coded and entered at the Centre for Social Research in Zomba in Epi-Info or SPSS.

3.h. Analyses

Proportions and 95% confidence intervals will be calculated for the priority indicators shown in tables 1 and 2. The WHO IMCI health facility survey provides detailed instructions on the calculation of these indicators.[15] The primary unit of analysis will be each sick child consultation; 95% confidence intervals will take into consideration the intra-class correlation coefficient at the HSA level.

4. Timeline

May 2009 – Revision of protocol and tools by evaluation team

June-July 2009 – Documentation of HSAs trained in CCM by district, with drug box availability
Revision of protocol and tools by Core Implementation team
Submission to IRB

July-August 2009 – Conduct Pilot Study, Analyze pilot data; feedback to MOH
Assess readiness of HSAs (e.g. drug boxes in place) for full scale quality of care evaluation

August 2009 – Training of evaluators (observers & clinical re-examiners)

September-October 2009 – Carry out full quality of care evaluation

November 2009 – Analysis and dissemination

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Appendix

Example of logistics for evaluation of one HSA and 3 sick child encounters in one day

Hour	Activity
0800	Evaluation team departs central health facility for HSA place of work.
0930	Arrival at HSA's place of work (home, village clinic, etc) to carry-out assessment. Explanation of study and informed consent of HSA obtained.
1000	No sick children are immediately available for evaluation. Therefore, Evaluator #1 explains the interview and oral case scenarios and begins assessment. Simultaneously, Evaluator #2 reviews the HSA's registers.
1100	Sick child #1 arrives. Evaluators determine if inclusion criteria are met. Informed consent is obtained from the caretaker.
1130	Evaluator #2 directly observes the encounter between the HSA, the caretaker and the child. Evaluator #1 is not present nor visible during this encounter.
1215	Evaluator #1 takes the sick child aside for re-examination. If caretaker allows, she/he will be interviewed separately by Evaluator #2. If not, the caretaker exit interview will take place immediately following the re-examination of the child.
1245	Debriefing; if any glaring errors made by the HSA that may endanger the child are present, these will be explained to the caretaker and appropriate action taken. If not, the caretaker and the child will be excused.
1300	Sick child #2 arrives. Evaluators determine if inclusion criteria are met and informed consent is obtained from the caretaker. Evaluator #2 observes the encounter.
1400	Evaluator #1 re-examines the child while Evaluator #2 conducts the caretaker exit interview. Debriefing with caretaker if needed. Debriefing with HSA if needed.
1430	Sick child #3 arrives. Evaluators proceed as above.
1600	Depart for central health facility. Rest of day is spent filling out evaluator's portion of data collection and planning for next day's visit to another HSA.