

Evaluating pneumonia diagnostic aids



About the learning paper series

Since starting operations in 2003, Malaria Consortium has gained a great deal of experience and knowledge through technical and operational programmes and activities relating to the control of malaria and other infectious diseases.

Organisationally, we are dedicated to ensuring our work remains grounded in the lessons we learn through implementation. We explore beyond current practice, to

try out innovative ways – through research, implementation and policy development – to achieve effective and sustainable disease management and control. Collaboration and cooperation with others through our work has been paramount and much of what we have learned has been achieved through our partnerships.

This series of learning papers aims to capture and collate some of the knowledge, learning and, where

possible, the evidence around the focus and effectiveness of our work. By sharing this learning, we hope to provide new knowledge on public health development that will help influence and advance both policy and practice.

www.malariaconsortium.org/learningpapers

A community health worker in in South Sudan counts a child's respiratory rate using coloured beads.
Photo: Tine Klein



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Executive summary

Malaria Consortium's Pneumonia Diagnostics project aimed to identify the most accurate, acceptable, scalable and user-friendly respiratory rate (RR) timers and pulse oximeters for the diagnosis of pneumonia symptoms in children by community health workers (CHWs) and first-level health facility workers (FLHFWs). This Learning Paper details the challenges and successes encountered in implementing the project, and provides recommendations to parties interested in conducting similar studies.

The project systematically reviewed the landscape for existing tools, aids and devices appropriate for low-resource settings. It did this through landscape analysis, formative research and pile-sorting. A scoring and ranking system was developed and used to compile a shortlist of suitable diagnostic aids. Laboratory testing assisted the final selection of devices for the performance evaluation phase.

Performance evaluations were conducted in regional hospital settings in each project country. They aimed to identify the performance of the diagnostic aids when used by the CHWs/FLHFWs, evaluated against two references defined in consensus with the project's Scientific Advisory Committee (SAC). Acceptability and usability evaluations followed, which were conducted through standard and structured assessments. These investigated the use of the selected RR timers and pulse oximeters during CHWs and FLHFWs' routine practice in their communities or health facilities.

Some of the main challenges that emerged while implementing this multi-country study included a rapidly changing device landscape, selecting suitable reference measures for the performance evaluation, difficulties finding qualified master trainers as well as identifying project sites that could meet the defined sample sizes and logistical considerations relating to shipping and clearance of medical devices.

The engagement of stakeholders throughout the study, as well as the establishment of the SAC were some of the successes of the project. One of the key recommendations, therefore, is early engagement of national and international stakeholders at all levels, from manufacturers to CHWs, as well as establishment of an advisory committee for continuous scientific input and oversight.

A strong focus on standardisation at every stage of the project, despite presenting some challenges, was key in achieving quality data and output. Standardisation was largely achieved through multi-country workshops to develop the protocol and standard operating procedures; however, it is recommended that sufficient time be allowed between the protocol design workshops and the training of the master trainers in order to be able to pre-test and finalise all materials.

Learning Papers

This Learning Paper, *Evaluating pneumonia diagnostic aids*, accompanies the Pneumonia Diagnostics project 'protocol' film, which is a 'how to' guide to designing and implementing a study on diagnostic aids. The film is available to view at: www.malariaconsortium.org/resources/video-library/847/



A mother and her child participating in a performance evaluation for the Pneumonia Diagnostics project in Uganda
Photo: Tine Frank

Introduction

Pneumonia is one of the leading causes of death in children under five years in both Southeast Asia and sub-Saharan Africa. A large number of children who die from pneumonia do so as a result of inappropriate treatment due to misdiagnosis of symptoms. In order to tackle the large number of childhood deaths from this preventable and treatable disease, ministries of health are investing in the delivery of life-saving diagnosis and treatment at community level, through two complementary strategies for the integrated case management of child health:

Integrated community case management

Integrated community case management (iCCM) is an approach whereby community health workers (CHWs) are trained to identify and treat pneumonia, diarrhoea and malaria in children under five years, as well as to refer severely ill cases to the nearest health facility. Evidence in African countries shows that CHWs, if properly trained and equipped, have the potential to reduce child deaths from malaria, pneumonia and diarrhoea by up to 60 percent through the delivery of iCCM¹.

Integrated management of childhood illnesses

Integrated management of childhood illnesses (IMCI) is an approach for first-level health facilities, such as clinics, health centres and hospital outpatient departments, that focus on the wellbeing of the child. IMCI aims to reduce death, illness and disability, and to promote improved growth and development among children under five years of age. IMCI includes routine assessment for general danger signs, common illnesses, malnutrition and anaemia, as well as activities for illness prevention.

The Pneumonia Diagnostics project

CHWs and first-level health facility workers (FLHFWs) diagnose pneumonia primarily through counting the respiratory rate (RR) of children who have a cough and/or difficulty breathing. However, counting RR is often challenging, even for highly trained health workers, and misclassification is common.

The Pneumonia Diagnostics project aimed to identify the most accurate, acceptable, scalable and user-friendly RR timers and pulse oximeters for diagnosis of pneumonia symptoms in children by CHWs and FLHFWs. RR timers measure a child's RR by facilitating counting of breaths, whereas pulse oximeters measure blood oxygen levels, with low levels indicating severe pneumonia.

This project took place in four countries: Cambodia, Ethiopia, South Sudan and Uganda. These countries were selected based on the high number of pneumonia deaths as well as the availability of community-level diagnosis and treatment.

Funded by the Bill & Melinda Gates Foundation, the project, led by Malaria Consortium, ran from November 2013 to April 2016 and worked with ministries of health and other national and international stakeholders. Malaria Consortium invited global representatives of the UN Children's Fund (UNICEF) and the World Health Organization (WHO), as well as child health and diagnostics experts and representatives of the four countries implementing the study, to form a Scientific Advisory Committee (SAC) to provide expertise and recommendations for quality assurance.



A Malaria Consortium staff member conducts a structured assessment as part of the acceptability and usability evaluation in Cambodia

“ Many innovations have become available in the area of pneumonia diagnosis. Malaria Consortium’s Pneumonia Diagnostics project is particularly important because all these innovations have been going on, but how are they actually working in the hands of community health workers and health facility workers?”

The output of this project will be very important to UNICEF, in particular to learn about which kind of products we should be procuring, which specifications we need to be writing and how we help shape some of these products.”

Jonathan Howard-Brand, ARIDA Project Manager, UNICEF

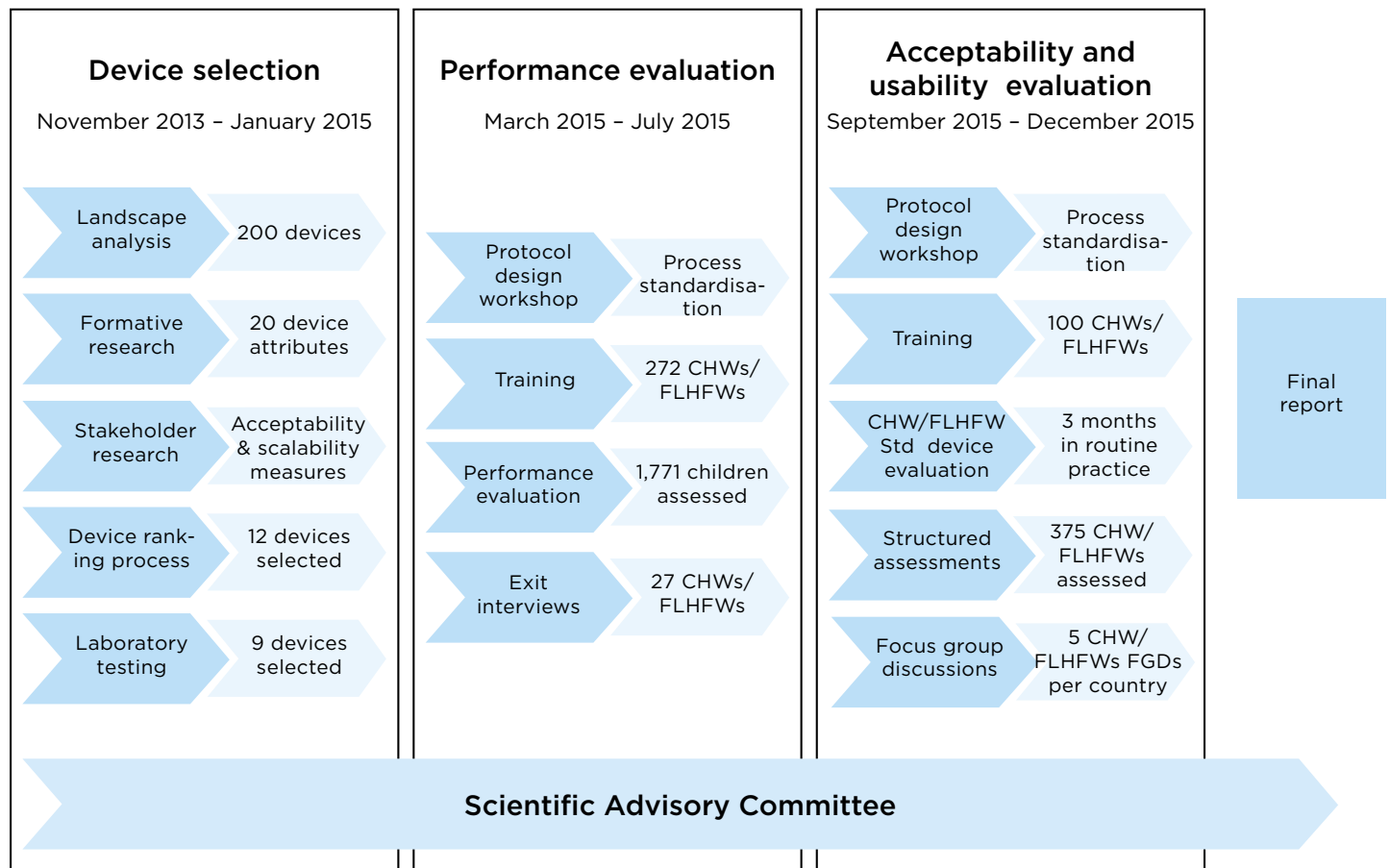
Implementing a device evaluation study

Malaria Consortium systematically 1) reviewed the landscape for existing tools, aids and devices that were appropriate for low-resource settings; 2) identified the most promising and appropriate aids for field testing; 3) established their performance in supporting the diagnosis of pneumonia symptoms by

CHWs and FLHFWs; and 4) explored their acceptability and usability as perceived by health workers and caregivers.

The Pneumonia Diagnostics project comprised a series of three phases, using both qualitative and quantitative methodologies:

Pneumonia Diagnostics project workflow



Scoring and ranking of diagnostic aids

Using the formative research findings, 20 diagnostic aid attributes were defined, and these attributes were aligned with the UNICEF Supply Division's 2013 framework*. The attributes were also ranked by relative importance, using an approach called MaxDiff, and then used to score the different devices identified during the landscape review. This work was conducted by an independent agency, IPSOS Healthcare².

| No. | Attribute | Score definition |
|-----|--|---|
| 1 | Usability | 3=Very simple to use with all patients regardless of state 2=Moderately difficult to use in some patients 1= Difficult to use in most patients 0=Cannot be used by CHWs/FLHFWs to detect the symptoms of pneumonia in children |
| 2 | High level of decision support | 3=CHW/FLHFW can get treatment options 2=CHW/FLHFW can get classification 1= CHW/FLHFW can get the result 0=CHW/FLHFW cannot use the device to detect the symptoms of pneumonia |
| 3 | Automation of diagnosis | 3=Fully automated result provided 2=CHW/FLHFW doesn't need to count but must observe 1= CHW/FLHFW manually counts 0=CHW/FLHFW cannot use the device to detect the symptoms of pneumonia |
| 4** | High accuracy of measured/ calculated result (e.g. RR/SpO2/etc.) | 3=Accurate to ± 2 breaths/minute (RR) or $\pm 1\%$ for SpO2 2=Accurate to ± 5 breaths/minutes (RR) or $\pm 2\%$ for SpO2 1= Accurate to ± 7 breaths/minutes (RR) or $\pm 5\%$ for SpO2 0=No accuracy measures available |
| 5 | No or little literacy and numeracy required | 3=No literacy or numeracy required 2=Low level of numeracy or literacy required (approximate reading and numeracy age of 5) 1= Relatively high level of literacy and numeracy required (reading and numeracy level more than 10 years of age) |
| 6 | No or little training required | 3=Requires up to a half day of training 2=Requires between one half day and a day of training 1= Requires more than a day of training |
| 7 | No or little familiarity with technology required | 3=No prior familiarity with technology required 2=Some prior familiarity with technology required (i.e. use a simple mobile phone) 1= High level of prior familiarity with technology required (i.e. knows how to use a smart phone) |

* These attributes were used in the UNICEF Supply Division's target product profile for pneumonia diagnostic aids issued in 2014.

** Not scored during the device selection process.

| No. | Attribute | Score definition |
|-----|--|---|
| 8 | Long operational life in the field – e.g. more than 2 years | 3=More than 2 years 2=Between 1 and 2 years 1= Less than 1 year |
| 9 | Does not require charging (solar, battery, grid) | 3=No charging required 2=Minimal charging required (maximum 1 time per week) 1= Frequent charging required (daily) |
| 10 | Does not require replaceable parts (non-rechargeable batteries, consumables) | 3=No replacement parts required 2=Minimal replacement parts required (1-2 over the life of the device) 1= Frequent replacement parts required (3+ over the life of the device) |
| 11 | Requires little or no maintenance | 3=No or little maintenance required 2=Some maintenance required (every 6 months) 1=High level of maintenance required (more than once every 6 months) |
| 12 | High durability/mechanical robustness | 3=Device does not break during its lifetime 2=Between 20% and 50% of the devices will break during their lifetime 1= \geq 50% of the devices break during their lifetime |
| 13 | High CHW/FLHFW confidence in measurements | 3=CHW/FLHFW feels completely confident in the reading provided by the device for all patients 2=CHW/FLHFW feels somewhat confident in the reading provided by the device in some patients 1= CHW/FLHFW does not feel confident in the reading provided by the device for most patients |
| 14 | High caregiver acceptability of diagnosis | 3=Caregiver feels completely confident and totally accepts the diagnosis offered by the CHW/FLHFW 2=Caregiver feels somewhat confident and somewhat accepts the diagnosis offered by the CHW/FLHFW 1= Caregiver is not confident and does not accept the diagnosis offered by the CHW/FLHFW |

| No. | Attribute | Score definition |
|-----|---|--|
| 15 | High patient comfort | 3=No discomfort caused 2=Some discomfort caused 1=Very uncomfortable for patient 0=Device can cause harm |
| 16 | High portability | 3=Device is completely portable (e.g. can fit in a pocket) 2=Device is somewhat portable (e.g. can fit in a bag) 1= Device has limited portability (e.g. can be wheeled between internal locations) 0=Device is not portable at all (e.g. stationary) |
| 17 | Easy to maintain hygiene | 3=Device does not need to be cleaned after each use 2=Device has to be cleaned some times 1= Device has to be cleaned every time it is used |
| 18 | Low price (less than \$50) | 3=\$0-50 2=\$50-100 1=\$100+ |
| 19 | Multifunctional (includes a minimum of RR and PO) | 3=Device has RR and pulse oximetry plus one other function 2=Device has both RR and pulse oximetry 1= Device has either RR and pulse oximetry functionality 0=Device has neither RR or pulse oximetry functionality |
| 20 | High level of safety | 3=Device is completely safe for the child and the CHW/FLHFW to use for the detection of the symptoms of pneumonia by CHWs/FLHFWs 2=Device comes with some potentially harmful features 1= Device comes with many potentially harmful features |

Respiratory rate timers

Laboratory testing

Through the scoring and ranking exercise, 12 out of the 188 diagnostic aids were selected. Further laboratory testing was performed for nine pulse oximeters selected as they had not been used in the field previously. In contrast, as the selected RR timers had already been used in the field, the SAC recommended laboratory testing of these aids was not necessary.

The objective of testing the pulse oximeters was to determine whether they were fit for field conditions in the four countries. This was done using a series of six environmental tests conducted in a laboratory setting, including heat, humidity and motion tests. Each pulse oximeter was also rigorously tested for accuracy using simulators.

Final selection process

The device selection activities culminated in the final selection of nine diagnostic aids based on their individual total score, laboratory test results and feedback from the SAC on the suitability of the aids in terms of cost, availability and country context.

A matrix was developed (see page 10) to maximise the opportunities to test as many aids as possible, within a realistic sample. The different types of diagnostic aids were spread across countries and matched according to the country context, with consideration given to current tools used by CHWs, the local environment and CHW levels of education and literacy.

Manual count



MK2 ARI timer

Features

Durable; low cost; long battery life; easy to use; requires little training

Price \$4.82

Country device evaluated in Cambodia, Ethiopia, Uganda



Counting beads and MK2 ARI timer

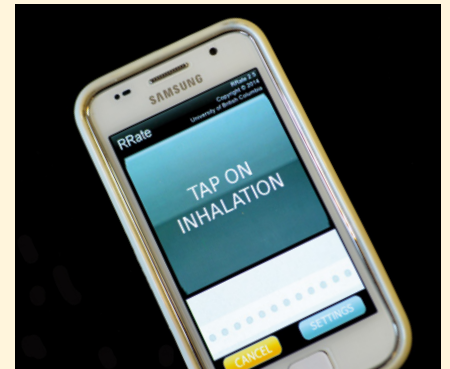
Features

Doesn't require counting skills; durable; low cost; long battery life; easy to use; requires little training

Price \$10 (beads) + \$4.82 (timer)

Country device evaluated in South Sudan

Assisted count



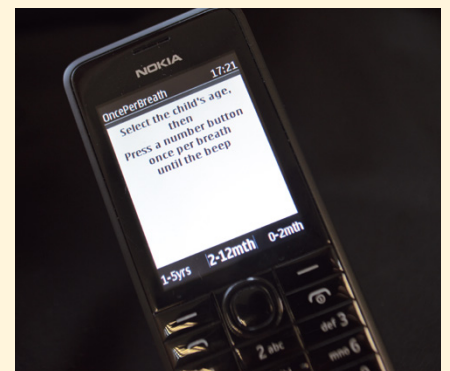
RRate smartphone application

Features

Easy to use; fast result; doesn't require counting skills; classifies result

Price Free + cost of phone

Country device evaluated in Cambodia, Ethiopia, Uganda, South Sudan



Respirometer feature phone application

Features

Easy to use; fast result; doesn't require counting skills; low cost; classifies result

Price Free + cost of phone

Country device evaluated in Ethiopia, Uganda, South Sudan

Pulse oximeters

Fingertip device



Contec CMS 50 QA

Features

Rechargeable batteries (charger provided)

Price \$40

Country device evaluated in
Cambodia, Ethiopia, Uganda,
South Sudan



Devon PC-60D

Features

Rechargeable batteries (charger provided)

Price \$95

Country device evaluated in
Cambodia, Ethiopia, Uganda,
South Sudan

Handheld device



Lifebox

Features

Rechargeable; long warranty life;
robust; reusable probes

Price \$250

Country device evaluated in
Cambodia, Ethiopia, Uganda,
South Sudan



UTECH UT100

Features

Rechargeable batteries; reusable
probes

Price \$108

Country device evaluated in
Cambodia, Ethiopia, Uganda,
South Sudan



Masimo iSpO2 Rx

Features

Anti-motion technology; neonatal
probe; high-specification phone
required

Price \$150 + cost of phone

Country device evaluated in
Cambodia, Ethiopia, Uganda,
South Sudan

Performance evaluation

The second phase of the study aimed to identify the performance of the nine diagnostic aids when used by the CHWs/FLHFWs.

Initially, CHWs/FLHFWs were trained on how to use the diagnostic aids by 'master trainers'. The diagnostic aids were then evaluated for accuracy when used by the CHWs/FLHFWs in a hospital setting in each country, against two references agreed in consensus with the SAC. The hospital setting was chosen based on workflow and proximity to the CHWs and FLHFWs. The performance evaluation was conducted in this setting to make it possible to achieve the sample of 47 children per device and a total of 450 children in each country.

The references included:

- Masimo Root patient monitoring and connectivity platform with Radical-7 for pulse oximetry and ISA capnography for RR, enabling a comparison of performance between diagnostic aids.
- A medical professional manually counting the respiratory rate, enabling a comparison of the CHWs and FLHFWs' performance with that of an expert clinician.

Malaria Consortium carried out training, assessment, data entry and analysis.

Training

The purpose of the training activities was to ensure the CHWs and FLHFWs were proficient in using the diagnostic aids and to standardise the use of the diagnostic aids in the project. This enabled collection of comparable data on the performance, usability and acceptability of the diagnostic aids.

Two training-of-master trainer sessions took place prior to the performance evaluation phase, with three master trainers attending per country. The master trainers were mostly doctors from the health facilities where the project was implemented. In some cases, they were nurses, clinical officers or project research assistants. The training included pneumonia detection and management, how to use the diagnostic aids and adult teaching techniques.

To ensure quality and standardisation following training, the Malaria Consortium team observed and evaluated the master trainers while they conducted training sessions. Each master trainer then returned to their host country, where they were also observed while conducting pilot trainings to CHWs and FLHFWs on pneumonia detection and management and use of the diagnostic aids.

“ The training was very good and very interactive. It was great to be with colleagues from other countries, because community health workers from , for example, Ethiopia have quite different backgrounds to ours in Uganda, so we shared a lot of experiences.”

Dr Jubilee John Abwooli,
Master Trainer, Uganda

Assessment

To identify the children who would participate in the study, the project staff screened children at hospital entry points. Those who qualified to participate in the trial were children under five years with a cough and/or difficulty breathing. Newborns without danger signs were also included in the trial regardless of their symptoms. Consent was then sought from the caregivers using standardised forms. The CHW/FLHFW assessed each child twice, using one set of diagnostic aids (consisting of two or three aids from the same category). Subsequently, an expert clinician assessed the child with the same diagnostic aids used by the CHW/FLHFW. The readings were recorded along with those from the other reference, the Masimo Root patient monitoring and connectivity platform.

Using structured checklists, a research assistant recorded the experiences and challenges of the CHW/FLHFW when using the diagnostic aids - whether they had attached the aid properly, determined the reading correctly, and provided the right diagnosis. Performance and lag time of the pulse oximeters were also recorded. At the end of the assessment, exit interviews were conducted with two CHWs and one FLHFW per diagnostic aid set (a total of nine interviews per country). This enabled insight into their experience diagnosing pneumonia with the new tools.

Data entry and analysis

Data entry teams, trained by Malaria Consortium project staff in the data entry process and in EpiData software, entered all data collected from the field. Research staff cleaned the data prior to entry, and each dataset was entered twice into the EpiData frame to ensure data quality. Weekly random checks were conducted to validate the data before they were sent for statistical analysis using Stata software.

The primary measure of diagnostic aid performance was the proportion of measurements within two, five or more than five breaths for RR timers and percent for pulse oximeters, from the reference. The positive predictive value and negative predictive value as well as sensitivity and specificity were also analysed to measure performance and lag time.

Kappa (κ) values for the agreement of classification of the reading obtained by the CHW and FLHFW compared to the reference standards were also calculated for each user group and per device and country.

A FLHFW uses a finger tip pulse oximeter during a performance evaluation at a health facility in Ethiopia.



Acceptability and usability evaluation

The final phase of the study aimed to investigate the usability and acceptability of introducing the RR timers and pulse oximeters in routine practice for CHWs and FLHFWs in their communities or health facilities, through 'standard' and 'structured' assessments.

All nine diagnostic aids tested in the performance evaluation were included in this phase. Five FLHFWs and 20 CHWs in each country participated, all of whom had taken part in the performance evaluation phase. CHWs/FLHFWs were purposively selected based on geographic proximity to the research centre, as well as to reflect a representative sample based on gender, age and experience.

Each CHW/FLHFW assessed one diagnostic aid set, including one RR timer and one pulse oximeter. RR timers were used according to iCCM and IMCI guidelines for CHWs and FLHFWs, respectively. As pulse oximeters had not previously been used in this type of setting, the project used a new algorithm in which CHW/FLHFW first took RR readings, followed by blood oxygen level readings only if fast breathing was detected. In addition to dispensing antibiotics in line with the national treatment guidelines, CHWs referred children to a higher health facility as needed. Oxygen facilities were made accessible to all participants as required during the study.

Training

In preparation for this phase, master trainers from Ethiopia, Uganda and South Sudan participated in a training-of-trainers workshop in Uganda. A similar workshop was conducted in Cambodia.

Competency checklists were developed again for master trainers to evaluate the CHWs/FLHFWs using the diagnostic aids. Once the CHWs and FLHFWs had been trained by the master trainers, the checklist was used to test the CHWs/FLHFWs; only those who passed were able to participate in the study. This was to ensure that CHWs and FLHFWs use of the diagnostic aids was standardised across the four research sites. The CHWs and FLHFWs were also provided with solar chargers to charge the aids (if required), as electricity was not readily available in the majority of the research sites.

“ This project is very important. First in saving the lives of children suffering from pneumonia and second in building the capacity of our health centre staff, most of whom are nurses.”

Dr Ung Rathana, Ratanakiri
Provincial Health Department
Director, Cambodia

Standard assessments

The standard assessments tested the utility of introducing these diagnostic aids in routine practice for CHWs and FLHFWs. Any child presenting to the CHWs/FLHFWs who met the eligibility criteria was invited to participate in the study on consent of the caregiver. The CHW/FLHFW then followed their routine process in assessing the child, according to the iCCM or IMCI guidelines^{***}. If the child presented with fast breathing, they took a reading with the pulse oximeter, referring the child if the blood oxygen level was below 90 percent. The CHW/FLHFW recorded all readings in their logbook or data form, with a required sample size of 15 assessments per CHW/FLHFW over a three month period.

Structured assessments

In each country, Malaria Consortium research assistants conducted routine structured assessments, where they video-recorded CHWs/FLHFWs use of the diagnostics aids while assessing device acceptability and usability using structured checklists – for example, could the CHW/FLHFW switch it on, use it correctly, etc. Research assistants made a record of each CHW/FLHFW's logbook to analyse routine data relating to use and utility of the diagnostic aids – for example, how often did they use them and what were the outcomes. They also held interviews with the CHW/FLHFW and caregivers on their perceptions of the tools used. Three structured assessments per CHW/FLHFW (a total of 375 assessments per

country) were conducted once a month during the field testing. This allowed for documentation and evaluation of the diagnostic aids' usability and acceptability over time.

At the end of the acceptability and usability evaluation, 10 exit interviews – for one CHW and one FLHFW per diagnostic aid set – were conducted in each country. These exit interviews were used to gain further insight into the CHW or FLHFWs' views on the aids tested.

Data entry and analysis

Data entry was repeated as previously described for the performance evaluation. For this final phase, the primary outcomes analysed were the usability and acceptability of the diagnostic aids. Usability scores were calculated using structured questionnaires and exit interviews with CHW/FLHFWs. Acceptability was determined through qualitative analysis based on users' and caregivers' perceptions to the different diagnostic aids.

Community health workers participate in a training session in South Sudan.



^{***} An additional RR reading was collected using the device set timer.

Lessons learnt and recommendations

The Pneumonia Diagnostics project was the first study that looked at the use of diagnostic aids by CHWs and FLHFWs. Building protocols and processes that are replicable was a main objective of the project, in order to build evidence around best practice in testing these types of diagnostic aids. The end result is a robust protocol that a wide range of stakeholders can use.

Standardisation

Lessons learnt

This project was designed to optimise standardisation between countries to ensure consistent and reliable data for all diagnostic aids. Standardised protocols ensured reliability and validity when comparing data between different countries and to strengthen the overall findings.

In addition, rigorous standard operating procedures (SOPs) were designed to ensure all trial locations followed the same process for all phases of the project. For the selection process, this included using an identical global thematic framework when analysing the data during the formative research. The training and the supporting tools, while standardised, were designed to meet the context and needs of the different countries, in particular to address variations in literacy and numeracy among the health workers.

For field testing, standardised data collection forms were designed and used in all sites. Regular site visits were conducted to ensure quality and standardisation in data collection. Entering the data twice also allowed for better data quality and standardisation.

Key recommendations

Protocol design workshops, SOPs, regular weekly group meetings with country teams and regular site visits by senior research staff to the four project countries helped ensure smooth implementation and standardisation of the project.

Stakeholder engagement

Lessons learnt

Global collaboration with pneumonia management experts, academics, donors, private industry and ministries of health early on in the project proved invaluable to capturing a wide range of perspectives and input on future pneumonia diagnostic aids, and to support the development of a robust protocol for conducting a multi-country project with community-level participants.

Key recommendations

Early, continual and reciprocal engagement with international and national stakeholders at all levels ensures continued buy-in and interest in the study findings.

Scientific oversight

Lessons learnt

Establishment of the SAC led to a more scientific and rigorous diagnostic aid selection process. In line with the SAC's recommendation, IPSOS Healthcare was procured to undertake ranking of the 20 agreed diagnostic aids attributes in order of relative importance, and to identify the most important attributes in detecting the signs of pneumonia for CHWs in low-resource settings. The findings helped prioritise the diagnostic aids CHWs and FLHFWs should test.

The SAC also recommended laboratory testing of the pulse oximeters before testing in-country, which made it possible to avoid field testing those diagnostic aids that were not sufficiently robust for CHW/FLHFW use.

Key recommendations

The SAC played an important role in providing ongoing, rigorous oversight throughout the project. It is essential that attributes for the diagnostic aids are scored and ranked using a scientific approach to ensure consistency in the selection process. It is highly recommended that diagnostic aids are laboratory tested prior to using them on study participants in the field to ensure the robustness of the tools.

Protocol design workshops

Lessons learnt

In preparation for field testing, a protocol design workshop was conducted, bringing together all country teams to reach consensus on the design and implementation of the study, accommodate country contexts in the different project sites, determine sample sizes and standardise protocols, procedures, implementation plans and training.

Key recommendations

Bringing country teams and master trainers together for protocol design and training was a good opportunity for sharing and learning for both staff and trainers. It also provided the opportunity for different technical and operational contexts to be reflected in standardising the protocols and its implementation.

Commercial considerations

Lessons learnt

Commercial considerations, such as those related to sharing product information, intellectual property, ownership of findings, gaining access to devices for testing, etc. proved crucial when designing a project of this type and scale. A reciprocal approach to manufacturers, such as building in requested research questions, ensured good relations throughout the project.

Key recommendations

It is recommended to sign collaboration agreements with each of the manufacturers involved, to ensure transparency about objectives and achievements.

Evolving project activities

Lessons learnt

Recommendations from the SAC resulted in significant changes to the selection process and the inclusion of additional activities to support a more thorough process, which extended the duration of the project. Initially, three months had been allocated to the diagnostic aid selection stage; this ultimately lasted close to 12 months.

Key recommendations

Despite the resulting delays, it is recommended to continuously evaluate project activities and processes, as the SAC inputs improved the overall process and outcomes.

Sample size

Lessons learnt

Hiring research staff from the actual project site was significant in achieving the required sample size, as they were familiar with the hospitals' patient flow, staff and logistics. Further considerations included ensuring the comfort of participants during the additional time they spent at the hospital to take part in the study. Refreshments and designated rooms with sufficient space were made available and, in some cases, reimbursement for travel costs where distances were particularly long.

Key recommendations

Hiring research staff from the actual project site and incorporating community mobilisation activities from the start of the project can further support achieving the required sample size.

Diagnostic aid landscape

Lessons learnt

A major challenge was to ensure relevance of the aids being tested, given a rapidly developing landscape where new devices were frequently launched. Constant updating of the diagnostic aids list during the landscape review was important, but could still mean potentially missing more valuable and current diagnostic aids.

Key recommendations

Connecting the project launch to a relevant forum or conference presents an ideal platform to introduce the project, in a transparent manner, to key manufacturers in one room, thereby obtaining early buy-in and, from there, building a relevant project timeline that can incorporate diagnostic aids that are soon to launch.

Selection of references

Lessons learnt

Assessing the accuracy of diagnostic aids involves comparing how the measurement of the device being tested agrees with the measurement of the reference or gold standard (the agreed best test currently available for detecting a disease). As no agreed gold standard existed not just at community level, but at large, to compare the accuracy of the aids being tested in detecting pneumonia symptoms, one of the key decision points for the SAC was to reach consensus on what the relevant reference standard would be. This had to take into consideration that the project would be looking not just at the device performance but also at the performance of the CHWs/FLHFWs using the devices.

Key recommendations

Selection of an expert clinician and an automated monitoring device as references allowed the project to look at both human and technical performance in relation to the devices being tested. However, without one gold standard to compare against, standard, interpretation of the data can be complex if there is disagreement between the expert clinician and the automated monitoring device results.

Training

Lessons learnt

Finding qualified master trainers was a challenge, as was finding training venues that were up to standard, which delayed operations in some of the project sites. For logistical and financial reasons, protocol design workshops and master training workshops were combined, which meant data collection tools were not finalised at the time of the master training.

Key recommendations

To achieve standardised and effective training, adequate timing is required in the preparation of materials and trainings.

Though this adds considerable time and costs to the project, it is recommended to allow sufficient time between protocol design workshops and master trainer activities to ensure all tools are pretested at the project sites and finalised prior to training of master trainers.

Project site selection considerations

Lessons learnt

Some project sites initially failed to achieve the set sample size, mainly as a result of population size, incidence of pneumonia signs and care-seeking behaviours. Adding one additional site in those locations meant that the required sample sizes were largely achieved. However, having two sites presented new challenges, such as moving equipment and staff between sites, which could negatively affect standardisation and data quality.

Key recommendations

Selection of project sites is key to successful implementation of this type of study. It is, therefore, highly recommended to spend the necessary time to select and validate the project site prior to data collection, to ensure the required sample size is achieved.

Quality assurance considerations

Lessons learnt

Despite rigorous attempts to standardise data collection methods in the four countries through adherence to global protocols and interview topic guides, there were slight discrepancies, some of which were attributable to internet and communications issues. With four project sites in four countries, there was a need for continuous monitoring to ensure consistency. This was at times affected by staff turnover, misunderstanding of protocols or processes, misinterpretation and lack of ongoing communications and quality checks.

Key recommendations

Having a senior member of the in-country research team on site at all times has a positive impact on the quality of data collection and eases ad hoc troubleshooting. Investing in non-online-based communication tools for project teams would also have significantly eased communication and, as such, minimised mistakes and improved standardisation.

Logistical considerations

Lessons learnt

Developing and implementing a diagnostic aid trial of this size and complexity presented significant logistical challenges. Operating in four countries that were greatly diverse in terms of CHWs' capabilities and training, ethics approval, protocols, shipping and customs regulations, etc. required in-depth planning and research to understand the logistical requirements. Furthermore, in a trial of this nature, devices can be new and, therefore, not yet registered, resulting in complications relating to customs clearance. This caused significant delays in some project sites.

Key recommendations

In order to minimise delays caused by logistical challenges for a diagnostic aid study, it is recommended to thoroughly research the shipping, customs and clearance processes in the individual countries and ensure the allocation of adequate time and budgets.

CHW considerations

Lessons learnt

The availability of CHWs was a challenge at times, as they often have competing priorities as government employees or with other stakeholders. Other matters, such as working during the farming season and family commitments, also affect their availability, which can disrupt or delay project activities.

Key recommendations

Considering CHWs' availability is important, as is engaging stakeholders in a transparent manner and keeping them updated on the time required from them to participate in the project's activities. To limit disruptions and delays, it is recommended to train more CHWs than needed, allowing for a 'back-up' pool of CHWs.

Data collection and quality

Lessons learnt

As there were four different teams in four countries collecting the same data, using 10 forms for each child, some human errors may be unavoidable. This was an ongoing challenge throughout the project. Issues such as regional differences in the format of recording dates, time and the age of a child meant additional time was needed to clean the data.

Key recommendations

The data collection forms should have transparent and clear language, standardised time should be used and the data entry frame should be finalised and available ahead of data collection. Research teams sending weekly, completed forms are also helpful in identifying any mistakes throughout the process. Collecting data electronically on tablet devices should also be considered to avoid these issues.

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Malaria Consortium

Malaria Consortium is one of the world's leading specialist non-profit organisations. Our mission is to improve lives in Africa and Asia through sustainable, evidence-based programmes that combat targeted diseases and promote child and maternal health.

We work across Africa and Asia with communities, government and non-government agencies, academic institutions, local and international organisations, to ensure good evidence is used to improve delivery of effective services.

Our uniqueness is in our ability to consistently design and apply tailored, technically excellent, evidence-based solutions, fit for effective implementation, with impact on the wider health system and economy.

Malaria Consortium works with partners, including all levels of government, to improve the lives of all, especially the poorest and marginalised, in Africa and Asia. We target key health burdens, including malaria, pneumonia, diarrhoea, dengue and neglected tropical diseases (NTDs), along with other factors that affect child and maternal health. We achieve our goals by:

- Designing and conducting cutting edge implementation research, surveillance and monitoring and evaluation.
- Selectively scaling up and delivering sustainable, evidence-based health programmes.
- Providing technical assistance and consulting services that shape and strengthen national and international health policies, strategies and systems and build local capacity.
- Seeking to ensure our experience, thought leadership, practical findings and research results are effectively communicated and contribute to the coordinated improvement of access to and quality of healthcare.

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A village malaria worker uses a pulse oximeter on a baby in Cambodia
Photo: Peter Caton





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