Pneumonia Diagnostics - Device Selection Report

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Established in 2003, Malaria Consortium is one of the world's leading non-profit organisations specialising in the prevention, control and treatment of malaria and other communicable diseases among vulnerable populations. 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.

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Acronyms

ARI	Acute Respiratory Infection
ARIDA	Acute Respiratory Infection Diagnostic Aid
CDD	Community Drug Distributor
CHW	Community Health Worker
eVMW	Extended Village Malaria Worker
FGD	Focus Group Discussion
FLHFW	First Level Health Facility Worker
HEW	Health Extension Worker
IRC	International Rescue Committee
iCCM	Integrated Community Case Management
IMCI	Integrated Management of Childhood Illnesses
MDG	Millennium Development Goals
MoH	Ministry of Health
NGO	Non-Governmental Organisation
PATH	Program for Appropriate Technology in Health
POx	Pulse Oximeter
RR	Respiratory Rate
SAC	Scientific Advisory Committee
SpO_2	Peripheral Oxygen Saturation
TPP	Target Product Profile
ToT	Training of Trainers
UNICEF	United Nations Children's Fund
VHSG	Village Health Support Group
VHT	Village Health Team
WHO	World Health Organization

Executive Summary

Background: Pneumonia is one of the leading causes of death in children under five years of age, with the majority of these deaths occurring in south Asia and sub-Saharan Africa. In countries where Community Health Workers (CHWs) provide health services at the village level, particularly in rural and hard to reach areas, CHWs have been trained to identify the signs and symptoms of pneumonia using basic Acute Respiratory Infection diagnostic aids. However, numerous challenges have been identified with the accuracy, use and acceptability of these tools, inspiring research and innovation to identify an improved and user-friendly device. Malaria Consortium, in collaboration with the United Nations Children's Fund, World Health Organization and ministries of health, are conducting a multi-country research project in Cambodia, Ethiopia, South Sudan, and Uganda to improve the diagnosis of pneumonia in children under five years of age. The aim of the project is to identify the most accurate, acceptable, scalable and user-friendly respiratory rate timers and pulse oximeters for use by CHWs and First Level Health Facility Workers in low-income settings. The research project is comprised of three phases: device selection, accuracy evaluation, and field testing. This report summarises the findings from the device selection process that determined which devices would be used in the accuracy evaluation and field tested in each country.

Methods: The device selection process consisted of a number of distinct stages. Firstly, a landscape review focused on documenting the overall landscape of possible diagnostic devices which could be used at community level. Formative research, including CHW focus group discussions, was conducted to document current practices and inform the attributes used in the subsequent device scoring and consultations with key Ministry of Health personnel in each country to assess device acceptability and scalability criteria All 200 possible devices were then scored and ranked and the final devices were tested in a laboratory for accuracy and robustness.

Outcomes: The range of activities undertaken to identify and select appropriate devices for the accuracy evaluation and field testing, informed by key experts and stakeholders, were essential to a comprehensive and rigorous selection process. Landscape reviews of pneumonia diagnostics aids on the market or in development, identified 188 devices, however a smaller number of these were available in time for the study timescales, affordable, and appropriate for low-resource settings.
Formative research with CHWs across the four country study sites captured challenges with the current pneumonia diagnostic aids; the difficulty of accurately counting respiratory rate and doubts from caregivers on the validity of the CHWs' diagnosis, among others. CHWs who participated in the study commonly preferred devices with the following attributes: easy-to-use, durable, safe, and accurate and with automated results; the latter of which was perceived to encourage caregiver acceptability.

In line with the UNICEF Supply Division's 2013 framework, twenty device attributes were defined according to the consensus reached through discussions with professionals working in pneumonia management, supported by the findings of the formative research with CHWs. Each of these attributes were scored and ranked in order of which were considered to be the most essential, then applied to all of the devices identified in the landscape reviews. In addition, each device was given an "availability" score, providing a final total score for each device; the top 11 devices, according to the scoring exercise, were selected for laboratory testing to ascertain accuracy and robustness, where relevant. All laboratory tested devices passed, with the exception of one fingertip pulse oximeter. After assessing the availability of the 11 devices, a final nine devices: four respiratory counters (automated and non-automated) and five pulse oximeters (fingertip, handheld and mobile phone), proceeded to the accuracy evaluation phase.

Recommendations: The device selection process highlighted the importance of clearly specifying the type of device from the outset to ensure equality in selection (for example differentiating market-ready devices versus prototypes) through thorough landscape reviews and strict selection criteria. Moreover, it is recommended that device attributes are scored and ranked using a scientific approach to ensure robustness in the device selection process. Lastly, it is essential to subject devices to laboratory testing prior to using the tools on study participants. It is hoped that this methodology can be adopted in future studies looking at

diagnostics tools at the community-level and will provide a best practice process model to follow when looking to select suitable devices for field trials of this type.

1. Background

Pneumonia is attributed to an estimated one million deaths of children under five years annually, with the majority of these deaths occurring in south Asia and sub-Saharan Africa (1). In low-resource settings, particularly in rural, remote and hard to reach areas, caregivers face challenges accessing health services, including pneumonia diagnosis and treatment. Children who are taken for treatment late are at risk of developing severe pneumonia. This, together with an inability of healthcare workers to adequately recognise danger signs, which indicate that the child needs urgent referral to a higher level of care, leads to the deaths of many children (2). Therefore, countries are increasingly adopting an integrated community case management (iCCM) approach, where local community health workers (CHWs) are trained to provide health services at this level for diseases causing the highest child morbidity and mortality in their villages, such as malaria, diarrhoea and pneumonia. To support CHWs' identification of pneumonia in children under five years, the World Health Organization (WHO) recommends using fast breathing as a key indicator for pneumonia diagnosis (see **Table 1**) and accompanying classification guidelines in addition to other signs and symptoms like cough and difficulty breathing.

Table 1. Fast breathing classification by age and respiratory rate

Child's age	Respiratory rate
<2 months	60+ breaths/minute
2-12 months	50+ breaths/minute
12-59 months	40+ breaths/minute

CHWs are trained to diagnose fast breathing using coloured counting beads and/or a simple Acute Respiratory Infection (ARI) timer available from UNICEF (see **Image 1**).

Images 1: ARI timer and counting beads

However, counting respiratory rate can be challenging and misclassification of the observed rate is common, leading to an incorrect diagnosis and consequently, inappropriate treatment (3-5). Counting a correct respiratory rate is often affected by factors such as movement of the child and irregularities in the child's breathing, both of which require the CHW to start counting all over again, and frequently the CHW may count the tick of the timer's clock rather than the child's breathing rate. If after a respiratory rate is determined and antibiotics are not indicated, the result is often challenged by the parent or caregiver, as they strongly believe that their child should receive treatment, irrespective of the respiratory rate measurement.

Low-levels of oxygen in the blood (hypoxemia) has been identified as a predictor for morbidity and mortality in children with respiratory illness (6). Pulse oximeters is a reliable and non-invasive tool to identify the levels of oxygen in children's blood, as hypoxemia is a symptom of severe pneumonia; a strong predictor for pneumonia-related death (6). But in resource-constrained countries relevant devices are rarely available outside higher-level health facilities (7).

In view of the above challenges, a growing number of research groups, funded by international organisations and donors such as WHO, UNICEF, the Bill & Melinda Gates Foundation and the Clinton Health Access Initiative, are focusing on innovative approaches for improving the detection of pneumonia signs through the development of easy-to-use mobile phone applications and electronic devices. For instance, in 2014

UNICEF developed a Target Product Profile for an Acute Respiratory Infection Diagnostic Aid (ARIDA) describing key attributes preferred in a device, to inspire innovation and facilitate procurement for governments and partners (8). Moreover, several international trials are being conducted to determine the role of new tools in community case management of pneumonia by CHWs. The range of new devices focus on different approaches, such as measuring respiratory rate and heart rate, using automated accelerometers or cough/lung sound detectors (9-11). However, the clinical performance, usability and acceptability of these tools in endemic settings are still largely unknown.

1.1 Overview of the Pneumonia Diagnostics Project

Malaria Consortium benefits from years of experience working with CHWs, through the implementation of iCCM and other disease control programmes in Africa and Southeast Asia. The organisation has a high level of expertise with the case management of malaria, pneumonia and diarrhoea and contributes to the growing evidence base for effective and sustainable public health interventions.

Malaria Consortium is currently implementing a project funded by an eighteen month grant from the Bill & Melinda Gates Foundation to carry out operational research on pneumonia diagnostic tools in Cambodia, Ethiopia, Uganda and South Sudan, to assess the tools' accuracy, usability and acceptability. These countries were selected to provide a range of geographic, socio-economic and cultural contexts from sub-Saharan Africa and Southeast Asia where pneumonia is responsible for significant child morbidity and mortality (see **Table 2**).

Table 2. Pneumonia and mortality statistics in study countries

Country	Under 5 mortality rate 2013 (per 1000 live births) (12)	Under 5 mortality caused by pneumonia (%)(13)	Children with pneumonia symptoms who receive antibiotics 2009-2013 (%)(14)
Cambodia	38	17	39
Ethiopia	64	18	7
South Sudan	99	20	33
Uganda	66	16	47

Furthermore, each of these countries are at different stages of iCCM implementation: Cambodia is piloting this approach, South Sudan is in the early implementation phase, Uganda has been implementing iCCM for several years whilst Ethiopia has a very developed iCCM programme. The differences between study settings are also reflected in the CHWs' levels of education and length of training on the management of childhood illness (see **Table 3**).

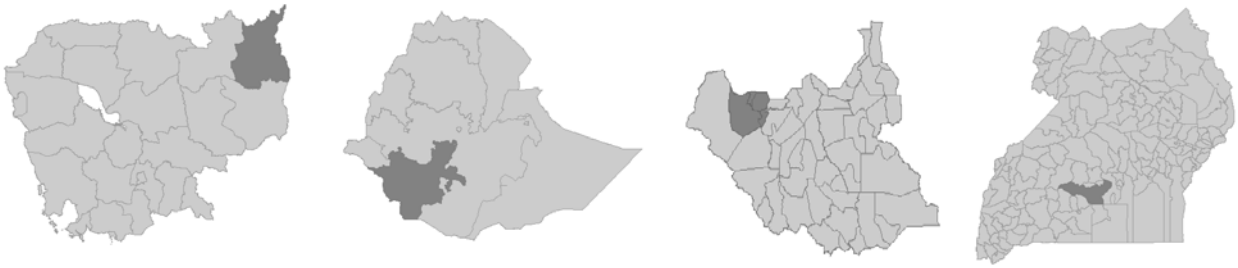
Table 3. Country characteristics of CHW programmes

Country	Local term for CHWs	Education level of CHWs	Length of training	Illnesses managed by CHWs	Instrument used to assess RR
Cambodia	Extended Village Malaria Worker (eVMW)	Low	5 days + refresher training every 2 years	Malaria Pneumonia Diarrhoea	ARI timer
Ethiopia	Health Extension Worker (HEW)	High	12 months	Malaria Pneumonia Diarrhoea Malnutrition	Wrist watch displaying seconds

South Sudan	Community Drug Distributor (CDD)	Extremely low	6 days	Malaria Pneumonia Diarrhoea Malnutrition	ARI timer + counting beads
Uganda	Village Health Team (VHT) member	Low-medium	11 days	Malaria Pneumonia Diarrhoea	ARI timer

In each country, a study site was identified in collaboration with the Ministry of Health; the selection prioritised locations where child mortality due to pneumonia was high compared to national rates and an iCCM (or equivalent programme) was in operation with CHWs who had been trained to manage pneumonia (See **Figure 1**).

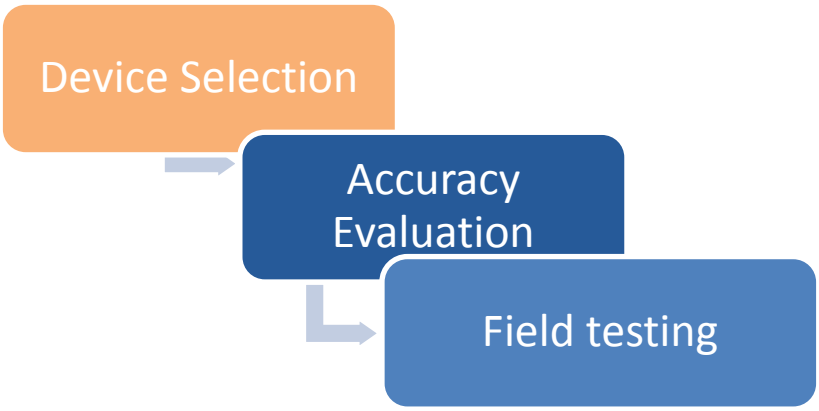
Figure 1: Study sites (highlighted) in Cambodia, Ethiopia, South Sudan and Uganda



The Pneumonia Diagnostics Project involves multiple partners and global experts whom Malaria Consortium has brought together to collaborate on one of the first, largest and most comprehensive studies on a range of pneumonia diagnostic devices in diverse settings. The study adopts a mixed-methods approach to scientifically validate and explore in-depth the accuracy, usability and acceptability of innovative tools to identify the signs of pneumonia in children under five years at the village level by CHWs and First Level Health Facility Workers (FLHFWs). Additionally, local and national stakeholders' perspectives on the feasibility and scalability of potential devices are captured.

The research comprises three main stages (see **Figure 2**) which include: 1) device selection, informed by global activities and formative research on device attribute preferences from CHWs in each of the four countries, 2) a multi-country clinical evaluation to assess the accuracy of the devices when used by FLHFWs and CHWs and 3) field testing to determine caregiver, CHW and FLHFW perceptions on the usability and acceptability of the new devices.

Figure 2. Research stages



The Pneumonia Diagnostics project received ethics approval from the national or regional ethics review boards of each country including: National Ethics Committee for Health Research, Ministry of Health,

Cambodia (Ref: 0146 NECHR); the Directorate of Policy, Planning, Budgeting and Research, Ministry of Health, Republic of South Sudan; the Southern Nation Nationalities Peoples' Region Health Bureau Health Research Review Committee, Ethiopia; and the Uganda National Council for Science and Technology (Ref: HS 1585). The clinical evaluation is registered with the Australia New Zealand Clinical Trials Registry (ANZCTR) Ref: ACTRrn126150003.

2. Aim

The purpose of the device selection process was to determine which devices would be used in the accuracy evaluation and field tested in each country. There were eight activity stages used to select the devices from the 188 possible devices to the final nine devices taken into the field for the accuracy evaluation and documented and any challenges and learnings highlighted.

3. Methodology

As depicted in **Figure 2**, the first stage of the research focused on device selection. The objectives of this process were:

- To systematically review the landscape for existing respiratory rate mobile phone apps, automated respiratory rate timing tools and pulse oximeter devices appropriate for low resource settings
- To identify, using pre-defined criteria, the range of the most promising and appropriate devices for field testing in sub-Saharan Africa and Southeast Asia
- To capture the current context and perceptions of CHWs who are detecting the signs and symptoms of pneumonia at the village level
- To select devices that are in line with the preferences expressed by key stakeholders involved in pneumonia management from around the world, national, sub-national stakeholders, FLHFWs and CHWs.

4. Results

The device selection process for the Pneumonia Diagnostics Project consisted of eight key activities with the following outcomes (see **Table 4**), described in more detail in the subsequent sections of the report.

Table 4. Device selection activities, purpose and outcomes

Process stage	Activities	Time period	Purpose	Outcome
1. Landscape Review	• Initial landscape review • Technical landscape review	January-June 2014	To identify the range of devices in development or on the market that could be available for procurement within the study timeframe	188 devices identified
2. Device attribute development process	Formative research with CHWs in each country	May-June 2014	To capture current situation on device use and define preferred device attributes	CHW preferred device attributes identified

3. SAC oversight process	Scientific Advisory Committee meetings	June 2014 & September 2014	To discuss attribute preferences and study recommendations	Recommendations to rank attributes and conduct lab testing
4. Device attribute selection process	UNICEF Acute Respiratory Infection Diagnostic Aid Innovation	Ongoing	To define device requirements and preferred attributes for suppliers and procurement purposes	ARIDA Target Product Profile
5. Device attribute ranking process	IPSOS Healthcare device attribute ranking exercise	June-July 2014	To assess which attributes global experts ranked as most important	Most important attributes ranked
6. Final device scoring process	Device scoring exercise	July-August 2014	To scale down and identify the most appropriate devices based on availability and attribute ranking and score	188 devices scored, 12 selected for further evaluation and laboratory testing
7. Laboratory testing process	Laboratory testing	January 2015	To test accuracy and robustness of devices in field conditions	Final 5 pulse oximeter devices selected
8. Final device selection process	Final device selection	January 2015	The ratify and agree on the final devices to be taken forward for accuracy evaluation with the SAC and the donor	Final 9 devices selected (4 RR counters, 5 pulse oximeters)

4.1 Landscape review

In 2013, the Program for Appropriate Technology in Health (PATH) drafted a comprehensive report and list of respiratory rate (RR) counters available and in-development (15). This report provided the starting point for two further landscape reviews conducted by Malaria Consortium in 2014. The landscape review and ranking exercise were carried out to ascertain the range of pneumonia diagnostic aids on the market or in development, identifying hundreds of potential devices in the process. These devices were considered in terms of availability and technical attributes to determine their suitability for field testing, in relation to criteria defined by the UNICEF Supply Division in a 2013 report (9) (see **Appendix 1**) and building on the list of devices identified by PATH.

4.1.1 Initial device landscape review

Background

The first landscape review was conducted in February 2014. The objective was to identify the range of pneumonia diagnostic tools and shortlist devices based on stated criteria for field testing (see **Table 9**).

Methods

The shortlisting of devices was carried out separately for respiratory rate counters and pulse oximeters. The search for appropriate respiratory rate counters was based on the list of devices (both available and in development) compiled in 2013 by PATH (16). The list of pulse oximeters was produced based on internet searches and a market-wide screening of models and brands which generated hundreds of potential devices. Extensive email and telephone interviews and communications were held with all 188 device manufacturers to ensure that the most update to date and complete data was included in the final analysis presented to the SAC. Data was sought from each of the device manufacturers on 9 data points as follows:
development Stage; cost; robustness; applicability; CHW skills; accuracy; creditability; extensibility; availability. These were based on the criteria agreed at the previous meeting at UNICEF Supply division in 2013. Out of these 188 devices two short lists were created for the range of respiratory rate counters (a final 21 devices out of a total of 158) and pulse oximeters (a final 24 devices out of 30). These shortlists were then presented for discussion at the SAC meeting in Geneva in June 2014.

Results

A variety of different types of RR counters and pulse oximeters were found during the review; these categories are described below for each type of device.

Respiratory rate counters

The respiratory rate counters fall into two categories: non-automated and automated devices. The full range of devices available within these categories is described in **Table 5.**

Non-automated devices include tools that support the manual counting of chest movements, by indicating when to start and stop counting. Within the manual count devices, only the currently implemented UNICEF ARI timer is included. The other devices support an assisted count, by automating or negating the need for manual counting of each chest movement. Assisted count devices include three sub-categories: counting beads (used in combination with ARI timers), digital devices and mobile software applications. Mobile software applications in the category of assisted count work when CHWs tap the screen or press buttons with each chest movement. Most of the mobile phone applications can be downloaded for free and, since they work on a smartphones, are portable with simple displays. However, some of them have been designed for exclusive use with iPhones, which have cost implications for implementation. In this category, two different applications were distinguished: those used as counters using the phone screen to tap with each chest movement and the ones used by measuring the exhaled breath. This last category may be difficult to

use with children under five year because of the small volume of exhaled air. Mobile phone applications demonstrate some drawbacks, including the lack of validation in paediatric ages and the fact that most of them are not designed for clinical purposes. Nonetheless, mobile phone applications allow the use of different types of applications for diagnosis on the same apparatus; for example, by combining applications to count respiratory rate by tapping on screen and measuring exhaled breath.

Automated devices are based on the measurement of several different parameters in order to derive respiratory rate. Within this category four groups are included, based on their measurement parameter: exhaled breath, thoracic effort, respiratory sounds and indirect effects on cardiovascular physiology. In general, few of the devices in this category were considered appropriate for the study, either because of the elevated cost, lack of suitability for their use with children and newborns, because they were not portable or due to their complexity and difficulty for community health workers to use. Other approaches that are not considered appropriate for children and neonatal are those which are based on the measurement of air pressure using spirometry. Further methods to calculate respiratory rate are based on the measure of body temperature by applying sensors on the skin. However, these are, in general, difficult to use with children under five years of age, since the technique requires the patient to keep still. For this reason, several research groups are working towards the development of sensors for non-contact measurement of respiratory rate. Unfortunately, at the time of the device selection process, these devices were still in development and not available for field testing.

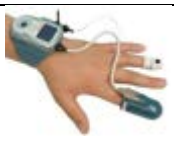
Many of the devices that measure respiratory rate have been designed for the monitoring of vital signs of patients within healthcare facilities, in post-surgical situations for example, or to be used in sleep laboratories. Therefore, most of these are difficult to adapt for use in low resource settings as they are based on the use of sophisticated equipment which is often expensive and not portable. Furthermore, they have typically been developed to send data to a central information system within the health facility where the patient is monitored, rather than as a stand-alone tool.

Within the category of devices that measure respiratory sounds, another group of mobile phone applications is included. These represented a suitable option because of the ease of use, the potential for increased credibility by CHWs and their affordability. However, none of these have been tested with children and neonates, and the results may not prove sufficiently accurate since they need to measure the sounds produced by the exhaled breath, which is a lower volume in children than in an adults.

Table 5. Potential types of respiratory rate counters and methods for the diagnosis of pneumonia (15)

Method		Description	Device example & developer	Photo	Outcome of landscape Review
Non-Automated					
Manual count (timer only)	**Analog device**	Timer used to inform the observer when to start and stop counting RR.	MK2 ARI Timer (UNICEF, WHO)		Included In scoring
Assisted count	**Counting beads**	Colour-coded string of beads eliminates the need for an observer to remember breath count and indicates diagnosis according to the child's age. Must be used in combination with a timer.	ARI Counting Beads (IRC, Save the Children)		Included in scoring as available and used in current programmes

(aids visual counting)	**Digital device**	Standalone digital tally counter with built-in one-minute timer eliminates the need for an observer to remember breath count by having the user press a button to register each breath.	Philips Breath Counter		Included in scoring and potentially will be available for testing
	Mobile software application	Software-based mobile phone or tablet application with timer eliminates the need for an observer to remember breath count by having the user press a button or touch the screen to register each breath.	Rrate University of British Columbia Children's Hospital)		Included in scoring as is available and suitable for this setting
Automated					
Exhaled breath	**Humidity**	RR derived from oronasal moisture sensors measuring increases in humidity in exhaled breath.	respiR8®(Anaxsys Ltd)		Included in scoring but concerns about suitability for this setting
	Temperature	RR derived from oronasal temperature sensors measuring increases in temperature in exhaled breath.	Respirometer (Profile Group of Companies)	*No photo available.*	Not included in scoring as device is not yet available
	Air pressure	RR derived from oronasal sensors measuring increases in air pressure in exhaled breath.	Pneumotach (Hans Rudolph, Inc)		Included in scoring but concerns about suitability for children under 5
	Carbon dioxide (ETCO2)	RR derived from oronasal capnography measuring carbon dioxide concentration in exhaled breath.	Capnomask (Mediplus)		Included in the scoring but concerns for suitability to the community setting
	Oxygen (ETO2)	RR derived from oronasal oxygen sensors measuring decreases in oxygen concentration in exhaled breath.	Datex-Ohmeda™ Ultima (GE Healthcare)		Included in the scoring but concerns about sitability to low resource settings
Thoracic effort	**Thoracic circumference**	RR derived from belt sensors measuring changes in thoracic circumference with respiration.	Nox-T3 (Vivonoetics)		Included in the scoring but concerns about availability
	Thoracic motion	RR derived from sensors measuring changes in thoracic motion with respiration.	Beddit Sleep Tracker (Beddit)		Included in the scoring but concerns about suitability for community setting

	Tidal volume	RR derived from electrodes measuring changes in lung volume with respiration.	Body Area Networks Health Patch (Holst Centre)		Included in the scoring but concerns about suitability for community setting
Respiratory sounds	**Oronasal**	RR derived from acoustic respiratory signals collected from exhaled breath near the oronasal area.	Breath Counter 1.1 (Softrove)		Included in the scoring but concerns about availability
	Tracheal	RR derived from acoustic respiratory signals collected from the throat or neck.	Rainbow® Acoustic Monitoring Respiration Cloth Sensor (Masimo)		Included in the scoring but concerns about suitability for low resource settings
	Thoracic	RR derived from acoustic respiratory signals collected from the chest, back, or armpit.	StrethoCloud (StrethoCloud)		Included in the scoring but concerns about suitability for community setting
Indirect Effects on Cardiovascular Physiology	**Electrocardiogram (ECG)**	Waveform morphology programs and signal processing techniques derive RR indirectly from the ECG measured using ECG electrodes.	Actiwave Cardio (Vivonoetics)		Included in the scoring but concerns about suitability for low resource settings
	Photoplethysmogram (PPG)	Waveform morphology programs and signal processing techniques derive RR indirectly from the PPG measured using pulse oximetry.	Foxconn Smartwatch (Foxconn)		Included in the scoring but concerns about suitability for community setting
	Arterial Blood Pressure (ABP)	Waveform morphology programs and signal processing techniques derive RR indirectly from arterial blood pressure.	Pulsewave™ Dx (BioSign)		Included in the scoring but concerns about suitability for community setting
	Peripheral arterial tonometry (PAT) waveforms	Waveform morphology programs and signal processing techniques derive RR indirectly from PAT waveforms.	WatchPAT (Itamar Medical Ltd)		Included in the scoring but concerns about suitability for children under five

Pulse oximeters

There are currently several types of pulse oximeters available on the market, but for this report only portable pulse oximeters were considered. These were divided into five main categories: mobile, fingertip, handheld, wrist and any-position pulse oximeters (see **Table 6**).

Table 6. Types of pulse oximeters

Device type	Description and additional information	Device example	Photo	Outcome of landscape review

Mobile application	• Oxygen values of the patient are shown on the display of the phone and can be easily understood by non-skilled CHWs • Free download, however, does not include the cost of phone and external finger sensor • **Limitation:** the majority of the mobile phone applications have not been designed for clinical purposes and have not been tested with children and newborns yet (or there is no information currently available)	Masimo iSPO2		Included in the scoring but concerns about cost
Fingertip Pulse Oximeter	• Most affordable option for measuring oxygen saturation (SpO2) in blood • Almost all of these devices show values of pulse rate in addition to the SpO2 • **Limitation:** some of the fingertip pulse oximeters designed for paediatric use have a limited age range of two to 13 years old or 15 kg weight; therefore not suitable for use with neonatals • Oxygen saturation values could be confused with pulse rate values, which are also depicted on the screen.	Contec		Included in the scoring as currently available and low cost
Handheld Pulse Oximeter	• Suitable for adults, children and newborns, since oxygen is measured using a finger external sensor that can be purchased separately for paediatric and neonatal use • Tend to be more expensive than fingertip pulse oximeters and are designed for professional rather than for home use • Shows values of SpO2 and pulse rate in different colours on the display • May require additional training of CHWs as they are more complex to operate/read	Lifebox		Included in the scoring as currently being used in these settings
Wrist Oximeter	• Shows several values (SpO2 and pulse rate only, or these plus other vital signs) on the screen • Transfers information via Bluetooth to a monitoring system, either on a computer or a mobile phone • **Limitation:** No information available on their suitability for use with children and newborns, but since measurement is carried out by placing the pulse oximeter on the wrist, these types of	WristClinic™		Included in the scoring but concerns about suitability for children under 5

	devices may not be suitable for children under five years old			
Any position pulse oximeter	• Only one suitable device identified: Inspire™ which also measures respiratory rate and can be used with children and newborns in different positions.	Inspire™		Included in the scoring but concerns about availability

Lessons learned

Once the initial information about each device was obtained and their appropriateness for the project was assessed, manufacturers were contacted by email and telephone to obtain further technical specifications, information on availability and prices. During the review process, it became apparent that some devices that had been presented as available and ready for further testing were, upon further investigation, not ready and available at that stage. The frequent launching of new devices also posed challenges, such as the need to constantly update the device list and the potential for missing the most recently released products.

Conclusions

In view of the majority of devices being under development, few respiratory rate counters were considered appropriate for the diagnosis of pneumonia in low-income, rural settings in Asia and Africa. Furthermore, the most appropriate devices are still under development and use methods that derive respiratory rate from other parameters (such as Electrocardiography (ECG), Photoplethysmography (PPG) or other vital signs), which require the use of further equipment and were too expensive and complex to be used by CHWs. Taking into account the respiratory rate counters that were available – commercially available or for research purposes at the time of the review – the mobile phone software applications were considered to be suitable for field testing.

For pulse oximeters, the most suitable type according to the review were the fingertip devices as these were: designed for paediatric and neonate use, affordable (if manufactured in China or India) and considered very easy to use (one single button), providing an on the spot result. The review added a special recommendation to use devices which have LCD screens showing black numbers. Additionally, handheld pulse oximeters with a paediatric and/or neonate sensor were considered to be appropriate.

For both RR counters and pulse oximeters, initially many appeared to be potentially promising diagnostic aids, however upon further investigation, were disqualified due to their lack of readiness for testing or suitability for the research conditions. With the remaining tens of devices, it became evident that in order to prioritise which would be most appropriate for further testing, an enhanced approach would be needed to rank and score these to narrow down to a feasible number of devices. In discussion with the SAC further methodology was developed to support a more scientifically robust device selection methodology and a full scoring of all possible devices. Full details of the findings are published here (17).

The SAC further recommended that a further technical analysis be undertaken to create a shorter, final list of devices to be taken forward for field testing.

4.1.2 Technical device review

Background

On reviewing the initial landscape review, the Scientific Advisory Committee providing oversight to the pneumonia diagnostics multi-country study recommended that a more technical review be conducted to assess the suitability and robustness of the devices in the field. In line with this recommendation, Malaria Consortium contracted an expert in the field of pulse oximetry, to carry out a more technical and pulse oximeter-focused review. This second review was conducted in May 2014 to provide a more technical assessment of suitable devices highlighted in the previous review.

Methods

The objective was to inform the final selection of diagnostic devices for field testing by evaluating the shortlisted 21 respiratory rate counters and 24 pulse oximeters according to technical criteria. The review stated that many potential devices could be eliminated on the basis of one or more of the technical criteria, summarised as follows:

- Cost – total cost to cover product lifetime and guarantees on components
- Robustness – duration of replacement of batteries and any recharge cycle
- Scale – manufacturer's supply capacity, scalability and sustainability
- Applicability – including use for the age range 0 to 5 years
- Accuracy – sensitivity and specificity with details of the display
- Extensibility – use of the device for more than one function
- Availability – whether or not the device is available for testing

Results

Respiratory rate counters

Upon evaluating each device according to three of the above criteria, namely, cost, accuracy and availability, only six of the 22 devices were considered suitable for future research stages. These included:

1. Counting beads – these are currently in use and suitable for low literacy and numeracy situations.
2. MK2 ARI timer – this was seen as an improvement on the existing widely used deice.
3. Philips automated breath counter – this automated device was considered very useful and suitable when available.
4. RRate Counter (mobile phone application) – seen as easy to use and provided a fast and simple to interpret result.
5. Respirometer (feature phone device) – seen as easy to use and on a low cost, widely available phone
6. Nanovations (breath sensor) – seen as useful and low cost, when available.

Pulse oximeters

An additional pulse oximeter device was identified and added to the previous 24 shortlisted in the initial landscape review, for a total of 25. In the second review, the pulse oximeters were divided into the following four categories: mobile phone applications (five devices), finger pulse oximeters (nine devices), handheld pulse oximeters (seven devices) and "other" (four devices). The mobile phone application devices were eliminated due to cost, but considered as future possibilities if the price could be reduced. The final shortlisted pulse oximeters were listed as:

1. Contec (fingertip) – seen as easy to use and low cost solution but concerns about accuracy and suitability for younger children.
2. Lifebox (handheld) – seen as easy to use and applicable for all age groups of children under 5.

3. UTECH UT100 (handheld) – seen as easy to use and low cost option handheld device.

Conclusions

Generally, there was inadequate information available on costing, to the extent to which complicated decision making on the suitability of devices for field testing. Devices which relied on an iPhone or laptop to function were considered too expensive, impractical for rural CHWs and were not assessed in-depth. Although other types of less expensive smartphones were deemed a possibility and facilitated a refresh of all possible devices to include some further options.

Further to the shortlisted devices, the review proposed other devices that could be suitable for field testing. These included joint respiratory rate counter and pulse oximeter devices (Lionsgate and Guardit/Inspire), a breath measuring device (Xhale) and the University of Queensland Cough Sound Analysis.

The review concluded that much more information would be needed in order to make a decision on whether any of the devices are likely to provide accurate data at an acceptable cost (a maximum annual expenditure of below USD 100). The review cites a paucity of information on the accuracy of devices, even for those stated to be commercially available. Finally, the report concluded that any assessment should focus on accuracy, cost implications and ideal device characteristics; with a comparison between respiratory rate counters and pulse oximeters to determine the most appropriate device for future research stages.

The landscape reviews were useful to illustrate the range of devices on the market and currently under development, which provided many different tools to sample from for the next stages of research. Despite challenges associated with determining which devices were ready for testing, their cost and availability from online sources and manufacturers, the reviews succeeded in providing a shortlist of distinct devices matching the aforementioned criteria that were suitable to go through to the next stage of research and that could be procured within the project's timescales.

Although the cost of mobile phone applications was identified as a challenge for future implementation, following guidance from the Scientific Advisory Committee, the recommendation was that it would be worth testing both the mobile phone RR counters and pulse oximeters to ascertain their accuracy and utility at the community level; for this reason such devices were included in the final shortlist. Full details of the findings are published here (18).

4.2 Device attribute development process

Background

Formative research with CHWs in each of the four countries was carried out to capture perspectives on which device attributes were considered important for managing pneumonia at the community level. Moreover, the research sought to compare which attributes were deemed preferable to CHWs with those defined previously by the UNICEF Supply Division and global experts working in pneumonia management.

Methods

Twelve focus group discussions (FGDs), three per country, were conducted between March and June 2014. The aim was to explore CHWs' current experiences when managing pneumonia, particularly in relation to the devices they are using and how these could be improved to facilitate pneumonia diagnosis and classification. The specific objectives were:

- To explore CHWs' experiences including current enablers and constraints that CHWs face when managing pneumonia in their communities

- To capture CHWs' views on ideal device attributes that could be used to identify pneumonia in children under five at the community level

Sample

CHWs were selected by representative purposive sampling to increase the external validity of results. Factors such as age, gender (where applicable), geographic location, education level, patient load and level of experience were considered to gain a heterogeneous and representative sample of CHWs in each country. A total of 91 CHWs attended stage one FGDs across the four countries, with three FDGs held per country (see **Table 7**). This sample size was considered sufficient to achieve theoretical saturation of the data.

Table 7. Number of participants

Country	Location	Number of FGDs	Cumulative number of FGD participants
Cambodia	Ratanakiri province	3	19
Ethiopia	Southern Nations, Nationalities and People's Regional State	3	24
South Sudan	Aweil Centre and West counties, Northern Bahr El Ghazal state	3	24
Uganda	Mpigi District, Central Region	3	24
		Total:	91

Data collection

Due to the formative nature of the study, and the desire to understand current experiences and gain in-depth opinions from CHWs and stakeholders, FGDs were employed to explore the research objectives. Focus groups contained five to eight people and were conducted in the major native language of each region, supervised by Malaria Consortium staff. The question topic guide covered: CHWs' knowledge of diagnosis and management of childhood pneumonia; challenges encountered in the assessment process; and important attributes of new diagnostic tools. Topic guides were translated from English into the FGD language and then back translated for accuracy. All FGDs were audio recorded then transcribed and translated into English.

Analysis

All transcripts were imported into NVivo 10 software for coding and analysis. Codes were assigned using a combination of inductive and deductive approaches. Inductive coding was used to explore some of the data relating to the diagnosis of pneumonia for CHWs. These codes and sub-categories were categorized and thematic content analysis performed. After the initial identification of main themes, the data was re-examined and codes re-assigned as required. All countries used an identical global thematic framework to analyse the data and produce country specific reports of the findings. A global analysis of the formative research data across the four study countries was conducted by an independent consultant. The findings are presented below.

Ethical considerations

All CHWs who participated in the FGDs gave written informed consent prior to participation in the study.

Results

Perceived important attributes for new diagnostic tools

During the FGDs many ideas were raised as to how pneumonia diagnostic tools could be improved and suggestions given on what attributes would be helpful in any future devices. Themes on this topic related to usability, accuracy, acceptability, and other characteristics such as a long battery life, durability, automation, cost and multi-functionality.

Table 8. Summary of key CHWs' preferred attributes in a pneumonia diagnostic aid

No.	Attribute	Description
1.	Usability - ease of use	Easy for CHWs to use the device i.e. can apply it appropriately e.g. switch on the device, select the correct settings, complete the assessment to get a result
"It should be easy to use so that I can easily determine whether a child has pneumonia or not." Ugandan CHW		
2.	High level of decision support	Allows CHWs to detect the symptoms of pneumonia without the need for decision making from them
"…if we could have a tool that you place on the child and it displays results that gives an indication of whether or not a child has pneumonia." Ugandan CHW		
3.	Automation of diagnosis	Automatically provides the CHW with a diagnosis of pneumonia symptoms
"The instrument is big, and the number can be adjusted…and the number of breath appears automatically." Cambodian CHW *"Mine would look and work like a digital thermometer but instead of numbers, it would display colours say red or green; red to indicate that a child has pneumonia and green to indicate that a child does not have pneumonia." Ugandan CHW* *"…What I saw at the health centre in the town when measuring blood pressure with BP apparatus it has sound and tells the measurement. Like that I like a device which count the RR and tells the count. Like that rather than counting by observation a device which count and tell us the count. So the diagnosis of pneumonia will improve." Ethiopian CHW*		
4.	High accuracy of measured/calculated result	The device consistently provides an accurate measure of the result tested for – either RR or PO
"I want all the instruments to be more modern, faster and more accurate." Cambodian CHW *"Yes is should be accurate, that means we don't dispense amoxyl to those that don't need it." Ugandan CHW* *"…we prefer another tool that will not be counted like beads, simple to use and it can give accurate results." South Sudanese CHW*		
5.	No or little literacy and numeracy required	The device only requires a very low level of literacy and/or numeracy to be operated by the CHW
"What makes me happy is to work device which indicate the number of count like a thermometer. Counting device [ARI timer] is difficult especially when counting while observing the child's abdomen." Ethiopian CHW		
6.	No or little familiarity with technology required	The CHW does not need any prior familiarity with technology to operate the device effectively to detect the symptoms of pneumonia
"Because [it] is not simple to operate such of phone by someone who is illiterate and also it have a lot of instructions to follow." South Sudanese CHW		
7.	Long operational life in	The device (not probes) will have an operational life while

	the field – e.g. more than 2 years	being used by CHWs of more than 2 years
"However, nowadays, this instrument [ARI timer] is not modern and sometimes, it is easy to be broken or runs out of battery…I need a modern device because it is used for a long time." Cambodian CHW		
8.	Does not require charging (solar, battery, grid)	The device does not require charging to be used by CHWs to detect the symptoms of pneumonia
"I would like for the battery life to be looked into. If we can get something that is rechargeable…" Ugandan CHW *"We need something durable you see, when clients get accustomed to a tool, the next time they visit and you say that it is broken; some take it that you do not want to assess their children. For this reason we would like a durable tool say a solar powered one or one with a long battery life." Ugandan CHW*		
9.	High Durability/Mechanical robustness	The device will not break during normal use by the CHW in the detection of the symptoms of pneumonia
"I need a change on tools that we are currently using that cannot break easily or get damaged." South Sudanese CHW		
10.	High Caregiver acceptability of diagnosis	The readings provided by the device help and support the caregiver/parent in accepting the diagnosis offered by the CHW
"Like that thing they wrap around the arm to measure [blood] pressure. I reckon children would not be so afraid and even if the child was agitated, it would still give results quickly, their movements would not stop you from measuring their respiratory rate. In addition, the mother would all see the result, you know, some parents don't believe in the timer, they wonder how you get result, some think you're making this up." Uganda CHW *"…it will be simple to use and it will be acceptable to the communities and also it will work well." South Sudanese CHW* *"While I count the RR, I may make a mistake. For example if I said it is cough or common cold, the mother can say 'you don't find the disease, she didn't find the disease, she is wrong.' If there is a tool, which gives result that get from the finding. For example, when we diagnosing malaria by RDT the community believe and accept the positive or the negative results which we found. They say the child examined and the health extension told us the result. If I say now it is cough or common cold, the mother starts to confront and did not accept the result." Ethiopian CHW*		
11.	High Patient comfort	The device does not cause hurt or discomfort to the patient while being used by the CHW in the detection of the symptoms of pneumonia
"Sometimes, I wish that if there is a tool that can measure the RR like thermometer, to overcome the disturbance of children during diagnosis." Ethiopian CHW *"I can make my own tool to look like a thermometer because a thermometer does not make noise to scare the child." South Sudanese CHW* *"Something that you place on a child and it displays results, you know, like a [digital] thermometer that you place in the armpit and seconds later it displays the temperature. That is what they should give us; it would save time and all children wouldn't be too frightened." Ugandan CHW*		
12.	High portability	The device is easy to carry by the CHW throughout a typical work day

"It looks like my cell phone, perhaps smaller than the timer. It is something portable that I can carry anywhere with me." Ugandan CHW		
13.	Multi-functional (includes a minimum of RR and PO)	The device incorporates several applications for the detection and classification of the symptoms of pneumonia
"I want to make a device that can measure temperature, respiratory rate and weight at the same time, and for my role to not go beyond simply registering the results, asking the mother questions, and not bringing discomfort to the child. Rather than taking each measurement separately, if I had the capacity and knowledge, I would be happy to make a tool that can accommodate this and give results of these three things at once." Ethiopian CHW		

Numerous features were considered by CHWs to increase the simplicity of tool use. Tools that produced automated results were most appreciated. When CHWs were invited to brainstorm their ideal tools, a significant number described devices that independently counted the child's breaths and then displayed the RR. They made specific comparisons to devices that only need to be placed on the child to give a result, such as digital thermometers.

In countries where some CHWs were illiterate or had low education levels, even more importance was placed on tools that were easy to use, regardless of education. Attributes of tools that were considered important for this purpose included: having a minimal number of steps to get results; requiring little or no reading; colour coded classification of results indicating presence or absence of disease; and requiring no advanced technological knowledge to operate the device.

Moreover, CHWs who were literate also stated that they preferred tools that incorporated some form of disease classification system to minimise the need to interpret the results using separate guidelines. Participants in Ethiopia particularly felt this attribute would make the assessment and referral process simpler.

Lastly, other factors mentioned for increasing the simplicity of device use included clear display of results in a large format for older CHWs with poor eyesight, and instructions and steps written in the local language rather than English.

Participants highlighted the need for accurate tools in order to correctly classify children with pneumonia, which would improve caregiver confidence in the diagnosis. Many CHWs emphasised the need for future tools to be acceptable to children and parents. They reported that children do not like noisy tools, such as the ARI timer ticking. CHWs also felt parents would prefer tools that displayed results they could read themselves and understand the implications.

Acceptability of tools by CHWs was also important. CHWs preferred tools that were: small and portable; "modern", but simple to use; able to perform multiple functions; and able to provide automated results. They expressed a preference for devices that produced fast results.

Discussion and conclusions

The formative research indicated that an improved pneumonia diagnostic tool, which can be used accurately and efficiently by CHWs and is acceptable to caregivers, is needed to facilitate correct identification of the signs of pneumonia. This supports much of the published and anecdotal evidence provided by global experts and stakeholders implementing programmes with CHWs responsible for pneumonia management in children under five at the village level.

The data highlights the important role of ARI diagnostic aids in the management of pneumonia by CHWs in a range of settings. Comments and perceptions on the usability, accuracy and acceptability of the current tools used in each of the countries suggest that there is a strong, widespread felt need by the CHWs for an improved device that provides accurate results, is easy to use, regardless of education level, and accepted

by children and caregivers; especially given the implications for caregiver trust in CHWs' competence in managing pneumonia.

The challenges associated with using the current tools suggest an unmet demand for devices CHWs can use to effectively manage pneumonia. These gaps in the type of tool desired by CHWs were reflected in the specific attributes proposed during the focus group discussions. The range of device attributes previously identified by the UNICEF Supply Division was validated by CHWs across four countries who described their preferred attributes in a diagnostic aid. Their preferences were taken into consideration throughout the device selection process to identify the most suitable and most acceptable devices for evaluation and field testing. These findings were then used in the later stages of the device selection process to inform future development and agreements with partners on the specific attributes used to score the devices. The results were subsequently published in a peer review journal (19).

4.3 Scientific advisory committee oversight process

Background

As part of the Pneumonia Diagnostics project, Malaria Consortium invited global representatives from UNICEF, WHO, child health experts, diagnostics experts and country representatives from the four countries implementing the research to form a Scientific Advisory Committee (SAC) that would provide expertise and recommendations for quality assurance (see **Appendix 2** for the list of participants).

Methods

An initial SAC meeting was convened in June 2014 in Geneva, Switzerland with the following objectives:

- To brief the SAC and approve the methodologies and stages involved in the project
- To ratify and agree on the product profiles for the respiratory rate and pulse oximeter devices to be used in the project
- To seek recommendations for advocacy and dissemination of project results

Outcomes and recommendations

Overall, the SAC approved of the study, protocols and activities presented. They highlighted the importance of the findings and its vital role in improving the detection of the symptoms of pneumonia in children under five in the community settings. The SAC also made several important recommendations on how to improve the study design and ensure the results were as scientifically robust as possible. The SAC's recommendations included:

- Taking a more scientific approach for device selection:
  1) device attributes should be aligned to the UNICEF Acute Respiratory Infection Diagnostic Aid Target Product Profile
  2) device attributes should be ranked
  3) devices should be scored accordingly
- Registering the clinical device evaluation stage as a clinical trial, with accompanying trials insurance procured
- Conducting laboratory testing of devices for accuracy and robustness prior to field testing

Malaria Consortium ensured that all of these recommendations were carried out and worked with UNICEF to agree on the ranking of device attributes with support from IPSOS Healthcare, who led a stakeholder exercise to determine the device attributes' perceived importance (discussed in **section 3.5**).

4.4 Device attribute selection process

Background

The UNICEF Acute Respiratory Infection Diagnostic Aid (ARIDA) project began in the mid-1980s with the distribution of respiratory timers to support CHWs managing acute respiratory infections in children. Since the introduction of the ARIDA project, there has been an ongoing collaboration between WHO, Save the Children and other stakeholders who have extensive knowledge of the users of these diagnostic aids and their needs, particularly regarding the deficiencies of the existing tools.

Methods

A workshop was held by the UNICEF Supply Division in early 2013 to consider how such devices could be improved. Representatives from WHO, the Bill & Melinda Gates Foundation, USAID and from civil society, industry and academia participated in the workshop.

Outcomes

Participants shared their perspectives on the challenges faced in the use of pneumonia diagnostic devices in low-resource settings and invited experts to share their insights on how to innovate, design and manufacture new tools. They also defined a criterion for the evaluation of products and devices (see **Table 9**).

Table 9 Device shortlisting criteria adapted from UNICEF, 2013

Criteria	Description
Cost	• The cost effectiveness and affordability of the product • The existence of recurring costs and rates of consumption of any consumables during the life cycle of the product • Cost and burden to government procurement
Robustness	• The duration of life cycle replacement, to be measured in years • The recharge frequency, duration, and life span of battery cells and charger • The need for a maintenance / care regime and recycling options
Scale/applicability	• The products ability to reach urban, rural, regional or global scale, fit and adaptability • User context and cultural sensitivity • Manufacturer supply capacity, scalability and sustainability
CHW skills	• Need for literacy and numeracy, to be measured in terms of high, medium or low necessity • Need for training, to be measured in terms of minutes, hours, weeks in duration • Familiarity with technology, to be measured in terms of whether based on analogue, mobile/smart phone or computer based technology
Accuracy/scope	• The level of sensitivity and specificity • The level of automation, to be defined in terms of whether the device is dependent on human count, assisted count or fully automated count • The level of decision making support, to be defined in terms of whether there is a classification, a classification to remedy, or a classification to remedy and treat • The level of functionality, to be defined in terms of whether the device measures breaths, multiple data points or multiple data points beyond pneumonia
Credibility	• The level of community trust the device inspires in how the device reads and presents the test results
Extensibility	• The presence and need for hard coding: device software can be adapted

	• Whether the device is a single device or provides a platform base for additional functions
Availability	• Whether the device is available to be tested at the next stage of the process

Subsequently, in 2014 UNICEF developed a Target Product Profile (TPP) to encourage the increased availability of improved tools for diagnosing pneumonia, which UNICEF, governments and partners could procure and supply to health workers globally to prevent child deaths due to undiagnosed and untreated cases of pneumonia (8).

The device attributes described in the TPP were derived from the initial criteria defined during the January 2013 UNICEF Copenhagen meeting and based on a ranking exercise conducted with 20-30 global experts. These attributes were validated using the findings from the formative research previously outlined and agreed upon with the SAC as appropriate measures to score the devices with. The final device attributes used in the later selection of devices for the Pneumonia Diagnostics Multi-Country study are presented in **Table 10.**

Table 10. Final agreed device attributes

No.	Attribute	Description
1.	Usability - ease of use	Easy for CHWs to use the device i.e. can apply it appropriately e.g. switch on the device, select the correct settings, complete the assessment to get a result
2.	High level of decision support	Allows CHWs to detect the symptoms of pneumonia without the need for decision making from them
3.	Automation of diagnosis	Automatically provides the CHW with a diagnosis of pneumonia symptoms
4.	High accuracy of measured/calculated result (e.g. RR/PO/etc.)	The device consistently provides an accurate measure of the result tested for – either RR or PO
5.	No or little literacy and numeracy required	The device only requires a very low level of literacy and/or numeracy to be operated by the CHW
6.	No or little training required	The CHW only requires minimal amounts of training to be able to use the device effectively to detect the symptoms of pneumonia
7.	No or little familiarity with technology required	The CHW does not need any prior familiarity with technology to operate the device effectively to detect the symptoms of pneumonia
8.	Long operational life in the field – e.g. more than 2 years	The device (not probes) will have an operational life while being used by CHWs of more than 2 years
9.	Does not require charging (solar, battery, grid)	The device does not require charging to be used by CHWs to detect the symptoms of pneumonia
10.	Does not require replaceable parts (non-rechargeable batteries, consumables)	The device does not require replaceable parts such as non-rechargeable batteries and/or consumables throughout its functional life in the field
11.	Requires little or no maintenance	The device does not require any maintenance throughout its operational life when used by CHWs to effectively detect the symptoms of pneumonia
12.	High Durability/Mechanical robustness	The device will not break during normal use by the CHW in the detection of the symptoms of pneumonia

13.	High CHW confidence in measurements	The readings provided by the device support the CHW in relation to detecting the symptoms of pneumonia
14.	High Caregiver acceptability of diagnosis	The readings provided by the device help and support the caregiver/parent in accepting the diagnosis offered by the CHW
15.	High Patient comfort	The device does not cause hurt or discomfort to the patient while being used by the CHW in the detection of the symptoms of pneumonia
16.	High Portability	The device is easy to carry by the CHW during normal working
17.	Easy to maintain hygiene	The device is hygienic and easy to maintain in this regard – i.e. doesn't require specialist cleaning procedures or products
18.	Low Price (less than $50)	The annualised device cost is less than $50 (Device = total package of device plus consumables such as batteries/probes and chargers)
19.	High level of safety	The device provides a high level of safety when it is being used for the detection of the symptoms of pneumonia
20.	Multi-functional (includes a minimum of RR and PO)	The device incorporates several applications for the detection and classification of the symptoms of pneumonia

4.5 Device attribute ranking process

Background

In line with the SAC's recommendation to adopt a more robust approach to the device attribute ranking and selection process, Malaria Consortium procured a supplier with experience of the most appropriate methodology and skill set to lead a ranking exercise to assess the importance of attributes of diagnostics tools for pneumonia. IPSOS Healthcare, a global leader in research methodologies used in device development and evaluation were selected as the most suitable supplier.

In June and July 2014, in collaboration with Malaria Consortium, IPSOS developed a study to rank the agreed 20 device attributes in order of relative importance. The aim of this exercise was to specifically identify which product features or attributes were most important in a diagnostic tool for the detection of signs of pneumonia for CHWs in low-income countries and rank them accordingly. The findings would help prioritise which devices should be field tested.

Methods

Sample

Respondents were purposively recruited from a list of professionals working in the field of pneumonia diagnostics and identified by Malaria Consortium in consultation with the SAC and shared with IPSOS. In total, 30 global experts took part in the scoring exercise, which included the Scientific Advisory Committee. Stakeholders who were not present for the SAC meeting were contacted by email. Respondents were based in nine different countries (UK, USA, Cambodia, Ethiopia, South Sudan, Uganda, Switzerland, Canada and Denmark). Respondents' professions profiles ranged from universities, government, non-governmental organisations, multi-lateral organisations and the private sector.

Data collection

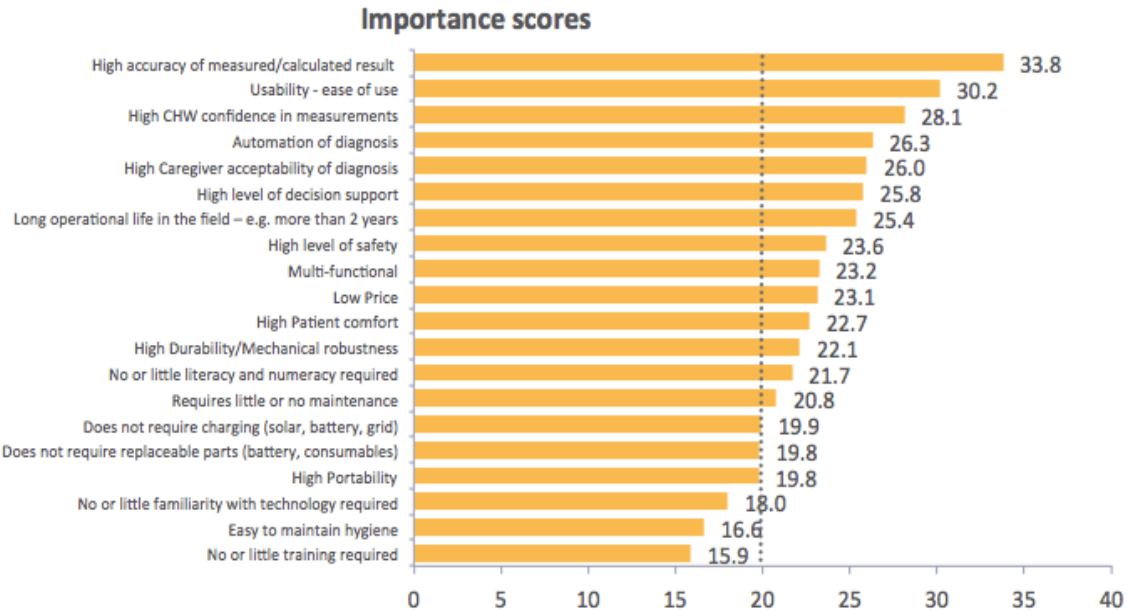
Respondents were asked to complete a 20 minute questionnaire on paper. Data was collected from 18th June- 17th July 2014. An anchored MaxDiff approach was adopted to encourage respondents to be more critical in their assessment of attribute importance. Instead of ranking each attribute individually, the Max Diff approach requires respondents to review several attributes at once based on a Latin Square (balanced order and pairing) design. Respondents see each attribute exposed and are asked to rank it three times, which provides a more robust evaluation than a one-time assessment. Lastly, for each group of statements,

respondents were asked whether: “all of them are actually very important,” “none of them are actually that important,” or “some attributes shown are more important than others.”

Results

The MaxDiff results showed that the vast majority of attributes tested (14 out of 20) were considered to be very important for a pneumonia diagnostic tool used by CHWs (anchor threshold = 20). The top three most important attributes were: high accuracy of measured/calculated result, usability/ease of use and high CHW confidence in measurements. The results presented in **Figure 3** are contextualised as respondents were able to comment on whether they find all of the attributes in a particular set to be important.

Figure 3. Anchored Max Diff results: importance scores



When asked to spontaneously recall the “must have” attributes of a pulse oximeter device, ease of use (100%), durability (80%), accuracy (70%) and low cost (60%) were the top attributes listed by respondents. The respondents were divided over whether the attributes tested were exhaustive. However, other attributes freely mentioned by respondents when asked to specify other factors important to a pneumonia diagnostic tool covered the same themes in terms of ease of use and accuracy, but provided greater detail on anticipated features. Some examples included:

- *“Minimal intervention/effort required from CHW for the measurement.”*
- *“CHW notification that a reading is being taken like through a vibration or beep. No counting is required by the CHW but needs to just press a button for each cycle of breath.”*
- *“Indicating the dosage of antibiotic for age group or colour coding.”*
- *“Results easy to read at night.”*

Conclusions

The results from the MaxDiff exercise, particularly the index scores that showed which attributes ranked as most important, were subsequently applied to the 188 diagnostic tools to assess which should be prioritised for field testing. The important scores from the MaxDiff exercise were combined with the product features of the devices to formulate an overall score for each product. This provided a rank order of devices to assist in the decisions to be made about which ones to field test.

4.6 Final device scoring process

The alignment of device attributes with the UNICEF ARIDA TPP and the agreed ranking of attributes informed by the IPSOS MaxDiff exercise provided a framework for scoring the many potential devices identified by the landscape reviews. A device scoring exercise was carried out to shortlist which devices, out of the total 188, would be the most appropriate for the clinical evaluation and field testing.

Methods

The device scoring exercise comprised of the following steps:

1. The initial number of 188 potential devices were scored with a measure of device readiness to reflect the current availability of the device to be taken into the field for further research and analysis as follows:
   3=device is commercial available now
   2=device will be market available within six months
   1=device is not available.
   All of the devices which had an availability score of 1 were eliminated.
2. All the devices which score a 3 or 2 in the availability scoring were then put forward for individual attribute scoring using each of the 20 product attributes where a score of:
   1=low
   2= medium
   3= high for each attribute (see **Table 11**).
3. The individual final scores from the MaxDiff exercise were multiplied with the individual attribute scores for each device and all of these were added together to give an ultimate score for each device.
4. The scored devices were subsequently ranked in three groups – the first group was a ranked group of market ready devices, the second group ranked devices that should be market ready within six months and the final group ranked devices that were not ready for field testing.
5. These groups were used by the SAC to make the final selection for the laboratory testing activity for future clinical evaluation and field testing.

Therefore, according to the device scoring exercise process:

A device's total score = the availability score x the attribute score x the IPSOS ranking of the attribute.

The availability, attribute scores, ranking and total scores were compiled in an Excel document and compared across the 188 devices to identify which scored the highest (20).

At this stage, accuracy was not given a score (remaining as "0") since the devices had not all been tested in a laboratory because it was not feasible to do so for many devices. The accuracy scores were factored in once the laboratory testing had been completed. Following the clinical evaluation and subsequent research stages, the devices will be re-scored and ranked.

Conclusions

The device scoring exercise facilitated the overall ranking and prioritisation of which devices were the most suitable for procurement, lab testing and upcoming research stages, narrowing a potential 188 products to 11: four RR counters and seven pulse oximeters.

Table 11. Device attributes and score definitions

No.	Attribute	Score Definition
1.	Usability - ease of use	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 to detect the symptoms of pneumonia in children
2.	High level of decision support	3=The CHW can get treatment options 2=The CHW can get classification 1=The CHW can get the result 0=The CHW cannot use the device to detect the symptoms of pneumonia
3.	Automation of diagnosis	3=Fully automated result provided 2=CHW doesn't need to count but must observe 1=CHW manually counts 0=The CHW 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 breathes/minute (RR) or ±1% for SpO2 2=Accurate to ±5 breathes/minutes (RR) or ±2% for SpO2 1=Accurate to ±7 breathes/minutes (RR) or ±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 (Approx. reading & 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 necessary 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)
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 six months) 1=High level of maintenance required (more than once every six 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=≥ 50% of the devices break during their lifetime
13.	High CHW confidence in measurements	3=The CHW feels completely confident in the reading providing by the device for all patients 2=The CHW feels somewhat confident in the reading provided by the device in some patients

		1=The CHW does not feel confident in the reading provided by the device for most patients
14.	High caregiver acceptability of diagnosis	3=The caregiver feels completely confident and totally accepts the diagnosis offered by the CHW 2=The caregiver feels somewhat confident and somewhat accepts the diagnosis offered by the CHW 1=The caregiver is not confident and does not accept the diagnosis offered by the CHW
15.	High patient comfort	3=No discomfort caused 2=Some discomfort caused 1=Very uncomfortable for patient 0=the device can cause harm
16.	High portability	3=Device is completed 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.	High level of safety	3=Device is completely safe for the child and the CHW to use for the detection of the symptoms of pneumonia by CHWs 2=Device comes with some potentially harmful features 1=Device comes with many potentially harmful features 0=Device is not safe to use for the detection of the symptoms of pneumonia by CHWs
20.	Multi-functional (includes a minimum of RR and PO)	3=Device has RR and PO plus one other function 2=Device has both RR and PO 1=Device has either RR and PO functionality 0=Device has neither RR or PO functionality

A follow up consultation with stakeholders was organised by Malaria Consortium in September 2014 and attended by representatives from WHO, UNICEF and SAC Chair and members. The purpose of the meeting was to provide updates on the device selection process, IPSOS results and final device scoring. It was explained that 188 potential devices were ranked according to the attributes from the MaxDiff exercise conducted in June 2014 by IPSOS. As described above, the final individual scores from the MaxDiff exercise were subsequently multiplied with the individual attribute scores for each device. All of these were then added together to get an ultimate score for each device. The SAC agreed on selecting the top 11 devices with the highest scores: seven pulse oximeters and four respiratory rate counters.

Meeting participants noted that the MaxDiff attribute rankings or weightings did not precisely match those developed by UNICEF in their TPP, although alignment was thoroughly sought. Nevertheless, due to the value placed on CHWs' needs and considering attributes such as multi-functionality, which were not foreseen in the TPP, it was agreed that both sets of attributes would be aligned as previously discussed and the final ARIDA TPP attribute scores would match the Malaria Consortium pneumonia diagnostics device attribute scores.

The SAC agreed devices that currently available would be sent for laboratory testing; however, this would only pertain to the seven pulse oximeters, as the mobile phones used for the selected respiratory rate counters were already on the market. It was, therefore, deemed robust enough and it would not add any value to the decision-making to test the non-automated RR counters (the ARI timer and counting beads).

The SAC concluded that once the devices had been tested in the laboratory, the clinical evaluation and field testing of all of the devices should begin in order to meet the project timescales.

4.7 Laboratory testing process

In accordance with the SAC's previous recommendation to test proposed devices *in-vitro* to determine accuracy and robustness in field conditions, seven pulse oximeters were sent for laboratory testing in December 2014. It was agreed that it was important to test more than one type of each pulse oximeter. Four fingertip, two handheld and one mobile phone application pulse oximeters were sent to be tested. After consulting with manufacturers on the device test design TUV Rheinland Laboratory in Budapest, Hungary, a laboratory with previous documented experience of evaluating similar medical devices, was chosen for testing the suitability of the devices.

Methods

Each device underwent both accuracy and functional testing (the latter conducted before the stress tests and after each stress test). All tests were based on ISO standard 80601-2-61 for pulse oximeters. Each device was subjected to the following:

1. Accuracy testing

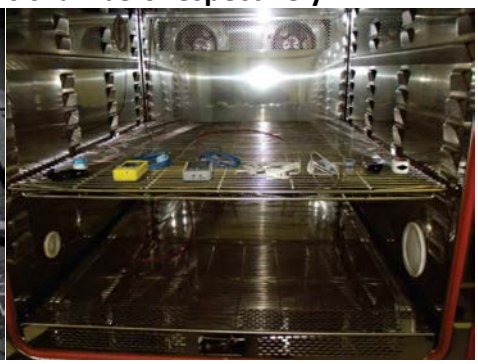
- An initial test to determine each device's accuracy of an oxygen saturation reading at eight different saturation points, ranging from 80 percent to 100 percent. The maximum allowable tolerance value for saturation (SpO_2) was ± two percent between the adjusted saturation value on the pulse oximeter tester and the displayed saturation value on the equipment being tested.
- Each set of tests was conducted ten times to calculate an average value, which included the following data points:
  - Performance time (PT): the total time in seconds from initiation to sensor placement to recording of an acceptable reading) and
  - Lag time (LT): the time in seconds from completion of sensor placement to acceptable reading being recorded)

2. Functional testing

- Cyclical heat: a 72 hour cycle ranging from -20 degrees to +40 degrees Celsius
- Damp heat: -50 degrees Celsius with 85 percent humidity over 72 hours
- Dry heat: -60 degrees Celsius over 72 hours
- Vibration and shock: 10 Hz to 1,000 Hz: 1,0 (m/sq)sp/Hz for 30 minutes
- Free fall: ten drops (five to front side, five to back side) of one metre onto concrete
- Dust – items placed in dust shed for eight hours (IP5X test)
  A final test after all of the stress tests had been completed

Battery life and recharge effectiveness, plus sensor life, where applicable, using pre and post testing with a Lightman (for probes) and a Fluke ProSim SPOTLight (for devices) were also tested.

Images 3 & 4: Tested samples in dust and climatic chambers respectively



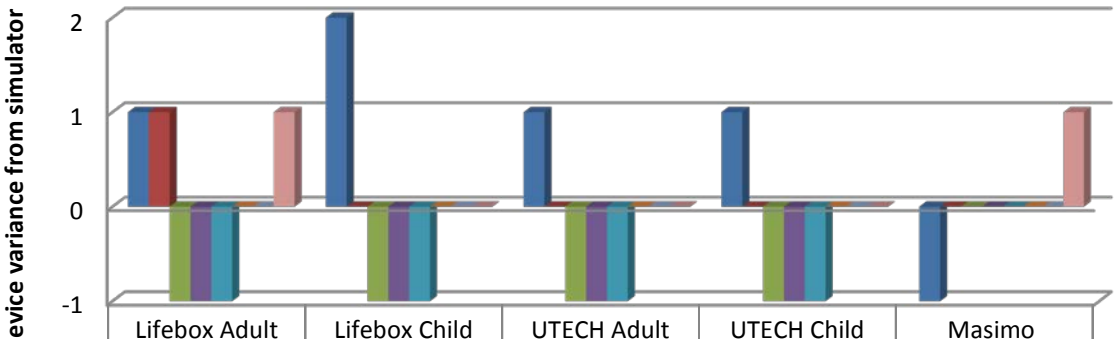
Results

Accuracy test results

The accuracy tests were conducted using simulators for each device and carried out prior to being sent for functional tests. For the hand held pulse oximeter devices, both adult and child probes were tested. All handheld pulse oximeter probes were tested with the Lightman SPO2 Sensor Tester using their cable test functionality. The accuracy of all devices was also tested using the Fluke Prosim SPOTLight SPO2 functional tester (21).
All of the device results were within ± 2% of the correct oxygen saturation (SpO2) given by the Pulse Oximeter Tester and therefore passed the accuracy testing stage. All devices performed well, with Masimo being the best with the device average variance from the simulator of 0.25 while the Lifebox handheld pulse oximeter used with the adult probe and the Contec fingertip pulse oximeter with the highest average variance reading of 0.75.

The performance and lag time of all the devices were also within the acceptable range of 30 seconds, except for the Lifebox paediatric probe, which subsequently proved to be because of a faulty probe and when retested was within the 30 second range. The full accuracy test results for each device are presented in **Appendix 3**. See **Graphs 1-4** below for average variance, performance and lag times for each device.

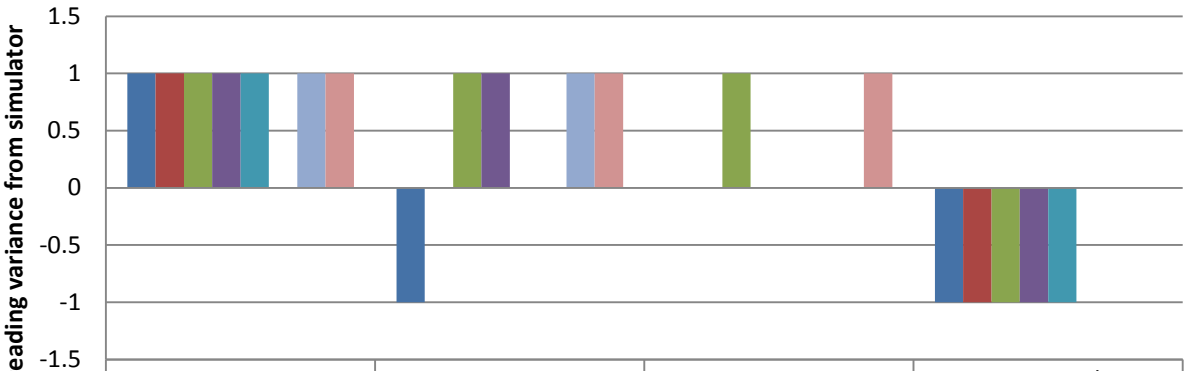
Graph 1. Handheld and phone pulse oximeters average variance by device



	Lifebox Adult	Lifebox Child	UTECH Adult	UTECH Child	Masimo
80%	1	2	1	1	-1
85%	1	0	0	0	0
90%	-1	-1	-1	-1	0
95%	-1	-1	-1	-1	0
97%	-1	-1	-1	-1	0
98%	0	0	0	0	0
99%	0	0	0	0	0
100%	1	0	0	0	1

Average variance	**0.75**	**0.625**	**0.5**	**0.5**	**0.25**

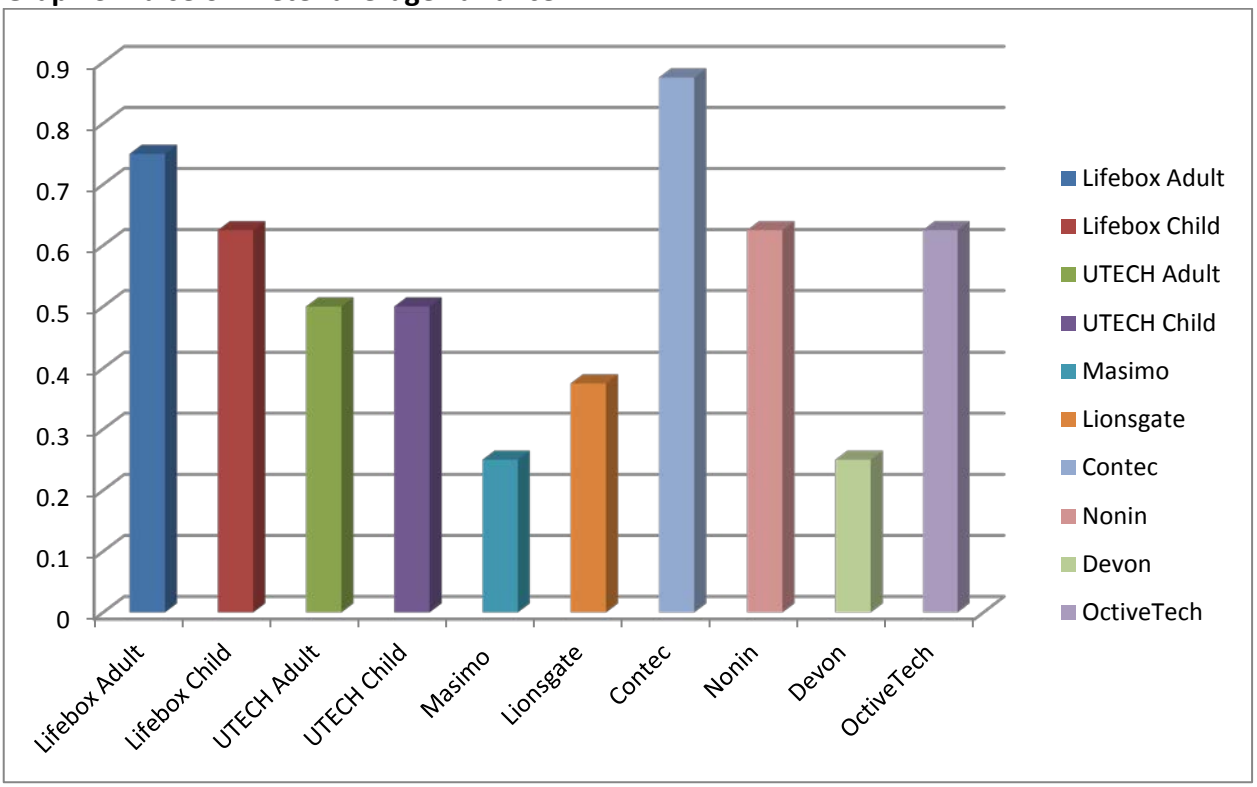
Graph 2. Fingertip pulse oximeter average variance by device



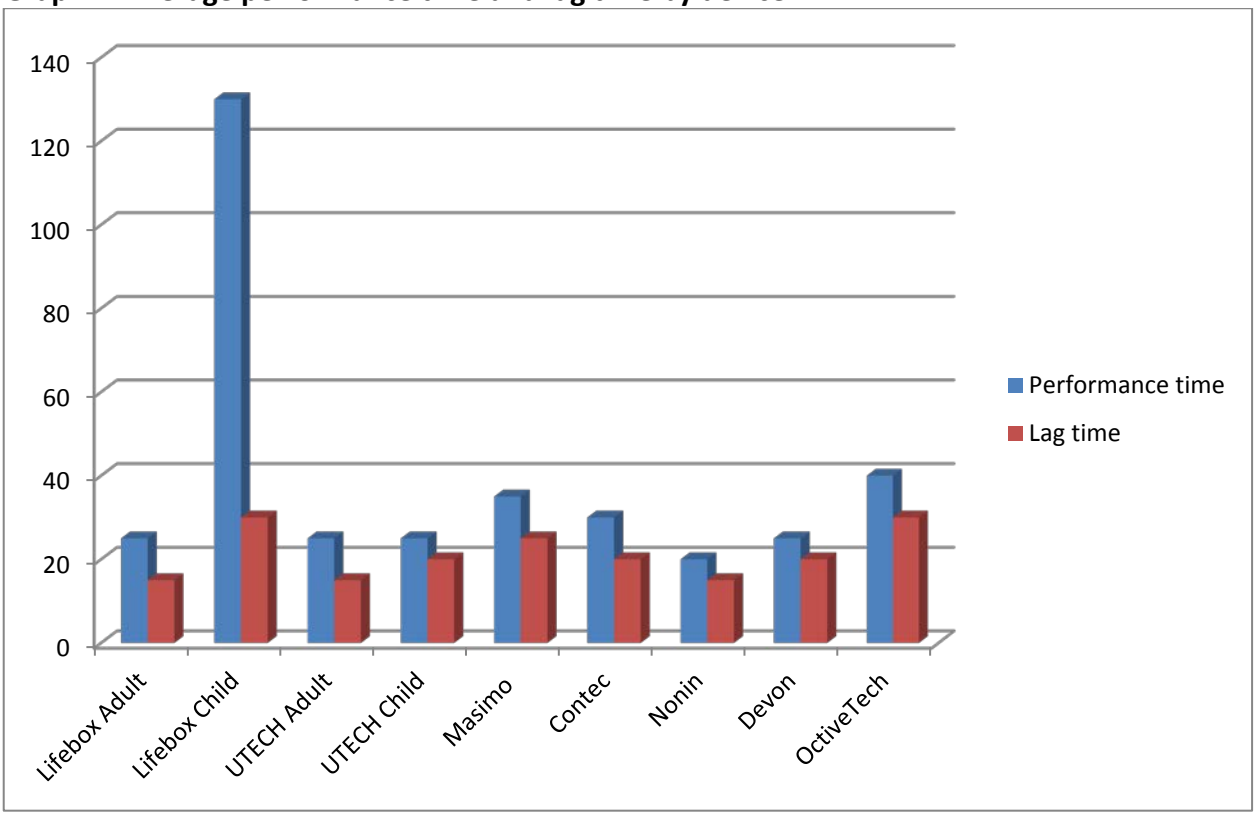
	Contec	Nonin	Devon	OctiveTech
80%	1	-1	0	-1
85%	1	0	0	-1
90%	1	1	1	-1
95%	1	1	0	-1
97%	1	0	0	-1
98%	0	0	0	0
99%	1	1	0	0
100%	1	1	1	0

Average variance	**0.75**	**0.625**	**0.5**	**0.5**

Graph 3. Pulse oximeter average variance



Graph 4. Average performance time and lag time by device



Functional test results

Out of the seven devices, two failed completely, one passed all of the tests except the dust exposure and the remaining five passed all of the tests and performed quite similarly. Of those which failed, one of the mobile phone devices (a prototype) was excluded from the selection after failing all of the tests (not reflected in the table below) whilst one of the fingertip devices did not provide an initial oxygen saturation accuracy reading, thus was not subjected to the other tests. The results are presented in **Table 12** and were shared with all manufacturers who signed collaboration agreements.

Table 12. Summary of test results of functional testing (P=Pass, F=Fail)

No.	Device	Sample type/serial number	Oxygen saturation accuracy before all stress tests*	Cycle heat	Damp heat	Dry heat	Vibration	Free fall	Dust	Final test after all stress tests	Overall pass or fail
1	**Hand held pulse oximeter Lifebox ACARE**	AH-M1/ M21821359	P	P	P	P	P	P	P	P	Pass
2	**Hand held pulse oximeter UTECH**	UT100/ UT1001410012	P	P	P	P	P	P	P	P	Pass
3	**iSpO2Rx pulse oximeter, MASIMO**	iSpO2Rx/ RX00022887	P	P	P	P	P	P	P	P	Pass
4	**Fingertip pulse oximeter OCTIVETECH**	300PN/ 122866300300	Could not get a reading, not tested further	/	/	/	/	/	/	/	Fail
5	**Fingertip pulse oximeter NONIN**	GO2 Achieve/ 501665134	P	P	P	P	P	P	P	P	Pass
6	**Fingertip pulse oximeter DEVON MEDICAL**	PC-60D/ XXG00KJ00379	P	P	P	P	P	P	P	P	Pass
7	**Fingertip pulse oximeter CONTEC**	CMS50QA/ 1402010251	P	P	P	P	P	P	F	F	Pass

*It is noted that oxygen saturation and heart rate stable values were displayed for at least 10 seconds on each of the devices being tested further.

4.8 Final device selection process

The culmination of the above activities resulted in the final selection of nine devices based on their individual total device score, laboratory test results and feedback from the SAC on suitability of the devices in terms of cost, availability and country context. For example, the Devon and Contec fingertip pulse oximeters scored higher due to their rechargeable batteries versus the Nonin, although all tested similarly in the lab. Subsequently, five pulse oximeters out of the seven sent for laboratory testing were selected in the final round in addition to four respiratory rate counters.

The SAC stipulated that only market-ready devices would be accepted, excluding prototypes. It is noted that the devices had a range of price points, but at this stage of the research the focus was to assess the usability and acceptability of the devices, with future consideration for cost and scale up implications once proof of concept had been demonstrated. The types of devices included in the final selection included are presented in **Table 13.**

Table 13. Final field Evaluation Devices

Respiratory Rate Devices					
Device Type	***Device Description***	***Devices selected***	***Features***	***Device score***	***Price***
a) Non Automated	Non-automated devices include tools that support the manual counting of chest movements, by indicating when to start and stop counting.	**MK2 ARI timer** 	Durable; Low cost; long battery life; easy to use; requires little training.	113	USD 4.82
b) Automated	Devices that support an assisted count, by automating or negating the need for manual counting of each chest movement. Mobile software applications in the category of assisted count work when CHWs tap the screen or press buttons for each chest movement.	**RRate Smartphone app** 	Easy to use; fast result; doesn't require counting skills; gives outcome.	103	Free + cost of phone
		Respirometer Feature phone app 	Easy to use; fast result; doesn't require counting skills; low cost; gives outcome.	118	Free + cost of phone
Pulse Oximeters					
Device Type	***Device Description***	***Devices selected***	***Features***	***Device score***	***Price***

a) Hand-held devices	Oximeters that were traditionally designed for professional rather than for home use. Many of them are suitable for adults, children and young infants, since oxygen is measured using a finger external sensor that can be purchased separately for paediatric and neonatal use.	**Lifebox** 	Rechargeable ; long warranty life; robust; reusable probes	110	USD 250
		UTECH 	Rechargeable batteries ;reusable probes	99	USD 108
b) Mobile phone applications	These devices function by connecting a pulse oximeter to a smartphone and the reading the oxygen saturation of the patient using an app installed on the phone with the oxygen values of the patient shown on the display of the phone.	**Masimo iSpO2** 	Anti-motion technology; neonatal probe; high spec phone required	96	USD 150 + cost of phone
c) Finger-tip devices	These affordable, easy to use pulse oximeter devices incorporate the probe and the device in one unit.	**Contec** 	Rechargeable batteries (charger provided)	102	USD 40
		Devon 	Rechargeable batteries (charger provided)	103	USD 95

A final device matrix was constructed to maximise the opportunities to test as many devices as possible with a realistic sample. Device types were spread across countries and matched according to the country context with consideration for current tools used by the CHWs, local environment, and CHW level of education and literacy (see **Table 14**). Each type of device was paired with its counterpart, i.e. the two fingertip pulse oximeters and the two handheld pulse oximeters, to serve as a comparator for the purpose of the evaluation.

Table 14. Devices to be clinically evaluated & field tested (by country)

Device Name	Type	Cambodia		Ethiopia	Uganda	South Sudan
Respiratory Beads & MK2 ARI Timer	RR Counter					X
MK2 ARI Timer only	RR Counter	X		X	X	
RRate SMART phone App	RR Counter	X		X	X	X
Respirometer Feature Phone App	RR Counter			X	X	X
Contec	Fingertip pulse oximeter	X		X	X	X
Devon	Fingertip pulse oximeter	X		X	X	X
Lifebox	Handheld pulse oximeter	X		X	X	X
UTECH	Handheld pulse oximeter	X		X	X	X
Masimo iSpO2	Phone pulse oximeter	X		X	X	X

5. Discussion

The range of activities conducted to support a scientifically robust device selection process developed and considered a range of attributes, stakeholder preferences and country contexts. Device accuracy, usability and acceptability were highlighted as essential by CHWs and national and global stakeholders, among other important characteristics detailed in this report which have implications for feasibility, sustainability and scale up.

Global collaboration with pneumonia management experts, academics, donors, private industry and ministries of health proved invaluable to capturing a wide spectrum of perspectives and input on future pneumonia diagnostic aids, and conducting multi-country research with community level participants.

The flexibility of the research team facilitated the evolution of the device selection process and recommendations from the SAC informed significant changes to include additional activities to support a more thorough selection. The adaptations to the methodology and increased number of stages based extended the duration of the project. Initially three months was allocated to this stage, but ultimately it lasted close to 12 months. Nevertheless, the SAC inputs improved the overall process and outcomes.

6. Recommendations

The global health community is advocating for pneumonia morbidity and mortality in children under five to be targeted as a priority in countries with the highest burden (22, 23). From the literature and formative research conducted as part of this multi-country study, it is evident that there is a demand for improved pneumonia diagnostic aids that can be used at the community level. Further research should explore the suitability of a range of new tools and contribute to the evidence base for appropriate pneumonia diagnosis by CHWs.

Based on the experience of leading the device selection process, the following recommendations are made:

- It is key to evaluate devices by their category i.e.: available devices, market ready devices and approved medical devices to easure equality in the selection process
- Device attributes should be scored and ranked using a scientific approach to ensure robustness in the device selection process

  It is essential to subject devices to laboratory testing prior to using the devices on study participants

  Investment and further research and development is needed to identify the most suitable tools for CHWs that are accurate, usable and acceptable in the local context

Appendices

Appendix 1. Criteria for the evaluation of devices from UNICEF

Cost	The cost effectiveness and affordability of the product
	The existence of recurring costs and rates of consumption of any consumables during the life cycle of the product
	Cost and burden to government procurement
Robustness	The duration of life cycle replacement, to be measured in years
	The recharge frequency, duration, and life span of battery cells and charger
	The need for a maintenance / care regime and recycling options
Scale / Applicability	The products ability to reach urban, rural, regional or global scale, fit and adaptability
	User context and cultural sensitivity
	Manufacturer supply capacity, scalability and sustainability
CHW Skills	Need for literacy and numeracy, to be measured in terms of high, medium or low necessity
	Need for training, to be measured in terms of minutes, hours, weeks in duration
	Familiarity with technology, to be measured in terms of whether based on analogue, mobile/smart phone or computer based technology
Accuracy / Scope	The level of sensitivity and specificity
	The level of automation, to be defined in terms of whether the device is dependent on human count, assisted count or fully automated count
	The level of decision making support, to be defined in terms of whether there is a classification, a classification to remedy, or a classification to remedy and treat
	The level of functionality, to be defined in terms of whether the device measures breaths, multiple data points or multiple data points beyond pneumonia
Credibility	The level of community trust the device inspires in how the device reads and presents the test results
	The presence and need for hard coding
Extensibility	Whether the device is a single device or provides a platform base for additional functions

Appendix 2. List of Scientific Advisory Committee Meeting participants (Geneva, Switzerland, June 2014)

Name	Affiliation
Prof James Tumwine	Makerere University, Kampala
Dr Hailu Tesfaye	Save The Children
Dominic Athian Dut	Ministry of Health, Aweil
Prof Chhuoy Meng	Calmette Hospital, Phnom Penh
Dr Mark Young	UNICEF
Helene Möller	UNICEF
Kristoffer Gandrup-Marino	UNICEF
Dr Shamim Qazi	WHO
Dr Adriana Velazquez-Berumen	WHO
Dr Debbie Burgess	BMGF
Prof Trevor Duke	RCH Melbourne
Dr David Peel	Ashdown Consultants
Dr Salim Sadruddin	Save the Children
Prof Rosanna Peeling	LSHTM
Pneumonia Diagnostics team	
Dr Karin Källander	Malaria Consortium
Kevin Baker	Malaria Consortium
Stefania Rigillo	Malaria Consortium
Other participants	
Kim Horn Hansen	UNICEF - speaker
Mark Newell	Global Good - observer
Melissa Moodley	IPSOS – speaker

Appendix 3. Device accuracy results

<table>
<tr><th>No.</th><th>Device name and results</th></tr>
<tr><td>1</td><td>Hand held pulse oximeter Lifebox ACARE</td></tr>
<tr><td></td><td>Adult
<table>
<tr><th rowspan="2">Fluke SpO2 parameter</th><th colspan="3">Acceptable reading criteria</th><th colspan="2">Accuracy</th><th rowspan="2">Performance Time (PT) (Sec)</th><th rowspan="2">Lag Time (LT) (Sec)</th></tr>
<tr><th>stable SpO2 ±2% for at least 10 sec</th><th>heart rate displayed</th><th>adequate signal indicator</th><th>Fluke reading</th><th>Device reading</th></tr>
<tr><td>80%</td><td>79</td><td>80</td><td>yes</td><td>80</td><td>79</td><td>25</td><td>15</td></tr>
<tr><td>85%</td><td>84</td><td>80</td><td>yes</td><td>85</td><td>84</td><td>25</td><td>15</td></tr>
<tr><td>90%</td><td>91</td><td>80</td><td>yes</td><td>90</td><td>91</td><td>25</td><td>15</td></tr>
<tr><td>95%</td><td>96</td><td>80</td><td>yes</td><td>95</td><td>96</td><td>25</td><td>15</td></tr>
<tr><td>97%</td><td>98</td><td>80</td><td>yes</td><td>97</td><td>98</td><td>25</td><td>15</td></tr>
<tr><td>98%</td><td>98</td><td>80</td><td>yes</td><td>98</td><td>98</td><td>25</td><td>15</td></tr>
<tr><td>99%</td><td>99</td><td>80</td><td>yes</td><td>99</td><td>99</td><td>25</td><td>15</td></tr>
<tr><td>100%</td><td>99</td><td>80</td><td>yes</td><td>100</td><td>99</td><td>25</td><td>15</td></tr>
</table>
Note: Cable test 3000 cycles ok.</td></tr>
<tr><td>2</td><td>Hand held pulse oximeter UTECH UT100</td></tr>
<tr><td></td><td>Child
<table>
<tr><th rowspan="2">Fluke SpO2 parameter</th><th colspan="3">Acceptable reading criteria</th><th colspan="2">Accuracy</th><th rowspan="2">Performance Time (PT)</th><th rowspan="2">Lag Time (LT)</th></tr>
<tr><th>stable SpO2 ±2% for at least 10 sec</th><th>heart rate displayed</th><th>adequate signal indicator</th><th>Fluke reading</th><th>Device reading</th></tr>
<tr><td>80%</td><td>80</td><td>80</td><td>yes</td><td>80</td><td>79</td><td>25</td><td>20</td></tr>
<tr><td>85%</td><td>85</td><td>80</td><td>yes</td><td>85</td><td>85</td><td>25</td><td>20</td></tr>
<tr><td>90%</td><td>91</td><td>80</td><td>yes</td><td>90</td><td>91</td><td>25</td><td>20</td></tr>
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</table>
Note: Cable test passed 3000 cycles</td></tr>
<tr><td>3</td><td>iSpO2Rx pulse oximeter, MASIMO</td></tr>
</table>

Fluke SpO2 parameter	Acceptable reading criteria			Accuracy		Performance Time (PT)	Lag Time (LT)
	stable SpO2 ±2% for at least 10 sec	heart rate displayed	adequate signal indicator	Fluke reading	Device reading		
80%	80	80	Yes	80	80	35	25
85%	86	80	Yes	85	86	35	25
90%	91	80	Yes	90	91	35	25
95%	95	80	Yes	95	95	35	25
97%	97	80	Yes	97	97	35	25
98%	98	80	Yes	98	98	35	25
99%	99	80	Yes	99	99	35	25
100%	100	80	Yes	100	99	35	25

4	**Fingertip pulse oximeter OCTIVETECH**

Fluke SpO2 parameter	Acceptable reading criteria			Accuracy		Performance Time (PT)	Lag Time (LT)
	SpO2 ±2% for at least 10 sec	heart rate displayed	adequate signal indicator	Fluke reading	Device reading		
80%	81	80	Yes	80	81	40	30
85%	86	80	Yes	85	86	40	30
90%	91	80	Yes	90	91	40	30
95%	96	80	Yes	95	96	40	30
97%	98	80	Yes	97	98	40	30
98%	98	80	Yes	98	98	40	30
99%	99	80	Yes	99	99	40	30
100%	100	80	Yes	100	100	40	30

5	**Fingertip pulse oximeter NONIN**

Fluke SpO2 parameter	Acceptable reading criteria			Accuracy		Performance Time (PT)	Lag Time (LT)
	stable SpO2 ±2% for at least 10 sec	heart rate displayed	adequate signal indicator	Fluke reading	Device reading		
80%	81	80	Yes	80	81	20	15
85%	85	80	Yes	85	85	20	15
90%	89	80	Yes	90	89	20	15
95%	94	80	Yes	95	94	20	15
97%	97	80	Yes	97	97	20	15
98%	98	80	Yes	98	98	20	15
99%	98	80	Yes	99	98	20	15
100%	99	80	Yes	100	99	20	15

6	**Fingertip pulse oximeter DEVON MEDICAL**

Fluke SpO2 parameter	Acceptable reading criteria			Accuracy		Performance Time (PT)	Lag Time (LT)
	stable SpO2 ±2% for at least 10 sec	heart rate displayed	adequate signal indicator	Fluke reading	Device reading		
80%	80	80	Yes	80	80	20	15
85%	85	80	Yes	85	85	20	15
90%	89	80	Yes	90	89	20	15
95%	95	80	Yes	95	95	20	15
97%	97	80	Yes	97	97	20	15
98%	99	80	Yes	98	98	20	15
99%	99	80	Yes	99	99	20	15
100%	100	80	Yes	100	99	20	15

7 **Fingertip pulse oximeter CONTEC**

Fluke SpO2 parameter	Acceptable reading criteria			Accuracy		Performance Time (PT)	Lag Time (LT)
	stable SpO2 ±2% for at least 10 sec	heart rate displayed	adequate signal indicator	Fluke reading	Device reading		
80%	79	80	yes	80	79	30s	20s
85%	84	80	yes	85	84	30s	20s
90%	89	80	yes	90	89	30s	20s
95%	94	80	yes	95	94	30s	20s
97%	96	80	yes	97	96	30s	20s
98%	98	80	yes	98	98	30s	20s
99%	98	80	yes	99	98	30s	20s
100%	99	80	yes	100	99	30s	20s

Note: Device switches off automatically if no signal detected.

References

1. Liu L, Oza S, Hogan D, Chu Y, Perin J, Zhu J, et al. Global, regional, and national causes of under-5 mortality in 2000-2015: an updated systematic analysis with implications for the Sustainable Development Goals. The Lancet.388(10063):3027-35.
2. Bojalil R, Kirkwood BR, Bobak M, Guiscafre H. The relative contribution of case management and inadequate care-seeking behaviour to childhood deaths from diarrhoea and acute respiratory infections in Hidalgo, Mexico. Tropical medicine & international health : TM & IH. 2007;12(12):1545-52.
3. Nanyonjo A. Counting breaths in children: A camparative study of the accuracy of the ARI timer alone, the ARI timer with beads and the Malaria Consortium mobile respiratory timer. Kampala: Malaria Consortium; 2012.
4. Mukanga D, Babirye R, Peterson S, Pariyo GW, Ojiambo G, Tibenderana JK, et al. Can lay community health workers be trained to use diagnostics to distinguish and treat malaria and pneumonia in children? Lessons from rural Uganda. Tropical medicine & international health : TM & IH. 2011;16(10):1234-42.
5. Kallander K, Tomson G, Nsabagasani X, Sabiiti JN, Pariyo G, Peterson S. Can community health workers and caretakers recognise pneumonia in children? Experiences from western Uganda. Transactions of the Royal Society of Tropical Medicine and Hygiene. 2006;100(10):956-63.
6. Subhi R, Adamson M, Campbell H, Weber M, Smith K, Duke T, et al. The prevalence of hypoxaemia among ill children in developing countries: a systematic review. The Lancet infectious diseases. 2009;9(4):219-27.
7. Duke T, Subhi R, Peel D, Frey B. Pulse oximetry: technology to reduce child mortality in developing countries. Annals of Tropical Paediatrics. 2009;29(3):165-75.
8. Division US. Target product Profile - Acute Respiratory Rate Infection Diagnostic Aid (ARIDA). Copenhagen: UNICEG Supply Division; 2014.
9. UNICEF. Pneumonia Diagnostics: Current Outlook and Perspectives. Copenhagen: UNICEF; 2013.
10. Abeyratne UR, Swarnkar V, Triasih R, Setyati A. Cough sound analysis - a new tool for diagnosing pneumonia. Conf Proc IEEE Eng Med Biol Soc. 2013;2013:5216-9.
11. Kallander K, Tibenderana JK, Akpogheneta OJ, Strachan DL, Hill Z, ten Asbroek AH, et al. Mobile health (mHealth) approaches and lessons for increased performance and retention of community health workers in low- and middle-income countries: a review. J Med Internet Res. 2013;15(1):e17.
12. UNICEF. Committing to child survival: a promise renewed progress report. New York: UNICEF; 2014.
13. UNICEF. Countdown to 2015. Tracking progress in maternal, neonatal and child survival: the 2008 report. New York: UNICEF; 2008.
14. UNICEF. Countdown to 2015. Tracking progress in maternal, neonatal and child survival: the 2008 report New York: UNICEF; 2008 [Available from: http://www.who.int/pmnch/Countdownto2015FINALREPORT-apr7.pdf.
15. PATH. Landscape of respiratory rate counters available and in-development. 2013.
16. Baltussen R, Norheim OF, Johri M. Fairness in service choice: an important yet underdeveloped path to universal coverage. Tropical medicine & international health : TM & IH. 2011;16.
17. Hernandez P, Baker K, Kallander K. Initial penumonia device short listing exercise report. London: Malaria Consortium; 2014.

18. Peel D, Baker K, Kallander K. Technical pneumonia device landscape review report. London: Malaria Consortium; 2014.
19. Spence H, Baker K, Wharton-Smith A, Mucunguzi A, Matata L, Habte T, et al. Childhood pneumonia diagnostics: community health workers' and national stakeholders' differing perspectives of new and existing aids. Global Health Action. 2017.
20. Baker K. Scoring sheet for all 188 possible pnuemonia diagnostic aids. London: Malaria Consortium; 2015.
21. Biomedical F. ProSim SPOT Light SPO2 Tester Pulse Oximeter Analyser 2014 [Available from: http://www.flukebiomedical.com/Biomedical/usen/patient-simulators/ProSim-SPOT-Light-SpO2-tester-pulse-oximeter-analyzer.htm?PID=74249.
22. Ginsburg AS, Sadruddin S, Klugman KP. Innovations in pneumonia diagnosis and treatment: a call to action on World Pneumonia Day, 2013. Lancet Glob Health. 2013;1(6):e326-7.
23. (IHME) IfHMaE. Pushing the Pace: Progress and Challenges in Fighting Childhood Pneumonia. Seattle: Institute for Health Metrics and Evaluation (IHME); 2014.