TARGET PRODUCT PROFILE

Acute Respiratory Infection Diagnostic Aid (ARIDA)

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1 Introduction

Pneumonia accounts for close to one million deaths in children under five years of age annually, representing 15 per cent of all annual under-five mortality worldwide [1]. Most of these deaths occur in south Asia and sub-Saharan Africa. Many of the countries in these regions face significant challenges in the provision of effective health care, diagnosis and treatment. Pneumonia is often overlooked or misdiagnosed as e.g. malaria by caregivers in resource-limited settings, with the risk of the pneumonia progressing to a severe stage.

Many of these deaths can be prevented through timely diagnosis and treatment. However, health services with diagnostic tools are often too far away and costly to be reached in time. To add to the complexity, antibiotics are sometimes used indiscriminately, which may increase bacterial antibiotic resistance and raise programme costs. Community Case Management (CCM) policies and programmes are therefore increasingly being adopted and implemented to enable diagnosis and treatment of pneumonia at the village level by local Community Health Workers (CHWs).

To support the CCM programmes and aid CHWs in diagnosing pneumonia, WHO recommends using fast breathing as a key indicator for diagnosing pneumonia among other important indicators.

UNICEF Supply Division has identified a need for improved tools to support CHWs with the diagnosis of pneumonia. To address this, UNICEF has compiled this Target Product Profile (TPP) in order to convey some of the vast experience and knowledge accumulated within UNICEF and its partner organizations to potential developers and suppliers to enable the availability of improved tools.

The TPP organizes the information into four levels of abstraction to convey as much as possible without assuming or describing a specific product or solution. Section 2 is the most abstract and describes the intended use, context of use, the users and environments. Sections 3.1 through 3.4 describe the user and stakeholder needs that an improved tool should satisfy. Section 3.6 describes the constraints that apply to such tools. Section 4 describes how UNICEF and its partners prioritise among a set of Key Parameters.

1.1 Purpose

The purpose of the TPP is to contribute to increasing the availability of improved tools to support diagnosing pneumonia, which UNICEF, Government's and implementing partners can procure and supply to health workers around the world and thereby prevent some of the deaths of children that occur due to pneumonia not being diagnosed and treated.

This TPP conveys information regarding the intended use, context of use, user needs and stakeholder needs to potential suppliers for tools that can be used to support the assessment of fast breathing as an aid to pneumonia diagnosis.

1.2 Scope

The scope of the TPP is the description of the needs and context for the development, validation, manufacturing, deployment, use, maintenance and disposal of a diagnostic aid to be used by health workers to classify fast breathing as an indicator of pneumonia.

This TPP describes the needs and context for a diagnostic aid for the diagnosis of pneumonia based on respiratory rate according to the current integrated Community Case Management (iCCM) and Integrated Management of Childhood Illness (IMCI) guidelines.

While the TPP aims to describe all the needs and constraints for an Acute Respiratory Infection Diagnostic Aid (ARIDA), it does not impose that a single device should meet all the needs. Several devices may be applicable to fulfil separate subsets of the needs identified.

1.3 Acknowledgements

This document is developed by UNICEF, who wishes to acknowledge the valuable input from WHO, Save the Children, the Malaria Consortium, the Bill and Melinda Gates Foundation and the Program for Appropriate Technology in Health (PATH), Industry and Academia in the compilation and review of this TPP.

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Terms and definitions

Term or abbreviation	Definition
ARI	Acute Respiratory Infections are bacterial or viral infections of the respiratory tract leading to breathing difficulties, fever and other complications. Pneumonia is the leading cause of death due to lower respiratory tract infections in children under five years of age
ARIDA	Acute Respiratory Infection Diagnostic Aid
CHW	Community Health Worker; health worker living and practicing in the community. May be referenced by other names depending on country
TPP	Target Product Profile
iCCM	Integrated Community Case Management; see http://www.unicef.org/health/files/iCCM_Joint_Statement_2012.pdf and http://ccmcentral.com/
IMCI	Integrated Management of Childhood Illness; see http://www.who.int/maternal_child_adolescent/topics/child/imci/en/
Fast Breathing	Respiratory rate higher than the normal resting respiratory rate, measured in breaths per minute. The normal resting respiratory rate is age dependent. Thresholds for fast breathing are published by WHO in IMCI guidelines. The thresholds for fast breathing are: Age 0 - 2 months: fast breathing if 60 or more breaths per minute Age 2 – 12 months: fast breathing if 50 breaths or more per minute Age 12 months to 5 years: fast breathing if 40 breaths or more per minute
Caregiver	The person responsible for the care of the child, that interacts with the health worker. The caregiver will typically be the mother of the child
SH	Stakeholder. Person with a legitimate interest in the ARIDA
Operator	The operator is the person operating the product. For ARIDA the operator and user will be the same and typically a CHW or PHW
MoH	Ministry of Health
PHW	Professional Health Worker. Typically educated nurses, clinicians, physicians, mid-wives and doctors working at health facilities
Health Facility	Health post, clinic, hospital or similar
Acquirer	The acquirer of ARIDA is most often the Ministry of Health implementing IMCI and iCCM programmes. The acquirer may also be other organizations responsible for running or supporting programmes

Table 1. Terms and definitions

2 Context of use

2.1 Intended use

The ARIDA is intended for aiding in diagnosing pneumonia by measuring the respiratory rate of the child. The ARIDA is intended to aid in the diagnosis of children in age group from 0 months to 59 months by health workers in both a resource limited community setting and in health facilities.

2.2 Concept of operation

Both IMCI and iCCM describe the methodology to assess suspected pneumonia/acute respiratory infection in children under-five in low-resource settings. They both advice on measuring the respiratory rate in children with cough to diagnose pneumonia.

IMCI is an integrated approach to child health that focuses on the well-being of the whole child. IMCI aims to reduce death, illness and disability, and to promote improved growth and development among children under five years of age. IMCI includes both preventive and curative elements that are implemented by families and communities as well as by health facilities.

Integrated Community Case Management (iCCM) is a strategy to extend case management of childhood illness beyond health facilities so that more children have access to lifesaving treatments. The iCCM package can differ based on the particular contexts, but most commonly include diarrhoea, pneumonia and malaria.

An example of an iCCM visit procedure can be found in Appendix 1 and is a short form of the “Manual for the community health worker” [3].

2.3 Current practice for pneumonia diagnosis

In current practice, the health worker will ask the caregiver to undress the upper body of the child. Then the health worker will count the child’s breaths by visually monitoring the chest movements of the child over a one-minute period, using a timing device (e.g. a timer or a watch). Based on the count result the health worker calculates the breathing rate in breaths per minute and classifies if the child has fast breathing using the WHO age-specific thresholds. If the child has a cough in combination with fast breathing the health worker will diagnose pneumonia, decide the proper course of action and communicate this to the caregiver.

2.4 User profiles

The intended users of the device can be divided into two groups. The primary target group are the CHWs since they can be considered the least trained users of the diagnostic aid. The secondary group are the PHWs that have clinical training as nurses, doctors, mid-wives or similar.

The CHWs in the target countries are often selected by their community to provide basic health services. The profile of CHWs can differ greatly between countries depending on the local programme design. They may not have any formal healthcare qualifications and the level of health training they receive ranges from two weeks to one year. Their basic education levels can differ from uncompleted primary education to high school graduates, and they have varying levels of literacy and numeracy.

Their health work may be unpaid or paid and may be part or full time. In some areas the CHW's are funded by the MoH. They usually work out of their own home or perform home visits in the nearby communities.

2.5 Environment profile

The environments for both the use and storage of CHWs' commodities can differ greatly from country to country, and in general a worst case approach should be taken when considering the climate and the physical areas for use.

The environment for use includes low-resource and remote settings that can be considered harsh environments, including dust, very high and/or low temperatures, high humidity and unhygienic conditions. Utilities such as electricity, sanitation and running water may not be available. The CHW will often conduct consultations in their own home, outdoors or in the home of the caregiver. Caregivers often bring their children to CHWs at night, so light may be low and lighting non-existent.

While the target environment is at the community level, the device is also intended to be used in health facilities where the environmental conditions can be considered more controlled, although they may differ based on the type of facility.

3 Needs and constraints

The following sections list the needs that devices should fulfil when in operation and the constraints that must be met. They serve to convey the needs of the operators and other stakeholders that have a legitimate interest in the developed device. The fulfilment of the needs listed will help ensure the developed device is successful when used. Meeting the constraint is a necessity for meeting UNICEF specific needs.

The needs have been categorised into four sections describing the functionality, performance, design and stakeholder needs. There may be overlap in the needs between categories.

The relevant stakeholder(s) is indicated in the last three columns in the tables below. This can be CHW, PHW or Other - or a combination - since a single need may have several stakeholders. The stakeholder group ”Other” represents all non-user stakeholders i.e. stakeholders that are not intended to operate the device e.g. MoH, UNICEF and sponsors.

3.1 Functional Needs

The Functional Needs describe the needs that are related to the functionality of the device i.e. the functions that the device should have to meet the needs of the operators and to enable the device to achieve its intended use.

ID	Need	Rationale	CHW	PHW	Other
FN-1	The operator needs to be able to turn the device on	To be able to use the device for measuring	X	X	
FN-2	The operator needs to be able to determine if the device is operational and functioning correctly	The CHW may use the device if they are unaware that it is faulty or non-operational due to e.g. calibration or start-up time. The use of a faulty or non-operational may lead to the wrong classification of fast breathing	X	X	
FN-3	The operator needs to know if the measurement just completed is valid	To be able to use the result to determine if the child has fast breathing	X	X	
FN-4	The operator needs to be able to turn off the device and/or know if device is turned off	To reassure optimal operational life span.	X	X	

ID	Need	Rationale	CHW	PHW	Other
FN-5	The operator needs the caregiver to understand the measurement and accept the results of the measurements	Some caregivers need to understand how the measurement is made in order to accept the diagnosis and treatment. Caregivers may want antibiotics despite the result of the measurement and need convincing if the child does not have pneumonia	X	X	
FN-6	The operator needs the device to compensate or allow for compensation if the child is moving in order to get accurate measurements	The child is likely to move during the measurement, necessitating discarding counts or requiring new measurement. Breathing irregularities, crying or a restless child may cause inaccurate measurement of the breathing rate.	X	X	
FN-7	The operator needs the device to automatically detect breaths and calculate the breathing rate	It may be very difficult to see the motions related to breathing and hence count the number of breaths. Some PHWs need motivation to use measured fast breathing for the diagnosis of pneumonia as the current method may be considered time consuming and inaccurate	X	X	
FN-8	The operator needs the device to do any mathematical calculations required to determine if the child is fast breathing	Some CHWs are numerically illiterate and are not able to perform mathematical calculations	X		
FN-9	The operator needs to be able to classify fast breathing without remembering the age specific thresholds	CHWs and PHWs may forget the age limits and/or breathing rates and classify based on the wrong breathing rate threshold	X	X	

Table 2. Functional Needs

3.2 Performance Needs

The Performance Needs relate to the performance of the device e.g. how well the device needs to perform.

ID	Need	Rationale	CHW	PHW	Other
PN-1	The operator needs the device to minimise the time, where the operator cannot do other activities, for measurements and classification of fast breathing	With manual counting, some operators do not count for a full minute because it takes too long. The caregiver expects to receive the diagnosis during the visit to the CHW and expects treatment immediately, if diagnosed. PHWs are often busy and if the measurement takes too long, they may be discouraged from using the device. A long measurement time will increase the risk of the child becoming restless and disturbing the measurement	X	X	
PN-2	The operator needs the device to support accurate determination of fast breathing. The accuracy of obtained respiratory rate should be at least +/- 2 breaths per minute when compared to the number of respiratory cycles (one cycle is an inhalation followed by an exhalation) measured over a period of 60 seconds.	The current method is difficult and not accurate. To be able to make diagnosis and decide on treatment. The breathing rate thresholds are close to each other	X	X	

Table 3. Performance Needs

3.3 Design Needs

The Design Needs are needs that can be attributed to the design of the device e.g. needs related to the user interface, shape and other needs not related to the functionality or performance of the device.

ID	Need	Rationale	CHW	PHW	Other
DN-1	The operator needs the device to be easy to place or position to get correct measurements	To ensure that measurements will be valid. Special focus should be on the least trained operators.	X	X	

ID	Need	Rationale	CHW	PHW	Other
DN-2	The operator needs to understand the indication (e.g. display) of the result of the measurement with respect to fast breathing	To be able to correctly determine if the child is fast breathing. Special focus should be on the least trained operators	X	X	
DN-3	The operator needs the device not to distress the child	If the child is unnecessarily distressed or disturbed by the device or its use, the breathing rate may be elevated and the child is more likely to move during measurement, potentially invalidating or delaying the measurement	X	X	
DN-4	The operator needs the device not to upset the caregiver	The caregiver will not allow the CHW to use device if they think it may harm the child	X		X
DN-5	The operator needs the device to allow for a comfortable position for the child when measuring the breathing rate	A comfortable position e.g. physical contact with caregiver and lying down, will help keep the child calm while measuring the breathing rate. If the child is restless the breathing may be irregular and difficult to measure	X	X	
DN-6	The operator needs the device to withstand rough handling, and harsh transport and storage conditions	The operational and storage environment may be rough when used by the CHW. Equipment may be exposed to rough handling by both CHWs and PWHs.	X	X	
DN-7	The operator needs the device to have as little as possible down time due to charging during their working day	Patient visits can occur from morning to evening and downtime due to e.g. 5-6 hours of solar charging may limit the time they can use the device on patients	X	X	
DN-8	The device shall support the lowest educated and least trained user	To enable the device to be used by everyone and make it more ready available			X

ID	Need	Rationale	CHW	PHW	Other
DN-9	The device shall require minimal training of the user to be able to successfully use the device	Training of CHWs adds significant cost to programmes and may limit availability			X
DN-10	The operator needs the device to be easy to carry	Some CHWs performs home visits thereby carrying the device when performing the initial visit as well as during the follow-up visits. CHW will also carry other equipment and medicines used in iCCM	X		
DN-11	The operator needs the device to remain hygienic without special cleaning	The hygienic conditions are generally poor and options for cleaning may be limited	X		
DN-12	The device shall allow for disposal as household waste without causing pollution to the environment	Communities will not comply with special requirements for disposal and environment. They will dispose the device as commonly as household waste			X
DN-13	The device shall be safe if given to a child	Non-functioning devices may be given to children as a toy and must not harm the child in any way			X
DN-14	The operator needs the device to consist of as few parts as possible i.e. pieces or parts that the operator is required to remove, adjust or assemble as part of the use of the device	Individual parts may get lost or break. Assembly prior to use adds to assessment time and complexity of diagnosis	X		
DN-15	The operator needs the technology of the device to match their educational level	The technology used for e.g. timing and manual counting of breaths may be thought of as below their “status” for some PHWs and prevent them from using the device to classify fast breathing		X	
DN-16	The operator needs to be able to look for other symptoms while measuring the breathing rate	Manual counting of breaths requires the full attention of the PHW or CHW and takes time that could be used to assess other symptoms. In a clinical setting the PHW is often busy	X	X	

ID	Need	Rationale	CHW	PHW	Other
DN-17	The operator needs to be able to store the device in a safe and protected way when it is not being used	Storage practices differ from user to user and do not necessarily protect or secure the device. Often, children are around and there are not necessarily places for safe keeping	X		
DN-18	The operator needs to be able to use the device when it is dark and there is very low levels of light	Often the caregiver will visit after work when it is dark. Or the CHW will visit the home of the child at night. Light may be provided by candle light or kerosene lamp	X		
DN-19	The operator needs to be able to use the device outdoors in direct sunlight	Often consultations are done outdoors	X		
DN-20	The operator needs the device to be compatible with charging equipment they have available (if the device requires re-charging)	Experience shows that solar chargers break more often than e.g. mobile phones, because the user forces the wrong connectors into the charger.	X		
DN-21	The operator needs to be able to see the indications given by the device even if they are colour-blind	Some CHWs are colour-blind and would need symbols as well as colours for indication	X	X	
DN-22	The operator needs a device that does not distract them from completing the diagnosis or intended task	Device features like ticking sounds and blinking light may distract the user from focusing on the patient and caregiver	X	X	
DN-23	The operator needs to know how to protect the device from the environment and surroundings	CHWs may have little or no knowledge or experience of how to handle and protect devices. If specific requirements (e.g. do not leave in rain or keep away from animals) this must be made clear to the CHW through e.g. training or instructions	X		

Table 4. Design Needs

3.4 Other needs

This section describes the needs that are not related to the functioning, performance or design of the device e.g. Needs related to procurement, transportation, logistics etc.

ID	Need	Rationale	CHW	PHW	Other
SN-1	The acquirer needs the device to be available in quantities that support their programmes	To be able to support the quantities needed for maintaining existing programs and implementing new programmes			x
SN-2	The acquirer needs to consider the total cost i.e. device price as well as other costs associated with availability and use of the device by the CHW	Distribution, training and device price all contribute to the total cost and hence how much funding is needed to establish and run the programmes			x
SN-3	The acquirer needs the device to balance the total cost and operational life	The cost of distribution is a major factor			x
SN-4	The acquirer needs the packaging of the device to allow for single distribution from health facility to CHW	So the CHW can get the device at the health facility			x
SN-5	The acquirer needs the device to be continuously available for procurement	So Governments can continue and support programmes through the routine procurement of devices			x

Table 5. Other needs

3.5 Constraints

The constraints describe the requirements and specifications that the device must fulfil to meet UNICEF specific needs. An "X" in the columns "CHW" and "PHW" indicates if the constraint is applicable to devices for use by CHW, PHW or both CHW and PHW.

ID	Requirement	Rationale	CHW	PHW
CR-1	The device and manufacturer shall comply with UNICEF's General Technical Provisions for Medical Devices. Exceptions may be applicable for evaluation purposes or if convergence toward the Technical Provisions is demonstrated. All exceptions need to be agreed with UNICEF	To ensure that the medical devices procured and supplied by UNICEF for its programmes and the projects of its partners are safe, effective and complies with applicable international quality, quality management and safety standards for medical devices.	X	X
CR-2	The device shall display the respiratory rate in breaths per minute if the respiratory rate is displayed	To ensure alignment with WHO's IMCI and iCCM guidelines	X	X
CR-3	The device shall achieve its operational life without replacing parts or components	Access, logistics and costs inhibit replacement of e.g. batteries or other supplies. Energy sources may not be available in the envisaged environment of use, and replenishment from remote source is to be avoided	X	
CR-4	The device shall have an operational life with a minimum of 2 years Note: Operational life refers to when the device is brought into use i.e. not including time in storage or transit. Note: It can be assumed that a CHW on average will assess fast breathing 2.5 times per day and a PHW 4 times per day for 365 days per year.	The costs associated with replacement and distribution would otherwise outweigh device cost. The complexity of programmes and logistics, as well as budgets, does not warrant frequent replacements.	X	
CR-5	The device shall be able to achieve is operational life after being stored for a minimum of 12 months	Logistics can be complex and require long time in storage and transit.	X	X

Table 6. Constraints that the device must fulfil

4 Priorities of Key Parameters

The Key Parameters are provided to convey how UNICEF and its partners prioritise among a set of detailed parameters that should inform the development of the ARIDA and aid in the selection, trade-off and evaluation of technology, concept and design. Combined with an assessment of the fulfilment of the needs and constraints listed in this document, the parameters and associated priority can be used to evaluate the applicability of devices.

The Key Parameters are all applicable to the device and a low priority does not indicate that they should be omitted from consideration in the development.

ID	Parameter	Description	Priority [1-5] 1=least priority, 5=most priority
KP-1	Usability – ease of use	Easy for operator to use the device, e.g. can apply it appropriately, switch on the device, select the correct settings, complete the assessment to get a result	5
KP-3	High accuracy of measured/calculated respiratory rate	The device consistently provides an accurate measure of the measured or calculated respiratory rate	5
KP-7	Long operational life in the field – e.g. more than 2 years	The device will have a long operational life while being used by operator, e.g. of more than 2 years	4
KP-2	High level of decision support/automation of diagnosis	Allows the operator to detect the symptoms of pneumonia and provide diagnosis, without the need for decision making from them. e.g. automatically detects breathing rate, applies age specific fast breathing threshold	3
KP-9	Does not require replaceable parts (battery, consumables)	The device does not require replaceable parts such as non-rechargeable batteries and/or consumables throughout its functional life in the field	3
KP-11	High durability/mechanical robustness	The device will not break during normal use, transportation or storage by the operator	3
KP-12	High CHW confidence in measurements	The readings provided by the device support the operator in relation to detecting the symptoms of pneumonia	3
KP-15	High portability	The device is easy to carry by the operator and does not restrict the operator in the location of use	3
KP-17	Low price	The cost of the device ex works is low	3
KP-18	High level of safety	The device provides a high level of safety to both the operator, patient and environment when it is being used for the detection of the symptoms of pneumonia, placed in storage and disposed off	3

ID	Parameter	Description	Priority [1-5] 1=least priority, 5=most priority
KP-4	No or little literacy and numeric literacy required	The device only requires a very low level of literacy and/or numeric literacy to be operated by the operator	2
KP-5	No or little training required	The operator only requires minimal amounts of training to be able to use the device effectively	2
KP-8	Does not require charging (solar, battery, grid)	The device does not require charging to be used by the operator	2
KP-10	Requires no maintenance	The device does not require any maintenance throughout its operational life	2
KP-13	High caregiver acceptability of diagnosis	The readings provided by the device help and support the caregiver/parent in accepting the diagnosis made by the operator	2
KP-14	High patient comfort	The device does not cause pain, discomfort or anxiety to the patient while being used by the operator in the detection of the symptoms of pneumonia	2
KP-16	Easy to maintain hygiene	The device is easy to clean in and hygiene can be maintained using locally available resources – e.g. does not require specialist cleaning procedures or products	2
KP-6	No or little familiarity with technology required	The operator does not need any prior familiarity with technology to operate the device effectively	1

Table 7. List of Key Parameters and their relative priority

5 Summary

As part of the fight against pneumonia, UNICEF has compiled this Target Product Profile to convey information regarding the intended use, context of use, user needs, constraints and stakeholder needs for an ARIDA to suppliers, and thereby to assist the development and the availability of products targeted for use by CHWs in resource-limited environments.

This document is thought to inspire and enable developers, manufactures and suppliers to develop and market products that can be procured by UNICEF and others and supplied to health workers around the world and thereby reduce the mortality of children due to pneumonia.

The information listed in this document convey context, needs and constraints that when met should provide for a successful ARIDA. The information herein is not intended to, and does not, represent procurement requirements or specifications. The compliance of products to the information listed in this document does not guarantee any form of procurement or commitment to procure.

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6 References

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Appendix 1. Short form iCCM procedure

The table below is a short form of the visit process described in the "Manual for the Community Health Worker" [3] it is listed here for reference only.

Task	Task name	Step	Step name
1	Fill in sick child recording form		
1		1	Greet caregiver and child
1		2	Retrieve sick child recording form
1		3	Record current date
1		4	Record CHW initials
1		5	Record child's name
1		6	Record child's age in years and/or months
1		7	Record child's gender
1		8	Record caregiver's name and relation to child
1		9	Record child's address
2	Identify Problems		
2		1	Ask caregiver if child has cough
2		2	Ask caregiver for how long child has coughed
2		3	Check if coughing is danger sign
2		4	Ask caregiver if child has diarrhoea or blood in stool
2		5	Ask caregiver for how long child has had diarrhoea
2		6	Check if diarrhoea is danger sign
2		7	Ask caregiver if child has fever
2		8	Feel child's stomach or underarm for fever
2		9	Ask caregiver if child has convulsions
2		10	Ask caregiver if child has difficulty eating or drinking
2		11	Ask caregiver if child is vomiting
2		12	Look at child for chest in drawing
2		13	Count number breaths per minute
2		14	Record number of breaths per minute
2		15	Determine if child is fast breathing
3	Decide to refer or treat child		
4	Inform caregiver to treat at home		
5	Give oral medicine and advise caregiver		
6	Refer urgently, begin treatment and advice caregiver		