Pneumonia Acute Respiratory Infection Diagnostic Aid - Target Product Profile Introduction

UNICEF Supply Division

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Pneumonia Acute Respiratory Infection Diagnostic Aid (ARIDA)
Target Product Profile (TPP) Introduction

1. Summary

- There are approximately 120 million cases of pneumonia a year, with Southeast Asia and Africa having the highest incidence.[1] Nearly half of all pneumonia mortality is concentrated in 10 high-burden countries. Improved diagnostic devices are required for better pneumonia diagnosis accuracy, which would support proper treatment decisions and reduce <5 child mortality from pneumonia.
- UNICEF has developed a target product profile (TPP) to support the development of a new pneumonia acute respiratory infection diagnostic aid (ARIDA) in close consultation with partners, industry and academia. The ARIDA TPP aims to guide the development of a device to improve the accuracy and effectiveness of diagnosing pneumonia in resource-poor contexts.
- The TPP addresses four categories of requirements including performance, function, stakeholder and design, which are meant to inform potential product development without prescribing a specific solution.
- UNICEF will launch an expression of interest (EOI) during 2Q 2015 to industry for a device that meets the TPP to be commercialised over a 12 month period. Criteria for consideration as well as the process for product selections that meet the TPP will be published with the EOI. Special contracting may be considered to facilitate bringing a new and improved ARIDA to market.

2. General Brief and Background

Pneumonia accounts for 935,000 under-five deaths annually, representing 15% of all under-five annual worldwide mortality.[2] 70% of these deaths occur in just 15 countries in Asia and Sub-Saharan Africa.[3] Many of these countries face significant challenges in the provision of effective health care, diagnosis and treatment. Pneumonia is often misdiagnosed by caregivers in resource-poor settings until it develops into a severe stage.[4] New and improved ARIDAs are needed to support community and primary health care workers' pneumonia diagnosis accuracy. Improved diagnostic tools would better guide the decisions made in providing treatment to reduce excess child mortality from pneumonia.

UNICEF's previous July 2013 Pneumonia Diagnostics Outlook highlighted the challenges in accurately diagnosing pneumonia, particularly in resource-poor contexts. The note profiled a sample of different pneumonia diagnostic support aid concepts already under development by industry, academia and partners, each applying a different innovative technology. A tentative timeline, outlook, criteria and suggested key aspects of an ARIDA were provided to help conceptualise the development of a TPP to guide the development of an ARIDA for use over a 3 year period.

3. ARIDA TPP Development

An ARIDA TPP has now been developed and is being shared with industry, partners and academia to encourage and solicit the development of new devices for field testing. Information on the strengthening of pneumonia diagnostic tools for low-resource settings is available here. The TPP can be accessed here. The TPP describes the need for diagnosis to be based on WHO's revised integrated

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[1] Fischer Walker, C. L., I. Rudan, et al., *Global Burden of Childhood Pneumonia and Diarrhoea*, The Lancet, Vol. 381, Issue 9875, p. 1405-1416, 20 April 2013.
[2] Liu L., S. Oza S, et al., *Global, Regional and National Causes of Child Mortality in 2000-13, With Projections to Inform Post-2015 Priorities: An Updated Systematic Analysis*, The Lancet, London, 1 October 2014.
[3] UNICEF, *Committing to Child Survival: A Promise Renewed, Progress Report*, UNICEF, New York, 2014.
[4] World Health Organization, *Key Problems in Pneumonia Diagnosis and Management*, WHO, Geneva, June 2014.

community case management (ICCM) and [integrated management of childhood illness (IMCI) guidelines](#) which recommends treatment with Amoxicillin dispersible tablets (DT) (Table 1).

Table 1 Amoxicillin DT Treatment for Pneumonia

Tools	Cat. of Pneumonia	Child Age/Weight	Dosage Amox. DT 250mg
IMCI tool for CHWs: **no change**	Fast breathing	2-12 months (4-<10kg)	1 tab x twice day x 5 days (10 tabs)
		12-60 months (10-19kg)	2 tabs x twice day x 5 days (20 tabs)
IMCI tool for health professionals at health facilities: **revised**	Fast breathing + chest indrawing	2-12 months (4-<10kg)	1 tab x twice day x 5 days (10 tabs)
		12-36 months (10-<14kg)	2 tabs x twice day x 5 days (20 tabs)
		36-60 months (14-19kg)	3 tabs x twice day x 5 days (30 tabs)

Source: WHO.[5]

During 2H 2013 and 1H 2014, UNICEF consulted industry, academia and partners to convey the need for an improved ARIDA, which should be of good quality, fit-for-purpose and affordable. The consultation drew on user and context insight; supply chain understanding; user skills; knowledge and lessons learned; as well as manufacturer experience, while profiling some of the available technologies. Figure 1 illustrates the TPP development process that was followed and describes the key activities and deliverables achieved at the different stages.

Figure 1 Target Product Profile Development

Source: UNICEF Supply Division.

The process involved literature review, surveys, research, analysis and stakeholder interviews to identify user needs and concept of operation (to be based on IMCI guidelines), this process resulted in defining user and environment profile and constraints. The ARIDA TPP lists the needs within four categories: Performance, functional, stakeholder and design (Table 2).

Table 2 ARIDA Need Category Requirements

Performance needs	Functional needs	Stakeholder needs	Design needs
- To minimise the time needed to measure and classify fast breathing in children <5 according to IMCI guidelines.	- Functional on / off switch. - Clearly signal device operational functionality. - Provide easy-to-read, valid measurements. - Compensate for child restlessness and excess movement.	- Available in sufficient programme quantity. - Cost to reflect total device price and associated costs. - Cost efficient ratio between price and	- Ease and comfort position for accurate reading. - Simple data display. - Does not engender anxiety or stress. - Heavy-duty robustness. - Short re-charge time. - Use of commonly available charge connectors. - Minimal training requirements.

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[5] World Health Organization, *[Revised WHO Classification and Treatment of Childhood Pneumonia at Health Facilities, Implications for Policy and Implementation](#)*, WHO, Geneva, 2014, p.02.

	- Automatically detect breathing. - Mathematically calculate breathing rate. - Remembers age specific breathing rate parameters.	life span expectancy. - Unit to be available in single packaging. - Continuous supply availability.	- Easily portable. - Remain hygienic. - Environmentally friendly upon expiry/waste disposal. - Safe for children. - Made up of as fewer parts as possible. - Free the operator to observe for other symptoms simultaneously. - Ensure safe storage. - Usable in low / limited light and direct sunlight.

Source: UNICEF Supply Division.

In addition to the needs, a rated list of key parameters is provided to guide developers in the prioritisation and selection trade-off of specifications. Different parameters have been assigned a numerical weight to communicate the relative importance of each parameter. A higher weighted parameter, however, does not imply that a lower parameter is not to be considered (Table 3). These parameters were reviewed by key stakeholders.

Table 3 ARIDA Priority Parameter Ranking

Parameters	Priority 5 highest / 1 lowest
- Ease of use, on / off switch and setting selections. - High consistent accuracy of respiratory rate calculation and measurement.	5
- Long operational life-span, greater than 2 years.	4
- High decision making support and diagnosis automation level. - No need for replacement spare parts or consumables. - Highly robust under harsh conditions and rigorous handling. - Generates high confidence and reliability in measurement readings. - Highly portable and unobtrusive. - Low cost. - High operational, storage and disposal safety level.	3
- Little or no need for literacy, numeracy or training. - Free from the need for any charging prior detection. - No need for maintenance. - Measurement readings to generate confidence in CHW and patients. - High level of patient operational comfort. - Ease of hygienic maintenance.	2
- Little or no familiarity need required with technology.	1

Source: UNICEF Supply Division.

A new ARIDA will also need to meet UNICEF requirements for procurement related to UNICEF programmes and partners. Products and manufacturers will need to conform with the international quality management system standards, norms, rules and regulations that apply to medical devices. UNICEF technical provisions for medical devices can be viewed here and are based on recommendations from the International Medical Device Regulators Forum (available here). Additional requirements include:

- To display the respiratory rate in breaths per minute, if displayed;
- No reliance on replaceable parts;
- To have a minimum operational life of 2 years;
- To have a storage/shelf life of 12 months.

4. Preliminary Market Opportunity

A new and improved ARIDA, as profiled in the TPP, would meet a significant unmet need in community healthcare support. Table 4 highlights the disease burden of pneumonia in the top 10 countries and presents the number of CHWs that are first line community care providers. It also lists the number of health care professionals in national health care facilities which are the secondary target user group for the ARIDA. The data presented could support potential market analysis of the need for an ARIDA.

Table 4 Pneumonia Caseload, Treatment and CHWs per Top 10 High Pneumonia Burden Countries

Country	<5 population	Est. <5 pneumonia cases/annum	Est. <5 pneumonia cases receiving treatment	% of total cases	Number of CHWs	Number of Health Care Professionals
India	130,810,023	45,459,248	6,000,621	13%	894,525	2,170,000
Nigeria	27,924,950	8,218,028	1,889,489	23%	85,000	252,635
DR Congo	12,491,563	4,346,127	1,891,304	44%	2,286	n/a
Ethiopia	12,445,717	4,543,543	271,704	6%	34,000	2,249
Kenya	7,024,608	2,147,372	1,058,225	49%	59,810	33,688
Pakistan	22,195,987	7,360,715	3,766,625	51%	110,000	205,264
Bangladesh	15,062,086	5,707,526	2,174,567	38%	97,000	21,700
Niger	3,306,645	1,346,802	390,572	29%	3,500	2,676
Uganda	6,884,046	2,125,773	1,024,283	48%	83,000	59,000
Tanzania	8,502,760	2,798,008	811,422	29%	12,110	11,946
Total for top 10	**246,648,385**	**84,053,142**	**19,278,812**	**23%**	**1,381,231**	**2,759,158**

Source: UNICEF / WHO / CHERG.[6]

Figure 2 Pneumonia Mortality in the Top 10 High Pneumonia Burden Countries 2014
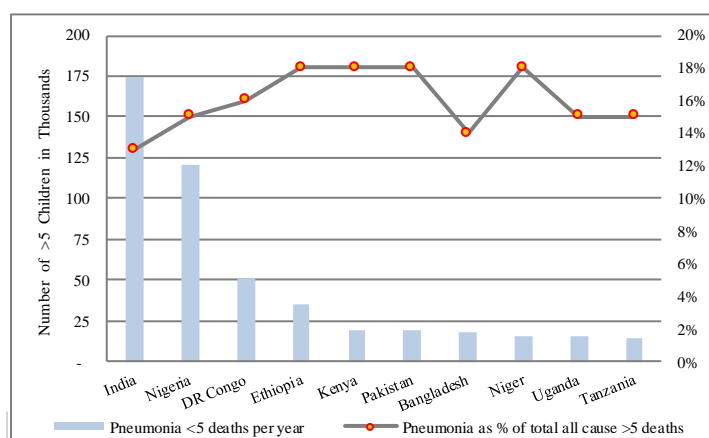
Despite a 44% reduction of global <5 pneumonia mortality (2000 – 2013), pneumonia still accounts for 15% of <5 mortality.[7] Figure 2 describes <5 child mortality due to pneumonia in the 10 highest burden countries in 2014 (which reached 480,000) as well as pneumonia mortality as a % of the total <5 deaths.

Source: UNICEF.

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[6] Data sourced, including various national health country estimates, Child Health Epidemiology Reference Group (CHERG) 2014, UNICEF's Access to Healthcare through Community Health Workers in East and Southern Africa, 2014.
[7] UNICEF, *Committing to Child Survival: A Promise Renewed, Progress Report 2014*, UNICEF, New York, September 2014, p.21.

Figure 3 ARI Timer UNICEF Procurement 2005-2014 YTD
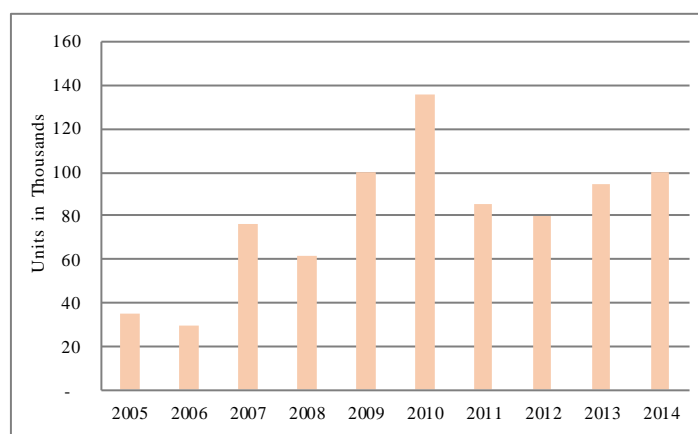
Source: UNICEF Supply Division.

The current pneumonia diagnostics aid tool, the Acute Respiratory Infection (ARI) Timer has been procured by UNICEF since the 1990s to supply health programmes. UNICEF procurement from 2005 to 2014 year-to-date reached ~800,000 units, averaging ~100,000 a year since 2009 (Figure 3). The level of ARI Timer offtake has been modest relative to the need, as the product was generally considered suboptimal. The offtake of ARI Timers was also not supported with any promotional activity.

A new ARIDA will be additive to the current ARI Timer and improve the options for country selection. It will not replace the existing ARI Timer (Mark 1) or the improved upcoming version (Mark 2).

5. Partnerships

UNICEF is collaborating with the Malaria Consortium. With support from the Bill and Melinda Gates Foundation (BMGF), it is identifying and conducting field trials of suitable respiratory rate timers and pulse oximeters[8] which have the potential to be more accurate and scalable in community and primary health care pneumonia diagnosis. Research is being conducted in Cambodia, Ethiopia, South Sudan and Uganda to assess different devices. UNICEF intends to leverage findings from such research and these partnerships.

6. Proposed Next Steps

- UNICEF will launch an expression of interest (EOI) during 2Q 2015 for a device that meets the TPP. UNICEF anticipates three devices could possibly be brought to market and commercialised over the next years to come. The selection criteria and the process for consideration will be published with the EOI. Special contracting may be considered to facilitate bringing a new and improved ARIDA to market.
- UNICEF will conduct end-user and fit-for-purpose feedback analysis and leverage partnerships to optimise the work undertaken by the Malaria Consortium in the field evaluation of different pneumonia diagnostic aid devices. UNICEF will also work with other partners and donors with an interest in supporting the development of a new and improved ARIDA.
- UNICEF will leverage the work through the UN Commission on pneumonia and diarrhoea to raise awareness and funding to help bring the ARIDA to market as early as possible.
- UNICEF will in the future work on developing a long term TPP for a device that can guide the development of a device that can differentiate between bacterial and viral pneumonia, and further improve the targeted use of antibiotics. In addition, UNICEF will work on guiding the integration of pulse oximetry into pneumonia diagnostic devices.

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[8] Pulse Oximetry: non-invasive O^2 saturation monitoring.

For further questions or additional information, please contact:

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