Acute Respiratory Infection Diagnostic Aid (ARIDA) Project
Evaluation of Innovation in UNICEF Work
Case Study: Acute Respiratory Infection Diagnostic Aid (ARIDA) Project

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This case study report for the Acute Respiratory Infection Diagnostic Aid (ARIDA) Project is one of thirteen innovation case studies which were conducted as part of a global evaluation titled ‘Evaluation of innovation in UNICEF work’. The case study component of the evaluation was conducted by Deloitte LLC. The ARIDA case study report was prepared by Edward Thomas, Katherine Arblaster, Ariel Kangasniemi, Laura Maxwell and Adarsh Desai. Beth Plowman, Senior Evaluation Specialist, Evaluation Office led and managed the overall evaluation process in close collaboration with Ana Cristina Matos, Supply Specialist, Supply Division.

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<th>Description</th>
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<tbody>
<tr>
<td>AC</td>
<td>Advisory Committee</td>
</tr>
<tr>
<td>ARI</td>
<td>Acute Respiratory Infection</td>
</tr>
<tr>
<td>ARIDA</td>
<td>Acute Respiratory Infection Diagnostic Aid</td>
</tr>
<tr>
<td>BMGF</td>
<td>Bill &amp; Melinda Gates Foundation</td>
</tr>
<tr>
<td>CE</td>
<td>Conformité Européenne</td>
</tr>
<tr>
<td>CHAI</td>
<td>Clinton Health Access Initiative</td>
</tr>
<tr>
<td>CO</td>
<td>Country Office</td>
</tr>
<tr>
<td>COI</td>
<td>Conflict of Interest</td>
</tr>
<tr>
<td>CHW</td>
<td>Community Health Worker</td>
</tr>
<tr>
<td>EC</td>
<td>Expert Clinician</td>
</tr>
<tr>
<td>EO</td>
<td>Evaluation Office</td>
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<tr>
<td>EOI</td>
<td>Expression of Interest</td>
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<tr>
<td>FMOH</td>
<td>Federal Ministry of Health</td>
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<tr>
<td>GAPPD</td>
<td>Global Action Plan for Pneumonia and Diarrhoea</td>
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<tr>
<td>HEW</td>
<td>Health Extension Worker</td>
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<tr>
<td>HSS</td>
<td>Health Systems Strengthening</td>
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<tr>
<td>HTC</td>
<td>Health Technology Centre</td>
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<tr>
<td>iCCM</td>
<td>Integrated Community Case Management</td>
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<tr>
<td>IMCI</td>
<td>Integrated Management of Childhood Illness</td>
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<tr>
<td>IMNCI</td>
<td>Integrated Management of Newborn and Childhood Illness</td>
</tr>
<tr>
<td>IRB</td>
<td>Innovation Review Board</td>
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<td>IU</td>
<td>Innovation Unit</td>
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<tr>
<td>IVAC</td>
<td>International Vaccine Access Centre</td>
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<td>LTA</td>
<td>Long Term Agreement</td>
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<td>MC</td>
<td>Malaria Consortium</td>
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<tr>
<td>MCEE</td>
<td>Maternal and Child Epidemiology Estimation Group</td>
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<td>MCHN</td>
<td>Maternal and Child Health and Nutrition</td>
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<td>MoH</td>
<td>Ministry of Health</td>
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<td>MSFIC</td>
<td>Markets, Supplier Financing, and Innovation Centre</td>
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<tr>
<td>NatCom</td>
<td>National Committee</td>
</tr>
<tr>
<td>PD</td>
<td>Programme Division</td>
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<tr>
<td>PFP</td>
<td>Private Fundraising and Partnerships Division</td>
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<tr>
<td>PHCW</td>
<td>Professional Health Care Worker</td>
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<td>PIP</td>
<td>Product Innovation Project</td>
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<tr>
<td>REOI</td>
<td>Request for Expression of Interest</td>
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<tr>
<td>RFI</td>
<td>Request for Information</td>
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<tr>
<td>RFP</td>
<td>Request for Proposal</td>
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<tr>
<td>RR</td>
<td>Respiratory Rate</td>
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<tr>
<td>SD</td>
<td>Supply Division</td>
</tr>
<tr>
<td>TPP</td>
<td>Target Product Profile</td>
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<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
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<tr>
<td>WFP</td>
<td>World Food Programme</td>
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<td>WHO</td>
<td>World Health Organization</td>
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EXECUTIVE SUMMARY

Since 2014, UNICEF has embraced innovation as one of its key strategies to achieve results for children. That commitment is reaffirmed in its current Strategic Plan, 2018-2021, and is evident in the organization’s programming and institutional architecture. Indeed, since 2014, significant progress has occurred in a relatively short period of time, backed by clear strategic intent and targeted investment. With the increased foothold of innovation in UNICEF, it is important and timely to take stock of these efforts through high quality evidence to inform decision-making, learning and accountability. In keeping with the need for this evidence, UNICEF conducted an global evaluation of innovation in 2018.

The objective of the global evaluation was to assess UNICEF’s ‘fitness for purpose’ to employ innovation as a key strategy to achieve the outcomes and goals defined in its strategic plans covering the period 2014-2021. A set of innovation case studies was a key element of this global evaluation, along with an organizational assessment and a synthesis project. The case studies were guided by three objectives:

• To provide detailed descriptions of a set of innovations across stages of the development continuum inclusive of contextual influences
• To assess the application of innovation principles or other standards for a set of innovations with particular attention to issues of ownership and scale
• To produce clear conclusions and considerations for policy, strategy and management decisions to further enhance innovation as key change strategy.

Case studies were conducted by Deloitte LLP over the period February 2018-January 2019. Mixed methods were utilized for data collection including key informant interviews, document review and observations in the field.

The innovation case examined in this report concerns Acute Respiratory Infection Diagnostic Aids (ARIDA) which are automated devices, developed for low-resource settings, to help health professionals determine respiratory rate and detect fast breathing. These devices aid in timely diagnosis and treatment of pneumonia, a key to reducing the global burden of the disease. The ARIDA project was initiated by the UNICEF Supply Division and funded by a grant from ‘la Caixa’ Banking Foundation. The project sought to accelerate market availability of devices that could enable accurate and easy-to-use respiratory rate counting and detection of pneumonia in children.

As a project in the Supply Division Innovation Unit portfolio, ARIDA was notable for its capacity to generate lessons on how to manage a product innovation. The most essential learnings through the ARIDA project include:

• ARIDA has been instrumental in leveraging internal skills and experience across Supply Division, Programme Division and country offices. In the context of ARIDA, Supply Division provides the technical expertise necessary to facilitate development of product-based solutions. Programme Division staff bring expertise on integrated prevention and care of children with pneumonia. Country offices provide valuable input on local context and coordination of activities. The expertise of each group is complementary and when combined can maximize potential for success
• The project also was an interesting learning space on leveraging donor funding as an incentive for downstream procurement. The Innovation Unit was able to lead developers to develop, test and commercialize two new products in the ARIDA class
• The project had a catalytic effect on the innovation ecosystem by successfully encouraging new players, including the Bill and Melinda Gates Foundation and UNITAID, into the ARIDA space
• Lessons learned from this complex project have led to a rapid evolution of the Innovation Unit approach to accelerating innovations to scale
• In the future, improving communications, both within UNICEF as well as externally, will be vital to project success.

Among the considerations set forth for UNICEF in regards to ARIDA:

Identify strategies to reduce the financial burden for scale-up: Strategies to lower the cost of ARIDA device implementation for governments are important for scale-up and sustainability of the project.

Develop the evidence necessary for the Ministry of Health decision-making: Evidence from implementation studies should be prepared to support government decision-making before national implementation and scale-up. If possible, UNICEF should complete a high-level cost-benefit analysis of national scale-up of ARIDA devices.

Review the implications of community and health professional trust in ARIDA devices as diagnostic tools: If acceptability studies demonstrate that health workers are over-reliant on ARIDA devices for diagnosis of pneumonia, UNICEF must consider the implications and should look to solutions (e.g. review training for practitioners to ensure their understand that the diagnostic aid is to be used in combination with other indicators).

Limit market distortion effects associated with the timing of field trials: UNICEF and Malaria Consortium should complete implementation studies for ARIDA devices simultaneously to reduce possible market distortion effects. Testing one product first could influence government decision-making, mainly if the testing takes multiple years to complete and the government seeks to implement and scale a new diagnostic aid rapidly.

Generate demand for the suite of product innovations developed: Although procurement policies restrict the ability of SD to generate demand for specific products, UNICEF should generate demand for a portfolio of innovations once the suite of products is available for procurement. Advocating for products as part of a broader portfolio would help to avoid conflicts of interest and would require leadership of Programme Division and country offices.

In sum, the approach used by UNICEF, providing incentive of potential procurement through Supply Division has advanced the development of automated respiratory rate devices. As of January 2019, agreement and acceptability field trials in Ethiopia and Nepal were completed and implementation studies in Ethiopia and Bolivia were in progress. The procurement strategy would be reviewed following analysis of the field trial results.
1. INTRODUCTION

The world is changing faster than ever before, and so too are the challenges facing its most vulnerable. Conflict and displacement, disasters and climate change, urbanization and disease outbreaks are growing increasingly complex and inter-related, demanding new strategies and approaches. Innovation for development – exploring new ways of delivering programmes, with new partners and new technologies – is increasingly recognized as crucial to meeting the Sustainable Development Goals and the promise of the 2030 Agenda for Sustainable Development.

Since 2014, UNICEF embraced innovation as one of its key strategies to achieve results for children. That commitment is reaffirmed in its current Strategic Plan, 2018-2021, and is evident in the organization’s programming and institutional architecture. Indeed, since 2014, significant progress has occurred in a relatively short period of time, backed by clear strategic intent and targeted investment. A number of formal structures have evolved, and new milestones achieved.

With the increased foothold of innovation in UNICEF, it is important and timely to take stock of these efforts through high quality evidence to inform decision-making, learning and accountability. In keeping with the need for this evidence, UNICEF conducted an evaluation of innovation in 2018. The evaluation comes at a time when the organization is considering how best to maximize its resources for innovation and is intended to inform those decisions in an impartial manner, backed by credible evidence.

The objective of the evaluation was to assess UNICEF’s ‘fitness for purpose’ to employ innovation as a key strategy to achieve the outcomes and goals defined in its strategic plans covering the period 2014-2021. It also sought to provide insights on how innovation contributes to UNICEF’s goals and objectives, as well as how innovation might contribute to increasingly effective organizational responses in the coming years. The global evaluation was designed with three core components including: an organizational assessment, a set of innovation case studies and a synthesis project.

The case studies are intended to serve organizational learning by unpacking and examining the multiple pathways and dynamics which underpin innovation within the organization. In addition, the case studies contribute to accountability by assessing the manner in which innovation work in practice reflects the strategies and principles which UNICEF has developed to guide these efforts.

Three objectives guided the work:

- To provide detailed descriptions of a set of innovations across stages of the development continuum inclusive of contextual influences
- To assess the application of innovation principles or other standards for a set of innovations with particular attention to issues of ownership and scale
- To produce clear conclusions and considerations for policy, strategy and management decisions to further enhance innovation as key change strategy.

Cases are defined as the processes an innovation was identified, developed, tested, implemented and taken to scale along with contextual factors such as underlying organizational and partnership arrangements. The primary audience for the case studies is internal to UNICEF including senior management and programme managers at HQ, regional and country level. Its uses include informing the implementation of the Strategic Plan 2018-2021 particularly the change strategy focused on innovation. UNICEF commissioned Deloitte LLP to conduct thirteen case studies to examine innovation across the spectrum of innovation types, country contexts and internal (UNICEF) and external (partner, supplier) actors.

All case studies were structured around a modified version of the Deloitte Doblin Framework for Innovation. Within this
framework, four thematic dimensions (i.e. approach, organization, resources and capabilities and metrics and incentives) are seen as necessary to enable successful innovation. Case studies employed a mixed methods approach to build a complete picture of the innovation process and identify findings related to these four thematic dimensions. The evaluation team collected qualitative and quantitative data through desktop review, case study informant interviews and field visits. More information on the methods used appears in Annex A. A listing of stakeholders and interviewees appears in Annex B. Documents reviewed appear in Annex C.

The innovation case examined in this report concerns Acute Respiratory Infection Diagnostic Aids (ARIDA) which are automated devices, developed for low-resource settings.

2. INNOVATION AT A GLANCE

Automated diagnostic aids

Timely diagnosis and treatment of pneumonia is key to reducing the global burden of the disease. The World Health Organization (WHO) guidelines for management of pneumonia in low-resource community settings depend on a health worker manually counting a child’s breaths for the duration of one minute (respiratory rate) to assess whether the rate is higher than what is considered normal (fast breathing vs. normal breathing). If the child has fast breathing, a symptom of pneumonia, per the guidelines, the health worker administers pneumonia treatment, antibiotics and if needed, oxygen therapy. However, counting respiratory rate is difficult, even for trained health workers.

Misclassification of an observed rate as fast breathing vs. normal breathing is common, which can lead to inappropriate treatment. Acute Respiratory Infection Diagnostic Aids (ARIDA) are automated respiratory rate counting devices developed for low-resource settings to help health professionals determine respiratory rate and detect fast breathing.

Intended innovation outcomes

ARIDA was an innovation project initiated by the UNICEF Supply Division and funded by a €5 million grant from ‘la Caixa’ Banking Foundation. The goal of the project was to accelerate the market availability of devices that could enable accurate and easy-to-use respiratory rate counting and detection of pneumonia in children. ARIDA could help alleviate the problem of misdiagnosis, particularly in low-resource settings.

Since project kick-off, two ARIDA technologies received regulatory approval (Conformité Européenne marking) as commercially available and were determined technically and commercially acceptable for UNICEF procurement. Philips ChARM is an automated respiratory rate counter available in two models. The ChARM community health worker model has a non-rechargeable battery. The ChARM professional health worker model has
data output capability and a rechargeable battery. Masimo Rad G is a joint respiratory rate-pulse oximetry device available in one model with a rechargeable battery. In a sense, the process brought forth two new classes of devices, respiratory rate only and multimodal, with different functionalities, price points and possibly different use cases.

Three levels of field trials were implemented: an accuracy study to assess the device performance, an acceptability study to determine the relationship between the device and its users and an implementation evaluation to determine the integration of the device and its users with the health care system. Supply Division continued to monitor the landscape for potential devices and aids that met its standards.

Table 1. Comparison of characteristics of ARIDA devices approved for procurement through Supply Division

<table>
<thead>
<tr>
<th></th>
<th>Philips ChARM</th>
<th>Masimo Rad G</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What it measures</strong></td>
<td>Automated respiratory rate using accelerometry</td>
<td>Automated respiratory rate, oxygen saturation, perfusion index and pulse rate using plethysmography</td>
</tr>
<tr>
<td><strong>Characteristics</strong></td>
<td>Battery operated, Fasten around the abdomen</td>
<td>Battery operated, Reusable finger-clip sensor</td>
</tr>
<tr>
<td><strong>Intended age group</strong></td>
<td>Children under five</td>
<td>Children under five (pulse oximetry sensor for all ages)</td>
</tr>
<tr>
<td><strong>Unit price</strong></td>
<td>€35 (equivalent to US$ 44)</td>
<td>US$250 for UNICEF procurement for field trials</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>Commercially available</td>
<td>Commercially available</td>
</tr>
<tr>
<td><strong>External support</strong></td>
<td>CA$602,000 grant from Grand Challenges Canada to scale manufacturing and distribution</td>
<td>A US$4.95 million grant from the Bill and Melinda Gates Foundation to support development</td>
</tr>
</tbody>
</table>

**Innovation users**

Respiratory illnesses were often under-recognized in the household, misdiagnosed at the community clinic and therefore undertreated. Advanced diagnostic tools were not readily available in low-resource settings, and health workers were trained to diagnose pneumonia by counting the respiratory rate of children. By providing appropriate tools that healthcare workers can use to present confident analysis of vital signs, the ARIDA device was intended to encourage and

increase fidelity to the proper Integrated Management of Childhood Illness (IMCI) and Integrated Community Case Management (iCCM) guidelines for diagnosis and treatment. Better treatment at the community centre was thought to encourage increased care-seeking behaviour.

Thus, with a single device, the intention was to address under-recognition, under-diagnosis, and under-treatment. Community health workers were the primary target users for the ARIDA devices. Those workers had variable
levels of formal education and health training. Given that they work on the frontlines, if properly equipped, they have the potential to save lives. Primary healthcare workers (PHCW) such as doctors, nurses and midwives, were the secondary target users.

Lessons learned

The ARIDA project was a long-term investment in the Supply Division Innovation Unit portfolio and was a valuable learning laboratory for product innovation. The project helped identify the following lessons:

- ARIDA was instrumental in leveraging internal skills and experiences across Supply Division, Programme Division and country offices. In the context of ARIDA, Innovation Unit could identify user needs and use scenarios and define a new class of product to address barriers experienced by community health workers.

- The project was a learning space on leveraging donor funding as an incentive for downstream procurement. Innovation Unit could lead developers to develop, test and commercialize two new products in the ARIDA class.

- The project had a catalytic effect on the innovation ecosystem by successfully engaging new players, including the Bill and Melinda Gates Foundation and UNITAID into the pneumonia innovation space.

The lessons learned from this complex project led to a rapid evolution of the Innovation Unit approach to accelerating innovations to scale. Since the implementation of ARIDA, new product innovation projects have become more sophisticated by using a portfolio approach that focuses on classes of products, rather than specific ones, and could support solutions that include multiple alternatives available to countries, adaptable and customizable to particular contexts.

3. CONTEXT FOR DEVELOPMENT OF ARIDA

<table>
<thead>
<tr>
<th>Key takeaways</th>
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<tr>
<td>- Pneumonia is the leading infectious cause of death in children under five years of age globally.</td>
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<tr>
<td>- In low-resource settings, health professionals rely on the measurement of respiratory rate for detection of fast breathing and examination of other symptoms to classify a child as having pneumonia, according to integrated management of childhood illness (IMCI) guidelines.</td>
</tr>
<tr>
<td>- The challenges associated with the widely used ARI timer used to count breaths per minute manually led UNICEF Supply Division to initiate a project to accelerate development of an automated pneumonia diagnostic aid.</td>
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3.1 Development/humanitarian context

Pneumonia, though treatable and preventable, remains a leading infectious cause of death of children under five years. Pneumonia accounted for approximately 16 per cent of the 5.6 million under-five deaths, killing around 880,000 children in 2016. Most of its victims were less than 2 years old. Taking children to a health care provider quickly can save their lives, yet, worldwide, only about two-thirds of children receive the necessary help and care when pneumonia symptoms arise. ¹ Deaths attributed to pneumonia are concentration among poor and marginalized populations.

UNICEF, together with WHO, has developed an Integrated Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea. This plan sets forth an integrated framework of key interventions proven to effectively protect children’s health, prevent disease and appropriately treat children who do fall ill with diarrhoea and pneumonia.

The one-minute Acute Respiratory Infection Timer was a manual diagnostic tool commonly used in low-resource countries to count one minute, the length of time required to count breaths in order to measure the respiratory rate in children. The device had several challenges, including distracting ticking sounds and beeps, lack of automation and users’ difficulty in manually counting breaths. Those challenges, and the need to decrease childhood mortality due to pneumonia, generated interest at UNICEF Supply Division for a new, automated diagnostic aid to improve diagnosis and subsequent treatment of childhood pneumonia.

3.3 UNICEF programme context

As with other innovation cases, the ARIDA project drew on UNICEF capacities across areas such as product innovation, programming, policy dialogue and advocacy. In 2018, UNICEF country offices implemented programmes to improve care and treatment of children affected by pneumonia. In the current strategy period, UNICEF has committed itself to reaching 30 million children with suspected pneumonia with appropriate antibiotics through its supported programmes (i.e. by 2021). The case study focuses on the role of the Supply Division which drives external product innovation to prompt and accelerate development of fit-for-purpose products with the potential to advance UNICEF programmes. The division leveraged UNICEF’s procurement power to drive the PIP, initiated when there was an unmet product need in UNICEF programmes and emergency response. The ARIDA PIP contributed to UNICEF’s medium- to long-term goal to reduce pneumonia-related mortality in children under five through the more efficient diagnosis of pneumonia and improved quality of care.

4. THE INNOVATION JOURNEY FOR ARIDA

Key takeaways

- The project team completed an exploratory study of users of the ARI device, intended to improve understanding of the context, user challenges and ideas for an improved method.
- In 2014, the Innovation Review Board was presented with a Project Charter for a project to support the diagnosis of pneumonia by ensuring the availability of automated respiratory rate counting devices, improving the quality of health services.
- Following completion of a market scan of products under development, a target product profile was developed, communicating the minimum and ideal characteristics of an automated respiratory rate counting devices, and followed by a Request for Proposals (RFP) process to select devices for limited procurement for field trials.
- Through and RPF process, UNICEF selected Malaria Consortium to design and conduct implementation studies, including a device performance (i.e., agreement and fit-for-purpose) and end user (i.e., acceptability) evaluation.

The innovation pathway for the ARIDA project followed the stage-gated innovation process utilized by Supply Division for PIPS (Appendix B). The process was not complete when this evaluation was conducted, as both products, ChARM and Rad G, were being assessed in acceptability and implementation studies.

Figure 1. Progression of the innovation process for ARIDA

Needs identification

Identifying the need for automated diagnostic aids

In July 2011, the Supply Division Innovation Unit, in collaboration with the UNICEF Uganda Country Office and its partner, Synovate completed an exploratory study of the user experience of the ARI Timer Device for pneumonia community case management. The research was intended to improve understanding of the context and user challenge with pneumonia diagnosis and to develop preliminary concept ideas for enhanced diagnostic aids. The need for improvements in pneumonia diagnostic aids came about when the study revealed that the ARI Timer Device was unreliable, had a short lifespan and could lead to the miscounting of breaths. Consultations with community health workers also included brainstorming activities to identify the specifications for a new pneumonia diagnostic aid.

Scanning the market

Supply Division hosted a consultative workshop attended by development partners, including WHO, Bill & Melinda Gates Foundation, United States Agency for International Development, civil society, industry and academia culminating in the development of a three to five-year roadmap. The objectives were to create a common understanding of diagnosis in low-resource settings, preview existing devices, define a common platform to address critical challenges and set the parameters of a future Target Product Profile.

A research report launched in May 2013 revealed that new devices were in the process of development by industry, academia and other partners to improve accuracy and effectiveness of pneumonia diagnosis in low-resource settings. However, at the time the research report was released, no devices met the need for a diagnostic aid that could improve the accuracy of diagnosis and differentiate between bacterial and viral pneumonia.
To map the market landscape, Supply Division released a Request for Information (RFI) in February 2014 to learn about partially and fully developed products or technologies with the potential to improve pneumonia diagnosis in low-resource settings. The RFI confirmed that there were no devices that were likely to be developed within 12 to 18 months from that date.

Recognition and exploration

Approval of ARIDA as a Product Innovation Project

A plan was proposed in August 2014 that would take the project through the RFP, procurement and scaling processes. The ARIDA Project Charter was approved by the Innovation Review Board, aiming to establish evidence to determine whether diagnostic aids were appropriate for scale-up in programme contexts, and to collect relevant country-level data to inform a potential scale up.

The approach to the project strategy included three field studies to understand the performance of devices, the challenges and needs of end users (health workers and caregivers) and health system integration of ARIDA. The Innovation Unit supported the Health Technology Centre with a project management framework and activities. Evidence revealed that diagnostic aids that were fit for purpose were not commercially available, making ARIDA acceptable as a Product Innovation Project, which was approved to commence Gate 1 (Table 2). The project moved from the exploration to the concept phase, in which more detailed analysis of concepts and user testing would take place.

### Table 2: Potential contribution of ARIDA device to quality health outcomes

<table>
<thead>
<tr>
<th>The potential contribution of ARIDA devices to quality health outcomes</th>
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<tbody>
<tr>
<td>• Prescribe the right treatment</td>
</tr>
<tr>
<td>• Increase caregiver trust in community health workers</td>
</tr>
<tr>
<td>• Improve the availability of antibiotics</td>
</tr>
<tr>
<td>• Avoid antibiotic resistance</td>
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<tr>
<td>• Empower community health workers</td>
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</tbody>
</table>

Developing a Target Product Profile (TPP)

Target Product Profiles (TPPs) were used to communicate requirements about a new or improved product that does not exist on the market, including the minimum and ideal performance criteria. The process was intended to stimulate greater creativity in the innovation process while guiding the industry toward a product that was fit for purpose. The ARIDA TPP was released in November 2014, describing the intended use, context, user and stakeholder needs for a new pneumonia diagnostic aid to support the assessment of breathing. The objective of the TPP was to accelerate development of a procurable, regulatory-approved (e.g. CE marking) device available for field trials by the end of 2016.

The document was based on the World Health Organization’s revised integrated management of childhood illness and integrated community case management guidelines for diagnosis and treatment of pneumonia in children under five years of age and included a list of needs and constraints for the development of new devices according to four needs categories: performance needs, functional needs, stakeholder needs and design needs.

**Publishing a Request for Proposals (RFP)**

A Request for Proposals (RFP) for ARIDA was released in 2016, offering the procurement of limited quantities of devices for a field trial. The technical criteria required for novel products
followed those specified in the Target Product Profile and included characteristics such as product availability, lower unit price, delivery lead-time, and production capacity. Five suppliers responded to the challenge. The first ARIDA technology, Philips ChARM automated respiratory rate counting device, is regulatory approved (CE marking), commercially available and acceptable for UNICEF procurement as of January 2017 (corrected devices as of December 2017). The second ARIDA technology and first multi-modal respiratory rate-pulse oximetry device, Masimo Rad G, is regulatory approved (CE marking), commercially available and acceptable for UNICEF procurement as of April 2018. The other three applicants have not progressed to regulatory approval.

Development and implementation

Selection of automated diagnostic aids for field trial

After the identification of the ARIDA products through the RFP process, approval was granted by the Innovation Review Board to move through Gate 2 of the stage-gated innovation process (Appendix B). An RFP for the ARIDA field trial protocol development and implementation was released in 2016. The RFP included a clinical and fit-for-purpose evaluation (Table 3). Through the competitive RFP process, Health Technology Centre completed a technical and commercial evaluation of the three offers submitted, and Malaria Consortium was selected for the Long-Term Agreement to develop protocols and to run field trials.

Table 3. Field trials and their objectives, as described in the RFP for field trial protocol development and implementation

<table>
<thead>
<tr>
<th>Field trial</th>
<th>Objective</th>
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<tbody>
<tr>
<td>Agreement</td>
<td>To determine the accuracy (agreement with reference) of the device when used by health workers to measure respiratory rate</td>
</tr>
<tr>
<td>Acceptability</td>
<td>To determine the suitability of the device for use by frontline workers and acceptance of caregivers</td>
</tr>
<tr>
<td>Cost-effectiveness</td>
<td>To model the programmatic costs of implementing the device at scale, in comparison to the implementation of the currently used ARI timer</td>
</tr>
</tbody>
</table>

At the time that Malaria Consortium was selected to design and conduct implementation trials for ARIDA devices, only one technology, Philips ChARM, had obtained the CE certification. The Innovation Review Board (IRB) questioned whether completing field trials for one product first could increase the risk of market penetration or limit competition; however, the project team believed there was a low likelihood of both devices being available in 2016. Further, the Masimo Rad G device had not yet met all criteria required by the TPP, had additional features such as pulse oximetry and the unit price was expected to be significantly more expensive than ChARM. Following input and discussion with the IRB and Advisory Committee, the decision was made to test the ChARM device first, rather than testing both devices under development simultaneously.

Looking forward for the ARIDA project

As of January 2019, agreement and acceptability field trials in Ethiopia and Nepal were completed and implementation studies in Ethiopia and Bolivia were in progress. The procurement strategy would be reviewed following analysis of the field trial results.
5. ARIDA FIELD TESTING

### Key takeaways

- **ARIDA field trials in Ethiopia**, a country in which delayed diagnosis and misdiagnosis were challenges, began in 2017.

- An accuracy (agreement with reference) study of the Philips ChARM device revealed a **programming error that Philips corrected**. UNICEF Innovation Review Board took the decision to **cancel further ARIDA accuracy studies** following analysis of the study data due to **lack of a gold standard reference** for measuring respiratory rate.

- **Acceptability studies of Philips ChARM and Masimo Rad G** are underway to understand if health workers could adhere to integrated community care management **algorithms** while using the identified device and **determine the benefits and barriers** of using the device.

- Next steps planned in Ethiopia included implementation studies of Philips ChARM and Masimo Rad G in five regions, expected to begin in fall 2018, to understand how best to plan for the integration of ARIDA in the national health system and help identify the practical, health system-level lessons that emerge to inform future scale-up.

#### 5.1 ARIDA field trials: Ethiopia

Recommendations for the selection of countries for field trials emerged out of criteria developed in consultation with the Advisory Committee of experts and discussions with the UNICEF Regional Health Specialists. Those recommendations stipulated that the countries follow integrated community care management (iCCM) and were able to conduct field trials and that the Ministry of Health was committed to deploying devices for assessment and partake in IMCI, iCCM and device training. Two countries, Ethiopia and Nepal, emerged as strong candidates and field trial efforts were undertaken in both countries. This case study however is focused on the experience in Ethiopia where the innovation was most advanced in its use.

**The burden of pneumonia in Ethiopia**

The Ethiopian Federal Ministry of Health had an interest in innovations to improve the quality of service as part of its National Medical Oxygen and Pulse Oximetry Scale up Road Map. The country had been engaged in a health extension programme since 2004 and followed integrated community case management (iCCM) guidelines. Health Extension Workers had been treating pneumonia cases by providing antibiotic treatment at the health post level since 2010. These characteristics made Ethiopia well suited to testing of ARIDA devices.

According to interviewees with Supply Division, Ethiopia Country Office, Malaria Consortium, and the Federal Ministry of Health, the challenges in Ethiopia included inadequate care seeking, delayed diagnosis, misdiagnosis of pneumonia and the failure to treat, in certain instances, relating to stock-out of antibiotic treatment.

**Accuracy studies**

Field trials of the Philips ChARM device began in Ethiopia in 2017, including an accuracy study of the Philips ChARM device at St Paul’s Hospital in Addis Ababa. The objective of the study was to determine agreement between the device and a panel of independent expert clinicians using a video panel reference standard for comparison. The research team identification of a programming error related to integrated management of childhood illness (IMCI) guidelines for fast breathing prompted

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Supply Division to notify Philips, which then issued a field safety notice that resulted in a device recall and an early end to the study. Philips addressed the programming error and provided corrected devices. Identification of the programming error was a significant finding of the field trial. The flaw in the algorithm did not affect the study design. Malaria Consortium analyzed the truncated data set with close engagement with UNICEF and the ARIDA Advisory Committee.

The findings from this study could neither support nor challenge ChARM accuracy. During the investigation, substantial differences were noted between human expert counters and were unusable as a reference standard, irrespective of video recordings of the breath sequence available. The ChARM device measured a different breath sequence to human counters and made adjustments for non-breathing movements. The mean-time to use the device, including failed attempts, was 79 seconds. Further research was encouraged to measure the performance of similar devices in this new class of products. Additional work would be needed to develop and establish agreed, validated and appropriate objective reference methods for determining respiratory rate accuracy in order to assess performance of ARIDA devices.

The project team received feedback from the Advisory Committee, the Zika Virus diagnostics Product Innovation Project team and Malaria Consortium. The project team analyzed and presented four possible scenarios and associated risks of accuracy studies with a recommendation to the Innovation Review Board to complete the body of work according to the existing evaluation framework to ensure that the evidence needed for decision-making was available.

The Innovation Review Board decided to forego further accuracy studies for lack of a reference and to forego development of the definition of a gold standard for respiratory rate due to scientific complexity. Instead, the ARIDA project would accept Conformité Européenne (CE) marking and move forward with acceptability and implementation studies, after which it would synthesize evidence derived from all studies followed by expert stakeholder consultations to assess the extent of the reference barrier and potential solutions and inform supply and demand side of the market, with the aim of gaining alignment on next steps toward improving pneumonia diagnostics.

Following this decision, the Ethiopia Country Office, Programme Division and Supply Division worked together to decide how to communicate the status and results of the accuracy study to the Federal Ministry of Healthy and project stakeholders in the global pneumonia community. The parties presented the importance of continuing with the acceptability study to the Federal Ministry of Health, and it was well received.

Acceptability studies

The objective of the ARIDA acceptability studies was to understand if health workers in programme contexts could adhere to Integrated Management of Newborn and Childhood Illness (IMNCI) algorithms while using the device, and to identify the benefits and barriers of using it. As the technical implementing partner, the Malaria Consortium was responsible for the development and execution of the acceptability study and UNICEF and the Federal Ministry of Health played essential roles throughout the agreement and acceptability studies (Table 4).
Table 4. Roles and responsibilities of UNICEF and Malaria Consortium for agreement and acceptability studies

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UNICEF Supply Division and Programme Division</strong></td>
<td>Ownership of ARIDA project and relationship with la Caixa Foundation and ARIDA Advisory Committee. Supply Division was responsible for procurement of test devices and amoxicillin required for studies.</td>
</tr>
<tr>
<td><strong>UNICEF Ethiopia Country Office</strong></td>
<td>Communications with country partners (e.g., World Health Organization, US Agency for International Development, Federal Ministry of Health) and quality assurance visits during the data collection period.</td>
</tr>
<tr>
<td><strong>Malaria Consortium</strong></td>
<td>Technical implementing partner contracted by Supply Division; develops protocols, training materials and job aids; responsible for design and set-up of research sites and implementation studies, including ethics committee oversight, quality assurance and data analysis.</td>
</tr>
<tr>
<td><strong>Federal Ministry of Health</strong></td>
<td>Interested in scaling innovations that improve the quality of services and health of children; The Maternal and Child Health and Nutrition (MCHN) directorate provided support to the ARIDA project, including ethics and customs clearance.</td>
</tr>
</tbody>
</table>

Districts for the acceptability study were selected based on the high pneumonia burden, accessibility from Malaria Consortium offices and right standing with zonal leadership. Following selection of districts, the training modules for health professionals were developed, including hands-on training on the use of the device and review of the protocol for treatment of childhood pneumonia. A Malaria Consortium capacity-building expert based in Nigeria developed the training materials. The study contained quantitative and qualitative components. For the quantitative component, Malaria Consortium observed health extension workers immediately after training (data collection 1) and six to eight weeks after the training (data collection 2) to document the device user experience and proportion of HEWs using ARIDA who correctly followed the protocol in line with Integrated Management of Newborn and Childhood Illness (IMNCI) guidelines to assess and classify children with cough and/or difficulty breathing. For the qualitative component, to document the user experience of ARIDA in a sick child consultation, Malaria Consortium conducted structured and semi-structured interviews with health extension workers and caregivers.

As part of this case study, feedback was collected from Ethiopia Country Office, Federal Ministry of Health, Malaria Consortium and health extension workers through semi-structured interviews. It was found that while the user experience with the ChARM device was overwhelmingly positive, areas for improvement remained (Figure 2).
Next steps in Ethiopia

An acceptability field trial of Masimo Rad-G in Ethiopia is planned. Beginning in October 2018, implementation studies of Philips ChARM and Masimo Rad G in five regions were planned. UNICEF and the Federal Ministry of Health plan to deliver cascading training, through which health extension workers would receive training and be equipped with an ARIDA device. UNICEF health specialists from field offices planned to conduct training with the regional health bureaus and iCCM/IMCI trainers, who would then train the next level down the health system, ending with training of front-line health workers. The training material would be based on material produced for the IMCI and iCCM refresher and device training of previous ARIDA acceptability study phases conducted by Malaria Consortium. The implementation studies will require an increase in efforts and engagement at the Ethiopia Country Office level, including significant coordination with the Federal Ministry of Health to organize training.

The National Child Technical Working Group, composed of representatives from different organizations, including implementing partners, provides technical advice to the Federal Ministry of Health (FMOH) on child health-related issues. Before any potential scale-up of decisions on ARIDA in Ethiopia by FMOH, the Working Group would need to endorse the proposed devices.
6. FINDINGS

6.1 Approach dimension

1. How does this innovation contribute to UNICEF country and global strategies?

The ARIDA project would contribute to several country-level and global initiatives related to pneumonia, such as the Global Action Plan for Pneumonia and Diarrhoea (GAPPD) which provided an approach to end preventable pneumonia and diarrhoea-related deaths by 2025. In alignment with the Sustainable Development Goals, these efforts contribute to target 3.2 and the achievement of ending preventable (pneumonia and non-pneumonia) deaths of newborns and children under 5 years of age (by 2030). For the Ethiopia UNICEF Country Office, the ARIDA project contributed to improving equitable and affordable coverage of health interventions for newborns, children, adolescent girls and women by 2020 (Outcome 1 of its programme components)4.

2. What is this innovation doing in terms of scaling up and out or working at greater efficiency and economy?

The project set out to accelerate development, validate and facilitate market availability of automated respiratory rate devices to assist assessment and classification of fast breathing as a critical indicator of pneumonia in children under five to improve clinical management in low-resource settings. By communicating the ideal device characteristics and UNICEF’s intent to assess and field trial regulatory-approved novel devices, the project will provide objective evidence allowing governments and organizations to select devices that are fit for purpose and best suit their needs.

The ARIDA project is a long-term investment in the Supply Division Innovation Unit portfolio, and as such has been a vital learning laboratory for product innovation strategies. The project helped raise the following lessons:

- ARIDA has been instrumental in leveraging internal skills and experience across Supply Division, Programme Division and Country Offices. In the context of ARIDA, the Innovation Unit could identify user needs and use scenarios and define a new class of products to address healthcare worker obstacles.
- The project was also a learning space on leveraging donor funding as an incentive for downstream procurement. The Innovation Unit could lead developers to develop, test and commercialize two new products in the ARIDA class.
- The project had a catalytic effect on the innovation ecosystem by successfully encouraging new players into the ARIDA space, including the Bill and Melinda Gates Foundation and UNITAID.

Lessons learned from this complex project have led to a rapid evolution of the Innovation Unit approach to accelerating innovations to scale.

3. How are end-user needs identified and considered and how did they shape the innovation?

The specifications of the performance categories of the Target Product Profile (TPP) and request for proposals included a user-centred design; however, feedback from one product developer selected for field trial indicated that the TPP did not actively influence project design given that its product had already been in the late stages of design at the time that the TPP was issued. The supplier has an internal user-centred design process through which it designs and tests minimum viable products with end users.

Insights: Feedback from Supply Division, Ethiopia Country Office, Malaria Consortium and health extension workers indicated that there is a risk that health practitioners and caregivers may consider diagnostic aids as ‘perfect’ measures of

respiratory rate. In Ethiopia, the presence of the device at the health post level and its perceived effectiveness to diagnose pneumonia increased community interest by word of mouth. It is unknown whether reliance on an automated respiratory rate counter alone and detection of fast breathing would lead to over- or under-diagnosis of pneumonia.

4. What challenges were faced during the innovation process and what strategies were used to overcome barriers?

The project has faced several challenges during the innovation process, including:

- **Restricted interaction with developers:** UNICEF was restricted in its interaction with developers and manufacturers, limiting opportunities for early product iteration, an essential component of innovation. Procurement policies restrict specific interactions with the private sector to avoid conflicts of interest or the appearance of endorsing one company over another. For example, there were restrictions regarding information that could be shared with suppliers before issuing an RFP, which could guide early product development. Limitations on UNICEF-supplier relations may, therefore, limit UNICEF’s influence on product design and opportunities to make improvements for devices to be more fit-for-purpose. However, based on its experience with product innovation, Supply Division was moving toward a model of co-creation with industry through competitive procurement processes. For some product innovation projects, UNICEF offered developers, selected through RFPs, the chance to participate in field trials, providing opportunities to observe the use of physical prototypes in the field and refine product design. This approach provided a valuable advantage for both the manufacturer (which often did not fully understand the context in which products would be used) and UNICEF (which would likely receive a better product because of product iteration based on field trials, and a stronger relationship with suppliers). Refined products could then be evaluated through manufacturers’ final technical offer, before moving to procurement.

- **Growing preference for pulse oximetry:** Throughout this project, the preferred features of pneumonia diagnostic aids shifted. The health community became more interested in multi-modal devices and inclusion of pulse oximetry as a pneumonia diagnostic aid. Such devices provided health professionals with the means to determine the severity of pneumonia according to blood oxygen content, which could improve timely identification of cases and referral of severe cases to the next level of care. Challenges with pulse oximetry included a lack of policy and guidelines on its use at the field level; concerns over demonstrating the impacts in comparison to other indicators; the lack of referral systems and capacity to provide oxygen therapy to children when needed in low-resource contexts; and price. The Masimo Rad G product was a multi-modal diagnostic aid (e.g., measuring temperature, oxygen saturation, respiratory rate, pulse), which could improve its likelihood for market success considering the shift in preferences toward integrated devices. Findings from the Ethiopia Rad G acceptability field trial will provide objective evidence about usability of pulse oximetry at the community level by health extension workers.

- **Frustration with long timelines:** According to members of the Advisory Committee and donor relations staff, the long-term timelines of the project and delays frustrated the donor. The ARIDA project spanned three stages of product development, which added to its complexity compared to other product innovation projects. Complications due to the highly technical nature of the project, including supplier delays, product recalls, lack of explicit reference led to additional delays. In Nepal, a country-wide decentralization effort delayed progress. Furthermore, the nature of product innovation for children’s health revealed
that there could be delays in the evidence of outcomes and impacts compared to standard UNICEF programmes since products move through the stages of development, regulatory approval, testing, and finally implementation and commercial availability

- **Internal communications:** Three informants stated that internal communication had occasionally been a problem and that messaging and communications should be aligned as much as possible. At times, events and decisions could shift (e.g., the status of field trials in Nepal following government decentralization) which added to the challenge with regard to communications. Interviewees, therefore found it important that Supply Division, Programme Division, Country Offices, Private Fundraising and Partnerships Division (PFP) and the National Committee (NatCom) were provided the same information promptly.

5. How was scale considered through the process, starting with the initial design of this innovation?

The Expression of Interest published by UNICEF specified that the project would begin facilitating scale-up and national implementation of the devices following positive results, from the implementation pilot. Conditionally, following upon positive results, the project team proposed to develop and launch a tender for scale-up following completion of field trials. (See question 26 for details on UNICEF’s involvement in demand generation.)

6. Was a proof of concept and business case developed for this innovation?

At the beginning of the ARIDA project, field trials were intended to include accuracy, acceptability, and cost-effectiveness studies. A cost-effectiveness analysis for pneumonia diagnostics was completed by HealthNet Consultancy in 2016. The objective of the study was to compare various pneumonia diagnostics, including the ARI timer, automated ARIDA devices and pulse oximetry. The study concluded that a pulse oximeter-respiratory rate combination would provide the highest marginal benefits, but that respiratory rate devices would be the most cost-effective alternative. There were assumptions, however, that ARIDA devices would be 95 per cent accurate, and that the pulse oximeter would cost US$100 and the respiratory rate device US$35. Ultimately, the project team decided to reject the study, due to the difficulty of quantifying the impacts of diagnostic devices.

**Insights:** There were several challenges to completing a useable cost-effectiveness study. Cost-effectiveness analysis is a tool used to assess, objectively, the value of new products by comparing the incremental health benefits and incremental costs. The results were intended to enable policymakers to make rational decisions regarding resource allocations. Standard analysis, which compares cost-increasing or saving, and less- or more-effective, requires a basic understanding of both the estimated cost of a product and its impacts on the target population. For ARIDA, the expected impact was projected using the Lives Saved Tool, which considered device effectiveness in reducing mortality and the scale of coverage of the intervention. However, the efficacy of diagnostic aids in indicating cases of pneumonia could not be determined based on respiratory rate without understanding device accuracy. Furthermore, the unit cost used in the study for the ARIDA device, while in line with the ChARM device, was lower than other devices identified through the RFP.

The decision to reject the cost-effectiveness model quantifying the impact of diagnostic technologies

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6 HealthNet Consult, 2016. Cost Effectiveness Analysis for Pneumonia Diagnostics.
together with the inability to complete accuracy studies presented decision-making challenges in the Ministry of Health. In Ethiopia, completion of an accuracy study would have provided a valuable piece of evidence for the Federal Ministry of Health and the Technical Working Group. Without understanding the device’s ability to indicate cases of pneumonia accurately, the impacts of devices could be guaranteed. A cost-effectiveness model would have been an effective means of demonstrating the value of an automated respiratory rate counter to the Government; however, due to resource constraints and difficulties completing this type of study for diagnostics, no further investigations were planned. Stakeholders interviewed from Supply Division, Ethiopia Country Office, Federal Ministry of Health and supplier groups identified the lack of evidence as a concern moving forward.

While the decision to complete field trials through an external third party provided the necessary expertise to carry out the studies, the absence of a standard against which to compare the effectiveness of devices meant that Supply Division was not well-positioned for success. The decision to complete cost-effectiveness and accuracy studies was problematic due to the absence of a reliable reference standard; however, the accuracy study completed for the ChARM device provided critical information that there was an error in the algorithm, which provided an opportunity to make corrections to the device before implementation. An interviewee from Supply Division stated that the time required to develop the protocol for the accuracy study should have been a signal that the reference would not be strong enough to produce the intended results. The results provided a valuable lesson for future accuracy studies as the disagreement between experts on how to determine the accuracy of a product, and the degree of difficulty to do so could indicate a low likelihood for success. One interviewee noted that, for products for which there was a lack of reliable reference, Supply Division could use third-party contractors to complete smaller-scale trials in-house before conducting accuracy studies in the field. Insight would be gained prior to beginning large-scale trials, and would help to avoid incurring unnecessary costs. As for cost-effectiveness studies, the early analysis could have been a useful decision-making tool for Supply Division as it developed the Target Product Profile and determined product specifications; however, the results of such an initial analysis (prior to field trials and finalization of unit price), even if successful, may not have yielded the materials intended to enable informed decisions by policy-makers. These issues may be avoided in the future, following the Innovation Review Board’s decision not to pursue accuracy studies for Product Innovation Projects for which there is no standard reference.

7. How does this innovation complement or build on existing knowledge and work conducted in the country and across programmes?

The ARI timer, the existing preferred diagnostic aid for use in low-resource settings, is included in the Supply Division’s Supply Catalogue. The device was a one-minute timer used by health workers to keep track of time while counting breaths of children with suspected cases of pneumonia. Challenges identified with the ARI timer included distracting noises, community trust in the device and difficulty for health professionals who were counting breaths manually. These challenges did not meet the objectives of the ARIDA project to accelerate the development of automated pneumonia diagnostics to circumvent these problems and to improve the design of the ARI timer itself to make it more user-friendly.

Implementation and scale-up of ARIDA devices would build upon operationalization of integrated management of childhood illnesses (IMCI) guidelines for the diagnosis of pneumonia, which include identification of fast breathing as an indicator. The results of acceptability studies would provide evidence of whether health professionals could adhere
to IMCI guidelines while using automated devices.

**Insights:** **Improvement of the design and continued supply of the ARI timer** would contribute to the ARIDA project’s objective to develop a suite of devices to assist in the diagnosis of pneumonia. The unit cost of the ARI timer was US$4, which provided a significantly lower estimated cost than ARIDA and pulse oximetry devices in the innovation pipeline. It ensured that countries that do not wish to procure automated devices could continue to purchase ARI timers at an affordable price through Supply Division. This is essential learning from the ARIDA project, which informed a new approach in product innovation where a portfolio of solutions, rather than a specific product, was the desirable innovation package.

8. How have the local environment/market (including legal, regulatory and technological) considerations influenced the design of the innovation?

Nine interviewees from across stakeholder groups identified regulatory approval as a significant challenge for this innovation. Four interviewees from the project team, Innovation Review Board and Advisory Committee expressed that the standards for regulatory approval of ARIDA devices (CE marking) were too low. Due to the lack of an agreed, validated, technology-agnostic reference standard, product developers and manufacturers presented their arguments for their choice of reference for regulatory approval. Moving forward, Supply Division would accept regulatory approval (e.g., CE marking) as evidence of the accuracy of devices. However, regulatory requirements remained an issue for this project as there was no agreed upon and validated approach to determine respiratory rate accuracy.

Local regulatory and legal processes presented an additional challenge for product developers. For example, CE marking for medical devices enabled sales in any market that accepted CE marking in the four available language translations. For markets that required labels for distribution in local languages, it was the manufacturer’s responsibility to ensure regulatory compliance. There was one example where the profits from the number of products ordered by UNICEF for field trials did not cover the cost of having the product localized for the market. As of September 2018, UNICEF was working to receive a regulatory waiver from the government of Ethiopia. However, upon commercialization of the device, the manufacturer would have needed to invest in label translations (approximately $US 20-30,000). The need for localized language labels could constitute a barrier to scale if procurement potential in programme countries that required local translations or other requirements was low.

9. What value does UNICEF bring to this innovation and what makes UNICEF suitable to scale it?

The most common comments made by interviewees on UNICEF’s value on this project were its significant procurement power, its ability to get products to market efficiently and effectively, and its ability to act as a convener between government, partner organizations, product developers, manufacturers and suppliers. Stakeholder groups provided a wide variety of opinions on the unique value provided by UNICEF. One supplier selected indicated that UNICEF’s value was serving as a sounding board to reflect on learnings and ways that the device could be improved.

10. What principles or standards have been applied and how?

The Principles for Digital Development were not applicable to this innovation. Supply Division followed its procurement policies, which ensured value-for-money, economy and effectiveness and avoided perceived conflicts of interest and the appearance of endorsing one company over another. Supply Division

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also required that manufacturers follow the UN Supplier Code of Conduct, which is based on human rights, environment-friendly, and anti-corruption approaches.8

11. What are the steps taken or methods used to assess and mitigate risks to children, users, and markets?

To mitigate risks to children, Supply Division required regulatory approval for medical devices.9 Accuracy and acceptability studies were conducted supported by approvals oversight from external ethics committees, including the Southern Nations, Nationalities and Peoples’ Region (SNNPR) for the field trial in Ethiopia, and the Liverpool School of Tropical Medicine ethics committees.

A competitive RFP process was used, following the issuance of a Target Product Profile to provide ideal device characteristics, to promote competition and healthy markets.

Insights: The process followed for the Product Innovation Projects may have market distortion effects. Decisions regarding which devices enter the project pipeline and the timing of implementation studies could affect future procurement and scale-up of products. Although the ChARM and Rad G devices had different functions and unit prices, the decision to test ChARM first in Ethiopia could affect the Government’s decision on which device to procure, although the Federal Ministry of Health would likely favour procurement of Rad G due to its alignment with the Oxygen Roadmap. Both products selected for limited acquisition for field trial as of September 2018 received external funding for product development or scale-up.

6.2 Organization dimension

12. What type of support was received from the leadership to enable the innovation process?

The Innovation Review Board (IRB) provided oversight of the ARIDA project and was the governing body for the Product Innovation Projects. In addition to approving the project to pass through stage-gates along the innovation pathway, members of the IRB provided valuable insight and guidance in response to project delays and pivots. The leadership supported engagement with ‘la Caixa’ Banking Foundation, through its presence on the Advisory Committee and the annual in-person meetings with the Foundation to provide project updates.

Insights: Two divisions coordinated communications with ‘la Caixa’ Banking Foundation within UNICEF:

- The Spanish National Committee (NatCom) engaged with the partner directly and was the focal point, managing the relationship with the donor and acting as the bridge between the donor, UNICEF Headquarters and Supply Division. This type of relationship management was standard for NatComs, which lead partner relationships in their markets.
- The Private Fundraising and Partnership (PFP) Division’s role was to maximize partnership with the private sector. PFP provided support to the Spanish NatCom to manage the relationship with the donor, including for communications activities, legal framework and finance processes, and playing a convening role between the NatCom and Supply Division.

Communication with the Foundation was challenging, especially on project progress and translating technical information into clear key performance indicators. UNICEF made an effort to provide ongoing updates and reports, but challenges to understanding the nature of innovation projects remained. For example, one interviewee noted that communicating the value of complex Product Innovation Project processes was difficult, while another interviewee stated that the Foundation lacked the technical expertise to understand project challenges and UNICEF lacked the appropriate know-how needed to communicate these back to the donor effectively. Ongoing changes to

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9 European Commission, 2018. CE Marking.
the project, such as field trials planned for only two countries and the lack of tangible outcomes, led to frustration as the Foundation had to communicate results and justify spending to its board and the public. Strategies to improve communication with the Foundation were its inclusion on the Advisory Committee and participation in a field mission to Ethiopia to observe challenges and progress firsthand.

An interviewee noted that communications were generally handled by the Private Fundraising and Partnership Division, which allowed the project team to focus on project implementation. On this occasion, however, the project team was in regular contact with the donor and the NatCom, which may have contributed to perceptions among interviewees that there were too many stakeholders involved in communications. There should be some clarification on the roles and responsibilities among divisions for better coordination.

13. What type of support and leadership facilitated the enabling environment for innovation?

The enabling environment for this project was supported through the development of the target product profile, which described the ideal device characteristics and the RFP with the potential to enter a long-term agreement following the success of the implementation studies. In theory, these tools, developed and approved by the leadership, signaled UNICEF’s interest in procuring ARIDA devices to industry, partners and academia, inviting the market to meet those needs. Feedback from a supplier and an Advisory Committee member suggested that the target product profile did not significantly influence product design, as product development was in its later stages when it was released. However, participation in the industry consultation and RFI prior to release of the target product profile guided product development, deepening the manufacturer’s understanding of UNICEF’s needs. The advantage of early engagement was further evidenced by the fact that the RFP targeted devices that were already developed and registered and did not require a significant role to catalyze the development of novel products. It was noted that the product innovation process may have accelerated development and market availability.

Insights: If the expression of interest and request for proposals process had been designed to include products in the early stages of development, the Product Innovation Project might have achieved greater success at shaping the design of novel products while conducting implementation studies of already-developed devices.

14. Who makes decisions with respect to the design and implementation of the innovation?

- The project team was responsible for the day-to-day management and rollout of the project. It was composed of representatives from various internal UNICEF groups, including the Innovation Unit, Health Technology Centre, Programme Division and Country Offices.

- The Innovation Review Board (IRB) was the decision-making body of Product Innovation Projects at Supply Division. The IRB was responsible for major project decisions, including project advancement through the stage-gated process of innovation. The IRB also had the power to close projects, if deemed necessary.

Insights: There were several other stakeholder groups involved that provided valuable input for decision-making (See Annex B).

15. What factors were considered when making decisions about governance and ownership of the innovation?

Supply Division, Programme Division and Country Offices established and followed a collaborative process on the ARIDA project; however, Supply Division was asked to lead the process based on its expertise and the technical nature of product innovation.
When considering ownership of the project, UNICEF assembled a project team that would bring the required technical, programme and local context expertise. For example, the project team selected several members from Country Offices that would be involved in the implementation to coordinate local activities and provide expertise on the local health context.

As of September 2017, the Advisory Committee was composed of 10 experts who reviewed and guided project activities and made recommendations as needed. Committee members included key stakeholders, technical experts, observers and representatives from ‘la Caixa’ Foundation.

**Insights:** Several Advisory Committee interviewees stated that the Committee lacked diversity regarding member subject matter expertise. A large percentage of members were academics and technical experts. Knowledge from other sectors such as marketing and the private sector could have further strengthened the Committee’s usefulness.

A representative of the ‘la Caixa’ Banking Foundation was a member of the Advisory Committee, which allowed the donor to stay up-to-date with project developments. However, other members of the Advisory Committee expressed that there could be a risk of principal funders having a stronger voice than other members. There was a risk of compromising the role of the Advisory Committee when donors were present, if the donors attempted to influence the scientific discussion. As of September 2018, this appeared not to have been an issue.

**16. How has the governance and ownership model influenced the innovation process?**

The Innovation Review Board (IRB) played a significant role in the decision-making process and approved project progression through gates. The process followed by the IRB during the field trial phase enabled Phillips to iterate product design upon discovery of the algorithm error. The IRB made the final decision not to proceed with accuracy studies, but instead to move to acceptability studies after requesting and reviewing the results of the accuracy study, and receiving input from the project team and Advisory Committee. Following completion of the implementation studies, the IRB decided whether the evidence was sufficient to move through the third gate to the scale-up phase.

The Advisory Committee provided valuable expert input for the project and was consulted at critical stages of the Product Innovation Project to validate and provide input on findings and decisions. However, feedback collected from Advisory Committee interviewees and a partner indicated that the model of consultation could be improved. Implied from those responses was that information was often presented to the Advisory Committee for feedback when decisions had already been taken by UNICEF and that the Committee was not a driving force for the project. Advisory Committee members stated that consulting the committee at points where the project was not going as expected, (for example, delays due to nationwide government decentralization in Nepal) might have yielded useful recommendations.

**17. When will this innovation be mainstreamed and what are the steps undertaken by UNICEF?**

Supply Division used Product Innovation Projects to drive research, development, availability and scale, and the stage-gated process that followed moves from the ‘explore’ through ‘scale-up’ phases. Therefore, these ARIDA devices would no longer be considered an innovation when the suite of devices offered through Supply Division reached scale.

**18. How, if at all, has the innovation team worked across UNICEF offices and divisions to leverage internal and external knowledge and expertise and share learnings?**

Members of the project team were selected to provide the technical, programme and local context expertise required. The resulting diverse composition of the project team strengthened the Product Innovation Project. The core project team included members from Supply Division (Innovation Unit, Health Technology
Centre), Programme Division, and the Ethiopia Country Office, which provided opportunities to incorporate different perspectives and expertise from each. For example, the procurement strategy was developed by the Health Technology Centre, while the Ethiopia Country Office representative provided input on the local context and coordinated activities on the ground during the planning and throughout the implementation studies.

Insights: Communication was a critical factor of success for field trials in Ethiopia, particularly with development partners. Alignment between project team members improved communication of the accuracy study outcomes to the Federal Ministry of Health. Communication between development partners, including the Clinton Health Access Initiative, Bill and Melinda Gates Foundation, Save the Children and the Technical Working Groups, was key to reducing redundancies.

6.3 Resources and capabilities dimension

19. How is the innovation funded?

Funding for the ARIDA project came from a €5 million grant from ‘la Caixa’ Banking Foundation, of which €4.9 million was dedicated to programmatic activities and €100,000 to communication activities managed by la Caixa Foundation. The funding agreement with ‘la Caixa’ Foundation covered four pillars:

- **Better diagnosis**: improve diagnosis by accelerating development of a suite of commercially automated respiratory rate devices
- **Increasing the procurement of amox DT for treatment**: devices should be user-friendly, and the project should increase availability and access to appropriate antibiotic treatment
- **Investing in the capacity-building of community health workers** as they can have a significant impact in reducing child mortality by timely diagnosis and correct treatment; and
- **Awareness and advocacy**: strategy, advocacy and communication activities should raise awareness of the partnership between the Foundation, UNICEF and the project, and the importance of responding to pneumonia mortality in children under five.

20. How much time and how many resources were invested at different points in the innovation process?

The following is a breakdown according to budget for project activities agreed-upon by la Caixa Foundation and UNICEF in November 2015:

- US$1.29 million for field trials – protocol development, implementation, analysis and reporting
- US$2.57 million for scale-up – including supply of ARIDA devices for implementation studies, Amox DT, local advocacy and training of community health workers participating in studies
- US$0.77 million for programme costs – two full time staff, including associated travel and administration
- US$0.51 million for management costs – UNICEF global recovery costs and partnership management by the Spanish National Committee.

The original grant agreement between UNICEF and la Caixa Foundation was for €5 million over two years. Following delays in use of funding caused by device availability (no commercially available devices in 2016) and required changes to the ChARM device following accuracy study results (corrected devices delivered December 2017), and time needed to prepare the Rad G device for field trial (not available until April 2018), UNICEF and la Caixa agreed to extend the grant for an additional year, set to expire April 2019.

In its 2017 Annual Report to la Caixa Foundation, UNICEF reported having spent and committed a total of US$1,443,191 of the €2 million (US$ 2.2 million) received as of 31 December 2017. The Innovation Review Board-approved workplan for the final year stipulates procurement of additional Amox DT with any unused project funds.
21. What ongoing resources (human, physical, and financial) are required from UNICEF to manage this innovation?

Resourcing for implementation studies in countries was essential to coordinate activities. The Monitoring and Evaluation Specialist from the Ethiopia Country Office who served on the ARIDA Project Team and Health Systems Strengthening Cluster was the focal point for coordination of activities between Malaria Consortium, Supply Division, Programme Division, the Federal Ministry of Health and other partners in Ethiopia. This presence on the ground was necessary to provide county-context expertise and to coordinate health research and pre-import clearance; however, project support was in addition to the specialist’s existing regular duties, which created time constraints. UNICEF Ethiopia Supply colleagues facilitated Federal Ministry of Health approvals for import and customs clearance of ARIDA devices and Amox DT. UNICEF Ethiopia Field Office colleagues facilitated the implementation study rollout in five regions of Ethiopia.

The Innovation Unit provided valuable project management activities, as project team members from Supply Division centres had other responsibilities that limited the amount of time available to dedicate to Product Innovation Projects. Project team member from the Supply Division Markets, Supplier Financing, and Innovation Centre (MSFIC). MSFIC served as contracting lead and facilitated procurement of ARIDA devices, pneumonia treatment and associated supplies, including liaising with procurement centres and managing contract review committee submissions. MSFIC also led the contracting for services for ARIDA field trial protocol development and implementation. The Innovation Unit project team member Operations Officer supported funds reservation process for transferring funds to country offices.

22. How, if at all, have partners external to UNICEF contributed to the innovation process?

Buy-in and support at the government level and political stability were essential to the success of implementation studies. In Ethiopia, the Federal Ministry of Health Directorate was receptive to the ARIDA project, and the ministry provided support as requested. Interview responses of two project team members and a representative of the Federal Ministry of Health indicated that the political environment in Ethiopia had little impact on the health sector and that the Government used science-based decision-making; which stated that the risk of loss of political will to continue with the ARIDA project was minimal. In Nepal, decentralization of government before the start of implementation studies posed significant challenges regarding government buy-in for the project, delaying the ability to begin any of the planned studies.

While Supply Division did not consider developers and manufacturers engaged through Product Innovation Projects as partners, their contributions to the ARIDA project were significant. The industry was involved in a two-day workshop in 2013 that helped to develop a common understanding of diagnosis in low-resource settings and existing devices and to define common parameters for a future Target Product Profile (TPP) to meet the agreed-upon needs. Manufacturers provided valuable input on the TPP during the consultation process, and two developers responded to the RFP with products that met UNICEF requirements, which have since moved to field trial.

Supply Division utilized the Advisory Committee to engage important partners in the pneumonia space, including the World Health Organization, Bill and Melinda Gates Foundation, US Agency for International Development, the project donor and thought leaders from academia.

23. How are partnerships designed to provide value to partners?

The design of the partnership with la Caixa Foundation, the principal donor for the Product Innovation Project, provided value to both parties. The Foundation committed €5 million to the project over two years, with a possibility for extension (if required), which was granted in April 2019 following project delays. The funding enabled UNICEF to carry out project activities (Annex E). To provide value to the partner, UNICEF prepared annual reports on project
throughout the innovation process, including:

The ARIDA used throughout the innovation process?

24. What methods, approaches or tools are used throughout the innovation process?

The ARIDA project utilized several tools throughout the innovation process, including:

- The project follows the stage-gated innovation process of Supply Division Product Innovation Projects. The procedure was meant to encourage iteration at the beginning of the project in response to new information and lessons learned, progressing through the phases from exploration to scale-up. The Innovation Review Board determines advancement through the process.
- A Target Product Profile was developed to communicate the ideal characteristics of ARIDA devices to industry, partners, and academia.
- A competitive RFP process was used to select devices for limited procurement for field trials, and to select a provider to design and conduct field trials (accuracy and acceptability studies).

Insights: Supply Division encouraged demand-driven product innovation. Based on feedback from developers, the demand forecast prepared by Supply Division was helpful. Data on preventable pneumonia-related child deaths was broken down according to care-seeking, under-diagnosed, under-treated and under-reported cases to provide an estimate of global demand for improved devices. For developers, the statement from UNICEF that it wanted to innovate in this space, coupled with demonstrated demand, helped open doors for product development within the company.

6.4 Incentives and outcomes

25. What incentives are encouraging/driving and discouraging/detering adoption of the innovation by users?

The use of a Target Product Profile and request for proposal with the potential for procurement of devices for field trials through Supply Division successfully pushed automated respiratory rate device development forward. As a large buyer, UNICEF could leverage its status to encourage developers and manufacturers to develop or improve existing products intended for low-resource settings by signaling its interest in procuring certain products; development of the ChARM device was initiated following expression of UNICEF’s interest in the space. However, it should be noted that both products selected for procurement for field trials received external funding to push development and that the potential for procurement through Supply Division may not have been able to drive development of novel products on its own.

The lack of volume purchase commitments, providing a guarantee that product developers would be subsidized, placed all the risk on the innovator. The ARIDA project did not utilize push (e.g., grant) or pull (e.g., advance purchase commitment) mechanisms to incentivize the development of devices, instead relying solely on the potential for procurement through Supply Division. Although the procurement incentive appeared to have contributed to accelerated development of new devices based on responses to the RFP, and progress of the ChARM and Rad G devices, developers and manufacturers reported that the sharing of some of the financial risks could help encourage
competition among developers and enable smaller companies to participate.

UNICEF was hesitant to play a role in demand generation for product innovations. Supply Division was attempting to obtain a product to market at an attractive price point but did not actively sell solutions or generate a demand for particular products to avoid a real or perceived conflict of interest. Interviewees from the Advisory Committee and developers noted that companies participating in the innovation process incurred significant costs, without support to generate demand and ensure there was a market for their device after the product was made available for procurement. The issue could potentially be problematic for companies that were required to generate a demand for products intended for low-resource environments.

Insights: The ARIDA Product Innovation Project did not influence smaller companies or those operating in programme countries to innovate. UNICEF’s Global Supply Strategies, launched in 2017, included the Products and Markets strategy, aimed to improve long-term competitiveness and sustainability of markets, focusing on product availability, affordability, quality, and appropriateness. For Ready to Use Therapeutic Foods (RUTF), the strategy seeks to incentivize local markets to manufacture products that contributed to healthy competition and innovation.\(^\text{1}\) However, the two product developers selected via standard UNICEF processes for implementation studies were larger companies with significant resources and external support available for product development and were able to accept higher levels of risk. For smaller companies and start-ups, particularly those operating in programme countries, the most significant barrier in the product development process was commercialization. There was potential for smaller companies and individuals to develop innovative products that the ARIDA project was not leveraging.

26. How were metrics designed and used to inform the development and scaling of the innovation?

Based on the documentation provided and interviews conducted throughout the evaluation, this innovation has a defined results framework to measure outcomes and impact in project proposal Section 6: Project outcome, results, and outputs: the results framework. The Innovation Unit results indicators measured include devices procured and field trials commenced and completed. Further, metrics and findings from field trials conducted by Malaria Consortium have provided actionable findings that have informed product iteration.

27. At what point were metrics considered? How was impact measured before scaling (or how is it intended to be measured)?

The project team defined three tiers of field trials focused on device performance, end users and health systems to generate objective evidence for decision-making. The device performance trial highlighted complexities inherent to measuring respiratory rate. At this point, in consultation with the expert Advisory Committee, UNICEF concluded that there is no agreed upon and validated approach to determine respiratory rate accuracy. This creates a fundamental barrier to rapidly scaling up automated respiratory rate counters. Synthesis of existing evidence derived from all ARIDA studies followed by expert stakeholder consultations will be useful to assess the extent of this barrier, potential solutions and UNICEF’s role in future scaling.

An evidence gap remains, as the cost-effectiveness study completed was rejected. Both the device performance and cost-effectiveness questions make it difficult to determine the impact of ARIDA devices on the improved diagnosis of pneumonia, or if they

should advance to procurement through Supply Division.

**Insights:** The accuracy study for the Philips ChARM device completed in Ethiopia was designed to determine agreement between the device and panel of independent expert clinicians (EC) watching a video (called the video expert panel, or VEP). The study screened 152 children, of which 128 were eligible and consented, yielding 108 readings, of which 92 had simultaneous ChARM, VEP and EC reading to determine agreement between ChARM and the reference standard respiratory rate counts. Preliminary results of the study indicated an algorithm error, which was corrected by Philips. The identification of this error was an important finding of the study; however, the study yielded several other significant findings, including:

- The root mean squared difference (RMSD) of 4.2 bpm of Video Expert Panel members and 6.6 bpm for Expert Clinicians indicate that human expert counters in the reference panel do not agree with each other perfectly. The RMSD was 2.4 bpm lower when measured by expert counters using video.

Given the lack of agreement between Video Expert Panel members and Expert Clinicians conducting manual counting, neither of the two measurements can be considered the gold standard for respiratory rate counting, and will therefore not be suitable when compared against the ChARM device. Based on this finding, the Innovation Review Board decided not to continue agreement/accuracy studies for ARIDA devices, and instead to accept CE marking, aligned with its standard approach to procurement. The lack of a gold standard reference prevents this type of study from achieving its primary objective, and while perfecting a reference method could overcome this challenge, UNICEF decided not to take the lead due to human, financial and time resources requirements.

28. How has data generated through the innovation process created value for UNICEF partners?

See question 28 for a description of the results of the accuracy study, which provided value to UNICEF and partners by identifying the algorithm error, later corrected by Philips, and important learnings on respiratory rate reference. There is no agreed upon and validated approach to determine respiratory rate accuracy. This creates a fundamental barrier to rapidly scaling up automated respiratory rate counters. Acceptability field trials provide important usability information to UNICEF, ministries of health and manufacturers. Implementation studies inform how to consider integration of the innovation into the health system.

29. How were workplans, processes, learnings and practices monitored, documented and shared within UNICEF and beyond?

The Product Innovation Project process required project teams to update the Project Charter each time they presented the project to the Innovation Review Board or pass through the next stage-gate. The ARIDA Project Charter included an overview of the project, intended outcomes and outputs, the strategy, project plan (including a timeline for activities) and resource requirements.

In addition to standard documentation and sharing within UNICEF, through the ARIDA Product Innovation Project, UNICEF and Malaria Consortium would submit a manuscript of learnings from the agreement and accuracy study completed in Ethiopia related to respiratory rate reference.

30. What does the ideal future state of this innovation ‘at scale’ look like?

Under 5 Years with Cough or Difficulty Breathing in a Controlled Setting in Ethiopia. Final Study Report.

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11 Malaria Consortium, 2017. The Performance of the Children’s Respiration Monitor (ChARM) Device in Children
The ideal future state of the innovation project would be to have a portfolio of validated ARIDA devices from which country governments and other organizations could choose the best suited to their local contexts and available resources. Ideally, ARIDA devices would be implemented and contribute to:

- Prescribing the correct treatment
- Improving availability of amoxicillin
- Improving caregiver trust and empower community health workers; and
- Avoiding antibiotic resistance through proper use of amoxicillin and gentamycin.

Unit price may be a barrier to scale at the country level. Twelve interviewees for this evaluation (including Supply Division, Ethiopia Country Office, Malaria Consortium, Federal Ministry of Health, a project partner, Advisory Committee and a developer) identified cost as a challenge to product uptake and scale. Ideally, when the project moved to the scale-up phase, the device would become less expensive, through competition and lowered manufacturer costs from increased production volume; however, this was not guaranteed. While the Ethiopia Federal Ministry of Health was interested in implementing an ARIDA device, assuming positive outcomes of the acceptability study, the resources required for implementation of the device nationally would be significant, particularly if the unit price remained the same. In the past, for similar opportunities where resourcing was an issue, development partners have provided the funding required for national scale-up. If evidence supporting the implementation of an ARIDA device was compelling, the Federal Ministry of Health planned to finance part of the scale-up itself and advocate for partners to provide additional support regarding diagnosis and treatment (i.e., the antibiotics to treat increased case volume) of pneumonia.

Continued engagement and leadership at the global level is still required and the Supply Division has identified the following as priority follow-on steps:

- A global pneumonia diagnostic aid research agenda with global coordination is needed. UNICEF has learnings to share and can provide technical assistance and guidance both on device design, prioritized research questions, study design, quality assurance and procurement
- A standardized way of assessing new technologies is needed in order to stimulate further innovation and avoid market confusion. Reference challenges are not limited to respiratory rate (for example, temperature). UNICEF sees itself playing an important role in coordinating activities toward answering the following questions:
  - How will the global community assess new technologies?
  - What is the target we need suppliers to hit?
  - What evidence do ministries, agencies and funders need to see to give the green light to scale?
  - In the multi-parameter space, how will the global community approach the trade off between added value and additional cost of each parameter?
  - Guidance is needed to provide clarity on use scenarios, user archetypes and how devices integrate with existing decision-making algorithms.

In 2019, the Supply Division Innovation Unit project team is focused on analysis, synthesis and dissemination of results from the ARIDA Project and engaging the advisory committee and thought leaders with the aim of gaining alignment on next steps toward improving pneumonia diagnostics.

31. How has this innovation considered and demonstrated development outcome/impact objectives? To what extent does the innovation contribute (or have the potential to contribute) to equitable results for children?

The Target Product Profile and RFP process utilized effectively signaled to industry, partners and academia the need and demand for ARIDA devices. The issue was evidenced by the five proposals submitted during the RFP process, from which two products were procured for field trial and implementation research as of September 2018. One developer with product procured for field trial
reported that development of its ARIDA device began in direct response to UNICEF’s statement of interest in this space through industry consultation and the current outlook report.

The outcome of the project, described in its Theory of Change (Annex F), would be improved programmatic results for children resulting from the availability of automated pneumonia diagnostic aids in low-resource contexts. The project partnership outcome agreed with 'la Caixa' Foundation was a target of 120,000 child beneficiaries to receive improved care from a healthcare worker trained and equipped with an ARIDA device. The Product Innovation Project was in the field trial phase as of September 2018 so the demonstrated outcomes and impacts were limited to the number of child beneficiaries from field trials and supply of amoxicillin (15,200 beneficiaries from field trials and 147,058 beneficiaries from supply of amoxicillin in Ethiopia as of April 2018). [UNICEF delivered the partnership outcome by January 2019.]

**Insights:** It was possible that health extension workers’ use of an ARIDA device would increase the demand for care seeking among caregivers at the respective health facilities. Such an increase would likely be associated at the field level with increased use of antibiotics (amoxicillin and gentamycin) to treat pneumonia in children under five. If the use of ARIDA devices increased the number of children diagnosed with pneumonia, their presence could lead to increased needs of ensuring appropriate antibiotic stocks.

### 7. CONCLUSIONS AND CONSIDERATIONS

The ARIDA devices identified for commercial availability could improve diagnosis of pneumonia and accelerate results by reducing pneumonia-related mortality in children under the age of five years. UNICEF employed an approach of co-creation of devices with industry, and commercial availability of devices was reached. The approach to product development was demand-driven and user-centred and the two products selected through a competitive process progressed to field trial, including agreement (ChARM device only) and acceptability studies.

One of the significant challenges experienced during the innovation project was poor communication between UNICEF and the donor, ‘la Caixa’ Banking Foundation, which committed €5 million for programmatic and communication activities. Some of the challenges included sharing project progress and translating technical information into clear key performance indicators that reflect the outcomes of the project. Periodic changes to the project were a source of frustration, for example, UNICEF’s decision not to pursue further accuracy studies due to lack of a gold standard reference. Communicating project updates and outcomes was further complicated by lack of effective coordination between Supply Division, Private Fundraising and Partnerships and the Spanish NatCom to communicate with the donor. Several interviewees noted a need for clarification of roles and responsibilities and improved coordination between internal divisions. The clarification of roles could strengthen the relationship with the donor and improve the chances of successfully achieving intended outcomes.

As a project in the Supply Division Innovation Unit portfolio, ARIDA was notable for its capacity to generate lessons on how to manage a product innovation. The most essential learnings through the ARIDA project include:

- **ARIDA has been instrumental in leveraging internal skills and experience across Supply Division, Programme Division and country offices.** In the context of ARIDA, Innovation Unit was able to identify user needs, use scenarios, and define a new class of product to address healthcare worker obstacles.
• The project also was an interesting learning space on leveraging donor funding as an incentive for downstream procurement. Innovation Unit was able to lead developers to develop, test and commercialize two new products in the ARIDA class.
• The project had a catalytic effect on the innovation ecosystem by successfully encouraging new players, including the Bill and Melinda Gates Foundation and UNITAID, into the ARIDA space.
• Lessons learned from this complex project have led to a rapid evolution of the Innovation Unit approach to accelerating innovations to scale.
• In the future, improving communications will be vital to project success.

As the project moves forward, several actions could be taken to strengthen the innovation pathway and chances for project success. These include identification of strategies to improve the chances of scale-up and sustainability of the project and lowering the cost of implementation for national governments (e.g., co-financing model). At the time of writing, actions under consideration included:
• To engage with the Advisory Committee to provide ARIDA project updates and to discuss external perception of catalogue inclusion as one of the several steps UNICEF can take to help move technologies along the ideation-to-impact continuum, as well as make key milestone threshold recommendations.
• To incorporate threshold recommendations from the Advisory Committee, review them with key Supply Division internal stakeholders and develop an action plan.
• Recommend the action plan with the Innovation Review Board and seek advice and decision-making; and
• Decision on the catalogue inclusion gets passed from the DO to the Procurement Centre for action.

Further considerations for UNICEF SD, as the ARIDA project progresses through the phases of innovation, appear in Table 5.

**Table 5. Practical considerations for ARIDA**

| Identify strategies to reduce the financial burden for scale-up | Strategies to lower the cost of ARIDA device implementation at the government level are important for scale-up and sustainability of the project. Developers and manufacturers would prefer not to have devices donated; however, other strategies might include funding part of the device, increasing production to lower unit price or co-financing models. |
| Develop the evidence necessary for the Ministry of Health decision-making | Evidence regarding findings and implications of implementation studies should be prepared to assist with government decision-making before national implementation and scale-up. If possible, UNICEF should complete a high-level cost-benefit analysis of national scale-up of ARIDA devices. Further, if the use of ARIDA devices is expected to increase care seeking and diagnosis of pneumonia, considerations for the continuum of care from prevention to diagnosis and treatment should be made when presenting the case to government. |
| Review the implications of community and health professional trust in ARIDA devices as diagnostic tools | If acceptability studies demonstrate that health workers are over-reliant on ARIDA devices for diagnosis of pneumonia, UNICEF must consider the implications and should look to solutions. Solutions could include reviewing the training delivered to practitioners to ensure they understand that the diagnostic aid is to be used in combination with other indicators, or facilitating a research study examining the usefulness of respiratory rate in determining which children should be prescribed antibiotics. |
### Develop a framework to define and track expected results

UNICEF should consider developing a results framework to complement existing key performance indicators (KPIs) (e.g., number of devices procured, number of ARIDA child beneficiaries) and the Theory of Change. A results framework would help to define targets and demonstrate how output-level KPIs contribute to outcomes and improved programmatic results for children.

### Limit market distortion effects associated with the timing of field trials

UNICEF and Malaria Consortium should complete implementation studies for ARIDA devices simultaneously to reduce possible market distortion effects. Testing one product first could influence government decision-making, mainly if the testing takes multiple years to complete and the government seeks to implement and scale a new diagnostic aid rapidly.

### Generate demand for the suite of product innovations developed

Although procurement policies restrict the ability of SD to generate demand for specific products, UNICEF should work to generate demand for the portfolio of innovations once the suite of products is available for procurement. Advocating for products as part of a broader portfolio would help to avoid conflicts of interest and would require leadership of Programme Division and country offices. Inclusion in the portfolio would also serve to incent developers, due to greater market potential.

The case study also generated a series of considerations for innovation more broadly at UNICEF, based on observed successes and challenges of the ARIDA Product Innovation Project. These appear in the table below.

#### Table 6. Innovation at UNICEF

| **Favour development of a portfolio of innovations when possible** | Developing a range of tools or products that can be applied and adapted to various contexts, needs and price points can improve the likelihood of success of an innovation project. In the case of the ARIDA PIP, the portfolio includes two products with a difference in function and unit price. This will allow organizations and governments to choose the product best suited to their needs, and reduce the risk to UNICEF through diversification of its innovation portfolio. Innovation portfolios may also reduce the risk of innovation projects becoming irrelevant, if international priorities shift over the course of the project. |
| **Innovation Project Teams should include members across divisions** | Formation of project teams with diverse membership, from across Supply Division, Programme Division and country offices should be encouraged. Supply Division provides the technical expertise necessary to facilitate development of product-based solutions. Programme Division staff bring insight and expertise on challenges for children globally. Country offices provide valuable input on local context and coordination of activities. The expertise of each group is complementary and when combined can maximize potential for success. |
| **Consider strategies to engage local developers** | To encourage competition among developers and manufacturers and drive down prices, UNICEF should consider strategies to reduce risk and enable private sector innovation in programme countries (including incubators and smaller companies). Strategies could include guaranteed procurement or availability of small grants to incent product development. This would align with the Products and Markets strategy, improving long-term competitiveness and sustainability of markets. |
| Develop mechanisms to collaborate with developers and manufacturers in the same market | The ability to interact more meaningfully with product developers and manufacturers could improve diversity, iteration and outcomes of products developed through Product Innovation Projects. This could be achieved through existing channels (e.g., funding for suppliers to meet local market regulations, greater information sharing) or through establishment of an innovation accelerator for product development, similar to that of the World Food Programme.\textsuperscript{12} |
| Streamline communications and define division of responsibilities | Communications with ‘la Caixa’ Banking Foundations was a challenge throughout the ARIDA project. To ensure effective communication with the donor, UNICEF should consider refining its internal communication network, to ensure that project progress and developments are shared with the appropriate divisions. For the ARIDA project, Supply Division might consider removing itself as a focal point for the Foundation, shifting responsibility to the Spanish NatCom, with support from Private Fundraising and Partnership. This might enable the project team to better focus on project implementation. |

ANNEX A: METHODOLOGY

Case study objectives

UNICEF approaches innovation as a strategy to tackle complex challenges faced by children around the world. For this reason, UNICEF defines, identifies, field trials and uses innovations to address bottlenecks or product gaps, thus achieving results that reduce inequities for children. UNICEF commissioned Deloitte to conduct case studies to examine innovation across the spectrum of innovation types, country contexts and internal (UNICEF) and external (partner, supplier) actors. Cases are descriptive and explanatory, identifying how the innovation process has played out in single instances and surfacing key issues, lessons, challenges and successes. During scoping and development of the Terms of Reference for this evaluation, the UNICEF Evaluation Office (EO) selected cases through a multi-step approach. Diversity across cases was considered as a factor for selection; however, the sample selected was not intended to be fully representative of innovation at UNICEF. The primary focus of this case is to understand the process of innovation for the Acute Respiratory Infection Diagnostic Aids (ARIDA) project.

Evaluation framework

Evaluation questions were structured around a modified version of the Deloitte Doblin Framework for Innovation. Within this framework, the approach to innovation must be enabled through four thematic dimensions, including: approach, organization, resources and capabilities and metrics and incentives. The four dimensions highlight the elements necessary to enable successful innovation. They are complementary to frameworks such as Supply Strategies and Public Procurement Principles.

Data collection approach

Deloitte employed a mixed methods approach to build a complete picture of the innovation process and identify findings related to the four thematic dimensions of the evaluation framework. The evaluation team collected qualitative and quantitative data through desktop review and case study informant interviews.

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<th>Desktop review</th>
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<tr>
<td>- <strong>Primary and secondary sources:</strong> Conducted review of demand forecasts, industry</td>
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<tr>
<td>consultation documentation, presentations, workplans, budgets, Target Product</td>
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<tr>
<td>Profiles, Requests for Proposals and Innovation Review Board documentation</td>
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<tr>
<td>- <strong>High-level organizational scan:</strong> Reviewed UNICEF Supply Division documentation</td>
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<td>related to Product Innovation Projects (PIP) and the stage-gated process of innovation</td>
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<th>Stakeholder engagement</th>
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<td>- <strong>Interviews:</strong> Conducted semi-structured interviews, guided by interview protocols, with ARIDA project team members, IRB chair and members, members of the Advisory Committee, partner organizations and developers and manufacturers</td>
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<tr>
<td>- <strong>Observations:</strong> Field mission to Supply Division in Copenhagen, Denmark to meet with key UNICEF stakeholders; Field mission to Ethiopia to meet with key UNICEF, partner and community stakeholders</td>
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Description of field visit activities

Two evaluation team members conducted a field mission to Copenhagen, Denmark 11-14 June 2018. Additionally, one evaluation team member carried out a field mission to Ethiopia 20-24 August 2018. The UNICEF Supply Division scheduled both visits based on guidance documents from the evaluation team outlining the desired list of stakeholders for engagement. Key activities included interviews with key stakeholders and observation of ARIDA device implementation studies.

Limitations of this case study

- **This case does not systematically assess the impact or outcome of innovation.** This case has captured perspectives on potential outcomes and impacts of innovations, when appropriate. However, given the early stage of development, limited scope of engagement and rapid approach to conducting the case, the evaluation does not make objective conclusions on outcomes or impacts related to the ARIDA Product Innovation Project.
- **A single case is not representative of the total population of innovations at UNICEF.** The sampling methodology for selection of cases (i.e., number, type and field visit locations) was not randomized and, due to the highly qualitative and contextual nature of case studies, findings from this case are not generalizable to innovation at UNICEF. As such, cross-case analysis performed by UNICEF should be done with consideration of this limitation.
- **Due to the nature of innovation, it is expected that some innovations will continue to evolve during case study implementation.** This case presents a reconstruction of the innovation process up to June 2018. Future activities and priorities shared by stakeholders will be captured but cases will not strive to make forward-looking statements or conclusions.
- **Field visits were intended to reflect the innovation project, rather than Supply Division.** As such, these case studies do not make inferences on Supply Division’s overall performance in innovation or on the impact of its innovation function.
- **Potential for bias in documentation received from UNICEF Supply Division:** It is noted that Supply Division has a strong process in place for documentation of progression of PIPs. However, the majority of documentation received was developed and used by project team members and could be positively biased. Where possible, external sources, including documentation and interviews, were reviewed to validate findings from the document review.
- **Potential for bias from case study informants:** Due to the limited nature of this case study, perceptions of stakeholders who were not involved in the process of development of the ARIDA PIP were not collected. As a result, perspectives of individuals with a stake in framing the innovation process positively are primarily presented. To minimize this bias, external sources of documentation were consulted to verify interviewee statements where possible.
ANNEX B: ARIDA STAKEHOLDERS

The table below summarizes various stakeholder groups internal and external to UNICEF that were involved in the ARIDA Product Innovation Project at various points along the innovation pathway.

Table 7. Organizations, role in ARIDA PIP, and status of engagement over the course of the evaluation

<table>
<thead>
<tr>
<th>ORGANIZATION</th>
<th>ROLE IN ARIDA PIP</th>
<th>ENGAGED?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Advisory Committee</strong></td>
<td>Composed of 10 technical experts who review and guide project activities and make recommendations when necessary</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Developers and manufacturers</strong></td>
<td>Developed novel ARIDA devices and responded to the RFP issued by SD; As of September 2018, Philips and Masimo supplied limited quantities of product for field trial</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Ethiopia Country Office</strong></td>
<td>Serves as the focal point between MC, SD, PD and FMOH, and coordinates activities on the ground; has representation on the project team</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Ethiopia Federal Ministry of Health</strong></td>
<td>Interested in scaling innovations that improve quality of services and health of children; the Maternal and Child Health and Nutrition directorate provided support to the ARIDA project, including ethics and customs clearance</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Health Extension Workers</strong></td>
<td>The end-users of ARIDA devices; use diagnostic aids in community settings to diagnose pneumonia in children under five</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Health Technology Centre</strong></td>
<td>Developed a procurement strategy, which includes a maintenance pack and approach for scale-up of devices tested; has representation on the project team</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Innovation Review Board</strong></td>
<td>Composed of Procurement Centre Chiefs (since 2018); is the decision-making body of PIPs and controls advancement through the stage-gated process of innovation</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Malaria Consortium</strong></td>
<td>Technical implementation partner contracted by SD; responsible for design and set-up of implementation studies</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>la Caixa Foundation</strong></td>
<td>Provided €5 million grant to identify and accelerate market availability of devices to automatically count number of breaths per minute</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Private Fundraising and Partnerships</strong></td>
<td>Division within UNICEF whose role is to maximize partnership with companies, through activities including relationship management, communications, legal development and finance processes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Project Team</strong></td>
<td>Responsible for day-to-day management and decision-making for the ARIDA project; membership includes representatives from SD, PD and COs</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Spanish National Committee</strong></td>
<td>Manages UNICEF’s relationship with la Caixa Foundation, the principle donor for the ARIDA PIP</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Supply Division Innovation Unit</strong></td>
<td>Provide support for the HTC in terms of project management, framework and resources for non-standardized activities; has representation on the project team</td>
<td>Yes</td>
</tr>
</tbody>
</table>
## Table 8. List of interviews completed for this case study

<table>
<thead>
<tr>
<th>Name</th>
<th>Organization</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agazi Ameha</td>
<td>Ethiopia CO</td>
<td>Monitoring and Evaluation Specialist</td>
</tr>
<tr>
<td>Quique Bassat</td>
<td>Barcelona Institute for Global Health / ICAEA</td>
<td>Research Professor</td>
</tr>
<tr>
<td>Bizuhan Birhanu</td>
<td>Ethiopia CO</td>
<td>Child Health Specialist</td>
</tr>
<tr>
<td>Jim Black</td>
<td>University of Melbourne / FREO2</td>
<td>Associate Professor</td>
</tr>
<tr>
<td>Niels Buning</td>
<td>Royal Philips</td>
<td>Business Development Manager</td>
</tr>
<tr>
<td>Kristoffer Gandrup-Marino</td>
<td>UNICEF SD</td>
<td>Chief, Innovation Unit</td>
</tr>
<tr>
<td>Solomon Gelaw</td>
<td>Ethiopia CO</td>
<td>Health Specialist</td>
</tr>
<tr>
<td>Gian Gandhi</td>
<td>UNICEF SD</td>
<td>Chief, Markets, Supplier Financing and Innovations Centre</td>
</tr>
<tr>
<td>Eskinder Goshu</td>
<td>Malaria Consortium</td>
<td>Program Officer</td>
</tr>
<tr>
<td>Leith Greenslade</td>
<td>Just Actions</td>
<td>CEO</td>
</tr>
<tr>
<td>Tedila Habte</td>
<td>Malaria Consortium</td>
<td>Health Professional</td>
</tr>
<tr>
<td>Jonathan Howard-Brand</td>
<td>UNICEF SD</td>
<td>Innovation Specialist</td>
</tr>
<tr>
<td>Dan Ilie</td>
<td>UNICEF SD</td>
<td>Contracts Officer</td>
</tr>
<tr>
<td>Stephanie Jacquier</td>
<td>UNICEF PFP</td>
<td>Corporate Partnership Specialist</td>
</tr>
<tr>
<td>Natalie Jones</td>
<td>UNICEF SD</td>
<td>Operations Officer</td>
</tr>
<tr>
<td>Paul LaBarre</td>
<td>UNICEF SD</td>
<td>Innovation Manager</td>
</tr>
<tr>
<td>Ana Cristina Matos</td>
<td>UNICEF SD</td>
<td>Evaluation Specialist</td>
</tr>
<tr>
<td>Cindy McWhorter</td>
<td>UNICEF SD</td>
<td>Project Officer</td>
</tr>
<tr>
<td>Diana Molina Grasa</td>
<td>‘la Caixa’ Banking Foundation</td>
<td>Program Officer, International Division</td>
</tr>
<tr>
<td>Macoura Oulare</td>
<td>Ethiopia CO</td>
<td>Chief, Health Programmes</td>
</tr>
<tr>
<td>Suvi Rautio</td>
<td>UNICEF SD</td>
<td>Deputy Director Supply Programmes</td>
</tr>
<tr>
<td>Ludo Scheerlinck</td>
<td>UNICEF SD (former)</td>
<td>Manager Supplies and Logistics Section</td>
</tr>
<tr>
<td>Habtamu Seyoun</td>
<td>CHAI</td>
<td>Senior Manager, Child Survival</td>
</tr>
<tr>
<td>Hayalnesh Tarekegn</td>
<td>UNICEF SD</td>
<td>Health Specialist</td>
</tr>
<tr>
<td>Dr. Abraham Tariku</td>
<td>Ethiopia FMOH</td>
<td>Child Health Officer</td>
</tr>
<tr>
<td>Dr. Agonafer Tekalegne</td>
<td>Malaria Consortium</td>
<td>Country Director</td>
</tr>
<tr>
<td>Regine Weber</td>
<td>UNICEF SD</td>
<td>Chief Strategy, Change and Communications Centre</td>
</tr>
<tr>
<td>Rocio Vicente Senra</td>
<td>Spanish National Committee</td>
<td>Programme Officer</td>
</tr>
</tbody>
</table>
In addition to the interviews listed above, during the field mission in Ethiopia, interviews were conducted with the Deputy Head of the District Health Office of Woreda, two health extension workers and an additional representative of Malaria Consortium.
ANNEX C: LIST OF DOCUMENTS CONSULTED

List of UNICEF files shared with the Evaluation Team

- 1. JD Project Officer (Pneumonia Diagnostics) P2 TA.docx
- 2. JD Health Specialist (Pneumonia Diarrhea) P3 TA 210 days
- 3. ARIDA Target Product Profile.pdf
- 4. Project Charter ARIDA 17.pdf
- 5. Advisory Committee List.xlsx
- 6. Advisory Committee ToR.docx
- 8. IRB Terms of Reference.pdf
- 11. ARIDA links docs.docx
- 14. Grant Extension Form la Caixa.docx
- 15. One Year Report la Caixa 01.03.2017.pdf
- 16. 2nd Annual Report la Caixa.pdf
- 17. 2nd Annual Report – Summary Caixa.pdf
- 18. ARIDA Acceptability Protocol – Nepal.docx
- 20. ARIDA Extension Programme Clean.docx
- 20a IU Workplan 2017.xlsx
- 20b 2018 MSFIC Workplan 2018 (draft).xlsx
- 21a – BCN June 2017 Trip Report.docx
- 21a. 1 – la Caixa Foundation Presentation CM.ppt
- 25. 2018.4.20 Update on ARIDA Financial Budget.xlsx
- 160624 Supplier Information Sheet (SIS).xlsx
- 2011.03.11 Minutes ARIDA 01.pdf
- 2014.01.21 Minutes ARIDA 03.pdf
- 2014.01.21 Project Update ARIDA 03.pdf
- 2014.02.26 Gate 1 Proposal ARIDA 04.pdf
- 2014.02.26 Minutes ARIDA 04.pdf
- 2014.08.27 Minutes ARIDA 05.pdf
- 2014.08.27 Project Charter ARIDA 05.pdf
- 2014.08.27 Project Update ARIDA 05.pdf
- 2015.02.11 Minutes ARIDA 06.pdf
- 2015.02.11 Project Charter ARIDA 06.pdf
- 2015.02.11 Project Update ARIDA 06
- 2015.03.25 Minutes ARIDA 07.pdf
- 2015.03.25 Project Charter ARIDA 07.pdf
- 2015.03.25 Project Charter ARIDA 08.pdf
- 2015.03.25 Project Update ARIDA 07.pdf
- 2015.04.22 Minutes ARIDA 08.pdf
- 2015.04.22 Project Charter ARIDA 08.pdf
- 2015.04.22 Project Update ARIDA 08.pdf
- 2015.05.18 Project Charter ARIDA 09.pdf
- 2015.05.18 Project Update ARIDA 09.pdf
- 2015.05.21 Minutes ARIDA 09.pdf
- 2015.09.10 Gate 2 Proposal ARIDA 10.pdf
- 2015.09.10 Minutes ARIDA 11.pdf
- 2015.09.28 Product Clarifications Beyond the TPP.docx
- 2015 09 29 ARIDA EOI form.docx
- 2015 09 29 ARIDA RQO.pdf
- 2016.01.28 Minutes ARIDA 11.pdf
- 2016.01.28 Project Charter ARIDA 11.pdf
- 2016.06.10 Project Update ARIDA 12.pdf
- 2016.06.10 Project Update ARIDA 12.pdf
- 2016.10.20 Minutes ARIDA 12.pdf
- 2016 03 16 RFPS presentation (1).pdf
- 2016 06 09 DPWG.pdf
- 2017.06.01 Minutes ARIDA 14.pdf
- 2017.06.01 Project Charter ARIDA 14.pdf
- 2017.06.01 Project Update ARIDA 14.pdf
- 2017.08.17 Minutes ARIDA 15.pdf
- 2017.08.17 Project Charter ARIDA 15.pdf
- 2017.08.17 Project Update ARIDA 15.pdf
- 2017.09.07 Project Update ARIDA 16.pdf
- 2017.11.23 Minutes ARIDA 17.pdf
- 2017.11.23 Project Charter ARIDA 17.pdf
- 2017.11.23 Project Update ARIDA 17.pdf
- ARIDA – Project Updates.pdf
- ARIDA – Target Product Profile – Ethiopia.docx
- ARIDA RFP – Q+A.pdf
List of external documents consulted

- International Vaccine Access Center (IVAC), 2017. Pneumonia and diarrhea progress report.
- UNICEF, 2016. One is too many: Ending child deaths from pneumonia and diarrhoea.
- World Food Programme, 2018: https://innovation.wfp.org/.
Supply Division Product Innovation Projects (PIPs) are intended to create impact for women and children through UNICEF programmes. They follow a defined process that covers all stages of innovation, from idea to implementation and scale. Supply Division designed the procedure to facilitate an iterative approach to innovation that is valuable and flexible, with effective governance for each individual PIP.

Innovation process: Supply Division has defined a stage-gated innovation process to cover all stages of the PIP lifecycle, from exploration to scale. The process is meant to be highly iterative at the beginning of the PIP in response to new information and/or lessons learned, with decreasing levels of iteration as the project progresses.

To advance from one phase of innovation to the next, PIPs must meet the criteria required to pass through a stage gate. A PIP may start and be closed at any gate/phase of the innovation process.

Governance of the innovation process: In order to pass through Gate 0 and enter the exploration phase, the Innovation Chief and Centre Chief must approve a project as an innovation project. Following approval as a PIP, advancement to the next phase of the innovation process requires the project to pass through a stage gate after presentation of its status to the Innovation Review Board (IRB). The IRB is the sole decision-making body for PIPs, responsible for deciding whether a product should advance to the next stage of innovation, remain in the same stage, or be abandoned. The project team presents the status of PIPs at meetings of the IRB at key points in the lifecycle of the innovation, for example to obtain resources for field-testing, or to receive input on significant decisions.

Documentation: Advancement through the phases of innovation is well documented at each stage of the project lifecycle, and typically includes:

- Project Charter
- IRB budget template
- Project updates to the IRB
- Gate proposal (case for passage through each gate)
- Presentation to the IRB (for input and/or passage through each gate)
- IRB minutes.
The ARIDA PIP is funded primarily by a grant from la Caixa Foundation of €5 million to identify and accelerate market availability of devices capable of providing an automated count of breaths per minute. Of the €5 million, €4.9 million was dedicated to programmatic activities, and €100,000 was dedicated to communication activities managed by la Caixa Foundation.

4. **Awareness and advocacy**: aligned on strategy advocacy and communication activities, the ARIDA PIP aims to raise awareness on the partnership between UNICEF and the Foundation, the project, and the importance of responding to pneumonia mortality in children under five; activities under this pillar included written articles and short documentaries.

Following significant delays in use of funding caused by issues with the Philips ChARM device algorithm and failed accuracy studies, UNICEF and la Caixa agreed to an extension of funding for an additional year, which is set to expire in April 2019.
ANNEX F: ARIDA THEORY OF CHANGE

The ARIDA Theory of Change developed by UNICEF is intended to show how project activities contribute to outcomes and impact at the global level.

Figure 5. ARIDA Theory of Change

<table>
<thead>
<tr>
<th>Activities</th>
<th>Output</th>
<th>Outcome</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Run product innovation projects</td>
<td>Development of new and improved products</td>
<td>Improved programmatic results for children</td>
<td>Realizing the rights of every child</td>
</tr>
<tr>
<td>Develop Target Product Profiles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consult industry and key stakeholders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incentivize the market</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Field trials and scaling</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

13 UNICEF SD, 2016. 2016.11.11 - ARIDA Theory of Change Graphic.