Portfolio Evaluation: Better Tools to Identify Severe Disease in Children

Final Report

Unitaid

31 May 2024

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Contents

STRUCTURE OF THE REPORT

Following an Executive Summary, this report has been organised in two self-contained parts:

- Part A provides an overview of the evaluation, summary findings, conclusions and lessons learnt as well as key recommendations for Unitaid based on learnings from this evaluation.
- Part B provides detailed findings and evidence-based by evaluation criteria and question.

The main report is supported by the following appendices:

- Appendix A provides the bibliography;
- Appendix B provides the list of global level consultations for this evaluation as well as the supporting interview guides;
- Appendix C provides overview of country progress against Unitaid country readiness domains and conditions; and

A Supplementary Appendix provides country case study reports for Burkina Faso, Guinea, India, Kenya and Senegal.

As explained in more detail in Part A below, this is the summative evaluation report for a two phased evaluation, with Phase 1 completed in October 2023.

ACRONYMS

Acronyms	Detail
ACT-A	Access to COVID-19 Tools (ACT) Accelerator
BEmONC	Basic Emergency Obstetric and Newborn Care
C19RM	Covid19 Response Mechanism
CCSE	Community and Civil Society Engagement
CDSA	Clinical Decision Support Algorithms
CHWs	Community Health Workers
CSO	Civil Society Organisations
EQ	Evaluation question
GC7	Grant Cycle 7
GF FR	Global Fund Funding Requests
GO_2AL	Global Oxygen Alliance
HCP	Health Care Provider
HSS	Health System Strengthening
HTM	HIV, TB, Malaria
iCCM	Integrated Community Case Management
IeDA	Integrated eDiagnostic Approach
IMCI	Integrated management of childhood illness
LMICs	Low- and middle-income countries
MM/MMS	Multimodal
PHC	Primary Health Care
PO/POX	Pulse oximeter/Pulse oximetry
PPG	Photoplethysmogram
PPR	Pandemic Preparedness and Response
PSM	Procurement and Supply Management
RMNCH	Reproductive, Maternal, Newborn, Child and Adolescent Health
ToC	Theory of Change
TPP	Target product profile

EXECUTIVE SUMMARY

Introduction and evaluation objectives

Unitaid appointed Cambridge Economic Policy Associates (CEPA) to conduct an evaluation of its investments under the "Better tools to identify severe disease in children" portfolio. The aim of this evaluation was to provide an independent assessment of the extent to which interventions under this portfolio contributed to accelerate the adoption, sustainability and scale up of diagnostic and triage tools (such as pulse oximeters and CDSAs) to identify severe disease in children and improve child survival.

Portfolio background

- In 2019 Unitaid invested in two grants under an Area for Intervention (AfI) focussed on addressing challenges related to integrated management of sick, febrile children. This effort sought to respond to persisting challenges around the poor detection, diagnosis and treatment of severe diseases in children contributing to child mortality.
- The two grants (1) Tools for Integrated Management of Childhood Illness (TIMCI) and (2) Amélioration l'Identification des détresses Respiratoires chez l'Enfant (AIRE) projects focused on pilot implementation of pulse oximeters (POs), a tool used to screen for hypoxaemia (or low oxygen saturation in the blood), as a key indication of severe disease. While the use of POs is standard at secondary care level in low and middle income countries (LMICs), it has not yet been widely adopted at primary health care (PHC) level, where most care-seeking for sick children takes place.
- This portfolio aims to address this issue by:
    - Introducing POs adapted for point-of-care use in children at the PHC level across 8 countries, delivered within Integrated Management of Childhood Illness (IMCI);
    - Piloting electronic clinical decision support tools (eCDST or CDSA) in select settings, to improve adherence to guidelines and decision-making, and prevent inappropriate treatment including overuse and wastage of malaria medicines and antibiotics;
    - Implementing market shaping activities for next generation multi-modal devices (MMDs) that can detect hypoxaemia and other vital signs (e.g., respiratory rate, temperature, haemoglobin level)
    - Running large-scale field evaluations to document evidence of feasibility, cost-effectiveness and impact, and enable evidence-based policy change, and;
    - Exploring sources of variability of PO accuracy on darker pigmented skins to support access to appropriate devices that work on all skin tones.

This evaluation was structured around three objectives:

- To assess the relevance, coherence, efficiency, effectiveness, impact, sustainability and lessons learned of the TIMCI and AIRE investments and their contribution to Unitaid's Strategic Objectives;
- To assess Unitaid's role as pathfinder (analysing complex access problems and designing a pathway to resolve them) and influencer (enabling impact by partnering with a wide range of stakeholders and leveraging its unique position); and
- To assess the overall contribution of Unitaid's 'Better tools to identify severe disease' investments between 2019 and 2024, with a view towards the complementarity and synergy of these investments with Unitaid's broader efforts to accelerate access to better tools for identification of severe disease in project countries and beyond.

The evaluation was implemented through a phased approach to provide an opportunity for learning and course correction during the portfolio implementation. Phase 1 was implemented between May and October 2023 and Phase 2 was conducted between January and March 2024. The Phase 1 evaluation entailed an end of project evaluation of the concluded AIRE grant alongside an interim assessment of the ongoing TIMCI grant with a view of providing recommendations for optimising the portfolio and the TIMCI project in its final months. Phase 2 provided a full end term portfolio evaluation, with a focussed assessment of results from the TIMCI grant and a post closure follow up of the AIRE grant looking more specifically at sustainability and scalability.

The evaluation was structured around the OECD DAC evaluation criteria and used a theory-based approach. The Theory of Change (ToC) underlying this evaluation was based on the one originally developed by Unitaid for this portfolio and subsequently updated by CEPA in Phase 1 and 2 of the evaluation. Figure 1 sets out the evaluation framework, structured around the OECD DAC evaluation criteria and linked to the Unitaid Strategic Objectives under the Strategy 2023-27. The evaluation's data collection and analysis methods across both phases are summarised in Figure 2.

Figure 1: Evaluation framework and questions

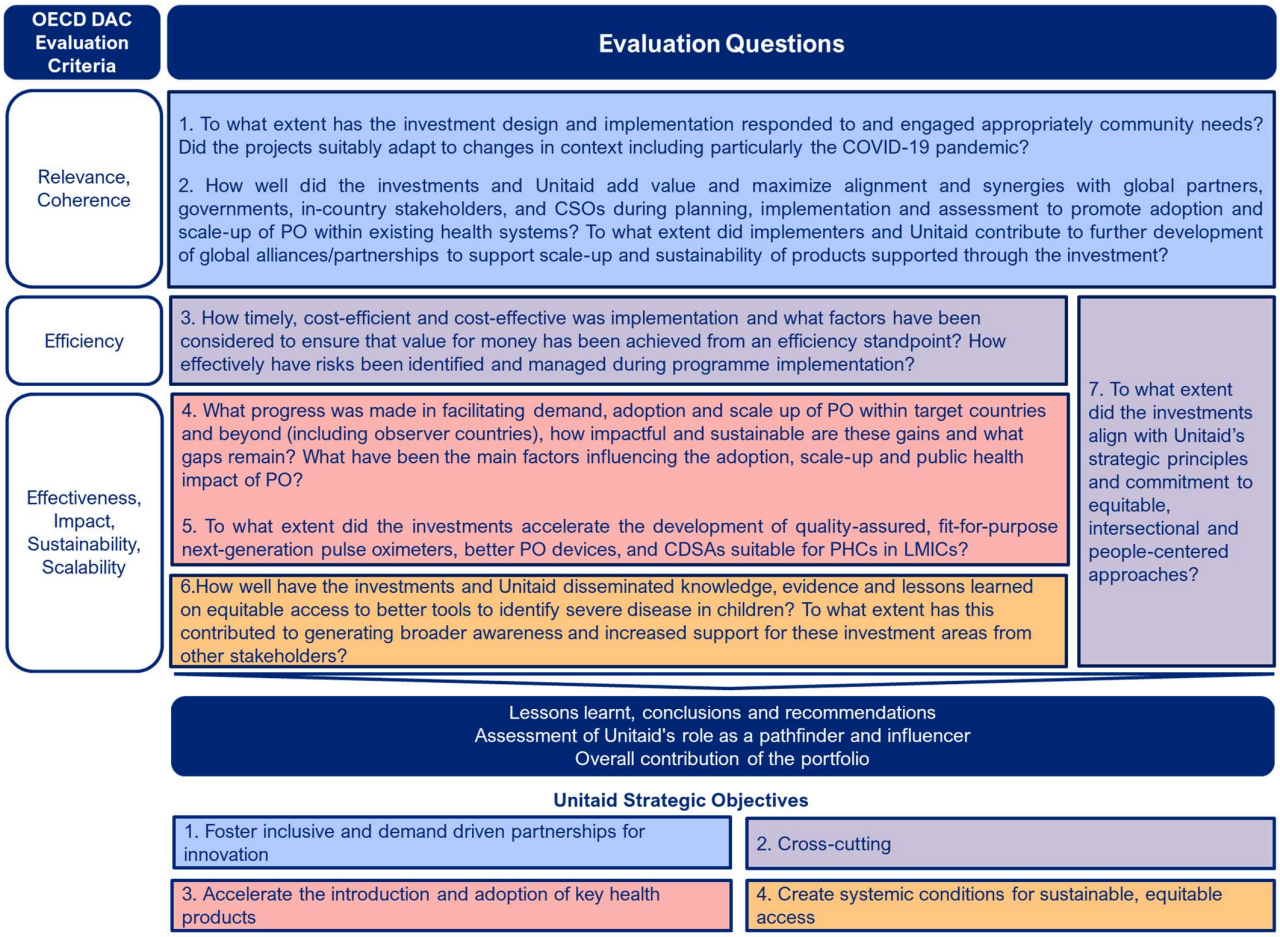
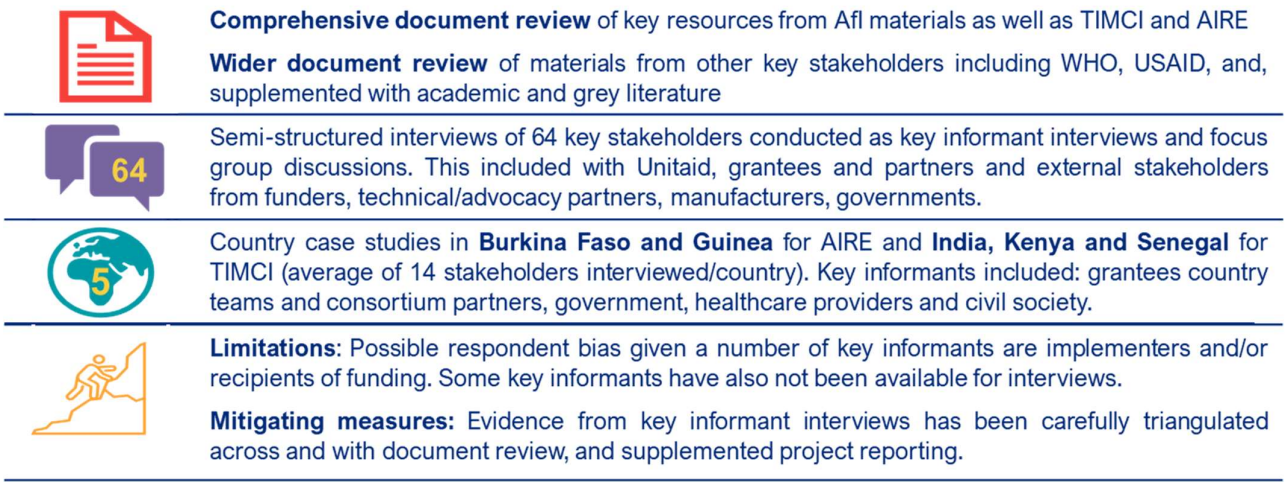


Figure 2: Evaluation methods



This Executive Summary presents the key findings from the evaluation, structured around the relevance, effectiveness, sustainability, efficiency and impact of the portfolio, as well as key learnings and recommendations to inform Unitaid's future work in this area.

KEY HIGH LEVEL FINDINGS

Cross-cutting high level findings are as follows:

Highly relevant and responsive portfolio

- Investments (TIMCI and AIRE) were highly relevant and responsive to country contexts and public health needs and highlighted key issues around lack of adapted tools to identify severe disease in newborns and children under five. Design changes in response to the COVID-19 pandemic and market landscape were appropriate to the evolving context.

Comprehensive research that calls for thoughtful interpretation and messaging around PO

- Evidence generated is comprehensive (in scope) and complex (wide variation between and within countries). In particular, it suggests a need for thoughtful positioning of PO at the primary health care level to be most effective and highlight the influence of health systems quality and health-seeking behaviour on ultimate intervention/ device effectiveness. These study results provide several lessons to inform investments in product introduction at lower levels of care and resonate with previous Unitaid work (e.g., from the CARAMAL evaluation).

Catalytic impact on PO adoption in country, highly aligned to national agenda, though long term sustainability remains an issue

- The portfolio has catalysed demand for PO at the primary health care level, and to a lesser extent the CDSA. This appears to be strongly driven by alignment with countries' agenda on strengthening primary health care and the priority of introducing health technologies and improving quality of care – with the research results overall being a less significant factor impacting country demand. Financing of this demand is still heavily reliant on donor funding in most countries, creating uncertainty around the sustainability and scalability of PO use in the medium to long term and in light of funding constraints and competing priorities.

Foundational rather than catalytic market shaping interventions

- Market shaping interventions contributed to raising awareness on available choices for pulse oximeters and next generation devices to promote demand, as well as generating valuable market intelligence outputs to promote better quality and availability of fit-for-purpose devices. However, it is unclear the extent to which these outputs will contribute to advancing the development of next generation pulse oximeters, especially in the absence of demand forecasts backed by evidence of funding.

Promising results on CDSA potential to support quality of care but limited sustainability and scale up as currently designed

- In countries where the e-CDSA was used, the TIMCI project highlighted the potential value of the tool in improving quality of care and data collection, in line with many national agendas. However, the sustainability and scale up of CDSA interventions is currently limited due to interoperability challenges compounded by a lack of necessary digital infrastructure and resources to sustain use.

Well designed portfolio including 'booster' initiatives that enhanced portfolio overall

- The portfolio design was found to be comprehensive and well-structured using a combination of initiatives to enhance technical credibility and operational reach. This includes the use of a partners consortium to implement the grants, international advisory group (IAG), observer country and community and civil society engagement (CCSE) initiatives. Though in practice, some of them were found to have been limited in their efficiency and effectiveness due to contextual and implementation challenges.

Exemplifies Unitaid's pathfinder and influencer role. Biggest legacy was to provide Unitaid with foundational assets for responding to the COVID-19 pandemic

- Forward looking portfolio – first with respect to the "orphan" issue of hypoxemia in children and solutions for primary care, and to address gaps in awareness and use of devices appropriate for children. Further, was people-centered/ disease-agnostic and fundamentally part of a health systems strengthening approach – with this aspect strengthened by addition of PO performance assessment on darker skin pigmentation. The portfolio provided Unitaid with 'know how' and networks to respond to the COVID-19 pandemic, and Unitaid's subsequent leadership on oxygen and later GO_2AL have since further solidified Unitaid's key role in this area.

SUB-FINDINGS BY EVALUATION QUESTION

Relevance and coherence

The section below outlines sub-findings under the relevance and coherence evaluation questions EQ.1 and 2 in Table 1 followed by key lessons and insights.

Table 1: Summary key findings Relevance, Coherence

Section sub-findings	
EQ1 – Relevance	
1.	The portfolio targeted a key strategic priority on national and global health agendas in terms of reduction of under-5 mortality and the lack of adapted POs to support hypoxemia detection in children, making it highly relevant and responsive to public health needs in countries.
2.	Stakeholders viewed TIMCI work on pulse oximetry accuracy on darker skin pigmentation (output 8) as highly relevant and essential to strengthen equity in diagnosis of all children regardless of skin pigmentation.
3.	Both TIMCI and AIRE were implemented at an opportune time and targeted key policy and programmatic gaps in LMICs.
4.	Redesign of the TIMCI market shaping interventions - to generate demand for next-generation multimodal devices (rather than providing a financial incentive to manufacturers) - was seen as an appropriate shift to influence the sector from the "bottom up". The new market intelligence activities were deemed forward looking overall but limited in their catalytic ambition. There were useful adaptations following the COVID-19 pandemic to generate insights on multimodal device use.

Section sub-findings
5. There was a strong interest across project country governments to standardise clinical practices, strengthen quality of care and improve data collection through digital health tools which highlighted the relevance of the CDSA component of the portfolio; however the appropriateness varied by country.
6. Evidence generation was viewed as a valuable component of the portfolio, although the approach taken (i.e. stringent study methods, including RCT) limited contextual adaptions. This potentially represented a missed opportunity to answer more operational questions and spearhead country progress given existing national efforts in that direction.
EQ2 - Coherence
7. Throughout its implementation, the TIMCI and AIRE projects maximised alignment and synergy with national stakeholders and relevant partners.
8. Involvement of local research partners further enhanced the credibility and country relevance of the projects. At the portfolio level, there were missed opportunities to engage earlier with local partners to formulate study objectives and to include a sufficient pilot phase to refine the intervention prior to starting the TIMCI study.
9. Stakeholders unanimously confirmed Unitaid instrumental role in positioning PO and oxygen systems on the global health agenda initially through ACT-A and subsequently through GO2AL, with an important foundation established through this portfolio.
10. Though COVID-19 responses did not raise awareness for and scale quality PO adapted to all age groups, Unitaid's role in GO_2AL is a critical opportunity to advocate for integration and procurement of adapted PO as part of broader oxygen roadmaps.

Relevance and coherence - key lessons and insights

- Policy objectives and the required supporting evidence should be interrogated at both the global and country level as part of investment design. In this portfolio, many countries were already interested in introducing PO at the primary level (and within IMCI) so may have had different evidence needs. The overall study design also limited the opportunity to iterate the intervention design and adapt to local context, especially for the CDSA in India. Engagement with local research partners earlier in the project design would have provided an opportunity to adjust the research design according to countries evidence needs and feasibility in the context.
- Introduction of health products at lower levels of the health system need to consider the supporting health systems investments required for intervention impact (e.g. referral system, quality improvements at referral sites). The focus by countries on Universal Health Coverage and expanding primary healthcare means that Unitaid investments working at the primary care level are likely to be coherent with country priorities, increasing the likelihood of their sustainability.
- The strong integration of the projects with national and sub-national governments and bodies, along with partners with existing country relationships, supported uptake of the interventions within the health system.
- Digital investments need to be more locally driven and owned, and consider interoperability with national digital systems from the start. Country digital health systems have matured since this portfolio was conceived, which may present opportunities in the future.
- Unitaid was pivotal in the COVID-19 oxygen response through ACT-A. While the focus of oxygen investments during the COVID-19 pandemic was on tertiary care and adults, GO_2AL is an important vehicle to continue to advocate for appropriate PO devices for children and health system access to oxygen as part of country oxygen roadmaps.

Box 1. The portfolio exemplifies Unitaid's role as pathfinder and influencer

The 'Better Tools' portfolio was forward looking of Unitaid – first with respect to the "orphan" issue of hypoxemia in children and the introduction of an effective tool (pulse oximetry) that was not accessible in primary settings, and where there were gaps in awareness and use of devices appropriate for children. Further, the portfolio was people-centered/ disease-agnostic and fundamentally part of a health systems

strengthening approach – with people-centeredness strengthened through adding assessment of PO performance on darker skin pigmentation to the portfolio.

Critically, the biggest legacy of the portfolio was to provide Unitaid with 'know how' and networks to respond to the COVID-19 pandemic. Unitaid's subsequent leadership on oxygen during the COVID-19 pandemic and later GO_2AL have since further solidified Unitaid's pivotal role in this area.

As one of Unitaid's earlier investments intervening within the health system (as compared to disease-specific focus), key learnings with respect to Unitaid's pathfinder and influencer role include:

- Need for Unitaid to potentially take a larger role in coalition building with a diversity of stakeholders in RMNCH and specific technical areas (e.g. oxygen, PPPR) to build political and financing support for intervention adoption and sale – recognising health systems interventions lack the traditional 'scale up' funders and advocates. For child hypoxemia and availability of pulse oximetry (and oxygen), this includes engaging with diverse coalitions in maternal, newborn and child health, in primary health care, as well as specific technical areas and funding sources such as oxygen roadmaps, Global Fund C19RM etc. In this regard, there may be greater need for Unitaid support to facilitate linkages between grantees and financing partners than in other portfolios.
- There is potentially a more significant role for country-level advocacy and dissemination than other Unitaid portfolio areas, given the diversity of funding partners and policy contexts in project countries, and greater emphasis on domestic financing to sustain and scale certain health system interventions (where decentralisation of health budgets is another consideration). Country advocacy may necessitate flexibility in timing to best leverage opportunities (e.g. linking to annual budgets cycles).

Efficiency

Evaluation findings on EQ3. for efficiency are presented in Table 2 followed by related key lessons and insights.

Table 2: Summary key findings Efficiency

Section sub-findings
EQ3 – Efficiency
11. The projects reported significant delays (across design, implementation and research studies) due to COVID-19 and a range of country-specific factors external to the projects which affected their overall efficiency.
12. Both AIRE and TIMCI engaged a wide range of community and civil society actors throughout the projects though these activities were limited in their efficiency and effectiveness due to budget and time constraints.
13. The portfolio provided important benefits (e.g., in terms of generating country interest and demand for PO), but not in the traditional way that Unitaid considers VfM of its investments as the results do not indicate straightforward adoption and uptake of adapted POs for children at PHC level. Multi-modal devices also had incremental benefits, but do not show catalytic impact on product availability and supplier improvements.

Efficiency – key lessons and insights

- Investments which intervene within complex health systems may not exhibit the traditional VfM pathway (e.g. evidence leading to financing for scale) of other Unitaid portfolios. Scale up and influence may run a longer course and be through more channels compared to disease-specific portfolios.
- Evidence generation within the same portfolio should have a common data analysis plan from the beginning, and (if relevant) ideally be completed in a similar timeframe to support comparability of results and leverage the entirety of the portfolio in dissemination and advocacy.
- Demand generation (e.g. through community and civil society engagement) should be implemented 'in-sync' with supply-side interventions where relevant, ideally underpinned in the project theory of change.

Effectiveness, impact, sustainability and scalability

This section provides sub-findings related to the portfolio effectiveness, impact, sustainability and scalability presented by evaluation question with EQ4 on tools adoption and scale-up in Table 3, EQ5 on Next generation devices in Table 4, EQ6 on knowledge dissemination in Table 5 and EQ7 on equity, intersectionality and people centeredness in Table 6. Each set of findings is followed by relevant key lessons and insights.

Tools adoption and scale-up

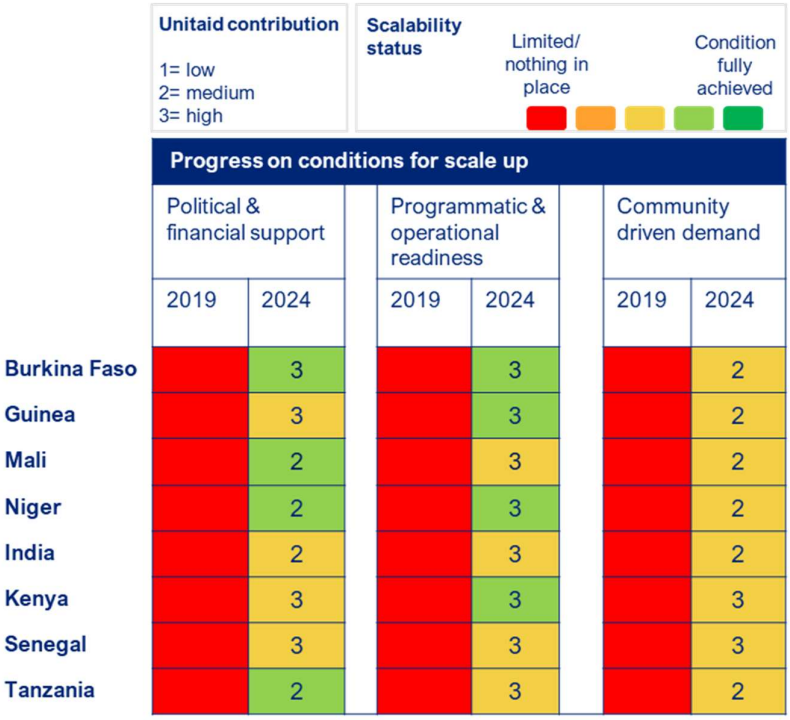
Table 3 presents the findings related to Tools adoption and scale-up assessed under EQ4.

Table 3: Summary key findings Effectiveness (tools adoption and scale-up)

Section sub-findings
EQ4 – Tools adoption and scale up
14. Research findings pertaining to the pathway for adoption of PO and their effect on health outcomes are mixed and may not provide a compelling case for PO scale up in the absence of broader efforts to strengthen demand and services along the pathway of care. However, they offer several good findings regarding management of severe illness in children across diverse contexts and health systems factors influencing outcomes.
15. Research demonstrated the potential added value of CDSA in supporting better quality of care (e.g., clinical standardisation, reduced antibiotic use) and data collection. However, the CDSA extended consultation time which constitutes a key barrier to uptake especially in high volume, under-staffed PHCs, and challenges around interoperability and resources constraints to maintain the tool hinder wider adoption and sustainability.
16. Both AIRE and TIMCI studies highlighted a number of factors at play in referral decisions including availability of transport, costs, and caregiver autonomy, with referral tending to be the outcome of exchange between health provider and caregiver.
17. All countries reported good acceptance of PO by healthcare providers and significant policy progress and commitment towards adopting child friendly POs to enable better detection of severe disease. Stakeholders unanimously recognized that the full impact of PO introduction can only be achieved if integrated as part of a "whole of systems approach".
18. The observer countries approach was highlighted as a cost efficient initiative to extend the portfolio benefits beyond the project countries. Though whilst there was evidence of positive influence across observer countries, the effectiveness of this approach was limited overall due to minimal engagement and lack of catalytic support.

Figure 3 presents an overview of progress across the portfolio against the Unitaid country readiness domains and conditions. Overall, a majority of countries made good progress towards country readiness for scale with more advanced progress in AIRE countries which may be due to earlier evidence dissemination and project closure in 2023. Assessment of TIMCI countries' readiness for scale was limited at the time of this evaluation as research results were still being disseminated, which stakeholders indicated could have an influence on the priority given to PO procurement for PHCs as part of national scale up plans.

Figure 3. Overview of country progress towards readiness for scale



PO and CDSA adoption and scale-up – key lessons and insights

- The prevalence of hypoxemia among children attending PHCs was low (0.4% overall in TIMCI), and slightly lower than evidence in comparable settings. Hypoxemia was higher among younger infants < 2 months compared to older children (0.7% vs. 0.4%). Whilst data collection approaches may account for lower levels of hypoxemia in the projects, a high proportion of hospitalised children in some countries bypass the primary care level. Health systems factors, distance, costs and caregiver perceptions appear to shape decisions on where to seek care for very sick children. This has implications on other child health interventions which involve the primary care level.
- Referral rates and referral completion for severely ill children from the primary level were low and a high proportion of children were managed at the primary care level, despite the indication for referral. This is highly relevant for design of interventions in which the referral system is integral to health impact, and investments should factor in referral system strengthening along with quality of care at referral sites.
- The expected health benefits of PO and CDSA were not observed in TIMCI and small event numbers limit some analyses. This is not an unexpected finding given the learnings on hypoxemia prevalence and referral. This portfolio along with learnings from the Unitaid CARAMAL evaluation emphasise that interventions at lower levels of care require a more health systems/diagonal approach, which may be slower to demonstrate visible progress.
- There is a demand at the primary level for appropriate health technologies, which need to consider the local contexts for appropriate introduction. The effect of the CDSA on extending consultation time was a key barrier to uptake in high volume and under-staffed PHCs such as in India where the average consultation time for a sick child is 1-2 minutes. CDSA use increased this to 6-15 minutes and was deemed not feasible and rejected.
- Future investments in tools or interventions involving screening and triage into care (e.g. multimodal diagnostics, non-invasive haemoglobin measurement) should factor in support for key health system conditions, such as referral and quality of care in referral sites, in order to influence health outcomes.
- Strong interest by governments to sustain and expand PO for children at the primary care level speaks to the high relevance of this portfolio to health priorities (primary care, quality, standardization, use of health technologies). Despite the challenges with the CDSA, there was strong interest among health managers and even health providers for solutions to improve the standardization of care in contexts with varied health provider skills, build health provider confidence, and generate data on patient care.

Next generation multi-modal devices

Table 4 presents the findings related to next generations devices assessed under EQ5.

Table 4: Summary key findings Effectiveness (next generation devices)

Section sub-findings
EQ5 – Next generation devices
19. Stakeholders recognised the overall value of the market shaping evidence generated through the TIMCI project in providing evidence and market intelligence on existing appetite as well as potential demand and supply for next generation multimodal devices (MMs).
20. The work under the market shaping interventions was found to be foundational rather than catalytic as, by design, it did not cover some key market barriers (such as demonstrating funded demand to manufacturers or addressing the issues of affordability) to encourage market entry and product availability.

Next generation devices – key lessons and insights

- Affordability remains a key barrier in the adoption of quality pulse oximeters adapted for children, where there is a substantial gap between willingness to pay and the current price point of devices. An absence of concrete evidence of financed demand, or aggregate demand, is one of several barriers to price reduction. Recognising constrained domestic health budgets affordability is highly relevant for future investments in multimodal devices, In the absence of an intervention to address affordability, scale up is likely to be incremental, emphasizing the importance of including pulse oximetry for children within national oxygen roadmaps and their financing.
- Based on stakeholder feedback, haemoglobin measurement was viewed as most likely to add substantially to improved identification and management of sick children, whilst other measurements and vital signs in multimodal devices were considered as only incremental improvements.

Knowledge dissemination

Table 5 presents the findings related to knowledge dissemination under this portfolio assessed under EQ6.

Table 5: Summary key findings Effectiveness (knowledge dissemination)

Section sub-findings
EQ6 – Knowledge dissemination
21. TIMCI and AIRE advocacy and knowledge sharing throughout project implementation highly contributed to drive policy changes at national level within project countries. However, dissemination of the final research results at both the national and global level was compressed due to projects delays. As a result, it is too soon to assess the effectiveness, impact and influence of evidence generated through this portfolio.

Knowledge dissemination – key lessons and insights

- AIRE and TIMCI responded well to high country demand for evidence, recognising this remains ongoing for TIMCI. The very limited time for dissemination in AIRE was however a missed opportunity for unpacking country-specific study results given the diversity of outcomes and health seeking behaviours.
- Different project timelines along with different analysis plans were the most significant missed opportunity to compare evidence findings across diverse contexts, particularly as there was intentional complementarity of the TIMCI and AIRE study protocols. The projects did well to identify joint opportunities for dissemination.
- Different communication formats to better leverage and disseminate comprehensive/ ‘dense’ products, such as the multimodal device landscape, might help to reach key audiences in project countries and globally. The policy primer (developed by TIMCI) and policy briefs (developed by AIRE) as well as other bite-sized communication outputs (e.g., online articles) demonstrate projects’ efforts in that direction although it was too early to assess the effectiveness of these outputs (especially for TIMCI).

- Engaging WHO through the IAG helped support alignment with WHO's process for guideline review, though opportunities for closer working with WHO within the portfolio may have been beneficial (noting WHO were consulted in developing the study questions). The opportunity to collaborate with WHO to review TIMCI and AIRE results alongside other evidence of pulse oximetry at the primary care level is important for supporting the uptake of the portfolio evidence and contributing to the global knowledge base related to hypoxemia in children.

RECOMMENDATIONS

Overall, the portfolio was highly relevant and contributed significantly to progress in the policy landscape to support PO adoption across project countries. The portfolio was instrumental in raising awareness on the lack of adapted tools to diagnose hypoxemia in children and newborns and, to a lesser extent, has generated nascent country demand for next-generation devices measuring vital signs among children.

As a result of the portfolio's evidence-emphasis, significant information across eight high burden countries has been generated on the clinical features of children presenting at the primary care level, care seeking and referral patterns, provision of oxygen at hospitals for hypoxemic children along with other quantitative and qualitative data which could contribute to improved design of health interventions in these settings. In addition, the portfolio offers key lessons to maximise the effectiveness and impact of future interventions looking at introducing products at lower levels of the health system.

Recommendations for Unitaid structured by Unitaid strategic objectives are as follows:

1 Accelerate the introduction and adoption of key health products

For this portfolio:

- **Ensure research results are packaged and disseminated appropriately, avoiding any knee-jerk rejection regarding use of POs adapted for children at PHC level** whilst also encouraging their nuanced and thoughtful introduction as part of a systems wide approach. This would include engaging in WHO's proposed global review of the evidence from TIMCI, AIRE and other studies.
- **Disseminate findings on pulse oximetry accuracy on darker skin pigmentations** to support greater equity in the development of medical devices.
- **Consider if there are any opportunities to build on the MM work under the portfolio –** particularly in terms of exploring options beyond respiratory rate such as non-invasive haemoglobin measurement, as well as furthering the impact of the numerous outputs produced under the projects by making them available for manufacturers, governments and donor partners.
- **Through Unitaid's partnerships, engage with Global Fund C19RM funding to encourage relevant PO funding for countries (including PO adapted for children) as well as oxygen systems development.** Where countries have secured financing for PO (e.g. Kenya), this includes engaging to track the extent funding is operationalised (e.g. through GO_2AL).
- Consider how to **facilitate country use of open access CDSA** which currently requires expert skills. This includes supporting translation of the algorithm into an easier to use format for countries and/or promoting national capacity building on specialist skills as part of national digital strategies.

For future Unitaid investments:

- **A more holistic approach to product and intervention introduction - particularly early in the continuum of care (e.g. community, primary level)** - could further enhance impact, considering the complexities and challenges at the primary level. This would include demand creation and social norms, referral decision making, quality at the point of care and referral sites, and referral linkages; with appropriate support depending on project objectives and local context (e.g. BCC approaches to encourage demand).
- **Maximise the 'observer/catalytic impact country' model**: If using a more 'observer based' model, ensure there is timely and regular engagement (e.g. site visits, webinars, timely and regular sharing of materials and tools), and potentially track this. For a more engaged/'early market access' model where more funding is

available, provide modest catalytic funding, tailoring to country readiness. Both approaches should support south-south learning.

- Need to **better balance service delivery and research objectives in Unitaid investments**: Unitaid should think through the balance between service delivery and research objectives within its grants. This includes carefully considering the trade-offs of selected research methods and encouraging more adaptive designs (e.g., implementation research) where possible. Intervention measures of success should also be tailored in line with selected methods and achievable attributable outcomes - in particular, impact KPIs which are usually service delivery focused (e.g. number of lives saved was the impact KPI for this portfolio despite projects' limited influence on this impact).
- Evidence generation for interventions early in the care cascade should **interrogate the validity of the theory of change and its assumptions early in the project period** (e.g. through a baseline or formative period). This should include key components of the continuum of care such as referral decision making, referral systems, and care at referral sites.
- **Ensure digital investments are oriented to sustainability** from inception (e.g. interoperability, local leadership).

2 Create systemic conditions for sustainable, equitable access

- **Continue to support PHC development including linking with PPPR**: Unitaid should continue to use its pathfinder and influencer role to encourage interventions at the PHC level, which forms the backbone of the health care system and assumes even more significance in the pandemic preparedness and resilience agenda.
- **Strengthen coordination in multi-partner evidence generation, and consider opportunities for greater involvement of local research partners** – align project timeline, and ensure coherence in the study design and data analysis plan to later have similar analytic outputs and facilitate comparability of results between grantees/studies. Build on learnings for engaging key consortium partners early in research design; consider greater inclusion of national research partners in study design – benefitting from their knowledge of local context and experience.
- **Interrogate advocacy goals and their level (global, country) in the design of new investments**, with consideration of the different needs and timing of advocacy efforts depending on the nature of the investment.
- **Expand WHO enabling support for future investments in the child health portfolio** to support greater visibility and alignment, with more regular WHO engagement.

3 Foster inclusive and demand-driven partnerships for innovation

- **Health systems investments potentially require more significant emphasis on country-level advocacy and dissemination** than other Unitaid portfolio areas, given the diversity of funding partners and policy contexts in project countries, and greater emphasis on domestic financing to sustain and scale. The nature and timing of country level advocacy may differ substantially and require flexibility to leverage local opportunities (e.g. budgetary reviews).
- Need for **Unitaid to potentially take a larger role in coalition building with a diversity of stakeholders in RMNCH** and specific technical areas (e.g. oxygen, PPPR) to build political and financing support for intervention adoption and scale – recognising health systems interventions lack the traditional 'scale up' funders and advocates. There may be greater need for Unitaid support to facilitate linkages between grantees and financing partners than in other portfolios.
- Recognising Unitaid's evolution in CCSE since the 'Better Tools' project were conceived, interventions at community and primary level should **include CCSE as a key component in the project Theory of Change**, with adequate investment, period of engagement, and view to sustainability.
- Consider how to best leverage the **IAG** model and create adequate opportunities for IAG members to weigh in at key decision and analysis timepoints.

PART A

1. INTRODUCTION, EVALUATION OBJECTIVES AND METHODS

The section below provides a brief introduction on the evaluation in Section 1.1. followed by a summary of the portfolio background and rationale in Section 1.2. An overview of the evaluation framework, approach and methods is outlined under Section 1.3. and details on the robustness assessment framework are provided under Section 1.4.

1.1. INTRODUCTION

Cambridge Economic Policy Associates (CEPA) was appointed by Unitaid to conduct a portfolio evaluation of the investments made under the Area for Intervention (AfI) on "Better tools to identify severe disease in children". This evaluation had three main objectives:

- To assess the relevance, coherence, efficiency, effectiveness, impact, sustainability (particularly focusing on effectiveness, impact, sustainability) and lessons learned for the TIMCI and AIRE investments and their contribution to Unitaid's Strategic Objectives;
- To assess Unitaid's role as pathfinder (analysing complex access problems and designing a pathway to resolve them) and influencer (enabling impact by partnering with a wide range of stakeholders and leveraging its unique position); and
- To assess the overall contribution of Unitaid's 'Better tools to identify severe disease' investments between 2019 and 2024, with a view towards the complementarity and synergy of these investments with Unitaid's broader efforts to accelerate access to better tools for identification of severe disease in project countries and beyond.

This report presents the overall findings from this evaluation.

1.2. PORTFOLIO BACKGROUND AND RATIONALE

In 2017, Unitaid developed an Area for Intervention (AfI) within the malaria portfolio focussed on addressing challenges related to integrated management of sick, febrile children ('Better tools for integrated management of childhood fever' AfI). Fever is a common symptom of the leading causes of child mortality (e.g. pneumonia, diarrhoea, malaria) and evidence suggests that non-malarial fevers are not appropriately managed, in part due to lack of diagnostic tools, resulting in progression to severe disease and increased risk of child mortality. Use of pulse oximetry (where pulse oximeters are available) to screen for hypoxaemia, a key indication of severe disease, is recommended within the WHO Integrated Management of Childhood Illness (IMCI) guidelines (2014).[1] While the use of pulse oximeters (POs) is standard at secondary care level in low- and middle-income countries (LMICs), it has not yet been widely adopted at primary health care (PHC) level, where most care-seeking for sick children takes place.

The two grants in scope for this evaluation aim to accelerate the availability, adoption and scale-up of improved tools to identify severe disease in children across selected countries: the Tools for Integrated Management of Childhood Illness (TIMCI), and the Amélioration l'Identification des détresses Respiratoires chez l' Enfant (AIRE). Under Unitaid's new Strategy 2023-27, the 'Better tools to identify severe disease in children portfolio' is now situated within the cross-cutting programmatic priority to 'Improve child survival with triage and treatment tools', reflecting its relevance to several Unitaid disease-specific and cross cutting priorities, where the portfolio has also served as an entry point for investments in women's and children's health and the wider oxygen portfolio initiated during the COVID-19 pandemic.

[1] Integrated Management of Childhood Illness: Chart booklet, World Health Organization, Geneva 2014

The TIMCI and AIRE investments aim to accelerate access to better tools to identify and manage severe disease in children under five through:

- Providing POs adapted for point-of-care use in children at PHC level across 8 project countries in LMICs, to improve identification of hypoxaemia, or low oxygen saturation in the blood, a key indicator of severe disease;
- Piloting electronic clinical decision support tools (eCDST or CDSA) in select settings, to improve adherence to guidelines and decision-making, and prevent inappropriate treatment including overuse and wastage of malaria medicines and antibiotics;
- Implementing market shaping activities for next generation multi-modal devices (MMDs) that can detect hypoxaemia and other vital signs (e.g., respiratory rate, temperature, haemoglobin level)
- Running large-scale field evaluations to document evidence of feasibility, cost-effectiveness and impact, and enable evidence-based policy change; and
- Exploring sources of variability of PO accuracy on darker pigmented skins. The aim of this additional output is to improve awareness, guidance, regulatory controls, and testing procedure for appropriate devices.[2]

The advent of the COVID-19 pandemic six months after the launch of the portfolio in March 2020, brought major disruptions globally with a knock-on effect on the projects, but was also a source of strategic opportunities. By putting access to oxygen and related tools such as pulse oximeters at the centre of global and national interests, the COVID-19 pandemic strengthened synergies between these grants and Unitaid's wider oxygen portfolio. As such, whilst this portfolio was designed under Unitaid's last strategy 2017-2022, it remained highly relevant to the new 2023-2027 strategy through its focus on child health and linkages to pandemic prevention, preparedness and response (PPPR) efforts. Table 1.1 provides further details on the two grants.

Table 1.1: Unitaid investments for the "Better tools for improved identification of severe disease" portfolio

Grant	**Tools for integrated management of childhood illness (TIMCI)[3]**	**Amélioration l'Identification des détresses Respiratoires chez l'Enfant (AIRE)[1]**
Grantee	PATH (lead grantee), Swiss Tropical and Health Institute (Swiss TPH), Unisante	ALIMA (lead grantee), Inserm, Solthis and Terre des Hommes, IRD
Objectives/ focus	Increasing the use, demand and equitable supply for PO (with CDSA) at PHC level through 1) capacity building and community sensitisation; 2) feasibility, impact and cost-effectiveness evidence generation; 3) strengthening pipeline of adapted MMs, and 4) exploration of PO variability and accuracy on darker skin pigmentation	Increasing the use and demand for pulse oximetry at PHC level through 1) equipment resourcing and capacity building; 2) in-country advocacy for policy/systems strengthening and community sensitization; and 3) acceptability and feasibility evidence generation
Duration	July 2019 – June 2023, with a no cost extension to March 2024 and a costed extension to June 2024 for output 8	July 2019 – December 2022, with a no cost extension to April 2023
Budget	US$ 28.4 m (plus US$ 1.36 m for output 8)	US$14.9 m
Project countries	India (Uttar Pradesh), Myanmar (ended 2021 due to coup), Kenya, Senegal, Tanzania	Burkina Faso, Guinea, Mali, Niger
Observer countries	Cote d'Ivoire, Malawi, Zambia, Uganda, India (Assam, Chhattisgarh, Odisha and Rajasthan)	Chad, Mauritania, Nigeria

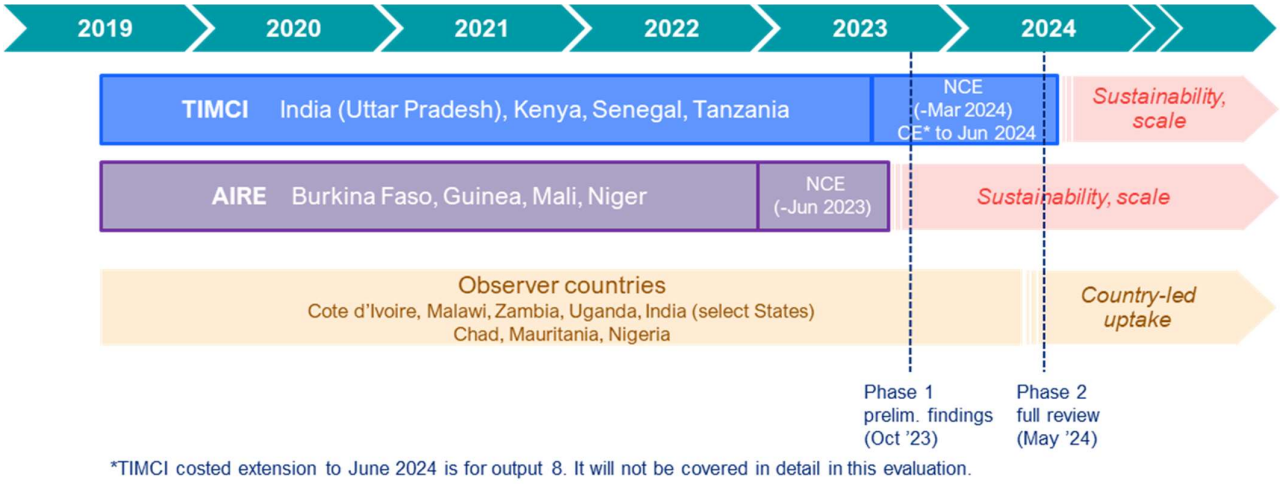
[2] This assessment focuses on the relevance and responsiveness of output 8 whilst results of these activities are out of scope for this evaluation.

[3] Evaluation of Unitaid's additional funding to partners for specific Covid-19 responses is not in scope, but this report does examine synergies and the extent grants leveraged the Covid-19 pandemic in support of project objectives.

1.3. EVALUATION FRAMEWORK, APPROACH AND METHODOLOGY

The evaluation was implemented through a phased approach with Phase 1 conducted between May and October 2023 and Phase 2 conducted between January and March 2024 (Figure 1.1). Phase 1 of the evaluation entailed an end of project evaluation of the concluded AIRE grant alongside an interim assessment of the ongoing TIMCI grant, followed by a full end term assessment of the overall portfolio in Phase 2, with an emphasis on reviewing the results from the TIMCI grant[4] and a post closure follow up of the AIRE grant.

Figure 1.1 Overview of phased evaluation of the TIMCI and AIRE projects

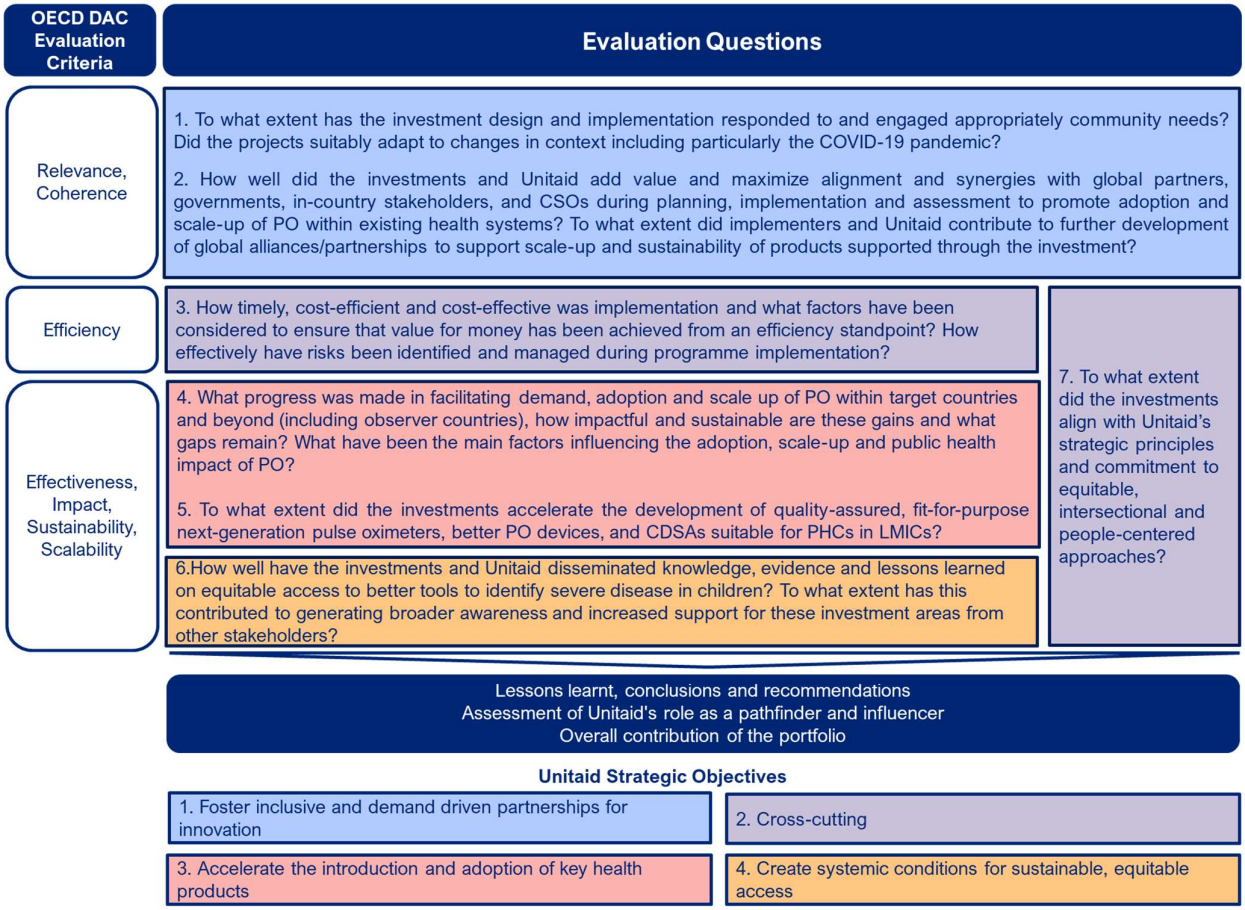


The evaluation was **structured around the OECD DAC evaluation criteria** and links the evaluation questions to Unitaid's Strategic Objectives under the Strategy 2023-27. The evaluation framework developed included 7 questions enabling an assessment of the relevance, coherence, efficiency, effectiveness, impact, sustainability, and scalability of the projects' interventions and identification of key lessons and recommendations from the portfolio overall.

Figure 1.2 (over page) presents an overview of the evaluation framework.

[4] With the exception of TIMCI output 8 activities with Open Oximetry closing in June 2024.

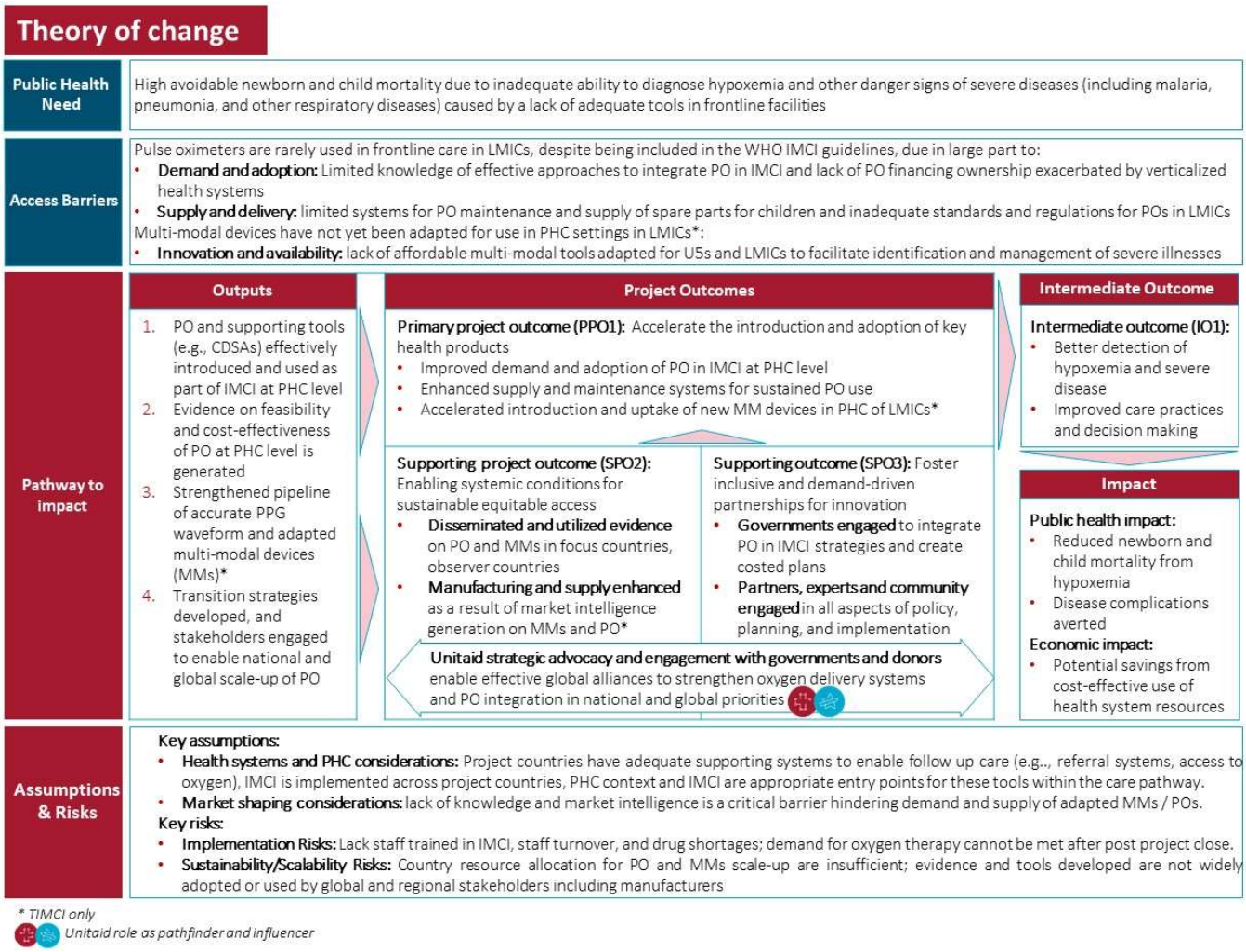
Figure 1.2: Evaluation framework and questions



The evaluation employed a **theory-based approach**, grounding the evaluation on the theory of what the objectives and activities of Unitaid's 'Better tools to identify severe disease' investments and portfolio were seeking to achieve, with a pathway to impact represented through a Theory of Change (TOC). The portfolio TOC was developed at the beginning of the portfolio and subsequently updated for this evaluation at the beginning of Phase 1 and 2 to refine key aspects such as reflecting the project access barriers, outcomes, assumptions and risks etc. As the portfolio included significant evidence-generation focused on clinical aspects of the intervention (i.e. feasibility, tool uptake, effect on health outcomes), the evaluation assessed progress against the TOC in two ways: firstly, through assessment of project outputs, supporting project outcomes and primary project outcomes, and secondly, through analysis of the evidence of intervention effectiveness as assessed by the TIMCI and AIRE research partners, and the implications of these findings on the overall progress against the TOC.

Figure 1.3. (over page) presents the final updated ToC as designed through this evaluation.

Figure 1.3: Revised Theory of Change for Phase 2 – Better tools for improved identification of severe disease



This evaluation entailed a comprehensive data collection and analysis methods, including (i) document review; (ii) key informant interviews (KIIs) across a number of key stakeholders; and (iii) country case studies. Figure 1.4 presents a summary of the methods used in this evaluation which are described further below.

- The desk-based review of documents entailed a comprehensive review of relevant documents in Phase 1 complemented in Phase 2, with particular attention to new resources made available since Phase 1. Documents reviewed included documentation from grantees (lead and consortium partners) including annual reports, budgets, grant outputs, especially research reports as well as any presentations, tools, guidelines, publications, and country specific documentation; wider Unitaid documentation such as the Unitaid Strategy, results framework, scalability framework, etc., and select Unitaid materials concerning investments at lower levels of the health system which require referral for case management and which have some similarities in lessons learned (e.g. CARAMAL evaluation); documents from other stakeholders including WHO, UNICEF, the International Advisory Group (IAG) established for these grants, Every Breath Counts Coalition, Hypoxia Lab, etc.; selected review of relevant academic and grey literature pertaining to diagnosis and management of severe childhood disease, use/development of multimodal pulse oximeters and use of CDSA in IMCI, and regarding the evidence-base of health systems interventions at lower levels of the health systems, and their requirements for impact.
- Stakeholder consultations included semi-structured key informant interviews (KIIs) and focus groups discussions (FGDs) which provided an important methodological tool for the evaluation, to gather a range of perspectives and insights across key informants. This included **interviews with internal stakeholders**, i.e., lead implementers,

mainly PATH and its consortium members (e.g., Swiss TPH, Unisante) as well as a follow up consultations with ALIMA and its consortium members (Inserm, Terre des Hommes, Solthis); interviews with Unitaid Secretariat including the project team, oxygen team and senior management team (SMT); as well as **consultations with key external stakeholders** such as technical agencies and key global partners (e.g., WHO, UNICEF, IAG members, Every Breath Counts Coalition, Hypoxia Lab), manufacturers, country stakeholder for non-case study countries from both TIMCI and AIRE, and selected observer countries/states and other relevant stakeholders involved with the respective grants. These interviews helped contextualise and validate findings from the document review. The final consultee list is presented in Appendix B1. and indicative interview guides are presented in Appendix B2.

- In total, the **evaluation covered five case studies** across eight project countries, Burkina Faso and Guinea for AIRE and India, Senegal and Kenya for TIMCI. Country case studies provided a critical opportunity to investigate the experience of the projects in terms of results, lessons learned, and the country-level factors across different contexts which have influenced these results and lessons.

Figure 1.4 Evaluation methods, limitations and mitigations

1.4. Robustness assessment framework

In line with good evaluation practice, findings have been assessed for robustness based on both the quality and quantity (e.g. triangulation) of evidence, as per the scale outlined in Table 1.2 below.

- *Quality of the evidence:* quality of the documentation and feedback by considering aspects such as the source and reliability of the quantitative data and qualitative information (where possible/relevant), and involvement of the consultee providing feedback on a specific issue (e.g. implementers may be conflicted to provide positive rather than critical feedback, etc.).
- *Quantity of the evidence:* the extent to which findings are consistent after being triangulated across sources of information. In terms of consultations, we will consider how many consultee responses will support the same view, or instances in which views might have been contradictory.

Table 1.2: Robustness rating for findings

Rating	Strength of evidence
Strong	• The finding is supported by data and/or documentation which is categorized as being of good quality by the evaluators; and • The finding is supported by majority of consultations, with relevant consultee base for specific issues at hand.
Moderate	• The finding is supported by majority of the data and/or documentation with a mix of good and poor quality; and/or • The finding is supported by majority of consultations responses.
Limited	• The finding is supported by some data and/or documentation which is categorized as being of poor quality; or • The finding is supported by some consultations as well as a few sources being used for comparison (i.e., documentation)
Poor	• The finding is supported by various data and/or documentation or poor quality; or • The finding is supported by some/few reports only and not by any of the data and/or documents being used for comparison; or • The finding is supported only by a few consultations or contradictory consultations.

2. OVERALL FINDINGS AND CONCLUSIONS

This section provides key evaluation findings and conclusions across the three evaluation objectives and range of evaluation questions.

Finding 1: The two investments within the portfolio (TIMCI and AIRE) were highly relevant and responsive to country contexts and public health needs and highlighted key issues around lack of adapted tools to identify severe disease in newborns and children under five.

Robustness: Strong, well supported in the documents review and consultations at the country level as well as with Unitaid and the grantees.

The portfolio was **highly relevant to country priorities and public health needs** both in terms of its objectives and implementation. Whilst pulse oximeters (PO) were already being used in LMICs, many stakeholders recognised the existing gap in the availability of adapted PO for newborns and children under-5 especially at lower levels of care, and the limited awareness of this issue. In addition, the projects were implemented in countries where there was an existing appetite for improving implementation of IMCI and updating relevant child health guidelines in most countries), supporting primary health care (PHC) development as a key means to support universal health coverage (UHC) goals and a keen interest in promoting the use of digital tools to increase quality of care (which were fostered through CDSAs linked with PO introduction by the projects). This enabled the projects to capitalise on a fertile environment to implement their interventions and engage with country stakeholders. In addition, the TIMCI output 8 implemented via the Open Oximetry project further strengthens the portfolio relevance and responsiveness to LMICs through its focus on pulse oximetry accuracy on darker skin pigmentation. Given the variable performance of pulse oximeters across manufacturers and potential risks this poses to the tool effectiveness, adoption and scale up in LMIC settings, **stakeholders viewed the work under output 8 as highly relevant and essential to strengthen equity in diagnosis of all children regardless of skin pigmentation**.

The **portfolio was also viewed to be forward-looking** (and thereby in line with Unitaid's "pathfinder" role) in terms of its focus on oxygen pre-COVID-19, and its alignment with the call by WHO to increase disease-agnostic diagnostic

capacity[5] as part of wider efforts to ensure quality, comprehensive and integrated primary health care and health services. More specifically, whilst the portfolio was initially designed in a context with limited attention to oxygen and pulse oximetry needs, the pandemic brought this issue to the forefront. This provided a key opportunity to leverage the attention on the need for better access to oxygen (and related tools such as POs) as part of lifesaving essential care at all levels of the healthcare system, including in maternal and child health. Indeed, **this portfolio has enabled Unitaid to extend its expertise in the oxygen space**, where today, following ACT-A, it is one of the key leaders in the field. In addition, through its market shaping interventions aiming at accelerating the development and market entry of next generation pulse oximeters, the portfolio was responsive to the need for market and performance-related information for these devices in LMIC contexts.

Implementation of the projects was astutely embedded in country health systems, with both TIMCI and AIRE working closely with government stakeholders and public health systems. This contributed to strong buy-in for the interventions and sustainability efforts (discussed in Finding 4 below).

Finding 2: The research findings from the portfolio are comprehensive (in their scope) and complex (wide variation between and within countries). In particular, they suggest a need for thoughtful positioning of PO at the primary health care level to be most effective, and highlight the influence of health systems quality and health-seeking behaviour on ultimate intervention/ device effectiveness. These study results provide several lessons to inform investments in product introduction at lower levels of care and resonate with previous Unitaid work (e.g., from the CARAMAL study).

Robustness: Moderate, supported by documents review (final research reports from AIRE and preliminary findings from TIMCI) and consultations at global level, with partners, Unitaid and grantees.

TIMCI and AIRE had different study designs and were conducted across a range of health systems and child mortality contexts, and each have contributed to quantitative and qualitative evidence concerning management of sick children at the primary health care level. A standout finding from AIRE was **that introduction of pulse oximetry within the IMCI consultation identified an additional 5% of children as 'severely ill' requiring referral**. These children would otherwise have been more likely to be managed at the primary care level or at home – and danger signs missed, with potentially fatal consequences – although it is important to note that a diagnosis of severe illness did not always result in transfer to hospital as outlined in section 2.3.1. This additionality represents a significant value-add in regard to addressing the global issue of missed opportunities to improve triage and risk stratification for sick children within primary care, with potential to improve timely access to life saving care.[6]

Differences in the design of the TIMCI and AIRE studies prevent a direct comparison of results, and there are also some methodological issues with regards to data collection approaches, but both projects raised a number of health systems-related considerations which influence the effectiveness of interventions like PO and their introduction at the primary health care level. First, that **hypoxemia prevalence was lower than expected** (0.9% across all AIRE sites[7]

[5] Through its 2023 WHA resolution on 'Strengthening diagnostics capacity', the WHO urged Member States to *"prioritize and review rapidly clinical evidence for new diagnostic interventions, services or products, and with an effort to integrate recommendations in a disease-agnostic way, where possible". WHO (2023). Resolution on strengthening diagnostics capacity. EB152(6)*

[6] Azevado et al (2024). Hard truths about under-5 mortality: call for urgent global action. Lancet

[7] TIMCI and AIRE had different eligibility criteria for use of PO as follows: **TIMCI** – all children (Kenya, India); all infants <2 months and children 2-59 months with cough/ difficulty breathing or red/yellow (severe/moderate) IMCI classifications, which equated to 60-80% of children (Senegal and Tanzania). **AIRE** – all infants < 2 months and children 2-59 months with respiratory symptoms (cough/ difficulty breathing) or red/ yellow (severe/ moderate) IMCI classifications.

and 0.4% across all TIMCI sites)[8] owing likely to care-seeking behaviours for severely ill children (which often bypass the PHC level) and potential methodological issues (e.g. sickest children not assessed in favour of immediate treatment). In the first six months of the AIRE study, only 21% of the expected 'severe cases' had been enrolled. This prompted the ITINER'AIRE study to understand care seeking pathways, which found significant inter-country disparities, from a high of 57% of children in Guinea admitted to hospital had bypassed the PHC level, followed by 25% in Mali, 15% in Niger and 3.4% in Burkina Faso. Reasons for these differences are complex, including distance to hospitals, user fee policies, caregiver perceptions of adequate care offered, and characteristics of the study sites (e.g. if urban). This suggests health seeking behaviours along with systems factors have a ripple effect on the proportion of severely sick children using PHC as a first point of entry into the health system.

Stakeholders consulted for this review **caution strongly that interpretation and dissemination of study results should be careful not to indicate POs should be de-prioritised at the PHC level** - though these findings do suggest a **need for thoughtful prioritisation of PO placement where resources are scarce and a greater consideration of health systems factors in the pathway to care**. WHO have recommended that an updated comprehensive systematic review of available evidence concerning pulse oximetry introduction at lower levels of care should be conducted jointly with a review of findings from TIMCI and AIRE to inform global guidance.

Second, while pulse oximetry is a widely accepted tool in the identification of hypoxemia (and essential for monitoring patients receiving oxygen therapy), **its impact is highly dependent on a number of pre-requisite health systems conditions** – in particular a functioning referral pathway to receive oxygen therapy, and timely provision of that treatment upon successful referral. Neither project had significant effect on completed referrals (and TIMCI referrals were exceptionally low), nor were they designed to influence referral systems nor provision of oxygen at referral sites (though there was some modest strengthening in study sites).

Relevant to this portfolio, and wider investments to introduce health products and technologies, were findings from the evaluation of Unitaid's CARAMAL project – which sought to demonstrate the effectiveness of pre-referral rectal artesunate (RAS) on under-5 mortality in Nigeria, DRC and Uganda and faced similar challenges as this portfolio. Key health systems components for RAS effectiveness, namely referral mechanisms for children receiving RAS, the provision of ACTs at referral facilities, and supply chain were not within the project scope and/or there was insufficient time within the project time period to strengthen these sufficiently to influence outcomes. The AIRE and TIMCI studies provide **critical insights on key influencing factors and pre-conditions that may enable or hinder the effectiveness and impact of product introduction at PHC level** including (i) an existing enabling policy environment (e.g., user fee exemption policies for attendance at PHC), (ii) functional supportive systems (e.g., operational referral systems) and provider perceptions of the adequacy of the referral system, and (iii) adequate capacity and resources to facilitate product adoption (e.g., HCWs, training, supportive supervision etc.) amongst other factors.

Finding 3: The portfolio has catalysed demand for PO at the primary health care level, and to a lesser extent the CDSA. This appears to be strongly driven by alignment with national agendas on strengthening primary health care and the priority of introducing health technologies and improving quality of care. Financing of this demand is still heavily reliant on donor funding in most countries, creating uncertainty around the sustainability and scalability of PO use in the medium to long term.

Robustness: Strong, well supported in the documents review and consultations at the country level as well as with Unitaid and the grantees

There is a strong appetite to sustain PO adoption across countries overall as demonstrated by the integration of PO into national guidelines and as part of existing or future national oxygen roadmaps in all project countries. This strong demand is supported by several study findings: importantly that PO use was highly acceptable and feasible to be

[8] Prevalence of hypoxemia varied widely across countries in both TIMCI and AIRE and across age groups as recorded in the TIMCI project.

used by primary care providers, along with the finding in AIRE that PO identified a small proportion of severely ill children who otherwise would not have been treated as urgent cases. The absence of evidence within TIMCI that use of PO and the CDSA influenced clinical outcomes, and thus also lack of cost-effectiveness evidence, appears to be less influential. One theory, is that the high relevance of this portfolio to national priorities concerning improving primary care, has to an extent mitigated an over-reliance on study results to guide decision-making. In fact, several country and global stakeholders interviewed for this evaluation acknowledged it was unlikely the study design would demonstrate impact on child outcomes due to the health system bottlenecks described earlier not addressed by the intervention. Still, some study evidence, notably the reduction in antibiotic prescription practise where the CDSA was used, have garnered interest by decision-makers, as evidence that the intervention has improved clinical decision-making and provided some cost-saving to the health system.

The evaluation found that the projects tangibly contributed to enhancing country programmatic and operational readiness for PO adoption by strengthening the policy landscape. By the end of the projects**, all countries reported having included PO across relevant guidelines including in their IMCI guidelines** (e.g., Burkina Faso and Mali for AIRE, and India and Senegal for TIMCI)[9], as well as including it in wider relevant policies and plans. Many countries also confirmed having developed (or being in the process of developing) costed scale up and/or procurement plans (i.e., in all AIRE project countries) and/or oxygen roadmaps that incorporated PO (in Tanzania and under development in Kenya and Senegal)[10]. In addition, the grantees proactively identified existing relevant initiatives from other partners to capitalise on for further funding with some support from Unitaid to link to key global partners (e.g., Global Fund) although many shared that Unitaid support in that regard could have been improved. This includes leveraging available resources from oxygen strengthening initiatives and wider health and system strengthening programmes (e.g. World Bank/USAID funding for PO scale up on Niger, identifying synergies with UNICEF SPRINT program in Senegal and BMGF funded SOURCE program across TIMCI countries, advocating to including PO in Global Fund C19RM country funding requests, Global Financial Facility (GFF) country investment cases). Most TIMCI countries expressed desire to continue to use the CDSA (Kenya, Senegal and Tanzania). In India, the Government also showed interest in exploring the use of CDSA at other levels of care to support adherence to guidelines. The TIMCI country team created a concept note to support them in this regard.[11]

However, the projects had **limited emphasis on (and capacity for) budget advocacy especially regarding domestic financing** (particularly relevant for India). As a result, few countries identified opportunities for financing PO procurement through domestic resources (India and Kenya are exceptions)[12] leaving transition and scale up plans heavily reliant on funding allocations from donors.

Finding 4: The portfolio market shaping interventions contributed to raising awareness on available choices for pulse oximeters and next generation devices to promote demand, as well as generating valuable market intelligence outputs to promote better quality and availability of fit-for-purpose devices. However, it is unclear the extent to which these outputs will contribute to advancing the development of next generation pulse oximeters, especially in the absence of demand forecasts backed by evidence of funding.

Robustness: Moderate, mostly supported by documents review and consultations at global level.

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[9] In AIRE, Guinea and Niger reported being in the process of reviewing their IMCI guidelines to include PO at the time of this evaluation. In TIMCI, Tanzania reported having included PO in IMCI guidelines within the projects sites only and Kenya did not report having included it.

[10] Scale up plan were being developed in some TIMCI countries (e.g., Senegal) but paused for further consideration in light of the study results with the option to pivoting to developing a lessons learned document instead. Further country progress is expected during the May 2024 WHO oxygen roadmap meeting in Dakar.

[11] PATH (2023). *TIMCI annual report. Version of 15 February 2024*

[12] Except in India where health financing predominantly comes from domestic resources

Through its market shaping interventions, the **TIMCI project created many beneficial outputs to close the knowledge gap between industry and LMIC markets**, and support better demand and supply of pulse oximeters and next generation devices. This includes providing evidence of next generation devices usability and acceptability through various studies[13], increasing market intelligence on available products and providing critical information on technical specifications and regulatory requirements through the landscape report and target product profile (TPP). The market shaping intervention underwent a major redesign in 2021, pivoting from providing a financial incentive to manufacturers to generating market research and device performance data to influence the sector from the "bottom up". This was considered an appropriate shift by most stakeholders (predominantly as the value of the incentive was deemed insufficient, and that many products were already under development). However, whilst many country and global stakeholders viewed the revised outputs helpful, our consultations indicated **limited evidence of wider reach or use of key outputs such as the TPP and landscape by industry or global stakeholders**. It is also worth noting that this evaluation was conducted before the dissemination of the hybrid study results, and as such, we were unable to fully assess evidence of added value and utility of the study results by stakeholders.

Most importantly, whilst some countries have developed costed plans to quantify the needs for PO and support better procurement planning, stakeholders have raised that this would not represent a strong enough incentive to encourage investments on the manufacturers side to improve supply. In particular, they flagged the absence of concrete evidence of demand (e.g., procurement orders) or evidence of funding, to justify investments in the costly technological and regulatory updates required from manufacturers. In addition, the project activities did not necessarily target affordability factors to lower the costs of quality tools and stimulate country-led demand. As such, the interventions implemented may have limited direct acceleration effect on encouraging development or market entry of new tools.

Another consideration is that most of the manufacturers engaged by TIMCI are adding respiratory rate measurement to POs, which numerous experts consider adds only marginal value. **Expert consensus is that non-invasive measurement of haemoglobin (Hb) would bring a much larger quantum of impact** than respiratory rate, especially in areas of high anaemia (noting this is a shift from the prioritisation of respiratory rate (RR) among stakeholders surveyed in developing the TPP). As identified in the TIMCI landscape report on next generation pulse oximeters, non-invasive Hb measurement is a more nascent technology compared to PO, the sensitivity and specificity of available devices is sub-optimal, and devices are expensive.[14] Based on the manufacturers interviewed for this evaluation, we were not able to determine the extent TIMCI market shaping work has helped to advance non-invasive Hb devices. Unitaid support for the open oximetry project, while not evaluated here, appears a highly important investment area and as noted above is forward looking and pro-equity.

Finding 5: In countries where the CDSA was used, the TIMCI project highlighted the potential value of the tool in improving quality of care and data collection, in line with many national agendas. However, the sustainability and scale up of CDSA interventions is currently limited due to interoperability challenges compounded by a lack of necessary digital infrastructure and resources to sustain its use.

Robustness: Moderate, mostly supported by documents review and with some divergent views from stakeholders captured during consultations.

The study results and our country-level interviews reported some benefits in using the CDSA to promote quality of care including a **reduction in diagnosis-inappropriate systemic antibiotic prescription** (35.1% and 13.9% reduction in Kenya and Senegal respectively[15]) and small improvements in coverage of certain symptoms/signs in PO + CDSA arm/period in Tanzania and Kenya (though no improvements was reported in Senegal).[16] In terms of

[13] Usability and acceptability data reported from various countries in TIMCI Post-market Landscape on Masimo Rad-G Pulse Oximeter Device, Market Intelligence Report on Multimodal Devices and TIMCI Hybrid Study preliminary results

[14] PATH and UNITAID (2022). Next Generation Pulse Oximeters: Technology and Market Landscape

[15] STPH (2023). TIMCI Cross-country quasi-experimental pre-post study: Final Statistical Analysis Report (Kenya and Senegal)

[16] STPH (2024). TIMCI IAG January 2024 slide deck of preliminary findings

adherence to using the tool, outside of India, the project reported varied adherence across countries (e.g., 40.5% in Senegal, 76.6% in Kenya).[17] In India, the CDSA was ultimately discontinued due in part to an inadequate intervention design, limited time, and resources constraints for iteration based on initial piloting as well as limited scope for adaptation within the study protocol; Although our country level interviews found that it could have been a relevant intervention seeing the government efforts to digitise system and strengthen decision making from low-skilled health workers. This interest in the CDSA intervention was observed across all countries interviewed and aligned with existing efforts to standardize clinical practices, strengthen quality of care and improve data collection from interventions through digital tools. For example, in Kenya, stakeholders considered the CDSA was valuable to reduce differences in clinical practices by providers of varying skill level, along with assisting providers working in short-staffing conditions.

However, despite these results and the interest shown by countries, we found **key concerns over the possibility to sustain or scale the CDSA tool as currently designed across all project countries**, except in Burkina Faso which had an existing digital algorithm for IMCI implemented at the primary care level to which oxygen saturation measurement was added under the AIRE project.[18] Key issues identified include challenges with interoperability to integrate the tool in existing digital systems and a lack of human and financial resources to maintain and sustain the tool, amongst other challenges. In addition, the project consistently reported a significant increase in consultation time when using the CDSA tool, further reducing its chances of being sustained in facilities with high patient flow and constrained human resources (i.e. opposite to the experience in Kenya highlighted in the paragraph above). This highlights the need to identify the most appropriate level of care where sustained CDSA use can be feasible depending on country contexts.

Finding 6: The portfolio design was found to be comprehensive and well-structured using a combination of initiatives to enhance technical credibility and operational reach. This includes the use of a partners consortium to implement the grants, international advisory group (IAG), observer country and community and civil society engagement (CCSE) initiatives. Though in practice, some of them were found to have been limited in their efficiency and effectiveness due to contextual and implementation challenges.

Robustness: Strong, supported by majority of documents reviewed and stakeholder consultations.

The majority of stakeholders shared the finding that the design and implementation approaches used in this portfolio have been valuable though each faced various challenges in practice. Overall, the **use of a consortium of partners and selection of grantees with strong operational presence in the project countries enabled the portfolio to capitalise on each partner's strengths** and their existing credibility in country. The combination of two grants covering different geographical locations was also cited as a good initiative to increase the complementarity of evidence and reach of projects interventions. Although in practice, the portfolio was limited in its ability to leverage this complementarity (especially for the dissemination of research results) due to a misalignment in projects timelines amongst other reasons. Stakeholders also confirmed the value of having research studies integrated as part of the projects to strengthen evidence-based recommendations from the portfolio. In particular, the use of local research partners was a key element to promote a locally-led research approach, and increase contextual credibility and relevance to the studies. However, stakeholders suggested that the **portfolio over-emphasis on the research components and choice of research design came at the expense of flexibility in the wider implementation**. Notably, the selected study methods (e.g. RCT in India, Tanzania) and rigidity this imposed on projects, limited their ability to better adapt to contextual challenges. Stakeholders also noted that the research partners were not party to

[17] CDSA adherence was evaluated comparing the number of children enrolled and the number of records in the CDSA database. *STPH (2023). TIMCI Cross-country quasi-experimental pre-post study: Final Statistical Analysis Report (Kenya and Senegal)*

[18] In Burkina Faso, the project AIRE integrated its intervention as part of the existing Integrated eDiagnostic Approach (IeDA) project which was being scaled across the country and led by Terre des Hommes (part of the AIRE consortium).

the Unitaid/grantee discussions which brought about inefficiencies in the design of the studies. The shift to virtual planning during COVID-19 and responsibilities of local partners to support national COVID-19 responses also affected efficiency in study design.

Other approaches that stakeholders found beneficial in this portfolio include the use of an IAG, the observer country model and community and civil society engagement (CCSE) activities. The IAG, which included representation from relevant technical partners and donors, was a key structure to provide additional technical capacity and independent scientific and programmatic expertise to support the projects design and implementation. However, many stakeholders highlighted that **more could have been done to leverage the capacity and network of IAG members**. The "observer country model" (i.e. limited budget to transfer learnings from the project countries to non-project countries) was cited as a beneficial approach to extend the benefits and learnings from the projects beyond project countries. However, **the impact of the observer country model was found to be limited in the absence of catalytic support** (e.g., technical assistance, modest procurement of POs, or catalytic funding) to encourage uptake in early adopter observer countries. Finally, the CCSE approach was useful to support community sensitization and promote equity and inclusivity in the project implementation. Though, the approach was found to be a 'light touch' overall and significantly limited in its effectiveness due to time and capacity constraints in both projects (especially in AIRE).

3. RECOMMENDATIONS

Overall, the portfolio was highly relevant and contributed significantly to progress in the policy landscape to support PO adoption across project countries. The portfolio was instrumental in raising awareness on the lack of adapted tools to diagnose hypoxemia in children and newborns and, to a lesser extent, has generated nascent country demand for next-generation devices measuring vital signs among children. As a result of the portfolio's evidence-emphasis, significant information across eight high burden countries has been generated on the clinical features of children presenting at the primary care level, care seeking and referral patterns, provision of oxygen at hospitals for hypoxemic children along with other quantitative and qualitative data which could contribute to improved design of health interventions in these settings. In addition, the portfolio offers key lessons to maximise the effectiveness and impact of future interventions looking at introducing products at lower levels of the health system.

Based on the evaluation findings as well as subsequent discussions with Unitaid and grantees, the following recommendations are suggested, organised according to Unitaid's strategic objectives:

1 Accelerate the introduction and adoption of key health products

For this portfolio:

- **Ensure research results are packaged and disseminated appropriately, avoiding any knee-jerk rejection regarding use of POs adapted for children at PHC level** whilst also encouraging their nuanced and thoughtful introduction as part of a systems wide approach. This would include engaging in WHO's proposed global review of the evidence from TIMCI, AIRE and other studies.
- **Disseminate findings on pulse oximetry accuracy on darker skin pigmentations** to support greater equity in the development of medical devices.
- **Consider if there are any opportunities to build on the MM work under the portfolio –** particularly in terms of exploring options beyond respiratory rate such as non-invasive haemoglobin measurement, as well as furthering the impact of the numerous outputs produced under the projects by making them available for manufacturers, governments and donor partners.
- **Through Unitaid's partnerships, engage with Global Fund C19RM funding to encourage relevant PO funding for countries (including PO adapted for children) as well as oxygen systems development.** Where countries have secured financing for PO (e.g. Kenya), this includes engaging to track the extent funding is operationalised (e.g. through GO_2AL).
- Consider how to **facilitate country use of open access CDSA** which currently requires expert skills. This includes supporting translation of the algorithm into an easier to use format for countries and/or promoting national capacity building on specialist skills as part of national digital strategies.

For future Unitaid investments:

- **A more holistic approach to product and intervention introduction - particularly early in the continuum of care (e.g. community, primary level)** - could further enhance impact, considering the complexities and challenges at the primary level. This would include demand creation and social norms, referral decision making, quality at the point of care and referral sites, and referral linkages; with appropriate support depending on project objectives and local context (e.g. BCC approaches to encourage demand).
- **Maximise the 'observer/catalytic impact country' model**: If using a more 'observer based' model, ensure there is timely and regular engagement (e.g. site visits, webinars, timely and regular sharing of materials and tools), and potentially track this. For a more engaged/'early market access' model where more funding is available, provide modest catalytic funding, tailoring to country readiness. Both approaches should support south-south learning.
- Need to **better balance service delivery and research objectives in Unitaid investments**: Unitaid should think through the balance between service delivery and research objectives within its grants. This includes carefully considering the trade-offs of selected research methods and encouraging more adaptive designs (e.g., implementation research) where possible. Intervention measures of success should also be tailored in line with selected methods and achievable attributable outcomes - in particular, impact KPIs which are usually service delivery focused (e.g. number of lives saved was the impact KPI for this portfolio despite projects' limited influence on this impact).
- Evidence generation for interventions early in the care cascade should **interrogate the validity of the theory of change and its assumptions early in the project period** (e.g. through a baseline or formative period). This should include key components of the continuum of care such as referral decision making, referral systems, and care at referral sites.
- **Ensure digital investments are oriented to sustainability** from inception (e.g. interoperability, local leadership).

2 Create systemic conditions for sustainable, equitable access

- **Continue to support PHC development including linking with PPPR work**: Unitaid should continue to use its pathfinder and influencer role to encourage interventions at the PHC level, which forms the backbone of the health care system and assumes even more significance in the pandemic preparedness and resilience agenda.
- **Strengthen coordination in multi-partner evidence generation, and consider opportunities for greater involvement of local research partners** – align project timeline, and ensure coherence in the study design and data analysis plan to later have similar analytic outputs and facilitate comparability of results between grantees/studies. Build on learnings for engaging key consortium partners early in research design; consider greater inclusion of national research partners in study design – benefitting from their knowledge of local context and experience.
- **Interrogate advocacy goals and their level (global, country) in the design of new investments**, with consideration of the different needs and timing of advocacy efforts depending on the nature of the investment.
- **Expand WHO enabling support for future investments in the child health portfolio** to support greater visibility and alignment, with more regular WHO engagement.

3 Foster inclusive and demand-driven partnerships for innovation

- **Health systems investments potentially require more significant emphasis on country-level advocacy and dissemination** than other Unitaid portfolio areas, given the diversity of funding partners and policy contexts in project countries, and greater emphasis on domestic financing to sustain and scale. The nature and timing of country level advocacy may differ substantially and require flexibility to leverage local opportunities (e.g. budgetary reviews).
- Need for **Unitaid to potentially take a larger role in coalition building with a diversity of stakeholders in RMNCH** and specific technical areas (e.g. oxygen, PPPR) to build political and financing support for intervention adoption and scale – recognising health systems interventions lack the traditional 'scale up'

funders and advocates. There may be greater need for Unitaid support to facilitate linkages between grantees and financing partners than in other portfolios.

- Recognising Unitaid's evolution in CCSE since the 'Better Tools' project were conceived, interventions at community and primary level should **include CCSE as a key component in the project Theory of Change**, with adequate investment, period of engagement, and view to sustainability.
- Consider how to best leverage the **IAG** model and create adequate opportunities for IAG members to weigh in at key decision and analysis timepoints.

PART B

This section provides detailed findings by evaluation criteria across the evaluation questions.

4. RELEVANCE, COHERENCE

Table 4.1 provides an overview of sub-findings for EQ1. Relevance and EQ2. Coherence presented under this section with further detail provided under each evaluation question.

Table 4.1: Relevance and Coherence sub-findings

Section sub-findings	Robustness rating
1. The portfolio targeted a key strategic priority on national and global health agendas in terms of reduction of under-5 mortality and the lack of adapted POs to support hypoxemia detection in children, making it highly relevant and responsive to public health needs in countries.	Strong
2. Both TIMCI and AIRE were implemented at an opportune time and targeted key policy and programmatic gaps in LMICs.	Strong
3. Redesign of the TIMCI market shaping interventions was seen as an appropriate shift from the original plan and the new proposed activities were deemed forward looking overall but limited in their catalytic ambition. There were useful adaptations following the COVID-19 pandemic to generate insights on multimodal device use	Moderate
4. There was a strong interest across project country governments to standardise clinical practices, strengthen quality of care and improve data collection through digital health tools which highlighted the relevance of the CDSA component of the portfolio; however the appropriateness varied by country.	Moderate
5. The research studies were seen as valuable components of the portfolio, although the approach taken limited contextual adaptions – to the detriment of wider implementation.	Moderate
6. Throughout its implementation, the TIMCI and AIRE projects maximised alignment and synergy with national stakeholders and relevant partners.	Moderate
7. Local consortia and especially research partners in both grants further enhanced the project credibility and relevance in countries.	Strong
8. Stakeholders unanimously confirmed Unitaid instrumental role in positioning PO and oxygen systems on the global health agenda initially through ACT-A and subsequently through GO_2AL, with an important foundation established through this portfolio	Strong
9. Though COVID-19 responses did not raise awareness for and scale quality PO, adapted to all age groups - Unitaid's role in GO_2AL is a critical opportunity to advocate for integration and procurement of adapted PO as part of broader oxygen roadmaps	Strong

4.1. EQ1 – Relevance

1. To what extent has the investment design and implementation responded appropriately to community needs? Did the projects suitably adapt to changes in context including particularly the COVID-19 pandemic?

The first evaluation question focuses on the relevance of the portfolio, including its continued relevance over time in terms of whether any lessons learnt or changing circumstances (like COVID-19) led to appropriate adaptations. Key findings are presented below by theme. The findings are largely based on consultations – global and country level.

Strategic focus and timely interventions

- **The portfolio targeted a key strategic priority on national and global health agendas in terms of reduction of under-5 mortality and the lack of adapted POs to support hypoxemia detection in children, making it highly relevant and responsive to public health needs in countries**. Globally, acute respiratory infections, such as pneumonia are amongst the leading causes of death for children under 5.[19] By focusing on pulse oximeter adoption through primary healthcare, the projects aimed to tackle key drivers of child mortality including the lack of tools to identify severe disease such as pneumonia and the limited access to timely quality services through primary health care. The pandemic popularized the use of pulse oximeters in all countries as portable (fingertip) POs became widely accessible and used in both clinical settings including PHCs and in homes.[20] However the majority of stakeholders recognised that in many cases, inadequate pulse oximeters (i.e., without the right probes) were being used on young children including in clinical settings, leading to inaccurate reading of oxygen saturation and suboptimal care of severely ill children. The pandemic also highlighted concerns regarding the accuracy of pulse oximetry on people with high levels of skin pigmentation, an issue which had been known for a while but had attracted little attention until then.[21] The portfolio was also positioned strategically to intervene in the two geographical regions that account for the majority of under-5 mortality, sub-Saharan Africa (including the Sahel region) and southern Asia, which account for more than 80% of total under-5 deaths globally.

- **Both TIMCI and AIRE were implemented at an opportune time and targeted key policy, programmatic and regulatory gaps in LMICs and at global level.** The projects were implemented at a time when most countries were looking at updating and/or harmonising relevant child health policies (e.g., IMCI and pneumonia guidelines) and increasing access to primary healthcare services for children. Mali, for example, had already prioritised access to PO at national level for neonatal asphyxia and was interested in identifying the cost of introducing PO. At the global level, WHO was also planning to start the review of the global pneumonia guidelines which presented a key opportunity for the portfolio to provide relevant evidence and inform the guideline updates. In addition, strengthening primary healthcare and increasing capacity of health care at lower levels was a key agenda item across project countries to enhance equitable and timely access to lifesaving care. For instance, both Senegal and Burkina Faso had adopted a national policy to enable free access to primary care services for children under five and were keen to encourage access to health care through PHCs, and Kenya had prioritized primary care within the Universal Health Coverage (UHC) strategy. The portfolio was also timely in terms of its implementation which preceded the COVID-19 pandemic (and thereby can be viewed as fairly forward-looking given the emphasis on oxygen systems today), although implementation during the COVID-19 pandemic brought its own sets of challenges as elaborated in section 2.2. However, the pandemic also provided a number of opportunities for this portfolio including enabling the projects to capitalise on the increased attention on oxygen, to identify synergies and opportunities for PO integration within existing oxygen systems strengthening investments.

  The recent pandemic brought to the surface existing concerns around PO variability on darker skins that could result in suboptimal clinical care and different patient outcomes. Whilst known for decades, this issue has received limited attention until now according to stakeholders despite its implications for a considerable proportion of the global population especially in LMICs. As such, the reprogramming of the TIMCI project and subsequent addition of output 8 to assess pulse oximetry performance on darker skin pigmentation further increased the relevance and equity approach of this portfolio. Stakeholders agreed that this provides a timely opportunity to leverage current global and countries efforts around access to oxygen to raise awareness on this issue, address current gaps in policy and regulatory processes and promote more equitable care through appropriate pulse oximeters. However, they highlight that results from this work may have less impact on LMICs in the short term given the

[19] WHO (2024). The global health observatory. Child mortality and causes of death.

[20] Stell et al (2021). Exploring the impact of pulse oximeter selection within the COVID-19 home-use pulse oximetry pathways.

[21] Shi et al (2022). The accuracy of pulse oximetry in measuring oxygen saturation by levels of skin pigmentation: a systematic review and meta-analysis

limited resource context but could help accelerate research and stimulate engagement on this issue (e.g., through the open access data repository accessible for free to all as a public good).

> *"This portfolio was very timely with regards to COVID as it provided an opportunity to have PO at [the] lower level and created a good momentum to ask country Ministries of Health to invest in these tools" - Global stakeholder*
>
> *"Current IMCI guidelines need to be more nuanced on the role of PO which is a gap. PO has clear role in risk stratification which is under-utilised in PHC and hospital level" - Global stakeholder*

- **Redesign of the TIMCI market shaping interventions was seen as an appropriate shift from the original plan and the new proposed activities were deemed forward looking overall but limited in their catalytic ambition. There were useful adaptations following the COVID-19 pandemic to generate insights on multimodal device use.** The TIMCI market shaping interventions were originally designed to include incentives (financial awards or technical assistance) to encourage the development of MMs from select manufacturers. This was later changed in 2021 to remove the incentive and add of a new set of activities including an evaluation of the implementation of an approved next generation device at PHC level as part of a hybrid study.[22] TIMCI also leveraged the opportunity presented by the COVID-19 pandemic[23] to conduct a post-market landscape on the Masimo Rad-G PO device in several African countries to increase understanding of multimodal devices acceptability in these contexts, and gather intelligence on issues such as provider training and maintenance needs. The TIMCI re-designed package of market interventions were relevant in establishing foundations for further development of next-generation POs by filling existing evidence gap (e.g., through the landscape analysis of next generation POs and development of TPPs for next-generation PO) and generating evidence to stimulate both demand and supply. These outputs come to complement available tools and existing intelligence in this area[24] to close a persisting knowledge gap according to stakeholders. As such, it would be fair to consider the portfolio's market shaping work as foundational rather than catalytic, as key manufacturer concerns, such as providing evidence of LMIC-committed demand, were beyond the project scope, as was the development of any particular next-generation devices.[25] There is also a dissonance between expert consensus that improvement in the performance of non-invasive haemoglobin (Hb) measurement offers significant impact potential, and the focus on adding respiratory rate to POs among the manufacturers engaged within the TIMCI coalition (as respiratory rate, while a 'low hanging fruit' functionally, is considered as having only marginal effect on clinical assessment). This may reflect a shift in expert opinion, as stakeholder surveys to develop the TPP initially prioritised respiratory rate for multi-modal devices.

  There was a strong interest across project country governments to standardise clinical practices, strengthen quality of care and improve data collection through digital health tools which highlighted the relevance of the CDSA component of the portfolio; however the appropriateness varied by country. Stakeholders reported that many project countries were already interested in developing their digital health

[22] The hybrid study included 3 main components, 1) a usability and diagnostic accuracy study of 6 benchmarked next generation devices in 2 facilities in Kenya, Tanzania and India, 2) a human-centered co-creation workshop to capture users' insights on products and co-design the integration of a select device in the implementation study and 3) implement the implementation study in 2 facilities in Kenya, Tanzania and Senegal. TIMCI (2024). TIMCI Hybrid Study preliminary results presentation. Version of 14 March 2024

[23] In 2022, PATH supported the procurement and distribution of 1,661 Rad-G multimodal devices for use in health facilities in Malawi, Senegal, Zambia, and the DRC using ACT-A funding. Although donated for COVID-19 response, devices were utilized across a wide range of health conditions and health facility settings including inpatient and outpatient units as well as on paediatric patients.

[24] Existing tools to support demand for POs and MMs include guidance on adapted PO to procure for LMICs such as UNICEF existing Pulse Oximeter Target Product Profile and Technical Specifications and Guidance For Oxygen Therapy Devices, as well as available evidence on MMs usability and acceptability in LMIC contexts (e.g., Baker et al, 2021; Sarin et al, 2021).

[25] As a comparison, the Bill and Melinda Gates Foundation historically invested to help develop the Masimo Rad-G PO which is now widely used in LMICs. *PATH and UNITAID (2022). Next Generation Pulse Oximeters: Technology and Market Landscape*

strategies and promoting the use of digital tools to strengthen quality of care and data monitoring. In Tanzania for example, the Government was implementing the Data Use Partnership, to digitalize PHC and enhance patient management across the continuum of care to strengthen health service delivery. The government was also in the process of developing the Tanzania Health Enterprise Architecture, to address interoperability issues in the digital ecosystem and standardise the use of data across the health sector.[26] In India, the government showed interest in integrating existing health digital tools and increasing digital health literacy amongst HCWs. It was notably implementing technology and web-enabled systems as part of the health management information system, Electronic Medical Records (EMRs), and supply chain management.[27] In this sense, the CDSA component of the TIMCI grant was found to be aligned with existing national initiatives. Country stakeholders were also interested in the CDSA potential to address the need for better clinical decision making and adherence to protocols, and to provide a tool can enable patient data to be aggregated more efficiently and reviewed centrally. National stakeholders were engaged to update the CDSA algorithm and align its clinical content to national protocols, thus supporting local relevance. Ultimately however, the appropriateness of CDSA tool as intervention was highly variable across country contexts. This was especially the case in India where the CDSA was ultimately discontinued due to challenges in implementing the intervention as designed for the Indian high-footfall facility context. Stakeholders also highlighted that the CDSA intervention was introduced at a time where digital ecosystems were still nascent in most TIMCI countries which limited the feasibility of now integrating the tool with maturing digital systems.

Limited scope for contextual adaptation in the project study design

- **The research studies were seen as valuable components of the portfolio, although the approach taken limited contextual adaptions – to the detriment of wider implementation.** Stakeholders viewed that the integration of research studies as part of the portfolio was valuable to generate contextual evidence and promote evidence-based decision making. In addition, the geographical coverage of the two grants provided an opportunity to generate evidence across a range of contexts and increase the relevance of the portfolio beyond project countries. However, stakeholders shared that the selected research methods allowed little flexibility to adapt the studies to country contexts. In particular, in India, the chosen research method (RCT) strongly limited possibilities to adjust the CDSA intervention to the context in public health settings in India. In addition, whilst stakeholders recognised the global and country significance of the project research, many countries had effectively updated their guidelines, policies and tools before the study results were made available (as was the case in Senegal, Kenya and Niger for example). Across many project countries, governments' decision to integrate PO in policies was mostly driven by pre-existing willingness to implement updates in that direction and further encouraged by insights from the project implementation and advocacy efforts in general. As such, the importance attached to the study results as a key factor to influence country decision around PO integration in national policies may have been overestimated (though noting this evidence was required by India and Tanzania prior to making any policy updates).

  Several stakeholders (country and global level) indicated they did not expect the TIMCI study to measurably impact child outcomes, as the intervention scope did not include referral system strengthening, nor improving the availability of oxygen and quality care at referral sites (though some minor strengthening was done at referral facilities included in the study). While these views may be influenced by hindsight, the relevance of the outcome study design is questioned. The design of the RCT, while bringing methodological rigour, was also such that program data were not routinely monitored – which precluded Unitaid and project staff from understanding the strength of intervention implementation (e.g. adherence to CDSA recommendations, referral rates) and possibly making adaptations to improve performance.

[26] PATH (2019). TIMCI project plan

[27] PATH (2019). TIMCI project plan

4.2. EQ2 – Coherence

2. How well did the investments and Unitaid add value and maximize alignment and synergies with global partners, governments, in-country stakeholders, and CSOs during planning, implementation and assessment to promote adoption and scale-up of PO within existing health systems? To what extent did implementers and Unitaid contribute to further development of global alliances/partnerships to support scale-up and sustainability of products supported through the investment?

The second evaluation question focuses on the evaluation criteria of coherence (coordination, alignment, synergies), both in terms of the approach to project implementation at the country level and harnessing of synergies at the global level. Key findings are presented below by theme. The findings are largely based on consultations – global and country level.

Integrated and coordinated approach

- **Throughout its implementation, the TIMCI and AIRE projects maximised alignment and synergy with national stakeholders and relevant partners.** Government stakeholders highlighted the significant involvement of national authorities in the projects' design and throughout implementation, which promoted country ownership and increased opportunities for policy adoption. Across countries, the TIMCI and AIRE project teams engaged a wide range of national stakeholders beyond government authorities, including civil society organisations, community and religious leaders, academia, community health workers and healthcare providers. Community and civil society engagement (CCSE) activities were designed and implemented in collaboration with national partners and leveraged existing HCW and CSO structures to increase the relevance of awareness raising and advocacy activities (details on CCSE activities is further elaborated under Section 2.2.1). In addition, both projects leveraged national systems to deliver their interventions by integrating projects interventions in existing facilities, streamlining supportive activities in national processes including training, supervision and procurement activities. The portfolio also actively engaged relevant global partners at both country and global level, notably through the International Advisory Group (IAG) which included representatives from key technical and donor organisations such as WHO, UNICEF, Global Fund, BMGF, USAID and CHAI. At the country level, the projects reported engaging with key partners such as WHO and UNICEF national teams, which facilitated better alignment between the projects and relevant partners.

- **Involvement of local consortia and especially research partners in both grants further enhanced the project credibility and relevance in countries.** By selecting grantees that already had a strong presence across project countries, the project was able to capitalise on grantees' existing credibility, contextual knowledge and relationships with national stakeholders. In Burkina Faso, feedback from government officials suggested that the reputation of Terre des Hommes (TdH), who had successfully led previous key interventions in the country[28], increased government confidence and buy-in into the AIRE project. In particular, the projects collaboration with local research partners was viewed as highly beneficial to foster a country led approach in the research, leverage national expertise and facilitate better uptake of research findings later on. In India for example, stakeholders shared that the project partnership with King George's Medical University (KGMU) increased the project profile and strengthened its influence on government decision making. Stakeholders indicated that more coordinated engagement between the local research partners and Unitaid and the grantees would help ensure more relevant research design (see also next section on EQ3).

Fostering global alliances for O2 and PO

- **Stakeholders unanimously confirmed Unitaid's instrumental role in positioning PO and oxygen systems on the global health agenda initially through ACT-A and subsequently through GO$_2$AL, with an important foundation established through this portfolio**. Through the TIMCI and AIRE projects, Unitaid was positioned as a key global partner in the child health and oxygen space, and expanded its leadership beyond its traditional HTM mandate (Box 4.1). Stakeholders unanimously commended Unitaid for stepping up at a critical time to fill a

[28] This include leading the successful leDA-REC pilot and scale-up in partnership with the government.

key gap at global level by taking a leadership role initially in the Access to COVID-19 Tools Accelerator (ACT-A) and subsequently the Global Oxygen Alliance (GO_2AL) to elevate the profile of medical oxygen and related accessories such as pulse oximeters. They viewed Unitaid's role as instrumental for bringing together key global health partners and public health entities under ACT-A, including intergovernmental and regional agencies, during critical phases of the pandemic. This collaboration significantly enhanced coordination efforts to streamline partner operations as they responded to a global emergency of unprecedented scale, and enabled fast resource mobilisation to strengthen vital COVID-19 responses (including by mobilizing over US$ 1 billion for oxygen provision). Unitaid also provided additional funding to the AIRE and TIMCI grants to support COVID-19 responses in countries. In doing so, Unitaid provided an opportune source of catalytic investments to support COVID-19 responses in countries early in the pandemic, further highlighting Unitaid's adaptability and responsiveness in crisis situations.

"Unitaid was clearly responsible for setting up GOAL – including providing funding and overseeing the development of strategy. They took a leadership role in both ACT-A and GOAL. If they had not done that, [the work on oxygen] wouldn't have progressed much as it was barely moving at the time"
– Global stakeholder

"Without Unitaid, it's likely that we wouldn't have had the ACT-A work, and thus wouldn't have GOAL.
– Global stakeholder

Box 4.1. The portfolio exemplifies Unitaid's role as pathfinder and influencer

The 'Better Tools' portfolio was forward looking of Unitaid – first with respect to the "orphan" issue of hypoxemia in children and the introduction of an effective tool (pulse oximetry) which was not accessible in primary settings, and where there were gaps in awareness and use of devices appropriate for children. Further, the portfolio was people-centered/ disease-agnostic and fundamentally part of a health systems strengthening approach – with people-centeredness strengthened through adding assessment of PO performance on darker skin pigmentation to the portfolio.

Critically, the biggest legacy of the portfolio was to provide Unitaid with 'know how' and networks to respond to the COVID-19 pandemic. Unitaid's subsequent leadership on oxygen during the COVID-19 pandemic and later GO_2AL have since further solidified Unitaid's pivotal role in this area.

As one of Unitaid's earlier investments intervening within the health system (as compared to disease-specific focus), key learnings with respect to Unitaid's pathfinder and influencer role include:

- Need for Unitaid to potentially take a larger role in coalition building with a diversity of stakeholders in RMNCH and specific technical areas (e.g. oxygen, PPPR) to build political and financing support for intervention adoption and sale – recognising health systems interventions lack the traditional 'scale up' funders and advocates. For child hypoxemia and availability of pulse oximetry (and oxygen), this includes engaging with diverse coalitions in maternal, newborn and child health, in primary health care, as well as specific technical areas and funding sources such as oxygen roadmaps, Global Fund C19RM etc. In this regard, there may be greater need for Unitaid support to facilitate linkages between grantees and financing partners than in other portfolios.
- There is potentially a more significant role for country-level advocacy and dissemination than other Unitaid portfolio areas, given the diversity of funding partners and policy contexts in project countries, and greater emphasis on domestic financing to sustain and scale certain health system interventions (where decentralisation of health budgets is another consideration). Country advocacy may necessitate flexibility in timing to best leverage opportunities (e.g. linking to annual budgets cycles).

- **Though COVID-19 responses did not raise awareness for and scale quality PO adapted to all age groups - Unitaid's role in GO_2AL is a critical opportunity to advocate for integration and procurement of adapted PO as part of broader oxygen roadmaps.** During the pandemic, global and country attention (rightly) focused on secondary and tertiary care and on adults given epidemiologic and clinical features of the disease. Efforts to scale access to oxygen and PO were oriented to these areas, which to some extent came at the expense of resourcing in PHCs and focus on children. In addition, whilst the pandemic popularised PO in all countries, according to stakeholders the majority of POs procured for COVID-19 were fingertip PO which are less accurate in children. This includes POs procured for hospitals and secondary healthcare settings. This response may have represented a missed opportunity for Unitaid to leverage the work done through ACT-A and early period of GO_2AL to raise awareness on the need for quality PO across partners and in countries and encourage procurement of tools adapted to all age groups through COVID-19 responses and their re-programming to PPPR. As Unitaid continues to co-chair GO_2AL, its role is viewed as a key opportunity to advocate for sustained access to oxygen and quality POs appropriate for all age groups as part of broader oxygen roadmaps.

Relevance and Coherence – Key Lessons and Insights

- Policy objectives and the required supporting evidence should be interrogated at both the global and country level as part of investment design. In this portfolio, many countries were already interested in introducing PO at the primary level with questions on how to integrate within IMCI, and so have had different evidence needs. Engaging early with local research partners to articulate evidence priorities could support this. The overall study design also limited the opportunity to iterate the intervention design and adapt to local context, especially for the CDSA in India.
- Introduction of health products at lower levels of the health system need to consider the supporting health systems investments required for intervention impact (e.g. referral system, quality improvements at referral sites). The focus by countries on Universal Health Coverage and expanding primary healthcare means that Unitaid investments working at the primary care level are likely to be coherent with country priorities, increasing the likelihood of their sustainability.
- The strong integration of the projects with national and sub-national governments and bodies, along with partners with existing country relationships, supported uptake of the interventions within the health system.
- Digital investments need to be more locally driven and owned, and consider interoperability with national digital systems from the start. Country digital health systems have matured since this portfolio was conceived which may present opportunities in the future.
- Unitaid was pivotal in the COVID-19 oxygen response through ACT-A. While the focus of oxygen investments during the COVID-19 pandemic was on tertiary care an adults, GO_2AL is an important vehicle to continue to advocate for appropriate PO devices for children and health system access to oxygen as part of country oxygen roadmaps.

5. EFFICIENCY

Table 5.1 provides an overview of sub-findings for EQ3. on efficiency with further details provided below under the evaluation question.

Table 5.1: Efficiency sub-findings

Section sub-findings	Robustness rating
10. The projects reported significant delays (across design, implementation and research studies) due to COVID-19 and a range of country-specific factors external to the projects which affected their overall efficiency.	Strong
11. Both AIRE and TIMCI engaged a wide range of community and civil society actors throughout the projects though these activities were limited in their efficiency and effectiveness due to budget and time constraints.	Moderate

Section sub-findings	Robustness rating
12. The portfolio has had important benefits, but not in the traditional way that Unitaid considers VfM of its investments.	Moderate

5.1. EQ3 – Implementation efficiency

3. How timely, cost-efficient and cost-effective was implementation and what factors have been considered to ensure that value for money has been achieved from an efficiency standpoint? How effectively have risks been identified and managed during programme implementation?

This question focusses on the evaluation of the grants in terms of their overall efficiency and examines how the projects ensured value for money.

- **The projects reported significant delays (across design, implementation and research studies) due to COVID-19 and a range of country-specific factors external to the projects which affected their overall efficiency.** COVID-19 was the lead factor in disruption of original milestones, as the projects were originally planned to start in 2019 but were delayed to 2021 due to the pandemic. In-country restrictions due to the pandemic continued to impact the project beyond 2021 when the projects had started, including limiting the capacity of the project team to engage with stakeholders, hindering the implementation of key activities such as procurement and supply of commodities. Stakeholders also flagged these restrictions may have potentially influenced health seeking behaviours which may have impacted enrolment into the research projects and uptake of PHC services during the study period. A no-cost extension was provided to both projects to provide additional time to adapt to delays from COVID-19, but both projects still required comprehensive re-prioritization of their activities to fit available budget. The most notable consequences included: i) shortening of the project time for advocacy and dissemination, most critically for AIRE which had very brief dissemination; ii) misalignment of complementary project activities (e.g., TIMCI CCSE activities in awareness raising and care-seeking ending before completion of the study period as outlined below[29]); and iii) different time periods between the two projects where AIRE was completed ~8 months before the TIMCI project.

  Beyond the COVID-19 pandemic, the projects also reported critical challenges in countries resulting in delays including the political instability in Myanmar which led to a cancelling the project in the country. Political instability was also reported in Burkina Faso as well as other challenges such as the HCP strike in Senegal and high staff turnover in India which exacerbated these delays and further hindered project efficiency.

  Furthermore, stakeholders highlighted significant delays in the design of the research component of the projects initially due to the pandemic and further exacerbated by lengthy approval processes (with Unitaid and various research ethics committees). On this, there was high consensus that limited inclusion of research partners (STPH and Inserm) in design discussions with Unitaid created inefficiencies, particularly given the complexity of the study designs and parallel planning between TIMCI and AIRE. This may have contributed to the projects not having aligned data analysis plans which would have supported a more cohesive analysis and comparison between countries (noting there is an opportunity for more direct comparison through further analysis).

- **Both AIRE and TIMCI engaged a wide range of community and civil society actors throughout the projects though these activities were limited in their efficiency and effectiveness due to budget and time constraints.** This was especially the case for AIRE in which community and civil society actors were invited to participate in the implementation of project activities but received minimal to no funding from the project to

[29] In both Kenya and India, CCSE implementation was approximately 6 months, excluding project planning time. CCSE was not extended to align with revised data collection periods, and it was indicated this was due to budget constraints.

conduct activities.[30,31] In Guinea for example, CCSE activities included training CHWs to raise awareness in the community and wider civil society, however community activities were highly hindered due to challenges with government payment of CHWs financial incentives. In Burkina Faso, local *Agents de santé à base communautaire* (ASBCs) faced various challenges hampering the implementation of CCSE activities including recurrent issues in payment of their financial allowances from the government and competing priorities especially during growing season when they manage crops.

TIMCI CCSE activities mostly faced similar challenges but demonstrated some initiatives to respond to implementation challenges and strengthen CCSE efficiency.[32] In India, community health volunteers ("Accredited Social Health Activist" or ASHA) received introductory and refresher trainings, but the time to conduct awareness raising activities was very short and CHVs reported being overburdened with multiple government programmes, leaving limited capacity to implement these activities effectively. In Kenya, community mobilisation was well regarded and leveraged existing community structures, but was under-resourced and ended prior to completion of the project study which had been extended to reach the sample size. On the other hand, in Senegal TIMCI was able to extend CSO contracts for an additional six months to align CCSE interventions with the study timeline. In Tanzania, TIMCI reported switching to direct engagement of CHWs for community awareness from the original plan to implement through CSOs. This was done in an effort to increase cost-effectiveness and efficiency following an assessment of CSO performance which highlighted suboptimal reach into communities (due to their own funding challenges).

- **The portfolio has had important benefits, but not in the traditional way that Unitaid considers VfM of its investments.** As discussed at length in the next section on effectiveness, the projects have shown multiple benefits or "value" in terms of supporting country policy updates for POs, overall country interest and demand, etc.; however the challenge is that the research results do not indicate straightforward adoption and uptake of adapted POs for children at the PHC level, likely as broader system level improvements are needed for PO introduction to lead to improvement in health outcomes. As such, portfolio closure will not result in the traditional catalytic and VfM impact of Unitaid's work where donors/ government scale-up the intervention. Indeed, the portfolio results mean that tailored implementation research is needed to understand how to best implement PO within existing health systems and how to strengthen the pathway to impact (through a more comprehensive set of interventions that address the gaps along the cascade of care). The market shaping work as well on multi-modal devices has had an incremental benefit, but also does not show catalytic impact in terms of product availability and supplier improvements – although it is noted that some uptake of this work may be beyond the timeline of this evaluation.

Efficiency – Key Lessons and Insights

- Investments which intervene within complex health systems may not exhibit the traditional VfM pathway (e.g. evidence leading to financing for scale) of other Unitaid portfolios. Scale up and influence may run a longer course and be through more channels compared to disease-specific portfolios.
- Evidence generation within the same portfolio should have a common data analysis plan, and (if relevant) ideally be completed in a similar timeframe to support comparability of results and leverage the entirety of the portfolio in dissemination and advocacy.
- Demand generation (e.g. through community and civil society engagement) should be implemented 'in-sync' with supply-side interventions where relevant, ideally underpinned in the project theory of change.

[30] AIRE countries had no funding provided to CHWs and CSOs except in Niger where funding was provided for the implementation of community activities. A one off financial allowance was also provided to ASBCs in Burkina Faso to cover activities related costs but ASBCs main allowance remained under the responsibility of the government. CSO received no payment at all from the project on the other hand but the project was able to leverage UNICEF existing financial support to CSOs to implement its activities.

[31] AIRE (2023) Final AIRE Research Results Report

[32] TIMCI (2023). Narrative 2022 annual project report

6. EFFECTIVENESS, IMPACT, SUSTAINABILITY AND SCALABILITY

The section below presents sub-findings for EQ4-7 regarding the portfolio effectiveness, impact, sustainability and scalability as outlined in Table 6.1 with further details subsequently provided under each evaluation question.

Table 6.1: Effectiveness, impact, sustainability and scalability sub-findings

Section sub-findings	Robustness rating
EQ4 – Tools adoption and scale-up	
22. Research findings pertaining to the pathway for adoption of PO and CDSA and their effect on health outcomes are mixed and not immediately compelling for scale, but offer a number of good findings regarding management of severe illness among children across diverse contexts and health systems factors influencing outcomes.	Moderate
23. Both AIRE and TIMCI studies highlighted a number of factors at play in referral decisions including availability of transport, costs, and caregiver autonomy, with referral decision tending to be the outcome of exchanges between health provider and caregiver.	Strong
24. All countries reported good acceptance of PO by healthcare providers and significant policy progress and commitment towards adopting child friendly POs to enable better detection of severe disease. Stakeholders unanimously recognized that the full impact of PO introduction can only be achieved if integrated as part of a "whole of systems approach".	Strong
25. The observer countries approach was highlighted as a cost efficient initiative to extend the portfolio benefits beyond the project countries. Though whilst there was evidence of positive influence across observer countries, the effectiveness of this approach was limited overall due to minimal engagement and lack of catalytic support	Moderate
EQ.5 – Next generation devices	
26. Stakeholders recognised the overall value of the market shaping evidence generated through the TIMCI project in providing evidence and market intelligence on existing appetite as well as potential demand and supply for next generation multimodal devices (MMs).	Moderate
27. The work under the market shaping interventions was found to be foundational rather than catalytic as, by design, it did not cover some key market barriers (such as demonstrating funded demand to manufacturers or addressing the issues of affordability) to encourage market entry and product availability.	Moderate
EQ.6 – Knowledge dissemination	
28. TIMCI and AIRE advocacy and knowledge sharing throughout project implementation was highly contributed to drive policy changes at national level within project countries. However, dissemination of the final research results at both the national and global level was compressed due to projects delays. As a result, it is too soon to assess the effectiveness, impact and influence of evidence generated through this portfolio.	Strong

6.1. EQ4 – TOOLS ADOPTION AND SCALE-UP

4. What progress was made in facilitating demand, adoption and scale up of PO within target countries and beyond (including observer countries), how impactful and sustainable are these gains and what gaps remain? What have been the main factors influencing the adoption and scale-up?

This evaluation question first examines the demand and adoption of PO and supporting tools at the primary care level and their influence on provider practises, health outcomes and impact, evidenced by the studies conducted by the project research consortia, assessed against the portfolio Theory of Change. It then assesses the extent the projects

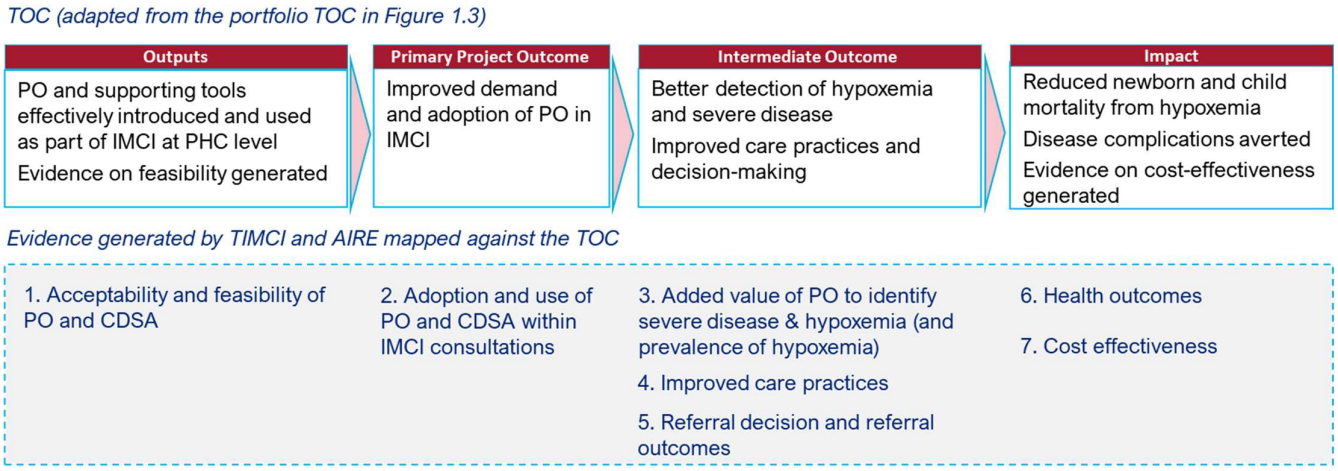
have supported an increased demand and uptake for POs at the PHC level in project countries and beyond through influencing national policies and financing. Implications on sustainability and scale up are assessed, and the range of factors determining country and global adoption and scalability.

Demand and adoption of PO and supporting tools, and effect on health outcomes and impact

TIMCI and AIRE generated evidence of acceptability, feasibility and uptake of PO and supporting tools at the primary care level, the effect on detection of hypoxemia and on care practices and decision-making – including referral, and health impacts of the interventions. This evidence is mapped against a simplified portfolio Theory of Change in figure 6.1, focused on aspects of the clinical care pathway. As both projects intervened predominantly at the primary care level, some measures captured by TIMCI and AIRE, particularly regarding referral and impact on mortality and disease complications, as previously noted are less within the projects' control.

To note, the projects employed different study designs across a diversity of child mortality and health systems contexts: i) the AIRE study involved a mixed-methods evaluation of the routine implementation of pulse oximeters into IMCI guidelines at PHC level in West Africa (Burkina Faso, Guinea, Mali and Niger); whilst ii) TIMCI research involved an evaluation of PO and CDSAs in primary care, through a cross-country quasi-experimental cost and modelled cost-effectiveness pre-post study in Kenya and Senegal and a pragmatic cluster RCT and cost and cost-effectiveness study in India and Tanzania. AIRE and TIMCI also had slightly different criteria for use of PO during IMCI consultations.[33]

Figure 6.1: Impact pathway as defined in the portfolio Theory of Change, and supporting evidence generated



Research findings pertaining to the pathway for adoption of PO and CDSA and their effect on health outcomes are mixed and not immediately compelling for scale, but with a number of good findings regarding management of severe illness among children across diverse contexts and health systems factors influencing outcomes. Key study findings against the impact pathway are unpacked below. All data presented pertaining to the indicators in figure 6.1 are based on analysis produced by the TIMCI and AIRE studies available at the time of this report.

PO use as part of IMCI consultations was broadly highly acceptable by health providers and patients. In TIMCI sites, CDSA acceptability by providers was more varied (and not accepted in India), with the most significant challenge cited as the time burden in low resource contexts.

- Across both TIMCI and AIRE, the tools were acceptable to providers (with the exception of the CDSA in India), with cited benefits including: use of PO improved diagnostic capacity, ease of PO use for those trained, helped

[33] Note that India does not use IMCI and so PO was used outside IMCI.

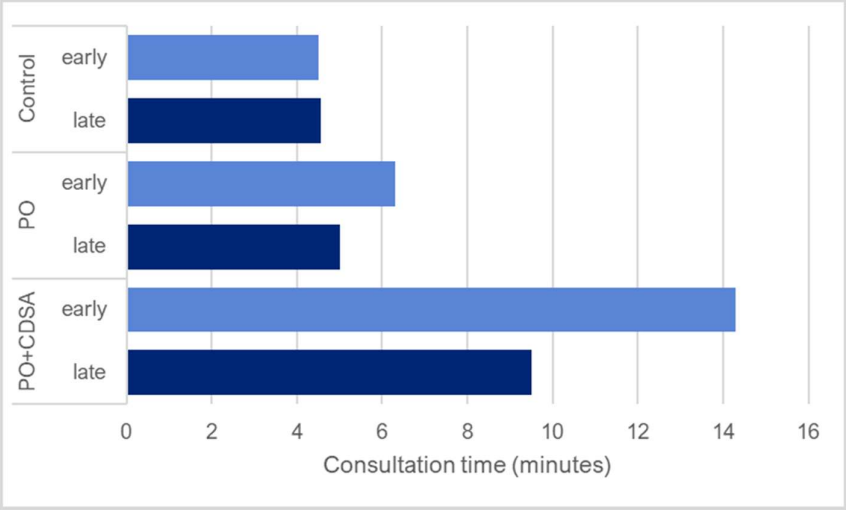
to make faster decisions, and improved the image and attendance at the health center. In AIRE sites, after six months of use 63% of HCPs viewed that PO and behaviours required to use it are not complicated and 69% perceived benefits from using the PO. Providers viewed the CDSA increased confidence in diagnosis and referral decisions and in most instances was an appropriate solution for their challenging context (refer to Box 6.1). Evidence from TIMCI also identified trust issues where certain providers did not always believe the PO reading or CDSA diagnosis to be accurate (which may reflect both the good practise of questioning results, and/or non-evidence-based practices).

Box 6.1: Acceptability of the CDSA in Kenya

In Kenya the CDSA was viewed positively by both health care providers and county health officials – both in regard to supporting standardization in healthcare provision, and as an aid for lower-skilled providers. County stakeholders professed the CDSA to be "game changer" as it supports a standardized assessment of the sick child in a context of variation in clinical skills and mitigates providers taking "shortcuts". Positive views on the CDSA were expressed by all levels (county to national), and further viewing the introduction of digital clinical decision tools as a milestone in Kenya's health service provision. One sub-county stated the CDSA was the first electronic case management tool used in PHCs with the exception of HIV electronic systems.

- The main challenges cited by HCPs were difficultly in using PO on agitated children and that use increased consultation time. In Tanzania a time flow study identified that **use of CDSA (and PO) could initially increase the duration of a consultation from 5 to 14 minutes** (Figure 6.1), which declined to 9 minutes over time as providers became accustomed to using the devices and other implementation bottlenecks were addressed. [34] A consultation using solely the PO added a median of < 1 minute to the consultation time. Time spent using devices did not account for the totality of the increase, suggesting introduction of the devices may on the other hand lead to improvements in consultation comprehensiveness.[35] Further analysis would be needed to understand other issues that could account for this time increase.

Figure 6.1: Consultation duration in Tanzania (Control vs. PO vs. PO+CDSA)



- In addition, preliminary findings from the TIMCI RCT and pre-post studies report that healthcare providers felt that the CDSA sometimes over-classified severe disease. This perception might could highlight an underlying perception of IMCI criteria sensitivity for severe disease (rather than CDSA) as the algorithm was created in alignment with IMCI (and relevant child health guidelines). Further exploration would be required to validate this

[34] STPH (2024). TIMCI IAG January 2024 slide deck of preliminary findings

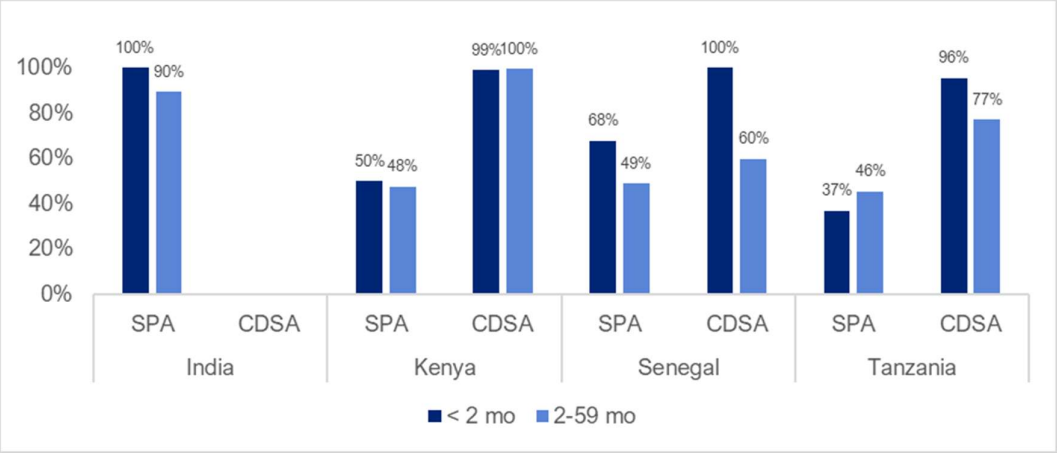
[35] STPH (2023). Preliminary report of the cross-country TIMCI study findings

hypothesis and understand more about HCPs perception, adherence and reasons for compliance (or not) with relevant IMCI guidelines for severe disease.

PO use as part of the IMCI consultation was high across study sites, and in TIMCI was influenced by use of the CDSA.

- In AIRE, 93.4% of indicated consultations used PO (88.3% in Burkina Faso, 95.7% in Guinea, 96.6% in Mali and 99.6% in Niger). Use in TIMCI sites was more variable (Figure 6.2), and was highest in India (over 90% of all children), followed by Senegal, Kenya and lowest in Tanzania. Differences between AIRE and TIMCI (and within TIMCI sites) may be influenced by numerous factors including different data collection methods, the HCP strike in Senegal, and differences in the indication to use a pulse oximeter depending on the research protocol and country.[36,37]
- The CDSA had a very positive influence on use of PO, potentially as entering the SpO2 reading was required to advance to the next step in the CDSA. For example, in Kenya, PO use among young infants < 2 months was 50% as measured through direct observation, and 99% if recorded in CDSA (Figure 2.3). More analysis for this gap is planned by the research team, and could be due to differences in the study populations for the different data collection methods, where for instance only 2-3% of consultations where observed.

Figure 6.2: Uptake of pulse oximetry in TIMCI sites by age, based on observation (SPA) or CDSA records



CDSA use varied between countries and facilities.

- CDSA uptake varied across facilities and over time. Uptake was highest in Kenya and Senegal (82.5% and 92.2% respectively when measured through direct observation[38]) and lowest in Tanzania (49%), where 19% of consultations did not have CDSA in room. Stakeholders pointed to a number of factors that may have influenced CDSA uptake, including wider contextual factors such as the HCP strikes in Senegal and time considerations noted above.

[36] PO eligibility criteria were as follows: **TIMCI** – all children (Kenya, India); all infants <2 months and children 2-59 months with cough/ difficulty breathing or red/yellow (severe/moderate) IMCI classifications, which equated to 60-80% of children (Senegal and Tanzania). **AIRE** – all infants < 2 months and children 2-59 months with respiratory symptoms (cough/ difficulty breathing) or red/ yellow (severe/ moderate) IMCI classifications.

[37] Observation data for Kenya may have missed some PO measurements performed at registration in some facilities. In Tanzania 19% of consultations did not have a CDSA in the consultation room. TIMCI also collected data on PO uptake through paper based records which is not included here.

[38] Adherence as reported in the pre-post study (Kenya, Senegal) was evaluated by comparing the number of children enrolled and the number of records in the CDSA database. STPH (2023). TIMCI Cross-country quasi-experimental pre-post study: Final Statistical Analysis Report (Kenya and Senegal)

Introduction of PO within the IMCI consultation identified an additional 5% of children with severe illness in AIRE sites (defined as SpO2 <90%) who otherwise would not have been deemed urgent and requiring referral. This was considered a significant value by key stakeholders.

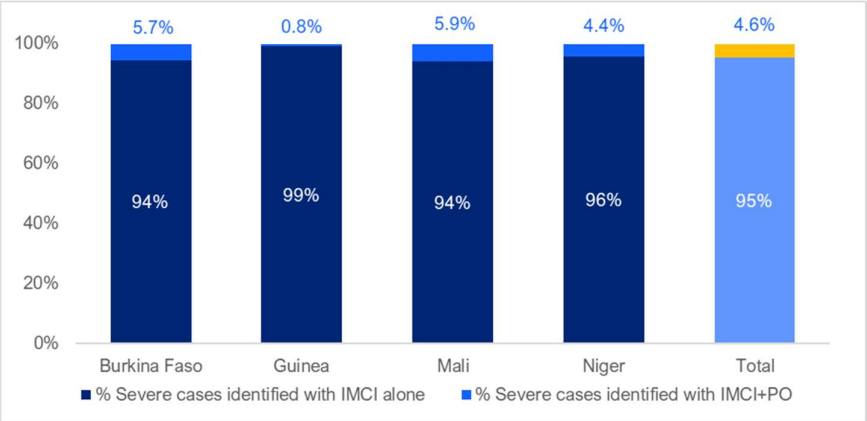
- Analysis by AIRE permits quantification of the additionality of PO to identify severely ill children requiring referral. Across the four countries, the use of pulse oximeters allowed the identification of an additional 4.8% of severe cases (n=956) (Table 6.2). [39,40] This was viewed as a significant value-add in that these children would otherwise have received a yellow or green IMCI classification (moderate/ simple case), their hypoxemia would not have been identified and they would not have been referred, with potentially fatal consequences. This specific analysis is not available for TIMCI sites. These results are also depicted in Figure 6.3, as the proportion of all severe cases identified by either IMCI alone or with the addition of PO. Guinea was an outlier in that PO identified only an additional 1% of severe cases – likely a consequence of Guinea's more sensitive IMCI protocol where '*presence of chest indrawing'* triggers classification as 'severe' illness. Global and country stakeholders consulted view the demonstrated 5% additionality of hypoxemia screening was significant when considering a scaled intervention.

Table 6.2: Added value of PO to identify severe illness in IMCI consultation, 202 AIRE PHCs [41]

	Burkina Faso	Guinea	Mali	Niger	Total
Severe cases identified (IMCI alone)	7,121	4112	6,232	2,286	**19,751**
Additional hypoxemia cases (IMCI+PO)*	*428*	*35*	*389*	*104*	***956***
Total severe cases (IMCI alone + additional hypoxemia*)	7,549	4147	6621	2390	**20,707**
Added value of PO to identify severe illness (95% C.I.)	6% (5.5-6.6%)	0.9% (0.6-1.2%)	6.2% (5.6-6.9%)	4.5% (3.7-5.5%)	**4.8% (4.5-5.1%)**

**Hypoxemia defined in AIRE countries as SpO_2 <90%*

Figure 6.3: Proportion of severe cases identified by either IMCI alone or PO+IMCI, 202 AIRE PHCs



[39] In AIRE, children with severe hypoxemia (SpO2 <90%) were automatically categorised as severe illness requiring referral.

[40] INSERM (2023). Rapport du volet recherche AIRE. In the subset of 16 study site PHCs where additional data were collected, the additionality of PO was substantially lower at 1.9% (95% CI, 1.5-2.5%), with Burkina Faso and Mali estimates outside the confidence limits of the 'global' analysis (202 PHCs).

[41] Overall denominator (i.e., number of IMCI eligible children for PO use) was 381874 globally with variation across countries: 182404 in Burkina Faso, 59252 in Guinea, 31690 in Mali and 108528 in Niger. AIRE consortium (2023). Routine pulse oximeter use into the integrated management of childhood illness guidelines at primary health centers in West Africa The AIRE research project, output 2 presentation. Version of June 2023

Despite the value attached to use of PO, the prevalence of hypoxemia and of severe illness among children presenting to PHC was lower than anticipated. Hypoxemia was slightly higher in children under 2 months of age compared to older children, which is consistent with global evidence.

- The overall prevalence of severe hypoxemia (SpO2 <90%) was 0.4% across all TIMCI countries, and varied by age group (higher among infants < 2 months, 0.7% vs. 0.4% among older children). The prevalence of hypoxemia in AIRE sites was double (0.93%)[42] this value, though likely due to different eligibility criteria for PO use between the projects described earlier. Figure 6.4 depicts the varied level of hypoxemia among children at TIMCI sites by country, which is consistently higher for children < 2 months, which is consistent with wider findings in the literature.[43] Altitude is considered the main factor for the higher prevalence detected in Kenya.

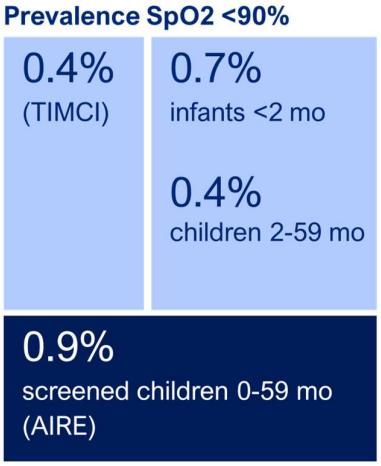
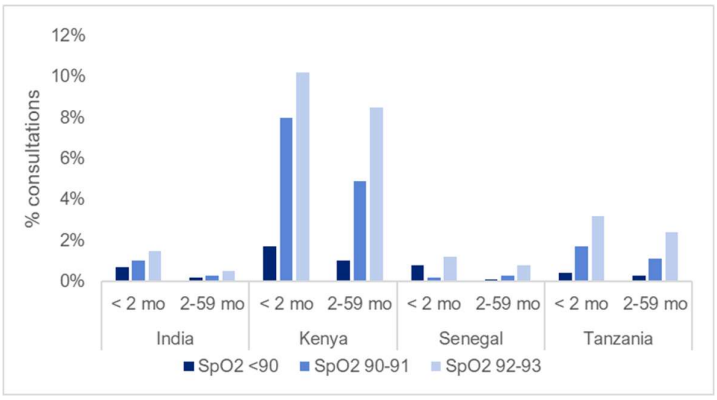


Figure 6.4: Hypoxemia prevalence in TIMCI countries based on paper records.[44]



- Stakeholders have suggested that the low hypoxemia prevalence may have been influenced by wider contextual factors including care-seeking behaviours (e.g., severely ill children potentially bypassing PHC level) potentially due to perceptions of poor quality of care and thereby "mistrust" of these health facilities, and understanding by caregivers that the severity of illness would require more specialised care. Methodological issues in data capture were also considered by the study team (e.g. the sickest children may have been immediately managed and not entered into the study). The prevalence of hypoxemia detected was slightly lower than the 1.3% (95% CI 0.9 to 2.1) prevalence reported at the primary level in Kenya, with many studies[45] finding higher prevalence among

[42] Based on 3325 children with SpO2<90% of 356,521 PO measurements taken. AIRE Consortium Meeting with Unitaid June 2023. Routine pulse oximeter use into the integrated management of childhood illness guidelines at primary health centers in West Africa. The AIRE research project, output 2 March 2020 to December 2022

[43] Graham et al. (2019), Hypoxaemia in hospitalised children and neonates: A prospective cohort study in Nigerian secondary-level hospitals, EClinicalMedicine 16 (2019) 51–63: participating hospitals (n=30) admitted 23,926 neonates and children during the study period. Pooled hypoxaemia prevalence was 22.2% (95%CI 21.2–23.2) for neonates and 10.2% (9.7–10.8) for children.

[44] PATH (2024). TIMCI preliminary results presentation. Version of 10 January 2024

[45] Subhi et al. (2009), The prevalence of hypoxaemia among ill children in developing countries, Lancet Infect Dis 2009; 9: 219–27: finding of 13% prevalence of hypoxaemia with WHO-defined childhood pneumonia requiring hospitalisation (severe and very severe classifications), with wide variation on prevalence across 27 studies; Rahman et al. (2022), Prevalence of hypoxaemia in children with pneumonia in low-income and middle-income countries: a systematic review and meta-analysis, Lancet Global Health 2022;10: e348–59: prevalence of hypoxaemia was 31% (95% CI 26–36; 101 775 children) among all children with WHO-classified pneumonia, 41% (33–49; 30 483 children) among those with very severe or severe pneumonia, and 8% (3–16; 2395 children) among those with non-severe pneumonia. As stated by Rahman et al. (2022) their updated systematic review paper is subsequent to WHO's revised clinical pneumonia classification for children in 2014, the introduction of pneumococcal and Haemophilus influenzae vaccines into the routine childhood immunisation programmes of many low-income and middle-income countries, and wider concerns about oxygen security in the context of the COVID-19 pandemic.

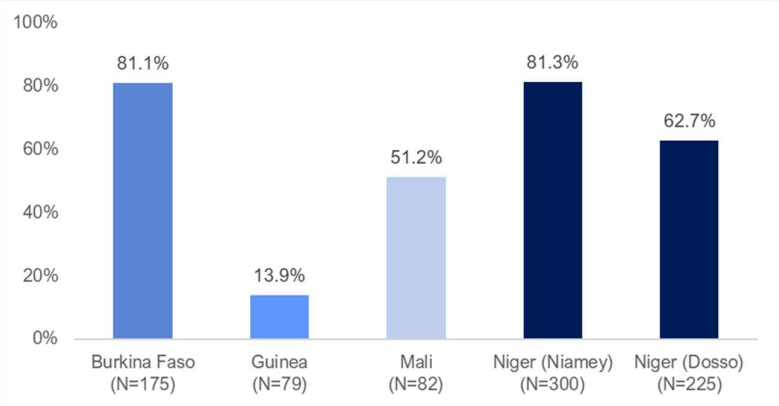
hospitalised children, and/or with pneumonia. Notably Rahman et al.,(2022)[46] finds that the prevalence of hypoxaemia is much higher in studies conducted in emergency and inpatient settings than in studies conducted in outpatient settings. As such, this consequently had an effect on small numbers of severely ill and hypoxemic children in both projects which is discussed in the sections below and Box 2.2.

- The AIRE project undertook an analysis of hospitalised children to understand care seeking practises. This revealed that in Guinea and Mali a high proportion of children hospitalised with a severe illness had not been referred, suggesting a different care seeking route not involving the PHC (See Box 2.2). The heterogeneity in care seeking practises across the four AIRE countries underscores the influence of community and health systems factors beyond the scope of the interventions.

Box 6.1: Sick children hospitalised in Guinea and Mali were less likely to have first attended a PHC facility than in Burkina Faso and Niger.

The AIRE study protocol aimed to enrol 1485 severe IMCI cases per county (5940 total) over one year, however at the midpoint, only 21% (n=1998) of severe IMCI cases had been identified at AIRE PHC study sites. The ITINER'AIRE study, initiated by the AIRE consortium, sought to describe the care pathway of 861 children admitted with a severe illness diagnosis to seven district hospitals included within the AIRE study, and measure the determinants of this pathway through interviews with caregivers. Figure 6.5 depicts the use of the primary care level across study sites, with selected study findings described below by country.[47]

Figure 6.5: Proportion of hospitalized children first seeking care at the primary level, AIRE study sites



Burkina Faso: 81% of children had attended a PHC. A policy of free healthcare is in place and the PHC is considered more financially accessible than the hospital (19% vs. 2.3%, p<0.001). High importance is attached to following the health pyramid is Burkina Faso and proof of referral is typically required for all hospital admissions which may also explain caregiver's preference for the PHC.

Guinea: only 14% of hospitalised children had attended a PHC and were more likely to have first consulted a private clinic or pharmacy than other AIRE countries. Caregivers reported having a better opinion of hospitals and none interviewed felt the PHC could meet their child's needs in the event of a serious illness. In Guinea there is less importance attached to the health pyramid. Of note, 66% of hospitalised children lived less than 30 minutes from the hospital, raising the question whether children in other communities were either attending a different hospital or not accessing hospital care for severe illness.

[46] Rahman et al. (2022), Prevalence of hypoxaemia in children with pneumonia in low-income and middle-income countries: a systematic review and meta-analysis, Lancet Global Health 2022;10: e348–59

[47] Subhi et al. (2009), The prevalence of hypoxaemia among ill children in d

Mali: 51% of children attended PHC prior to the hospital. Traditional healers play an important role - 25.6% of hospitalised children consulted a traditional healer before going to hospital.

Niger: Use of the PHC was 81% at Niamey hospital and 63% at Dosso hospital. The particularly high use of PHCs before attending the hospital may have been influenced by the urban location of the Niamey hospital (Dosso hospital is in a rural area) and that the PHC was considered more affordable than the hospital. As in Burkina Faso, Niger has a free healthcare policy.

Across the three countries where the CDSA was implemented (Kenya, Senegal and Tanzania), some benefit was observed in clinical practises, with variation between countries and facilities. Use of antibiotics declined substantially in Kenya and Senegal. Stakeholders, especially at country level, considered these findings important to inform efforts to strengthen quality of care, including digital solutions.

- **Antibiotic prescriptions:** In both Kenya and Senegal, CDSA use correlated with a reduction in antibiotic prescription. This decline was largest in Kenya where antibiotic prescription declined by 25.7% in Kenya for infants < 2 months and 29.1% for older children. In Senegal there were 16.7% fewer prescriptions for infants < 2 months and 14% fewer for children 2-59 months.[48]
- **Quality of IMCI assessment:** Small improvements in coverage of certain practices during IMCI assessments were found in the PO + CDSA arm in Tanzania and Kenya (e.g., better assessment of weight, temperature, respiratory rates and difficulty breathing, inability to eat/drink, history of convulsions). No improvements were reported in Senegal (which had a higher baseline than other TIMCI countries) though health worker strikes may have limited the effect of the CDSA.

For children with a severe disease classification, the decision to refer was rare. A number of factors are at play in referral decisions including availability of transport, costs, and caregiver autonomy, with referral tending to be the outcome of exchange between health provider and caregiver. In Tanzania the intervention did not have a statistically significant impact on completed referrals.

- In AIRE, data from 16 research PHCs indicate only 23% of all severe cases were referred to a hospital, with Niger an outlier with 67% (of a total of 1998 severe cases). Most severe cases were managed at the PHC level, despite the indication for referral. Having hypoxemia increased the likelihood of referral to a hospital (82% transferred vs. 23%), suggesting an additional benefit of use of PO at the primary level. Referral in TIMCI was lower, with only 1.1% of children < 2 months and 0.3% of children 2-59 months with a severe disease referred. This compares to 2% of children being diagnosed with severe illness in Kenya and 7.5-10% in Tanzania (noting actual numbers of referred children were extremely low, and analysis for remaining countries is ongoing).
- In TIMCI, referral completion and hospitalisation rates were low and investigators indicate that the small numbers limit the ability to draw conclusions. As an example, in Tanzania and India, 0.0-0.4% of all enrolled children had completed referral in the different study arms; in Kenya and Senegal there were single digit referrals which were slightly lower in the intervention vs. control period.
    - Primary hospitalisations within 24 hours following the PHC consultation was a proxy for appropriate referral and expected to increase in the intervention arm. In Tanzania, PO was not associated with a statistically significant difference in hospitalisation within 24 hours compared with control arm (OR 1.43 (0.400, 5.086, p 0.584)), and PO + CDSA was not associated with a statistically significant difference compared with control (OR 2.05 (0.618, 6.826, p 0.240)).[49]
- In AIRE, the median delay for hospital transfer across all countries was 2.2 days, and highest in Guinea (6.1 days). Interestingly, 38% of children with hypoxemia successfully referred were found not to have hypoxemia when

[48] STPH (2024). TIMCI IAG January 2024 slide deck of preliminary findings

[49] TIMCI (2023) Preliminary report of the cross-country TIMCI study findings

assessed at the referral facility. This has not been possible to explore further with the AIRE study team for this evaluation.

- Qualitative analysis suggested caregivers faced a number of challenges in the referral decision – including gender-based imbalance in autonomy and decision-making, costs, and persistent health system challenges (even when referral support was provided) - many of which HCPs would be aware of and which are believed to have influenced the referral decision.

The expected health benefits of PO and CDSA were not observed in TIMCI. Where differences were observed between intervention and control arms, the small number of events limit the extent conclusions can be drawn.

- TIMCI health and clinical outcomes were based on presence of severe complications by Day 7 defined as: mortality, hospitalisation without referral, hospitalisation with referral but delayed >24 hrs after Day 0 (day of consultation). Results in the two study arms were as follows:
    - In the RCT (India, Tanzania), the number of events and rates were low, and below the pre-study assumption (Day 7 complications of 0.5% among <2 months and 0.1% among 2-59 months compared to assumption of 1.1%). This result is not surprising given the lower prevalence of hypoxemia than expected. However, slightly higher proportions of severe complications were reported in intervention arms compared to control arms, for both age groups, and across countries and arms – **leading to a conclusion of no measurable intervention effect.**
    - In the pre-post study (Kenya, Senegal), cases of severe complications at Day 7 were also very low. **Differences between the control and intervention were marginal for children aged 2-59 months**. Senegal reported slightly higher severe complications in the intervention arm vs control for children under 2 months, whereas this was opposite in Kenya. The number of children with severe complications reported were insufficient to draw conclusions about the observed differences.
- The study explored various hypothesis and factors that could explain the observed results including potential distortion of clinical practice (e.g. modified interaction / reduced attentiveness, false reassurance, increased classification of severe disease), possible imbalance between arms beyond (e.g., effect of the intervention in modifying care-seeking behaviour for severe illness towards intervention facilities). Additional analyses are being undertaken by the TIMCI study team on these results.
- In light of the TIMCI study findings of no detectable intervention effect, cost-effectiveness analysis was not conducted. A detailed costing has been undertaken however which could inform future investments and country support for introducing PO.

AIRE found the likelihood of death was significantly associated with severe hypoxemia and occurred a median 1 day following PHC visit. Only 35% of children with hypoxemia $SpO_2 \leq 90\%$ received oxygen therapy.

- The AIRE study did not include non-intervention comparator data; however it did produce evidence on the clinical outcomes of children identified with hypoxemia and severe disease at the primary care level.
    - Among the 1,998 severe cases at the 16 AIRE PHC study sites, 95 (4.7%) died within 14 days from the initial consultation.[50]
    - Among these severe cases, 142 children had hypoxemia (7.1%), and access to oxygen varied significantly by country, with overall only 35% of hypoxemic children receiving oxygen. The mortality rate for severe cases diagnosed with hypoxemia was 26% overall with wide differences across countries (16.7% in Niger, 20% in Guinea, 30% in Burkina Faso, and 35.5% in Mali). The probability of severe cases dying within 14 days following the initial PHC consultation increased significantly with hypoxemia severity (severe vs. moderate hypoxemia ($90\% \leq SpO_2 \leq 93\%$) and no hypoxemia).[51]

[50] AIRE (2023). Rapport des résultats de la recherche. Version du 12.06.23

[51] log-Rank test; $p<0.0001$

- Views are mixed whether there were missed opportunities within the AIRE study to measure intervention effectiveness or impact on health outcomes, noting that it was expected evidence of impact and cost-effectiveness would be provided by TIMCI which has not been feasible in light of project results.

> *"What was missing [in the AIRE study] was to understand what happens next to children and what was their outcome including moderate cases. Moderate cases (non-severe with mild signs) are also important to capture so this was a missed opportunity in the research"*
>
> *- Global stakeholder*

In view of the project results, stakeholders recommended careful analysis and dissemination of the study results to avoid misinterpretation of the study findings (i.e., not to indicate POs should be de-prioritised at the PHC level).

- In addition, they highlighted the opportunity to leverage available findings across the two projects to provide a more comprehensive overview of lessons learnt across the portfolio and examples of best practices to support future similar interventions. Irrespective of the settings and results, both projects highlighted the influence of a number of health systems-related factors on the effectiveness of interventions for introducing PO (and CDSA where relevant) within primary care. This emphasises that the case for PO adoption and scale up at PHC level should be very context dependent.

PO demand and policy adoption

- **All countries reported significant policy progress during the time of the projects, and showed a strong commitment in adopting child friendly POs to enable better detection of severe disease in children.** The AIRE and TIMCI projects enabled considerable progress across countries to facilitate programmatic and operational readiness for PO adoption, as evidenced by the range of feedback collected during consultations across countries and with global partners in Phase 1 and 2 of the evaluation. In AIRE project sites, all countries reported significant policy progress, notably by including PO across relevant polices, supportive guidelines and tools. This includes adding specific recommendations around PO use in national IMCI guidelines and tools (e.g., in Burkina Faso, Guinea, Niger, Senegal, India) and incorporating PO in relevant MNCH protocols and guidelines (e.g., in Mali, Kenya). Beyond policy change, the projects were also instrumental in strengthening Procurement and Supply Management (PSM) processes to enable effective procurement of PO. As a result, many countries reported having strengthened their procurement for PO (e.g., in Burkina Faso, Mali, Niger) and integrated PO in their national Essential Medical Device Lists (EDLs) (e.g., in Niger, Senegal) to support consistent procurement and distribution. In addition, the projects also contributed to strengthening healthcare provider (HCP) capacity by providing trainings during the project (e.g., IMCI, use of PO, value-based procurement (VBP)), supervision, and importantly, contributing to revising training and supervision materials at national and subnational levels to facilitate continued capacity strengthening beyond the projects. Availability of PO in project sites and countries was also reported to have increased by the end of the projects. Baseline data from the AIRE project reported that only 1% of all PHC sites had PO available before the project. At project close all AIRE sites had been provided with POs and additional funding was secured in some countries that enabled procurement of PO in Mali (partial procurement) and Niger (full PO procurement for 100% of PHCs).

  To achieve this progress, the projects benefited from pre-existing country interest, as stakeholders confirmed that in many countries, governments were already considering updating their policies. In India for example, the decision to add the use of pulse oximeters in the IMNCI guidelines (in 2023) was driven at national level whilst the project advocacy was mostly done at the state level in Uttar Pradesh. Nonetheless, stakeholders highlighted that the AIRE and TIMCI projects played a key role in facilitating and encouraging these changes which in their view, *may not have happened as fast and as comprehensively in the absence of the projects*. They recognised the key value add of the projects in promoting meaningful engagement across stakeholders by bringing together different actors to contribute to these policy updates (e.g., national and subnational actors, partners) and driving further political support and commitment on this issue. In particular, they highlighted the *contribution of the projects in*

advocating for countries to include specific recommendations on the need for appropriate pulse oximeters adapted for all age groups including newborns, as opposed to having more generic recommendations around PO. As a result, many countries reported adding specific mentions around the need for appropriate devices (i.e., handheld devices with necessary probes for infants and young children) as well as reflecting this across procurement guides to support more accurate quantification and procurement in countries.

- **There was evidence of positive influence across observer countries but limited effectiveness overall due to limited engagement and lack of funding support.** The observer countries approach was highlighted as a cost-efficient initiative to extend the portfolio benefits beyond the project countries. Stakeholders shared that a key benefit of this approach had been to raise awareness on the need for adapted POs for children in observer countries (which have a diversity of awareness of this issue), in addition to promoting knowledge sharing across countries with similar interests and challenges. However, they highlighted the limited impact of this initiative to promote early adoption of PO in observer countries, beyond initial awareness raising. Some activities implemented under this approach were viewed as helpful (e.g., in person visit of TIMCI project sites in 2022, attendance at Dakar conference during AIRE results dissemination in 2023). However, most stakeholders consider observer country engagement remained suboptimal overall throughout the projects, with delays in engaging focal points, sparse communication and lack of updates beyond the sites visit and Dakar conference, and poor document sharing to facilitate further review and dissemination in observer countries. Despite diversity across observer countries in relation to availability of PO and oxygen systems, the observer country approach was not tailored to leverage potential entry points and country 'readiness'.

- **A number of challenges were encountered in using the CDSA, with concerns around the integration of the tool in existing systems, creating major inefficiencies and hindering likelihood of adoption in the short term.** The significant increase in consultation time when using CDSA was one key challenge for using the tool especially in busy PHC settings. In addition, the CDSA tool as introduced could not be integrated with existing health information / digital systems (which were themselves maturing at the time of TIMCI design), leaving HCPs with multiple devices to use during their practice and leading to duplication of work for HCPs and fragmentation of data collection in the health system. This is also issue hindering CDSA transition to MoHs after project closure and limiting the chances of sustaining and scaling the tool beyond the project.

- **The projects implemented a wide range of CCSE activities across projects countries to engage local CSO and communities and enhance the reach of its activities, however, there was limited evidence of the effectiveness of these interventions.** Both TIMCI and AIRE used an array of activities as part of their CCSE intervention to sensitise communities on the ongoing projects' interventions (i.e. use of PO and CDSA in facilities) and raise awareness around health seeking behaviours in an attempt to drive community led demand for PO. Both projects reported training CHWs on PO and relevant danger signs of severe diseases to strengthen their capacity ahead of outreach and awareness raising activities. For AIRE, the project reported including CSOs and community representatives such as community and religious leaders, traditional healers, local researchers and the medical / scientific community (in Paediatrics, Gynecology-Obstetrics, pulmonology etc.) in training sessions on PO, project meetings and dissemination activities. The project also used of various communication channels (e.g., posters, radio spots translated in local languages) in addition to in-person outreach activities to increase the reach of their activities. In TIMCI, the project reported implementing a combination of engagement and outreach activities too including in-person session (talks, social mobilizations, awareness-raising session in the health posts), radio shows, and engagement of community leaders and champion, as well as home visits, to increase activities reach across communities. The project aimed to re-engage CSOs during dissemination activities.

  Whilst recognising the breadth of activities implemented, most stakeholders shared that CCSE interventions in the portfolio have had limited effectiveness overall due to a number of factors. There were some reports of CCSE activities effectiveness to sensitise communities to facilitate caregivers acceptance of projects interventions e.g., in Burkina Faso, facility staff feedback shared that CCSE interventions led to easier acceptance of PO during consultations. However there was limited feedback and evidence to corroborate this across project countries. In addition, as outlined in section 2.2.1, the projects faced multiple constraints and challenges during the implementation of their activities including reduced scope and time allocated for CCSE activities (in AIRE and part of TIMCI countries) and budget constraints (especially for AIRE) which would have impacted their

effectiveness. The project use of existing CHWs also brought some additional challenges as most CHWs were contracted directly by the government (e.g., ASHAS in India, ASBCs in Burkina Faso) and had other livelihoods activities. Whilst the integration of CCSE activities in existing CHWs structures provided many benefits, it also meant that CCSE activities were often dependent CHWs availability (sometimes limited due to competing priorities) and susceptible to external factors (e.g., government payment of CHWs allowances). A key feedback from stakeholders was also that behaviour change takes a long time and as such, CCSE interventions were likely to not results in significant and/or sustainable change in care seeking behaviours unless they were continued beyond the projects.

Implications for sustainability and scalability and gaps remaining

The findings above indicate a dichotomy – on the one hand, there is country interest and demand for adapted POs for children at the PHC level and good progress made on updating policies and guidelines to encourage their introduction, on the other hand, the research studies may not provide a compelling case for this in the absence of broader efforts to strengthen demand and services along the pathway of care. Countries are interested because of the IMCI and PHC strengthening objectives, and also the observed wider benefits of POs and CDSAs in terms of clinical standardisation, improved quality of care, reduced antibiotic use, amongst others.

One explanation on the limited effectiveness of the interventions was that they were limited in their ability to influence wider health systems conditions and community engagement and not sufficient on their own to have impact. Both projects reported having considered wider health systems factors when designing their interventions (e.g., including health systems factors such as the availability of operational referral systems and oxygen availability at referral sites in the sites selection criteria)[52,53], as well as implementing measures to mitigate any related confounding factors. This includes by providing additional support to PHC and referral facilities in the form of treatment tools provision (e.g., antibiotics, oxygen), capacity strengthening (e.g., on use of IMCI and PO) etc. as described above, to strengthen service delivery. However resolution of wider HSS issues (e.g. quality of care at PHCs, effective functioning of referral systems, etc.) was beyond the scope of the projects. Community and civil society engagement (CCSE) activities were also implemented with the intention of influencing health seeking behaviours though these activities had limited effectiveness in both projects as explained above due in part to implementation challenges as well as the nature of the desired impact on behaviours which would require sustained engagement over a much longer time period. The use of existing CSOs and CHWs in both projects was meant to promote sustainability by enabling CSOs and CHWS to leverage new skillsets and project materials beyond their interventions. In AIRE, transition plans were also developed with CSOs inputs and included considerations for continued CSO engagement after the end of the project (e.g., post-project CSO Engagement Plan developed including activities for domestic budget advocacy in Guinea). However, there is no guarantee that these activities will be sustained after project closure. During follow up consultations with AIRE stakeholders in Phase 2, there was no update suggesting continued CSO or CHWs activities on PO or related health seeking behaviours. In TIMCI countries where CCSE activities had ended earlier (India and Kenya), there was limited evidence of further use of the project's awareness raising materials in general CSO and CHWs activities. Stakeholders pointed that sustained efforts to raise awareness on PO and appropriate health seeking behaviours would be unlikely to continue after the projects close without strong political will.

Country and global stakeholder unanimously recognized that the full impact of PO introduction can only be achieved if integrated as part of a "whole of systems approach". Despite the unexpected research results, stakeholders welcomed the findings generated by the TIMCI and AIRE studies as in their view, they have allowed to capture critical lessons on the extent to which wider health systems factors may influence the effectiveness of PO introduction at PHC level. Further, data from the AIRE study provided helpful insights in that regards including data on out-of-pocket (OOP) healthcare associated costs incurred by households across different project countries as well as data on patient healthcare pathway, estimated proportion of children attending PHC as first point of care (POC) and factors influencing patient's decision making. In the cost to household study, the reported direct medical costs to

[52] PATH (2019). TIMCI project plan

[53] ALIMA (2019). AIRE project plan

household for the treatment of severe cases were US $1.6 and US $14.4 in Burkina Faso and Niger respectively (who both had full PHC fees exemption policies in place), US $7.4 and US $9.6 in Mali and Guinea respectively (who had partial PHC fees exemption policies).[54] This represents significant amounts considering minimum monthly wage in these countries vary between US$54 to US$72). Reported direct cost of care was highly influenced by the existence and comprehensiveness of supporting policies in each country, with a ripple effect on service utilization, especially for the poorest households.[55] In Mali and Guinea that only have partial fee exemption policies, only 10% and 18% of severe cases were cared for at PHC and transferred to hospital for further treatment compared to 29% and 75% in Burkina Faso and Niger which have full fee exemption policies.[56] The AIRE ITINER'AIRE study also documented valuable evidence on the influence of perception and attitudes towards PHC on care seeking pathways and their impact on intervention effectiveness at PHC level. The study provided estimates on the proportion of children bypassing PHCs in each country (presented in Box 6.1 above) as well as potential reasons for doing so. For example, in Burkina Faso, 81% of children attended PHC as first point of care (POC), against only 14% in Niger. Decision to attend PHC as first POC was influenced by a range of factors including cultural norms, education level, PHC accessibility and understanding and perception of the level of care provided at PHC level.[57] These results highlight the importance of behaviour change interventions as a highly complementary intervention when introducing innovations at the lower levels of care.

> "*Risk stratification and integration with referral pathways for sick children is a space ripe for systems innovation" - Global stakeholder*

At present, there is variation across project countries on plans for sustaining and/ or scaling up adapted PO use for children: As mentioned previously, most countries have made significant progress in updating relevant policies and guidelines to promote the use of adapted PO across levels of care including PHC, especially AIRE countries. However, there is a mixed picture in terms of success in sustaining and/ or scaling up POs, with several discussions/ plans ongoing at the time of this evaluation that merit tracking to ensure whether or not these tools are actually sustained in these countries. The following are the details this evaluation has been able to secure:

- Niger and Mali reported having secured funding to scale up PO through various partners (notably Global Fund, the World Bank and USAID). In Niger this funding allowed procurement of POs for all PHCs at national level.
- Burkina Faso and Tanzania reported having included PO in their respective country funding request for Global Fund GC7. In Tanzania, PO is included in the oxygen roadmap, with a subsequent version expected to specify child appropriate devices, and stakeholders have highlighted that whilst discussions to scale up PO are ongoing, prioritisation of PHC level in procurement plans may be reviewed in light of the study results. Oxygen roadmaps are under development in Kenya and Senegal with progress expected during the WHO oxygen roadmap meeting in Dakar in May 2024.
- Other countries reported strong government interest and commitment to sustain the tool beyond the project but without evidence of allocated financing or procurement order. For example, in Kenya PO was included in Kakamega and Kitui counties' annual budgets but no procurement had been made yet. In India, the Uttar Pradesh state government expressed interest to procure adapted PO in the next Social Awareness and Action to Neutralise Pneumonia Successfully (SAANS) initiative procurement order however this will require follow up and budget advocacy around budget planning time to ensure it is not deprioritised. In Mali, the MoH committed to procure POs for 50% of the country community health centres but this had yet to be done. In Senegal PO is being included in the strategic health plan, and in Guinea, the AIRE project transition and scale up plan was developed and validated by the MoH but there was no evidence of further PO procurement after the project ended.

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[54] INSERM (2023). AIRE_Rapport Final AIRE-cout-des ménages

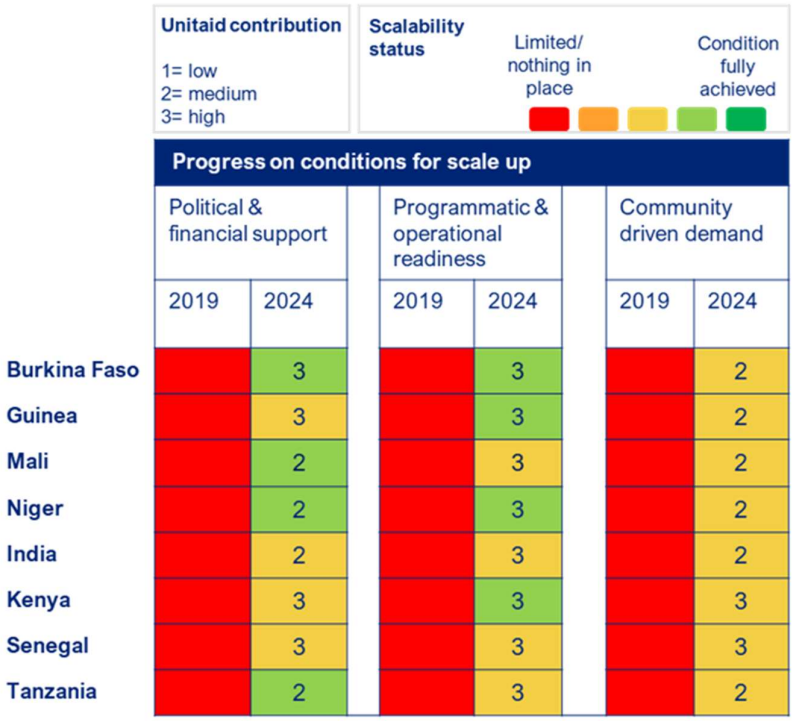
[55] Offosse et al (2023). Effectiveness of the Gratuité user fee exemption policy on utilization and outcomes of maternal, newborn and child health services in conflict-affected districts of Burkina Faso from 2013 to 2018: a pre-post analysis

[56] INSERM (2023). AIRE_Rapport Final AIRE-cout-des ménages

[57] INSERM (2022). ITINER'AIRE study

Appendix C provides further details of country progress against Unitaid country readiness domains and conditions as reported at the time of this evaluation which is summarised below in Figure 6.6.

Figure 6.6: Achievements in Unitaid country level conditions for scale-up



	Progress on conditions for scale up					
	Political & financial support		Programmatic & operational readiness		Community driven demand	
	2019	2024	2019	2024	2019	2024
Burkina Faso		3		3		2
Guinea		3		3		2
Mali		2		3		2
Niger		2		3		2
India		2		3		2
Kenya		3		3		3
Senegal		3		3		3
Tanzania		2		3		2

Our assessment of the implications of the above are as follows:

- **There is a need to take a nuanced approach to PO introduction and scale-up across countries, with their appropriate positioning being determined based on the specific country context and health system characteristics.** The mixed evidence on effect of PO introduction at the primary care level suggests a need for thoughtful positioning of PO within the health system to be most effective, and highlights the influence of health systems quality and health-seeking behaviour on ultimate intervention/ device effectiveness. Strong interest by governments to sustain and expand PO for children at the primary care level speaks to the high relevance of this portfolio to health priorities (primary care, quality, standardization, use of health technologies). The progress in policy change noted earlier in this section demonstrates the desire by countries to scale the TIMCI and AIRE interventions. Global stakeholders cautioned against an interpretation of TIMCI results that PO are not effective at the primary care level.

- **The projects results raise a number of important questions for Unitaid and offers valuable insights to strengthen similar interventions in the future.** The AIRE and TIMCI results provide key lessons to Unitaid for designing and implementing interventions to introduce tools such as PO at lower levels of care. In particular, the projects point to a number of important features for supporting effective adoption, sustainability and scale of products: such as working within the health system, assessing providers acceptability and adoption, integrating product as part of a package of care alongside holistic health systems strengthening (HSS) and ensuring essential health system conditions are in place. This is a similar finding as the one reported from the CARAMAL study which found that contextual challenges (including inadequate referral systems and suboptimal health seeking behaviours) substantially limited the effectiveness of an intervention to introduce Rectal Artesunate (RAS) in the community to reduce Case Fatality Ratio (CFR).[58] Stakeholders shared that this portfolio adds to a body of existing evidence (e.g., CARAMAL study) highlighting the complexity of intervening at lower levels of care level such as

[58] BroadImpact (2021). End-of-Grant Evaluation Report. Community Access to Rectal Artesunate for Malaria (CARAMAL) Project and Output 3 of the Supply Side Grant.

PHC, which can be very different from traditional HTM interventions (where the direct pathway to impact on mortality is more direct and continuum of care is well/ better established). In contrast, interventions at lower levels of care require a more health systems/diagonal approach, which may be slower to demonstrate visible progress and would necessitate the identification of intermediate impact outcomes (as opposed to direct impact on mortality).

- This finding also applies to the introduction of next-generation pulse oximeters (including interest in non-invasive Hb measurement). As with the PO and CDSA, introduction of next-generation POs will need to factor in adaptation of clinical guidelines based on the vital signs/ measurements taken by the devices and consider the key issue of referral and clinical care at referral sites. Therefore to be effective in influencing health outcomes, these interventions would need to ensure a number of health system conditions are in place – particularly referral systems which are a universal need for any intervention that involves screening, triage and transfer to higher levels of care, with appropriate quality of care at referral sites tailored to the intervention.

PO and CDSA adoption and scale-up – Key Lessons and Insights

- The prevalence of hypoxemia among children attending PHCs was low (0.4% overall in TIMCI), and slightly lower than evidence in comparable settings. Hypoxemia was higher among younger infants < 2 months compared to older children (0.7% vs. 0.4%). Whilst data collection approaches may account for lower levels of hypoxemia in the projects, a high proportion of hospitalised children in some countries bypass the primary care level. Health systems factors, distance, costs and caregiver perceptions appear to shape decisions on where to seek care for very sick children. This has implications on other child health interventions which involve the primary care level.
- Referral rates and referral completion for severely ill children from the primary level were low and a high proportion of children were managed at the primary care level, despite the indication for referral. This is highly relevant for design of interventions in which the referral system is integral to health impact, and investments should factor in referral system strengthening along with quality of care at referral sites.
- The expected health benefits of PO and CDSA were not observed in TIMCI and small event numbers limit some analyses**.** This is not an unexpected finding given the learnings on hypoxemia prevalence and referral. This portfolio along with learnings from the Unitaid CARAMAL evaluation emphasise that interventions at lower levels of care require a more health systems/diagonal approach, which may be slower to demonstrate visible progress.
- There is a demand at the primary level for appropriate health technologies, which need to consider the local contexts for appropriate introduction. The effect of the CDSA on extending consultation time was a key barrier to uptake in high volume and under-staffed PHCs such as in India where the average consultation time for a sick child is 1-2 minutes. CDSA use increased this to 6-15 minutes and was deemed not feasible and rejected.
- Future investments in tools or interventions involving screening and triage into care (e.g. multimodal diagnostics, non-invasive haemoglobin measurement) should factor in support for key health system conditions, such as referral and quality of care in referral sites, in order to influence health outcomes.
- Strong interest by governments to sustain and expand PO for children at the primary care level speaks to the high relevance of this portfolio to health priorities (primary care, quality, standardization, use of health technologies). Despite the challenges with the CDSA, there was strong interest among health managers and even health providers for solutions to improve the standardization of care in contexts with varied health provider skills, build health provider confidence, and generate data on patient care.

6.2. EQ5 – Next generation devices

5. To what extent did the investments accelerate the development of quality-assured, fit-for-purpose next-generation pulse oximeters and better PO devices for PHCs in LMICs?

This evaluation question provides an assessment of the extent to which TIMCI contributed to stimulate demand and encourage supply of improved POs and multimodal (MM) devices for LMIC markets.

Outputs generated by TIMCI as part of the market shaping work included: (i) Target Product Profiles (TPP), which define minimum and optimistic product attributes for a non-invasive MM device adapted for use in all patients including children in LMICs; (ii) a public facing Next Generation Pulse Oximeters Technology and Market Landscape, providing an overview of available and pipeline MM devices including details on product features as well as wider information on market barriers and opportunities for multimodal PO devices; (iii) a Market Interventions for Multimodal Devices Barrier Assessment and Next Steps report highlighting key barriers preventing the uptake and market entry of multimodal devices and providing an overview of potential solutions to tackle these challenges. TIMCI also conducted a post-market surveillance assessment of the Rad-G PO device distributed across several LMICs during the COVID-19 pandemic, and a comprehensive "Hybrid study" in TIMCI countries which assessed the diagnostic accuracy of six MM devices, and generated market intelligence to support demand and supply of next generation MM POs.

The following are key findings with regards to the contribution of this work to accelerating development of next-generation devices:

- **Through its market shaping interventions, the TIMCI project provided a wide range of evidence and market intelligence on existing appetite as well as potential demand and supply for next generation multimodal devices (MMs).** The project was able to document valuable information on country appetite for MMs including evidence around MM acceptability, usability and feasibility in LMICs contexts as well as potential for MM adoption and use cases across countries.
    - The TIMCI project reported that MMs were overall well-accepted and integrated into existing clinical practices across various LMIC settings[59] and were preferred over stand-alone POs[60] due to their ability to measure multiple vital signs.[61,62] In the Hybrid study in particular, the project was able to document end users feedback on MM satisfaction, usability and learnability across six different devices, including performance in different age groups (refer to Box 7.1 for insights from Kenya). The study reported high user satisfaction, ease of use and usefulness reported (for three of the six devices tested), and varied degree of learnability[63] over time across the six devices. Other perceived benefits reported included better accuracy (i.e., for respiratory rate (RR) compared to manual counting) and time saved when using MMs.[64] In addition, the hybrid study also provided valuable information on MMs diagnostic accuracy and performance across tested devices (e.g., reported better device performance in older children, higher accuracy of SpO2 and pulse rate (PR) compared to RR).

Box 7.1: Hybrid study findings in Kenya

[59] Inputs collected in TIMCI project countries and beyond notably in Malawi and Zambia through the TIMCI Post-market Landscape on Masimo Rad-G Pulse Oximeter Device.

[60] PO preference and reported use cases varied among stakeholders across geographies. *PATH (2021). Market Intelligence Report on Multimodal Devices.*

[61] PATH (2021). Market Intelligence Report on Multimodal Devices.

[62] PATH (2023). Post-market Landscape on Masimo Rad-G Pulse Oximeter Device.

[63] The study measured the difference in task completion times over time across each device as a measure of learnability.

[64] PATH (2023). Post-market Landscape on Masimo Rad-G Pulse Oximeter Device.

In Kenya, one stakeholder with knowledge of the study considered the weaker device performance in children under one year of age as a common issue in medical devices and an important gap in development of diagnostics for the youngest children where the mortality burden is highest (70% of child mortality in Kenya occurs in the first year of life). Reasons for lower performance are due to both weaker mechanical fit of probes to smaller children, children are often distressed and move during assessment, along with the fact that young child vital signs can vary widely.

- Small, handheld devices that offer continuous monitoring were considered a better alternative to "fingertip" POs as they could be used for both spot check and patient continuous monitoring in inpatients and outpatients settings that could not afford and/ or operate tabletop POs/ patient monitors.[65] In particular, MMs greater functionality and ability to measure multiple vital signs (e.g., respiratory rate (RR) in addition to SpO2) was seen as a key value add to increase diagnostic and monitoring accuracy and save time during patient assessment.[66,67] In addition to the existing added parameters for most available MMs (temperature and RR), countries expressed a strong interest in the potential for MMs that could measure non-invasive haemoglobin which would be particularly relevant in countries with a high prevalence of anaemia. Insights from the TIMCI market shaping research is corroborated by case studies and other country level interviews conducted in this evaluation, all of whom expressed a strong interest in next generation multimodal devices.

"Anaemia parameters for MMs would be very important seeing need and difficulty in measuring threshold of anaemia for further referral."

- Global stakeholder

- In addition, the project was able to document end user feedback around key challenges hindering the effective use of POs in facilities including challenges around device durability, lack of adapted sensors to fit very young children, poor availability of spare parts to purchase locally and the need for training and maintenance to enable full adoption and integration of MMs in facilities.[68] This information offers valuable and practical feedback to suppliers and procurement stakeholders that may contribute to improve the demand and supply of MMs in LMICs markets.
- It is worth noting some dissonance between where the MM device market appears to be heading first – which is to add RR to existing PO devices - and global expert consensus that improvement in the performance of non-invasive haemoglobin (Hb) measurement offers the most exciting impact potential. The TIMCI landscape report identified a number of non-invasive Hb tools, but with issues in sensitivity and specific to address before they could be scaled in LMICs (as well as affordability). The manufacturers engaged by TIMCI all described focusing on adding RR to POs, which is considered more of a 'low hanging fruit'.

Beyond end user feedback, the project delivered additional market intelligence to strengthen the demand and supply for MMs.

- This include notably providing an estimate of the market size for POs and estimated price range for MMs to meet buyers' willingness to pay (WTP) in LMICs. The project reported a modelled estimate of total market for multimodal PO devices in LMICs between 3.9 million and 7.6 million units.[69] The reported

[65] MM devices perceived to be better than fingertip POs and equivalent or better than patient monitors and handheld POs. *PATH (2021). Market Intelligence Report on Multimodal Devices.*

[66] PATH (2021). Market Intelligence Report on Multimodal Devices.

[67] PATH (2024). TIMCI Hybrid Study preliminary results. Version of 14 March 2024

[68] PATH (2023). Post-market Landscape on Masimo Rad-G Pulse Oximeter Device.

[69] PATH and UNITAID (2022). Next Generation Pulse Oximeters: Technology and Market Landscape

estimated market size for POs in TIMCI countries alone was ~353K units across all four countries,[70] including ~93K units market size for MMs over the next five years in these countries across various market segments.[71,72] The project documented evidence of WTP for MM devices between ~US$145 to US$160 to be able to compete with both fingertip and handheld devices. In comparison, current global health price for the Rad-G is between $250 and $545 (depending on the number of probes).[73]

- **Stakeholders recognise the overall value of the market shaping evidence generated through the TIMCI project, but it has not been accessed by key players including manufacturers and governments. The scope of work has not covered the key market barriers in terms of demonstrating funded demand to manufacturers or addressing the issues of affordability. The work has therefore not been catalytic in terms of encouraging market entry and product availability.** This evaluation found limited evidence that market shaping outputs had reached or had been used by key stakeholders who can action market development in terms of manufacturers, governments, donor partners, etc. Amongst stakeholders who were aware of these outputs, the majority considered them valuable to complement existing tools and evidence in this area and for closing the knowledge gap on demand and supply for MMs in LMICs. However, stakeholders also shared that on their own these outputs may not be enough to encourage manufacturer investment to commercialise improved tools for LMICs, or tangibly increase demand and procurement in LMICs.
    - Stakeholders interviewed including manufacturers flagged that the main barrier deterring further investments from suppliers was the high market entry costs to develop and commercialise products in LMICs. This high cost is mostly driven by the complexity of regulatory requirements that necessitate long and costly product updates. In addition, they highlighted the absence of concrete evidence of demand (e.g., existing procurement orders, evidence of funding) and lack of aggregate demand (e.g. pooled procurement providing visibility on large volumes), making it hard for manufacturers to justify R&D investments and regulatory updates in addition to other costs required for commercialisation, distribution etc. to enter the LMIC market. This is aligned with findings reported by the TIMCI project, which highlighted that whilst some manufacturers have signalled being able to offer more competitive prices for MM products designed for low-resource settings (~US$150-200), they expressed hesitation in investing before a credible market is demonstrated in these countries.[74]

> *"Key challenges are around complex regulations that keep changing, take long and cost money to manufacturers to stay compliant. This is exacerbated by a lack of visibility on demand or procurement orders to justify or encourage investments from manufacturers"*
>
> *- Industry stakeholder*

    - On the demand side, the project reported various underlying causes hindering uptake and demand for better tools including limited product awareness and high price of MMs compared to substitute products.[75] Whilst the TIMCI outputs may offer a solution to the first barrier, affordability was not directly targeted in this project. This is all the more critical as stakeholders highlighted that product affordability was the strongest barrier hindering the procurement of better tools and MMs in LMICs. This echoes feedback documented through the TIMCI project which reported for example, that *despite its availability on the UNICEF procurement catalogue, the Rad-G had limited uptake in LMIC settings prior to COVID-*

[70] Estimate in India was only done at state level (Uttar Pradesh)

[71] Market size estimated for PO needs across relevant use cases and all facility levels in the public and private sectors. *PATH (2021). Market Intelligence Report on Multimodal Devices.*

[72] The MM market is estimated to take a portion of the existing PO market, primarily the following market segments: paediatric inpatient and outpatient (all countries), triage (all countries), and critical care at the PHC level (all countries except India). *PATH (2021). Market Intelligence Report on Multimodal Devices.*

[73] PATH (2021). Market Interventions for Multimodal Devices: Barrier Assessment and Next Steps

[74] PATH (2021). Market Interventions for Multimodal Devices: Barrier Assessment and Next Steps

[75] PATH (2021). Market Interventions for Multimodal Devices: Barrier Assessment and Next Steps

19 due in part to its price, cited as a significant barrier to its uptake.[76] In the Post-Market Landscape report, the project reported that 94% of respondents interviewed indicated they would purchase the Rad-G device, but only half were able to afford it due to limited budgets.[77]

- As such, the interventions implemented under the TIMCI market shaping output may have limited direct acceleration effect to encourage the development or market entry of new tools, or have catalytic impact to stimulate better demand from LMICs**.** It is important to recognise that uptake of the evidence and market insights produced by TIMCI may occur beyond the period of this evaluation and therefore are not captured here, particularly use of the hybrid study results, which is only recently completed.

Next generation devices – Key Lessons and Insights

- Affordability remains a key barrier in the adoption of quality pulse oximeters adapted for children, where there is a substantial gap between willingness to pay and the current price point of devices. An absence of concrete evidence of financed demand, or aggregate demand, is one of several barriers to price reduction. Recognising constrained domestic health budgets affordability is highly relevant for future investments in multimodal devices, In the absence of an intervention to address affordability, scale up is likely to be incremental, emphasizing the importance of including pulse oximetry for children within national oxygen roadmaps and their financing.
- Based on stakeholder feedback, haemoglobin measurement was viewed as most likely to add substantially to improved identification and management of sick children, whilst other measurements and vital signs in multimodal devices were considered as only incremental improvements.

6.3. EQ6 – KNOWLEDGE DISSEMINATION

6. How well have the investments and Unitaid disseminated knowledge, evidence and lessons learned on equitable access to better tools to identify severe disease in children? To what extent has this contributed to generating broader awareness and increased support for these investment areas from other stakeholders?

This question aims to assess whether the research evidence from the projects have been well disseminated and communicated to the right stakeholders/audiences at both global and country levels. This will also include assessing the effectiveness and impact on the TIMCI advocacy efforts on national stakeholders and policies.

- **TIMCI and AIRE advocacy and knowledge sharing throughout project implementation was highly effective and contributed to drive policy changes at national level within project countries.** All countries interviewed reported strong engagement from the project teams and effective knowledge sharing throughout implementation. Across countries, TIMCI and AIRE integrated the projects into relevant technical working groups (TWGs) and participated in key policy meetings where they were able to influence decision making and advocate for PO integration in relevant policies and supporting tools.
    - The projects used a wide range of communication channels to disseminate knowledge, evidence and lessons learned from the projects, including meetings with key stakeholders (e.g., regular meetings with MoH and national and district authorities in both projects), national conferences (e.g., AIRE presentation of preliminary results at the 21st Health Sciences Days in Bobo-Dioulasso, Burkina Faso) written dissemination tools through published research protocols, blogs (on grantees and partners websites as well as external media platforms), policy briefs and poster presentations etc. Stakeholders highlighted the regional conference in Dakar in 2023 as a particularly valuable dissemination event providing a space for effective knowledge sharing and exchange across a wide range of stakeholders. The AIRE policy

[76] PATH (2021). Market Interventions for Multimodal Devices: Barrier Assessment and Next Steps

[77] PATH (2023). Post-market Landscape on Masimo Rad-G Pulse Oximeter Device.

briefs created for each country were also found to be very helpful and provided an accessible, easily digestible communication tool to disseminate knowledge. This enabled project evidence to reach a wide audience across key stakeholders including national authorities, the scientific community, medical professionals etc.

- Stakeholders also noted the projects' efforts to promote equitable knowledge sharing (e.g., TIMCI dissemination activities in Kenya included events at both subnational/district level and national level). Through their CCSE activities, the projects reported using various media such as national radio, online platforms and various in-person awareness raising activities to reach a wide range of population groups and sensitise relevant communities.
- All these efforts contributed to promote 'just-in-time' learning by national stakeholders (including national authorities, technical partners, civil society and communities etc.) throughout the projects, strengthened knowledge sharing overall and facilitated better visibility of PO need at PHC, as well as need for adapted tools for children overall.

- **Still, there were some missed opportunities to strengthen knowledge dissemination and advocacy at national level.** Some key aspects are as follows:
  - Whilst the projects engaged both national and global partners to identify opportunities for further funding for POs, there was **limited evidence of in-country budget advocacy** to promote identification of opportunities for funding through domestic resources – and this was reported as an under-funded area in both projects. For TIMCI, local budget advocacy may also have been tempered in countries (notably Tanzania and Kenya) which had indicated a desire to review the study results prior to scale up decisions. There were some exceptions to this, and local budget advocacy increased in the final year of the TIMCI project, along with linked activities such as value-based procurement workshops (to support accurate forecasting and understanding of need to procure quality PO devices). As noted in the Kenya case study, all three project counties had committed financing for some TIMCI activities.
  - An **insufficient knowledge dissemination with observer countries** - due to a lack of updates and poor document sharing amongst other issues (as highlighted in section 2.3.1) to facilitate further review and dissemination beyond project countries. A final observer country dissemination event which will emphasize south-south learning will be held in Tanzania in June 2024.
  - The **limited reach of TIMCI market shaping outputs** – as described in EQ5 above – which may have been exacerbated by the lack of diverse formats to disseminate intelligence and evidence generated. For example, it was suggested that the use of 'bite size' communication tools and summaries would be more accessible to general audiences and complemented existing outputs (mostly available through dense reports) that are better suited for technical audiences.
  - A **suboptimal use of the IAG to strengthen dissemination** – for example by using IAG meetings to think through the research results well in advance during analysis stage and before dissemination to identify gaps, strengthen results analysis and interpretation and anticipate key questions. This was notably flagged as a missed opportunity before the Dakar conference (for AIRE research results) and before TIMCI national dissemination events. They also suggested that the project teams could have better leveraged IAG members for advocacy (e.g., by encouraging them to raise awareness of the projects in their networks and providing them with talking points whenever they had relevant opportunities), and for enabling greater coordination and linkages with donor partners in country to identify sustainability and scalability opportunities earlier in the projects.

- **Due to project delays, dissemination of the final research results at both the national and global level was compressed. As a result, it is too soon to assess the effectiveness, impact and influence of evidence generated through this portfolio**. Key findings are as follows:
  - The projects reported various efforts to disseminate evidence at national and global levels. The AIRE consortium disseminated its preliminary research in global, regional and national conferences and scientific events (e.g., reported participation and presentation at Health Systems Research conference in

Bogota, MSF Paediatric Days online, the 2nd International Conference on Public Health in Africa (CPHIA) in Kigali, the Senegal Public Health Days, the World Congress of Public Health Italy, Annual Meeting of the European Society for Paediatric Infectious Diseases (ESPID) in Togo and in Portugal). The TIMCI project reported similar efforts to disseminate knowledge and learning from the project at global level through various high-level meetings (e.g., side events WHA, advocacy at UNGA as part of HLM on UHC and PPPR) and conferences at national, regional and global level (e.g., participation at the 2nd Global Forum on Childhood Pneumonia, International Conference for Primary Health Care in Ethiopia, Paediatric Association of Tanzania conference, abstract shared for World Congress on Epidemiology 2024 meeting in South Africa). This includes knowledge sharing regarding the project work on skin pigmentation with UCSF.

- However, in both projects, time and capacity for advocacy and evidence dissemination had been highly compressed, due to delays as a result of the COVID-19 pandemic as well as inherent project challenges as describe in section 2.2.1. Stakeholders highlighted that these delays significantly hindered the effectiveness of knowledge dissemination activities for both projects. As a result, the dissemination period, originally planned to be over a year, was considerably reduced (e.g., ~6 months). Research findings ended up being disseminated through standalone activities at the end of the projects, rather than being integrated as part of ongoing project implementation.
- Joint dissemination between the AIRE and TIMCI projects also ended up being significantly limited due to different timelines between the projects as a results of these delays. Only a few joint dissemination activities were reported (e.g., TIMCI project team attendance at the AIRE Dakar dissemination conference, TIMCI presentation of both projects results at ASTMH in 2023, a planned "learning lab" with AIRE and TIMCI observer countries in 2024). This was seen as a missed opportunity to present a comprehensive assessment of the introduction of PO at PHC (and within IMCI) and strengthen interpretation of study findings across different contexts.
- In addition, analysis and dissemination of TIMCI research results (from the RCT, pre-post and hybrid study) were still in progress at the time of this evaluation in the final months of the project. As a result, this evaluation was limited in its ability to investigate the effectiveness of the TIMCI dissemination activities, and it is unclear how evidence from both the AIRE and TIMCI projects will continue to be shared after the portfolio has ended.

Going forward, stakeholders recommended that further analysis of TIMCI research data should be conducted to strengthen the interpretation of the study results and drafting of key messages and encouraged joint dissemination of both AIRE and TIMCI results whenever possible. WHO also recommended that a wider systematic review of available evidence concerning pulse oximetry introduction [at lower levels of care] should be done jointly with a review of findings from TIMCI and AIRE to inform global guidance.

Knowledge dissemination – Key Lessons and Insights

- AIRE and TIMCI responded well to high country demand for evidence, recognising this remains ongoing for TIMCI. The very limited time for dissemination in AIRE was however a missed opportunity for unpacking country-specific study results given the diversity of outcomes and health seeking behaviours.
- The different timelines of the projects along with different analysis plans were the most significant missed opportunity to compare evidence findings across diverse contexts, particularly as there was intentional complementarity of the TIMCI and AIRE study protocols (though now less important in light of TIMCI findings). The projects did well to identify joint opportunities for dissemination.
- Different communication formats to better leverage and disseminate comprehensive/ 'dense' products, such as the multimodal device landscape, might help to reach key audiences in project countries and globally.
- Engaging WHO through the IAG helped support alignment with WHO's process for guideline review, though opportunities for closer working with WHO within the portfolio may have been beneficial (noting WHO were consulted in developing the study questions). The opportunity to collaborate with WHO to review TIMCI and AIRE results alongside other evidence of pulse oximetry at the primary care level is important for supporting

the uptake of the portfolio evidence and contributing to the global knowledge base related to hypoxemia in children.

6.4. EQ7 – EQUITY, INTERSECTIONALITY AND PEOPLE-CENTEREDNESS

7. To what extent did the investments align with Unitaid's strategic principles and commitment to equitable, intersectional and people-centred approaches?

Through this question, the evaluation assessed how the AIRE and TIMCI investments integrated equitable, intersectional and people-centred approaches in the project implementation. Key findings are as follows:

- **The projects demonstrated strong equity, intersectionality and people-centeredness focus by design and during implementation.** The design and implementation of the projects promoted equity and inclusivity in their approach, including by targeting severe disease in children in a disease-agnostic way, focusing at the PHC level, using CHWs to reach to hardest to reach communities, raising awareness on the issue around poor accuracy of POs on pigmented skin (PPG), and adopting participatory, user focused approaches to engage with stakeholders (e.g., TIMCI HCD). The project implementation across various geographic locations (i.e., different countries – including the Sahel region, rural and urban sites) also enhanced inclusivity and equity by providing services and enabling evidence generation across a wide range of population groups. The implementation of inclusive CCSE strategies further increased projects' reach across population groups (e.g., engagement of traditional healers in Burkina Faso).
- **Potential missed opportunities** in this area include lack of disaggregated analysis by gender within the prioritised, early analysis, particularly trends in care seeking behaviour and health outcomes (though gender-disaggregated data are included in detailed reports and planned publications). Areas where a more people-centred approach may have been beneficial in intervention design include appropriate factoring of the time constraints of busy health providers and the difficulty of referrals within under funded health systems in LMICs.

APPENDIX A BIBLIOGRAPHY

Appendix B provides the list of documents and references used for this report. It is *not complete and will be updated in second draft report.*

Azevado et al (2024). Hard truths about under-5 mortality: call for urgent global action

ALIMA (2019) grant agreement executive summary

ALIMA AIRE (OPTIFARE) project plan 2019-2022

AIRE (2023) project overview evaluation kick off presentation

AIRE narrative annual reports 2021, 2022

AIRE scalability matrices 2021, 2022

AIRE (2020) project plan amendment

AIRE (2022) project plan amendment (NCE)

Hedible et al. (2022) Evaluation of the routine implementation of pulse oximeters into integrated management of childhood illness (IMCI) guidelines at primary health care level in West Africa: AIRE research protocol

AIRE (2023) Household Costs_Final Report

AIRE (2023) Process Evaluation Final Results Report

AIRE (2023) ITINER'AIRE Study Results Report

AIRE (2023) Final AIRE Research Results Report

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Offosse et al (2023). Effectiveness of the Gratuité user fee exemption policy on utilization and outcomes of maternal, newborn and child health services in conflict-affected districts of Burkina Faso from 2013 to 2018: a pre-post analysis

PATH (2019) grant agreement executive summary

PATH TIMCI project plan 2019-2023

TIMCI (2023) project overview evaluation kick off presentation

TIMCI (2021) project plan amendment - output 3 revision

TIMCI (2022) project plan amendment (NCE)

TIMCI (2022, 2023, 2024) narrative annual project reports 2021, 2022, 2023

TIMCI scalability matrices 2021, 2022

TIMCI (2023) project plan amendment - output 8 scope A and B (CE)

TIMCI (2022) Next Generation Pulse Oximeters Technology and Market Landscape

Tan et al. (2023) ePOCT+ and the medal-suite: Development of an electronic clinical decision support algorithm and digital platform for paediatric outpatients in LMICs; PLOS Digit Health.

TIMCI (2023) CDSA Learning Report

TIMCI (2022) CDSA Scale_Sustainability Report

TIMCI (2022) CDSA India Clinical Decision Support Tool (CDSA) Extended Pilot

TIMCI (2022) CDSA Implementation of electronic medical records and clinical decision algorithms (Senegal, Kenya, Tanzania reports)

TIMCI (2020) TPP for CDSA

TIMCI (2021) Pulse Oximeters and Multimodal Devices, Market Reports (India, Kenya, Senegal, Tanzania)

TIMCI (2021) Research Protocol_Cross-country Quasi-experimental Pre-post Study in Kenya and Senegal

TIMCI (2021) Research Protocol_Evaluation of Pulse Oximetry and Clinical Decision Support Algorithms in Primary Care

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PATH (2021). Market Intelligence Report on Multimodal Devices

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APPENDIX B CONSULTATION LIST AND INTERVIEW GUIDE

B.1. GLOBAL CONSULTATION LIST

This appendix provides a list of stakeholders interviewed at the global level across phase 1 and 2 of this evaluation in Table C.1.

Table C.1: Global list of stakeholders

Stakeholder group/ Organisation/	Name(s)	Position	Phase interviewed
Unitaid SMT	Robert Matiru	Director, Programme Division	Phase 1
	Alexandra Cameron	Former Unitaid (now WHO)	Phase 1
Unitaid Secretariat	Matthew Black	Program Manager for AIRE, TIMCI	Phase 1 & 2
	Rachel Evans	Program Officer	Phase 1 & 2
	Priyanka Soni	Results Officer	Phase 1 & 2
	Pablo Vega Rojas	Technical Officer, oxygen portfolio	Phase 1 & 2
	Tanya Guenther	Monitoring and Evaluation Manager	Phase 2
	Aroosha Sadaghianloo	Legal Officer	Phase 1
	Katerina Galluzo	Technical Manager, Strategy	Phase 1
	Katie Huang	Programme Manager, GOAL	Phase 2
	Gamu Gwaza	M&E Manager, oxygen portfolio	Phase 2
PATH consortium			
PATH	Mike Ruffo	Director	Phase 1 & 2
	Mira Emmanuel-Fabula	Deputy Director	Phase 1 & 2
	Elena Pantjushenko	Communications/Advocacy manager	Phase 1 & 2
	Viviana Rivas	Market Access Lead	Phase 1 & 2
	Helen Storey	Research and product development advisor	Phase 2
Swiss Tropical and Public Health Institute (STPH)	Fabian Schaer	Program Manager	Phase 1 & 2
	Fenella Beynon	Research Scientist	Phase 1 & 2
	Kaspar Wyss	PI and Head of Department	Phase 1 & 2
	Leah Bohle	Technical Expert and Project Manager	Phase 1 & 2
Unisante	Valerie D'Acremont	Clinical epidemiologist	Phase 1 & 2
University of Waterloo	Sue Horton	Professor	Phase 2
PATH India	Dr. Kovid Sharma	Project lead, TIMCI	Phase 1 & 2
	Neeraj Dixit	State Program Officer, TIMCI	Phase 1 & 2
PATH Tanzania	Deusdedit Mjungu	Tanzania PATH country lead	Phase 1 & 2
ALIMA consortium			
ALIMA	Marine Vignon	Responsable projet	Phase 1 & 2
	Désiré Néboua	Responsable médical	Phase 1 & 2
Terre des Hommes (TdH) - Regional	Sandrine Busiere	Regional Coordinator, Health Program in Africa	Phase 1 & 2
Solthis - Niger	Franck Lamontagne	Référent technique pour AIRE Niger, Solthis Paris	Phase 1
	Roubanatou Abdoulaye - Mamadou	Directrice Pays Solthis NIGER	Phase 2
	Moutari Baraya Oumarou	Superviseur clinique du projet AIRE à Niamey	Phase 2
IRD	Valéry Ridde	Directeur de recherche	Phase 1 & 2

Stakeholder group/ Organisation/	Name(s)	Position	Phase interviewed
Inserm	Valériane Leroy	Directrice de recherche	Phase 1 & 2
	Boris Hedible	AIRE Research manager	Phase 2
TdH Burkina	Adama Hema	Chef de Projet AIRE	Phase 1 & 2
MSHP DSF - Burkina	Moussa Kinda	Point focal AIRE, MoH	Phase 1 & 2
ALIMA Guinea	Sory Keita	National project manager/Head of mission	Phase 1
MoH - Guinea	Djeney Fadima Kaba	PI - Directrice Nationale de la Santé Familiale et de la Nutrition (DN)	Phase 1 & 2
IAG members			
Clinton Health Access Initiative CHAI	Audrey Battu	Senior Director, essential medicines	Phase 1 & 2
UNICEF	Noah Mataruse	Health Product Innovation Manager	Phase 1
Global Fund	Nicholas Furtado	Advisor RSSH-RMNCAH, Technical advice and partnerships	Phase 1
University of Melbourne	Hamish Graham	Consultant Pediatrician and research fellow	Phase 2
Technical Agencies			
WHO	Yasir Bin Nisar	Medical Officer, Department of Maternal, Newborn, Child and Adolescent Health and Ageing	Phase 1 & 2
UNICEF	Anne Detjen	Health Specialist Integrated Service Delivery (iCCM/IMNCI)	Phase 1
	Denis Muhoza	Health Specialist, Child Health & Community Systems, West and Central Africa Regional Office	Phase 1
	Martha Mulerwa	Biomed/coordinator for Health & HIV Section, WCA Regional Office	Phase 1
	Habtamu Tolla	Health Specialist, Access to Essential Child Health Medicines	Phase 1
Africa CDC	Dr Raji Tajudeen	Head, Division of Public Health	Phase 2
WHO Tanzania	Dr Iriya Nemes Joseph	Programme Officer at WHO	Phase 2
UNICEF Burkina	Fatoumata TONI SANOU	Section Santé. Pédiatre-Spécialiste Santé Maternelle et Néonatale	Phase 1 & 2
Other international organisations			
Every Breath Coalition - EBC	Leith Greenslade	EBC coordinator	Phase 1
Hypoxia Lab	Michael Lipnick	Anesthesiologist, UCSF	Phase 2
Manufacturers			
Masimo	Grant Aaron	Vice president, Global Health at Masimo	Phase 1
Acare	Linda Cheng	CEO	Phase 2
Sinopharm	Tian Zhen	Product Specialist & Business Manager	Phase 2
Biolight	Doris Pan	Sales and Marketing Manager	Phase 2
Donors /early stage funders			
BMGF	Rasa Izadnegahdar	Director, Maternal, Newborn & Child Health Discovery & Tools	Phase 1
USAID	Leah Greenspan		Phase 2
	George Siberry	Chief Medical Officer, Acting Deputy Director, Office of HIV/AIDS (OHA) Senior Medical Advisor, COVID-19	Phase 1

Stakeholder group/ Organisation/	Name(s)	Position	Phase interviewed
		Response Team, Bureau of Global Health (GH)	
Observer countries			
Malawi	Dr. Humphreys Nsona	IMCI Manager, MoH	Phase 1
Uganda	Robert Mutumba	Principal Medical Officer, Reproductive and Infant Health Division (National MoH)	Phase 1
	Sabrina Kitaka	Paediatrician and University Professor	Phase 1
Nigeria	Professor Garba Mohammed Ashir	Responsable du service pédiatrique à l'hôpital universitaire	Phase 2
Cote d'Ivoire	Dr Elysee Ndrin	Chargé de programmes et des Projets, MoH	Phase 2
	Dr. Kone	Adjoint au chargé de programmes et des Projets, MoH	Phase 2
India (observer state)	Dr. Dipankar Hazarika	Consultant in national health mission, Assam state	Phase 2
Chad	Dr Djidita Hagre Youssouf	Pediatrics Service, Mother-Child University Hospital, N'Djamena, Chad	Phase 1
Mauritania	Dr Mohamed Ahmed TAGHI	Coordinateur PN Télémédecine	Phase 2

B.2. INTERVIEW GUIDES

Appendix C.2. provides a list of interview guides used for global level consultations (including for non-case study countries interviews) in phase 2 of this evaluation.

B.2.1. Unitaid Secretariat

1. What do you view as the most significant progress achieved through this portfolio since Phase 1?
2. In your opinion, to what extent have the grants contributed to creating sustainable access for pulse oximeters (POs), CDSAs and next generation multimodal (MMs) devices for PHCs in LMICs, with regards to:
    i. Country adoption and readiness to scale?
    ii. Alignment and coordination with global donors to leverage existing opportunities for PO funding?
3. To what extent has TIMCI been successful in accelerating the development and availability of next generation multimodal (MM) devices?
    i. What are key areas of progress and gaps remaining?
    ii. With the benefit of hindsight, is there anything Unitaid/TIMCI might have done differently?
4. The following questions focus on the emerging findings of the TIMCI and AIRE studies:
    i. In your view, what are the implications of the TIMCI and AIRE study results on efforts to improve diagnosis of hypoxemia through PO at PHC level in LMICs?
    ii. What are the implications regarding adoption and scale up of CDSAs and MMs in LMICs?
    iii. What assumptions did the project initially have (e.g., regarding referral systems and care seeking behaviour) and how do you think these have played into the emerging study findings?
    iv. What are the wider implications for Unitaid and other partners aiming to improve child health outcomes by intervening at lower health system levels (and beyond vertical disease-specific approaches)?
5. What have been Unitaid's and this portfolio's overall contributions to enhancing global-level conditions for PO scale up/ hypoxemia management for children?
    i. How effective have knowledge sharing, evidence dissemination and advocacy activities been overall? What more could have been done?
    ii. Could anything more have been done to maximize synergies with global donors and partners existing efforts (e.g., Gates, WHO, IAG members)?
6. How well has Unitaid leveraged its role and position within global alliances (e.g., GO_2AL) to support scale-up and sustainability of PO in LMICs?
    i. What more could Unitaid do to support the sustainability and scalability of interventions and gains achieved through this portfolio?
7. What are the key lessons learned and recommendations from this portfolio to guide Unitaid's future investments, in particular regarding:
    i. Interventions at lower levels of the health system (e.g., PHC) and relying on wider system level factors for impact (e.g., referral)
    ii. Market shaping interventions especially for non-disease specific products (e.g. MNCH)?

B.2.2. Unitaid Oxygen Team

1. Could you share a brief overview of your knowledge of this portfolio?
2. How relevant was this portfolio to Unitaid especially in relation to its investments in the oxygen space?

3. To what extent has this portfolio contributed to strengthening Unitaid's role and engagement with global partners and global alliances (e.g., GO_2AL)?
    i. To what extent is the need for appropriate PO tools for children U5 and PHCs highlighted in wider conversations on oxygen systems strengthening?
4. What are key opportunities for Unitaid to leverage the knowledge and gains from this portfolio within other existing portfolios?
    i. Within the oxygen portfolio?
    ii. In other relevant programmatic priorities (e.g., women and children's health, other Unitaid priority areas)?

B.2.3. Grantees (TIMCI consortium - Project Team)

1. Since September, what progress has been made in facilitating the demand, adoption and scale up of pulse oximeters (POs) and the use of CDSAs across project countries (and beyond) in relation to:
    i. Country adoption and readiness to scale? (e.g., evidence of scale beyond project sites, consolidation of policy environment, supply chain systems, financing or political commitment)
    ii. Alignment and coordination with government and donors to leverage opportunities for PO funding?
    iii. Evidence of spillover effect in observer countries?
2. In your opinion, to what extent can these results be attributed to the TIMCI grant?
    i. Which factors or interventions from the project have had the biggest impact and why?
    ii. How sustainable are these gains with regards to both the adoption of PO and CDSAs?
3. What has been the added value of the evidence generated regarding PO use within IMCI? And regarding CDSA use within IMCI? *(This question will be covered in more depth during the consultation on output 2)*
    i. What are the implications of the study results on efforts to promote PO adoption to improve identification of hypoxemic children at PHC level?
    ii. How effective have knowledge sharing, evidence dissemination and advocacy activities been overall and especially since September 2023?
    iii. What evidence/project dissemination in your view have been most significant for influencing decision-makers to date? How has this differed between countries?
4. In your opinion, what worked well and less well in the design and implementation of the project and Unitaid's engagement in the project overall?
    i. Which assumptions were considered (or not) at the design stage and what were the implications?
    ii. What aspects worked well and less well in regard to CCSE within the project? How sustainable are these interventions?
5. What are in your opinion, some of the main lessons learnt and recommendations from the project overall with respect to:
    i. PO (and CDSA) sustainability and scale in project countries and beyond, based on the project experience and study results.
    ii. Recommendations for future Unitaid investments, particularly where interventions are reliant on wider health systems components for health impact.
    iii. Recommendations for Unitaid investments to generate evidence of intervention impact and influence policy/programming.

B.2.4. Grantees (TIMCI consortium – Research)

1. What do you view as the added value of the TIMCI research to the existing body of evidence on this issue?
    i. What are the implications of the study results on efforts to promote PO adoption and improve identification of hypoxemic children at PHC level?
    ii. In your view, how did the research promote equity, intersectionality and people-centeredness in its design and implementation?
2. How effective was the overall management and implementation of the research?
    i. Could Unitaid (or others) have done anything more to support the research aspect of TIMCI?
3. How effective have knowledge sharing and evidence dissemination been overall and especially since September 2023? Could anything further have been done?
    i. In your view, how effective was joint results review / dissemination with AIRE ?
4. What do you think are areas for further research or future priorities for evidence generation following the TIMCI research?
5. What are in your opinion, some of the main lessons learnt and recommendations from the project overall with respect to:
    i. PO (and CDSA) sustainability and scale in project countries and beyond, based on the project experience and study results?
    ii. Recommendations for future Unitaid investments, particularly where interventions are reliant on wider health systems components for health impact?
    iii. Recommendations for how Unitaid invests in evidence generation?

B.2.5. Grantees (TIMCI consortium – Market Shaping)

1. What progress has been achieved with regards to accelerating the development and market entry of next generation multimodal devices (MMs) suitable for PHCs in LMICs, since the beginning of this project? Was PO a good
    i. What intervention has had the biggest difference/impact, and why?
    ii. How sustainable are those successes? What challenges remain?
    iii. With the benefit of hindsight, is there anything Unitaid/TIMCI might have done differently to strengthen their market shaping approach through this portfolio?
2. What were the key findings of the hybrid study and what was the added value of this research?
    i. What are implications of these results on efforts to promote better supply and demand for MMs?
3. How effective has dissemination of market shaping knowledge/outputs and study results been overall, and especially since the end of Phase 1 in September 2023? What more could have been done?
4. How has engagement with the manufacturers been throughout this project?
    i. How valuable was this engagement?
    ii. What have been the key learnings from engaging manufacturers on PO/MM devices?
5. How well have the project market shaping interventions maximized alignment and synergy with existing global partners efforts on this issue?
6. What are some of the main lessons learnt and recommendations from the project with respect to:
    i. The sustainability and scalability of market shaping interventions in project countries and beyond, based on the project experience and study results?

ii. Future investments from Unitaid's in MM devices and market shaping more widely?

B.2.6. Grantees (AIRE consortium)

1. Could you please share what progress has been made in facilitating the demand, adoption and scale up of pulse oximetry (PO) and CDSAs in project countries since the end of the AIRE project and following Phase 1, in relation to:
    i. Country adoption and readiness to scale? (e.g., evidence of scale beyond project sites, consolidation of policy environment, supply chain systems, financing or political commitment)
    ii. Evidence of alignment and coordination with global donors to leverage existing opportunities for PO funding?
    iii. Evidence of spillover effect in observer countries?
2. Has there been any further dissemination of AIRE project research results since Phase 1?
    i. How have the research results been received by stakeholders? Do you have a sense which study findings are considered most influential to country stakeholders?
    ii. In your view, what are the implications of the AIRE study results on efforts for PO scale up at country and global level?
    iii. How effective have knowledge sharing, evidence dissemination and advocacy activities been overall and especially since Phase 1? What more could have been done?
3. How well did the project support intersectional and people-centered approaches? What more could have been done?

4. In hindsight, were there any key assumptions that should have been considered at the design stage that were not, and what were the implications?
5. What are in your opinion, some of the main lessons learnt and recommendations from the project overall with respect to:
    i. PO sustainability and scale in projects countries and beyond based on the project findings?
    ii. Unitaid's future investments to introduce innovations within the patient health pathway and in LMICs?
    iii. How Unitaid supports the generation and dissemination of evidence to influence policies and uptake of product 'innovations'?

B.2.7. Technical partners/IAG

1. Please describe your engagement with Unitaid and the two grants TIMCI and AIRE since September 2023?
2. What are the implications of the TIMCI and AIRE research studies on efforts to improve diagnosis of hypoxemia through PO and CDSAs at PHC level in LMICs?
    i. What do you see as the main value add and limitations of the AIRE and TIMCI evidence?
    ii. What impact do you think these results will have on countries and global partners (e.g., implications for WHO's recommendations)?
    iii. How effective has evidence dissemination been throughout the projects? In hindsight should anything have been done differently (e.g. engaging IAG, technical experts, results review and dissemination)
3. In your view, what are the implications of the projects market shaping interventions to improve the supply and demand of adapted multimodals (MMs) for global partners and countries?

   i. What intervention/output has been most valuable, and why?
   ii. How effective has knowledge dissemination been in that regards?
   iii. How sustainable are those successes? What challenges remain?
4. What is your view on the sustainability and scalability of the project interventions and progress made overall?
   i. What more could Unitaid do to mobilise further support on this issue?
5. What are some lessons learned and recommendations to guide Unitaid's investments in this area going forward?
   i. What are lessons learned and recommendations for investments that focus on intervening within health systems more widely (for e.g. where referral pathway and decision making play an important role in intervention impact)?

B.2.8. Technical partners (country)

1. What has been your engagement with the work done in this portfolio through the [TIMCI/AIRE] grant?
2. What is the current situation concerning regarding the use of PO in IMCI at PHC level in the country ?
   i. To what extent has the [TIMCI/AIRE] project contributed to enabling sustainable access conditions for pulse oximeters (POs), CDSAs and next generation multimodal devices (MMs) in the country (e.g. policies, procurement, budget allocation)?
   ii. What is your view on the sustainability and scalability of these interventions?
3. What is the key value add of the [TIMCI/AIRE] interventions and evidence generated through this portfolio?
   i. What are implications of the projects and study results on efforts to promote better supply and demand for POs, MMs and CDSAs at PHC level in LMICs?
   ii. What evidence generated by [TIMCI/AIRE] has been most influential to decision makers, and why?
4. To what extent were the project interventions aligned with existing efforts on this issue?
   i. Could anything more could have been done to leverage existing opportunities with other partners/funders at country level?
5. What recommendations do you have to inform:
   i. Future investments where referral of sick children is an integral part of the care pathway
   ii. Future work on multimodal devices, and appropriate levels of care for these devices

B.2.9. Donors

1. What has been your engagement with Unitaid on this portfolio and with TIMCI and AIRE projects?
2. To what extent has this portfolio contributed to enabling better access to pulse oximeters (POs), CDSAs and next generation multimodal devices (MMs) adapted for children at PHC level in LMICs?
   i. How relevant was this portfolio of work to public health and market needs for better tools to diagnose severe diseases in children?
   ii. To what extent were the portfolio interventions aligned with donors existing efforts on this issue?
3. In your opinion, what are the implications of the projects research results on efforts to promote better supply and demand for POs, MMs and CDSAs at PHC level in LMICs?
   i. What is the key value add of Unitaid's interventions and evidence generated through this portfolio?
4. What is your view on the sustainability and scalability of these interventions?

i. What more could have been done to leverage existing opportunities through global partners?

5. In your view, what was the extent of Unitaid's role in developing global alliances to support scale-up and sustainability of pulse oximetry for children at PHC level?
    i. What might have been the progress in this space in the (hypothetical) absence of Unitaid's projects?
    ii. How might Unitaid further leverage their position and optimize relationships with global partners to increase support on this issue?
6. What recommendations do you have to inform Unitaid wider strategy and future investments in the area?

B.2.10. Government

1. Please describe your awareness and engagement with the work done by the [TIMCI/AIRE] project.
2. What was the situation regarding the use of pulse oximeters (PO) adapted for children under 5 and CDSAs within IMCI at PHC level in the country at the start of [TIMCI/AIRE] in 2019?
3. What progress has been made since 2019 regarding country readiness for PO, CDSAs adoption and scale up, especially with regards to:
    i. Strengthening the national environment (e.g., policy landscape, infrastructure, supply chain, financing, political will)?
    ii. Addressing challenges at PHC level (e.g., availability of adapted tools, HCWs capacity)
    iii. Improving community level awareness and engagement (e.g., care seeking behaviors)
4. In your opinion, to what extent has the [TIMCI/AIRE] grant contributed to this progress?
    i. What interventions have had the biggest impact and why?
    ii. How relevant were the project interventions with regards to country needs and priorities?
    iii. Are there any best practices or challenges from this project that you would like to highlight in relation to the project's alignment or engagement with country stakeholders?
5. What has been the added value of the evidence generated regarding PO use within IMCI at PHC level? And regarding CDSA use within IMCI?
    i. What are the implications of the study results on efforts to promote PO adoption and improve identification of hypoxemic children at PHC level in LMICs?
    ii. How has the project supported country stakeholders to interpret study results?
    iii. How effective have knowledge sharing, evidence dissemination and advocacy activities been overall?
6. Is there demand for introducing multimodal devices (MMs) suitable for children, and in what settings? (TIMCI countries only)
    i. Are there any concrete plans for introducing MM devices at the PHC level?
    ii. To what extent was TIMCI useful in informing the country's plan and choice of MM device?
7. Do you have any recommendations regarding opportunities to sustain the progress achieved to date?

B.2.11. Manufacturers

1. Please describe how have you engaged with PATH and the TIMCI project.
    i. Please describe the markets your pulse oximeter (and/or multi-modal device) is tailored to.
2. Have you found the work by PATH/TIMCI to be useful? If so, what aspects have had the biggest impact and why?

i. Do you think this has helped to accelerate innovation and the development of pulse oximeters and multimodal devices for low and middle-income countries. If so, how specifically?

ii. What might have been the progress in this space in the (hypothetical) absence of the PATH project?

3. What do you consider the main issues for increasing volumes of pulse oximeters and multimodal devices in low and middle-income countries? For example:

   i. Demand factors at country level in low and middle-income countries (procurement, financing etc.)?

   ii. Supply factors (appetite for innovation, pricing, distribution etc.)?

4. From your perspective to what extent did PATH/ TIMCI engage well with manufacturers during this project? What was missing or could have been done better?

5. What recommendations do you have to inform how partners like PATH and Unitaid support the market for pulse oximeters and multimodal devices for low and middle-income countries?

B.2.12. Observer countries

1. Please describe your awareness and engagement with the work done by the [TIMCI/AIRE] project implemented by [PATH/ALIMA] to support the introduction and scale-up of pulse oximetry (PO) within IMCI at PHC level.

2. What was the situation regarding the use of pulse oximeters (PO) and CDSAs in your country at the beginning of your engagement with the [TIMCI/AIRE] project?

   i. What progress was made in facilitating demand, adoption and scale up for PO and CDSAs since then?

   ii. To what extent has the [TIMCI/AIRE] project contributed to these progress?

3. In your view, what has been the key value add of this project to support the adoption of PO and CDSAs within IMCI at PHC level in your country and the region more broadly?

   i. What are the implications of the study results on efforts to promote PO adoption to improve identification of hypoxemic children at PHC level?

4. What has worked or less well in the project's approach to engage observer countries to disseminate knowledge and lessons learnt on this issue? What more could be done?

5. Are there any recommendations that you would like to highlight to Unitaid in relation to future investments in this space and engagement with country/regional stakeholders?

APPENDIX C COUNTRY PROGRESS AGAINST UNITAID COUNTRY READINESS DOMAINS & CONDITIONS

Appendix D provides an overview of project countries progress towards sustaining and/ or scaling up PO and CDSA in Table D.1, as understood at the time of this evaluation:

Table D.1: Overview of country progress against Unitaid country readiness domains and conditions[78,79]

Project countries	Secure political and financial support	Ensure programmatic and operational readiness	Create community-driven demand
Burkina Faso	• Engagement of government officials and country stakeholders throughout project • IMCI technical steering committee being created • Transition and scale up plan developed • PO included in Global Fund country funding request for GC7 • Projects results leveraged in new UNICEF pilot project to introduce PO as part of community health program including in AIRE project region	• PO included in national IMCI (PCIME) algorithm and guidelines • Training of trainers (ToT) in the project region (Boucle du Mouhoun) region to support sustainable capacity building on PO	• Engagement with CHWs during project for community sensitisation and awareness raising
Guinea	• Engagement of government officials and country stakeholders throughout project • Transition and scale up plan developed	• PO introduced in national IMCI (PCIMNE) protocols and algorithm • PO integrated on the national EDL • Acceleration plan (*Plan d'acceleration*) being developed to scale key interventions to reduce pneumonia, including PO procurement	• Engagement with CHWs during project for community sensitisation and awareness raising • Post project CSO Engagement Plan finalised including activities for domestic budget advocacy
Mali	• Engagement of government officials and country stakeholders throughout project	• Revision of IMCI tools to include POs • PO integrated in technical sheet to be validated in next revision medical materials for MNCH	• Engagement with CHWs during project for community sensitisation and awareness raising

[78] Unitaid (2021). Unitaid's Scalability Framework – Guidance for Applicants and Grant Implementers

[79] Progress as reported across various sources including projects latest annual and scalability reports and stakeholders consultation feedback

Project countries	Secure political and financial support	Ensure programmatic and operational readiness	Create community-driven demand
	• Commitment by MoH to include POs in 50% of the 1,400 Community health centers (Centres de Sante Communautaire - CSComs) • Commitment by MoH to make oxygen available in 50% of the 74 district hospitals • Global Fund, the World Bank and USAID, funded PO for health facilities • Transition and scale-up plan and accelerated action plan developed and validated • Costed operational plan developed and awaiting validation		
Niger	• Engagement of government officials and country stakeholders throughout project • USAID, World Bank and Global fund funded PO for all country's health facilities • Commitment from partners such as UNICEF, Save The Children and Catholic Relief Services international (CRS) to continue funding IMCI/PO after project closure	• Revision of national IMCI recommendations to include PO – ongoing • Revision of IMCI materials (register, reports and supervision grid) to include PO • Training provided to HCWs throughout project on IMCI in partnership with Save The Children	• Engagement with CHWs during project for community sensitisation and awareness raising
India	• Engagement of state officials and country stakeholders throughout project • Govt' expressed interest in the outcomes of the hybrid study and use case for MMs • Govt' expressed interest in exploring use of CDSA in other levels of care	• PO included in IMNCI guidelines • Ongoing advocacy to update SAANS guidelines recommendation to specify the use of age appropriate PO (as opposed to generic POs) • Training provided to HCWs on PO during project and training materials to be shared with the govt for use and integration with existing national tools • Roadmap of a TIMCI implementation package developed that can be updated to a scalability plan for a larger adoption and uptake of paediatric-appropriate PO in primary and secondary care	• Engagement with CHWs (ASHAs) during project for community sensitisation and awareness raising

Project countries	Secure political and financial support	Ensure programmatic and operational readiness	Create community-driven demand
Kenya	• Engagement of government officials and country stakeholders throughout project • PO included in Kakamega and Kitui counties annual budgets • MOH committed to include CDSA in upcoming digital health platform •	• PO incorporated in Essential Medical Supplies List, Basic Paediatric Protocol and National Standards for Improving the Quality of Care for Children and Small and Sick Newborns • Oxygen roadmap that incorporates PO under development • Outline of scale up plan shared with and endorsed by MOH – to be adapted to a "lessons learnt" document • Training provided during project including PSM Value based procurement workshop with MoH staff as well as on-the-job training to HCWs, supportive supervision and mentorship • PO supply landscape study initiated	• Engagement with CHWs during project for community sensitisation and awareness raising
Senegal	• Engagement of government officials and country stakeholders throughout project • MOH Directorate of Maternal and Child Health (DSME) Director shared commitment to use TIMCI results to inform next RMNCH five-year strategic plan • Scale up plan being developed in partnership with MoH - considering a pivot to documenting the lessons learned in light of study results • New digital team created within MoH to work on national digital health architecture	• IMCI booklet reviewed and integrating recommendation for SpO2 measurement with PO • PO being included in strategic health plan which would be costed - ongoing • Oxygen roadmap that incorporates PO under development	• Engagement with CHWs during project for community sensitisation and awareness raising

Project countries	Secure political and financial support	Ensure programmatic and operational readiness	Create community-driven demand
Tanzania	• Engagement of state officials and country stakeholders throughout project • Government committed to support integration of CDSA into national Health Operational Management Information System (GoTHOMIS) • PO included in Global Fund country funding request for GC7 • [Project] District authorities agreed to include PO in next planning cycle for district budget • Medical Store Department (MSD) asked [by Ministry] to ensure availability of handheld POs in 2024 catalogue • Oxygen investment roadmap developed with quantification of PO for each health facility	• IMCI guidelines in project sites updated to include PO[80] • Development of a Tanzania oxygen investment road map • Training provided including PSM Value based procurement workshop with MoH and MSD staff and training of trainers (ToT) • CDSA scale-up plan discussions ongoing • Medical Equipment and Infrastructure Management Information System for PO and other medical devices developed[81]	• Engagement with CSO and CHWs during project for community awareness raising

[80] Implemented in research facilities but scale up beyond projects sites is yet to be confirmed in light of research results. PATH (2024). TIMCI scalability report

[81] In collaboration with the BMGF funded SCALE project

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