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Expanded Retrospective:
Pulse Oximeter

This retrospective was developed to inform Discerning Demand: A Guide to Scale-Driven Product Development and Introduction, a publication developed by the Center for Innovation and Impact, USAID that explores how global health practitioners (including funders, investors, innovators, implementing partners, etc) can better account for actual demand of new products. This retrospective is an in-depth historical analysis of how demand for this product was understood by different stakeholders supporting its development and introduction. The insights generated from this retrospective informed the recommendations in the full report.

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Expanded Retrospective: Pulse Oximeter (PO)

1. Introduction

1.1. Product Summary

A pulse oximeter (PO) is a non-invasive and relatively low-cost device that measures blood oxygen saturation and pulse rate. POs can range from basic fingertip devices to more robust, medical-grade handheld devices. Pulse oximetry is widely referred to as the fifth vital sign alongside temperature, blood pressure, pulse, and respiratory rate.[1] PO is useful for identifying patients needing oxygen therapy, screening newborns for respiratory distress, monitoring patients with lung and heart disorders, monitoring patients before, during, and after surgery, and assessing lung function of people with respiratory conditions. POs have the potential to lower mortality and morbidity across a number of disease areas if their use prompts immediate action to provide needed therapy (for example, oxygen). Notably, they can be useful for illnesses such as pneumonia, which causes 14% of deaths in children under age five, and asthma, which affects 262 million people and caused 455,000 deaths in 2019.[2]

1.2. Fast Facts

Fast Facts (Note: sources noted in retrospectives)	Pulse Oximeter (PO)
Health Area	Oxygen
Market Archetype	Generic/commodity – Many suppliers
CII Global Health Innovation Index	Incremental
Expected Buyers/Procurers	Local govt, private providers, global donors
Funders	USAID, Unitaid, Welcome Trust, BMGF, GAVI, World Bank, Global Fund, WHO, CEPI, FIND
Countries	>100 countries around world
Manufacturers	Many (e.g., Acare Tech, Masimo, Nonin, Edwards Lifesciences, Phillips)
Intended Delivery Setting	Primary, secondary, & tertiary facilities
Cost	~$25-$50 – Fingertip, $100-$250 – Handheld
Uptake	50-70% of health facilities in LMICs lack functional pulse oximeters

Fast fact sources: CII Innovation Index,[3] Uptake.[4]

1 LifeBox, SmileTrain. A Critical Gap: Pulse Oximetry in LMICs. London: Lifebox; 2022.

2 WHO. WHO Pneumonia Fact Sheet. Geneva: WHO; 2022; WHO. WHO Asthma Fact Sheet. Geneva: WHO; 2022.

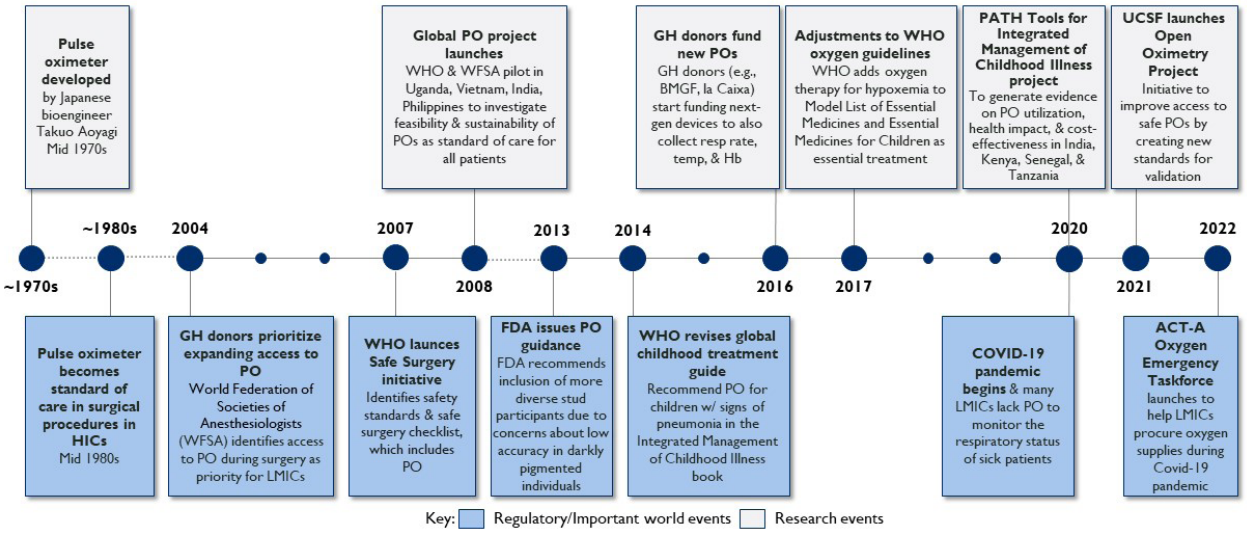
3 USAID Center for Innovation & Impact. Global Health Innovation Index – A tool for identifying the most promising Global Health Innovations. USAID: Washington, DC; 2020

4 Rahamn AE, et al. Managing pneumonia through facility-based integrated management of childhood management (IMCI) services: an analysis of the service availability and readiness among public health facilities in Bangladesh. BMC Health Serv Res 2021; 21; Unitaid. Fever Diagnostic Technology Landscape, 1st Edition. Geneva: Unitaid; 2018; Simkovich SM, et al. Resources and Geographic Access to Care for Severe Pediatric Pneumonia in Four Resource-limited Settings. Am J Respir Crit Care Med 2022; 205: 183–197;Hadler RA, et al. Anesthesia Care Capacity at Health Facilities in 22 Low- and Middle-Income Countries. World Journal of Surgery. 2016; 40: 1025–1033.

2. Demand Story

2.1. Product Development Timeline[5]

Product development timeline | Pulse oximeter



Abbreviations: ACTA, Access to COVID-19 Tools Accelerator; BMGF, Bill & Melinda Gates Foundation; FDA, Food & Drug Administration; GH, global health; HIC high-income country; LMIC, low- and middle-income country; NEST360, Newborn Essential Solutions and Technologies; PO, pulse oximeter; WHO, World Health Organization

Before COVID-19: Lack of global focus on pulse oximetry

Pulse oximetry was developed in the mid-1970s to measure oxygen saturation in the blood, identify patients in need of oxygen therapy or closer monitoring, and support clinical decision-making for anesthesia and critical care.[6] They quickly became the standard of care in HICs for surgical purposes, while LMICs lagged behind in utilizing them.[7] Starting in 2004, a global push to increase global access to pulse oximetry began, starting with the launch of the Global Oximetry Project by the World Federation of Societies of Anesthesiologists to investigate feasibility and sustainability of pulse oximeters as a standard of care to prevent mortality during surgeries around the world.[8] In 2008, WHO endorsed the PO as a mandatory monitoring tool during anesthesia as part of its **Safe Surgery Saves Lives** and **Patient Safety Pulse Oximetry** initiatives.[9] While there were already POs on the market, there were additional investments from BMGF in the **Masimo Rad-G**, Grand Challenges Canada in the **LGT medical Phone Oximeter** and **UAlberta Multimometer,** and more from Unitaid in the Tools for Integrated Management of Childhood Illness project[10] and the Improving the Identification of Respiratory Distress in Children project, but these were small and struggled to scale.

These historic efforts did not lead to a coordinated, global effort to widely expand access to POs for vital screening and diagnostics outside of a surgical context in LMICs. Though data is currently very limited, research studies in Bangladesh,[11] Nigeria,[12] India,[13] and other LMICs before 2020 indicated that functional POs were present in about 30% to 50% of facilities (with estimates ranging from as low as 12% of hospitals in Tanzania to as high as 100% of hospitals in Guyana),[14] primarily funded with public-sector financing.

5 WHO. Model Lists of Essential Medicines, 20th List. Geneva: WHO; 2017.

6 Miyasaka K, et al. Tribute to Dr. Takuo Aoyagi, inventor of pulse oximetry. J Anesth. 2021 Oct;35(5):671-709.

7 LifeBox, SmileTrain. A Critical Gap: Pulse Oximetry in LMICs. London: Lifebox; 2022

8 Walker IA, et al. Global oximetry: An international anesthesia quality improvement project. Anesthesia 2009; 64: 1051–1060; Thoms GMM, McHugh GA, O'Sullivan E. The global oximetry initiative. Anesthesia 2007; 62: 75–77.

9 WHO. WHO Guidelines for Safe Surgery: Safe Surgery Saves Lives. Geneva: WHO; 2009.

10 PATH, Swiss TPH, UNITAID. Improving access to tools that detect severe illness. Seattle: PATH; 2020.

11 Rahamn AE, et al. Managing pneumonia through facility-based integrated management of childhood management (IMCI) services: an analysis of the service availability and readiness among public health facilities in Bangladesh. BMC Health Serv Res 2021; 21; Unitaid. Fever Diagnostic Technology Landscape, 1st Edition. Geneva: Unitaid; 2018; Simkovich SM, et al. Resources and Geographic Access to Care for Severe Pediatric Pneumonia in Four Resource-limited Settings. Am J Respir Crit Care Med 2022; 205: 183–197;Hadler RA, et al. Anesthesia Care Capacity at Health Facilities in 22 Low- and Middle-Income Countries. World Journal of Surgery. 2016; 40: 1025–1033.'

12 WHO. WHO Guidelines for Safe Surgery: Safe Surgery Saves Lives. Geneva: WHO; 2009."

13 PATH, Swiss TPH, UNITAID. Improving access to tools that detect severe illness. Seattle: PATH; 2020. "

14 LifeBox, SmileTrain. A Critical Gap: Pulse Oximetry in LMICs. London: Lifebox; 2022.

During COVID-19: Strong push to finance and buy POs

The COVID-19 pandemic exposed significant gaps in access to oxygen across most countries, but particularly LMICs.[15] In February 2021, Unitaid, Wellcome Trust, BMGF, GAVI, The Global Fund, WHO, the World Bank, Coalition for Epidemic Preparedness Innovations, and Foundation for Innovative New Diagnostics, along with over 20 UN and global health agencies, launched the Access to COVID-19 Tools Accelerator (ACT-A) Oxygen Emergency Taskforce, which mobilized over $700 million in grants to help LMICs procure oxygen supplies. From 2020 to 2022, ACT-A, excluding the World Bank, has funded $10 million worth of POs to 53 countries—about 50,000 devices.[16]

Current challenges in understanding demand

Resource mobilization in response to COVID-19 has catalyzed an unprecedented availability of POs across many low-resource settings and more global awareness about the value of the devices for monitoring and screening. However, PO utilization is still lower than needed and key challenges remain in understanding demand.

- **Lack of funding and fragmented buyer ecosystem:** In the absence of global pooled procurement for oxygen products (with the recent exception of ACT-A for oxygen), most oxygen products are expected to be paid for with government financing. In 2021, the WHO Oxygen Emergency Taskforce estimated an immediate need of $90 million to address urgent needs in oxygen access and delivery in up to 20 LMICs.[17]

- **Lack of data to understand unmet need and demand:** For global donors interested in supporting oxygen interventions, there is not a reliable source of information that estimates the number and types of POs needed across LMICs. Also, demand estimates are largely unknown, and global estimates of the serviceable obtainable market do not incorporate willingness or ability to pay.

- **No clear programmatic champion:** In health ministries where funding decisions tend to be verticalized and focus on one therapeutic area at a time, there is no clear champion or market access pathway to support a cross-cutting system device like the PO that is beneficial for multiple morbidities. This has led to the PO being excluded as an essential device from many regional or national guidelines.

- **Lack of quality assurance pathways:** There is a lack of quality assurance pathways for medical devices that are procured by global donors for LMICs; for instance, the WHO does not have a PQ process recommending specific quality medical devices (such as a PO). Substandard devices that do not meet WHO technical specifications and International Organization for Standards regulatory standards[18] are widely available in LMICs, imposing hidden costs on the healthcare systems due to poor decision-making from measurement error and device failures, weakening the perceived value of the devices and confounding the decision on which device to purchase.[19]

- **Lack of perceived value among clinical health workers:** For many health workers, pulse oximetry is a fundamentally new method that requires training and support to become routine practice. PO and oxygen skills are not often part of traditional teaching modules, and lack of training, policies, or guidelines governing use is often cited by providers as a barrier to use.[20] PO usefulness is undermined by limited abilities among healthcare providers to make prompt decisions based on their results. For instance, referrals to places where oxygen is available or immediate use of oxygen at the same level. This lack of understanding about the usefulness of POs among clinical healthcare workers, combined with limited available recourse, further inhibits product demand.

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15 WHO. WHO Technical Consultation on Oxygen Access Scale-up for COVID-19. Geneva: WHO; 2021; Mallick LM, Amo-Adjei J. A Call to Action: Reinvigorating Interest and Investments in Health Infrastructure. Global Health Science and Practice. 2021, p. 711–715.

16 Based on personal correspondence with Leith Greenslade on 23 November 2022.

17 WHO. COVID-19 oxygen emergency impacting more than half a million people in low- and middle-income countries every day, as demand surges. Press Release 2021. Accessed Dec 6, 2022.

18 WHO, UNICEF. Technical Specifications & Guidance for Oxygen Therapy Devices Geneva: WHO; 2019.

19 Lipnick MS, et al. The Accuracy of 6 Inexpensive Pulse Oximeters Not Cleared by the Food and Drug Administration: The Possible Global Public Health Implications. Anesthesia and Analgesia 2016; 123: 338–345

20 Asian Development Bank. Strengthening Oxygen Systems in Asia & the Pacific. Mandaluyong: Asian Development Bank; 2022; King C, et al. Opportunities and barriers in paediatric pulse oximetry for pneumonia in low-resource clinical settings: A qualitative evaluation from Malawi and Bangladesh. BMJ Open 2018; 8; Ginsburg AS, et al. Oxygen and pulse oximetry in childhood pneumonia: A survey of healthcare providers in resource-limited settings. Journal of Tropical Pediatrics 2012; 58: 389–393.

Looking forward

Current versions of POs are prone to inaccurate readings on darker skin tones,[21] which limits their applicability in sub-Saharan Africa and parts of Asia. In 2022, researchers at UCSF (with funding from USAID and Unitaid) launched the Open Oximetry Project to improve access to safe pulse oximeters worldwide by sharing data and creating new standards and technologies for oximeter validation that better account for skin color. In collaboration with global partners such as WHO, UNICEF, and PATH, this project is supporting ongoing efforts to develop tender and procurement guidance and a performance validation mechanism for global and national agencies to identify high-quality POs.

Additional innovations in the PO space, even after improved accuracy for darker skin tones, are unlikely to solve the aforementioned system challenges facing current POs unless there is a clear use case and demonstration of value-add, particularly related to the immediacy of action that saves lives. Future innovations in PO devices must demonstrate improved cost-effectiveness across various clinical applications relative to current diagnostic practices with multiple devices or current POs, improved quality of care, or a quantifiable health impact.[22] Ongoing efforts, such as the Tools for Integrated Management of Childhood Illness project,[23] are generating evidence on PO utilization, health impact, durability, and cost-effectiveness in primary healthcare settings, as well as post market surveillance of the durability and use of POs in field settings.

3. Learnings

Four key learnings from the demand story:

1. **Lack of robust co-financing options to help local governments purchase at scale**

   Recall the challenge: Governments have been able to acquire POs via donations as part of the COVID-19 response without integrating into their annual budget, which is a temporary and unsustainable acquisition strategy. This can be further exacerbated by the lack of financing to pay for ongoing costs such as routine maintenance/calibration and as needed repairs.

   Forward-looking learning: Globally led co-financing options are needed to help local governments purchase high-quality POs at scale, integrate them into the national budget and health systems, and fund operational costs, maintenance support, and HCW training. The Global Fund is leading this effort by allowing countries to use GF resources for PO procurement and other oxygen needs.

2. **Limited demand forecasting that is not setting- or device-specific**

   Recall the challenge: Many national governments lack accurate estimates of their current pulse oximetry needs. In addition, top-down estimates and the inability to capture willingness and ability to pay limits accurate forecasting based on serviceable obtainable market.

   Forward-looking learning: More accurate estimations from the ground up based on type of PO, different service delivery levels of the health system, or a demonstrated willingness and ability to pay are needed.

3. **Lack of clear use case and value-add for new devices**

   Recall the challenge: Planned or proposed innovations in POs lack a clear use case and do not address health system challenges related to insufficient quality assurance pathway, lack of cofinancing options, health worker awareness, and quality data inputs for demand forecasting.

   Forward-looking learning: There is a need to interrogate the use case and value-add based on the current demand challenges before funding innovation of new global health products.

21 Usha Lee McFarling. "FDA panel asks for improvements in pulse oximeters". STAT News. Nov 1, 2022; Feiner JR, Severinghaus JW, Bickler PE. Dark skin decreases the accuracy of pulse oximeters at low oxygen saturation: The effects of oximeter probe type and gender. Anesthesia and Analgesia 2007; 105.

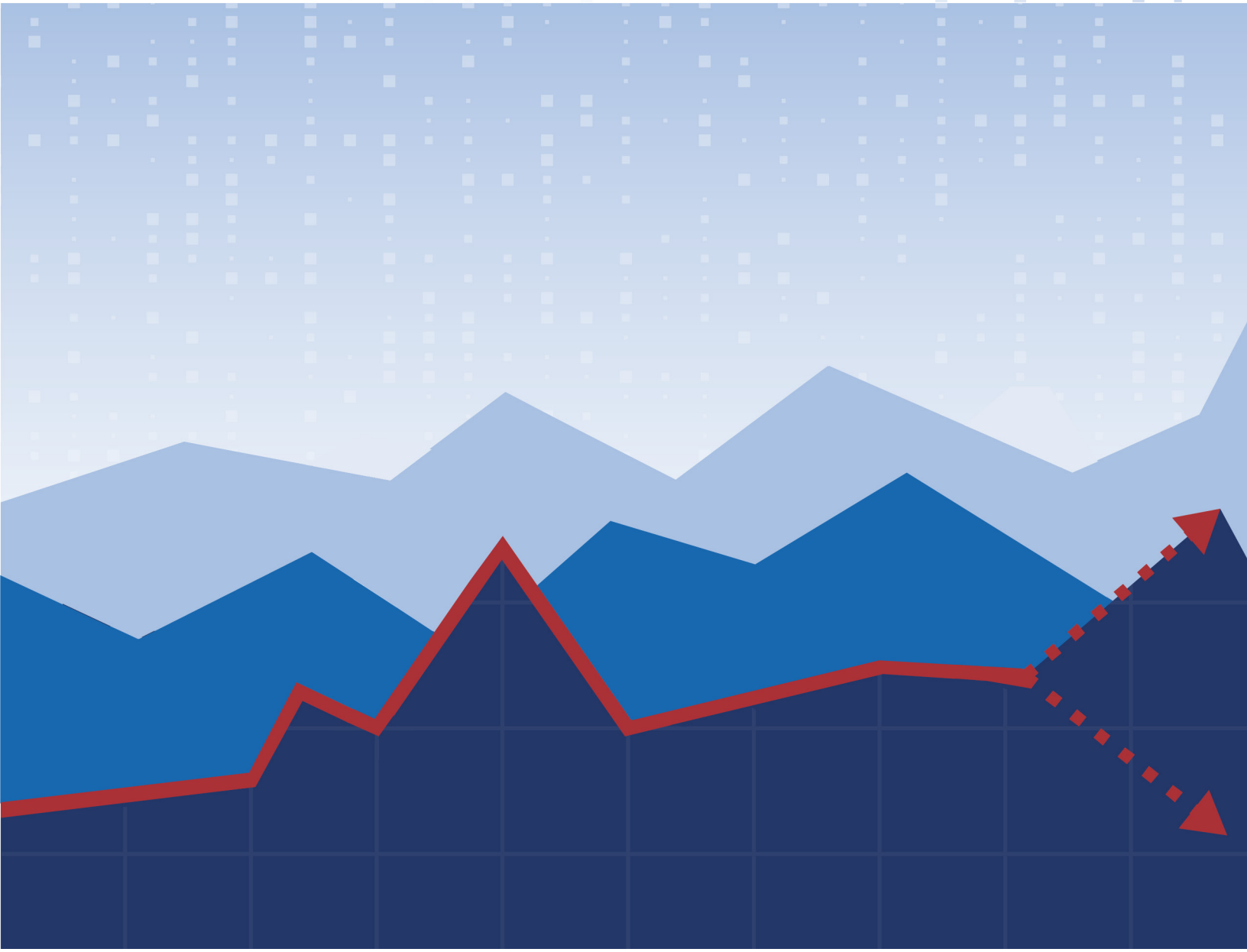
22 PATH, Unitaid. Next Generation Pulse Oximeters: Technology & Market Landscape. Seattle: PATH; 2022.

23 PATH, Swiss TPH, Unitaid. Improving access to tools that detect severe illness. Seattle: PATH; 2020..

4. **Unclear regulatory framework and lack of independent evaluation pathways**

   Recall the challenge: There is a lack of independent pathways to validate and evaluate monitoring tools like PO, leading to a wide availability of low-quality devices in LMICs that do not meet minimum technical specifications.

   Forward-looking learning: There is a need for independent performance validation to indicate to buyers which devices are of high accuracy and durability, and will not create additional costs for the health system in clinical errors or replacement devices



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