An Analysis of the Pulse Oximetry Supply Chain in Kenya

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Introduction

In our world, certain countries experience a disproportionately higher level of suffering and mortality compared to others. These nations, often referred to as underserved or "third-world" countries, face the challenges of underdevelopment and limited access to resources. Among the major contributors to the suffering in low-income countries is the burden of diseases. Respiratory illnesses, such as pneumonia, are particularly prevalent among children under the age of five and account for a significant number of child deaths (Walsh, 1989). Consequently, the availability of medical technologies like pulse oximetry, which measure oxygen saturation in the blood, becomes crucial for monitoring the health and vital signs of these populations. Unfortunately, underserved countries lack adequate access to pulse oximetry, leading to further compromised health outcomes. This raises the question: What is the underlying cause of this inadequate access to technology?

The goal of this STS research paper is to shed light on this theme by investigating a critical aspect of medical technologies: the supply chain. Specifically, I will examine the supply chain practices related to pulse oximetry as a representative medical device in Kenya, an underdeveloped nation. By delving into the intricacies of the supply chain practices, my objective is to focus on key stakeholders involved in this process, including pulse oximetry manufacturers/distributors, hospitals, ministry of health, non-governmental organizations (NGOs) and regulatory bodies. Through this analysis, I aim to uncover the strengths and weaknesses in Kenya's supply chain practices and analyze how these factors contribute to the worsening outcomes experienced by underserved countries.

By shedding light on the supply chain dynamics, this research endeavors to provide valuable insights into the root causes of inadequate access to medical technologies in

underserved regions. Understanding these factors is crucial for developing strategies and interventions that can help improve healthcare outcomes and bridge the technology gap between developed and underdeveloped nations.

Background and Context

Sociotechnical Situation

The sociotechnical context of my research project delves into an intricate web of actors influencing the supply chain practices of pulse oximeters in Kenya, hence attempting to untangle the roots of the disparity in medical device accessibility in this region. Pulse oximeters are critical devices used to monitor the oxygen saturation levels in the blood. They play a pivotal role in healthcare by measuring the vital signs of a person, yet its availability is disproportionately skewed across the globe. Hence, understanding the sociotechnical landscape involves exploring the interconnectedness of social, economic, and technological factors that shape the distribution and accessibility of these devices.

In Kenya, economic factors take center stage in influencing the pulse oximeter supply chain. Limited financial resources impact purchasing power, shaping the affordability and accessibility of medical devices. The state of healthcare infrastructure is another pivotal actor with gaps affecting the distribution and maintenance of pulse oximeters. Navigating the regulatory environment presents additional challenges as the efficiency and capacity of regulatory frameworks in Kenya may differ from those in developed nations. Likewise, the limited financial resources likely contribute to the reduced number of technology companies who can create a big market for this product.

Hence, we can see that technology companies, regulatory bodies, healthcare providers and economic factors contribute to a sociotechnical landscape of pulse oximeter accessibility.

Understanding the roles of these actors and uncovering the barriers faced by this country can provide a better insight into understanding the complexities of pulse oximeter supply chain and identifying potential avenues for intervention to address disparities in medical device access.

Literature Review

Pulse oximetry is crucial to healthcare, and one example of this is in surgical settings. Illnesses that need surgical treatment account for a substantial amount of the global burden of disease. The pulse oximeter can play a significant role in these surgical scenarios by monitoring the oxygen saturation of blood. In fact, according to the World Federation of Societies of Anesthesiologists, tissue oxygenation should be monitored continuously during procedures hence pulse oximetry is highly recommended (Merry et al., 2010). Incorporation of pulse oximetry can also systematically reduce health outcomes. For example, according to a clinical study conducted in five hospitals in Papua New Guinea, the mortality rates associated with pneumonia reduced by 35% upon incorporation of pulse oximetry for detection of hypoxaemia – low oxygen saturation in the blood (Duke et al., 2008). This highlights that pulse oximetry is critical to healthcare and can have tangible impacts in the world.

However, there are disparities in access to medical devices in underserved countries, particularly in the Sub-Saharan African regions. According to a study that attempts to quantify the global operation theater distribution and pulse oximeter supply, there was approximately 1 operation theater per 100,000 people in west sub-saharan africa and 70.4% of operation theaters in east sub-saharan africa, where Kenya is located, lacks pulse oximetry (Funk et al., 2010). This emphasizes the presence of disparities in pulse oximetry access which can ultimately lead to negative consequences for the healthcare system in these countries, such as increase in poor health outcomes and lack of efficient protocols for treatment/diagnostics.

Now that it has been established that there is a significant need for pulse oximetry and disparity in access to it in lower income populations, the challenges surrounding its adoption in African healthcare systems need to be investigated. A critical obstacle that opposes the entry of pulse oximetry in low-resource settings is its high cost. This financial challenge intertwines with logistical complexities within the supply chain, encompassing taxation, import costs, and the imperative need for battery-operated devices due to erratic electricity supply (Herbert & Wilson, 2012). Moreover, healthcare facilities in low and middle-income countries face a trifecta of hurdles: insufficient device supply, operational failures, and inadequate training, all impeding effective utilization (Enoch et al., 2019). Insights from studies in Kenya accentuate the necessity of examining healthcare dynamics when integrating pulse oximetry into pediatric guidelines. The barriers span from equipment malfunctions and oxygen shortages to misconceptions among healthcare providers (Sheikh et al., 2023). These complexities parallel challenges found in South Africa's healthcare system, revealing broader impediments in technology adoption, including ambiguous guidelines, cost considerations, and overestimations of technology capabilities (Fawzy et al., 2022). Consequently, a pivotal theme emerges across these diverse literature sources: the inadequate supply of pulse oximeters in certain underserved Sub-Saharan African countries. This critical issue underscores the imperative for understanding and rectifying supply chain practices in healthcare, forming the focal point of my research paper.

Methods

This study used a qualitative document review methodology to analyze the pulse oximetry supply chain in Kenya. Data sources were collected between March-May 2022 to understand key components of access and distribution.

Documents reviewed included Ministry of Health (MOH) 2020 guidelines on the Management of Health Products and Technologies, MOH 2020 Supply Chain Strategy for Health Products, Standards for Maternal Care, National Guidelines on Newborn Care, and Basic Pediatric Protocols. Program evaluation reports in Kenya from PATH and Lifebox, which are global NGOs, provided supply chain context in similar developing markets. These reports also included information about the key foreign manufacturers and local distributors in Kenya. The key regulatory body in Kenya, i.e. the Pharmacy and Poisons Board, was also reviewed for any published standards or registration procedures pertaining to medical devices.

A structured analysis of themes was conducted across collected documents relating to policy and regulatory frameworks, product availability, training support models, and barriers faced within the Kenyan supply environment. Information extracted was synthesized into a review of strengths and limitations across areas like governance, importation, last-mile delivery and technical support. Identification of gaps informed recommendations for strengthening the pulse oximetry supply system based on best practices in other resource-constrained settings. This document review methodology provided a comprehensive examination of the available primary literature to characterize the current pulse oximetry supply landscape in Kenya. Future research could incorporate more primary data collection to further validate findings.

Results

Ministry of Health

The MOH has established several policies and guidelines related to health products and technologies (Ministry of Health, 2020b). A review of the supply chain strategy by the MOH found that Kenya has increasingly adopted international standards through documents like essential medicine lists, clinical guidelines, and commodity management protocols. However,

from the MOH guidelines on management of Health Products and Technology, low implementation of health products policy was noted due to key systemic issues. The guidelines highlight “inadequate budgetary allocation for supply chain management costs” and “high outstanding debt and pending bills by both MOH and Counties to suppliers including KEMSA” as significant financial barriers (Ministry of Health, 2020a). Additionally, “poor logistics information management” and “weak regulations, laws and poor enforcement of the same” are identified as critical challenges undermining effective policy implementation. Addressing these issues is essential for improving health outcomes and ensuring equitable access to health products across Kenya.

Pulse oximetry should also be a critical component in the care for newborns, however according to many Kenyan guideline documents, there is no evidence of its advocating. For example, the Standards for Maternal Care in Kenya list oxygen for delivery rooms but not pulse oximetry (Kenya Clinical Officers Association et al., 2002). This guideline is currently under review, presenting an opportunity to include oximetry. The Basic Pediatric Protocols document does instruct the healthcare worker to check the oxygen saturation but does not explicitly state to use pulse oximetry (Ministry of Health, 2022b). Furthermore, the Nation Guidelines on Essential Newborn Care say that about one-fourth of resuscitated babies require oxygen after four to five minutes of resuscitation, but they do not indicate the use of pulse oximetry nor the use of an oxygen blender to avoid the risk of retinopathy of prematurity as a result of over oxygenation (Ministry of Public Health and Sanitation, 2015). Similarly, the Health Infrastructure Norms and Standards only cover oximetry for higher level facilities (Smith, n.d.). Oximetry should be expanded to primary care, but policy changes are needed to support this. The MOH recognizes more can be done to strengthen inclusion of oximetry in guidelines. While these revisions are

important initially, ongoing advocacy and dedicated county budgets will also be crucial for procurement, training and encouraging oximetry use in lower-level facilities.

Regulatory Bodies

The current system for medical device standards and registration is owned by multiple entities that charge separate fees for use of the product (e.g., Kenya Bureau of Standards, Pharmacy and Poisons Board, Nursing Council of Kenya, Laboratory Equipment Association). There have been incidences of inadequate coordination by regulatory bodies – Pharmacy and Poisons Board (PPB), Medical Laboratory Technologists Board (MLTB), National Quality Control Laboratory (NQCL), and Kenya Bureau of Standards (KEBS) – leading to inefficiencies in some of the HPT Supply Chain functions such as quality testing, quantification and planning, and procurement (Ministry of Health, 2020b).

At the national level, procuring entities' contract terms include delivery to the warehouse of point of use in the case of large equipment. The Pharmacy and Poisons Board has developed and rolled out good pharmaceutical distribution practices that include importation procedures. The procedures include issuance of import permits by the board and physical inspection of all device imports (Ministry of Health, 2022a). However, no such systems are in existence for KEBS and the KMLTTB for medical supplies and diagnostic supplies, respectively.

Market

According to the 2015/2016 National Health Accounts, the Total Health Expenditure was estimated at KES 346 Billion and accounting for 5.2% of the nominal GDP while per capita health expenditure was KES 6,602 (Ministry of Health, 2020b). This is considered below the desired target investment of about KES 23,407 per capita for coverage of Essential Health Benefits. In terms of sources of financing, the government remains the biggest healthcare

financier accounting for 33%, followed by households, donors, and corporations at 33%, 22% and 12% respectively.

According to the assessment by PATH, stakeholders acknowledged the value of pulse oximetry and that it should be prioritized in budgeting (Smith, n.d.). It remains feasible to scale pulse oximetry with implementation and policy support. It is unclear how much counties are spending on oxygen presently as record-keeping of past purchases is poor; this makes it difficult to compare oxygen delivery and pulse oximetry solutions.

NGOs

While there are limited local NGOs in Kenya, the majority of the support for pulse oximetry supply in Kenya comes from global NGOs. The Program for Appropriate Technology in Health (PATH), is a global NGO that focuses on ensuring health equity in lower income countries. PATH did a consultation with manufacturers of oxygen concentrators and pulse oximetry in low income countries to discover barriers and solutions to inaccessibility (*Ensuring Oxygen and Pulse Oximetry Access for Treatment of Children in Low-Resource Settings*, 2015). While the consultation focused on countries such as Nigeria and the Republic of Congo, their findings on gaps in accessibility to these devices may be partially applicable to Kenya, given similarities in certain healthcare system dynamics and economic factors. However, specific validation is required to determine the extent of applicability, considering potential differences in local healthcare policies and funding priorities. PATH research on barriers to access in similar markets identified several issues relating to awareness. Top-down purchasing, a procurement method where purchasing decisions are centralized at higher organizational levels rather than made by end users such as hospitals, can potentially hinder the procurement of appropriate technologies. In this system, hospitals do not make their own product selection and purchasing

decisions, which may not align with their specific needs. Additionally, a lack of training represented a major challenge as costs, availability or transportation barriers too often prevented healthcare workers from receiving necessary instruction. With relatively small markets compared to diseases such as chronic obstructive pulmonary disease, PATH also found that despite existing needs for devices like pulse oximeters, historical lack of demand had failed to spur adequate consideration and investment from manufacturers. Addressing these awareness gaps through mechanisms that give end users more input and enable widespread training programs could therefore help strengthen accessibility in contexts resembling Kenya's healthcare system. Issues of affordability also posed significant challenges according to PATH's research. Manufacturers expressed wanting a deeper comprehension of medical device financing mechanisms within government budgets. The regulatory environment and distribution requirements were found to be complicated and varying between nations as well. Establishing dedicated service support and maintenance systems was deemed necessary for ensuring reliable device functionality over the long-term. Given the small market size in these contexts, manufacturers additionally worried about both competition and lacking exclusivity agreements to motivate product development. Furthermore, the industry experienced high pressures to continually decrease costs. Consequently, manufacturers called for an improved grasp of price sensitivity within such markets in order to make pulse oximetry and other technologies financially sustainable and accessible. Addressing these interlinked financial barriers would be imperative to better serve the healthcare needs of populations like Kenya's.

Lifebox is another global NGO that has worked with a diverse range of partners across Kenya – ranging from the global cleft lip/palate charity Smile Train to Tennessee-based Vanderbilt International Anesthesia supporting nurse provider training at Kijabe Hospital.

Lifebox partnered with the KSA in 2013-2016 and one of East Africa's leading marketing firms WPP-Scangroup Ltd., which provided 300 pulse oximeters and training to providers across the country (*Lifebox in Kenya*, 2017). This collaboration not only provided safer anesthesia for patients in Kenya, but also served as a model of sustainability and an example of how local businesses can support local healthcare initiatives.

Manufacturers/Distributors

Based on the conducted research, there are no major manufacturing companies in Kenya. However, there are several foreign companies who make pulse oximeters who sell it to local distributors in Kenya due to this lack of significant production. PATH conducted an assessment of available supply based on desk research and interviews with manufacturers, local distributors, and programmatic decision-makers (Smith, n.d.). Through these methods, they identified 21 models of oxygen concentrators from 12 different manufacturers and 30 models of pulse oximeters and multiparameter devices from 20 manufacturers.

Kenya Medical Supplies Authority (KEMSA) is a state organization under the MOH that procures warehouses and distributes drugs and medical supplies for public health programs. It has a national network of storage, packaging, and distribution facilities. KEMSA currently focuses on providing pharmaceuticals and medical supplies such as band aids, gloves, beds, laboratory supplies, etc. KEMSA does not currently procure or distribute durable medical goods like oxygen concentrators, oxygen plants, or pulse oximeters (Smith, n.d.).

Several weaknesses were identified that could negatively impact the reliability and effectiveness of this distribution network. Firstly, the regulatory environment for medical device imports is complex, without clear standardized processes equivalent to those governing pharmaceuticals. This lack of coordination could introduce inefficiencies. Furthermore, supply

chain disruptions like stock outs were reported, implying weak inventory management or fulfillment challenges. The distribution system also seems ill-equipped to maintain consistent access in remote regions, where last-mile delivery obstacles are exacerbated. Without dedicated service and training support accompanying device distribution, proper use and maintenance is likewise at risk. Given these deficiencies, policymakers should explore reforms and partnerships that streamline regulations, bolster distributor capacity, and strengthen integrated supply from port to point-of-care — particularly in underserved areas. A more robust distribution system would significantly improve pulse oximetry availability in Kenya.

Hospitals

Kenya's network of over 256 public hospitals faces significant challenges in obtaining reliable access to pulse oximetry according to MOH guidelines and stakeholder interviews. Larger regional referral centers like Nairobi's Kenyatta National Hospital likely have some devices due to higher patient volumes, but smaller district and primary facilities struggle with limited budgets that constrain regular equipment renewals (Smith, n.d.). Equitable distribution is also an issue, as donor-donated oximeters are sporadically allocated rather than following clear need-based plans, leaving some rural clinics severely under-resourced. Poor records further impede planning replacement cycles and assessing true equipment requirements across all levels of care. Stockouts are a documented problem, implying weak distribution networks fail to consistently restock depleted supplies. Without strengthening coordination between national standards, dedicated hospital procurement budgets, and efficient supply chain management capable of maintaining stocks long-term even in remote areas, equitable pulse oximetry access will remain a challenge for Kenya's public healthcare system to overcome.

Discussion/Analysis

The results provide valuable insights into Kenya's pulse oximetry supply chain landscape. Analysis of MOH policies and guidelines indicates opportunities exist to strengthen inclusion of pulse oximetry. Revisions currently underway present a window to expand recommendations for use in primary care. However, ongoing advocacy will also be needed to secure necessary county-level prioritization and dedicated budgets. Regulation of medical devices is currently split between bodies, introducing inefficiencies. Centralizing standards and processes under a single oversight agency could streamline importation and quality monitoring. Coordinating registration with the PPB model for pharmaceuticals merits consideration.

Budget constraints were a prominent challenge reported. With total health spending below recommended levels, prioritizing essential technologies like oximetry requires significant planning. Record-keeping improvements would aid comparison between oxygen delivery solutions. Stakeholder commitment to pulse oximetry indicates value is recognized, yet financing gaps persist. NGO research highlights key awareness and affordability barriers facing manufacturers. Small, fragmented markets in Sub-Saharan Africa hamper sustained investment absent coordinated demand-generation or exclusivity incentives. Training accessibility additionally impacts appropriate adoption and use. National strategies that incorporate end-user input and public-private partnerships may help address sustainability concerns. Weaknesses in the distribution system jeopardize reliable availability, especially in remote regions. Streamlining regulations, bolstering regional distributor networks, and strengthening the last-mile supply chain from central warehouses represent priority reforms. Consistent stocking through coordinated procurement, budgets and maintenance support is likewise needed.

In summary, Kenya's public healthcare system confronts supply challenges restricting pulse oximetry access. However, findings indicate opportunities through collaborative policy reforms, financing models, and optimized implementation pathways. With coordinated prioritization and planning, equitable scale-up appears feasible.

Conclusion

In conclusion, this study provides a comprehensive examination of Kenya's pulse oximetry supply chain landscape based on an extensive document review. The results identify both opportunities and challenges across key components like policy, regulation, financing, distribution and utilization. Ongoing revisions to MOH guidelines present avenues to mainstream oximetry recommendations. However, overcoming budgetary shortfalls, distribution inefficiencies and barriers to sustained private sector engagement will require concerted multi-stakeholder action. Strengthening medical device governance, bolstering regional procurement models, and establishing dedicated training and maintenance support networks could help address several pressing issues. With coordinated prioritization between national standards and county implementation, more equitable pulse oximetry access appears feasible. Yet realizing this potential will depend on transformational collaborative efforts between government, regulatory bodies, healthcare facilities, NGO partners and industry. Addressing the gaps in a phased manner through pilots and demonstration projects also merits exploration. Future research incorporating qualitative data collection could further validate findings to inform such scale-up initiatives.

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