## **Technical Research Problem: Designing a Low-Cost Neonatal Pulse Oximeter for Underserved Countries**

# STS Research Problem: A Comparative Analysis of pulse oximetry supply-chain practices in the US and Kenya

A Thesis Prospectus
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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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## General Research Problem: Ensuring Equity in Pulse Oximeter Accessibility in Underserved Nations

Why is there a gap in the availability of pulse oximeter technology and limited accessibility in African countries?

In the landscape of healthcare equity, the promise of life-saving pulse oximeter technology stands sharply contrasted against its limited accessibility and efficacy in underserved regions, notably in Sub-Saharan African countries like Kenya, Nigeria, and Tanzania. Despite their potential to save countless lives, pulse oximeters encounter a labyrinth of technical, social, economic, and cultural barriers, impeding their full realization in neonatal healthcare contexts. In my technical project, I not only focus on engineering a neonatal pulse oximeter that is more secure and accurate at gaining measurements, but I also focus on designing an affordable oximeter manufactured from cheap materials that is tailored to address the issue of accessibility in these regions. Concurrently, my STS research involves a comparative analysis of supply chain practices between the USA and Kenya. These supply chains wield significant influence over technology access, and comprehending how socio-economic factors intersect with pulse oximeter adoption and distribution forms the crux of our investigation.

My overarching goal transcends the creation of a medical device; it encompasses contributing to the discourse on equitable healthcare access. By tackling the pervasive issue of pulse oximeter accessibility and effectiveness, our work seeks to underscore the significance of technological innovation and streamlined supply chain practices in advancing healthcare outcomes for marginalized communities. Through our research, we aspire to unveil solutions that enhance the availability, affordability, and impact of pulse oximeters, not only in Sub-Saharan African nations but also globally. This comprehensive exploration of pulse oximeter adoption, encompassing both technical and socio-economic dimensions, lays the foundation for further research, policy formulation, and initiatives aimed at fostering a more equitable healthcare landscape worldwide.

## Technical Paper: Designing a low-cost neonatal pulse oximeter for underserved countries

How can a neonatal pulse oximeter be designed from cost-effective materials while accounting for motion artifacts from the newborn?

The primary causes of neonatal (newborn) mortality in underserved countries are diarrhoeal disorders and acute respiratory infections (ARIs) (Schindler et al., 2017). Pneumonia is the highest contributor to infant mortality rates and accounts for 28-34% of deaths globally (Marangu & Zar, 2019) according to recent estimates. Pneumonia is a disease where the air sacs in your lungs are filled with fluid, hence making it very difficult for a person to breathe. It can lead to a condition called hypoxia, which is poor oxygen saturation (SpO<sub>2</sub>) in the blood. To assess the health of neonates during hospital emergency admissions, it is crucial to collect its

vital signs. In the case of pneumonia, it is even more critical to have information such as  $SpO_2$  and pulse rate, so that they can be treated.

Hence, the pulse oximeter is an electronic medical device that measures the  $(SpO_2)$  in the red blood cells.  $SpO_2$  is determined by measuring the absorption of infrared light at a specific wavelength and is converted into a concentration value through Beer-Lambert's law. Light can be absorbed and reflected (transmitted) by all molecules. This basically means that the IR light that is sent from the device to the skin is absorbed by the oxygen molecules in the patient's blood. The amount of light that is reflected back by the  $O_2$  molecules can allow one to quantify the amount of oxygen, i.e., concentration, in the blood. Existing designs of pulse oximeters are usually placed on a patient's body part such as finger, palm, sole, toe or earlobe (Das et al., 2010).

However, pulse oximetry is posed by a variety of challenges. Firstly, according to estimates, pulse oximetry is unavailable in 51-70% of operating theaters in low-income countries (Burn et al., 2014), with the primary factor being its high cost. Secondly, pulse oximeters struggle to provide accurate readings for neonates due to their erratic movements and it has been shown that motion artifacts can have a negative impact on the signal quality of pulse oximetry and can lead to erroneous readings (Dormishian et al., 2023). Thirdly, the current design of the Masimo neonatal pulse oximeter (*Masimo LNCS Neo Neonatal SpO2 Adhesive Sensor 18 in* | *AED.US*, n.d.), a standard used in most hospitals, is that it is very cumbersome to use due to its disposable nature and adhesive features of attachment to the skin. This can lead to slow collection of vital signs during emergencies that only need a one-time measurement of O<sub>2</sub> saturation.

Therefore the objective of this capstone project is to address the problems listed above by creating a novel mechanical component of the neonatal pulse oximeter. The goal of the project is to (i) develop an affordable oximeter component catered to underserved regions that can be built from low cost materials, (ii) addressing the erratic movement constraint posed by neonatal patients, by creating a more secure attachment of the oximeter to the limbs or extremities of the neonate, and (iii) creating an oximeter that has a larger shelf life and is non-disposable.

The first step of our project is to ideate various designs of the mechanical component of a pulse oximeter. The design would be optimized for a location in the body of a neonate that is least resistant to motion artifacts, which will be determined from the scientific literature. After ideation, we will begin prototyping by using materials such as silicone which is both cheap and durable. Finally, the device will be statistically tested on a large sample size thoroughly for accuracy and precision.

# STS Research Paper: A Comparative Analysis of pulse oximetry supply-chain practices in the US and Kenya

How do supply-chains of pulse oximeters differ between the United States and Kenya, and what factors influence these differences?

In an era of global healthcare disparities, this study delves into the comparative supply chain of pulse oximeters in the United States and Kenya. It examines how these two countries differ in terms of medical device distribution and access, aiming to uncover the complex interplay between technology, society, and healthcare infrastructure. This research sheds light on critical issues of affordability, quality, and equity that impact healthcare outcomes on a global scale.

### Background

The utilization of the pulse oximeter in the USA and Kenya is influenced by a complex socio-technical system which comprises a number of groups and organizations. Primary stakeholders include the patients and the healthcare providers such as physicians, nurses, and technicians who rely on pulse oximeters for monitoring health. In the USA, regulatory bodies such as the Food and Drug Administration (FDA) establish safety and efficacy standards and approve devices for the market. Likewise, in Kenya, it is the Pharmacy and Poisons Board (Hubner et al., 2021). Healthcare administrators make key decisions on resource allocation and policy, which impacts the accessibility of the device in various hospitals or clinics. NGOs and aid organizations who often play an important role in supporting underserved communities with these technologies. Finally, there is a supply-chain, which includes manufacturers, distributors, and regulators (this include regulatory bodies described above), whose main role is to create pulse oximeters and distribute them to various locations around them. The goal of this research paper is to focus on the practices of the supply-chain actors.

### Literature Exploration

The challenges surrounding the adoption of pulse oximetry in African healthcare systems are multifaceted and interconnected. A critical barrier emerges from the high costs associated with pulse oximeters, presenting a substantial entry obstacle in low-resource settings. 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 Africa. This critical issue underscores the imperative for understanding and rectifying supply chain practices in healthcare, forming the focal point of my research paper.

Theoretical Framework

Actor-Network Theory (ANT) can provide a good framework for understanding the comparative supply chain of pulse oximeters in the United States and Kenya. ANT emphasizes the relationships and interactions between various actors, including human and non-human entities, within complex networks. In this context, ANT allows for the examination of the dynamic roles played by diverse stakeholders such as manufacturers, distributors, healthcare providers, regulatory bodies, and end-users, as well as the technological components of pulse oximeters themselves. By mapping these networks and understanding how different actors influence the pulse oximeter supply chain in distinct sociocultural and economic contexts, ANT can provide valuable insights into the complex socio-technical dynamics that shape medical technology distribution and accessibility, ultimately contributing to a deeper understanding of healthcare disparities on a global scale.

Moving forward, I will collect evidence from a variety of sources, including statistics from news reports and interviews, documentary analysis (specifically examining regulatory documents and industry reports), as well as data from prior studies. Quantitative data will be obtained from market research and pricing metrics, while qualitative insights will be gathered through stakeholder interviews, case studies, and actor-network mapping. This comprehensive approach will provide a robust foundation for analyzing the pulse oximeter supply chain in the United States and Kenya, facilitating a thorough examination of the factors influencing healthcare disparities in both contexts.

#### **Conclusion:**

To conclude, my STS research will aim to conduct a comparative analysis on pulse oximetry supply-chain practices in the USA and Kenya. From this project, I hope to learn more about the various social and economic factors that are affecting pulse oximetry accessibility in underserved nations. For my technical project, my group intends to design a low cost neonatal pulse oximeter that accounts for various important errors such as motion artifacts introduced by babies. Additionally, in this project we hope to create a pulse oximeter that can be made cost-effective materials, hence making it more affordable for lower and middle income countries. From this work, I hope to acquire a nuanced understanding of the socio-economic and regulatory determinants that underpin the availability of life-saving medical technology. By developing a low-cost neonatal pulse oximeter, we aim to make a tangible difference in underserved regions. This combination of research and innovation has the potential to significantly impact healthcare disparities, fostering a brighter future for underserved communities.

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