Thesis Project Portfolio

Designing a Mechanical Housing Component for Neonatal Pulse Oximetry

(Technical Report)

An Analysis of the Pulse Oximetry Supply Chain in Kenya

(STS Research Paper)

An Undergraduate Thesis

Presented to the Faculty of the School of Engineering and Applied Science

University of Virginia • Charlottesville, Virginia

In Fulfillment of the Requirements for the Degree

Bachelor of Science, School of Engineering

Anirudh Seshadri Krishnan

Spring, 2024

Department of Biomedical Engineering

Contents of Portfolio

Executive Summary

Certain countries around the world are recognized as 'underserved' due to their inadequate infrastructure and limited access to essential services and resources. These shortcomings critically impair their ability to address basic public health needs, rendering their populations, particularly neonates, highly vulnerable to diseases. Among these, respiratory illnesses like pneumonia are prevalent, leading to conditions such as hypoxia—characterized by dangerously low oxygen saturation levels (SpO2) in the blood. This is especially critical for neonates who are at a higher risk and require continuous monitoring to manage emergencies effectively. In such settings, pulse oximeters become indispensable tools. However, their high cost and the complexities surrounding their availability—affected by factors such as manufacturing, distribution, and regulatory challenges—severely limit their accessibility. This thesis aims to tackle the dual challenge of designing a suitable pulse oximeter for neonates in underserved countries and dissecting the supply chain barriers that hinder access to such vital medical devices in contexts exemplified by Kenya.

Pulse oximetry is a crucial device needed in underserved settings for monitoring SpO_2. However, a lot of pulse oximeter designs are either too cumbersome to attach to the finger or too costly, which can lead to issues of low working efficiency and inaccessibility. Existing designs don't have a secure fit to the finger and since neonates pose erratic movements/motion artifacts, these designs fail to accurately capture the SpO_2. Moreover, rapid growth of neonates in the first five years demands an adaptable design that can accommodate significant changes in finger size. Addressing these issues, my capstone project focused on developing a mechanical housing for pulse oximetry sensors that adjusts to finger size variations and secures the device against dislodgement. Through an iterative process using Autodesk Fusion 360, our team developed various drawings and computer aided design (CAD) sketches of potential housing components. We settled on two final designs: (i) a zipper lock mechanism that sandwiches a finger between a furrow and a ridge component and snaps securely on the finger just like a ziploc cover. (ii) a

unique housing component that can simply be placed on the finger and tied around using string. These designs were manufactured using 3D printing and PLA plastic as the material and finite element analysis (FEA) was used to model the stress and strain experienced by the design based on a hypothetical load force. For future prototypes, we intend to change the material to a flexible type such as TPU. Our team also intends to address the low cost aspect of our design through reducing dimensions of it. This will optimize the amount of material needed and reduce cost.

The STS research component of my thesis investigates the systemic barriers to accessing essential medical devices in underserved countries, with a specific focus on the pulse oximetry supply chain in Kenya. The methods used to conduct this study is through document review of guidelines listed on the Kenyan Ministry of Health (MOH) website and Pharmacy and Poisons Board (PPB), the key regulatory body in Kenya. This study also reviews various reports of NGOs such as the Program for Appropriate Technology in Health (PATH) and the supply chain strategy reports from MOH. According to the results, there seems to be little to no manufacturers for pulse oximetry, hence making most of the supply from foreign companies and NGOs. A review of the current MOH guidelines states that there is on-going advocacy for securing prioritization budgeting for medical devices such as pulse oximetry. Larger primary care hospitals such as Kenyatta National Hospital have access to devices, however smaller districts and facilities struggle with limited budget and improper replacement of depleted stock. PPB indicates clear standard procedures for importation of devices, however upon further review from the supply chain strategy report, there seems to be multiple regulatory entities that are involved in device regulation which can lead to inefficiencies in coordination. To conclude, with coordinated prioritization between national standards and county implementation, more equitable pulse oximetry access appears feasible.

Reflecting on this year's work, the dual focus of my thesis on developing a new pulse oximetry design for neonates and analyzing the supply chain barriers in underserved countries has been both challenging and enlightening. While the technical project successfully led to innovative designs that promise greater adaptability and security for neonatal use, not all initial goals were met, particularly in fully optimizing the cost-effectiveness of the devices. The STS research illuminated critical supply chain issues that hinder the distribution of medical devices in Kenya, providing a foundational understanding for targeted interventions. Despite some disappointments in not achieving all intended outcomes, such as the complete cost reduction of the pulse oximeter designs, the projects were fruitful in setting the stage for future advancements. Researchers who wish to continue this work should focus on refining the material and manufacturing aspects of the pulse oximeter to further reduce costs and enhance usability. Additionally, deeper collaboration with local stakeholders in Kenya could provide more nuanced insights into effective supply chain improvements. The next steps would ideally involve field testing the redesigned pulse oximeters in clinical settings to validate their efficacy and gather direct feedback, which could drive further iterations and improvements critical to real-world application.