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Closing the design gap: Conducting usability studies in low-middle income countries for inclusive medical device design

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Statement of the Problem: Human factors studies are essential in identifying potential risks and improving the functionality of devices to prevent harm. They play a crucial role in the design and development of medical devices, ensuring that they are safe, intuitive and effective for the end users. One of the key factors in ensuring these studies provide unbiased data is in considering the intended use environment and understanding the unique systems in which these devices will operate.

The growing demand for equity in healthcare requires us to account for the diverse environments in which medical devices are used. However, in many low- and middle-income countries (LMICs), human factors studies are not conducted within their intended use environments, creating barriers to the appropriate design of medical products in these geographies.

Medical devices are frequently designed for high-resource environments with well-trained staff and robust infrastructure. However, LMICs face challenges like limited infrastructure, unreliable power, personnel shortages, and cultural nuances that affect usability. Devices that perform well in well-resourced hospitals can fail when used in environments facing these challenges, yet they are often tested in settings that don't reflect this reality and are intended for use across a wide range of settings, including the one mentioned above.

To address this gap, ClariMed has taken a practical approach by supporting the African Foundation for Premature Babies and Neonatal Care (AFPNC) in improving preemie and maternal care in Ghana. This initiative integrates human factors studies early in device development, focusing on understanding local context, identifying key challenges and opportunities, and forming actionable recommendations. The research will inform the design of a cost-effective and sustainable medical device tailored to the needs of premature infant care in Ghana, demonstrating the importance of equity-driven design.

Biography

Lengwe Bupalo Sinkala is a Human Factors Consultant at ClariMed's UK office, bringing a wealth of medical expertise and a strong commitment to excellence. She holds a medical degree from Privolzhsky Research Medical University in Russia and has managed medical and surgical wards while working for the Ministries of Health in both Botswana and Zambia. Lengwe furthered her academic career by earning a Medical Sciences research degree from the University of Edinburgh, supported by the prestigious Beit Trust Scholarship. Her diverse experience in healthcare and research are instrumental in driving ClariMed's next phase of innovation and growth.

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