Realizing Accessible and Environmentally Sustainable Medical Devices in Low-Resource Healthcare Settings in Sub-Saharan Africa

Personal Narrative of the Designer's Roles and Competencies

Samenjo, Karlheinz Tondo

DOI
10.1016/j.sheji.2025.01.005

Publication date
2025

Document Version
Final published version

Published in
She Ji

Citation (APA)
Samenjo, K. T. (2025). Realizing Accessible and Environmentally Sustainable Medical Devices in Low-Resource Healthcare Settings in Sub-Saharan Africa: Personal Narrative of the Designer's Roles and Competencies. *She Ji*, *11*(1), 99-122. https://doi.org/10.1016/j.sheji.2025.01.005

she ji
[ʃə: ʤi:]

Project

Realizing Accessible and Environmentally Sustainable Medical Devices in Low-Resource Healthcare Settings in Sub-Saharan Africa: Personal Narrative of the Designer's Roles and Competencies

Karlheinz Tondo Samenjo

Keywords
designer roles and competencies
medical device design
circular economy
low-resource setting
sub-Saharan Africa
design for environmental sustainability

Received
June 18, 2024
Accepted
January 27, 2025

KARLHEINZ TONDO SAMENJO
Faculty of Industrial Design Engineering, Delft University of Technology, The Netherlands
k.t.samenjo@tudelft.nl

Abstract
This personal narrative outlines my evolving roles and competencies as a designer in developing a reusable medical device for low-resource healthcare settings in sub-Saharan Africa. The region suffers significant disease burdens and poor health outcomes, especially among women and vulnerable groups. The scarcity of medical devices deepens these disparities. I responded by developing a context-specific, reusable medical device that improved accessibility and was environmentally sustainable. However, integrating such devices into routine care poses challenges, requiring designers to move beyond an artifact-focused approach and adopt roles that facilitate implementation. Through eight years of longitudinal research, I identified five critical roles: shaper of collaboration, design facilitator, and knowledge broker — each essential for medical device design and validation. Also, the expanded roles of a policy advocate and designer-entrepreneur were essential for successful implementation into routine care. These roles are crucial for sustainable medical devices in low-resource settings but may conflict with systems reliant on stringent regulations. Securing buy-in requires ongoing stakeholder engagement. Equipping designers to perform these roles effectively remains a challenge. My experience highlights on-the-job learning and integrates formal education with practical training. Future research should explore how this combination best equips designers to design and implement new solutions.

http://www.sciencedirect.com/journal/she-ji-the-journal-of-design-economics-and-innovation
https://doi.org/10.1016/j.sheji.2025.01.005

Introduction

Healthcare challenges in low-resource settings across sub-Saharan Africa are a global concern.[1] This context faces complex issues, including limited infrastructure, shortages of materials, supplies, and human resources, and a scarcity of essential, accessible, and cost-effective medical devices crucial for quality healthcare delivery.[2] The lack of medical devices leads to poor health outcomes, disproportionately affecting vulnerable populations, especially women.[3] Major medical device companies from industrialized economies supply more than 80% of these devices, yet over 40% become inoperable.[4] This is due to poor design suitability for low-resource healthcare facilities and susceptibility to issues such as unavailable spare parts and a lack of repair services. As a result, these devices are discarded as waste, contributing to environmental pollution.[5] Figure 1 presents a collage of images gathered by the author, showing obsolete or donated medical devices discarded in the corridors of a low-resourced hospital in sub-Saharan Africa.

The World Health Organization (WHO) recommends designing medical devices for low-resource healthcare settings with a focus on affordability, accessibility, and long-term reusability.[6] Integrating concepts such as context-specific design and the circular economy in healthcare supports this recommendation. Designers apply these approaches to improve device accessibility and reduce the environmental impact of premature medical device disposal. However, they often struggle to integrate these devices into healthcare systems, even when the devices are fully developed.[7]

One factor contributing to this challenge is the need for designers to transition from their traditional focus on tangible artifact design to roles that support integration into routine care.[8] The process of bringing a medical device to market and then into routine care is typically not considered part of a designer's role.

Field experience, aligned with existing literature, indicates that introducing medical devices into low-resource routine care typically follows a top-down or technology-push approach. Major medical device companies—equipped with substantial human, financial, and legal teams—design devices in highly industrialized economies, obtain approvals from reputable certification bodies such as the European Medicines Agency (EMA) or the United States Food and Drug Administration (USFDA), and leverage these approvals to enter low-resource markets. Designers are often involved in this process through a top-down approach, primarily contributing to the development of tangible medical device products, services, and systems.

In contrast, designers—especially those working in low-resource settings—must adopt a bottom-up approach due to a limited access to the resources available to large medical companies. They develop devices based on local needs, while navigating complex, stringent regulations designed to safeguard patient safety, as well as poorly defined approval and certification pathways.[9] Since regulatory compliance is not typically inherent to design practice, designers must assume roles and competencies beyond their usual scope. Understanding how they adapt to these expanded responsibilities is vital to the design discourse, particularly in sub-Saharan Africa, where design education is still emerging.

1 Stella C. E. Anyangwe and Chipayeni Mtonga, "Inequities in the Global Health Workforce: The Greatest Impediment to Health in Sub-Saharan Africa," *International Journal of Environmental Research and Public Health* 4, no. 2 (2007): 93–100, https://doi.org/10.3390/ijerph2007040002.

2 Clara Beatriz Aranda-Jan, Santosh Jagtap, and James Moultrie, "Towards a Framework for Holistic Contextual Design for Low-Resource Settings," *International Journal of Design* 10, no. 3 (2016): 43–63, https://www.ijdesign.org/index.php/IJDesign/article/view/2596/751.

3 Henry V. Doctor, Sangwani Nkhana-Salimu, and Maryam Abdulsalam-Anibilowo, "Health Facility Delivery in Sub-Saharan Africa: Successes, Challenges, and Implications for the 2030 Development Agenda," *BMC Public Health* 18, no. 1 (2018): article no. 765, https://doi.org/10.1186/s12889-018-5695-z.

4 Lora Perry and Robert Malkin, "Effectiveness of Medical Equipment Donations to Improve Health Systems: How Much Medical Equipment Is Broken in the Developing World?," *Medical & Biological Engineering & Computing* 49, no. 7 (2011): 719–22, https://doi.org/10.1007/s11517-011-0786-3.

5 Robert Tamale Ssekitoleko et al., "The Status of Medical Devices and Their Utilization in 9 Tertiary Hospitals and 5 Research Institutions in Uganda," *Global Clinical Engineering Journal* 4, no. 3 (2022): 15–25, https://doi.org/10.31354/globalce.v4i3.127.

6 World Health Organization, *Medical Devices and eHealth Solutions: Compendium of Innovative Health Technologies for Low-Resource Settings 2011–2012* (Geneva: World Health Organization, 2013), https://www.who.int/publications/i/item/9789241505918.

7 Brenda T. Nakandi et al., "Experiences of Medical Device Innovators as They Navigate the Regulatory System in Uganda," *Frontiers in Medical Technology* 5 (April 2023): article no. 1162174, https://doi.org/10.3389/fmedt.2023.1162174.

8 Natalia M. Rodriguez et al., "Thinking Beyond the Device: An Overview of Human- and Equity-Centered Approaches for Health Technology Design," *Annual Review of Biomedical Engineering* 25 (June 2023): 257–80, https://doi.org/10.1146/annurev-bioeng-081922-024834.

Figure 1
Sample image collage gathered by the author, depicting obsolete or donated medical devices discarded as waste in the corridors in a low-resource hospital in sub-Saharan Africa. Photos by the author.

Few studies offer contextual knowledge for designers tackling multidimensional challenges in low-resource settings, such as in Africa. Existing research rarely focuses on how designers operate within such contexts, especially in the medical device domain. For instance, Sanghamitra Chakravarty highlights the need for innovation strategies and collaborations to overcome institutional voids, enabling frugal design, engineering, and manufacturing in South Africa.[10] Santosh Jagtap emphasizes the importance of integrated solutions that not only tackle weak infrastructure, limited resources, and low literacy, but also leverage the strengths of resource-constrained societies.[11] Davide Piaggio et al. present a comprehensive overview of key considerations in medical device design for low-resource settings, including cost, materials, lifespan, user type, health technology management, and external factors—many of which are often overlooked.[12]

9 Sarah Hubner et al., "The Evolving Landscape of Medical Device Regulation in East, Central, and Southern Africa," *Global Health: Science and Practice* 9, no. 1 (2021): 136–48, https://doi.org/10.9745/GHSP-D-20-00578.

10 Sanghamitra Chakravarty, "Resource Constrained Innovation in a Technology Intensive Sector: Frugal Medical Devices from Manufacturing Firms in South Africa," *Technovation* 112 (April 2022): article no. 102397, https://doi.org/10.1016/j.technovation.2021.102397.

11 Santosh Jagtap, "Design and Engineering for Low Resource Settings: An Integrated Methodology," in *Design and*

Beyond the established discourse, clarifying the designer's roles and competencies in navigating design challenges—particularly in real-world medical device development for low-resource settings—is vital. This research advances understanding of the critical design competencies needed to address pressing societal issues, particularly in medical device design for low-resource contexts.

Background on Expanded Designer Roles and Competencies

A role is often defined as an expected pattern or set of behaviors within a specific domain.[13] Role expansion occurs when additional responsibilities are incorporated into a defined role.[14] Evidence indicates that expanded roles can be facilitated by job characteristics or the development of new knowledge and skills.[15] The evolving landscape of modern work and flattened organizational structures, characterized by dynamic, uncertain, and interdependent work systems, makes it increasingly challenging to formalize roles.[16] As a result, roles continuously expand and require new competencies—defined as a functionally linked, complex combination of knowledge, skills, and attitudes that enable successful task performance and effective problem-solving.[17]

Traditionally, design knowledge and skills have centered on developing products and services for mass manufacture. This aligns with the historical emphasis on designing objects as an end in itself (product-centric) or focusing solely on the users (user-centric).[18] Such a narrow definition does not accurately reflect the innovation landscapes at the core of contemporary practice.[19]

Designers are increasingly tasked with creating experiences and services mediated by non-physical products.[20] Behind these endeavors are design agendas that extend beyond manufacturing, promoting social impact, enhancing health and well-being, and advancing pathways toward more environmentally sustainable futures. For example, Arnim Wiek et al. highlight system thinking, critical thinking, anticipatory, normative, strategic, interpersonal, and communication skills as key competencies in sustainability for higher education,[21] which are also applicable to the design profession. Denis Weil and Matt Mayfield advocate for designers to embrace complexity, cultivate possibilities, and drive impactful change—critical for design in the 21st century.[22] Conny Bakker, Ruud Balkenende, and Flora Poppelaars propose essential designer competencies for environmentally sustainable products from a circular economy perspective, emphasizing the preservation of economic and environmental value by extending product lifespan or reintegrating into the system for reuse.[23] These include key roles and competencies such as system thinking, business propositions, user engagement, materials and manufacturing, collaboration, storytelling, impact assessment, design for recovery, and multiple-use cycles—all essential for creating environmentally sustainable products aligned with circular economy objectives, as advanced by Deborah Sumter et al.[24]

Design roles and competencies—such as those discussed by Wiek et al.—apply to designers tackling healthcare-related innovation, including medical device design. They are also relevant to design efforts supporting the transition from the current linear "take-use-throw-away" approach in healthcare to more sustainable reuse practices. This study presents the author's

Engineering for Low Resource Settings: A Practical Guide, ed. Santosh Jagtap (Cham: Springer, 2024), 1–12, https://doi.org/10.1007/978-3-031-66156-3_1.

12 Davide Piaggio et al., "A Framework for Designing Medical Devices Resilient to Low-Resource Settings," *Globalization and Health* 17 (June 2021): article no. 64, https://doi.org/10.1186/s12992-021-00718-z.

13 Daniel R. Ilgen and J. R. Hollenbeck, "The Structure of Work: Job Design and Roles," in *Handbook of Industrial and Organizational Psychology*, 2nd ed., ed. M. D. Dunnette and L. M. Hough (Palo Alto, CA: Consulting Psychologists Press, 1991), 165–207.

14 Sharon K. Parker, Toby D. Wall, and Paul R. Jackson, "'That's Not My Job': Developing Flexible Employee Work Orientations," *Academy of Management Journal* 40, no. 4 (1997): 899–929, https://www.jstor.org/stable/256952.

15 Frederick P. Morgeson, Kelly Delaney-Klinger, and Monica A. Hemingway, "The Importance of Job Autonomy, Cognitive Ability, and Job-Related Skill for Predicting Role Breadth and Job Performance," *Journal of Applied Psychology* 90, no. 2 (2005): 399–406, https://doi.org/10.1037/0021-9010.90.2.399.

16 Mark A. Griffin, Andrew Neal, and Sharon K. Parker, "A New Model of Work Role Performance: Positive Behavior in Uncertain and Interdependent Contexts," *Academy of Management Journal* 50, no. 2 (2007): 327–47, https://doi.org/10.5465/AMJ.2007.24634438.

17 Arnim Wiek, Lauren Withycombe, and Charles L. Redman, "Key Competencies in Sustainability: A Reference Framework for Academic Program Development," *Sustainability Science* 6, no. 2 (2011): 203–18, https://doi.org/10.1007/s11625-011-0132-6.

18 Suzana Dias and Ana Baptista, "Rethinking the Role of the Contemporary Designer: Is There a Mismatch between Theory and Practice in Design Education?," in *Perspective on Design: Research, Education and Practice*, ed. Daniel Raposo, João Neves, and José Silva, vol. 1 of *Springer Series in Design and Innovation* (Cham: Springer, 2020), 17–26, https://doi.org/10.1007/978-3-030-32415-5_2.

19 Paul Gardien et al., "Changing Your Hammer: The Implications of Paradigmatic Innovation for Design Practice," *International Journal of Design* 8, no. 2 (2014): 119–39, https://www.ijdesign.org/index.php/IJDesign/article/view/1315/635.

personal narrative, exploring the roles and competencies in designing accessible, sustainable medical devices for low-resource healthcare in sub-Saharan Africa. It focuses on how designers navigate these contexts.

Author's Positionality

Growing up in resource-constrained environments in Cameroon and Kenya exposed me to the critical deficiencies in healthcare caused by the absence of essential medical devices. One example was witnessing women enduring painful gynecological treatments without pain medication due to the lack of an appropriate device. Furthermore, women endured this pain against the stark backdrop of numerous piles of discarded, broken, and obsolete medical devices (see Figure 1). This reality exacerbates medical device shortages and contributes to medical waste, leading to significant environmental repercussions and substantial economic impact across Africa. The failure to design and integrate medical devices for these settings, as recommended by WHO, perpetuates inhumane treatments, particularly affecting vulnerable women.

Over the past decade, I have focused on medical device design and healthcare in sub-Saharan Africa, collaborating with local hospitals on 3D-printed spare parts. I am committed to environmental sustainability, social justice, equity, and the use of design and innovation to improve healthcare outcomes in marginalized regions. This commitment inspired me to develop a medical device that improves women's access to gynecological treatments. However, my professional experiences have highlighted that addressing the challenges of medical device design — while also minimizing environmental repercussions — requires skills beyond traditional design practices, many of which remain insufficiently articulated in existing literature. This underscored the need to understand expanded roles and competencies that enable designers to integrate devices into routine care, ensuring their availability and accessibility in low-resource settings.

Since 2015, while discussing the need for 3D-printed medical devices with a doctor, I could hear yet another woman endure painful gynecological treatment without pain relief due to the absence of essential devices. This experience led me to conduct longitudinal research in low-resource Kenyan settings. The aim was to design and facilitate the integration of a medical device for administering pain relief during gynecological procedures, addressing gaps in medical device accessibility and environmental sustainability. Concurrently, the research sought to contribute to the scientific discourse on the essential and expanded roles and competencies of designers in developing and integrating sustainable medical devices into routine care in low-resource settings in sub-Saharan Africa.

Method

To explore the roles and competencies of designers in implementing sustainable medical devices in low-resource settings in sub-Saharan Africa, I used the action research method. Also known as community-based study or action learning,[25] action research fosters participatory engagement, curiosity, and inquiry into practical issues.[26]

20 Birgit Mager et al., "Product-Service Systems Design Education: Normalize, Grow, and Evolve," *She Ji: The Journal of Design, Economics, and Innovation* 9, no. 2 (2023): 213–33, https://doi.org/10.1016/j.sheji.2023.06.004.

21 Wiek et al., "Key Competencies in Sustainability."

22 Denis Weil and Matt Mayfield, "Tomorrow's Critical Design Competencies: Building a Course System for 21st Century Designers," *She Ji: The Journal of Design, Economics, and Innovation* 6, no. 2 (2020): 157–69, https://doi.org/10.1016/j.sheji.2020.03.001.

23 Conny Bakker, Ruud Balkenende, and Flora Poppelaars, "Design for Product Integrity in a Circular Economy," in *Designing for the Circular Economy*, ed. Martin Charter (Abingdon, OX: Routledge, 2018), 148–56.

24 Deborah Sumter et al., "Circular Economy Competencies for Design," *Sustainability* 12, no. 4 (2020): article no. 1561, https://doi.org/10.3390/su12041561.

25 Kin Wai Michael Siu and Jia Xin Xiao, "Public Facility Design for Sustainability: Participatory Action Research on Household Recycling in Hong Kong," *Action Research* 18, no. 4 (2020): 448–68, https://doi.org/10.1177/1476750317698027.

26 Peter Reason, "Choice and Quality in Action Research Practice," *Journal of Management Inquiry* 15, no. 2 (2006): 187–203, https://doi.org/10.1177/1056492606288074.

The action research in this study followed the "engaged scholarship" approach, where scholarship extends beyond research, and engagement serves as the means for scholarship to flourish.[27] The action research structured into four key stages within a cyclical process: planning, acting, and observing, while concurrently reflecting and consolidating each step.[28] This aligns with my objective to document my learning journey as a designer, highlighting evolving roles and competencies from the design phase of a medical device through to its realization within the healthcare system in Kenya, a sub-Saharan African region. Kenya was selected due to my interest in solving health-related issues and my firm grasp of the local healthcare context.

Due to the exploratory and design-driven nature of this research, the planning step simply entailed starting and then identifying the next steps through investigation and community engagement. Once a critical action was identified, it was added to the planning and registered chronologically, capturing start and end dates of each action. A Microsoft Excel sheet captured this data. Discussion and community engagement included contextual observations, one-on-one expert interviews and semi-structured focus group interviews. Data was captured in diaries as field notes.

Outcomes

Below, I detail the planning phase, field actions (summarized in Figure 2), and critical observations, reflecting on and consolidating my expanded roles and competencies as a designer.

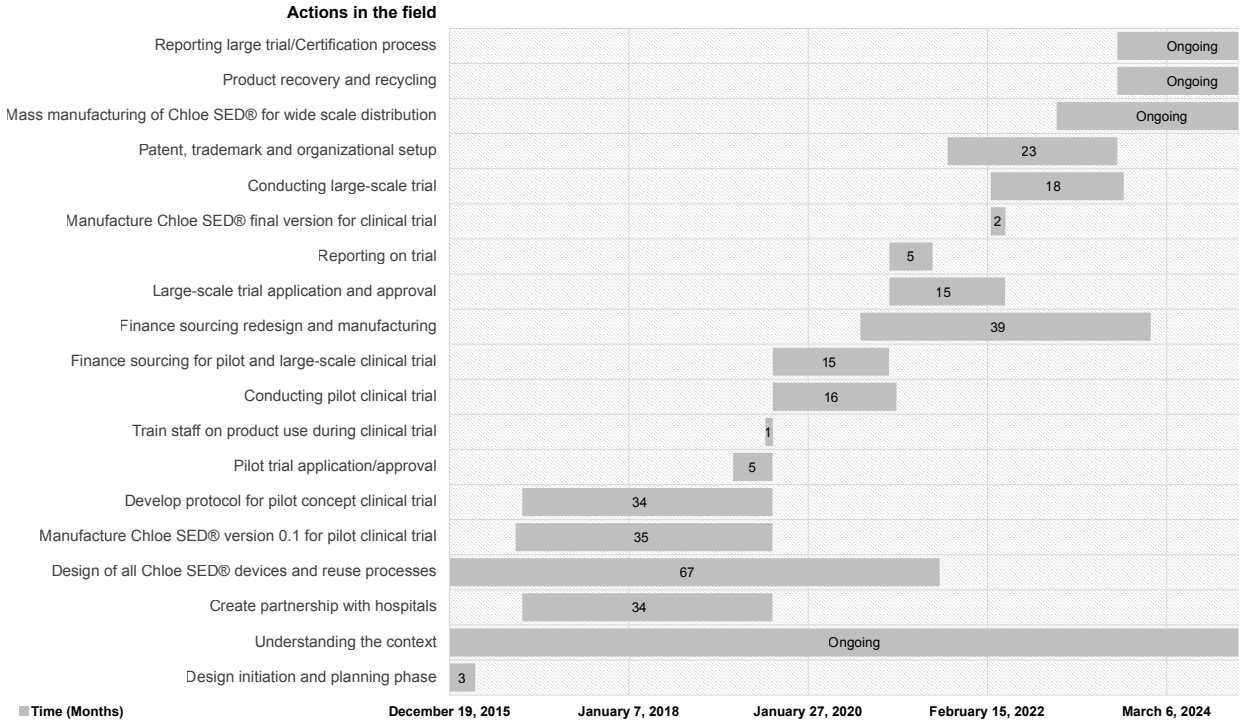

Figure 2
Summary of the actions in the field throughout the research against time in months. © 2024 Karlheinz Tondo Samenjo.

27 Andrew H. Van de Ven, *Engaged Scholarship: A Guide for Organizational and Social Research* (Oxford: Oxford University Press, 2007).

28 Rebecca Price, Cara Wrigley, and Judy Matthews, "Action Researcher to Design Innovation Catalyst: Building Design Capability from Within," *Action Research* 19, no. 2 (2021): 318–37, https://doi.org/10.1177/1476750318781221.

December 2015–April 2016: Design Initiation and Planning Phase

In 2015, I began a journey to design a tangible medical device to address a societal and healthcare challenge in low-resource healthcare settings in Kenya. The goal was to design a device to support the administering of a paracervical block during gynecological procedures. A paracervical block—a regional nerve block—provides pain relief by injecting an anesthetic solution around the cervix to numb nearby nerves and alleviate discomfort.[29] During this procedure, a long syringe needle—such as a spinal needle—is used to reach the cervix and administer anesthesia. Gynecological procedures requiring a paracervical block include loop electrosurgical excision procedures, cervical biopsies, placement of contraceptives in the uterus, curettage, and manual vacuum aspiration for the treatment of miscarriage or incomplete abortion.[30] Neglecting a paracervical block unnecessarily heightens anxiety and pain, compromising the quality of care.[31] However, gynecologists and medical practitioners in low-resource healthcare facilities in Kenya were unable to perform this procedure due to the unavailability of spinal needles.

Delving deep into the case, walking through the corridors of the low-resourced hospital, and witnessing women resting against gigantic piles of broken or obsolete medical devices was a stark reality. These women had just experienced a miscarriage and were about to undergo treatment without pain relief medication. As they waited for their turn, the agonizing screams of another woman undergoing the same procedure across the room were unmistakable. This further underscored how women in this setting suffer to access essential healthcare services due to the unavailability of medical devices. This moment marked the inception of the design challenge—understanding the context and developing a tangible artifact that could be reused over time and remain environmentally sustainable.

Actions in the Field

December 2015–Ongoing: Understanding the Contextual Situation and Wanting to Bring Improved Outcomes

To address the absence of pain relief medication during gynecological procedures, I recognized the need to understand the healthcare setting and the root causes of the issue. My participatory approach—characterized by stakeholder engagement, curiosity, and inquiry—required immersion in the hospital environment to understand gynecological, medical, and hospital processes. However, I quickly realized that, as a designer, I could not simply walk into a healthcare facility and engage stakeholders. As such, I initiated open discussions about the lack of medical devices for pain relief in gynecological procedures with doctors and healthcare workers.

Healthcare professionals such as gynecologists, nurses, and clinical officers are directly involved in the administering of paracervical blocks. They are trained, licensed, and regulated as the point of contact for providing patient care. Auxiliary staff handle cleaning and reprocessing, as well as medical device maintenance, while hospital management oversees administrative and logistical functions. Discussions with doctors and healthcare workers provide contextual

29 Huseyin Aksoy et al., "Comparison of Lidocaine Spray and Paracervical Block Application for Pain Relief during First-Trimester Surgical Abortion: A Randomised, Double-Blind, Placebo-Controlled Trial," *Journal of Obstetrics and Gynaecology* 36, no. 5 (2016): 649–53, https://doi.org/10.3109/01443615.2016.1148681.

30 Scott Chudnoff, Mark Einstein, and Mark Levie, "Paracervical Block Efficacy in Office Hysteroscopic Sterilization: A Randomized Controlled Trial," *Obstetrics & Gynecology* 115, no. 1 (2010): 26–34, https://doi.org/10.1097/AOG.0b013e3181c51ace.

31 World Health Organization, *Abortion Care Guideline* (Geneva: World Health Organization, 2022), https://www.who.int/publications/i/item/9789240039483.

insights into the problem, potential solutions, and even interest in a collaborative investigation of the issue. This emerged as the strategic choice for moving forward. The following steps included preparing consent forms, which the doctors or healthcare professionals signed before any discussion happened.

In pursuing collaboration with healthcare professionals, I assumed the role of a shaper of collaboration, building partnerships and interdisciplinary working relationships to address the healthcare issue—specifically, the absence of paracervical block. In this role, key activities included networking, identifying and recruiting stakeholders, and establishing a local community of healthcare professionals to investigate the issue together. Once a healthcare professional in a community was identified and consent was obtained, I conducted regular visits and meetings to raise awareness about the importance of providing women with proper care, including access to paracervical blocks, thereby fostering trust.

Establishing trust with healthcare professionals required actively listening to and understanding their perspectives on paracervical blocks while steering discussions toward environmentally conscious solutions. To build trust, I initiated regular visits, roundtable discussions, and brainstorming sessions with healthcare professionals to emphasize the importance and necessity of paracervical blocks.

Some of these activities required long travel times of two to four hours, followed by extended waiting periods to accommodate healthcare professionals' schedules. In some cases, the travel and waiting proved futile, as the healthcare professionals were pre-occupied. Despite these challenges, being present and demonstrating a genuine interest in the healthcare professionals' work and a desire to collaborate to address the issue of lack of pain relief medication was crucial. In pressured systems, actions speak louder than words. Discussions with doctors were informal, often occurring at the front desk, during breaks, or after work, focusing on their experiences, particularly those shared in public publications or reports. Discussions regarding access to unpublished information or hospital premises closed to the public were not permitted.

During discussions with doctors, I shared real-world case stories on the impact of the lack of paracervical blocks during gynecological procedures. Encouraging healthcare professionals to discuss their experiences with the absence of paracervical block and how it hindered or slowed their work processes was essential. For example, gynecologists highlighted their commitment to finding a lasting solution to alleviate women's suffering. They were troubled by the distress caused when procedures had to be conducted without pain relief. However, the local unavailability of the required spinal needle hindered their ability to offer pain relief. Additionally, hospital procurement officers were primarily concerned with identifying an affordable yet durable solution to this pressing issue, as spinal needles were either too costly or unavailable locally.

Understanding these frustrations shed light on the issue and taught me about the intricacies and challenges faced by healthcare facilities when providing pain relief medication. Conversations with medical technicians emphasized the importance of device durability, maintainability, and minimizing premature disposal as environmental waste. Additionally, discussions

with device reprocessing staff revealed the practice of reusing medical devices, which helps lessen the environmental impact of disposables.

These conversations, which began in 2015, about medical device gaps for pain relief medication in gynecological procedures, continued through 2016–2019 (see next section). They led to identifying gaps, sparking a desire among healthcare professionals to drive change, and inspiring me to quickly draft a low-fidelity prototyped design concept which was manufactured. What started as an ordinary discussion with doctors evolved into a tangible device prototype, attracting more interest in collaboration.

After thirty-four months of discussions (2016–2019), two of the six hospitals I had engaged with through discussions with doctors agreed to join the challenge and collaborate toward a Hospital Institutional Review Board approval to involve the hospital staff in an in-depth collaboration and develop a device that is clinically validated under a trial. Details on the trial are provided in the section below. The other hospitals declined to participate, citing reasons such as not prioritizing paracervical blocks for gynecological procedures and limited staff capacity to participate in activities other than ongoing clinical procedures—despite several months of discussions aimed at establishing collaboration. It is important to note that throughout the process, no direct patient contact or on-site observations were conducted.

The collaboration with the two hospitals, each requiring Institutional Review Board approval (approved in 2019), initiated a partnership and also allowed in-depth collaboration with obstetricians, gynecologists, nurses, clinical technicians, and administrative and auxiliary officers. The goal was to develop and clinically validate a solution that ensures women have access to pain relief medication during gynecological procedures while minimizing environmental impact.

Collaboration with healthcare professionals granted me access to invaluable expert knowledge on gynecology, as well as insights into healthcare facility processes and contextual needs related to addressing the lack of paracervical blocks. Processes included medical device cleaning, sterilization, storage, purchasing, disposal, and patient administration. Understanding the contextual situation and striving for improved outcomes must continue until the medical device solution is implemented in routine care.

December 2015–July 2021: From Contextual Needs to the Design of Tangible Artifacts and Reuse Processes

Through ongoing discussions with healthcare professionals, it became evident that the primary cause of inhumane gynecological procedures without pain relief was the unavailability or high cost of essential medical devices, particularly spinal needles suitable for reaching the cervix. Over time, these discussions — twenty-six in total — took the form of co-design sessions among healthcare workers, where they exchanged ideas and explored potential solutions. Details on the co-design sessions, including participant numbers, data collection, and analysis, are detailed in my earlier study.[32]

During the co-design discussion sessions, my role evolved into a design facilitator. This involved coordinating the design process across multiple areas of expertise, including technology, medicine, clinical and health facility operations, and environmental impact. Activities included, simplifying and

32 Karlheinz Tondo Samenjo et al., "Design of a Syringe Extension Device (Chloe SED®) for Low-Resource Settings in Sub-Saharan Africa: A Circular Economy Approach," *Frontiers in Medical Technology* 5 (2023): 1–18, https://doi.org/10.3389/fmedt.2023.1183179.

establishing a common understanding of the concept of design with healthcare professionals, and instilling the confidence to actively pursue a sustainable medical solution.

Facilitating stakeholder idea generation and collaborative design with non-designers—particularly healthcare professionals—was a new experience. My previous endeavors predominantly involved interactions with designers familiar with design terminology and approaches. However, this fresh context required me to engage with medical professionals who primarily associated design with fields such as fashion. In response to this shift, I recognized the need to establish a common understanding of design. Whether in the context of fashion or medical devices, the essence of design remains the same—it aims to address specific problems and needs. While those needs may vary, the fundamental principle of using design for problem-solving remains steadfast. The medical staff grasped how design could address challenges when the concept of design was simplified and related to their existing knowledge. This gave them confidence to actively engage in designing a medical and environmentally sustainable solution. They voiced concerns about the lack of paracervical blocks based on their medical expertise, as well as their knowledge of the associated environmental issues and potential future solutions.

For instance, obstetricians and gynecologists demonstrated how a spinal needle, although expensive and scarce, provided the necessary length to reach the cervix for administering pain relief medication. Notably, they employed a 10 cc syringe with a shorter needle to illustrate the extended length of a spinal needle. Through further questioning, dialogue, and rapid prototyping, it became evident that while 10 cc syringes were readily available and cost-effective, they lacked the necessary length to reach the cervix, leading to a reliance on spinal needles. As the discussions progressed, I relied on the stakeholders' expertise to understand the gynecological procedures and continue guiding and facilitating co-design. The challenge lay in embracing my inexperience while guiding medical experts, such as experienced gynecologists, given that I am not an expert in the field. However, I co-designed and facilitated discussions to enable gynecologists to share their expertise, creating an on-the-job learning experience and a context for my own learning. For example, they used gynecological anatomical models to explain a process as it would be performed on a patient.

Over the course of fifteen interviews conducted as co-design sessions—captured in diaries as field notes and analyzed through descriptive coding and reflection by a design team of six—several design iterations emerged.[33] This marked the inception of the concept known as the reusable Chloe Syringe Extension Device (SED®) (Figure 3). At this point, healthcare stakeholders contributed to developing a solution suited to paracervical blocks, born out of a facilitated design process.

Chloe SED is a modular and reusable medical device that snap-fits onto any 10 cc syringe, providing additional length to reach the cervix and provide pain relief medication during gynecological procedures.[34] A Chloe SED (Figure 3-B2), costs USD 1.50 (polypropylene, twenty-five reuses), USD 10.00 (polyetheretherketone, twenty-five reuses), or USD 15.00 (aluminum, one thousand reuses), offering a reusable alternative to disposable spinal needles. This innovation facilitates pain relief while emphasizing affordability and an environmentally

33 For detailed information, see Samenjo et al., "Design of a Syringe Extension Device."

34 Extensively discussed in Samenjo et al., "Design of a Syringe Extension Device."

Figure 3
Syringe Extension Devices (Chloe SED) where (A) illustrates a 10 cc syringe with a spinal needle on the left and Chloe SED Version 0.1 attached to a 10 cc syringe; (B1) illustrates a 10 cc syringe with a spinal needle on the left and final Chloe SED design attached to a 10 cc syringe; (B2) displays different Chloe SED final design models in polypropylene, polyetheretherketone, and metal; (B3) shows a hand-sized demonstrator of the final Chloe SED design on a pelvic model; and (B4) depicts the Chloe SED final design used in the local context to provide a paracervical block. © 2023 Karlheinz Tondo Samenjo.

sustainable medical device design approach. Affordability was achieved with a unit cost as low as USD 1.50. This result supported environmental sustainability—which focuses on reusability, modular design, and recycling—by ensuring products and materials remain in use rather than being discarded.

Environmental sustainability emerged from a knowledge exchange on the circular economy concept—preserving products and materials by extending their lifespan or enabling their reuse within Earth's ecosystem. Chloe SED embodies circularity by utilizing reusable and recyclable materials. In facilitating interactive processes to foster knowledge exchange, I assumed the role of knowledge broker.

As a knowledge broker, my role focused on facilitating knowledge exchange, translating ideas, and mediating potential tensions in integrating healthcare practices with circular economy principles. This included communicating and illustrating circular economy principles, emphasizing durability, maintenance, repair, remanufacturing, upgrades, recontextualization, refurbishment, and product recycling back into their original material. For instance, designing for longevity through product durability can extend the lifespan of medical devices. Durable devices would also reduce the financial burden of replacing parts or relying on single-use devices, ultimately minimizing environmental waste. Furthermore, durable and functional medical devices could guarantee women access to essential care, addressing challenges associated with device unavailability, such as the reliance on spinal needles.

Facilitating knowledge exchange not only raised awareness of the importance of reusable devices in healthcare but also highlighted potential tensions within the local healthcare setting. For instance, using more durable devices might mean higher initial costs compared to less durable alternatives, requiring

a shift from the familiar use-and throw-away disposable culture to a reusable one. At times, this received pushback. Healthcare stakeholders resisted transitioning from disposable to reusable devices due to the additional workload and costs associated with disinfecting devices, which is essential to prevent cross-contamination and health risks. However, through continuous engagement during the design process, healthcare professionals remained open to exploring circular economy concepts and working toward a feasible solution. The durable Chloe SED (USD 1.50–15.00), which can be reused 25–1,000 times, offered an affordable alternative to disposable spinal needles (USD 1.50–28.00) while fitting within hospital processes, making it a viable solution.

Developing an affordable, accessible, and reusable device that integrates seamlessly with existing hospital processes secured the support of healthcare staff and encouraged buy-in for a circular healthcare model. The device enables healthcare professionals to administer pain relief, particularly to women undergoing gynecological procedures, while being durable, recyclable, and reducing the environmental impact associated with single-use disposables.

The design of Chloe SED, while incorporating circularity, supports the transition from a linear use-and-throw-away economy to a reuse-focused one. This shift required ongoing stakeholder engagement and knowledge sharing to develop a workable, accepted solution. This transition aligns with United Nations' Sustainable Development Goal (SDG) 3 for good health and well-being, as well as SDGs 12 and 13, which promote responsible consumption, environmental impact reduction, and climate change mitigation.[35]

September 2015–August 2019: Manufacturing of the Device to Clinical Standard to Be Tested under a Pilot Clinical Study

Following the design of Chloe SED Version 0.1 (see Figure 3-A), the critical task was to manufacture the device to clinical standards to ensure patient safety. However, a significant challenge arose in producing a limited quantity of sample devices for clinical testing—only five were required for trials. Local manufacturers in Kenya primarily focused on large-scale production, requiring substantial initial investments exceeding USD 100,000 and a minimum production capacity of over 1,000 copies. With limited resources, I explored alternative manufacturing techniques that were both affordable and high-quality.

Drawing on my understanding of emerging technologies in Kenya, collaboration with local 3D printing manufacturers enabled the production of five samples at USD 25 per device. Crucially, the 3D printing manufacturing process had to comply with Kenya's regulatory standards for medical devices, set by the Kenya Bureau of Standards (KEBS) and the Pharmacy and Poisons Board (PPB). However, Kenyan standards for 3D-printed medical devices were still undefined. As a result, Chloe SED Version 0.1 could not progress to clinical trials, as the process required the device to meet established medical device clinical standards.

As a policy advocate, I actively supported the establishment of new standards or regulations that facilitate medical device design, manufacturing, and use. This involved analyzing the design and manufacturing parameters of Chloe SED Version 0.1 to ensure compliance with Kenyan and ISO standards, aiming to set a benchmark paracervical block for evaluating similar medical devices designed for use in healthcare facilities. Competencies in

35 For more information, see https://sdgs.un.org/goals.

this role involved writing and communicating a technical document used to draft a new standard. The technical documentation of Chloe SED detailed 3D printing technology and material used for small-scale production. Additionally, it outlined how the technology and material conform to medical standards, ensuring durability, reusability, and the ability to be recovered and recycled back into raw material — aligning with circular economy principles. This technical document incorporated scientific evidence, including the strength-stress engineering experiments on the materials used in 3D printing Chloe SED and the deteriorating effects of disinfection.[36]

As a policy advocate, I engaged iteratively with the Kenya Bureau of Standards and the Pharmacy and Poisons Board over thirty-five months (2016–2019) to help establish standards for 3D-printed medical devices aligned with circular economy principles, supported by evidence provided through technical documentation. While this initiative advocated for the adoption of a circular medical device manufacturing process and aimed to support local designers in achieving small-scale production, it also delayed progress toward clinical trials.

October 2016–January 2021: Pilot Clinical Trial of the Chloe SED Device

Clinical trials are pivotal in evaluating investigational products and pinpointing potential adverse reactions.[37] In Kenya, the Pharmacy and Poisons Act, Cap 244,[38] mandates clinical evaluations of all medical devices. Therefore, conducting a pilot clinical trial is imperative. Pilot studies serve as essential groundwork for planning comprehensive, controlled large-scale trials.[39]

The execution of clinical trials is restricted to licensed medical practitioners operating under strict regulatory conditions, which extends beyond my expertise as a designer. My prior role as design facilitator paves the way for co-designing and evaluating the device designs within a clinical trial alongside healthcare professionals. This involved formulating study protocols, obtaining clinical trial licenses, training staff, securing financial resources for large-scale trials, reporting, and carrying out product redesign and manufacturing iterations. All these steps were completed within fifty-one months (2016–2021). Below, I delve into each stage.

October 2016–August 2019: Development of Study Protocols and Application of Pilot Trial License

These protocols served as comprehensive guides, outlining critical trial aspects such as methodology, participant selection criteria and consent, ethical considerations, data management, budget, and timelines.[40] While healthcare professionals contributed medical expertise to assess the efficacy and potential adverse effects of using the Chloe SED Version 0.1 in gynecological procedures requiring a paracervical block, I provided insights on engineering, design, and environmental aspects, framing the designed-led solution in measurable clinical terms.

The development of the study protocol spanned thirty-four months (2016–2019) and involved securing research licenses from the National Commission for Science, Technology and Innovation (NACTOSTI), obtaining ethical approval from the Hospital Institutional Review Board, and ensuring the availability of medical device technical documentation and manufacturer ISO certificates.

36 As detailed in Samenjo et al., "Design of a Syringe Extension Device."

37 Chalachew Alemayehu, Geoffrey Mitchell, and Jane Nikles, "Barriers for Conducting Clinical Trials in Developing Countries — A Systematic Review," *International Journal for Equity in Health* 17 (2018): article no. 37, https://doi.org/10.1186/s12939-018-0748-6.

38 Pharmacy and Poisons Board, "Guidelines for Registration of Medical Devices Including In-Vitro Diagnostics," last modified January 2022, https://web.pharmacyboardkenya.org/download/guidelines-for-registration-of-medical-devices-including-in-vitro-diagnostics/.

39 Sandra M. Eldridge et al., "Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework," *PLOS ONE* 11, no. 3 (2016): e0150205, https://doi.org/10.1371/journal.pone.0150205.

40 Azzam Al Jundi and Salah Sakka, "Protocol Writing in Clinical Research," *Journal of Clinical and Diagnostic Research* 10, no. 11 (2016): ZE10–13, https://doi.org/10.7860/JCDR/2016/21426.8865.

Throughout these processes—in my role as designer—I developed and facilitated the documentation of the Chloe SED design and engineering principles, ensuring alignment with healthcare ethics and patient safety.

Other administrative and regulatory processes not necessarily dependent on the designer included securing healthcare insurance for pilot trial participants, obtaining medical practice licenses, ensuring indemnity cover for lead medical researchers, and registering the study with the Pan African Clinical Trial Registry (PACTR). The study protocol application, along with support letters from the healthcare facilities, was submitted to the Kenyan Pharmacy and Poisons Board for clinical trial approval. The application, which included essential regulatory documents, was reviewed under PPB/ECCT/19/03/01/122 and received approval within five months in 2019.

August 2019–Jan 2021: Pilot Clinical Trial Staff Training and Study

Following trial approval, staff training for the pilot clinical trial was completed within one month in 2019. Medical professionals, including doctors, nurses, and medical officers, were recruited to conduct the trial. The training included both initial instruction and refresher sessions on the clinical procedure for administering pain relief medication in the cervix. Within the training, I assumed the role of knowledge broker, ensuring healthcare professionals were well-versed in the effective use of the medical device on patients, as well as its circular economy principles, including reuse cycles. This role also involved communicating proper device usage and closely observing both intended and unintended ways medical professionals used the device. These observations were pivotal for refining future product final design iterations and optimizing reuse cycles.

The trained staff and the medical experts conducted a sixteen-month pilot clinical trial (2019–2021) with n = 61 patients using the Chloe SED Version 0.1. The patient count was determined through non-inferiority testing, which involved quantitatively analyzing the primary outcome—identifying clinically meaningful differences in pain scores between Chloe SED and a standard spinal needle used for administering pain medication in the cervix. Notably, since the pilot clinical trial required funding, I took on the responsibility of securing financing.

September 2019–April 2022: Finance of the Pilot and Large-Scale Trial

The pilot trial, which cost USD 5,000, was funded by grants from local and international collaborators. Securing this funding stemmed from my role as a designer-entrepreneur, which combines design and entrepreneurial activities to implement sustainable design-led interventions. In this capacity, I conducted fundraising and business activities, such as seeking grants, and establishing a business start-up venture as a conduit for securing initial funding to validate and implement the device in a low-resource healthcare setting. While raising finances for the pilot trial, plans for funding a large-scale trial were also initiated.

Large-scale clinical trials incur significant costs due to research scale, strict regulations, and safety requirements. To secure funding for our large-scale randomized controlled trial, we pursued various grants totaling USD 195,000—a

process that spanned fifteen months from early 2019 to late 2020. Adequate clinical trial financing is crucial, serving as a pivotal milestone in advancing a product through clinical validation and integration into routine care. Without sufficient funding, conducting and completing a trial becomes challenging. Further collaborative efforts among local and international partners over a thirty-nine-month period (2020–2023) facilitated the acquisition of technological and financial resources valued at USD 179,000, aimed at supporting redesign and future manufacturing endeavors.

Concurrently, the approval processes also commenced. Both the pilot and large-scale trial required application and approval. The application procedure for this large-scale trial mirrored the pilot trial and received approval within fifteen months (2021–2022).

January 2021–April 2021: Reporting on the Pilot Study, Redesign, and Manufacturing of the Device

Within five months in 2021, following the successful pilot clinical study, a comprehensive report was submitted to regulatory authorities, demonstrating the proven efficacy of the Chloe SED Version 0.1 in administering pain relief medication. The report presented the scientific and clinical evidence supporting the effectiveness of the device, contributing to the generation of new knowledge, as also published in Aparna Ramanathan et al.[41]

Based on the pilot study findings, design modifications were implemented to enhance the device, resulting in the final version of Chloe SED (see Figure 3-B2). In my roles as a design facilitator, I guided the design process, translating clinical trial results into the final version of the device. This involved simplifying pilot trial findings, aligning with healthcare professionals, and preparing the product for large-scale trials and scaling. This marked the completion of the product design of Chloe SED (from version 0.1 up to the final version) as a medical device for administering paracervical blocks, a process spanning sixty-seven months (2015–2021).

Next, twenty-four 3D-printed, medical-grade Chloe SED final versions were manufactured and ensured regulatory compliance for validation in a large-scale clinical trial within two months in 2022. Achieving manufacturing and regulatory compliance within this timeframe represented a significant improvement over the thirty-five month duration required during the pilot clinical trial phase. Progress was facilitated by prior engagement in policy advocacy from September 2016 to August 2019, which focused on manufacturing Chloe SED Version 0.1 to a standard suitable pilot clinical study testing. This involved collaborating with regulatory bodies to integrate 3D printing as a manufacturing standard for medical devices in Kenya.

March 2022–September 2023: Large-Scale Randomized Trial

Following the manufacturing phase, a large-scale randomized clinical trial involving 210 patients was conducted within eighteen months from 2022 to 2023. The sample size was based on the findings of the pilot study. During this trial, twelve Chloe SED units were repeatedly reused as intended to work in a circular economy.

41 Aparna Ramanathan et al., "Validation of a Novel Medical Device (Chloe SED®) for Administration of Analgesia during Manual Vacuum Aspiration: A Randomized Controlled Non-Inferiority Pilot Study," *Frontiers in Pain Research* 5 (2024): article no. 1326772, https://doi.org/10.3389/fpain.2024.1326772.

September 2021–August 2023: Device Patent and Trademark, Large-Scale Manufacturing and Organizational Structure to Engage with Other Stakeholders

Before proceeding with large-scale manufacturing, it was crucial to ensure that Chloe SED could enter legal agreements with implementation partners. For example, producers and distributors required a patent for Chloe SED, registered with the Kenya Intellectual Property Institute (KIPI) and the World Intellectual Property Organization (WIPO). The former oversees intellectual property rights in Kenya,[42] while the latter promotes and standardizes international intellectual property laws.[43] Additionally, this involved establishing Chloe Innovation Limited Liability Company, which spearheaded and facilitated legal agreements to advance implementation. Completing these activities over a twenty-three-month period (2021–2023) led to large-scale manufacturing for market entry, which is currently underway.

August 2023–Ongoing: Product Recovery and Recycling, Trial Reporting, and Entering Certification Process and Market

An essential aspect of the design and use of Chloe SED is its material and environmental sustainability. This involved the reuse and recovery of Chloe SED during the clinical trial and material recycling. However, attempts to recover and recycle raised unresolved questions regarding responsibility for ensuring sterility. Specifically, it was unclear whether sterility should be ensured by the healthcare facility or the recycler, and whether this responsibility should be fulfilled before or during recovery and recycling. Current local regulations do not provide clear guidance. This insight came about from collaboration between the healthcare sector, manufacturers, recyclers, and regulatory bodies, working toward a more sustainable solution—a process in which I played a role as a shaper of collaboration. Similarly, in my role as a policy advocate, I have been working with local regulatory bodies to explore this concern further.

While addressing the recovery and recycling of Chloe SED, efforts have been ongoing since August 2023 to generate a clinical trial report and provide recommendations to regulatory bodies. This pivotal process is closely linked to the certification and market licensing of Chloe SED, both of which are required for distribution and use in healthcare facilities.

Discussion

This study presents the author's personal narrative on the roles and competencies involved in designing accessible, sustainable medical devices for low-resource healthcare in sub-Saharan Africa. Over eight years, this study developed and implemented Chloe SED, a medical device for administering pain relief during gynecological procedures, addressing both accessibility gaps and environmental sustainability while elucidating the roles and competencies of designers. Roles and competencies included designer as *shaper of collaboration*, *design facilitator*, and *knowledge broker* in achieving device design and validation. Additionally, the expanded roles of *policy advocate* and *designer-entrepreneur* were essential to ensure its societal incorporation (see Table 1).

42 Eliud Dismas Moyi, "Role of Various Institutions in Providing Technology Support Services to MSEs in Kenya," *Public Policy and Administration Research* 4, no. 9 (2014): 169–77, https://iiste.org/Journals/index.php/PPAR/article/view/15686.

43 James Boyle, "A Manifesto on WIPO and the Future of Intellectual Property," *Duke Law & Technology Review* 3, no. 1 (2004): 1–13, https://scholarship.law.duke.edu/dltr/vol3/iss1/6.

Table 1 **Designer's expanded roles and competencies and the context of emergence.**

Roles		Designer competencies and specialized knowledge needed	Summarized designer activities and contexts in the field as per research on a design solution for paracervical block			
			Activities in the field	*Stakeholders engaged*	*Stakeholder role*	*Barriers encountered during activities*
Essential	**Shaper of collaboration**	Building partnerships and collaborative working relationships across multiple disciplines to address healthcare challenges while minimizing environmental impact.	Networking, identifying, recruiting, developing and sharing consent and Institutional Review Board approval, and building a local community of professional healthcare teams to collaboratively investigate and address the lack of paracervical blocks, while working toward an environmentally sustainable solution.	Healthcare professionals, including hospital management, gynecologists, nurses, clinical officers, and auxiliary staff responsible for cleaning, reprocessing, and device, maintenance.	Accepting and consenting to collaboration, provide expert knowledge on gynecological care, and granting access to hospital procedures such as device use and reprocessing and hospital management to support design-led interventions for administering paracervical blocks.	Engaging hospitals in collaboration is a continuous process, requiring sustained effort until stakeholder buy-in is achieved. In my case, it took twelve months to onboard two out of six hospitals successfully.
			Establishing trust with healthcare professionals through active listening, regular visits, roundtable open discussions, collaborative brainstorming, and understanding their perspectives on the healthcare issue, while steering toward environmentally conscious solutions.			Access to hospital premises was only granted after trust was established, and it was confirmed that this research aligned with the goal of providing a solution for administering paracervical blocks.
						Several months of discussions on collaboration were cut short when the hospital team did not deem it necessary to provide pain medication during gynecological procedures. Other reasons for the lack of collaboration included limited staff capacity, with staff unable to engage in activities beyond their ongoing clinical responsibilities.
			Connecting the healthcare sector with other key actors, such as manufacturers, recyclers, and regulatory bodies, to integrate insights and develop more sustainable solutions.	Healthcare professionals including, hospital management, gynecologists, nurses, clinical officers, auxiliary staff responsible for cleaning, reprocessing, and device, maintenance.	Providing insights to support the development of a more environmentally sustainable medical device.	Responsibility for ensuring sterility before or during recovery and recycling remains unclear — whether it lies with the healthcare facility or the recycler.
				Regulatory bodies, including KEBS and PPB.		
				Manufacturers and distributors, and recyclers.		
	Design-facilitator	Leading the design process by integrating expertise from technology, medicine, clinical and health facility operations, and environmental impacts.	Simplifying and establishing a common understanding of the concept of design with healthcare professionals and building their confidence to actively pursue the design of sustainable medical solutions, such as Chloe SED, to provide paracervical blocks.	Healthcare professionals including, Zhospital management, gynecologists, nurses, clinical officers, auxiliary staff responsible for cleaning, reprocessing, and device, maintenance.	Voicing concerns about the lack of paracervical blocks based on their medical expertise and knowledge of the associated environmental issues and potential future solutions. Contributing to the development of a solution suitable for administering paracervical blocks.	I embraced my inexperience in guiding medical experts, such as gynecologists, to design a medical device for administering paracervical blocks despite my lack of expertise in medical device design and gynecology. Nevertheless, I forged ahead, gaining knowledge and experience as I facilitated the design process.
			Conducting and reporting clinical trials.	Hospital Institutional Review Board, including the National Commission for Science, Technology and Innovation and Pan African Clinical Trial Registry.	Providing registration, licensing, and clearance for research and design activities to be conducted in the hospital premises.	The application and execution of clinical trials are restricted to licensed medical practitioners operating under stringent regulatory conditions. This exceeds the designer's expertise, necessitating strict reliance on hospital medical practitioners who work within the framework of these rigorous regulatory requirements.
				Regulatory bodies, including KEBS and PPB.	Providing approval for the trial, evaluating, and reporting the trial outcomes.	

Table 1 ***(continued)***

Roles		Designer competencies and specialized knowledge needed	Summarized designer activities and contexts in the field as per research on a design solution for paracervical block			
			Activities in the field	*Stakeholders engaged*	*Stakeholder role*	*Barriers encountered during activities*
Essential	**Knowledge broker**	Facilitating knowledge exchange, translation, and meditating potential tensions when integrating healthcare practices with circular economy principles, product sustainability, and environmental considerations.	Facilitating knowledge exchange on environmental sustainability through the concept of the circular economy and its application in the healthcare sector, specifically in relation to paracervical blocks.	Healthcare professionals including, hospital management, gynecologists, nurses, clinical officers, auxiliary staff responsible for cleaning, reprocessing. Regulatory bodies, including KEBS and PPB.	Applying learning of the concept of circular economy principles into the design and utilization of a medical device to support the provision of paracervical blocks with minimal environmental impact.	Pushback from the healthcare stakeholders arose when moving from the familiar use and throw-away disposable culture to a reusable model, which could lead to higher initial costs and the need for reprocessing. This resistance was resolved when the final design ensured that both device cost and processing procedures remained comparable to existing costs and processes.
Expanded role in societal incorporation	**Policy advocate**	Advocating for and actively supporting the establishment of new standards or regulations that support medical device design, manufacturing, use, and reuse within limited environmental impact.	Analyzing the design and manufacturing parameters of Chloe SED in compliance with Kenyan and ISO standards, with the primary goal of establishing a benchmark for evaluating similar medical devices designed and produced for use in healthcare facilities with minimal environmental impact. Advocating for and demonstrating the use of 3D printing materials that conform to medical standards are durable, reusable, and can be recovered and recycled to their original material form, thereby operating in a circular economy.	Regulatory stakeholders including KEBS and PPB.	Analyzing and establish standards for evaluating the design and manufacturing of Chloe SED and other medical devices to ensure they operate with limited environmental impact.	The absence of manufacturing standards for 3D-printed medical devices necessitated advocating for standards with the local regulatory body over an additional thirty-five months. Without these standards, the device could not proceed to clinical trials. However, once the standard was established, the approval of Chloe SED for a large-scale trial required only two months to validate the manufacturing process.
	Designer-entrepreneur	Combining design and entrepreneurial activities to implement sustainable, design-led interventions in the healthcare sector.	Engaging in initiatives such as grants and start-up and venture-building competitions to secure funding for implementing the circular economy-driven design solution Chloe SED in a low-resource healthcare setting. Entering legal and non-legal agreements with implementation partners to ensure implementation of Chloe SED.	Funding agencies, grantors, investors. Manufacturers and distributors.	Providing financial resources, opportunities, connections, and access to avenues for implementing Chloe SED with minimal environmental impact.	Adequate financing for clinical trials is crucial, serving as a pivotal milestone for advancing a product through clinical validation and its incorporation into routine care. Without sufficient financial resources, conducting and completing a trial becomes challenging, often leading to delays or even causing a standstill. It was necessary to set up an organizational body, Chloe Innovation LLC, to facilitate legal and non-legal agreements, thereby enabling progress toward implementation.

The roles of shaper of collaboration, design facilitator, and knowledge broker are intrinsic to the field of design and were crucial in the design and validation of Chloe SED. These interdisciplinary roles, which are inherent to the design domain—as also seen in the work of Wiek et al.[44] and Sumter et al.[45]—presented a steep learning curve when applied to sustainable healthcare and a bottom-up approach, as explored in this research. For instance, achieving

44 Wiek et al., "Key Competencies in Sustainability."

45 Sumter et al., "Circular Economy Competencies for Design."

environmental sustainability in the design process of the Chloe SED required alignment with the healthcare system and operational processes.

The healthcare system traditionally depends on stringent procedures to ensure patient safety, which has led to the increased use of disposable medical devices. However, the pressing need to shift toward more sustainable healthcare practices—while ensuring accessibility, affordability, and patient safety—led to seemingly irreconcilable demands. Shaping collaboration, facilitating design, and sharing knowledge based on these demands sometimes elicited concerns and stakeholder pushback. Resistance arose due to increased workload required for cleaning and sterilizing reusable devices, the potential rise in hospital operating costs associated with device reuse, and ambiguity regarding responsibility for device sterility before disposal or recycling. Achieving a desired, workable, and accepted solution required continuous stakeholder engagement—a process full of uncertainty. While bottom-up change can be instigated, it is important to recognize that such change depends on sustained stakeholder engagement, often over a long period (see Figure 2).

In addition to roles such as shaper of collaboration, design facilitator, and knowledge broker, this study also required me to adopt the roles of a policy advocate and designer-entrepreneur. As a policy advocate, my focus was on supporting the establishment of new standards to facilitate the manufacturing and sustainable use and reuse of Chloe SED in routine care. This aligns with the need to expand regulatory capacity for the development and adoption of new medical devices in sub-Saharan Africa.[46] Similarly, as a designer-entrepreneur, my role ensured that the necessary activities and resources were in place to enable Chloe SED to reach healthcare professionals. Both roles were centered on ensuring Chloe SED successfully transitioned into societal use.

While the roles of policy advocate and designer-entrepreneur were pivotal, they significantly expanded my responsibilities beyond core design. For instance, I had to familiarize myself with legal language in policy regulations and manufacturing contracts and translate these into technical terms for designing Chloe SED. Similarly, understanding how regulatory standards are organized was essential for successfully advocating for changes to those standards. In the realm of entrepreneurship, I had to communicate the value of Chloe SED in non-technical terms to attract funding. This diverted my focus from core design activities, yet their absence would have made it impossible to integrate Chloe SED into routine care. As illustrated in Table 1, all five project roles required engagement with legal, regulatory, and entrepreneurial stakeholders.

The roles of policy advocacy and designer-entrepreneur are pivotal not only in new product development but also in integrating innovations into society. Scholarly literature highlights a significant decline in innovation activities during periods of policy uncertainty.[47] In the context of sub-Saharan Africa, research literature indicates that harmonizing regulatory standards across African countries can be facilitated when medical device companies or developers take a leading role.[48] This implies that designers can actively advocate for policies that support innovation benefitting society, especially in areas where no policies are available. Beyond policy advocacy, entrepreneurial activities are essential for understanding societal challenges and opportunities. This aligns with the idea that design, engineering, and

46 Hubner et al., "Evolving Landscape of Medical Device Regulation."

47 Utpal Bhattacharya et al., "What Affects Innovation More: Policy or Policy Uncertainty?," *Journal of Financial and Quantitative Analysis* 52, no. 5 (2017): 1869–1901, https://doi.org/10.1017/S0022109017000540.

48 Hubner et al., "Evolving Landscape of Medical Device Regulation."

entrepreneurship are crucial for product advancement[49] — an approach that is particularly relevant in developing regions, where access to basic necessities remain limited.

The expanded roles identified highlight the designer's varied roles and responsibilities in addressing critical medical device gaps and driving environmental sustainability, particularly in low-resource settings in sub-Saharan Africa. The expanded roles emerging from this study align with the pathway of role expansion occur, where a broader set of responsibilities is integrated into a defined role.[50] However, is it necessary for a single designer to adopt all these roles? Developing local capacity and infrastructure to enable teams to fulfill these roles may offer better support for the design and implementation of medical devices in low-resource settings. A pertinent question remains: How can designers' competencies be developed to take on these expanded roles and competencies in crafting and executing environmentally conscious design-led innovation that ensures access to healthcare for all? This is a key consideration within current design pedagogy.

The current design curriculum should include a course on environmental assessment, focused on building competencies to evaluate the environmental and human impacts of materials and medical devices, while also developing effective mitigation strategies. Additionally, higher education could incorporate elements of product regulations, equipping designers — particularly those aspiring to launch their own ventures — with the knowledge to design products that account for environmental, regulatory, and business implications necessary for successful integration into society.

Achieving my project goal required taking on new tasks and unfamiliar roles. This often necessitated on-the-job learning to bridge the gap between theory and practice in designing and integrating Chloe SED with environmental considerations. I did not always transition neatly between roles; at times, I was thrust into them unexpectedly. Other times, I was unaware of my role until I was already in it — feeling as though I was everything and nothing within a vast, unfair system. The changing nature of these roles, as demonstrated in this research, is important when understanding how to develop designers' competencies for taking on expanded roles.

Although this study provides a conclusive answer to which capabilities must be developed to successfully take on these extended roles and competencies, it also emphasizes the importance of further investigation into this topic. This question is particularly crucial for global design education, especially in sub-Saharan Africa, where the integration of design into higher education presents an opportunity to prioritize sustainable healthcare design.

Study Limitation

This research is based on findings from a longitudinal design case study, conducted through action research over the past eight years. While the findings from action research are generally not broadly applicable, the insights gained remain pertinent, demonstrating the expanded role of designers in developing and integrating medical devices with environmental sustainability considerations in low-resource sub-Saharan Africa.

49 Ronald J. Odora, "Integrating Product Design and Entrepreneurship Education: A Stimulant for Enterprising Design and Engineering Students in South Africa," *Procedia Technology* 20 (2015): 276–83, https://doi.org/10.1016/j.protcy.2015.07.044.

50 Elizabeth Wolfe Morrison, "Role Definitions and Organizational Citizenship Behavior: The Importance of the Employee's Perspective," *Academy of Management Journal* 37, no. 6 (1994): 1543–67, https://www.jstor.org/stable/256798; Parker et al., "That's Not My Job."

Conclusion

In conclusion, this study focused on the design and implementation of the Chloe SED medical device to address healthcare accessibility gaps and environmental sustainability. Over an eight-year period, the project highlighted essential and intrinsic designer roles — shaper of collaboration, design facilitator, and knowledge broker — which were crucial for device design and validation. Within these roles, integrating environmentally sustainable elements into design process to advance sustainability in healthcare proved complex, often encountering resistance due to established norms and operational concerns. Ongoing stakeholder engagement was essential to secure buy-in for an environmentally sustainable device, while also recognizing the non-linear, bottom-up change process involving regulators and industry. Consequently, the designer — as a policy advocate and designer-entrepreneur — plays a crucial role in ensuring the transition of the device into societal use.

Collectively, these roles underscore the importance of considering products, processes, diverse expertise, and organizational and regulatory aspects of healthcare in medical device design. Medical device designers striving to environmentally sustainable design in low-resource settings must understand these expanded roles, though building the necessary capabilities remains a challenge. Future research should focus on how designers' capabilities can be developed to take on these expanded roles and develop the required competencies. Similarly, it should explore how these roles can be developed within formal higher education, integrating learning-on-the-job activities. Nurturing these capabilities is key for shaping future designers who can effectively address the design and implementation of medical devices for low-resource healthcare settings in sub-Saharan Africa, while prioritizing environmental sustainability.

Declaration of Generative AI and AI-assisted Technologies in the Writing Process

While preparing this work, the author used ChatGPT and Grammarly to edit self-written text for clarity and brevity. After using these services, the author reviewed and edited the content as needed and takes full responsibility for the publication's content.

Declaration of Interest

There are no conflicts of interest involved in this article.

References

Aksoy, Huseyin, Ulku Aksoy, Sezin Ozyurt, Nil Ozoglu, Gokhan Acmaz, Turgut Aydın, Özge İdem Karadağ, and Ahter Tanay Tayyar. "Comparison of Lidocaine Spray and Paracervical Block Application for Pain Relief during First-Trimester Surgical Abortion: A Randomised, Double-Blind, Placebo-Controlled Trial." *Journal of Obstetrics and Gynaecology* 36, no. 5 (2016): 649–53. https://doi.org/10.3109/01443615.2016.1148681.

Al Jundi, Azzam, and Salah Sakka. "Protocol Writing in Clinical Research." *Journal of Clinical and Diagnostic Research* 10, no. 11 (2016): ZE10–13. https://doi.org/10.7860/JCDR/2016/21426.8865.

Alemayehu, Chalachew, Geoffrey Mitchell, and Jane Nikles. "Barriers for Conducting Clinical Trials in Developing Countries—A Systematic Review." *International Journal for Equity in Health* 17 (2018): article no. 37. https://doi.org/10.1186/s12939-018-0748-6.

Anyangwe, Stella C. E., and Chipayeni Mtonga. "Inequities in the Global Health Workforce: The Greatest Impediment to Health in Sub-Saharan Africa." *International Journal of Environmental Research and Public Health* 4, no. 2 (2007): 93–100. https://doi.org/10.3390/ijerph2007040002.

Aranda-Jan, Clara Beatriz, Santosh Jagtap, and James Moultrie. "Towards a Framework for Holistic Contextual Design for Low-Resource Settings." *International Journal of Design* 10, no. 3 (2016): 43–63. https://www.ijdesign.org/index.php/IJDesign/article/view/2596/751.

Bakker, Conny, Ruud Balkenende, and Flora Poppelaars. "Design for Product Integrity in a Circular Economy." In *Designing for the Circular Economy*, edited by Martin Charter, 148–56. Abingdon, OX: Routledge, 2018.

Bhattacharya, Utpal, Po-Hsuan Hsu, Xuan Tian, and Yan Xu. "What Affects Innovation More: Policy or Policy Uncertainty?" *Journal of Financial and Quantitative Analysis* 52, no. 5 (2017): 1869–1901. https://doi.org/10.1017/S0022109017000540.

Boyle, James. "A Manifesto on WIPO and the Future of Intellectual Property." *Duke Law & Technology Review* 3, no. 1 (2004): 1–13. https://scholarship.law.duke.edu/dltr/vol3/iss1/6.

Chakravarty, Sanghamitra. "Resource Constrained Innovation in a Technology Intensive Sector: Frugal Medical Devices from Manufacturing Firms in South Africa." *Technovation* 112 (April 2022): article no. 102397. https://doi.org/10.1016/j.technovation.2021.102397.

Chudnoff, Scott, Mark Einstein, and Mark Levie. "Paracervical Block Efficacy in Office Hysteroscopic Sterilization: A Randomized Controlled Trial." *Obstetrics & Gynecology* 115, no. 1 (2010): 26–34. https://doi.org/10.1097/AOG.0b013e3181c51ace.

Dias, Suzana, and Ana Baptista. "Rethinking the Role of the Contemporary Designer: Is There a Mismatch between Theory and Practice in Design Education?" In *Perspective on Design: Research, Education and Practice*, edited by Daniel Raposo, João Neves, and José Silva, 17–26. Vol. 1 of *Springer Series in Design and Innovation*. Cham: Springer, 2020. https://doi.org/10.1007/978-3-030-32415-5_2.

Doctor, Henry V., Sangwani Nkhana-Salimu, and Maryam Abdulsalam-Anibilowo. "Health Facility Delivery in Sub-Saharan Africa: Successes, Challenges, and Implications for the 2030 Development Agenda." *BMC Public Health* 18, no. 1 (2018): article no. 765. https://doi.org/10.1186/s12889-018-5695-z.

Eldridge, Sandra M., Gillian A. Lancaster, Michael J. Campbell, Lehana Thabane, Sally Hopewell, Claire L. Coleman, and Christine M. Bond. "Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework." *PLOS ONE* 11, no. 3 (2016): e0150205. https://doi.org/10.1371/journal.pone.0150205.

Gardien, Paul, Tom Djajadiningrat, Caroline Hummels, and Aarnout Brombacher. "Changing Your Hammer: The Implications of Paradigmatic Innovation for Design Practice." *International Journal of Design* 8, no. 2 (2014): 119–39. https://www.ijdesign.org/index.php/IJDesign/article/view/1315/635.

Griffin, Mark A., Andrew Neal, and Sharon K. Parker. "A New Model of Work Role Performance: Positive Behavior in Uncertain and Interdependent Contexts." *Academy of Management Journal* 50, no. 2 (2007): 327–47. https://doi.org/10.5465/AMJ.2007.24634438.

Hubner, Sarah, Caroline Maloney, Sarah Dunn Phillips, Pratik Doshi, Julius Mugaga, Robert Tamale Ssekitoleko, Jenna L. Mueller, and Tamara N. Fitzgerald. "The

Evolving Landscape of Medical Device Regulation in East, Central, and Southern Africa." *Global Health: Science and Practice* 9, no. 1 (2021): 136–48. https://doi.org/10.9745/GHSP-D-20-00578.

Ilgen, Daniel R., and J. R. Hollenbeck. "The Structure of Work: Job Design and Roles." In *Handbook of Industrial and Organizational Psychology*, 2nd ed., edited by M. D. Dunnette and L. M. Hough, 165–207. Palo Alto, CA: Consulting Psychologists Press, 1991.

Jagtap, Santosh. "Design and Engineering for Low Resource Settings: An Integrated Methodology." In *Design and Engineering for Low Resource Settings: A Practical Guide*, edited by Santosh Jagtap, 1–12. Cham: Springer, 2024. https://doi.org/10.1007/978-3-031-66156-3_1.

Mager, Birgit, Marco Susani, Elena Pacenti, Erico Fileno, and Michael W. Meyer. "Product-Service Systems Design Education: Normalize, Grow, and Evolve." *She Ji: The Journal of Design, Economics, and Innovation* 9, no. 2 (2023): 213–33. https://doi.org/10.1016/j.sheji.2023.06.004.

Morgeson, Frederick P., Kelly Delaney-Klinger, and Monica A. Hemingway. "The Importance of Job Autonomy, Cognitive Ability, and Job-Related Skill for Predicting Role Breadth and Job Performance." *Journal of Applied Psychology* 90, no. 2 (2005): 399–406. https://doi.org/10.1037/0021-9010.90.2.399.

Morrison, Elizabeth Wolfe. "Role Definitions and Organizational Citizenship Behavior: The Importance of the Employee's Perspective." *Academy of Management Journal* 37, no. 6 (1994): 1543–67. https://www.jstor.org/stable/256798.

Moyi, Eliud Dismas. "Role of Various Institutions in Providing Technology Support Services to MSEs in Kenya." *Public Policy and Administration Research* 4, no. 9 (2014): 169–77. https://iiste.org/Journals/index.php/PPAR/article/view/15686.

Nakandi, Brenda T., Owen Muhimbise, Ashley Djuhadi, Martha Mulerwa, Janet McGrath, Philippa Ngaju Makobore, Andrew M. Rollins, and Robert T. Ssekitoleko. "Experiences of Medical Device Innovators as They Navigate the Regulatory System in Uganda." *Frontiers in Medical Technology* 5 (April 2023): article no. 1162174. https://doi.org/10.3389/fmedt.2023.1162174.

Odora, Ronald J. "Integrating Product Design and Entrepreneurship Education: A Stimulant for Enterprising Design and Engineering Students in South Africa." *Procedia Technology* 20 (2015): 276–83. https://doi.org/10.1016/j.protcy.2015.07.044.

Parker, Sharon K., Toby D. Wall, and Paul R. Jackson. "'That's Not My Job': Developing Flexible Employee Work Orientations." *Academy of Management Journal* 40, no. 4 (1997): 899–929. https://www.jstor.org/stable/256952.

Perry, Lora, and Robert Malkin. "Effectiveness of Medical Equipment Donations to Improve Health Systems: How Much Medical Equipment Is Broken in the Developing World?" *Medical & Biological Engineering & Computing* 49, no. 7 (2011): 719–22. https://doi.org/10.1007/s11517-011-0786-3.

Pharmacy and Poisons Board. "Guidelines for Registration of Medical Devices Including In-Vitro Diagnostics." Last modified January 2022. https://web.pharmacyboardkenya.org/download/guidelines-for-registration-of-medical-devices-including-in-vitro-diagnostics/.

Piaggio, Davide, Rossana Castaldo, Marco Cinelli, Sara Cinelli, Alessia Maccaro, and Leandro Pecchia. "A Framework for Designing Medical Devices Resilient to Low-Resource Settings." *Globalization and Health* 17 (June 2021): article no. 64. https://doi.org/10.1186/s12992-021-00718-z.

Price, Rebecca, Cara Wrigley, and Judy Matthews. "Action Researcher to Design Innovation Catalyst: Building Design Capability from Within." *Action Research* 19, no. 2 (2021): 318–37. https://doi.org/10.1177/1476750318781221.

Ramanathan, Aparna, Karlheinz Samenjo, Robert Bailey, Javan Imbamba, Stella Odenyo, Erin Koksal, Jan Carel Diehl, Jackton Omoto, and Stephen Gwer. "Validation of a Novel Medical Device (Chloe SED ®) for Administration of Analgesia during Manual Vacuum Aspiration: A Randomized Controlled Non-Inferiority Pilot Study."

Frontiers in Pain Research 5 (2024): article no. 1326772. https://doi.org/10.3389/fpain.2024.1326772.

Reason, Peter. "Choice and Quality in Action Research Practice." *Journal of Management Inquiry* 15, no. 2 (2006): 187–203. https://doi.org/10.1177/1056492606288074.

Rodriguez, Natalia M., Grace Burleson, Jacqueline C. Linnes, and Kathleen H. Sienko. "Thinking Beyond the Device: An Overview of Human- and Equity-Centered Approaches for Health Technology Design." *Annual Review of Biomedical Engineering* 25 (June 2023): 257–80. https://doi.org/10.1146/annurev-bioeng-081922-024834.

Samenjo, Karlheinz Tondo, Aparna Ramanathan, Stephen Otieno Gwer, Robert C. Bailey, Fredrick Odhiambo Otieno, Erin Koksal, Benjamin Sprecher, Rebecca Anne Price, Conny Bakker, and Jan Carel Diehl. "Design of a Syringe Extension Device (Chloe SED®) for Low-Resource Settings in Sub-Saharan Africa: A Circular Economy Approach." *Frontiers in Medical Technology* 5 (2023): 1–18. https://doi.org/10.3389/fmedt.2023.1183179.

Siu, Kin Wai Michael, and Jia Xin Xiao. "Public Facility Design for Sustainability: Participatory Action Research on Household Recycling in Hong Kong." *Action Research* 18, no. 4 (2020): 448–68. https://doi.org/10.1177/1476750317698027.

Ssekitoleko, Robert Tamale, Beryl Ngabirano Arinda, Solomon Oshabahebwa, Lucy Kevin Namuli, Julius Mugaga, Catherine Namayega, Emmanuel Einyat Opolot et al. "The Status of Medical Devices and Their Utilization in 9 Tertiary Hospitals and 5 Research Institutions in Uganda." *Global Clinical Engineering Journal* 4, no. 3 (2022): 15–25. https://doi.org/10.31354/globalce.v4i3.127.

Sumter, Deborah, Jotte de Koning, Conny Bakker, and Ruud Balkenende. "Circular Economy Competencies for Design." *Sustainability* 12, no. 4 (2020): article no. 1561. https://doi.org/10.3390/su12041561.

Van de Ven, Andrew H. *Engaged Scholarship: A Guide for Organizational and Social Research*. Oxford: Oxford University Press, 2007.

Weil, Denis, and Matt Mayfield. "Tomorrow's Critical Design Competencies: Building a Course System for 21st Century Designers." *She Ji: The Journal of Design, Economics, and Innovation* 6, no. 2 (2020): 157–69. https://doi.org/10.1016/j.sheji.2020.03.001.

Wiek, Arnim, Lauren Withycombe, and Charles L. Redman. "Key Competencies in Sustainability: A Reference Framework for Academic Program Development." *Sustainability Science* 6, no. 2 (2011): 203–18. https://doi.org/10.1007/s11625-011-0132-6.

World Health Organization. *Medical Devices and eHealth Solutions: Compendium of Innovative Health Technologies for Low-Resource Settings 2011–2012*. Geneva: World Health Organization, 2013. https://www.who.int/publications/i/item/9789241505918.

World Health Organization. *Abortion Care Guideline*. Geneva: World Health Organization, 2022. https://www.who.int/publications/i/item/9789240039483.