Circular Medical Device Design for Low Resource Settings in sub-Saharan Africa

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Circular Medical Device Design for Low Resource Settings in sub-Saharan Africa

Circular Medical Device Design for Low Resource Settings in sub-Saharan Africa

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by

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Summary

The circular economy is increasingly acknowledged worldwide, including in healthcare. It focuses on extending the lifespan and value of products and materials by ensuring their continuous use within the system. This approach is crucial as it shifts away from the prevalent "take-use-dispose" linear model. Given the rapid growth and mounting pressures on healthcare systems, adopting a circular economy is essential to improving sustainability and ensuring broader access to healthcare.

In healthcare, particularly in low-resource settings in Sub-Saharan Africa, circular economy principles can improve access to medical devices and overall healthcare. As the global awareness of health as a fundamental human right grows, there is an increasing push towards universal health access. However, this access is heavily dependent on the availability of medical equipment and qualified medical staff. Unfortunately, medical devices and healthcare technologies are often inaccessible in low-resource settings. Not only does this undermine healthcare delivery, but it sometimes also results in environmental issues, such as the improper disposal of non-functional devices and medical waste, which leads to the loss of valuable materials.

Recent trends in medical device design are shifting from a linear model towards a circular economy approach. This shift aims to ensure that devices are robust, durable, reusable and have an extended lifespan to provide healthcare for all. However, the full implications and complexities of integrating circular economy principles into medical device design in low-resource contexts, is poorly understood. This thesis addresses these through a series of studies focused on designing and implementing medical devices in low-resource settings while incorporating circular economy principles.

The first study is a foundational study which provides a literature review of how circular economy principles have been applied in designing medical devices for low-resource settings in Sub-Saharan Africa. The study highlights existing practices such as durability, maintenance, and repair that enhance the longevity of medical devices. However, it also identifies a notable gap in the consideration of refurbishment, remanufacturing, and recycling in these designs. Building on this, the second study utilises a practical framework to design a medical device from a circular economy perspective, examining the complexities and trade-offs involved. It introduces the Chloe Syringe Extension Device (Chloe SED®), designed to provide pain relief medication during gynaecological procedures in Kenya. The study identifies trade-offs between, on the one hand, material selection, cost price, durability, reprocessing methods and costs, and on the other hand environmental impact, highlighting the need for ongoing assessment to ensure the device remains accessible, affordable, and environmentally sustainable.

The third study assesses the implementation of Chloe SED® in routine care through a large-scale clinical trial. The findings show that the device performs comparably to standard

care, integrates well into existing procedures, and has potential to enhance healthcare access. This study highlights the importance of aligning medical device design with local healthcare systems to ensure effective integration and impact. The fourth study explores the designer's journey in creating and implementing Chloe SED®. This study highlights the diverse roles a designer must assume: collaborator, facilitator, knowledge broker, policy advocate, and entrepreneur, while recognising the need to shift between these roles. The study underscores the iterative nature of the design process and the necessity for ongoing stakeholder engagement to achieve successful adoption and integration of new devices into healthcare systems.

This thesis provides an in-depth analysis of designing and implementing medical devices for low-resource settings in Sub-Saharan Africa, focusing on circular economy principles. It highlights the significance of context-specific design, the challenges of integrating new devices into routine care, and the essential roles of designers in fostering innovation and driving societal change.

Samenvatting

De circulaire economie wordt wereldwijd steeds meer erkend, ook in de gezondheidszorg. Deze richt zich op het verlengen van de levensduur en de waarde van producten en materialen door ervoor te zorgen dat ze binnen het systeem gebruikt blijven worden. Deze benadering is van cruciaal belang omdat het een verschuiving is weg van het lineaire model van "nemen, gebruiken en weggooien". Gezien de snelle groei en toenemende druk op de gezondheidszorg, is het aannemen van een circulaire economie essentieel voor het verbeteren van duurzaamheid en het garanderen van bredere toegang tot gezondheidszorg.

In de gezondheidszorg, met name in omgevingen met weinig middelen (Low Resource Settings) zoals Sub-Sahara Afrika, kunnen de principes van de circulaire economie de toegang tot medische hulpmiddelen en de algehele gezondheidszorg verbeteren. Nu wereldwijd het besef groeit dat gezondheid een fundamenteel mensenrecht is, wordt er steeds meer gestreefd naar de universele toegankelijkheid van de gezondheidszorg. Deze toegang is echter sterk afhankelijk van de beschikbaarheid van medische apparatuur en gekwalificeerd medisch personeel. Helaas zijn medische apparatuur en gezondheidszorgtechnologieën vaak ontoegankelijk in omgevingen met weinig middelen. Dit ondermijnt niet alleen de zorgverlening, maar leidt ook tot milieuproblemen, zoals het verkeerd weggooien van niet-functionele apparaten en medisch afval, waardoor waardevolle materialen verloren gaan.

In recente trends van het ontwerpen van medische hulpmiddelen is er een verschuiving van een aanpak met lineair model naar een circulaire economie. Deze verandering moet ervoor zorgen dat hulpmiddelen robuust, duurzaam en herbruikbaar zijn en een langere levensduur hebben, zodat iedereen van gezondheidszorg gebruik kan maken. Er is echter nog weinig inzicht in de volledige implicaties en complexiteit van het integreren van de principes van de circulaire economie in het ontwerp van medische hulpmiddelen in contexten met weinig middelen. Deze dissertatie richt zich hierop door middel van een reeks onderzoeken gericht op het ontwerpen en implementeren van medische hulpmiddelen in omgevingen met weinig middelen, waarbij de principes van de circulaire economie worden geïntegreerd.

De eerste studie is een fundamenteel onderzoek dat een literatuuroverzicht geeft van de manier waarop de principes van de circulaire economie zijn toegepast bij het ontwerpen van medische hulpmiddelen voor omgevingen met weinig hulpmiddelen in Sub-Sahara Afrika. Dit onderzoek belicht bestaande praktijken zoals duurzaamheid, onderhoud en reparatie die de levensduur van medische hulpmiddelen verlengen. Echter, werd er ook vastgesteld dat er nog te weinig aandacht is voor overwegen van renovatie, revisie en recycling in deze ontwerpen. Hierop voortbouwend, gebruikt de tweede studie een praktisch framework om een medisch hulpmiddel te ontwerpen vanuit het perspectief van de circulaire economie, waarbij de complicaties en afwegingen die hier een rol in

spelen werden onderzocht. Deze studie introduceert het Chloe Syringe Extension Device (Chloe SED®), ontworpen om pijnstillende medicatie toe te dienen tijdens gynaecologische ingrepen in Kenia. Het onderzoek identificeert afwegingen tussen enerzijds materiaal keuze, kostprijs, duurzaamheid, methoden voor herverwerking en kosten hiervan, en anderzijds de impact op het milieu, waarbij de noodzaak van continue evaluatie wordt benadrukt om ervoor te zorgen dat het hulpmiddel toegankelijk, betaalbaar en ecologisch duurzaam blijft.

Het derde onderzoek beoordeelt de implementatie van Chloe SED® in de routinezorg door middel van een grootschalig klinisch onderzoek. De bevindingen tonen aan dat het apparaat vergelijkbaar presteert met standaardzorg, goed integreert in bestaande procedures en het potentieel heeft om de toegang tot gezondheidszorg te verbeteren. Deze studie benadrukt het belang van het afstemmen van het ontwerp van medische hulpmiddelen op lokale gezondheidszorgsystemen om effectieve integratie en impact te garanderen. De vierde studie onderzoekt de reis van de ontwerper bij het creëren en implementeren van Chloe SED®. Het benadrukt de verschillende rollen die een ontwerper moet spelen, zoals medewerker, facilitator, kennismakelaar, beleidsverdediger en ondernemer. Het onderzoek onderstreept de iteratieve aard van het ontwerpproces en de noodzaak van voortdurende betrokkenheid van belanghebbenden om succesvolle adoptie en integratie van nieuwe apparaten in gezondheidszorgsystemen te bereiken.

Het derde onderzoek beoordeelt de implementatie van Chloe SED® in de gebruikelijke zorg door middel van een grootschalig klinisch onderzoek. De bevindingen tonen aan dat het apparaat vergelijkbaar presteert met standaardzorg, goed integreert in bestaande procedures en het potentieel heeft om de toegang tot gezondheidszorg te verbeteren. Deze studie benadrukt het belang van het afstemmen van het ontwerp van medische hulpmiddelen op lokale gezondheidszorgsystemen om effectieve integratie en impact te garanderen. De vierde studie onderzoekt de reis van de ontwerper bij het creëren en implementeren van Chloe SED®®. Deze studie benadrukt de verschillende rollen die een ontwerper moet aannemen - collaborateur, facilitator, kennismakelaar, beleidsverdediger en ondernemer - en erkent tegelijkertijd de noodzaak om tussen deze rollen te schakelen. Het onderzoek benadrukt de iteratieve aard van het ontwerpproces en de noodzaak van voortdurende betrokkenheid van stakeholders om succesvolle adoptie en integratie van nieuwe apparaten in gezondheidszorgsystemen te bewerkstelligen.

Deze dissertatie biedt een diepgaande analyse van het ontwerpen en implementeren van medische hulpmiddelen voor landen met weinig middelen in Sub-Sahara Afrika, waarbij de nadruk ligt op de principes van de circulaire economie. Het benadrukt het belang van context specifiek ontwerp, de uitdagingen van het integreren van nieuwe hulpmiddelen in de routinematige zorg en de essentiële rol van ontwerpers bij het bevorderen van innovatie en het stimuleren van maatschappelijke verandering.

1

Introduction

1

Access to health is a fundamental right, deserved by all regardless of location or socioeconomic status, as outlined in Sustainable Development Goal 3. Low-resource settings (areas with limited infrastructure, materials, supplies, and human resources) in Sub-Saharan Africa [1, 2] still lag in areas of healthcare coverage. Healthcare provision is largely influenced by the available and functioning medical devices, in addition to other factors such as cost of healthcare, available trained medical staff, and institutional infrastructure.

1.1 Medical Device status and life cycle

The Sub-Saharan Africa's healthcare system relies heavily on donated or imported medical devices from high-income countries due to its nascent medical device design and manufacturing industry. Donations and imports make up 80% of medical devices in this region's healthcare facilities [3, 4]. These devices are often not designed or optimized for low-resource healthcare settings [5–8]. Conditions in these settings differ from those the equipment was originally designed for, and this leads to challenges where devices operate ineffectively [1].

According to the World Health Organization (WHO), 70% of medical equipment from high-income countries frequently fails in low-resource hospitals due to factors like insufficiently trained personnel, infrastructure limitations, and inadequate spare parts or support [3, 6, 9]. In addition, most donated devices are already obsolete or poorly functioning upon arrival in low-resource hospitals [3, 9–12]. These obsolete donated devices need to be serviced before being used, or repaired when broken down. In case this is not possible, the devices are usually directly disposed of as waste in medical device graveyards [13], leading to severe social and environmental challenges. Figure 1.1 illustrates the life cycle of medical devices, showing how donations or imports from high-income countries reach low-resource settings in Africa, where some are discarded, others are used, repaired if possible, and those beyond repair are disposed of. Figure 1.2 shows an image collage of a medical device graveyard (photos by author) in a low-resource hospital in sub-Saharan Africa, where obsolete devices are stored in boxes or left to rot, and sometimes spare parts may be salvaged for other devices.

When medical devices malfunction or become obsolete, it hampers healthcare delivery to those in need, depriving them of their fundamental right to good health and well-being. Improper disposal of non-functional or obsolete medical devices exacerbates environmental concerns, adding to the existing burden of medical waste. Inadequate waste management also results in valuable materials from devices being lost in waste streams. Failure to address these social and environmental issues is anticipated to worsen with population growth and rising healthcare demands [14, 15].

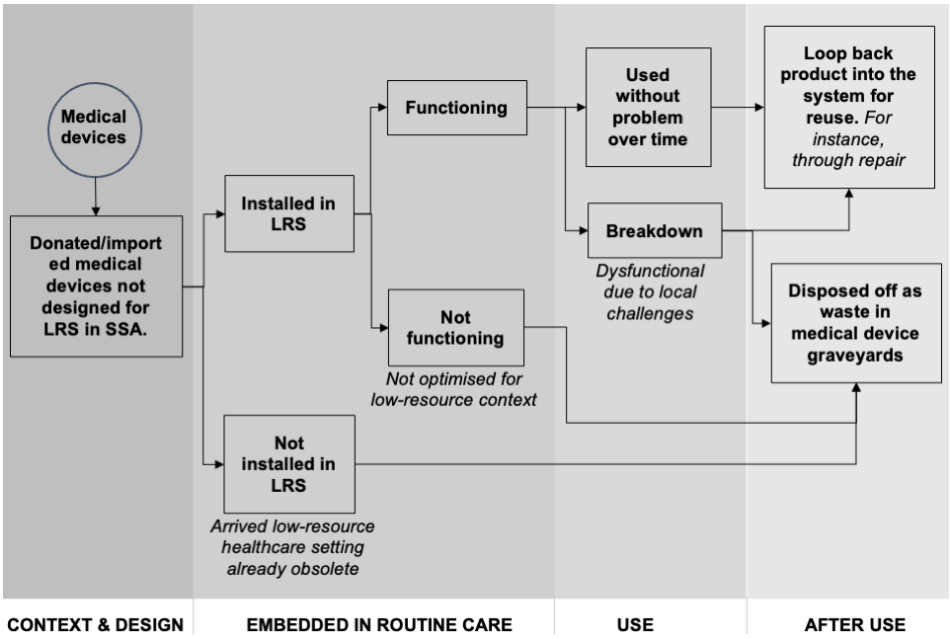

Figure 1.1: Medical devices status and life cycle in a low-resource setting, showing how donated or imported devices from high-income countries reach low-resource healthcare settings in Africa. Some devices are discarded upon arrival, ending up in medical device graveyards. Others are installed, used successfully, and repaired if spare parts are available. Devices that break down beyond repair are also disposed of.

1.2 Current trends against non-functional medical devices

To address social and environmental challenges associated with the disposal of non-functional medical devices and the scarcity of functional ones in low-resource healthcare settings, stakeholders including designers in academia, the private sector, and NGOs are actively designing medical devices tailored specifically for these contexts. This aims to improve healthcare delivery and reduce environmental impact in such settings.

These designers, often referred to as engineers, innovators, or researchers [1], are focused on creating optimally functional and durable devices for low-resource settings. For instance, a team of designers developed and clinically validated a bubble Continuous Positive Airway Pressure (bCPAP) device for treating neonates with respiratory distress [16]. This device (See Figure 1.3 A), costing USD360 compared to USD6,000 for imported versions, aims to meet the needs of low-resource healthcare with a focus on affordability, safety, durability, reusability, and local repair, ensuring sustained accessibility over time. Another example includes the design and evaluation of an electrosurgical device explicitly tailored for such settings. This device prioritizes safety, robustness, local manufacturing, and repairability, ensuring its long-term functionality within healthcare facilities [17].

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Figure 1.2: Image collage taken by the author showing obsolete medical devices dumped in corners of a low-resource hospital, left to rot, with some spare parts potentially salvaged to repair other devices.

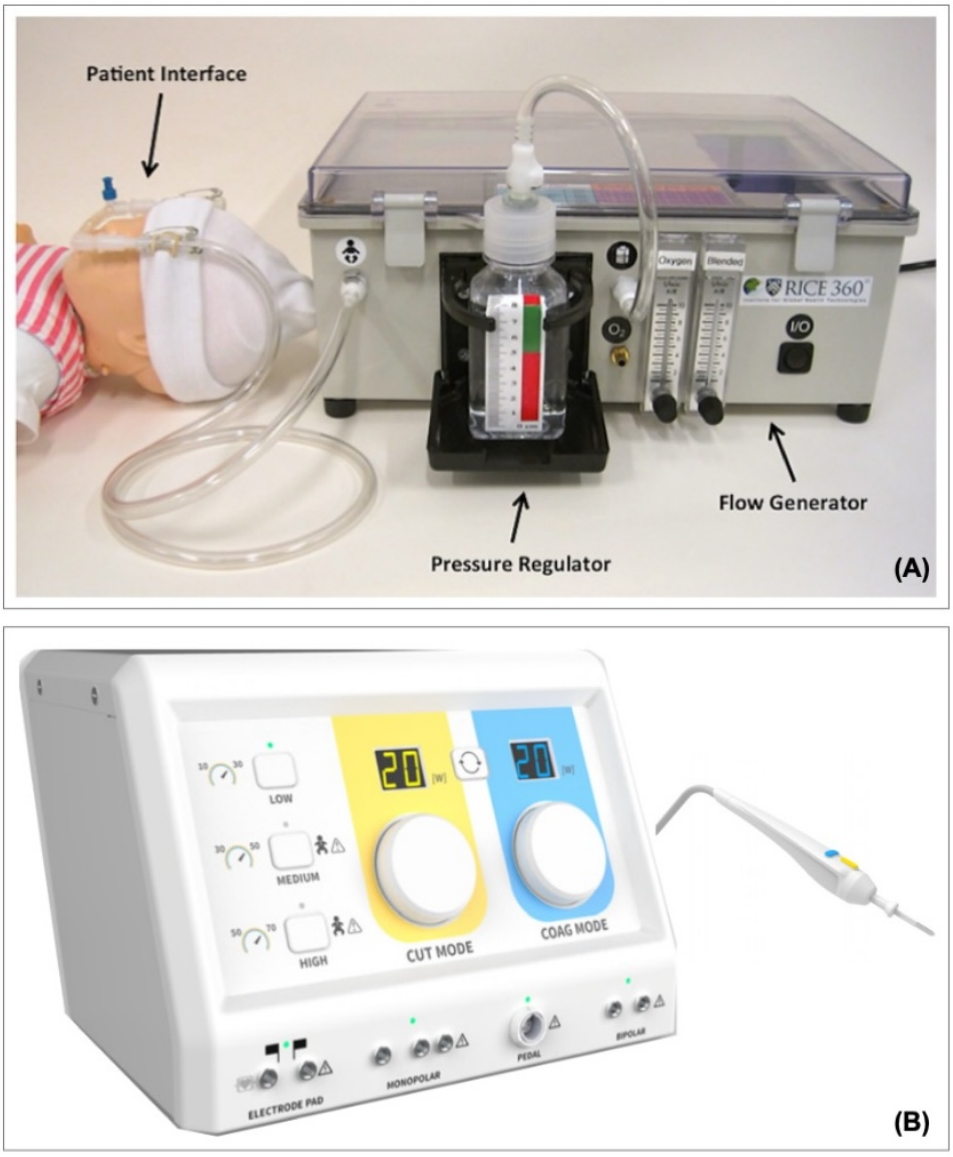

Figure 1.3: Example of a **(A)** Bubble Continuous Positive Airway [16] and **(B)** Electrosurgical device [17], designed to optimally function, be durable and affordable for low-resource clinical settings

Emerging trends in medical device design, such as with bubble Continuous Positive Airway Pressure and electrosurgical equipment, are increasingly tailored to local needs and contexts, ensuring operational effectiveness. There's also a move away from the linear

1

"take-use-dispose" model towards one that advocates for reuse and extended lifespan. This transition is supported by strategies that improve medical device robustness, durability, repair, and maintenance processes to enable reuse. These strategies align with the principles of the circular economy, aiming to eliminate waste by prolonging product life and material reuse [18, 19]. A shift towards medical devices designed for low-resource settings, combined with circular economy principles can ensure device availability, functionality, and sustainability, thereby enhancing healthcare access in these regions. Integrating medical device design with circular economy principles could shift from the current life cycle (Figure 1.1) to a looped product and servicing system (see Figure 1.4), where devices are designed, installed, and functioning and when broken down can be for example repaired and looped back into the system for reuse. However, further research is required to grasp the implications and potential of this transition comprehensively.

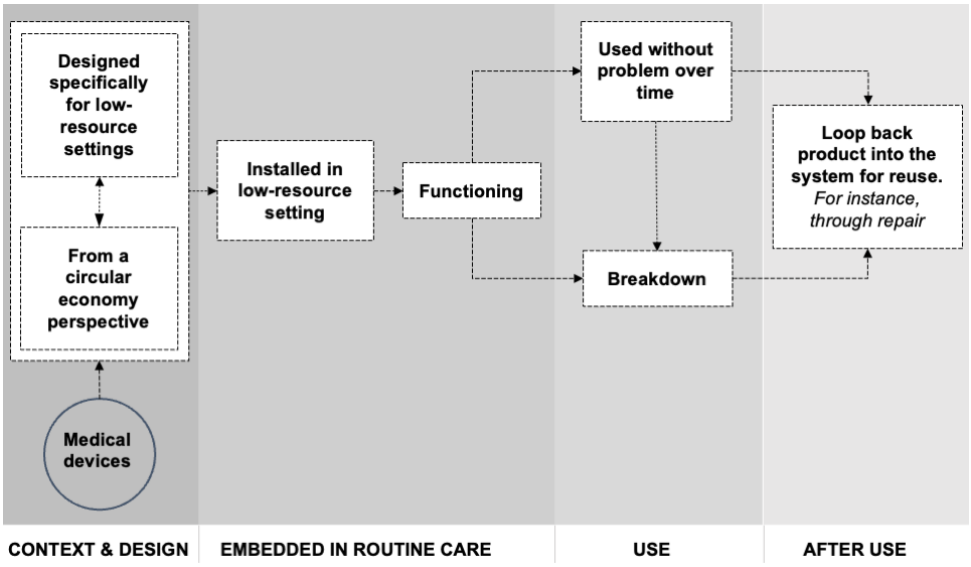

Figure 1.4: . An example of a looped product and servicing system in which medical devices can be designed for low-resource settings can be integrated with circular economy principles, installed and functioning and when broken down can be for example repaired and put back into the system for reuse.

1.3 Gaps towards a context-specific and circular economy design of medical devices

While contextualised medical device design for low-resource settings adopts strategies similar to circular economy principles, literature on this topic remains limited. Evidence on integrating context-specific medical device design and circular economy to deliver healthcare for all while preserving environmental and economic value remains limited. Similarly, realising and integrating medical devices designed from a circular economy

perspective into low-resource routine care adds challenges that are not yet fully understood. For example, integrating medical devices into routine care requires authorisation from medical and regulatory bodies. Adherence to stringent safety standards, and incorporating circular economy aspects adds further complexities to navigate [20–23]. Without addressing these gaps, designers may struggle to implement circular medical devices for healthcare in low-resource settings while minimizing environmental impact. This research adopts a series of studies to expand knowledge on this topic.

1.4 Thesis Goal

Context-specific medical devices integrating circular economy principles can enhance healthcare access in low-resource settings with minimal environmental impact, though it remains an emerging field. Cases of circular economy principles in context-specific medical device designs for low-resource settings need a thorough analysis to build a solid foundation and comprehensive understanding. Therefore, the overall goal of this study is:

To gain insights into the complexities of designing and implementing medical devices for low-resource healthcare settings in sub-Saharan Africa, while leveraging circular economy principles.

Toward this goal, four studies focused on specific research aim were conducted as presented in Figure 1.5 below. The chapters can be read independently and incorporate a literature review.

In **Study 1** the research aim is to assess the extent to which circular economy principles have been applied in the design of medical devices for low-resource settings in Sub-Saharan Africa. The study uses a systematic review to examine how circular economy principles are used in designing medical devices for this context and the underlying motivation. Study 1 establishes a theoretical basis for applying circular economy principles to medical devices for sub-Saharan Africa's low-resource healthcare settings, guiding future design and implementation. The study also establishes the knowledge gaps in circular economy thinking and practices.

Study 2 builds on study 1 and catalogues the development of an actual medical device: the Chloe Syringe Extension Device (Chloe SED®) for providing pain relief medication during gynaecological procedures in low-resource settings in Kenya. The case showcases both the opportunities and challenges encountered when employing circular economy principles in a real-world low-resource context. The study lays a foundation to observe the interconnected conflicting or divergent trade-offs between circular economy and low-resource contextual factors.

Study 3 examines the implementation of the designed intervention Chloe SED® from Study 2 under a large-scale clinical trial. Study 3 aims to compare the efficacy of the intervention to the current standard care.

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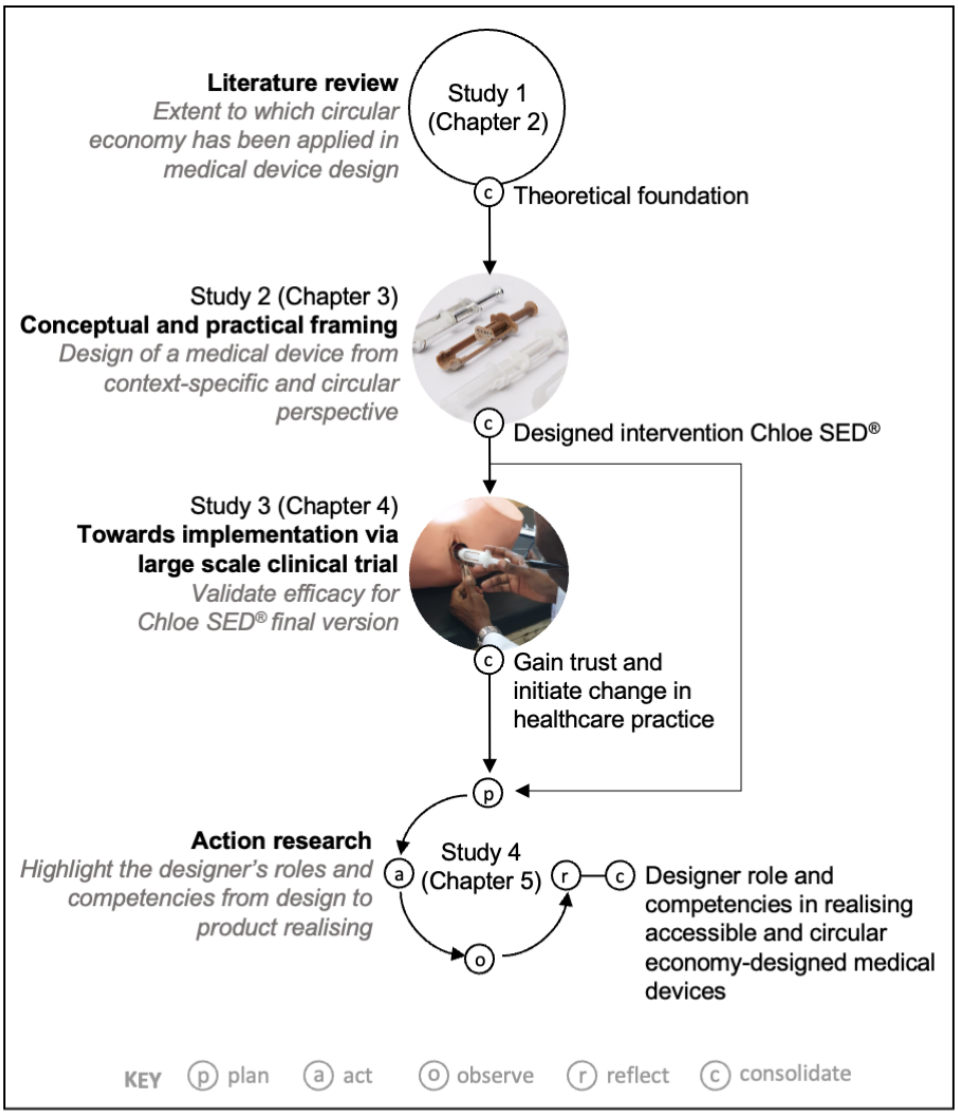

Figure 1.5: Studies in this thesis and how they relate to each other.

Finally, **Study 4** builds on Studies 2 and 3 to depict the designer's journey in designing and implementing Chloe SED®. The aim was to highlight the designer's role in creating an accessible, circular economy-based medical device, aligning with the thesis goal of gaining insights into the complexities of design and implementation.

All studies in this thesis, except Study 1, adopt a practice-based approach, generating new knowledge through investigating practice. This was essential as the medical device

domain in low-resource settings in sub-Saharan Africa is still emerging and poorly understood, as noted in Study 1. Similarly, scholarly work on healthcare and circular economy integration is in its early stages, with context-specific insights from sub-Saharan Africa just beginning to emerge. This approach allowed for the investigation and documentation of unique factors, offering a detailed understanding of medical device design and implementation in this setting.

The next chapters present studies 1, 2, 3, and 4 as published or submitted to peer-reviewed journals.

1

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2

The extent to which circular economy principles have been applied in the design of medical devices for low-resource settings in Sub-Saharan Africa

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Abstract

Healthcare facilities in low-resource settings in Sub-Saharan Africa are plagued with issues of non-functional and obsolete medical devices, which ultimately end up prematurely disposed of as waste. With increasing healthcare demands, stopping medical device disposal is imperative. One way to achieve this is to leverage circular economy principles in designing medical devices. Circular economy principles aim to retain products and their constituent materials to be reused over time in the economic system. However, to what extent this has been applied in designing medical devices specifically for low-resource settings in Sub-Saharan Africa is missing in literature. Based on a systematic review of 29 out of 1,799 screened scientific papers, we identified the use of circular economy principles of durability, maintenance, repair, and upgrade in designing medical devices for this setting. Whether these principles were intentionally applied from a circular economy approach could not be inferred in this study. The motivational basis for using these principles was to ensure medical device longevity to providing healthcare. No attention was given to the circular economy principles of refurbishment, remanufacturing, and recycling, ensuring that device components and constituent materials are recovered. These study findings serve as a launchpad for exploring how circular principles can be used to support the design of medical devices for low-resource settings in Sub-Saharan Africa. Academicians and designers of medical devices can leverage this research to contribute towards developing medical devices that support access to healthcare for people in low-resource settings and preserve earth's finite resources.

2.1 Introduction

To provide healthcare for all, medical devices are highly needed. This need is significantly felt in low-resource settings (LRS) in Sub- Saharan Africa (SSA), which are areas with limited infrastructure, materials, supplies and human resources [1–3]. According to the World Health Organization (WHO), this region suffers from most of the world's diseases and medical devices are highly needed to overcome this burden [4]. So far, the need for medical devices in this region has primarily been met through international donations or by importing medical devices from high-income countries [5, 6]. These devices donated or imported with the best intentions towards providing healthcare are usually not optimised to work in the LRS healthcare system [7]. Once installed, they face context-specific challenges in LRS, such as a lack of spare parts, repair or maintenance services, accessories, and consumables, which render them obsolete [8, 9].

Estimates suggest that 30–40% of medical devices in LRS are non-functional due to these context-specific challenges [6, 10], resulting in their premature disposal as waste [11]. Apart from the fact that non-functioning devices do not contribute to improving access to healthcare, their disposal contributes to the 282,447 tonnes of waste generated by the healthcare sector in Africa each year [12, 13]. These medical devices, which are prematurely disposed of as waste, still contain valuable parts and materials that could be reused or recycled. Given the increasing healthcare demands and population growth in SSA [14, 15], it is imperative to slow down or stop the disposal of medical devices.

One of the ways to slow down or stop the disposal of medical devices is to leverage the concept of circular economy (CE). The goal of CE is to preserve the economic and

environmental value of products and their constituent materials as long as possible [16]. CE is vital for moving away from the current global linear economy. In a linear economy, materials are taken from the Earth, made into products, and eventually, at some point, thrown away as waste [17]. In contrast, CE aims to eliminate "waste". This means that products and their constituent materials that enter CE must always remain accountable. To achieve this, rethinking the design of products is critical [18].

Rethinking the design of products from a CE perspective will mean first designing products to remain in their original state or as close as possible to their original state by leveraging on CE principles of physical durability and product maintenance, repair and upgrade [19]. In the event that products and their constituent material reach their lifespan, they can be recovered by leveraging CE principles of recontextualisation, refurbishment, and remanufacturing. When these products cannot be recovered, they can be disintegrated and returned to their material form through the CE principle of recycling. Note that though product design is vital, it is but one factor in the transition to CE. A successful transition will require other factors such as changes in business models, government policies, rules, and regulations. However, this paper focuses only on the aspect of design.

CE integration in medical device design, while promising, remains an emerging field, showing initial initiatives in scientific literature [20]. For instance, recent literature advocates for the design of medical devices for low-resource settings with extended lifespan [21]. While this literature does not explicitly stem from the CE mindset, it however, advocates for extending product lifespans, echoing a principle intrinsic to CE. More explicit examples demonstrating the practical use of CE in medical device design can be inferred in industry. Koninklijke Philips exemplifies the CE principle in their Diamond Select X-Ray machine, designed for reliability and durability [22, 23]. It's modular design allows for upgrades, refurbishment, and remanufacturing, promoting prolonged use. While this case exemplifies the integration of medical device design and CE, it is crucial to note that this is an exceptional case, supported by substantial financial resources and numerous research and development iterations, not available to other medical devices.

Traces of CE integrated in the design of products in other domains are also growing. In Europe, the Fairphone mobile phone company embraces CE principles like durability, reuse, and recycling, extending the life cycles of mobile phones for positive social and environmental impact [24]. China 4.0 plan, also known as "Made-in-China 2025", emphasises the use of CE to minimise resource input, maximise economic output, lessen the influence on the natural environment and improve resource recycling efficiency. Such a plan underscores CE adoption to reduce resource input, boost economic output, mitigate environmental impact, and enhance resource recycling efficiency [25].

Particularly in Sub-Saharan Africa, initiatives in Kenya, Uganda, and Rwanda implementing plastic bag bans have received acclaim from global circular economy and environmental leaderships [26]. This ban advocated for a transition from single-use plastic disposable packaging to reusable alternatives [27, 28]. Single-use plastics negatively impact the environment aesthetically and pose serious health challenges [29–31] and transitioning into reusable alternatives as in CE was essential. In Nigeria and Ghana, practices involving electronics repair, refurbishment for reuse, and component harvesting for new product manufacturing are prevalent. In Ghana, the Suame Magazine Automotive Centre applies

CE principles of repair and refurbishment in the automotive industry to prolong vehicle use [32]. These CE principles aim to restore and preserve the value of goods and materials for extensive reuse, often stemming from a frugal approach necessitated by resource scarcity in daily life. Such principles, encompassing durability, repairability and others may likely be applied in medical device design for low-resource settings in SSA. This is the starting point of this study and aims to understand the *to what extent have CE principles been applied in the design of medical devices specifically for use in low-resource settings in SSA?*

This study, through a literature review, aims to enrich the CE literature in Africa by revealing the application of CE principles in medical device design for low-resource settings in SSA. Similarly, this study contributes to the CE discourse in Africa by showing the gaps that need to be addressed when designing future medical devices in this region while considering sustainability concerns.

2.2 Theoretical background

2.2.1 Circular economy

Several schools of thought have defined circular economy (CE) since its inception in the 1970s [33]. The definition adopted in this paper stems from the field of industrial ecology and defines CE from a material flow perspective [34–37]. That is, CE aims to preserve the economic and environmental value of products and their constituent materials as long as possible by lengthening their lifespan or looping them back into the system to be reused [16, 20]. Fundamentally, CE seeks to eliminate the notion of "waste" and ensure products and their materials re-enter the economic system to be reused [20, 38]. Although there will always be a certain amount of unavoidable "waste" [39], CE intends to work towards a closed loop [18, 40, 41]. In this closed loop, resources that have entered the CE must always remain accounted for [42, 43].

The notion of CE aims to support the shift from the "take-make-waste" linear economy [44, 45]. In a CE, "waste" should not exist as products and materials are reused as long as possible over time. The mechanism by which products become "waste" in a linear economy is "obsolescence"—defined as a loss of perceived value of the product, which leads to it being discarded as waste [19]. According to the core principles of a CE, obsolescence should not lead to waste. Instead, CE activities of "recovery"—defined as any operation with the primary aim of reversing obsolescence, should be performed [42].

With CE activities of recovery, products and materials can be removed from their obsolete state and their perceived value restored and returned to the economic system for reuse. Recovery activities in CE can be ranked according to the "inertia" principle proposed by Walter Stahel: "Do not repair what is not broken, do not remanufacture something that can be repaired, do not recycle a product that can be remanufactured. Replace or treat only the smallest possible part in order to maintain the existing economic value of the technical system" [36, p. 195]. As such, keeping a product in, or as close as possible to the original state is at the core of CE. In product design terms, this is considered the maximisation of "product integrity"—defined as the extent to which a product remains identical to its original state over time [19].

Based on the inertia principle and the concept of product integrity, product design in CE should first prevent a product from becoming obsolete. That is, designed for long and extended use. Designing products for prolonged use can be achieved by creating products with high physical and emotional durability [19]. Designing products for extended use can be achieved by providing opportunities for product maintenance (also known as preventive maintenance), repair (also known as corrective maintenance) and upgrade. Secondly, CE-oriented design must ensure that obsolete products can be recovered with utmost integrity for reuse within the system. This involves creating items that can be contextualised (or repurposed), refurbished, and remanufactured. These first two guiding principles aim to preserve product integrity, but products will eventually reach their lifespan. Product lifetime starts when a product is released for use after manufacture and ends at the moment a product becomes obsolete beyond recovery at the product level [46–49].

When products reach their lifetime in a CE, the last resort of recycling is needed. Recycling involves the dismantling and disintegration of a product and its constituent components to material form materials. This process is the least preferred option in CE since it destroys a product's integrity. However, it ensures that product materials are captured and looped back into the economic system for reuse. Figure 2.1 shows an overview of these CE principles that underpin product design with a focus on tangible durable consumer products.

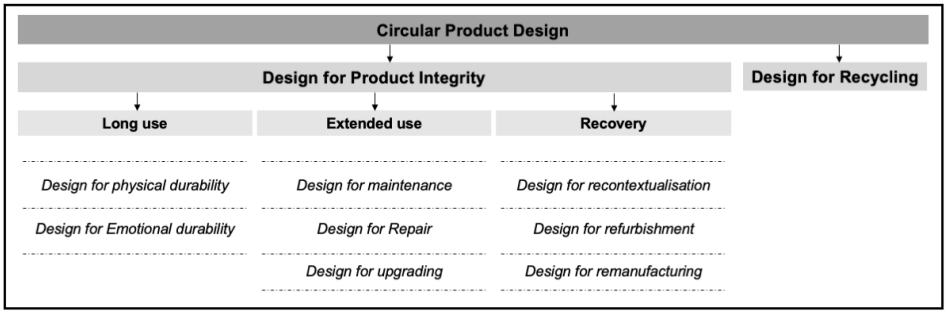

Figure 2.1: Guiding principles that underpin product design for a CE [19]

2.2.2 Circular economy design principles for medical device design

As established, CE can be instrumental in the domain of medical devices and healthcare as a whole to ensure product, material and environmental sustainability. But this domain, is placed under stringent standards to ensure patient safety. Safety standards, for instance, include the safe functioning of medical devices before they are used on patients. In other cases, safety standards require medical device cleaning or reprocessing before use. Cleaning or reprocessing medical devices involves disinfection or sterilisation to ensure hygienic safety for reuse [50], assessed by the Spaulding scale [51, 52].

The Spaulding scale categorises products based on hygiene criticality, outlining reprocessing requirements for medical device reuse. "Critical items," such as surgical devices penetrating tissue or the vascular system, necessitate sterilisation through high pressure or steam. “Semi-critical items” such as respiratory therapy and anaesthetic equipment come in contact with the mucus membrane and require high-level chemical disinfection before reuse. Lastly, "Non-critical items," like stethoscopes which donot enter the body are lightly disinfected before reuse. These hygienic safety standards are crucial in medical device. This also means that circular product design principles in this context of medical device must align with these standards to safeguard patients’ health.

So far, the aforementioned CE principles that underpin product design as in Figure 2.1 have focused on consumer products, not specifically on medical devices. For example, the CE principle of physical durability only considers how product performance over time degrades slower than comparable consumer products [42]. But in the healthcare domain, medical devices designed for physical durability must withstand degradation after reprocessing over their intended lifespan [53]. Another example involves emotional durability, a CE principle focusing on consumer-product relationships and their impact on decisions regarding product replacement [42, 54]. However, unlike consumer products driven by emotional durability, a medical device’s function or reuse isn’t dictated by consumer-product attachment. Rather, these devices are designed to meet strict safety and regulatory standards to enhance health outcomes. The CE principle of emotional durability, while relevant for consumer products, falls outside the scope of medical device design domain. Table 2.1 shows definitions of CE design principles from a medical device perspective as derived from the literature.

The definitions in Table 2.1 are drawn from publications by regulatory bodies such as the Food and Drug Administration (FDA) and World Health Organization (WHO) Medical Devices, which define medical devices, their safety requisites, and appropriate use or reuse. These authorities are in charge with the task of defining what constitutes a medical device, its safety requirement, and its effective use or reuse [59]. These authoritative sources serve as crucial references for formulating CE definitions specific to medical devices, as presented in Table 2.1. Notably, the CE definitions in Table 2.1 encompass stringent safety standards intrinsic to the medical domain. Unlike CE definitions in other domains, these definitions prioritize patient safety while enhancing health outcomes. This emphasis on safety underscores the distinctiveness of medical device CE definitions, crucial for this literature review study examining the application of CE principles in designing medical devices for low-resource settings in SSA.

Table 2.1: Circular economy design principles from a medical device perspective from literature.

Circular Economy principle	Definition
Physical Durability	Withstand fatigue and deterioration after reprocessing and repeated use over its intended lifespan [53]
Maintenance (Preventive Maintenance)	Scheduled activities are performed to ensure the device is functioning correctly and safely over its intended lifespan. Preventive maintenance is usually scheduled at specific intervals and includes specific activities and procedures. These procedures and intervals are established by the manufacturer. In some cases, the user may change the frequency to accommodate local environmental conditions [55].
Repair (Corrective Maintenance)	Perform activities that can restore or correct the performance, physical integrity and safety of the device after a failure [55].
Design for Upgrading	Improving a medical device by adding or replacing components and/or updating software. The improvements made to a medical device must be relative to the Original Equipment Manufacturer's (OEM's) specifications, safety requirements, functionalities and capabilities [56].
Recontextualise (Repurposing)	Removal of an obsolete medical device from its originally intended uses to an alternative use. All used or potentially used medical devices must be cleaned as in the instructions specific to the device or type of device [56]
Refurbishment	Refurbishment is where a device is subjected to a systematic process to ensure safety and effectiveness of the medical device without significantly changing the device's or medical device's performance, safety specifications and/or changing intended use as defined by Original Equipment Manufacturer's (OEM's) [57]
Remanufacturing	A medical device is processed, conditioned, renovated, repackaged, or undergoes any other activity that significantly changes the finished device to an as-new condition, performance, safety specifications or better. The remanufacturing process can be performed by a third-party or OEM and must be in line with specific technical specifications, including engineering, quality, testing standards, and medical device regulatory requirements and typically yields fully warranted products [58].
Recycling	Safely converting 'waste' (obsolete medical device, component, or material) into reusable materials or returning materials to an earlier stage in a cyclic process [56].

2.3 The literature review method

Table 2.1 now outlines CE principles applicable to medical device design. However, the extent to which these principles have been applied in medical device designed specifically to low-resource settings in SSA, is unknown. To address this gap, which is also the main goal of this chapter, a literature review was performed (see Figure 2.2). Studies were searched in databases such as Google Scholar, Pubmed, Scopus, and IEEE Xplore. Using logical operators AND or OR, the key terms *medical, device, equipment, use, design, frugal, low cost, development, implementation, low-resource settings, Sub-Saharan Africa, Africa, developing countries, low and middle-income countries, remanufacturing, repair, refurbishing, recycling, circular economy, sustainability* were combined and searched. The search resulted in a total of 1,799 scientific papers that mention the design of medical devices. Only studies in English were included.

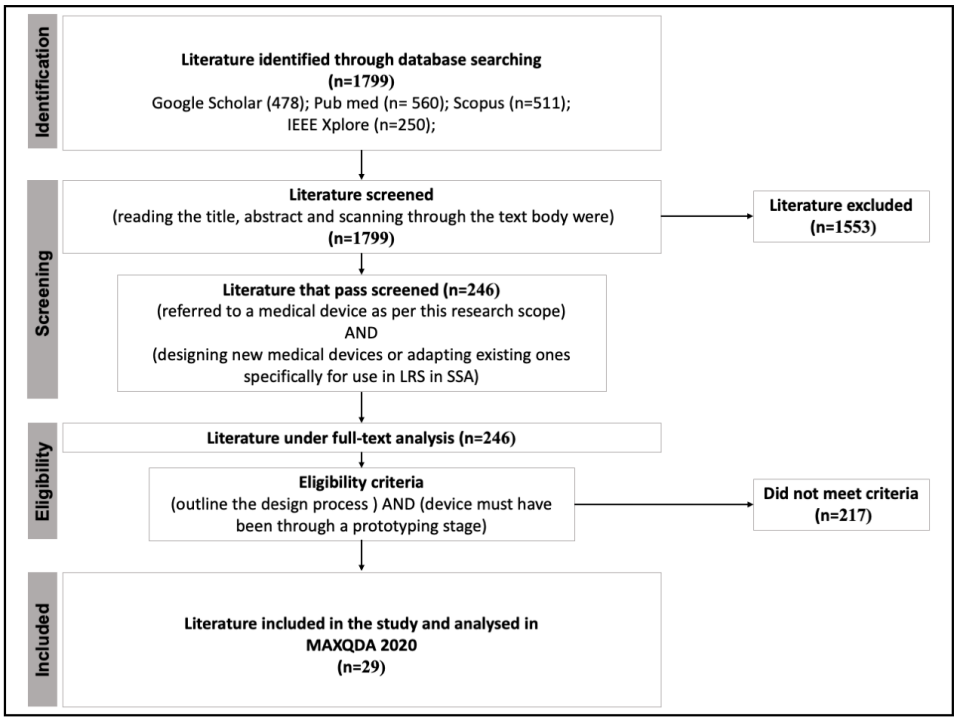

Figure 2.2: Summary of the systematic review process. Acronyms LRS and SSA are low-resource settings and Sub-Saharan Africa, respectively

Next, studies were screened by title, abstract and text body scan read by two reviewers according to the following criteria. The study must refer to a medical device as per this research scope. That is, a medical device is "any instrument, apparatus, or appliance, manufactured specifically to be used for diagnosis, prevention, monitoring, and alleviation of disease or treatment of the human body, that are not solely pharmaceutical goods" [3, 60, 61]. Due to our interest in hardware design for hospitals in low-resource settings, medicines, devices for home care, vaccines, in-vitro, mHealth or eHealth, and other telecommunication systems in healthcare were out of scope in this research.

For the second criteria, studies must focus on designing new medical devices or adapting existing ones specifically for use in low-resource setting in SSA. Studies that described misuse or unintended use of medical devices were excluded. As a result, 246 studies fulfilled the above two criteria. Subsequently, studies included in the full-text analysis were selected based on the third and fourth eligibility criteria. That is, the study must refer to and outline the design process of the described medical device. This criterion ensured that the medical device being described could be examined for content relating to the application of circular economy principles. Lastly, the described device must have been through a prototyping stage. Consequently, 29 studies met the third and fourth inclusion criteria and were entered into a qualitative data analysis tool (MAXQDA 2020) for analysis.

In MAXQDA, the 29 studies were analysed to identify CE principles (see Table 2.1) applied in the design of medical devices for low-resource settings in SSA. The analysis was done by descriptive coding. During descriptive coding, a text fragment was highlighted and assigned a code [62, 63] whenever a CE principle was mentioned as in Table 2.1. These text fragments that explained CE principles were identified in the selected studies by code recording units in Table 2.2. A recording unit is a portion of text, sentence, word or word meanings to which an evaluator applies a code [64]

The recording units were established in two stages. In stage one, recording units were compiled from preliminary reading through the 29 selected studies and recording keywords, text, and sentences that explained the respective CE principles as in Table 2.1. For example, design for "robustness" is a word that described the CE principle of "design for durability". This process continued until the repetition of compiled recording units began to emerge. In stage two, the compiled recording units were examined by two experts with expertise in CE and medical device design. Experts reviewed the compiled recording units to confirm the inclusion of all possible ones. None of them suggested removing any recording unit, nor did they propose any new ones.

Using the established codes and recording unit, the analysis of the 29 studies by descriptive coding was performed by two persons. This was done to avoid confusion or misalignment of terms and definitions during the coding process. After the first coding round, a second and third iteration was conducted and finalised. Supplementary material with all the coded segments can be retrieved from doi:10.3389/frsus.2023.1079685 [65]. The systematic review produced an overview of the different CE principles applied in the design of medical devices for low-resource settings, as detailed in the next section.

2.4 The review findings

To understand the extent to which circular economy (CE) principles have been applied in the design of medical devices specifically for use in low-resource settings in SSA, a literature review of 29 scientific articles was performed. These articles were published between 2006 and 2021 and described the design of 45 medical devices with different hygienic criticality and value as seen in Table 2.3. Examples of these 45 devices included a surgical suction pump, wrist flexion contracture, phototherapy unit, blood salvage device, custom-designed implants, a vest for treating jaundice, bubble continuous positive airway pressure—(bCPAP), low field MRI, electrosurgical unit, mechanically powered wound-pump, oxygen delivery system and many others. See Table 2.3 for the complete list of medical devices.

From Table 2.3, it can also be inferred that overall, 55.6% (25) of the devices were electromechanical (i.e., comprised electrical and mechanical parts), and 44.4% (20) were purely mechanical (i.e., had no electronic components). All 45 devices were designed for reuse. None of the devices was designed for single use (i.e., disposable).

Table 2.2: Circular economy principles, codes and their respective recording units.

Principles	Codes	Code recording units.	
		Keywords	**Variation of text and/or sentence for coding**
Physical Durability	DL1	"durable", "robust", "long-lasting", "reusable","rigid", "strong", "strength", "rugged", "withstand"	A medical device is designed to: 1. Be used repeated after reprocessing by means of chemical and/or heat sterilization and still withstand deterioration. 2. Withstand rough environmental conditions (high temperature, humidity, dust, rain) and handling. For example, rain, rough and bumpy terrain. 3. Withstand tear over its lifespan. 4. Be rigid, rugged, and/or robust. 5. Withstand shock, stress, vibration, pressure, and force that can cause damage. 6. Be waterproof and/or dustproof against damage. 7. Maintained its mechanical strength over its lifespan. 8. Have part geometry that prevents cracks and weakening joints. 9. Prevent part failure caused by an electric power surge. 10. Be made from materials that are selected to ensure the medical device is durable and reliable for use over its lifespan.
Maintenance (Preventive Maintenance)	DE1	"maintenance", "maintain", "preventive maintenance", "planned maintenance", "servicing"	A medical device is designed so that: 1. It can be maintained. 2. Regular performance inspections can be carried out to ensure the device keeps on functioning correctly as per original specifications. 3. Scheduled activities are carried out by qualified professionals (for example biomedical engineers, or OEM professionals) to prevent any breakdowns. 4. Monitoring of device functionalities for safety and/or continuous operation is possible. 5. The use of service contracts can be made to ensure a medical device is working correctly and safely. 6. Regular adjustments and calibrations on medical devices to ensure correct functionality as per original specifications. 7. Parts of the device are scheduled to be replaced frequently.
Repair (Corrective Maintenance).	DE2	"repair", "corrective-maintenance", "repairability"	A medical device is designed so that: 1. It can be repaired back to its original specification by a third-party of OEM. 2. Replacement of broken parts or components after failure is possible. 3. Adjustment to a part or device after failure or malfunction is possible. 4. Spare parts for repair are available. 5. Faults can be diagnosed, for example, using manuals. 6. Tools are available to support repair. For example, using a 3D printer to print repair parts.
Upgrading	DE3	"upgrade", "enhance"	A medical device is designed so that enhancement/customisation of device performance by replacing/adding components is possible.For example, through modularity.
Recontextualise (Repurposing)	DR1	"repurpose", "reassigned", "recontextualise"	1. Medical device and/or components can be transferred to be used in another medical context than it was originally designed for. 2. Device or component is used as a medical device even though it was not originally designed for that purpose.
Refurbishment	DR2	"refurbish", "recondition", "restore"	1. Medical device that is labelled as "refurbished" "reconditioned", "restored". 2. An old medical device has undergone activities to ensure device performance, safety specification is restored as per the OEM.
Remanufacturing	DR3	"remanufactured"	Medical device that is labelled as "remanufactured".
Recycling	DCY1	"recycle"	1. A medical device and/or its component can be transformed into its basic materials and processed into new materials. 2. Activities that retrieve the value of product/component materials before disposal, are possible. 3. An obsolete medical product is disassembled, and components are retrieved to be converted into raw materials so that they don't become waste.

A detail examination of the medical device reviewed as in Table 2.3 revealed two key findings. Firstly, these medical devices designed for low-resource settings in SSA significantly took into account CE principles aimed at ensuring medical device longevity. All 29 studies reviewed in this study made use of design for long use by ensuring product durability. Design for extending device use through maintenance was identified in 18 studies, repair in 12, and upgrade in 10. Whether these principles were intentionally applied from a CE thinking approach could not be inferred in this study.

These principles aimed at product longevity were intended to ensure that medical devices are available to provide healthcare. This is, for example, demonstrated in one of the studies reviewed in this study whereby an electrosurgical unit which is often lacking in low-resource settings, is designed to be durable, repairable, upgraded, and reusable over time even in conditions of electrical failures [66]. In the event of electrical failures, this electrosurgical unit can be repaired and upgraded by using local foot-paddle power technology to keep it functioning and thus provide surgical healthcare service for people in low-resource settings. In another example, we observe the adaptation of existing medical devices for (re)use. For instance, the 3D printing of components or spare parts in rural Kenya to ensure obsolete medical devices can remain functional towards providing healthcare [67] .

Secondly and most remarkably, the CE principle of recovery through recontextualisation (repurposing) could be inferred in five of the 29 studies used (see Table 2.3). CE principles of recovery through refurbishment, remanufacturing and recycling could not be identified in any of the studies. The reason why these recovery and recycling principles were not considered could not be inferred in this study.

2.5 Discussion of finding

This study began with the recognition that principles of circular economy (CE) can be instrumental in ensuring medical devices designed for low-resource settings in Sub-Saharan Africa (SSA) do not end up as waste. However, to what extent these principles have been applied in designing medical devices for this setting remained a gap in literature evidence. To filled this gap a performed a literature review was conducted.

As expected, the review revealed considerable emphasis on CE principles in designing devices for these regions, particularly centred around device longevity. Aiming for longevity was to ensure that medical devices are available, functional, and used over time to provide access to healthcare, a fundamental human need. In so doing, the use of CE design principles such as durability, maintenance, repair, upgrade and recontextualisation was evident. The motivation behind applying these principles for medical device longevity diverges from the presumed environmental or material flow motives in current CE literature. In this context, the emphasis shifts towards device longevity due to scarcity, prioritizing the sustained availability of products to ensure healthcare access for all. However, whether these principles were intentionally applied from a CE thinking approach could not be inferred in this study.

Table 2.3: The CE principles applied in the design of medical devices for low-resource settings in SSA as pinpointed in the literature.

Studies by	Long use	Extended Use			Recovery			Recycle	Medical Device and properties			
	Physical Durability	*Maintenance*	*Repair*	*Upgrade*	*Recontextualise*	*Refurbish*	*Remanufacture*	*Recycling*	*Device*	*Electro mechanical OR Mechanical*	*Economic Value*	*Criticality*
Abu-Haydar et al., 2021 [68]	X	X	X	X					Pneumatic Infusion Pump	Electro mechanical	Medium-high	Semi-critical
Abu-Zaineh and Gershenson, 2020 [67]	X	X	X	X					Microscope aperture adjustment knob	Mechanical	Medium-low	Non-critical
									Blood pressure monitor value (repair part for a blood monitor machine)	Mechanical	Medium-low	
									Stethoscope earpiece (repair part for stethoscope)	Mechanical	Medium-low	Semi-critical
									Full-cap humidifier (repair part for oxygen regulator)	Mechanical	Medium-low	Non-critical
									Half-cap humidifier (repair part for oxygen regulator)	Mechanical	Medium-low	
									Humidifier gasket (repair part for a humidifier in an oxygen regulator)	Mechanical	Medium-low	
									Suction machine gasket (repair part for a suction machine)	Mechanical	Medium-low	
									Oxygen regulator knob (repair part for an oxygen regulator)	Mechanical	Medium-low	
Agbana et al., 2019 [69]	X	X	X						Schistoscope: Diagnostic device for schistosomiasis.	Electro mechanical	Medium-High	Non-critical
Ahmed et al., 2020 [70]	X			X					Biofuel-powered autoclave	Mechanical	Medium	Non-critical
Arivoli et al., 2020 [71]	X				X				Gastroschisis Silo	Mechanical	Low	Critical
Ayah et al., 2020 [72]	X	X	X						Suction Machine	Electro mechanical	Medium-high	Critical
									Phototherapy unit			Non-critical
									Vacuum extraction			Critical
									Examination light			Non-critical
Battinelli et al., 2012 [73]	X	X	X	X	X				Surgical suction device.	Electro mechanical	Medium-High	Critical
Berges et al., 2020 [74]	X								Core needle biopsy device	Electro mechanical	Medium	Critical
Booysen et al., 2019 [75]	X	X		X					Custom design implants	Electro mechanical	High	Critical
Bradley et al., 2011 [76]	X	X		X					Battery-powered oxygen Delivery System	Electro mechanical	High	Semi-critical
Brown et al., 2013 [77]	X	X	X						Bubble Continuous Positive Airway Pressure - (bCPAP)	Electro mechanical	High	Semi-critical
Buchan et al., 2015 [78]	X								Surgical drill cover	Mechanical	Medium-low	Non-critical
Crede et al., 2014[79]	X		X						Pulse Oximeter	Mechanical	Medium	Non-critical

Studies by	Long use	Extended Use			Recovery			Recycle	Medical Device and properties			
	Physical Durability	*Maintenance*	*Repair*	*Upgrade*	*Recontextualise*	*Refurbish*	*Remanufacture*	*Recycling*	*Device*	*Electro mechanical OR Mechanical*	*Economic Value*	*Criticality*
Diehl et al., 2020[80]	X	X	X						Low field Magnetic Resonance Imaging (MRI) device.	Electro mechanical	High	Semi-critical
Ditai et al., 2021 [81]	X		X						Resuscitator	Mechanical	Medium	Semi-critical
Kenney et al., 2019 [82]	X	X	X						Body power prosthesis	Mechanical	High	Critical
Lawn et al., 2006 [83]	X								Pulse oximetry for babies	Electro mechanical	Medium	Non-critical
Mathern et al., 2013 [84]	X		X						Weighing scale	Mechanical	Medium	Non-critical
									Blood pressure device	Electro mechanical	Medium	Non-critical
									Spirometer	Electro mechanical	Medium	Semi-critical
									Thermometer	Electro mechanical	Medium	Non-critical
Mody et al., 2015 [85]	X	X							Mechanical power wound-pump	Mechanical	Medium	Critical
Mucha et al., 2021 [86]	X	X		X	X				Surgical suction pump connector	Mechanical	Medium	Critical
Ngoie et al., 2020 [87]	X	X		X					Wrist flexion contracture	Mechanical	Medium-High	Semi critical
Oosting et al., 2020 [66]	X	X	X	X					Electrosurgical unit	Electro mechanical	High	Critical
									Monopolar handheld	Electro mechanical	High	Critical
Piaggio et al., 2021 [88]	X	X							Vest for treating jaundice	Electro mechanical	Medium	Semi-critical
Pretorius and Ferreira, 2021 [89]	X								Interlocking intramedullary nailing system for forearm fractures	Mechanical	Medium	Critical
Read and Taylor, 2012[90]	X	X							Portable glostavent	Electro mechanical	High	Semi-critical
Schopman et al., 2013[91]	X								Blood pressure monitor	Electro mechanical	Medium	Non-critical
									Pulse Oximeter	Electro mechanical	Medium	Non-critical
									Adult weighing scale	Electro mechanical	Medium	Non-critical
Sluiter et al., 2020[92]	X	X							Schistosomiasis diagnostic device	Electro mechanical	Medium	Non-critical
Vargas et al., 2013[93]	X			X	X				Makeshift loop cauter	Mechanical	Medium-high	Critical
Winget et al., 2015 [94]	X	X							Blood salvage device	Mechanical	Medium-high	Critical
No. of studies that mention CE principles.	29	18	12	10	5	0	0	0				

Similar observations in low-resource settings in SSA indicate practices aligning with CE principles, focusing on preserving or restoring the value of goods for extended periods, albeit without explicit association with the term "CE". For example, Korsunova and colleagues noticed resource scarcity in low-resource settings that resulted in “necessity-driven CE” practises such as “repair” and “reuse” to retain the goods in circulation for as long as possible [95]. This necessity-driven CE practise adopts a mindset that looks at the long-term functionality of goods and materials that are often unavailable. As expected, this was also seen in this study whereby in providing medical devices that are often unavailable, CE principles that retain the product to be used over time are taken into account.

Designing medical devices for low-resource settings to remain in use over a long time is certainly valuable. This can ensure that healthcare facilities in this region have access to medical devices to provide healthcare. On the other hand, what happens when these devices reach their end of life or become obsolete? Besides, a product can be declared obsolete prematurely though still functional. For example, a product can be declared obsolete if outperformed by a newer product (i.e., technological obsolescence) [20, 96] or no longer legal to be used (i.e., regulatory obsolescence). In another case, a product might become obsolete when its use is no longer profitable (i.e., economic obsolescence) [20]. These different forms of obsolescence might push medical devices designed for longevity to be obsolete and end up disposed of as waste. It’s crucial to put in place processes that ensure medical devices that become obsolete or reach end of life can be recovered and put back in the economic system for reuse. For example, recovery through refurbishment, remanufacturing, or recycling of medical devices.

Products designed to be recovered and recycled can continue circulating in the economic system at the highest value and not end up disposed of as waste [97, 98]. However, this study found no explicit mention of circular economy (CE) principles supporting the recovery of medical devices through refurbishment, remanufacturing, or recycling. These processes hold potential for medical devices, rejuvenating them for reuse and restoring essential components to their original condition [99–103].

Although not evident in this review, refurbishment and remanufacturing processes are prevalent in low-resource settings within SSA, particularly in the electronics domain. For instance, Nigeria’s Otigba computer village serves as a hub for refurbished devices, with daily sales exceeding 2,500 units, encompassing assembly, repair, and refurbishment [104]. This sector, spanning Accra and Lagos, provides income for over 30,000 individuals through repair, refurbishment, and remanufacturing activities [105] Despite existing barriers, refurbishment and remanufacturing offer substantial economic prospects for low-resource settings in SSA.

In the context of low-resource settings in SSA, several barriers related to the lack of refurbishment and remanufacturing of medical devices exist. These barriers encompass the absence of supportive legislation and infrastructure, as well as the lack of established Medical Device Original Equipment Manufacturers (OEMs) offering such services within SSA [101]. However, this review couldn’t confirm whether these barriers contributed to the exclusion of CE principles like refurbishment or remanufacturing.

Also, refurbishment or remanufacturing is also dependent on the type of device. Typically, high-value medical devices, such as Magnetic Resonance Imaging machines, are

among the commonly refurbished or remanufactured items [20, 106, 107]. In other cases, small and medium-valued equipment is refurbished by replacing specific components [108]. Based on this rationale, this study's devices designed for longevity, as indicated in Table 2.3, might also benefit from refurbishment or remanufacturing processes, particularly the high-value devices mentioned. Nevertheless, other factors are necessary to consider before entering refurbishing or remanufacturing processes.

Another aspect to consider before refurbishment or remanufacturing includes financial viability [107]. Similarly, hygienic criticality is another factor. High-criticality devices must be hygienically recovered to be refurbished or remanufactured using more aggressive chemical decontamination or sterilisation processes than low- or medium-criticality devices [20]. This will mean designing devices with materials which can withstand such chemical decontamination or sterilisation processes [20] and recovered back into a functional product or recycled into back to its material form.

Recycling is critical to ensure that medical devices and their constituent material are conserved in the economic system. Though none of the studies reviewed mentioned the use of this CE principle in designing medical devices, it is essential to consider them in the future. This is because recycling which is the last resort for resource conservation can ensure a product's constituent materials stay in the economic system and do not end up as waste [97, 98, 109]. For example, recycling electronics allows for precious and unique metals to be recovered and thus reducing the environmental impact associated with electronic manufacturing from raw materials [110]. In essence, all the devices identified in this study (see Table 2.3) could benefit from recycling processes.

Recycling processes and infrastructure are present in low-resource setting in SSA [95] and can support recycling of medical and other electronic devices. For example, the WEEE centre [111–113] in Kenya provides electronic waste recycling services in East and Central Africa. The Hinckley recycling centre in Lagos, Nigeria, provides recycling of electronic services in West Africa [114, 115]. These recycling services include collection, sorting and separating electronic waste to be reused or broken down into raw material form. Similarly, the company Mr. Green Africa provides plastic recycling services in East and Central Africa [116]. Its services include collecting, sorting, pelletising, trading and reprocessing recycled plastics into high-quality products. With such recycling infrastructures, capturing medical devices' material value is possible in low-resource settings in SSA as per this review study.

The limitation of this study is that it only investigates the extent to which CE principles have been applied in the design of medical devices from a scientific literature review perspective. CE design principles could also be implemented at the industry level and has yet to make its way into scientific literature. We speculate that investigating the same topic using industry case inquiry methods can reveal new findings on the extent to which CE has been applied in designing medical devices for low-resource settings in SSA.

2.6 Review conclusion

This study is an endeavour to understand to what extent Circular Economy (CE) principles have been applied in the design of medical devices, specifically for low-resource settings (LRS) in Sub-Saharan Africa (SSA). Based on a systematic review and as expected, this

study shows that CE principles of durability, repair, maintenance, and upgrade and medical device longevity can be inferred in the domain of medical device design for LRS in SSA. Whether these principles were intentionally applied from a CE approach could not be inferred in this study. The motivation for using these principles is to ensure medical devices are available to provide access to healthcare in LRS as opposed to the environmental or material flow motivation often found in CE literature. The motivational basis towards providing healthcare for people should remain a core aspect when designing medical devices for LRS in SSA.

This research further revealed that other CE principles that ensure medical devices and constituent materials are recovered (i.e., through refurbishment and remanufacturing) and recycled were hardly taken into account. Underlying reasons for this could not be established in this review. This, therefore, presents an opportunity for further research. It is vital to understand why CE principles of refurbishment, remanufacturing, and recycling are not considered when designing medical devices for LRS. And what needs to be in place if these CE principles were considered in medical device design?

The findings in this study are intended to be used as a starting point to explore how CE principles can be used to support the design of medical devices for LRS in SSA. This study now provides insights into the extent to which CE has inadvertently been applied in designing medical devices for LRS in SSA. It further shows the gaps in the lack of attention to recovery and recycling considerations when designing medical devices for LRS in SSA. Designers of medical devices can leverage this research to contribute towards developing medical devices that support access to healthcare for people in LRS and preserve earth's finite resources.

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3

Design of a syringe extension device (Chloe SED®) for low-resource settings in sub-Saharan Africa: A circular economy approach

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Abstract

Underfunded healthcare facilities in low-resource areas of sub-Saharan Africa face shortages of essential medical devices, such as those required for paracervical blocks during gynaecological procedures. The unavailability or high costs of these devices impedes the delivery of essential gynaecological care, affecting procedures such as loop electrosurgical excision, miscarriage treatment, and incomplete abortion. Consequently, this compromises the standard of women's healthcare. Urgent interventions integrated into low-resource healthcare systems are needed to address this gap and provide necessary paracervical blocks for women. This research presents Chloe SED®, a new medical device intentionally designed using circular economy principles and a context-specific approach. The device, priced at US$ 1.5 in polypropylene, US$ 10 in polyetheretherketone, and US$ 15 in aluminium materials, attaches to a 10-cc syringe to achieve the necessary length for reaching the cervix and administering paracervical blocks. Chloe SED® aims for durability, repairability, maintainability, upgradeability, and recyclability, addressing environmental sustainability concerns in healthcare. Designing Chloe SED® from a circular economy and context-specific approach highlighted complex relationships between material choice, initial cost, device durability and reuse cycle, reprocessing methods and costs, and environmental impact. These interconnections represent conflicting trade-offs requiring continuous assessment to deliver a healthcare device with limited environmental impact, aligned with circular economy principles.

3.1 Introduction

Over the past century, healthcare provision in low-resource settings (LRS) in sub-Saharan Africa (SSA) has been hampered by underfunded healthcare infrastructures [1–3]. This results in a lack of medical devices crucial to provide healthcare for all [4, 5]. Medical devices, which are used for a variety of purposes in the prevention, diagnosis, or treatment of illnesses or diseases, or to detect, measure, restore, and modify the body's structure for health purposes, are a vital component of any functioning healthcare system [6]. However, these devices are expensive and often unaffordable to the healthcare systems in LRS [7]. The high cost of medical devices has often resulted in LRS relying on international donations to equip healthcare facilities with medical devices. Estimates suggest that approximately 80% of medical device availability in healthcare facilities in LRS is covered by donations [8, 9]. Presumably, this high volume of donations should drastically improve the availability of functioning medical devices in LRS [3]. Nevertheless, these initiatives have been estimated to be unsuitable and unsustainable [3]. About 40% of medical devices donated are non-functional, thus leaving healthcare facilities in LRS with the issue of medical device unavailability and excessive waste streams of defunct devices [10–12].

Philanthropic donations may help provide medical devices in low-resource settings, but these initiatives are fraught with considerable limitations[13]. For example, the non-prioritisation of essential medical devices has previously been highlighted as a significant limitation[10]. Also, these donated medical devices are usually not optimised to function or operate in low-resource healthcare systems, coupled with the lack of trained personnel to use and maintain them [14]. Donations also require long-term commitments to ensure the availability or continuous functioning of the device, but these are usually not provided

or not sustained over time [15, 16]. Other limitations include a lack of an adequate supply chain system, which prevents donated medical devices or consumables from reaching local communities [17, 18]. Ultimately, low-resource healthcare facilities remain with limited or no medical devices to provide healthcare for all. A representative example of this scenario is the case of medical devices needed to provide women with a paracervical block (PCB) during gynaecological procedures.

PCB is a type of regional nerve block used to provide pain relief during gynaecological procedures [19, 20]. It is performed by injecting an anaesthetic solution around the cervix to numb nearby nerves and reduce any discomfort [21]. Examples of gynaecological procedures requiring PCB include loop electrosurgical excision procedure (LEEP), cervical biopsies, placement of contraceptives in the uterus, curettage, or manual vacuum aspiration (MVA) for the treatment of miscarriage or incomplete abortion [21–24]. Neglecting PCB unnecessarily increases anxiety and pain, and compromises the quality of care for women requiring gynaecological procedures [25]. However, providing this procedure is often difficult or impossible without access to the proper medical device.

Medical devices used to provide PCB include syringes with long enough needles to inject 20ml of 1% lidocaine or 10ml of 2% lidocaine to a depth of 3cm in the cervix [26, 27]. Examples of such needles include 20 gauge by 130mm long pudendal block needles [28], standard or extended-length spinal needles, or needle extenders. Although these syringe needles are commonplace medical devices in medical facilities, they are often unavailable in low-resource settings [29, 30]. When available, the prices can range between US$ 1.5 and 28 per needle [31–34]. These prices can be high for low-resource settings, particularly for those at the average poverty line of US$ 1.25 per day [35].

Philanthropic initiatives, such as the United States Agency for International Development (USAID) Post Abortion Care program [36] and Pathfinder International's Youth-Friendly Post Abortion Care Project [37], are at the forefront of providing women in low-resource settings in SSA with PCB-related procedures. As mentioned, relying on philanthropic initiatives is fraught with limitations, especially with the growing healthcare demand caused by an increasing African population [38, 39]. Research shows that up to 90% of patients in a 100-bed acute gynaecology ward in low-resource settings have pregnancy-related complications requiring PCB [40]. The World Health Organization explicitly recommends providing PCB to women seeking gynaecology procedures such as miscarriage treatment and uterus evacuation-related procedures [25].

Designing a medical device intervention for PCB that can be integrated into low-resource healthcare system is paramount. This ensures that medical devices can match the local conditions and needs [14, 41, 42]. Similarly, it ensures aspects important to low-resource healthcare systems such as affordability, availability, accessibility, appropriateness, and robustness of the device, for example, after multiple use, chemical or steam reprocessing cycles are considered [43, 44]. Designing new medical devices for PCB, while considering aspects important to low-resource healthcare systems, can ensure local healthcare facilities no longer have to depend on donations to provide health services.

New initiatives designing medical devices to be integrated into low-resource healthcare systems have emerged. This is demonstrated in the design of a blood salvage device

for ruptured ectopic pregnancy [45]), uterine balloon tamponade to treat postpartum haemorrhage in under-resourced settings [46, 47], and the design of a portable ultrasound unit for healthcare service in the Lugufu refugee camp, Tanzania [48]. Other initiatives further leverage context-driven approaches to consider factors critical to the healthcare system in LRS throughout the medical device design process. This is demonstrated in the context-driven design of an electrosurgical unit [49] or the context-driven design of a retractor for abdominal insufflation-less surgery [50].

Utilizing a context-driven approach, as suggested by Oosting [51] and depicted in Figure 3.1, is pivotal in comprehending the intricacies associated with designing medical devices for low-resource healthcare settings. This approach takes the form of: first, identifying a clear need for a new medical device (Phase 0), then exploring context-specific factors such as patient barriers to accessing care within the local healthcare system (Phase 1), followed by developing requirements for the new medical device (Phase 2), and, finally, carrying out device design and validation actions with local stakeholders (Phase 3). This approach holds potential in designing a medical intervention for PCB in low-resource settings, ensuring an understanding of PCB-related contextual factors. Moreover, it can facilitate the development and validation of a medical device intervention tailored to fit within the low-resource healthcare system, offering sustained healthcare support to women requiring PCB.

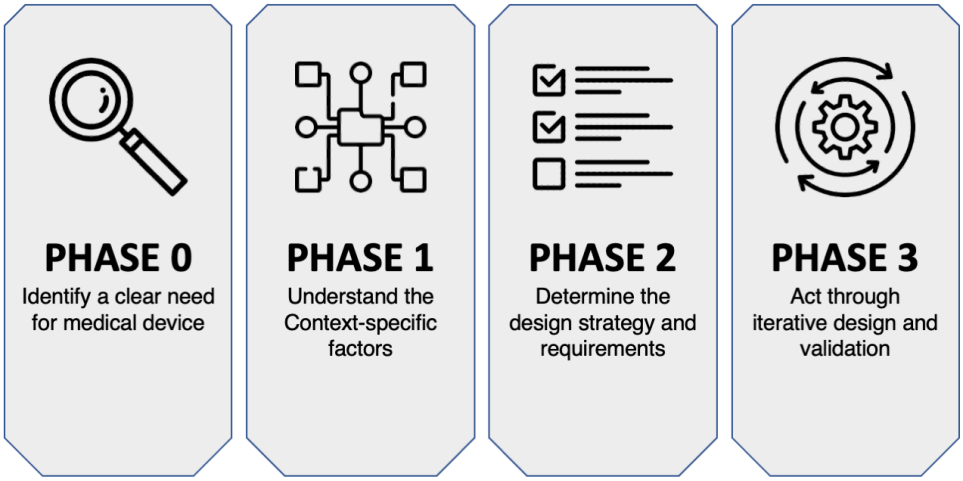

Figure 3.1: The context-driven design approach for medical devices as proposed by Oosting [51]

Ensuring that medical devices are designed to fit the local context and used over time in low-resource settings is beneficial for multiple reasons. Firstly, medical devices will be available to support healthcare provision. Secondly, using medical devices over time can curb the reliance on single-use disposable medical devices that contributes to the 282,447tonnes of waste generated by the healthcare sector in Africa each year [52, 53].

Single-use disposables are representative of a linear (or "take-make-waste") economy in which products are manufactured, used once, and disposed [54]). This inherently unsustainable model of production, consumption, and disposal contributes to global environmental destruction [54]) and is expected to grow with the increasing global population [55, 56].

As established in Chapter one, embracing circular economy (CE) stands as a promising approach towards a sustainable healthcare sector. This can be achieved by designing durable, maintainable, repairable, upgradable, recontextualised, remanufactured, and recyclable devices, as summarised in Figure 2.1. These circular economy principles ensure product, material, and environmental sustainability over time [57] and are therefore essential to be incorporated in the design of medical devices such as the one needed to provide PCB in low-resource settings.

A review of the scientific literature reveals no documented efforts to design a medical device for providing PCB that specifically caters to the contextual needs of low-resource settings while incorporating circular economy principles. For this reason, this research adopts a novel conceptual and practical framing. The research outcome catalogues the development of an actual new medical device that can be used to support the provision of PCB in low-resource setting in SSA, aligning with the United Nations' Sustainable Development Goal 3—Good health and well-being. Furthermore, this study will demonstrate the possibilities and tensions that arise when developing medical devices for low-resource settings while considering context-specific requirements and circularity issues of product, material, and environmental sustainability. In this article, we present the design of a medical device used to support the provision of the PCB in low-resource settings in SSA while intentionally employing context-driven and circular economy approaches.

3.2 Context-driven and circularity approach

A context-driven design approach (Figure 3.1) was applied to design a medical device to support the provision of PCB during gynaecological procedures while leveraging circular economy principles (see Figure 2.1). The context-driven design approach emphasises understanding the nuances particular to low-resource healthcare contexts for innovating appropriate solutions. At the same time, circular economy principles emphasise product, material, and environmental sustainability needed in the healthcare domain. In the next sections, the implementation of this approach is described in two parts, that is, Phase 0–2—understanding essential needs and requirements for the medical device design and Phase 3—concept development and validation.

3.2.1 Phase 0–2—understanding requirements for design

The starting point for designing a medical device to support PCB during gynaecological procedures in low-resource setting was to understand the context of use [51, 58]. This included, for example, the device users (healthcare workers), their needs, tasks involved in administering PCB, why and how these tasks are performed, and barriers encountered by the patients in accessing PCB. To achieve this, extensive field research was conducted in low-resource settings in Kisumu, Kenya, including semi-structured interview discussions in five healthcare facilities. These healthcare facilities were onboarded as partners in this

study and included one county (provincial) referral hospital, one primary hospital, and three health centres (one public and two NGO-based), as shown in Table 3.1. Though PCB and other gynaecological interventions are needed in all sub-Saharan countries, we prioritised Kenya as an entry point due to our vast network with local hospitals, knowledge of local production, and medical device regulatory systems. In the future, we expect to conduct similar research in Western, Central, and Southern regions of SSA.

Table 3.1: Healthcare facilities and respective participants interviewed.

Hospital level	Expertise	No of participants	No of interviews
County (provincial) referral hospital	Medical doctor Obstetricians and Gynaecologists (OB/GYN)	4	9
	Nurse	3	2
	Medial Officer	3	3
Primary hospital (private hospital)	Medial Officer	1	1
Public health centre	Nurse	2	2
NGO-based health centre 1	Medial Officer	1	1
NGO-based health centre 2	Medical doctor Obstetricians and Gynaecologists (OB/GYN)	1	8
Total		**15**	**26**

Within these healthcare facilities, 15 participants (as seen in Table 3.1) were available to be interviewed: five obstetricians/gynaecologists (OB/GYN), five nurses, and five medical officers. The semi-structured interviews were carried out while these healthcare workers performed their respective tasks on PCB or related gynaecological procedures such as the administration of PCB. In some cases, participants were interviewed more than once to gather more information about the PCB and other gynaecological procedures in the local context. Concurrent with the semi-structured interviews, observations were carried out in these healthcare facilities. This included the observation of gynaecological processes such as MVA, which requires the administration of a PCB before uterus evacuation procedures. Likewise, the hospital operating theatre was observed to understand how medical devices for gynaecological procedures are decontaminated, sterilised, and stored before and after use. During interviews and observations, information was recorded as field notes, which were entered into a qualitative data analysis tool (MAXQDA) for analysis.

In MAXQDA, data analysis was performed to generate and specify design requirements. The analysis was done by descriptive coding. During descriptive coding, a text fragment was highlighted and assigned a code [59, 60] when information pertaining to a design requirement was mentioned in the interview discussion notes. Codes were derived from

the context-driven design approach for surgical equipment [51] and summarised in Table 3.2. These codes present context-specific factors for establishing design requirements for developing medical devices specifically for low-resource settings.

Table 3.2: Codes and list of requirements for the design of a medical device to support PCB.

Code	Code description as derived from Oosting (51)	Context-specific design requirement	
		Design requirement	**Identifier**
MD-N	Identify a clear need for certain surgical equipment in a specific context.	Design a medical device that must assist the administration of pain control medication during a paracervical block during gynaecologic procedures. These paracervical block procedures are administered in public and private hospitals in low-resource settings.	M1
CF-C	Identify the (surgical) procedures that need to be performed with the medical device needed.		
CF-A	Identify and design against barriers encountered by patients seeking (surgical) care.	The device must be able to reach and provide pain control in the cervix/uterus.	C1
CF-D	Identify the need to provide and/or organise anaesthesia, sterilisation.	The device must be cleaned and sterilised using locally available disinfection and sterilisation methods. These include high-level disinfection by means of using a chemical solution or the use of pressurised steam or heat sterilisation in an autoclave.	C2
CF-E	Who is part of the team providing surgery, and how are they trained?	The device must be easy to use by medical personnel after training on the device use. Medical personnel include doctors, nurses, midwives, clinical offices, and anaesthetists. These medical personnel are also involved in the device's procurement (via the procurement department).	C3
CF-F	Identify who is involved during procurement and usage of device.	Design the device to be locally accessible and available. Health workers should beable to access the device and/or its related accessories locally without relying on import.	C4
CF-G	Is the infrastructure working properly (water, electricity, etc.)?	Ensure the device can function in areas without electrical power grid connection	C5
CF-H	Identify what other equipment is available and used.	The device must leverage on existing medical devices such as 10-cc syringes locally available. For example, a solution that extends locally available standard 10-cc syringe with standard 18 or 22-gauge needles and provides additional length to administer the paracervical block in the uterus/cervix.	C6
IS-F	What type of accessories are required (consumables or reusable)		
IS-A	Determine if equipment will be bought, donated or leased to the hospital.	Ensure the device is affordable, costing (selling price) approximately between US$4 and 50. This price range is comparable with other devices used in procedures requiring a paracervical block. For example, a manual vacuum aspiration kit.	I1
IS-B	What costs are feasible?		
IS-C	What is required to make the device durable?	The device must be reusable multiple times. For example, 25–400 use cycles or more after disinfection and sterilisation.	I2
IS-D	How will maintenance and repair be organised?	Design the device such that after-sales services can be provided. This includes providing spare parts for repair, maintenance, and upgrade. Or in other cases, recovery (that is through recontextualisation, refurbishment, and remanufacturing) and/or recycling of obsolete parts.	I3
IS-E	Determine how the relationship between the providers of the equipment and the hospital will be during the usage and disposal	Ensure the device must be manufactured through locally available large-scale or decentralised manufacturing processes that support local after-sale services.	I4
		Ensure the device can be included and sold with other devices used in procedures requiring a paracervical block. For example, the device could be sold in a pack with 10-cc syringes or sold in a pack with existing MVA kits.	I5

Using the established codes Table 3.2, the coding exercise was performed. After the first coding round, second and third iterations were conducted. This resulted in a list of coded segments that specify requirements to guide the design of a medical device to support the provision of a PCB. **Supplementary material 1** with all the coded segments can be retrieved from doi:10.3389/fmedt.2023.1183179 [61]. The coded segments were re-written by the design team into actionable design requirements as seen in Table 3.2.

Finally, the design requirements were presented to the healthcare workers in table 3.1 for a member-check. Member-check is a technique for exploring the credibility of results [62]. Data or results are returned to participants to check for accuracy and resonance with their experiences [62]. Each healthcare worker was assigned to read the design requirements (see Table 3.2) and, after that, remove or provide additional requirements for designing a medical device for PCB specifically for low-resource settings. None of the healthcare workers opposed a design requirement or proposed additional requirements that were not already captured.

3.2.2 Phase 3—concept development and validation

Phase 3 comprised activities necessary to move from specified design requirements into physical and tangible design artefacts. Using the established design requirements in Table 3.2, design ideas and prototypes were developed through a Waterfall Design Process [58, 63]. This process allowed for structuring iterative design activities from early conceptual designs through analysis and testing [63] while enabling stakeholders from the five partner healthcare facilities in Kenya to evaluate designs and contribute ideas throughout the process. The activities performed during this concept development stage resulted in a final design called a syringe extension device (Chloe SED®) and manufactured in three specific material options. Figure 3.2 shows the syringe extension device (Chloe SED®) achieved after three successive design iterations. All concepts were 3D-modelled in Solidworks Education Edition.

Homopolymer polypropylene (PP), polyetheretherketone (PEEK), and aluminium (6061 grade) were selected as the material options for manufacturing Chloe SED®. These materials were selected for several reasons. Firstly, these materials were available for manufacturing in low-resource settings by means of 3D printing or injection moulding manufacturing techniques. Secondly, these materials have been widely established in science and practice to be safe in manufacturing medical devices intended to be used on patients seeking care [64–66]. Also, these materials are durable and can be reused multiple times after reprocessing through high-level chemical disinfection (HLD) and chemical or steam (autoclave) sterilisation [67].

Product design validation activities were conducted at five key design evaluation milestones. These were (1) evaluating whether Chloe SED® fulfilled the established design requirements, (2) evaluating the device's structural quality using finite element analysis, (3) evaluating the extent to which the device is reusable and durable after the expected amount of use cycles, (4) environmental analysis of the device through a life cycle assessment (LCA), and, lastly (5) evaluating the clinical utility of the device when used to administer PCB within a clinical trial. Below, are details about each of the evaluations carried out.

Evaluation of final design against the established context-specific design requirement

The first validation step evaluated the extent to which the Chloe SED® met the context-specific design requirements. This evaluation represented an important milestone in the development cycle to assess how effectively the essential needs and design requirements have been captured. The validation activity was designed as a structured questionnaire

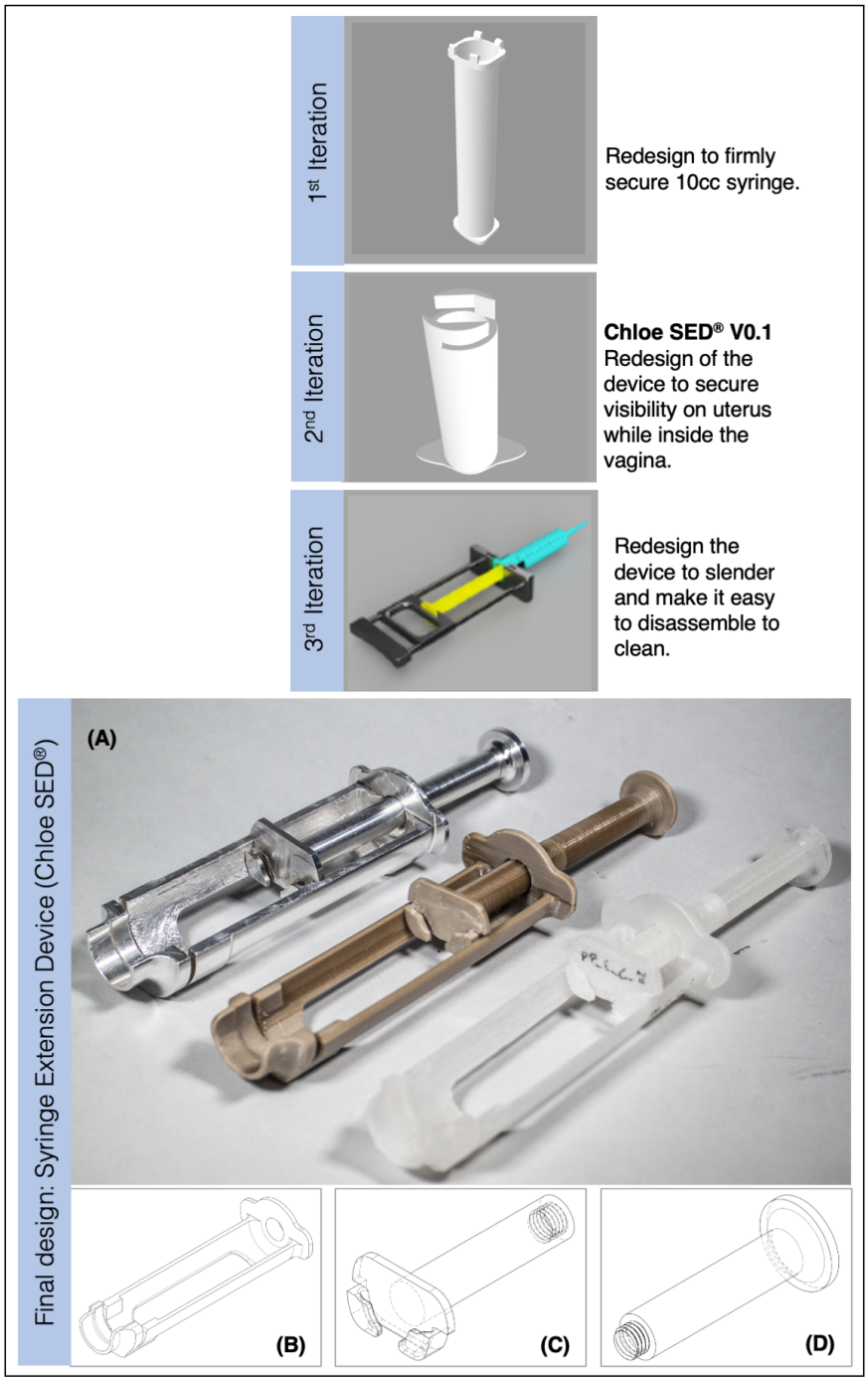

Figure 3.2: Iterative design process resulting in a final design of the syringe extension, where **(A)** from left to right is the Chloe SED® manufactured in aluminium grade 6061 and attached with a 10-cc syringe, Chloe SED® in PEEK, and the rest is the device in homopolymer PP with one of them attached to a 10-cc syringe. **(B)** Body, **(C)** plunger, and **(D)** thumb-press are the modular parts of the device.

feedback after using the device to administer a PCB on a life-size female pelvis model. A total of five respondents at a county (provincial) referral hospital conducted this evaluation: two OB/GYN, two nurses (midwives), and a healthcare researcher on interventions for PCB. This evaluation was conducted under ethical clearance NO. PPB/ECCT/21/10/03/2022 (113).

Each respondent received an initial briefing about the Chloe SED® and the purpose of the evaluative study. Participants were asked to complete two tasks: (1) use the device to perform a simulated administration of PCB on a life-size female pelvis model, and (2) complete a questionnaire that measured the extent to which the final design met the context-specific design requirements. A "Yes" or "No" response on whether the final design met context-specific design requirements C1, C5, and C6 (see Table 3.2) was sufficient. Measuring the extent to which the final design met design requirements, M1, C2, C3, C4, and I1-I5 (see Table 3.2) required opinions with a greater degree of nuance than a simple yes or no answer. As such, participants indicated on a Likert scale whether they "strongly agree," "agree," "neutral," "disagree," or "strongly disagree" that the final design met these requirements.

Finite element analysis to test for the structural quality of the final design

A finite element method analysis in Solidworks Education Edition 2022 was performed to assess the Chloe SED® structural quality. Before analysis was performed, homopolymer PP, PEEK, and aluminium (6061 grade) material properties were applied to the final design model in Solidworks Education Edition 2022. Finite element analysis conditions as set in Solidworks were standard measure mesh type, solid mesh element type, and point load and fixed geometry boundary conditions. This analysis was essential to confirm that the device will not fail, excessively deform, or otherwise be rendered ineffective when impacted with a maximum expected force of 24N (including a safety factor of 3 as established in **Supplementary material 2**, retrieved from doi:10.3389/fmedt.2023.1183179 [61]). Consequently, von Mises stress and displacement values were measured against force exerted on the device. von Mises stress measures the internal resistance per unit area of a body to an external applied force [68] and the displacement is determined in response to the applied force [69].

Evaluation of the reusability and durability of the device after reprocessing

A reprocessing test was performed in a laboratory setting to evaluate the extent to which Chloe SED® is reusable and durable after expected amounts of use cycles. Reprocessing was performed through HLD or sterilisation. These two reprocessing methods are commonly used in low-resource settings [70–73]. It was expected that the device would be reprocessed likewise and thus was evaluated in this study. Only the Chloe SED® manufactured in homopolymer PP and PEEK using 3D printing were reprocessed and evaluated. 3D printing offered an affordable option to manufacture a few prototype samples instead of injecting moulding. However, injection moulding remains a viable option for mass production in future. The device manufactured in aluminium was not reprocessed and evaluated in this study. Research showed that medical devices made from aluminium can be reused over

1,000 times after reprocessing using chemical or steam methods [74] and thus was left out in this reprocessing evaluation study.

The reprocessing of the device through HLD and sterilisation included the following critical steps proposed by the World Health Organization [75]. Firstly, decontaminate the device by soaking it in 0.5% chlorine solution for 10min and rinse it with cool water. Secondly, wash in lukewarm water with detergent, rinse all parts with clean water, and dry by air or with a clean towel. Thirdly, for HLD, soak the device in 2% glutaraldehyde for 20min and remove with sterile gloves or forceps. Alternatively, for sterilisation, soak in 2% glutaraldehyde for 10h and remove with sterile gloves or forceps. Lastly, rinse under running sterile water, then air dry or dry with a sterile cloth, and reuse the device.

Following the established reprocessing procedure, four Chloe SED® prototypes (two in PP and two in PEEK) and 20 3D printed standard American Society for Testing and Materials (ASTM) dog bones samples (10 in PP and 10 in PEEK) were reprocessed. Reprocessing the prototypes was explicitly aimed at evaluating the extent to which Chloe SED® is reusable after reprocessing. The reprocessing of the standard ASTM dog bones was aimed at evaluating the device's durability in terms of tensile strength after reprocessing. In evaluating the extent to which the device is reusable after reprocessing, one Chloe SED® prototype in PP and another in PEEK were subjected to reprocessing using HLD. Similarly, one prototype in PP and one in PEEK were subjected to reprocessing through chemical sterilisation. After every reprocessing cycle, each prototype was assembled, used, and examined for any damages. Damages examined included cracks, breakages, or part shrinkage that would render the device unusable. A total of 25 reprocessing cycles were performed and examined for any damages. Twenty-five cycles were performed since similar devices used for gynaecological procedures requiring PCB in low-resource settings, such as IPAS MVA kit, are reprocessed through HLD or sterilisation up to 25 times [76]. As such was a suitable base for comparison.

Lastly, in evaluating the extent to which the Chloe SED® remains durable after reprocessing, five standard ASTM dog bones in PP and five in PEEK were subjected to reprocessing using HLD. Similarly, five standard ASTM dog bones in PP and five in PEEK were subjected to reprocessing through chemical sterilisation. After 25 reprocessing cycles, a tensile test was performed on each of the reprocessing ASTM dog bones to measure the durability in terms of tensile yield strength.

Life cycle assessment and environmental impact

To assess the environmental impact of the production and (re)use cycles of the Chloe SED®, an LCA [77] was performed. LCA looks at the environmental impacts and resources used throughout a product's life cycle, from raw material acquisition, via production and use phases, to the end-of-life [78]. This was performed using Activity Browser software, which builds on the brightway2 python package for LCA calculations. The main data source was Ecoinvent v3.9.1, augmented with literature values for PEEK from Hytechcycling RefA 08/05/2018 [79]. This study's LCA assessed the environmental impacts of material sourcing (homopolymer PP, PEEK, and aluminium 6061 grade) and production of the final design using injection moulding technique, and its use phases in the healthcare facility.

Because the exact intended manufacturing materials (homopolymer PP, PEEK, and aluminium 6061 grade) or production process (injection moulding) were unavailable in the Ecoinvent v3.9.1 database, proxy materials and processes were used. Granulated PP and wrought aluminium alloy were used as alternatives to homopolymer PP and aluminium 6061 grade, respectively. Pipe and section bar extrusion was used as alternation production techniques for injection moulding the final design in PP and aluminium, respectively. End-of-life was not taken into account due to the complexity of defining the exact end-of-life pathways in the local context within the timeframe of this research study.

The sterilisation process in Ecoinvent v3.9.1 was modelled as follows. A single sliding door horizontal autoclave with an energy consumption of 7kWh per cleaning cycle (1.5–2h per cycle) of 40kg of material was considered. Note that a single sliding door horizontal autoclave was available at the County (provincial) referral hospital as in Table 3.1. 6% sodium hypochlorite was used to model chemical HLD or sterilisation since 2% glutaraldehyde was unavailable in Ecoinvent v3.9.1. Both chemicals are universally accepted for medical device sterilisation [80, 81]. Data on chlorine solution and water, which are needed for chemical HLD or sterilisation, could be inferred in Ecoinvent v3.9.1.

Before the LCA was performed, a quantified description (also known as a functional unit) that serves as the reference basis for all calculations regarding impact assessment was established. The quantified description (functional unit) was defined as the "use of final device design in a hospital for 1 year." The number of procedures requiring using the final design within 1 year of clinical operation was approximately 500. This number was established during the semi-structured interviews within the healthcare facilities detailed in Table 3.1. During these interviews, it was noticed that each healthcare facility performed approximately three to nine procedures requiring PCB weekly. Taking an upper limit of nine procedures per week amounts to 477 procedures per year. For easy calculations, the number of procedures per year was rounded up to 500.

Note that the number of reuse cycles of a medical device varies as per the reprocessing technique and thus affects the number of devices needed as per the functional unit. For example, a medical device in PP can be reprocessed using chemical sterilisation for approximately 25 times [82–84] and in an autoclave approximately five times [85, 86] before deformation. In effect, this means the number of Chloe SED® needed as per the functional unit will be 100 or 20 when prioritising reprocessing in an autoclave or chemical sterilisation, respectively. Table 3 shows the number of devices needed per LCA functional unit when prioritising chemical or autoclave sterilisation. Based on these established parameters, the LCA was performed to measure the environmental impact of the syringe extension device as per the defined functional unit. Detailed calculation of the LCA can be seen in **Supplementary material 3**, retrieved from doi:10.3389/fmedt.2023.1183179 [61]). The selected impact category was Intergovernmental Panel on Climate Change (IPCC) 2021 GWP100, so that the unit of analysis is $kgCO_2$-eq.

Clinical trial

The last validation test in the form of a clinical trial under the approval of the Poison and Pharmacy Board of Kenya—NO. PPB/ECCT/21/10/03/2022 (113) was performed. The clinical trial evaluated the clinical utility and effectiveness of the device in providing a PCB to patients in need. This clinical study is detailed in Chapter 4.

Table 3.3: Number of devices needed as per the LCA functional unit.

Chloe SED® device type (in material)	Device weight (grams)	Reprocessing method and reuse cycles		Number of devices needed per year as per the functional unit
		Method	Estimated reuse cycles as per material type	
Homopolymer PP	151	Autoclaving	5 [85, 86]	100
		Chemical sterilisation	25 [82–84]	20
PEEK	220	Autoclaving	25	20
		Chemical sterilisation		
Aluminium (6061 grade)	451	Autoclaving	1,000 [74]	0.5
		Chemical sterilisation		

3.3 Context-driven and circularity design outcome

3.3.1 Concept development and validation

The outcome of the context-specific design of a medical device to support the provision of a PCB while leveraging on circular economy principles resulted in a syringe extension device (Chloe SED®). This device is snap-fitted on any 10-cc syringe to provide additional length to reach the cervix during PCB and other gynaecological procedures requiring a syringe extension (see Figure 3.3). **Supplementary material 4**, retrieved from doi:10.3389/fmedt.2023.1183179 [61] shows an example of 15 different 10-cc syringes collected from healthcare facilities in the context and used on the device.

Chloe SED® was designed in three modular parts, that is, body, plunger, and thumb-press (see Figure 3.2 **B-D**). The modular design provided the opportunity to maintain, repair, and upgrade the individual parts when needed without affecting the other parts. For example, repairs can be made by replacing a malfunctioning thumb-press instead of disposing of the device as a whole. Upgrades can be achieved by offering Chloe SED® body and plunger parts for syringes smaller than 10-cc without changing the thumb-press. Similarly, these modular parts can be recovered for recycling when the device or its constituent parts break and reach their end of life. The ability to repair, maintain, upgrade, and recycle this device were the circular economy principles successfully integrated within this study. Circular economy principles such as refurbishment or remanufacturing were not integrated into the design of the Chloe SED®. Incorporating these principles in the Chloe SED® required industrial processes that were technically or financially not feasible for local manufacturers. The device is estimated to cost (selling price) US$ 1.5 per device when produced in homopolymer PP, US$ 10 per device in PEEK, and US$ 15 in aluminium grade 6061. These are estimated prices per injection moulding of the device with a minimum production of 1,000 units by a local manufacturing company in Kenya.

3.3.2 Evaluation of Chloe SED® against design requirements

Seeking to evaluate the proposed design, 5 healthcare workers (2 OBGYN and 2 nurses and a medical officer as in Table 3.1) rated the extent to which the Chloe SED® met the established context-specific factors in Table 3.2. All the healthcare workers responded with a "Yes," indicating that the Chloe SED® device met the design requirements C1, C5, and C6 (Table 3.2 details these requirements). These design requirements concerned the

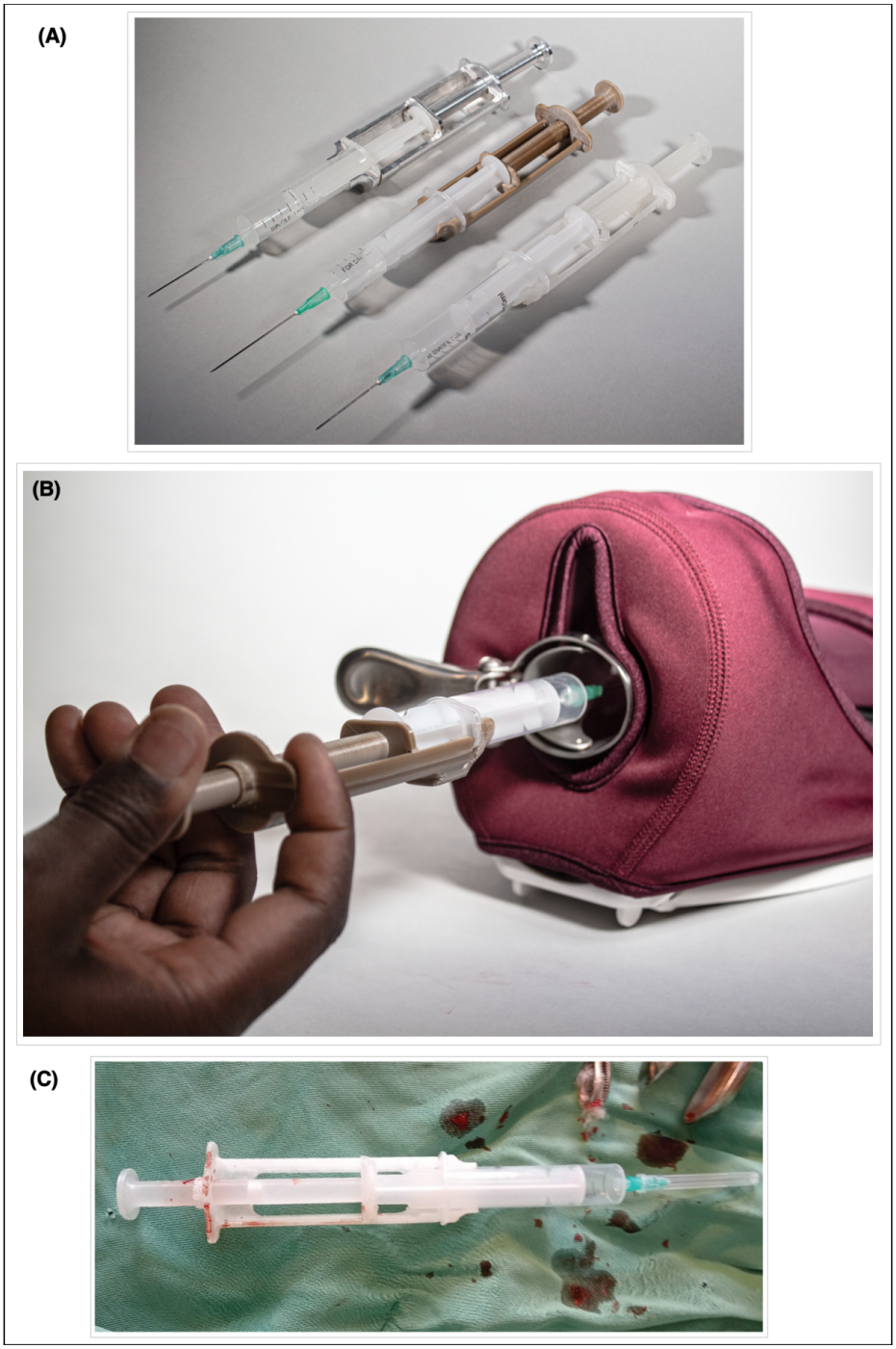

Figure 3.3: Syringe extension device (Chloe SED®) where **(A)** is the different models attached to a 10-cc syringe; **(B)** is a hand size demonstrator on a pelvic model; and **(C)** Chloe SED® used in the local context to provide paracervical blocks.

ability of Chloe SED® to reach and provide pain control in the cervix, function in areas without electrical power grid connection, and leverage on locally available 10-cc syringes, respectively. Similarly, all the ratings except for two either "strongly agreed" or "agreed" that the design met the rest of the other context-specific requirements as seen in Table 3.4. Two context-specific factors were rated "neutral," that is, design requirements I1 and I3 (see Table 3.4). These factors concerned the affordability of the device and the after-sales services in providing spare parts for repair, maintenance, upgrade recovery, and recycling of obsolete parts. These ratings were marked neutral since the participants doubted whether providing after-sales services would influence the initial or operating cost of the device.

Table 3.4: Ratings that show the extent to which the final designed Chloe SED® fulfilled the established context-specific design requirements.

Design requirement		Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Identifier	Requirement					
M1	Chloe SED® is designed to assist in the administration of pain control medication during paracervical blocks during gynaecologic procedures.	0%	0%	0%	20%	80%
C2	Chloe SED® can be cleaned and sterilised using locally available methods of disinfection and sterilisation. These include high-level disinfection by means of using a chemical solution or the use of pressurised steam or heat sterilisation in an autoclave.	0%	0%	0%	60%	40%
C3	Chloe SED® is easy to use by medical personnel after having undergone training on the device use. Medical personnel include doctors, nurses and midwives, clinical officer, and anaesthetics. These medical personnel are also involved in the procurement (via the procurement department) of the device.	0%	0%	0%	40%	60%
C4	Chloe SED® is designed to be locally accessible and available. Health workers can be able to access the device and/or its related accessories locally without relying on import.	0%	0%	0%	60%	40%
I1	Chloe SED® is affordable, costing (selling price) approximately between US$ 4 and 50. This price range is comparable with the prices of other devices used in procedures requiring a paracervical block. For example, a manual vacuum aspiration kit.	0%	0%	20%	40%	40%
I2	Chloe SED® is designed to be reusable multiple times. For example, 25–400 use cycles or more after disinfection and sterilisation.	0%	0%	0%	60%	40%
I3	Chloe SED® is designed such that after-sales services can be provided. This includes providing spare parts for repair, maintenance, and upgrade. Or in other cases, the recovery (that is through recontextualisation, refurbishment, and remanufacturing) and/or recycling of obsolete parts.	0%	0%	40%	20%	40%
I4	Chloe SED® can be manufactured locally available large-scale or decentralised manufacturing processes that support local after-sale services.	0%	0%	0%	80%	20%
I5	Chloe SED® can be included and sold together with other existing devices used in procedures requiring a paracervical block. For example, the device could be sold in a pack with 10-cc syringes or sold in a pack with existing MVA kits.	0%	0%	0%	20%	80%

3.3.3 Chloe SED® analysis on structural quality

Finite element analysis performed to check for the structural quality of Chloe SED® resulted in the following. The analysis showed that when impacted with a maximum expected force of 24N, the Chloe SED® presented stress-displacement levels. Figure 3.4 highlights an example of the finite element analysis outcome for the device in PP and the most likely failure points by displaying the regions of lowest stress-displacement levels (in blue) to greatest (in red). Stress levels between 14.5 and 35.6MPa and displacement of 0.27–0.84mm were presented for Chloe SED® in PP (as illustrated in Figure 3.4), 13.1–27.4MPa and displacement of 0.12–0.38mm for PEEK, and 13.3–29.5MPa and displacement of 0.007–0.02mm for aluminium. See Supplementary Data 5 for the simulations of PEEK and aluminium.

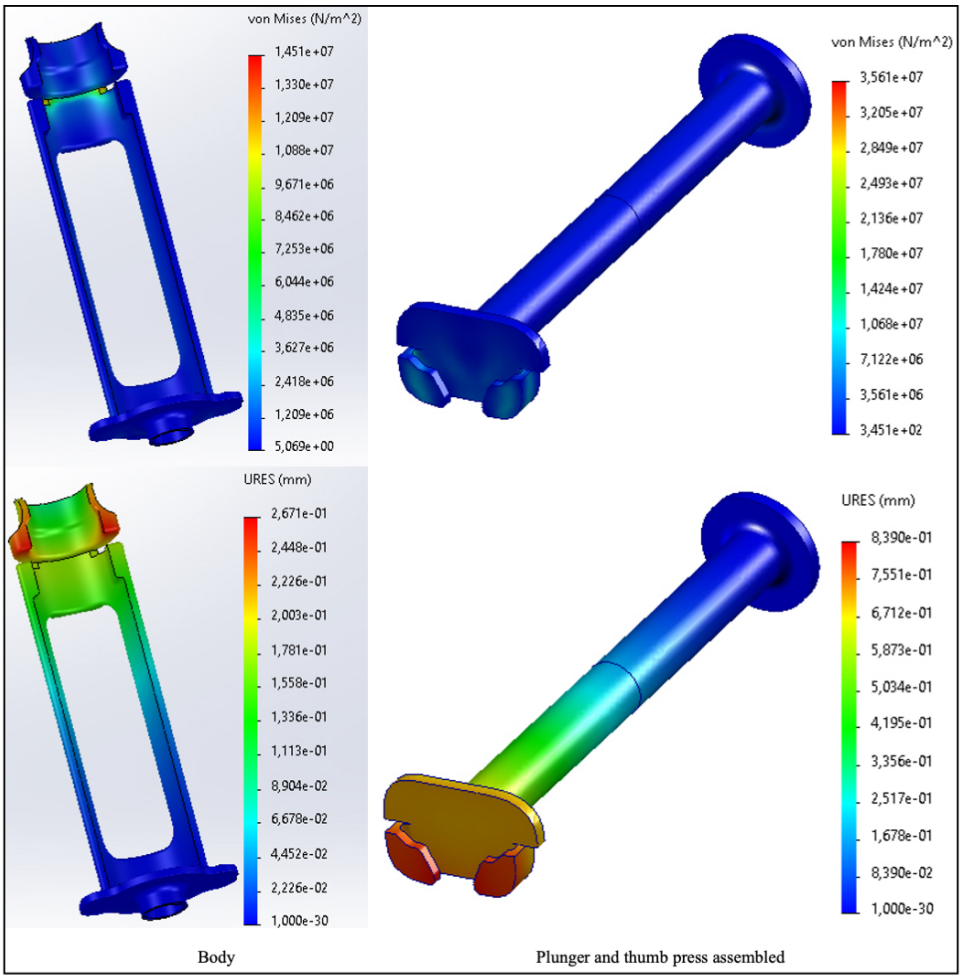

Figure 3.4: Finite element analysis simulation in von Mises stresses and resulting displacement (URES) for the Chloe SED® (body and plunger–thumb-press assembly) in Polypropylene.

The stress levels of Chloe SED® in PEEK and aluminium are acceptable since they are lower than the material yield strength, that is, 70–103MPa for PEEK and 124–290MPa for aluminium. These lower stress-displacement levels imply minimal deformation, and the device's efficacy will be unaffected by the required force needed to operate the device. On the other hand, the stress levels of Chloe SED® in PP (14.5–35.6MPa) fall within the yield material strength of 19–45MPa and thus increase the chances of PP failing.

3.3.4 Chloe SED® reusability and durability evaluation after reprocessing

The evaluation to check for the reusability of the Chloe SED® after repeated use cycles and reprocessing using HLD or sterilisation resulted in the following. All four Chloe SED® (two in PP and two in PEEK) were still in good condition and reusable after the 25 cycles. The devices were functional as a 10-cc syringe could be firmly attached and used to pull in and push out liquid through the syringe needle. Similarly, none of the devices was observed to be broken or had any cracks. On the other hand, slight surface wear on the four reprocessed Chloe SED® was noticed, as seen in Figure 3.5. The shrinkages and surface wear were more noticeable in the Chloe SED® printed in PP material than on the Chloe SED® in PEEK.

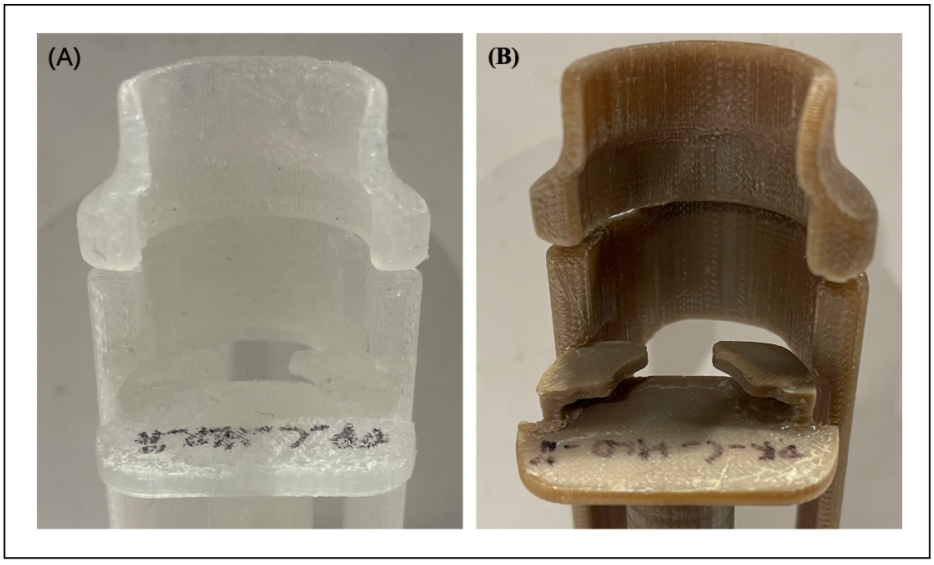

Figure 3.5: Image showing slight surface wear after 25 cycles of reprocessing **(A)** Chloe SED® in Polypropylene and **(B)** in PEEK.

Similarly, the tensile strength test of 20 dog bone samples (10 in PP and 10 in PEEK) aimed at evaluating the device's durability after multiple reprocessing cycles yielded results as follows. PP samples after 25 cycles of reprocessing had a tensile yield strength

ranging from 16.93 to 19.55MPa while PEEK produced yield strength ranging from 75.15 to 90.27MPa. The tensile yield strength values fall within the material yield strength. These results imply that PP and PEEK materials used to manufacture the syringe extension device have an increased chance of failing after 25 cycles of reprocessing using high-level chemical disinfection or sterilisation.

3.3.5 Environmental assessment

The environmental assessment through an LCA as per the functional unit showed that the Chloe SED® in aluminium generated the least environmental impact, regardless of the sterilisation method used as seen in Figure 3.6. These results imply that the environmental impact of Chloe SED® depends on what type of cleaning method is employed to render the device reusable.

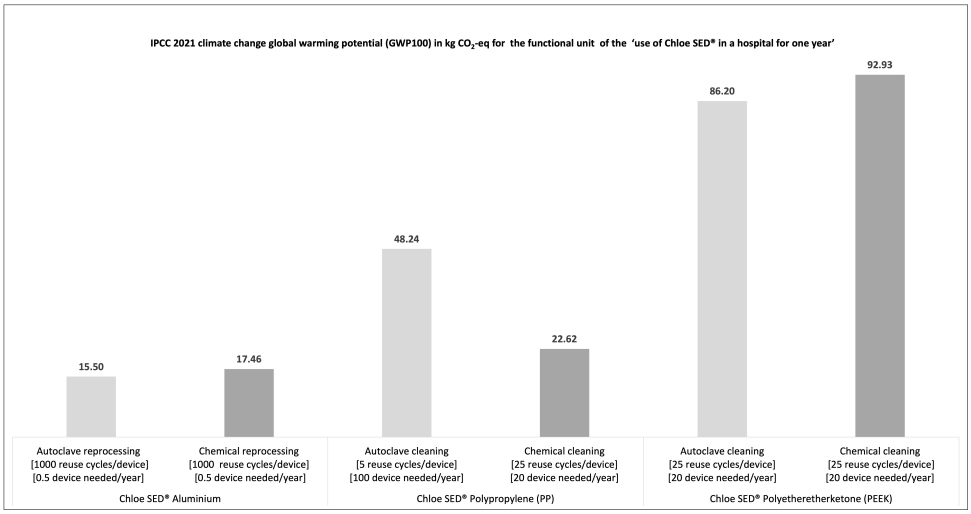

Figure 3.6: Environmental impact in kgCO_2-equivalent for the production and use ofChloe SED® in a hospital for 1 year.

Similarly, the cleaning method employed to render the device reusable affects the number of devices needed to run clinical operations for 1year in a hospital as per the LCA functional unit Figure 3.6. For example, only 0.5 Chloe SED® in aluminium was needed to run a PCB clinical operation for 1 year. This is related to the fact that aluminium material can be reused over 1,000 times after reprocessing through chemical or steam sterilisation. Similarly, 20 Chloe SED® in PP were needed each year in a hospital if chemical sterilisation is prioritised over autoclaving requiring 100 devices. This can be attributed to the fact that PP as a material has lower reuse cycles (five reuse cycles) when continuously exposed to high temperatures in an autoclave than when exposed to chemical reprocessing (at least 25 reuse cycles).

Chloe SED® in PEEK, requiring 20 devices per year, produced the highest environmental impact despite having at least 25 reuse cycles after chemical or autoclave reprocessing.

This can be attributed to the fact that PEEK is labelled as an emerging critical material, and the environmental impact of sourcing the raw material and production is much higher than for PP or aluminium. The environmental impact of material sourcing and production of PP, PEEK, and aluminium is 2.3, 17.4, and 13.8kgCO_2-eq, respectively. **Supplementary material 3**, retrieved from doi:10.3389/fmedt.2023.1183179 [61]).

3.4 Discussion

This chapter presented the design and validation of a medical device, Chloe SED® to support the provision of PCB during gynaecological procedures in low-resource settings in SSA countries, in this instance, Kenya. The aim of this study was twofold: firstly, to develop a medical device that can be available, affordable, and support healthcare in LRS to provide PCB; secondly, to design the medical device from a context-specific and circular economy perspective. Context-specific approach captured nuances particular to low-resource healthcare contexts, and circular economy accounted for product, material, and environmental sustainability. The design of the medical device started with first understanding the use context, which resulted in a list of context-specific design requirements, next through concept development, and validation while leveraging on circular economy principles. The study's outcome produced a medical device used to support the provision of PCB called the syringe extension device Chloe SED®.

Chloe SED® is snap-fitted onto any standard 10-cc syringe found in low-resource settings to provide the additional length needed to reach and administer local pain medication around the cervix during PCB or other gynaecological procedures. With this device, healthcare facilities do not have to rely on spinal needles, usually expensive or unavailable in the local context. Instead, low-resource healthcare facilities can make use of the widely available and affordable standard 10-cc syringes attached to the Chloe SED® and administer PCB.

Chloe SED® addresses the issue of a medical device needed to support women to access PCB, which is vital in sexual reproductive healthcare services such as the treatment of miscarriages and abortions. This is in line with the WHO's call to support and strengthen the access and availability of medical devices [42], which can be used to provide comprehensive sexual reproductive healthcare access for women in low-resource settings in SSA [25, 87]. With the SED costing approximately US$ 1.5 in homogenous PP, US$ 10 per device in PEEK, and US$ 15 in aluminium, healthcare facilities can afford to provide women with PCB services.

For as low as US$ 1.5, healthcare facilities can secure a Chloe SED®, which is reusable between five and 25 times, depending on method of sterilisation. This price point tackles the issue of medical device affordability. Research shows that an affordable initial cost price is particularly important in low-resource settings due to constraints in financial capacity [88, 89]. Healthcare facilities in low resource settings will likely purchase a medical device at a price below or within their set budget [90, 91]. Chloe SED®, particularly in polypropylene (PP), priced at US$1.5, coupled with a 10-cc syringe costing US$0.1, offers healthcare facilities an alternative device for PCB. This cost aligns with the price range of the currently utilised disposable spinal needle, which, at US$1.5–28, is often inaccessible

or expensive and used only once. Providing affordable medical devices resonates with agendas of the Sixtieth World Health Assembly in May 2007, which aims at ensuring that medical devices are affordable to populations in need [92].

On the other hand, the initial cost of Chloe SED® in PEEK (US$ 10) and aluminium (US$ 15) is higher than the initial cost of Chloe SED® in PP (US$ 1.5). Though these costs are higher, it, however, provides healthcare facilities with the option to have access to the device with many reuse cycles. As seen in this study (see Section 3.2.2), the Chloe SED® in PEEK has a reuse cycle of at least 25 times. Estimates in the literature suggest that PEEK materials can be reused more than 25 times [93, 94] and aluminium more than 1,000 times after reprocessing [74]. We anticipate that Chloe SED® in PEEK and aluminium will exhibit comparable reuse cycles, thereby serving as a supportive tool for healthcare facilities offering PCB, particularly in remote settings where access to spinal needles is challenging or unattainable. Suppose affordability issues arise in remote healthcare facilities, the device in PP costing US$ 1.5 remains an option, though having a lower reuse cycle than the device in PEEK and aluminium.

Ensuring many reuse cycles in the design of the Chloe SED® remained a key component, especially when considering aspects of circular economy. In a circular economy, products should remain used in the economic system for as long as possible and thus ensure product, material, and environmental sustainability [95]. This study takes into account these circular economy aspects in different ways. Firstly, by designing a durable device through leveraging durable materials (PP, PEEK, aluminium) with multiple reuse cycles. Secondly, the Chloe SED® modular design (see Figure 3.2 B,C,D) provides the opportunity for maintenance, repair, and upgrade of individual parts without affecting the other parts. As such, the device can remain reused over an extenuating period of time. Thirdly, if the Chloe SED® breaks down beyond repair, its material can be recovered through recycling. Chloe SED® is produced from a single material without colourants and coatings, which makes it suitable for relatively high-quality mechanical recycling. All these factors go a long way to ensuring that the Chloe SED® and its constituents remain in the economic system. However, the environmental impact of this product remains a critical consideration in a circular economy.

The Chloe SED® in PP, PEEK, or aluminium has different environmental impacts regarding CO2 emissions. Environmental impact in terms of CO2 emissions is a contributing factor to challenging problems of global environmental destruction [96]. Considering the manufacturing and use of products with low carbon emission levels is vital in addressing global environmental issues [97], as demonstrated in this study. As seen in Figure 3.6, Chloe SED® produced in aluminium and reused after reprocessing in an autoclave generated the least environmental impact compared to Chloe SED® in aluminium reuse after reprocessing through chemical cleaning and Chloe SED® in PP produced and reused after reprocessing through autoclaving or chemical sterilisation. This is attributed to the fact that Chloe SED® in aluminium material is durable and has a much higher reuse cycle (1,000 reuse cycle) after reprocessing by chemical or autoclave sterilisation than that of PEEK and PP. Based on these facts, the Chloe SED® produced in aluminium and reused over time after reprocessing in an autoclave is more environmentally friendly than in PP and PEEK.

A Chloe SED® produced in aluminium with over 1,000 reuse cycles achieved a more environmentally friendly status than that in PP and PEEK with 25 reuse cycles. This means

that Chloe SED® in aluminium can be considered a desirable product when prioritising environmental issues of material sourcing and production, and clinical use of the device over time. On the other hand, Chloe SED® in aluminium might be less desirable compared to that in PP when considering factors of the initial device cost often emphasised in healthcare facilities in low-resources settings. In addition, the issue of cost is magnified when considering the initial and operational cost of device reprocessing. For example, the initial cost of an affordable autoclave designed for low-resource setting can be approximately US$ 85–620 or more [98, 99] and possess an operational cost of US$ 50 per hour [100].

Similarly, estimates suggest that one cycle of chemical sterilisation can cost US$ 5–10 [101]. In essence, healthcare facilities will incur reprocessing costs in order to render any of the Chloe SED® reusable. As such, a correlation between the material choice used to manufacture the device, the device's initial cost, product durability or reuse cycle, reprocessing method and cost, and environmental impact emerge. This correlation is in line with other studies [102] that describe these correlations as conflicting or divergent trade-offs. These trade-offs are interconnected and can include many other societal challenges. Levänen et al. also noted that these trade-offs could be particularly large in LRS and thus go as far as affecting strategic planning or use of a product [103]. These trade-offs are inevitable and must be continually assessed to deliver a workable product that achieves the greatest synergy between meeting the needs of people and preserving the environment.

The limitation of our investigation is that it only shows the correlation between material choice, initial cost, product durability, and environmental impact specific to design and production before use. Other aspects such as environmental impact or cost associated with the provision of after-sales services such as repair or maintenance will amplify the conflicting or divergent trade-offs in designing medical devices for low-resource settings. The evaluation of the Chloe SED® against context-specific design, as in Table 3.4, already starts to demonstrate this trade-off. In Table 3.4, neutral ratings were provided since the survey participants were conflicted about how providing after-sales services such as repair and manufacturing that can ensure the device remain used in a circular economy would influence the initial or operating cost. Such trade-offs are bound to happen, especially when designing for low-resource settings that are already plagued with resource scarcity, institutional voids, and market affordability [103–105]. However, continuous efforts to understand the local context are vital to navigating such trade-offs and delivering functional products that empower local communities [103].

The context-specific design approach used in this study was vital in understanding the local setting and delivering a functional product such as the SED. This approach was necessarily unique as it provided stepwise guidance to understanding the local setting and the medical device design needs. However, in using this approach, it was remarkable to observe that circularity considerations needed to be explicitly detailed. It is vital to explicitly include circularity issues in the design of medical devices. Transformation of the medical device industry to a more circular economy would advance the goal of providing healthcare while considering product, material, and environmental sustainability [54]. As such, there is an opportunity for future research to develop context-specific design approaches or tools while ensuring product, material, and environmental sustainability.

Such tools can facilitate medical devices to depart from linear operational models into circular ones.

3.5 Conclusion

This study designed a medical device to provide PCB that meets the context-specific needs of low-resource settings in SSA while considering matters of circular economy. Through understanding the context-specific needs in a low-resource healthcare setting and iterative concept development and validation phases, this study catalogues the development of an actual new medical device for PCB called the syringe extension device (Chloe SED®). Chloe SED®, priced at US$ 1.5 per device when produced in homopolymer PP, US$ 10 in PEEK, and US$ 15 in aluminium, is snap-fitted on any 10-cc syringe in LRS to provide PCB for women in need. With this device, low-resource healthcare systems do not have to rely on expensive or often unavailable tools such as spinal needles to provide PCB. By simply attaching a 10-cc syringe to Chloe SED®, healthcare facilities can provide women with PCB required in many gynaecological procedures such as LEEP or treatment of miscarriage or incomplete abortion.

Designing Chloe SED® to be embedded within low-resource healthcare setting was achieved by leveraging on a context-specific design approach. This approach emphasised understanding the nuances particular to low-resource healthcare contexts, such as the availability and affordability of devices that can be used over time to provide healthcare for all. Ensuring that Chloe SED® remained used over time was achieved by leveraging circular economy design principles of durability, repairability, maintainability, upgradeability, and recyclability. These principles ensured that modular parts of Chloe SED® and its constituent material could remain reused for as long as possible in the economic system, thus, desirable from an environmental sustainability perspective.

However, in ensuring that Chloe SED® is desirable for the environment and meets context-specific needs in low-resource settings, correlations between material choice used to manufacture the device, the device's initial cost, product durability or reuse cycle, reprocessing method and cost, and environmental impact emerged. These correlations can be seen as interconnected conflicting or divergent trade-offs and can include many other societal challenges. These trade-offs are inevitable. It is recommended that (biomedical) engineers and medical device designers must continually assess and navigate these trade-offs to deliver a workable product that achieves the greatest synergy between meeting the needs of people and preserving the environment.

Achieving the synergy between meeting the needs of people and preserving the environment in medical device design can be actualised by leveraging on context-specific and circular economy approaches. However, these approaches still operate in a silo. We recommend that designers and researchers can explore developing context-specific design approaches or tools that explicitly consider circularity product, material, and environmental sustainability. Such tools can facilitate medical devices to depart from linear operational models into circular ones.

This study is intended to be seen as an effort to make available medical devices to support women in accessing sexual reproductive health services, specifically in low-resource

settings in SSA. With Chloe SED®, healthcare facilities and organisations can continue supporting women with PCB during gynaecological procedures. The next chapter details the first steps in using Chloe SED® provide women with gynaecological related services under a pilot validation clinical trial with 61 patients.

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4

Efficacy of a novel medical device Chloe SED® for administration of analgesia during manual vacuum aspiration: A randomized controlled non-inferiority multisite clinical trial

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GSO, SKT,RA, BRC, and OF conceived the study. AJ AND OPN collected the data. RA, GSO, and BRC conducted the data analysis. RA, SKT, and GSO wrote the manuscript with all authors reviewing and editing. GSO, SKT, and RA made the final decision to submit for publication.

Data availability and disclosure. Study raw data can be accessed upon reasonable request. Data is treated as clinical and requires adherence to ethical procedures.

Abstract

To evaluate the efficacy of a novel medical device, Chloe SED® for provision of paracervical block during manual vacuum aspiration, a single-blinded, randomised controlled non-inferiority trial was performed at Jaramogi Oginga Odinga Teaching & Referral Hospital and Kisii Teaching & Referral Hospital in western Kenya. This study involved 210 patients who underwent manual vacuum aspiration. Patients requiring manual vacuum aspiration were randomised to receive paracervical block either with Chloe SED® and a standard-length needle, or a spinal needle. Patients were block randomised by provider. Semi-structured interviews were used to collect feedback from the patients and providers. An intention-to-treat analysis was performed. The primary outcome was non-inferiority of pain score during uterine evacuation as measured on an 11- point Numerical Rating Scale (NRS). Secondary outcomes included non-inferiority of pain score at 5 other time points and patient satisfaction. Chloe SED® showed non-inferiority of the primary outcome with a difference in means of 0.3 (-0.2 – 0.9). Non inferiority was demonstrated at the other timepoints except during speculum insertion where the difference in means was 0.7 (0.2 – 1.2). Only a small number of patients required cervical dilation, so non-inferiority was not able to be assessed at this time point. No adverse events were reported. Chloe SED® is a viable alternative to the spinal needle for PCB during manual vacuum aspiration, and can be integrated into standard manual vacuum aspiration practice, improving patient experience.

4.1 Introduction

Approximately 75 million women worldwide experience pregnancy loss each year [1], making the treatment of abortion related complications a leading cause for acute gynaecological admissions globally [2, 3]. Many of these patients are treated using manual vacuum aspiration (MVA). Worldwide over 42 million MVA procedures are performed annually [4]. MVA is expedient, does not require electricity, and can be done as a day procedure [5–7]. However, it is painful, invasive, and requires adequate and humane analgesia[8].

The WHO recommends the use of a paracervical block (PCB) as the minimum mode of analgesia for MVA [9]. PCB involves injecting local anaesthesia around the cervix; conscious sedation may be co-administered where available [9]. However, in Kenya and in many countries, MVA is being conducted with inadequate analgesia making this life saving procedure traumatizing for patients and providers [8, 10]. A major reason for this inequity is the unavailability and cost of spinal needles or needle extenders necessary to provide a PCB [11].

To address this issue, Chloe Syringe Extension Device (Chloe SED®) [12] was developed. The device provides the additional length to a standard 10 cc syringe required to administer PCB with a standard-length needle. This reusable, low-cost device precludes the need for more costly equipment (See Figure 3.3 in Chapter 3).

An initial pilot single-blinded randomised controlled trial (RCT) with 61 patients and 11 providers was completed to validate the initial Chloe SED®) version 0.1 iteration model [3]. Chloe SED® version 0.1 iteration model is depicted in Chapter 3, Figure 3.2 and Appendix A details its RCT. The results of Chloe SED® version 0.1 iteration model informed the design

of the final Chloe SED®) and this efficacy trial. The objective of this study was therefore to evaluate the efficacy of final Chloe SED®) version in the administration of PCB. The study hypothesised that Chloe SED®) would be non-inferior to the standard spinal needle for administration of PCB.

4.2 Trial Method

A single-blinded, non-inferiority RCT was conducted at two sites: Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH), and Kisii Teaching and Referral Hospital (KTRH) in Western Kenya.

4.2.1 Participants

Medical Officers (MOs), Clinical Officers (COs) and nurses performing MVA at either of the two sites were invited to participate in the study. Interested providers were approached by a member of the study team who described the study aims and procedures. Following all questions and discussion regarding the study, interested providers gave written informed consent for participation. Eligibility criteria for providers were English-speaking over the age of 18 and experienced with provision of MVA.

Patient-participants were recruited from women coming to either of the two sites for first-trimester care. Once a patient was assessed by a provider and determined to require an MVA, she was approached by the research assistant (RA) and invited to participate in the study. If the patient was interested in participating, the RA screened the patient to ensure she met the eligibility criteria for participation. These criteria included: aged 18 years and older, requiring MVA, and fluent in English, Swahili, Luo, or Ekegusii. Exclusion criteria were: any contraindication to lidocaine, including known hypersensitivity, infection in tissue adjacent to proposed site of injection, concomitant anticoagulation therapy, abnormal bleeding tendency, severe anaemia or heart disease. Severe anaemia was defined as per the WHO as anaemia associated with symptoms or known haemoglobin concentration less than 7.0 g/dl [13].

4.2.2 Randomization and masking

Patients provided written informed consent and were randomised to receive PCB with either the Chloe SED® (experimental arm) or with a standard spinal needle (control arm). One of the study investigators, Gwer SO, created a computer-generated 1:1 randomization scheme in blocks of 10. A separate investigator, Ramanathan A, concealed the randomization in a series of numbered envelopes for each block. Two RAs, Ongoto PN and Auma J, enrolled participants, assigned them to the trial groups using the sequential envelope numbers, and completed the data collection. Because the Chloe SED® and spinal needle are different in appearance, providers and research assistants could not be blinded to the treatment arm assignment. As patients were in the lithotomy position during the procedure and the instruments were kept out of their view, and thus were blinded to treatment arm assignment. Study team members analysing the data were also blinded to group assignment.

4.2.3 Description of the Chloe SED® Intervention

Chloe SED® was designed by medical providers and design engineers familiar with the local healthcare context, and improvements to this version were made based on feedback from our pilot study (See Appendix A and B. Chloe SED® attaches to a 10cc syringe body and plunger, thus extending syringe length to make administration of a PCB possible using a standard-length 21-gauge needle. These syringes needles are widely available in Kenya at all health facility levels. Chloe SED® can be made from polypropylene plastic or alumium metal. The lower cost polypropylene plastic version, which was tested in this trial, can be sterilized in the same manner as the Karman cannulas that are used for MVA, requiring no additional equipment at the health facilities where MVAs are completed. The sterilization of the metal device can be accomplished with an autoclave. The Chloe SED® used in this study were manufactured from polypropylene by Roboze S.P.A in Italy.

4.2.4 Description of the Control Arm Intervention

Patients randomised to the control arm received PCB with a single-use disposable 22-gauge spinal needle. The needles were purchased at local medical supply shops.

4.2.5 Procedures

Each provider was expected to conduct ten MVAs - five in each study arm. Prior to the onset of the first procedure, each provider was asked about their previous experience with MVA and their perceptions about pain control. Providers were trained in the use of the Chloe SED® by one of the RAs and also completed a refresher training on PCB administration. A second interview was conducted after completion of the ten procedures about the experience of using Chloe SED® compared with the spinal needle.

When a provider determined a patient was clinically eligible for MVA, the RA was contacted and administered the informed consent process. Patient participants then completed an initial face-to-face semi-structured interview about their experience with and perceptions about MVA. Following this, the provider completed the patient's MVA procedure with PCB. Patient pain level was assessed using an 11-point numerical rating scale (NRS) at 6 time points: just before the procedure, during speculum placement, at the time of PCB injection, during cervical dilation, during uterine evacuation, and 30 minutes post-procedure. Thirty minutes after the MVA, the patient completed a second semi-structured interview about their experience with the procedure. All interviews were conducted by the RA in the language of the participant's choosing.

4.2.6 Outcomes

The primary outcome was the mean difference of pain score on the 11-point NRS during uterine evacuation between patients receiving PCB with the Chloe SED® versus with the spinal needle. Participants defined their pain score as an integer between 0 and 10, inclusive. Secondary outcomes included pain scores at the five other time points as well as any adverse event (including failure of the procedure, death, haemorrhage, hospitalization, need for emergent surgery, uterine or cervical injury, lignocaine toxicity), qualitative data on patient and provider experience and perceptions, use of additional pain medications,

patient satisfaction, and provider feedback on Chloe SED® design and usability compared with the spinal needle.

4.2.7 A core outcome set (COS)

For studies about pain related to PCB administration, a COS does not currently exist. In 2021, a COS for general abortion research was developed, and many outcomes that pertained to MVA were assessed in this study [14]. Long-term follow-ups on infection rates or information regarding gastrointestinal symptoms were not collected in this study. Patients with uterine infection at the time of the procedure were excluded from this study based on trial recommendations made by the Kenya Pharmacy and Poisons Board. No patients or members of the public were directly involved in the design of this trial.

4.2.8 Statistical analysis

Non-inferiority testing was used for quantitative analysis of the primary outcome. The study was powered to detect a difference of 1.0 points on the NRS, as change ranging from 1.3 to 2 points on this scale has been previously considered to be clinically meaningful [15, 16]. The sample size was based on a one-tailed alpha of 0.05. A sample size of 91 patients per group provided 90% power to detect a 1-point difference based on a mean pain level of 3.9 on an 11-point NRS with a standard deviation of 2.3. These values are the mean and standard deviation figures obtained in our pilot study of Chloe SED® [3] (see Apendix A. Mean pain scores cited in previous studies ranged from 5.4 to 6.3 with the standard deviation ranging from 2.3 to 3.2 [4, 17, 18]. To account for dropouts and to facilitate an equal number of patients being recruited by each of the 21 providers, we planned to recruit 210 patients: 105 in each arm.

Microsoft Forms 2016 was used for data entry, then exported into Stata BE 18.0 for analyses. Differences in mean pain scores at all time points and their 90% confidence intervals were compared using an intention-to-treat approach. Descriptive statistics were used for analysis of other secondary outcomes including patient satisfaction with the procedure, ease of use of the device, and incidence of adverse events.

A Data Safety Monitoring Board (DSMB) composed of three individuals monitored the study data. A midpoint (when 11 providers had completed the study with 110 patients), meeting was conducted to review safety concerns, no reason was found to stop the study.

4.3 Trial Results

Between May, 2022 and September, 2023, 220 patients were approached by a study provider. Four declined to undergo an MVA while one declined to participate in the study. Of the remaining 215, five were excluded due to age. 210 patients were recruited and randomised, 105 to the spinal needle arm and 105 to the Chloe SED® arm across the two facilities. Due to internet connectivity failure during data entry, case data for two participants were not captured after the point of randomization. Both were in the control arm and assignment was maintained for the purpose of intention-to-treat analysis. All other randomised patients received treatment per protocol in Figure 4.1. Twenty-one providers were recruited and retained until completion of their ten cases. Baseline patient participant characteristics did not differ (Table 4.1). The median age of the participants was 26 (IQR 22, 32). Most

(83.3%) had received at least secondary schooling, had never had an MVA (88.1%), and were multiparous (68.6%). The mean age of gestation for completion of the MVA was 9.6 weeks, with a minority (36.2% control arm, 41.0% experimental arm) of procedures in each group being completed for retained products of conception.

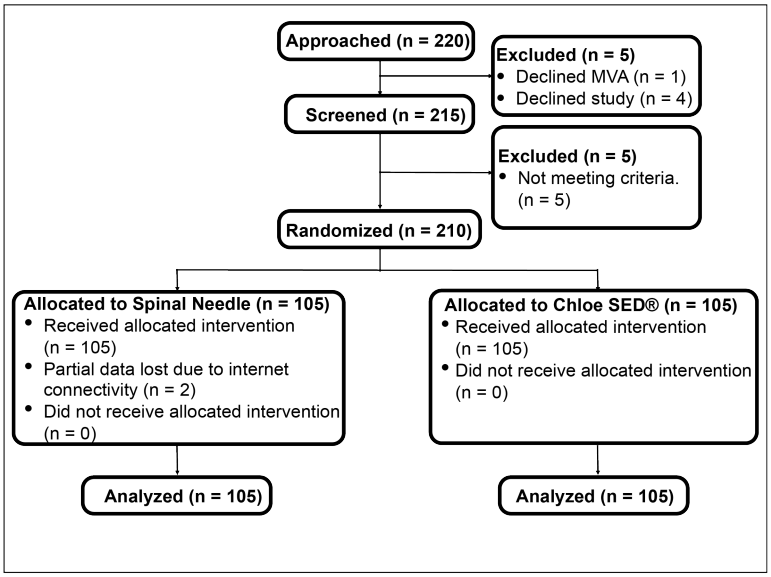

Figure 4.1: CONSORT (Consolidated Standards of Reporting Trials) flow diagram. To be completed...

The intention-to-treat outcomes for NRS during uterine evacuation (primary outcome) and at four other timepoints including before MVA, during speculum insertion, during injection of PCB, during cervical dilation, and 30 minutes following the procedure (secondary outcomes) are summarized in Table 4.2 and Figure 4.2. Pain score during cervical dilation was also measured, with a very low number of patients (6 in the control arm, 3 in the experimental arm) requiring dilation for the procedure. The mean pain score for this time point was 2.5 (SD 3.1) in the control arm and 2.0 (SD 3.5) in the experimental arm.

Non-inferiority of Chloe SED® for administration of PCB was found at the primary outcome and at three out of four of the other timepoints including before MVA, during injection of paracervical block, and at 30 minutes following the procedure. The upper bound of the 90% CI of the difference in means at these timepoints was less than the 1-point difference set as the non-inferiority margin. Non-inferiority was not found during speculum insertion. No adverse events were reported.

Pre-procedure and post-procedure semi-structured interview data from both patients and providers were collected. Twenty-three patients (11.0%) had previously experienced MVA outside of this study and reported a mean procedure pain score for this previous MVA

Table 4.1: Participant Characteristics - Data are median (interquartile range 1,3), n (%), or mean (SD). Median was used for Age; n (%) was used for Parity, Education, Procedures for retained products of conception; mean (SD) was used for Gestational Age.

Characteristics		**Spinal Needle (n=105)**	**Chloe SED® (n=105)**	**Total (n=210)**
Age (y)		27 (22, 31)	28 (22, 32)	26 (22, 32)
Parity	Nulliparous	35 (33.3)	29 (27.6)	64 (30.5)
	Parous	68 (64.8)	76 (72.4)	144 (68.6)
Education	None	1 (1.0)	2 (1.9)	3 (1.4)
	Primary school	17 (16.2)	13 (12.4)	30 (14.3)
	Secondary school	48 (45.7)	56 (53.3)	104 (49.5)
	University or beyond	37 (35.2)	34 (32.4)	71 (33.8)
Gestational Age (weeks)		9.4 (SD 2.1)	9.6 (SD 2.7)	9.6 (SD 2.4)
Procedure for retained products of conception		38 (36.1)	43 (41.0)	81 (38.6)

of 7 (SD 2.6). Twelve of the 23 reported pain equivalent to labour pains or worse using the McGill index. Fourteen of the 23 (60.9%) patients received some form of pain medication during their previous procedure. Only two patients (8.7%) reported having been offered a choice about whether or not to receive pain medication.

In the total cohort of 210 patients, all were asked prior to the procedure what was the most concerning aspect of the MVA procedure for them; 149 (71.0%) reported being most concerned about procedure pain. This was the most common response followed by anxiety or fear of the unknown (13.8%) and medical risks of the procedure (11.4%). During the post-procedure interviews, 202 out of the 210 patients (95.2% spinal needle arm, 97.1% Chloe SED® arm) noted that the procedure was satisfactory or tolerable. Of the six people who noted that they were very unhappy with the experience (3 in each arm), three people noted the speculum insertion was too painful, one noted that the evacuation was too painful and the other two noted that there was overall too much pain experienced during the procedure. Regarding speculum insertion specifically, 13 people in the cohort (4.8% spinal needle arm, 7.6% Chloe SED® arm), specifically commented on the excessive pain of speculum placement when asked for feedback on areas for procedure improvement. One hundred and eighty-seven of the 210 patients (86.7% spinal needle arm, 91.4% Chloe SED® 2 arm) would want to receive PCB for a future MVA procedure.

Table 4.2: Primary and Secondary Outcomes (Intention-to-Treat Analysis). Data are mean pain scores (90% confidence interval) on an 11-point NRS. * Primary outcome. Non-inferiority of Chloe SED® for administration of PCB was found at the primary outcome and at 3 out of four of the other timepoints including before MVA, during injection of paracervical block, and at 30 minutes following the procedure. The upper bound of the 90% CI of the difference in means at these timepoints was less than the 1 point difference set as the non-inferiority margin. Non-inferiority was not found during speculum insertion. The sample size of patients requiring cervical dilation was too small to draw a conclusion about non-inferiority. No adverse events were reported.

Pain Score timepoints	Spinal Needle (n=105)	Chloe SED® (n=105)	Difference of Means	90% CI of the Difference
Before MVA	3.5 (3.2-3.8)	3.7 (3.3-4.1)	0.2	(-0.3-0.7)
During speculum insertion	3.8 (3.4-4.2)	4.5 (4.1-5.0)	0.7	(0.2-1.2)
During injection of PCB	5.0 (4.6-5.4)	4.4 (5.0-5.7)	0.4	(-0.1-0.9)
During uterine evacuation*	3.6 (3.2-4.1)	4.0 (3.5-4.4)	0.3	(-0.2-0.9)
30 minutes after procedure	2.6 (2.2-2.9)	2.7 (2.3-3.1)	0.1	(0.4-0.6)

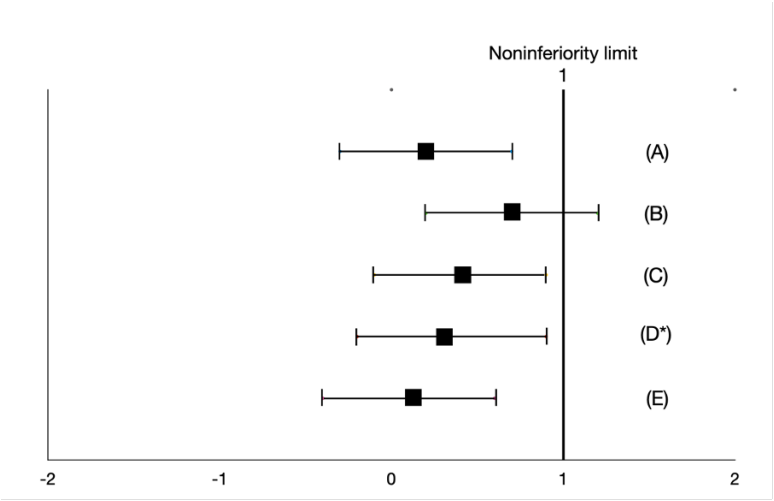

Figure 4.2: Difference in mean pain scores and 90% confidence intervals do not cross the non-inferiority limit at four of the five time points. Time points: (A) Before MVA, (B) During speculum insertion, (C) During PCB injection, (D*) During uterine evacuation, and (E) 30 minutes after procedure. The non-inferiority limit was set at 1 point on the NRS. * Primary outcome .

4.4 Discussion

The results of this trial comparing pain experienced by women undergoing MVA show that PCB administered via Chloe SED® is not inferior to that administered with a spinal needle. Thus, the Chloe SED®, as a reusable and low-cost option, is likely preferable to the spinal needle in low-resource settings where adequate analgesia is frequently not available.

The pain scores reported by women in this study are similar to those in other studies of PCB. Remarkably, despite random patient selection, the baseline pain score for the intervention group was marginally higher and this small difference persisted at all time points. For both groups, the pain was highest during PCB injection with mean scores of 5.0 and 5.4 for the spinal needle and Chloe SED® respectively.

It is not unusual that many participants found speculum insertion to be an unhappy event. Speculum insertion is an intrusive, anxiety inducing procedure that can cause pain even before it occurs [19, 20]. Some women have even likened the speculum to an instrument of torture [21]. In fact, our decision to evaluate this time point in the analysis was a result of qualitative feedback in the pilot study, where patients complained that speculum insertion was extremely painful. For this study participants, the pain scores for speculum insertion were exceeded only by those of the actual PCB injection in both groups, with the Chloe SED® arm (4.5) being higher than the spinal needle arm (3.8). Non-inferiority was not shown at this time point. Explanation for this difference between study arms is unknown, as the patients' characteristics including age and parity were not different. The difference in pain was not related to the Chloe SED® because at the point of speculum insertion, the device has not yet been introduced in the procedure. Data on the size of the speculum used was not collected; we are unaware if a difference in speculum size may have contributed. However, given that the study was randomised in blocks for each provider, it is expected that differences in speculum practice across sites or providers would have been minimal or absent. It is appreciated that pain during speculum insertion continues to be a point of concern for patients undergoing MVA in Kenya, and this study's team plan to direct innovative efforts to this problem and work towards an MVA procedure experience that is compassionate and respectful of women.

The most concerning aspect of the procedure as mentioned by participants was pain. Those who had experienced the procedure prior to the study indicated a mean pain score of seven, with 12 of the 23 indicating that the pain was worse than that experienced during labour. Some describe it as the worst imaginable pain [11, 22, 23], making its management an integral part of the MVA procedure. Nearly all study participants in both arms agreed that MVA under PCB is satisfactory and tolerable and would be willing to receive PCB again in the future.

Pain during MVA is multidimensional with the emotional and psychological aspects influencing procedural pain [21]. Continued study is warranted in the development of a comprehensive procedural protocol that takes these complex factors into account. The development and implementation of Chloe SED® for the administration of PCB is an essential component of such a protocol.

Chloe SED® has a projected cost of US$ 1.5 for the plastic version, which can be reused approximately 25 times, and US$ 15 for the metal version, which can be used approximately

more than 400 times. Chloe SED®, especially the plastic version, paired with a US$ 0.1 10-cc syringe, provides an affordable PCB alternative. It costs less per procedure than single-use disposable spinal needles, which range from US$ 1.5 to US$ 28 and are often unavailable. This lowers the economic barrier for clinics to offer PCB during MVA, enabling compliance with WHO standards for adequate analgesia.

Within the precincts of conventional medicine, there is no room for inhumane treatment during a life-threatening event, particularly when the tools to ease this suffering have been developed. In 2023, the Kenya Obstetrics and Gynaecological Society joined the WHO in advocating for humane pain control during MVA – including the universal offering of PCB with every procedure. As the safe and measured implementation of Chloe SED®® for administering PCB in Kenya and beyond is considered, awareness is maintained of the social stigmas, lack of training, and political fear-mongering that significantly affect women's access to life-saving care. Advocacy, education, and the development of novel and low-cost tools are all essential in meeting the goal of safe and compassionate reproductive care for women - particularly those most vulnerable in low-resource settings.

4.4.1 Study Strengths and Limitations

Strengths of our study included patient randomisation and blinding to treatment group, as well as blinded data analysis. A standard scale for measurement of pain was used and the study had no dropouts. The study maintained a uniform methodology for PCB administration. Provider and patient feedback from the pilot study was used to improve the device and trial methodology - notably in the use of less brittle materials for device construction and in the deeper exploration of speculum related discomfort.

This trial had limitations. Cervical dilation was required in a small minority of patients, and noninferiority at that time point was not accessed. This study's findings may not be generalizable to patients and providers beyond western Kenya, although challenges and conditions encountered in many sub-Saharan African settings are similar. Providers were unable to be blinded due to the difference in appearance between the Chloe SED® and the spinal needle. While this trial was powered to assess device efficacy, 210 patients is inadequate for a comprehensive assessment of device safety, particularly for rare adverse events. Safety data will continue to be collected in accordance with the guidelines outlined in the Lancet IDEAL framework [24].

4.5 Conclusion

Pain is the most concerning aspect for women undergoing MVA. PCB is an internationally recommended mode of pain relief and is acceptable to most women undergoing the procedure. Chloe SED® is non inferior to the spinal needle for provision of PCB and is thus a viable alternative to more expensive tools, increasing access to humane gynaecologic care for women worldwide.

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5

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

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Abstract

The absence of medical devices exacerbates health disparities in low-resource sub-Saharan Africa, particularly affecting vulnerable groups. Designers address this by creating context-specific medical devices for multiple reuse cycles, ensuring accessibility and reducing environmental impact. However, implementing these devices into routine care poses challenges, requiring designers to shift from an artifact-focused approach to roles that facilitate implementation. Through 8 years of action research, I identified five critical roles: 'shaper of collaboration', 'design facilitator', and 'knowledge broker' as essential for medical device design and validation, alongside expanded roles of a 'policy advocate' and 'designer entrepreneur' which are essential for the successful implementation of a new medical device into low-resource routine care. These roles are vital for ensuring environmentally sustainable medical devices in low-resource healthcare settings but can conflict with traditional healthcare systems' reliance on single-use disposables due to stringent regulations. Engaging stakeholders and iterating through feedback loops are crucial for securing buy-in throughout the design and implementation process. Enhancing designers' abilities to perform these roles effectively remains a significant challenge. My experience has been enriched by on-the-job learning, and future research should explore combining formal education with practical learning to equip designers with the skills needed to implement novel solutions, ensuring these ideas are realised in society.

5.1 Introduction

Healthcare challenges in low-resource settings of sub-Saharan Africa (SSA) are a global concern [1]. This context faces complex issues, including limited infrastructure, materials, supplies, human resources [1–3], and a scarcity of essential, accessible, cost-effective medical devices crucial for quality healthcare delivery [4]. The lack of medical devices, in particular, leads to poor health outcomes, disproportionately affecting vulnerable populations, especially women [5]. Major medical device companies from industrialised economies supply more than 80% of medical devices in this context [6–8], but over 40% become inoperable [9]. This is attributed to a lack of design suitability for low-resource healthcare facilities and susceptibility to issues like spare parts unavailability and repair services absence [10]. Subsequently, these devices are discarded as waste, contributing to environmental pollution [11].

The World Health Organization (WHO) recommends designing medical devices for low-resource healthcare settings, prioritising affordability, accessibility, and long-term reusability [12]. The integration of concepts such as context-specific design [13] and circular economy healthcare [14, 15] support achieving WHO recommendations. Designers employ these concepts aiming for device accessibility [16] and reduce environmental impact [15] caused by medical device (premature) disposal. However, often a designer will struggle to integrate these devices into healthcare systems effectively despite these being fully developed [17].

One factor contributing to this challenge is the necessity for designers to transition from traditional roles focused on designing tangible artifacts towards roles that facilitate integration into routine care [18]. 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 suggests that bringing medical devices into low-resource routine care primarily follows a top-down or technology-push approach. This entails major medical device companies, equipped with substantial human, financial, and legal teams, designing devices in highly industrialised economies [19, 20], obtaining approvals from reputable certification bodies such as the European Medicines Agency or the U.S. Food and Drug Administration (FDA), and leveraging these approvals to enter markets in low-resource setting [21].

In contrast, designers, especially those based in low-resource settings, lacking resources comparable to those available to large medical companies, are forced to favour a bottom-up approach. They design devices based on local needs and navigate through stringent regulations to safeguard patient safety and various undefined local approvals and certification pathways toward market entry [21]. Navigating healthcare regulations and approvals is not inherent to design practice, requiring designers to assume roles and competencies beyond their usual scope. Literature addressing the fundamental roles and competencies of designers for developing and integrating medical devices into low-resource settings, particularly within the context of sub-Saharan Africa, is non-existent. Without understanding the fundamental roles and competencies of designers in developing and integrating medical devices into low-resource settings, particularly in sub-Saharan Africa, the lack of life-saving contextual medical devices will persist.

Growing up in resource-constrained environments in Cameroon and Kenya revealed the critical deficiencies in healthcare due to the absence of essential medical devices. An example is witnessing women endure painful gynaecological treatments without pain medication due to the lack of a necessary device. The failure to design and incorporate medical devices for such settings, as advised by the World Health Organization, perpetuates such inhumane treatments, particularly impacting vulnerable women. This underscores the need to comprehend expanded roles and competencies empowering designers to integrate devices into routine care, ensuring availability and accessibility of medical care in low-resource settings. Furthermore, as I observed low-resource healthcare facilities, the stark sight of numerous piles of discarded broken and obsolete medical device waste is undeniable. This exacerbates existing medical device shortages and medical waste issues with significant environmental repercussions and substantial economic impact across Africa [22]).

Addressing this challenge and integrating locally designed medical devices tailored to local needs with minimal environmental impact will require designers to assume roles beyond their usual scope, yet the specifics of these roles and competencies are currently absent in literature. Hence, this research aims to address this gap.

From 2015, I undertook action research in low-resource Kenya to investigate this issue. The aim was to design and facilitate the integration of a medical device (n=1) for administering pain relief during gynaecological procedures, addressing gaps in medical device accessibility and reducing the device's environmental impact. Concurrently, the aim was to contribute to the scientific discourse on the essential and expanded roles and competencies of designers in designing and realising sustainable medical devices into routine care in low-resource sub-Saharan Africa.

Action research, also known as community-based study or action learning [23, 24], was employed in Kenya to foster participative engagement, curiosity, and question-posing on practical issues [25–28]. The action research followed four key stages in a cyclical process: planning, acting, observing, and reflecting. It aligns with my objective to describe my learning journey as a designer, highlighting evolving roles and competencies from the design phase of a medical device and through clinical trials and beyond. The depiction of this action research and reflections employs a combination of formal and personal writing styles to articulate and convey my experiences and reflections from the positionality of a medical device designer from sub-Saharan Africa, designing medical devices for low-resource settings, from a context-specific and environmentally or circular economy sustainable approach.

5.1.1 Theory on expanded designer roles and competencies

A 'role' is often defined as an expected pattern or set of behaviors within a specific domain [29, 30]. Role expansion occurs when a broader set of responsibilities is integrated into a defined role [31, 32]. Evidence indicates that expanded roles can be facilitated by job characteristics [33–35] or, in other instances, due to growing knowledge and skills [33]. The evolving landscape of modern work and flattened organisational structures, characterised by dynamic, uncertain, and interdependent work systems, makes it increasingly challenging to formalise roles [30, 36–38]. As such, roles constantly expand and require new competencies – defined as a functionally linked complex overview of knowledge, skills and attitudes that enable successful task performance and problem-solving [39].

Traditionally, design knowledge and skills have centred around the design of products and services for mass manufacture [40]. This aligns with the historical emphasis on designing objects as an end in itself (product-centric) or sole focus on the users (user-centric) [41]. Whilst this is a traditional endeavour for a designer, such a narrow definition does not accurately represent the innovation landscapes in which contemporary practice is centred [42].

Designers are increasingly tasked with creating experiences and services mediated by tangible, yet often non-physical, products ([43]. Behind these endeavours lie agendas for design beyond manufacturing concerns, promoting social impact, enhancing health and well-being, or advancing pathways towards more environmentally sustainable futures [42]. For example, Arnim Wiek mentions developing system and critical thinking, anticipatory, normative, strategic, interpersonal, and communication skills as key competencies in sustainability for higher education [39], which is also applicable to the design profession. Bakker and Poppelaars propose essential designer competencies for environmentally sustainable products from a circular economy perspective, emphasising preserving economic and environmental value by prolonging product lifespan or integrating them back into the system for reuse ([44]. 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 to ensure environmentally sustainable products aligned with circular economy objectives [45].

Roles and competencies towards sustainability, for example as discussed by Wiek [39]) and Sumter [45], apply to designers addressing challenges in healthcare-related innovation

such as medical devices design. This could facilitate the transition from the current linear 'take-use-throw-away' approach in healthcare towards more sustainable reuse practices. Similarly, could these roles be relevant for designing and implementing medical devices needed to foster healthcare provision in low-resource settings in sub-Saharan Africa? This research aims to explore this as I reflect and share my experiences regarding expanded roles and competencies in designing a medical device for low-resource healthcare settings, aiming to ensure device accessibility while reducing its environmental impact.

5.1.2 Action Research Method

I employed an action research method to design one medical device and implement this device into a care routine to address a healthcare challenge in Kenya while leveraging the environmental sustainability concept of the circular economy. The design of the medical device in Kenya was selected due to my interest in solving health-related issues and my firm grasp of the local healthcare context. Action research, also known as community-based study, cooperative enquiry, action science and action learning, [23, 24] was used to create participative qualities of engagement, curiosity and question-posing on practical issues ([25, 28] at hand. Similarly the method encourages collaboration among various stakeholders ([27] when needed to identify and address the challenges at hand ([26].

This study's action research in the local context employed 'engaged scholarship' [46] across four key stages in a cyclical action research process: planning, acting, and observing while concurrently reflecting and consolidating each step [47]. Due to the exploratory and design-driven nature of this research, the planning step simply entailed starting and, thereafter 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. Discussion and community engagement included contextual observations, one-on-one expert and focus group semi-structured interviews. Data was captured in diaries as field notes and analysed through reflective journaling.

5.2 Outcomes

Below, I detail the planning phase, actions in the field (summarised in Figure 5.1), and critical observations while reflecting and consolidating on the designer's expanded roles and competencies.

5.2.1 Design initiation and planning phase

December 2015 – April 2016

In 2015, I embarked on a journey to design a tangible medical device to address a societal and healthcare challenge in low-resource healthcare setting in Kenya. The aim was to design a device to support the administering of Paracervical Block (PCB) during gynaecological procedures. PCB, a regional nerve block, is used to provide pain relief by injecting an anaesthetic solution around the cervix to numb nearby nerves and alleviate discomfort [48]. During PCB a long syringe needle, such as a spinal needle, is used to reach the cervix to administer anaesthesia. Gynaecological procedures requiring PCB include loop electrosurgical excision procedure (LEEP), cervical biopsies, placement of contraceptives in

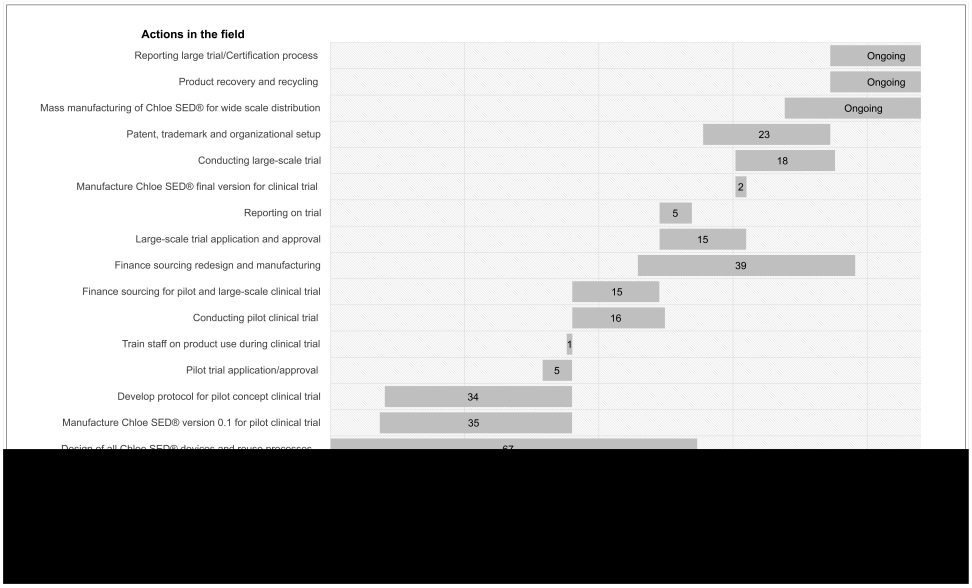

Figure 5.1: Summary of the actions in the field throughout the research against time in months.

the uterus, curettage, or manual vacuum aspiration (MVA) for the treatment of miscarriage or incomplete abortion [49]. Neglecting PCB unnecessarily heightens anxiety and pain, compromising the quality of care [50]. However, the gynaecologists and medical practitioners in low-resource healthcare facilities in Kenya were unable to perform PCB due to the lack of a spinal needle.

Delving deep into the case and 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 medication. As they waited for their turn, the agonising screams of another woman undergoing the same procedure across the room were loud. This further underscored the issue of how women in this setting suffer to get access to essential healthcare services due to medical device unavailability. This was the inception of the design challenge towards understanding the context and the plan to develop a tangible artefact that can be reused overtime and environmentally sustainable.

5.2.2 Actions in the field

December 2015 – Ongoing: Understanding the contextual situation and wanting to bring improved outcomes

To facilitate the transition from the current absence of pain relief medication during gynaecological procedures, I recognised the necessity of comprehending the healthcare setting and the root causes of this issue. My participative qualities, including stakeholder engagement, curiosity, and question-posing to gain insight, meant immersion in the hospital

context to understand gynaecology, medical and hospital processes. However, it became evident that, as a designer, I couldn't simply walk into a healthcare facility and engage stakeholders.

Healthcare professionals such as gynaecologists, nurses, and clinical officers are directly involved in the administration of PCB. They are trained, responsible, and licensed by regulation to be the point of contact for providing patients with care. Auxiliary staff are responsible for cleaning and reprocessing, medical device care, and hospital management staff cover the operation. Without their buy-in, access towards understanding the gynaecological procedure, device reprocessing and hospital management proved impossible.

A collaborative approach with healthcare professionals, emerged as the strategic choice to move forward. Collaborating with the healthcare professional will bring about the ability to jointly investigate the lack of access to pain relief and what kind of contextualised solution is needed. Similarly, the collaboration will grant access to the hospital premises to engage and observe patients and processes surrounding PCB.

In pursuing collaboration with healthcare professionals, I took the role of 'shaper of collaboration', building partnerships and collaborative working relationships across various disciplines to address the healthcare issue at hand. That is, addressing the absence of PCB meanwhile aiming for an environmentally sustainable solution. In this role, key activities included networking, identifying, recruiting, and establishing a local community of healthcare professionals to collaboratively investigate the issue at hand. Once healthcare professionals and communities were identified, I conducted regular visits and meetings to raise awareness about the importance of providing women with proper care, including access to PCB, thereby fostering trust.

Establishing trust with healthcare professionals involved actively listening to and understanding their perspectives regarding PCB and steering towards environmentally conscious solutions. Similarly, establishing trust included regular visits, roundtable open discussions, and collaborative brainstorming sessions with healthcare professionals to raise the issue of PCB and why it is needed. Some of these activities required long travel time of 2-4 hours and long waiting hours to allow healthcare professionals to complete their workload. In some cases, the long travel and waiting hours were futile as the healthcare professionals were tasked with increasing patient load. Despite these challenges, being present and engaged was crucial, demonstrating genuine interest in the healthcare professionals' work. Actions speak louder than words in pressured systems. Simply cohabitating the space with professionals garnered their respect and likely led to trust.

During these regular visits, I communicated and demonstrated real-world case stories on the impact of lack of PCB during gynaecological issues. It was crucial to encourage healthcare professionals to share their experiences with the lack of PCB and how it hinders or slows down their work processes. For example, gynaecologists highlighted their commitment to finding a lasting solution to alleviate the suffering of women. They were troubled by the distress caused when procedures had to be conducted without pain relief. However, the locally unavailability of the required spinal needle hindered their ability to offer pain relief that can alleviate the pain. Also, hospital procurement officers were

primarily concerned with identifying an affordable yet robust solution to this pressing issue since procuring spinal needles proved costly or unavailable locally.

Understanding these frustrations not only shed light on the current issue but also educated me about the intricacies and challenges that healthcare facilities face when providing pain relief medication. Conversations with medical technicians emphasized the importance of device durability, maintainability, and avoiding premature disposal of devices as environmental waste. Additionally, interactions with device reprocessing staff showed the practice of reusing reprocessed medical devices, lessening the environmental impact of disposables.

These conversations and inquisitive discussions identified gaps and sparked a desire among healthcare professionals to drive change. After several discussions for thirty four months (2016-2019), two of the six hospitals I engaged agreed to address the identified challenge collaboratively. With this collaboration, I could formally access the hospital premises and engage with patients and healthcare professionals following the successful application and approval of ethical clearances from the Hospital Institutional Review Board. The other hospitals declined to participate, citing issues such as non-prioritising PCB for gynaecological processes and limited staff capacity to participate in activities other than ongoing clinical procedures, despite several months of discussions.

The collaboration with the two hospitals kick-started a partnership involving obstetricians, gynaecologists, nurses, clinical technicians, and administrative and auxiliary officers, aimed at a solution to ensure women have access to pain relief medication during gynaecological procedures while keeping environmental effects low. This collaboration with healthcare professionals granted me access to invaluable expert knowledge on gynaecology, access to healthcare facilities formalities and contextual needs towards solving the lack of PCB. Healthcare facilities' formalities included medical device cleaning, sterilisation, storage, purchasing and disposal of medical devices, and patient administration. Understanding the contextual situation and wanting to bring improved outcomes continues till the medical device solution is implemented in routine care.

December 2015 – July 2021: From contextual needs to the design of tangible artefacts and reuse processes

Through ongoing discussions with healthcare professionals, it became evident that the primary cause behind the inhumane gynaecological 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 evolved into co-design sessions among healthcare workers, exchanging ideas and potential solutions to resolve this issue. Consequently, my role evolved into a 'Design-facilitator'. This role involved coordinating the design process from a multiplicity of expertise including technology, medicine, clinical and health facility operations, and environmental impact. Activities within this role included, simplifying and establishing a common understanding of the concept of design with healthcare professionals and instilling the confidence to actively pursue a sustainable medical solution.

Facilitating idea generation and collaborative design with non-designerly stakeholders, particularly healthcare professionals, introduced a new experience. My previous endeav-

ours predominantly involved interactions with designers familiar with design terminologies and approaches. However, this fresh context demanded that I interact with medical professionals who primarily associated design with, for example, fashion. In response to this shift, I recognised the necessity of establishing a common understanding of design. Whether in the context of fashion or medical devices, the fundamental essence of design remains consistent – it aims to address specific problems and satisfy particular needs. While the particular needs may differ, the fundamental principle of employing design for problem-solving remains steadfast, as I explained. The medical staff grasped how design could address challenges by simplifying the design concept and relating it to their existing knowledge. This gave them the confidence to actively engage in the design of a medical and environmentally sustainable solution. They voiced concerns about the lack of PCB based on their medical expertise and knowledge of the associated environmental issues and future solutions.

For instance, obstetricians and gynaecologists 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 10cc syringe with a shorter needle to illustrate the extended spinal needle. Through further probing, dialogue and rapid prototyping, it became evident that 10cc syringes were readily available and cost-effective but lacked the necessary length to reach the cervix, resulting in reliance on spinal needles. As the probing continued, I had to rely on the healthcare stakeholder's expertise to understand the gynaecological procedures and continue to guide and facilitate co-design. The challenge here was embracing my vulnerability to guide medical experts, such as gynaecologists, in designing a medical device for PCB, despite lacking expertise in gynaecology. Moving forward with courage and acquiring knowledge and experience in gynaecology as I progressed through the project was a viable path. Over time and with several design iterations, the solution began to take shape as it became apparent that extending the 10cc syringe to reach the cervix could effectively replace the spinal needle. This marked the inception of Chloe Syringe Extension Device - SED®. At this point, the healthcare stakeholders contributed to developing a solution fitting for PCB, born out of a facilitated design process.

Chloe SED® is a reusable medical device snap-fitted on any 10-cc syringe to provide additional length to reach the cervix and provide pain medication during gynaecological procedures, as extensively detailed in the previous chapters. This innovation facilitates pain relief and emphasises affordability and environmental sustainability. The implementation of environmental sustainability came from a knowledge exchange on the circular economy concept. This knowledge exchange on circular economy emphasised the importance of product and environmental sustainability and its importance to the healthcare domain. In facilitating interactive processes to foster knowledge exchange I assume the role of 'knowledge broker'.

As a 'knowledge broker', the focus was facilitating the exchange of knowledge, translation, and mediation of potential tensions when integrating healthcare practices with circular economy principles, product sustainability, and environmental considerations. This included communicating and illustrating the principles of the circular economy, emphasising durability, maintenance, repair, remanufacturing, upgrade, recontextualisation,

refurbishment, and product recycling back into their original material. These principles conveyed the need for product and environmental sustainability to ensure the continuous healthcare. For instance, designing for long-use through product durability can extend the lifespan of medical devices to be used over time. Durable devices would also reduce the financial burden of replacing parts or single-use devices, ultimately minimising environmental waste. Furthermore, durable and functional medical devices could guarantee women access to essential care, addressing challenges associated with device unavailability, as observed with reliance on spinal needles.

Facilitating knowledge exchange not only generated awareness of the importance of environmental sustainability in healthcare but also highlighted potential tensions in the local healthcare setting. For instance, using more durable devices to ensure longevity might mean higher initial device costs than less durable alternatives. At some point, this received pushback from the healthcare stakeholders from moving from the easy 'use and throw-away' disposable culture to a reusable one, which might necessitate an increase in initial device cost and reprocessing procedures. However, with the continuous iteration of the design process over, healthcare professionals continued to explore the circular economy concepts in designing a medical device to support the provision of PCB with limited environmental impact. For example, Chloe SED® in plastic (Polypropylene) costs USD 1.5 and can be reused up to twenty-five times after high-level disinfection and chemical sterilisation as practised in the local hospital. Chloe SED® produced in durable plastic (Polyetheretherketone) and aluminium cost USD 10 and USD 15 and can be used between 25 to 1000 times, respectively (See Figure 2-B2). At this point, the device was comparable to disposable spinal needles, often unavailable or costing between USD 1.5 – USD 28.

The design of Chloe SED® while taking into account circularity, supports the transition from a linear use-and-throw-away economy to a reuse-focused one. This aligns with Sustainable Development Goal (SDG) - 3 for good health and well-being, as well as environmental concerns of SDG Goals 12 and 13 which promotes responsible consumption, limiting environmental impact, and mitigating climate change.

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® V0.1, a version prior to a final one as detailed in Chapter 2, 3, 4 (See Figure 2-A), the critical task was to manufacture the device to clinical standards and thus ensure patient safety. However, a significant challenge arose in producing a limited quantity of replicas for clinical testing. Five copies sufficed for clinical trials. Local manufacturers in Kenya predominantly focused on large-scale production, requiring substantial initial investments exceeding USD 100,000 and a production capacity exceeding 1,000 copies. With limited resources, I explored alternative affordable yet high-quality manufacturing techniques.

Drawing on my understanding of emerging technologies in Kenya, collaboration with local 3D printing manufacturers enabled the production of five samples for USD 25 per device. Crucially, the 3D printing manufacturing process had to adhere to Kenya's regulatory standards for medical devices set by the Kenya Bureau of Standards (KEBS) and the Pharmacy and Poisons Board (PPB). However, 3D printing of medical devices in line with

Kenyan standards was still undefined. As a result, Chloe SED® V0.1 could not progress to the clinical trial process, which required ensuring that the device met medical device clinical standards.

As a 'Policy advocate', I advocated and actively supported establishing new standards or regulations that support medical device design, manufacturing and use within limited environmental impact. This involved analysing the design and manufacturing parameters of Chloe SED® V0.1 to ensure compliance with Kenyan and ISO standards, aiming to set a benchmark for evaluating similar medical devices designed for use in healthcare facilities with minimal environmental impact. Similarly, the proposed standard included advocating for 3D printing technology and material that conforms to medical standards, is durable, reusable, can be recovered and recycled to its material form, and, thus, operates in a circular economy.

In this expanded role as a 'Policy advocate', I actively engaged iteratively with KEBS and the PPB for over thirty five months (2016-2019) to establish standards for medical devices manufactured by 3D printing and aligned with a circular economy. While this initiative advocated for adopting a circular medical device manufacturing process and supporting local designers in achieving small-scale production, it delayed progress to a clinical trial.

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 [51]. In Kenya, the Pharmacy and Poisons Act, Cap 244 [52] mandates clinical evaluations for all medical devices. Conducting a pilot clinical test was imperative to comply with these regulations. Pilot studies are the essential groundwork for planning comprehensive controlled large-scale trials [53].

The execution of clinical trials is confined to licensed medical practitioners under strict regulatory conditions, surpassing my expertise as a designer. My prior role as a 'Design-facilitator' paved the way to co-design and evaluate the device designs within a clinical trial with healthcare professionals. This included formulating study protocols, obtaining clinical trial licenses, training staff for the trial, securing financial resources for large-scale trials, reporting, and product redesign and manufacturing iterations, all completed within fifty-one months (2016-2021). Below, I delve into each step.

October 2016 – August 2019: Development of study protocols and application of pilot trial. These protocols serve as comprehensive guides, delineating critical trial aspects such as methodology, participant selection criteria and consent, ethical considerations, data management, budget, and timelines [54]. While the healthcare professional contributes medical expertise to assess the efficacy and potential adverse effects of using the Chloe SED® V0.1 in gynaecological procedures requiring PCB, I provide insights on engineering, design, and environmental aspects, framing the designed-led solution in measurable clinical terms.

The study protocol development took a total of thirty-four months (2016-2019) that included ensuring the presence of research licenses from the National Commission for Science, Technology and Innovation (NACOSTI), Hospital Institutional Review Board

ethical approval, medical device technical documentation, manufacturer ISO certificates, healthcare insurance for participants, medical practice licenses, indemnity cover for lead medical researchers, and Pan African Clinical Trial Registry (PACTR) registration.

The study protocol application and support letters from the healthcare facilities were submitted to the clinical trial regulatory body PPB Kenya for approval. The application (PPB/ECCT/19/03/01/122) 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 in a month (in 2019). Medical professionals including doctors, nurses and medical officers were recruited to conduct the trial. The training included (re)familiarisation of the clinical procedure of providing pain medication in the cervix. Within the training, I assumed the role of 'knowledge broker' responsible for healthcare professionals in the effective use of medical device on patients and its circular economy use and reuse cycles. This role also communicated the use of device and keenly observed the medical professional's intended and unintended device usage. These observations were pivotal for refining future product final design iterations and optimising reuse cycles.

The trained staff and the medical experts conducted a sixteen month (2019-2021) pilot clinical trial with n=61 patients using the Chloe SED® V0.1. The patient count was determined through non-inferiority testing, which involved quantitatively analysing the primary outcome. This focused on identifying clinically meaningful differences in pain scores [55] between Chloe SED® and a standard spinal needle used to administer pain medication in the cervix. Notably, the pilot clinical trial required funding and I had to take on a role in securing the trial's finances.

September 2019 – April 2022: Finance of the pilot and large-scale trial. The pilot trial, costing USD $5,000, was funded by grants from local and international collaborators. Securing funding resulted from my role as a 'designer entrepreneur', which combines design and entrepreneurial activities to implement sustainable design-led interventions in the healthcare sector. In this capacity, I conduct fundraising and business activities such as seeking grants, establishing a business start-up venture to secure finances for validating and implementation in a low-resource healthcare setting. In raising finances for the pilot trial, plans for financing a large-scale trial were also initiated.

Large-scale clinical trials incur significant costs due to research size, strict regulations and safety requirements [56]. To secure funding for our large-scale randomized controlled trial, we pursued various grants totaling USD 195,000, a process spanning fifteen months from early 2019 to late 2020. Adequate financing for clinical trials is crucial, serving as a pivotal milestone for advancing a product through clinical validation and incorporation into routine care. Without sufficient financial resources, conducting and completing a trial becomes challenging. Further collaborative efforts among local and international partners over a thirty-nine-month period from 2020 to 2023 facilitated the acquisition of technological and financial resources valued at USD 179,000, aimed at supporting redesign and future manufacturing endeavors.

Concurrently with securing funding for the large trial, approval processes for a large clinical trial commenced. The pilot and large-scale trial necessitated its application and

approval. The application procedure for this large-scale trial mirrored the pilot trial detail above and was approved within fifteen months (2021 to 2022).

Jan 2021-Apr 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® V0.1 in providing pain relief medication. The report presented the scientific and clinical evidence supporting the devices' effectiveness and thus contributing to the generation of new knowledge. This was within my capacity as 'design-facilitator' in clinical trial design, execution, and reporting on the outcomes.

Based on the findings from the pilot study, design modifications were implemented to enhance the device, resulting in a Chloe SED® final version (See Figure 2-B2). This signifies the completion of a pivotal phase in spearheading the design of the Chloe SED® (V0.1 up to the final version) medical device for PCB over a period of sixty-seven months (from 2015-2021). Subsequently, twenty-four redesigned and 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 marked a significant improvement compared to the thirty-five months duration in pilot clinical trial phase. Prior engagement in policy advocacy from September 2016 to August 2019 in manufacturing Chloe SED® V0.1 to a standard suitable for testing under a pilot clinical study facilitated this progress. 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 randomised trial

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

September 2021 – August 2023: Device patent and trademark, large-scale manufacturing and organisational structure to engage with other stakeholders

Before proceeding with large-scale manufacturing, ensuring that the Chloe SED® could enter (non) legal agreements with implementation partners was crucial. For example, implementation partners such as producers and distributors required a patent for Chloe SED® with Kenya Intellectual Property Institute (KIPI) and World Intellectual Property Organization (WIPO). KIPI oversees intellectual property rights in Kenya [57], while WIPO promotes and standardises international intellectual property laws [58]. Additionally, this effort involved establishing Chloe Innovation Limited Liability Company (LLC) to spearhead and facilitate (non) legal agreements to progress towards implementation. Completing these activities over a period of twenty-three months from 2021 to 2023 has led to the initiation of 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 Chloe SED® design and (re)use is its material and environmental sustainability. This involved the reuse and recovery of Chloe SED® during the clinical trial and material recycling. Attempts to recover and recycle Chloe SED® raised unresolved questions regarding the responsibility for ensuring sterility. Specifically, it was unclear whether the responsibility lies with the healthcare facility or the recycler in ensuring sterility before or at recovery and recycling. Regulations at moment in the local context did not provide clear guidance. This insight came about from collaborative work between the healthcare sector, manufacturers, recyclers, and regulatory bodies to achieve a more sustainable solution within my role as a 'shaper of collaboration'. Similarly, engaging in the role as a 'policy advocate' to explore this concern with local regulatory bodies is currently ongoing.

Simultaneously 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 intertwines with Chloe SED® certification and market licensing, which is required to enter distribution and use in healthcare facilities.

5.3 Discussion

This study aimed to design and implement a medical device (Chloe SED®) for administering pain relief during gynaecological procedures, addressing accessibility gaps and environmental impact, while elucidating designers' roles and competencies. Over 8 years, the design of Chloe SED® highlighted the essential roles of designers as 'shaper of collaboration', 'design facilitator', and 'knowledge broker' in achieving device design and validation, as well as the expanded roles of a 'policy advocate' and 'designer-entrepreneur' to ensure its societal incorporation (See Table 5.1).

The roles 'shaper of collaboration', 'design facilitator', and 'knowledge broker' are intrinsic to the field of design and were crucial in designing and validating Chloe SED®. These essentially interdisciplinary roles inherent to the design domain as also seen in the work of Wiek [39] and Sumter [45] were not without a steep learning curve when employed in sustainable healthcare and utilizing a bottom-up approach as per this research. For instance, incorporating environmental sustainability into the design process of the Chloe SED® proved complex and sometimes conflicted with my roles as a collaborator, design facilitator, and knowledge broker.

The healthcare system traditionally depends on stringent procedures to ensure patient safety, which has led to the increased use of disposable medical devices. Given the pressing need to shift towards more sustainable healthcare practices, while simultaneously ensuring accessibility, affordability of medical devices and guaranteeing patient safety, led to seemingly irreconcilable demands. Shaping collaboration, facilitating design, and sharing knowledge based on these demands sometimes elicited concerns and pushback from stakeholders. Examples include resistance due to increased workload for cleaning and sterilizing devices for reuse, potential rise in hospital operating costs for ensuring device reuse, and ambiguity regarding responsibility for device sterility before disposal or

Table 5.1: Expanded designer roles and competencies.

Roles		Designer competencies and specialised knowledge needed	Summarised designer activities in the field as per research on a design solution for Paracervical Block (PCB)			
			Activities in the field	*Stakeholders engaged*	*Stakeholder role*	*Barriers encountered during activities*
Essential	**Shaper of collaboration**	Building partnerships and collaborative working relationships across various disciplines to address the healthcare issue at hand within limited environmental impact.	Networking, identifying, recruiting and building a local community of professional healthcare teams towards collaboratively investigating and addressing the lack of PCB and walk towards a solution that is environmentally sustainable.	Healthcare professionals including, hospital management, gynaecologist, nurses, clinical officers, auxiliary staff (cleaning, reprocessing, and device, maintenance, hospital management.	Accept collaboration, provide expert knowledge on gynaecological care and grant access to hospital procedures such as device use and reprocessing and hospital management towards design led intervention for Paracervical Block	Engaging hospital to collaborate is a continuous process until stakeholders buy-in is achieved. In my case, took period of twelve months to successfully onboard two out of six hospitals.
			Establishing trust with healthcare professionals by active listening, regular visits, roundtable open discussions, collaborative brainstorming and understanding their perspectives on the healthcare issue and steering towards environmentally conscious solutions.			Could only get access into hospital premises after trust was established and that this research will keep in line with the goal to provide a solution for Paracervical Block. Discussions on collaboration is cut short when hospital team does not deem it necessary to provide pain medication during gynaecological process even after several months of continuous discussion. Other reasons for not collaboration is the limited staff capacity to engage in other activities other than ongoing clinical procedures.
			Connecting healthcare sector with other key actors, such as manufacturers, recyclers, and regulatory bodies in order to integrate insights leading to more sustainable solution.	Healthcare professionals including, hospital management, Gynaecologist, Nurses, Clinical Officers, Auxiliary staff (cleaning, reprocessing, and device, maintenance, hospital management. Regulatory bodies including the Kenya Bureau of Standards (KEBS) and Pharmacy and Poisons Board (PPB).Manufacturers and distributors and recyclers	Provide insights towards a more environmentally sustainable medical device	Unclear whether the r esponsibility lies with the healthcare facility or the recycler in ensuring sterility before or at recovery and recycling.
	Design-facilitator	Leading design from a multiplicity of expertise including 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 instilling the confidence to actively pursue the design of sustainable medical solution. For example, the design of Chloe SED® to support the provision of PCB.	Healthcare professionals including, hospital management, gynaecologist, nurses, clinical officers, auxiliary staff (cleaning, reprocessing, and device, maintenance, hospital management).	Voicing the concerns on the lack of PCB based on their medical expertise and knowledge regarding and also the environmental the issue associated with the problem and future solution. Contributed to developing a solution fitting for PCB.	Embracing my vulnerability to guide medical experts such as gynecologist to design a medical device for Paracervical Block despite my lack in medical device expertise gynaecology. Yet forging ahead, gaining knowledge and experience in gynecology as I facilitate the design process.
			Conducting and reporting clinical trials.	Hospital Institutional Review Board including the National Commission for Science, Technology and Innovation (NACOSTI) and Pan African Clinical Trial Registry (PACTR)	Provide registration and license and clearance for research and design activities to be conducted in the hospital premise.	The application and execution of clinical trials are confined to licensed medical practitioners under stringent regulatory conditions. This exceeds the designer's expertise, necessitating strict reliance on the hospital medical practitioners who operate within the bounds of rigorous regulatory requirements.
				Regulatory bodies including the Kenya Bureau of Standards (KEBS) and Pharmacy and Poisons Board (PPB)	Provide approval for trial to be performed, evaluate, report and trial outcomes.	
	Knowledge broker	Facilitating the exchange of knowledge, translation, and mediation of potential tensions when integrating healthcare practices with circular economy principles, product sustainability, and environmental considerations.	Facilitate knowledge exchange on the environmental sustainability concept of circular economy and its application in the healthcare domain related to Paracervical Block.	Healthcare professionals including, hospital management, gynaecologist, nurses, clinical officers, auxiliary staff (cleaning, reprocessing, and device, maintenance, hospital management.	Understanding and applying knowledge of circular economy principles in the design and utilisation of a medical device to support the provision of Paracervical Block within limited environmental impact.	Pushback from the healthcare stakeholders from moving front the easy "use and throw-away" disposable culture to a reusable one which might necessitate increase in initial cost and reprocessing. Resolved when the design considered device cost and processes of device comparable to the present cost and processes.
				Regulatory bodies including the Kenya Bureau of Standards (KEBS) and Pharmacy and Poisons Board (PPB)		
Expanded role in societal incorporation	Policy advocate	Advocating and actively supporting the establishment of new standards or regulations that support medical device design, manufacturing and (re)use within limited environmental impact.	Analyzing the design and manufacturing parameters of Chloe SED® in compliance with Kenyan and ISO standards primarily aimed at establishing a benchmark for evaluating similar medical devices designed and produced for use in healthcare facilities with minimal environmental impact. Advocating and demonstration for using 3D printing material that conforms to medical standards, is durable, reusable, can be recovered and recycled to its material form, and, thus, operates in a circular economy.	Regulatory stakeholders including Kenya Bureau of Standards (KEBS) and Pharmacy and Poisons Board (PPB) Kenya	Analyse and establish standards for evaluating the design and manufacturing of Chloe SED® and other medical devices to operate within limited environmental impact in healthcare facilities	No manufacturing standards for 3D printed medical devices necessitating advocating for standards with local regulatory body over an additional thirty-five months. Without this standard, device could not proceed into clinical trial processes. The approval of Chloe SED® in a large-scale trial required only two months to validate the manufacturing process due to the standard established.
	Designer-entrepreneur	Combines design and entrepreneurial activities to implement sustainable design led interventions in the healthcare sector.	Engaging in initiatives such as grants, start-up and venture building competitions to secure finances to implement a circular economy-driven design solution Chloe SED® in a low-resource healthcare setting.	Funding agencies, grantors, investors.	Provide financial resources or opportunities, connection, and access to avenue to implement Chloe SED® within limited environmental impact.	Adequate financing for clinical trialsis crucial, serving as a pivotal milestone for advancing a product through clinical validation and incorporation into routine care. Without sufficient financial resources, conducting and completing a trial becomes challenging, prolonged or even comes to a standstill.
			Enter into (non) legal agreements with implementation partners to ensure implementation of Chloe SED®	Manufacturers and distributors		Necessitated setting up an organisational body as Chloe Innovation LLC to facilitate (non) legal agreements and thus to move towards implementation.

recycling. It required that I continued stakeholder engagement until buy-in was reached, which was an uncertain process. While recognising that change can be instigated from the bottom-up, it also needs to be recognized that this requires continuous engagement with stakeholders, often over a long period (See Figure 1).

In addition to roles such as 'shaper of collaboration,' 'design facilitator,' and 'knowledge broker' in this study, I adopted the role of a 'policy advocate' and 'designer-entrepreneur'. Policy advocacy aimed at supporting the establishment of new standards to support Chloe SED® manufacturing and sustainable (re)use in routine care. This aligns with the need to facilitate the expansion of regulatory capacity for developing or creating new medical device in Sub-Saharan Africa [21]. Similarly, the role of designer-entrepreneur ensures activities and resources to enable SED® reach the hands of healthcare professionals. As such, both roles centred around ensuring Chloe SED® did not end in the product development phase but transitioned into societal use. While these roles were pivotal for this, they significantly expanded my role from the 'core' of the design domain. For instance, familiarizing myself with legal language in policy regulations or manufacturing contracts, and translating them into technical terms for designing Chloe SED® was required. Similarly, understanding how standard development is organized was essential for advocating for standard changes. In the realm of entrepreneurship, communicating the value of Chloe SED® in non-technical terms to attract funding was required. These aspects diverted my focus from core design activities, yet their absence would have made it impossible to integrate Chloe SED® into routine care. In fact, as illustrated in Table 1, all five roles undertaken in this project involved engagement with stakeholders in legal, regulatory, or entrepreneurial spheres.

The roles of 'policy advocacy' and 'designer-entrepreneur' are pivotal in both new product development and its integration into society. Scholarly literature highlights a significant decrease in innovation activities during periods of policy uncertainty [59]. Specific to Sub-Saharan Africa, literature indicates harmonising regulatory standards across African countries can be facilitated by medical device companies or developers taking a leading role [21]. This implies designers can take action towards advocating policies that can support innovation that benefits society, especially when no policy is available. Besides policy advocacy and entrepreneurial activities are essential for understanding societal challenges and opportunities, aligning with the idea that design, engineering, and entrepreneurship are crucial for product advancement [60], especially in developing regions with limited access to basic necessities [61].

The expanded roles identified in this study highlight the designer's roles in addressing critical medical device gaps and driving environmental sustainability, particularly in low-resource sub-Saharan Africa and globally. The expanded roles emerging from this study align with the pathway in which role expansion occurs, that is when a broader set of responsibilities is integrated into a defined role [31, 32]. However, a significant challenge remains: how can designers' competencies be developed to achieve these expanded roles and competencies in crafting and executing environmentally conscious design-led innovation that ensures access to healthcare for all? Current design curriculum should have a course on environmental assessment, aimed at building competencies to identify the material or device environmental or even human impacts and mitigation strategies. In other instances, education could incorporate snippets of product regulations. With such,

designers especially for those aspiring to launch their own ventures, can design products while keeping in mind the environmental, regulatory, and business implications needed to transition into society.

The demands of achieving my project goal required undertaking new tasks and assuming unfamiliar roles, necessitating on-the-job learning by establishing explicit links between theoretical knowledge and practical application in real-life contexts, and consistently yielding outcomes towards designing and integrating the Chloe SED® while considering environmental impact. From a personal level, I did not always transition neatly between roles; sometimes I was thrust into them unexpectedly. Other times did not know my role until I was already in it, feeling I was everything and nothing within a vast, unfair system. These complexities of changing roles are evident in this research and are important to understand for developing designers' competencies to achieve these expanded roles. Although this study does not offer a conclusive answer to the question which capabilities have to be developed to achieve these extended roles and competencies, it emphasizes its importance as a topic for further investigation. This question holds significant relevance for both global design education and, particularly, for SSA, where design education still needs to be incorporated into higher education and presents an opportunity to instil a focus on healthcare design with minimal environmental impact.

5.3.1 Study limitation

This research is based on findings identified from a longitudinal case design conducted through action research spanning the past eight years. Findings from action research are generally not broadly applicable. However, the insights gained from this approach remain pertinent, demonstrating the expanded role of designers in developing and integrating medical devices with minimal environmental impact in low-resource sub-Saharan Africa.

5.4 Conclusion

In conclusion, this study focused on designing and implement the Chloe SED® medical device to address healthcare accessibility gaps and environmental impact. Over an 8-year period, the project highlighted essential and intrinsic designers' roles of 'shapers of collaboration', 'design facilitators', and 'knowledge brokers', crucial for device design and validation. Within these essential roles, integrating environmentally sustainable elements into design process to advance sustainability in healthcare proved complex, encountering resistance due to established norms and operational concerns. Continuous stakeholder engagement was imperative until buy-in for transitioning to an environmentally sustainable device was secured, acknowledging the non-linear nature of a bottom-up approach to change and involving higher-level stakeholders such as policy regulators and industry. Consequently, this expanded the designers' role towards the roles of a 'policy advocate' and 'designer-entrepreneur', crucial for transitioning the device into societal use.

Collectively, these roles underscore the importance encompassing product, processes, diverse expertise, organizational and regulatory aspects of healthcare, which extend beyond traditional designer competencies. Designers involved in developing medical devices with the goal to ensure minimal environmental impact in low-resource settings should be aware of these roles, although the challenge lies in effectively developing the necessary

capabilities to fulfil them. Future research should concentrate on how the designer's capabilities can be developed to undertake these extended roles and competencies especially within formal higher education settings combined with learning-on-the-job activities in practice. Understanding and nurturing these capabilities will be pivotal in shaping future designers capable of addressing the design and implementation of medical devices for low-resource healthcare settings in sub-Saharan Africa issues while prioritising environmental sustainability.

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6

Discussion & Conclusion

6.1 Introduction

This thesis goal was to gain insights into the complexities of designing and implementing medical devices for low-resource healthcare in sub-Saharan Africa using circular economy principles. Four research projects with specific aims that contribute toward this goal were conducted and presented in Chapters 2-5.

The thesis began with understanding the current landscape of circular economy medical device design in literature and progressed to gaining practical experience in designing and implementing such devices. The first study (Chapter 2), a theoretical foundation, aimed to understand the application of circular economy principles in designing medical devices, based on literature. The second study (Chapter 3) adopted a novel conceptual and practical approach for designing a context-specific medical device intervention, the Chloe Syringe Extension Device (Chloe SED®). Circular economy principles were applied while addressing trade-offs during the design of the Chloe SED® device. The third study (Chapter 4) advanced Chloe SED® toward implementation in routine care, comparing efficacy with the standard of care. Finally, the fourth study (Chapter 5) used a reflexive approach through action research to identify the roles and competencies of designers in creating and implementing accessible and environmentally sustainable medical devices for low-resource healthcare settings in sub-Saharan Africa. Figure 6.1 summarises the four studies, their interrelations and main outcomes as detailed below.

6.1.1 Theoretical Foundation

Several scientific literature and industry exposés feature medical devices for low-resource settings in Africa, as seen in WHO's Compendium of Innovative Health Technology [1–3]. These devices are robust, durable, and repairable to endure harsh conditions, ensuring sustained healthcare provision. This design philosophy aligns with circular economy principles (2), which aim to keep products and materials in use over time. To establish a foundation for this thesis, the first study (Chapter 2) aimed to therefore understand the extent to which circular economy principles have been applied in the design of medical devices for low-resource settings in Africa. Towards this aim a literature review was conducted, resulting in an overview of circular economy principles applicable to the design of medical devices for sub-Saharan low-resource settings.

An examination of 45 medical devices, based on a literature review of 29 out of 1,799 screened studies, showed that circular economy principles such as durability, maintenance, repair, and upgrade were commonly applied in designing medical devices for low-resource settings. The primary motivation was to ensure the longevity of medical devices, often not available in low-resource settings. Due to resource scarcity, design of long-lasting, maintainable, repairable, and upgradable devices that ensure sustained healthcare provision over time were commonplace. No attention was given to principles like refurbishment, remanufacturing, and recycling, though available in low-resource settings and vital for healthcare circularity and sustainability. The reasons for this omission could not be inferred in the reviewed studies and a logical next step was to explore this further in the proceeding study.

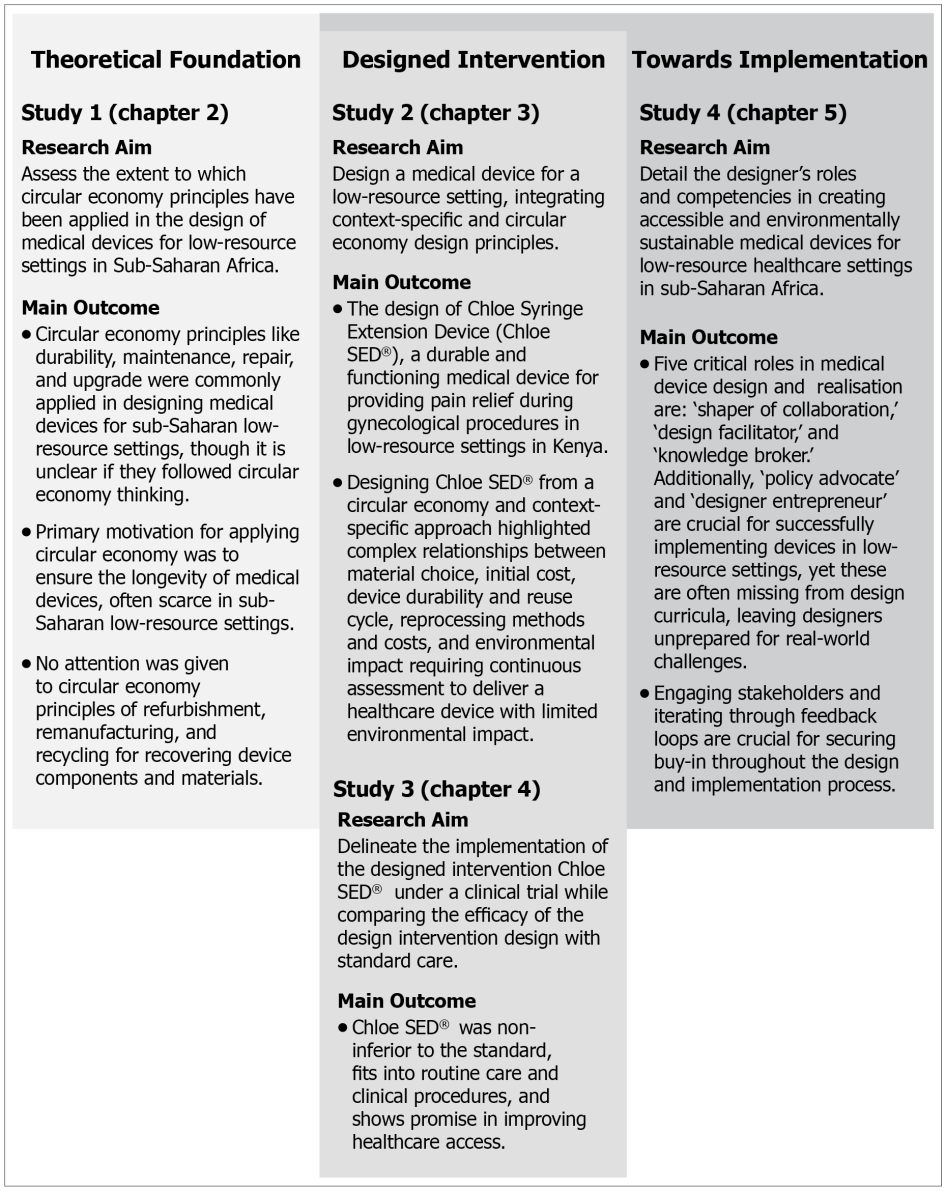

Figure 6.1: Summarises the four studies and their main outcomes.

6.1.2 Designed Intervention

The second study (Chapter 3) used a novel conceptual and practical framework to design a medical device from a circular economy perspective for a real-world low-resource setting. This approach involved learning by 'doing' and drawing relationships in the use of context-specific and circular economy design. The outcome was the Chloe Syringe Extension Device (Chloe SED®), a durable medical device for providing pain relief during gynaecological procedures in low-resource settings in Kenya. Its modular design allows for maintenance, repair, and upgrade of individual parts without affecting others, aligning with the circular economy principles identified in the first study (Chapter 2). Chloe SED® was made from homopolymer polypropylene (PP), polyetheretherketone (PEEK), and aluminium to enable recycling back to material form. In alignment with Study 1, circular economy principles like refurbishment and remanufacturing were excluded from Chloe SED®'s design. This was due to technical and financial impracticalities. However, these principles can still be retrospectively applied as evaluative criteria to identify circular economy principles within the design.

The design of Chloe SED® from a context-specific and circular economy approach exhibited conflicting trade-offs between material choice, initial device cost, durability, reprocessing method and cost, and environmental impact. These trade-offs required balancing desirable but incompatible features toward achieving accessible, affordable, and environmentally sustainable healthcare. Without considering environmental sustainability, the healthcare sector will keep contributing to the planet's degradation, exacerbating existing global challenges that also negatively affect human health.

6.1.3 Towards implementation

Upon designing the Chloe SED® device, the next logical step was to explore its implementation into routine care. Innovation should extend beyond academic discourse to create societal impact. Thus, the third study (Chapter 4) examined the implementation of Chloe SED® into routine care, intending to compare its efficacy with standard care. The study demonstrated that Chloe SED® is non-inferior to the standard, fits into routine care and clinical procedures. Also, the device shows promise in improving healthcare access. Medical devices must fit into routine low-resource healthcare systems to deliver benefits to practitioners and ultimately patients. So far this has not been the case with the dependency on donated medical devices not designed for the local context. The belief that simply donating medical devices to countries with different healthcare systems ensures clinical benefits is misguided, as it overlooks the need for integration into local routine care.

The fourth study outlines the designer's (author's) journey in creating and implementing Chloe SED® for low-resource settings, using a context-specific and circular economy approach. Designers often drive societal change through design-led innovation, but a new design intervention does not necessarily guarantee its incorporation into healthcare. Although designers are not solely responsible for ensuring interventions are adopted, understanding the processes and roles involved remains invaluable.

Detailing the designer's journey throughout this study revealed a shift between five critical roles: 'shaper of collaboration', 'design facilitator', 'knowledge broker', essential for medical device design and validation. Additionally, the roles of 'policy advocate' and

'designer entrepreneur' were crucial for successfully implementing a new medical device into low-resource routine care, though often lacking in design curricula, leaving designers unprepared for the real world.

Role shifts are not always seamless; they may occur unexpectedly due to stakeholder demands and contextual factors. At other times, a shift to a new role is anticipated only once one is already in it, leading to a sense of being everything and nothing within a complex and inequitable system. The finding in this study encourages designers to remain within a context and navigate design and implementation challenges rather than stepping out after a final concept. Constant stakeholder involvement is crucial for securing buy-in. So too, is navigating design and implementation feedback loops with stakeholders as they encounter their own challenges to implementation. The design process is iterative, extending beyond the final concept. Final concepts still need to be realised, monitored, and continuously improved to enhance impact over time. In the next section, the main outcomes are synthesized into an overall conclusion.

6.2 Overall main conclusions

Zooming out of the four studies, their outcomes (Section 6.1), are summarised in four insights of interest: improved access and circularity; achieving circular medical devices requires balancing trade-offs; environmental sustainability in contextually aware design; and aligning design curriculum with the real world.

6.2.1 Improved access, a consequence of circular economy application

Resource scarcity is a fundamental issue in low-resource settings [4], necessitating efforts to improve resource supply and ensure continuous access. This thesis identifies that medical device shortages in sub-Saharan Africa pose a significant threat to healthcare provision, exacerbating inadequate delivery, increased mortality, and challenges in effective diagnosis and treatment.

Addressing the issue of medical device shortage, as seen in this thesis, shows circularity aspects focusing on durability, maintainability, repairability, and upgradability, with the end goal of product availability and longevity to ensure access to healthcare. This demonstrate a connection between circularity and access – defined as the ability to obtain and appropriately use good quality health technologies when they are needed [5]. By applying circular economy principles, the medical devices designed for example, in Chapter 2 and 3 aimed to improve access to safe, high-quality, and reliable medical technologies and services.

From this thesis, circularity is interlinked and leads to access in several ways. Medical devices within a circular system provide sustained access, as their extended use maximises product value, allowing hospitals to deliver essential healthcare that is often scarce. Functioning medical devices facilitate access to healthcare, while recycling their materials at end-of-life contributes to the availability of feedstock, creating a closed loop that minimises resource input and waste output. While circularity typically focuses on material

conservation and economic value, this thesis shows how circular economy principles can contribute to ensuring access, especially in contexts of scarcity.

An example of circularity linked to access can also be found in the concept of product servitisation and circularity. Servitisation, where a company shifts from a product-centric to a service-centric model[6], can promote product longevity and improve access [7]. In this model, customers pay for product use, and durable, long-lasting designs can also empower underserved communities by providing access to high-quality products [8]. Cases illustrating this servitisation and circularity concept that leads to access can be traced in practice in low-resource settings. For example, Drop Access's locally produced, repairable, and upgradable solar healthcare fridges in Kenya offer vaccine cooling to hospitals that cannot afford conventional refrigerators [9].

In the circularity and servitisation model, businesses may struggle to create viable access models due to high upfront investments, while resource-constrained customers may find subscription fees burdensome. Similarly, in circularity and medical device design for healthcare access, factors such as the (initital) cost, durable materials, sterilisation methods and several other contextual factors must be carefully considered to ensure succesful prolonged product use to provide healthcare access.

6.2.2 Achieving Circular Medical Devices Requires Balancing Trade-offs

A circular medical device, as demonstrated in this study, depicted a product, components and materials reused over time to provide healthcare and with reduced environmental impact. Achieving this requires carefully balancing trade-offs among technical factors and environmental, patient, and healthcare system needs.

Material choice, cost, durability, reuse cycles, reprocessing methods, and environmental impact are crucial in ensuring that a medical device remains affordable, accessible, and circular as seen in the previous chapters. These technical and environmental factors, are, however, often interrelated and occasionally conflicting, necessitating careful balancing. On the other hand, achieving balance sometimes necessitates difficult moral compromises, especially when prioritising the patient's health.

In Chapter 3, the design of Chloe SED® aimed to create an affordable and accessible medical device for providing paracervical blocks to women in need. While the aluminium version of Chloe SED® is more durable, fits in the circular economy aimed at product, material and environmental sustainability, its affordability is realised only over its full lifespan. The initial cost of the aluminium version is higher than the polypropylene version, which, though less durable and less environmentally friendly, has a lower upfront cost. Low-resource settings may opt for the polypropylene version due to budget limitations and the need for immediate affordable healthcare solutions to save a life. Consequently, applying circular economy principles in medical device design involves a moral trade-off between sustainability and saving lives.

The choice to save a life at the expense of environmental sustainability though morally sensible is however paradoxical. Evidence show an unsustainable planet due to climate

change can cause a significant number of excess deaths [10]. Unsustainable healthcare may heal some people but as the mortality cost of carbon rises, it will kill many others.

The thesis tackles affordable, accessible and environmentally sustainable healthcare by proposing solutions that balance saving lives with environmental sustainability, ensuring medical devices gradually reduce emissions. Whether using the Chloe SED® aluminium or the less sustainable polypropylene version, the goal is to save lives with minimal environmental impact. Optimal changes from gradual emissions reductions to full decarbonization when mortality is considered remains key [10].

6.2.3 Contextually aware design must include technical, system, societal, and environmental sustainability considerations

Context-aware design refers to the idea that devices or systems can respond to their environment and user's situation [11].

Several context-aware approaches for designing medical devices for low-resource settings have been proposed in the literature. For instance, "A Framework for Designing Medical Devices Resilient to Low-Resource Settings" (See Figure 6.2(A)) identifies key considerations such as user type, health technology management (including spare parts, consumables, and maintenance), design factors (portability, robustness), reliance on external resources (power and water), material durability, cost, and lifespan (functionality of its parts)[12]. Similarly, "Towards A Framework for Holistic Contextual Design for Low-Resource Settings" [13] emphasises technical and manufacturing factors, socio-cultural, institutional, economic, and public health systems, alongside physical factors like infrastructure, geographic location, and weather. The context-driven design method [14], also aligns with these principles, highlighting the importance of designing with local conditions in mind.

The aforementioned context-aware approaches cover essential technical, structural, and geographic aspects of medical device design. While this thesis concurs with these factors, it also advocates for expanding the frameworks or new ones that include circularity elements that will not only ensure that medical devices are available to provide healthcare but also to operate in an environmentally sustainable way. For example, none of the frameworks takes into account product use, end-of-life and its environmental sustainability. Similarly, aspects of product recovery, such as remanufacturing and refurbishment circularity considerations, are absent.

Building on Piaggio et al.'s "Framework for Designing Medical Devices Resilient to Low-Resource Settings" [12], which already includes product lifespan, an extended version—such as in Figure 6.2(B)—could integrate product recovery, end-of-life management, and environmental impact, thereby enhancing considerations for product, material, and environmental sustainability. Although developing such a framework was beyond the scope of this thesis, Figure 6.2(B) illustrates a potential extension that incorporates these elements. Further research and analysis are, however, still required.

Although technical and financial limitations in low-resource settings hinder the application of recovery principles like remanufacturing and refurbishment, as seen with the

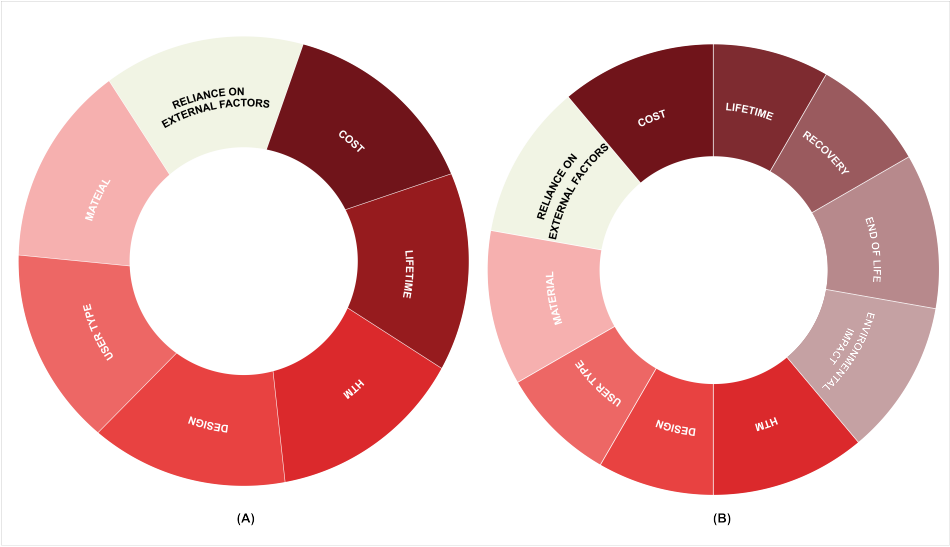

Figure 6.2: (A) The original "Framework for Designing Medical Devices Resilient to Low-Resource Settings," by [12] and **(B)** this thesis' first attempt to update the framework to include, product recovery, end-of-life and environmental impact.

6

Chloe SED® (Chapter 3), these principles are essential for product, material, and environmental sustainability. This underscores the need for further analysis to incorporate these aspects into the existing or a new framework that promotes medical device circularity and environmental sustainability.

Medical device operating in a circular and environmentally sustainable manner can promote healthcare provision in alignment with planetary sustainability. Healthcare contributes to global environmental impacts, ranging from 1% to 5%, and exceeding 5% in some national contexts (i.e. the Netherlands) [15]. This will increase if nothing is done, especially with the increase in healthcare demand due to population growth and ageing.

Updating or creating new frameworks for context-aware design that integrate circularity and environmental sustainability is essential. This ensures both new and existing medical devices meet healthcare needs while remaining environmentally sustainable. Low-resource settings have historically depended on medical device donations from high-income countries, often resulting in waste. Devices that are not tailored to the specific needs of these settings frequently arrive obsolete and are discarded, losing value that could benefit both people and the environment. Reassessing the technical, systemic, societal, and environmental aspects of donated medical device for low-resource healthcare settings is crucial to reducing obsolescence and waste.

The transition to accessible and environmentally sustainable medical devices for low-resource healthcare requires various factors, including access to sustainable materials, production techniques, and systems, as well as non-technical aspects such as implementing

sustainable healthcare policies. Achieving this will necessitate transdisciplinary collaboration, as shown in this thesis, where designers, regulators, and healthcare workers jointly work towards sustainable medical device solutions.

6.2.4 Aligning design curriculum with a real-world healthcare design practice

As outlined in Section 6.2.3, achieving accessible and sustainable healthcare design requires both technical and non-technical factors. However, as discussed in Chapter 3, design education often prioritises technical aspects like problem analysis and solution development. Chapter 4 demonstrates how the Chloe SED® progressed from problem definition to implementation, requiring roles such as 'policy advocate' and 'designer entrepreneur' to realise interventions in low-resource settings in sub-Saharan Africa.

Aligning design curricula with real-world skills, such as entrepreneurship and policy advocacy, is essential but raises concerns about expanding without compromising core design values. This thesis found that competencies in these areas are often gained through hands-on experience, rather than in classrooms or studios. Integrating formal education with real-world learning is complex, requiring action-based learning, time investment, and managing uncertainties. Internships, industry placements, and practitioner mentoring can bridge this gap and should be part of design education. Achieving synergy between education and real-world experience is key to equipping designers for sustainable innovation, though it also requires quality monitoring [16].

In addition to expanded roles, often gained through hands-on experience rather than formal education, real-world learning is complex, requiring the management of both design processes and systems. As shown in Chapters 3, 4, and 5, the design of Chloe SED® required a holistic approach to the design process and local healthcare and regulatory systems, considering interactions from multiple perspectives while focusing on patient needs. This reflects an understanding of system and design thinking, known in literature as systemic design—a thinking orientation that integrates design and systems theory for complex social and service systems [17]. Designers adopting a systemic design approach can maintain an overview of complex systems, enabling them to "zoom out" for a broader perspective and "zoom in" to create practical solutions—all while managing the time constraints and varied roles of designers as demonstrated in this thesis.

Expanded roles in design challenge curricula to prepare designers for planning and estimating timelines and costs beyond the final product, as design and implementation are iterative processes. Similar to software development, where continuous updates are prioritised [18], how might this approach apply to medical device design field especially considering high-end, complex electro-mechanical devices in remote areas? The Chloe SED® case illustrates that some steps can be planned, but unexpected factors like policy or entrepreneurial hurdles can extend timelines and increase costs. Designers must anticipate and account for these extensions within fixed deadlines and budgets. Field experience shows that even large international companies struggle with anticipating the unexpected. Even though some Large companies can partner with local suppliers for maintenance and updates, yet limited infrastructure and reaching the distant communities remains challenging and thus medical device obsolescence. Iterative design and implementation

beyond the initial concept remain key and, thus, valuable areas for further research to prepare designers for real the real world.

Role expansion also affects stakeholder organisations, introducing changes in workflows and also aspects of circularity and environmental sustainability. Involving stakeholders from the outset, as seen in the Chloe SED® case, fosters solution ownership and limits role shifts. Co-creation and feedback loops aligned the product with hospital processes without increasing workloads. Cross-disciplinary efforts between design, healthcare, and regulators demonstrate the value of transdisciplinary approaches. Despite feedback loops, resistance can still arise within stakeholder organisations especially if role shift is needed and require systemic change, thus, extending timelines and costs. How will designers manage these extensions and cost, and how will education prepare them? While this thesis does not address these questions, it proposes directions for future research.

Initiatives aim to bridge the gap between designer competencies and practical skills are emerging. For instance, Kenyatta University in Kenya plans to launch a Global Medical Innovation (GMI) course that covers MedTech design from problem identification to implementation [19]. This course will address factors beyond artefact design, including local regulatory issues, investment in small-scale prototyping and manufacturing, and integrating entrepreneurial elements through collaboration with local incubators and industry. This poses an opportunity to learn and understand, for example, a model for timeframe extension beyond the recommended project timeline and cost associated, and thus prepare designers for real-world healthcare design practice. Similarly, this thesis aims to contribute to and support the development of a (bio)medical engineering and healthcare design program with African universities, equipping designers with competencies for medical device design in sub-Saharan Africa.

6.3 Contributions

6.3.1 Contributions to science

This thesis contributed to the research in the field of the design of circular and environmentally sustainable medical devices for low-resource settings in sub-Saharan Africa. The thesis contributions include;

- A first overview of the current application of circular economy principles in the design of medical devices for low-resource settings in sub-Saharan Africa (Chapter 2). Although sustainability aspects have been examined, a clear connection to circular economy thinking in medical device design remains unestablished. This thesis provided an overview, the motivations, gaps, and advancements needed to develop circular medical devices that promote accessible healthcare with minimal environmental impact in low-resource settings in sub-Saharan Africa.
- Comprehensive evidence on applying circular economy principles to medical device design that achieve basic healthcare within environmental sustainability limits (Chapter 3). The successful design of the Chloe SED®—a device for delivering paracervical blocks—demonstrates that circular economy principles can effectively minimise environmental impact while enhancing healthcare access.

- Provides empirical grounding on the trade-offs involved in designing circular medical devices for low-resource settings (Chapter 3). While the circular economy aims to conserve product and material flow, the underlying tension within the healthcare domain in low-resource contexts is the first. It reveals the interconnected yet conflicting trade-offs among material selection, initial costs, device durability, reuse cycles, reprocessing methods, and environmental impact. This evidence highlights the need for continuous assessment of these factors to develop healthcare devices that conserve resources while minimising environmental impact.

- Aligns and deepens insights into the expanding role in the design domain resulting from the integration of medical device design and implementation from a circular economy perspective (Chapter 5). Role expansion involves incorporating a wider range of responsibilities into established roles. Transitioning to circular medical devices includes both traditional technocentric designer roles and those that support integration into routine care.

6.3.2 Contributions to practice

This thesis not only contributes to academic knowledge but also offers practical insights for practitioners involved in healthcare systems. The following practical implications are highlighted.

- Circular economy in medical device design: A set of key circular economy design principles and definitions pertinent to medical device design, addressing the specific considerations of healthcare, regulatory, and safety standards (Chapter 2). While the concept of circular economy has traditionally focused on resource conservation for consumer products, this thesis provides terminologies and definitions aligned with the specific demands of medical device product design.

- Medical device design steps in the real-world: An overview of the steps involved in designing and implementing a medical device, from problem identification to routine care (Chapters 3 and 5). This process, often ambiguous in practice, is clarified through the case study of Chloe SED®, offering practical guidance for practitioners, academics, and organisations in structuring medical device design projects.

- Advanced knowledge on key design roles: Chapter 5 highlights essential design roles and competencies arising from integrating circular economy principles in medical device design and implementation. These include roles such as ‘shaper of collaboration’, ‘design facilitator’, and ‘knowledge broker’, vital for design and validation. Expanded roles like ‘policy advocate’ and ‘designer entrepreneur’ are also crucial for implementation in low-resource settings, though often overlooked in traditional design education but essential in practice.

6.3.3 Contributions to society

This thesis not only advances science and practice but also makes a significant societal impact as follows.

- New Medical Device: The Chloe SED® offers women in low-resource settings access to paracervical blocks, a crucial pain management procedure during uterine evacuation. The thesis reports that 105 patients successfully received paracervical blocks using Chloe SED®, indicating its potential to improve humane gynaecological care. Efforts are underway to expand its availability across Sub-Saharan Africa.
- Empowering local healthcare: The thesis details the design and implementation of a new device in collaboration with healthcare professionals, thereby equipping the local healthcare community with essential knowledge to use design for solving local problems.
- Towards new local policies: Ongoing testing and approvals of Chloe SED® from local regulators have expanded the manufacturing methods and materials used for locally produced medical devices in Kenya.
- Incorporating on-the-job learning into formal education: The Chloe SED® has served as a teaching case for over 500 students, bridging the gap and preparing designers for real-world healthcare practices. Likewise, Lessons from the design journey in this thesis are contributing to the development of a program in sub-Saharan Africa, aimed at equipping designers with innovative competencies and practical skills to address medical device design for the region.

6.4 Recommendations for future work

Based on the observations from the research presented in this dissertation, several recommendations can be made.

- *Update or propose new context-specific design approaches to include circular and environmentally sustainable aspects.* Existing literature on medical device design for low-resource settings emphasises context-specific frameworks, methods, and approaches. However, these often overlook the importance of circularity and environmental sustainability. Given the increasing pressure from resource depletion and scarcity alongside rising healthcare demands, it is essential to update these frameworks to incorporate circular economy and environmental sustainability. An example is demonstrated in Figure 6.2.
- *Exploration of Circular Design for High-Value Electromechanical Devices in Low-Resource Settings in Sub-Saharan Africa.* Designing high-value electromechanical devices involves significant technological challenges, integrating both electronic and mechanical systems. These devices are for example, capital-intensive and require reliable infrastructure, such as energy supply, maintenance and repair services, and recycling needs which are often lacking in low-resource settings. Applying circular economy principles to their design under these constraints presents considerable difficulties. Research in this area could yield insights into the conflicts between circularity and contextual factors in advanced technologies and could guide Africa in developing high-value technologies that provide affordable, accessible healthcare in resource-limited environments. Future studies should investigate the complexities,

trade-offs, and tensions in designing such devices, which often include intricate components and demand advanced systems for longevity.

- *Policy and regulations to advance circular medical design and environmentally sustainable healthcare for low-resource settings.* Policy is crucial for advancing circular design and environmentally sustainable healthcare in low-resource settings. While design is a key factor, effective policies and regulations are also essential to incentivise circular economy practices. Research should focus on identifying existing and necessary policies and regulations to facilitate the transition to environmentally sustainable medical devices and healthcare. A comprehensive policy and regulatory framework that promotes circular medical device design and its implementation will support the growth of Sub-Saharan Africa's emerging medical device design sector.

- *The transition from medical device design for low-resource settings healthcare to universal healthcare for all.* The transition from designing medical devices for low-resource settings to achieving universal healthcare for all requires addressing disparities between low-resource and affluent areas within Sub-Saharan Africa. Progress in poverty alleviation and technological advancement underscores the need for a unified healthcare system. Medical devices and healthcare services should be standardised to ensure equitable access regardless of local conditions or income levels. Currently, the disparity between healthcare services in low-resource and affluent communities exacerbates inequalities. Research aimed at developing medical devices for a cohesive healthcare system will help reduce these disparities and ensure equal access to healthcare for all.

- *Approaches to manage continuous iterative medical device design and realization beyond final concept.* Medical device design goes beyond achieving a final design into realisation. Likewise, design iterations are commonplace and require stakeholder buy-in and organisational change. Sometimes, this will necessitate project extension with a long timeline and associated cost. How will designers be prepared for these uncertainties in low-resource settings? Approaches that can guide uncertainties remain invaluable.

In conclusion, this thesis offers insights into designing medical devices for low-resource settings, highlighting the complexities of incorporating a circular economy. It identifies gaps in circularity and demonstrates a clear link between circular design and access to healthcare through devices designed for longevity.

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A

Appendix to Chapter 3

Validation of a novel medical device (Chloe SED®) for administration of analgesia during manual vacuum aspiration: A randomized controlled non-inferiority pilot study.

Ramanathan A, Samenjo KT, Bailey RC, Imbamba J, Odenyo S, Koksal E, Diehl JC, Omoto JO, Gwer SO (2024). Validation of Chloe SED® V0.1: A randomized controlled non-inferiority pilot study. *Frontiers Pain Research: Clinical Trials, Methods, and Evidence Synthesis, Volume 5 - 1326772.* doi:10.3389/fpain.2024.1326772.

RA, SKT, RBC, IJ, and GSO conceived the study. IJ and OS collected and curated the data. RA, GSO, and BRC conducted the data analysis. RA, SKT, and GSO wrote the manuscript, and BRC, IJ, OS, KE, DJC, and OJ reviewed and edited it. RA, SKT, and GSO had final responsibility for the decision to submit for publication.

Data availability and disclosure. Study raw data can be accessed upon reasonable request. Data is treated as clinical and requires adherence to ethical procedures.

Abstract

Millions of women worldwide annually undergo manual vacuum aspiration (MVA) with no pain medication, which is a violation of their basic human dignity. We designed a novel device (Chloe SED®) to administer paracervical block (PCB) during MVA in countries where pain medication is not typically given due to the high cost of the necessary tools. We conducted a single-blinded, randomized controlled non-inferiority trial including 61 patients at two hospitals in Kisumu, Kenya, to validate Chloe SED® for administration of PCB during MVA. PCB administered with Chloe SED® was compared to PCB administered with a standard spinal needle. Patients requiring MVA were block randomized in blocks of six, each provider completing six PCBs—three with the Chloe SED® and three with the standard spinal needle. The trial was registered with the Kenya Pharmacy and Poisons Board, ECCT/19/03/01 . An intention-to-treat analysis was completed. The primary outcome was the non-inferiority of the pain score during uterine evacuation with a non-inferiority margin of 2 points on an 11-point numerical rating scale. Secondary outcomes included

the non-inferiority of the pain score at four other time points and patient satisfaction. Chloe SED® showed non-inferiority of the primary outcome with a mean pain score during evacuation of 3.8 [90% confidence interval (CI): 3.1–4.6] compared with the spinal needle at 4.1 (90% CI: 3.5–4.7). Non-inferiority of the pain score was shown at all time points. Most patients expressed a desire for the continued use of the device to administer PCB for MVA. No adverse events were noted. In summary, the Chloe SED® appears non-inferior to the spinal needle and desirable for the administration of PCB during MVA.

A.1 Introduction

Approximately 75 million women globally experience pregnancy loss each year [1]. Manual vacuum aspiration (MVA) is a common method for the treatment of first-trimester pregnancy loss worldwide. It is arguably the least expensive and most expedient method of evacuating the uterus, associated with fewer complications and side effects than dilation and curettage [2]. MVAs are widely used in low-resource countries, are often performed by nurses or midwives, and do not require electricity or an operating theater. Currently, more than 300,000 women undergo MVAs in Kenya annually [3, 4].

MVAs cause considerable pain from the manipulation of the cervix and uterine suction [2]. They are often performed in Kenya (and elsewhere in low-resource settings) without any analgesia [5, 6]. The reasons cited for these pain control gaps in Kenya include the belief of the surgical provider that pain medication is unnecessary; the lack of availability of medication and equipment; and inadequate training in the provision of pain control including paracervical block (PCB) [6]. Importantly, in a study of Kenyan women, all who underwent MVA without pain medication desired it for future procedures, even at additional cost (6). Similarly, in an Ethiopian study, fear of pain was a factor for women in choosing medical over surgical treatment for miscarriage [7].

In March, 2022, the WHO published new safe abortion guidelines recommending that PCB be used universally for pain control during MVA [8]. This marks a significant change from the previous guidance, which did not specifically recommend any analgesics [9]. However, clinics in low-resource settings face barriers in following these recommendations due to cost and supply chain interruptions in sourcing the spinal needles or needle extenders required for PCB.

We have developed a novel, reusable, low-cost syringe extension device (SED), named Chloe SED®, that attaches to a 10-cc syringe to provide the additional length required to administer a PCB with a standard-length 21-gauge needle (Figure A.1). The device is designed to be reused multiple times after sterilization, taking into account environmental sustainability issues and moving away from the use-dispose approach currently practiced in the healthcare sector. Previous chapters outline the context-driven approach to the design of this device and newer versions [10]. Chloe SED® has the potential to expand access to humane pain relief for women requiring MVA and even other gynecologic procedures such as excision treatment of cervical precancer, diagnostic uterine curettage, and intrauterine device insertion. The primary objective of this study was to validate the functionality of Chloe SED® for the provision of PCB during MVA in a pilot study. Functionality was assessed via measurement of patient pain scores during MVA utilizing

either Chloe SED® (experimental arm) or a standard spinal needle (control arm) to administer PCB.

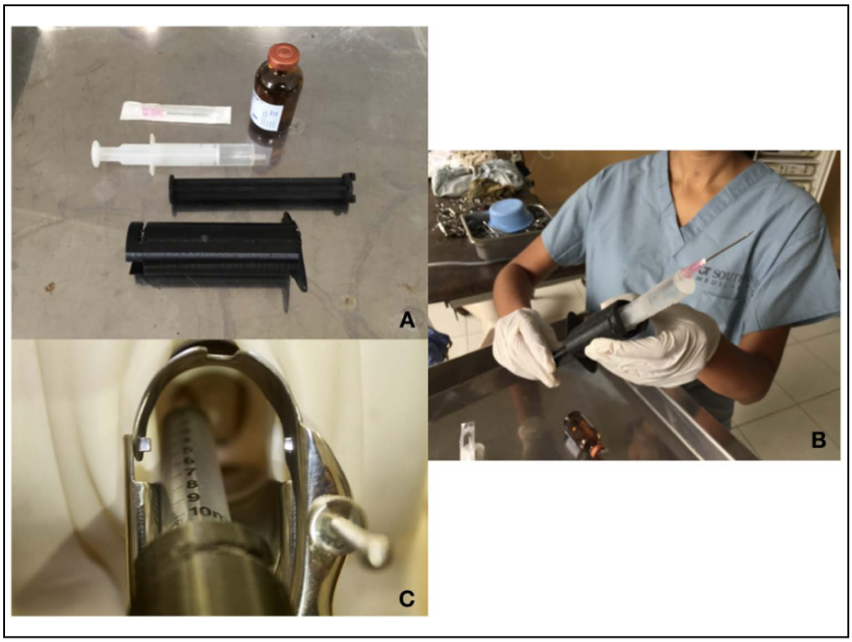

Figure A.1: Chloe SED®®. Chloe SED® is comprised of two components that attach to the syringe body and the syringe plunger of a 10cc syringe. Components and syringe are shown disassembled **(A)** and assembled **(B)**, Chloe SED® is also demonstrated on a pelvic mannequin **(C)**.

By the time of this study, Chloe SED® had 3 iteration before the final design. Only iteration Chloe SED® V0.1 [10] (see Figure 3.2 in Chapter 3) was considered viable and tested before a final design was acheived. The other designs were deemed less viable, as their aspects were already captured in both V0.1 and the final version. Figure A.1 shows both Chloe SED® and the final models fit for clinical trial. Validation through a clinical trial is essential for assessing efficacy and implementing it into routine care. This study focuses on validating Chloe SED® V0.1, which provided the inputs for design changes in the final version and its clinical validation, detailed in Chapter 4.

A.2 Pilot clinical trial materials and methods

A.2.1 study design

We conducted a single-blinded, randomized controlled non-inferiority trial at Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH) and Kisumu County Hospital (KCH) in Kisumu, Kenya, from September 2019 to January 2021. It was a mixed methods

study that included both quantitative and qualitative data collection in a convergent parallel design.

A.2.2 Trail Participants

Licensed Kenyan Medical Officers (MOs) or Clinical Officers (COs) performing MVAs at either of the two sites were invited to enroll in the study. As the assignment of MOs and COs to the gynecology ward occurs on a rotational basis, providers were approached once they started their rotation on the gynecology ward by a member of the study team who described the study's aims and procedures. Following all questions and a discussion regarding the study, interested MVA providers consented to enroll. Our major eligibility criteria for providers were English-speaking providers over the age of 18 who were experienced with the provision of MVAs.

Participants were recruited from patients coming to the health facility who required uterine evacuation for spontaneous or induced abortion. Once a patient was determined to be clinically eligible for MVA by a recruited provider and elected to have this treatment, that patient was invited to participate in the study. The eligibility criteria for patients were aged 18 years and older; evaluated by a recruited provider to be eligible for MVA; and fluent in English, Swahili, or Luo. Exclusion criteria were any contraindication to lidocaine including known hypersensitivity, infection in tissue adjacent to the proposed site of injection (including uterine and cervical infection), concomitant anticoagulation therapy or reported abnormal bleeding tendency, severe anemia, or heart disease. Severe anemia was defined as per the WHO as anemia associated with symptoms of fatigue, weakness, dizziness, and drowsiness, or a known hemoglobin concentration of less than 7.0. All provider and patient participants gave written informed consent.

A.2.3 Randomisation and masking

After patients completed their written informed consent, they were randomized to receive PCB with either the Chloe SED® experimental device or with a standard spinal needle (control arm). One of the off-site study investigators, GSO, created a computer-generated 1:1 randomization scheme in blocks of six. A separate investigator, AR, concealed the randomization in a series of numbered envelopes for each block. A research assistant (RA), IJ, enrolled participants, assigned them to the trial groups using the sequential envelope numbers, and completed the data collection. Given that the Chloe SED® and spinal needle are different in appearance, the providers and research assistant could not be blinded to the treatment arm assignment. As patients were positioned in the lithotomy position for this gynecologic procedure, they were blinded to treatment arm assignment and the instruments were kept out of view. Study team members analyzing the data were not blinded to the group assignments.

A.2.4 Description of the Chloe SED® V0.1

Patients randomized to the experimental arm received PCB with the Chloe SED® experimental device. Chloe SED® was designed by medical providers and design engineers familiar with the local context. It has one or two components (depending on the design version) that attach to a 10cc syringe body and plunger. The model tested in this study has

two components: one that attaches to the body and a second that attaches to the plunger. They act to extend syringe length such that administration of a PCB is possible using a standard-length 21-gauge needle. These 10cc syringes and 21-gauge needles are widely available in Kenya at all health facility levels. The syringe extension device is made of plastic and can be sterilized with locally available glutaraldehyde in a similar manner to the Karman cannulas that are currently used for MVA, requiring no additional equipment at the health facilities where MVAs are completed. The Chloe SED® experimental devices used in this study were manufactured at AB3D 3D Printing in Nairobi, Kenya. They were made from polylactic acid (PLA) plastic.

A.2.5 Description of the Control Arm Intervention

Patients randomized to the control arm received PCB with a 22-gauge spinal needle. The needles are single-use and were disposed of after use. The spinal needles used in the study were purchased within Kenya at local medical supply shops. Neither 21-gauge spinal needles nor 22-gauge standard-length needles were available in Kenyan medical supply shops. Therefore, the needles selected were the closest to the same gauge available and represent the needles commonly used in medical practice.

A.2.6 Procedures

Each provider who enrolled in the study participated in a semi-structured interview prior to the onset of any procedures about their experience with MVA and their perceptions about pain control. Each provider was then trained in the use of the Chloe SED® experimental device by one of the two principal investigators, AR and SG, who invented the device and could instruct on device use. Each provider also completed a refresher training on PCB administration. A second interview was conducted with each provider after the completion of their six procedures about their experience using Chloe SED® compared with the spinal needle.

When a provider evaluated a patient who was clinically eligible for MVA and elected to have this procedure, they contacted the study RA who administered the informed consent process. Patient participants then completed an initial face-to-face semi-structured interview about their experience with and perceptions about MVA. Following this, the provider completed the patient's MVA procedure with PCB. The PCB was administered per the training guidelines published by Ipas, an international organization that works globally to advance reproductive justice. Following Ipas guidelines, each patient received 200mg of plain lidocaine during PCB, administered as either 20cc of 1% lidocaine or 10cc of 2% lidocaine depending on which formulation was available in the clinic at the time of the MVA. A small amount of lidocaine was injected at 12 o'clock to facilitate tenaculum placement with the remainder of the lidocaine equally distributed at 2, 4, 8, and 10 o'clock at the cervicovaginal junction [11]. Patient pain level was assessed by the RA using an 11-point numerical rating scale (NRS) at five time points: just before the onset of the procedure, at the time of injection of the paracervical block, during cervical dilation (if dilation was required to complete the MVA), during the uterine evacuation, and 30min post-procedure (figure A.2). Following the MVA, the patient completed a second semi-structured interview about their experience of the procedure. All interviews were conducted by a study RA.

The interview guide was structured as multiple choice and Likert scale questions with opportunities to probe ideas presented at greater depth.

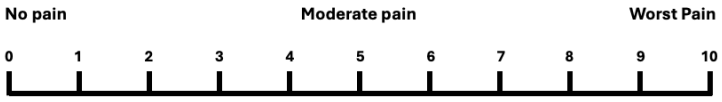

Figure A.2: Numerical rating scale. Instructions for patients as administered by the study RA: Using this scale from 0 to 10, where 0 is "no pain," 5 is "moderate pain," and 10 is the "worst pain imaginable," how much pain are you feeling right now?

A.2.7 Outcomes

Our primary outcome was the comparison of pain scores on the 11-point NRS during uterine evacuation between patients receiving PCB with the Chloe SED® with the spinal needle. Participants defined their pain score as an integer between 0 and 10, inclusive. Secondary outcomes included pain scores at the four other time points. Other secondary outcomes included: any adverse event, data on patient and provider experiences and perceptions, use of additional pain medications, patient satisfaction with pain management, and provider feedback on Chloe SED® design and usability compared with the spinal needle.

A core outcome set (COS) was not used in the design of this trial as a COS did not exist at the time of study design. When comparing our measured outcomes to those reported in a recent 2021 COS for general abortion research, outcomes that pertained to MVAs were assessed [12]. No patients or members of the general public were involved in the design of this trial.

A.2.8 Statistical analysis

Non-inferiority testing was used for quantitative analysis of the primary outcome. We powered the study to detect a difference of 2 points on the NRS, as a change ranging from 1.3 to 2 points on this scale has been previously considered to be a clinically meaningful difference in pain level [13, 14]. As we were only interested in non-inferiority and not equivalence, the sample size calculation was based on a one-tailed alpha of 0.05. A sample size of 28 patients per group provided 80% power to detect a 2 point difference based on a mean pain level of 6 on an 11-point NRS with a standard deviation of 3. Mean pain scores cited in previous studies ranged from 5.4 to 6.3 with the standard deviation ranging from 2.3 to 3.2 [15–17]. To facilitate an equal number of patients being recruited by each of the 10 providers, we planned to recruit 60 patients, 30 in each arm. The mean and 90% confidence intervals (CIs) of the pain scores were calculated and the significance of the difference between the arms was estimated by a t-test. Pain level comparisons at the other four time points were compared in a similar fashion. Descriptive statistics were used for

analysis of other secondary outcomes including patient satisfaction with the procedure, ease of use of the device, and incidence of adverse events.

Microsoft Access 2000 was used for data entry. Data were then exported into Stata 17.0 for statistical analyses. We analyzed our primary cohort using an intention-to-treat approach.

A Data Safety Monitoring Board (DSMB) comprised of three individuals with no conflict of interest monitored the study data. At the study midpoint (when 5 providers had completed the study with 30 patients), a qualitative assessment of the data was undertaken specifically looking for adverse events. There being none, the trial was continued.

A.2.9 Role of the funding source

This study was funded by the Department of Obstetrics and Gynecology at the University of Illinois at Chicago. The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

A.3 Pilot trail results

Between September 2019 and January 2021, 61 patients were recruited and randomized (31 to spinal needle and 30 to syringe extender) across the two facilities. One provider left the study after the enrollment of a single patient due to new employment in another city, so that block had only a single participant. This patient was not excluded and was retained in the syringe extender arm as per their randomization. In one block of six patients, there were four randomized to the spinal needle arm and two to the syringe extender arm due to an error in the creation of one randomization envelope. In one case, the syringe extender was noted not to fit the available syringe and was unable to be used for the paracervical block. In this case, a spinal needle was used to administer the block instead. This participant kept their assignment in the syringe extender group for the purpose of intention-to-treat analysis. One patient in the spinal needle arm requested cessation of PCB after 160mg of lidocaine had been injected due to the pain from the injection. This patient kept their assignment in the spinal needle group for the purpose of intention-to-treat analysis. All other randomized patients received treatment per protocol (Figure A.3). In total, 11 providers were recruited to participate in the study. Baseline patient participant characteristics did not differ between groups (Table A.1). The median age of the participants was 26 (IQR 22–32). Most (67.2%) had received secondary schooling, had never before had an MVA (90.2%), and were multiparous (67.2%). The mean age of gestation for completion of the MVA was 10.0weeks, with a minority (16.7%, 12.9%) of procedures in each group being completed for retained products of conception.

The intention-to-treat outcomes for NRS during uterine evacuation (primary outcome) and at four other time points including before the MVA, during injection of PCB, during cervical dilation, and 30min following the procedure (secondary outcomes) are summarized in Table A.2 (Figure A.4). Non-inferiority of Chloe SED® for administration of PCB was found at all time points; the upper bound of the 90% CI was less than the 2 point difference set as the non-inferiority margin. No adverse events were reported. In one case, a finger pad

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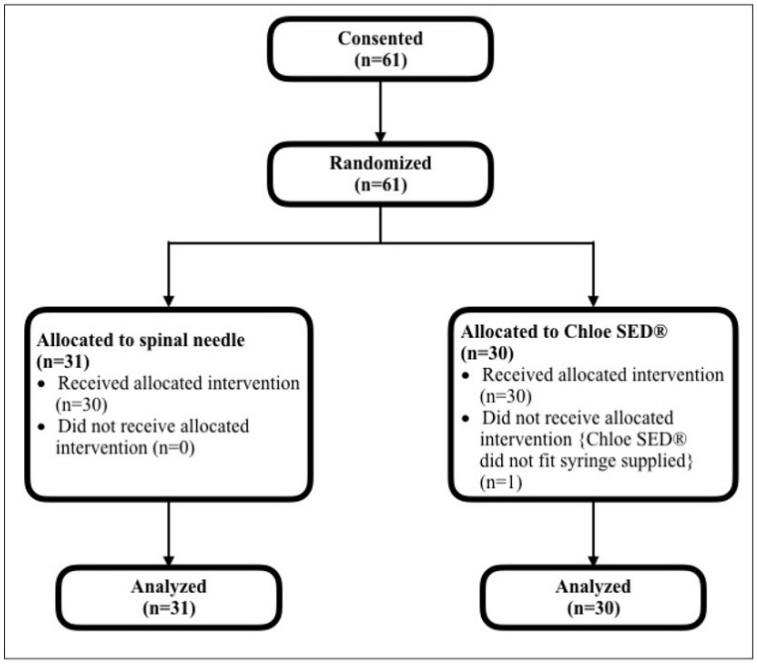

Figure A.3: CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

on the Chloe SED® broke after the administration of the PCB and that case was completed. This breakage did not result in any injury to the patient or provider.

We also collected pre-procedure and post-procedure semi-structured interview data from both patients and providers. These data were analyzed using descriptive statistics. All enrolled patients and providers completed both interviews. A small number of patients (three in each arm) had previously experienced an MVA outside of this study. In the pre-procedure interview, five of the six (83.3%) patients reported not receiving any pain medication during their previous procedure and these five patients noted that they were unhappy with their previous experience. One patient said, "It [MVA] hurts, it is disgusting. But it is better than oral medication." None of the six patients were given any choice about whether or not to receive pain medication. In the total cohort of 61 patients, all were asked what was the most concerning aspect of the MVA procedure for them; 30 (49.2%) reported being most concerned about procedure pain. This was the most common response given ranking over other concerns including medical risks of the procedure (3.3%), anxiety or fear of the unknown (19.7%), and fear of passing out (1.6%).

In contrast, during the post-procedure interviews, 60 out of the 61 patients (98.4%) noted that the procedure was satisfactory or tolerable. One person (1.6%), who was in the spinal needle group, reported unhappiness with the procedure due to inadequate pain control. Fifty-eight of the 61 patients (95.1%) would want to receive PCB for a future MVA procedure.

In the provider post-procedure semi-structured interviews, 7 out of 10 providers reported that it was easy or very easy to use Chloe SED® for PCB. Three providers described the ease of use as moderate. In the spinal needle arm, 6 out of 10 providers reported that it was easy or very easy to use the spinal needle for PCB with 4 providers describing the ease of use as moderate. One provider said, "*It [Chloe SED®] is efficient in administering the block; easy to assemble and reuse after cleaning.*" All providers (100%) noted that they would use Chloe SED® if it became available in the future. A detailed qualitative analysis of patient and provider interviews is discussed in a separate paper (See Appendix B which is currently under review.

Table A.1: Participant Characteristics: Data are median (interquartile range 1,3), n (%), or mean (SD). Median was used for Age; n (%) was used for Parity, Obstetric History, Education, Procedures for retained products of conception; mean (SD) was used for Gestational Age.

Characteristics		**Spinal Needle (n=31)**	**Chloe SED® V0.1 (n=30)**	**Total (n=61)**
Age (y)		25 (22.5, 29.5)	28 (22, 32)	26 (22, 32)
Parity	Nulliparous	9 (29.0)	8 (26.7)	17 (27.8)
	Parous	22 (71.0)	19 (63.3)	41 (67.2)
Obstetric History	Prior vaginal deliveries	21 (67.7)	17 (56.7)	38 962.3)
	Prior MVA	3 (10.0)	3 (10.0)	6 (9.8)
Education	None	1 (3.2)	0 (0.0)	1 (1.6)
	Primary school	10 (32.3)	9 (30.0)	19 (31.1)
	Secondary school	15 (48.4)	15 (50.0)	30 (49.2)
	University or beyond	5 (16.1)	6 (20.0)	11 (18.0)
Gestational Age (weeks)		9.4 (SD 3.0)	10.8 (SD 3.1)	10.0 (SD 3.1)
Procedures for retained products of conception		4 (12.9)	5 (16.7)	9 (14.8)

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Table A.2: Primary and Secondary Outcomes (Intention-to-Treat Analysis) Data are mean pain scores (90% confidence interval) on an 11-point VAS. Not all MVAs required cervical dilation to be completed. One patient did not report a pain score 30 minutes post-procedure. * Primary outcome.

Pain Score timepoints	Spinal Needle (n=31)	Chloe SED® V0.1 (n=30)
Before MVA	2.7 (2.0-3.4)	3.5 (2.6-4.4)
During injection of PCB	4.3 (3.6-5.0)	4.5 (4.0-5.0)
During cervical dilation	3.1 (2.6-3.7) n=28	3.1 (2.6-3.7) n=26
During uterine evacuation*	4.1 (3.5-4.7)	3.8 (3.1-4.6)
30 minutes after procedure	0.4 (0.1-0.7) n=30	0.4 (0.2-0.7)

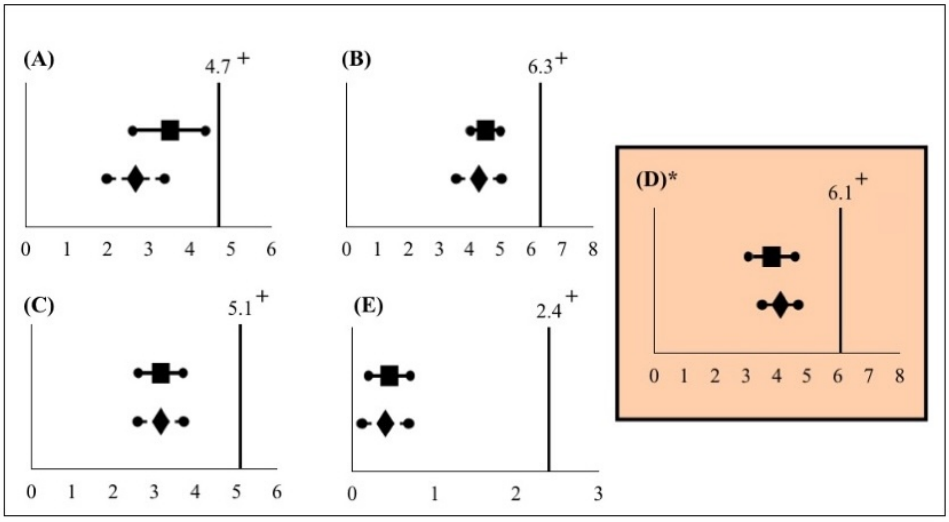

Figure A.4: Figure 3. Mean Pain Scores in Relation to Non-inferiority Limit (Intention-to-Treat Analysis) Mean pain scores and 90% confidence intervals do not cross the non-inferiority limit at any of the five time points: (A) Before MVA, (B) During injection of PCB, (C) During cervical dilation, (D) During uterine evacuation, and (E) 30 minutes after procedure. The non-inferiority limit was set at 2 points on the VAS. * Primary outcome, ◆ Spinal needle mean pain score, + Non-inferiority limit, ■ Chloe SED® V0.1 mean pain score.

A.4 Discussion

A.4.1 Main Findings

This study found that Chloe SED® was non-inferior to the standard spinal needle in the administration of PCB at both the primary time point (during uterine evacuation) and at all secondary time points. The mean pain scores in both arms of this study were lower than those previously reported in the literature, with a similar standard deviation of 2.3 points on the NRS [18].

A.4.2 Interpretation

Manual vacuum aspiration in Kenya and in other low- and middle-income countries is commonly performed without the administration of any pain medication whatsoever. Patients receive what is called "local vocal" or "keep quiet" anesthesia, which is the presence of a support person to issue words of comfort. While this presence of support is certainly important, it cannot be considered adequate or humane pain management for all women and in fact does not measure up to the standard of care seen in high-income countries, where non-steroidal anti-inflammatory drugs, PCB, anxiolytics, and moderate sedation are commonly provided for MVAs [11, 19].

In busy Kenyan clinics and hospitals, where women wait in line for MVAs, we have seen women who are actively bleeding and in need of medical care leave treatment wards upon hearing the screams coming from the treatment room as the woman ahead of them receives an MVA with no pain medication. The desire for more choice and autonomy in pain management is borne out in our study results as well, with a majority of women citing pain as their primary concern in having an MVA and greater than 95% of women desiring PCB for any future MVA procedure. Lack of humane pain control is an unacceptable limitation of a patient's right to access safe, quality medical care.

Several barriers to the use of PCB have been cited, including inaccurate beliefs among providers that pain control is not necessary for an MVA, lack of adequate medications and tools, and lack of training in providing PCB [6]. With the successful results noted in this pilot study, we aim to alleviate one of these barriers—lack of access to tools required for administration of PCB. Chloe SED® is a novel and reusable device. With a projected cost at scale of 5 USD and a projected lifespan of 400 procedures, the Chloe SED® would reduce the cost of administration of PCB by greater than 90% compared to the use of single-use spinal needles. The cost of a standard 21-gauge needle is 0.01 or 0.02 USD per needle. This makes the incremental cost per procedure of Chloe SED® approximately 0.03 USD compared to 1–2 USD for each spinal needle procured, which is a cost savings of 97%–99% per procedure. Furthermore, 1–2 USD would easily translate to a full day's wages when that cost is transferred to the patient. The Chloe SED® would be a more affordable alternative.

As is largely the case for family planning services worldwide, the battle fought over the past 50years has been about access to safe, affordable care and services. In Kenya, as well as in several other countries, there have been major victories in care access with the introduction of MVA and the ability to move procedural abortion care from hospitals to outpatient clinics. However, low-quality or inhumane treatment does not constitute meaningful access to care. The Lancet Commission recently stated that metrics reporting service quantity are meaningless if those services are not of high quality and do not fulfill a basic right to humane care [20]. Chloe SED® has the potential to empower marginalized women to access respectful family planning services and to enable clinics to comply with the WHO's most recent safe abortion guidance, recommending PCB with every MVA performed [8].

A.4.3 Study Strengths and Limitations

Our clinical trial has several strengths related to study design. It was a randomized, multi-center trial. Patients were blinded to the study intervention, which should have reduced bias in the reporting

of pain scores. Due to the short duration of PCB and lack of need for long-term follow-up after administration of the block, all patient data were complete with no loss to follow-up. Previous studies of PCB efficacy have been heterogeneous in methodology. Our study had a comprehensive methodology with a standardized method for PCB application and measurement of pain scores at five different time points, which is an improvement on the previously existing data. The Chloe SED® device is novel and there are no other studies testing this device or anything of a similar design. Our study also acknowledged that patient autonomy and preference are critical in the development of an ideal pain control strategy for MVA. As such, patient experiential and satisfaction data was collected.

Our trial has several limitations. As a pilot study, the sample size is small and cannot provide a comprehensive review of safety and adverse events. In addition, data regarding the number of patients who were approached by the study team and refused participation or who were unable to consent due to not meeting inclusion and exclusion criteria was not collected. Although we estimate based on case volume at the two sites that the rate of refusal or exclusion was less than 15%, we did not collect this information during the trial and are relying on data collected by the hospital wards for their own reporting purposes. Third, due to the difference in appearance between the spinal needle and Chloe SED®, the study providers were unable to be blinded. This could introduce bias in the administration of the PCB or evaluation of pain. The statistical analysis of pain scores was also completed unblinded, which may have introduced bias. Since the procedure was standardized and monitored by research assistants who are proficient in the provision of PCB, this type of bias is unlikely to have had a major effect on the results. Fourth, for the purposes of this pilot study, the higher end of the range of values noting a clinically significant difference in pain score was chosen for the non-inferiority limit. Based on the findings of this study, which show that the Chloe SED® is functional for administering PCB and that conduct of an RCT for this novel device is feasible in our target population, we are conducting a larger clinical trial for further assessment with a more narrowly defined non-inferiority limit. Fifth, we know that reporting of patient satisfaction in abortion studies tends to be high, likely because access to procedures is difficult and patients are generally thankful to receive medical treatment. However, albeit with a very small sample size, we do see a trend in greater satisfaction than among patients who previously experienced MVA without PCB. Finally, we know that a numerical unidimensional scale such as the NRS does not adequately capture the complex biopsychosocial experience of pain. However, it is a validated quantitative tool in pain assessment that we felt would be adequate in measuring differences between the two tools in their efficacy of administering PCB.

A.5 Conclusion

In summary, the Chloe SED® is non-inferior to the standard spinal needle in the administration of PCB for a difference of 2 points on the NRS. Further study is needed in larger sample sizes to further demonstrate safety and efficacy at a narrower non-inferiority margin. The Chloe SED® shows promise in breaking the cost barrier to the administration of PCB and in enabling compassionate, humane, high-quality care to women undergoing an MVA.

A

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B

Appendix to Chapter 3

Validation of Chloe SED®: Patient and provider perspectives on pain management during manual vacuum aspiration.

Gwer SO, Samenjo KT, Bailey RC, Imbamba J, Odenyo S, Koksal E, Diehl JC, Ramanathan A. (2024). Patient and provider perspectives on pain management during manual vacuum aspiration. *African journal of reproductive health, 28(12), 21–28.* DOI: 10.29063/ajrh2024/v28i12.2

GSO, SKT, RBC, IJ, and RA conceived the study. IJ and OS collected and curated the data. RA, GSO, and BRC conducted the data analysis. GSO, SKT, and RA wrote the manuscript, and BRC, IJ, OS, KE and DJC reviewed and edited it. GSO, SKT, and RA had final responsibility for the decision to submit for publication.

Data availability and disclosure. Study raw data can be accessed upon reasonable request. Data is treated as clinical and requires adherence to ethical procedures.

Abstract

Manual vacuum aspiration (MVA) is a painful procedure often conducted without analgesia. The World Health Organization (WHO) recommends a paracervical block (PCB) as the mode of pain relief during MVA. Few studies have assessed patient perspectives on pain control during MVA. We investigated the perspectives of health workers and patients on MVA under PCB. This study was nested within a pilot randomized controlled trial (RCT) evaluating the Chloe SED® (syringe extension device) for PCB provision. Eleven providers and 61 patients were enrolled. All providers had MVA experience. They had not provided pain relief on 20% of occasions, and only one had previously administered PCB for MVA. Both patients and providers indicated MVA was painful and deserving of analgesia. Pain was the most common reason for difficulty completing an MVA. Providers noted that PCB made the procedure more tolerable. For patients, efficacy, remaining conscious, and same-day discharge were key considerations when selecting pain relief. Notably, 84% of patients expressed satisfaction with MVA under PCB. PCB is a vital component of the MVA care package. Considering patient and provider perspectives is essential to optimizing a humane and effective procedural experience.

B.1 Introduction

It is estimated that each year there are 120 million unintended pregnancies of which over 70 million end up in abortion [1]. This would be in addition to the spontaneous abortions that occur in wanted

pregnancies. Although not all women undergoing abortion need treatment, it is one of the leading indications for acute admission to the gynaecological wards in sub–Saharan Africa. In Kenya, the abortion rate is approximately 48 per 1000 women ages 15 – 49 years [2, 3] and many of them require manual vacuum aspiration (MVA). The MVA procedure is a combination of curettage and suction of uterine contents and is an expedient way of treating abortions and its complications [4, 5]. It is a safe, quick method of evacuating the uterus, precluding the need for general anesthesia (GA) in an operating theatre, and allowing for same day discharge from hospital [6–9]. Unlike dilation and curettage that is performed only by doctors, MVA can be done by nurses and other lower cadre practitioners, making it less expensive and more accessible [10]. This procedure is very painful and should be conducted in a humane manner with adequate pain relief [11].

When MVA was first introduced, the need for provision of adequate pain relief was downplayed and many times it was done under "verbocaine" variously referred to as "oral analgesia," which is when the provider or a support person provides words of comfort during the procedure [6]. Often in Kenya and other under-resourced settings, the procedure is done either without pain relief or with inadequate pain relief [11, 12]. A variety of reasons to support this suboptimal care have been described and include the belief that the pain is bearable and "vocal local" is sufficient. For a long time, this has been accepted as a standard of care and the pain has been considered a fair exchange for the expediency of the procedure. However, many studies have shown that the pain endured by women during MVA is severe [11]. In addition to the physical pain, women may also be experiencing psychological and emotional trauma. Notably and unfortunately, as has all too often been the case in reproductive medicine worldwide, these standards of care were made without taking patient autonomy and preferences into account. Although MVA is widely performed around the world, studies examining patient and provider perspectives regarding MVA are few.

In 2022, the WHO issued new abortion care recommendations that prescribe paracervical block (PCB) as the minimum pain relief required during MVA, with additional conscious sedation provided where possible [13]. In the context of the guidelines, conscious sedation is defined as the use of a combination of medicines – a sedative to relax and an anaesthetic to block pain – to induce a depressed level of consciousness during a medical procedure. The WHO notes that neglecting pain control compromises quality of care and increases the difficulty in performing the procedure [13].

A PCB involves the injection of local anesthesia into the cervix to prevent the transmission of afferent pain impulses from the cervix. It requires the use of a spinal needle to provide the additional length required to give the injection with a standard syringe. Unavailability of spinal needles and needle extenders in Kenya and other low-resource settings precludes provision of PCB. To address this barrier, a low-cost and reusable syringe extension device named Chloe SED® was designed to be attached to a 10-cc syringe, provides the additional length required to administer a PCB, as detailed in Chapters 3 and 4. Note that, by the time of this study, Chloe SED® had 3 iteration before the final design. Only iteration Chloe SED® V0.1 [14] (see Figure 3.2 in Chapter 3) was considered viable and tested before a final design was acheived. The other designs were deemed less viable, as their aspects were already captured in both V0.1 and the final version. Validation through a clinical trial is essential for assessing efficacy and implementing it into routine care. This study focuses on validating Chloe SED® V0.1, which provided the inputs for design changes in the final version and its clinical validation, detailed in Chapter 4.

A single-blinded non non-inferiority randomized control trial (RCT) was conducted to validate the utility of Chloe SED®, comparing it to the standard spinal needle. The main outcome was assessment of pain scores during uterine evacuation. During the study, data on the perspectives of both the patients and their caregivers on pain before, during and after the MVA procedure was collected. Given that patient and provider experiential data on MVA is so limited, we conducted

this study to better understand patient and provider experiences and preferences such that a more optimal and compassionate procedure protocol may be designed.

B.2 Method to understand patient and provider perspectives

This study was nested within a single-blinded non inferiority RCT to compare the efficacy and safety of the Chloe SED® to the standard spinal needle for administration of PCB during MVA. The study sites were Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH) and Kisumu County Hospital (KCH) both in western Kenya.

The study participants were health providers in the facilities who were designated to provide MVA in the gynaecological wards, and women who had been admitted with first trimester pregnancy for evacuation. The inclusion criteria were; women's health providers providing MVA services at the study sites, adult female patients receiving MVA at the study sites having been determined clinically eligible for MVA treatment by a licensed practitioner. All participants provided signed informed consent to participate in the study. Exclusion criteria for the patient participants included: cervicitis, anticoagulant therapy or an abnormal bleeding tendency, severe anemia, heart disease, under age 18 years, and any contraindication to lidocaine such as known or suspected hypersensitivity.

Approval to conduct the study was obtained from the hospitals, the Maseno University (No. MSU/DRP/MUERC/00639/18), JOOTRH ethical review committee, and the Kenya Pharmacy and Poisons Board (ECCT/19/03/01). A data safety and monitoring board made up of three independent experts found no reasons to stop the study after a midpoint analysis.

Recruited providers were trained on the provision of PCB using both the spinal needle and Chloe SED®. A semi structured interview was conducted with the providers prior to the recruitment of the first patient that explored their experience with MVA and perceptions on pain control for the procedure. Another interview was conducted after the completion of the last MVA to assess their experience with the Chloe SED® compared to the standard spinal needle. With each patient an interview was conducted that included assessments before, during and after the procedure. We collected data on their demographic characteristics, previous experiences with MVA, perceptions about the procedure, preferences regarding pain control, pain scores during the procedure on an 11-point visual assessment scale (VAS) and levels of satisfaction after the procedure.

The primary outcome of the study was comparison of pain scores using the 11-point VAS during uterine evacuation. Other outcomes included assessment of pain scores at other time points of the procedure, documentation of adverse events, patient and provider perceptions on MVA.

A sample size was arrived at based on a one-tailed alpha of 0.05, with 80% power to detect a 2-point difference on the VAS with a mean pain level of 6 and a standard deviation (SD) of 3. This gave 28 patients to each arm which was then rounded off to 30. Microsoft Access 2000 was used for data entry, and data exported to Excel and Stata 17.0 for analysis.

Results on the pain scores and inferiority testing have been documented in a separate paper [15]. Since no differences in pain scores were found between procedures using Chloe SED® versus the standard needle, this paper combines the results from all participants in the trial to examine provider and patient perspectives on MVA. All data were collated and are presented here in narrative form and tables.

B.3 Results

Results from Provider Interviews

Eleven providers were enrolled in the study; they included one registered clinical officer, three medical officer interns, four medical officers and three registrars (gynecologists in training). Nine (82%) were male; their mean age was 28.3 (range 23 – 38) years. They had an average of 5.5 years in practice, four of them were in their first year of medical practice, while the rest had been in practice for between four and 12 years. Most (8/11) had received their initial training on MVA as part of their professional training, while two indicated that they had undergone formal training by an NGO. One was informally trained on the job by someone who was proficient in the procedure. After their formal training, five (45.5%) had received follow-up training. Prior to recruitment into the study, the providers conducted on average 22.4 MVAs per month (range 0 to 100) in the facilities where they worked.

Patients being in excessive pain was cited by seven (63.6%) of the 11 providers as the most common reason for difficulty in completing an MVA prior to the study. Only two indicated difficulties with using the MVA kit. Table Table B.1 gives a summary of the Characteristics and Perceptions of 11 Health Providers Conducting MVA.

Table B.1: Characteristics and Perceptions of 11 Health Providers Conducting Manual Vacuum Aspiration (MVA): Pre-Study Interview

Variable		Number	Percent[1]
Type of Provider	Medical Officer	4	36
	Medical Officer Intern	3	27
	Clinical Officer	3	27
	Registrar*	1	9
Sex	Male	9	82
	Female	2	18
Age	Mean (range)	28.3 (23-28)	
Years in practice	Mean (range)	5.5 (1-12)	
Number MVA done monthly	Mean (range)	22.4 (0-100)	
Reasons for difficulty with MVA	Excessive patient pain	7	64
	Problem with MVA kit	2	18
	Other	2	18
Best means to improve MVA	Improved pain control	6	55
	Better equipment	3	27
	Improved pre-procedure counseling	1	9
	Other	1	9
Estimated patient pain level	Mean VAS[2] (SD)	(2.5)	

[1]The percents may not total 100 due to rounding , [2]VAS = Visual Analog Scale
*A registrar is a gynaecologist in training.

Provision of improved pain control was mentioned by 6 (55%) providers as the primary thing they would wish could be improved during MVA. One indicated that there was a need to improve pre-procedure counseling, while three indicated that better or complete MVA equipment was needed.

When the providers were asked how painful they thought the MVA procedure is they gave it an average VAS score of 6.5 (SD 2.5). All the providers indicated that prior to the study, they provided pain relief to patients during MVA, with most (7/11) providing diclofenac injection and just one a PCB. Pain relief was not provided for all the procedures with an estimated 20% being done without analgesia. The inability to offer PCB was mostly (57.1%) attributed to lack of spinal needles or syringe extenders. One individual cited lack of training in PCB, while the remainder of the cohort (28.6%) did not provide a reason.

Five providers reported that there were no protocols on pain management for MVA at their facility. Six described protocols consisting mainly of parenteral diclofenac used singly or combined with tramadol. Only one of them described the use of PCB as part of a pain management protocol.

The providers reported that when PCB was administered, patients were more tolerant of the MVA procedure, yet syringe extenders, which were required for effective PCB, were not always available. Once the study was completed, all (100%) providers noted that they would use syringe extenders in the future to provide PCB if they became available because they are efficient and make administration of PCB easy.

"With paracervical block, patients were more cooperative during the procedure and this makes our work easier."

Results from Patient Interviews

The median age of participants was 26 years - interquartile range IQR 22, 32. Most (67.2%) had received secondary schooling and had had at least one prior pregnancy. Table Table B.2 summarises the Characteristics and Perceptions of 61 patients undergoing MVA. The mean gestational age at time of MVA was 10.1 weeks with a range of 3 to 14 weeks. Six (10%) had prior experience of an MVA; among these, all but one were dissatisfied with their previous experience. Only one had been offered pain medication, which was a PCB, and she was not given a choice on the mode of pain relief provided. The majority (63.9%) of patients chose their MVA provider based on whether that provider was known to be skilled at the procedure.

Prior to the MVA more than half (51%) of the 61 patients enrolled in the study indicated that pain was their biggest concern, with anxiety and fear of the unknown expressed by 12 (20%). Sixteen (26%) reported no fears nor concerns. When asked on how painful they thought the MVA would be, the mean score on the VAS was 6.8 (SD 2.3) This contrasted with the 4 (SD 2.1) mean pain score they reported during evacuation.

In describing the desirable characteristics of pain provision during MVA, the need to remain awake and aware during the procedure was the most common (42%), with efficacy of analgesia being second. Some of the participants indicated they would tolerate some pain if this was necessary for the safe completion of the procedure. A fear of not awakening from sedation or anesthesia was also expressed. Some patients felt the need to be able to witness the procedure and thus later explain it to their friends and kin. Fourteen (23%) expressed a desire to be totally asleep during the procedure. The ability to leave the facility on the same day was also listed as a good attribute. Parenteral medication was preferred to oral.

"I prefer less pain. I hate hospitals so that is why I said to leave immediately. I don't like taking oral medications. I prefer to remain awake due to fear of not waking up from sedation."

Fifty-one (84%) were satisfied with the provision of MVA under PCB, and nearly all (95%) would want to be offered PCB again if they were to have MVA, with 97% indicating they would recommend it to a friend. Of the patients who were not satisfied, reasons for dissatisfaction included pain with speculum insertion, pain with injection of the PCB, and a desire for the procedure to be done under

Table B.2: Characteristics and Perceptions of 61 Patients Undergoing Manual Vacuum Aspiration

Variable		Number	Percent
Age	Mean (Interquatile range - IQR)	26 (22,32)	
Education	None	1	1.6
	Any primary	19	30.6
	Any secondary	50	50
	Any post secondary	11	17.7
Number Previous Pregnancies		1 (0,2)	
Gestational Age of Fetus (weeks)		11 (9.5, 120)	
Prior experience with MVA	Yes	6	10
	No	55	90
Biggest Concern	Pain	31	51
	Anxiety/Fear of unknown	12	20
	No fear	16	26
Desired qualities of pain control	Retains consciousness	26	42
	Effectiveness of analgesia	17	27
	Wanted to be unconscious	14	23
	Others [1]	4	6
Mean reported pain score on VAS (SD)	Expected	6.8 (SD 2.3)	
	Actual pre procedure	3.1 (SD 2.6)	
	During uterine evacuation	4 (SD 2.1)	
	Post procedure - 30 minutes	0.4 (SD 0.8)	
Would recommend MVA with PCB to a friend	Yes	59	97
	No	2	3

[1] Others include – memory erasing, oral, injectable, allows same day discharge,
[2] patient indicates she was not given any analgesia

general anesthesia. When asked if they would be willing to pay an additional cost to receive pain medication during an MVA, 44.3% said they would with 43% saying they would be willing to pay more than KES 200 (1.67 USD). Of those who said they would not pay an additional cost, 83% cited financial instability.

"My previous expectation was of pain. The experience of the injection was good."

B.4 Discussion

This study is one of few documenting perceptions of pain among women during MVA treatment. In addition, our results contribute insights gained from providers practicing MVA.

The wide range in experience of the providers (1 – 12 years) is not unusual in internship centres where newly qualified practitioners practice under the wings of their more experienced mentors. Providers pointed out that excessive pain was a common reason that made the MVA procedure difficult to perform.

Providers perceived the procedure as painful for their patients, giving it a score of 6.5 on the VAS. Notably, this was little different from the 6.8 that the patients reported as expecting prior to the procedure. Despite their perception that the procedure is painful, the providers reported that in 20% of the instances they offered no pain relief whatsoever. This is in keeping with Solo's description that, after training on MVA, most aspects of care improve except pain management [16].

A study in Malawi when MVA was being introduced to the country reported 25% of the participants describing the procedure as painful and intolerable, and yet half saying the pain was tolerable [6]. The paucity of data on and wide heterogeneity in patients' experiences of pain during MVA, sometimes even with provision of analgesia, might have contributed to the delay in recommending humane care for the service [17, 18].

Lack of equipment and proper training were pointed out as the reasons for inadequate pain control. These have been described in previous publications [16]. Other causes for poor pain control have been described and include the opinion of some providers that the procedure can be completed with only prior counseling and verbal reassurance, or that an open cervix obviates the need for analgesia [16]. Studies have also reported that some providers have personal biases on abortion care that make them see patient pain as a deserved punishment for terminating an unwanted pregnancy [16, 19]. Indeed, incidences have been described where patients will be interrogated to establish whether they had an induced or spontaneous abortion as a determinant of whether they deserved pain relief. This discriminates against the unmarried and young, yet some studies have demonstrated that adolescents are biologically more susceptible to higher pain scores than adults [11, 20].

The varied responses from the providers on pain control during MVA highlights the lack of standard facility-based protocols for MVA analgesia and are similar to findings in Kilifi, Kenya [11]. That MVA is a painful procedure is not a recent realization, with papers going back decades advocating for the provision of wholistic pain relief for women undergoing MVA [16].

This study participants listed pain along with fear of not waking up from the procedure as their main concern prior to the procedure. This is similar to other work in Tanzania, Kenya, and India [3, 16, 21]. Infertility, incomplete abortion and death have variously been described as other principal concerns for women seeking abortion care either by medication or surgery [3, 16, 21]. Across these studies, this one included, one encounters the ardent voice of women's lamentation for adequate pain relief during MVA. In an exploration of the lived experiences of girls receiving MVA treatment in Kilifi, all the study participants described MVA as very painful, some saying it was worse than child birth; whereas some women screamed, others bore the excruciating pain in silence, fearing that their expression would breach confidentiality. The screams of patients receiving MVA with inadequate pain control during one procedure is evident and, as witnessed in hospitals, can impact many others. Women waiting for MVA care, hearing the screams of those before them, will sometimes leave treatment facilities, exposing them to the risk of severe morbidity or even death. This highlights the need for adequate analgesia in addition to comprehensive pre-procedure counselling [11].

Abandonment of the MVA procedure due to severe pain has also been described in other studies [11]. This is particularly distressing considering the consequences of incomplete abortion include death. In the Kilifi study the health provider turned around to blame the uncooperative patient for the failure of treatment [11]. All six of this study's participants who had ever had an MVA reported a negative experience during which pain relief had not been provided except in one instance. Even when pain control was provided, that patient was not given a choice or preference in the matter. Abandonment of the procedure lends credence to assertions that provision of MVA without pain relief can be traumatizing to the provider and unsafe for the patient [16].

The ideal pain relief experience described by the patients in this study would include parenteral medications that are effective and do not induce loss of awareness and allow one to go home on the same day.

The need for the provision of pain control should not lead to over-medicalization of the procedure or a loss of access to the procedure outside of an operating theatre; general anaesthesia would be excessive and undesirable in most cases [16]. A fear of not reversing after general anesthesia should not be downplayed. This is similar to a fear of death during the procedure that was expressed by women seeking abortion services in Kenya and India [16].

Paracervical block fits many of these criteria and most of the clients (95%) were agreeable to having the block if ever they would undergo MVA again. The findings support the World Health Organization's change in guidelines to offer PCB at a minimum with every MVA conducted. Importantly, we recommend that pain control options and recommendations be part of the informed consent discussion prior to any MVA procedure and that shared decision making between a patient and provider take place to create a pain management plan that best respects her humanity and bodily autonomy. As demonstrated in this study, a small subset of women found PCB alone inadequate for pain control during MVA. Paracervical block is but one tool in the armamentarium of possible pain management options. We advocate for thoughtful pre-procedural counseling where a patient is given all the options with risks and benefits to decide a best approach with the provider.

B.4.1 Study Strengths and Limitations

Both the study sites were public facilities and may not be reflective of the experiences of abortion services in the general population considering a widely held perception in Kenya that provider and client experiences in public facilities are different from those in private facilities [3]. The sample size especially of the providers is small. Because the results are based on face-to-face interviews, they may be subject to social desirability bias. This was minimized this by establishing a rapport with the participants and by constructing questions in a neutral, non-leading manner.

B.5 Conclusion

The experiences shared in this study reveal the need for adequately addressing pain management during MVA. The current WHO guidelines on pain management during MVA can be adopted as the default template that hospitals could use in formulating domesticated protocols. Health workers who conduct MVA should be trained on pain provision, including PCB for MVA and to be sensitive to the varied expectations of their clients. Facility managers should ensure commodity safety that guarantees provision of humane treatment for abortion. It is no longer acceptable to provide MVA without taking into consideration a patient's concerns regarding pain relief.

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List of Publications

Journal publications within this thesis

- *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: The Journal of Design, Economics, and Innovation.* doi:10.1016/j.sheji.2025.01.005
- Gwer, S., *Samenjo, K.T*, Bailey, R. C., Imbamba, J., Odeny, S., Koksal, E., Diehl, J.-C., & Ramanathan, A. (2024). Patient and provider perspectives on pain management during manual vacuum aspiration. African Journal of Reproductive Health, 28(12), 21–28. doi: 10.29063/ajrh2024/v28i12.2
- Ramanathan A, *Samenjo, K. T.*, Bailey RC, Imbamba J, Odenyo S, Koksal E, Diehl JC, Omoto J and Gwer S (2024) Validation of a novel medical device (Chloe SED®) for the administration of analgesia during manual vacuum aspiration: a randomized controlled non-inferiority pilot study. Front. Pain Res. 5:1326772. doi: 10.3389/fpain.2024.1326772.
- *Samenjo, K. T.*, Ramanathan, A., Gwer, S. O., Bailey, R. C., Otieno, F. O., Koksal, E., ... & Diehl, J. C. (2023). Design of a syringe extension device (Chloe SED® V0.1) for low-resource settings in sub-Saharan Africa: a circular economy approach. Frontiers in Medical Technology, 5. doi: 10.3389/fmedt.2023.1183179
- *Samenjo, K. T.*, Oosting, R. M., Bakker, C., & Diehl, J. C. (2023). The extent to which circular economy principles have been applied in the design of medical devices for low-resource settings in Sub-Saharan Africa. A systematic review. Frontiers in Sustainability, 4, 1079685. doi: 10.3389/frsus.2023.1079685

Other Publications During the Thesis

- **Book chapter** Diehl, J. C., Agbana, T., Van, G. Y., Lambers, L. H. R., & *Tondo, S. K. H.* (2023). The frugal design of a medical centrifuge: distributed production as a frugal technology to increase access to medical devices in low-and middle-income countries. In Handbook on Frugal Innovation (pp. 176-196). Edward Elgar Publishing. doi: 10.4337/9781788118873.00022.
- **Journal paper** *Samenjo, K. T.*, Bengtson, M., Onasanya, A., Zambrano, J. C. I., Oladunni, O., Oladepo, O., ... & Diehl, J. C. (2022). Stakeholders' Perspectives on the Application of New Diagnostic Devices for Urinary Schistosomiasis in Oyo State, Nigeria: A Q-Methodology Approach. Global Health: Science and Practice, 10(4). doi: 10.9745/GHSP-D-21-00780
- **Conference paper** Bengtson, M., Onasanya, A., Oyibo, P., Meulah, B., *Samenjo, K. T.*, Braakman, I., ... & Diehl, J. C. (2022, September). A usability study of an innovative optical device for the diagnosis of schistosomiasis in Nigeria. In 2022 IEEE Global Humanitarian Technology Conference (GHTC) (pp. 17-22). IEEE. doi: 10.1109/GHTC55712.2022.9911019.
- **Conference paper** *Samenjo, K. T.*, van Oudheusden, A., Bolaños, J., Flipsen, B., & Faludi, J. (2021, May). Opportunities For 3D-Printable Spare Parts: Estimations from Historical Data. In Proceedings of the 4th PLATE Virtual Conference, Limerick, Ireland (pp. 26-28). doi: 10.31880/10344/10236']

Acknowledgments

Many women worldwide still endure a lack of basic healthcare. Though we observe small increments of progress, we must strive for a point where true change comes from our hearts. Laws, policies, and legislation serve as instruments to ensure equality and equity. The day will come when our hearts mature to perceive everyone as equal and important to access the healthcare they need. This thesis and everyone who contributed tirelessly dedicate it to every woman with limited access to gynaecological care. I acknowledge you and things will be better someday.

Biographical note

Karlheinz Samenjo, born in Cameroon, is a global citizen with a passion for designing medical devices for low-resource (aka resource-constrain) settings. After earning a BSc in Mechanical Engineering from the University of Nairobi, he co-founded African Born 3D, focusing on 3D printers made from recycled electronic waste and 3D-printed medical devices in Kenya. Karlheinz is dedicated to sustainable design and turning ideas into practical solutions, a commitment he strengthened through a dual MBA in Global Social & Sustainable Enterprise at the United States International University of Africa and Colorado State University, USA. He believes that science should not remain confined to published papers but should benefit people, the planet, and organisations, advancing humanity. Karlheinz's passion is designing medical technology and systems from a scientific and entrepreneurial perspective. He leverages these domains to improve livelihoods in low-resource settings, including low-income countries, conflict-affected areas, and regions struck by natural disasters. During his PhD, Karlheinz designed the Chloe SED®, integrating it into routine care. Chloe SED® is established under Chloe Innovations LLC, a start-up which aims to ensure its implementation and use in low-resource hospitals globally. His next step is using his skills and lessons learnt to build the future generations of medical designers, especially those in Africa.