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

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13. 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

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13.1. INTRODUCTION

13.1.1. Lack of Medical Devices in Low-resource Settings

A growing awareness of health as a human right, mainly in low- and middle-income countries, is promoting universal health access for increasing numbers of people (Bianchi, Bianco, Ardanche and Schenck, 2017). Universal access to health to a large extent depends on access to medical equipment and medical staff. In this chapter, we focus on the access to medical equipment, more specifically, equipment for diagnostics and how frugal innovation and distributed manufacturing can contribute to an increase of access to these devices. We present a case study of a frugal design for a centrifuge for sample preparation for schistosomiasis. This neglected tropical disease impacts the lives of over 240 million people, mainly in sub-Saharan Africa.

Technology is making a substantial contribution to global health. Yet it could do much more (Howitt et al., 2012). While medical devices are indispensable to healthcare, many device technologies are inaccessible to the majority of people who need them, particularly in Low- and Middle-Income Countries (LMICs) (Aranda-Jan, Cruickshank and Moultrie, 2015; Hood and Rubinsky, 2020; Sinha and Barry, 2011; Verma, 2017). One of the reasons is the fact that the majority (95 per cent) of medical devices have been developed in and for the healthcare context in high-income countries, despite a significant need to expand healthcare services in LMICs (Aranda-Jan et al., 2015; Vasan and Friend, 2020).

Poorly functioning or non-existent supply chains, along with high purchase and import costs, make it very difficult for hospitals to get access to basic, but essential supplies. The World Health Organisation (WHO) estimates that 70 per cent of medical equipment exported from high-income countries does not work in hospitals in low-income countries due to lack of trained personnel, limitations with infrastructure and the lack of spare parts for equipment maintenance and technical support (Howitt et al., 2012). These technologies are developed to function in fully operational healthcare facilities with reliable and stable electrical supplies, large capital, consumables budgets and highly qualified clinical and technical professionals. Since conditions in LIMCs are different from those the equipment was initially designed for, the imported technologies are typically challenged by practical problems such as intermittent electric power outages and shortage of spare parts (Aranda-Jan et al., 2015). These challenges limit the functionality and optimal performance of this medical equipment. As a result, Kenyan healthcare facilities, for example, are on average sustained by only 77 per cent of the equipment that the WHO lists as necessary (IHME, 2014). For Kenyan dispensaries (usually the only option in rural settings), this number drops to 60 per cent, and even further to about 23 per cent in some remote dispensaries. In conclusion, there is a tremendous need for medical equipment pre-designed to function regardless of the practical operational challenges and limitations in LMICs. In the current situation, there is either a lack of access to medical equipment or the available equipment does not function.

A promising alternative approach to the healthcare setting in LMICs is to develop more frugal medical technologies and products that are specifically designed to meet the needs of low-resource settings (LRS) (Howitt et al., 2012; Vasan and Friend, 2020). Those most in need in LMICs are not well served by hand-me-down technology and donations from high-income countries. Technologies that account for constraints in finance, healthcare workers and even reliable electricity supplies (Howitt et al., 2012) are needed. The healthcare sector is expected to benefit most from frugal innovation – the idea that more can be done for less for many more people – globally (Bhatti et al., 2017).

Bhatti et al. (2017) define frugal innovations in this healthcare context as products, processes or policies that leverage means and ends to do more with less for many and therefore have the potential to increase the value and provision of healthcare (Bhatti et al., 2017). In addition, frugality is about affordability, but in moving beyond early perspectives of frugal innovations as simply 'good-enough' or 'no-frills' products, we must recognize that frugality is also about adaptability and accessibility. Adaptability in healthcare encompasses 'fit' for use in the local and clinical setting, and accessibility in healthcare relates to universal coverage and scale (Bhatti et al., 2017; Winterhalter, Zeschky, Neumann and Gassmann, 2017; Zeschky, Winterhalter and Gassmann, 2014). Frugality in this perspective also means minimal use of resources (financial, human, and material) without giving up efficient functioning (Bianchi et al., 2017). Finally, Niemeier et al. (2014) bring to the fore the idea that designing for healthcare in LMICs is equivalent to designing for scarcity (frugal design) and scalability (with strong value propositions and support from the private sector).

In general, two forces drive frugal innovation and contribute to the development of these tools, processes and/or techniques. One is from companies or is supported by organizations such as the WHO to provide accessible technologies by simplifying existing high-tech tools. For example, the WHO compendium of innovative health technologies for low-resource settings in 2017 resulted in 39 prototypes and 29 commercially available products that facilitated the access to a series of innovative health technologies for low-resource settings, hence providing a neutral platform for technologies which are likely to be suitable for use in less resourced settings (WHO, 2018). The other force that drives frugal innovation is low-cost homegrown "fixes", which use low-tech (or even "no-tech") solutions to solve unmet needs (Tran and Ravaud, 2016). For example, Uganda's bicycle ambulances made by bicycles and electric scooters help the pregnant, sick and injured in rural villages access healthcare facilities (Wallrapp and Faust, 2008).

Tran and Ravud (2016) propose distinguishing between four types of frugal innovation in medicine (see Table 13.1) to better understand, define and help people identify frugal innovation.

Table 13.1 Four types of frugal innovation in medicine (Tran and Ravaud, 2016)

High-tech	Lean tools and techniques	Opportunistic solutions	Contextualized solutions	Bottom-up solutions	Home-grown
	Simplification of existing techniques or technologies	Use of modern technologies to tackle ‘old problems’	Deployment of existing tools for entirely different purposes	Use of low-tech approaches to solve local unmet needs	

Bianchi et al. (2017) nicely summarized the main frugal features of the health technological developments as:

1. Affordability.
2. Good quality and performance.
3. Ease of operation.
4. Use of cutting edge technology.
5. Sustainable design.
6. Involvement of users as co-designers.

Systematic approaches for frugal design are still limited. Some of them focus on specific frugal features from the list above. For example, Rao in Chapter 16 of this *Handbook* proposes a frugal design approach that facilitates and quantifies minimal consumption of materials during the realization of frugal innovations. The approach focuses on ‘sustainable design’ (feature 5) and ‘good quality and performance’ (feature 2). In our frugal design approach, as presented in this chapter, we aim at a holistic design approach that includes all 6 features. Consequently, additional attention is provided to ‘use of cutting edge technology’ (feature 4), ‘ease of operation’ (feature 3) and ‘involvement of users as co-designers’ (feature 6). This is closely in line with the description of frugal innovation as presented throughout this *Handbook* (see, for instance, Chapters 1, 5, and 17): The frugal innovation process is – in contrast to sophisticated top-down R&D led innovation – one that employs bottom-up, human-centric, appropriate, local and cost-efficient approaches through processes such as design thinking, bricolage, creative improvisation and lean and reverse engineering. Although none of these design-thinking concepts are independently new, it is the combination and the shift in how these all work together through varied actors that is new and distinctive (Beers and Leliveld, 2020).

13.1.2. Distributed Production as a Frugal Technology for Medical Devices

In subsequent sections of this chapter, we will present a frugal design case of a medical centrifuge with a focus on distributed production (3D printing) as a frugal technology to increase access to medical devices in LMICs. In reference to the categorization of Tran and Ravaud (see Figure 13.5, later), we would classify our frugal design case as an ‘opportunistic solution’ sub-type in which a cutting edge technology is applied to tackle old problems.

In manufacturing, the focus has been on centralized production systems. Large concentrated machinery, capital required and energy consumption characterize mainstream manufacturing and have pushed manufacturing towards a centralized model. This model, despite having been the norm for manufacturing, has set huge dependencies for products and services to travel long distances to reach consumers. In some cases, the complexities of transportation and supply-chain systems prevent products and services from reaching distant or remote areas. Most medical devices are currently centralized and produced in high-income countries and do not reach or fail in low-income countries. Recently, 3D printing technology has emerged as a convenient method for the rapid development and production of cost-effective diagnostic tools (Chan, Tan and Wu, 2017). Distributed manufacturing in the context of sub-Sahara Africa, such as 3D printing for medical devices, could be an alternative and more promising production strategy. Distributed manufacturing can be described as a production system consisting of small-scale manufacturing units equipped with physical and digital technologies, which enable the localization of manufacturing facilities and comprehensive communication between all supply-chain actors in order to facilitate customer-oriented production (Petrulaityte, Ceschin, Pei and Harrison, 2020; Vezzoli et al., 2018). The spectrum of production is decentralized to allow very small- and large-scale production through aggregated networks and coordination. This is clearly illustrated within the 3D Hubs Maker Movement, as it demonstrates a mature example of distributed manufacturing. There is a growing synergy between globally accessible knowledge commons and local digital fabrication technologies (Kostakis and Papachristou, 2014). This creates a powerful blend to restructure manufacturing towards a more decentralized model with an optimal goal of meeting global demand. And, as such, it is a promising alternative for the production and use of medical devices in sub-Saharan Africa.

Distributed manufacturing fits very well with the polycentric nature of frugal innovation, which combines top-down and bottom-up innovation processes, as well as different actors, and which is expected to enable more inclusive forms of innovation and development (Knorringa, Peša, Leliveld and van Beers, 2016; Radjou, 2009).

Distributed manufacturing through 3D printing, for example, is one of those cutting-edge technologies that could tackle the current challenges (James and Gilman, 2016). By using 3D printers to produce goods at a "hyperlocal" level, a new type of distributed or localized manufacturing is emerging which radically reduces lead-time and costs as well as dependence on complex international supply chains. Moreover, it can empower local markets and provide goods and products tailored to local needs (Birtchnell and Hoyle, 2014; Gwamuri, Wittbrodt, Anzalone and Pearce, 2014; James and Gilman, 2016; Ramadurai, 2017). Distributed manufacturing through 3D printing creates a social, environmental and economic opportunity that is invaluable to sub-Saharan Africa (SSA). Specific foreseen opportunities of distributed production of medical devices in SSA are as follows.

- *No dependence on import*. Healthcare systems in low-resource settings such as East Africa usually rely heavily on importing medical equipment, due to the unavailability of local manufacturers. However, poorly functioning or non-existent supply chains lead to excessive transportation costs and long lead times (Gwamuri et al., 2014). According to the World Bank, importing goods into areas such as sub-Saharan Africa is, on average, ten times as expensive, and can take up to 25 times longer, than importing goods into high-income countries. By stationing 3D printers in close proximity to where medical equipment is needed (i.e. healthcare centres), a new type of distributed or decentralized manufacturing can emerge. This greatly reduces the reliance on complex international supply chains, therefore drastically reducing costs and lead times and ultimately increasing access to medical equipment in low-resource settings (Gwamuri et al., 2014; James and Gilman, 2016).

- *Producing equipment tailored to local needs*. There is a huge mismatch between medical equipment shipped to low-resource settings and what these settings actually require. Currently, much of this equipment was designed for use in countries with adequate resources and infrastructure, and therefore does not match the need in low-resource settings of robust and affordable equipment (WHO, 2010). 3D printing can be used to produce equipment tailored to these local needs. For example, Gwamuri et al. (2014) developed 3D-printable self-adjustable glasses for low-resource settings that are customizable to fit each individual's needs. These glasses can be produced for around $6 and therefore also offer a significant cost reduction.

  Another notable example is a 3D-printable stethoscope that can be produced for $4 and performs similar to a conventional stethoscope, which is typically sold for about $80 (Pavlosky et al., 2018). At the TU Delft, likewise, the ExcelScope and the Schistoscope (Agbana et al., 2020; Agbana et al., 2018; Agbana et al., 2019), which are currently under development, are low-cost, 3D-printed diagnostic devices that use a smartphone to diagnose malaria and schistosomiasis, respectively. Part of their design goal is to ensure that low-skilled community healthcare workers can operate these devices.
- *Production of spare parts*. In LRSs, 40 per cent of medical equipment in hospitals is broken (Perry and Malkin, 2011), of which 28 per cent just requires spare parts to repair (Malkin and Keane, 2010). Unfortunately, these spare parts are rarely available, due to lack of standardization, lack of access to maintenance manuals and the previously mentioned badly functioning supply chains (WHO, 2010). With the help of free CAD design software, 3D printing can be used to produce spare parts locally and on-demand. The Kijenzi team in Kisumu (Kenya), for example, was able to fix a dozen microscopes which initially cost approximately $1,000 each. The broken microscopes, which were lying around in a rural hospital in Kenya, were fixed by replacing the broken focus control knob with a 3D-printed knob that cost a few cents to produce (Kats, Spicher, Savonen and Gershenson, 2018). Many similar examples were identified in which 3D printing had a significant impact through production of small and cheap spare parts (John, John, Cuthbertson, VanKoevering and Green, 2017).
- *Stimulating the local economy and entrepreneurship*. By producing medical devices locally, the economy can benefit from an increase in job opportunities, capacity building, as well as local value creation. The distributed manufacturing model can also aid in stimulating the local economy, as it increases economic independence through local production of medical equipment instead of having to rely on imported equipment (this has proven to be even more crucial during pandemics such as Covid-19). According to Rogge et al. (2017), 3D printing can create opportunities for small businesses to enter markets producing and selling 3D-printed products, with lower costs and fewer barriers to entry. Unlike traditional manufacturing methods such as injection moulding, 3D printing does not require any form of tooling, and therefore upfront investments are much less.
- *Circular economy*. according to Despeisse et al. (2017) "3D-printing holds the potential to enable the shift towards a circular economy". The production technology itself is resource-efficient, the production of each unit leads to (almost) no excess production waste. By recycling used 3D-printed products into filament, and using this for 3D-printing purposes, a closed-loop material circulation system can be created (Baechler, DeVuono and Pearce, 2013). The Digital Blacksmiths in Nairobi have already started working on a recycling system that can produce filament from PET bottles (Baechler et al., 2013;

Mohammed et al., 2016; Rogge et al., 2017). In a country such as Kenya, there is an abundance of plastic waste and putting this to good use is a treasure waiting to be unlocked.

A mature example of how SSA is leveraging specific foreseen opportunities of distributed production of medical devices is the vibrant entrepreneurial and open access to makerspaces which have become a one-stop-shop for rapid manufacturing. Makerspaces have become a centre for manufacturing in Africa with classic examples in Nairobi, such as Gearbox Kenya, Kumasi Hive and MakerSpace Nairobi. Makerspaces in Africa are also beginning to assume the role as a connector between formal and informal manufacturing players with the goal to continuously expand the means of distributed manufacturing.

With the knowledge in mind of the lack of access to medical devices in low-resource settings as well as the opportunities provided by local distributed manufacturing, we will move on to the second part of this chapter: the Frugal Design Case Study on the development of a centrifuge for sample preparation for the diagnosis of *Schistosoma haematobium* (a neglected tropical disease).

13.2. FRUGAL CENTRIFUGE: A CASE STUDY

Within the Diagnostics for All research programme at Delft University of Technology, a range of frugal medical devices are being developed, such as the Schistoscope. In this chapter, we will describe the design process of the Frugal Centrifuge. We will start by describing the healthcare context in which these medical centrifuges are being used, as well as their function. Next, we will explain the Frugal Design Process with an emphasis on design for energy efficiency, design for distributed production, design for usability and design for repair and maintenance.

13.2.1. Diagnostics of Schistosomiasis

Schistosomiasis is a debilitating disease that affects over 240 million people, with the highest burden of morbidity and mortality in SSA countries. Despite its huge impact on the health and socioeconomic burden of society, it remains a so-called ‘neglected tropical disease’, with limited attention from governments and stakeholders in healthcare settings (Ajibola, Gulumbe, Eze and Obishakin, 2018). The disease is characterized by chronic infections with significant residual morbidity and is of considerable public health importance, with substantial socio-economic impacts, especially on impoverished communities (Weerakoon, Gobert, Cai and McManus, 2015).

Schistosomiasis can be cured without progressing to complications if there is an accurate diagnosis. Early and accurate diagnosis will enable prompt treatment and killing of worms in the infected host during the initial stages of infection. Hence, the use of appropriate, sensitive diagnostic tools to identify infected individuals is imperative (Ajibola et al., 2018; Weerakoon et al., 2015). However, access to accurate diagnoses is lacking in many parts of rural Africa (Bogoch et al., 2017). Inadequate laboratory capacity is a key obstacle to the delivery of quality healthcare in resource-constrained settings. This frequently results in undertreatment or overtreatment of infectious diseases, as diagnosis is most often based on clinical assessment alone. Laboratory infrastructure is typically clustered in urban settings and is relatively inaccessible in rural regions where significant portions of the affected population reside (Bogoch et al., 2017; Rajchgot et al., 2017).

Conventional methods for diagnosing schistosomiasis using urine or faeces sample are still widely used because they are cheap, fast and relatively simple. In our case, we focus on the diagnosis of *Schistosomiasis Haematobium*, which is done by identifying parasite eggs in urine. The urine-based diagnostic procedure can be divided mainly into 'filtration method' and 'urine sedimentation method'. Urine filtration does depend on importation and use of specialized membrane filters and filter holders with its consequent costs and long delays in the supply chain. In order to reduce costs and become independent of import of consumables such as filters, the design process of a Frugal Centrifuge (sedimentation method) was initiated.

The urine sedimentation method aims at visualizing urine sediments under a microscope. A centrifuge is critical for the preparation of the sample in this procedure. In the case of schistosomiasis, typically, four 15 mL tubes containing 10 mL of urine are centrifuged at 2,800 revolutions per minute (rpm) for 5 minutes. This process speeds up the sedimentation of the parasite eggs, and after that the sedimentation is examined for the presence of the target parasite eggs by an expert microscopist.

The tubes are placed inside the rotating part of the centrifuge, called the rotor. Rotation of the rotor generates a Relative Centrifugal Force (RCF), expressed in multiples of the Earth's gravitational '*g*' force. The magnitude of the RCF depends on the speed of the rotor, the revolutions per minute (rpm) and the radius of rotation (*r*). Next to the rotor, the damper is a critical component of the centrifuge. The main function of the damper is to keep the device stable while the rotor is spinning. Without the damper any imbalance of the rotor would be directly transferred to the device, causing the device to move or become unstable, consequently triggering the exertion of excess force on the internal structure, such as the motor axis. This can also put the user's safety at risk. The rotor is powered by an electrical motor which is fixed to the damper.

Centrifuges are commonly available in standard laboratories, but their application in the field is limited by the following: high cost, size and bulkiness, lack of spare parts and high dependency on electricity, which is not commonly available in remote areas. There is a clear need for a low-cost, reliable, easy to operate and easy to maintain centrifuge for point-of-care diagnostics in low-resource settings (Bhamla et al., 2016; Sule, Petsiuk and Pearce, 2019; Zhang et al., 2018).

Several initiatives have been made to develop frugal centrifuges and, as such, they have become more accessible to low-resource settings. Bhamla et al. (2017), for example, developed the so-called "paperfuge". By uncovering the fundamental mechanics of an ancient whirligig toy (3,300 BCE), they designed an ultra-low-cost (20 cents), lightweight (2 g), human-powered centrifuge that is made out of paper (hence "paperfuge"). Although the paperfuge is capable of centrifuging samples at speeds of up to 125,000 rpm and exerts centrifugal forces of 30,000 *g*, it is limited by the sample volume it can hold (20 µL per capillary tube). To increase volume capacity, other research groups have been developing 3D-printed variants based on the paper-based centrifuge. Byagathvalli et al. (2019) developed the 3D-Fuge, which increases the volume capacity to 2 mL and can reach hand-powered centrifugation speeds up to 6,000 rpm (Byagathvalli et al., 2019). Still, 2 mL is not close to the 10 mL required for diagnosing schistosomiasis in urine. Sule et al. (2019) developed another low-cost, human-powered 100 per cent 3D-printed centrifuge, which can process larger samples. The downside to this frugal device is its lower rotational speed (1,750 rpm), which leads to impractical centrifugation times for a simple urine sedimentation (> 10 min) (Bhamla et al., 2016). Even though human-powered devices are a perfect solution for overcoming the lack of access to power in rural settings, they do increase the human error in the sample preparation process since the rpm and time are less under control. In addition, the field staff would spend a serious amount of time on sample preparation when the centrifuge is human-powered.

A Frugal Design Project was initiated to combat the challenge of the lack of accessibility to medical centrifuges in rural areas and to overcome the limitations of the current centrifuges.

13.2.2. The Frugal Design Process

The Frugal Design Project was initiated based on the following design brief.

Design brief: develop an affordable centrifuge specifically for the preparation of urine samples for the diagnosis of *Schistosoma haematobium* in low-resource settings in sub-Saharan Africa. The vision is to produce the device in Africa by distributed production (i.e. 3D printing) and use off-the-shelf components to increase availability as well as maintenance and repair. The device will be used in primary healthcare centres (PHC) and field labs (off the grid) without the need for much technical training or expertise (see Figure 13.1).

This design brief includes the six frugal features as defined by Bianchi et al. (2017): *affordability* (cost-effective solution), *good quality and performance* (in line with WHO standards), *ease of operation* (by limited trained healthcare workers), *use of cutting edge technology* (3D printing as production method), *sustainable design* (creating social value and limit environmental impact), and *involvement of users as co-designers* (in early stage of design process co-creation with end-users).

Figure 13.1 Field lab setting (left) and primary healthcare setting (right)

In order to achieve a successful result within a limited time period and a minimal budget (frugality), the design process for this frugal design project was intentionally:

- *Multidisciplinary*: in addition to a core design team, a range of experts from different disciplines were continuously involved, including public health experts in the Netherlands and Nigeria, distributed production experts in the Netherlands and Kenya, and human-centred design experts.
- *Short iterations*: the team applied ‘Scrum’ during the project as a method for planning and managing the project. The project planning was split into smaller windows, called sprints.

Each sprint took two weeks. The goal of this method was to have short, flexible working cycles in order to adjust quickly as the project develops.

- *Experimentation*: during the sprints, multiple mock-ups and prototypes were developed. Technology tests were carried out in labs, and user tests were executed accordingly. This was done in order to get fast confirmation or rejection of ideas and solution directions. See Figure 13.2 as an example of the evolution of design iterations.

Figure 13.2 Fast iterations and experimentations during the Frugal Design Process

- *Initial frugal technical principle*: the project started with an initial frugal technical principle created by one of the researchers from the Diagnostic for All research programme. The idea was to develop a portable Frugal Centrifuge based on a rechargeable drilling machine in combination with some off-the-shelf electronics and 3D-printed parts. Within a few days a first mock-up was prototyped (3D-printed rotor, a DC motor, custom electronics and a potentiometer, mounted on a laser-cut wooden base) – see Figure 13.3.

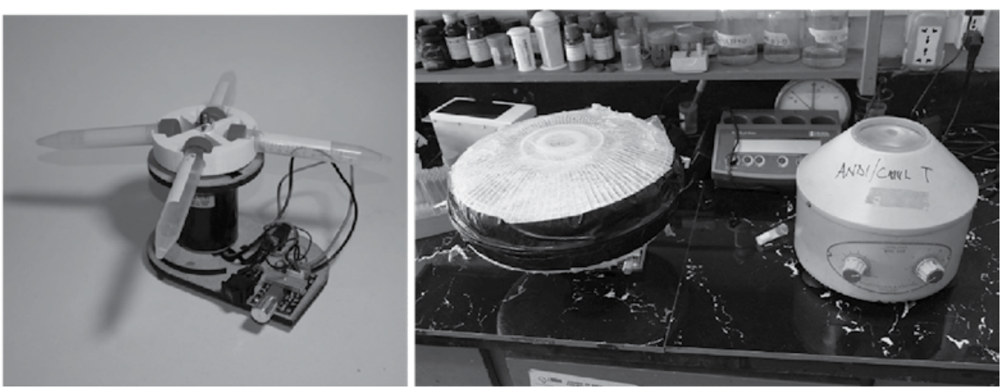

Figure 13.3 Mock-up of initial technical principle (left), picture of a Chinese centrifuge currently mostly used (right) and the mock-up covered by fan protectors (middle) during field research

The mock-up of the initial technical principle was shipped to the potential user context in Nigeria to get reactions and feedback from potential end-users as well as to co-create directions for improvement. For safety reasons, the mock-up had to be covered (see Figure 13.3, middle) with fan protectors. This early in the product development process, field tests provided direct, valuable feedback. Through observations and user testing, the following design challenges were discovered.

- The most currently used centrifuges are too big and too heavy for transport to the field on motorbikes on Nigerian roads.
- The centrifuges need a power grid, which is nearly absent in the field lab settings. The power consumption of the centrifuge has to be considerably decreased for use in the field. The current models would need too much external power back-up and or PV-Panels.
- The current centrifuges are not designed for use by local healthcare workers, who have minimal experience with these kinds of devices. They are not suitable for unskilled users.
- The control allows variations in the operational speed, but the actual speed of the device is not precisely monitored. Preset speed and duration would be preferred to avoid errors due to human operation and to stick to recommended protocols.
- The initial design of the sample holders holds the tubes in a horizontal position (see Figure 13.3). Although this is the best orientation during the spinning procedure, the samples need to be inclined at an angle once they are unmounted. This is to prevent the sediment from remixing with the liquid after removal.

These direct inputs from potential end-users helped further specify the design brief. In the next section, we will discuss some of the elements of the Frugal Design Process, the Design for Energy Efficiency, Design for 3D Printing, Design for Usability and Design for Reparability.

13.2.3. Design for Energy Efficiency

From the start, it was clear that the centrifuge should be designed for low-energy consumption. The current centrifuges are designed for Western lab settings in which electricity is continuously available at a consistent quality. However, electricity remains a shortage in almost all sub-Saharan African countries. A large part of the continent is still not connected to the grid (Narayan et al., 2016, 2018). Moreover, even if areas have access to electricity, the power grid remains very unstable and frequent power outages can be expected. In the case of the use of the centrifuge in a field lab setting, the electricity has to be stored in the device itself, or be provided by a power bank or PV panels. During the first field research, healthcare workers indicated that they would need a centrifuge that could be operated without external power supply for a few days. External power supplies such as power banks and PV panels were not seen as a proper solution since they would create additional challenges during transport and setup. As a result, the design team decided to develop an integrated power storage solution.

Since the power storage is directly linked to the energy consumption per cycle, it is therefore essential that the power consumption is decreased as much as possible. The rotor should have minimal air friction, as this will enable the device to sufficiently operate long enough on battery power. Currently available centrifuges are not energy efficient; the open rotor (see Figure 13.4, left) model used in the design creates a large amount of air resistance within the device, and consequently consumes a lot of energy. The higher the revolutions per minute (RPM), the higher the loss of energy efficiency. 3D printing as a production technique offers the opportunity to develop a much more aerodynamic alternative rotor (see Figure 13.4, right). The rotor fully encloses the tubes, and the shape of the rotor is as symmetrical around the axis as possible. This serves to lower the air resistance by a factor of almost ten compared with a conventional open rotor design. In addition, the power required to spin two or four tubes does not differ, which makes it easier to achieve a consistent performance in terms of sedimentation and battery life.

Figure 13.4 Traditional open rotor (left) and 3D-printed aerodynamic rotor (right)

A second factor influencing the energy efficiency is the radius of the rotor. By creating a design in which the tubes are closely mounted at a 55° angle (instead of the standard 45°), the energy efficiency could be further improved. In addition, the smaller radius also creates a better fit with the dimensions of the print bed of the 3D printer (see the next section).

A comparison between the open rotor and closed rotor at a speed of 3,000 rpm (use scenario) demonstrated a reduction of the energy consumption by a factor of ten (see Figure 13.5).

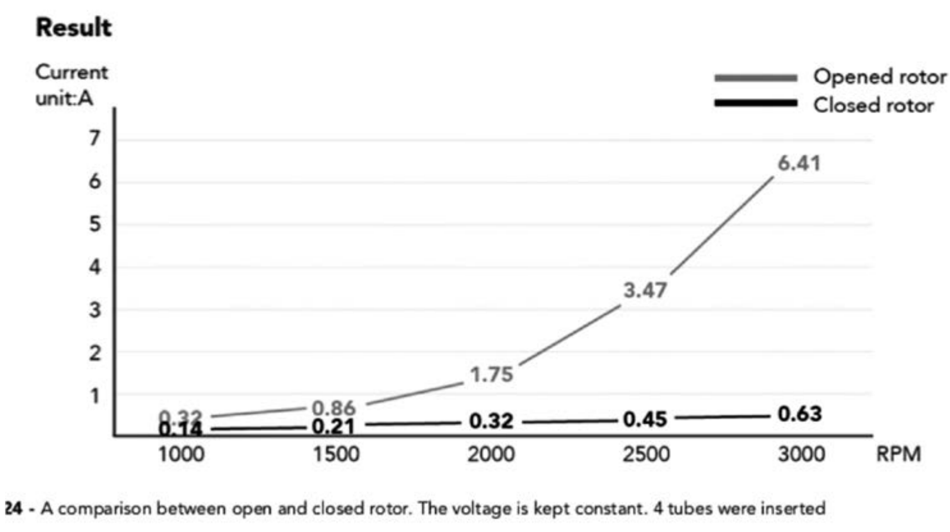

Figure 13.5 Energy consumption by a traditional open rotor (grey upper line) and a new developed closed rotor (black lower line)

This has a range of (positive) consequences for the design. Reduction in energy consumption results in a decreased need for energy storage. Consequently, the size and costs of the batteries can be reduced (the batteries are responsible for about a quarter of the total production costs).

Finally, the decreased friction makes it possible to select a smaller motor in terms of power, size, weight and costs, which has a positive impact on the design of the damper and production costs. The final design was capable of running 53 operating cycles (4 hours and 25 minutes) on the built-in batteries, which translates to the processing of over 200 patient samples.

13.2.4. Design for 3D Printing

The design of the centrifuge had to take into account the limitations of 3D printing (i.e. the limited dimensions of the printing bed), on the one hand, and requirement to leverage the strengths of 3D printing (i.e. freedom in shape and material density), on the other. We will discuss four design considerations below.

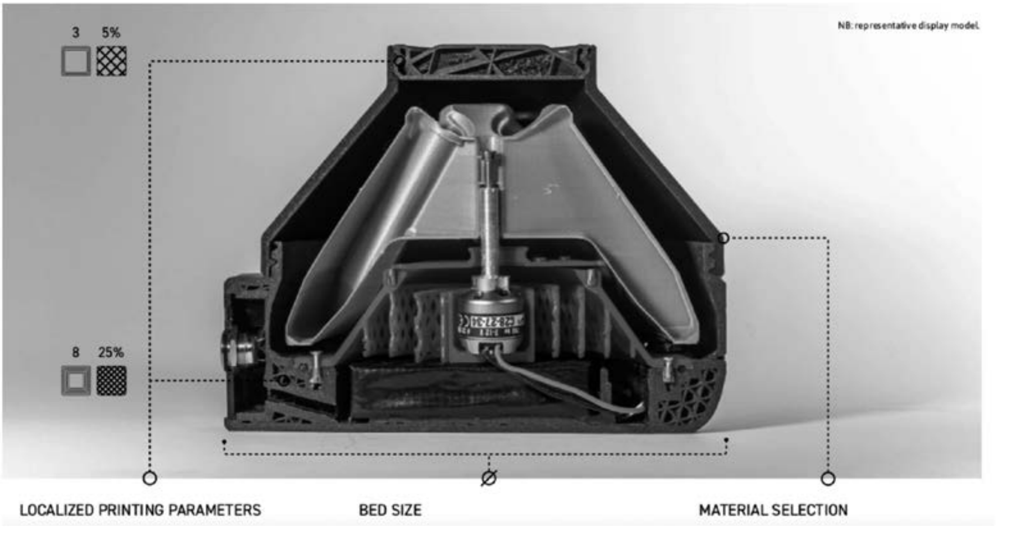

Figure 13.6 Cross-section of the Frugal Centrifuge (Around motor=damper, light grey in middle = rotor, dark grey outside = housing) with design considerations

- *Localized printing parameters*. To ensure efficient and cost-effective 3D printing that maximizes product performance, localized areas of the 3D-printing matrix could be altered using modifier meshes in the slicing software. For example, the lower areas of the housing base contained a denser fill (25 per cent) and thicker wall section than higher up (5 per cent fill and thin wall) to shorten printing durations, whilst ensuring strength in critical areas (see Figure 13.7). Digital simulations were performed to assess the effect of varied printing parameters (fill density and perimeter thickness) and part geometry on the strengths of critical parts and find the best trade-off in between reliability, printing time and materials consumption.
- *Bed size*. The 3D-printed components of the device were required to fit within the printing bed size of 20 cubic centimetres of popular 3D printers. Thus, the layout and geometry of internal components to fit within this design space was a prominent challenge to overcome. Owing to the limited print bed size, the rotor's maximum diameter should fit in the base

with some clearance. With the initial rotor angle of 45°, we encountered the problem of the housing and base not being able to fit on the print bed due to the large diameter. It was therefore decided to design the rotor with a tube positioning and wall angle of 55° degrees.

- *Material selection*. To withstand the high temperatures, 80 per cent humidity and rough terrain in sub-Saharan Africa, the use of an appropriate material was key to the robustness of the device. PETG was chosen as the most suitable material, following theoretical analysis and practical validation during experiments.
- *Integrated damping functionality*. The main function of the damper is to keep the device stable while the rotor is spinning. In addition, excessive vibration consumes a lot of energy, decreasing the battery life. The design challenge was to develop a new damper that absorbs vibration and keeps the device stable during operation. 3D printing as a production method offers the opportunity to develop a tailor-made and integrated damping solution instead of being dependent on off-the-shelf supplied standard dampers. Consequently, a design process was initiated to develop a damper consisting of a cone in which an integrated spiralling 3D structure supports the motor (see Figure 13.7). By allowing the motor to align itself with the rotational centre of mass of the rotor, and by absorbing energy from this movement, little force is transferred to the device. After 16 3D-printed prototypes and extensive testing and simulations, a satisfactory geometry was found. The new 3D-printed integrated dampers led to improved product experience by a reduction in noise and vibration.

Figure 13.7 3D-printed and integrated damper

13.2.5. Design for Usability

A key objective of the frugal technology is to deliver contextualized solutions by carefully taking into account the user(s) and healthcare context. To ensure successful adoption of the Frugal Centrifuge by the community-based health workers in remote and rural areas, their knowledge level and educational backgrounds were taken into account during the design process. Owing to limited training, they often have a lack of knowledge of the diagnostics methods. Consequently, usability was considered one of the crucial design aspects. As a first step, in-depth understanding of the target user and context of use was gathered by means of field research and a literature review. This was further defined and visualized by creating personas and experience maps (Figure 13.8) to describe the key characteristics.

Health workers at the primary level are the closest healthcare providers to the community (Ogunfowora and Daniel, 2006). These health workers often do not have a formal education and have limited professional training. They are trained to provide the first point of contact for

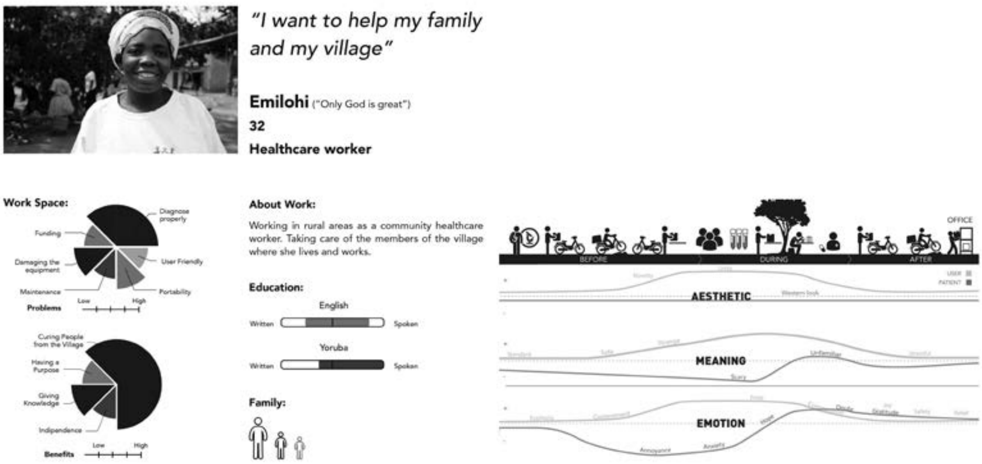

Figure 13.8 *Persona (left) and experience map (right)*

the community (Haines et al., 2007). The health workers provide basic treatment and referral to a higher level of care providers, while also performing simple point-of-care diagnostics for common diseases such as malaria (Paintain et al., 2014). Since they are not used to operating more advanced diagnostic tools, extra training will be required to use a new medical device. Considering the limited resources available for providing training, the device should be easy to learn how to operate. In order to prevent incorrect usage during sample preparation, potentially causing damage to the device, it should be as error-proof as possible.

Next, these requirements were translated into the detailed usability specifications. These requirements were taken into consideration for overall embodiment, interface and interaction design. Based on our insights, we defined the key requirements for usability as the following.

- Intuitive and simple.
- Easy to learn and requiring minimal training.
- Clear feedback on the performed action.
- Low maintenance from the users.
- High affordance to ensure safe and correct usage.
- Error-proof.

The initial interaction concept designs were developed and tested with participants who were not familiar with a centrifuge. The most promising elements were integrated into the final design, which are the following (Figure 13.9).

- *Simple operation with one-button*. It takes only one press on the button to run the centrifuge. More choice in functionality could lead to improper use. The button indicates its operation status with colour contrast once it is pressed. This simple operation will enable use of the device with basic training and limited healthcare experience.
- *Minimal but not limited functionalities*. The interaction is designed to be simple and straightforward. By pushing the button, the centrifuge will run a preset cycle which in the case of urine filtration will be 5 minutes at 3,000 rpm. This predefined setting prevents

human error, and it also allows easy device operation for non-technical users. Built-in digital sensors measure the speed to ensure compliance with health standards. The presets (duration and speed) can be adjusted for other types of sample preparation by the main operator through WIFI or Bluetooth access. This allows for the potential use of the centrifuge for other purposes than the diagnosis of *Schistosoma haematobium* alone.
- *Clear and Intuitive display*. The display provides a clear indication of the key functions: power, remaining cycle time, and battery level. The power button gives clear feedback once it is pushed. The 5-minute timer indicates one minute per one LED and it turns off automatically. The battery level is indicated by LEDs turning off from the right to the left side, which is a common analogy used for mobile phones.

Figure 13.9 Interface design with indication of power, remaining cycle time, and battery level

13.2.6. Design for Repair and Maintenance

Maintenance and repair is one of the main challenges to keep medical devices operational in sub-Saharan Africa, due to a lack of spare parts. The usage of 3D-printed components enables not only local distributed manufacturing, but also means that parts can easily be reprinted and replaced in case of a breakdown. The centrifuge is designed with the vision that it will be locally repaired. It can be disassembled for easy part replacement based on the designed product architecture and the use of uniform fixtures (requiring one single tool to be used when (dis)assembling). An overview of the estimated lifespan and the effort to replace all part has been made. This overview shows a positive relation between parts that are prone to break, and parts that are easy and cheap to replace. Parts with the shortest lifespan are the cheapest/easiest to reprint. Repairing the device will make the user or owner less dependent on external supply chains.

13.3. CONCLUSION, DISCUSSION AND RECOMMENDATIONS

13.3.1. Conclusion

The final Frugal Centrifuge (Figure 13.10) was tested in a lab setting by medical and technical experts using urine samples spiked with cultured *Schistosomiasis haematobium* eggs obtained from the Leiden University Medical Center. The urine samples were sedimented correctly.

Figure 13.10 Final Frugal Centrifuge

These urine samples were analysed under the microscope, and in all cases parasite eggs were found. The centrifuge device operated smoothly and safely, without excessive vibration or noise. Control systems operated as desired, and for a full 5 minutes.

The final design of the Frugal Centrifuge has proven to be a fully functioning centrifuge according to medical standards. It can be produced locally through 3D printing and off-the-shelf components and with its ‘one button’ use can be operated by minimally trained healthcare workers. The Frugal Centrifuge is capable of processing over 200 samples on one full battery set. The overall production cost of the device is estimated to be €122, which makes it an affordable sample preparation device. The performance, safety and usability of the device have been validated through our testing, where the device was able to spin uninterrupted for 5 minutes without compromising the safety of the user. Interaction with the device is intuitive and straightforward, which prevents possible errors. The device’s portability is enabled by its compact size and lightweight production, making it convenient for transportation. Ideally, the device will be delivered in its own protective padded bag.

For the internal components and housing, 3D printing has been chosen as the most suitable method of production and has proven to be a suitable distributed production method for local production and, as such, reduces dependence on long and delayed supply chains. 3D printing also offers a solution for repair and maintenance through the reprinting of broken and worn out parts. In addition, 3D printing allows freedom in shape. This resulted in a new rotor, with strongly improved aerodynamics, which is 10 times more energy-efficient than current models. 3D printing made it possible to design and print an integrated damper. Last but not least, simple but ‘smart’ electronics make it easy to operate, avoid human-error and secure the proper speed and duration of the centrifugation.

13.3.2. Discussion

Despite the advantages of 3D printing, there were also limitations we faced during the design process. First, high quality 3D printers are not yet as widely available and accessible in Africa as we envisioned. The success and quality of the produced device greatly depends on the quality of the 3D printer. This means that the quality of the machine itself, maintenance and the printing parameters should be taken into consideration, as they are not yet optimized in LMICs. Moreover, the 3D-printing costs are relatively expensive due to scarcity. In addition, the time to print a single part was not yet time-efficient, and this will be a significant challenge to producing the device at large scale. External barriers to 3D printing were also found, such as lack of material supply, low quality of prints and inconsistent energy supply. As described in Section 1.2, we expect that distributed manufacturing, including 3D printing, has a high potential to grow in a short time and overcome these barriers and challenges. However, we should not consider 3D printing as an ultimate solution, but as one of the opportunities that can widen our design choices. But even more, it can make LIMCs resilient in producing and maintaining their own medical devices.

With regard to the frugal design process, it is an inclusive design process with its own challenges. As Bhaduri, Corradi, Kumar and Sheikh mention in Chapter 5 of this *Handbook*, the emerging discourse on frugal innovation has necessitated new forms of interdisciplinary investigations, especially if one is interested in understanding how a frugal innovation process unfolds. Likewise, frugal design approaches for medical devices have to adopt interdisciplinary design methods and tools. For a successful frugal medical design, it is crucial to have a good understanding as well as the involvement of all disciplines and stakeholders within the ecosystem. This will make the design process more complex (multiple perspectives, multiple inputs), but the outcome is what we would call 'richer'. More considerations have been taken into account and the successful adoption of the new frugal innovation by the multiple stakeholders (medical staff, policymakers, makerspaces, NGOs) is expected to be higher (Kersten, Diehl and Engelen, 2018). In practice, this means, among other things, that the design team has to be flexible and adaptive to manage the complexity.

The practice of frugal design also brings together different economical and educational levels. From this perspective, Leliveld and Knorringa (2017) envisage a collaboration between the so-called 'top-down' and 'bottom-up' forms of frugal innovations for a fruitful future of the frugal innovation agenda, with which we agree. The 'bottom' (i.e. local producers and entrepreneurs) can learn tremendously from the 'top' about new emerging technologies and systematic design processes. Meanwhile, the other way around, the 'top' can acquire crucial knowledge concerning the specific characteristics and needs of the local distributed manufacturing ecosystem and healthcare system in place. For this, it is crucial to eliminate 'the gap' between the 'top' and the 'bottom' and to stimulate mutual understanding and stimulate informal communication via WhatsApp, for example, to create a common trust and an open sharing of ideas and knowledge.

13.3.3. Recommendations

With our frugal design case of the development and production of a Frugal Medical Centrifuge, we have explored and demonstrated the potential of distributed production technology for frugal innovations in the healthcare sector in sub-Saharan Africa. Even though many potential benefits came to the fore, many challenges still lie ahead before a mature local distributed production ecosystem is in place.

There is a growing and developing ecosystem of 3D printing in Africa, yet the access to 3D printers is limited to central locations in the urban cities. This means that there is a robust 3D-printing support system (access to 3D-printing consumables and maintenance) in the big cities that is largely inaccessible to peri-urban and rural areas. Overall, this could be overcome by setting-up 3D-printing kiosks that could be incorporated into the distributed manufacturing framework and lowering the boundary to accessing 3D-printing in peri-urban and rural areas. We recommend more research into distributed ecosystem development in urban and rural areas.

Furthermore, DIY starter kits and off-the-shelf 3D printers are popular within the 3D-printing ecosystem in sub-Saharan Africa. These DIY starter kit printers are affordable yet not designed to produce the highest quality of 3D prints for medical devices. This consequently limits the output quality of 3D prints. In order to achieve quality medical 3D-printed components the printer speed must be drastically reduced, which ultimately increases the production time for a particular device. It is vital to look into developing or accessing 3D printers that produce high-quality prints and can be locally maintained.

In our case, we explored the use of one specific distributed production method, 3D printing, which as discussed above also has its limitations. We recommend the further exploration of and experimentation with other distributed production methods such as laser cutting. We expect that a combination of different distributed production methods will be the ultimate solution.

Our Frugal Design projects are intended to be open-source and available to makerspaces all over the world. However, open source should not be at the expense of quality. For open-source production, quality control measures should be in place. However, regulations for open-source products are not clearly stated as it is an emerging market. It would thus seem necessary to look further into how to ensure the quality in manufacturing and assurance.

Furthermore, obtaining certification is necessary for a medical device. The current device is designed to comply with the criteria of WHO on sample preparation. However, extensive quality testing, clinical trials and documentation are required before field application and deployment. This has not been sufficiently considered in our frugal design process.

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