SYMBA: AN EXPLORATION OF APPROPRIATE MEDICAL DEVICE DESIGN FOR THE SOUTH AFRICAN CONTEXT

Ashton Moseley, University of Johannesburg, South Africa, abullock@uj.ac.za
Angus Donald Campbell, University of Johannesburg, South Africa, acampbell@uj.ac.za

Abstract
Medical devices are essential for the successful delivery of almost every form of health care. The medical device industry is currently one of the fastest-growing and dynamic sectors of the global economy. However, the global market is heavily dominated by high-income countries (HICs) with low to middle-income countries (LMICs) constituting only 13% of the global market. As a result, up to 80% of medical devices in LMICs are donated or imported. A medical device needs to be appropriate for the context in which it is intended. Imported medical devices, which are manufactured for use in high-income countries, however, are often inappropriate and ineffective when used in low-resource settings. This results in approximately 40% of donated/imported medical devices being out of service, 70–90% never functioning as intended, and up to 98% broken within five years. The lack of appropriate medical devices in LMICs suggests the need for a shift towards a more human-centred, design-orientated medical device industry, which promotes local manufacture. Like many LMICs, South Africa's local medical device industry is underdeveloped. Approximately 90-95% of medical devices in South African hospitals are imported/donated. However, in a 2014 World Health Organisation feasibility study, South Africa showed great capacity to support the local production of medical devices. Furthermore, recent success stories such as Jed Aylmer's Symba paediatric bed indicate that local designers and manufacturers can successfully compete with international suppliers of sophisticated equipment - highlighting an opportunity for increasing medical device design in South Africa. This paper presents the design process followed in the development of Symba in the form of a retrospective case study. The purpose of the paper is to share appropriate local design strategies, which better enable local industrial designers to pursue more appropriate medical device design outcomes in the South African context.

Keywords: Medical Device Design, Human-Centred-Design, Appropriate Healthcare

INTRODUCTION

Hospital environments, designed appropriately, can promote healing and enhance operational efficiency (McAndrews, 2005:7). Medical devices (MDs) used by staff and patients in hospitals are a large contributing factor to what constitutes a "hospital environment". However, there is scant literature on the importance or effect of medical device development (MDD) and its effect on the hospital environment and experience. This highlights an opportunity for involving designers in the MDD industry, moving past the purely functional approach of biomedical engineers, towards a more human-centred design approach.

The MD industry is one of the fastest-growing and dynamic sectors of the global economy (Frost & Sullivan, 2017; World Health Organisation, 2010:14). Despite rapid progress within the development of medical technologies, the fact that MD innovation is mainly targeted at high-resource contexts means that the majority of the world's population lack access to MDs that are *appropriate* for their specific epidemiological needs (Cheng, 2003; World Health Organisation, 2010; World Health Organisation, 2016; Dyro, 2004).

The lack of *appropriate* MDs, particularly in low to middle-income countries (LMICs) suggests the need for a shift towards a more human-centred, design-orientated MD industry, which promotes local manufacture. This paper reports on a retrospective case study of the design of the Symba Paediatric Hospital bed by Industrial Designer Jed Aylmer, of Praestet Healthcare Design, for the Nelson Mandela Children's Hospital (NMCH) as a means to explore more appropriate medical device *design* (MDDes) in South Africa (SA).

CONTEXT

Design for Healthcare

For most people, illness is a source of stress that is further aggravated when placed into a healthcare setting, an environment where many people experience strong emotions of fear and anxiety (Kopec, 2012:261; Dellinger, 2009:49). Stress not only affects patients in hospitals but is also a very intense emotional experience for healthcare providers (Dellinger, 2009:48). 'Product experience' refers to the subjective experiences involved in human-product interaction (Desmet & Hekkert, 2007; Desmet, 2004). When people interact with products emotions are elicited by one's judgement of the significance of a situation's benefit or harm for one's well-being (Scherer, 2001; Desmet & Hekkert, 2007). A growing body of research recognises that well-designed physical settings play an important role in making hospitals safer, more efficient, and less stressful, promoting healing for patients and improving the work environment for staff (Zimring, Augenbroe, Malone, & Sadler, 2008; McCullough, 2009).

MDs are essential for the successful delivery of almost every form of health care and improvement of the health of individuals and populations (World Health Organisation, 2010). Staff and patients are exposed to and interact with MDs for most of their time in hospitals. When designed appropriately, hospital environments can reduce stress and promote healing ultimately improving recovery time (McAndrews, 2005:7; Kopec, 2012). Furthermore, design can enhance usability and operational efficiency while reducing the chance of human error, further improving the work experience for staff. Providing environments that help mitigate stress and enhance operational efficiency should, therefore, be a primary concern when developing and designing healthcare facilities (Kopec, 2012:261). This suggests the importance of the appropriate design of MDs, suited to the emotional and functional needs of users.

Technological Diffusion, Context and the Mismatch

Not only do MDs need to be appropriate for the psychological and clinical needs of users, but they need to be appropriate for the context or setting in which they are used. One of the main barriers to the optimal use of MDs in LMICs is the "mismatch" between the *design* of the device and the *context* in which it is ultimately used (World Health Organisation, 2010). For decades, developed countries have exported MDs from 'developed' to 'developing' settings in the form of low-cost sales or donations (Dyro, 2004). As a result, up to 80% of MDs in LMICs are donated or imported (World Health Organisation, 2011:8). In many cases, donations bypass local procurement systems of the recipient country, and as a result, actual local requirements, capabilities, and the available level of technical expertise to provide maintenance, are not considered appropriately (World Health Organisation, 2011:8). It is also common for multinationals to "strip down" devices, originally intended for High Income Country (HIC) markets, for LMICs rather than developing products specifically designed for

their contexts (World Health Organisation, 2012:16). Donated MDs are *rarely* accompanied by ongoing maintenance, user training and technical support (Prestero, 2010:86; Dyro, 2004:155). As a result, although MDs may be *available* in LMICs, they are often ill-suited for local conditions and therefore cannot be used effectively (World Health Organisation, 2010). As a result, approximately 40% of MDs in LMICs are out of service, 70–90% of all donations never function as (Malkin & von Oldenburg Beer, 2013:1847; Chan, 2010); and up to 98% of donated medical equipment is broken within five years (Prestero, 2010:86).

Appropriate Technology through Local Production

The WHO identifies local production as a way to increase access to appropriate MDs in LMICs (World Health Organisation, 2016:1). In a 2014 study, SA showed great capacity to support local production of MDs (World Health Organisation, 2016). Furthermore, recent success stories (Praestet, 2020; CapeRay, 2018; Lodox, 2015) indicate that local designers and manufacturers can successfully compete with international suppliers of sophisticated medical equipment. However, except for a handful of examples, SA's MD industry is still relatively underdeveloped. Most local industry is constituted of multinational subsidiaries, importers and distributors with very little local design and manufacture (Mitchell, 2017; KPMG, 2014:11-12). Like many LMICs, approximately 90-95% of MDs in South African hospitals are imported or donated (Mitchell, 2017). Local MD production consists mostly of small to medium-sized businesses combining distribution activity with manufacturing, which is limited mostly to consumables, basic hospital furniture and low technology items (SAMED). The lack of MDD in SA could be attributed to the complexities of designing for healthcare, such as navigating expensive regulatory controls and certifications (Mitchell, 2017); the myriad of end-users and stakeholders (Kopec, 2012:268; Ogrodnik, 2012); the social complexities of designing in "developing/third-world" countries (Prestero, 2012); the lack of formal MDD training in South African institutions; and finally, until June 2017, the absence of a MD regulatory framework/body in SA.

RESEARCH DESIGN

The design and planning phase of this study involved five steps: conducting a literature review, identifying a research problem/project aim, constructing a theoretical framework, designing research questions and interview schedules, and purposively selecting the sample/case (Merriam, 1998)

Literature Review

This study began with an in-depth review of the relevant literature for the construction of the research aim and questions and theoretical framework that would guide the inquiry (Merriam, 1998) Reflecting on a body of literature, three key themes/factors/omissions were identified. Firstly, the most notable influence on MDD is *the regulatory requirements*[1] of MD development and manufacture; secondly, the complexity of the number and *variety of stakeholders and/or users* involved throughout the process; and thirdly, very few of the authors referred to *contextual considerations* outside of regulatory/standards concerns.

Regulatory Controls & Context

Although the scope of this paper doesn't delve into the specific complexities of MDD controls and regulations, it is important to note that all authors refer to European (CE) and

[1] The scope of this paper does not delve into the specific complexities regarding MDD controls and regulations. For more detail on this, refer to (Bullock, 2019), Chapter 2 and 7.

United States (FDA) regulatory requirements and processes. It is also important to note that until 2017, SA lacked its own regulatory body, and has very limited/outdated design standards related to MDs. Therefore any MDs designed or procured would have to reference/meet the requirements of international (European/USA) standards; hence the contextual mismatch. Furthermore, the significant cost involved in getting approved by these international bodies is a potential limiting factor to local MDD.

Stakeholders

For a MD to be considered successful, it must be clinically effective, safe and meet the needs of the several people using and being treated by the device (Martin, Clark, Morgan, Crowe, & Murphy, 2012:184; Santos, Gazelle, Rocha, & Tavares, 2012). This highlights the importance of meeting user needs, however, defining who a MD *user* is, can be far more complicated than it seems (Teixeira, 2014:13). MD *users* are not a homogenous group, but rather, consist of various people each with different roles and interests (Shah, Robinson, & Alshawi, 2009:3). The term *user* can refer to patients, nurses, doctors, clinical specialists, carers, cleaners, maintenance staff, friends and family members (Shah, Robinson, & AlShawi, 2009:3; Teixeira, 2014:13). Furthermore, *other* stakeholders, such as regulatory bodies, manufacturers, investors, procurement officers and hospital management also have needs, requirements and expectations which the designer and device must accommodate (Shah *et al.*, 2009:3). Various authors, therefore, stress the importance of forming multi-disciplinary project teams to identify and understand the needs of these users and to understand the system of which the device is a part (Martin *et al.*, 2012:184; Money *et al.*, 2011: 1).

Problem identification and Research Aim

The synthesis and review of the existing literature identified that although various MDD process models and case studies documenting appropriate MDD *have* been defined, none of them describes the *South African* MDD regulatory landscape; and most describe the MDD process from an *engineering or business* perspective rather than a *design* point of view. As a result, 'design' is portrayed as a *step* in the overall development process. The absence of design-related insights in existing MDD literature, and the lack of documentation of local MDD outcomes/processes, informed our decision to conduct a case study documenting MDD from a *designer's* perspective. The aim of this study was therefore to document the design process and outcome of an appropriate South African MD as an example of how to design appropriate MDs for LMIC contexts.

Theoretical Framework

Framed within the *pragmatic* paradigm, the purpose of this study was to generate prescriptive/guiding design knowledge and serve as an example of best practice for the design and manufacture of appropriate MDs in LMICs (Goldkuhl, 2012:8; Zimmerman, Stolterman, & Forlizzi, 2010:313). In this study, constructive knowledge was formulated and supported by the *interpretivist* elements of interpretation and understanding of the perceptions and lived experiences of participants, through a case study (Thanh & Thanh, 2015:25; Goldkuhl, 2012:15; Munro, 2014).

Research Objectives

Using the case study method, this study explored and analysed a local, design-led product design process and outcome of a MD to identify the:

1. *challenges, shortfalls and problems* faced in the process and how they were overcome
2. *stakeholders/key role-players* in the design process, their involvement and impact on the design process

3. *design considerations* and their effect on the outcome.

These objectives, informed by the literature review, guided the provisional set of interview questions (Gray, 2004).

Case Selection

To ensure the gathering of valuable information, the chosen case had to meet four predetermined criteria. First, the case had to represent an industrial design-led project (not engineering or biomedical perspective) to provide appropriate design-related information. Second, to ensure the entirety of the design process could be documented, the case had to have been an already completed project. This was, therefore, a *retrospective* case study (Starman, 2013). Third, the case had to have been documented to some extent outside of this case study to allow for fact-checking and data triangulation (Flick, 2004). Lastly, the case had to represent the correct context, therefore it had to be a South African design/product. Based on these selection criteria, *Symba*, the paediatric hospital bed designed and manufactured by Praestet was purposively selected as the case.

Methods

To enhance the rigour, credibility and validity of this research, this study adopted the strategy of triangulation of data, whereby data was gathered using multiple methods and sources (Gray, 2004; Baxter & Jack, 2008). Before conducting interviews, preliminary desktop/background research was conducted to establish a basic understanding and overview of the case and the South African MDD context (Kothari, 2004:111). In Praestet's case, the design and development of *Symba* were relatively un-documented. Therefore the primary data gathering tool was semi-structured interviews. This case began with an introductory interview and an overview analysis of the process. Thereafter, the in-depth retrospective visualization of Praestet's process took place over a series of nine 'brainstorm sessions' over five months. All interviews were recorded using written notes, mind mapping (Fig. 1), audio recording and photographs, with the participant's consent (Gray, 2004; Baxter & Jack, 2008).

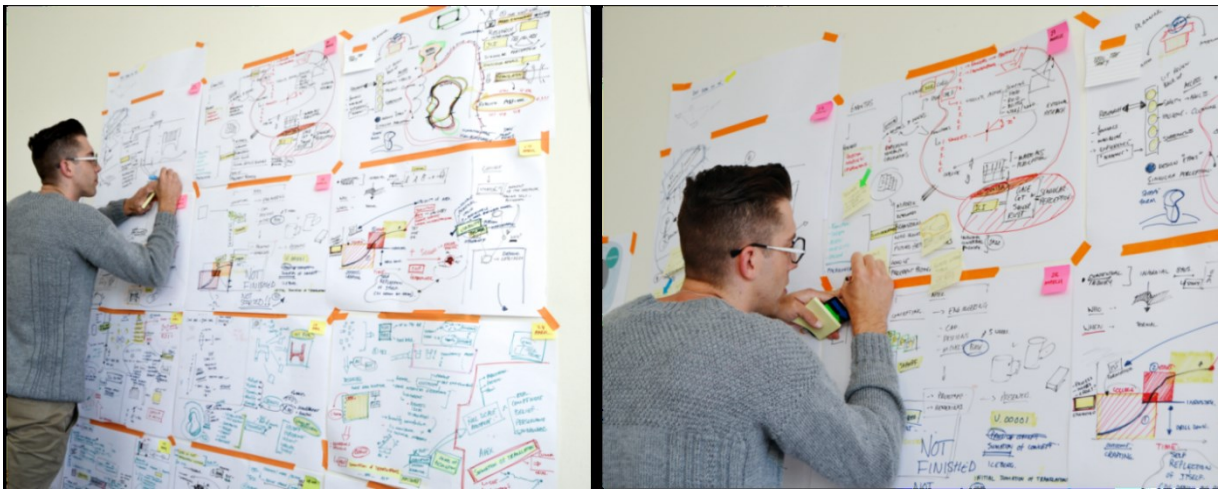

Figure 1: *Aylmer's Spatialization process, 2018 (author)*

Once all the data had been externalized, we began a process of classification, searching for and reviewing potential themes by rearranging the data, finding areas of similarity and clustering words related to similar concepts together or according to objectives 1-3 (Braun & Clarke, 2012; Kolko, 2010). This analysis took place in a four-hour-long design session

whereby the pages produced over the five months were condensed and summarised into a single page/model through a spatialization process (Kolko, 2010). To further enhance the validity of this research, the case was interpreted from three viewpoints (summarised by the author in three visual formats: a timeline, process model and tabulated overview) providing a complete, thick case description (Gray, 2004; Baxter & Jack, 2008).

Once data collection and analysis were completed the case was documented in an in-depth case report (Baxter & Jack, 2008). To ensure or enhance the credibility of this research, the case report and process models were reviewed by the participant to verify accuracy, completeness, terminology correctness and redundancy (Gray, 2004; Yin, 1981; Medina, Okudan Kremer, & Wysk, 2013). Finally, to fully understand and accurately interpret findings, case study data were compared with published literature of existing MDD process models (Baxter & Jack, 2008) and this comparison was documented at the end of the case report.

CASE STUDY

In 2013, Jed Aylmer was a BTech Industrial Design student at the University of Johannesburg (UJ). To complete the programme, Aylmer was required to undertake a practical final semester-long design project of his choosing; this was documented in the format of a mini-dissertation. Aylmer saw an opportunity to use his university project to design a MD for the visionary NMCH paediatric healthcare facility (Aylmer, 2017a).

A hospital bed forms the environment in which a child patient spends most of their time when in hospital, it is also the object in which parents see their child during hospitalization (Aylmer, 2013). A variety of paediatric hospital beds are available on the market however the bed most commonly found in South African paediatric wards is the steel cot (Fig. 2), as it can be used for both young toddlers and children up to the age of five years old (Aylmer, 2013). The design and overall cage aesthetic of these cots have remained the same as beds used in the 1920s. According to Aylmer, the cage-like appearance of most paediatric beds "subject[s] children to a psychologically disturbing micro-environment" (Aylmer, 2013). Furthermore, observations indicated that the outdated tubular steel construction acts as a hindrance to medical professionals' access to the child during respiratory procedures (Aylmer, 2013) and creates various safety hazards for nurses, with reports of the heavy steel cot side falling into nurses' feet (Aylmer, 2017a).

Figure 2: *Hospital cot at Rahima Moosa Mother and Child Hospital (Aylmer, 2013)*

Aylmer set out to redesign an appropriate paediatric hospital cot that offered an alternative to the cold cage-like beds that he had observed (University of Johannesburg, 2017; Aylmer, 2013). He aimed to improve the *product experience* of the primary user, the child, and product *usability, safety* and *accessibility* by considering the needs and requirements of medical professionals by addressing/improving aesthetics, material choice, durability, accessibility, manufacture quality and audible properties (University of Johannesburg, 2017; Aylmer, 2013). Completing the university project in November 2013, Aylmer has since gone on to develop and manufacture his paediatric hospital bed and founded a MD design and development company, Praestet (Pty) Ltd.

Design Process Model/Description

Various authors have attempted to visualize process models that describe the MDD landscape, however, most diagrams speak to a linear process, which fails to accurately describe the various loops, turns and stops that occur in reality (Ogrodnik, 2012:32). Aylmer described a "plasmodial soup model" (Fig. 3), an attempt to visually depict how the design process, design thinking and design outcome are constantly changing as the designer operates within and is affected by various external influencing factors such as users, stakeholders, regulations and standards, considerations and context. According to Aylmer, this balancing act compromises of five factors: the *singular perception,* the *nexus cloud,* the *premise, transmutation* and the *fragile culmination* (Aylmer, 2018i; Aylmer, 2018j).

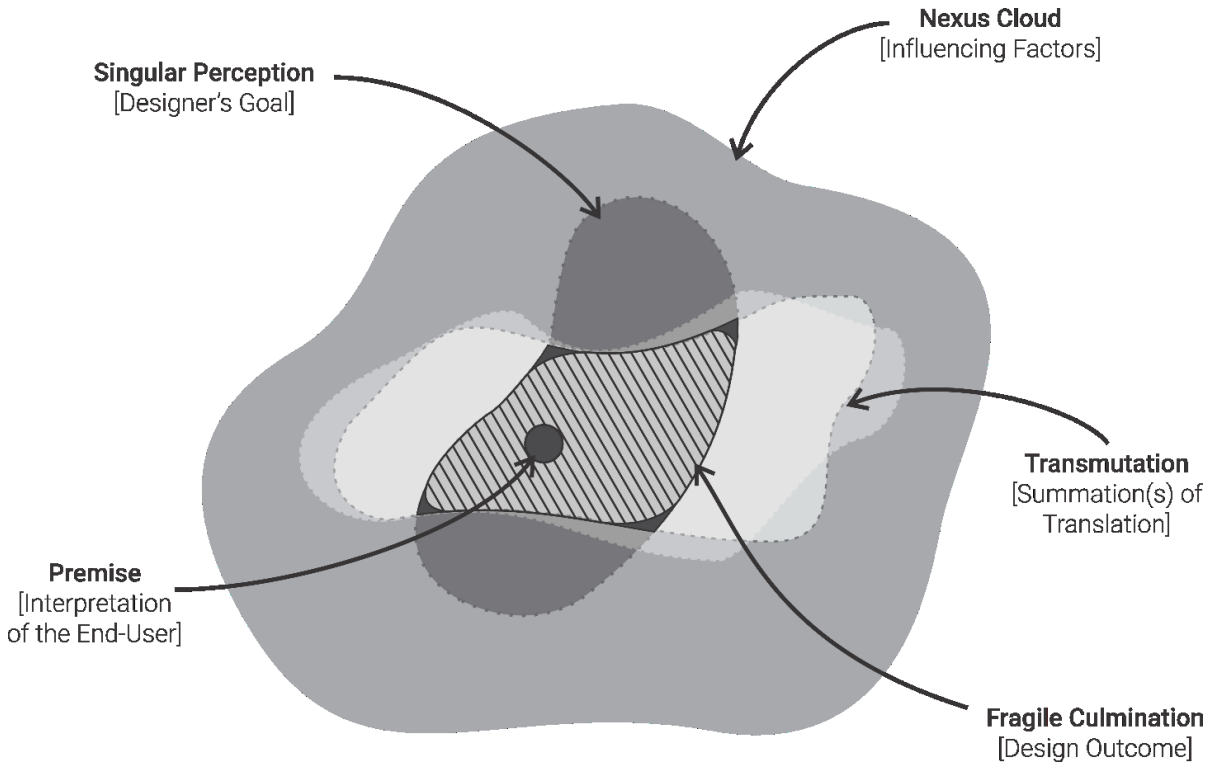

Figure 3: *Aylmer's plasmodial soup model summary, 2018 (author)*

The singular perception refers to the designer's own goals of what the product should be. Aylmer's "singular perception" was to improve overall product experience by addressing the emotional and functional requirements of users (Aylmer, 2018b). *The premise* represents the designer's interpretation of the end-users' needs. *The nexus cloud* refers to all tangible

(physical/written) and intangible (thought/feeling) factors (relevant and irrelevant) influencing the design process. “Tangible factors” included: standards, manufacturing constraints, market variables, context/locale and design considerations. “Intangible factors” included: external influences, experiences and feelings (Aylmer, 2018i). As the process progressed, the nexus cloud grew/changed as more information became available (Aylmer, 2018i). *Transmutation* refers to the act of translating the relevant information (identified and drawn from the nexus cloud) into a device design to best satisfy the user (Aylmer, 2018i; Aylmer, 2018j). Aylmer explained that the tensions between the internal influences of the user and designer and external influences, constantly morphed and shaped the process, resulting in various iterations. Finally, *the Fragile Culmination* is the design outcome that represents the best compromise between all of the above. The “fragile culmination” was the point of resolution that best suited the product requirements, specific to its context (the nexus) (Aylmer, 2018i; Aylmer, 2018j).

Analysis of Aylmer's description of his process identified three key categories/influences in the nexus cloud: user needs, stakeholder needs (manufacture and regulators), and financing and project management.

User Needs

To understand the needs of users/stakeholders of a MD, one must also understand the context/s in which it operates. Aylmer consulted with and gathered insights from over 150 nurses, doctors and health professionals throughout the process through interviews, questionnaires, panel discussions, prototype testing and clinical evaluations (Aylmer, 2017a).

Symba was designed for children between the ages of 6-months to 6-years-old. From a human-centred design perspective, Aylmer acknowledged that the challenge of designing for paediatrics is that the primary “exposed” end-user cannot directly inform the process through communicating their needs, wants and feelings (Aylmer, 2017a). Therefore, Aylmer had to uncover insights using methods such as observation, looking at the way that children interact with objects, case studies and psychological research (Aylmer, 2017a). The second group of users identified by Aylmer included patients’ parents or guardians, medical doctors and nurses (Aylmer, 2018k). Although classified as “secondary users”, Aylmer acknowledged that this group of users were in fact “also primary users” because they utilise the product on the outside where a child utilises the product from the inside (Aylmer, 2017a). A significant amount of insights and data were collected from secondary users throughout the Symba design and development process. According to Aylmer, secondary users focused on medical functionality and operational and usability concerns (Aylmer, 2017a). Aylmer also consulted with various discipline experts including biokineticists, physiotherapists, psychologists and hospital procurement officers. Aylmer acknowledged that all users, informants and stakeholders have different perspectives and that the design process is very much about balancing those different perspectives to come to a compromise (Aylmer, 2017a).

Stakeholder Needs

Aylmer identified regulations, standards and manufacturing considerations as a key challenge/influencing factor in the MDDes process (Aylmer, 2017a). “The medical realm is particularly complicated because manufacture, engineering and design have to follow and work around the regulatory constraints and rules that are given and dictate how a product should be designed” (Aylmer, 2017a). Aylmer (Praestet) was both the designer and manufacturer (in the regulatory sense), working in close relation with local suppliers, manufacturers and a team of biomedical engineers (BMEC). Aylmer worked with

approximately 16 different manufacturing suppliers who provided practical knowledge regarding the constraints and costs of manufacture (Aylmer, 2018k). The team of biomedical engineers at BMEC was responsible for assessing the stresses, strains and sheer points on parts and provided guidance/assistance regarding safety and the certification procedures and requirements (Aylmer, 2018k). Aylmer's role as the designer was to balance the information coming from the biomedical engineers and the constraints of manufacture while maintaining his design intent. As part of the CE Marking application process, Aylmer elected an Authorised Representative (from Sweden) with whom he consulted during the compilation of the technical file (Aylmer, 2018k).

Financing and Project Management

Aylmer defined the overarching challenge as getting the device to fruition by combining money, planning, timing and luck. Securing funding, knowing where to turn to next, knowing where in the process you are, and how to get to "the end" were all "massive challenge[s]"; all of which he claims to "still face daily" (Aylmer, 2017a). Securing funding throughout the project was particularly challenging. Aylmer approached various public and private investors and funding organisations throughout the project. The two most significant donors/funding agencies involved in the product development phase of the project were the UJ Technology Transfer Office (TTO) and the Technology Innovation Agency (TIA) seed fund, which financed the build of the full-scale prototype and certification. Working as a sole-designer, manufacturer and business owner in SA, Aylmer stressed the importance of strong partnerships (Aylmer, 2017a). Aylmer identified the NMCH trust as a key partner throughout the process because, although not directly involved in the project, their interest and support stimulated the undertaking of the process in the first place (Aylmer, 2017a; Aylmer, 2018k). The UJ TTO was also identified as a key partner during the project, assisting with initial funding, early-stage commercialisation advice, structuring the initial stages of the business plan, intellectual property protection, and assisting with initial refinement on the product, through Resolution Circle's team of engineers (Aylmer, 2017a; Aylmer, 2018k).

CONSIDERATIONS, REQUIREMENTS AND DESIGN OUTCOME

Aylmer's initial four guiding design principles (based on his singular perception) were: *cage, rust, get-in* and *squeak*. These principles spoke to product experience, material choice/durability, safety/accessibility, and manufacture quality (2017a). While navigating the various views, insights, requirements and considerations of the role players and factors in the nexus cloud, the core design considerations can be divided into *functional* considerations (safety, hygiene, access, mobility, medical functionality and usability) and *product experience/aesthetics* (Aylmer, 2017a).

Appropriate Product Experience and Aesthetics

Appropriate aesthetics can reduce stress for patients and improve clinical adoption leading to more staff using it, and using it more often (Core77 , 2016)**.** According to Aylmer, MDDes is about perception (Aylmer, 2017a). "Hospitalisation is a horrible experience" and his primary concern was, therefore, that of *product experience* (Aylmer, 2017a). Aylmer's goals were to reduce the psychological impact of the cage-like beds on child patients through revaluating/re-approaching aesthetics and the way that it appealed to the senses (Aylmer, 2017a), and to meet the needs of nurses who "also want to feel that they've got products in their ward that inspire confidence in the product and the equipment that they have" (Aylmer, 2017a). Abandoning the heavy cold steel cage-like bars of existing cots, Symba's injection

moulded clear cot side panels provide visibility (visual access) of the patient while allowing patients to feel less constrained by the cot. This also creates an environment in which the child can engage with parents, medical professionals and other patients. The soft forms and bright colours of Symba's body "bring life to hospital rooms" and create a softer, more comforting environment for children (Praestet, 2020). The high-tech, high quality aesthetic of Symba, far removes it from the old, "basic" aesthetic of the metal cages, which improves faith and pride in the product and its clinical efficiency. Aylmer also paid particular attention to the *sound* of the device (such as wheels, buttons, brakes) and the effect of these sounds on the patient environment (Aylmer, 2018b). The change in material, from cold hard metal to a warm soft plastic drastically changes the aesthetic, tactile and audible/sound quality of the product (Fig. 4).

Figure 4: *Symba Paediatric Hospital Bed (Praestet, 2020)*

Appropriate functionality, safety and maintenance

The change in material, manufacture and form-giving/aesthetics not only improved product experience but also addressed the functional requirements of safety, hygiene, access, mobility, medical functionality, usability. The seamless design of the rotational moulded main components are easier to clean and reduce the chances of bacteria hiding in crevices, improving hygiene and infection control (Praestet, 2020). The individually operated cot sides are controlled using a dual-locking spring system, allowing the user to position each cot side in four safety configurations, locking properly and securely into place quickly in an emergency (Praestet, 2020). The spring system reduces strain on nurses when operating the sides and prevents injury/risk of collapsing/dropping sides. Unlike existing cots, each cot side can be lowered, providing access to the patient, from all sides, which improved usability/operation during respiratory procedures (Praestet, 2020). Symba has four, lockable, easy to manoeuvre medical-grade casters to enhance safety and ease of mobility (Praestet, 2020).

Appropriate References

Although Symba was designed *in* and *for* the South African context, Aylmer explained that the South African Bureau of Standards (SABS) did not have a recent standard for paediatric

hospital beds. According to Aylmer (2018a), the German Institute for Standardization (DIN), had the most comprehensive standard for paediatric hospital beds (DIN 32623:2009-11) and he, therefore, referred to that standard when designing Symba. Furthermore, he explained that, at the time, SA had no local regulatory authority or framework in place. Aylmer, therefore, chose to pursue CE Marking certification as it would allow him to trade in Europe and made good business sense as the CE Marking is an international "mark of quality" that many procurement agencies look for when choosing MDs (Aylmer, 2018a).

FINDINGS AND DISCUSSION

Design is the process

When comparing Aylmer's design process to that seen in existing literature, two similarities were identified. Firstly, Aylmer's MDDes description of the nexus cloud links strongly to an existing MDD process description of a *data cloud* (Ogrodnik, 2012:88). Both of these "clouds" describe the various regulatory, market, user, IP, manufacture (and more) considerations that "float around" the project and influence the design process. The difference, however, is that Ogrodnik speaks only to the data cloud when defining product specifications at the beginning of the process. Aylmer's description differs in the sense that he described the nexus cloud as a constant undertaking at every step and within every phase of the project. Secondly, one can draw similarities between Aylmer's "Plasmodial Soup Model" and IDEOs model of innovation (Fig. 5), whereby 'design' is described as the balancing act of feasibility, viability and desirability, and achieving a balance of all three of these constraints will arrive at successful, innovative outcomes (Brown, 2009:18). Similarly, Aylmer's model depicts the balance and alignment of the designer's goal, the user needs, design activities and feasibility and viability concerns as defined in the nexus cloud. The overlap, the "fragile culmination" refers to the design outcome that serves as the best compromise of all factors. It is interesting to note that Aylmer's process description links to IDEOs description of design thinking (IDEO, 2015). This highlights that design and design thinking are fundamentals of the MDD (hence the new term MDDes used in this paper) process and not only a small component within the process, as is suggested in the existing literature.

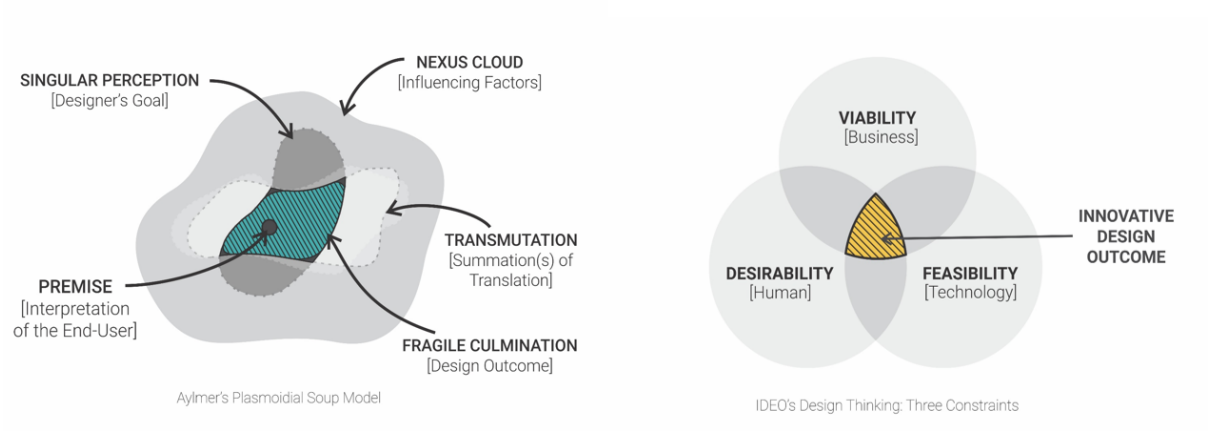

Figure 5: *Plasmodial soup model and IDEO constraints model comparison, 2018 (author)*

Human-Centred vs Regulation-Centred

User involvement in the MDDes process increases the likelihood of producing MDs that are safe, usable, compliant, clinically effective and appropriate to cultural context (Money *et al.*, 2011:3; Shah *et al.*, 2009:4; Martin *et al*., 2012:189). The fact that the Symba project was led by an industrial designer is evident in the fact that early phases focused mostly on desirability/human-centred concerns first (emotional and functional needs of users), then only followed by market, feasibility, and viability and regulatory concerns. The main difference between Aylmer's case and process outlined in the literature was the significant focus on user involvement throughout the whole process with a strong focus on human factors and product experience, not only standards and regulatory controls and requirements.

Locally suited to an international Standard

Aylmer's need to pursue CE Marking certification highlighted a significant insight that up until very recently (2017) SA had no framework in place to regulate and monitor MDs. The absence of an established regulatory framework in SA may explain the limited local MDD activity. As a result, Aylmer had to refer to European standards and regulations. In a way, this served as an advantage in Aylmer's case. Unlike products that are designed to suit international standards in international contexts, designing and manufacturing a device for and within the South African context allowed Aylmer to consult frequently with local experts, with experience valuable insight into the appropriate design of this bed. The design of Symba was informed by the South African context and local experts and experiences while meeting the quality requirements of international (European) standards and regulations. In doing so, the product is suited to local needs, while maintaining an international standard. This debunks the notion that products in LMICs should be stripped-down versions of 1st world products. Furthermore, suited to international contexts, allows for exporting and industry participation. Symba has since been exported and shown at international expos, showing that although this device is suited to the local context, it holds its own in international HICs as well.

Locally Trained & Maintained

Symba is manufactured locally. This allows for appropriate training, maintenance, monitoring and design improvements (none of which are available when a device is donated/imported). The ability to maintain the product, without waiting for months at a time for parts to be repaired or replaced, makes Symba more appropriate solution than imported designs.

CONCLUSION

The introduction of a new regulatory framework in SA serves as an opportunity for increased local development of MDs. This case study serves as an example of how MDs should be designed to be appropriate for user's needs, but also benefit local design and manufacture towards good quality, suitable outcomes for an LMIC context, and the world. This case study showed that, for a MD to be appropriate in LMICs, it must be design-led, human-centred, contextually-embedded, locally manufactured and supported, whilst meeting the requirements of quality/international standard, which in turn offers the potential for international retail opportunities.

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