The Mismatch: A Model for Sustainable Medical Device Design in South Africa

Ashton Margarete Moseley and Angus Donald Campbell

University of Johannesburg, RSA

ABSTRACT The medical device industry is one of the fastest-growing sectors of the global economy, however, it is dominated by high-income countries (HICs) such as The United States, Germany, Japan and China. Approximately 80% of medical devices in low-to-middle income countries (LMICs) are donated or imported (World Health Organisation 2011). Due to a mismatch between the design of these devices and the context in which they are used, approximately 40% are out of service, 70–90% never function as intended, and up to 98% are broken within five years (Prestero 2010; Malkin and von Oldenburg Beer 2013; Chan 2010). To overcome this mismatch, the World Health Organisation identifies local production as a possible way to increase the sustainability of medical devices in LMICs. South Africa's (SA) medical device development (MDD) industry is underdeveloped and approximately 90-95% of medical devices in SA hospitals are imported or donated (SAMED n.d., Mitchell 2017). Although MDD process models have been defined, none describe the SA MDD regulatory landscape and most describe the MDD process from an engineering or business perspective rather than a design point of view. The lack of appropriate, sustainable medical devices, particularly in LMICs suggests the need for a shift towards a more human-centred, design-orientated medical device industry, which promotes local manufacture. This paper explores a study that aimed to define a design process model for paediatric Medical Device Design (MDDes) in the South African context to better enable local industrial designers to participate in the field. This paper presents key case study findings in comparison to existing MDD process literature and introduces an MDDes process model more suited to arriving at sustainable medical device outcomes in the South African context.

Keywords: Sustainability, Medical Device Design, Process Model, South Africa

Introduction

To be sustainable, a medical device (MD) needs to be appropriate for the context or setting in which it is intended and meet the needs of the people using and being treated by it. Despite the rapid development of sophisticated medical technologies globally, issues of centralised manufacture and the lack of human-centred design (HCD) methodologies in medical device development (MDD) processes, 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).

One of the barriers to the optimal use of imported/donated MDs is the 'mismatch' between the design of the device and the context in which it is used (World Health Organisation 2010). The global market is dominated by high-income countries (HICs) (World Health Organisation 2012), with up to 80% of MDs in low-to-middle income countries (LMICs) donated or imported (World Health Organisation 2011). In many cases, donations bypass local procurement systems of the recipient country hence local requirements, capabilities, and available levels of technical expertise for maintenance are not considered (World Health Organisation 2011, 8). As a result, approximately 40% of MDs in LMICs are out of service, 70–90% of all donations never function as intended (Chan 2010) and up to 98% of donated medical equipment in developing countries is broken within five years (Prestero 2010). The World Health Organisation (WHO) identified local production and decentralised manufacture as a way to increase access to appropriate MDs in LMICs (2016, 1).

When designed appropriately, hospital environments can reduce stress and promote healing (McAndrews 2005, 7; Kopec 2012). Furthermore, design in healthcare can enhance operational efficiency while reducing the chance of human error, improving the work experience for staff (Kopec 2012). Devices that fail to meet user needs or misunderstand the context, potentially contribute to use error and harmful incidents (Martin, et al. 2012). However, the complexities of involving users throughout the MDD process, coupled with business constraints and fast turnaround demands, often leads to manufacturers making the mistake of prioritising the perspectives of medical experts and those making purchasing decisions, rather than the perspectives of end-users (Money, et al. 2011). The lack of appropriate, sustainable MDs, particularly in LMICs suggests the need for a shift towards a more human-centred, design-orientated MD industry, which promotes local manufacture.

Approximately 90-95% of MDs in South African hospitals are imported or donated (SAMED n.d.; Mitchell 2017). The limited amount of local medical device design in South Africa may be attributed to the lack of formal MDD training at any South African design institution, and until 2017, no local regulatory framework. Although underdeveloped (SAMED n.d.), in a 2014 study, South Africa showed great capacity to support strong local production of MDs (World Health Organisation 2016). Coupled with the introduction of the new regulatory framework, there is an opportunity for increased local development of MDs specifically geared towards local needs.

This paper provides an overview of a study (Bullock 2019) that aimed to define a design process model for paediatric medical device design (MDDes) to better prepare local industrial designers for sustainable MD outcomes for the South African context. The paper begins by identifying the key

findings from the literature review and multiple case study, and thereafter, introduces and describes the MDDes process model.

Methodology

The study consisted of three phases, *identify, analyse* and *model* (Figure 1), inspired by Yin's (2003) multiple case study model. **Phase 1** involved an in-depth literature review, problem identification, case selection and case study planning. **Phase 2** aimed to investigate, analyse and report on three MDD processes using the *multiple case study* method. Our study added a phase to Yin's model in that **Phase 3** went beyond a cross-case comparison and used abductive thinking (Flick, von Kardorff and Stienke 2004) to synthesise the case study data and the existing MDD literature into the design of a final MDDes process model. This section briefly describes the activities and tools used in each phase

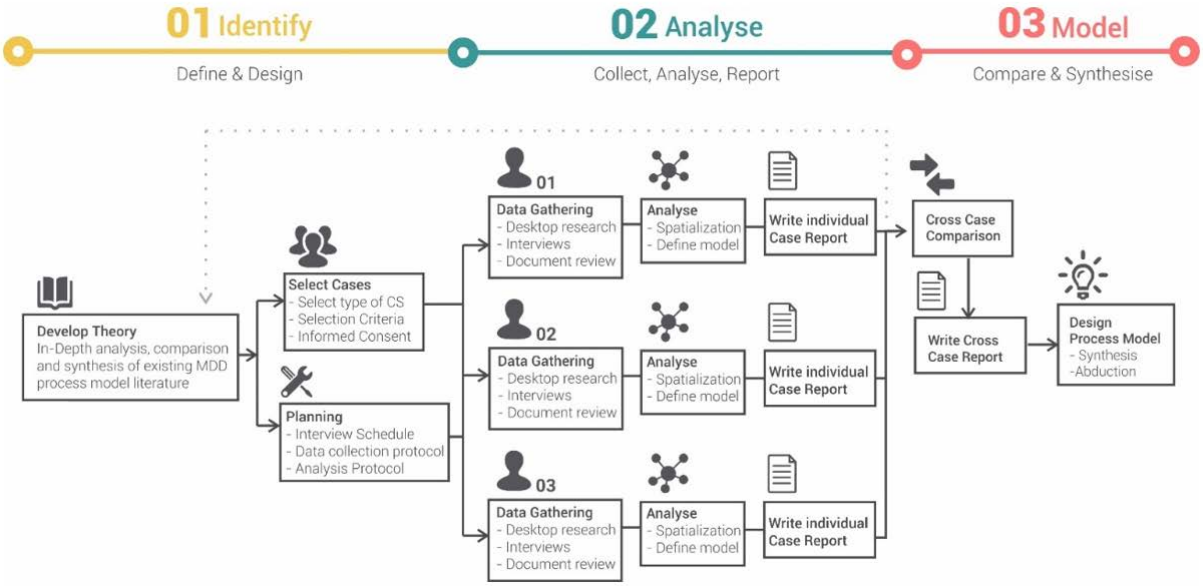

Figure 1: Research design (Bullock 2019)

Phase 1 - Identify

An in-depth literature review on existing MDD process models was conducted. Upon reviewing the literature, three key themes were identified. First, although numerous explanations of the MDD process exist, none identify or discuss South African specific data regarding regulatory bodies, authorities or procedures, with almost all literature focused on the EU and USA regulatory systems. Secondly, almost all of the models reviewed were written by authors in the fields of engineering and published in engineering or biomedical journals. Finally, it was found that no existing models or literary sources take into account or specifically discuss *paediatric* MDs. These three observations highlighted an opportunity and directly informed the research aim of this study to: 'define a design process model for paediatric medical device design in the South African context' (Bullock 2019).

To fully understand the influence and complexities of *context* on the MDD process, a multiple case study (Yin 1981) was conducted. Cases were purposively sampled (Etikan, Abubakar Musa and Sunusi Alkassim 2016) using predetermined criteria (Gray 2004). The absence of design-related insights in existing MDD literature informed the decision to document MDD processes from

designers' perspectives, therefore, each case represented an industrial design-led project. To ensure the entirety of the design process could be documented within the given timeframe, each case had to have been an already completed project, resulting in a retrospective multiple case study (Starman 2013). Each case had to have already been publicly documented to some extent to allow for fact-checking and data triangulation (Flick 2004). According to Yin (2014), each case should be carefully selected so that it either predicts similar results (literal replication) or produces contrasting results for predictable reasons (theoretical replication). The last three criteria, therefore, stipulated that each case had to represent a different context, age group (of the patient) and device complexity/classification. In doing so, contrasting results were predicted and when found, could be attributed to these three factors. Based on the above selection criteria, the following three cases were selected:

1. PearsonLloyd's *DBO Commode* designed in a HIC for HICs.
2. Design that Matters' *Firefly*, a newborn phototherapy device designed in a HIC for LMICs.
3. Praestet's *Symba*, a hospital cot designed in South Africa for HICs and LMICs.

Beyond the selection criteria, each of these cases had been recognised as particularly noteworthy design outcomes.

Phase 2 - Analyse

This phase investigated, analysed and reported on the three design process models. Each process was documented in a comprehensive case report and visualised in three visual formats a summary table, project timeline and process model.

Phase 3 - Model

In this phase, the cases were compared, analysed and synthesised. Synthesised case study data was then compared to synthesised MDD literature, highlighting similarities and key differences (Figure 2) unpacked below. Finally, abductive thinking (Flick, von Kardorff and Stienke 2004) was used to further synthesise the case study data and the existing MDD literature into a final MDDes process model, with particular focus on the South African context.

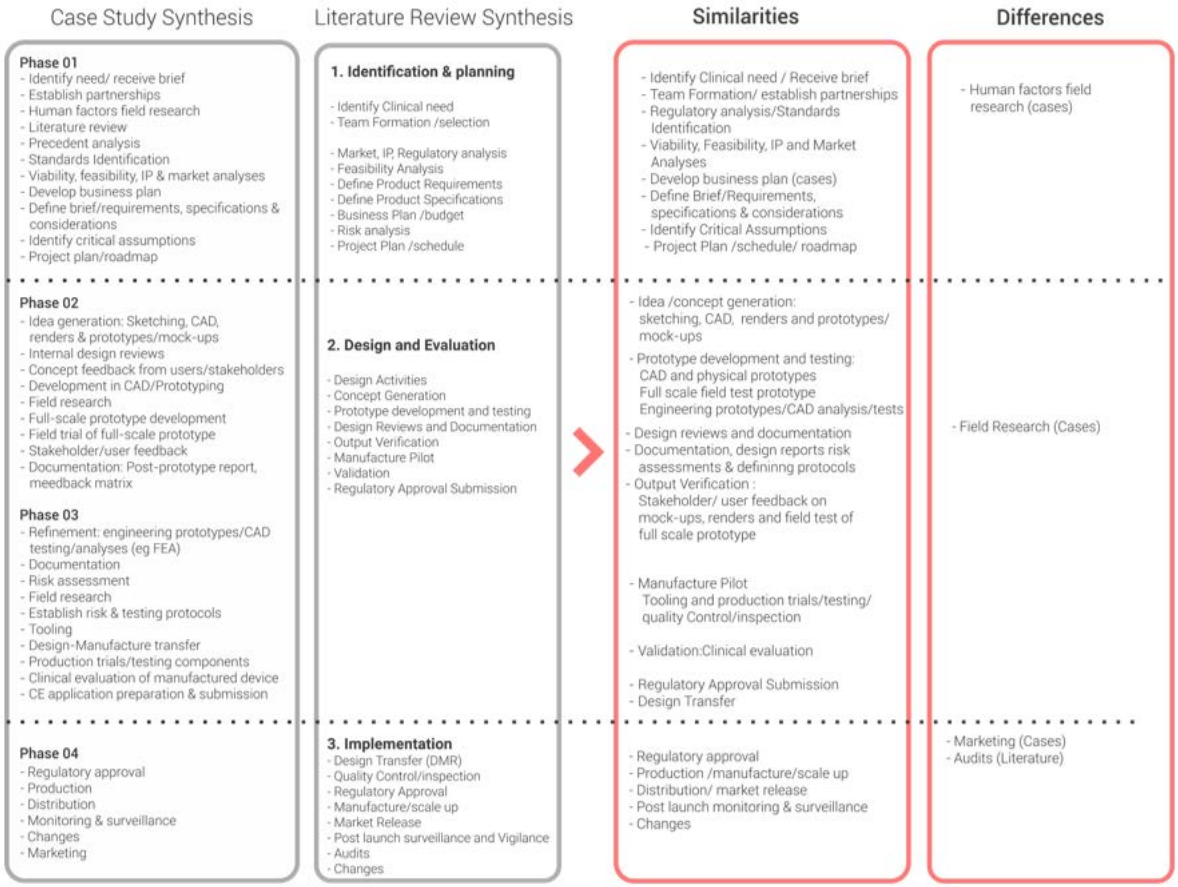

Figure 2: Case study and literature synthesis comparison (Bullock 2019)

Findings

and business requirements and meeting clinical needs. As a result, most existing models define the 'design process' as only a small component of the overall process. We argue, however, that this is not a suitable delimitation and that the entire process is design. The multiple case study highlighted the important role and value of *design* in the MDD process to appropriately address *user* needs rather than just clinical needs. This finding motivated and supported our decision to use the term *medical device design* (MDDes), rather than *medical device development* (MDD). This differentiated our model from existing MDD literature and highlighted the focus on the role of *design* in the development of MDs. Furthermore, case study findings and analysis highlighted the integral role of users and human factors in the process. This supported the notion that HCD is not only *useful* but *essential* in successfully meeting the user and clinical needs of a MD. The key finding from the comparative analysis of case study data was that although one would expect the design process to differ in different contexts, the reality was that the process itself was universally consistent. The main differences between each case were attributed to the country-specific regulatory requirements and processes. This suggested that two separate resources were required: firstly, a generic process model illustrating the overarching MDDes process; secondly, a country-specific 'regulatory document road-map'[1] that guides/directs designers to the essential resources and documentation needed for the process. Although this study initially aimed to define a *paediatric* MDDes process

[1] An explanation of this regulatory framework has not been included in this paper, however, for more information read Bullock (2019).

model, it was found that there is no considerable difference in the process when designing for paediatrics.

Process Model Description

This section illustrates and describes our MDDes process model. The purpose of the model is to serve as a resource/tool for designers to enable their increased participation in the field. Many of the existing process models illustrate the process as a linear series of steps linked by lines to suggest a chronological order/progression (Figures 3 and 4). This flowchart diagramming method does not accurately describe the organic nature of the design process.

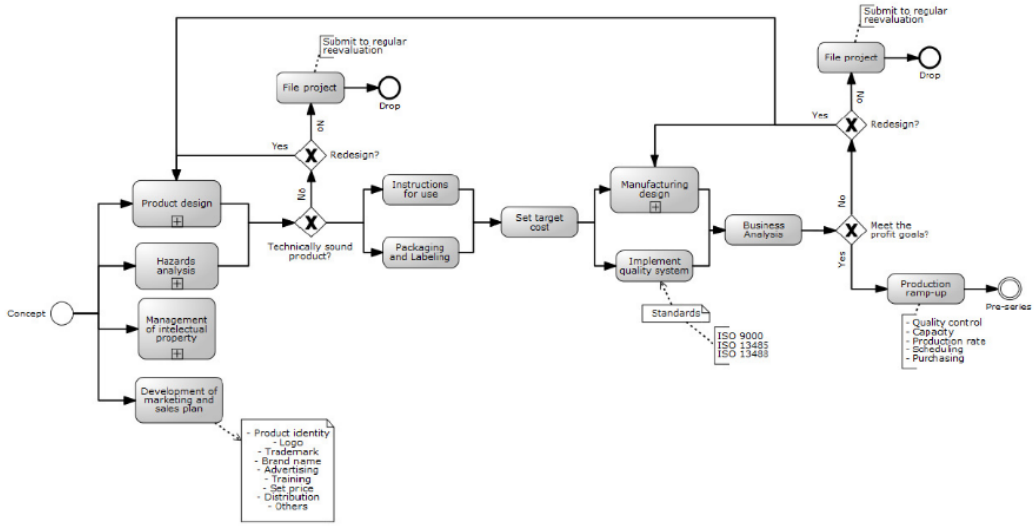

Figure 3: Medical Device Design Process (Santos, et al., 2012)

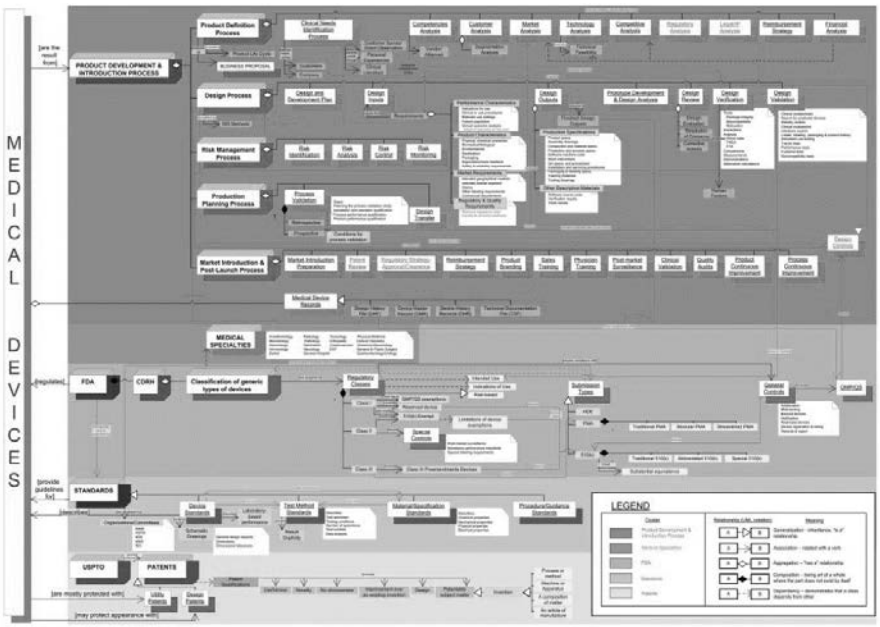

Figure 4: Product Design Process Model for Medical Devices (Medina, Okudan Kremer and Wysk 2013)

Although most of the information included in our model (Figure 5) is similar to that of the existing MDD literature, informed by the design process models described in each case study, our model attempts to encapsulate the *nature* of the process more accurately. The entire cyclical design process is situated within a *cloud* that represents all the factors that influence and inform the design process and outcomes during each phase of the MDDes process. The centre of the diagram represents the users, informants and project stakeholders whose needs and expectations also directly inform and influence the design process and outcome. Placing *users* centrally in the model highlights their pivotal participatory role in the design process. The doughnut-shaped ring represents the *project*, situated within a context of influencing factors (the cloud) and guided by the needs of users and stakeholders. Each *phase* is represented with a 'cycle' icon rather than a block, this describes the iterative cyclical nature of each phase rather than a linear step-by-step flow chart as seen in existing MDD models. The dual-direction arrows between each phase in the design process, the cloud and the centre, illustrate the designer's interaction with and consideration for the users and stakeholders, and contextual factors during each phase of the project/process. Each cycle aims to achieve a particular *milestone* and various activities are conducted and repeated until the relevant critical deliverables of that phase are achieved. Only once a milestone has been achieved can the designer move to the next phase/cycle. To improve the readability of the final MDDes model, textual information was provided in a separate table (Figure 6) so as not to over-populate the visual. Unfortunately, the scope of this is paper does not allow us to delve into the specifics regarding the activities involved in the 4 phases, but for more detail on this please refer to Bullock (2019), Chapter 8.

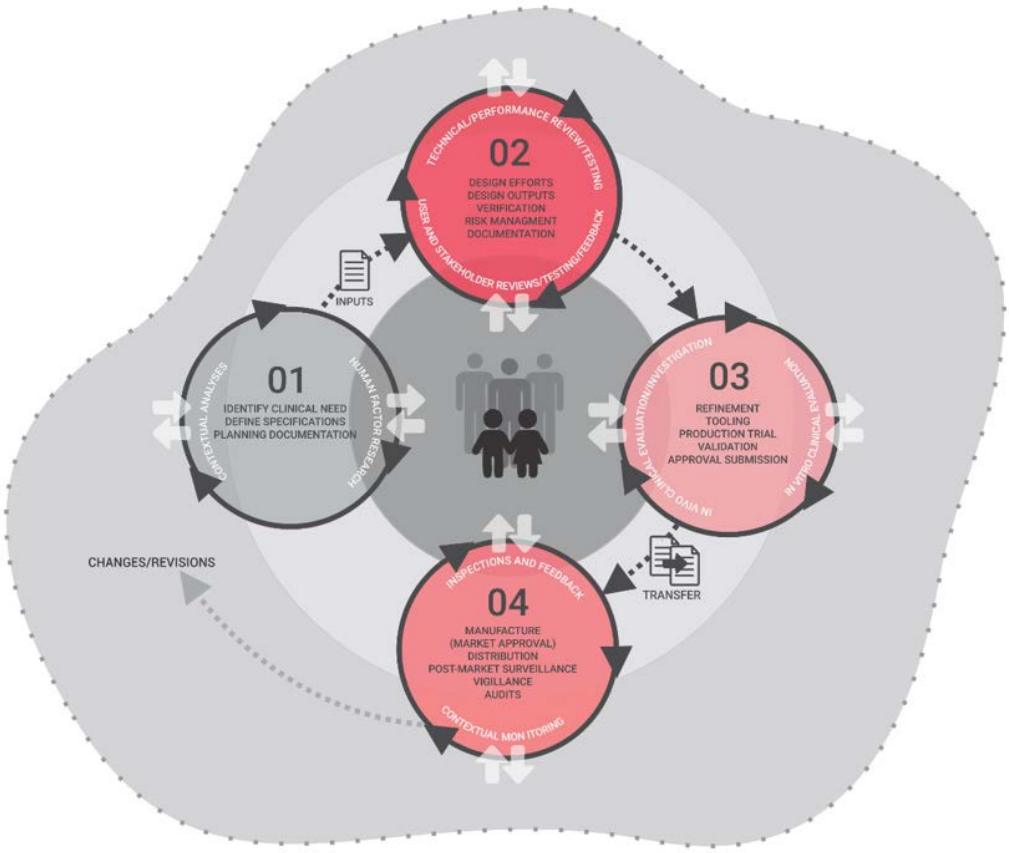

Figure 5: Medical Device Design (MDDes) Process Model (Bullock 2019)

Figure 6: Medical Device Design (MDDes) Process Phases Summary Table (Bullock 2019)

Conclusion

For MDs to be sustainable they need to meet the emotional and operational needs of the people using them and be suited to the context in which they are used. Current MDD is driven mostly by clinical, engineering and business concerns that focus on regulatory requirements and reliance on best practice insights from medical experts. This risks neglecting users' needs and local requirements. Our research suggests a shift towards a HCD approach that promotes and supports local manufacture as essential in the success of medical device design and implementation, particularly in LMICs.

Our study found that *design* cannot be confined to a small step in the MDD process, as in the existing MDD literature, but rather *design* (particularly HCD) is the entirety of the process. Our study aimed to raise awareness of the need/value of design in healthcare and the participation of designers in the MDDes process. Three best practice design-led cases served as examples of successful, sustainable MDDes solutions in different contexts. The resulting design-informed, and human-centric MDDes process model and regulatory road map aimed to demystify the MDDes process to encourage and enable more designers to enter this field both locally and internationally.

References

Bullock, Ashton Margarete. 2019. "Defining a Design Process Model for Paediatric Medical Device Design in the South African Context." Johannesburg: University of Johannesburg.

Chan, Margaret Dr. 2010. “Medical Devices: an Area of Great Promise.” *Opening Address at the Global Forum on Medical Devices.* Bangkok: http://www.who.int/dg/speeches/2010/med_device_20100909/en/, 9 September.

Cheng, Michael. 2003. Medical Device Regulations: Global Overview and Guiding Principles. Geneva: World Health Organisation.

Dyro, Joseph. 2004. *Clinical Engineering Handbook.* New York: Academic Press.

Etikan, Ilker, Sulaiman Abubakar Musa, and Rukayya Sunusi Alkassim. 2016. “Comparison of Convenience Sampling and Purposive Sampling.” *American Journal of Theoretical and Applied Statistics* 5 (1): 1-4.

Flick, Uwe. 2004. *A Companion to Qualitative Research.* Edited by Uwe Flick, Ernst von Kardorff and Ines Stienke. London: Sage Publications.

Flick, Uwe, Ernst von Kardorff, and Ines Stienke. 2004. *A Companion to Qualitative Research.* Edited by Uwe Flick, Ernst von Kardorff and Ines Stienke. London: Sage Publications.

Gray, David E. 2004. “Doing Research in the Real World.” London: Sage Publications.

Kopec, D. 2012. *Environmental Psychology for Design.* New York : Fairchild.

Malkin, Robert, and Kim von Oldenburg Beer. 2013. “Diffusion of Novel Healthcare Technologies to Resource Poor Settings.” *Annals of Biomedical Engineering* 41 (9): 1841-1850.

Martin, Jennifer L, Daniel J Clark, Stephen P Morgan, John A Crowe, and Elizabeth Murphy. 2012. “A User-Centred Approach to Requirements Elicitation in Medical Device Development: A Case Study from an Industry Perspective.” *Applied Ergonomics* 43: 184-190.

McAndrews, L A. 2005. “Introduction.” In *Designing the World’s Best Children’s Hospitals 2: The Future of Healing Environments*, edited by Bruce King Komiske, 7. Victoria: Images Publishing.

Medina, Lourdes A, Gül E Okudan Kremer, and Richard A Wysk. 2013. “Supporting Medical Device Development: A Standard Product Design Process Model.” *Journal of Engineering Design* 24 (2): 83-119.

Mitchell, Louise. 2017. “The Supply and Manufacture of Medical and Surgical Equipment and Orthopaedic Appliances.” Accessed May 06, 2018. https://www.whoownswhom.co.za/store/info/4504?segment=Healthcare.

Money, Arthur, G, Julie Barnett, Jasna Kuljis, Michael P Craven, Jennifer L Martin, and Terry Young. 2011. “The Role of the User Within the Medical Device Design and Development Process: Medical Device Manufacturer's Perspectives.” *BMC Medical Informatics and Decision Making* 11 (15).

Prestero, Timothy. 2010. “Better by Design:How Empathy Can Lead to More Successful Technologies and Services for the Poor.” *Innovations*, 79-93.

SAMED. n.d. “The South African Medical Device Industry- Facts.” Accessed April 23, 2018. http://www.samed.org.za/DynamicData/LibraryDownloads/224.pdf.

Santos, Isa C T, G Scott Gazelle, Luis A Rocha, and Joao Manuel R.S Tavares. 2012. “An Ontology Model for the Medical Device Development Process in Europe.”

Starman, Adrijana Biba. 2013. “The Case Study as a Type of Qualitative Research.” *Journal of Contemporary Educational Studies* 28-43.

World Health Organisation. 2012. Local Production and Technology Transfer to Increase Access to Medical Devices. Geneva: World Health Organisation.

World Health Organisation. 2011. Medical Device Donations: Considerations for Solicitation and Provision. Geneva: World Health Organisation.

World Health Organisation. 2010. Medical Devices; Managing the Mismatch : An Outcome of the Priority Medical Devices Project. Geneva: World Health Organisation.

World Health Organisation. 2016. Towards Improving Access to Medical Devices Through Local Production. Geneva: World Health Organisation.

World Health Organisation. 2016. Towards Improving Access to Medical Devices Through Local Production, Phase 2, Report of a Case Study in Four Sub-Saharan Countries. Geneva: World Health Organisation.

Yin, Robert K. 2014. Case Study Research : Design and Methods. Los Angeles: SAGE.

—. 2003. Case study research: Design and methods. 3. CA: Thousand Oaks.

Yin, Robert K. 1981. “The Case Study as a Serious Research Strategy.” *Knowledge: Creation, Diffusion, Utilization* 3 (1): 97-114.