

# **Gordon Institute of Business Science**

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## **Dealing with performance-based health technology assessment outcomes for medical devices: A South African perspective.**

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## ABSTRACT

The rising costs of healthcare have resulted in the rise of health technology assessment (HTA) in efforts to manage health budgets that are under pressure. Disruptive health technologies have necessitated the adoption of relatively new contracting mechanisms where prices require real-world evidence to prove their claims. The emergence of performance-linked market entry agreements (MEA) is one such contracting mechanism where payments are linked to health-outcomes. The rise of these outcomes-based contracts (OBCs) also known as PBAs has been inundated with challenges that have led to questions about their effectiveness. The challenges in PBAs for medical devices are unique due to the features of medical devices, in particular their dependency on use by physicians.

Qualitative research on dealing with HTA outcomes that require PBAs in medical devices was undertaken to explore the implementation considerations of coverage with evidence development (CED) and performance-based risk sharing agreements (PBRsAs) including the funding mechanisms. A total of 12 interviews was conducted with actors in South Africa from different backgrounds who are experienced in conducting the implementation of CED schemes and PBRsAs for medical devices. The heterogeneous sample of representatives from payers, medical device manufacturers and hospitals allowed for different perspectives to be considered in efforts to gain insight into the challenges of implementing these medical device PBAs and how they are overcome.

The key findings of the study highlight the need to contextualize the health economic tool used in the HTA submission to the local country environment. Other key findings supported the themes in literature with a unique finding that defines the risk in PBRsAs as the risk to profitability. The findings were consolidated and compiled into a model framework that proposes adaptive pathway design planning for uncertainty in emerging markets. The research adds to the growing body of literature on the implementation and practical considerations related to PBAs in medical devices.

## DECLARATION

*I declare that this research project is my own work. It is submitted in partial fulfilment of the requirements for the degree of Master of Business Administration at the Gordon Institute of Business Science, University of Pretoria. It has not been submitted before for any degree or examination in any other University. I further declare that I have obtained the necessary authorisation and consent to carry out this research.*

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## LIST OF ABBREVIATIONS

|                                               |            |
|-----------------------------------------------|------------|
| Alternative reimbursement model.....          | ARM        |
| Adaptive Pathways.....                        | AP         |
| Competition Commission.....                   | Commission |
| Complex Adaptive System.....                  | CAS        |
| Coverage with evidence development.....       | CED        |
| Chief executive officer.....                  | CEO        |
| Corona virus.....                             | COVID-19   |
| Diagnostic related grouping.....              | DRG        |
| Fee for service.....                          | FFS        |
| Finance-based agreements.....                 | FBA        |
| Health market inquiry.....                    | HMI        |
| Health Technology Assessment.....             | HTA        |
| Key opinion leader.....                       | KOL        |
| Learning curve.....                           | LC         |
| Managed entry agreement.....                  | MEA        |
| Minister of Health.....                       | MOH        |
| National Department of Health.....            | NDOH       |
| National Health Insurance.....                | NHI        |
| National Health Insurance Fund.....           | NHIF       |
| Outcomes-based contracting.....               | OBC        |
| Participant.....                              | P          |
| Performance-based agreements.....             | PBA        |
| Performance-based risk-sharing agreement..... | PBRSA      |
| Profit and loss model.....                    | PNL        |
| Personal protective equipment.....            | PPE        |
| Risk-adjusted mechanism.....                  | RAM        |
| Risk-sharing agreement.....                   | RSA        |
| Randomised clinical trial.....                | RCT        |

Specific, measurable, actionable, relevant and time-bound.....SMART  
Supply-side regulator for health.....SSRH  
United States of America.....USA  
World Health Organization.....WHO

## 1. Chapter One: Introduction to Research Problem

### 1.1. Introduction

South Africa is one of the most unequal countries in the world with a Gini Coefficient of 0,65 in 2015 (Statistics South Africa, 2019). Using the Palma ratio, Statistics South Africa (2019) reported the spend by the top 10% of the population to be 7.9 times more than the bottom 40% in 2015. Some of the contributors to inequality are related to a racialised and gender biased labour market and the dependence on social grants by 60% of the bottom households (Statistics South Africa, 2019). Harris, Goudge, Ataguba, McIntyre, Nxumalo, Jikwana, and Chersich (2011) reported that significant inequities to health access exist in South Africa. Mayosi and Benatar (2014) proposed universal health care as one of the suitable means to address the health challenges that remain in South Africa years after the end of apartheid. The national health insurance (NHI) Bill 11 of 2019 has proposed policy amendments and restructuring of the current health service delivery model(s) in South Africa. The department of health has tabled the envisaged pathways to be undertaken in order to achieve the establishment of universal access to healthcare (Department of Health, 2017).

In efforts to improve access to healthcare, through universal coverage, governments are required to introduce cost containment measures as a pre-requisite to roll out of benefit packages (Department of Health, 2017). The financial cost containment requirement is to ensure that once implemented, healthcare delivery through NHI is financially sustainable (Department of Health, 2017). Health Technology Assessment (HTA) is an evidence-based tool that is proposed for identifying and setting health priorities and allocating resources (Department of Health, 2017). The role of HTA is to balance timely availability of health technology to patients whilst ensuring the technology is financially valuable and sustainable for the healthcare system (Brugger, 2014).

Reimbursement decisions are outcomes of HTA. The reimbursement decisions made as outcomes of HTA are sometimes made at a time where there might be insufficient evidence of the economic cost-effectiveness, which is based on clinical outcomes achieved by the health technology (Martelli & van den Brink, 2014; Carlson, Sullivan, Garrison, Neumann, & Veenstra, 2010; Hutton, Trueman, & Henshall, 2007). Insufficient evidence may result in delayed reimbursement decisions and patient access (Kanavos, Ferrario, Tafuri & Siviero, 2017). According to Kanavos et al., (2017) managed entry

agreements (MEAs) emerged as formal agreements between manufacturers and payers as a means to facilitate access to new technologies. The objective of MEA is to share the financial risk in the introduction of new technology due to uncertainty whilst enabling access (Kanavos et al., 2017).

MEA have a number of names, however, their common goal is to enable access to new health technology in the context of uncertainty (Ferrario et al., 2017). MEAs are also known as performance-based agreements (PBAs), outcomes-based contracts (OBCs), coverage with evidence development (CED), and performance-based risk-sharing agreements (PBRsAs; Carlson, Chen, & Garrison, 2017; Drummond, 2015; Nazareth et al., 2017). The uncertainty is described by Ferrario et al., (2017) as knowledge gaps “around effectiveness and/or use in real-life and high prices” (p. 1272). Reckers-Droog, Federici, Brouwer, and Drummond (2020) further clarified that the uncertainty could include safety and clinical effectiveness, the value of the technology in context of resources available, and utilisation rates, which have implications for budget impact.

These innovative MEAs are not without risks as they do not always yield outcomes hoped for by the manufacturers and payers (Drummond, 2015). There are additional challenges in HTA processes for medical devices even in well-established HTA agencies in developed countries (Chapman, Taylor & Girling, 2014; Craig, Carr, Hutton, & Sims, 2015; Pecchia, 2017). The overall purpose of this study was to contribute to the understanding of how adaptive pathways could alleviate some of the challenges and practical issues related to the implementation and funding of MEAs in medical devices, specifically, CEDs and PBRsAs.

## **1.2. Background of the Research Problem**

South Africa has proposed a National Health Insurance Fund (NHIF) through the introduction of the NHI Bill 11 of 2019, which seeks to promulgate into law the establishment of the NHIF. The NHIF is to be “financed through a compulsory prepayment that aims to achieve sustainable and affordable universal access to quality health care services” (NHI Bill 11 of 2019, 2019, p.1). It was proposed that, once the Bill is promulgated into law, it shall apply to all health establishments, which are required to be accredited (NHI Bill 11 of 2019, 2019). Section 7(4) of the Bill specifically outlines reimbursement mechanisms, stating that payments will “only [be for] treatments that are

cost-effective and explicitly excludes payment for treatments that are not cost-effective” (NHI Bill 11 of 2019, 2019, p. 10).

The Competition Commission’s (Commission) final report of the health market inquiry (HMI) on the private health sector in South Africa detailed an environment of escalating healthcare costs (Competition Commission, 2019). According to Jödicke et al., (2019), increasing health costs is both a global economic and public health matter. The Commission’s final report and recommendations described the private health market as being “characterised by high and rising costs of healthcare and medical scheme cover, and significant overutilization [sic]” (Competition Commission, 2019, p.30) whilst the corresponding improvement on health outcomes is missing. This lack of improvement in health outcomes despite the increasing healthcare costs is attributed to the fee for service (FFS) payment models, currently being used for payment of healthcare service providers (Competition Commission, 2019).

The Commission (2019) defines fee for service as [method of billing for health services under which a health practitioner charges separately for each patient encounter or service rendered. Under a fee-for service payment system, expenditures increase if the fees themselves increase, if more units of service are provided, or if more expensive services are substituted for less expensive ones] (p.18). Kruk, Gage, Joseph, Danaei, García-Saisó, and Salomon (2018b) and the World Health Organization (WHO, 2018a) however, stated that there is general evidence of poor quality in health services globally across countries and that improvement in health outcomes can be achieved through improvements in quality.

The Commission envisioned a health market that is “efficient and effective through implementation of innovations in the delivery and funding of health and by competing on price, cost and quality, and not on risk avoidance” (2019, p. 30). To encourage this, the Commission proposed that a standard benefit package across all medical funders be implemented, this package would have risk adjustment mechanism (RAM) (Competition Commission, 2019). RAM is defined as a regulatory aspect of income cross subsidization for a base fund across all schemes, where schemes with low risk will subsidize those with high risk demographic profiles (Competition Commission, 2019, p. 237, 239). Interestingly, if one analyses this recommendation, the implication of private health funders pooling funds and sharing risk to cover a minimum standard benefit package whose administration

would be overseen by the regulator of funders is essentially an establishment of a universal health coverage benefit within the private sector (Gonzalez, 2019). As part of its recommendations the Commission details the “establishment of a supply-side regulator for health (SSRH) which is envisioned as part of its mandate to conduct HTA” (Competition Commission, 2019).

It is evident that there is a policy intention to establish NHI and with it, a regulatory agency that will be responsible for HTA to manage health technology adoption through cost-effective purchasing. The WHO (2011) highlighted that HTA is important to manage the diffusion of medical devices to “encourage the adoption of cost-effective innovative medical devices, while delaying those which are consistently demonstrating uncertainties and inhibiting the increasing market penetration of those with doubtful value” (p. 18-19). Pearson (2018) argued that cost-effectiveness thresholds should be considerate of affordability, specifically short-term budget impact versus just on value demonstrated over the long-term, as not all cost-effective treatments are immediately affordable.

Kruk et al., (2018a) asserted that quality should be the core in establishing universal healthcare. The authors proposed that “governments should start by defining what people can expect through a health service level and user experience quality guarantee” (Kruk et al., 2018a, p. e1196). The WHO (2018) contended that quality improvement should form part of the national health strategy with supporting policy and regulation for its implementation. Further, Kruk et al., (2018b) argued that healthcare coverage expansion could potentially be unsuccessful in improving results of health intervention due to poor quality of care provided (p. 2230).

The target of the NHIF is to be a “strategic single purchaser and payer of defined healthcare services” (National Health Insurance Bill 11 of 2019, 2019, p. 1). The Minister of Health (MOH) is empowered through Section 41(4) that they may, through issuing of regulations, enter into and make payments utilising OBC agreements with healthcare workers or healthcare providers (National Health Insurance Bill 11 of 2019, 2019, p. 24). Further to this, Section 10(1) of the Bill specified that “payment rates should be based on quality and value of services provided, with monitoring of national health outcomes proposed” (National Health Insurance Bill 11 of 2019, 2019, p.11). Khan and Hashmani (2018) contended that acting against low-quality providers has considerable political difficulties that are seldom addressed. The authors further argued that measures against

low-quality private providers in areas where no alternatives exist could be despised by local communities who do not have visibility on quality issues from the provider (Khan & Hasmani, 2018). Further, Hanefeld, Powell-Jackson, and Balabanova, (2017) stated that patient assessment of quality is based on perceptions that are formed over time and are a social construct influenced by community interconnectedness, individual factors and power dynamics, and may at times not correlate with clinical outcomes. Hanefeld et al., (2017) recommended a number of quality measures along the clinical pathway to assess quality and further proposed that clinical outcome quality needs be measured against perceived quality from a patient perspective.

The Commission proposed the implementation of feedback systems to measure and report on health outcomes to encourage “strategic purchasing, value-based contracting where reimbursement is linked to performance” (Competition Commission, 2019, p. 179) using real-world outcomes data. Khan and Hashmani (2018) argued that strong measures against low-quality private providers could in turn jeopardise local political re-election aspirations, resulting in “pressure on the government to improve public health sector services” (p. 2146). The quality of health is important as poor quality could put the health of individuals at risk, decimating trust on the part of the users, thus opening up the entire health system to risk (Ghebreyesus, 2018). This political conflict of interest, raised by Khan and Hasmani (2018), if not addressed, may undermine efforts to implement system wide quality improvements. Ghebreyesus (2018) stated that quality is achieved through “vision, planning, investment, compassion, meticulous execution, and rigorous monitoring, from the national level to the smallest, remotest clinic” (p. e1141). This makes data collection and transparency on health outcomes critical.

### **1.3. Purpose of the Research**

The overall purpose of this study was to contribute to the understanding of how adaptive pathways could alleviate some of the challenges and practical issues related to the implementation and funding of MEAs in medical devices, specifically, CEDs and PBRsAs. It is proposed that, for policy considerations; lessons can be learnt from the few private health insurance scheme administrators who have implemented means of effective purchasing through the practices of conducting HTA (Kahn, 2019).

The benefit of CED schemes for medical devices has come under question (Reckers-Droog et al., 2020). Reckers-Droog et al., (2020) posited that CED schemes are important for medical devices as generally medical devices have limited evidence at the time of market entry, further clarifying the cost-effectiveness of medical devices as highly reliant on how the medical device is adopted into regular clinical practice. CED for medical devices, however, has been fraught with additional challenges (Reckers-Droog et al., 2020).

According to Reckers-Droog et al., (2020) conducting interviews with stakeholders experienced in applying CED schemes should provide additional insights into the challenges related to medical device CED studies and could be relevant for stakeholders who intend to apply them. The adaptive pathways theory is utilised as the lens to explore the research problem. The study is conducted with managers and executives experienced in the implementation of medical device CED and PBRsAs who represent funders, medical device manufacturers, and hospitals including their consultants. This study intended to shed deep insights into how the challenges of implementation of PBAs in medical devices are navigated in practice. The study sought to highlight hurdles in implementation of PBAs of medical devices for consideration and debate in policy formulation.

#### **1.4. Research Problem**

Discovery Health chief executive officer (CEO), Adrian Gore, argued that thousands of medical devices enter the South African market annually, some of them with no evidence of safety, efficacy or cost-effectiveness to justify funding (Kahn, 2019). HTA of medical devices is challenging due to limited clinical data requirements required to obtain regulatory approval, leading to an increased tendency to require generation of additional evidence to conduct HTA (Martelli, van den Brink and Borget, 2016). According to the South African medical technology industry association (SAMED) (2017) and at the time of writing, South Africa had not implemented a regulatory process to review medical devices prior to market entry, meaning the safety and effectiveness was not evaluated. In practice the private payer health sector has adapted by leveraging the safety and effectiveness review of medical devices by international regulatory authorities (SAMED, 2017).

Medical device regulatory review is generally still considered to be less stringent than regulatory review of medicines (Reckers-Droog et al., 2020). The result is that HTA outcomes for innovative medical devices that are priced at a premium compared to the current standard level of care are showing an increasing trend towards the requirement of CED studies (Martelli, van den Brink and Borget 2016). In a study done by Pouwels, Grutters, Bindels, Ramaekers, and Joore (2019) stakeholders contended that research outcomes of CED studies failed to address the uncertainties, pointing to some failure in research design. The Commission noted that “alternative reimbursement models (ARMs) are implemented without risk transfer and with carveouts available that effectively render payment rates at non-ARM rates, resulting in payment similar to fee for service” (Competition Commission, 2019, p. 187), meaning they are not health outcomes based. Further, Dabbous, Chachoua, Caban, & Toumi (2020) predicted a decreasing trend towards the implementation of health outcomes PBAs. Nazareth et al., (2017) acknowledged that there are significant challenges in OBC operationalising and implementation due to their complexity.

Martelli, van den Brink, and Borget (2016) found that over a five-year period in France, only two of several eligible medical devices had benefitted from the introduction of a CED scheme, pointing to a medical devices CED policy that needed improvements to address unresolved issues. The updated French CED medical devices policy is considered to have clear processes, requirements and improved transparency (Martelli et al., 2016). However, there was concern about limited funding, which had the potential to run out as the funding mechanism was not risk-adjusted for the policy makers (Martelli et al., 2016). Martelli and van den Brink (2014) stated that in “France, Germany and the UK, the nature of the evidence is specified, however there is no clarity on the CED study design” (p. 3). As such the authors argued that “CED schemes still require improvements to make them more operational” (Martelli & van den Brink, 2014, p. 4).

According to Dabbous et al., (2020), MEAs are “counterproductive in extending patient access and emergence of innovation” (p. 425). The trend observed is the increasing implementation of finance-based agreements (FBAs; Dabbous et al., 2020). South Africa have proposed policies that relate not only to the establishment of a national HTA regulatory agency, but also to the establishment of a single purchaser whose intention is to implement health outcomes performance-based payment contracting mechanisms. Ferrario et al., (2017) provided caution to the acceptability of confidential discounts used

in FBAs in publicly funded health insurance systems. In the literature, there are reports of seemingly unsurmountable challenges related to PBAs (Dabbous et al., 2020). The aim of this qualitative exploratory study was to understand the implementation and management of challenges related to PBAs, specifically CED studies and PBRsAs, including their financing. The researcher targeted individuals with experience in implementing PBAs in order to fulfil this aim.

## **1.5. Business and Theoretical Implications of the Research**

### **1.5.1. Business Need**

The Commission made the recommendation to establish a SSRH, whose mandate included the initiation of a national HTA agency and the use of ARMs in order to stimulate competition in the market (Competition Commission, 2019). The HMI report's final recommendations have called out for the implementation of health outcomes monitoring which should be used to evaluate performance and as a feedback loop into HTA (Competition Commission, 2019). The NHI Bill 6 of 2019 proposed that the emergence of new health technologies be evaluated for their cost-effectiveness. The National Department of Health (NDOH) has issued a call out for service providers who can assist towards the goal of establishing the national HTA agency (National Department of Health, 2019). The current private healthcare market has seen an increase in the implementation of performance-based HTA outcomes for health technologies by medical schemes. The current trends of increasing HTA requirements for medical devices, the rise in the use of MEAs by private funders and the anticipated future requirements where PBAs are expected to increase make a compelling business case for research into implementation of MEAs.

Understanding the implementation processes and requirements will assist businesses in planning market entry strategies for innovative medical devices. Further, understanding the challenges associated with the implementation of PBAs in medical devices will enable business managers to anticipate and plan for them. The research will equip businesses by sharing knowledge which currently is limited in literature and sits with a few individuals within the country facilitating market access understanding. Overall, the research sheds light on market entry reimbursement processes for PBAs of medical devices.

### 1.5.2. Theoretical Need

According to Haasnoot, Kwakkel, Walker, and ter Maat (2013), the current climate for decision makers is plagued by serious uncertainties, making planning difficult, as future consequences of decisions made may be quite different than anticipated, resulting in plan failure. The authors claim that, under these uncertainties, policy makers could learn as the future unfolds and alter their decisions in response to the new reality being observed (Haasnoot et al., 2013). This ability to alter course based on what is being experienced in contrast to what had previously been anticipated is defined as adaptation (Haasnoot et al., 2013). As decision makers adapt, they form part of the story of uncertainty (Haasnoot et al., 2013). According to Bouvy, Sapede, and Garner (2018), conditional approval based on an initial favourable benefit-risk assessment outcome with the requirement to gather additional evidence to support the initial assessment fits into the definition of adaptive pathways, which includes the managed introduction of health technology “at the earliest appropriate time in the product life-cycle” (p. 1). Bosomworth and Gaillard (2019) called for “greater publication of details regarding how participatory approaches to methods such as AP planning have been undertaken not just what was undertaken” (Bosomworth & Gaillard, 2019, (p. 2).

Haasnoot et al., (2013) posited that the concept of adaptive pathways is essentially planning under uncertainty. It involves creating scenarios where, based on evidence and through reaching a tipping point which is the actionable risk level, an alternative course of action is chartered (Haasnoot et al., 2013). Rosenzweig and Solecki (2014) proposed adoption of flexible adaptation pathways as a risk management approach. The authors advised that flexibility is critical in adaptative pathways as “inflexibility is simply a mitigation strategy and eventually leads to crossing acceptable risk levels” (Rosenzweig & Solecki, 2014, p. 396). Khan and Hasmani (2018) stated that inflexible means of dealing with poor performing or low-quality health service providers poses a system wide risk if it results in undermined quality improvement efforts. The use of adaptive pathways in health outcomes monitoring and managing low-quality health service providers may mitigate the threat of crossing acceptable risk levels. Rosenzweig and Solecki (2014) stated that “more permanent and inflexible approaches are likely to be costlier and less effective in the long term” (p. 396). Effectively, as per Khan and Hasmani (2018), inflexible approaches pose a conflict of interest to individual political careers aspirations and may not be enforced in local regions.

According to Vella Bonanno et al., (2017), adaptive pathways should be premised on iteration where the use of a health product is approved for a limited population whilst gathering evidence. Should the evidence be compelling, the use of health technology intervention can be expanded (Vella Bonanno et al., 2017). Haasnoot et al., (2013) clarified that decision makers form part of the story of uncertainty as they adapt. This highlights the importance and usefulness of collaboration to get to “...a jointly agreed data generation plan which meets the needs of regulators and health technology assessors...” (Ermish et al., 2018, p. 2). The criticism of adaptive pathways in health product introduction MEAs (i.e. CED and PBRsAs) is that it does not address the real-life challenges of MEAs (Ermish et al., 2018). This research aimed to align with Bouvy et al., (2018) on the interpretation that conditional MEAs, specifically the implementation of CED and PBRsAs in medical devices, are adaptive pathways and to review their implementation and challenges experienced and to identify critical considerations for decision makers.

## 1.6. Limitations

The researcher could not find the use of the theory of adaptive pathways as a lens through which to review the implementation of MEAs in medical devices, however few authors point to knowledge gaps in literature. According to Tarricone, Torbica, Drummond and MedtechTA (2017a) “further research could explore the actual implementation of such policies and explore practical issues such as determining who should fund the research and issues of study design” (p.151). Reckers-Droog et al., (2020) state that “our finding that challenges with CED schemes for MDs are infrequently researched is further illustrated by the fact that this, to our knowledge, is the first systematic review of the literature that focuses specifically on this topic” (p. 9). The authors further propose future research with payers who are experienced in conducting CED schemes, calling for engagement of stakeholders who can share how they addressed challenges in implementation (Reckers-Droog et al., 2020). Dabbous et al., (2020) stated that CED revision is needed, including a revision of its funding mechanisms, and proposed funders may be open to new funding mechanisms. According to Reckers-Droog et al., (2020) costs associated with funding the exorbitant transactional costs of CED schemes are a barrier to conducting cost effective studies. Finally, Nazareth et al., (2017) state that the absence

of a guiding framework, specifically key parameters is a critical challenge related to the implementation of outcomes-based or performance-linked agreements.

This theoretical lens is found in the review of MEAs in medicines and medicine related journal articles are utilised as a mechanism to delimit the constraint. In practice, the use of medicine related theories as the lens through which to view medical devices is common. It is widely accepted that healthcare related phenomena is generally observed first in pharmaceuticals and lessons learnt are taken to medical devices. Whilst all these health products are considered to fall under the umbrella term of health technologies, the differences between medicines and medical devices have become apparent, and the challenges of medical devices have introduced complexities that are otherwise not routinely found in medicines. The researcher aimed to manage the limitations of leveraging a theoretical lens based on medicines by acknowledging and incorporating the known differences between medicines and medical devices and by maximising medical device specific literature in the review.

### **1.7. Contribution**

The research sought to make a theoretical contribution through the adaptation of the dynamic adaptive policy pathways framework to the implementation of performance-based MEAs. This model for dealing with performance-based agreements as HTA outcomes for medical devices will have a business contribution as it assists funders, medical devices companies and policy makers by establishing a predictable environment and factors for consideration in the implementation of MEAs.

### **1.8. Conclusion**

In its efforts to address health access inequalities, South Africa has intentions to implement policies related to NHI in conjunction with the establishment of a national HTA agency. An NHIF is envisioned to be a single purchaser with aims to utilise performance-based payment mechanisms with health outcomes monitoring as a feedback loop into the HTA decisions and payment mechanisms. Value-based purchasing with innovative means to allow for the managed adoption of cost-effective health technologies has been tabled as the mandate of the HTA agency.

Health outcomes related PBAs have been found to be ineffective or inefficient. Medical devices experience additional challenges in their HTA processes. The practical implementation challenges in adaptive pathways of MEAs remain unsolved. The research aimed to explore the factors considered in the creation and implementation of health outcomes performance-based MEA in the private healthcare sector in South Africa to elucidate lessons learnt and facilitate policy debate. A qualitative explorative study is undertaken using the lens of adaptive pathways planning to gain insights on dealing with uncertainties and the challenges of performance-based MEA.

## 2. Chapter Two: Literature Review

### 2.1. Introduction

Vom Brocke, Simons, Riemer, Niehaves, Plattfaut and Cleven (2015) stated that the literature review is the foundation of research as it helps to identify knowledge gaps and can be used to justify the relevance of the research problem. It sought to illustrate “what needs to be done from what has already been done” (Randolph, 2009, p. 2). According to Gopaldas (2016) the literature review should be focused on relevant concepts to introduce the theoretical phenomenon. Thus, the following literature review explored adaptive pathways, complex adaptive systems, HTA of medical devices, performance-linked outcomes of adaptive pathways, adaptive pathways in medicine, CED of medical devices, funding of CED of medical devices, and PRBAs.

### 2.2. Theoretical Framing

#### 2.2.1. Adaptation Pathways, Adaptive Policy Making and Dynamic Adaptive Policy Pathways

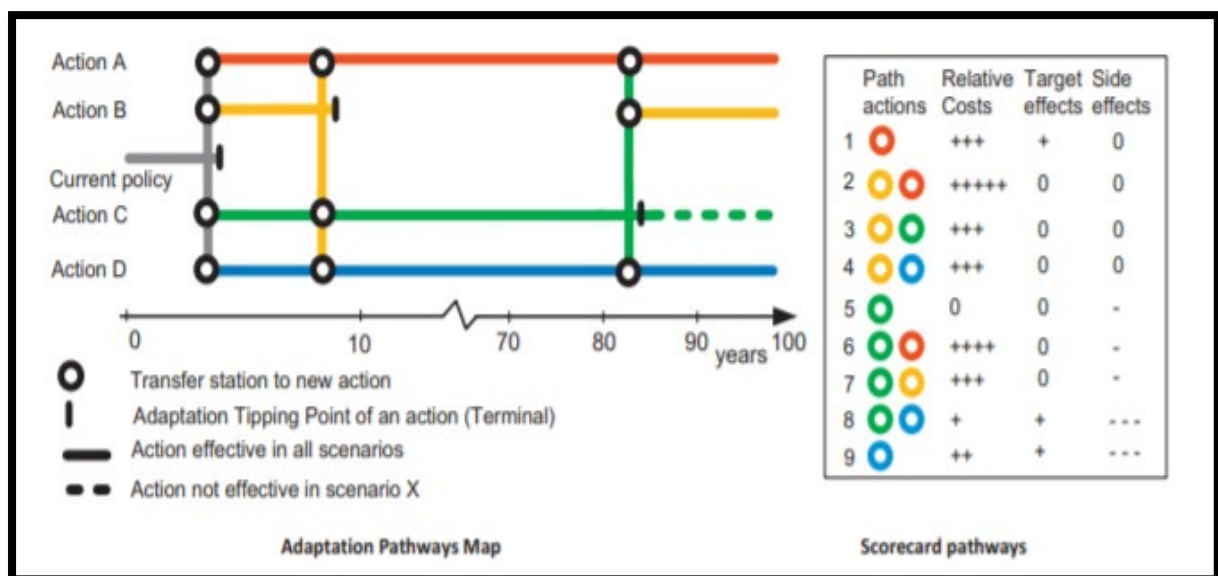
Hermans, Haasnoot, ter Maat, Kwakkel (2017) explained that “adaptation pathways approaches support long-term planning under uncertainty” (p. 29). Sequences of possible routes of actions are presented in a decision roadmap or decision tree and are triggered by reaching a tipping point (Haasnoot, Kwakkel, Walker, & Maat, 2013). Tipping points are central as they signal additional actions required and the emergence of a different pathway (Haasnoot et al., 2013). According to Haasnoot et al., (2013) any route is an adaptation pathway. Further, Hermans et al., (2017) explained that “different decisions are possible, whereby path-dependence links different decisions in a longer-term pathway” (p. 29). The background requirements to reaching adaptation pathways need consideration as there are possible actions that could influence path actions both positively and negatively. Factors that can confer bias need to be identified and managed.

Hermans et al., (2017) argued that the importance of monitoring and evaluation to track implementation progress and inform timely decision making is implied in adaptation pathways. In addition, Hermans et al., (2017) explained that “adaptation pathways plans typically deal with uncertain dynamic settings and involve and affect multiple actors, which means that monitoring needs to feed into a process of collaborative learning” (p. 30).

Elements that affect monitoring could result in ineffective pathway implementation and should be understood and incorporated into adaptation pathways. Paina and Peters (2012) claimed that path dependence often occurs when there are heterogeneous actors, further the authors caution that path dependence can lead to different outcomes, and complicates predictions even when the starting points and rules are similar.

Figure 1 below presents the process of setting up an adaptation pathways map proposed by Haasnoot et al., (2013), with a score card for measuring and comparing the different pathways. The adaptation tipping point of an action in challenging the current reimbursement policy could be the introduction of a PBA, CED scheme or PBRsAs. The alternative pathway action triggers could be both an ineffective and effective adaptation pathway, which can result in termination of the PBA if it is the former or the adoption of the health technology into routine practice and change to agreements if it is the latter.

**Figure 1: Adaptation Pathways Map and Path Scorecard**



**Haasnoot et al., (2013) explain the above Fig. 1.** as “An example of an Adaptation Pathways map (left) and a scorecard presenting the costs and benefits of the 9 possible pathways presented in the map. In the map, starting from the current situation, targets begin to be missed after four years. Following the gray lines of the current policy, one can see that there are four options. Actions A and D should be able to achieve the targets for the next 100 years in all climate scenarios. If Action B is chosen after the first four years, a tipping point is reached within about five years; a shift to one of the other three actions will then be needed to achieve the targets (follow the orange lines). If Action C is chosen after the first four years, a shift to Action A, B, or D will be needed in the case of Scenario X (follow the solid green lines). In all other scenarios, the targets will be achieved for the next 100 years (the dashed green line). The colors in the scorecard refer the actions A (red), B (orange), C (green), and D (blue).” (p. 488)

Source: Haasnoot, M., Kwakkel, J. H., Walker, W. E., & ter Maat, J. (2013).

Dynamic adaptive policy pathways: A method for crafting robust decisions for a deeply uncertain world. *Global Environmental Change*, 23(2), 485-498. p. 488.

Hermans et al., (2017) argued that “adaptation pathways provide an analytical framework that helps position short- and medium-term policy decisions within longer-term strategic ambitions” (p. 31). Paina and Peters (2012) contended that outcomes are sensitive to history, to initial conditions and decisions made along the way with possible system-wide effects that may be long-lasting. There is an argument that due to path dependence, health policy reforms cannot simply be copied from developed market economies and be expected to work in countries without the same institutional or political processes in place (Paina & Peters, 2012). The researcher suggests the development of a framework for planning and designing PBAs based on current experiences in the country.

### ***Adaptive Policy Making***

According to Haasnoot et al., (2013) “adaptive policymaking is a generic structured approach for designing dynamic robust plans and is rooted in assumption-based planning (p. 487). The authors further described adaptive policy planning as “a dynamic planning process where a basic plan is developed using a stepwise approach and with it, contingency plans to adapt the basic plan based on new information over time” (Haasnoot et al., 2013, pp. 486-487). The adaptive policy action changes are triggered by sign posts, these are points where current plan objectives are not being achieved and should be pre-defined as thresholds (Haasnoot, 2013).

Adaptive policy and adaptation pathways have the common objective of assisting decision makers with planning under deep uncertainty (Haasnoot, 2013, p. 487). Further, Haasnoot et al., (2013) claimed that “they both offer support in choosing near-term actions, while keeping open the possibility to modify, extend, or otherwise alter the plans in response to how the future unfolds” (p. 487). Haasnoot et al., (2013) proposed that an adaptation pathways map plans action which should be based on a strategic vision, namely; the adaptive policy, a high-level framework plan on how the adaptation pathways should be approached, and should contain identifiers of risks and vulnerabilities. Haasnoot et al., (2013) own criticism of the adaptive is that “it supports the decision maker in a different way by specifying a stepwise approach to designing a plan, however it offers no clear guidance beyond these concepts” (p. 489).

A new concept emerged from the combination of the strengths of Adaptive Policymaking and Adaptation Pathways, called Dynamic Adaptive Policy Pathways (Haasnoot et al.,

2013). The Dynamic Adaptive Policy Pathways explicitly specified the actions, sequencing and monitoring requirements.

### *Dynamic Adaptive Policy Pathways*

The combined Dynamic Adaptive Policy Pathways shown in Figure 2 below details the steps involved in the planning design to reach the adaptation pathways roadmaps. The steps are self-explanatory, however, it is critical to note the additional summary details of the steps provided below:

Haasnoot et al., (2013) described the first step requirement to be the definition of success by specifying outcomes requirements through indicators and targets to be used in performance evaluation. The study area description should include the specification of the uncertainties that affect decision making, as well as the uncertainties related to data or models required for evaluation (Haasnoot et al., 2013). The system characteristics, objectives, current constraints and future potential constraints should be described and consideration taken (Haasnoot et al., 2013).

The second step involves identifying risks and enablers in achieving objectives which should be considered (Haasnoot et al., 2013). These can be based on reference cases (Haasnoot et al., 2013). The third step identifies possible actions to meet the success requirements in light of risks and enablers (Haasnoot et al., 2013).

The fourth step is the evaluation of the effects of the individual actions on the outcome indicators (Haasnoot et al., 2013). These are assessed for each of the scenarios and can be presented using scorecards (Haasnoot et al., 2013). Furthermore, the risks and enablers need to be reassessed under this step (Haasnoot et al., 2013). Haasnoot et al., (2013) stated that the question to be answered is under this is step is “whether actions taken were able to reduce or remove a specified vulnerability” (p. 490).

Haasnoot et al., (2013) described the fifth step as an iterative process where information generated in previous step is used to identify new or additional actions and to reassess the vulnerabilities. (back to step 3). Haasnoot et al., (2013) explain that “once the set of actions is deemed adequate, pathways can be designed resulting in an adaptation map,

which summarizes all logical potential pathways in which ‘success’ (as defined in step 1) is achieved” (p. 490). A monitoring system can be implemented.

The Dynamic Adaptive Policy Pathways is a combination of Adaptive Policy Making and Adaptation Pathways. It provides guidance on the design planning required prior to initiating and comparing Adaptation Pathways Map (Haasnoot et al., 2013). It requires dynamic capabilities and shared learning from participants. A planned adaptation of the below diagram of dynamic adaptive policy pathways is proposed to create a framework model for dealing with PBA as outcomes of HTA for medical devices.

**Figure 2: Dynamic Adaptive Policy Pathways**



Source: Haasnoot, M., Kwakkel, J. H., Walker, W. E., & ter Maat, J. (2013). Dynamic adaptive policy pathways: A method for crafting robust decisions for a deeply uncertain world. *Global Environmental Change*, 23(2), 485-498. p. 489.

### 2.2.2. Complex Adaptive Systems (CAS)

Uhl-Bien and Arena (2018) stated that for organisations to cope effectively with uncertainty, leadership needs to facilitate dynamic capabilities to enable development of new competencies and adapt. Absorptive capacity is a core element of developing dynamic capabilities, and involves the assimilation and application of new knowledge to help organisations adapt to pressure triggers like technology and disruptive innovation or regulatory change (Uhl-Bien & Arena, 2018). The ability to explore opportunities in response to a changing environment is enabled by leaders who set up their organisations to deal with uncertainty and adapt in the face constant change (Uhl-Bien & Arena, 2018). Dynamic Adaptive Policy Pathways is one possible way leaders can set up their organisations to provide direction in an ambiguous environment (Haasnoot et al., 2013).

Disruptive innovations in healthcare technologies are forcing stakeholders into uncharted territories, the required investments are a challenge and they need to be proven to work. Healthcare providers are concerned with availing health technologies at the right time for patients to benefit. HTA and PBAs are emerging paradigms to deal with the uncertainties in performance of these new health technologies. Organizations are required to adapt and learn fast these skills which will enable them to build capabilities to manage the uncertainties whilst still providing healthcare.

Organisations who have amassed the required adaptation capabilities are able to be at forefront of innovation and will have a competitive advantage be they as funders or as medical device manufacturers. The uncertainty management requires that organizations engage with the uncertainty in efforts manage their risks as they shape their future. According to Haasnoot et al., (2013) the practical challenges in implementation of adaptation pathways in health can be further influenced by its various agents who interact with the uncertainty in a complex manner and potentially impacting the unfolding emergent phenomena (Haasnoot et al., (2013). Uhl-bien and Arena (2018) defined complexity as rich interconnectivity where the interaction of connections can lead to unexpected and unpredictable outcomes with the potential to be irreversible. Cilliers (2000) argued that a complex system has numerous feedback loops, and the essence of the interactions both direct and indirect, determine the behaviour of the system. Cilliers (2000) explained that the interactions are rich, dynamic, fed back, and, above all, nonlinear. The behaviour of the system as a whole cannot be predicted from a review of its individual components

(Cilliers, 2000). Hinson and Osborne (2014) describe complex adaptive systems (CAS) as being comprised of differing agents that are connected and are interdependent.

Paina and Peters (2012) further define the understanding of CAS as the behaviour of diverse, interconnected agents and processes from a system-wide perspective. CAS are described as such because in addition to being comprised of many interacting components, they have the capability to self-organise, adapt or learn from experience” (p. 367). The inability to predict outcomes results in emergence and requires adaptation to emergent phenomena (Cilliers, 2000). Health can be described as a CAS (Paina & Peters, 2012). Further, the inability to predict the future is further compounded by path dependencies (Paina & Peters, 2012). The result is that organizations and stakeholders should develop capabilities to engage with uncertainty and to understand how to manage the uncertainty and related risks whilst knowing that their interaction with the uncertainty also shapes the phenomena that emerges.

### 2.2.3. Conclusion

Dynamic Adaptive Policy Pathways offers a possible theoretical lens through which to manage the designing of plans and actual planning in dealing with uncertainty (Haasnoot et al., 2013). Adaptation Pathways provide a roadmap where decisions taken can be measured through pathways and the relative costs of different paths, including their associated actions, can be scored and compared. Depending on priorities and available resources, short- to medium-term decisions can be taken with the Adaptive Policy providing the desired long-term strategic objectives. The health system is a CAS with path dependencies that have the potential to impact the system in an unpredictable manner. Actors within the system are continuously learning and adapting as the future unfolds and decisions by individuals have the potential to impact the system in a manner that is not easily reversible. Path dependencies pose a challenge to the transferability of health policies between countries and are influenced by history, institutions and political processes. Paine and Peters (2012) highlight that planning for unpredictability is important in CAS, and flexibility to emerging issues emphasise the importance of learning and adaptation.

### 2.3. Health Technology Assessment (HTA)

Healthcare delivery is inundated by limited resources and inequitable access. HTA assesses the cost-effectiveness or economic impact of a health intervention focusing on the health technologies used to achieve the clinical benefit outcome. HTA is thus a means to control the escalating costs of healthcare by analysing the costs of new health technologies in relation to the clinical outcomes they achieve. HTA is an evidence-based decision-making tool that can be used to assist in priority setting and can be used as a gatekeeper to control which health technologies will be reimbursed and how.

HTA outcomes seek to “assist policy makers and or funders in making reimbursement or coverage decisions including medical benefit package design” (Ciani et al., 2017, p. 341). In simple terms, an HTA outcome determines whether or not a health technology is approved for payment by health funders Nazareth et al., (2017). HTA outcomes may also determine or specify the conditions of use including the clinical or diagnostic event (what), the clinical guideline (when), the clinical setting (where) a health technology is approved for use. HTA outcomes can also stipulate the reimbursement mechanisms (how) or payment levels (amount). Schwarzer & Siebert (2009) explain that HTA is based on the context of the health system which differ by country due to the structure and financing of the health system and the country legal framework. Saunders, Blüher, Mittard, Torres, Davis and Saunders (2019) state that “the economics of healthcare provision is a local challenge, and it has been suggested that the outcomes and interpretation of economic evaluations help to explain the heterogeneity in coverage recommendations and decision making across Europe” (p.2)

By this definition HTA includes a review of both pharmaceutical, biological and medical device products, however this study focuses specifically on medical devices. This role is different from the “mandatory regulatory approval” which authorises legal market entry by “ensuring safety and efficacy, with the role of preventing harm” (World Health Organization, 2011, p. 13). There are additional challenges in HTA processes for medical devices even in well-established HTA agencies in developed countries (Ciani et al., 2017; Pecchia, 2017). The role of HTA is to “balance timely availability of health technology to patients” whilst ensuring the technology is financially valuable and sustainable for the healthcare system (Brügger, 2014, p. 7).

Whilst HTA is championed as having the interests of the total population as a whole, it has been found that “HTA can and may lead to inequality in patient access to innovative health technologies due to the different bodies responsible for HTA who may reach different outcomes” (Akehurst, Abadie, Renaudin, & Sarkozy, 2017, pp. 67, 70, 75). Furthermore, there is a variation in the diffusion of health technologies, especially in medical devices, and factors that influence this diffusion can be influenced by HTA outcomes and thus need to be studied (Tarricone et al., 2017a). HTA processes and outcomes have the potential to exacerbate geographic market access disparities (Tarricone et al., 2017a). The diffusion of specialist healthcare providers in between rural and urban areas, locations of academic health research centres or centres of excellence, hospital locations, and general economic factors influence health access (Tarricone et al., 2017a). The HMI, for instance, identified that Gauteng had a significantly higher spend in health compared to other provinces (Competition Commission, 2019). The number of hospitals available in Gauteng is also disproportionately higher even when population distribution is adjusted (Competition Commission, 2019).

In the literature, HTA has been viewed as good practice to curb the rising costs of healthcare that are driven by introduction of innovative technologies (Bodenheimer, 2005a). Considerations of the acceptable cost of HTA as a percentage of healthcare is critical. Bodenheimer (2005b) reported that the cost of administering health in the US in 1999 was 24% of the total national health spend (p. 934). Healthcare funding should not move a sizeable and unpalatable amount of health spend from patient care to health administration (Competition Commission, 2019). HTA can also potentially deny valuable health technology to patients when errors in assessments are made (Brugger, 2014).

There is sufficient evidence to show that the rising costs of healthcare have not necessarily led to improved health and patient outcomes (Feldscher, 2018). Whilst HTA is a valuable tool and can be used to link costs to outcomes and to improve health outcomes, its blind spots must be acknowledged and managed. HTA seeks to manage the rising costs of healthcare by assessing and selecting which health technologies will be reimbursed. Due to the nature of medical devices, HTA for medical devices is challenging (Drummond, 2015).

### 2.3.1. Introduction

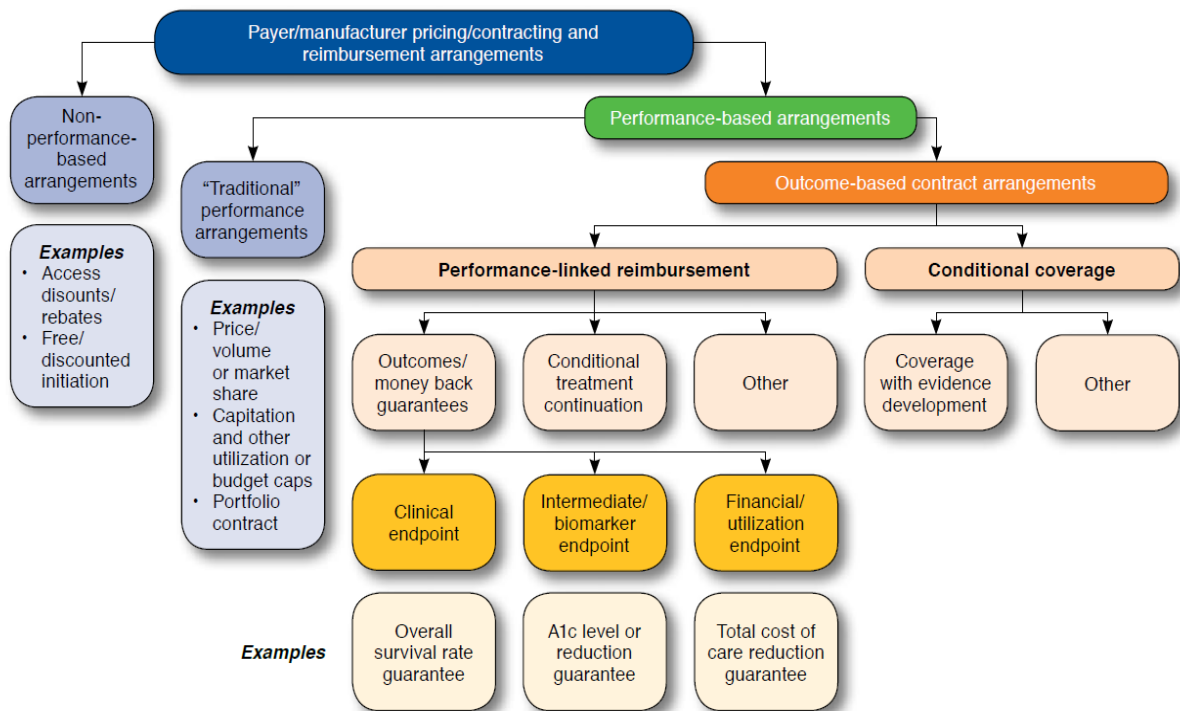
HTA can be categorised according to outcomes obtained which inform the type of contracting arrangements that will follow or clarify the next steps following the initial HTA outcomes (Carlson et al., 2010; Nazareth et al., 2017). The different types of HTA outcomes are discussed below. HTA outcomes seek to assist policymakers and or funders in making reimbursement or coverage decisions including the type of contracting to be implemented with suppliers and the different medical benefits package design (Doherty, Wilkinson, Edoka, & Hofman (2017) Department of Health, 2017).

Figure 3 below illustrates the range of possible HTA outcomes with the exclusion of rejected or no payment as a possible outcome.

### 2.3.2. Different Types of HTA

PBAs are outcomes of HTA, in figure 3 below, the different types of HTA outcomes are presented to showcase where the location and scope of the research. The blue shade highlights the general contracting mechanisms which form the financial or price-based performance-based contracting arrangements. The performance agreement is characterised as being non-clinical. These traditional performance contracting arrangements relate to price/volume-based discounts and rebates which are not linked to health outcomes (Carlson et al., 2010a). These traditional performance arrangements can include utilisation or budget caps where the payment to manufacturers is capped to ensure that utilisation does not exceed expected budget allocations (Carlson et al., 2010a; Nazareth et al., 2017). Dabbous, et al., (2020) collectively identified these as FBA, the authors contended that these are the type of agreements that will see growth in the future. These arrangements are helpful in curbing over-utilisation, and tend to affect rate of diffusion of technology and market share. Klemp, Frønsdal, and Facey (2011) posited that “managing budget impact risks is critical for medical insurers, and providers” (p. 79). According to Ferrario et al., (2017) the primary focus of MEA in central and eastern Europe was budget impact. Further, Pearson (2018) emphasised that cost-effectiveness on its own is not sufficient especially when value is viewed from a long-term cost-effectiveness to the system whilst the short-term budget impact makes the health technology unaffordable.

**Figure 3: Linking payment to health technology assessment outcomes:**



Source: Nazareth, T., Ko, J. J., Sasane, R., Frois, C., Carpenter, S., Demean, S., ... Navarro, R. P. (2017). Outcomes-based contracting experience: Research findings from U.S. and European stakeholders. *Journal of Managed Care and Specialty Pharmacy*, 23(10), 1018–1026. p. 1020.

The orange showcases health OBC, which was the focus of this research. OBCs are split into performance-linked reimbursement, done through health outcomes and CED. In performance-linked reimbursement or PBRsAs, the final net price is tied to a pre-agreed clinical end point outcome, however it could also include cost-effectiveness outcomes (Carlson et al., 2010a; Nazareth et al., 2017). The financial utilisation end point is itself linked to a clinical outcome where there is a claim of cost savings resulting from utilisation of new technology compared to the old or current level of care (Nazareth et al., 2017). This type of performance-linked reimbursement reviews how the new technology saves costs compared to the current or old technology. There are instances where the clinical outcomes are similar, however the new technology offers savings and the assessment looks at the extent of those cost savings which may be benefits realised in the long-term.

Nazareth et al., (2017) explained that conditional coverage arrangements are those that require additional evidence which may be restricted to use in research only, however, the research only arrangements were not in scope of the research. CED is the process where

the reimbursement of the technology is approved by the medical insurer whilst the requirement to generate additional evidence is imposed (Carlson et al., 2010; Felgner et al., 2018; Nazareth et al., 2017). The reimbursement price is usually at a price point below that, which is proposed by the supplier. The evidence generated will inform whether or not reimbursement is continued and expanded beyond the study or withdrawn (Carlson et al., 2010). CED was one of the key areas of focus of this research.

CED studies in literature have previously been perceived as undoubtedly positive. Walker, Sculpher, Claxton, and Palmer (2012) described CED studies and performance-linked reimbursement as progress as “it moves us forward from the binary decision of yes or no response from payers and allowing patients access to promising health technology” (p. 570). Ludwig and Dintsios (2016) argued that price negotiations between manufacturers and suppliers sometimes fail and as such OBCs are a progressive and acceptable middle ground that does not disadvantage patient access to life improving technologies. Klemp et al., (2011) argued that “MEA effectiveness has not been evaluated and that these agreements are administratively complex” (p. 77). The authors contend that MEA should only be an outcome of HTA when there are “key concerns about outcomes” or uncertainties to manage the tensions that arise between “obtaining value for money and funding new but expensive technology” (Klemp et al., p. 77-79). These innovative MEAs are not without risks as they do not always yield outcomes hoped for by the manufacturers and payers (Drummond, 2015). PBAs, OBCs and PBRsAs are known by a number of different names including: “risk-sharing agreements (RSA)”, “managed entry agreements (MEAs)”, (Carlson, Chen, & Garrison, 2017, p. 1063; Drummond, 2015, p. 569; Nazareth et al., 2017, p. 1018).

These contracting arrangements are viewed as being valuable to both manufacturers of health technology and payers in that they provide early market access for manufacturers, albeit limited, and enable payers to obtain the necessary data to clear up any uncertainties related to clinical and economic effectiveness (Drummond, 2015; Nazareth et al., 2017). Dabbous et al., (2020) stated that PBAs as MEAs are the most troublesome to apply and have failed to show their effectiveness in the healthcare system as they do not always meet their objective goals. There should be agreement on the uncertainty to ensure the data generated by the CED study is fit for purpose and closes the uncertainty gap (Chalkidou, Lord, Fischer, & Littlejohns, 2008). Some of the challenges in implementing OBCs relate to over extended hospital staff who fail to manage claims or do not fill all the

required information in the forms, thus failing to provide the required evidence and failing to give back the return on investment for payers (Dabbous et al., 2020). Dabbous et al., (2020) contended that costs of setting up and managing PBA which are managed through registries are always higher than estimated.

### 2.3.3. Adaptive Planning (AP) in the context of HTA

HTA outcomes pertaining to medical devices that are riddled with uncertainties but hold promising benefits are subjected to risk-management processes under conditional reimbursement (Reckers-Droog et al., 2020; Bouvy et al., 2018; Ermish et al., 2016; Eichler et al., 2015). According to Lawrence and Haasnoot (2017), dynamic adaptive pathways planning has been used in real-life to make scenario-based decisions on water management related climate change uncertainty. Eichler et al., (2015) proposed that in practice, decision makers and health technology companies need to be transparent about the process, as well as clarify the assessment of the known factors and the remaining uncertainty and risks. Haasnoot et al., (2013) stated that in adaptation pathways risk levels need to be defined together with the tipping points that will inform the decision in order to alter current course of action. In practice, this would mean defining not only uncertainty but also the confounding factors and specifying the thresholds that would necessitate a change of direction. In adaptive pathways of MEA, the benefits should outweigh the risks (Eichler et al., 2015) and the benefits should be significant (Bouvy et al., 2018).

Bloemen, Reeder, Zevenbergen, Rijke, and Kingsborough, (2018) noted there was insufficient research to evaluate the current use of adaptation pathways and their utility to practitioners and decision makers (p. 1083). Bosomworth and Gaillard (2019) described Adaptive Pathways (APs) planning as “a planning method that helps to guide decision makers under conditions of uncertainty” (p. 1). Bosomworth and Gaillard (2019) argued that APs need to be participatory. The authors further emphasised that the framing of the problem, selection of goals, and tabling the means or mechanisms to achieve said goals is driven by the knowledge and values of the stakeholders involved (Bosomworth & Gaillard, 2019). The authors argued that APs need to consider the diversity of the stakeholders and should have procedural equity, elevating the participatory approach in planning and design, thus enhancing the capacity for learning (Bosomworth & Gaillard, 2019). The theoretical lens of APs itself also concludes with “a call for greater publication of details regarding how participatory approaches to methods such as AP planning have been undertaken not just what was undertaken” (Bosomworth & Gaillard, 2019, p. 2).

One of the biggest vulnerabilities of PBA has been identified as absence of electronic patient data collection infrastructure, which limits the feasibility of evidence collection and reduces interest in evidence collection for long-term outcomes (Reckers-Droog, 2020).

Evidence collection is critical for the monitoring of the effectiveness of the adaptive policy as the triggers for alternative pathways depend on the analysis of the evidence collected. Poor evidence collection itself can be identified as a trigger for alternative pathways, which may be exiting the conditional reimbursement agreement.

Bouvy et al., (2018) argued that evidence collection of quality data can be improved through proper incentives for prescribers i.e. doctors. Reckers-Droog et al., (2020) further supported this, stating that the robustness of the data collection “often depends on physicians and they are not always compensated for data collection” (p. 7). The funding of the administrative burdens without protection and the lack of incentives for high quality data evidence collection contribute to the ineffectiveness of MEAs and adaptive pathways (Reckers-Droog, 2020; Bouvy et al., 2018). The researcher is of the view that adoption of the adaptive policy approach to designing adaptive pathways maps provide an opportunity to improve the effectiveness of MEAs. For payers, the complexity and ineffectiveness of PBAs in addressing the uncertainties results in reluctance to use AP through CED studies and PBRsAs, further the difficulties in exiting an ineffective MEA adds to the reluctance due to public image risks (Bouvy et al., 2018).

Payer perception is that evidence generation cost is for the manufacturers and is part of the costs of bringing their medical device to market. Manufacturers, on the other hand, argued the benefit of adopting cost-effective health technology is for the funders. According to Bouvy et al., (2018) “in the absence of a comprehensive national data collection system, use of a mutually trusted third party for outcome measurement could facilitate trust” (p. 7). Ermisch et al., (2016), Bonano (2017), and Bouvy et al., (2018) acknowledged that the difficulties of evidence collection present a key challenge to the effective implementation of adaptive pathways.

The process to manage uncertainty and unpredictable health outcomes is through the use of adaptive pathways, making it an appropriate theoretical lens for this research. Adaptive pathways, CED studies and PBA in medical devices are plagued by challenges and their implementation and utility in practice, requires investigation in how they are undertaken (Reckers-Droog et al., 2020; Bosomworth & Gaillard, 2019; Bloemen et al., 2018; Tarricone et al., 2017). The healthcare industry qualifies as a complex adaptive system. Adaptive pathways require design planning which should be based on agreed objectives,

arrived at through participatory goal setting, with risks identified and mitigation strategies identified.

## 2.4. Coverage with Evidence Development (CED)

CED is the HTA outcome that imposes conditional reimbursement with the aim of undertaking real-world studies to address uncertainty gaps (Reckers-Droog et al., 2020; Tarricone et al., 2017). Tarricone et al., (2017) and Felgner et al., (2018) stated that medical devices generally have insufficient clinical evidence at the time of obtaining regulatory market access, which reviews the safety and effectiveness. Post-market studies for HTAs are encouraged as a means of generating the necessary data to perform cost-effectiveness studies on medical devices (Tarricone et al., 2017). The authors implored medical funders/payers and governments to utilise conditional CED requirements for MDs in order to perform evidence-based HTA (Tarricone et al., 2017).

In contradiction, Pouwels et al., (2019) identified that uncertainties in CED studies are not always systematically or completely identified. This is to ensure the data generated by the CED study is fit for purpose and closes the uncertainty gap (Chalkidou, Lord, Fischer, & Littlejohns, 2008). This could result in CED studies that do not close the uncertainty gap, resulting in wasteful expenditure. Further to this, Reckers-Droog, Federici, Brouwer and Drummond (2020) stated that the difficulties in assessing medical device CED schemes bring to question their claimed benefits. CED studies seem to continue to be implemented even with questionable evidence of their value, this continuation despite evidence is attributed to political pressure (Dabbous et al., 2020).

Payers are motivated to share the risk with manufacturers of innovative health interventions to allow patients to access innovative products whilst using these novel contracting arrangements to gain real-world data on the value of the innovation (Carlson et al., 2010; Nazareth et al., 2017). This allows healthcare funders to “link the value of the health intervention to the real-world health outcomes” it achieves (Nazareth et al., 2017, p. 1018). Manufacturers are motivated to engage in CEDs as they provide the opportunity for their products to demonstrate the “value and differentiation they provide as opposed to just cost” (Nazareth et al., 2017, p. 1023). In implementing CED studies, “real-world health outcomes are tracked and reviewed over a specified period of time and the final approved reimbursement price is based on real-world health outcomes obtained”, as well

as the value the innovative health technology provides to the healthcare system (Drummond, 2015, p.569).

For medical devices, the lack of evidence related to clinical effectiveness is more prevalent as medical device regulatory approval reviews of safety and performance does not have to include randomised clinical trials, which are not always possible for medical devices (Drummond, 2015; Tarricone et al., 2017). Randomised clinical trials are challenging to perform after regulatory approval. According to Drummond (2015) once post-market access reimbursement is obtained, “observational studies can be considered to obtain evidence on effectiveness” (Drummond, 2015, p. 570). Tarricone et al., (2017) recommended accepting that when it comes to medical devices, post-market studies are one of the ways to generate real-world data. Observational studies are, however, onerous on the physicians and do not always contain complete information resulting in ineffective evidence collection (Dabbous et al., 2020).

The study designs add further challenges in the evidence collection. Reckers-Droog et al., (2020) identified that the uncertainty is not always clearly defined or the decision question that must be answered by the CED is not always explicit. Further, the type of study design and data required should be explicitly stated in order to ensure the study addresses the uncertainty (Reckers-Droog et al., 2020). Medical devices have the added challenge of being user dependent, where optimal effective use improves with training and increases user experience (Tarricone et al., 2017). This learning curve can impact CED study outcomes (Tarricone, Giuditta, Marko, and Valentina, 2017b). The acknowledgement and estimation of the learning curve (LC) will go a long way in ensuring a fair and balanced study report as the LC can be disadvantageous to the effectiveness of medical devices, which improves with time, and use (Drummond, Tarricone, and Torbica, (2018); Rothery, Claxton, Palmer, Epstein, Tarricone & Sculpher (2017); Tarricone et al., 2017b).

Implementing CED studies for medical devices has serious challenges. The challenges include the lack of a guiding framework for the studies, aligning data needs with expectations, and the coordination and monitoring of the studies (Tarricone et al., 2017; Drummond, 2015). Reckers-Droog et al., (2020) recommended that future studies be undertaken to gain insight into the challenges linked to medical device CED schemes by conducting interviews with the payers and manufacturers who apply CED schemes for medical devices. Considering the context specific effects of HTA, there is no study known

to the researcher that is related to how HTA, and specifically, how CED studies for medical devices are implemented and how the related challenges addressed in South Africa. The challenges experienced in conducting medical device CED studies need to be explored within their implementation framework.

#### 2.4.1. Funding of CED studies for Medical Devices

Reckers-Droog et al., (2020) proposed that the implementation of a CED study may continue in perpetuity if there are no time frames or patient numbers restrictions should the reimbursement position be that funding will continue until there is sufficient evidence for evaluation. CED studies for medical devices are associated with exorbitant funding costs, and there are difficulties in execution which may result in increased duration of the study (Reckers-Droog et al., 2020). Manufacturers of medical devices funding their own CED studies and analysis may result in biased study as there exists a conflict of interest (Reckers-Droog et al., 2020).

According to Watering, van Excel, and Brower (2017) payers have found that it is not easy to withdraw reimbursement funding once conditional reimbursement has been initiated. Reckers-Droog et al., (2020) agreed that patients may pressurise politicians to maintain reimbursement funding availability, sparking public debate. Funders subsidising the CED scheme could ensure that uncertainties are clearly defined and that the study design is reviewed, approved and capable of addressing uncertainties (Reckers-Droog et al., 2020). Practical considerations related to the implementation, the study design, research methodology, and funding need to be taken into account (Tarricone et al., 2017).

There are a number of considerations and stakeholders who are likely to be involved, including: the surgeons in the case of medical devices who need to document the data; hospitals, depending on the clinical setting required for the intervention; and the clinical associations to which healthcare professionals belong (Drummond, 2015).

Whilst proving to be quite useful for healthcare budget finance management, there is an argument that there is a cost to implementing HTA and the cost of conducting these CED studies is not always measured (Tarricone et al., 2017). HTA is gaining momentum, so are OBCs, which are also a market access tool utilised for innovative health technologies

in efforts to contain and/or curb the increasing costs of healthcare (Nazareth et al., 2017). Chapman, Taylor, and Girling (2014) and Craig, Carr, Hutton, and Sims (2015) revealed that HTAs of medical devices are challenged by methodological difficulties. There are operational constraints, high administrative burdens, resource costs, data availability challenges and complexities that make OBCs unsuitable for every product (Nazareth et al., 2017). Rothery et al., (2017) explained that manufacturers may not have incentive to bear the costs of conducting CED studies and may accept the reimbursement pricing at the current level of care. In such circumstances, the value of the device and the value of future research might be shared between the manufacturer and the health sector (Rothery et al., 2017). In such instances, the funding of CED studies should be shared by payers and manufacturers.

While these managed entry contracting agreements (MEA) have value to both medical device manufacturers and payers, the value achieved lies in the detail included and considered prior to finalising the agreements (Drummond, 2015). The commitment to providing the detail of explicitly stating uncertainties, reaching consensus on study design that addresses the CED research question may be influenced by how much investment each stakeholder is bringing into funding the CED scheme. Reckers-Droog et al., (2020) stated that manufacturers may be reluctant to make investments into funding CED schemes as they have no protection against competitor new market entrants who could obtain reimbursement approval.

There is a need to make the financing of CED schemes cost effective, in a fragmented market the investment requirements and difficulty in conducting CED studies becomes a challenge for manufacturers (Reckers-Droog et al., 2020). The high costs associated with executing CED studies relates to the high administrative requirements which may involve pre-authorisation as per study protocol inclusion criteria and complex billing processes required by funders (Reckers-Droog et al., 2020). There is a need to explore how CED studies are funded in South Africa and to identify the considerations that influence the willingness to fund CED studies from both the manufacturer and payer perspectives.

## 2.5. Implementation of Alternative Performance-Based Risk-Sharing Agreements (PBRsAs)

CED studies aim to prove performance at a population level, whilst the alternative is PBAs that look at performance at a patient or individual level (Dabbous et al., 2020). The challenges in PBRsAs include the lack of a guiding framework for the studies, aligning data needs with expectations, coordination and monitoring of the studies (Gonçalves, Santos, Silva, & Sousa, 2018). The patient level PBAs are characterised by risk-sharing and as such collectively identified as PBRsAs. These agreements look at individual level patient outcomes as part of risk and value management (Piatkiewicz, Traulsen & Holm-Larsen, 2018). Value in healthcare can be described as the treatment outcomes obtained by utilising a certain health intervention relative to its cost (Yu, Chin, Oh & Farias (2017). Consequently, value-based pricing is the process of linking the manufacturer's proposed price to actual clinical and economic outcomes (Yu et al., 2017). Healthcare costs have been rising and there is a need to manage health budgets (Yu et al., 2017). According to Carlson, Chen, and Garrison (2017) “enthusiasm for PBRsAs continues but at variable pace across countries, despite many challenges” (p. 1063)

Edlin, Hall, Wallner, and McCabe (2014) proposed an alternative and innovative technology leasing reimbursement scheme. The authors argued that current PBRsAs actually end up risk-shifting once the final price for HTA outcome is determined (Edlin et al., 2014). The authors advocated for extending the payment period linked to individual patient outcomes, where full reimbursement is given to the manufacturer if the outcomes meet expectations, but reimbursement would be withdrawn when undesirable outcomes are observed (Edlin et al., 2014). On the other side of this proposed spectrum of leasing and dynamic pricing is additional and continued payment to medical device manufacturers when better than expected outcomes are obtained (Edlin et al., 2014). The authors posited that this method minimises risk to payers as it reduces the impact of upfront payments and is more aligned with the risk-sharing concept than current practices (Edlin et al., 2014). Dabbous et al., (2020) reported on new and innovative financing mechanisms for health technology that is linked to outcomes.

The implementation of PBRsAs has not been without challenges. Manufacturers are motivated to engage in PBRsAs as they provide the opportunity for their products to demonstrate the value and differentiation they provide as opposed to just cost (Nazareth

et al., 2017). Whilst proving to be quite useful for healthcare budget finance management, there is an argument that there is a cost to implementing these health outcomes evaluation studies (Dabbous et al., 2020).

Dabbous et al., (2020) reported that most PBRsAs use surrogate end points which are less effective at monitoring patient outcomes than monitoring of performance at real life patient level. Research shows that most PBRsAs do not get to the intended end points and change to being discount-driven agreements due to the complexities in data collection even when facilitated by electronic infrastructure and costs associated with them (Dabbous et al., 2020).

Nazareth et al., (2017) reported that adoption of OBC or PBRsAs would continue to be limited due to their complexities and challenges. Carlson, Gries, Yeung, Sullivan, and Garrison (2014) showed that these types of agreements were in decline. In contradiction, Piatkiewicz et al., (2018) reported that interest PBRsAs continued to grow. Dabbous et al., (2020) echoed Nazareth et al., (2017) and stated that these types of MEAs are expected to decline as they are not conducive to expanding patient access, however a future is still possible if manufacturers pool together in sponsoring global registries. There is no consensus on the future possibilities of PBRsAs and this may be influenced by complexities in implementation. Further, PBRsAs require additional monitoring requirements that are limited by unavailable infrastructure that could facilitate monitoring for example through electronic health records (EHR). Insufficient evidence is highlighted as one of the key contributors to the failure of PBRsAs in meeting their objectives and the anticipation is that EHR would alleviate this issue.

## 2.6. Conclusion

CED studies as an outcome of HTA are prevalent in medical device reimbursement evaluations. CED studies aim to address the uncertainties identified during the initial HTA, making the study design, research methodology, coordination, monitoring and funding of CED studies important, however knowledge gaps exist in the practical implementation and methodologies used in CED schemes. These knowledge gaps are identified in section 1.9 above. The funding of high cost CED studies still remains a challenge for manufacturers who are small to medium enterprises and they may benefit from a nationally sponsored funding (Martelli, van den Brink and Borget 2016).

Medical device manufacturers have the additional challenge that is not found in medicines of fast-followers (Drummond, Tarricone & Torbica, 2016). Medical device manufacturers may not be incentivised to fund CED studies as they do not have protection against new entrants which may be cheaper and obtain reimbursement and render their investment obsolete (Reckers-Droog, 2020). OBC or PBRsAs have not seen the increasing trend expected of it, in an era of outcome-based healthcare (Dabbous et al., 2020). An understanding of the management of complexities related to implementing PBAs in medical devices will shed light on when these contracting arrangements are suitable and the challenges experienced in implementing them.

### **3. Chapter Three: Research Questions**

#### **3.1. Introduction**

The research questions were formulated based on the literature review in the preceding chapter 2, which identified gaps in the current body of literature. Health as a complex adaptive system contributes to the challenges in the implementation of health outcomes related agreements. The overall purpose of this study was to contribute to the understanding of how adaptive pathways could alleviate some of the challenges and practical issues related to the implementation and funding of MEAs in medical devices, specifically, CEDs and PBRsAs.

#### **3.2. Primary Research Question**

Recent studies have evaluated the effectiveness of PBAs and CED schemes and the value they provide has come under question. The heterogeneity of actors, their interconnectedness and path dependencies create an unpredictable environment that poses a challenge to planning. The primary aim of the study was to explore how do adaptive pathways alleviate some of the practical issues related to implementation of MEAs in medical devices, specifically CEDs studies and PBRsAs. A review of the lessons learnt in private health sector by those stakeholders with experience in dealing with PBAs was conducted.

#### **3.3. Sub-Research Questions**

##### **3.3.1. Research Question 1: What are the Factors Considered in Implementing CED Studies for Medical Devices?**

This research question sought to establish the critical considerations that are important in the implementation of CED studies. The research aimed to learn from the private health sector in the country, as this sector has experience in the implementation of CED studies, benefiting from lessons learnt and insights gained. The research question endeavoured to make a theoretical contribution to the current available literature through an adaptive framework model.

### 3.3.2. Research Question 2: What are the Funding Considerations for CED Studies?

This research question aimed to understand how CED studies are funded. CED studies are resource intensive and funding them poses a challenge. Additionally, the funding of CED studies could influence the ownership of the information provided by the study outcomes and this in turn influences the bias and thus study outcomes. The funding of CED studies contributes to the lack of transparency of outcomes of these schemes to clinicians and other stakeholders. Funding CED schemes require critical and contextual consideration as these studies could unearth information that could potentially be crucial to certain epidemiological and demographic population profiles and could be of interest to policy decision makers.

### 3.3.3. Research Question 3: What are the Factors that Influence Implementation of Alternative PBRsAs?

The last question of the research sought to shed light on when performance-based risk-sharing agreements is deemed a suitable consideration. The implementation of PBRsAs is said to be fraught with challenges, the question strove to unearth these challenges and highlight critical parameters for consideration in addressing them based on South Africa's private health sector experiences. Stakeholders with experience in implementation of PBRsAs have invaluable insights that can facilitate robust policy debate, aid policy considerations and mitigate the risk of the country implementing ineffective PBA resulting in wasteful expenditure.

The following is a table (1) that links the research questions to their corresponding sources in the literature review in Chapter 2.

**Table 1: Linking Research Questions to Literature**

| Research Questions | Section in literature review                                                                                                                     | Sources of Knowledge Gaps                                                                                                                          |
|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| RQ1                | 2.3.3. Adaptive Planning (AP) in the context of HTA<br><br>2.4. Coverage with Evidence Development (CED)                                         | Bosomworth and Gaillard (2019)<br><br>Reckers-Droog et al., 2020; Tarricone et al., 2017; Craig et al., 2015; Chapman, Taylor, and Girling, (2014) |
| RQ2                | 2.4.1. Funding of CED studies for Medical Devices                                                                                                | Reckers-Droog et al., (2020); Dabbous et al., (2020); Tarricone, Torbica, Drummond, (2017).                                                        |
| RQ3                | 2.3.3. Adaptive Planning (AP) in the context of HTA<br><br>2.5. Implementation of Alternative Performance-Based Risk-Sharing Agreements (PBRsAs) | Dabbous et al., (2020); Bosomworth and Gaillard (2019); Nazareth et al., (2017)                                                                    |

Source: Author's own.

## 4. Chapter Four: Methodology

### 4.1. Introduction

Reckers-Droog et al., (2020) and Tarricone et al., (2017) recommendations for future research specifically call out for the exploration of the practical issues related to challenges in implementation of CED studies of medical devices. According to Peters, Adam, Alonge, Agyepong and Tran (2013) “implementation research is especially concerned with the users of the research and not purely the production of knowledge (p. 2). Peters et al., (2013) stated that “implementation research seeks to understand and work in the usual practice settings, paying particular attention to the context in which implementation occurs, and the factors that influence implementation” (p. 4).

Historically CED studies were viewed in literature as an inherently good thing, as they allowed for diffusion of medical devices that could be clinically relevant and cost effective (Tarricone et al., 2017). However, CED studies on medical devices have various confounding factors and a number of stakeholders that could impact outcomes (Reckers-Droog et al., 2020). Pouwels et al., (2019) stated that there have been CED studies conducted that did not address the uncertainties that necessitated the research; as such the study design becomes critical.

The investment of payers as stakeholders who are funding a CED scheme may influence the articulation of uncertainties and the involvement in study design (Reckers-Droog et al., 2020). Ermish et al., (2016) called for a joint agreement on data generation plan in implementing AP to ensure that MEAs meet the requirements of HTA assessors. Bouvy et al., (2018) proposed that issues related to implementation AP for MEA can be resolved by identifying enablers that reduce process risks. Dabbous et al., (2020) painted a bleak future for PBRsAs, which were expected to be on the rise, and called for the revisiting of CED studies to improve their value and success.

The research processes started with the identification of knowledge gaps in literature, which led to the construction of the research questions. A research discussion guide was created as the data collection tool to be used in the semi-structured interviews, which were initially conducted using the face to face method. However, the outbreak of the global pandemic of the corona virus (COVID-19) at the data gathering phase began to create panic, as such some participants requested telephonic interviews. As the country went

into full lockdown, telephonic interviews became the only method through which data was collected. The interviews were transcribed through the use of a consultant. The data analysis, coding and thematic analysis was done manually on Microsoft Excel. The findings are discussed in chapter 5 and found in Appendix 5.

An interpretivist philosophy was selected as the study wished to understand a phenomenon, “among its social actors in their natural environment” (Saunders & Lewis, 2012). Thanh and Thanh (2015) explained that by using the interpretivist philosophy, “researchers discover reality through their participants’ views, their own background and experience” (p. 24). HTA is a relatively new requirement in South Africa and stakeholders who have been impacted by it have had to interpret the new rules of engagement and adapt their roles in the healthcare delivery system in line with this distinctive phenomenon.

The interpretivist perspective is pertinent in understanding what is occurring, how it is occurring and the meaning (why) given to the actions (Welch & Piekari, 2017). Interpretivism is able to “accommodate multiple perspectives and versions of the truth” (Thanh & Thanh, 2015, p. 25). Interpretivism is more suited to accommodate a heterogeneous sample population as it accepts differing viewpoints from participants of different backgrounds (Thanh & Thanh, 2015). According to Thanh and Thanh (2015), the inclusiveness of interpretivism results in a more comprehensive understanding of phenomena. Interpretivism is associated with qualitative research as these research methods allow for in depth understanding of individual experiences gained through participatory interaction (Thanh & Thanh, 2015). The research aims to extract insights into the implementation of PBAs and this is done through the experiences of the respondents, as such the interpretivist philosophy is more suited to elucidate insights from each participant own perspective interpretation (Saunders & Lewis, 2012).

Qualitative, exploratory studies are suitable in efforts to gain understanding of new phenomena (Creswell, 2003). Qualitative studies are “useful for unpacking complexity and identifying processes” and the “evidence from the studies can be used to facilitate communication with politicians and decision makers” (Carrasco & Lucas, 2015, p. 168). As HTA of medical devices is at its infancy in South Africa, where the regulation of medical devices is new and has not yet been implemented (Department of Health, 2017), a qualitative, exploratory study was deemed appropriate for this research. The selected scope of study, CED schemes and PBRsAs, which are outcomes of HTA for medical

devices, is currently a niche area and exposure is limited to companies that are considered leaders in medical device innovation.

## **4.2. Population**

The total research population for this study comprised a diverse group of stakeholders including managers and consultants whose shared commonality was their involvement and experience in HTA and MEAs for medical devices (Zikmund, Babin, Carr, & Griffin, 2003). Sources with knowledge and experience were deemed as having potential to answer the research question and were included in the total population (Van Rijnsoever, 2017). The population included executives responsible for managing reimbursement approval processes for innovative medical device manufacturers, reimbursement managers in medical schemes, and hospital managers involved in HTA.

## **4.3. Unit of Analysis**

The researcher identified manufacturers and distributors who supplied innovative, less invasive medical devices and their consultants, the medical schemes who are conducting CED studies and PBRsAs, and hospital managers involved in the procurement of medical devices. The chosen sample was selected based on their experiences in conducting CED studies and PBRsAs from the perspective of medical device companies, medical insurance schemes, and hospitals.

Analysis was done at research question and individual participant level as the group of respondents had some variations within themselves. The experience of the processes involved in the implementation of CED studies and PBRsAs were expected to have some individual bias depending on the side of the industry they represented. The individuals represented the suppliers, the payers and hospitals. The heterogeneity of the group was important in that it gave different perspectives of the process of implementation. The objective of the study was the process of implementation, funding and the practical challenges in CED studies and PBRsAs of medical devices as previously identified in the literature review.

The group of individuals who were involved and experienced in implementation and management of medical device CED studies and PBRsAs were interviewed to gain an understanding of the process. The group comprised of: (i) Managers and consultants in the medical devices sector who held strategic and decision-making positions and were responsible for applying and obtaining reimbursement approvals for HTA submissions with a specific focus on innovative medical devices that had required CED studies and PBRsAs. (ii) Managers who were in the medical insurance industry who were responsible for reviewing medical device HTA submissions; who made the decisions to request implementation of CED studies and PBRsAs relating to medical devices. (iii) Hospital managers who were responsible for medical device procurement and had experience in HTA, the related HTA CED studies and PBRsAs at hospital levels.

#### **4.4. Sampling Method and Size**

A combination of non-probability sampling and snowball sampling was used. Some of the participants were identified with the assistance of the SAMED CEO, Tanya Vogt. The sample was heterogeneous, in order to obtain the various perspectives of the different agents involved. The heterogeneous nature of the sample also allowed for data triangulation (Welch & Piekkari, 2017). The number of people who have experience in CED and PBRsAs in medical devices is limited as this is a niche market in South Africa. As part of protecting the identities of the respondents in the data analysis section, the respondents are given identifiers not linked to the duties they perform in the industry.

A combination of non-probability purposive sampling and snowballing methods was used (Saunders & Lewis, 2012). Non-probability sampling is a suitable sampling method when the researcher has limited time and resources as found in the Master of Business research process (Etikan, Musa & Alkassim, 2016). The HTA process encompassed numerous stakeholders within the healthcare delivery system, thus it necessitated heterogeneous sampling of private health players who had experience in conducting CED studies and PBRsAs. According to Etikan et al., (2016) non-probability purposive sampling “involves identification and selection of individuals or groups of individuals that are proficient and well-informed with a phenomenon of interest” (p. 2). The heterogeneity of the sample gave balance to the possible selection biases created by this sampling method as it countered the similarities that would be found in a homogenous sample.

The sample purposefully included key executives in hospitals, medical device suppliers and medical schemes who have been involved in the implementation and design of CED studies and PBRsAs. The researcher could not predetermine all the knowledgeable actors in the country. During the interviews, the researcher would enquire if the participants had any individuals, they believed could add valuable insight to the study. Some respondents from their own volition, identified other possible respondents for inclusion they deemed important and knowledgeable in the research topic, resulting in a snowball effect (Saunders & Lewis, 2012). The total number of study participants interviewed was 13. Participant's 8 telephonic interview was incomplete, with the participant stating that their knowledge is more theoretical as a researcher in the field of HTA than it is practical and was set aside as part of quality control. The final number of interviews was 12, which is within the recommendations of 12 to 30 participants for heterogenous samples (Saunders & Lewis, 2012).

#### **4.5. Secondary Data Method**

The researcher utilised desktop research methods to conduct secondary research including the review of articles in academic journals to formulate the literature review. In addition, national and international government or industry association relevant reports were also used. The literature revealed that there is a paucity of information in the understanding of the implementation and management of CED studies and PBRsAs, when they are an outcome of HTA (Reckers-Droog et al., 2020; Tarricone et al., 2017). The AP theory lens also further called out for investigation on how the AP processes are implemented in practice (Bosomworth & Gaillard, 2019).

#### **4.6. Primary Data Collection**

##### **4.6.1. Measurement Instrument**

A combination of face to face and telephonic semi-structured interviews was conducted with individuals, where a set of pre-composed questions was used to provide guidance and structure (Jamshed, 2014). Semi-structured interviews are considered to be at the heart of qualitative research as they provide the option to pivot in order to obtain a deeper understanding (Gioia, & Hamilton, 2013). In an effort to understand the experience from the interviewee's perspective, semi-structured interviews are optimal as they allow the researcher

flexibility to enhance the questions (Saunders & Lewis, 2012). Semi-structured interviews are considered to be at the heart of qualitative research as they provide the option to pivot in order to obtain a deeper understanding (Gioia, Corley & Hamilton, 2013). In an effort to understand the experience from the interviewee's perspective, semi-structured interviews are optimal as they allow the researcher flexibility to enhance the question(s) (Saunders & Lewis, 2012).

#### 4.6.2. Credibility

Masters students have been found to erroneously associate quantitative terms like validity and reliability in discussing trustworthiness of research results in qualitative studies (Anney, 2014). In qualitative research, rigour is ensured through credibility and transferability. Validity, is about ensuring that research findings are reflective of the researchers claims whilst reliability is about reproducibility of results based on data collection and analysis methods (Saunders & Lewis 2012),

According to Anney (2014) "credibility establishes whether or not the research findings represent plausible information drawn from the participants' original data and is a correct interpretation of the participants' original views" (p. 276). Data triangulation was utilised to establish rigour of the qualitative research (Anney, 2014). Credibility was established by recruiting experienced professionals and eliminating participants whose knowledge was theoretical. Pezalla, Pettigrew, and Miller-Day (2012) stated that the researcher forms part of the research instrument in semi-structured interviews and as such self-reflexivity can improve the credibility of the research. Continuous verification is another method used to improve trustworthiness, the researcher through the audio recordings revisited data and performed verification checks (Noble & Smith, 2015). Transferability of the results may be limited due to the contextual nature of the research, considering that the findings are time bound and may change with experience. Data triangulation of research findings with literature aims to overcome this limitation.

The construct validity of the research is ensured by drawing the research questions from knowledge gaps identified in literature using data collection matrix found in Appendix 3 and generating the research questions to be included in the research instrument, found in Appendix 4. The choice of the qualitative research method is informed by the research questions which are exploratory in nature. The exploration of the implementation and

practical issues of OBCs in MDs is itself informed by literature (Reckers-Droog, 2020; Bosomworth & Gaillard, 2019; Tarricone et al., 2017). The implication is that the inductive approach is undertaken due to the qualitative nature of the research.

#### 4.6.3. Data Gathering Process

The research invitation process for participants involved an initial contact through a brief email or use of a message system and sometimes a voice call which provided a summary of the nature of the study. For those participants whose email addresses the researcher did not have, the initial contact was made through telephonic and direct message system in LinkedIn. This initial contact was always followed up with an email detailing the study and the informed consent letter formed part of the email as an attachment.

Data was collected using face-to-face semi-structured interviews as well as telephonic interviews. The duration of interviews was between 30 minutes to an hour. A request to record the interview was made at the beginning of each interview to allow for transcribing and this was also detailed in the informed consent forms sent prior to conducting the interview discussion. Participants on telephonic interviews were informed that, their continuation with the interview was considered to be an indication of their consent. This approach was forced by the COVID-19 lockdown regulations which meant that participants could no longer go to their offices to print and sign the consent letters. In all interview instances, participants were informed that their names and the names of their companies would be kept confidential. The respondents were informed of the data management processes. Some respondents had to first obtain approval from their respective companies prior to participating in the study.

#### 4.6.4. Analysis Approach

Post completion of data collection, all audio recordings were transcribed into text using a consultant. The process of analysis followed the six-steps described by Xu and Zammit, (2020), where the researcher initially familiarised herself with the data. The next step was the inductive approach of generation of initial codes from the data through with coding of the interview transcripts and the researcher assigning different codes (Kiger & Varpioe, 2020). Using Microsoft Excel, the analysis was done at the research question level using

manual coding, with codes generated at a meaningful unit of measure for the researcher. Further, the researcher analysed the codes in search of themes (Xu & Zammit, 2020). The researcher continued to engage the data and sort codes manually until themes emerged through additional levels of data analysis. As per Xu and Zammit (2020), step four included the review of themes and ensuring that codes were grouped and collated in the correct themes. The second last step involved deriving shorter names for the themes where the overall story about the data was considered (Zu & Zammit, 2020). Finally, through continuous engagement with the data and additional analysis a report about the data was generated (Xu & Zammit, 2020).

Thematic analysis is the process of organising data into meaningful patterns by identifying patterns and analysing themes (Clarke & Braun, 2017). According to Kiger and Varpioe (2020), thematic analysis goes beyond describing the data into interpretation of the data. Emerging and recurring themes were identified and used to analyse and compare themes between the different respondents. The emerging patterns and themes were grouped and ascribed to the relevant research questions. The data was compiled and reviewed together with literature in chapter six where possible theoretical and business contributions derived and discussed (Morse, 2020). This process also lent itself to triangulation of data, thus giving credibility to the study findings.

#### **4.7. Ethics**

Prior to initiating data collection, ethical clearances were obtained from both Gordon Institute of Business Science's Research Ethics Committee and the University of Pretoria's Health Ethics committee. As part of the interview meeting scheduling, participants were emailed the participant consent form which formed part of the interview discussion guide. Participants were informed prior to each interview that participation was voluntary and could be withdrawn without any reason. Consent was also obtained for data recording for transcription and analysis purposes with the proviso that all data would be kept confidential.

#### 4.8. Limitations

By its nature, qualitative research is subjective and a number of biases arise as a risk including researcher bias (Saunders & Lewis, 2012). The interpretation of data by the researcher may also be create bias (Saunders & Lewis, 2012). The researcher has made an effort to overcome the researcher bias by having a heterogenous sample population. The sample population excluded some stakeholders whose role is also key and this may impact the research outcomes

Patton's (2002) criticism of the snowball sampling method is that it creates bias as the referrals tend to share similar characteristics. The researcher managed this limitation by combining the sampling method with a purposive sampling method and ensuring that the sample population was heterogenous.

Time was a limitation and resulted in a limited sample size. Further, the global pandemic outbreak resulted in limitations to the research process. A number of participant interviews had to be rescheduled and some participants could not be reached within the timeframes of the study even when interest to participate had initially been observed.

The preferred face-to-face interview process had to be adapted to telephonic interviews as participants sought to minimise their risk to the COVID-19 pandemic; further, due to lockdown regulations, telephonic interviews became the only option to conduct interviews.

According to Peters et al., (2013) "contextual factors that influence implementation, interact with each other, and change over time highlights the fact that implementation often occurs as part of complex adaptive systems" (p. 2). This limited the replicability of the research and transferability of the research outcomes.

## 5. Chapter 5: Results

### 5.1. Introduction

This chapter shares the research findings based on the data obtained from the semi-structured interviews. The findings of what respondents perceived to be critical factors in the implementation and management of MEA pathways are presented. The presentation of data is through the themes identified based on multi-level analysis code generation. The interview process findings were grouped into codes, code groups and themes, samples of thematic analysis by research question is presented in (Figure 4, Figure 5 and Figure 6) whilst complete coding and thematic analysis presented in Appendix 5. The themes are discussed under relevant research questions following the flow of the research questions in chapter 3. The sequence of the research questions is followed in organising this chapter. The findings of the research are discussed and, to maintain confidentiality participants, are referred to in the numerical order of interviews. In an attempt to show that selected participants meet the criteria of the identified sample population, a summary of the relevant work experience of each participant is presented below (Table 2). The sector is niche and presenting the participants through their job roles could pose a risk to confidentiality. The summarised presentation of findings is through the analysis and interpretation of the researcher.

**Table 2: Summary of research participants industry work experience.**

| Numerical Order of Interviewee as participants | Industry Work Experience of Participants is presented in no particular order. All participants are senior and high-level managers or directors. |
|------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| Participant 1                                  | MD company                                                                                                                                      |
| Participant 2                                  | MD company, Regulatory Authority                                                                                                                |
| Participant 3                                  | MD company                                                                                                                                      |
| Participant 4                                  | MD company                                                                                                                                      |
| Participant 5                                  | Funder, MD company                                                                                                                              |
| Participant 6                                  | Funder                                                                                                                                          |
| Participant 7                                  | Consultant, Researcher                                                                                                                          |
| Participant 8                                  | Excluded. Not relevant for analysis and presentation of findings.                                                                               |
| Participant 9                                  | Consultant, Funder                                                                                                                              |
| Participant 10                                 | MD company                                                                                                                                      |
| Participant 11                                 | Hospital, Researcher                                                                                                                            |
| Participant 12                                 | Funder, MD company                                                                                                                              |
| Participant 13                                 | MD company                                                                                                                                      |

Source: Author's own.

## 5.2. Research Question 1: What are the Factors Considered in Implementing CED Studies for Medical Devices?

### 5.2.1. Theme 1a: Evidence Requirements or Quality and Level of Evidence

Participants P1, P4, P7, P6, P9 and P13 explained that CED studies as an outcome of HTA was related to some question of safety and efficacy compared to the current standard of care. Participants P1, P3 and P10 raised the issue of evidence requirements for medical devices being based on randomised clinical trials (RCTs) which were more suited to medicines. Participant P1 voiced the ethical difficulties of RCT in medical devices, stating:

*“When it comes to medical devices, we’re shifting that thinking of always having the idea that the gold standard should always be the same as in the pharmaceutical space, because of the nature of the technology. Wherein from an ethics point of view you may not even be allowed to do randomised clinical trials in the medical device space” (Participant P1).*

Participants P2, P4 and P5 highlighted that novel or breakthrough technology is likely to have HTA outcomes that require CED studies to evaluate their impact in the real-world as this technology tended to be disruptive. Participants P1, P3 and P5 identified the level of existing evidence may be deemed insufficient due to: quality of data, providing the clinical or economic evidence or study sample size in the initial HTA study, resulting in questions about the reproducibility of results. The initial HTA outcome would then require CED studies. Participant P6 explained that the available level of evidence should be promising. Participants P1, P2, P4, P5, P7, P9, P11 and P13 raised pricing and budget impact as some of the financial factors in question, where there is a concern about the cost and affordability of the medical device. The cost-effectiveness and value addition claims of disruptive technology may result in the requirement for real-world contextual evaluation of the financial impact utilising patient demographic related claims data as explained below:

*“[The] thing with disruptive technology is that it upsets what the current norm would be and in a lot of cases the norm would be, let’s say for instance it’s going to be normal surgery versus minimal invasive surgery. Now, to do minimal invasive surgery the equipment would normally be much more expensive, but the recovery rate would be a lot quicker. So, the funder for example would say, ok this is a lot more expensive than what we normally pay for a procedure. But then you have to*

*prove to them that because this patient doesn't have to go to ICU, it could be a day procedure versus a normal theatre procedure where the patient has to go to ICU, because all those things are a cost, and then you have to prove obviously that ok you claim that this is what's happening but now we want to see it in action"* (Participant P4).

CED studies can be based on novelty or disruptiveness of the medical device raises with superior claims (Participant P5). Participant P2 and P4 explained that novel technology underwent CED studies to evaluate the resultant changes in current health pathway practices as a result of their adoption into practice implementation.

*"It could be novel, new technology that has not been used in this space before. So, those are usually the two situations, so if it's a completely new technology in the space and it could be potentially replacing current practice"* (Participant P2).

#### 5.2.2. Theme 1b: HTA Localisation

P1, P4 and P10 explained that the context of HTA is based on clinical inputs, such as the various elements and pathways that are involved in costing a clinical event, and these can be country-specific based on clinical guidelines and norms. Participant P1 claimed that the itemisation of the costing inputs that go into the management of a clinical event is important and should match the current country norms in the health economic tool utilised as a comparator. This is what makes HTA context-specific. The inputs are inclusive of all the pre- and post-procedure actions, which comprise of all the costs of the clinical intervention (Participant P1). The pricing for health technologies differs across regions and the costs charged by health professionals and hospital facilities are also not the same, leading to the requirement for the localisation of costs used in the health economic tool (Participant P4). Participant P1 highlighted that localisation of inputs and pricing is what leads into the contextual nature of HTA, and localised costs that may have been cost-effective in one country may not be cost-effective in another geographic region. Adding to this:

*"Local data in South Africa is not that big in terms of generating data to influence reimbursement, however, it becomes more relevant and more ideal to use whatever tool that you might have had as part of your reimbursement tool to*

*support your device entry into the market, that specific tool must have input for South Africa. But not necessarily that the patients must be treated first with this device in the context of South Africa and then we use that outcome as a way of reimbursement. So, you look at and compare the inputs for the health economics tool, which are specific for South Africa and costed at the rate of South Africa, which will be a different costing if for example they would have been in Germany. Meaning, cost per minute theatre time in Germany might be R120.00, but in South Africa you might find out it is R85.00” (Participant 1).*

*“I find that our data versus European or American data is very different, because we measure a lot more than what they do. In our private sector for instance theatre time gets measured, you measure the anaesthetist cost, which I think the equation is every 15 minutes the price goes up. This then is a record of not just the actual procedure to happen, but pre-operative, operative and post-operative. So, everything gets measured” (Participant P4).*

Participant P3 explained that sometimes a medical device combines an existing medical device with either a diagnostic or pharmaceutical component, creating a new category of a medical device whose comparator would be the combination costs of all the consolidated cost inputs:

*“a combination kind of product; was classified in its own category at an international level, because of the unique qualities of the technology. So, in that field they were literally reimbursing every single one of the individual components in the combination product and when they did the HTA research on their side, they came back to say that there’s not enough clinical evidence so they’re not going to reimburse it. Then I went back and I had to prove to them that all the different products in that category are the standard in that treatment field. The level of evidence that they require does not exist” (Participant P3).*

In such an instance the required level of evidence may simply not exist, however there is an argument to be made that if all components combined in the new medical device are already reimbursed then that should be the discussion (Participant P3).

### 5.2.3. Theme 1c: Local Data and Demographic Profiles

There was a divergence of views on the importance of local data. Different participants had different experiences and opinions. P1, P2, P6, P10 and P12 were of the view that local data was not necessary:

*“I don’t think it’s essential in terms of every product that you put forward a case for reimbursement for. Because I believe that you can leverage off the data that has been collected based on outcomes internationally to be able to build a case for local”* (Participant P2).

Participant P10 agreed, stating that it is all international data in the country of origin or they refer to training centers in the US or in Europe. Another participant concurred, claiming that “if there are world-wide guidelines that have been proven to be working, then there would be no need for local data, we could just extrapolate that” (Participant P12). Participant P12, however highlighted that generally, if there is evidence of different patient responses to the device, then local data would in all likelihood be required:

*“I’ve never had one submission, where they ask me for local data. It’s all international data in the country of origin or they refer to training centres in Europe or US”* (Participant P10).

Other participants (P2, P11, P12, & P13) had different opinions and experiences, stating that local data is important due to population profiles. P5 stated that local data was required when it was relevant and the funder felt that the local population could have different results. P7 felt that the funders are inconsistent on their stand on local data requirements stating: “When there’s international evidence that shows efficacy and safety and budget impact benefits and everything you want, the push back from funders will be this is foreign data, we need local data”.

P5, P6, P13, P12 and P9, who are proponents of local data collection, stated that country demographic profiles are unique and should be the basis of local data requirement. The participants representing the funders’ perspective agreed that local data is not necessary, they can work with international data. Participant P6, however, clarified that when the patient population demographic profiles are likely to affect performance, then they will

request local studies. The participants further explained that this is treated and funded differently from normal CED studies (Participant P6):

*“If we know for sure that the outcomes are different, so for instance if there was a product that was used internationally and we know that it’s likely to be very different in our world, because of factors like HIV, then we may want to ask if the outcomes are different for us. But we differentiate the two. So, we may have a funding policy where we say let’s see if it’s different in the South African context”* (Participant P6).

The hospital executive P11, further detailed that clinically relevant local data is difficult to collect. One of the difficulties in collecting local data is the absence of EHR (Participant P11). P9 stated that local data could allow funders to pick up nuances in terms of what’s happening in the South African environment and could be used for cross country performance comparisons globally, giving the following example:

*“for a hip implant these guys have said to us that globally they know that their revision rates are 2% and it’s good to see that in the South African market, the revision rates are also similar”* (Participant P9).

#### 5.2.4. Theme 1d: Framing Uncertainty

Having a market access reimbursement strategy has been identified as critical (Participant P2). P7 highlighted the need to identifying all key stakeholders and engaging them prior to planned product launch. Participant P2 implored medical device manufacturers to understand their product, understand the therapeutic area and understand the current treatment practices well, as they will serve as their comparator. This requires constant engagement with funders and in these discussions better understanding of the uncertainty is possible (Participant P2 & P7). Participants P3, P5 and P7 specified the need to engage the specialist doctors who are key opinion leaders (KOL) in the market. Doctors should be interested in having the medical device in the market and believe in its positive clinical benefit potential (Participants P3, P5 & P7). Participants suggested constantly liaising with funders to understand the uncertainty and involve them in building the study (Participant P2 & P7).

Participants P1 and P4 alluded to a written document that will form the basis of agreement on the uncertainty, which specifies the gap and clarifies the required information. Participant P4 and P13 advocated for “a mutually agreed upon evaluation form that needs to measure everything that is important for both the funder and the supplier, and a record of this has to be kept”. Participant P1 contended that whenever possible the existing protocol that was used to gather the currently available evidence should be used as a base and modified to respond to the uncertainty. There is evidence of some mutual agreement as practice: “That form was reviewed and it was approved” (Participant P13),

The consultant with international experience advised that medical device manufacturers should “Try to include as many stakeholders as possible. When you get them involved in the study it builds credibility and rapport and it’s just generally a smart way of doing business” (Participant P7). Participants P1 and P3 highlighted the need for engagement and management of stakeholders as a number of stakeholders are involved in framing the pilot study protocol to respond to the knowledge gap. The proposed pilot study protocol passes through various stakeholders and they pose a risk of making changes that reframe the uncertainty resulting in collection of evidence that does not address the gap (Participant P3). Pre-engagement with various stakeholders to reach consensus is advised; “I’ve had a consensus approach with all the different role players and then the final consensus would come from the funder” (Participant P3).

Participant P1 cautioned that stakeholders can make additions or alterations to the pilot protocol influenced by their own biases and interests, and care should be taken to stay focused on achieving the CED study primary or secondary endpoints. Participant P7 advised that in order to manage the administrative burden, it is imperative that data that is not addressing the ambiguity is not collected as it risks rephrasing of the uncertainty. Participant P1 stated that incorporating pilot end points that do not relate to the uncertainty adds to the administrative challenges of collecting evidence, increasing risks to the effectiveness of the pilot study and exaggerating costs whilst not providing value.

The current health intervention practice and what it achieves should always be borne in mind in the study design as it is the comparator. The financial information aspects of the comparator need to be known and this information is asymmetrical, available to funders through their claims data, however, health financing data companies are alleviating the information asymmetry. Medical device manufacturers should strive for an environment

that condones transparency and mutual learning between themselves and funders as this improves dialogue and opens negotiation channels.

*“Let’s say you are trying to work with the funder and you cannot do so because there is conflicting evidence, their evidence is going a certain way and yours is pointing to another direction. In that case then ask them to open their books to you, because you were transparent and opened up your data, ask them for the same and state that you wish to find out where the disparity is. And express that through that you both can learn from each other” (Participant P7).*

Participant P11 emphasised the importance of following good research practices in identifying the knowledge gaps and in designing the study protocol to be used to manage the scope of the investigation, as well as to manage bias coming from stakeholders with different interest agendas.

#### 5.2.5. Theme 1e: Setting Scope and Parameters

CED studies in medical devices are plagued by a number of possible confounding factors that create risks and vulnerabilities. Participant P7 and P9 agreed that confounding factors that could create biased study outcomes should be identified, and where possible restricted. Participant P7 commented that whenever restrictions are not possible their impact should be estimated, acknowledged and accounted for in outcomes data analysis. Some confounding factors, for example patient criteria, are easily managed as the medical device itself and treatment guideline specifies the CED study entrance qualifying criteria and the criteria should be stipulated in the study protocol (Participants P1, P3, P4, & P12). Management of confounding factors is crucial one responded clarified the process, “We must firstly identify them, it’s like risk management. We quantify that risk by doing scenario analysis. So, if this thing comes out negatively then there will be a refund at A, B, C or whatever. But those are all the possibilities” (Participant P7).

The location of the CED study itself can create bias (Participant P2). The proficiency of the user can have positive influence on outcomes and funders need to bear this in mind as a factor to manage for once the medical device is approved for use outside the CED scheme (Participant P2 & P3). Generally, most medical device companies train physicians

to be proficient users, prior to starting a CED study through use of proctorships (Participants P1, P2, P3, P4, P5, P7, P13).

The impact of the hospital facility environment on CED study outcomes should not be understated (Participant P5). Participant P10 stated that the “risks and vulnerabilities are different for different medical devices”, further making the case for the importance of stakeholder engagement in planning. There should be alignment on the methodology, dimensions of study and metrics to be measured (Participant P9). This should include the detail of the action items to be taken when thresholds are reached.

Training doctors to overcome the LC prior to engaging in CED studies is critical (Participants P3 & P5). This training is done through proctorships, international training with some type of accreditation processes through clinical societies utilised (Participants P3, P2 & P5). Professional education programs are important in addressing the learning curve (Participant P5). Participant P1 stated that medical device companies can use internal professional education programmes to introduce the medical device to doctors, engaging KOL and testing their interest. Some novel training mechanisms are emerging, simulated lab environments are gaining traction and may be more cost-effective for manufacturers (Participant 1). Funder participants P6 stress that CED schemes are not for training doctors, nor are they funding mechanisms for manufacturers to exploit. Participant P6 clarified that the LC should not be in question as it is not about getting physicians proficient but rather about addressing an uncertainty.

Participant P3 agreed that the LC should not influence CED studies. Sometimes it is impossible to overcome the LC. Participant P7 explained the case of robotic surgery, stating the LC became evident as the CED scheme continued, the proficiency of the users improves and with it, the cost-effectiveness of the medical device. When there is sufficient evidence of a LC, manufacturers and funders should negotiate to come to an acceptable criterion of adjusting for the LC (Participant P4 & P7). Where possible, if the CED study size allows, cases that should be excluded should be identified, or one must adjust for LC in evaluating the cost-effectiveness of the medical device (Participant P4 & P7). According to Drummond et al., (2018) whenever possible, there should be benchmarking of the LC and training plans should be adjusted to overcome the LC prior to market introduction. One participant, highlighted that there are added advantages to professional training “If you get doctors on the actual training through your professional education it’s easy to get

them to adopt, because now they have trained. So, you find that the buy-in is better” (Participant P5).

In practice, one is yet to observe a mechanism or instrument to adjust for the LC, however a sliding scale threshold model is suggested and should be linked to the funder premium using differential pricing to adjust for the LC and related cost-effectiveness achievements (Participant P7).

From the funders’ perspective, conducting CED studies is done through a pilot, which is meant to manage some of the challenges that arise from evidence collection, including a lack of resources (Participants P6 & P10). A health service centre is approved to conduct the pilot study and doctors are accredited through clinical societies and approved to take part in the CED pilot (Participant 13). This introduces the challenge of patient numbers which may result in the pilot CED study taking much longer than anticipated (Participants P6 & P13).

*“We call it a pilot. So, it may not be a formalised benefit, it may be that we agree to small centres with limited patient numbers to try and find or solve where the gap is”* (Participant P6).

Participant P11 shared the impact of competition between health facilities and doctors who are also in competition with each other. The participant claimed that within the approved hospital setting a patient consulting with a non-accredited specialist may not necessarily be referred to partake in the pilot study due to competition between the independent doctors (Participant P11). Further, patients who may qualify in a non-approved hospital will not necessarily be referred to the hospital conducting the CED scheme due to competition between hospitals. Participant P13 highlighted the advantage of performing financial feasibility checks of the pilot based on requirements. Participant P13 stressed that restrictions imposed by the approved hospital and accredited doctors could increase the duration of the study. This financial feasibility study can be used as a negotiation tool with funders to increase the number of centres for the pilot and the approved physicians (Participant P13):

*“We actually went back to the funder and we told them that it’s not feasible as it looked like we’d be doing this forever and at the end of it we were not sure what the benefit would be. So, they allowed us to increase the number of patients that*

*could do the therapy. So, I don't think it's a cast in stone type of situation"*  
(Participant P13).

#### 5.2.6. Summary of Results

**Table 3: Research Question 1**

| Participants                             | Theme                               |
|------------------------------------------|-------------------------------------|
| All Participants                         | Evidence Requirements               |
| P1, P4, P7, P10                          | HTA Inputs or Localization          |
| All Participants                         | Local Data and Demographic Profiles |
| P1, P2, P3, P4, P5, P6, P7, P11, P12     | Framing Uncertainty                 |
| P1, P2, P3, P4, P5, P6, P7, P9, P12, P13 | Setting Scope and Parameter         |

Source: Author's own.

**Figure 4: Research Question 1 Sample of Thematic Analysis**

| Participant | Theme                       | Second Level Analysis                                              | First level Analysis                                                                                                                                                                                                                                                                                                                       |
|-------------|-----------------------------|--------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| P4          | Evidence Requirements       | Patient safety                                                     | So that's something we also have to look at, the other is patient safety.                                                                                                                                                                                                                                                                  |
| P9          | Evidence Requirements       | Safety & Efficacy compared to current STD Comparator Pricing       | There were also some questions around the safety and efficacy compared to standardised care. How do you compare to them, are you way above their pricing                                                                                                                                                                                   |
| P6          | Evidence Requirements       | Safety & Efficacy                                                  | There is two components to it, the first component would be is the health technology safe, ethical and clinically effective.                                                                                                                                                                                                               |
| P7          | Evidence Requirements       | Safety & Efficacy<br>Impact & Cost Saving                          | Budget The first thing they look at is empirical evidence of efficacy and safety. The second thing is usually budget, budget impact and as you know it's the traditional budget. Is there cost saving?                                                                                                                                     |
| P5          | Evidence Requirements       | Premium Price compared to benchmark                                | So, you then have to prove that you are legible for the premium compared to what the current benchmark looks like                                                                                                                                                                                                                          |
| P4          | Evidence Requirements       | Cost                                                               | One is cost                                                                                                                                                                                                                                                                                                                                |
| P2          | Evidence Requirements       | Premium Price                                                      | It may be new technology, which you could be asking a premium price.                                                                                                                                                                                                                                                                       |
| P13         | Evidence Requirements       | Price point                                                        | Or we can't justify the price point etc.                                                                                                                                                                                                                                                                                                   |
| P11         | Evidence Requirements       | Cross-effectiveness & Affordability                                | Cost effectiveness. So, is it the same or has better outcomes? Is it affordable?                                                                                                                                                                                                                                                           |
| P10         | Evidence Requirements       | RCT                                                                | looking for RCT (Randomized Controlled Trial) studies, so that's the first criteria.                                                                                                                                                                                                                                                       |
| P3          | Evidence Requirements       | Pharmaceutical Methods                                             | so currently in my opinion from my experience that I have had with funders is that they are very focused on pharmaceutical methodology                                                                                                                                                                                                     |
| P2          | Evidence Requirements       | Novel Technology                                                   | It could be novel new technology that has not been used in this space before                                                                                                                                                                                                                                                               |
| P5          | Evidence Requirements       | Superior Claim for breakthrough                                    | It's a new technology. Superior to the existing, it's like a breakthrough                                                                                                                                                                                                                                                                  |
| P6          | Evidence Requirements       | Promising Evidence                                                 | Ideally there needs to be some level of evidence that we're comfortable with, so it's human trialed, it's well designed, but there maybe some element that's missing.                                                                                                                                                                      |
| P4          | HTA Localization            | Costs of Specialist & Theatre time                                 | Ok, specific to South Africa now I find that our data versus European or American data is very different, because we measure a lot more than what they do. In our private sector for instance theatre time gets measured, you measure the anaesthetist cost, which I think the equation is every 15 minutes the price goes up              |
| P10         | HTA Localization            | Local cost per event                                               | Then they go to the cost per event.                                                                                                                                                                                                                                                                                                        |
| P12         | No need for local data      | Local Data not necessary, world-wide guidelines used               | If there are world wide guidelines that have been proven to be working, then there would be no need for local data, we could just extrapolate that.                                                                                                                                                                                        |
| P2          | Local Data is Important     | Local data is important depending on product                       | I think that local data is important depending on the product.                                                                                                                                                                                                                                                                             |
| P13         | Demographic Profiles        | Unique population, local data                                      | With the uniqueness of our population, I think that local data is the best                                                                                                                                                                                                                                                                 |
| P12         | Demographic Profiles        | Patient responses                                                  | But, I think when the problem comes in is when patients respond differently to certain types of devices. That's when you'd need local data.                                                                                                                                                                                                |
| P2          | Framing Uncertainty         | Study design based on uncertainty                                  | If you understand the uncertainties then you ensure that your study design meets those uncertainties.                                                                                                                                                                                                                                      |
| P3          | Framing Uncertainty         | Engage with Stakeholders                                           | I've had a consensus approach with all the different role players and then the final consensus would come from Funder                                                                                                                                                                                                                      |
| P2          | Framing Uncertainty         | Engage with Funder                                                 | But what you want to do is to engage upfront with the funder, this is absolutely essential                                                                                                                                                                                                                                                 |
| P3          | Framing Uncertainty         | Meetings to engage with Funder                                     | Yes, because there is definitely no formal process. So, my experience with the one that we're putting together is that I had meetings with them.                                                                                                                                                                                           |
| P12         | Framing Uncertainty         | Outcome Focused                                                    | I think you need to know what your outcome must be to incorporate those patients.                                                                                                                                                                                                                                                          |
| P2          | Framing Uncertainty         | Outcome Focused                                                    | The outcomes of the study should meet the requirements in terms of what they're looking for                                                                                                                                                                                                                                                |
| P4,         | Framing Uncertainty         | Mutual Agreement using a form                                      | I think it should be a mutually agreed upon evaluation form that needs to measure everything that is important for both the funder and the supplier, and a record of this has to be kept. This then is a record of not just the actual procedure to happen, but pre-operative, operative and post operative. So, everything gets measured. |
| P5          | Framing Uncertainty         | Physician buy in to understand uncertainty                         | So, in order to prevent this and to give the physicians time to make sure that this is actually a study,                                                                                                                                                                                                                                   |
| P6          | Framing Uncertainty         | Uncertainty is specified upfront so gap is understood              | We run a pilot programme where we measure primarily claimed outcomes. All of that is specified upfront. So, the manufacturer understands where the gap is, what exactly we are looking for.                                                                                                                                                |
| P3          | Framing Uncertainty         | Document uncertainty                                               | So, they have a document, which I can share with you but I'm sure they would also give it to you. So, this document they put together as a guide for when you do a pilot or something like that.                                                                                                                                           |
| P2          | Framing Uncertainty         | Understand Therapeutic Area & Comparator                           | Understand the current therapeutic area. Also understand what the current sets of requirements are.                                                                                                                                                                                                                                        |
| P2          | Framing Uncertainty         | Understand Product                                                 | Firstly, you need to understand your product.                                                                                                                                                                                                                                                                                              |
| P1          | Setting Scope and Parameter | Accounting for LC if it is evident                                 | Then you can be able to argue with the payer and say that on average, clinically or practically you can see a little bit of a difference with that particular doctor. It's a learning curve and it should be accommodated as one.                                                                                                          |
| P6          | Setting Scope and Parameter | International benchmark to determine cases required to overcome LC | So, I think we look to the technology company as well as any international experience to say what number of patients does a doctor perhaps need to do to be proficient in it.                                                                                                                                                              |
| P13         | Setting Scope and Parameter | Accreditation Process to overcome LC                               | So, the doctors who would be most proficient would be identified. There's usually an accreditation process.                                                                                                                                                                                                                                |
| P12         | Setting Scope and Parameter | Train through proctor to overcome LC                               | I think it's very important that they need to be trained properly, so for me you have to have someone to proctor                                                                                                                                                                                                                           |
| P12         | Setting Scope and Parameter | Patient Selection & Qualifying Criteria                            | So with patient selection you need to look at all those, not everyone must enter into the clinical trial.                                                                                                                                                                                                                                  |
| P4          | Setting Scope and Parameter | Disease stage Criteria, Patient Selection & Qualifying Criteria    | So, it's really important to establish qualifying criteria beforehand.<br>An example, a person who had a particular disease had failed in previous treatment.                                                                                                                                                                              |
| P2          | Setting Scope and Parameter | Patient Selection & Qualifying Criteria                            | The product itself outlined what the entrance requirements would be for this study. We were absolutely clear at the outset that this product was not for all patients, hence we were able to set what those entrance requirements were.                                                                                                    |
| P6          | Setting Scope and Parameter | Patient Selection & Qualifying Criteria                            | Engaged with clinical society and they would have drafted up the patient selection criteria and all of that.                                                                                                                                                                                                                               |
| P5          | Setting Scope and Parameter | Doctor choice                                                      | This is why there's the choice of the physicians.                                                                                                                                                                                                                                                                                          |
| P12         | Setting Scope and Parameter | Patient Selection & Qualifying Criteria                            | So with patient selection you need to look at all those, not everyone must enter into the clinical trial.                                                                                                                                                                                                                                  |
| P6          | Setting Scope and Parameter | Protocol                                                           | So, there's almost a protocol that's drawn up prior.                                                                                                                                                                                                                                                                                       |
| P9          | Setting Scope and Parameter | Protocol to manage confounders                                     | There's a lot to consider, for example the confounding factors, you're right to say that you need to compare similar patient populations that would mean you are not doing the right comparison. All of those do influence CED study outcomes. It's important that the patient populations are comparable.                                 |

Source: Author's own.

### 5.3. Research Question 2: What are the Funding Considerations for CED Studies?

#### 5.3.1. Theme 2a: Financial and Profitability Management

Some participants have accepted that suppliers who want to place their medical device in the market should take responsibility for funding CED schemes (Participant P10, P2, P1, P6 & P7). Participant P5 argued that the benefit of CED schemes is for the medical insurance and its members, and that the funders should fund. Other participants argued for a shared funding responsibility (Participant P11, P12 & P13) whilst P1 and P4 stated that reimbursement during a CED scheme is funders taking some shared responsibility. Participant P1 argued that the challenge with medical device manufacturers funding CED schemes is that it poses a barrier to market entry for smaller companies who cannot afford to fund the studies. Participant P7 highlighted that when there is a vested interest for the funder, then perhaps there should be a sharing of costs related to conducting the CED scheme.

Participant P5 stated that in principle, funders claim that they are willing to fund promising studies for the benefit of their members, whilst in practice funders tend to have insufficient funds to assist with the study related costs beyond paying for the device. Participant P7 claimed that the issue for all stakeholders is profitability whilst conducting a CED scheme. According to Participant P3, profit margin of the medical device of the price that funders are willing to fund should at least cover the costs of the CED study itself. Participant P1 and P3 stated that the agreed price is dependent on negotiation and perhaps the level of uncertainty but at minimum, it is reimbursement to the current level of care of the comparator. This raises interesting challenges in negotiation when dealing with an unmet clinical need, which some of these medical devices are addressing (Participant P3). Whatever the nature of the medical device or uncertainty, participant P11 raised the issue of the financial impact in conducting a CED scheme, which remains a challenge to funding.

Participant P11 stated that there are internal stakeholders with vested interests in annual company performance, making the duration of the financial impact of these CED schemes critical. Participant P7, stated that during a CED scheme, funders study the potential impact to their budgets the medical device poses. Hospital managers have to report on return on asset when a CED scheme capital equipment is purchased (Participant P11). The length of the CED study is dependent on a number of factors, including the approval

of centres and doctors (Participant P13). Most participants agreed that the type of medical device is noted to play a significant role on the duration of the CED scheme and so does the CED study design. Patient availability has the ability to impact the feasibility of the CED scheme, which is influenced by the approved facilities, doctors and even geographical locations (Participant 13).

Participant P6 contended that funders try to provide fully funded options for their members, however if the medical device poses a risk to the medical insurance scheme, a co-payment may become necessary and doctors accept this. Co-payment does impact market penetration (Participant P2 & P13). Participant 2 commented “So, the fact that there is a co-payment or not hugely impacts your success in the market. Your reimbursement strategy is vital in terms of the sustainability of the product” (Participant 2). Negotiation with internal and external stakeholders therefore plays an important role in ensuring that the duration of margin erosion is minimised even when the CED study is breaking even (Participant P11 & P13). The financial focus of CED schemes silences the voice of the patient as doctors are reluctant to offer interventions that have a co-payment; however, the patient perspective is critical as patients have to live with the impact of quality of life (Participant 10). The discussion should move beyond reimbursement, to be more holistic and consider patients (Participant 9)

### 5.3.2. Theme 2b: Public Image Management

Participants P6, P9, and P11 highlighted that a critical challenge to the sharing of funding is data ownership. Although companies are willing to fund, there is a cloak of confidentiality that is required by all actors. The public risks of negative outcomes are unpalatable to both medical device manufacturers and doctors who may face possible medico-legal issues (Participant P9). Participant P11 stated that patients tend to view the entire health intervention experience through the hospital brand, the result is a risk that perceptions of poor quality are associated with the hospital, impacting the image. Most multinational companies are willing to fund CED schemes, however they are reluctant to put their brands at risk resulting in lack of transparency (Participant P4).

Participant P9 supported joint funding as a key to lifting the veil of the study outcomes with aim of publishing. According to participant P5, the financial risk management rebate agreements in joint funding introduce a public image risk for funders who may be seen as

enjoying rebates at the expense and risk of patients. Participant P1 argued that any funder who agrees to a CED scheme where device companies are sponsoring the study should be prepared to respond in a public platform providing detail of whose interests were considered when a medical device was authorised for use on members. One of the funder participants stated that “most stakeholders do not like to implement partial payment member co-payment, however this is done within reasonable limits of risk management” (Participant 6). Participant P7 agreed that the concept of co-payments undermines the concept of health insurance and should be used selectively. Participant P10 stated that co-payments don’t work because patient willingness and affordability is limited. Participant P13 highlighted that partial reimbursement can work if a supplier has supporting infrastructure to assist doctors in managing the administrative burdens.

Participants P2 and P3 argued that the public health skills development and good that medical device manufacturers play is underrated. The companies train doctors and health teams on new, less invasive technologies, moving the country skills forward and helping to improve health outcomes (Participant P2 & P3).

### 5.3.3. Theme 2c: Independent Evaluation

A number of participants (P2, P4, P7, P5 and P12) have raised the need to have independence in funding and execution of CED schemes. There is hope that academia can get more involved and that a national and publicly managed body will be available in future to reduce the biases and conflicts of interest (Participant P5). A public funder should take the epidemiological interests under advisement in deciding the implementation of CED scheme (Participant P3). Participant P12 argued that whenever the funder or medical device supplier funds the CED scheme, the results are biased.

An independent evaluator would also be able to publicly share CED study findings, as participant P4 points out. At minimum these findings should be shared with the relevant clinical societies even when outcomes are not favourable (Participant P4). Participant P2 raised the issue of health funder fragmentation as impacting medical device suppliers’ ability to conduct different CED schemes for different funders, stating an independent evaluator would reduce the financial barriers of conducting CED studies. Participant P7 noted that clinical societies can provide the required independence and influence clinical policy. The National Department of Health (NDOH) could have incentive to fund, however,

the source of funding for the independent evaluators was raised as unsolved issue (Participants P2 & P7). Participant P5 stated that the NDOH can fund CED schemes which are for societal good, arguing that as it stands most health insurers do not conduct CED schemes due to lack of funding.

#### 5.3.4. Theme 2d: Funding Exit Strategies

Funders generally do not terminate the conditional reimbursement until the data requirements are met and review of outcomes is performed (Participant P6). Participant P11 stated that there is insufficient acknowledgement on the investments made by hospitals when having to participate in capital equipment CED schemes. When capital equipment CED schemes do not produce the expected outcomes, the financial loss can weigh heavily on hospitals when funders decide to discontinue funding if the hospitals purchase the equipment upfront (Participant P11). Participant P11 implored hospitals to detail the costs of equipment and those of building adaptations and ensure that there are governance structures to protect themselves. Participant P13 observed that there are CED scheme projects that are based on financial risk-management where there are legal agreements to pay back funders when claimed outcomes are not achieved. In the meantime, participants P12 and P5 advised that the requirement for medical device suppliers to pay back the money when outcomes are not met was considered to be acceptable.

#### 5.3.5. Summary of Results

**Table 4: Research Question 2**

| Participants                              | Theme                                  |
|-------------------------------------------|----------------------------------------|
| P1, P2, P3, P4, P5, P6, P7, P10, P11, P13 | Financial and Profitability Management |
| P1, P3, P4, P5, P6, P7, P9, P11           | Public Image                           |
| P2, P4, P5, P7, P12                       | Independent Evaluation                 |
| P5, P6, P11, P13                          | Defining Exit Strategies               |

Source: Author's own.

**Figure 5: Research Question 2 Sample of Thematic Analysis**

| Participant | Theme                                  | Second Level Analysis                                                                            | First level Analysis                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------------|----------------------------------------|--------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| P1          | Financial and Profitability Management | Whose cost of doing business does CED fall under?                                                | from a company point of view it is the responsibility of a company to fund a certain portion of the study. So, why should I as a funder put up any money into what you are offering? So it then becomes a win-win situation.                                                                                                                                                                                                                                            |
| P3          | Financial and Profitability Management | Willing to fund and take risk if there is agreement of price going up once claims are proven     | So, if you are starting a CED then I think if the funders buy into it and the doctors buy into it and it's a real need, I think if there is current gold standard. If you can bring in a technology at the price of the gold standard for your trial                                                                                                                                                                                                                    |
| P7          | Financial and Profitability Management | CED studies are expensive companies should look into product portfolio and target growth markets | Price. These are expensive studies and I'm specifically talking about South Africa, which is such a small market and it's actually a shrinking market. I think I'm going to stick to my original answer that the initial research should be funded by the supplier. It's growing markets, . So, I guess it's very dependent on the product portfolio                                                                                                                    |
| P2          | Financial and Profitability Management | CED funded by supplier                                                                           | the current practice is that the company will be responsible for the cost associated with this study.                                                                                                                                                                                                                                                                                                                                                                   |
| P4          | Financial and Profitability Management | Supplier can fund study, however need protective mechanism                                       | In my opinion, it might be the responsibility of the supplier to actually fund that, but in a lot of these cases what I think is going to really be the biggest risk is you've got really innovative companies down the line is that some cheap product will come in to the market and say, ok this technology has been proven, here's ours at half of the price and I don't think that's fair.                                                                         |
| P6          | Financial and Profitability Management | Risk to scheme                                                                                   | I think there are a lot of uncertainties so it could increase the scheme risk without us knowing.                                                                                                                                                                                                                                                                                                                                                                       |
| P13         | Financial and Profitability Management | Loss of margin Feasibility of CED                                                                | Usually products that cause a loss of margin to market, other factors include the number of patients that can receive it. We actually went back to the funder and we told them that it's not feasible as it looked like we'd be doing this forever and at the end of it we were not sure what the benefit would be.                                                                                                                                                     |
| P5          | Financial and Profitability            | Benefit is for Funder members                                                                    | because nobody knows who is correct to do the funding. Rightfully I would say the funder, because their members would benefit at large.                                                                                                                                                                                                                                                                                                                                 |
| P3          | Public Image                           | Funders don't want patients to Co-pay.                                                           | In my experience, it seems that in the last couple of years that initially some of the funders were saying that they don't want their patients to co-pay.                                                                                                                                                                                                                                                                                                               |
| P9          | Public Image                           | No one wants to own CED study                                                                    | The problem with funding a CED is that nobody wants to own it, however if funders and suppliers have faith in their product then there should be no reason they won't fund it                                                                                                                                                                                                                                                                                           |
| P13         | Public Image                           | No regulation, funders have to protect reputation                                                | The fact that we had no regulations in place. The medical funders then started acting as a regulatory body too.                                                                                                                                                                                                                                                                                                                                                         |
| P7          | Public Image                           | Co-pay undermines insurance                                                                      | It's a risk management thing. When you get to co-payments, it undermines that whole principle of collective insurance                                                                                                                                                                                                                                                                                                                                                   |
| P4          | Independent Evaluation                 | Impartial evaluation                                                                             | That needs to be impartial, so if you want a really good clinical outcome that's also costed.                                                                                                                                                                                                                                                                                                                                                                           |
| P7          | Independent Evaluation                 | Academia and Prof societies                                                                      | I do think that there's a place for academia to also do that, which becomes more independent, professional societies,                                                                                                                                                                                                                                                                                                                                                   |
| P6          | Funding Exit Strategies                | Reimburse till CED study is complete                                                             | But when we commit to these types of fundings, until all the data is collected and we've discussed, we generally do not terminate funding. Unless there is a real safety issue that comes up.                                                                                                                                                                                                                                                                           |
| P13         | Funding Exit Strategies                | Risk share, if claimed outcomes not reached, pay back funder                                     | There are certain projects that are built on risk sharing models, so for example if a certain outcome is not possible to be reached then the medical funder is paid back. Ultimately the responsibility lies with the funder to pay for it.                                                                                                                                                                                                                             |
| P5          | Funding Exit Strategies                | Process to exit study required with payback clauses                                              | But in a risk sharing model what should happen is that one of you should say, wow this study reached 2 years and it's almost at its success rate there's no need for each of us to pay anyone back. But Should the study fail the company should pay the funder back, because what you've paid for has not been fulfilled or has not materialized. So, it's almost like the funder has wasted money, because it means that even initial studies were not up to scratch. |

Source: Author's own.

#### **5.4. Research Question 3: What are the Factors that Influence Implementation of Alternative PBRsAs?**

##### **5.4.1. Theme 3a: Incentives**

Most participants (P1, P3, P4, P10 and P11) agreed that the biggest advantage of PBRsAs is their ability to facilitate market entry when there is ambiguity of performance outcomes. Participant P1 stated that, it should be clear that traditional reimbursement agreements are preferred by medical device suppliers; however medical device companies understand the need for PBRsAs from the funders' perspective. Participants P1, P3, P5 and P9 stated that the ambiguity can be based on a number of issues, starting from the level of clinical evidence, the cost versus benefit claim, utilisation rates that can have serious impact on budget resulting in affordability issues, or new technology addressing an unmet need. Regardless of the type of uncertainty, the funder is attempting to provide their members with access to better technology within the optimal time frames whilst managing the huge financial risks involved (Participant P6).

From medical device suppliers' perspective, PBRsAs are a suitable avenue when trying to prove that a product provides superior outcomes to other similar products in that category at patient level (Participant P2 & P9). The ability to conduct PBRsAs and prove one's product superiority provides a competitive advantage (Participant P9). PBRsAs also help to elevate the price discussion into a value discussion (Participant P2), this is important for medical devices whose performance outcomes can be long term. (Participant P5). Implantable medical devices have been cited as one of those product categories that benefit from the value discussion of linking prices to outcomes achieved as comparators provide different value bases on total costs analysis to the health system (Participant P9).

Price benchmarking of medical devices poses a challenge if it does not consider outcomes achieved in the long term (Participant P7). PBRsAs provide an opportunity to review not just the cost of the health intervention, but to include cost analysis of the patient journey, inclusive of readmission rates or revision requirements (Participant P9). Examples of same category or same clinical indication medical device implants that have longer time intervals prior to revision requirements or those that have less readmission rates provide better value when compared (Participant P2, P5, & P9).

When medical device manufacturers have evidence of better performance outcomes, they are incentivised to propose PBRsAs even when they have obtained traditional market agreements (Participant P9). Conducting these performance reviews even with traditional FBAs provides the opportunity to open the premium pricing discussion versus comparator which is an incentive for manufacturers who have superior products (Participant P1). Healthcare providers and healthcare facilities are incentivised to use PBRsAs as they provide opportunities for doctors and hospitals to treat unmet needs, and to improve patient outcomes, all of these in turn offer an opportunity for a competitive advantage (Participant P9 & P11).

The result is that medical device manufacturers consider PBRsAs to be advantageous and of high value in obtaining premium pricing and in providing a competitive advantage (Participant P9). Funders use PBRsAs mainly as a risk management option in trying to provide access for their members whilst controlling for the risks (Participant 1).

#### 5.4.2. Theme 3b: Disincentives

The costs associated with conducting PBRsAs are burdensome (Participant P2). In practice respondents agree there are disincentives that cannot be easily resolved. Participant P5 contended that every touch point along the patient journey is a risk to effectiveness. The implementation and management of PBRsAs is challenged by numerous and varied challenges (Participant P5, P7, P9 & P11). Beyond lack of knowledge or uncertainty in understanding what is being measured, issues of data ownership and capacity are observed (Participant P6). According to P7, the risk thresholds which determine when the risk-sharing comes into effect are proving elusive. This vagueness impedes fair negotiations.

*“...from an implementation level it’s very difficult...that whole model with the risk sharing is too complex. It is too ambiguous; it is so difficult to have smart goals of what would be the lever point for sharing risk or not or whatever the way you design it” (Participant P7).*

There is a financial disincentive for suppliers as there is a loss of margin whilst implementing PBRsAs (Participant P10). Participant P11 stated that the high-risk costs of implementing PBRsAs to hospitals is managed by not doing enough of them. Participant

P11 further argued that there should be a financial incentive for doctors to collect high quality evidence as the time taken to meet study data requirements is in conflict with providing care which arguably has better marginal returns. There are a number of obstacles, particularly poor evidence gathering by healthcare professionals who find the administration requirements onerous, and the risk of medico-legal issues that doctors may face when there is evidence of poor performance outcomes (Participants P5, P9, & P11). According to Participant P11, doctors have an interest in protecting the power dynamics and themselves as evidence of below par performance compared to colleagues could lead to poor image within the hospital resulting in lack of transparency.

The funder participants stated that PBAs are a huge challenge in South Africa, as funders, they have inadequate resources to conduct these agreements and they try to keep their costs as low as possible (Participant P6). Participant P10 argued that there should be cost transparency to determine the true costs to the funder but there is information asymmetry, whilst participant P4 emphasised that once a product has met the pre-agreed clinical outcomes, funders should pay the price when treatment is cost-effective. Participant P2 agreed that funders are reluctant to share their patient demographic data, making it difficult to move beyond price to value-based discussions. Participant P1 stated that, for the funder, it is beyond cost-effectiveness and suppliers need to gain better understanding of the funder perspective.

For medical device suppliers, the high costs associated with implementing and monitoring PBRsAs is prohibitive, it erodes profitability and yet the evidence returned lacks the robustness required to make it useful (Participant P10). The LC for doctors can also result in poor cost-effectiveness and should be mitigated (Participant P4 & P12). Participants P3 and P5 raised the lack of electronic health records as a disincentive for suppliers as it would facilitate evidence collection.

Most respondents agreed that there are challenges in implementation of PBRsAs (Participants P4, P5, P7, & P13). Participant P9 contended that the level of understanding and implementing these agreements is unsophisticated in South Africa. Further, participant P12 agreed that in the country the processes of HTA rely on international HTA outcomes due to lack of expertise. Most participants had consensus on the view that PBRsAs should be required by funders to address instances of unmet needs or be life-saving interventions, stating that utilisation and budget impact analysis are financial

agreements (Participants P3 & P12). This demonstrated a thorough understanding of PBAs. Participant P1 and P3 highlighted that medical device suppliers do initiate the requests for PBRsAs when they believe their medical devices produce superior health outcomes within the product category. Participant P3 emphasised that without clinical outcomes measures, these agreements are just financial and not measuring performance, stating “From my perspective, because if you cannot measure clinical outcomes how can you enter into any kind of alternative reimbursement model? Because then it’s not alternative, then it’s just a price or it’s a price volume” (Participant 3).

Participant P1 pointed out that currently in South Africa, there is only one funder who is willing to engage in PBRsAs. These PBRsAs are onerous to implement (Participant P7 & P13). Participants P5, P9 and P11 emphasised the need for patient considerations when measuring clinical outcomes, with Participant P5 stating that sometimes the patient reported outcomes are in stark contrast to the provider reported clinical outcomes. Participant P4 and P12 argued that one of the major challenges is that the clinical outcome needs to be defined and be measurable; with Participant P4 concurring that there should be upfront agreements with all stakeholders involved.

#### 5.4.3. Theme 3c: Performance Management

According to participant P7, measuring the performance in PBRsAs has proven difficult. Participant P7 argued that the starting point should be a simple unambiguous agreement that is understood by all parties, otherwise it is doomed to fail, citing that even with pharmaceuticals, implementation of PBRsAs has been ineffective. Participant P4 agreed that the patient outcomes and what is to be measured should have solid definitions agreed upon by all parties involved, with clear linkage of performance and pricing. Participant P6 further emphasised the requirement for setting up a clearly defined measurement criteria against clearly defined outcomes. Further participant P7 added that these agreements should also have upfront, legally binding clauses for assessing risk added to them. According to participant P7, the key is setting up specific, measurable, actionable, relevant and time-bound (SMART) performance agreement goals:

*“Unless you have a very simplified way of ensuring that the goal settings, specific measurables and so forth, unless you can have a very smart goal that is highly measurable, attainable and not ambiguous or it’s going to fail and you’re actually*

*going to mess up your relationships, because there's too much thought in it"*  
(Participant P7).

Participant P7 shared that in practice all parties are risk-managing for profit and are trying to minimise losses. The quality of the clinical outcome in these types of agreements is a risk taken by the patient, and it becomes important to have the patient voice (Participant P5). Participant P5 argued that new medical devices should have their effectiveness checked through PBAs due to the level of evidence that medical devices have at market entry. Participant P5 highlighted that new medical devices still under a PBA should ideally not be put into global fee structures until the clinical pathways and quality of outcomes have been assessed. The participant P5 emphasised patient involvement as some pathways can look impeccable on paper whilst in reality they are not working for patients. In addition, participant P5 stated "With the patients that we interviewed, you'd have cried tears because of what they had gone through and it was not what was supposed to be".

Practically the management of risk is done through converting the risk model and levels into a profit and loss (PNL) model (Participant P7). A thorough understanding of the risk is required. Participant P7 shared that different scenarios are proposed and imposed into the this PNL risk model and their impact on the PNL measured. As the reality unfolds, there is continuous monitoring and management of risk, continuously feeding into the model scenarios as they play out and this requires capacity (Participant P7). The implication is that all "parties involved should enter into these agreements with a win-win mentality as there is potential to increase patient access to healthcare where higher volumes are treated at lower prices" (Participant P7). Participant P2 emphasised that transparency is required from funders in terms of the actual cost impact of the PBRSA, however there is reluctance to open the books. Participant P7 argued that funders are experienced risk-managers whilst medical device companies still need to develop this skill to manage risk for profitable company performance stating:

*"So, let's take the supplier as the first element of risk. Firstly, they are driven by a PNL, they need to meet their PNL targets. But the same applies to the other side of the coin of the people who co-share the risk. So, this is the funder, the insurer. They also do their risk managing, they also want to see that they don't pay more"*  
(Participant P7).

Participant P5 and P9 emphasised that hospitals are a critical component in risk-sharing and management, stating that the hospital environment can pose as a risk that can impact performance. Issues like hospital infections can lead to hospital acquired infections, resulting in readmissions, so all touch points, including the LC hurdle are a risk and should be managed with training (Participant P5). Participant P11 claimed that the power dynamics at play with doctors being independent makes hospitals powerless in managing their performance, stating perhaps alternative reimbursement models could alleviate this issue. The implementation of global fees and managing for margins during PBRsAs has been highlighted as not ideal with huge potential to impact negatively on patients, the recommendation is that in managing PBRsAs for new medical devices, pricing should be dynamic (Participants P5 & P11).

#### 5.4.4. Summary of Results

**Table 5: Research Question 3**

| Participants                 | Theme                  |
|------------------------------|------------------------|
| P3, P4, P5, P7, P10, P13     | Incentives             |
| P1, P4, P5, P7, P9, P11, P13 | Disincentives          |
| P3, P4, P5, P7, P13          | Performance Management |

Source: Author's own.

**Figure 6: Research Question 3 Sample of Thematic Analysis**

| Participant | Theme                  | Secondary Level Analysis                                                                 | First Level Analysis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------------|------------------------|------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| P4          | Disincentives          | Cost is a deterrent                                                                      | The appetite and the costs of it. If you're only going to get your data in a year to two years down the line. That's two years of revenue lost.                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| P7          | Disincentives          | Difficult, Complex, No Benefit to Hospital                                               | So, we've done a lot of that work and we've not been very successful to implement. Implementation level it's very difficult. So, I'll share my experience with you, that whole model with the risk sharing is too complex. It is too ambiguous; So, the hospitals very seldom make money out of devices. Cost, because this is an expensive exercise.                                                                                                                                                                                                                                                                 |
| P13         | Disincentives          | Revenue Margin Loss, Laboursome, Costly, Administration Burden                           | I'm not sure if the financial model is going to work for the suppliers, because they're definitely giving up margin to allow this. So, long term the longevity of having the technology in the market after the initial phase is going to be a challenge or risk. Like I mentioned in the beginning, the funder mechanisms are just very labour some.                                                                                                                                                                                                                                                                 |
| P5          | Disincentives          | Lack of Knowledge, Lack of EHR, Staff Turnover, Medico-legal Risks Doctors Profitability | Lack of understanding. But they don't have staff and they don't have time. They don't have knowledge base everywhere. The nurses come and go, they can't assist. The physicians are chasing money and are going through cases as fast as they can, because they need to make more cases. Because they are not sure if they are not putting their necks or careers on the line or whether their names will be published for one or two mistakes.                                                                                                                                                                       |
| P11         | Disincentives          | Disadvantage is High Investment Risk                                                     | There's too much fear of that financial loss that we only do them only when there's somebody who feels strongly that it's a No-loss situation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| P1          | Disincentives          | Investment Requirements                                                                  | But at the same time, as an industry we probably don't have that much investment in terms of our budget to consider this or propose it to a funder.                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| P9          | Disincentives          | Low compliance in evidence submission, No framework for risk,                            | So, maybe an important point to make here is that the use of registry in this type of data. There's very low compliance in terms of the registries. That's your risk. It's difficult, I don't think that there's a standard framework for these type of risk agreements. I think the process is still very immature                                                                                                                                                                                                                                                                                                   |
| P4          | Incentives             | Long Term Benefits for Funder                                                            | Ultimately, the payer has certainty that they are funding the best possible solutions for their clients, which is the patients. Holistically, the benefit is going to be economically for the funder at the end of the day                                                                                                                                                                                                                                                                                                                                                                                            |
| P3          | Incentives             | Superior Outcomes Claim                                                                  | So, there were early indicators that marked positive, but the real hard and fast outcomes were similar, but there was a price difference. So if you apply health economic outcomes, why would you pay extra? And the price was more. So then we entered into a peer financial risk model to make the technology available.                                                                                                                                                                                                                                                                                            |
| P5          | Incentives             | Entry route into Market                                                                  | So unfortunately most of the time with medical devices that's the only way you can get your HTA fully endorsed. So for medical devices it's a little bit tricky, because they take long to be where they're supposed to be or to prove whether or not the product works. For some devices it works faster, for some it works normally.                                                                                                                                                                                                                                                                                |
| P10         | Incentives             | Life Saving Technology Market Entry                                                      | I think it's a difficult one to answer, because I think it depends on a few factors. Which again I would say is the urgency of the technology, if it's a life saving technique I think then maybe you can consider this as a supplier from my view.                                                                                                                                                                                                                                                                                                                                                                   |
| P9          | Performance Management | Claims versus Real World Performance                                                     | So, for example the company could have gone back to the funders and said we're saving you a certain percentage over a period of time, we're looking at a risk sharing model where you do a premium price for this particular product, because we're saving a certain amount over a period of time. and we can have this for a year and we expect that the results will be better and if they're not then the funder can go back to the supplier and say based on your outcomes you said you'd save a certain percentage therefore we're not paying this balance.                                                      |
| P7          | Performance Management | SMART goals difficult, Risk Manage for Profit                                            | It is so difficult to have smart goals of what would be the lever point for sharing risk or not or whatever the way you design it.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| P7          | Incentives             | Increased Patient Access, Price protection and Volumes                                   | On a social level, the benefit of risk sharing is that you could potentially provide access to more patients at a lower price and that's a win-win, because as a devices company you wouldn't mind having more revenue, more volume at a lower price, because you know that your revenue and your cost model will make sure that your PNL looks better and not worse. So there's the socio-economic aspect and we can open up to more patients, because we have more money or less money to spend on more people or the same budget to spend on more people, because ultimately the price is reduced to risk sharing. |
| P13         | Incentives             | Innovator companies at the forefront. Prove claims                                       | So, from a supplier's perspective I feel that to enable market access they really need to be looking at this at an earlier stage and they are aware that the evidence is not going to be up to scratch or it's going to be questioned from the perspective of the medical funder and at that point I'd rather try and put forward a proposal. So if you want to be at the forefront, you're going to have to be at the forefront of putting these risk sharing agreements into place. I think one of the high level benefits is being able to trust your product, being able to put your money where your mouth is.   |
| P3          | Performance Management | Must measure clinical outcomes                                                           | So, here I think it's clinical outcomes. From my perspective, because if you cannot measure clinical outcomes how can you enter into any kind of alternative reimbursement model? Because then it's not alternative, then it's just a price. A devaluing price or it's a price volume. So, this is currently a real weakness and the fact that there's no real clinical evidence. But I suppose if you had a clinical outcome, you could do a negotiation based on pre-determined clinical outcomes. Yes and the fact that there are no electronic records of clinical outcomes                                       |
| P1          | Performance Management | Defined pay back mechanisms                                                              | So, from a funder point of view in terms of cost then Yes. But not just the cost of implementation. but the cost of budget wherein you have to fund something that you're not confident with. But normally these contracts are drafted in such a way that says "failure to do that, you will give me this." information that you sometimes agree upon to go back and look at their claims data and then they will do their own analysis. the analyst of the funder had to spend some hours pulling out claims data. .                                                                                                 |
| P10         | Performance Management | Defined review periods                                                                   | But, also it shouldn't be just risk sharing there should be a period linked to it and after a period of 12 months or so many patients being treated it should be reviewed again against all their costs of the normal patient pool. I think it's all about transparency and we know that the funders are not going to share that with us.                                                                                                                                                                                                                                                                             |
| P7          | Performance Management | Risk Management,                                                                         | the devices company must become a risk manager in itself. They need to continuously manage their risk; they need to continuously monitor that.                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| P12         | Performance Management | Can you actually measure it? Did it work?                                                | That's a huge issue if you're looking at an outcome, if you've got measurables in place. Because it's sometimes very difficult from a tangible perspective. So, when it's measurable and you can look at the evidence, did it work? Yes or no?                                                                                                                                                                                                                                                                                                                                                                        |
| P5          | Performance Management | Patient Voice important in measuring. Clinical vs Patient Outcome                        | So I have seen an instance where there were a number of pathways that had gone wrong. With the patients that we interviewed, you'd have cried tears because of what they had gone through and it was not what was supposed to be. From the funders societies to say if we put an ARM who is there monitoring the outcome? Who is there interviewing the patients to see if the pathway is indeed working for the patient and not for the doctor?                                                                                                                                                                      |
| P5          | Performance Management | Clinical vs Patient Outcome,                                                             | Some pathways look really good on paper, for example one of the doctors was already part of the model and he was starting to query and he suggested that we all get together and figure something out and subsequently they eased up some rules within the pathway, they added more pain medication while the patient was in theatre.                                                                                                                                                                                                                                                                                 |
| P9          | Performance Management | Agreement on methodology                                                                 | Another factor is that everyone has to be aligned on the methodology, the dimensions and metrics that are used to measure. That's a consideration in implementing it. The benefit of implementing it is that you have better outcomes, it costs the healthcare system less especially in the constrained environment that we're in right now                                                                                                                                                                                                                                                                          |

Source: Author's own.

## **6. Chapter 6: Discussion of Results**

### **6.1. Introduction**

The research findings discussed in the preceding chapter are juxtaposed and contrasted against the findings of the literature review in chapter 2 and are discussed in an attempt to answer the research questions in chapter 3. The sequencing of the constructs and concepts follows the flow of the research questions in chapters 2, 3 and 5. The research contributed to the understanding of performance-linked reimbursement outcomes with a focus on the management of non-financial agreements. The findings illustrated the need for a planning system to govern the management of these HTA outcomes and a dynamic adaptive framework model in the context of PBA is proposed and presented in chapter 7.

### **6.2. Research Question 1: What are the Factors Considered in Implementing CED Studies for Medical Devices?**

This research question sought to identify the elements that should be considered as critical requirements for inclusion in establishing an implementation of CED schemes. The question aimed to identify the challenges that plague these health outcomes PBAs and attempt to elucidate those elements that contribute to successful CED scheme implementation from participants experienced in conducting CED studies. The benefit of hindsight from experience and from literature was combined and an attempt to make a theoretical contribution to the current body of knowledge was made through a model for dealing with performance-based HTA outcomes.

#### **6.2.1. Evidence Requirements in HTA of Medical Devices**

Ciani et al., (2017) argued that the HTA and economic evaluation of medical devices has largely been based on the evaluation of pharmaceuticals. The regulatory requirements for medical devices generally have lower licencing requirements than regulatory requirements for medicines (Tarricone et al., 2017a). Ciani et al., (2017) further stated that the level and quality of evidence in medical devices is a challenge with an array of confounding factors that lead to problems in the quality of evidence available, further stating that RCTs are not prevalent, nor always possible in medical devices. Further,

Reckers-Droog et al., (2020) posited that “the use of CED schemes seems particularly relevant to medical devices, since clinical evidence is often limited at the time of launch and the long-term effectiveness and cost-effectiveness is heavily dependent on how they are adopted into routine clinical practice” (p. 2). Participants argued that the basis of the HTA evidence requirements was still RCT or pharmaceutically based, however they acknowledged that there was some recognition of differences of medical devices and funders were slowly moving away from medicine requirements (Participant 1). A framework for medical device HTA is still a challenge (Saunders et al., 2019). Funder stakeholders should acknowledge the differences between medicines and medical devices, further the differences between different medical devices require a device category approach to evidence level requirements. Funders should continue to leverage international available evidence as the country context is largely import based. All stakeholders are encouraged to continuously keep abreast of international developments in HTA and evidence requirements for medical devices. Collaboration with other HTA agencies is advised for funders, whilst international medical device HTA association membership is proposed for medical device company stakeholders.

#### 6.2.2. The Environmental Context of HTA for Medical Devices

The theme 5.2.2 HTA Localisation is combined with theme 5.2.3 Local Data and Demographic Profiles under the environmental context discussion as they are about country factors. Participants P1 and P4 specified that the country-specific inputs of the cost contributors of a health event need to be incorporated in the health economic tool selected for HTA evaluation for both the proposed medical device and its comparator. Ferrario et al., (2017) noted that differences exist even in HTA agencies within the same country.

The contextual nature of HTA is described by Schwarzer and Siebert (2009) as existing within legal policy and health system context. The authors agreed with the assertion that differences in HTA will exist based on country specific contextual framing factors (Schwarzer & Siebert, 2009). The respondents had divergent views on the routine requirement for local studies. Some respondents stated that the international studies can be leveraged if the HTA inputs and cost information that enables localisation is available (Participants P2, P6, P10, & P12), whilst others argued that the country-specific population demographics should be considered as unique and thus local CED studies can be

encouraged (Participants P5, P11, & P13). Saunders et al., (2019) argued that HTA is influenced by local economic considerations. There is an opportunity to harmonise requirements that facilitate the ability to leverage cross country HTA evidence.

The funder participant(s) 6 clarified that the CED knowledge gap is not based on demographic profiles of the country, however demographic profiles are considered in HTA and if they result in ambiguity, the local studies required are managed differently compared to routine CED. A number of sources in literature argued that HTA is influenced by the contextual nature of the environment, from epidemiological profiles to structure of healthcare including the structure of the healthcare financing (Saunders et al., 2019; Schwazer & Siebert, 2009). The legal, structural and clinical context of the HTA agency thus has become the starting point of consideration as the contextual framing factors in the economic evaluation for the introduction of medical devices (Schwazer & Siebert, 2009).

Further both respondent P6, emphasised that one needs to go beyond ensuring that all input costs are accounted for, there is a need to incorporate costs based local cost estimates and using country specific currency (Participant P1 & P4). This means that all actors and processes and costs required to meet the clinical pathway requirements of the health indication of the proposed medical device and those of the comparator should be localised. Participants P2 and P3 highlighted that these costs are not easily available due to information asymmetry. Reckers-Droog et al., (2020), noted that one of the challenges contributing to ineffectiveness of CED studies is the lack of transparency. In literature, funders have also highlighted a lack of transparency from manufacturers who conduct CED studies which has led to a distrust between stakeholders (Reckers-Droog et al., 2020). There needs to be transparency about what is known. Haasnoot et al., (2012) argued for identifying the vulnerabilities and risks in designing an adaptive policy. Tarricone et al., (2017b) identified that the cost-effectiveness of medical devices itself is impacted by its adoption in practice adding that the scale of use will also impact the return on investment of CED studies.

### 6.2.3. Evidence Requirements: Framing Uncertainty

Tarricone et al., (2017b) proposed that HTA methods for medical devices should rely on iterative approaches to economical evaluation. The iterative approach should consider the specific particulars of a medical device, the confounding factors in medical device use, and the mitigation adjustments required to manage confounders when formulating the design of comparative effectiveness studies (Tarricone et al., 2017b). Tarricone et al., (2017b) described medical devices as characterised by features that are not regularly found in drugs, and these features should be considered as they impact the appropriateness of the assessment method applied to medical devices. Participant 1 echoed these assertions, explaining that it might even be unethical to perform studies similar to pharmaceuticals when it comes to certain medical device.

Participant P2 stressed that critical knowledge of the treatment area, current treatment methods, and the proposed medical device assists in understanding the uncertainty. Pouwels et al., (2019) found that some CED studies are conducted whose outcomes do not address the uncertainty that led to their requirements. Participant P2 and P7 emphasised the need for continued engagement with funders to ensure explicit agreement on the uncertainty. Bosomworth and Gaillard (2019) proposed that the framing of uncertainty should be done through a participatory approach. This is echoed by participant P3, who highlighted the need for engaging KOL, and participant P7 argued for the collective engagement of all stakeholders in order to ensure there is complete understanding of the uncertainty.

Participant P1 stated that the already existing protocol should be used to frame the uncertainty and establish the primary end points for the CED scheme. Participants P4 and P13 stated the uncertainty should be documented and agreed on. The multiple actors who are involved in the implementation of the CED scheme need to be involved through a participatory approach to understand the uncertainty. Participant 3 used the multi stakeholder consensus approach, engaging with doctors with the final agreement documented and signed with the funder. Participant P5. P7 and P9 highlighted the need to include hospitals as stakeholders.

Bosomworth and Gaillard (2019) stated that the body of work on participatory approaches is still being explored and cautioned that institutional drivers of problem framing can

impede the participatory approach. The authors claimed that the methods used in designing the participatory approach to arrive at defining the adaptive pathway plan goals and objectives are important and will enhance learning exchange (Bosomworth & Gaillard, 2019). Reckers-Droog et al., (2020) pointed to a lack of project management and coordination as a hurdle for CED schemes, adding that stakeholders with conflicts of interest need to be removed from the process to ensure independence. Participant P1 echoed the warning against conflicts of interests which may lead to reframing of uncertainty resulting in CED studies that do not address the gaps.

#### 6.2.4. Setting Scope and Parameters

In setting the scope and parameters, participant P13 raised that hospitals and doctors are approved and accredited respectively, however this can impact the duration of the CED scheme if there are insufficient patient numbers. This was echoed by participant P11. Participant 13 advised that the hospital and doctor approval requirements in forming part of a CED scheme can impact feasibility and this should be negotiated with the funder if financial impact due to extended duration. Participants P1, P4, P5, and P6 stated that a patient selection criterion is specified through the CED study protocol. Participant P9 and P13 argued that patient population should be kept as uniform as possible. Reckers-Droog et al., (2020) stated that this patient population scope restriction has been raised as possibly unethical by stakeholder like patient advocacy groups. The restricting of treatment to a subset of patients and withholding potentially beneficial treatment to other patients during a CED is raises a concern of inequity to health access (Reckers-Droog et al., (2020). Patient selection and criteria should endeavour to not disadvantage population groups and should be guided by clinic practice guidelines to make the selection of patients palatable to various stakeholders.

Participant P1 stated that during analysis any cases that present clear confounders should be excluded or have confounders adjusted for in the analytical evaluation. This approach may be more ethical than efforts to make the patient population in CED studies uniform. Participant P4 also argued that when the LC is evident with continued use, it should be adjusted for when performing the cost-effectiveness adjustments. Participant P6 argued as funders, they should not be funding the LC; however, they will consider adjustments when it is clearly evident.

The LC as a possible confounder should ideally be removed through training mechanisms prior to CED scheme as funder participants expect doctors who are proficient in medical device use to minimise the LC as an issue. Most participants have a high value on professional training and understand that only doctors who are trained and proficient should form part of a CED scheme which is an opportunity to prove the value of the medical device. Professional training of doctors and related teams is done through various avenues to manage the possible confounder presented by the LC, thus unless it is unavoidable, the LC as a confounding factor is restricted. When there is evidence of a LC impact, it should be accounted for in analysis.

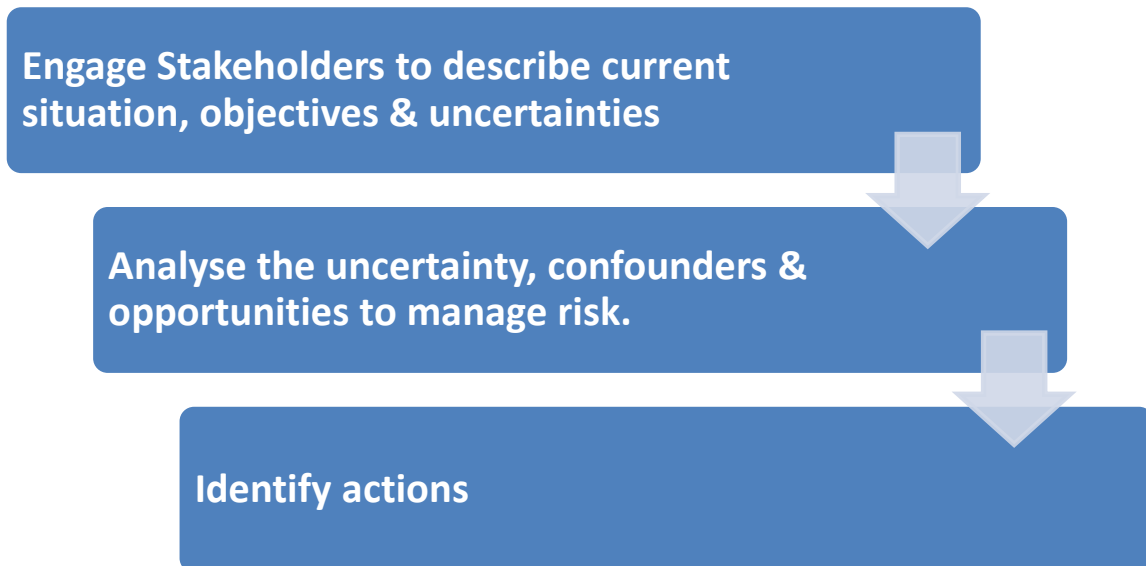
Participant P7 claimed that the ideal approach to managing confounders is to quantify them and test for their significance. Insignificant confounders can be ignored, whilst significant confounders need to be adjusted for depending on their impact (Participant P7). Transparency should be the foundation of identifying, managing and adjusting for confounders and the agreement on the vulnerabilities that confounders pose. Haasnoot et al., (2013) argued for risk thresholds to be identified and triggers for altering the adaptive pathway established and agreed upon. In defining adaptive pathways Haasnoot et al., (2013) explicitly called for the recognition of how decision makers become part of the uncertainty story as they engage with it. Reckers-Droog et al., (2020) agreed, stating that “One of the complexities associated with the evaluation of medical devices is the fact that any decision about the adoption of the medical device will interact with the ability to gather more evidence (p. 6).

Participants P5, P6 & P9 highlighted the importance of hospitals as stakeholder, further P5 and P9 cautioned for awareness on the possible impact of hospitals on CED study outcomes, stating it cannot be under estimated. In literature, the impact of healthcare professionals on CED schemes has been raised, however the hospital environment has not been found in literature as a consideration. The hospital environment consideration may be perhaps more highlighted in developing countries.

Confounding factors pose risks to CED study outcomes and create vulnerabilities that may result in erroneous decision making or triggering. The process is iterative to get to the point where the uncertainties and study design are agreed on and documented together. The understanding of the comparator clinical pathway versus the medical device under the CED scheme is important as the two pathways are competing (Participant 2). Once

the required actions are identified, the funding considerations and feasibility of the CED scheme are the next steps (Participant 13). Figure 7 below outlines the summary of results for research question 1.

**Figure 7: Summary of Results for Research Question 1**



Source: Author's own.

### **6.3. Research Question 2: What are the Funding Considerations for CED Studies?**

This research question aimed to understand how CED studies are funded. According to Tarricone et al., (2017) CED studies are resource intensive, with exorbitant costs associated with funding posing a challenge.

#### **6.3.1. Financial and Profitability Management**

Rothery et al., (2017) cautioned that the value of the research to be conducted may hold little value to manufacturers of medical devices, resulting in the acceptance of a price point below the manufactures' ideal when they consider the costs of doing the research versus the return. Participant P4 noted that a lack of a protection mechanism could be a disincentive in funding health outcomes research, claiming that any new competitor can

enter the market with lower prices and obtain reimbursement without the company conducting the PBA obtaining a return on their investment. Participant P4 claimed that the funding of PBAs should be shared based on this, as it leads medical device suppliers to question the value of gathering additional evidence especially considering the associated costs. Reckers-Droog et al., (2020) agreed with this challenge, stating new entrants pose a disincentive for manufacturers to perform CED studies. Further, Reckers-Droog et al., (2020) added that the incremental innovation nature of medical devices may mean that by the end of the study, the value of information generated is obsolete.

Dabbous et al., (2020) supported the proposition from Rothery et al., (2017) that one could use dynamic pricing so as to address the issue of return on investment when better outcomes are achieved. Ferrario et al., 2017 stated that budget impact is the primary focus for all stakeholders as noted by payback mechanisms. Dabbous et al., (2020) claimed that this focus results in almost all PBAs becoming FBAs. The investment in funding CED schemes versus the benefits in profitability or reductions in operating costs should be shared by all the parties who stand to benefit.

Reckers-Droog et al., (2020) listed one of the difficulties in funding CED schemes as high transaction costs associated with them with no protection from new entrants. The high transaction costs are exacerbated by payer systems that are fragmented making the conducting of CED schemes not cost-effective (Reckers-Droog et al., 2020). Participant P2 echoed this sentiment, stating that in South Africa there are potentially five dominant payers and all conduct their own HTA and may require their own CED scheme, making it a barrier to financing the various CED schemes. Participant P1 stated that CED investments are a barrier to market entry for small companies. Additional issues are staff turnover, errors in claims submitted and the lack of data infrastructure, which pose a challenge in long-term outcomes data (Reckers-Droog et al., 2020). Participant P3 and P5 made similar comments naming some of the challenges in funding studies being lack of EHR and trained staff turnover. Participant P11 highlighted that even the doctors can relocate to another country whilst in the middle of a scheme.

There should be recognition that CED schemes are an investment for medical device manufacturers and there needs to be a return. Further when novel medical devices prove their cost-effectiveness, the return on investment is shared with funders through savings generated. The investment costs to medical device companies should be acknowledged

and some form of protection should be considered. The protective mechanism may be to have funders commit to paying for the investment costs should the medical device prove cost-effective and funders allow new entrants. The medical device companies on the other hand should commit to paying back funders when their claims cannot be proven in the real-world. These protective mechanisms would be mutually beneficial and ensure reward for risks taken.

### 6.3.2. Public Image Management

Reckers-Droog et al., (2020) details the risk of heated public debate in media driven by patients or even doctors when funding that is cost-effective but not affordable is withdrawn. Khan and Hashmani (2018) discuss the political barriers which may prevent politicians from acting against low-quality health service providers when no alternatives exist in a community or when community members do not understand performance measures. These authors raise the importance of public image and the participants in the study have raised some public image risks that funders and manufacturers have to mitigate. Both funders and manufacturers expressed a keenness to get to a reimbursement price point with no co-payments, stating that it is in every stakeholder's interest to increase patient access. A few participants stated that co-payments impact the market penetration of medical devices. Participant 6 claimed that as funders, they would like to avoid co-payments as much as possible unless it is reasonable. Participant P7 echoed the need to avoid co-payments as it undermined the objective of health insurance.

Participant P4 and P9 claimed that medical device manufacturers may not be keen on conducting a CED study and did not want their names on the studies. Funders can and should do a lot more to educate their members about cost-effectiveness and affordability. Medical devices that are cost-efficient but unaffordable should be funded with co-payments and the reasonable grounds should be explained to doctors and patients. Hospitals and funders who adopt innovative health technologies should leverage the public image of having patients at the forefront of their organisational values.

### 6.3.3. Independent Evaluation

Reckers-Droog et al., (2020) pointed to the need for neutral, publicly funded research organisations with experience in conducting research and collecting data to perform CED studies. Participant P2 and P5 proposed an independent entity, academia was also proposed due to their experience in research to implement and manage CED studies to reduce conflicts of interest and manage bias. Participant P5 suggested that a national HTA has potential to address the issue of independence in funding CED studies, whilst participant P2 was concerned about their source of funding. Dabbous et al., (2020) anticipated that funding of PBA studies will be improved by global funding schemes where the industry strives to have independent funders, analysis and review of medical devices. A national HTA to conduct CED studies would address also the issues of smaller companies who cannot afford to invest in CED schemes as pointed out by participant P1. The publicly funded French model for CED as discussed by Martelli et al., (2016) can be considered for national epidemiological areas of interest prioritised together with areas of unmet clinical needs as highlighted by.

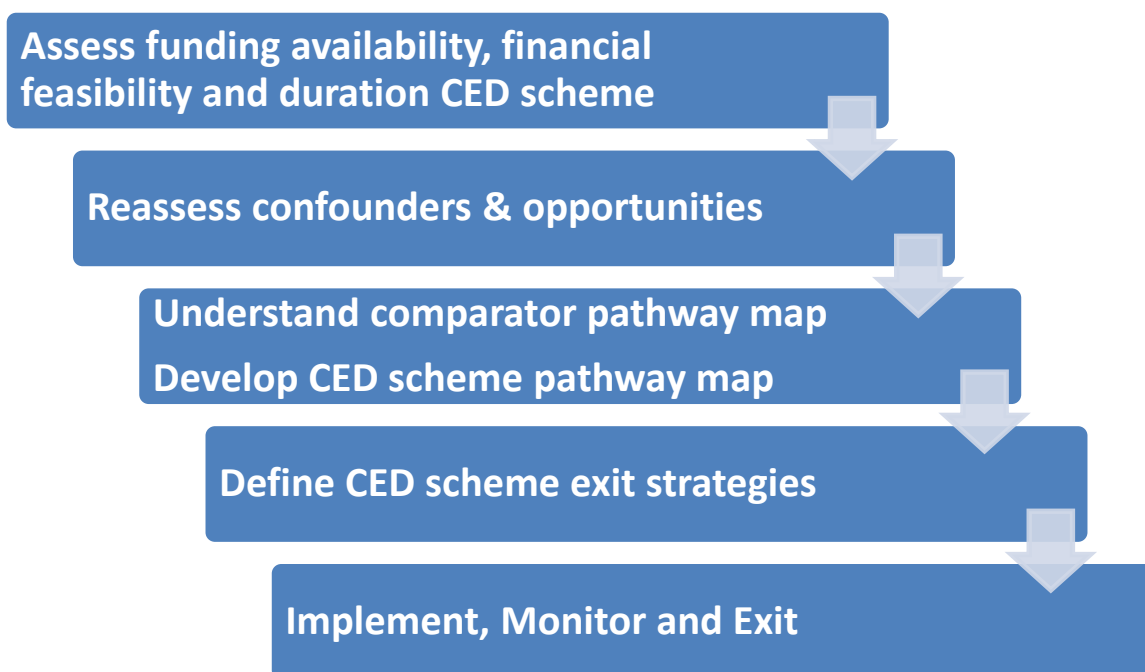
Non-independent funding of CED studies can result in conflicts of interests that create biases in study outcomes (Participant 5). Participant P9 and P11 explained that data ownership is a critical issue in CED schemes and each stakeholder withholds the information at their disposal due to issues with trust. According to Reckers-Droog et al., (2020) the non-independent funding of CED studies contributes to the lack of transparency of outcomes of these schemes to clinicians and other stakeholders. The researcher suggests that funding CED schemes requires critical and contextual consideration, as these studies could unearth information that could potentially be crucial to certain epidemiological and demographic population profiles and should be of interest to policy decision makers.

### 6.3.4. Funding Exit Strategies

Participants 6 commented that they continue with reimbursement of a product under a CED scheme until completion of the study. Reckers-Droog et al., (2020) cautioned that this could be an incentive for extending the duration of a CED scheme where the quality of evidence generated is insufficient to make a decision on the uncertainty. Watering et al., (2017) cautioned that in public financing of healthcare exiting CED studies that prove

to be either not cost-effective or unaffordable is very difficult. Reckers-Droog et al., (2020) pointed to possible difficulties in discontinuing reimbursement due to public pressure by patients. Participant P9 called out for the implementation by hospitals of protective governing agreements to ensure palatable return on investments when funding is stopped. Participant P7 argued for the implementation of agreements that are legally binding for all stakeholders. The documentation and agreement of the uncertainty together with expected outcomes and transparency of outcomes should facilitate exiting of CED schemes when expected outcomes are not achieved and reimbursement is discontinued. Figure 8 below presents the summary of results for research question 2.

**Figure 8: Summary of Results for Research Question 2**



Source: Author's own.

#### **6.4. Research Question 3: What are the Factors that Influence Implementation of Alternative PBRsAs?**

This research question sought to understand when the implementation of patient level PBAs was considered suitable. According to Dabbous et al., (2020), the implementation of PBRsAs is said to be fraught with challenges resulting in less uptake than previously anticipated, with future predictions expecting a drop of adoption of health outcomes-based

PBAs, leaving only FBAs. The question strove to unearth these challenges and highlight critical parameters for consideration in addressing them in light of continued use of PBRsAs and anticipation of health outcomes policy plans.

#### 6.4.1. Incentives

CED schemes evaluate the uncertainty related to the impact or performance of a health technology at population level, PBRsAs evaluate the uncertainty related to a health technology at patient level (Dabbous et al., 2020). Participant P1 claimed that as a medical devices manufacturer, the preference is to avoid PBRsAs due to their costs; however, a few participants expressed appreciation of PBRsAs stating that, when necessary, PBRsAs facilitate market access. Medical device manufacturers may have incentives toward PBRsAs, more so when superiority of medical device related health outcomes in the same class can provide a competitive advantage (Participant P9).

Participant P2 argued that in the country context, the available international data should be leveraged. However participant P5 contended that all medical devices should be subject to PBRsAs. The research findings offered insights that show some divergence of views from medical device manufacturers on their perception of PBRsAs, however there is agreement that they facilitate early market entry and as such are an advantage to medical device companies.

The findings are consistent with Dabbous et al., (2020) in showing that medical device suppliers are keen on PBRsAs compared to funders. This reveals a propensity for manufacturers to propose their use in efforts to prove superiority in class. These studies tend to take the shape of registries and the associated challenges of missing evidence or lack of quality evidence that lead to PBA being ineffective have also been found in this research. EHR are proposed as a hopeful counter measure in dealing with evidence collection and for tracking long-term outcomes.

#### 6.4.2. Disincentives

According to Reckers-Droog et al., (2020) the quality and completeness of data is an issue, and evidence collection is highly dependent on doctors. Participant P6 highlighted

the issues related to data ownership and the limited resources to fund and monitor PBRsAs. These participants echoed the findings of Reckers-Droog et al., (2020), stating that even if the administrative issues were to be resolved, the data ownership issue is still prohibitive to evidence collection. Participants P5, P6, P10 and P13 were in agreement that there is insufficient expertise in South Africa. Ferrario et al., (2017) claimed that even in Europe, the expertise differed across countries and across different HTA agencies. Further participant P9 stated that PBRsAs in South Africa were not yet sophisticated, adding that medical device manufacturers are starting to perceive them as tools for competitive advantage. Dabbous et al., (2020), however, predicted a dim future for PBAs arguing that the data problem results in them being FBA with confidential discounts. It is imperative that without the improvement in the challenges faced in PBRsAs that they be considered for unmet clinical needs, especially those that greatly impact productivity, quality of life and life-saving medical devices

Rothery et al., (2017), Tarricone et al., (2017) and Reckers-Droog et al., (2020) argued that the value of the PBA and the information it will provide should be evaluated in comparison to the anticipated price of the medical device, stating that these are linked. Bosomworth and Gaillard (2019) contended that the implementation of adaptive pathway plans should consider the challenges of required investments and understand all the planning is worthless if there is no implementation. Medical device companies and funders should evaluate if implementing PBAs is worthwhile considering the challenges raised.

#### 6.4.3. Performance Monitoring

The future of PBRsAs is questionable as the concept buckles under the complexity of the healthcare system, however, according to Piatkiewicz et al., (2018) interest in them continues to be observed. The complexity of setting the systems, agreeing on SMART goals, and the performance monitoring required with the use of limited resources is a disincentive for funders (Participant P7, P6 and P13). There are conflicts of interest between the actors required in the implementation and monitoring of PBRsAs (Reckers-Droog et al., 2020). Participants P9 and P11 reveal complexity related to the contributors of ineffective PBRsAs, stating that there are power dynamics with doctors wanting to maintain the patient custodian status, thus not giving clinical data.

These conflicts of interest are informed by a need to protect industry structure dynamics between the various agents and the need to protect future profitability considerations, which are influenced by the power of suppliers. Paine and Peters (2012) stated that health being a CAS results in the path dependencies and this path dependency of evidence collection interferes with the feedback loop system required for effective implementation of PBRsAs.

Reckers-Droog., (2020) submitted that some of the challenges related to evidence gathering are related to the negative perception where doctors view this as a tool to monitor and control them. Further Dabbous et al., (2020) stated that individual level PBAs fail when they use surrogate ends points as they do not really measure real performance at patient level, thus do not provide the funder with valuable data in addressing the uncertainty. Further, Hanefeld et al., (2017) called for health outcomes monitoring that includes patient perception of quality, as it can differ from clinical quality evaluation. In addition, Khan and Hasmani (2018) cautioned that health outcomes monitoring that link the quality of health outcomes to payments and contracting arrangements are challenged by political conflicts of interest that can undermine the efforts to improve the health system. Participant P9 argued that if medical devices were subjected to routine PBRsAs, health-outcome comparison data could identify where inefficiencies in the quality of health were if significant differences in performance are discovered between countries.

Participant P3 and P5 proposed EHR as a means to improve data collection and quality of available evidence, this requires a national infrastructure to be set up, echoing Reckers-Droog et al., (2020). Ferrario et al., (2017) commented that when implementing a MEA, monitoring systems are required from manufacturers. Participant P9 argued for the voice of the patient in measuring health outcomes. Participant P5 agreed, claiming that ARM may look good on paper, however the efforts to maximise profits by healthcare providers may be a risk to patients. Patient participation has received increasing advocacy even in literature (Hanefeld et al., 2017). Another issue raised by participant P9 is the risk of medico-legal action against doctors as the primary care givers, echoing Reckers-Droog et al., (2020), who stated that doctors' reluctance and view of PBRsAs as possible methods of controlling their actions and clinical decisions was a challenge

The complexity of setting SMART performance goals, combined with the feasibility of monitoring the performance of PBRsAs, is a challenge that requires critical consideration

in setting up PBRsAs. There is evidence that EHR are infrastructural requirements, however they do not in themselves address the issue of power dynamics and conflicting earning avenues for doctors that impact on evidence collection. Further, the requirement of patient reported quality of outcomes is not addressed by EHR which collect clinical outcomes only. Participants P3 and P13 highlighted the loss of profitability whilst conducting these studies. Ferrario et al., (2017) stated that implicitly the risk being managed is related to overspending with limited real-life value add. In addition, participant P7 claimed that the risk sharing in reality is actually managing risks to profitability. Further Dabbous et al., (2020) stated that PBAs tend to eventually be converted into FBAs, based on various challenges in collecting evidence. Ferrario et al., (2017) cautioned that confidential discounts could become an issue in publicly funded health insurance systems. The South African private health sectors experience of these agreements is aligned with Dabbous et al., (2020) findings, where complexity abounds and budget impact from all stakeholders takes centre stage.

The advantages of PBRsAs are outweighed by the disadvantages experienced in the implementation of these agreements. Medical device manufacturers are willing to engage in PBRsAs if this is the only route to market entry. Participants pointed out that funders should agree to the consideration of PBRsAs especially for life-saving treatments or unmet clinical needs and for disruptive breakthrough innovations. Further, medical device suppliers stated there are benefits to funders and to patients when superior health outcomes claim are proven through PBRsAs. In conclusion, it seems that whilst these agreements are difficult to implement, there is still room for their use and guiding frameworks will assist in improving the complexities in implementation. The role of EHR infrastructure and how physician as stakeholders affect the effectiveness of PBRsAs implementation should not be undervalued.

## 7. Chapter 7: Conclusion

### 7.1. Introduction

In chapter 2, the literature review conducted aimed to determine what is known about dealing with HTA outcomes for medical devices that require the implementation of PBAs. The secondary data revealed the factors considered in the implementation of these CED schemes, the challenges associated with CED schemes, the funding considerations, and the incentives and challenges in the implementation of PBRsAs. The research interviews sought to understand how local stakeholders deal with the implementation of PBAs of medical devices and the challenges highlighted with the aim of building on the literature findings. The dynamic adaptive policy pathways model was used as the base framework, this model was adapted to build a model for dealing with performance-based HTA for medical devices. The literature review and research findings were organised into a planning and governing framework that proposes the steps and factors to be considered to overcome the challenges found in dealing with HTA outcomes that require PBAs. The findings are presented in Figure 9 below and are discussed in this chapter.

### 7.2. Presentation of Model

The model details the action steps for manufacturers of medical devices and funders:

**Step 1:** A participatory approach is required, where stakeholders engage to define the uncertainty to ensure that both manufacturer and funders are clear about the uncertainty. The knowledge gap is clearly defined together with the expected performance outcomes of the PBA that are being measured should be.

**Step 2:** Explains the need for stakeholders to engage in study design considerations, where they analyse the uncertainty, identify risks of biased study outcomes by listing possible confounding factors, identify how they will be measured including details of processes to manage the risks. At this step is important to have the involvement of the doctors who are KOL and likely will form part of the accredit doctors. The importance of the presence of this stakeholder in the engagement should not be under estimated. The collection of evidence by doctors is one of the challenges to effectiveness of PBAs, thus,

there is a need to minimise administrative requirements from doctors to manage the risk of incomplete evidence collected.

**Step 3:** Includes identifying actions like, determining the required size of the study, identifying which hospitals are approved and which doctors are accredited. If the medical device requires new dexterity skills from doctors, then training requirements to address the learning curve and accredit doctors should be stipulated.

**Step 4a:** Details the business case analysis. The CED scheme requirements, scope and parameters which should include the management of the confounding factors and estimation of the duration of the CED study based on step 3 above are analysed through the financial feasibility lens and. The financial analysis takes into consideration; the CED scheme estimated funding costs based on duration versus funder proposed price under the CED scheme analysed against and the market size and proposed price after CED scheme. If the analysis is positive, then CED scheme study design should go ahead in step 5.

**Step 4b:** Details the iterative process to allow for negotiation based on financial constraints, processes for managing confounding factors, the scope and parameters of study. New additions would require changes to actions identified in step 3 above, and the process resumes to the next steps.

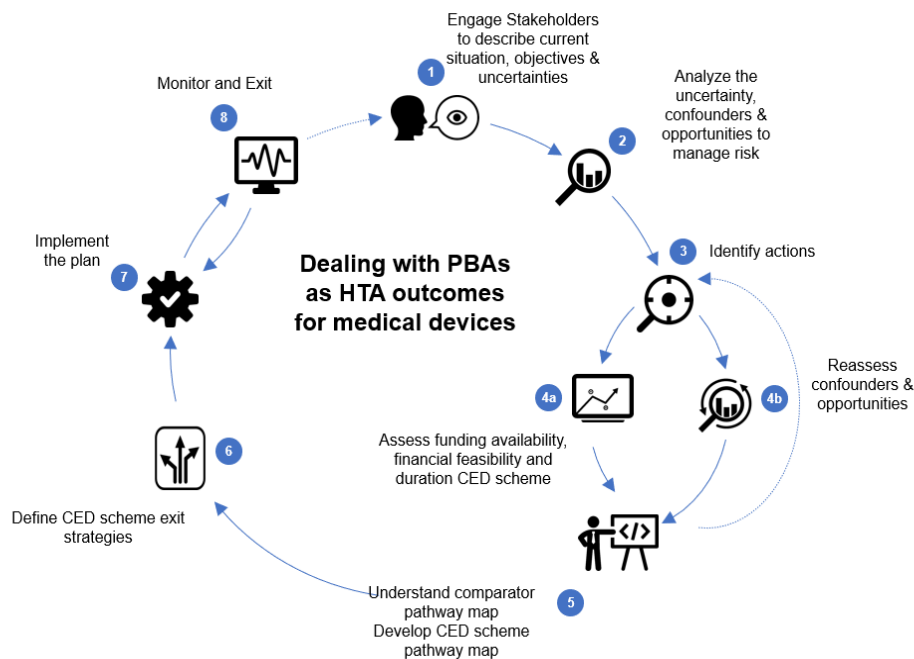
**Step 5:** The CED scheme pathway is designed with due consideration of the comparator product. In this step, the costs of both products and their clinical pathways maps are mapped against each other as described by Haasnoot et al., (2013) in figure 1 adaptation pathways map.

**Step 6** This step involves the documentation of the exit strategies for the CED scheme. The financial risks of stakeholders are linked to profit and loss and these are linked to the uncertainty performance outcomes being measured. A sliding scale mechanism for linking performance to PNL is suggested to be fair to all parties as the outcomes will not be a black or white scale. This documentation should be legally binding with payback mechanisms in place.

**Step 7:** The implementation of the CED scheme commences and should include monitoring to manage evidence generation issues.

**Step 8:** Once the required numbers are achieved, an analysis of results is performed together with the required negotiations and as per previously agreed mechanisms of equating health outcomes to profit or loss. This step marks the exiting point of the CED scheme.

**Figure 9: Dealing with Performance Based Agreements as HTA outcomes for medical devices**



Source: Adapted from Haasnoot, M., Kwakkel, J. H., Walker, W. E., & ter Maat, J. (2013). Dynamic adaptive policy pathways: A method for crafting robust decisions for a deeply uncertain world. *Global Environmental Change*, 23(2), 485-498. p. 489.

### 7.3. Principal Findings

#### 7.3.1. Research Question 1: What are the Factors Considered in Implementing CED Studies for Medical Devices?

The research established that CED studies are required when there is an uncertainty related to clinical or economic outcomes of the medical device. Most participants agreed that the disruptive nature of a medical device is a big factor in leading to CED studies. The contextual nature of HTA can influence HTA outcomes and is related to inputs in clinical

pathways and the costing of those inputs. These inputs need to be adapted to the country relevant context, including the related pricing prior to incorporation into the selected health economics tool. The understanding of the current standard level of care is required for use as a comparator. Further, the in-depth knowledge of the disease treatment pathway and medical device offering enables improved grasp of the uncertainty. The country demographic and epidemiological profiles can be a factor in the request for a local study, however current practice makes a distinction on the factors leading to the requirement of a CED study.

The framing of uncertainty and ensuring that medical device companies understand the knowledge gap is crucial in ensuring successful CED schemes. Stakeholder engagement to understand the uncertainty is the key to success, together with the management of the different stakeholders involved. The uncertainty should be documented and whenever possible so should expected outcomes. In a country such as South Africa, which is majorly an importer of medical devices, the existing study design and protocol should be used to expressed uncertainty. The protocol should be used to document study end points and set the scope and parameters of the study so as to manage the various possible confounding factors. The documentation control of the protocol is important as it moves through various stakeholders to ensure that changes do not change study end points or add unnecessary data collection requirements.

Stakeholders have different interests; thus, conflicts may arise and should be managed. The LC should be addressed through training to eliminate it as a possible risk to CED study outcomes as the CED scheme should ideally use doctors who are proficient. Any possible confounders that cannot be eliminated should be identified and, when possible, measured and accounted for in the analysis of results. Any obvious confounding factors, including the LC when there is evidence of improvement should be taken into consideration during CED scheme outcomes analysis. A sliding scale related to cost-effectiveness is proposed as ideal. The financial feasibility of the CED scheme should be checked and when necessary, negotiations with funders should be done to minimise financial risks. Exit strategies should be defined and agreed with outcomes linked to financial indicators. Actions should be taken to minimise the financial risks of all stakeholders involved and, whenever possible, these should be documented in a legally binding agreement.

All the activities to explicitly state the uncertainties, agree on outcomes or clinical end-points including the participatory engagement of stakeholders to identify confounders and means to manage them can be governed by use of dynamic adaptive policy pathways. The execution of CED schemes can be managed through using adoptive pathways maps to guide decision making and course of action, as well as to identify the triggers that signal the adoption of an alternative approach as part of feedback on when current methods are either ineffective or insufficient.

Bosomworth and Gaillard (2019) encouraged the use of a participatory approach to ensure that the understanding of the uncertainty is clear across all stakeholders and a planning method is designed that will guide the CED scheme pathway planning. This PBA plan is based on Haasnoot et al., (2013) dynamic adaptive policy planning and acts as a project management plan to define goals and objectives, risks, and possible actions in risk management. Reckers-Droog et al., (2020) identified the lack of governance and project management as one of various challenges in implementing CED schemes.

### 7.3.2. Research Question 2: What are the Funding Considerations for CED Studies?

Funding CED schemes continues to be a challenge for medical devices. In France, the issue of funding CED schemes was ineffective five years into policy adoption, where medical devices suppliers were submitting applications and conducting CED studies, however no reimbursement decisions were taken (Martelli, van den Brink & Borget, 2016). Funding CED schemes should preferably be done by independent entities, as the conflict of interest, which can bias study outcomes, lead to questions on the reliability of evidence generated.

The characteristic features of medical devices including the learning curve (LC) and their cost-effectiveness dependency on adoption into routine use and economies of scale pose a challenge in assessing them through CED studies. There are proposals for dynamic pricing both in literature and from the participants. CED studies can go on for extended lengths of time depending on device, the number of hospitals approved and doctors accredited to use them, this in turn affects the financial feasibility of the CED scheme. Tarricone et al., (2017) promoted a considered approach to financing CED studies encouraging that the costs of CED studies to be measured. CED scheme exit strategies

need to be defined and the possibility of public debates and fall outs can be managed with transparency (Recker-Droog et al., 2020).

### 7.3.3. Research Question 3: What are the Factors that Influence Implementation of Alternative PBRsAs?

In PBRsAs, Participant P7 defined the risk being managed as the risk to profitability and as such, activities that maximise profitability will be preferred over those that bring lesser income by all stakeholders. Doctors are critical stakeholders whose buy in is required and can hinder effectiveness of PBRsAs in practice. The financial considerations for doctors should not be undermined as all stakeholders will choose activities to maximise earning potential. The implication is that in efforts to minimise budget impacts defection is the default route, however it results in inefficiency.

Although PBAs including CEDs have historically been viewed as progressive, they have been found to be ineffective and plagued by exorbitant costs that result in reluctance of their implementation. Medical device PBAs are characterised by additional features that add to these challenges and the lack of patent protective mechanisms is a disincentive for manufacturers to engage in them. PBRsAs are complex to set up; issues relating to agreement on SMART goals are highlighted by participants and in literature. The monitoring of PBRsAs is inundated with more challenges related to public image perception of various stakeholders. Doctors are a path dependency to collecting clinical evidence and there are serious challenges in the level and quality of evidence collected. Further, doctors have personal professional reasons in wanting to hold on to their role as custodians of patients and their clinical information. There are fears of policing clinical decision making and medico-legal risks when faults are found through evidence, further doctors stand to forfeit more of their power as suppliers in the industry structure.

## 7.4. New Findings

Whilst there is evidence found in the literature review that the risk of PBA is majorly a financial budget risk, risk is not defined across most HTA agencies in Europe (Ferrario et al., 2017). The mechanism of operationalising the financial risk as a PNL model is finding that the researcher has not come across. Participant P7 stated that all stakeholders are

risk managing for profitability. The consideration from the researcher is that the stakeholders' decision-making framework is based on Game Theory. The current environment shows evidence of non-collaborative repeated games with incomplete information sharing resulting in inefficiency.

Considering that the stakeholders have a common interest of providing quality patient care, that is valuable and that the stakeholders themselves are not direct competitors, the researcher proposes a collaborative approach to decision making that is founded in transparency. Transparency and information asymmetry are highlighted as challenges in literature and in research findings, resulting in decision making by stakeholders that is non-collaborative, utilising incomplete information. Game theory could explain the ineffectiveness of PBA as non-collaborative decision making with incomplete information generally leads to a prisoner's dilemma. A consideration of mutual shared risk in funding and in profit sharing utilising the Shapley value to measure marginal contributions thus sharing in gains and losses could perhaps overcome a number of challenges without contravening competition laws.

The hospital environment was raised by participants as being important for medical device manufacturers. Participant P6 stated that the hospital as a stakeholder and the medical device is used in their environment and their buy-in is required to have the CED studies conducted in their environment. The medical device should meet the value definition by Yu et al., (2017) for hospitals. Further, participant P5 and P9 highlighted that the hospital environment could impact CED study outcomes. A stakeholder management theoretical lens is suggested as a future study recommendation on the investigation of CED schemes from the perspective of other stakeholders like doctors and this research should include hospitals as an important stakeholder.

## **7.5. Implications for Management and other Relevant Stakeholders**

The research highlighted the need to test the feasibility and cost-effectiveness of conducting the PBAs, as well as the need for a positive promising benefit as the starting point. Medical device manufacturers whose products actually deliver better health outcomes in real life should be encouraged to fund PBAs with outcomes of studies used as a competitive advantage and a price negotiation tool. The establishment and use of

independent reviewers and monitors will facilitate the acceptance of evidence by stakeholders and should be utilised when available.

South Africa, whether through the recommendations of the HMI or through NHI, has ambitious goals and the research findings highlighted the difficulties that should be expected in implementation, with current literature not encouraging some of the policy goals at all, having found them ineffective. The costs of PBRsAs are high and these types of MEAs should ideally be for life saving medical devices, as current research indicates that health outcomes performance-based reimbursement policy ambitions are not yet a viable option. Finally, healthcare is a CAS and this can pose a challenge to political career ambitions, making it difficult to implement system wide changes if the quality levels of healthcare are not first improved as perceived by patients.

## **7.6. Limitations of the Research**

The contextual and highly evolving nature of HTA limits the replicability of the research although the research findings are also similar to findings in literature. The structural elements of the healthcare industry could potentially prohibit replicability unless there are high similarities in the industry analysis, including the regulatory and financing of health landscapes. The model that combines the adaptive policy and adaptive pathways map as a project management planning process can however be replicated and adjusted based on case scenarios. The sample population represents a niche market in South Africa with ties to global companies, limiting the number of local medical devices manufacturer involvement. However, considering that the market is a 90% import market, the impact of sample is insignificant.

The research questions did not include the exit strategies, owing to the knowledge that the adoption and implementation of PBA is still in its infancy in South Africa and as such the few funders that offer this opportunity are viewed as pioneers. The patient knowledge of the opportunities medical devices offer as therapies is under developed, resulting in limited patient advocacy and posing little threat of igniting public debate. Hospital management however, as highlighted by participant P11, needs to have strong governance structures and mechanisms to limit their financial investment risk exposure, especially when it comes to capital equipment.

Neither clinical societies, nor doctors as healthcare providers who are cited as high contributors to lack of available quality evidence data, are included in the research. Understanding the challenges, they face can go a long way in addressing them in efforts to overcoming the ineffectiveness of PBA. The adoption of EHR by doctors, which has been cited as an infrastructural barrier to health outcomes evidence collection and long-term outcomes, has not been researched.

### **7.7. Suggestions for Future Research**

The impact of stakeholders like doctors, hospitals and patients on the effectiveness of CED schemes using stakeholder management theory is suggested and should include an analysis of the power dynamics between industry players. Patient advocacy groups can be approached as representatives of patients.

Studies looking into the management of exit strategies of PBAs, whilst a few articles were identified in literature that raised the difficulties in exiting CED studies and the public image risk it poses, exit strategies were not included in the scope of research. Participant P11 raised the need to have legally binding exit strategies especially for capital equipment CED schemes as high investments are required from the hospital as a stakeholder. Participants P5 and P9 raised the payback mechanisms clauses as requirements for exiting CED schemes.

Studies that look to review whether public health payers and medical device manufacturers are more collaborative in funding PBAs and risk management processes to split the costs versus profits employed could shed light on the feasibility of using the Shapley value for decision making on conducting PBAs.

The adoption of EHR by doctors and the opportunities or barriers it poses to implementing performance-based reimbursement systems should be studied. EHR systems are suggested as one of the avenues to improve evidence collection by doctors, however low adoption may pose a risk.

Studies to evaluate the attitudes of doctors towards performance-linked reimbursement.

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## Appendices

## Appendix 1: Ethical Clearance Approvals GIBS and UP



04 October 2019

Anele Vutha

Dear Anele

*Please be advised that your application for Ethical Clearance has been approved subject to the following conditions.:*

Please note that as this topic is related to Health Sciences, it will require Ethics approval from main campus Health Sciences Research Ethics Committee as well as GIBS approval

*Please put a detailed cover page of the amendment you have made and also page numbers of this amendment.*

*Once you have made this minor amendment and submitted the changes on Aspire, you will be allowed to continue collecting your data when your resubmission has been approved.*

*We wish you everything of the best for the rest of the project.*

Kind Regards

GIBS MBA Research Ethical Clearance Committee



UNIVERSITEIT VAN PRETORIA  
UNIVERSITY OF PRETORIA  
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

- FWA 00002567, Approved did 22 May 2002 and Expires 03/26/2022.
- IRB 0000 2235 ICRG0001782 Approved did 22/04/2014 and Expires 03/14/2020.

3/02/2020

### Endorsement Notice

**Ethics Reference No: 758/2019**

**Title:** GIBS: Dealing with performance-based health technology assessment outcomes for medical devices: A South African perspective.

Dear Mrs AZ Vutha

The **New Application** as described in your documents specified in your cover letter dated 21/10/2019 received on 21/10/2019 was approved by the Faculty of Health Sciences Research Ethics Committee on its quorate meeting of 20/01/2020.

Please note the following about your ethics approval:

- Please remember to use your protocol number **758/2019** on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

**Ethics approval is subject to the following:**

- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

**Dr R Sommers; MBChB; MMed (Int); MPharm, PhD**

**Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria**

*The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health).*

Research Ethics Committee  
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Fakulteit Gesondheidswetenskappe  
Lefapha la Dihalefi tsa Maphelo

## Appendix 2: Data Collection Matrix

| Research Questions                                                                                                          | Literature review                                                                                                                                                                                                                              | Data collection tools      | Analysis technique                                  |
|-----------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|-----------------------------------------------------|
| <b>RS1:</b><br>What are the factors considered in implementing CED studies for medical devices?                             | Adaptive Planning (AP) in the context of HTA.<br>Coverage with Evidence Development (CED).<br><br>Bosomworth and Gaillard (2019); Reckers-Droog et al., 2020; Tarricone et al., 2017; Craig et al., 2015; Chapman, Taylor, and Girling, (2014) | Semi-structured interviews | Qualitative Analysis.<br><br>Thematic codification. |
| <b>RS2:</b><br>What are the funding considerations for CED studies?                                                         | Funding of CED studies for Medical Devices<br><br>Reckers-Droog et al., (2020); Dabbous et al., (2020); (Tarricone, Torbica, Drummond, 2017).                                                                                                  | Semi-structured interviews | Qualitative Analysis.<br><br>Thematic codification. |
| <b>RS3:</b><br>What are the factors that influence implementation of alternative performance-based risk-sharing agreements? | Adaptive Planning (AP) in the context of HTA.<br>Implementation of Alternative Performance-Based Risk-Sharing Agreements (PBRsAs).<br><br>Dabbaous et al., (2020); Bosomworth and Gaillard (2019); Nazareth et al., (2017)                     | Semi-structured interviews | Qualitative Analysis.<br><br>Thematic codification. |

Source: Author's Own

## Appendix 3: Informed Consent and Interview Guide

PIC 4:

University of Pretoria Ethics Reference No: 758/2019

### **PARTICIPANT'S INFORMATION CONSENT DOCUMENT FOR SEMI-STRUCTURED INTERVIEW**

**Researcher's name: Anele Zukiswa Vutha**

**Student Number: 18398112**

**Department of: Masters in Business Administration - External (GIBS)**

**University of Pretoria: Gordon Institute of Business Science**

### **TITLE OF STUDY**

**Dealing with performance-based health technology assessment outcomes for medical devices: A South African perspective.**

Dear Participant

I am currently a student at the University of Pretoria's Gordon Institute of Business Science and completing my research in partial fulfilment of an MBA. You are invited to volunteer to participate in our research project on **Dealing with performance-based health technology assessment outcomes for medical devices: A South African perspective.**

This letter gives information to help you to decide if you want to take part in this study. Before you agree you should fully understand what is involved. If you do not understand the information or have any other questions, do not hesitate to ask. You should not agree to take part unless you are completely happy about what we expect of you.

The purpose of the study is to conduct research on Health Technology Assessment (HTA) outcomes specifically the coverage with evidence development (CED) studies in medical devices and when performance-based risk-sharing agreements (PBRsAs) are considered as a suitable HTA outcome for medical devices. The proposed research will help gain understanding on the management of the practical implementation challenges of these HTA outcomes, from design to funding. The insights gained could be useful in policy formulation for national health technology assessment.

The interview is expected to last about 45 – 60 minutes, and will help us understand how the South African healthcare system is managing HTA outcomes for medical devices that require real-world data to prove their clinical performance outcomes. Through this interview process, the researcher hopes to get an understanding of the management of complexities related to implementing performance-based reimbursement outcome requirements in medical devices.

The Research Ethics Committee of the University of Pretoria, Faculty of Health Sciences, telephone numbers 012 3541677 / 012 3541330 granted written approval for this study under Ethics Reference No: 758/2019.

**Your participation in this study is voluntary. You can refuse to participate or stop at any time without giving any reason. Consent is requested for data recording for further analysis.** All data will be kept confidential and no source, individual or organisation, will be identified in the text of the final report. With your permission, our interview will be transcribed for purposes of analysis, however, no direct attribution will be made to you by name. All data will be stored without identifiers to preserve confidentiality. As an indication of consent please sign below.

**Note: The implication of completing the interview is that informed consent has been obtained from you. Thus, any information derived from your participation (which will be totally confidential) may be used for e.g. publication, by the researchers.**

We sincerely appreciate your help.

Yours truly,

**Anele Zukiswa Vutha**

**Participant's & interview details**

|                  |                              |                            |
|------------------|------------------------------|----------------------------|
| <b>Name:</b>     | <b>Title:</b>                | <b>Organization:</b>       |
| <b>Location:</b> | <b>Interview start time:</b> | <b>Interview end time:</b> |

Participant's signature: \_\_\_\_\_ Researcher  
signature: \_\_\_\_\_

Researcher: Anele Vutha

Phone: 083 345 3044

Email: [18398112@mygibs.co.za](mailto:18398112@mygibs.co.za)

Research Supervisor: Colin Rowley

Phone: 082 858 5413

Email: [colinrowley@vodamail.co.za](mailto:colinrowley@vodamail.co.za)

## Interview Schedule

### Key Construct A: Coverage with evidence development (CED)

CED is a type of conditional reimbursement approval or health technology assessment (HTA) outcome where payers agree to pay for the medical technology at a price point that is below the proposed price by the manufacturers (Brugger, 2014). This initial price is conditional upon the gathering of real-world evidence with the intention of resolving the uncertainties identified in the initial HTA (Nazareth et al., 2017). The clinical outcomes achieved by the medical device in the real world are evaluated to give the final HTA outcome (Carlson, Sullivan, Garrison, Neumann, & Veenstra, 2010).

### Key Construct B: Performance-based risk-sharing agreements (PBRsAs)

PBRsAs are contracting arrangements where payers contract with medical technology manufacturers to link value-based payment to real-world performance outcomes, the level of payment is related to the real-world health outcomes achieved (Nazareth et al., 2017).

#### Research Question 1

#### Notes to Researcher

#### What are the factors considered in implementing CED studies for medical devices?

1. What results in the requirement of CED as an outcome of HTA for medical devices?
2. What is the influence of local data as a requirement in CED as an outcome of HTA in medical devices? *Local data is clinical evidence generated utilising country specific data.*
3. What is the process of ensuring that the uncertainties that necessitated the CED study are incorporated into the study design?
4. What type of measures are implemented to manage the confounding factors (for example patient selection, disease stage, bias) that could influence CED study outcomes managed? *Confounding factors are those that can obscure the performance outcomes of the CED study, whether positively or negatively.*

5. What processes are implemented to account for the user-dependent learning curve in the medical devices and how it may influence CED study outcomes? *Learning curve is the physician's proficiency at utilising the new medical device which is improved at an incremental rate with increasing use until it reaches steady state.*
6. What is the effect of a partial reimbursement on health technology acceptance and use or market penetration?

### **Research Question 2**

#### **What are the funding considerations for CED studies?**

7. Who is responsible for funding CED studies?
8. What are the challenges in funding CED studies?
9. How long do CED studies typically last for?
10. When should funding for CED studies be shared?

### **Research Question 3**

#### **What are the factors that influence implementation of alternative performance-based risk-sharing agreements?**

11. When are different types of PBRsAs a suitable consideration as a HTA outcome? *What influences whether the HTA outcome is a CED or PBRsAs?*
12. Discuss the key considerations and critical parameters in implementing PBRsAs
13. Describe the benefits of implementing PBRsAs in medical devices?
14. What are the challenges in implementing PBRsAs in medical devices?
15. How is the cost impact of implementing, managing and monitoring PBRsAs managed?

***Do you have any other points that you deem important for consideration?***

## Appendix 4: Code List

| Participant | Theme                      | Second Level Analysis                                                         | First level Analysis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------|----------------------------|-------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| P1          |                            |                                                                               | It might be more of on the clinical evidence that you already have, but we want to have more information on the claims that you make.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|             | Evidence Requirements      | Information gap on existing evidence                                          | So, if we then consider what would call for one to generate further evidence prior market entry with a conditional reimbursement it would basically be lack of certain information or high-level information.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| P4          | Evidence Requirements      | Patient safety                                                                | So that's something we also have to look at. the other is patient safety.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| P9          | Evidence Requirements      | Safety & Efficacy compared to current STD                                     | There were also some questions around the safety and efficacy compared to standardised care                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| P6          | Evidence Requirements      | Safety & Efficacy                                                             | There is two components to it, the first component would be is the health technology safe, ethical and clinically effective.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| P7          | Evidence Requirements      | Safety & Efficacy                                                             | The first thing they look at is empirical evidence of efficacy and safety like you would find in pharmaceuticals and the more invasive the technology is, the more they will insist on this.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| P13         | Evidence Requirements      | Efficacy                                                                      | once that evaluation is done and it comes back to say it's lacking in efficacy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| P9          | Evidence Requirements      | Pricing compared to comparators                                               | The second part of it would have been a pricing component, which would have been who are the comparators in the market, how do you compare to them, are you way above their pricing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| P7          | Evidence Requirements      | Budget Impact? Is there a cost saving?                                        | The second thing is usually budget, budget impact and as you know it's the traditional budget impact question in terms of towards what extent would this extend our budget?                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| P5          | Evidence Requirements      | Premium Price compared to benchmark                                           | Is there a cost saving.<br>So, you then have to prove that you are legible for the premium compared to what the current benchmark looks like                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| P4          | Evidence Requirements      | Cost                                                                          | One is cost                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| P2          | Evidence Requirements      | Premium Price                                                                 | It may be new technology, which you could be asking a premium price.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| P1          | Evidence Requirements      | Price & Affordability                                                         | Another factor, it could be issues related to pricing.<br>You've got the best clinical evidence for your technology but then when you look at the price and affordability in the context of South Africa.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| P13         | Evidence Requirements      | Price point                                                                   | Or we can't justify the price point etc.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| P11         | Evidence Requirements      | Coss-effectiveness                                                            | Or at least the same, and then I guess cost effectiveness.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| P10         | Evidence Requirements      | RCT                                                                           | So, is it the same or has better outcomes? Is it affordable?                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| P3          | Evidence Requirements      | Pharmaceutical Methods                                                        | looking for RCT (Randomized Controlled Trial) studies, so that's the first criteria.<br>so currently in my opinion from my experience that I have had with funders is that they are very focused on pharmaceutical methodology                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| P1          | Evidence Requirements      | RCT                                                                           | There is a certain level of evidence that they would look at, which is mostly in pharmaceuticals. We know that randomised clinical trials are like the gold standard. "<br>And when it comes to medical devices we're shifting that thinking of always having the idea that the gold standard should always be the same as in the pharmaceutical space, because of the nature of the technology. Wherein from an ethics point of view you may not even be allowed to do randomised clinical trials in the medical device space. .                                                                                                                                                                                                                                                                                                                                                                                                                              |
| P2          | Evidence Requirements      | Novel Technology                                                              | It could be novel new technology that has not been used in this space before                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| P5          | Evidence Requirements      | Superior Claim for breakthrough                                               | It is usually if the supplier makes a claim that my product is superior.<br>It's a new technology. Superior to the existing, it's like a breakthrough                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| P4          | Evidence Requirements      | Breakthrough Technology                                                       | I think the one thing that I've noticed in a lot of new technology, and by new I mean disruptive technologies. the other thing with disruptive technology is that it upsets what the current norm would be and in a lot of cases the norm would be, let's say for instance it's going to be normal surgery versus minimal invasive surgery.<br>Now, to do minimal invasive surgery the equipment would normally be much more expensive, but the recovery rate would be a lot quicker. So the funder for example would say, ok this is a lot more expensive than what we normally pay for a procedure. But then you have to prove to them that because this patient doesn't have to go to ICU, it could be a day procedure versus a normal theatre procedure where the patient has to go to ICU, because all those things are a cost, and then you have to prove obviously that ok you claim that this is what's happening but now we want to see it in action. |
| P3          | Evidence Requirements      | Level of evidence in MDs                                                      | So, which is really difficult because a majority of medical devices don't have that level of information. Or level of evidence available to them and it's only much later in a phase of technology where it then becomes available.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| P1          | Evidence Requirements      | Size of study not sufficient                                                  | The second is, it's the quality of your data that you would have been providing with clinical evidence. Or the size of the study or the number of people that were involved in the study is not sufficient enough to meet a specific criteria.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| P5          | Evidence Requirements      | Level of evidence in MDs                                                      | Maybe longer term data and for me I think that's a big gap, because there often are companies that come with very limited data and they want to use some sort of pilot programme and there's not any real level of comfort from that point                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| P6          | Evidence Requirements      | Promising Evidence                                                            | Ideally there needs to be some level of evidence that we're comfortable with, so it's human trialled, it's well designed, but there maybe some element that's missing.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| P4          | HTA Localization           | Costs of Specialist & Theatre time                                            | Ok, specific to South Africa now I find that our data versus European or American data is very different, because we measure a lot more than what they do.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| P10         | HTA Localization           | Local cost per event                                                          | In our private sector for instance theatre time gets measured, you measure the anaesthetist cost, which I think the equation is every 15 minutes the price goes up<br>Then they go to the cost per event.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| P1          | HTA Inputs or Localization | Localization input costs per event. Converted into country costs and currency | So, basically the cost of an event. So you put those as your input into that economic tool, then you can say ok conventionally I'm treating with XYZ but with the new Medical device treatment I don't need two gastroenterologists, I only need one, I don't even need a scrub nurse and so forth. So you look at and compare the inputs for the health economics tool, which are specific for South Africa and costed at the rate of South Africa, which will be a different costing if for example they would have been in Germany. Meaning, cost per minute theatre time in Germany might be R120.00, but in South Africa you might find out it is R85.00. So, all these costs they always need them to be localised and they have a huge influence in terms of affecting the decision that is going to be made by the funder unlike if you didn't have.                                                                                                   |
| P1          | No need for local data     | Local data is not a big influence                                             | At this point in time local data in South Africa is not that big in terms of generating data to influence reimbursement, generating extra clinical evidence to influence reimbursement. However, it becomes more relevant and more ideal to use whatever tool that you might have had as part of your reimbursement tool to support your device entry into the market, that specific tool must have input for South Africa.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

|     |                              |                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----|------------------------------|---------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| P2  | No need for local data       | Leverage International data to build a case for local                                             | Because I believe that you can leverage off the data that has been collected based on outcomes internationally to be able to build a case for local. I don't think it's essential in terms of every product that you put forward a case for reimbursement for.                                                                                                                                                                                 |
| P6  | No need for local data       | Local Data not a necessary requirement                                                            | So it there's a big international trial then we don't ask that South Africa is a part of it So if we are only dealing with evidence development, so we're acknowledging that there's some gap in the data. Therefore in that case we'd need local data, because often if you're very comfortable with the clinical evidence then we accept that there might be limitations when it comes to including South Africa.                            |
| P10 | No need for local data       | No requests for local data, it is all international                                               | We haven't had much requests for local data. I think, because they know that there are no resources to compile the local data. We haven't had that. I've never had one submission, where they ask me for local data. It's all international data in the country of origin or they refer to training centres in the US or in Europe                                                                                                             |
| P7  | No clear stand on local data | No clear stand on requirements related to local data                                              | Then the converse to that is, you come with local data showing efficacy, safety and budget impact as well as neutrality and whatever cost saving then they will say No, international evidence doesn't show this.                                                                                                                                                                                                                              |
| P12 | No need for local data       | Local Data not necessary, world wide guidelines used                                              | This doesn't comply with international evidence, so what I'm seeing is that some funders will play this thing according to the outcome they want                                                                                                                                                                                                                                                                                               |
| P11 | Local Data is Important      | Issue of EHR in Local Data Collection                                                             | If there are world wide guidelines that have been proven to be working, then there would be no need for local data, we could just extrapolate that.                                                                                                                                                                                                                                                                                            |
| P2  | Local Data is Important      | Local data is important depending on product                                                      | I think the challenge in South Africa particularly is that we don't have electronic records, so the local data that we've got, the data that we collect is not sufficient to actually measure clinical outcomes.                                                                                                                                                                                                                               |
| P5  | Local Data is Important      | Demographics make local data important                                                            | I think that local data is important depending on the product.                                                                                                                                                                                                                                                                                                                                                                                 |
| P7  | Local Data is Important      | Push back is need for local data                                                                  | So, most of the time you find that the products are studied internationally and the demographics are not the same. So, sometimes the funders will claim that if you use the local samples the outcome might be different to what has already been studied. It is always best to have the outcome based within your local environment.                                                                                                          |
| P11 | Local Data is Important      | In theory, local data is the way to go                                                            | When there's international evidence that shows efficacy and safety and budget impact benefits and everything you want, the push back from funders will be this is foreign data, we need local data                                                                                                                                                                                                                                             |
| P12 | Local Data is Important      | Local data is important, but it's difficult to get local data, because we don't have the numbers. | I think in theory real world evidence and registries and the local data that we collect is definitely the way to go.                                                                                                                                                                                                                                                                                                                           |
| P13 | Local Data is Important      | Local Data Important but not a requirement                                                        | So to me, the influence of local data is very important                                                                                                                                                                                                                                                                                                                                                                                        |
| P5  | Demographic Profiles         | Demographic disease profile                                                                       | So, as much as you can say well look at the European data let's extrapolate that for South Africa. It's not the same. The pragmatics and logistics behind getting local data, I think is where the issue comes in. So, local data is important, but it's difficult to get local data, because we don't have the numbers.                                                                                                                       |
| P13 | Local Data is Important      | Unique population, local data                                                                     | I think it's very important because we can never really transpose anything from Europe or the US onto our population. I do find that it's usually questioned by the funders as maybe not being as vigorous.                                                                                                                                                                                                                                    |
| P6  | Demographic Profiles         | Population Epidemiological profile                                                                | You take for instance thyroid is more prevalent in Black female societies and that has been proven. So that is why sometimes they have that notion that yes they will accept your international studies.                                                                                                                                                                                                                                       |
| P12 | Demographic Profiles         | Patient responses                                                                                 | With the uniqueness of our population, I think that local data is the best                                                                                                                                                                                                                                                                                                                                                                     |
| P9  | Demographic Profiles         | Population disease profile considerations                                                         | If we know for sure that the outcomes are different, so for instance if there was a product that was used internationally and we know that it's likely to be very different in our world, because of factors like HIV then we may want to ask if the outcomes are different for us. But, we differentiate the two. So, we may have a funding policy where we say let's see if it's different in the South African context.                     |
| P1  | Framing Uncertainty          | Uncertainty stated in Study Protocol Design                                                       | But, I think when the problem comes in is when patients respond differently to certain types of devices. That's when you'd need local data.                                                                                                                                                                                                                                                                                                    |
| P2  | Framing Uncertainty          | Study design based on uncertainty                                                                 | So, I think the funders are becoming more stringent in pushing for local data in the South African environment, because remember in this environment you have a diverse population, there are factors like HIV related diseases, so the profile of the population might be different to the profile of the population in Europe for example. I think local data is extremely relevant.                                                         |
| P3  | Framing Uncertainty          | Engage with Stakeholders                                                                          | Because you also pick up nuances in terms of what's happening in the South African environment. For me, I think local data is very important.                                                                                                                                                                                                                                                                                                  |
| P5  | Framing Uncertainty          | Engage with Stakeholders                                                                          | What is good is that you could use the local data to compare against what's happening globally. So, for example for a hip implant these guys have said to us that globally they know that their revision rates are 2% and it's good to see that in the South African market, the revision rates are also similar.                                                                                                                              |
| P7  | Framing Uncertainty          | Engage with Stakeholders                                                                          | So already you already have the protocol in terms of if you want to further generate data in relation to this device or this technology depending on what your primary and secondary endpoints are. You would then adapt the protocol that is already in existence. You will only focus entirely on what you want to achieve based on your primary or secondary endpoint and the key determinant is the protocol that is already in existence. |
| P2  | Framing Uncertainty          | Engage with Funder                                                                                | So, you literally just adopt the protocol and then you obviously shape it to your current need in the country, because the main objective is proving that the technology does what you say it does.                                                                                                                                                                                                                                            |
| P3  | Framing Uncertainty          | Meetings to engage with Funder                                                                    | If you understand the uncertainties then you ensure that your study design meets those uncertainties.                                                                                                                                                                                                                                                                                                                                          |
| P12 | Framing Uncertainty          | Outcome Focused                                                                                   | I've had a consensus approach with all the different role players and then the final consensus would come from Discovery.                                                                                                                                                                                                                                                                                                                      |
|     |                              |                                                                                                   | Locally another thing is that you have to get the buy-in of the professional doctors. The buy-in of the hospitals. Buy-in of the patients.                                                                                                                                                                                                                                                                                                     |
|     |                              |                                                                                                   | Try to include as many stakeholders as possible. When you get them involved in the study it builds credibility and rapport and it's just generally a smart way of doing business. That is the first point. The third one is to include Key Opinion Leaders (KOLs) immediately, so use your clinical KOLs and get them on board in terms of the design of your study, the publication of your study, and the presentation of your study.        |
|     |                              |                                                                                                   | But what you want to do is to engage upfront with the funder, this is absolutely essential                                                                                                                                                                                                                                                                                                                                                     |
|     |                              |                                                                                                   | Yes, because there is definitely no formal process. So, my experience with the one that we're putting together is that I had meetings with them.                                                                                                                                                                                                                                                                                               |
|     |                              |                                                                                                   | I think you need to know what your outcome must be to incorporate those patients.                                                                                                                                                                                                                                                                                                                                                              |

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| P2  | Framing Uncertainty         | Outcome Focused                                                                    | The outcomes of the study should meet the requirements in terms of what they're looking for.                                                                                                                                                                                                                                                                                                                                                      |
| P4, | Framing Uncertainty         | Mutual Agreement using a form                                                      | I think it should be a mutually agreed upon evaluation form that needs to measure everything that is important for both the funder and the supplier, and a record of this has to be kept. This then is a record of not just the actual procedure to happen, but pre-operative, operative and post operative. So, everything gets measured.                                                                                                        |
| P5  | Framing Uncertainty         | Physician buy in to understand uncertainty                                         | So, in order to prevent this and to give the physicians time to make sure that this is actually a study, because the physicians need to keep data, they need to follow up, they need to get the patients' buy-in, they need the patients to keep coming for whatever check ups they need. In that way, once it has been formulated into a proper piloting then we can revert it to and the data has been kept specifically relating to the study. |
| P6  | Framing Uncertainty         | Uncertainty is specified upfront so gap is understood                              | So, I think the one thing that we are very clear of is that we do not run a clinical trial. We run a pilot programme where we measure primarily claimed outcomes. We try and integrate it with clinical information but it can somewhat be limited. all of that is specified upfront. So, the manufacturer understands where the gap is, what exactly we are looking for.                                                                         |
| P3  | Framing Uncertainty         | Document uncertainty                                                               | So, they have a document, which I can share with you but I'm sure they would also give it to you. So, this document they put together as a guide for when you do a pilot or something like that.                                                                                                                                                                                                                                                  |
| P2  | Framing Uncertainty         | Understand Therapeutic Area & Comparator                                           | Understand the therapeutic area. Also understand what the current sets of requirements are. The current treatment regimens available within that therapeutic area are.                                                                                                                                                                                                                                                                            |
| P2  | Framing Uncertainty         | Understand Product                                                                 | Firstly, you need to understand your product.                                                                                                                                                                                                                                                                                                                                                                                                     |
| P1  | Setting Scope and Parameter | Accounting for LC if it is evident                                                 | Then you can be able to argue with the payer and say that on average, clinically or practically you can see a little bit of a difference with that particular doctor. It's a learning curve and it should be accommodated as one.                                                                                                                                                                                                                 |
| P4  | Setting Scope and Parameter | Benchmark first phase cases versus next and last group & account for LC if evident | Let's say what I would do in hindsight to a previous study is that we're benchmarking the first 10 cases and the next 10 cases or something like that to take the learning curve out of the equation. Because in a lot of the times and I'm going to relate it back again. The first 10 cases took twice as long as the next 10 cases and obviously there's a cost to that. So yes, that's a very good question.                                  |
| P6  | Setting Scope and Parameter | International benchmark to determine cases required to overcome LC                 | So, I think we look to the technology company as well as any international experience to say what number of patients does a doctor perhaps need to do to be proficient in it.                                                                                                                                                                                                                                                                     |
| P13 | Setting Scope and Parameter | Accreditation Process to overcome LC                                               | So, the doctors who would be most proficient would be identified. There's usually an accreditation process, so the proctors would have to ascertain whether or not this particular doctor is proficient enough to do the procedure.                                                                                                                                                                                                               |
| P12 | Setting Scope and Parameter | Train through proctor to overcome LC                                               | I think it's very important that they need to be trained properly, so for me you have to have someone to proctor these surgeons.                                                                                                                                                                                                                                                                                                                  |
| P12 | Setting Scope and Parameter | Patient Selection & Qualifying Criteria                                            | So with patient selection you need to look at all those, not everyone must enter into the clinical trial.                                                                                                                                                                                                                                                                                                                                         |
| P4  | Setting Scope and Parameter | Disease stage Criteria, Patient Selection & Qualifying Criteria                    | So, it's really important to establish qualifying criteria beforehand. For instance I'm going to relate this to an example. What we did was, we had qualifying criteria where a person who had a particular disease had failed in previous treatment.                                                                                                                                                                                             |
| P2  | Setting Scope and Parameter | Patient Selection & Qualifying Criteria                                            | The product itself outlined what the entrance requirements would be for this study. We were absolutely clear at the outset that this product was not for all patients, hence we were able to set what those entrance requirements were.                                                                                                                                                                                                           |
| P6  | Setting Scope and Parameter | Patient Selection & Qualifying Criteria                                            | Most of the time we would have engaged with some sort of clinical society and they would have drafted up the patient selection criteria and all of that.                                                                                                                                                                                                                                                                                          |
| P5  | Setting Scope and Parameter | Doctor choice                                                                      | This is why there's the choice of the physicians.                                                                                                                                                                                                                                                                                                                                                                                                 |
| P1  | Setting Scope and Parameter | Protocol                                                                           | It all goes back to the protocol, because the protocol tells you. The assessor for reimbursement was also making such recommendations, but we quickly stated that they were both asking us to conduct an investigation in an area that is not our interest, nor is it our primary endpoint and ultimately is simply not what we want to prove.                                                                                                    |
| P12 | Setting Scope and Parameter | Patient Selection & Qualifying Criteria                                            | So with patient selection you need to look at all those, not everyone must enter into the clinical trial.                                                                                                                                                                                                                                                                                                                                         |
| P6  | Setting Scope and Parameter | Protocol                                                                           | So, there's almost a protocol that's drawn up prior.                                                                                                                                                                                                                                                                                                                                                                                              |
| P9  | Setting Scope and Parameter | Protocol to manage confounders                                                     | <b>There's a lot to consider, for example the confounding factors, you're right to say that you need to compare similar patient populations that would mean you are not doing the right comparison. All of those do influence CED study outcomes. It's important that the patient populations are comparable.</b>                                                                                                                                 |

| Participant | Theme                                  | Emerging Theme                                                                                                                                               | Direct Quotations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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| P1          | Financial and Profitability Management | Whose cost of doing business does CED fall under? Companies must meet investment requirements to enter market.                                               | <p>from a company point of view it is the responsibility of a company to fund a certain portion of the study. This is because, you're coming with your technology that you are wanting to enter the market with, but I as a funder am not convinced of what you are telling me based on clinical evidence and all the other health economics reimbursement information that you have is sufficient.</p> <p>So, why should I as a funder put up any money into what you are offering? So it then becomes a win-win situation. There are always negotiations between the two. And depending on whether you have the best negotiator in your company or not, because the funder might initially state that they are not going to fund at your proposed price and therefore it will depend at which level you are funded. But, if you are a small company and you've already invested enough money in R&amp;D (Research and Development) The biggest medical schemes say they can't fund unless you generate a certain level of evidence. And depending on how small you are to influence POLS (Physician Office Laboratories) to adopt your technology might also be a big challenge.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| P3          | Financial and Profitability Management | Willing to fund and take risk if there is agreement of price going up once claims are proven                                                                 | <p>So, if you are starting a CED then I think if the funders buy into it and the doctors buy into it and it's a real need, I think if there is current gold standard. If you can bring in a technology at the price of the gold standard for your trial and then you prove that you are better then there should be an agreement in the price going up. If there is no gold standard, I think there should be a negotiated process whereby everybody sticks to the agreement that there's no profit until proven.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| P7          | Financial and Profitability Management | CED studies are expensive companies should look into product portfolio and target growth markets                                                             | <p>Price. These are expensive studies and I'm specifically talking about South Africa, which is such a small market and it's actually a shrinking market. If you sit with a product portfolio that doesn't complement the bigger South African population and you don't really have a private and a public sector portfolio. You're in a big trouble, because you absolutely cannot afford to do these studies. Maybe the diagnostics guys are better off, they are strong in this, in certain diseases like diabetes, I think they're better off because they can fund it. I guess theoretically when there's a vested interest for both and I can't think what that vested interest for both would be, because the one wants to make money and the other one has to pay money. I think I'm going to stick to my original answer that the initial research should be funded by the supplier. I think maybe in the public sector yes, the department of health might have an incentive to co-fund something, but they don't have the budget. It's big markets, it's growing markets, diabetes is a big public health issue. So, I guess it's very dependent on the product portfolio</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| P2          | Financial and Profitability Management | Fragmented funder system increases cost to do different CED studies. Select profitable funders because of costs of CED                                       | <p>the current practice is that the company will be responsible for the cost associated with this study. This means that you are basically responsible for collating and presenting the data and the costs associated with it. Because if there are 5 to 7 key administrators, then you need to have 5 to 7 studies and you need to ensure that when you budget in terms of launching your product that you have generated the revenue to support those studies in the field. So, it becomes extremely onerous then for companies to be able to do and my sense is that companies will then start asking where do they put their money and which schemes do they go for. But right now it's being done in individual clusters in the private sector, which is problematic for companies, because if you think about it if the cost is approximately half a million Rands per administrator, then the company is most likely to simply choose the top 3 administrators and leave it at that.</p> <p>Which then impacts your penetration into other areas as well as access to your product in other schemes.</p> <p>But then if you select a private hospital, you have to work again with the HTA and reimbursement people of the groups to get their buy in. Because, they will not be impacted but it's still something that's going to happen in their hospitals. So, I'm not sure what their view will be. Again, I think it depends on the technology itself, and again if there's an additional cost let's say they have to buy a generator later on should this be approved. Then there will be a cost involved for all the private hospitals to offer this technology.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| P4          | Financial and Profitability Management | Supplier can fund study however protective mechanism to protect investment made on proving technology                                                        | <p>In my opinion, it might be the responsibility of the supplier to actually fund that, but in a lot of these cases what I think is going to really be the biggest risk is you've got really innovative companies like the Boston and various others who all have to foot the bill for getting these technologies into the market.</p> <p>and then you have all these Indian and Chinese competitors that once the market is in place, all they do is to jump in and they don't get to share in this cost and at the end of the day there's no benefit for a multi national that's innovative to really want to fund studies like this. What I'm trying to say is that, a company like ours will manufacture a new innovative stent technology, a company like ours would then have to fund the study, a company like ours would then have to create the market and then once it's proven, the only thing that's going to happen down the line is that some cheap Chinese stent will come in to the market and say, ok this technology has been proven, here's ours at half of the price and I don't think that's fair.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| P6          | Financial and Profitability Management | Risk to scheme                                                                                                                                               | I think there are a lot of uncertainties so it could increase the scheme risk without us knowing.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| P13         | Financial and Profitability Management | Loss of margin Feasibility of CED                                                                                                                            | Usually products that cause a loss of margin to market, other factors include the number of patients that can receive it. For example we did a projection on the project that we're working on and it looked like it would take 2 years for it to reach the outcome that was required. We actually went back to the funder and we told them that it's not feasible as it looked like we'd be doing this forever and at the end of it we were not sure what the benefit would be.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| P10         | Financial and Profitability Management | Patients already paying for medical insurance don't have capacity to co-pay. Focus is Cost                                                                   | <p>a patient doesn't have capacity additional to what they're already paying for their medical aid to cover the partial reimbursement that's not covered. So, to me that's also just a mechanism from the funder to make sure that they don't spend much on the technology. That's my opinion. Yes, because they know that the patient pool will be much smaller. It all depends on the value of the co-payment. Well, it depends on what your situation is on submission if you are the distributor then you cannot do it, it's impossible. If you are the manufacturer, it's a cost review that you need to do. In pharma for example it works easier, because they've got volumes behind them. But, on devices which are specific for a treatment you don't always have the volumes behind you to justify spending the cost. I've never experienced that they are willing to find mechanisms to make it work for the benefit of the patient outcome. It's always the cost outcome. That's my experience</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| P11         | Financial and Profitability Management | Business case, acceptable losses in the short run but should determine breakeven point to test acceptability. Also agreement on tariff increase once proven. | <p>So, there needs to be a business case and there needs to be an agreement in place and the partial reimbursement is often a tricky one, because what you need to do is you need to say this is what the funders are prepared to pay now and it is 6 times out of 10 going to cost us more than that, but 4 times out of 10 is going to cost us less than that and somewhere along the line we'll either break even</p> <p>Or for a short period of time run at a loss.</p> <p>But then, once we've proven it works the funder will pay at the increased tariff and the big benefit to us is that we attract another neurosurgeon and they bring additional patients along with them.</p> <p>Or we can offer a new service line to our private paying patients, who like the idea of shorter hospital stays and so we may be able to charge people more on that basis.</p> <p>But you need to really be able to quantify how many people are going to be willing to pay that much more for two days less in hospital and is that going to be able to balance out the days we were unable to charge for a hospital stay? So, there is a willingness on our side to engage in projects like that, but there are realities, there are bottom lines, there are shareholders who want a return on their investment. I think it's a bit of a shared responsibility in terms of paying for the medical device to be put into place, or any building adaptations or any changes that need to be implemented in order for the actual equipment to actually come into place so I think that responsibility actually sits with the hospital.</p> <p>But if there's an agreement with a funder and we're working together at an agreed tariff until enough evidence is in place then at least the funder is covering us at the sort of usual rate</p> <p>Or whatever agreed rate and then I think the suppliers often come to the party and say that they also need the evidence as badly as we do in order to get it to market so they'll give the equipment on loan or on a reduced fee.</p> <p>So I think it's shared, but I think often the larger capital investment sits with the hospital and the gamble once we've bought this piece of equipment and we don't make our investment return, what are we going to do?</p> |

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| P1  | Public Image            | Funder is answerable to the public and should be able to defend decisions                                             | Therefore, you need to be able to answer on a public space for example if you are being asked on CNN that when you authorised that particular product for members who are part of this particular health insurance were you considering the fact that it is indeed clinically effective, or the safety aspect of the technology was a tick, the quality of the technology was a tick and the cost of the affordability point of view of that technology was a tick. Furthermore, was it addressing the unmet healthcare needs of the people in South Africa? You should be able to answer Yes to all these questions.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| P4  | Public Image            | Funder should do what's best for Patient. Companies don't want to put their name on these studies                     | So if both the funder and the supplier both meet half way and just have the objectives set out over a time frame then patients at the end of the day will benefit. I think it's different for every company, from a company point of view they are not likely to put their name on a study like this. They should do what's best for the patient and if for instance it comes to your device being inferior and proven to be inferior, then I think that Funder should say No we're not going to fund.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| P3  | Public Image            | Funders don't want patients to Co-pay. If they are paying under CED they are contributing. Everyone develops          | In my experience, it seems that in the last couple of years that initially some of the funders were saying that they don't want their patients to co-pay. At this point in time funders will tell you that they are sharing it. If they're paying for the patient to receive the technology then they're also contributing. It's actually about development. The country keeps on developing, the doctors keep on developing.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| P6  | Public Image            | No one likes Co-payment                                                                                               | So, I don't think anyone really likes a partial payment especially when it comes to the member and the co-payment. You know we always try to negotiate, when we enter into these pilots for our scheme we like to negotiate fully funded options. There could be an alternative, but we always like to give the member an option, a fully funded option. However, I think that when the technology companies and the doctors acknowledge that there's a gap or uncertainty there is almost a willingness or an acceptance that a co-payment may be reasonable. But I think on our side, we try as far as possible to give them the benefit as much as that doesn't increase scheme exposure to minimize the member co-payment as far as possible. Most importantly it's around any risk exposure for the patient and that's why I think safety is the main priority.                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| P9  | Public Image            | No one wants to own CED study                                                                                         | The problem with funding a CED is that nobody wants to own it, however if funders and suppliers have faith in their product then there should be no reason they won't fund it.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| P11 | Public Image            | Fear of losing in shared risk Reputational Risk Damage Industry Stakeholders are suspicious about each others motives | But it all becomes very complicated, because people start asking about data sharing and who's going to own the data. Everyone's sort of got their vested interest. Though we have the money to, but everybody is scared to open themselves up to an agreement or a shared risk situation, because historically that is not how we've worked and everybody in this industry is suspicious of the other person's motive. Everybody is a bit scared of losing their place. And reputational risk and feedback is huge to us. The patient is often unaware or oblivious of all the stuff that happens in the background, they associate everything with Hospital Brand, they associate their entire experience including how much it costs with Hospital Brand, because that's their provider in their mind. So, we're very aware of that and that does come through in our patient experience surveys that we do. So, we do try to include the patient experience in our outcomes that we collect when we're looking at things that include a shorter hospital stay for the patient or quicker recovery- so we do factor that in a lot. But I do think that the one thing that we are starting to do well is realise that the patient has a choice and they choose to come to us or they choose to go elsewhere. |
| P13 | Public Image            | No regulation, funders have to protect reputation                                                                     | The fact that we had no regulations in place. The medical funders then started acting as a regulatory body too.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| P7  | Public Image            | Co-pay undermines principle of collective insurance                                                                   | It's a risk management thing, which I personally don't like, because when you sit with a good technology, actually for me and you as part of the insured population we are insuring a risk that you and I cannot carry. When you get to co-payments, it undermines that whole principle of collective insurance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|     | Public Image            | Perception is companies are paying rebates to funders to use or study their products                                  | Whereas with the funder, they may seem biased if they take funding from me and it's my products, then it might look like we are paying them a rebate to use our products or to even go into a study with our product.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| P2  | Independent Evaluation  | Independent evaluation body for all companies                                                                         | So the question is, in that type of situation when will we be able to share that in terms of the funding and you know the only way that I can actually see this actually panning out for both is to be able to create an independent sort of evaluation body that companies would have to apply to in order for that funding to take place and then look at what the need is.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| P4  | Independent Evaluation  | Impartial evaluation                                                                                                  | That needs to be impartial, so if you want a really good clinical outcome that's also costed.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| P7  | Independent Evaluation  | Academia and professional societies                                                                                   | I do think that there's a place for academia to also do that, which becomes more independent, I think academia should get involved. I think there's a role for professional societies, so for example the HPV board, which is a policy making organisation. They look at evidence and make policy, they could institute research. I just don't know where the funding would come from.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| P12 | Independent Evaluation  | Academia have capacity but not funding                                                                                | The fact that in the private healthcare sector that we don't have an affiliation with the academic institutions, we don't have access to research support as much as I think the public institutions do. I think the challenges on their end is resource, it's funding. So, they could do a lot more if they had more money.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| P5  | Independent Evaluation  | National system required funders don't have money to fund CED                                                         | The problem is that locally, the government is not overseeing these studies when we move through the NHI(National Health Insurance) it might be easier, because then a company will say I will partially fund to the results that I'm saying should be the outcome and the government must endorse it. But it's neither here nor there, because half of the time they'll say that they don't have funding. So, what will help us is the national system. The government will give its own funding, because it's helping the society.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| P5  | Independent Evaluation  | Unbiased study assists funders to engage evidence without question                                                    | It is difficult in that the supplier wants to get their evidence out and support, but then to me I think the payer also needs to come to the party for new technology and put it out there. So, it's difficult because then who owns it? Because then it becomes an issue of, it was the buyer's study and they paid for it and so it needs to be an unbiased party. So then maybe a payer and a supplier can contribute towards the costs, that it's not the buyer's type of study. I think it comes back to the endorsement from association and not being bought by association. So a funder needs to know that it is a very unbiased point of view and unbiased evidence that we're looking at. Then they're happy to engage without having questions at the back of their minds.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| P6  | Funding Exit Strategies |                                                                                                                       | But when we commit to these types of fundings, until all the data is collected and we've discussed, we generally do not terminate funding. Unless there is a real safety issue that comes up.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| P12 | Independent Evaluation  |                                                                                                                       | It is difficult in that the supplier wants to get their evidence out and support, but then to me I think the payer also needs to come to the party for new technology and put it out there. So, it's difficult because then who owns it? Because then it becomes an issue of, it was the buyer's study and they paid for it and so it needs to be an unbiased party. So then maybe a payer and a supplier can contribute towards the costs, that it's not the buyer's type of study.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| P11 | Funding Exit Strategies |                                                                                                                       | So I think it's shared, but I think often the larger capital investment sits with the hospital and the gamble once we've bought this piece of equipment and we don't make our investment return, what are we going to do? The funders don't lose out, because they can just decide that they are not going to pay for that, the suppliers also don't lose out because the hospital has purchased the piece of equipment. So, our research governance structure is set up to protect us, so for studies like this we usually say that there should be no additional cost to the hospital. So often the equipment provision is by the supplier or an outside funder. The health professional is often the one driving this, because they want to offer this to their patients. They could just decide tomorrow that they're going to work in Australia or they're going to work for Netcare and then we've invested all of this time and all of this resource and money to try and do it for the doctor and the patient and of course the greater good. However, there isn't as much buy in, they don't have as much to lose.                                                                                                                                                                                   |
| P13 |                         |                                                                                                                       | There are certain projects that are built on risk sharing models, so for example if a certain outcome is not possible to be reached then the medical funder is paid back. Ultimately the responsibility lies with the funder to pay for it.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| P5  | Funding Exit Strategies | Process to exit study required with payback clauses                                                                   | But in a risk sharing model what should happen is that one of you should say, wow this study reached 2 years and it's almost at its success rate there's no need for each of us to pay anyone back. But Should the study fail the company should pay the funder back, because what you've paid for has not been fulfilled or has not materialized. So, it's almost like the funder has wasted money, because it means that even initial studies were not up to scratch. Because the rule was, we would pay you at the fee of the current technology should the product be what you say at the end of the allocated 6 months, we'll pay you in full for all the amount we should have paid.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

| Participant | Theme                  | Secondary Analysis                                                                       | First Level Analysis                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-------------|------------------------|------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| P1          | Disincentives          | Traditional reimbursement is preferred                                                   | Ok, it can never be suitable from my perspective as an employee of a company that needs its product in the market, that has already invested enough money to generate clinical evidence, health economic evidence if that information is already available.                                                                                                                                                                                      |
| P7          | Disincentives          | Cost is a deterrent                                                                      | Cost, because this is an expensive exercise.                                                                                                                                                                                                                                                                                                                                                                                                     |
| P4          | Disincentives          | Cost is a deterrent                                                                      | The appetite and the costs of it. If you're only going to get your data in a year to two years down the line. That's two years of revenue lost.                                                                                                                                                                                                                                                                                                  |
| P7          | Disincentives          | Difficult, Complex, No Benefit to Hospital                                               | So, we've done a lot of that work and we've not been very successful to implement. Implementation level it's very difficult. So, I'll share my experience with you, that whole model with the risk sharing is too complex. It is too ambiguous; So, the hospitals very seldom make money out of devices.                                                                                                                                         |
| P13         | Disincentives          | Revenue Margin Loss                                                                      | I'm not sure if the financial model is going to work for the suppliers, because they're definitely giving up margin to allow this. So, long term the longevity of having the technology in the market after the initial phase is going to be a challenge or risk.                                                                                                                                                                                |
| P13         | Disincentives          | Laboursome, Costly, Administrative Burden                                                | Like I mentioned in the beginning, the funder mechanisms are just very labour some.                                                                                                                                                                                                                                                                                                                                                              |
| P5          | Disincentives          | Lack of Knowledge, Lack of EHR, Staff Turnover, Medico-legal Risks Doctors Profitability | Lack of understanding. But they don't have staff and they don't have time. They don't have knowledge base everywhere. The nurses come and go, they can't assist. The physicians are chasing money and are going through cases as fast as they can, because they need to make more cases. Because they are not sure if they are not putting their necks or careers on the line or whether their names will be published for one or two mistakes.  |
| P11         | Disincentives          | Disadvantage is High Investment Risk                                                     | There's too much fear of that financial loss that we only do them only when there's somebody who feels strongly that it's a No-lose situation.                                                                                                                                                                                                                                                                                                   |
| P1          | Disincentives          | Investment Requirements                                                                  | But at the same time, as an industry we probably don't have that much investment in terms of our budget to consider this or propose it to a funder.                                                                                                                                                                                                                                                                                              |
| P9          | Disincentives          | Low compliance in evidence submission, No framework for risk, process immature.          | So, maybe an important point to make here is that the use of registry in this type of data. , there's very low compliance in terms of the registries. That's your risk. It's difficult, I don't think that there's a standard framework for these type of risk agreements. I think the process is still very immature                                                                                                                            |
| P4          | Incentives             | Long Term Benefits for Funder                                                            | Ultimately, the payer has certainty that they are funding the best possible solutions for their clients, which is the patients. I think from a cost saving point of view, it's going to be beneficial for the funder in the long run if they've established what's best for their pockets and their patients beforehand. Holistically, the benefit is going to be economically for the funder at the end of the day                              |
| P3          | Incentives             | Superior Outcomes Claim                                                                  | So, there were early indicators that marked positive , but the real hard and fast outcomes were similar, but there was a price difference. So at that point, we then agreed that we would enter into a risk sharing agreement. So, that was a peer price model. So if you apply health economic outcomes, why would you pay extra? And the price was more. So then we entered into a peer financial risk model to make the technology available. |
| P5          | Incentives             | Entry route into Market                                                                  | So unfortunately most of the time with medical devices that's the only way you can get your HTA fully endorsed. So for medical devices it's a little bit tricky, because they take long to be where they're supposed to be or to prove whether or not the product works. For some devices it works faster, for some it works normally.                                                                                                           |
| P9          | Incentives             | Superior Outcomes Claim                                                                  | Globally they've shown that their implants are better, they have a 3% lower revision rate and they want to understand what is the real world view in South Africa So this is tangible evidence of how you would want to do a health technology assessment when you measure the downstream cost of devices. Do these different implants have different outcomes? It's more a comparative study between the different players in the market.       |
| P10         | Incentives             | Life Saving Technology Market Entry                                                      | I think it's a difficult one to answer, because I think it depends on a few factors. Which again I would say is the urgency of the technology, if it's a life saving technique I think then maybe you can consider this as a supplier from my view.                                                                                                                                                                                              |
| P9          | Performance Management | Claims versus Real World Performance                                                     | So, for example the company could have gone back to the funders and said we're saving you a certain percentage over a period of time, we're looking at a risk sharing model where you do a premium price for this particular product, because we're saving a certain amount over a period of time. and we can have this for a year and we expect that the results will                                                                           |

|     |                        |                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----|------------------------|--------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| P7  | Performance Management | SMART goals difficult, Risk Manage for Profit                                                                | <p>it is so difficult to have smart goals of what would be the lever point for sharing risk or not or whatever the way you design it.</p> <p>Unless you have a very simplified way of ensuring that the goal settings, specific measurables and so forth, unless you can have a very smart goal that is highly measurable, attainable and not ambiguous it's going to fail and you're actually going to mess up your relationships, because there's too much thought in it. The premise must be simple and understandable by both parties, non-ambiguous otherwise it's going to fail right from the start. You have to have a trusting relationship; it's got to be two parties who trust each other knowing that we want to get to a win-win not a lose win or a win-lose. I</p> <p>It's got to be a win-win or a No deal. So, trust is the most important and tangible ingredient of this thing. And then there are several important factors. In a risk sharing agreement, it's all about risk.</p> <p>So, let's take the supplier as the first element of risk. Firstly they are driven by a PNL(Profit and Loss), they need to meet their PNL targets. This is not risk sharing for revenue, this is risk sharing for PNL and not the L part, the P part, they want profit and not loss. understand their risk in terms of the risk sharing model and we convert that into a PNL model to say if we do this scenario versus this and that scenario how would it impact on PNL.</p>                                                                                                                                                                                                                                         |
| P7  | Incentives             | Increased Patient Access, Price protection and Volumes                                                       | <p>On a social level, the benefit of risk sharing is that you could potentially provide access to more patients at a lower price and that's a win-win, because as a devices company you wouldn't mind having more revenue, more volume at a lower price, because you know that your revenue and your cost model will make sure that your PNL looks better and not worse. So there's the socio-economic aspect and we can open up to more patients, because we have more money or less money to spend on more people or the same budget to spend on more people, because ultimately the price is reduced to risk sharing.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| P13 | Incentives             | Innovator companies at the forefront. Prove claims                                                           | <p>So, from a supplier's perspective I feel that to enable market access they really need to be looking at this at an earlier stage and they are aware that the evidence is not going to be up to scratch or it's going to be questioned from the perspective of the medical funder and at that point I'd rather try and put forward a proposal. So if you want to be at the forefront, you're going to have to be at the forefront of putting these risk sharing agreements into place. I think one of the high level benefits is being able to trust your product, being able to put your money where your mouth is.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| P3  | Performance Management | Must measure clinical outcomes                                                                               | <p>So, here I think it's clinical outcomes. From my perspective, because if you cannot measure clinical outcomes how can you enter into any kind of alternative reimbursement model? Because then it's not alternative, then it's just a price. A devaluing price or it's a price volume. So, this is currently a real weakness and the fact that there's no real clinical evidence. But I suppose if you had a clinical outcome, you could do a negotiation based on pre-determined clinical outcomes. Yes and the fact that there are no electronic records of clinical outcomes</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| P1  | Performance Management | Defined pay back mechanisms                                                                                  | <p>So, from a funder point of view in terms of cost then Yes. But not just the cost of implementation. But the cost of budget wherein you have to fund something that you're not confident with. But normally these contracts are drafted in such a way that says "failure to do that, you will give me this." information that you sometimes agree upon to go back and look at their claims data and then they will do their own analysis. the analyst of the funder had to spend some</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| P10 | Performance Management | Defined review periods                                                                                       | <p>But, also it shouldn't be just risk sharing there should be a period linked to it and after a period of 12 months or so many patients being treated it should be reviewed again against all their costs of the normal patient pool. I think it's all about transparency</p> <p>and we know that the funders are not going to share that with us.</p> <p>So you will have to have your market intel to understand what their cost is, because you will know what your cost of the technology is.</p> <p>But I'm not sure if you will always know what the cost is on their side. The true cost.</p> <p>the devices company must become a risk manager in itself. They need to continuously manage their risk; they need to continuously monitor that.</p> <p>So we fulfil that role, we build a risk model and we monitor the risk for the clients, because that's the first thing.</p> <p>You've got to have internal risk capacity, risk measurement, risk management capacity or outsource it to a company like ours that can do it. That's important and then the next step is to convert that on a timeous basis and a regular basis into a PNL metrics to project the PNL to look into the future and you need to continuously do that.</p> <p>But the same applies to the other side of the coin of the people who co-share the risk. So, this is the funder, the insurer. They also do their risk managing, they also want to see that they don't pay more.</p> <p>But they already have things like that in place. Insurers are good with that, because that is their primary function to be risk managers.</p> <p>So, it's more on the supplier side as it's a new skill that they need to acquire or outsource.</p> |
| P11 | Performance Management | High Risk Gamble, Managed by not taking risk                                                                 | <p>To be honest with you, I think most of the time we're guided by the funders on what would satisfy you to pay this tariff or to give us a tariff for this.</p> <p>Then they will generally say that they want data from a certain number of cases and they want it to be done a certain way.</p> <p>Like I said we're not a research strong organisation and we haven't in the past been early innovators, however though this is not our historical background we are trying to drive things a lot more.</p> <p>But I think at the moment, it's being guided by the funders. Better technology, better outcomes and offerings to patients, better quality of life, hopefully quicker return to work.</p> <p>Shared risk means that nobody bears the full brunt when it goes wrong, but also we're all taking a little bit of the ownership. We put in our best guess of what the impact is going to be and we hope for the best and I think we understand that we're taking a gamble, but we need to be pretty sure and so they are very much managed with caution and almost aversion</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| P12 | Performance Management | Tangible measurements required. Can you actually measure it? Did it work?                                    | <p>That's a huge issue if you're looking at an outcome, if you've got measurables in place.</p> <p>So if you've got performance based, so for an example when the patient goes into theatre they'll only be in hospital for two days and then they'll get discharged.</p> <p>So there's a performance based and you can actually measure it, because it's sometimes very difficult from a tangible perspective.</p> <p>So, when it's measurable and you can look at the evidence, did it work? Yes or no?</p> <p>That's also another performance-based risk sharing agreement, as well as if the cost is going to be X you know what the risk is.</p> <p>That's another performance based; you're managing the risk of the actual cost. It's when you have a specific outcome that you can actually track and manage.</p> <p>Then the benefits would be exactly that, so for example if you want to put a 10% increase on your device, but your hospital costs are going down, your medication costs are going down, then that to me would be the benefit of implementing a performance based, because then it's from a cost perspective outcome or the efficiency costs would go down. So the challenge is to manage those costs to make sure that everyone is trained efficiently.</p> <p>You have to have a registry, which you can track and track the costs, the training, and the outcomes.</p> <p>So, to me the only way to manage them is really by registries</p>                                                                                                                                                                                                                                                       |
| P5  | Performance Management | Real life Outcomes, Patient Voice, Confounding Factors by patient, Patient pathway training, data collection | <p>So, in this country you have to have the right hospital, the right housing or the environment.</p> <p>can give you a hospital and say do your study there, but perhaps in that hospital for example there might not be care bundles for infection controls.</p> <p>So your procedure will fail.</p> <p>So, for that reason everything must be in line with every bundle that needs to work towards showing results must be in place. So, you have to get the buy-in from all the stakeholders.</p> <p>If you don't and you go ahead and you start giving it to doctors to use, it won't work.</p> <p>So everything must be taken into consideration, especially the environment.</p> <p>So for example even if you use a patient whose body is not in an optimal state to show the optimal results, the study will fail because the body is not ready.</p> <p>So everything should be taken into consideration, there should be a pre-pathway of the patient done. As well as of the hospital, is the technician trained? Does everyone who is involved know where their positions should be? Even the registry capturing person, do they know what to capture? Do they have a sheet that guides them of the tick boxes to look for?</p> <p>So all those factors add up. You are also allowed to go and do your own assessment of the clinic of hospital so that you know that every touch point has been ticked off.</p>                                                                                                                                                                                                                                                                                                     |
| P5  | Performance Management | Patient Voice important in measuring outcomes. Clinical vs Patient Outcome Measure                           | <p>So I have seen an instance where there were a number of pathways that had gone wrong. With the patients that we interviewed, you'd have cried tears because of what they had gone through and it was not what was supposed to be. Need to be monitored and we don't have that from the government point of view, from the funders societies to say if we put an ARM who is there monitoring the outcome? Who is there interviewing the patients to see if the pathway is</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| P5  | Performance Management | Patient Voice important in measuring outcomes                                                                | <p>Some pathways look really good on paper, for example one of the doctors was already part of the model and he was starting to query and he suggested that we all get together and figure something out and subsequently they eased up some rules within the pathway, they added more pain medication while the patient was in theatre.</p> <p>I always say that I'm always proud to be a part of these things, because if I was that voice for the patient, because that I think what's important for me is the outcomes measure.</p> <p>We have to be very clear about what we're measuring.</p> <p>Over what period, so there are clear outcomes to be measured</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| P5  | Performance Management | Clear goals, Defined time lines                                                                              | <p>Another factor is that everyone has to be aligned on the methodology, the dimensions and metrics that are used to measure. That's a consideration in implementing it.</p> <p>The benefit of implementing it is that you have better outcomes, it costs the healthcare system less especially in the</p> <p>So, it's hospitals keeping their environment sterile and making sure that patients are not exposed to infections or risks, from a clinician level it's also their level of training and their level of skill. All of that plays an important role.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| P9  | Performance Management | Agreement on methodology                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| P9  | Performance Management | Environment Impact on outcomes. Clinician Skills impact                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

## Appendix 5: Informed Consent & Audio Recording Forms

The interview is expected to last about 45 – 60 minutes, and will help us understand how the South African healthcare system is managing HTA outcomes for medical devices that require real-world data to prove their clinical performance outcomes. Through this interview process, the researcher hopes to get an understanding of the management of complexities related to implementing performance-based reimbursement outcome requirements in medical devices.

The Research Ethics Committee of the University of Pretoria, Faculty of Health Sciences, telephone numbers 012 3541677 / 012 3541330 granted written approval for this study under Ethics Reference No: 758/2019.

**Your participation in this study is voluntary. You can refuse to participate or stop at any time without giving any reason. Consent is requested for data recording for further analysis.** All data will be kept confidential and no source, individual or organisation, will be identified in the text of the final report. With your permission, our interview will be transcribed for purposes of analysis, however, no direct attribution will be made to you by name. All data will be stored without identifiers to preserve confidentiality. As an indication of consent please sign below.

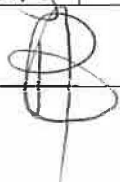
**Note: The implication of completing the interview is that informed consent has been obtained from you. Thus, any information derived from your participation (which will be totally confidential) may be used for e.g. publication, by the researchers.**

We sincerely appreciate your help.

Yours truly,

**Anele Zukiswa Vutha**

| Participant's & interview details |                             |                           |
|-----------------------------------|-----------------------------|---------------------------|
| Name: Bukhwa Mpongo               | Title: HEM                  | Organization: BSC         |
| Location: Johannesburg            | Interview start time: 15:00 | Interview end time: 16:00 |

Participant's signature: 

Researcher: Anele Vutha

Phone: 083 345 3044

Email: [18398112@myqibs.co.za](mailto:18398112@myqibs.co.za)

Researcher signature: 

Research Supervisor: Colin Rowley

Phone: 082 858 5413

Email: [colinrowley@vodamail.co.za](mailto:colinrowley@vodamail.co.za)

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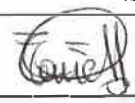
We sincerely appreciate your help.

Yours truly,

**Anele Zukiswa Vutha**

| Participant's & interview details |                                    |                                       |
|-----------------------------------|------------------------------------|---------------------------------------|
| Name: <u>NIRI BHIMAN</u>          | Title: <u>Head: HTA</u>            | Organization: <u>DISCOVERY HEALTH</u> |
| Location:                         | Interview start time: <u>11:00</u> | Interview end time: <u>12:00</u>      |

Participant's signature: 

Researcher signature: 

Researcher: Anele Vutha

Research Supervisor: Colin Rowley

Phone: 083 345 3044

Phone: 082 858 5413

Email: [18398112@mygibs.co.za](mailto:18398112@mygibs.co.za)

Email: [colinrowley@vodamail.co.za](mailto:colinrowley@vodamail.co.za)

The interview is expected to last about 45 – 60 minutes, and will help us understand how the South African healthcare system is managing HTA outcomes for medical devices that require real-world data to prove their clinical performance outcomes. Through this interview process, the researcher hopes to get an understanding of the management of complexities related to implementing performance-based reimbursement outcome requirements in medical devices.

The Research Ethics Committee of the University of Pretoria, Faculty of Health Sciences, telephone numbers 012 3541677 / 012 3541330 granted written approval for this study under Ethics Reference No: 758/2019.

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Yours truly,

**Anele Zukiswa Vutha**

| Participant's & interview details |                 |                              |                |
|-----------------------------------|-----------------|------------------------------|----------------|
| <b>Name:</b>                      | KERSHNEE CHETTY | <b>Title:</b>                | HEAD SURGICALS |
| <b>Location:</b>                  | DISCOVERY       | <b>Interview start time:</b> | 11:00          |
|                                   |                 | <b>Interview end time:</b>   | 12:00          |

Participant's signature:  Researcher signature: 

Researcher: Anele Vutha Research Supervisor: Colin Rowley  
 Phone: 083 345 3044 Phone: 082 858 5413  
 Email: [18398112@myqibs.co.za](mailto:18398112@myqibs.co.za) Email: [colinrowley@vodamail.co.za](mailto:colinrowley@vodamail.co.za)

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Yours truly,

**Anele Zukiswa Vutha**

| Participant's & interview details |                                    |                                  |
|-----------------------------------|------------------------------------|----------------------------------|
| Name: <u>Donata Kuroake</u>       | Title: <u>HEMA</u>                 | Organization: <u>J+J</u>         |
| Location: <u>BRYANSTON</u>        | Interview start time: <u>09H00</u> | Interview end time: <u>10H00</u> |

Participant's signature: 

Researcher signature: 

Researcher: Anele Vutha

Research Supervisor: Colin Rowley

Phone: 083 345 3044

Phone: 082 858 5413

Email: [18398112@mygibs.co.za](mailto:18398112@mygibs.co.za)

Email: [colinrowley@vodamail.co.za](mailto:colinrowley@vodamail.co.za)

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Yours truly,

**Anele Zukiswa Vutha**

*SENIOR BUSINESS & MARKETS ALLIANCE MANAGER*

| Participant's & interview details |                       |                                      |
|-----------------------------------|-----------------------|--------------------------------------|
| Name: <i>HETIE LUYEN</i>          | Title: <i>MRS</i>     | Organization: <i>BAROQUE MEDICAL</i> |
| Location: <i>BAROQUE MEDICAL</i>  | Interview start time: | Interview end time:                  |

Participant's signature: *[Signature]* Researcher signature: *[Signature]*  
Researcher: Anele Vutha Research Supervisor: Colin Rowley  
Phone: 083 345 3044 Phone: 082 858 5413  
Email: [18398112@mygibs.co.za](mailto:18398112@mygibs.co.za) Email: [colinrowley@vodamail.co.za](mailto:colinrowley@vodamail.co.za)

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We sincerely appreciate your help.

Yours truly,

**Anele Zukiswa Vutha**

| Participant's & interview details |                                    |                                  |
|-----------------------------------|------------------------------------|----------------------------------|
| <b>Name:</b> RUWAIDA SHAIKH       | <b>Title:</b> CEO BATO PELE        | <b>Organization:</b>             |
| <b>Location:</b> ROSEBANK         | <b>Interview start time:</b> 16:00 | <b>Interview end time:</b> 17:00 |

Participant's signature: 

Researcher signature: 

Researcher: Anele Vutha

Research Supervisor: Colin Rowley

Phone: 083 345 3044

Phone: 082 858 5413

Email: [18398112@myqibs.co.za](mailto:18398112@myqibs.co.za)

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