Factors influencing innovation in public healthcare in South Africa: A critical analysis.

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Declaration

I declare that this dissertation is my own, unaided work, except where otherwise acknowledged. It is being submitted for the degree of Master of Science in Engineering at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other university.

Signed this 06th day of December 2024

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Abstract

Healthcare innovation has proven to reduce morbidity and mortality rates by enhancing healthcare delivery. Most of the South African population depends on the public healthcare system for health needs. The morbidity and mortality rates in South Africa are much higher compared to other middle-income countries in the world. To enhance healthcare delivery in South Africa, understanding the factors that influence innovation in public healthcare is important. Therefore, this research aims to provide a comprehensive understanding of the factors influencing innovation in public healthcare in South Africa and the potential impact of innovation on the country's healthcare system.

The main objectives of this study are to determine the level of successfully implemented innovation in public healthcare and the factors influencing it. Existing literature identifies several factors that influence innovation in public healthcare, including design empathy, technological infrastructure, decision-makers, human capital, and organisational culture. This study also investigates the readiness of the public health sector to embrace innovation and the strategies in place for implementing innovation in public healthcare. A gap was identified in the existing literature. There is evidence in literature is that healthcare innovation centres in South Africa and their impact on the adoption of innovation in public healthcare were only covered marginally by existing literature. To bridge this gap, this study provides results on the status of suitable research and development hubs for testing healthcare innovation prototypes in South Africa and their impact on the adoption of innovation in public healthcare. Currently, there are limited health innovation centres in South Africa. This study posits that an increase in the number of healthcare innovation centres would increase evidence-based innovation which would increase the uptake of innovation in public healthcare.

A qualitative research approach was used to acquire descriptive information on the factors that influence innovation in healthcare through interviewing participants. Semi-structured interviews were used as the primary instruments of data collection. The interviews were then subjected to a thematic analysis. One of the significant findings of this research is that the lack of funding in public healthcare hinders innovation in the public healthcare system. Also, the rigorous regulatory requirements pertaining to healthcare innovation tend to cause uncertainty and delays, which in turn reduces the funding available for innovative projects.

For my beloved late father, Dumisani Cosmos Nkosi, Proverbs 23:22

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1 CHAPTER 1 - INTRODUCTION TO THE STUDY

1.1 Introduction

Blood transfusion today is known as a routine procedure that saves innumerable lives annually (Jones & Mackmull, 1928). Prior to the 20th century, blood transfusion had not been established in medicine (ibid). It was the alarming number of obvious deaths caused by post-partum haemorrhage that prompted London obstetrician and surgeon James Blundell to investigate and research the concept of blood transfusion (Jones & Mackmull, 1928). Blundell experimented with transfusions of both animal and human blood, and eventually developed a method of using a syringe to transfer blood from a donor to a recipient (Dzik, 2018). Blundell's early experiments were met with mixed results, and there were many obstacles to successful transfusion (Dzik, 2018). Over time, other researchers have built on Blundell's work, and blood transfusion has become an increasingly common medical practice and one of the most potent life-saving medical innovations (ibid). Blundell's pioneering work on blood transfusion is an important reminder of the role that research and innovation can play in advancing medical knowledge, improving human health, and ultimately saving human lives (Jones & Mackmull, 1928).

The development of anaesthetics is another invention that revolutionised the field of medicine, allowing for more complex and invasive surgical procedures to be performed with greater safety and success (Robinson, Lyne & Blaise, 2022). The military was a monumental influence in the development of anaesthetics in American medical practice (Metcalfe, 2005). The bulk of research and empirical experiments for the development of anaesthetics for surgical purposes occurred in the period between the American Civil War [1861-1865] and the First World War [1914-1918] (Metcalfe, 2005).

Early anaesthetic techniques were however not without risks, and patients sometimes suffered from adverse effects such as respiratory depression or cardiac arrest (Metcalfe, 2005). Over time, new anaesthetic agents and techniques were developed, and the field of anaesthetics became more specialised and sophisticated through innovation (Robinson *et al.,* 2022). The evolution of anaesthetics has been marked by significant advancements in medical science and technology, leading to the development of safer, more effective, and reliable anaesthetic agents and techniques (Robinson *et al.*, 2022). The innovation of anaesthetics in the medical field is among many that have contributed to improving healthcare delivery globally (Robinson *et al.*, 2022). This observation has led to an interest in exploring the factors that influence innovation in public health care in South Africa. The aim of this study is to understand why the successful implementation of innovation in health care is an uphill battle. To fulfil this aim, an indepth understanding of the factors that influence innovation in health care is required.

Invention and innovation are inevitable in our society, given that humanity exists (Mpofu, 2013). The major reason why a consistent introduction and improvement of inventions is important is because it improves the

standard of living in a society (Mpofu, 2013). The quality of life of a nation's citizens is one of the benchmarks used to gauge a nation's wealth (Bedir, 2016a). On a global scale, South Africa ranks low in terms of standard of living (Bedir, 2016a). However, this ranking is not applicable to all citizens because of the prevalent high rate of inequality (Mpofu, 2013). The disparity in the standard of living for South African citizens is explicitly demonstrated by the state of the public health sector (Mpofu, 2013).

1.2 Background

1.2.1 Definitions

Invention and innovation are interrelated phenomena; however, an important distinction exists between them. Invention is the generation of new ideas (Şener, Hacıoğlu & Akdemir, 2017). Innovation is an improvement to an already existing idea (Şener *et al.*, 2017). Kobayev (2017) states that innovation is the creation of a new concept and its transformation into a commercial process, product or service that creates economic growth for a country. Arthur (2007) believes that the creation of new technologies is known as invention and not innovation. Rutan (1959) defined invention as the emergence of new things created through professional skills. Invention, according to Usher (1964), is the creation of a commercially profitable product or service.

Ion and Cristina (2014) stipulate that innovation should be viewed as a process of creating new combinations from existing technologies rather than as the conversion of new concepts into new procedures, goods, and services. Sener et al. (2017), on the other hand, believe that both invention and innovation involve the process of translating ideas into a product or service that will create value or enhance the quality of life. Not only do these ideas need to be implemented in a manner that will not be destructive to society, but they also need to be sustainable, effective, and scalable in the long run (Duderstadt, 2005). Amongst other things, innovators are also responsible for the management of innovation (Duderstadt, 2005). They need to ensure that innovation amalgamates with the natural functions of society and does not completely replace the natural modus operandi of society, which can cause an imbalance (Duderstadt, 2005). Ziyavitdinovich & Ulugbekovna (2022) have formulated two definitions of innovation. Innovation may be defined as a new perspective on an established procedure or the effective implementation of a new idea or discovery in the business world or in other areas of human endeavour (Ziyavitdinovich & Ulugbekovna, 2022).

An alternative definition of innovation, as given by Ziyavitdinovich & Ulugbekovna (2022), is that innovation is the process by which a creation or concept gains commercial value. Arora, Cohen, Lee & Sebastian (2023) define innovation as the actual application of ideas that result in a variety of new offerings, such as products, services, processes, and business models, with the purpose of improving existing applications or inventing new solutions. Arora et al. (2023) also define invention as a brand-new or authentic procedure, idea, or product. An invention can be used to enhance the functioning or reduce the cost of a product or process (Arora et al. 2023). As there are many definitions of invention and innovation, Peter (2017) concluded that innovation

is a multifaceted and rather complex concept that should not be boxed into one definitive definition of innovation as an improvement to an already existing idea (Şener *et al.*, 2017).

1.2.2 Current state of healthcare in South Africa

Public healthcare in South Africa is inundated with challenges that need to be addressed (Leonard et al., 2019). These challenges include poor healthcare quality, rising healthcare costs, an ageing population, and a lack of efficient healthcare management (Leonard et al., 2019). Healthcare is mainly divided into two segments: the public and private sectors (Kautzky & Tollman, 2008a). Several scholars have identified the main issues that pertain to the inefficient delivery of healthcare in both the public and private sectors (De Villiers, 2021; Malakoane et al., 2020; Kautzky & Tollman, 2008a). These issues have been identified to be the ineffective use of services, preventable mistakes, inadequate resources, erroneous diagnosis and treatment, maldistribution of funds, and poor record keeping (De Villiers, 2021; Malakoane et al., 2020; Kautzky & Tollman, 2008a). The overall health and lives of patients are jeopardised by these flaws, which also increase healthcare expenses and decrease productivity (Galvani et al., 2020).

1.2.3 History of the South African healthcare system

The flaws of the healthcare system stem from the apartheid era which was based on separate development (Kautzky & Tollman, 2008a). Maphumulo and Bhengu (2019) also state that the dilapidated state of the South African public health sector was caused mainly by the apartheid regime. In another study, it was stated that based on the apartheid philosophy, the health system was divided by race and location (Rakate, 2007). The division of healthcare in accordance to race and, the liberation of the health industry from being regulated were incredibly destructive to the nation's healthcare and systems development (Kautzky & Tollman, 2008a). Under the apartheid principles of separate development for the citizens of South Africa, the apartheid government developed the Bantustans that Africans were forced to live in (Kautzky & Tollman, 2008a).

The responsibility for providing health care and other public services fell to the organisational structures of each homeland (Maphumulo & Bhengu, 2019). An overwhelming majority of the Bantustan health services failed to provide proper medical and public healthcare due to a lack of resources and ill management of health facilities (Kautzky & Tollman, 2008a). It is also stated by Rakate (2006) that prior to 1994, the public sector was characterised by poor service quality, a lack of commitment, inefficiency, ineffectiveness, and disrespect for citizens. After the establishment of Bantustan health services, there was a creation of departments of health based on ethnicity and an establishment of racial-based health services (Kautzky & Tollman, 2008a).

Additionally, the involvement of political agendas in health services and the racial segmentation of its workforce and resources all contributed to the persistence of discrimination in access to medical care (Kautzky & Tollman, 2008a). Mahlathi (2017) also agreed that the discrepancy in healthcare during the apartheid era escalated because of differing spending on healthcare based on racial ideologies. The way services were

provided was incredibly unbalanced, and it was inevitable that the increase in demand for public sector services would be exorbitantly expensive and ineffective (Maphumulo & Bhengu, 2019). The public sector therefore needed to change to reform and correct existing inequities because of the country's turbulent past (Rakate, 2007).

Tollman (2008) also affirmed that the apartheid government had to deregulate the health sector due to an economic recession that was imminent coupled with the intense pressure that was exerted by the healthcare sector on the government. The increase in hospital-based health services brought about by the privatisation of healthcare was expected, which escalated the existing stark differences in the allocation of staff and aresources to rural and urban areas and raised the cost of accessing services, which significantly disadvantaged low-income groups (Mahlathi & Dlamini, 2018).

The entire public sector was subjected to pro-equity policies and programmes launched for the purpose of reconstructing South Africa, that were developed by the democratic government at the end of the apartheid era (Rakate, 2007). A potent building programme named the Reconstruction and Development Programme (RDP) for public health care was established, which consisted of the provision of free maternal, paediatric, and primary healthcare for all users of public health facilities (Kautzky & Tollman, 2008a). The reformation of national healthcare was received with good spirits by the public because there was an explicit policy outlined in the National Health Plan to be followed by the newly formed National Department of Health (Malakoane *et al.*, 2020).

Successfully implementing the new development policies created by the democratic government became an extremely onerous exercise at both the local and provincial levels (Kautzky & Tollman, 2008a). It became evident that the strategy which was used for implementing the development policies was not well-thought out and lacked rationale (Kautzky & Tollman, 2008a). This position was echoed by Maphumulo (2019), who stated that the government had implemented numerous quality improvement programmes in public hospitals post-apartheid, which are the provision of strategic leadership, improvement of human resources management, revitalisation of healthcare infrastructure, management of communicable diseases, and strengthening research and development. Despite refining and modifying these programmes, they still failed at producing the desired quality of service (Maphumulo & Bhengu, 2019).

The new government had failed to prepare healthcare facilities and healthcare workers for the increasing volume of individuals who would inundate healthcare centres for free health services (Kautzky & Tollman, 2008a). The influx of clinics that followed was indicative of a population that was becoming more and more dependent on the government for even the most basic needs (Kautzky & Tollman, 2008). The healthcare system in South Africa is still plagued by the issues that were prevalent during and just after the apartheid era (Kautzky & Tollman, 2008). Malakoane et al. (2020) state that the severe lack of qualified healthcare workers coupled with the failure of the government to fill critical posts in public healthcare is still a significant obstacle

to implementing and providing district-based health services in South Africa. This problem is extreme and systemic in nature; it is deeply embedded in the disparities of the national health system combined with the exodus of health workers for greener pastures (Malakoane *et al.*, 2020).

1.2.4 Importance of a functional healthcare system

One of the main elements of an economy that should be considered is healthcare spending because of the results it bears on the performance of the economy (Hammond & Levine, 2010). It has been demonstrated in a research study that quality healthcare in a nation can result in a higher GDP value (Isham, Mair & Jackson, 2020). In his study reviewing the development of a nation, Bleakley (2010) established that the quality of human capital a nation possesses is highly determined by the state of healthcare in a nation. Bleakley (2010) also observed that the efficiency of human capital rises as healthcare spending rises, so positively influencing economic growth.

(Raghupathi, 2020) conducted a study to assess the relationship between the health of a nation's citizens and the state of the economy of that nation. In his study, Raghupathi (2020) collected economic data and the health data of citizens across the United States from 2003-2014 and analysed using statistical comparisons. The findings of Raghupathi (2020) clearly support the idea that there is a positive association between healthcare spending and economic measures of income like the (gross domestic product) GDP and labour productivity. Raghupathi's (2020) findings confirm the position of various researchers that a healthy population positively affects the nation's economy (Goodarzi, 2016; Ion & Cristina, 2014; Okebukola, 2014). This theory is demonstrated in Figure 1, a graph showing data collected by the World Bank, which shows a positive correlation between healthcare spending and a rise in the GDP.

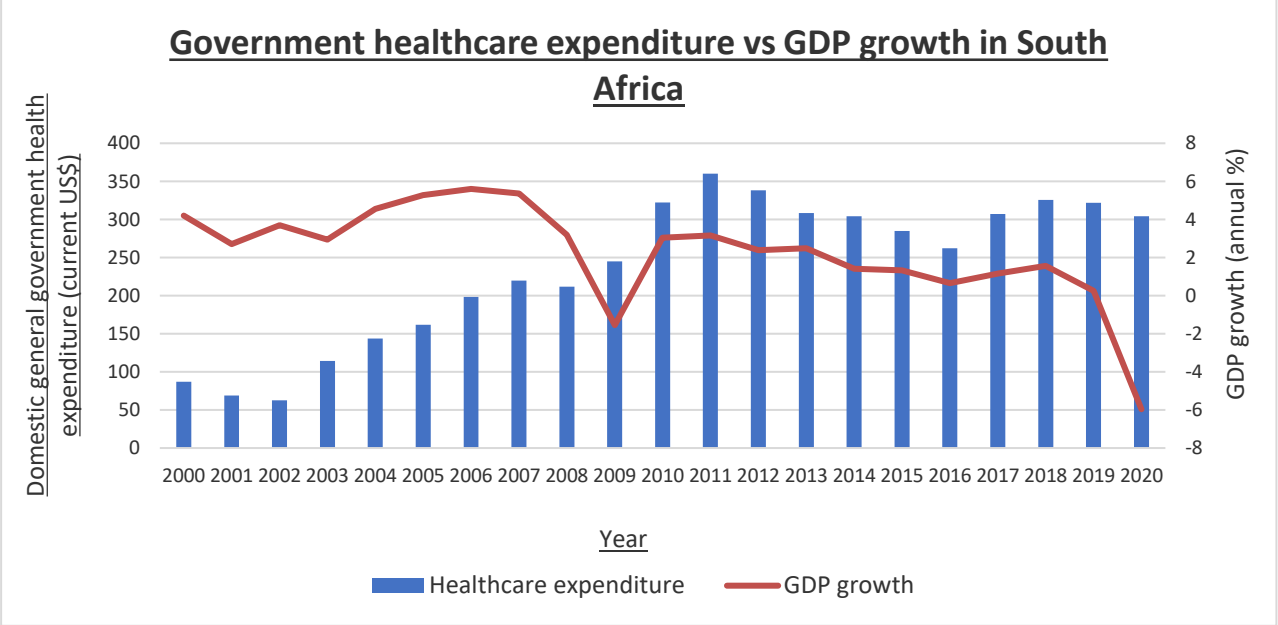

Figure 1: Graph showing the relationship between government healthcare expenditure and gross domestic product (GDP) growth in South Africa (The World Bank, 2023).

The cost of health in South Africa is about 8 per cent of the Gross Domestic Product (GDP) (Uthman et al., 2015). This constantly increasing value, shown in Figure 2, decays the economic future of tax-paying individuals and entities who are required to foot the bill (Goodarzi et al., 2016). The outdated modus operandi of public hospitals exacerbates the impacts of having patients that far surpass the number of available skilled medical staff (Erasmus, 2012). This causes medical staff to be grossly overworked through excessive hours of overtime (ibid).

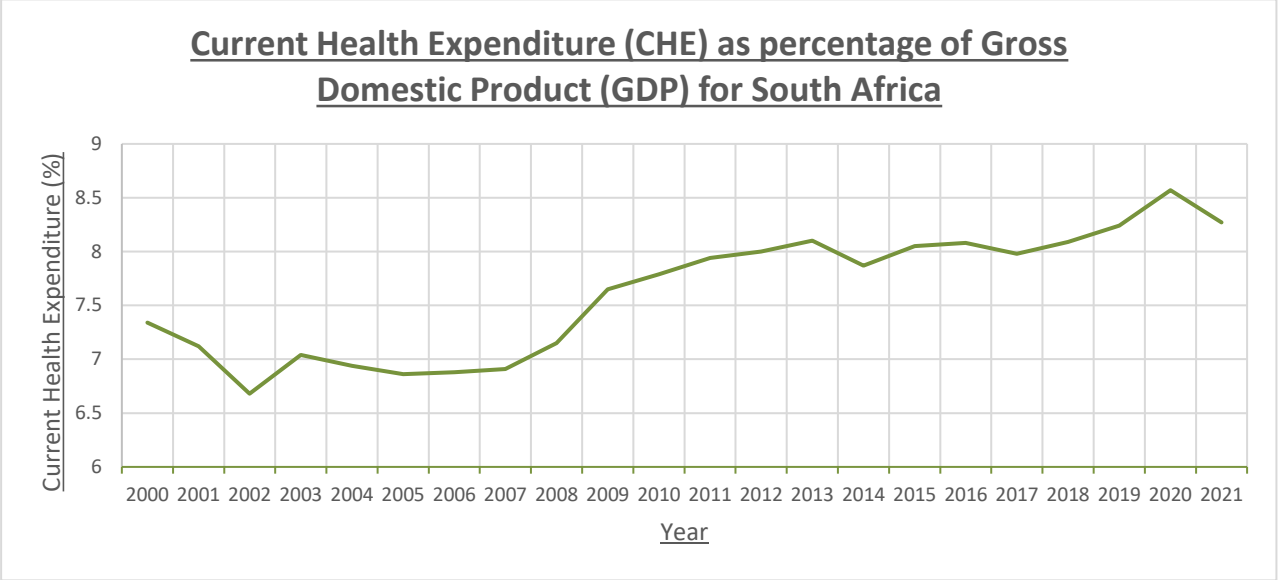

Figure 2: Graph showing the current health expenditure (CHE) as a percentage of the gross domestic product (GDP) in South Africa (World Health Organisation, 2023).

Figueiredo & Eiriz (2009) established that the introduction of innovation in healthcare has improved the quality of life and the life expectancy of patients. This idea was reinforced by DiClemente et al (2019) who have jointly agreed that innovation in healthcare is the cornerstone to reducing morbidity and mortality of patients. The collaboration of innovators and healthcare professionals is a faster and cost-effective method in providing solutions to healthcare problems (Omachonu & Einspruch, 2010a). Therefore, a new scalable model at the interface of innovation and health care is needed (Omachonu & Einspruch, 2010a).

1.2.5 Innovation in public healthcare in South Africa

South Africa has implemented several progressive initiatives for public healthcare over the past years (Maphumulo & Bhengu, 2019). The establishment of public mobile clinics have increased in South Africa and as such brought medical services to rural communities, many people reside in rural or isolated locations with little access to healthcare, mobile clinics have therefore made medical services more accessible to these communities (Maphumulo & Bhengu, 2019). These clinics have the necessary medical equipment and are manned by specialists who offer the community's basic healthcare needs (Maphumulo & Bhengu, 2019). In South Africa, the use of technology in some tertiary public healthcare institutions has escalated (Maphumulo & Bhengu, 2019). Inkosi Albert Luthuli Hospital in Durban is an example of a hospital that has successfully

implemented innovative initiatives to enhance public healthcare (Mandisa et al., 2021). The tertiary hospital is a cutting-edge healthcare facility that focuses on specialised treatment for patients with chronic and complicated illnesses (Mandisa et al., 2021). The hospital has implemented an electronic medical records system (EMRs) that allows healthcare providers to access patient records electronically (Mandisa et al., 2021). Additionally, a telemedicine initiative at Inkosi Albert Luthuli Hospital enables medical professionals to consult with patients remotely. The hospital has also created a smartphone application that gives patients access to crucial health data, including reminders for appointments and prescription regimens (Mandisa *et al.*, 2021). To counter the effects of fragmentation within the hospital, Inkosi Albert Luthuli Hospital has implemented a health information system that integrates data from various sources, including laboratory results and radiology reports (Mandisa *et al.*, 2021). This system helps healthcare providers to make educated decisions about patient care and to enhance the overall quality of care (Mandisa *et al.*, 2021). Unlike Inkosi Albert Luthuli Hospital, the adoption of innovative initiatives does not span across all public healthcare facilities (Mandisa *et al.*, 2021). Initiatives such as those implemented at Inkosi Albert Luthuli Hospital have helped to improve access to healthcare services and improve health outcomes where implemented (Maphumulo & Bhengu, 2019). However, majority of public hospitals in South Africa still have challenges that need to be addressed, such as improving infrastructure and increasing funding for public healthcare services (Maphumulo & Bhengu, 2019).

1.2.6 Status of innovation in public healthcare

Innovation in healthcare often requires significant investments of time and resources (De Villiers, 2021). By researching the factors that influence innovation, healthcare organizations can make well-informed resource allocation decisions and maximize their impact (ibid). Also, by understanding the factors that influence innovation, healthcare organisations can stay competitive and remain at the forefront of healthcare delivery (De Villiers, 2021). The need for innovative solutions in the healthcare sector has been apparent to the government since South Africa became a democratic country (Ngobeni et al., 2020). The National Development Plan states that a phased implementation of a national health insurance system is required by 2030, along with a decrease in the relative cost of private medical treatment and improved human capacity and health systems in the public sector (ibid). To respond to this need, the government, through the National Health Research Policy (2001), committed to allocating 2% of the total public sector health expenditure to health research and development (Paruk et al., 2014). Despite this vast investment in research and development, it is an issue that the investment does not directly translate to successfully implemented innovation (Maphumulo & Bhengu, 2019). However, it is important to note that the distorted allocation of funds within healthcare research and development contributes to the lack of a direct correlation between investment in research and development and the successful implementation of innovation (ibid). A framework for prioritising how funds should be effectively allocated within healthcare research was put into place (Schneider, 2001). However, the prioritisation process still needs further refinement to achieve efficiency

(ibid). To test the effectiveness of the distribution of funds within the healthcare sector, the successful implementation of innovation in public healthcare must be measured at predetermined intervals.

1.2.7 Summary

Scholars have studied the factors that influence innovation in healthcare to be human capital, technological infrastructure, organisational culture, policy, and decision-makers (Akenroye, 2012; Herzlinger, 2006; Scott *et al.*, 2008). Innovation centres for creating prototypes and testing innovations are still emerging and extensive research has not yet been done on what innovation centres can achieve for healthcare innovation (Bhattacharyya et al., 2022). The one significant gap in literature that persists is that there hasn't been much discussion on the existence or suitability of prototype testing environments for healthcare innovation in South Africa (Fleuren, 2004). Evidence-based innovation cannot be developed and adopted if a suitable environment for testing innovation is not created (Fleuren, 2004). Without prototyping and testing the prototype, research is incomplete (Fleuren, 2004). This research focuses on exploring the existence and suitability of the research and development hubs for healthcare innovation in South Africa. To bridge this existing gap, this study focuses on how to create suitable research and development hubs and environments for testing innovation prototypes in South African public healthcare, that would yield realistic results.

1.3 Problem Statement

1.3.1 Context

In South Africa, the public health care system has a track record of being overloaded and under strain (Maphumulo & Bhengu, 2019). It is predominantly characterised by inadequate infrastructure and a severe lack of resources (Khong & Ghista, 2006). Medical institutions in South Africa are not producing enough medical personnel at the required rate because training medical professionals is costly (Mpofu, 2013). "Africa is said to have less than one health worker per 1000 compared to 10 per 1000 in Europe" (Maphumulo & Bhengu, 2019, p9. The continuously rising healthcare costs, ageing population and exodus of professional medical staff have brought about a need to create cost-effective models that will improve efficiency in public hospitals (Khong & Ghista, 2006).

Poor healthcare quality does not only have monetary costs, but it also costs lives (Rispel et al., 2019). It has been reported that a quarter of neonatal deaths are preventable as they are mostly caused by a combination of failing health systems and gross staff shortages (ibid). Efficiency in the health system will not be realised through the use of human capital given that the annual production of medical graduates in South Africa is 1300 for a population of 59 million (Maphumulo & Bhengu, 2019).

Without a doubt, medical treatment has made some staggering advances in terms of technological innovation over time (Meyer et al., 2017). However, these advances are often not used to their maximum efficiency which results in a reduction in their utility (ibid). In both developing and developed countries, a prevalent

concern is the failure of innovative ideas being introduced to the healthcare market and the failure of innovation to adopt and diffuse in the healthcare market (Dixon-Woods et al., 2011).

It is quite evident that innovation is rather unsuccessful in healthcare (Herzlinger, 2006). In South Africa, it is therefore important for healthcare executives to address the impediments to the successful adoption and implementation of innovation, as innovation will continue to be a driving force in achieving the objective of lowering healthcare costs while increasing healthcare quality (Leonard et al., 2019).

1.3.2 Issues that arise from a dysfunctional and inefficient healthcare system.

The problems that inundate public healthcare beget a need for innovative solutions to be implemented in every single facet of the healthcare system (De Villiers, 2021). These problems include but are not limited to poor quality healthcare, medical malpractice, health information system gaps, medical personnel shortages, and dilapidating healthcare facilities (Rispel et al., 2019). South Africa's failing healthcare system is a serious issue for several reasons (Maphumulo & Bhengu, 2019). When the healthcare system is dysfunctional, people cannot get access to high-quality care when they need it (Maphumulo & Bhengu, 2019). People may, therefore, experience avoidable illnesses, accidents, and chronic disorders (Maphumulo & Bhengu, 2019). As a result, the population may experience worse health outcomes and have a shorter life expectancy.

The economy may suffer because of a defective healthcare system (Rakate, 2007). People may be unable to work or may require time off from their jobs to care for ill family members when they are unable to receive healthcare (ibid). In the long run, this may lead to decreased productivity, slower economic expansion, and higher healthcare expenses (ibid). It's important to increase and sustain productivity in a developing country like South Africa because it aids in boosting GDP growth and raising living standards (Albury, 2005). A failing healthcare system can exacerbate social inequality in South Africa (ibid). Better treatment may be provided to individuals who can afford private healthcare than to those who must rely on the public healthcare system (ibid).

Research has produced evidence that South Africa is one of the leading countries in HIV/AIDS and tuberculosis infection rates in the world (Malakoane et al., 2020). Sedentary lifestyle diseases such as diabetes in South Africa are also on the rise (Ataguba et al., 2011). While there has been a notable advancement in the medical field and an increased expenditure on healthcare, it is also worthy to note that low-income communities are still subjected to poor access to basic healthcare services (Ataguba et al., 2011). Low-income communities in South Africa mostly rely on the public health system, which is almost dysfunctional, under-resourced, and ill-managed (Lehmann, Dieleman & Martineau, 2008). A challenge that many face in rural and informal communities is that healthcare centres and hospitals are located quite a distance away from the residential areas, which makes it extremely difficult for these residents to get proper diagnosis and treatment,

in the event that they do find healthcare facilities with medical personnel and functioning equipment (Lehmann et al., 2008).

This may result in an increase in wealth disparity and contribute to societal discontent and instability (Kautzky & Tollman, 2008b). South Africa has one of the highest rates of HIV/AIDS in the world, and a failing healthcare system can make it difficult to address this epidemic effectively (Kautzky & Tollman, 2008b). Without comprehensive HIV/AIDS prevention, treatment, and care available to all, the pandemic may continue to expand, increasing mortality rates and placing further strain on the healthcare system (Kautzky & Tollman, 2008b).

When compared to other upper middle-income countries and high-income countries as per the World Bank income groups, South Africa has the lowest number of medical doctors per 10 000 population (World Health Organisation, 2023). This notion is clearly demonstrated in Figure 3, which shows the number of medical doctors per 10 000 population in South Africa, Brazil, China, Germany, the United States of America, and the United Kingdom of Great Britain in the year 2019.

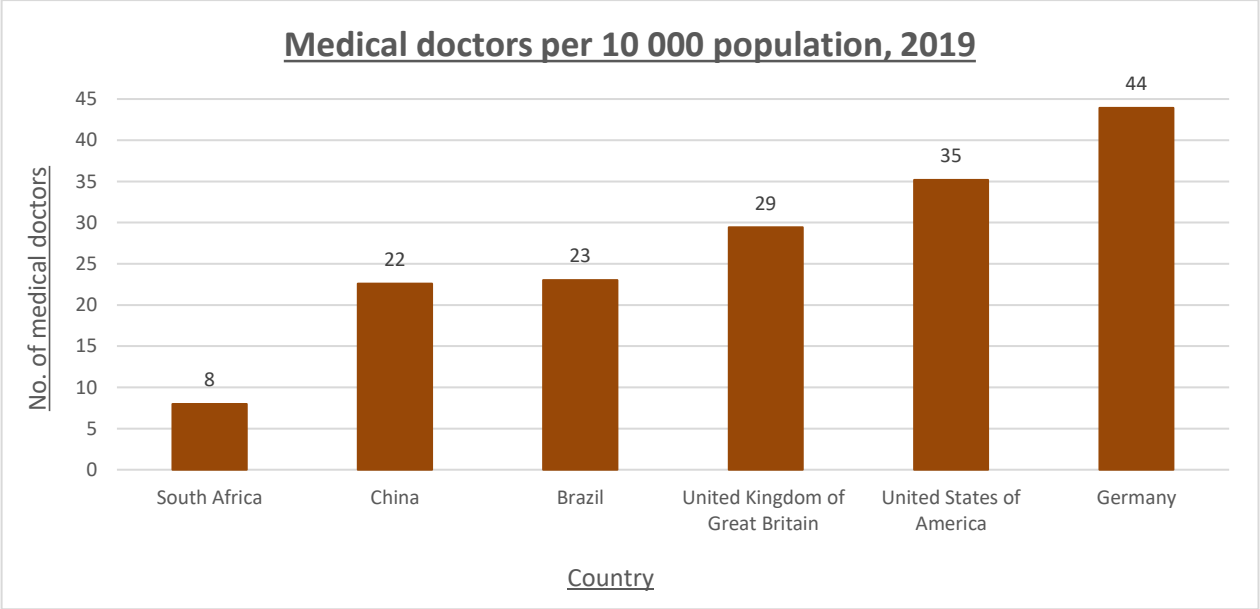

Figure 3: Number of medical doctors per 10 000 population in 2019 (World Health Organisation, 2023)

The dysfunctional public healthcare system in South Africa degrades the quality of life for the majority of the South African population. The successful use of innovation in healthcare has the potential to enhance healthcare delivery. This study therefore aims to assess the macro-environmental and micro-environmental factors that influence the uptake of healthcare innovation in South African public hospitals.

1.4 Motivation

The public healthcare system in South Africa is overburdened and highly inefficient. Not only does a dysfunctional healthcare system exacerbate the existing health disparities in society, but it also has negative

impacts on the economy and the overall socioeconomic status of a society. Part of the South African Department of Health's mandate is to improve the healthcare delivery system, focusing on efficiency and sustainability inter alia (Paruk et al., 2014). Inefficiency in the public health care system can be addressed through innovation, such as the use of machines, devices, medical procedures, pharmaceutical drugs and computerized systems, which can increase the efficiency of healthcare (Furusa & Coleman, 2018). In South Africa, there has been a rise in new healthcare innovations that have been developed by firms in the private sector, which aim to enhance healthcare delivery more specifically in underprivileged communities (Lehmann et al., 2008). Innovative solutions to improve elements of healthcare, on the other hand, are frequently not adopted in the facilities where they are needed (Lehmann et al., 2008). Leonard et al (2019) concluded that a variety of obstacles are preventing these solutions from being implemented in practice. As a result, there is a need to assess the healthcare system, specifically healthcare institutions, with the goal of identifying the constraints and restrictions to the adoption of innovative solutions (Leonard et al., 2019).

1.4.1 Importance of innovation in healthcare

Innovation in healthcare is incredibly important for numerous reasons. Innovative medical technologies, treatments and drugs can significantly improve health outcomes for patients (Fleuren, 2004). An example of such is the invention of vaccines against lethal diseases, which have increased survival rates and improved the quality of life for many patients (ibid). Innovation in medicine has helped to address unmet medical needs such as occasionally encountered diseases (Fleuren, 2004). The development of new medical devices and diagnostic tools address the needs of patients with rare medical diseases (ibid4). Patients with conditions that have no effective treatment, also benefit from the development of new drugs and medical devices (Fleuren, 2004). Innovation in healthcare is important because it can also increase access to healthcare (Dixon-Woods et al., 2011). Telemedicine and mobile health technologies are developments that have made healthcare more accessible and affordable for populations that are based in remote areas (ibid). The economic growth that comes with medical innovation cannot be dismissed (Bedir, 2016). The development of new medical drugs and devices can stimulate economic growth and assist in job creation (Bedir, 2016). Above and beyond all other considerations, medical innovation is primarily important in South Africa because it can improve the dire state of public healthcare (ibid). Lepore et al (2023) resonate with the thoughts that innovation in medicine is crucial for resolving unmet medical needs, expanding access to treatment, fostering economic growth, and enhancing public health in addition to improving health outcomes.

Okebukola (2014) developed a model that shows the relationship between innovation and the socio-economic status of a society. The model demonstrated innovation to have a direct impact on socio-economic development. The model proved innovations to be catalysts of production which society benefits from (ibid). Historically, it has been observed that innovations are the oxygen that socio-economic growth and development require (Okebukola, 2014).

It has been proposed that innovation could provide marginalised populations a few remedies for societal problems including having access to potable water and good healthcare (Chutukuta & Grobbelaar, 2016). Chutukuta and Grobbelaar go on to state that communities may develop into a vibrant consumer market or a varied source of supply through inclusive innovation. Innovation that facilitates development in the areas that are typically excluded from mainstream development is defined as inclusive innovation (Heeks et al., 2013). Inclusive innovation, as defined by (Peerally et al., 2019) refers to innovation that specifically focuses on the development of marginalised groups. Schillo & Robinson, (2017) describes inclusive innovation as the creation and use of novel concepts that aim to open possibilities and improve the social and economic well-being of disadvantaged sections of society. Typical examples of inclusive innovation include the invention of machines that produce sanitary towels at low cost which allows economically disadvantaged women to afford them (Schillo & Robinson, 2017). The production of low-cost, fuel-efficient vehicles is also considered as an inclusive innovation, as it allows low-income groups to afford vehicles (Heeks et al., 2013). In healthcare, the creation of inexpensive cancer-treating equipment is an inclusive innovation that is still being extensively researched (Noel & Ellison, 2020).

1.4.2 The impacts of innovation in healthcare

The Fourth Industrial Revolution (4IR) is defined as significant technological advancements in the fields of automation and information technology (Pereira & Romero, 2017). One of the industries that is undoubtedly being most impacted by the 4IR is the health sector (Pereira & Romero, 2017). Technological advancement is transforming healthcare delivery which affects all stakeholders including patients, healthcare personnel and the government (Atwine, 2019). Innovative delivery of healthcare through new methods of diagnosis and healthcare management are also an outcome of the 4IR (Akenroye, 2012). It is crystal clear that the 4IR technologies are not only advantageous to the suppliers, but they are also designed to accommodate and aid consumers as well (Fleuren, 2004). For example, the development of mobile technologies will broaden access to diagnosis, treatment and ultimately healthcare as a whole (Fleuren, 2004).

The results of a study conducted by Araújo (2020) to explore the impact that the 4IR has on the health sector concluded that the 4IR is significantly improving the health sector. The qualitative study conducted by ibid (2020) was based on interviews conducted among professional healthcare workers and the analysis of the results show that the 4IR has a direct impact on healthcare efficiency and effectiveness. The 4IR was also found to have a direct financial impact on the healthcare sector in developing countries (Araújo, 2020).

In healthcare, innovation occurs in numerous ways (Dixon-Woods et al., 2011). It could take shape in the form of the establishment of novel drug therapies, the establishment of advanced devices and surgical procedures, or even the improvement of service delivery models (Länsisalmi et al., 2006). Existing literature shows contradictory thoughts from different scholars regarding the impacts of innovation in healthcare (Grol, Wensing, Eccles & Davis, 2013; Dixon-Woods et al., 2011). (Grol et al., 2013) haven't been convinced that there is a direct link between the performance of healthcare and the implementation of innovation. In fact,

Grol et al., (2013) suggest that hospital administrators need to start developing innovation policies with the idea that innovation does not always have positive benefits for healthcare. The risks and costs of implementing innovation sometimes outweigh the positive impacts they bring (Dixon-Woods et al., 2011). Kimble (2017) also reiterates that even though an innovation may be beneficial, it may have far more significant disruptive effects.

On the other hand, some acknowledge the importance of innovation in healthcare. The paper system used in healthcare prohibits efficiency in the delivery of healthcare (Omachonu & Einspruch, 2010b). Paper storage creates silo systems and exacerbate the detrimental impacts of the fragmentation of healthcare says ibid. Healthcare innovations such as electronic record-keeping systems are extremely advantageous for healthcare delivery (Omachonu & Einspruch, 2010b). The errors that usually occur from paperwork are significantly reduced by using innovative solutions and the amalgamation of healthcare delivery is also realised through the effective use of innovative solutions says Omachonu & Einspruch (2010). This view is supported by Fuchs & Sox (2001) who revealed that technological innovations were the most effective in improving healthcare delivery when compared to other forms of innovation in healthcare. A research study conducted by Länsisalmi et al (2006) reviewing innovation in healthcare concluded that it is important for all healthcare organisations to possess innovation as a vital component that improves healthcare delivery. McGinnis et al (2011) have stated that some scientists are convinced that innovation for healthcare is beneficial. This conviction has been seen in the past decades through the proliferation of innovation aimed at extending longevity, improving the standard of living, and improving the efficiency of healthcare delivery (Fridsma, 2011).

The extensive digitalisation of healthcare services and information, which frequently entails the incorporation of automation and artificial intelligence technologies is due to the enhanced service delivery accuracy, and efficiency it creates (Toivanen et al., 2016). In his analysis of healthcare in innovation, Ngobeni (2020) also states that the use of innovation in healthcare should become a widespread phenomenon as it has the potential to influence every element of healthcare and create new opportunities for cross-sector cooperation. Islam (2021) in consensus with Ngobeni (2020) argues that social care and healthcare systems are encouraged to converge by using innovation, which has an impact on the organisation, provision of services, and technology infrastructure of both public and private sectors. Islam (2021) goes on to say that developing digital health systems incorporates individualised and collaborative healthcare approaches which result in the expansion of healthcare delivery.

A measurable improvement in healthcare innovation can be noticed at intervals of a decade, however, this improvement has not been consistent across all countries and regions (Consoli & Mina, 2009). When organisations constantly investigate how to minimise overall costs by using integrated healthcare services to enhance the end-user's experience, this is referred to as evolving healthcare innovation (Singhal et al., 2020). The integration of various processes that add to the creation of a services which have a common goal of creating improved and efficient stakeholder experience is known as an ecosystem (ibid).

1.5 Research Questions and Objectives

1.5.1 Research Questions

The central research question that guides this study is: “What are the factors that affect the successful implementation of innovation in public healthcare in South Africa?”

The research sub-questions are as follows:

i) Is there a need for innovation in public healthcare in South Africa?
ii) How is the successful implementation of innovation in public healthcare measured in South Africa?

1.5.2 Research Objectives

The research objectives of this study are as follows:

a) To assess the need for innovation in public healthcare in South Africa.

b) To identify the strategies in place for implementing innovation in public healthcare in South Africa.

c) To establish the level of successfully implemented innovation in public healthcare in South Africa.

1.5.3 Assumptions of the Research

a) Data collection tools

It is assumed that the interviews used to acquire the data, are legitimate and trustworthy for gathering the intended information.

b) Research Participant Responses

It is assumed that the research participants are qualified, have the ability to understand the questions, and responded honestly to the questions asked.

1.6 Research approach

A qualitative approach was used in this study to obtain the necessary insight into the opinions of medical doctors and the Department of Health’s officials of the factors that affect innovation in healthcare. The insights gathered can be used to further inform future quantitative as well as qualitative research. To address the question of what are the factors that influence innovation in healthcare, qualitative data is acquired in the form of literature and interviews. Purposive sampling was used to select the participants. The research methodology is described more thoroughly in Chapter 3.

The main limitation of this study is that the nature of qualitative research makes it prone to subjectivity when interpreting results (Goundar, 2012). To ensure that validity and reliability as redefined for qualitative research were achieved in this study, the triangulation analysis technique was used (Goundar, 2012). The small sample size of this study was another limitation. Medical doctors work under strict time constraints, it is therefore difficult to find and interview a fair number of them. The total sample size of the study consisted of 10 participants. However, a minimum of 5 participants in a qualitative study have been proven to attain saturation (Dworkin, 2012). The limitations of the study are explained in depth in Chapter 3.

1.7 Overview of the study

In the second chapter of this study, the theoretical foundation of the study is presented. The review of theoretical and empirical literature related to the factors that influence innovation in public healthcare is also introduced in the second chapter of the study. The research methodology used to meet the study's goal is presented in the third chapter. In the fourth chapter, the results from the conducted interviews are discussed. A comparative analysis between the results of the study and the reviewed literature is presented in the fifth chapter. The study is then concluded in the sixth chapter. Finally, the limitations of the study and future research areas are discussed in the seventh chapter.

2 CHAPTER 2 - LITERATURE REVIEW

2.1 Introduction

The purpose of this study is to determine the factors that hinder the implementation and optimisation of innovation in public healthcare in South Africa. The problem addressed in the study is the existence of a dysfunctional and inefficient public healthcare system in South Africa, which results in grievous monetary and moral ramifications. Throughout the literature studied, the authors reveal that the efficient use of innovation in healthcare has the potential to enhance healthcare delivery (Bhattacharyya et al., 2022; Araújo, 2020; Alaofin, 2015). Authors are in consensus that the effective use of innovation in healthcare is hindered by macro-environmental factors and micro-environmental factors related to public healthcare organisations and innovation firms (ibid) The precise details of these factors will be explained later in this chapter. Existing literature faintly addresses the question of the existence or suitability of prototype testing centres for healthcare innovation in South Africa and what these centres can achieve for healthcare innovation (Dryden-Palmer et al., 2020).

Academic databases were searched for information on healthcare innovation, public healthcare delivery in South Africa, innovation implementation methodologies, healthcare quality improvement, and other topics to investigate what previous literature has covered on this topic. The literature review consisted of older references from the year 1993 to capture longstanding frameworks and concepts and more recent references from the year 2023 to cover the latest empirical and theoretical studies.

Innovation is defined as “a new idea, device or method”, it is also defined as “the act or process of introducing new ideas, devices or methods” (Kimble & Massoud, 2017, p. 89). Innovation is not a new concept at all and the definition of innovation in healthcare has been adopted from the definition of innovation in other fields such as marketing, technology, and business (ibid). The World Health Organisation (WHO) defines innovation in healthcare as any policy, service, practice, technology, or system of product that “improves the efficiency, effectiveness, quality, sustainability, safety and the affordability of healthcare” (Nolte et al., 2018, p. 8). A concise and summarised definition of innovation in healthcare is the optimisation of the performance of the healthcare system (ibid). It is important to distinguish between what is innovation and what is not innovation in healthcare (Thakur et al., 2012). Not every solution in healthcare qualifies to be labelled as an innovation (ibid). Conversely, not all innovations are necessarily solutions (Thakur et al., 2012). Certain solutions in healthcare are just developments within the field (ibid).

The main topics that will be covered in this chapter are as shown in Figure 5. The quality of healthcare in South Africa is discussed to establish whether it's efficient or not. The need for innovation in public healthcare because of healthcare quality is then discussed, followed by defining what exactly innovation in public healthcare is. Thereafter the evolution of innovation in healthcare is discussed to show the significant impact of innovation in healthcare over the years. Next is the discussion on the level of successfully implemented

innovation in public healthcare followed by a thorough discussion of the micro-environmental and macro-environmental factors that influence innovation in public healthcare in South Africa.

To answer the research questions, a section is dedicated to each research question to reviewing how innovation is measured in public healthcare in South Africa. The chapter is concluded by discussing the public's expectations of health delivery systems to benchmark the performance of healthcare against the public's expectations. To answer the research objectives, the chapter is ended by discussing the level of successfully implemented innovation in public healthcare in South Africa.

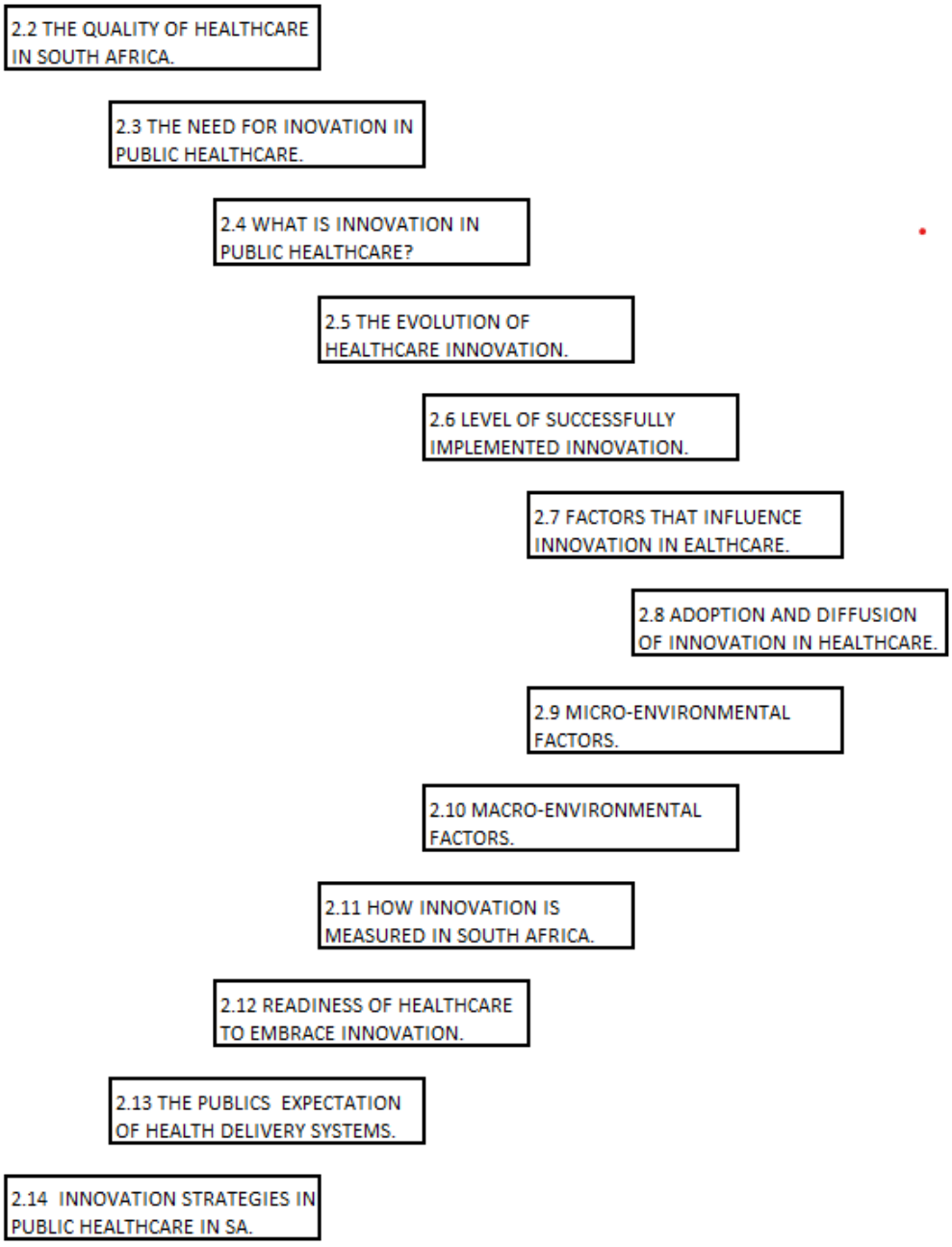

Figure 4: Overview of Chapter 2

2.2 The quality of healthcare in South Africa

South Africa is a middle-income country with health systems that are more inferior than lower-income countries, this is caused by a scarcity of human resources coupled with an influx of economic migrants (Ngobeni et al., 2020). The disparities in health-care access between black and white individuals in South Africa that were onset by the unjust policies of apartheid still persists, however, the divide in post-apartheid South Africa is caused by economic status and not race (ibid). It has also been reported by Maphumulo and Bhengu (2019) that numerous state hospitals in South Africa are in a dire and dysfunctional state. This greatly compromises the quality of healthcare and usually leads to premature patient discharges (ibid). The public sector serves approximately 83% of the population but only accounts for 49.7% of the total hospitals that exist in South Africa (Dell & Kahn, 2017). The nursing personnel accounts for 63% of the total health personnel in South Africa, while medical doctors only account for 9% (Dell & Kahn, 2017). Although medical doctors make up a small percentage of overall healthcare professionals, 70% of them work in the private sector, signalling shortages in the public sector (Dell & Kahn, 2017). The statistics quoted by Dell & Kahn, (2017) reinforce the theory of staff shortages in the public health sector. Ramjee (2013) further justifies human capital shortages by stating that South Africa has the greatest costs for medical doctor education; however, a brain drain has resulted in a loss of returns on this investment. Another important issue in the healthcare system in South Africa is the high cost of medical care, which is already significant and has been quickly increasing over the last three decades (Ramjee, 2013). Weak political and management leadership has a negative impact on the health sector which results in poor quality healthcare services (Victor Ngobeni, 2020).

Over the course of its existence, the private healthcare market in South Africa has seen chronic cost increases (Van Den Heever, 2001). Certain services, such as those provided by hospitals, pharmaceutical companies, and specialists, have, however, seen higher price increases than others (ibid). In addition, medical plans have seen a huge growth in intermediate and non-health expenditures in the recent years, far outpacing increases in medical costs (Van Den Heever, 2001). Travis et al (2004) reported that hospitals, drugs, and specialists experienced a combined increase of over 8.5 percent in medical system expenditure over a period of 10 years (1991-2001). Public hospital spending has decreased significantly, whilst private hospital spending has increased substantially (Travis et al., 2004). Although some of this increase in hospital spending can be attributed to medical scheme patients moving out of public hospitals, the increased spending in private hospitals is not directly proportional to the spending decrease in public hospitals, indicating that the increased utilisation of private hospitals has been caused by a significant increase in hospital medical costs schemes (Travis et al., 2004).

The exorbitant increase in costs for private medical care is indicative of the poor quality of healthcare patients get subjected to in public healthcare facilities (Andaleeb, 2001). The research study further explains that over the last two decades, real cost rises in South Africa's private health market have been both consistent and dramatic (Andaleeb, 2001). The rising membership of open medical plans, which had fewer incentives to limit

medical costs and had significantly higher non-medical costs, caused a cost acceleration during the period of deregulation from 1989 to 1999 (Andaleeb, 2001).

McIntyre (2018) suggests that poor healthcare has been an ongoing phenomenon in South Africa because the administration that was elected in the country's first democratic elections in 1994 acquired a health system that was severely segmented, with distinct public and private sectors. Another research study further stated that historically, during the apartheid era, 'black' institutions and health departments in the 'homelands' were deliberately underfunded (Andaleeb, 2001). The distance individuals should commute to reach a health institution is an important aspect of the accessibility dimension of healthcare which in turn can be used to gauge the quality of healthcare (Andaleeb, 2001). In South Africa, there are significant discrepancies in residential closeness to a medical centre between rural and urban locations between socioeconomic levels (Andaleeb, 2001). According to statistics from 2002 to 2018, around 20% of households in the lowest income quantile lived an hour or more from the nearest public clinic, compared to less than 5% of homes in the top income quantile which indicates inferior levels of healthcare (Mcintyre & Ataguba, 2018).

In a study comparing health indicators in middle income countries, it was found that despite allocating a significant volume of resources to the health sector, South Africa had very low health indicators when compared to comparable middle-income nations, showing inefficient utilization and allocation of available health care resources (Auriacombe & Meyer, 2020).

2.3 The need for innovation in public healthcare

When Bedir (2016) explored the correlation between healthcare and economic prosperity, it was established that there exists a two-way relationship between economic growth and healthcare advancement. In summary, Bedir (2016) discovered that a population that is healthy leads to more productivity which ultimately leads to economic growth, and the reverse also being true.

The element of worker productivity is a crucial component of the relationship between health spending and economic performance (Ion & Cristina, 2014). Higher levels of worker productivity are correlated with well-being (Isham et al., 2020). In developing countries, a decline in the health of the workforce is likely to lead to a loss in labour productivity and a decline in the economy since economic growth is dependent on labour productivity (Ion & Cristina, 2014). It is therefore extremely vital to heed to health expenditure issues and the public health of a country (Ion & Cristina, 2014). Arora (2015) concluded that wise investment in numerous healthcare issues would increase economic output and result in a direct reduction of poverty. Arora (2015) also discovered that there is a significant correlation between the well-being of individuals and the economic growth of industrialised nations. A study conducted by Khan (2018) revealed that the development of public healthcare in developing countries caused a considerable surge in economic performance. Likewise, a research study conducted by Mohammad (2016) highlighted that the long-term productivity of human capital thrives on the overall well-being of the population more than the levels of education within the population.

Grobbelaar (2016) substantiates the need for innovation in society through the distribution of wealth and income-generation capacity in developing countries is shaped like a pyramid. The wealthy, who have high education levels and high-income levels form the top of the pyramid, while the base of the pyramid is occupied by the underprivileged majority (Chutukuta & Grobbelaar, 2016). Statistics show that more than 67% of the world's population form the base of the pyramid and are subjected to negative socio-economic conditions (Chutukuta & Grobbelaar, 2016). Under-resourced individuals are frequently sold inferior products, such as expired medications, and frequently end up paying more than the people located in affluent areas for the same goods or services (Beninger & Robson, 2015). Frequently, products and services are not created for these people and their unique requirements in mind (ibid). Furthermore, Beninger (2015) states that conventional low-cost, low-margin business concepts where the underprivileged are only classified as customers can only thrive where the cost of production gets significantly reduced using innovation.

The successful implementation of universal health coverage (UHC), as defined by the Sustainable Development Goals, requires a high-quality health system (Rispel et al., 2019). The National Health Insurance (NHI) in South Africa is planned to be a health-financing system that collects funding to offer quality health care to all South Africans, regardless of socioeconomic background (ibid). The National Health Insurance (NHI) intends to restructure the health-care system in order to attain Universal Health Coverage, it also aims to give implementation to Section 27 of the South African National Constitution, which recognizes everyone's right to health care (Rispel et al., 2019). However, South Africa has not achieved the objectives of the Sustainable Development Goals and the National Health Insurance as the South African Lancet National Commission discovered that prevailing unethical leadership, inferior management, and governance deficits contribute to poor healthcare and avoidable deaths (ibid).

2.4 What is innovation in public healthcare?

The World Health Organisation (WHO) defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (Saracci, 1997, p. 1409). The Department of Health in South Africa is mandated to provide a framework for a coordinated and unified health system for South Africa by the National Health Act No. 61 of 2003 (National Health Act No 61, 2003, 2004). The Act specifies the functions that each of the three levels of government must do to provide healthcare services. The core functions of the government are to provide social, physical, and mental healthcare (ibid). This constitutes of identifying and examining community health issues, creating strategies and policies to aid in promoting good health and researching into new and innovative solutions to health issues amongst other things (National Health Act No 61, 2003, 2004).

The term innovation is broad when used in the health care environment. This term can be further refined by differentiating between the different types of innovation that exist in the health care sector (Herzlinger, 2006). To be precise, there are three types of innovation that can increase the efficiency of health care (ibid). The

first type of innovation is one that changes the ways in which consumers buy and use health care, this is known as customer-focused innovation and it usually results in a more convenient experience for the customer (Kelly & Young, 2017). The second type of innovation is one that uses technology to develop new products and treatments to improve health care, this is known as technology innovation and it generally results in a reduction of medical errors, increase the accuracy of diagnoses and result in a reduction in health care costs (ibid). The third type of innovation which is known as business model innovation is one that develops new business models to integrate separate health care organisations or activities (Kelly & Young, 2017).

Innovation in public health therefore refers to the development of a new procedure, rule, item, or plan that boosts effectiveness, impact, and the quality of healthcare (Flessa & Huebner, 2021). In their definition, ibid (2021) add that innovation in healthcare is an iterative procedure that can be carried out gradually or drastically; it is not a final result. Flessa & Huebner (2021) continue to state that collaboration and co-production are both extremely necessary elements of the innovation process. Milella (2021) believes that innovation in healthcare is a new activity that alters the status quo and adds value in a way that makes it possible for others to copy or adapt it. Ibid (2021) continues to define healthcare innovations to be any advancements, no matter how simple or advanced, that enhance patient experiences and health outcomes. The simplification of both business and healthcare processes is innovation in healthcare according to (Herzlinger, 2006). The implication of this definition is that healthcare organisations must work to enhance patient care and save costs to transition to value-based care (ibid). Kimble (2017) believes that to enhance treatment, diagnosis, education, outreach, prevention, research quality and delivery, and access to healthcare, innovations in the healthcare sector should theoretically result in scalable solutions and improvements in health policies, systems, products, technologies, services, and delivery methods.

2.5 The evolution of healthcare innovation

The second world war which ended in 1945 was a turning point for healthcare globally (Singhal et al., 2020). As a result of World War II, the focus of healthcare post-1945 was on contagious diseases and workplace accidents (Singhal et al., 2020). Today, however, the focus has shifted to preventing and effectively managing chronic diseases (ibid). This shift has led to stakeholders creating an ecosystem-based model of care through the various activities taking place in the health sector (Singhal et al., 2020). Between 2014 and 2018 the United States recorded high rates of investment in healthcare technology in the form of more than 580 healthcare technology agreements, totaling more than $83 billion (ibid). Safavi (2020) also observed a pattern of technology giants investing billions of US dollars into healthcare R&D in his research study. This investment has resulted in the constant modification of health systems and pharmaceutical products (ibid). An evolution in the technology of electronic health records over the past decade has been reported by Safavi (2020) as well. Safavi (2020) noted that the interoperability of electronic health records has helped to eliminate the data silos that had previously hindered end-to-end care analytics.

2.5.1 The evolution of healthcare innovation in South Africa

The provision of healthcare in South Africa is split between the private and public sectors which exist on opposite ends of the spectrum (Maphumulo & Bhengu, 2019). The type of innovation required in both sectors is different, hence the evolution of healthcare in South Africa differs significantly between the sectors (Maphumulo & Bhengu, 2019).

The Department of Sciences and Technology in South Africa has affirmed that health is one of the primary components of building wealth in a nation (Mcintyre & Ataguba, 2018). Having a healthy workforce in a country contributes substantial input to the economy (Raghupathi & Raghupathi, 2020). The Department has stated that primary healthcare in South Africa is not acceptable in certain areas, therefore, there is an urgent need to focus on research and development in South African healthcare (Mcintyre & Ataguba, 2018).

South Africa largely depends on the importation of innovative medical devices to advance health care in the country (de Jager et al., 2019). However, many citizens in South Africa do not receive the benefits of these devices due to various constraints (de Jager et al., 2019). The most contributing constraints are societal barriers, environmental and financial limitations (de Jager et al., 2019). It is believed that these obstacles can be overcome by the local development and production of medical devices that are based on identified needs (de Jager et al., 2019). De Jager et al (2019) also believe that the local development and production of these devices would increase access to innovation for South African citizens and ultimately improve health. Innovation in healthcare is a multi-disciplinary process, it almost always requires the collaboration of different sectors (Karam et al., 2018). The World Health Organisation (WHO) has identified three key factors which create a need for collaboration among different sectors (Geneva, 2006). These factors are identifying health needs, providing a research base, and gaining support from industry (WHO) (Geneva, 2006). This aligns with the findings of Kimble and Massoud (2017), who concluded that the successful development of innovation in healthcare is anchored on the identification of a problem, extensive research and development and the support of key stakeholders. Karam et al (2018) further finds that the key sectors that ought to collaborate for the development of successful innovation in healthcare are as follows: academia in the form of institutions of higher learning; healthcare institutions which consist of clinics, hospitals, and private practices, and finally, corporate industry which consists of firms, companies and organisations which are responsible for the scaling and commercialisation of medical innovation. Each of these sectors offers an important contribution to the development of innovative solutions for healthcare (Karam et al., 2018). Academia provides research and empirical evidence backing up the feasibility of the innovation, healthcare identifies the needs of patients and medical personnel also, corporate industry has the expertise with the ability to develop and supply innovative devices to the public (Ibid). Karam et al (2018) studied that there was a direct correlation between a rise of healthcare innovation in South Africa and effective collaboration among key institutions over 13 years.

2.6 The level of successfully implemented innovation in public healthcare in South Africa

2.6.1 Telemedicine

The delivery of healthcare and healthcare data between various regions using information and communication technology is known as telemedicine (Mars & Erasmus, 2012). Over the years, there has been a gradual rise in the use of telemedicine in South Africa (ibid). The use of store and forward technology in telemedicine has gained considerable traction in South Africa, especially in rural areas (Mars & Erasmus, 2012). Store and forward telemedicine are basically the transfer of medical information from one place to another (Mars & Erasmus, 2012). For example, for an expert to evaluate medical information, such as X-ray scans or lab findings, the information would be transferred from one site to another. Another kind of telemedicine is live interactive video conferencing, which allows the patient to view the doctor in person although they are separated by a physical distance and makes use of specialised tools to facilitate clinical assessment (Mars & Erasmus, 2012). A research study conducted by (Haleem, 2021) found that store-and-forward telemedicine has improved access to specialized treatment in remote regions with a severe shortage of medical personnel. The same study also found that the reluctance to recognise the advantages of telemedicine by policy makers in South Africa has obstructed the rapid uptake of telemedicine in healthcare (Haleem et al., 2021).

2.6.2 Diagnostic Tools

The rate of medical malpractice claims in public healthcare is extremely high due to medical misdiagnoses (Maphumulo & Bhengu, 2019). Therefore, medical diagnostic equipment is crucial because it enables medical practitioners to accurately identify and diagnose disorders (ibid). The adoption of diagnostic tools in South Africa, where public healthcare is mostly underfunded and overloaded, has been gradual but steady over time (Maphumulo & Bhengu, 2019). The use of point-of-care (POC) HIV testing is a great example of the successful uptake of diagnostic technologies in South African public healthcare (Jani, 2013). POC tests are rapid, easy tests that may be completed at the patient's bedside or in a clinic without the use of specialist equipment or people (ibid). POC tests for HIV have significantly increased access to testing and care for persons living with HIV in South Africa, especially in rural regions where laboratory facilities are sparse (Jani, 2013). A study conducted by (De Broucker et al., 2021) concluded that the percentage of patients who received their test results the same day jumped from 29% to 98% using POC testing.

2.6.3 Pharmaceutical Innovations

The successful adoption of pharmaceutical innovation adoption in South Africa has improved patient outcomes, decreased morbidity rates, and helped keep healthcare costs down (Garone et al., 2011). Antiretroviral therapy (ART) is one of the most prominent pharmacological innovations that was successfully adopted in South Africa (ibid). A national effort to offer free ART to all HIV-positive people in need was started by the government in 2004 which has dramatically increased the lifespan of infected persons in South

Africa (Garone et al., 2011). The use of combination treatment to treat tuberculosis (TB) has also made steady progress in South African public healthcare. However, TB remains a significant public health concern in South Africa (ibid).

2.7 Factors that influence innovation in healthcare.

There are several factors that can influence innovation in healthcare (Akenroye, 2012). Legal and regulatory obstacles are among the anti-innovation factors in healthcare that both domestic and international innovators must contend with (Akenroye, 2012). A persistent ideology in literature is that large bureaucratic, government-controlled, centrally planned organisations are notoriously difficult to modify (Akenroye, 2012; Omachonu & Einspruch, 2010). Herzlinger (2006) concedes that the healthcare sector is extensively regulated, it is therefore challenging to create and commercialise innovative technology, treatments, or products. This may involve protracted approval procedures, expensive regulatory compliance fees, and a lack of understanding of regulatory standards (Omachonu & Einspruch, 2010a). Limited funding is also a crucial factor that influences innovation in healthcare (Herzlinger, 2006). Healthcare innovation often requires significant investment, and limited funding can hinder the development and adoption of new technologies and treatments (Herzlinger, 2006). This can be particularly challenging for start-ups and small businesses, which may struggle to secure the necessary funding to develop and commercialise their innovations (Herzlinger, 2006). Inefficient healthcare systems hinder innovation in healthcare (Omachonu & Einspruch, 2010a). Adopting new technology and treatments might be challenging for healthcare professionals in inefficient healthcare systems (Omachonu & Einspruch, 2010a). For example, if a healthcare system is resistant to change or has outdated processes and technologies, it may be difficult for new innovations to gain traction (Omachonu & Einspruch, 2010a). Data fragmentation in healthcare has shown to be a daunting and costly problem in South Africa (Akenroye, 2012). Healthcare data is often fragmented across different systems and organisations, which can make it difficult to gather and analyse data to support innovation (Akenroye, 2012). This can also make it challenging to develop new technologies that rely on data interoperability (Akenroye, 2012). One of the main obstacles to the implementation of successful practice change in healthcare has been identified as resistance (Herzlinger, 2006). Stakeholders may be resistant to change in the healthcare business since it is complicated and sometimes moves slowly (Herzlinger, 2006). Alaofin (2015) also agrees that healthcare professionals, patients, and lawmakers could be reluctant to accept new technology or treatments owing to worries about safety, efficacy, or cost.

2.8 Adoption and diffusion of innovation in healthcare

Pereira (2017) stated in a study he conducted with Romero (2017) that a counterintuitive reality of innovation in healthcare is that it is incorrect and misleading to think that innovation is always positive. Pereira's (2017) observations are supported by Dixon-Woods et al (2011) who stated that one of the paradoxes of innovation is that despite having unproven or limited efficacy, some new practices enjoy swift adoption and diffusion in

healthcare. The rate at which undeserving inventions get adopted while effective innovations never reach the adoption stage is alarming (Ossebaard, et al.,). There is an incorrect mindset that exists in healthcare were doing something whether it is effective or not is deemed as better than doing nothing (Duderstadt, 2005). This incorrect mindset is the basis for why uncertain innovations end up being adopted in healthcare (ibid).

There are several reasons why unproven innovations are sometimes favoured and adopted by the healthcare system. Using new technologies or treatments increases the thrill of novelty which results in the uptake of some innovations which have not been empirically tested for evidence (Dixon-Woods, et al., 2011). Another reason why some innovations in healthcare spread quickly without any scientific justification is that in hopeless or difficult situations it is challenging to deny any available remedy (Kelly & Young, 2017). Some innovations receive uptake in healthcare and get put into practice because they have a lot of logical validity or appeal to people intuitively as workable solutions, even though at a later stage they fail to produce evidence of efficiency (Williams & Brown, 2014a). Innovations are another strategy that organisations can use to combat fear to avoid accusations that any failure was the result of non-adoption (Kelly & Young, 2017).

Profit-seeking behaviour from those that benefit from innovation also creates a rapid diffusion of innovation in healthcare (Jacobides, Knudsen & Augier, 2006). Dixon-Woods (2011) also agrees that the force driving innovation could very well be profit-oriented enterprises that are prepared to resort to creating a false need for new products by inventing “diseases” or repackaging existing treatments as expensive ones. New devices in healthcare especially diagnostic type, only need to show that they adhere to the fundamental safety criteria as stipulated in South African legislation, and not to produce any proof of effectiveness, this opens room for the implementation of innovation that is not evidence-based (Aranda-Jan et al., 2014). Dixon-Woods et al (2011) noted that businesses that stand to benefit from the adoption of innovation may use cutting-edge and opportunistic marketing strategies such as frequently coercing patients into believing that the new technology will be beneficial to them and pushing political agendas to win support. While Jacobides (2006) affirms that incompetent innovation gets adopted because it might be difficult to withstand the desperation of patients for therapies, Aranda-Jan (2014) argues that undeserving innovation gets implemented because institutions have an absolute interest in recouping expenses after making an investment in innovation.

The failure of adoption and diffusion of innovations with established utility is a problem that has severe ramifications as the issue of adopting innovations without proven efficacy (Dixon-Woods *et al.*, 2011). On the contrary, Dixon-Woods (2011) observed that the reason why some innovations with proven efficacy end up not being adopted in healthcare is because some innovations are not complex technologies, and therefore generate little to no excitement. Other innovations require extensive investment and training that healthcare organisations usually do not have the ability to achieve (Albury, 2005). Other effective innovations do not make it to healthcare because they threaten existing products, while others do not make it simply because they are tedious to implement (Albury, 2005). Some innovations on the other hand lack the support of an influential stakeholder in healthcare who would advocate for the innovation to be adopted (Utterback & Suárez, 1993).

The acceptability of innovation in healthcare is not only dependent on the physical characteristics of the innovation, but it is also highly dependent on additional factors, such as cultural and social aspects (Atwine, 2019). To increase the acceptability of innovation in healthcare, it is important to customize the innovations to be user specific (Araújo, 2020).

While other industries have utilised the emergence of innovation at full force, the public healthcare sector has been slacking to absorb the benefits of innovation, especially when it comes to the improvement of healthcare delivery (Leonard *et al.*, 2019). There are numerous innovative ideas for the improvement of healthcare delivery, but only a small number of those ideas are ever put into practice (Leonard *et al.*, 2019). A successfully implemented innovation in healthcare is one that has maintained a steady rate of diffusion over time (Leonard *et al.*, 2019). Scott et al (2008) gathered that it is difficult to diffuse innovations in healthcare once they have been developed. The reason is that the adoption and diffusion processes of innovation in healthcare are not straightforward (Scott, et al., 2008). They highly depend on multiple factors which all have a significant impact on the adoption and diffusion processes (Scott *et al.*, 2008). Healthcare organisations are complicated systems, which consists of numerous complex sub-systems (Kelly & Young, 2017). Innovation in healthcare mainly consists of three interconnected operations which are generation, implementation, and the adoption of innovative ideas (Kelly & Young, 2017). Each of these three main operations is entrenched in bigger cultural, economic, and political processes that affect how quickly and widely innovations spread (Kelly & Young, 2017).

The use of innovation in healthcare is very much about getting away from the conventional outdated artisanal style of organising and delivering healthcare which has a low rate of efficiency due to the limited availability of trained medical personnel and resources (Akenroye, 2012). Access to healthcare is being improved through the application of the fourth industrial revolution (4IR) technologies (Akenroye, 2012). The 4IR is seen as the beginning of the technological revolution that is altering the way humans interact, live, and work (Mhlanga, 2022). Unlike the first three industrial revolutions which focused solely on the mechanisation of production, "the 4IR is characterised as "a fusion of technologies that is blurring the lines between the physical, digital, and biological spheres (ibid), p5". Signe (2021) states that the fourth industrial revolution is a term that describes how multiple physical, digital, and biological systems are combining to bring about perpetual technological development. The Fourth Industrial Revolution has the potential to significantly alter and advance the healthcare industry (Signé, 2021). Large amounts of medical data, including patient records and medical imaging, can be analysed by artificial intelligence and machine learning algorithms, which form part of the fourth industrial revolution, to help with disease diagnosis (ibid). This may result in quicker and more precise diagnosis, allowing for prompt actions (ibid). The inability of the public health care sector to adopt innovation at an accelerated rate has financial and moral implications (Kelly & Young, 2017). The problems that stem from this inability are medical errors, increase in medical costs and a non-conducive work environment (Kelly & Young, 2017).

It has been established that innovation in healthcare does not easily diffuse in an uncomplicated manner (Cain & Mittman, 2002). The adoption and diffusion of innovation that has not been tested for evidence of efficiency poses a serious threat to quality improvement in the health sector (Ossebaard et al., n.d.). Patients are always the most exposed to the high risks of implementing such innovations (ibid.). Previous research on innovation states that the generation process of innovation as shown in Figure 5 is highly dependent on the cross-pollination of ideas and collaborative approaches which enable an exchange of ideas (Fitzgerald et al., 2002). It has been discovered that the development of healthcare innovation is facilitated by research and development (Cain & Mittman, 2002) as well as the depth and diversity of the available information base (Fitzgerald et al., 2002). Specialised innovation firms are more likely to excel in the generation of innovation because they have better access to information and knowledge (Cain & Mittman, 2002). An organisational culture that rewards creativity becomes conducive for the generation of innovation (Akenroye, 2012). On the other hand, strict rules and rigid job descriptions have adverse impacts on the generation stage of innovation (Fitzgerald et al., 2002). The uptake of innovation by healthcare professionals is reliant on a range of factors consisting of the existence of empirical evidence of the innovation being sound; the innovation's suitability for many patients; and the cost implications of adopting the innovation (ibid). The attitude of management and human resources personnel can either favour or hinder the adoption phase of the innovation process (Herzlinger, 2006). The significance of financial resources becomes relevant at the diffusion stage of the innovation process (Cain & Mittman, 2002).

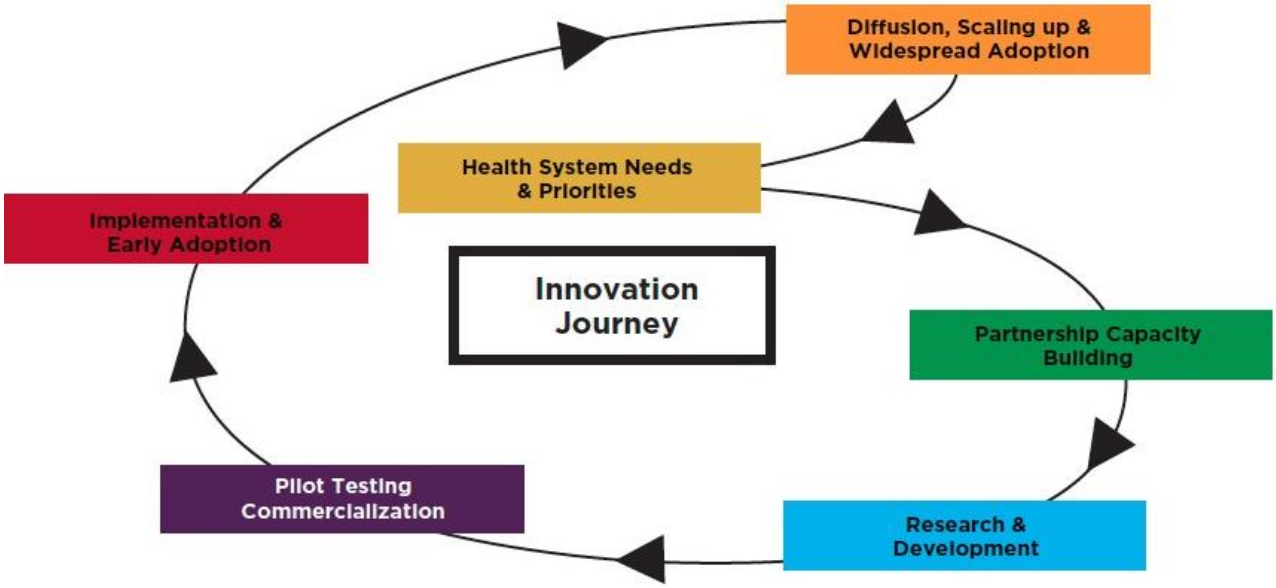

Figure 5: The generation of healthcare innovation (Advisory Panel on Healthcare Innovation, 2015)

2.9 Micro-environmental factors that influence innovation in public healthcare

In general, the outcome of the implementation of innovation in any type of market, is dependent on micro and macro environmental factors (Chaudoir et al., 2013). The micro-environmental dynamics of innovative firms

and healthcare organisations are just as crucial as the macro-environmental factors (ibid). The micro-environments factors are discussed in sections 2.7.1 to 2.7.4.

2.9.1 Empathy

The lack of empathy in product design can contribute to unsuccessful innovative developments (Postma et al., 2012). Empathic design is a form of design research that focuses on developing an understanding of users and the challenges they face in their daily lives to create new products (ibid).

Design-thinking is a method of problem-solving that uses human empathy and intuition rather than logic and analytical procedures (Marufu & van der Merwe, 2019). The purpose of design-thinking is to use instincts and pattern-recognition abilities to design and develop functional products and services that appeal to the needs and emotions of the end-user (Postma et al., 2012). It has been observed through studies that products and services created on assumptions about the end-user tend to be unsuccessful as they fail to address the true needs of the end-user (ibid). Williams & Brown (2014) who advocate for design-thinking, argue that more effective solutions are found when product and service development, based on the perspective of those they are designed for, is coupled with rapid prototyping. A known argument is that it is often difficult to convert end-users' ideas into commercial products and services (Postma et al., 2012). In a study conducted in 2018, Alex Marufu et al (2018) concluded that for innovators to develop effective and successful innovations in healthcare, they must fully comprehend the conditions of persons for whom the innovations are to be developed for, assume the perception of the stakeholders, and their situations when creating solutions to problems and engage the system's stakeholders in the process.

A study conducted by Carmel-Gilfilen and Portillo (2016) showed that medical personnel who were more involved in healthcare innovation development by using an empathy-focused design process also came up with other innovative ideas in the process. The study also found that those who design healthcare facilities can better engage holistically with the user and adopt an empathetic design approach through the process of assimilation (ibid). It is possible to fund the optimum balance between excellent design and patient-centered care by explicitly adopting a mindset that prioritizes empathy in the design process and hence lead to the implementation of efficient innovations in healthcare (Carmel-Gilfilen & Portillo, 2016).

Empathy in healthcare is understood as a necessity that is required to shift the designer from focusing on system functionality to focusing on a human-centred design that incorporates the subjective experiences, values, and feelings of the end-user (McDonagh, 2010). The role of empathy in healthcare design has become extremely important as the challenges and complexities that confront healthcare keep escalating (Thieme et al., 2014). However, it has been noted by McDonagh (2010) that there has been very limited discussion in the health fraternity on what empathy in design really means and how it can be supported. Another challenge that confronts healthcare workers is that it becomes difficult to disclose sensitive and confidential information to

designers to assist in the empathy-design process (Thieme et al., 2014). Some patients also tend to struggle to express how they feel and some of the challenges they encounter in healthcare facilities, this greatly compromises the empathy design process (ibid).

There has been a trend of healthcare researchers that have gained an increased interest in empathic design because of its human-centered approach which provides a unique structure to the research process and increases the prospects of the development of a successful innovation (van der Westhuizen et al., 2020). To measure the effectiveness of empathic design, it is necessary to identify, assess and understand its advantages, disadvantages and the practicality and challenges of carrying out the empathic design (Van der Westhuizen et al., 2020). The findings of a research study carried out by Jamal et al (2021) indicated that the empathic design process offered opportunities for creating engagements between end-users and universities. The most noteworthy of these findings is the structured context that empathic design offers designers to explore an altogether new way of thinking, allowing them to explicitly compare their own assumptions to those of their teammates and the perspective of the end-user (Jamal et al., 2021). Empathic design is extremely beneficial in healthcare innovation as it is a way to engage people and encourage camaraderie between academic institutions and end- users (Marufu & van der Merwe, 2019). van der Westhuizen et al (2020) observed that empathic design created enthusiasm and transparency among designers and end-users. However, the concept of empathic design first emerged and is rooted in the technological and business industries, therefore, for empathic design to be used effectively in healthcare, it needs to be refined specifically for the healthcare environment (van der Westhuizen, 2020).

Empathic design carries immense potential as design process for healthcare innovation that is sympathetic to the needs of end-users in the unique and complex environment (Marufu & Van der Merwe, 2019). However, the skill set that is required for effective empathic design requires time and practice to master, in some cases, the successful application of empathic design in healthcare will require additional tool kits to be devised and tailored to the specific needs of innovation projects (ibid). Empathic design has become mandatory for the development of successful innovation (Jamal et al., 2021). However, some firms have not made the full switch of designing using empathic approaches instead of rational approaches (ibid).

2.9.2 Technological infrastructure

Technological infrastructure, such as computers and monitoring devices, which is required to implement innovation in hospitals is rather expensive to establish (Almazroi et al., 2022). The lack of adequate technological infrastructure in public hospitals is one of the factors that affect the implementation of innovation in public health care (ibid).

Lennon et al (2017) conducted a study to evaluate the processes of designing and delivering digital health in the United Kingdom. The findings of the study revealed that national infrastructure in the UK varied

significantly (Lennon et al., 2017). Rural and distant residents expressed concerns about poor internet connectivity as a barrier to using digital health services (Lennon et al., 2017). Urban health centres were found to lack the connectivity required for patients to access the newest digital health services (Lennon et al., 2017). Similar findings were reported in a study conducted by Atwine (2019), who concluded that if digital services are to be implemented and supported effectively, local and national organisations must invest in information technology (IT) infrastructures. It has been found that even healthcare personnel that are proficient in computers still find it difficult to advance new digital health services due to technological infrastructure problems (Addotey-Delove et al., 2023). An example of technological infrastructure problems would be the lack of mobile devices, such as tablet computers which impedes the use of innovative digital health services and applications (ibid). Another challenge that was cited is that basic technologies such as up-to-date internet browsers are still non-existent in the public sector which prevents accessing new digital healthcare tools (Addotey-Delove et al., 2023).

Grossman (2011) concurs with the findings of Addotey-Delove et al (2023) that the current technical failures of the healthcare system are due to incompatibility between the technology used and the structure of the system. Furthermore, Grossman (2011) suggests that one of the ways to improve technological infrastructure is by having technical staff readily available for assistance at healthcare facilities. Addotey-Deloye et al (2023) suggest that an improvement in technological infrastructure can be obtained through enabling secure uses of health data. He suggests that this can be accomplished by using scalable data transport techniques and transformations that make data clear and calculable, as well as by using policy enforcement regarding the management of health data (Addotey-Delove et al., 2023). Grossman (2011) believes that the size and complexity of biology and medicine will increase, which will result in more cooperative projects and the sharing of technological and data resources. Since government-hosted services like grids and clouds offer scalable ways to utilize already-existing dispersed data, transport protocols, and human knowledge, they promise to be an essential component of the digital infrastructure (McGinnis et al., 2011).

Besides being expensive to establish, technological infrastructure also requires skills and expertise for the effective implementation of innovation (Furusa & Coleman, 2018). The lack of Information and Communication Technologies (ICT) skills among some healthcare professionals negatively influences innovation in healthcare (ibid).

2.9.3 Decision makers

The health industry has benefited greatly from the 4IR even though it is still in its early stages (Araújo, 2020). Governments, health professionals, stakeholders, and society should all work together for innovative technologies to be implemented effectively and efficiently (ibid). It has also been observed that when introducing new health technology, such as medical devices, decision-making is a complicated process that involves many disciplines and stakeholders (Poulin et al., 2013). In their study, Poulin et al (2013) reveal that

decisions concerning the adoption and dissemination of health technologies are made by stakeholders at various levels of the healthcare system.

There is evidence that health service providers are using "conditional approvals" more frequently when deciding if a new technology should be implemented (Oelze et al., 2019). These can offer chances to grant access to technologies in situations where it might not otherwise be possible, while also gathering more information to reduce uncertainty and possible hazards (ibid). However, for conditional approvals to be effective, stakeholders must agree on who will collect what data, how it will be used, and when it will be utilized to affirm final approval or not (Oelze et al., 2019). However, some people worry that using conditional permissions excessively could unnecessarily slow access to innovative technology (ibid).

Generally, if a decision-making process is seen as transparent, based on evidence, and includes an appeals system, a wide range of stakeholders, including health professionals, industry, and patient representatives, are more likely to accept the decision (Driever et al., 2022). Poulin (2013) also confirms that decisions within health systems seem to be implemented based on whether stakeholders accept those decisions. Driever et al (2022) emphasized the value of people actively participating in organizational decision-making. The characteristics of decision-makers and the decision-making process in public hospitals have been observed to be determinants that affect the innovation process (ibid). A study conducted by Williams & Brown (2014) has shown that the characteristics of decision-makers such as values, cognitive style, age, and education influence the decision-making process of implementing innovation in hospitals. Aspects of the decision-making process such as the risk-tolerance and the extent of rationality in decision-making, for example, can be influenced by the characteristics of the decision-makers (ibid).

A transparent, equitable, and consistent decision-making process for the approval and deployment of new health technologies has been demonstrated to be a critical factor in the successful implementation of innovation in healthcare (Poulin et al., 2013). It has also been observed that presenting evidence-based judgments in a way that increases the likelihood of innovation being implemented in real practice seems to be receiving more and more attention currently (Dryden-Palmer et al., 2020). Another noteworthy discovery is that the effectiveness of innovation in healthcare seemed to be higher when the decision to implement the innovation was taken by various individuals in the health care system (Williams & Brown, 2014a). Dryden-Palmer (2020) discovered that when the scientific data that shows the efficiency of an implemented innovation, is not the same per region, the cause is usually due to the differences of the decision makers per region. In the early 2000's, Lavis et al (2003) revealed that a recommendation for technology adoption in one local environment may not be suitable in another due to cultural and organizational variations. As a result, gathering objective scientific information is just as important as carefully considering the unique concerns pertaining to local requirements, objectives, legislation, policies, values, and norms, as well as personnel and material resources (Lavis et al., 2003).

The effectiveness of innovation in healthcare should be evaluated largely in terms of its subsequent effects on health outcomes and the effectiveness of health systems (Dryden-Palmer et al., 2020). Many countries across the world are preparing their health systems for a time when measurement, accountability, value for money, and evidence-based policies and procedures will be more important than ever (ibid). However, the difficulty for many policymakers is to create instruments that try to accomplish several health system objectives at once, and in particular, to create procedures that detail how decisions based on evidence may have an immediate influence on health outcomes (Dryden-Palmer et al., 2020).

Decisions must be made even though there is still a lot of uncertainty around new health technologies, since delaying a choice or not making one at all basically means that the technology will not be provided and/or paid for (Oelze et al., 2019). Krick et al (2019) revealed that an effective method for managing uncertainty around healthcare innovation is by establishing closer ties between technical specialists and decision-makers. It has also been established that features of the health system, such as provider payment structures, may strongly disincentivise efficient decision-making, potentially resulting in the underutilisation of cost-effective technology (ibid). Although important, access to high-quality data is insufficient to guarantee the sensible adoption and spread of medical technology (Dryden-Palmer et al., 2020). It is becoming more widely acknowledged that the decision-making process and the institutional, organizational, political, and cultural aspects of healthcare systems have a significant role in the rational use of evidence (ibid). To increase the rate at which evidence-based technologies are implemented in healthcare, there needs to be extensive communication between decision makers, producers and consumers (Dryden-Palmer et al., 2020).

2.9.4 Human capital and Organisational Culture

Human capital is defined as a supply of acquired or inherent knowledge or characteristics of an individual which contributes to his or her productivity (Okebukola, 2014). A technical definition of human capital is that it is the combined abilities, expertise and skill set of people which can be utilized towards the creation of economic improvement for society at large (Bartel et al., 2014). From an economic perspective, human capital is a person's qualities and skills, more importantly those earned through spending money on education and training, which increase their capacity for generating money (Mandal, 2018). It is called human capital because unlike tangible and financial assets, an individual’s expertise, skills, health, and standards cannot be detached from them (ibid). According to Goodarzi (2016), human capital is defined as a collection of traits, expertise, creativity, life experiences and energy that people choose to use to their work, and it is regarded as vital and necessary for the development and growth of societies and industries.

Suitable human capital in an innovative firm is of utmost importance (Galindo-Rueda, 2019). The availability of competent human capital in an innovative firm determines how successful a firm will be in launching and implementing innovation (ibid). The human resources management in a firm plays a critical role in attaining and retaining the critical skills an organisation requires (Galindo-Rueda, 2019). The proficiency of the human

resources personnel is therefore one of the internal factors that affect the ability of an organisation to introduce and commercialise innovation (ibid).

The components of human capital which are knowledge, skills and values have a direct bearing on innovation (Bartel et al., 2014). Bartel et al (2014) also noted that education and a supportive environment beget innovation through the development of expertise and competence. Ibid (2014) study indicate that the ability of various forms of capital to be translated into resources and other forms of economic gain, is the basis of the relationship between human capital and innovation at the national level. This phenomenon is otherwise known as the conversion process and Okebukola (2014) studied several researchers who have examined and verified this conversion process at the individual level (Becker 2014; Marshall 2014; Dakhli 2004).

The findings of various research studies conducted on the topic have narrowed down to show that there is a direct and indirect correlation among human capital development, innovation, and socio-economic development (Prasetyo & Kistanti, 2020; Galindo-Rueda, 2019; Mandal, 2018; Bartel et al., 2014). There has been a consensus among academics that one of the key elements explaining why some nations are wealthy while others languish in poverty is human capital (Galindo-Rueda, 2019; Mandal, 2018; Bleakley, 2010). Nonetheless, there is still a difference of opinion regarding the ways in which human capital promotes economic growth. From one perspective, human capital is viewed as an alternative for technology (Goodarzi et al., 2016). From another viewpoint though, human capital is seen as a pivotal input to the research and development equation, which therefore makes it a complement to technological development (Mandal, 2018). In his research study, Okebukola (2014) concluded that the production capacity of a society should increase because of an increase in human capital which would therefore provide an increase in the development of innovation and technology (ibid).

Knowledge, which is a component of human capital is regarded as the primary constituent of innovation (Santos-Rodrigues, 2013). Creativity, which is also a raw material of human capital, provides a method for knowledge to advance beyond the original concept (ibid). Human capital and innovation therefore complement each other (Santos-Rodrigues, 2013). It is important for organisations to constantly improve themselves by reinstating and absorbing human capital as an asset that belongs to the organisation (Prasetyo & Kistanti, 2020). Dar & Mishra (2021) argues that the benefit of human capital to innovation is actualised by an effective organisational structure. He goes on to state that a corporation won't be able to utilise the human capital housed in a person with a high intellectual capacity if the organisation they work for has a poor organisational structure (ibid).

“Structural capital is the institutionalized, codified, and applied knowledge, skills, experience, and information that is employed in databases, patents, manuals, structures, systems, routines, and procedures of an organisation” (Rodrigues, 2022, p.2). Structural capital serves as a framework, an agent of change, and a source of infrastructure support for human capital (Prasetyo & Kistanti, 2020). There is a proposal that

innovativeness and structural capital are related, thus it is crucial for organizations to eliminate organisational barriers and complexities in the innovation process (Dar & Mishra, 2021). To encourage learning and innovation, an organization's culture needs to foster such an environment (ibid). Organizations ought to value a culture that prioritizes expertise and training (Dar & Mishra, 2021). The development of talents and resources for innovation depends on culture (ibid). According to a study conducted by Dar (2021), an organisation's capacity for innovation is correlated with its human capital.

The extent of bureaucracy and complexity of an organization determines its structure (Santos-Rodrigues, 2013). Formalization in an organisation has a detrimental impact on innovation since it affects how employees are classified and assigned tasks (ibid). Prasetyo (2020) contends that a corporation's size affects its capacity for innovation, and that there is a direct correlation between firm size and innovation capacity (ibid). Santos-Rodrigues (2013) discovered a link between decentralised organisations and the ability to innovate. Hospitals typically have rigid hierarchies where it is difficult for creativity to flourish, yet there are organizations that encourage innovation (ibid). In his study, Santos-Rodrigues (2013) concluded that the hospital's inability to innovate is a result of the lack of a framework for gathering and utilizing employee ideas.

According to Akenroye (2012, p.2), “in order for innovation to disseminate successfully in an organisation, innovation must be part of the organisational culture”. Public hospitals in South Africa are highly centralised organisations as the South African health system is governed by the Department of Health (Ngobeni, 2020). A spirit of entrepreneurship in centralised organisations is uncommon, which makes it difficult to implement innovation in those environments (Ngobeni et al., 2020).

2.10 Macro-environmental factors that influence innovation in public healthcare

The macro-environmental factors that help or impede healthcare innovation are usually beyond the control of an organisation (Chaudoir et al., 2013). The external factors that influence the implementation of innovation by organisations in health care are the key players, funding, policy, regulatory bodies, technology, customers, and accountability (ibid). To fully assess and understand what the barriers to innovation in the healthcare sector are, these seven factors need to be acknowledged and managed in their entirety. These factors will be discussed in sections 2.8.1 to 2.8.7.

2.10.1 Key Players

The healthcare sector is operated by various stakeholders, each with their own underlying motives (Herzlinger, 2006). Public policy is a crucial element in the administration of the health care sector (ibid). More often than not, the various stakeholders have the resources and the clout to influence public policy which either works in favour or against the innovator (Herzlinger, 2006). A firm that has monopolised an industry

becomes the dominating key player in that industry (Utterback & Suárez, 1993). Any innovative firm that tries to launch a product in that space suffers a great disadvantage because of the power of the dominating key player (ibid).

In consumer-focused innovation, the existence of hostile industry players is usually a great barrier in the implementation of innovation (Segarra-Oña et al., 2020a). Hostile industry players are typically industry-dominating organisations and owners of private medical practices (ibid). An example of hostile industry players would be a group of physicians opposing direct consumer-pharmaceutical relations (Segarra-Oña et al., 2020a). This would disconnect the link between physicians and profitable customers, causing a reduction of profit margins for the physicians (ibid). In such instances, a cynical manipulation of public policy would be executed by the key players (Segarra-Oña et al., 2020a). Implementing innovation in the market is a resource-consuming activity. It is also an extended process that requires the meticulous management of all the resources involved. Therefore, it is important that an innovative firm has a key role player that has enough power, influence and the cognitive ability required to control the innovation process effectively (Flessa & Huebner, 2021).

It's important to note that innovation in healthcare is a complex phenomenon (Kimble & Rashad Massoud, 2017). In the Harvard Business Review, Herzlinger (2006) stated that innovation in healthcare is mainly based on technology, consumer focus and business models and stakeholders and their interests are usually the main factors that affect the adoption and implementation of innovation in healthcare. Stakeholders not only determine whether something is fit to be considered as an innovation, but they also determine whether it should be adopted and implemented in healthcare (Kimble & Massoud, 2017). This, therefore, means that the adoption of innovation in healthcare is dependent on whether the stakeholders see an advantage in adopting and implementing the innovation (ibid). Stakeholders tend to accept a healthcare innovation if they have the capacity to do so at an organisational and individual level, it is in line with their interests, simple enough to adopt readily, can be tested on a small scale, is observable, and involves little risk (Lambooij & Hummel, 2013). However, the advantage of the innovation as deemed by the stakeholders, does not guarantee the successful implementation of innovation in healthcare, other factors such as the complexity and the risk of the innovation may negatively affect the adoption and implementation of the innovation (Segarra-Oña et al., 2020a).

De Jager (2019) has noted that collaboration and information networks have been proven to be advantageous for health innovation in general. Stakeholder factors have been reported to be very crucial when it comes to the adoption and adaptation of innovation (de Jager et al., 2019). Hendrick (2021) further emphasizes that the entire innovation process in the healthcare process is governed by key stakeholders. To understand the innovation process, one must analyse the needs, wants and expectations of the key stakeholders (Hendricks, 2021). The patients are the prominent stakeholders, other major stakeholders include medical personnel, innovation companies and regulatory bodies (Hendricks, 2021). Khan et al, (2022) also concur that for health

innovation to be successful, it must address how the patient is seen, how the patient is heard, and how the patient's needs are met. Therefore, the successful implementation of innovation is centred around the patient (Khan et al., 2022). However, Segarra-Oña (2020) discovered that meeting the criteria related to the patient does not remove the barriers that exist for the identification and adoption of innovation in healthcare. The process of identifying and adopting innovation in healthcare is very interactive and hence requires extensive communication and collaboration among the stakeholders involved (ibid). This also extends to the process of implementing innovation in healthcare, it is a multifactorial process that involves different individuals, political, economic, and cultural influences and also the policies that govern that particular environment (Segarra-Oña et al., 2020b).

The successful introduction and implementation of innovation requires the collaboration of different stakeholders. Where different stakeholders are involved, effective communication because a determining factor of the success of the project (Dennison, 2013a). It is therefore essential for the relevant stakeholders to hone their communication skills (ibid). External stakeholders should be involved in an innovation project as soon as possible (Afuah, 2020). This is because their expertise is required to contribute to the product development and solution to the problem (ibid). The sooner the expertise of external stakeholders get involved in an innovation project, the higher the chances of the success of that project become (Afuah, 2020). New business model innovations tend to also suffer the same fate as consumer-focused innovations (Herzlinger, 2006). Public policy is also used as a weapon by industry key players to oppose the implementation of business models that threaten the autocracy of physicians and industry-dominating organisations (ibid).

2.10.2 Funding

South Africa faces two types of challenges when it comes to funding health care innovation (Bindman et al., 2018). A challenge is funding the actual innovation from concept to commercialisation, including the allocation of which role player will pay how much for the innovative product or service (ibid). Directly linked to this drawback, is the issue that many traditional sources of capital are not familiar with healthcare, making it difficult for innovators to secure insightful investors (Bindman et al., 2018). The other existent challenge that is related to funding is the length of time it takes for new drugs or therapies to be approved by the South African Health Products Regulatory Authority (SAHPRA) (ibid). This problem also affects investors who must wait for periods as long as 10 years or more just to find out whether a new innovation will be approved for use before profits are realised if any (Bindman et al., 2018). Venture capitalists are starting to have a diminished appetite for investing in new innovations because of macroeconomic uncertainty (Metrick & Yasuda, 2021). It is much safer for venture capitalists to invest in already existing products than to launch new ones (ibid).

It is difficult to estimate the returns of an innovative project upfront. Innovation is a risky venture which is often accompanied by failure (Metrick & Yasuda, 2021). This causes fund providers to have a resistance towards investing substantial amounts of money in innovation (ibid).

Another difficulty pertaining to the funding of health care innovation in South Africa is the intricate system of payments and compensation for services and products offered by the investor (Metrick & Yasuda, 2021). Often, these payments are not made by the primary consumer (ibid). Rather, they would typically come from a third party such as the government or an insurance company (Metrick & Yasuda, 2021). This arrangement gives the third parties or the reimbursors' supremacy over the investors (ibid). This supremacy comes in the form of insurers reserving the right to approve new products or services and their prices before they agree to pay for those products or services (Metrick & Yasuda, 2021).

2.10.3 Policy

There are different types of policies that influence the development of innovation (Herzlinger, 2006). Some policies are specifically designed to regulate all classes of innovation while other policies focus directly on regulating innovation within the health sector (ibid). These policies can either work for or against the successful implementation of innovation in health care (Herzlinger, 2006).

(a) The *Constitution of the Republic of South Africa, Act 108 of 1996*

Three provisions of the South African Constitution guarantee the right to health services. They provide access to essential paediatric health care, reproductive health services, emergency services, and medical treatment for detained persons and prisoners (Constitution of the Republic of South Africa, 1996, n.d.). Section 27(1)(a) of the Constitution of the Republic of South Africa (1996, p.11), which declares that "Everyone has the right to have access to health care services" provides for universal access. According to Section 27(2) of the Constitution, "appropriate legislative and other measures, within its available means, should be taken by the State to achieve the gradual realisation of the right", (Constitution of the Republic of South Africa, 1996, p.11). According to the Limburg Principles, gradual realisation does not imply that the state can put off actions to ensure the right to healthcare is fully realized indefinitely (Ramcharan, 2011). State Parties must, however, work as quickly as they can to ensure that the right is fully realised and take urgent action to fulfil the bare minimum of essential rights (Ramcharan, 2011).

Financial limitations are without a doubt one of the most significant problems preventing the achievement of the strategic framework goals (Ramcharan, 2011). The Director General of Health claims that due to financial limitations, resource redistribution has become challenging (Rakate, 2007). There was a noticeable decrease in actual per capita health spending since 1997/1998 (ibid). Also, the disparities in provincial comparative expenditure have widened (Rakate, 2007).

The South African Constitution is known to enable a conducive environment for innovation in healthcare (Gazette & Notice, 1997). It honours access to healthcare as a pivotal right for South African citizens (ibid). Therefore, the constitution was drafted to include statutes that allow for the development and enhancement of healthcare systems and services (Gazette & Notice, 1997). Further to adequate food, water and social security, Section 27 of the Constitution grants all citizens the right to access healthcare (ibid). Additionally, the constitution mandates the state to implement legislation and other statutory measures to ensure that the right to healthcare for all is gradually achieved (Constitution of the Republic of South Africa, 1996, n.d.). The importance of the advancement of science and technology in healthcare is highly emphasized by the Constitution (ibid). The independence of scientific inquiry and technical innovation, which includes the creation of novel medical technology and treatments, is specifically guaranteed under Section 16 of the Constitution (Constitution of the Republic of South Africa, 1996, n.d.). In addition, the South African government has implemented programs and laws that encourage innovation in healthcare, such as the Bioeconomy Strategy of the Department of Science and Innovation and the National Health Research Ethics Council (Auriacombe & Meyer, 2020).

(b) *The National Development Plan*

The National Development Plan (NDP) of South Africa is an example of the policies that support innovation (Auriacombe & Meyer, 2020). It offers a long-term perspective by providing a blueprint for South Africa's transition towards a diversified economy mostly through innovation, however extensive development on this plan is required to realise its long-term goals (ibid).

Provisions to encourage healthcare innovation are included in South Africa's National Development Plan (NDP) (Auriacombe & Meyer, 2020). The National Development Plan (NDP) is a framework for policy that sets the nation's strategy for growth and identifies the major industries in need of funding and development (ibid). The NDP recognizes the need for innovation in healthcare to raise the standard of care provided and deal with the nation's healthcare issues (Auriacombe & Meyer, 2020). Strengthening the capability of the healthcare system to deliver high-quality, affordable, and accessible healthcare services is one of the main goals of the NDP's healthcare plan (ibid). This involves funding innovative healthcare delivery methods and technology (Auriacombe & Meyer, 2020).

The South African government has launched numerous initiatives and programs to promote healthcare innovation (Lucas et al., 2022). For instance, the government-funded Technology Innovation Agency (TIA) supports the development and commercialisation of cutting-edge technologies, particularly those that are connected to healthcare (ibid). The mission of TIA is to encourage and support the creation of novel technologies that can advance both the social and economic well-being of the nation (Lucas et al., 2022).

In addition, the South African government has established the Health Innovation Hub, a platform designed to assist the growth of new medical innovations and technology (Lucas et al., 2022). Entrepreneurs and innovators in the healthcare industry have access to funding, mentoring, and networking opportunities thanks to the Health Innovation Hub (Lucas et al., 2022).

(c) *The National Health Insurance (NHI) Policy for South Africa*

On 11 August 2011, South Africa published its green paper on the Policy of National Health Insurance (NHI), marking a bold and innovative move for the country's National Health System (Amollo, 2012). In South Africa, the National Health Insurance (NHI) program is a government-led project designed to guarantee that all residents have access to inexpensive and high-quality healthcare services (Amollo, 2012). By combining revenues from diverse sources, such as taxes and private donations, the NHI seeks to function by establishing a single fund that will cover the cost of healthcare for every South African (Naidoo, 2012). The goal of the policy is also to lessen the gaps that now exist in the healthcare system by ensuring that everyone has access to the same standard of healthcare services, regardless of their financial or social standing (Chuene & Kgarose, 2023). Pauw 2022 further declares that the goal of the NHI is to give all South Africans access to adequate, effective, and high-quality medical care.

Those who contend the policy argue that implementing it would be too costly and that the government is incapable of managing such a large healthcare system (Bangalee, 2023). On the other hand, supporters contend that the NHI is essential for addressing the country's healthcare inequities and that it would ultimately result in improved health outcomes for all South Africans (Amollo, 2012). Businesses, opposition political parties, activists, and healthcare professionals' associations have praised and criticised the National Health Insurance Bill since it was approved on 13 June 2023 (Makoni, 2023).

It is important to note that the impact of the NHI on innovation in healthcare will largely depend on how it is implemented, and the policies and regulations put in place to encourage innovation while still providing universal access to healthcare for all South Africans (Naidoo, 2012). The NHI will not necessarily impede the adoption of innovation in healthcare, even though it is still in the planning and implementation stages (Naidoo, 2012). Pauw 2022 supports this view by stating that the NHI may potentially promote healthcare innovation by providing a more structured and coordinated method of providing healthcare. The NHI might motivate healthcare practitioners and organizations to employ innovative techniques and tools to improve patient care while cutting costs (Muinde & Prince, 2023). Additionally, the NHI might offer a standardized framework for healthcare delivery, opening the door for the country as a whole to adopt innovative medical practices (Auriacombe & Meyer, 2020).

Lastly, the NHI may foster cooperation and partnerships between healthcare practitioners, researchers, and innovators, facilitating the sharing of information and resources that may result in new innovations in

healthcare (Naidoo, 2012). It is important to remember that the NHI can provide a welcoming atmosphere that encourages healthcare innovation, leading to improved health outcomes and increased patient access to care (Muinde & Prince, 2023). Amollo (2012) also states that although the NHI's implementation may not directly encourage innovation in healthcare, it can help to create an environment that does in a number of ways.

There are worries though that the NHI might stifle innovation in the healthcare industry by placing limitations on access to technology and medications, as well as on price and payments (Muinde & Prince, 2023). Additionally, the NHI may prioritize providing basic medical care, which could limit the funding available for the use of innovative techniques or equipment (Mhlanga, 2022).

(d) *The Intellectual Property (IP) Policy*

The Intellectual Property (IP) Policy seeks to strike a balance between the public interest and the interests of patent holders, particularly when it comes to the availability of inexpensive medications (Hill, 2014). While ensuring that everyone in South Africa can access and afford them, the plan encourages the development of innovative healthcare products and services (Hill, 2014).

Even though South Africa had made tremendous progress in the deployment of Intellectual Property (IP) prior to 2018, the government still needed a comprehensive IP Policy that would support local manufacturing, preserve, and leverage the nation's resources and heritage, foster innovation, and give voice to domestic businesses and individuals who want to benefit from the IP system (Williams, 2016). Therefore, in May 2018, the South African Cabinet approved the South African Intellectual Property (IP) policy (phase 1) (Williams, 2016).

South Africa needs a coordinated and balanced strategy to intellectual property (IP) that offers effective (intellectual property rights) IPR protection and takes into account the country's particular innovation and economic dynamics (Mackey & Liang, 2012). The spirit of the South African Constitution must be the first and main goal of South Africa's intellectual property policy (Dos Santos et al., 2022). The design of the IP Policy must be carried out using a dynamic, phased approach to allow the government to take immediate action in some areas, perform additional in-depth research and consultation in others, and adapt to a rapidly expanding discipline (Mackey & Liang, 2012).

2.10.4 Regulatory Bodies

Regulatory bodies are essential to South Africa's innovation in public healthcare (Keyter, Banoo, Salek & Walker, 2018). These organisations make ensuring that patients may access innovative therapies and technology that are both safe and efficient (Keyter et al., 2018).

(a) *The South African Health Products Regulatory Authority (SAHPRA)*

The South African Health Products Regulatory Authority (SAHPRA) has established regulations that must be followed by medications, medical devices, and other health goods (Moeti, Litedu & Joubert, 2023). By creating a level playing field where companies must meet requirements before their products can be sold, SAHPRA ensures that all products meet safety standards before allowing them to be used in the country, which in turn encourages innovation (Dureja & Dhiman, 2021).

On the other hand, it is believed that the South African Health Products Regulatory Authority (SAHPRA) is a regulatory organization that does not appear to support innovative endeavors (Ravigopal, 2019). This impression stems from the lengthy approval processes for innovative pharmaceuticals and innovative medical treatments (Ravigopal, 2019). The establishment of SAHPRA resulted in a significant backlog in product registration due to a capacity deficit, which has slowed down South Africa's acceptance of innovation (Moeti et al., 2023). The new legislation for medical devices in South Africa does not specify a timeframe for processing registration requests (Keyter et al., 2018). Testing medical innovation prototypes in healthcare is exceedingly challenging due to policies imposed by SAHPRA (ibid).

(b) *The Health Professions Council of South Africa (HPSCA)*

Healthcare practitioners in South Africa are governed by the Health Professions Council of South Africa (HPCSA), a statutory authority (Dhai & Mkhize, 2006). By establishing standards for professional practice, assuring adherence to ethical norms, and encouraging research and development, the HPCSA plays a critical role in supporting and influencing innovation in public healthcare (ibid). One method the HPCSA influences innovation is through the accreditation process it offers to educational institutions (Schneider, 2001).

To receive certification, institutions must meet standards related to the quality of their infrastructure and course offerings which encourages businesses to invest in technology and innovation, which could lead to breakthrough discoveries and better medical practices (Moore & Hawarden, 2020).

Additionally, the HPCSA has established committees focused on certain areas of healthcare, such as research, ethics, and education (Townsend & Scott, 2019). These committees provide guidance and support to professionals who wish to pursue innovative approaches to patient care (Townsend & Scott, 2019). The Ethics Committee, for example, offers advice on topics like genetic testing and end-of-life care, which may help professionals navigate challenging moral dilemmas when implementing innovative medical techniques or technologies (Moore & Hawarden, 2020). Through its Research Ethics Committees (RECs), the HPCSA not only offers advice on ethical matters but also encourages research and advancement in the healthcare industry (Schneider, 2001).

The HPCSA aids in advancing medical technology and therapies that eventually benefit patients by establishing standards for professional conduct, offering guidance on ethical concerns, encouraging research and development, influencing public policy, and creating cooperation with other organisations (Al-Alawy & Moonesar, 2023). In order to ensure that South Africa stays at the forefront of healthcare innovation, its involvement is crucial (Al-Alawy & Moonesar, 2023).

2.10.5 Technology

Understanding technology plays a crucial role in its successful implementation (Herzlinger, 2006). The inability to put technology to work effectively has an adverse effect on the inherent value the technology has (Herzlinger, 2006). If a technology is too complicated for the market, it might not be adopted, which could reduce the likelihood that it will succeed (Smith, Ayuk & Scalzo, 2023). The innovator needs to have a meticulous understanding of the type of technology they intend to implement (Dennison, 2013b). Disruptive innovation and radical innovation, for example, will not receive the same adoption in any given market (Dennison, 2013b). Disruptive innovation is an innovation that changes a market's performance measures or customer expectations (Nagy, Schuessler & Dubinsky, 2016). Radical innovation on the other hand, is one that promotes significant technological advancements (Tiberius, Schwarzer & Roig-Dobón, 2021).

The time in which the technology is used is also very important (Malungana & Motsi, 2023). Launching the innovation before the supporting infrastructure it needs is in place, may hinder its successful adoption in health care (Dennison, 2013b). Though technology might increase safety and offer other advantages, it can also introduce new hazards and increase the expense of healthcare (Poulin et al., 2013). Health organisations should ideally have a methodical procedure for gathering pertinent scientific data on a technology's effectiveness and safety, as well as for determining if the technology is appropriate for the local environment (Poulin et al., 2013). The doctor–patient relationship is a complex relationship in healthcare (Maphumulo & Bhengu, 2019). The use of innovation, more specifically technological innovation in healthcare can either improve or impair the doctor-patient relationship which then determines the suitability of that innovation in healthcare (ibid).

2.10.6 Customers

Customer or end-user participation is a key element that affects how well innovation in public healthcare works (Miraldo et al., 2019). The so-called “passive patient” is an outdated idea (Miraldo et al., 2019). Now that they are more informed, patients are speaking up to healthcare professionals about what they need (Russo-Spena & Mele, 2012). It is impossible to ignore the influence that customer relationship management has on the adoption of innovation in the healthcare industry (Williams & Brown, 2014b). Participation of customers in innovation ensures that products and services are customized to meet their specific needs (Wu, Wang & Lin, 2007). Crucial sources of information regarding what works and doesn't work in the delivery of care in public healthcare are patients and other stakeholders (Addotey-Delove et al., 2023). Therefore, including end-

users in the design and testing stages of new products or services, guarantees that they deal with actual problems that customers really encounter (Miraldo et al., 2019). A research study conducted by (Mburu, 2022), claims that user input was crucial in creating the unique mobile app MomConnect, which offers pregnant women maternal health counselling via SMS messaging. The app has since increased pregnant women's prenatal care attendance rates (Mburu, 2022).

Better customer involvement leads to improved user and service provider communication (Russo-Spena & Mele, 2012). End users get the chance to share their experiences and offer recommendations for improvement when they are participating in the innovation process (Sharma, Conduit & Rao Hill, 2014). This relationship strengthens trust between customers and service providers, encouraging greater collaboration in the achievement of common goals (Sharma et al., 2014). Customer participation also encourages innovation acceptance and long-term use (Russo-Spena & Mele, 2012). When consumers engage in the innovation process, new products or services are promoted and become more widely accepted in their groups or networks (Addotey-Delove et al., 2023).

2.10.7 Accountability

The successful implementation of innovation requires accountability from all stakeholders involved (Herzlinger, 2006). As more people have easy access to information, informed customers are pressing health care innovators to answer for their actions (Rispel et al., 2019). Consumers' top priorities are affordability and long-term safety, and they hold inventors responsible for meeting these (Scott et al., 2008). Accountability can either hinder or facilitate the implementation of innovation in health care increasing competition among innovators (Herzlinger, 2006).

Accountability supports effective innovation in public healthcare by fostering a culture of transparency (Côté-Boileau, 2022). When innovators are held accountable for their decisions and actions, they are more likely to be transparent about their processes and outcomes (Scott et al., 2008). By encouraging openness, interested parties can identify areas for development and, if necessary, take corrective action (Almazroi et al., 2022). Accountability also improves stakeholder collaboration, which is a bonus (Côté-Boileau, 2022). Khan et al (2022) state that accountability enables several parties to contribute their unique views and abilities towards reaching a shared objective, therefore collaboration is crucial for effective innovation. People are more willing to cooperate to ensure the success of an innovation project when they all feel accountable for its success or failure (ibid).

Accountability contributes to ensuring that funds given to innovation initiatives are used effectively (Côté-Boileau, 2022). Since public healthcare facilities usually have limited resources, it is essential that they be used carefully to make the biggest possible impact (Furusa & Coleman, 2018). It is more likely that people

will use the resources that have been given to them wisely if they are held responsible for their usage (Côté-Boileau, 2022).

In summary, the dire state of public health care in South Africa has a direct impact on the rate of morbidity and mortality in patients. The strategies that have been implemented to improve the state of public health care have been negated by insufficient planning. From the existing literature that has been reviewed, it is apparent that the effective collaboration of key role players and stakeholders is mandatory for successfully implementing innovation in the public health sector. The procurement of innovative goods and services is extremely costly for the government and the unavailability of sufficient funds is also one of the prominent issues that hinder the public health sector from implementing innovation successfully.

2.11 How is the successful implementation of innovation in public health care measured in South Africa?

In South Africa, there are several techniques used to assess the successful implementation of innovation in healthcare (de Jager et al., 2019). One excellent way to assess the effectiveness of innovation in healthcare is to look at improvements in patient outcomes (Dar & Mishra, 2021). An overall reduction in mortality rates, an improved quality of life for patients, a reduction in misdiagnosis, shorter hospital stays, patient satisfaction, an increase in successfully treated illnesses are all examples of improved patient outcomes (de Jager et al., 2019).

In the context of both the public and private sectors, the level of successfully implemented innovation is measured by the level of the creative destruction of particular markets in healthcare (Lucas et al., 2022). This is the process of developing new products, services, or markets that leads to the total dismantling of the previous structures, procedures, and systems (Heeks et al., 2013).

The successful implementation of innovation in public healthcare is often measured by the cost-effectiveness of the innovation (Chaudoir et al., 2013). Two examples of technology that is already being used to improve patient outcomes and reduce expenses are artificial intelligence and telemedicine (Johansson & Udén, 2008). Drug and medical technology advancements also enable cost savings (Johansson & Udén, 2008). Medical advancements that facilitate less invasive surgery or expedite operations can reduce hospital stays and recovery times, which can save a significant amount of money (Aranda-Jan et al., 2014). The development of advanced pharmaceutical drugs, which are more efficient than conventional treatments and have fewer side effects, can also reduce the costs of healthcare considerably (Chaudoir et al., 2013).

An improvement in leadership performance is also a measure of successfully implemented innovation in public healthcare (Lucas et al., 2022). It has been observed that bottom-up innovations developed by patients, front-line public servants, and middle management are successful and closely linked to well executed

innovations in the healthcare industry (Schneider, 2001). Another excellent sign of successfully applied innovation in healthcare is a leader's capacity to act quickly in the face of emergencies (Aranda-Jan et al., 2014). Effective political leadership in a crisis calls for decision-making that makes use of a wide-ranging information search, wide-ranging consultation, and evaluation of a wide-ranging variety of possibilities (Lucas et al., 2022).

There is unanimity among scholars that the adoption rate of innovation is also a key indicator of how successful the implementation of that innovation was (de Jager et al., 2019), (Chaudoir et al., 2013) and (Lucas et al., 2022). Innovative practices have likely been well embraced by healthcare professionals and stakeholders who see value in them as a tool for providing improved care, if they are widely implemented throughout several areas, hospitals, or clinics (Chaudoir et al., 2013). Measuring patient happiness with newly implemented innovative initiatives is another method for evaluating the effectiveness of innovation in healthcare (Signé, 2021). If a patient is not happy with their experience receiving care, they may look for other treatments or decide not to seek care at all (Krick et al., 2019).

2.12 The readiness of the public health sector to embrace technology in South Africa

Implementing innovation programs in healthcare successfully is extremely challenging and it usually has high failure rates (Malungana & Motsi, 2023). Most failures might not be due to technology at all, but rather to other issues such a lack of preparation (Chuene & Kgarose, 2023). To increase innovation readiness in healthcare, Leonard et al (2019) suggests that decision-makers pay closer attention to building and infrastructural development. If the health sector's innovation readiness was thoroughly evaluated using a proven tool, the success rate of innovation implementations would rise (Lennon et al., 2017; Fusheini 2016) conducted a systemic literature review to investigate the opportunities and challenges of achieving universal healthcare in South Africa. To provide the study with authenticity and reliability, Fusheini (2016) gathered materials from many sources, including policy briefs, and academic papers. The results of the study revealed that South Africa is not able to achieve universal health coverage as the disparities in health performance across the healthcare sector prohibit healthcare facilities to adopt technological advances at the same pace (Fusheini & Eyles, 2016).

There are still many people in South Africa who do not have access to the internet and who do not know how to use the internet at all (Kgasi & Kalema, 2014). Before the health industry can be considered ready to accept innovation, it is necessary to address the issue of internet literacy in South Africa (Chuene & Kgarose, 2023). To address digital access and inclusion, a number of government organisations have consciously embarked on community-asset based projects, such as establishing digital hubs and designating digital champions (Leonard et al., 2019). Those from lower socioeconomic categories, who are frequently most in need of health and social care services, are the ones who suffer the most from digital access and inclusion (Kgasi & Kalema, 2014).

Cellular phones and digital gadgets complement the effective use of the internet (Fusheini & Eyles, 2016). Many people still lack basic access to cellular phones and digital tablets, albeit these devices have become an integral part of life (Fusheini & Eyles, 2016). This demographic is inherently disqualified from benefiting from the technologically advanced health sector (Krick et al., 2019). The same findings are revealed in a study conducted by Lennon (2017) in Dallas, that although the adoption of innovation is increasing in Dallas, many people are unable to take advantage of some of these improvements due to the high cost of technology or limited access to computers and free Internet. A few consortiums in Dallas have resorted to offering free internet and digital assistance to reduce exclusion to technological facilities (Lennon et al., 2017).

Rural areas have the greatest levels of digital illiteracy in South Africa (Kgasi & Kalema, 2014). The population of rural areas is diverse, primarily made up of older individuals who have little to no prior knowledge of or comprehension of basic information technology and younger individuals who are somewhat familiar with using digital technologies (Schillo & Robinson, 2017). Initiatives to improve digital literacy in rural communities are essential and beneficial to the development of a technologically sophisticated healthcare industry (Schillo & Robinson, 2017).

2.13 The public's trust and expectations in health delivery systems

Kruszynska-Fischbach (2022) found that there are healthcare professionals who fear the development of technology would render them obsolete. Through further investigations, Kruszynska-Fischbach (2022) found that it was the lack of knowledge and skills in connection to digital health that was the biggest obstacle. People's readiness to use technology in healthcare was significantly impacted by their lack of knowledge in digital health (Rakate, 2007). Healthcare workers were hesitant to adopt healthcare innovation because they were afraid of losing their jobs (Meyer et al., 2017). Some medical practitioners think that the antiquated paper approach is still preferable because it is easy to use and doesn't require any further training (Naidoo, 2012). A group of healthcare professionals expressed that their frustrations with innovation in healthcare would disappear if they received adequate training for innovations implemented in healthcare (Kruszyńska-Fischbach et al., 2022). Clinicians usually struggle to keep up with new and emerging advancements due to the rate of technological change in healthcare, particularly the expansion and lack of regulation of the mobile app industry (Lennon, 2017).

Clinicians become extremely worried about data security when working with private enterprises (Tarantini et al., 2019). This lack of trust becomes an obstacle to the adoption of innovation in healthcare (ibid). According to a report, several medical professionals were worried that patient data wouldn't be kept secure or confidential or that it would be sold or shared with for-profit businesses without the consent of the patients or their awareness (Meyer et al., 2017). Furthermore, several medical experts were reluctant to embrace new technology due to their extensive experience with numerous digital health initiatives that had come and gone throughout time and failed to become standard treatments within the healthcare system (Raghupathi &

Raghupathi, 2020). Over and above the physicians, patients also dread digital health because they think it aims to remove the element of empathy provided by healthcare practitioners when performing their duties (Smith et al., 2023). Healthcare givers fear digital health may be used to weaken them and, in some circumstances, replace them as caregivers (Tarantini et al., 2019). To integrate new technology into routine working procedures, there has to be professional confidence in health professionals which can be acquired by introducing a type of technology in healthcare in incremental stages (Lennon, 2017).

The preparedness of patients to accept technologies that need data entry or a change in daily routines was found to be minimal (Smith et al., 2023). People's hectic lifestyles with conflicting family, professional, financial, and social obligations, make it difficult to conduct sessions of preparing the public with technologies in healthcare before they are launched (Smith et al., 2023). There are healthcare practitioners who worry that technology innovations in healthcare are not always suitable for their patients, both older and younger (Kruszyńska-Fischbach et al., 2022). The same goes for new digital solutions; although some people welcome them, others do not (Smith et al., 2023). The language used on digital platforms affects the feasibility of the innovation in healthcare (Lennon, 2017). English is a universal language, therefore most digital platforms operate in the English language (ibid). Using English as the sole language offered on digital platforms creates a barrier given the increasingly heterogeneous makeup of modern society (Lennon, 2017).

Patients have indicated a lack of trust in digital health security due to high-profile data breaches in the past. Some patients are concerned about the security and protection of personally identifiable information and whether it would be shared with firms without their knowledge or consent (Mhlanga, 2022). While some people may comprehend the idea of anonymizing data, who owns permission, and everything else, but communicating those ideas to the general public may be an extremely difficult task (Smith et al., 2023).

2.14 Strategies in place for implementing innovation in public healthcare in South Africa

Several measures have been used in South Africa to promote innovation and raise the standard of healthcare services provided to the population.

Research and Development (R&D) is a key tactic for encouraging innovation in public healthcare (Flavia, 2012). The government has funded R&D initiatives in the health sector with large sums of money (Lucas et al., 2022). A study conducted by Flavia (2012) gathered that the necessity of advancing indigenous health research in South Africa is becoming more and more apparent. The Academy of Science of South Africa produced recommendations for the revival of clinical research because of the decline in investigator-initiated original clinical research activity in the mid-2000s (ibid). The NDoH also recognized the vital role that health research plays in guaranteeing a long and healthy life for all South Africans through its 10 Point Plan, which lists "strengthening of research and development" as its tenth objective (Maphumulo & Bhengu, 2019, p.6).

In July 2011, the National Health Research Committee convened a National Health Research Summit in response to policy instructions from the National Department of Health. The summit identified seven obstacles and made suggestions for the revitalization of the health research system in South Africa (ibid). Partnerships between academic institutions and the corporate sector are also encouraged, since this fosters cooperation on creative research initiatives aimed at enhancing the delivery of public healthcare (Flavia, 2012).

Using digital technologies to increase rural areas' access to healthcare services is another important tactic for fostering innovation (Leonard et al., 2019). To meet the demands of rural communities, there has been a proliferation of telemedicine initiatives implemented by the government between the years 2000 and 2020 (Lucas et al., 2022). The lockdowns and physical distancing requirements that were imposed by the COVID-19 pandemic have forced a marked growth on telemedicine to maintain connections and safety between patients and their healthcare professionals (Lucas et al., 2022). Aiming to enhance the knowledge-based skills required for the effective use of innovations such as Electronic Health Records (EHR), for instance, the government launched training programs for frontline medical personnel at all levels (Afuah, 2020). The training programs also seek to develop creative approach capability and foster an innovative culture within the public healthcare system (Lucas et al., 2022).

Most often, innovation designed to improve a variety of aspects of healthcare is not implemented in settings where it is needed the most (Leonard et al., 2019). It is crucial to analyse or examine the healthcare system, in particular healthcare facilities, in order to determine what obstacles and constraints prevent the adoption of innovative ideas in healthcare (Afuah, 2020). Using efficient assessment instruments, management at healthcare facilities would be able to resolve the problems impeding the successful adoption and integration of innovative solutions at their facilities, guaranteeing that the system is supportive of the adoption of innovations (ibid). A group of scientists saw this gap as an opportunity to develop a healthcare innovation adoption readiness assessment tool to be used in the public sector in South Africa (Leonard et al., 2019).

2.15 Conclusion

This review has examined both theoretical and empirical literature, which to some degree yield the same conclusions. Existing literature has determined that the factors that influence innovation in healthcare are either within the control of a healthcare organisation, or completely beyond the control of a healthcare organisation (Akenroye, 2012). Internal factors, which are within the control of the organisation, vary considerably and they have impacts of different magnitudes. They range from incorporating empathy in design to the culture within an organisation. The calibre of decision-makers and stakeholders has one of the greatest impacts on the successful implementation of innovation in public healthcare (Herzlinger, 2006). The key findings of the external factors that influence innovation in public healthcare are that funding innovation from conception to commercialisation is a challenge for innovative firms (Akenroye, 2012). This usually results in innovations, which would have benefited healthcare, not being developed or implemented (Chaudoir

et al., 2013). Public policy and key stakeholders usually have a negative impact on the implementation of innovation in public healthcare (Chaudoir et al., 2013).

The term innovation is generally misunderstood in healthcare. There is a misconception that innovation is technological advancement, when in fact innovation in healthcare is broad. The lack of uniform comprehension of the term innovation in public healthcare has resulted in the inappropriate use of the term innovation, to describe different developments in healthcare. It has therefore been difficult to accurately establish the level of successfully implemented innovation in public healthcare in South Africa. The need for innovation in healthcare stems from the quality of healthcare in South Africa. The principles of separate development which the apartheid regime was founded on are largely responsible for the failing healthcare system in South Africa today. Innovation has been proven to enhance healthcare delivery. Innovation has been labelled as one of the critical solutions to the public healthcare crisis in South Africa (Mhlanga, 2022).

A policy on "Quality in Healthcare in South Africa" was drafted by the National Department of Health in 2007 with the goal of raising standards for healthcare in both the public and private sectors (Rakate, 2007). Applying techniques that are evidence based is described in this text as one of the key strategies to improve the health status of South Africans (Rakate, 2007). In South Africa, the majority of medical procedures, however, are not supported by scientific research (Dryden-Palmer et al., 2020). The commitment to offering evidence-based healthcare demands a persistent effort to evaluate both new and existing medical practices (Dryden-Palmer et al., 2020).

Few studies have examined the existence of an environment for testing innovation prototypes in healthcare. The one significant gap in literature that persists is that there has not been much discussion on the existence of suitable testing environments for healthcare innovation in South Africa and their impacts on healthcare. Evidence-based innovation cannot be developed and adopted if a suitable environment for testing innovation is not developed by the government, which is the major stakeholder of South African healthcare in terms of patient numbers. Over the last decade, research and development has been prioritised in South Africa. However, there hasn’t been an emphasis on the creation of prototyping and testing environments. Without prototyping and testing the prototype, research is incomplete.

It is impossible to overstate the significance and advantages of innovation in healthcare in society. Innovation is essential for raising the standard of patient care, optimizing therapeutic results, and propelling general medical developments (Jacobides et al., 2006). Healthcare practitioners may successfully solve difficulties, enhance efficiency, and ultimately save lives by implementing innovative solutions. Within the healthcare industry, innovation fosters economic growth and the creation of jobs by increasing productivity and opening up the possibility of exporting pharmaceutical or medical technology.

3 CHAPTER 3 - METHODOLOGY

This aim of this chapter is to set out the methodological research approach undertaken to explore the factors that influence innovation in public healthcare, in South Africa. The purpose of the study and the chosen methodology will be presented in this chapter. It will outline the methods utilised for data collection as well as the data analysis process. It will present the characteristics of the research participants that were selected. It will also go over any ethical concerns, the research paradigm, and the study's limitations.

3.1 Research Design

Research methods should always be selected because of their suitability to best serve the study goals and assist in addressing the research questions of a study (Hubberman et al., 2014). A qualitative research approach was used to conduct this study. Qualitative research methods enable researchers to get a thorough grasp of a subject, by exploring the meanings that individuals attribute to their behaviours, circumstances, people, and objects in their life through collecting and interpreting non-numerical data, such as words, images, and observations (Leavy, 2022). Qualitative research techniques follow a methodological framework that is based on inductive designs that produce meaningful and rich descriptive data (ibid). Hammarberg (2016) also states that the richness of meaning, as well as people's subjective experiences and their processes for making sense of the world are valued in qualitative research method

Taylor et al (2015) state that qualitative research is based on the idea that meaning is constructed by the perceptions and views of individuals within a society. The main philosophy of qualitative research is contradictory to that of quantitative research, which holds the idea that reality is a fixed or measurable phenomenon (Hennink, Hutter & Bailey, 2020). The objective of qualitative researchers is to understand the different and diverse interpretations of reality by society at a certain point in time and in a specific context (Allan, 2020). Qualitative research is usually characterised by core themes within the study, which are based on people’s attitudes, feelings, beliefs and understandings (Hubberman et al., 2014). It is common for quantitative research to have a pre-determined hypothesis before the research commences (Leavy, 2022). However, qualitative research never has a pre-established hypothesis (Allan, 2020). Instead, qualitative research may be used to formulate a hypothesis (Hennink et al., 2020).

Although a qualitative method of research may be the best method to use for this research study, it is worthy to note that qualitative research is not without weaknesses and limitations (Gounder, 2012). Qualitative research does not yield conclusive results. Instead, the findings from qualitative research will provide the researcher with enough data to shape a solid decision-making foundation (Gounder, 2012). Objectivity therefore becomes diminished, and subjectivity gets introduced in the study. This subjective nature of qualitative research makes it difficult to achieve adequate validity and reliability (Dworkin, 2012). Despite its limitations, qualitative research was the best method for this study because this research study is descriptive in nature. Qualitative research aims to analyse and provide information about the factors that influence

innovation in public healthcare in South Africa. A qualitative research approach was therefore best suited to acquire descriptive information of the factors that influence innovation in healthcare (Hubberman et al., 2014). In this study, the aim was not to obtain a correlation of any sort between the factors that influence innovation. No information was quantified, therefore, a quantitative research method in this instance would not be effective (Hubberman; Miles & Saldana, 2014). A qualitative analysis alone would be able to assess and answer the research questions of the study (Allan, 2020). It would also enable the objectives of the study to be met (Allan, 2020). Studies using qualitative research methods are becoming more and more accepted in the field of medicine (Renjith et al., 2021). Qualitative research has been found to be effective in helping researchers understand health innovation, healthcare behaviours, and sickness experiences (ibid). The ultimate strength of qualitative research in healthcare comes from the richness of the data, as well as the descriptions and depth of exploration it provides (Renjith et al., 2021).

3.2 Research Paradigm

A research paradigm is a framework that directs the execution and interpretation of research. This study is based on a constructivist (interpretivism) research paradigm. The constructivist research paradigm helps to understand and interpret the research question, by examining the experiences of medical doctors and the Department of Health officials. To understand constructivism, it is essential to have a basic understanding of a positivist research paradigm (Abdul Rehman & Alharthi, 2016). Positivism is founded on the concept of realism (Kamal, 2019). The premise of positivism is that reality exists independently of people, and it is governed by immutable and irrefutable laws (Bogna, Raineri & Dell, 2020). In positivism, there is no room for researchers to be subjective because reality is not affected or influenced by the researcher or even humanity (Abdul & Alharthi, 2016). According to positivists, there are rules regulating social processes, and by using scientific procedures, these laws can be developed and presented as factual assertions (Bogna et al., 2020).

Contrary to positivism, the idea that there is one distinct reality that can be verified outside of our senses is rejected by constructivism (Kivunja & Kuyini, 2017). Instead of reality being a product of immutable laws, constructivists on the other hand, think that various realities are socially produced and are highly influenced by subjectivity (Bogna et al., 2020). Rehman et al (2016) explain that a constructivist research paradigm believes that researchers are integrated with the reality being examined. They essentially cannot be separated from the research (Abdul & Alharthi, 2016). A constructivist research paradigm acknowledges that different individuals have different perspectives of the same phenomenon (Kivunja & Kuyini, 2017). Bogna et al (2020) state that a constructivist paradigm does not favour one interpretation or the other but embraces the existence of broad and diverse knowledge.

The research methods that are generally used by constructivist researchers are those that generate qualitative data (Lee, 2012). Qualitative data allows constructivists to obtain different interpretations of the same phenomena effectively (Kivunja & Kuyini, 2017). Thus, in-depth interviews were conducted with 5 medical doctors and 5 employees of the eThekwini District of Health, making a total of 10 research participants. The

obtained data was closely examined to comprehend the participants perception of the factors that influence innovation in public healthcare in South Africa.

A constructivist research paradigm has been criticized for lacking the ability to produce propositions that can be applied to larger populations (Kivunja & Kuyini, 2017). It has also been quoted to be subjective because of the involvement of the researcher with the participants' which reduces objectivity (Goundar, 2012). However, Ellis (2014) contrasts this view by stating that the nature of qualitative research requires meticulous attention to detail. A constructivist research paradigm has been thought to be an ideal research paradigm to use to explore the complex constructs of society (Goundar, 2012). To ensure that an interpretive (constructivist) research study is sound research, Ellis (2014) suggested that it should possess validity, dependability, and objectivity.

3.3 Instrumentation

Research instrumentation refers to the instruments, gadgets, or machinery used in a scientific study to obtain data and information (Thieme et al., 2014). Numerous tools may be used to collect and analyse data, including survey questionnaires, microscopes, spectrometers, interviews, and software programmes. In qualitative research, instruments like document analysis, observations, and interviews are frequently employed to gather comprehensive data regarding participant experiences, viewpoints, and behaviours (Hubberman et al., 2014). The qualitative data used in this study was gathered in the form of literature and interviews. A comparison of existing literature and the findings of the interviews is then made and discussed in the fifth chapter.

3.3.1 Literature review

Literature reviews are brilliant tools for collecting research data because they provide a comprehensive overview of the body of knowledge already available on a given subject (Chuene & Kgarose, 2023). They can help identify gaps in the literature and areas for further research. It is however worthy to note that literature reviews are not without flaws (Karam et al., 2018). The calibre of the studies that were included in the literature review determines the validity and dependability of the data that was collected, and the chosen literature may contain bias, which could compromise the accuracy of the results (Karam et al., 2018). The literature review, therefore, consisted of references spanning over 30 years from 1993 to 2023 to capture longstanding concepts and more recent theories to increase the validity and dependability of the study.

3.3.2 Interviews

An interview is a typical research method used in qualitative studies (Hubberman et al., 2014). The different types of interview methods that are available to qualitative researchers are unstructured, semi-structured, and highly structured interviews. Interview techniques typically use conversation as a data collection tool (ibid).

Using interviews as a data collection methodology for qualitative research is highly recommended (Leavy, 2022). Through interviews, researchers can delve into the thoughts, experiences, and perspectives of participants in a detailed manner (Allan, 2020). Interviews offer flexibility to adapt questions based on participant responses, allowing for clarification or further probing when necessary (Malterud, Siersma & Guassora, 2016). As participants can communicate their thoughts, emotions, and unique experiences in-depth during interviews, rich qualitative data is produced (Malterud et al., 2016). By conducting interviews, researchers can build a rapport with participants that may increase trust and promote more frank and open responses (Driever et al., 2022). In addition to verbal responses, non-verbal cues such as body language, facial expressions, and tone of voice can offer researchers extra information (Rabiee, 2004). Instant feedback is available to researchers throughout interviews, enabling them to quickly address any misunderstandings or pose follow-up queries (Driever et al., 2022). The interactive nature of interviews often leads to higher participant engagement compared to other data collection methods (Lopez & Whitehead, 2013). Using interviews, researchers can customise questions based on the background or level of knowledge of each participant, providing meaningful and focused data collection (Lee, 2012). Due to the dynamic nature of the interaction, interviews may reveal surprising insights or opinions that the researcher had not initially anticipated (Hammarberg et al., 2016).

Semi-structured interviews were used to conduct this study. A preset list of open-ended questions was used in these interviews to provide participants the opportunity to express their opinions and give thorough answers on the topic under investigation (Leavy, 2022). Compared to other interview formats, the semi-structured method has several advantages. First, because participants are free to openly share their ideas, emotions, and experiences related to the research issue, this increases the validity of the study and researchers are able to gather rich and detailed data (Ruslin et al., 2022). Since the questions are open-ended, participants are also encouraged to give thoughtful answers that reveal important details about their viewpoints (Rabiee, 2004). Another advantage of semi-structured interviews is that they let researchers modify their style of inquiry in response to the distinct answers from each participant (Ruslin et al., 2022).

The disadvantages of collecting data using interviews should also be considered when conducting a research study. When conducting interviews with big sample sizes, it may be time-consuming for both researchers and participants (Goundar, 2012). The interviewer's presence may inject subjectivity into the data collection process because of their influence on participants' responses or their own interpretation of the results (Goundar, 2012). Results from interviews may not be applicable outside of the specific environment in which they were performed or indicative of the entire community (Thieme et al., 2014). During face-to-face interviews, participants may feel under pressure to give socially acceptable answers, which may skew results (Ruslin et al., 2022). These challenges were overcome by conducting the interviews at the participants location and guaranteeing confidentiality to allow them to feel comfortable. In qualitative research interviews, choosing a location that a participant is comfortable with promotes a sense of security for the participant and helps maintain confidentiality, which encourages them to talk openly (Rabiee, 2004). The interviews were

also conducted during lunch-time to allow the participants to not be time-conscious. Literature suggests that when participants are afforded adequate time to respond to questions without being under time pressure, it can encourage cooperation and trust, which encourages participants to be more forthright and honest in their responses (ibid). Conducting interviews effectively does not only require the interviewer to have cognitive skills, but the use of soft skills such as "verbal communication skills, time management and flexibility" is also recommended when conducting interviews (Ruslin et al., 2022, p.7). The questions asked were open-ended to avoid leading or suggestive language that may cause answers to be bias and thus lead to subjective data. (ibid) state that when an interviewer asks open-ended questions, they allow the subjects to reveal different aspects of the phenomena being studied which increases the validity of the study.

The two groups that were interviewed are described as follows:

(a) Interviews for medical doctors in public institutions

The purpose of this interview group was to find out if there is a need for enhanced innovations in public hospitals from the perspective of medical professionals. The purpose of interviewing these group was also to determine what hinders innovation from being implemented in healthcare and the challenges that medical doctors face with the technology that is already available in hospitals.

(b) Interviews for members of the Department of Health

The purpose of this interview group was to determine the perspective of policy makers with regards to the aggressive implementation of innovation in public hospitals. According to the National Health Act, 2003 (Act 61 of 2003, p.34), the mission of the Department of Health in South Africa is to "improve health status through the prevention of illnesses and promotion of healthy lifestyles and to consistently improve the healthcare delivery system by focusing on access, equity, efficiency, quality and sustainability". This survey seeks to find out what strategies the government uses to introduce efficiency and sustainability in the health care delivery system. It also seeks to measure how effective those systems are.

3.4 Sampling

In qualitative research, sampling is the process of choosing individuals or cases to examine from a broader population (Lopez & Whitehead, 2013). It is a crucial component of qualitative research because it enables investigators to collect information that reflects the viewpoints, experiences, and understandings of a particular community or group (Lopez & Whitehead, 2013).

Purposive sampling was used to select a public hospital that is a true representation of the public health system in South Africa. Purposive sampling was also used to select all study participants from the public hospital and from the eThekwini Department of Health.

Purposive sampling is a non-probability selection method used in research to choose participants or cases that meet predetermined criteria related to the study's goals (Malterud et al., 2016). This selection method entails carefully weighing the study's objectives and purpose to choose participants who can offer insightful commentary or who best reflect specific qualities or experiences (ibid). Lopez (2013) also states that the main purpose of purposive sampling is to gather comprehensive and in-depth data regarding a certain event or group of interest. By carefully choosing people who have firsthand knowledge of the topic, researchers can gather detailed and comprehensive insights that may be difficult to obtain through other sampling strategies (Rabiee, 2004). Purposive sampling's primary goal is to collect data from people who can offer insightful commentary and further the objectives of the study (Allan, 2020). When accessing the full target population is impractical or when researchers want to get in-depth information on a specific occurrence, they frequently use this strategy (Lee, 2012). Researchers select volunteers by hand who possess pertinent knowledge, experiences, or viewpoints in order to collect high-quality data that closely relates to their study goals (Lopez & Whitehead, 2013).

One of the many advantages of purposeful sampling is its versatility (Lopez & Whitehead, 2013). It is the responsibility of researchers to define and refine their selection criteria considering the unique requirements of their work (Theron, 2015). This enables them to concentrate on specific groups or individuals who can provide valuable insights into their research subject (ibid). Saving time and resources is another benefit of purposive sampling (Ruslin et al., 2022). While probability sampling approaches require large sample sizes for generalizability, purposeful sampling focuses more on depth than breadth (ibid).

It is critical to understand some of the limitations associated with purposive sampling. Firstly, because this method relies on subjective judgment during participant selection, there is always a possibility of researcher bias (Leavy, 2022). The extent to which the results can be applied is limited because it is probable that the chosen individuals do not fairly represent the entire population (Hammarberg et al., 2016). Despite its drawbacks, purposive sampling is nevertheless an essential method in qualitative research for obtaining comprehensive and contextualised data from selected participants.

The focus of the study is on public hospitals in South Africa. There are more than 327 government-owned hospitals in South Africa (Dell & Kahn, 2017). The interviews were conducted in Durban because the researcher resides in Durban.

The Addington Hospital is a district and regional public hospital run by the provincial department of health (DoH) of KZN. Patients in the eThekwini metropolitan area of KZN can receive both specialized and non-specialized care from the Addington Hospital, which has a capacity of over 500 beds and about 2200 staff members. Having 3.9 million residents, the eThekwini metropolitan area is South Africa's third-largest municipality. Having a varied economy, eThekwini is known as the economic powerhouse of the KZN

province. In the province of KZN, Addington Hospital is one of just three public healthcare facilities offering cancer services which makes it a highly specialized hospital that can be used to represent the public healthcare system in South Africa.

Purposive sampling was used to select 5 medical doctors to be interviewed from Addington Hospital and 5 members to be interviewed from the Department of Health making a total of 10 participants. Purposive sampling was used because the suitable participants for fulfilling the purpose of this study had been determined beforehand.

The participants at Addington Hospital were selected based on their experience working as medical doctors. Three general practitioners, who have more than six years' experience working in a public hospital and two specialists (in any branch of medicine) with more than three years' experience in specialty were selected. This caliber of doctors was required because their years of experience have given them enough time to monitor the technological/innovation environment in public hospitals, and the factors that influence this environment. The specialists also understand how the technological/innovation environment and the factors that influence it, is in a specialised department of the hospital. However, it's important to note that the exact number of years it takes to become a seasoned medical doctor can vary depending on various factors.

The participants at the eThekwini Department of Health were selected according to their positions within the structure of the district health department. The manager of community health centers, the manager of district clinics, the manager of district hospitals, the computer and information systems manager and the finance manager were selected as the 5 participants. It is a requirement for individuals who occupy these strategic positions to have a minimum of 5 years management experience prior to appointment (National Health Act: Policy on the management of hospitals, 2011). All interviewed candidates had a minimum of 5 years management experience. One research participant had an undergraduate degree, three participants were in possession of a post-graduate degree and one participant had both a post-graduate degree and a post-graduate diploma. The aim of interviewing people who occupy these specific positions was to determine how each tier of the district health structure is contributing to the fulfillment of the mandate of the Department of Health.

3.4.1 Sample Size

A total sample size of 10 research participants is an adequate sample size for the study. A fundamental difference between qualitative and quantitative research is that qualitative research methods typically use a smaller sample size than quantitative ones due to their focus on in-depth understanding of phenomena and meaning, rather than numerically measurable results (Dworkin, 2012). It is important though to note that there isn't a set formula or clear-cut rules regarding how many people should be included in qualitative research (Hubberman, Miles & Saldana, 2014). Vasileiou; Barnett; Thorpe & Young (2018) also reveal that researchers in qualitative research contend that there is no simple answer to what an appropriate sample size is. Vasileiou

et al. (2018) further state that sample size depends on a variety of variables such as methodological guidance, practical constraints, data saturation and research question.

It is suggested that the more useful the data collected from each person, the fewer participants are required (Vasileiou et al., 2018). In fact, a study conducted by Subedi (2021), whereby 80 total articles were scanned, revealed that an appropriate number of participants depends on the problem being studied. Furthermore, in one of the articles scanned, one participant was proven to be enough to gain insight into the research issue (ibid).

The nature of qualitative research interviews is inductive, so they tend to focus less on making generalisations to a larger population of interest, rather, their goal is to categorise the collected data and then examine how the categories relate to one another (Dworkin, 2012). In qualitative studies, the determining factor for sample size is saturation (Malterud, et al., 2016). Data saturation is the point at which the data being collected is not yielding any new insights or information (ibid). When researchers have acquired enough information to thoroughly comprehend and examine the phenomenon they are studying, data saturation happens (Lopez & Whitehead, 2013). Dworkin (2012, pp.1319) suggests "a minimum of 5 participants in the study to attain saturation while also reducing the risk of having repetitive data". Repeated or redundant information may start to become a risk if more data is collected and examined. In this study, a total of 10 interviews were conducted. It was noted that answers to the questions posed were slightly similar between the participants interviewed in each group.

3.5 Data Collection and Analysis Procedures

3.5.1 Data Collection

In qualitative research the main instrument for data collection and data analysis is the researcher (Taylor, Bogdan & DeVault, 2015). Some of the main pros of having a human instrument in research are that the human being is not rigid, they are able to immediately process and respond to data, check for the accuracy of interpretation with the participant and explore uncommon responses (Lopez & Whitehead, 2013). There are also shortcomings of having a human research instrument which are important to identify and monitor how they shape the results of the study (Ruslin et al., 2022). Qualitative research is subjective in nature, which tends to affect the reliability of the study (Kamal, 2019).

Interviews with each participant were audio recorded as the interviews took place. Field notes were also taken in parallel with the audio recordings. The interviews took place in a vacant office at the hospital or the Department of Health offices. Only the interviewer and participant were present during the interview at any given time. Verbatim transcripts of each interview were generated using the transcribe feature on Microsoft Word. The field notes were used to check the accuracy of the transcriptions.

3.5.2 Data Analysis

Once the data was collected, wasit coded using in-vivo coding (also known as verbatim coding) and categorized into themes. In-vivo coding was the optimal coding method to use in this study because of its ability to reduce subjectivity when compared to other coding methods (Theron, 2015). The coding process was started as soon as data collection commenced to make the process more manageable. Upon going through the responses of each participant, words and phrases that kept re-occurring were detected using the find tool on Microsoft Word. These words and phrases were then grouped into codes based on any similarities that existed between them. The data was then consolidated by exploring the relationships between the different codes. The codes were then grouped into themes. The data was analysed using the Huberman and Miles (2014) thematic analysis process. This method recommends coding as soon as data collection begins, to avoid overloading (Miles, et al., 2014).

A thematic analysis is a qualitative research method used to identify and analyse patterns, themes, and meanings within a dataset (Page et al., 2021). It entails the methodical discovery, arrangement, and interpretation of any themes or patterns that show up in the gathered data (Bogna et al., 2020). Researchers can gain an understanding of complicated phenomena by using thematic analysis to look at the underlying themes or concepts that are present in the data (Bogna et al., 2020). The themes generated from the data were refined through an iterative process. An interpretive analysis of the themes was then done to answer the research questions, aim and objectives. This process is elaborated in chapter four of the study.

3.6 Reliability and Validity

The validity of qualitative research refers to the accuracy and credibility of the findings, while reliability refers to the consistency and repeatability of the results (Rabiee, 2004). These factors can be influenced by various aspects of the research such as the research design, data collection methods, researcher bias, and interpretation of findings (Hubberman et al., 2014). It is important for researchers to consider these factors to enhance the validity and reliability of their qualitative research.

Reliability differentiates sound research from fiction. Reliability and validity give research its utility (Morse et al., 2002). Reliability is simply a gauge of how much a measurement method used to conduct the study provides repeatability and accuracy (Goundar, 2012). Validity refers to the use of proper processes in the search for solutions to a question or query (ibid). These concepts of reliability and validity make sense when they are used in quantitative research. Since the findings produced by qualitative research are not quantitative in nature, the concept of reliability and validity as applicable to quantitative research becomes irrelevant in qualitative research (Golafshani, 2003). Therefore, in qualitative research, reliability and validity can be represented by the quality and trustworthiness of the study (ibid). To ensure that validity and reliability as defined for qualitative research are achieved in this study, the triangulation analysis technique was used. The data obtained from the interviews was triangulated with the data obtained from the literature review by

reviewing multiple data sources. Triangulation is a methodology for analysing the outcomes of a single study using multiple data sources (Nightingale, 2009). Triangulation also aids in the validation of study findings by examining if the results from various methods of the same phenomenon event are consistent (ibid). The triangulation of the results is shown in Chapter 5 of this study. The discussion of the results of this study shows that the findings of this research tie up with existing literature. This shows that the study has a high degree of validity and reliability.

3.7 Ethical Concerns

Data collection was through interviews and reviewing existing literature. A tool used to assess if a research procedure has been conducted ethically is the Research Ethics Clearance. The research involved interviewing human participants. Therefore, a research ethics approval (approval no. – M211184) before conducting the research. Ethics approval was obtained to conduct research at the Addington Hospital and the eThekwini Health District offices in June 2022. The research was conducted in Durban, therefore it was also a requirement to apply for ethics clearance from the University of KwaZulu Natal (UKZN) as well. The UKZN research ethics committee granted reciprocity to the University of Witwatersrand's ethics approval for the research study. Using the research ethics approval letters, permission was obtained to conduct research at the Addington Hospital and at the eThekwini Health District offices. It is important to ensure that human participants are protected when conducting research interviews. This was achieved by getting each participant to complete a consent form detailing amongst other things that the identity of the participant would not be revealed and that their participation is voluntary, therefore, they are free to withdraw at anytime.

3.8 Study's limitations

The limitations of the research methodology used in this study are outlined in this section. Only ten research participants were interviewed. This small sample size limits the generalisability of the study. Previously, qualitative researchers were of the view that generalisation is less important in qualitative research than in quantitative research (Rabiee, 2004). However, several researchers in qualitative research have started to emphasise the significance of addressing generalisation (Rabiee, 2004). Subjectivity and bias may also be introduced into qualitative research because qualitative research mostly depends on the researcher's interpretation (Hubberman et al., 2014). Two researchers may interpret the same interview responses differently, producing different findings. The sampling method used in this study is purposive sampling which does not reflect the general population. This results in a limitation known as a sample bias or selection bias (Dworkin, 2012).

4 CHAPTER 4: RESULTS

4.1 Introduction

The primary purpose of this study was to understand the factors that influence the successful implementation of innovation in public healthcare in South Africa. This was achieved through analysing data provided by medical doctors at Addington Hospital in KZN, and employees of the Department of Health (eThekwini District). In this chapter raw data obtained through interviews is reviewed and analysed. Three main objectives were established to guide this research project. The objectives of this study were to assess the need for innovation in public healthcare; to identify the strategies in place for implementing innovation in public healthcare; and to establish the level of successfully implemented innovation in public healthcare in South Africa.

The experiences and comments of the participants shed light on the study's research questions and objectives. Through examining the experiences of the participants meaningful information regarding the factors that influence innovation in public healthcare in South Africa was obtained.

4.2 Demographics of participants

The interviews of medical doctors at Addington Hospital and professionals from the eThekwini Department of Health served as the foundation for this qualitative study's findings. All participants reside and work in Durban, they also voluntarily participated in the study. The medical doctors were solicited through the Medical Manager at Addington Hospital. The medical manager randomly selected the participants who fit the research requirements and were willing to participate in the study. The research participants that were interviewed at the eThekwini Department of Health were selected as outlined in chapter three of this study. The two groups consisting of research participants who were interviewed individually are abbreviated as follows: MD = Medical Doctor and DHO = Department of Health Official. The numbers attached to the abbreviations refer to specific participants in each group. The demographics of the participants are summarised in Table 1 and 2 below:

Table 1:Characteristics of interview participants - medical doctors

Characteristic	**Value**
Women (%)	40%
Men (%)	60%
Age group	35 years -55 years
Specialised (%)	40%
Highest level of education	Post graduate degree

Table 2: Characteristics of interview participants - Department of Health officials

Characteristic	**Value**
Women (%)	60 %
Men (%)	40 %
Age group	40 years – 55 years
Percentage in management level (%)	100
Highest level of education	Post graduate degree

4.3 Results

The data collected from all the participants was transcribed by the principal investigator. The qualitative data consisted of 10 interview transcripts, 180 documents, and 10 observation field notes. Deductive coding was used to generate the initial codes. The initial codes that were generated were prompted by the literature review findings, the research questions, and the research objectives. To ensure trustworthiness of the study, a thematic analysis was conducted in six steps as follows:

Step one: data familiarisation.

The first step that took place was to store the records of the collected raw data on Microsoft Excel. Then the data was read thoroughly for an in-depth understanding of the content of the collected data. During this process, the analysis of the data began by noting down thoughts and ideas of interest which were developed while collecting and reading the data. The data was repeatedly read to actively search for patterns and interesting thoughts.

Step two: Generation of initial codes.

Once patterns and ideas were noted from reading the data repeatedly, the initial generation of codes commenced. A line-by-line analysis of the interviews data was done, and the initial codes were generated by marking important sections of the text and attaching a label/code to those sections. An iterative process of refinement was done, and 26 codes and 7 themes were eventually derived from all 10 interviews.

Step three: Generating themes.

The codes that were generated from the data were listed on a Microsoft excel spreadsheet. The number of times the codes appeared on the data was counted and recorded on the excel spreadsheet. Some of the codes that were extracted were removed from the list of codes because they didn't appear frequently in the data.

The remaining codes that were extracted from the data were finally grouped into themes which are summarised in Table 3.

Table 3: Research codes and themes generated from interview data

Theme	Codes
Lack of design empathy	• contribute to design • participation • inclusive design • staff engagement • awareness
Reactive approach to innovation	• malpractice insurance • incident response teams
Regulatory environment	• regulatory uncertainty • legislation red-tape • decision-making
Lack of staff training	• knowledge • education levels • hospital staff • work conditions
Healthcare innovation customers	• autonomous characteristics • consumer resistance
Funding issues in healthcare	• budget constraints • finances • allocations • investors • start-ups
Innovation incubators	• testing • laboratories • hubs • technological resources • medical devices • design

Step four: Reviewing themes

At this stage, the codes assigned to every theme were examined to determine that there was a consistency of patterns in all themes. The coded data extracts were examined for every subtheme to see whether any consistent patterns emerged. During the reviewing of themes, it became apparent that two themes lacked

sufficient evidence to justify them. These themes, being a) reactive approach to innovation and b) healthcare innovation customers, were then removed from the list of themes.

Step five: Finalisation of themes

Each theme was named and defined by determining the story each theme conveyed and considering how each theme fits into the larger narrative about the complete data set in connection to the research objectives. "Funding issues in healthcare" was renamed to "Lack of funding" and "Innovation incubators" was renamed to "Lack of innovation testing centres". After refining and renaming the themes, the final dominant themes observed from the interviews conducted were the lack of design empathy in healthcare innovation, regulatory environment issues, lack of staff training, lack of funding, and the lack of testing centres for healthcare innovation as shown in Figure 6. These themes are discussed in detail in the paragraphs that follow.

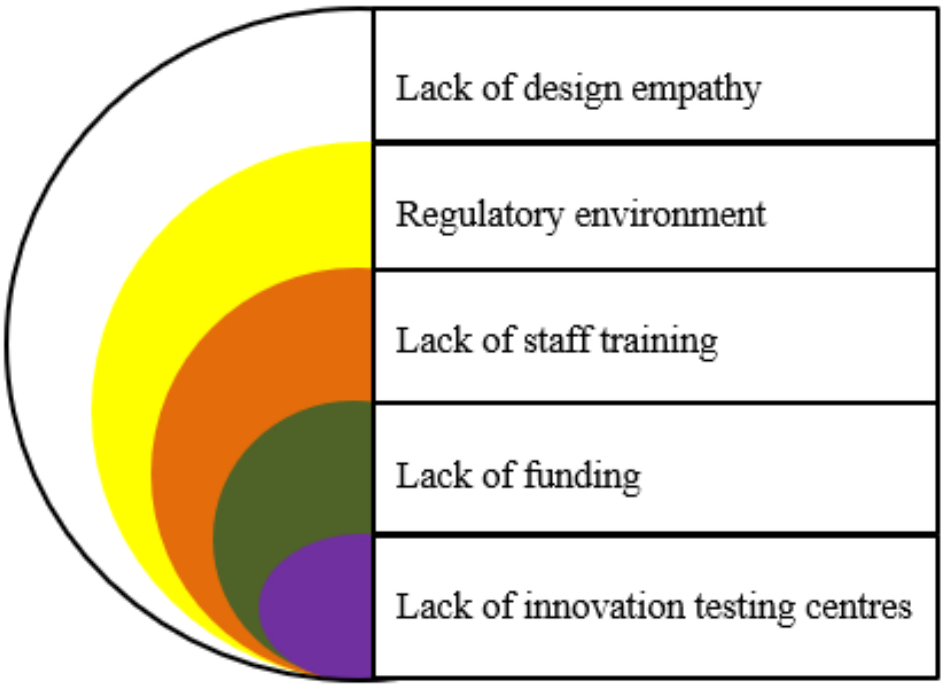

Figure 6: Overview of research findings.

It was important to establish what the research participants understood innovation in healthcare to be. The first question that was posed to each individual is what is innovation in healthcare? Different responses were received from each of the participants. In general, medical doctors saw innovation as the improvement of medical problem-solving procedures. "*In medicine, when a problem is encountered, there is generally an established potential-solution path to conform to. We get to improve these solution paths as we encounter the same problem over time*" (MD3). Another medical doctor stated that "*Innovation is an intrinsic part of medicine. What people do not understand is that doctors innovate all the time. During certain surgical operations for example, you may have to improve certain processes on the spot to address patient-specific issues*" (MD5). It is also important to add that medical doctors feel strongly about innovation in healthcare being a shift towards personalised medicine. An oncologist uttered that "*I've witnessed the brutality of cancer*

as an illness in patients. I've also witnessed the brutality of cancer treatments in patients, especially the commonly used ones such as chemotherapy and radiation therapy. Patients respond differently to administered treatments and therefore the treatment plan should not be the same for all cancer patients. I've realised through oncology that innovation in healthcare is actually shifting towards personalised medicine" (MD2).

Officials from the Department of Health had a different perspective of innovation in healthcare which is summed up as the improvement of policy and technology to enhance healthcare delivery. An official stated that "*innovation is creating new technology to make the delivery of healthcare services efficient*" (DHO1). Another official stated that "*as the custodians of public policy, we know that policy needs to enable healthcare innovation. The improvement of policy is also innovation in itself*" (DHO3).

4.3.1 Lack of design empathy

Medical doctors are aware that they must be involved in the process of healthcare innovation as some of the key personnel in healthcare delivery. MD5 stated that "*Engaging medical professionals in all aspects of healthcare innovation ultimately creates better outcomes for patients*." Sometimes medical doctors do not get involved in time in the innovation process, which is worrisome for medical professionals. It was further pointed out by a medical doctor who works at the Trauma Unit that "*Physicians can only be effective in the innovation process if they are involved neither too late nor too early in the process. When involvement is too early, it may be difficult to provide valuable input considering that the problem may not be accurately defined at that stage. If doctors voice their opinions too late in the innovation process it may end up being too late to be taken into consideration"* (MD4).

Most participants (medical doctors and Department of Health officials) were in consensus that to promote innovation in healthcare, collaboration between the public and private sectors is crucial. When it comes to healthcare innovation, there was a general view that effective collaboration in South Africa is hindered by certain factors such as poor channels for technology commercialisation, poor channels for information transfer or a lack of established relationships across different stakeholders. Without effective collaboration amongst stakeholders, there can't be empathy in the design of healthcare innovation.

"It is seldom for innovation companies to solicit our professional opinion as medical professionals whenever they design new technologies. We are always expected to use new technologies to perform our duties effectively when the medical fraternity was not consulted during the design stage. Some of us do research on such technologies and we often discover that there was very little medical input in the design of these medical devices. (MD1)*"*

The Department of Health through various initiatives has posed the question of the lack of design empathy to innovation companies before. It became clear that healthcare innovation frequently puts financial savings or

technical improvements ahead of the human element of providing care as alluded to by DHO 4 "*We've had a workshop with healthcare innovation start-ups before. What we got from the workshop is that most healthcare innovation start-ups have a short financial runway. Their main objective when innovating therefore becomes cost minimization and not necessarily empathy incorporation*". Therefore, designers and innovators end up downplaying the significance of empathy in understanding the many demands and experiences of stakeholders in the healthcare industry.

Medical doctors do not downplay the importance of involving patients in innovation and decision -making processes. Doctors have noticed that innovators tend to overlook that the primary beneficiaries of healthcare delivery are patients. Patients are therefore instrumental in the design of healthcare innovation. Patients have critical end-user knowledge which could contribute the design of successful healthcare innovation.

MD 2 mentioned that "*a vital fact that many innovation companies tend to forget is that the primary beneficiaries of healthcare innovation are patients. It is crucial that patients participate in change decision-making processes, given their extensive understanding of being on the receiving end of healthcare delivery. This deep understanding contained by patients is very important when it comes to catalysing healthcare innovation.*''

Innovation is slowly getting eroded in healthcare. It's important for medical doctors to be empathetic so that they become effective healers and innovators. As empathy continues to decline amongst doctors, their ability to contribute meaningfully towards innovation also decreases.

"*The importance of empathy when practicing medicine is not a foreign concept to us. In fact, in medical school we get taught about the role of empathy in healthcare. An empathetic doctor becomes a better healer as they are able to put themselves in their patients' shoes. This same empathy allows doctors to improve processes in their line of work. We are not as empathetic as we should be. If anything, the level of empathy amongst medical doctors is declining. Its difficult to practice empathy as a doctor in the public sector when you are overworked, constantly emotionally exhausted and desensitized to the suffering of patients due to ill working conditions*" (MD4).

4.3.2 Regulatory environment

It has been observed by the Department of Health that long approval procedures and regulatory obstacles tend to deter investment in innovative healthcare practices. Companies end up being discouraged from investing in innovative technologies because they believe that the regulatory environment is unreliable and burdensome:

"*A lot of innovators and investors that have interacted with this department over the years state they have opted to avoid the health space because of the numerous regulatory barriers to entry. These barriers lengthen*

the time it takes to develop and raise the amount of capital required, which ultimately increases the risks in the end. I am not an innovator, but I have to say that I completely agree with these innovators. There is a high level of regulatory scrutiny which is a straining process for the innovator or investor. I have to make it known though that I think the level of regulatory scrutiny is appropriate and necessary, as much as innovators see it as barriers. What must happen is that regulatory authorities must improve how they work with innovation start-ups. The working model that must be adopted is one that meets the regulatory requirements, while also supporting innovation in healthcare" (DHO1).

Healthcare practitioners also concur that in South Africa, getting regulatory approval for innovative medical equipment, pharmaceuticals, and other products can be a difficult and time-consuming process. The lengthy approval procedures have highly contributed to the slow rate of healthcare innovation by delaying the release of innovative products onto the market. "*The ethics protocol for healthcare research is a cumbersome process. I understand that there is a need for it because the healthcare environment is a sensitive one, but it shouldn't be such a laborious process. A lot of applications are received, and some are not approved by our Research Ethics Committee. Various people including innovators are interested in conducting healthcare research in the hospital but cannot if they cannot obtain an ethics clearance certificate. This can discourage and demotivate innovators*" (MD5).

An excellent observation was made by MD3 when they stated that "*the regulatory environment works in favour of life insurance companies. This works in favour of healthcare innovation because I sincerely believe that life insurance companies are going to bring about innovation revolution in healthcare. With the NHI implementation being imminent, life insurance companies as a cohort have the potential to challenge and possibly overthrow the NHI by offering better healthcare delivery through innovation.*" This shows that the regulatory environment does not influence healthcare innovation in a negative manner only. The regulatory environment as it stands has the potential of encouraging innovation in healthcare through life insurance companies.

Medical doctors want to infiltrate the healthcare innovation sector in South Africa. This desire stems from the frustration of working in insufficiently equipped public healthcare facilities in South Africa. However, the South African regulatory bodies, such the South African Health Products Regulatory Authority (SAHPRA), have strict compliance criteria that healthcare innovators must follow. It ends up becoming very difficult to meet these standards, especially for small businesses or startups with little funding, which puts obstacles in the way of innovative solutions. Uncertainty around regulatory standards and procedures usually discourage investment in innovative healthcare practices in South Africa. A participant also stated that "*businesses may be reluctant to invest in research and development projects or to release innovative goods or services onto the market because they believe that regulatory risks are excessive or uncertain"* (MD4).

The Department of Health has observed that obtaining funds for healthcare innovation projects from investors or government grants frequently requires regulatory approval. This requirement usually hampers funding availability due to the uncertainty or delays in the regulatory approval procedure. The resultant effect is that the amount of money available for innovative projects is often reduced. "*Innovators are usually not able to produce the required regulatory approvals to in order to obtain funding grants because of the complicated regulatory environment*" (DHO4).

Medical doctors also pointed out that there is no synchronicity and alignment of goals between the major stakeholders that make up the health system. The South African Health Products Regulatory Authority as a significant constituent of the health system does not display any form of alignment with the goal of enhancing healthcare delivery through innovation. MD1 articulated "*I suppose I should begin by stating that, according to my experience, I've realised that the health system is complex. What I've discovered is that the health business is made up of numerous stakeholder groups, including insurance companies, pharmaceutical companies, hospitals, regulators, research institutes and many others. Each of these stakeholder groups have different goals, which are frequently not aligned to the goals of another stakeholder. I'll make an example with the South African Health Products Regulatory Authority. The rigorous process that has been set up for the approval of healthcare products shows that the South African Health Products Regulatory Authority is not completely aligned with the goal of improving healthcare through innovation in South Africa*."

4.3.3 Lack of staff training

There is existing innovation that does not get adopted in healthcare because staff typically don't know how to use it. Training for using new healthcare technologies does not get offered as soon as the technology is implemented. "*Some of the healthcare innovation that is available in the market does not get adopted in our hospitals because our staff simply cannot use it effectively. It is important for staff to get trained for using new technologies. However, that does not always happen in public hospitals.* (MD1)"

The traditional training of medical doctors does not prepare them for the adoption of new healthcare technologies. Times are changing and there is increasing demand of the use of technology in healthcare in this technical era which medical doctors have not been adequately trained for. "*We are living in times that truly demand the use of innovation in healthcare. We are in the midst of a technological revolution in healthcare, and we have witnessed a lot of health tech businesses emerging. The problem though is that, because medical doctors usually have only experience with brick-and-mortar practices, they struggle to adopt and be efficient with health technology rapidly. We need both medical doctors and technology leaders to join hands and provide training for using such technologies*" (MD4).

An example told by MD2 highlighted how the lack of staff training has adverse impacts on the implementation of new technologies in healthcare. "*When I was still working at the private sector, I was charged with implementing the Electronic Health Records (EHR) Systems when it was first introduced at that hospital. It*

wasn't easy for the doctors to adjust to this system because they didn't have all the resources they needed, and they didn't understand why using the EHR systems would benefit them. I discovered that not everyone can use technology, regardless of level of education. When a new technology is introduced in a hospital, it's important to provide training on how to use the new technology and explain the advantages of using the new technology to the people who will be using it". This example shows that healthcare practitioners want to understand what they are doing and why they are doing it. The rollout of innovation in healthcare must always be accompanied by a training program so that the innovation may be used successfully.

One of the major problems in South Africa is that public healthcare facilities frequently run on a tight budget, which includes financing for training of staff. These budgetary restrictions then result in limited funds made available for training initiatives. Over and above the limited availability of funds for staff training, the public sector's healthcare workforce frequently handles a large patient load and puts in long hours, leaving little time for professional development and training. Because of this, it is often extremely difficult for employees to prioritize training over their clinical duties. "*There is a gross scarcity of qualified healthcare staff in many South African public healthcare facilities. This lack of employees and budgetary restraints makes training more difficult since current employees always have to fill open positions, which reduces their availability for training. Sometimes, lack of training facilities or geographical limitations means that healthcare professionals in rural or distant areas have restricted access to training programs. This then causes the lack of training opportunities to be exacerbated*" (MD1).

Research and development are instrumental in bringing forth innovation in healthcare. The lack of staff training has been shown to slow down research and development and ultimately innovation in healthcare. When researchers or healthcare professional cannot use equipment that is meant to assist them conduct their research effectively, they are not able to come up with findings that will result in effective innovation in healthcare. *"As I have mentioned earlier, I also lecture medicine students and conduct medicine research. There was a period when I was conducting extensive research on cancer and at that time the use of sophisticated technologies to assess carcinogenic material was just becoming a reality. We were struggling to make any meaningful progress because we could barely use these machines. Though a representative from that company was sent to give us a short course on how to use the machine, they did not give us the full information we required to be successfully conduct our research. That whole experience made me realise that while access to technologies and innovation enables the research, the success of that research is dependent on the proper us of the technology or innovation. I saw how important it is for end-users of technology to be empowered by being taught how to properly use technological equipment. Over and above that, I had wished technology had more features which would have allowed us to conduct certain tests that would have led to more meaningful findings* (MD2)*."* This statement also shows how crucial empathy is, in the design of healthcare innovation. Healthcare innovation runs the risk of being inutile when end-users do not form part of the design process.

4.3.4 Lack of funding

The main hinderance to the implementation of innovation in public healthcare has been discovered to be an insufficient budget allocation to public healthcare. "*We cannot purchase the equipment we really need to perform our duties effectively, due to an insufficient budget allocation for hospital equipment*" (MD1). This statement also suggests that there is useful innovative equipment that exist in the market. However, they do not get adopted in the South African public healthcare system because of a lack of funding. An insufficient budget allocation for public healthcare has been a long-standing issue in South Africa. The negative impacts of consistently not having an adequate budget allocated to healthcare compounds and exacerbates over the years. "*If this ill-funding pattern persists, it is concerning how the government will implement the National Health Insurance Fund effectively*" (MD1).

Decision-makers in public healthcare are well aware of the issue of funding. "*We are definitely not ignoring the funding issue. It is a multi-dimensional issue which cannot be solved in one go*" (DHO4).

"The procurement of innovative equipment is a stringent process. The Supply Chain Management policy for the hospital is watertight because it is guided by national regulations and legislation" (MD2). This statement supports the findings of existing literature that was reviewed which show that in some instances, regulations do not support the implementation of innovation. An example is the policies imposed by the South African Health Products Regulatory Authority which hinders innovation in healthcare by having a lengthy approval process for healthcare innovations.

"*There has not been much procurement of technological devices over the past few years due to a limited availability of funds*" (MD5). This statement from a medical doctor suggests that there are various healthcare technologies available in the market that don't get used in public healthcare institutions because of insufficient budgets.

There has also been a concerning increased expenditure on medical malpractice claims. The amount spent on medico legal claims constantly exceeds the allocated budget for medico legal claims in any given financial year. *"The costs of medico-legal claims are an animal that just keeps growing. It's very difficult to control these costs without addressing the issue of medical negligence or malpractice"* (DHO4).

Another observation is that the South African government has limited available public finances which must be distributed to several important issues, such as infrastructure development, poverty alleviation, and education. "*Our mandate is not just to improve innovation in healthcare. We look at the health system holistically and we have various objectives that we need to focus on in order to improve healthcare delivery in South Africa such as reducing the rates of HIV/AIDS and tuberculosis infections. Unfortunately, our budget is limited, and it has to be spread across various objectives not just innovation only*" (DHO5). As a result, healthcare innovation does not get enough financing or the attention it requires. These findings from the

Department of Health also revealed that the national healthcare system tends to put the needs of healthcare innovation behind long-term public healthcare needs, such as treating infectious diseases like HIV/AIDS and tuberculosis. This emphasis on pressing healthcare issues causes the government to take funds away from initiatives aimed at healthcare innovation.

"I got to a point whereby I realised that the current status quo of investors not been keen on funding healthcare innovation projects from start-ups is deliberate. Venture Capitalists are mostly aligned with the giant healthcare innovation companies that have almost monopolised the industry. These companies are obviously interested in not having any competition, so their "investor friends" will keep the competition low for them. But that's just my take, I could be wrong. I stopped trying to become an innovator when I had this realisation" (MD5). There seems to be an issue of frustration when it comes to securing funds for innovation purposes. Medical doctors complain that its not easy for them to branch off into innovation and secure funds from investors. They do suspect that it may be foul play by investors, which may not be the case as well. But nonetheless, it's not easy to get a buy in from investors. Innovation will never take off without securing the necessary capital funds required to start the innovation process. The lack of access to funding for innovation start-ups leads to the industry being dominated by only a few innovation companies that have financial prowess, therefore limiting the variety of innovation available in the market.

The impact of the Covid-19 pandemic on healthcare innovation must not be taken lightly. The Covid-19 pandemic was not anticipated and planned for, it therefore resulted in financial turmoil for healthcare. It was an international crisis which had to be prioritised as it came with the cost of lives. All other health reform plans unfortunately had to take a backet including the enhancement of innovation in healthcare. A lot of funds that had been allocated to other aspects of the health system had to be redirected to cater for the pandemic. Other healthcare goals were therefore neglected, and the Department is still trying to recover. *"We have received reports from one of our committees that they have found that funding challenges have contributed to the non-implementation of innovation in healthcare and other health reforms as well. This is obviously a concern to us because we have a mandate to fulfil, which is to enhance the efficacy and efficiency of healthcare in South Africa. Not that our finances were on track prior to the 2020 hard lockdown, but the Covid-19 pandemic really distorted our alignment to the financial goals we had set for the public health sector. We received a lot of financial strain when we had to divert our financial resources to cater for an unexpected pandemic. Furthermore, the Financial Fiscal Committee has also reported an increased expenditure on settling medico-legal claims which contributes to the financial strain the department has been subjected too. It's not easy to recover but we are trying our best"* (DHO3).

4.3.5 Lack of innovation testing centres

Results from the study show that innovation testing centres promote innovation in healthcare. It was stated by DHO3 that "*Studying the barriers to innovation in healthcare is quite an interesting topic. We have not*

been oblivious to the need of innovation in healthcare. We are also trying to collate data to assist us in understanding where exactly the hinderances are. Our interaction with healthcare innovation start-ups has led us to understand that first-to-market beats having the best product all the time. Ideally healthcare products should undergo clinical trials before being launched into the market. Start-ups do not easily have access to clinical trials. It would help to have innovation testing centres specifically dedicated to healthcare innovation and conducting clinical trials. This could help effective innovations to also get a chance to be first to market". Medical doctors are also interested in joining the healthcare innovation market as innovators. Medical doctors are aware that they cannot work in silos, but they need to foster relationships that will enable them to be successful innovators through a central point:

"*Well, I think everyone knows how important relationships are in life. Who you know determines how far you get in life. We need a space whereby innovators can meet with investors and other collaboration partners. I had so many ideas gushing through my mind during the Covid-19 pandemic. Other medical doctors as well had brilliant innovation ideas during that time which never saw the light of day due to not having access to collaboration partners. There really should be a hub that promotes collaboration for healthcare innovation*" (MD4).

Medical doctors also revealed that they have been trained to base their decisions on evidence and empirical data. The acceptance of innovation in the medical fraternity is based on evidence of its effectiveness. Medical doctors want to be involved in the testing of healthcare innovation, which is currently not the case. MD1 stated that "*for us to be comfortable with adopting innovation, we want innovators to show us that their innovation is based on research and proven results. We want to know how their innovation was tested and proven to be efficient. Innovators seldomly invite us to testing laboratories to demonstrate the effectiveness of their innovation to us. It is concerning how we barely get to witness the testing of healthcare innovation*.''

Findings from the Department of Health also greatly reveal that the development and application of innovative healthcare technology and solutions in South Africa is hampered by the absence of innovation testing facilities. The findings reveal that there is a dire lack of innovation testing centres for healthcare innovations in South Africa. "*There aren't many tech hubs specifically created for healthcare innovation in South Africa. These tech hubs should exist, and they should bring together communities of researchers, innovators, medical professionals, and investors. If there was a central point where all key stakeholders of healthcare innovation met, the rate of healthcare innovation would be much higher in South Africa*" (DHO3). The qualitative research findings show that innovation testing centres or tech hubs would promote collaboration among the various key stakeholders of healthcare innovation. Without specialised testing facilities, innovators have trouble getting the resources and facilities they need to assess and improve their healthcare innovations. Researchers, startups, and smaller businesses then become disproportionately impacted by the lack of resources and infrastructure to carry out independent testing.

The lack of healthcare innovation testing centres is usually discussed at medical conferences that are attended by medical professionals. When innovators present the innovations at conferences, they are usually questioned about the effectiveness and testing methods used to determine the effectiveness of their innovations. It becomes apparent that start-ups struggle with access to innovation testing labs which den's them the opportunity to test their innovation for effectiveness.

MD2 stated that "*a trend that I've observed when attending medical conferences is that some innovators cannot offer doctors concrete evidence on the benefits of their innovation simply because their innovations haven't gone through rigorous testing. As a medical doctor, I simply lose interest in innovations that haven't been proven to be effective. It is unfortunate that innovators don't know where to find fully kitted testing laboratories*."

"*We have partnered with the Department of Science and Innovation to encourage the use of innovation in dealing with the quadruple burden of disease in South Africa. The Department of Science and Innovation aims to do this by supporting research and development through the R&D ecosystem, that being the government, industry, academia, and the society. The efforts of the Department of Science and Innovation have not gained traction in this regard as their spending on R&D is still relatively low*" (DOH 2). This statement shows that government departments recognise the importance of innovation in addressing social problems in South Africa. A flaw that was observed from this statement is that the Department of Science and Innovation has a general approach to promoting innovation in society and not an industry-specific approach because if it was industry specific, there would be a focus on building healthcare innovation testing labs specifically.

4.4 Conclusion/Summary

The frustration among the participants was sensed when the interviews were conducted. The medical doctors and the Department of Health officials alike had a lot to say regarding the factors that influence innovation in healthcare. The findings reveal that medical doctors have a great appetite for becoming healthcare innovators. This mainly stems from the frustrations they encounter from the healthcare systems as it is currently coupled with their understand of the importance of empathy in healthcare innovation. Empathy is one of the critical factors that influence innovation in healthcare. Medical doctors are worried that innovators do not see the importance of patients in the innovation process. Patients are the ultimate end-users or beneficiaries of healthcare innovation, and they know best what they need. Medical doctors are also cognisant of how healthcare professionals are not consulted as much as they should be during healthcare innovation process. When medical doctors become exposed to healthcare innovation that does not assist them to perform their duties effectively, it becomes apparent to them that there was minimal empathy during the design process. Officials from the Department of Health are also aware that there is minimal empathy in healthcare innovation

design. They state that this is mainly caused by innovation star-up companies focusing on cost minimisation when designing and not empathy.

The regulatory environment is perceived to be extremely opposed to healthcare innovation. The devastating impacts of the regulatory environment being a barrier to innovation is that an increasing number of innovators are refraining from healthcare innovation. It is a bit if a quagmire for the Department of Health because their mandate is to improve healthcare delivery and one of their aims is to improve healthcare delivery through innovation. The research participants also revealed that having a high level of regulatory scrutiny is necessary for healthcare innovation, however, it should be done in such a way that does not hinder innovation in healthcare.

An interesting finding from the interviews is that a lack of staff training hinders innovation in healthcare. Medical doctors become frustrated when they do not get training to use innovative healthcare device. Lack of training on how to use new healthcare devices has a negative impact on the adoption of that innovation in healthcare. The training of staff has become extremely challenging because of existing staff shortages and funding constraints. Healthcare workers in remote or rural locations end up having limited access to training programs due to a lack of training facilities or geographic constraints.

The lack of funding as an obstacle of healthcare innovation, is a finding that was expected. The Department of Health cannot easily fund innovation initiatives because of budgetary constraints. Medical doctors cannot procure the innovative products they need either because of budgetary constraints. The ever-increasing medico-legal claims increase the financial constraints that hinder innovation in healthcare. There is an existence of innovative medical equipment in the market. Unfortunately, the shortage of funding prevents the use of such equipment in the public healthcare system in South Africa. South Africa is plagued by a plethora of healthcare issues whilst only having a finite amount of funds at its disposal. The major challenge is that the limited funds be equally distributed to the several programmes aimed at improving the quality of life in South Africa. This then results in there being only a few funds left for healthcare innovation initiatives.

5 CHAPTER 5 – DISCUSSION OF RESULTS

5.1 Introduction

The genesis of this study was to find the factors that influence innovation in public healthcare. From the qualitative results, it is quite evident that there is an alignment between existing literature and the findings of this study. The findings of this study that were conducted through interviews, not only tie up with existing literature, but they are also supported by raw data which was obtained from various organizations and available on the public domain.

The two groups of research participants that were interviewed did not have the same understanding of what innovation in healthcare is. It was clear that each group understood innovation to be related to their line of work. Medical doctors view innovation as an improvement in their medical procedures while the Department of Health officials view innovation as an improvement of public policy and technology related to healthcare. Existing literature that was reviewed also reveals that there are various definitions of innovation. Sener et al. (2017) state that innovation is a multifaceted and complex phenomenon which cannot have one definition. Furthermore, literature states that though people tend to use the terms innovation and invention interchangeably, there is a clear distinction between the two terms (Sener et al., 2017).

5.2 Design Empathy

The importance of empathy in healthcare innovation design was revealed by the interviewed participants. The current lack of empathy in healthcare design contributes to some of the innovation failures that have been experienced by the healthcare sector. A specialist medical doctor recalled that "*In the past, healthcare was more provider-centric than patient-centric, with medical professionals driving innovation and decision-making rather than patients. This has caused a gap to arise between the needs and preferences of patients and the priorities of healthcare providers. It is therefore necessary to comprehend the various viewpoints and experiences of both the medical professionals and the patients in order to design empathetically. A lack of diversity and inclusivity in healthcare innovation initiatives has lead to solutions that fall short of fully meeting the requirements of the end-users of healthcare innovation*" (MD2). The importance of empathy in innovation is also reinforced by literature. Postma et al (2012) observed that products and services developed without the end-user in mind typically don't work because they don't meet the end-user's actual demands. Williams & Brown (2014) similarly stated that empathetic design coupled with rapid prototyping lead to effective product and service development.

The Department of Health acknowledges that healthcare systems are by nature complex because there are several parties involved, complicated procedures, and different degrees of access to care. "*As the Department of Health, we are aware that the healthcare system is multi-faceted in nature. The key participants that are*

involved in healthcare each come with their own complexities and objectives. Innovation in healthcare is not the priority that participants have. We all have different objectives as healthcare participants, and nobody has figured out how to synergise our objectives to enhance healthcare delivery" (DHO2). Furthermore, it was expressed by (DHO1) that "*We are starting to learn about the importance of empathic design in healthcare, though the concept is still new to us.*" It therefore becomes difficult for designers to prioritise empathy in the face of conflicting expectations and limitations. It is further noted that the research participants are aware of the concept of empathetic design and its importance. However, this is a new concept to them, and they are still learning about the role of empathy in healthcare design. Existing literature also ties up to this finding by showing that there are discussions on the meaning of empathy in healthcare design, however, they have been limited (McDonagh, 2010).

5.3 Regulatory Environment

Literature shows that the regulatory environment is deemed to influence innovation negatively in healthcare due to the stringent regulatory processes that innovators get subjected to (Akenroye, 2012). This perspective is backed up by the findings of this study. Department of Health officials stated that as much as they support the high level of regulatory scrutiny in the innovation process, there has to be a balance between meeting regulatory requirements while also supporting innovation. "*Healthcare is a very specialised and sensitive sector. It is very important that this industry is regulated for the safety and benefit of all who participate in it. I just think that the regulatory framework needs to be re-evaluated because currently, it seems to be defeating its own purpose*" (DHO2). Another official from the Department of Health also seconded this opinion by stating that "*The regulatory environment that governs healthcare in South Africa is kind of dysfunctional. As much as I fully understand why it exists and concur with its aims, I just think the implementation of healthcare regulations is completely wrong. It actually does more harm than good to healthcare innovation*" (DHO3). A medical doctor opposed the perspective of the Department of Health by sharing that "*Hats off to the healthcare regulatory system for not covering services provided by people who are not registered healthcare practitioners. A lot of medical clinics that are being operated by people who are not healthcare professionals have emerged. This is a health hazard for unsuspecting patients. It helps that patients have to pay for the expensive services out of pockets, which discourages some pages from seeking these services*" (MD2).

Furthermore, there is alignment between the Department of Health and existing literature in the view that the South African Products Regulatory Authority does not support innovative endeavours. Literature states that the lengthy approval process for innovative pharmaceuticals and medical devices results in a product registration backlog and ultimately slows down the acceptance of innovation in healthcare (Ravigopal, 2019). Medical doctors share the same sentiments by stating that the South African Products Regulatory Authority is a significant stakeholder in the health system. However, there is no alignment between the goals of the major stakeholders that make up the health system. Medical doctors stated that they feel that there is no sense

of urgency of accelerating the implementation of innovation displayed by the South African Products Regulatory Authority.

Data obtained from the World International Property Organisation, which shows the total number of patent applications filed for in 2022 across various countries of the world. The findings shown in Figure 7 reveal that the appetite for filing for patents is incredibly lower in South Africa compared to other countries. This ties up to the stance presented by the Department of Health that the regulatory environment in South Africa tends to discourage innovation in South Africa due to its flaws.

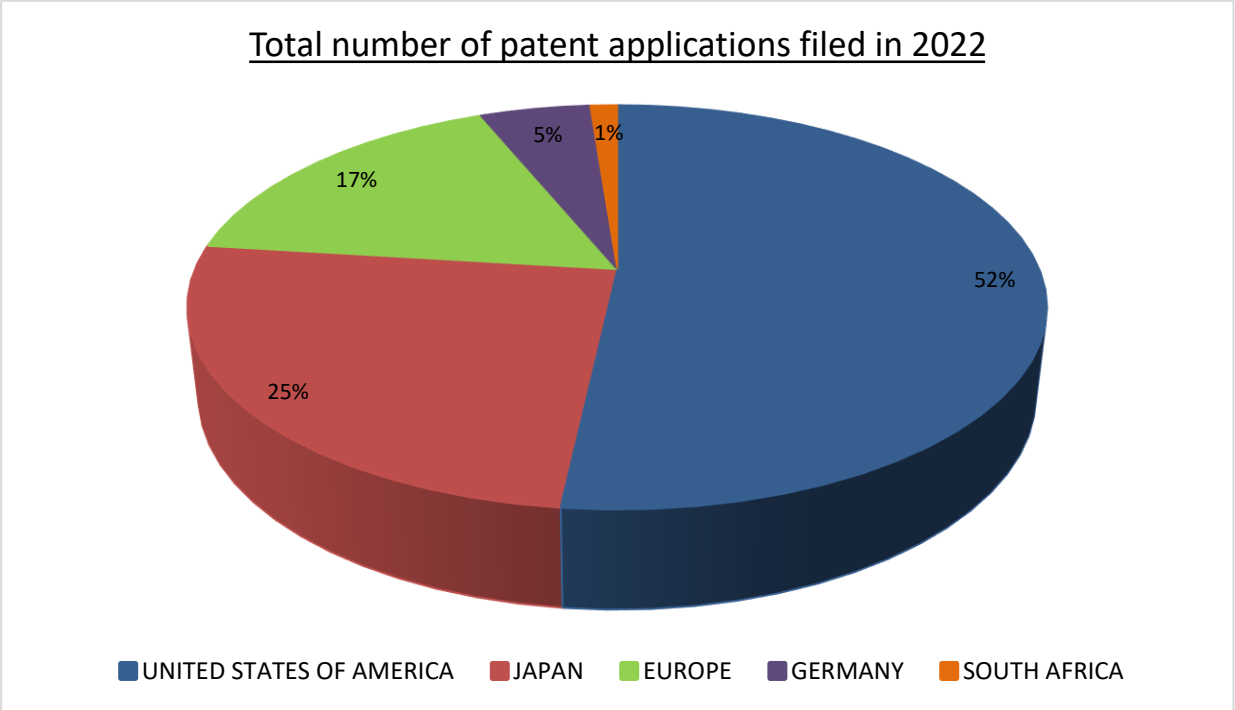

Figure 7: Total number of patents applied for in various countries in the year 2022 (World International Property Organisation, 2023)

A contradiction to the notion of the regulatory environment negatively influencing innovation was brought about by a medical doctor "*The regulatory environment works in favour of life insurance companies. This works in favour of healthcare innovation because I sincerely believe that life insurance companies are going to bring about innovation revolution in healthcare. With the NHI implementation being imminent, life insurance companies as a cohort have the potential to challenge and possibly overthrow the NHI by offering better healthcare delivery through innovation.*" (MD3). Their view was that life insurance firms as a group have the ability to oppose and even overturn the NHI by providing better healthcare through innovation because the regulatory landscape benefits life insurance providers.

Another contradiction appears when medical doctors view the process of obtaining a research ethics clearance as a hinderance to innovation while literature praises the beneficial impact of the Health Professions Council of South Africa on healthcare innovation through its Research Ethics Committees (Schneider, 2001).

Literature further states that the Research Ethics Committees provide direction and assistance to innovators who wish to pursue innovative methods of patient treatment (Townsend & Scott, 2019).

5.4 Lack of Skills

Furusa and Coleman (2018) state that healthcare innovation is not only costly to set up but also needs knowledge and experience to implement successfully. Innovation in healthcare is negatively impacted by the lack of skills among some healthcare professionals (Furusa & Coleman, 2018). Medical doctors share the same sentiments by stating that "*Nothing is more frustrating than not being able to effectively use the tools at your disposal. Trying to figure out how to use tools and equipment is a time-consuming exercise. That time could be spent on assisting patients. We need to be trained on how to use our working tools, it just makes sense"* (MD1).

Table 4 shows how there was no availability of continuous professional development training in the treatment of substance abuse in South Africa in 2014 compared to other countries which did have this type of training. This data shows that the lack of staff training is a factual and serious issue in South Africa.

Table 4: The availability of continuous professional development activities in the treatment of substance abuse in 2014 (World Health Organisation, 2017)

Location	Medical doctors	Psychologists	Nurses	Psychiatrists
Brazil	YES	YES	YES	YES
China	YES	YES	YES	YES
Germany	YES	YES	YES	YES
South africa	NO	NO	NO	NO
USA	YES	YES	YES	YES

Another medical doctor also aligns with literature's findings of there being a lack of staff training in healthcare, "*Did you know that there is certain healthcare technological equipment that need a certification in order to operate? When you don't have an operating license, you are no different to someone who has a car but does not have a driver's license. The car loses its utility because it becomes of no service to you. The same applies to technological equipment that we cannot operate due to not being trained for it, it loses its utility*" (MD4).

5.5 Lack of Funding

When it comes to the challenge of funding, findings of literature and the results of the interview are synchronised. Funding is one of the biggest challenges that the Department of Health faces when it comes to

fulfilling their mandate. "*The lack of funding for healthcare innovation significantly contributes to innovation not being implemented in South Africa's public healthcare system*" (DHO2).

Medical doctors had expressed their concerns regarding how difficult it is for them to procure medical equipment. "*Besides the supply chain management process being too cumbersome, it is difficult to find funds to purchase the required tools for working*" (MD3). Data from the World Health Organisation shown in Table 5 further confirms that there is a minimal rate of medical device procurement in South Africa as it shows that in the years 2010, 2013 and 2021 there were no medical devices procured at a national level in South Africa.

Table 5: The procurement of medical devices at national level in South Africa (World Health Organisation, 2023)

Year	Were medical devices procured at a national level?
2021	No
2013	No
2010	No

The continuous rise of medico legal expenditure on an annual basis has become an issue that is not easy to control. Officials from the Department of Health have admitted that it is such a difficult predicament to get around because it can only be addressed through reducing medical negligence or malpractice incidents which is complex altogether. One participant from the Department of Health stated that "*The issue is far bigger than what we see. Though we can measure the numerical increase of medicolegal costs on a yearly basis, those results are distorted because there is always a backlog of claims that do not get attended to at any given year*" (DHO3).

Data from the South African National Department of Health shown in Figure 8 demonstrates the increase in medico legal expenditure in public healthcare in South Africa. Figure 8 shows a 100% increase in public healthcare medico legal expenditure between the 2021/2022 financial year and the 2022/2023 financial year.

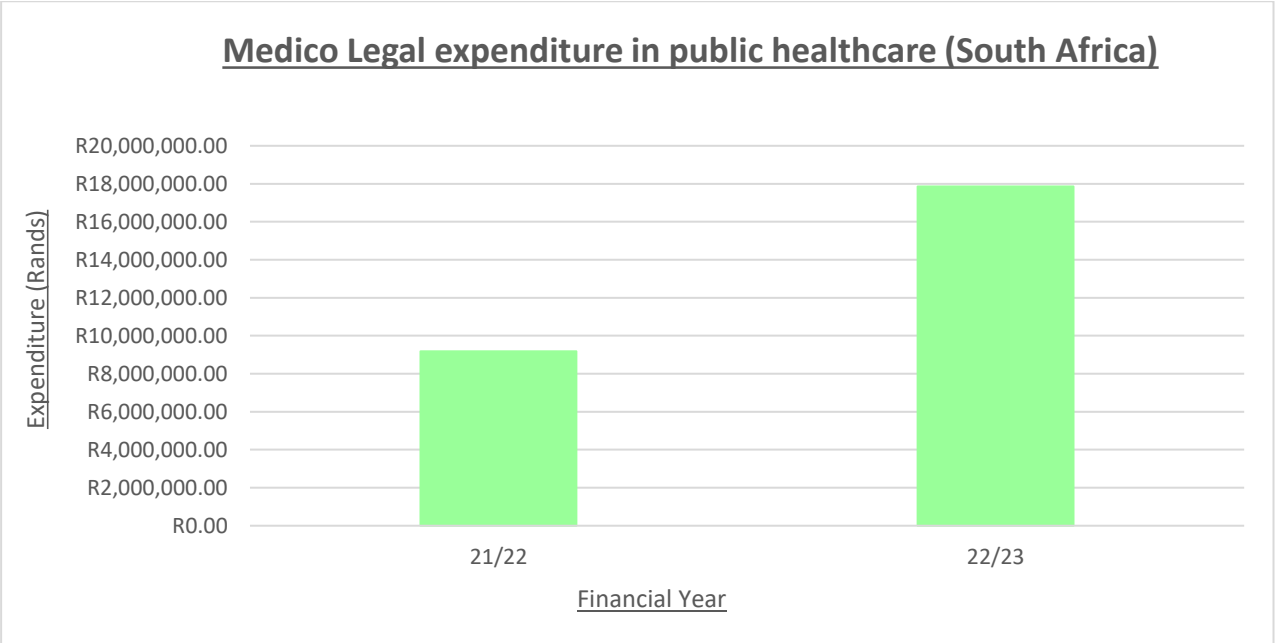

Figure 8: Expenditure on medicolegal claims by the National Department of Health between the 21/22 and the 22/23 financial years (South African National Department of Health Annual Report 2022/2023).

Medical doctors have also noticed and have been frightened by this pattern of continuously increasing medical claims. "*There has just been a sudden surge of medical claims against doctors in public healthcare. One fears taking decisions now because you just never know if your decisions will result in a medical case against you. The rise in medical claims obviously has negative impacts on healthcare budgets and the implementation of innovation in healthcare*" (MD5).

The exodus of medical doctors due to medico legal claims is also a testament to the rise of medico legal claims in healthcare sector. "*I've contemplated emigrating to the United Kingdom like some of the colleagues I used to work with so many times before. The only reason why I'm still here is because of my family. The number of malpractice claims against doctors is unbelievable. I don't think that patients understand that doctors don't have control over the death of a patients, or complications after surgery.*" (MD1).

It's interesting how the research participants did not delve deep into the different sources of funding for public healthcare in South Africa and what percentage of the healthcare budget is contributed by each source. The research participants did not mention much about the grant funding that gets received by public healthcare. Silence on this topic could probably allude to there being minimal financial donations received by South Africa for public healthcare. Literature does suggest that compared to other countries, South Africa receives a small amount of financial assistance for healthcare. Data from the World Health Organisation shows that most external funding for innovation in healthcare gets directed to other countries instead of South Africa. This data is represented graphically in Figure 9.

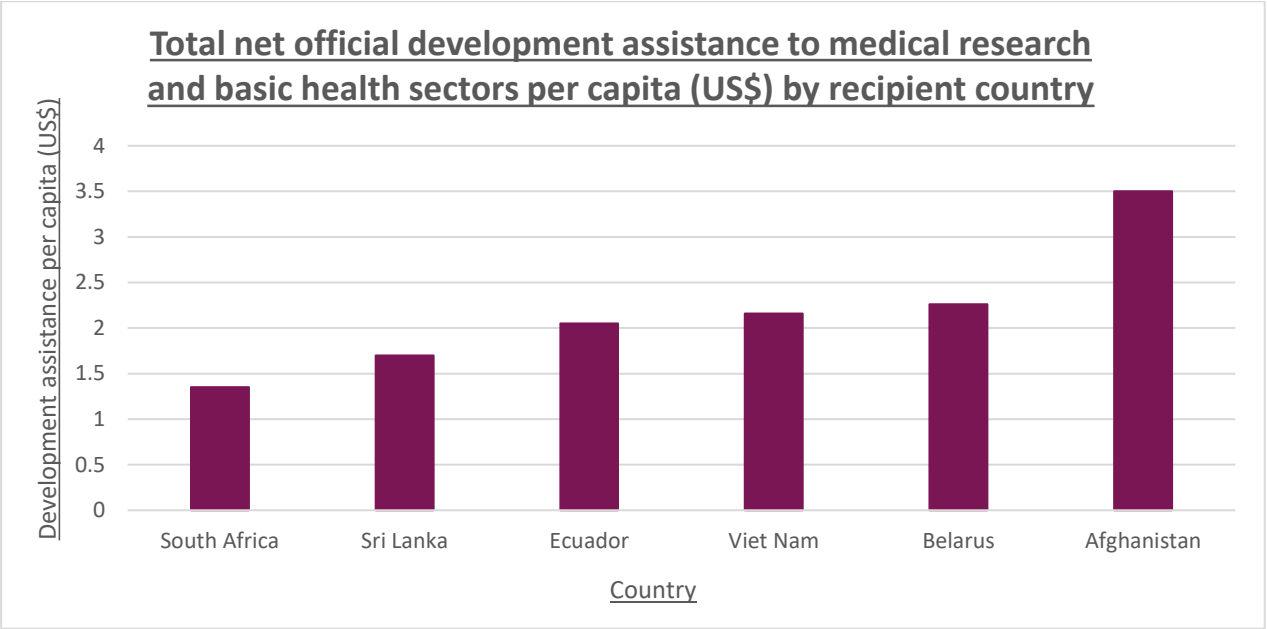

Figure 9: Total official development assistance flowing to developing countries for medical research and basic health sectors (World Health Organisation, 2023)

5.6 Innovation Testing Centres

From existing literature, it was observed that there were not many studies that have examined the existence of an environment for testing innovation prototypes in healthcare. However, literature shows that the South African government has established a Health Innovation Hub which is designed to assist the growth of healthcare innovation (Lucas et al., 2022). Findings from the interviews conducted also display a lack of healthcare innovation testing hubs in South Africa. There is consensus that this is a deficiency that requires urgent attention to increase the level of successfully implemented innovation in public healthcare. "*Well, I think everyone knows how important relationships are in life. Who you know determines how far you get in life. We need a space whereby innovators can meet with investors and other collaboration partners. I had so many ideas gushing through my mind during the Covid-19 pandemic. Other medical doctors as well had brilliant innovation ideas during that time which never saw the light of day due to not having access to collaboration partners. There really should be a hub that promotes collaboration for healthcare innovation*" (MD4).

Literature also reveals that to build sustainable health care systems importing technological equipment alone is insufficient, even though expanding instant access to medical treatment and current health technologies is crucial (Chaturvedi, Hanlin, Mugwagwa, Smith & Wield, 2007). Countries also need to establish the laboratory facilities necessary to enable them to develop their own innovations and technologies that are suited to their local needs (Chaturvedi et al., 2007). DHO4 sympathised with this belief by stating that "*Through our partnership with the Department of Science and Innovation, we are still in the planning process of building government-owned innovation facilities to support the development of healthcare innovation and improve healthcare delivery through science, technology and innovation*."

Furthermore, the Department of Health has held plenty workshops whereby start-ups have expressed the need for innovation testing centres. "*Innovation companies have repeatedly raised the concern of them not having access to innovation testing labs. Innovation cannot be tested for its effectiveness in the absence of such labs. As the government, we really need to look into providing such centres if we want to see the rate of evidence-based innovation rise in healthcare*" (DHO2). This statement is paralleled by literature findings which state that effective innovation centres are creating by establishing them close to learning institutions so that they may encourage the collaboration of ideas across otherwise disparate stakeholder groups (Rodrigues et al., 2022).

It is further stated by Rodrigues et al (2022) that fostering the development of innovation ecosystems in public healthcare settings can be achieved through establishing an atmosphere that is conducive to innovation, which includes favourable regulations, financing sources, and networking opportunities, this can promote entrepreneurship and teamwork as well as make it easier to put research into reality.

Data from the South African Department of Science and Innovation supports the notion of there being a lack of tech hubs in South Africa. Figure 10 shows South Africa to have the lowest tech hubs amongst other African countries in the year 2021.

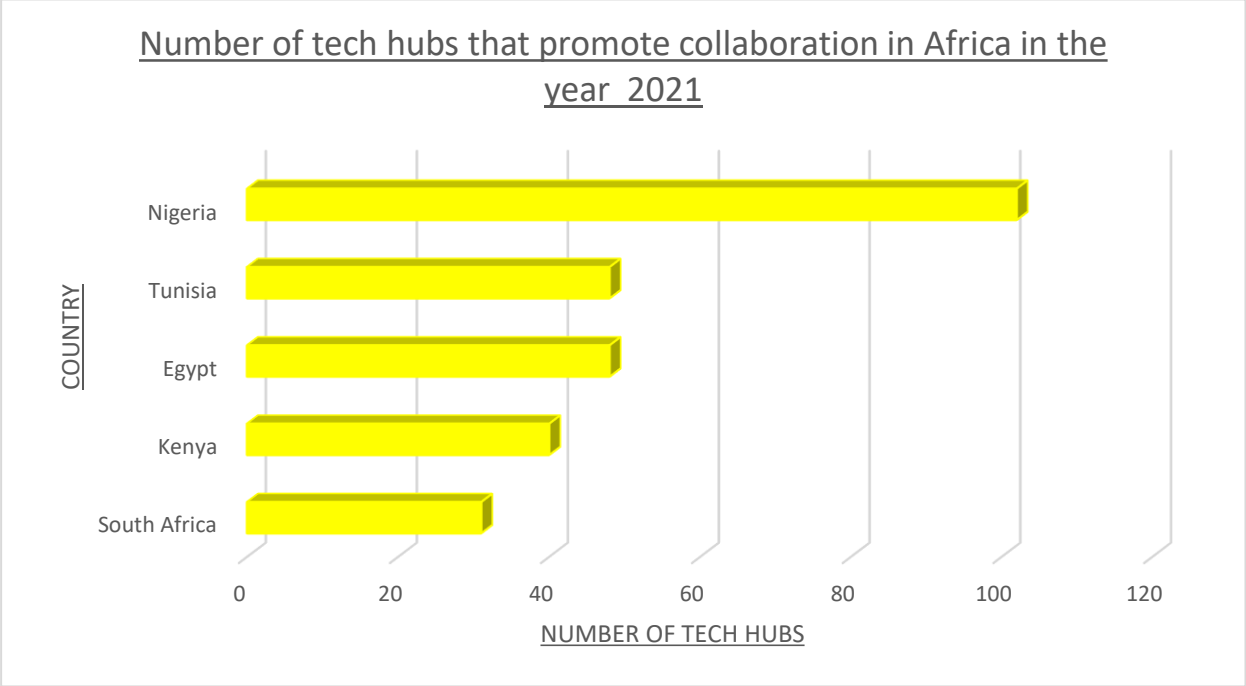

Figure 10: The number of tech hubs that promote collaboration in Africa (South African Department of Science and Technology, 2021)

Medical doctors also confirmed that the adoption of healthcare innovation in public healthcare settings is significantly slowed by the absence of suitable testing centres. This results in patients not benefiting from innovative technology and therapies since it is a struggle to test, validate, and integrate healthcare innovation into clinical practice. "*There should be established and fully equipped innovation testing centres within public*

healthcare facilities that are supported and funded by the government. Through such facilities innovator would be able test and validate their ideas so they get easily adopted by clinicians for both doctors and patients to benefit from" (MD1). Another medical doctor stated that "Healthcare workers would be able to acquire the abilities and information required to take part in innovation testing activities with the support of training programs and healthcare innovation centres. If we had tis type of support, a lot of healthcare workers would be encouraged to partake in the innovation process. Furthermore, we really need to be trained in technology evaluation, appropriate research methodologies for innovation, and regulatory compliance" (MD4).

It is well understood that in South Africa, public healthcare facilities often struggle with a lack of resources, such as money, supplies, and qualified staff. DHO5 stated that "*Unlike the private healthcare sector, we don't have the luxury of unlimited funds. We also have a severe shortage of qualified medical doctors which puts a lot of pressure on the public healthcare system*." MD4 suggested that "*We suffer from a lack of resources, mostly funding, staff, and working equipment. Healthcare innovation should be put at the top of the national healthcare agenda which could guarantee that funds are distributed properly to encourage innovation and accelerate the adoption and implementation of innovation in healthcare provision*." A great amount of funding is needed to establish and run innovation testing labs, which can be difficult for the government to provide in the face of conflicting healthcare objectives. "*The only way to overcome the funding hurdle is for stakeholders to work together to also address South Africa's lack of funding for healthcare innovation. Stakeholders should unite and contribute towards increasing public funding for research & development and attracting investment from the private sector*" (DHO3).

Literature suggests that only a small number of developing countries are equipped with the essential skills and resources to conduct scientific research, produce pharmaceuticals, or develop medical equipment. Despite this research and development projects in healthcare are gaining traction in South Africa, and there is a foundation from which to grow (Chaturvedi et al., 2007). Furthermore, (ibid) note that the adoption of innovation in healthcare heavily relies on the validity and safety of the innovation. DHO1 reconciled with these literature findings by stating that "*Research and development is one of the dimensions of health innovation systems. We are still trying to grow and advance healthcare research and development in South Africa. There is still a lot of work to be done in order to be on par with other countries research and development standards*."

MD2 stated that "*a trend that I've observed when attending medical conferences is that some innovators cannot offer doctors concrete evidence on the benefits of their innovation simply because their innovations haven't gone through rigorous testing.*" This statement shows that to assess the safety and effectiveness of new treatments and innovations, clinical trials are an essential part of healthcare innovation. Innovations that are not properly tested run the risk of not living up to quality and safety standards which may endanger the

health and safety of patients. Without access to tech hubs to design and test prototypes, it is challenging to obtain this evidence and therefore adopt and implement innovation in public healthcare.

It seems like hospital management is not open to exploring new strategies that can increase the uptake of innovation in healthcare. "*Management tends to be stiff and not open to trying strategies that are outside of the norm. Times are changing and our appetite should also be open to change. Surely the procurement strategies that were used a decade ago should not be used any longer because the procurement environment has changed a lot. In this technological age, it can't be an expectation to justify why doctors needs new diagnostic equipment when we've been conducting some diagnoses manually and literally through the book. It doesn't make sense to me that we have to justify why we need to move to technological ways of practicing medicine when we are in the fourth industrial revolution*" (MD5). This opinion is solidified by literature as Sharma et al (2014) state that hospital administration sets the tone for creating an innovative culture in healthcare institutions. It is imperative for leaders to give priority to innovation, convey its significance, and promote experimentation and risk-taking among employees by providing a helpful atmosphere where ideas are appreciated, acknowledged, and rewarded (ibid). Hospital management is also responsible for overseeing the process of implementing innovation within healthcare organisations (Mandisa et al., 2021).
Adoption of innovations is not possible without effective change management techniques, including as performance monitoring, stakeholder involvement, and strategic planning (ibid). Hospital administrators also need to support innovation projects, address resistance to change, and make sure that they are in line with company aims and goals (Mandisa et al., 2021).

The lack of funding in healthcare seems to be a persistent theme throughout this study. A medical doctor confirmed that there are not enough funds in the hospital to enable them to explore and benchmark against how other countries healthcare delivery systems. "*Benchmarking is such an important exercise. I learnt this during my stint with the private sector. We would travel internationally to study the technological advancements that are being used in other countries hospitals. We would know how outdated our innovations were and derive strategies on implementing new healthcare technologies so that we wouldn't be too far behind the international healthcare standards. Even in terms of education and knowledge, we still travelled abroad to acquire knowledge because medical knowledge and practices are constantly changing and updated continuous knowledge is required. It's difficult for us to have this approach to learning in public healthcare because there's not enough money for such endeavours.*" (MD3). Furthermore, literature shows that it is the role of management to enable such endeavours. Hospital management should make it easier for innovation to be incorporated into routine operations by encouraging a culture of ongoing learning and improvement through providing the necessary means and resources (Mandisa et al., 2021). This promotes long-lasting change and advancement in the provision of healthcare (ibid).

An additional finding of this study is that there appears to be a strong resistance to the NHI with medical doctors threatening to leave the country once it becomes implemented. "*Once the NHI comes into effect I will*

pack my bags and leave this country. South Africa is a capitalist country which is meant to be a free market. The implementation of the NHI will basically be the government overtaking the health sector, leaving little room for medical professionals to participate in the market at their individual capacities" (MD2). Doctors are very explicit about their disapproval of the NHI as they feel that their involvement on the drafting of the bill was marginal. "*I don't support the NHI. I don't want to be part of it. None of my friends who are doctors support it either. Once the NHI is implemented, I know that conditions for both doctors and patients in healthcare will be much worse because I don't think it will be managed effectively. Four of my colleagues are currently in the process of emigrating to New Zealand. As medical doctors, we were not adequately consulted when the NHI bill was drafted, and we do not think it will be implementable*" (MD1).

5.7 Summary

Clinical trials and testing are an important part of the healthcare innovation process. Testing facilities are not easily available to innovation start-up companies. Establishing innovation testing facilities with a focus on healthcare innovation and clinical trial execution would is necessary. This may grant successful healthcare innovations an opportunity be the first to market. Physicians also disclosed that they have received training in making decisions based on empirical data and evidence. Evidence of innovation's efficacy serves as the foundation for its adoption within the medical community. The lack of healthcare innovation testing centres facilities significantly reduces the prospects of some innovations being successfully implemented in healthcare.

6 CHAPTER 6 – CONCLUSIONS

The main aim of the research was to determine the factors that affect the successful implementation of innovation in public healthcare in South Africa. Viewpoints of medical doctors and officials from the Department of Health were sought to answer this question. The findings of the study revealed that there are various factors that affect the successful implementation of innovation in public healthcare in South Africa. The main factors that affect the successful implementation of innovation in public healthcare were found to be a lack of funding, a lack of design empathy, regulatory environment issues, a lack of staff training in healthcare and the lack of healthcare innovation testing centres. To a certain degree, these factors are interlinked and addressing one of them requires another one to be addressed first. Addressing these factors is not a simple process because they require the unique involvement of the various stakeholders that influence innovation in healthcare. It is therefore concluded that the successful implementation of innovation in healthcare requires more than just the active participation of the public health sector and innovators. It will require a strategic alliance between all affiliated stakeholders. It is imperative that no stakeholder is left behind in this process as the involvement of every stakeholder is critical in ensuring that innovation in public healthcare is implemented successfully.

The research sub-questions that were analysed are as follows:
i) What is innovation in public healthcare in South Africa?
ii) How is the successful implementation of innovation in public health care measured in South Africa?

When assessing the aim of the first research sub-question, the responses that were obtained from the different research participants revealed that there is no consensus on the definition of innovation in public healthcare. The research findings revealed that each person affiliated with the healthcare sector has a definition of innovation in healthcare which is aligned to their line of work. It was also discovered in the literature review that there seems to be different meanings of innovation in healthcare among scholars. This research study highlighted that shortcoming, and it must be investigated by future researchers who conduct research on this topic. The lack of a uniform definition for healthcare innovation in public healthcare directly affects the second research sub-question. It makes it difficult to measure the level of successfully implemented innovation in healthcare without a consistence definition of innovation in public healthcare in South Africa. Research findings revealed that it's not easy to quantify something that is not clearly defined.

The three research objectives were defined as follows:

a) To assess the need for innovation in public healthcare in South Africa.
b) To identify the strategies in place for implementing innovation in public healthcare in South Africa.
c) To establish the level of successfully implemented innovation in public healthcare in South Africa.

The objectives of this research study have been fulfilled. Through existing literature and the findings of this study, it was revealed that in terms of the first research objective, there is a need for innovation in public healthcare in South Africa. The World Health Organisation's sustainable development goal for healthcare is to stop unnecessary suffering from diseases that can be prevented and early mortality by concentrating on key targets that improve the general health of a country's people (World Health Organisation, 2014). Existing literature reveals that the current state of public healthcare in South Africa is sub-standard. When compared to other middle-income countries in the world using the World Health Organisation's healthcare indicators, South Africa has an inferior quality of public healthcare. These findings therefore show that there is a pressing need for innovation in healthcare to be able to achieve the sustainable development goals for healthcare by 2030. Over and above the WHO goals, concern was expressed by research participants that the current state of public healthcare in South Africa will not be able to accommodate the National Health Insurance which is planned to be implemented in 2026.

In terms of the first research objective, the strategies in place for implementing innovation in South Africa have been identified. The government has implemented strategies for the revival of clinical research (Flavia & M, 2012), and integrated digitisation into public healthcare (Lucas *et al.*, 2022) to increase innovation in healthcare. These strategies have proven to be ineffective because there are multiple factors that influence innovation in public healthcare which must be addressed holistically and not in silos. This research has also identified several strategies which could be adopted to increase the successful implementation of innovation in South African public healthcare. The collaboration of the South African public healthcare, policymakers and stakeholders can contribute to the development of a more proficient and adaptable workforce that is able to provide quality treatment to every patient through addressing the lack of staff training. An effective strategy for addressing the lack of staff training would include making more funding available for staff training initiatives and materials, which would guarantee that medical professionals have access to the education required to provide patients with superior care. Applying user-centred design techniques to comprehend the needs, preferences, and experiences of stakeholders in the healthcare industry, such as empathy mapping, user interviews, and co-design workshops is one of the tactics that can be used to address the lack of empathy design in healthcare innovation.

Policymakers, industry stakeholders, regulatory authorities, and other pertinent parties should work together to also address how South Africa's regulatory environment sometimes negatively affects healthcare innovation. Simplifying regulatory approval procedures, giving innovators clearer guidance and support, encouraging transparency and predictability in regulatory decision-making, and coordinating regulatory requirements with global standards and best practices are some possible strategies to promote a more favourable regulatory environment for healthcare innovation. Stakeholders must work together to also address South Africa's lack of funding for healthcare innovation. This could entail increasing public funding for research & development, strengthening research institutions, streamlining regulatory procedures, enhancing the business climate to draw in investment from the private sector, and encouraging cross-sector cooperation.

Finally, establishing and equipping innovation testing centres within public healthcare facilities which would require government funding and support. By making this investment, innovators would be able to guarantee that they have access to the facilities and resources they need to test and validate their innovation.

In terms of the third research objective, it has been difficult to establish the level of successfully implemented innovation in healthcare in the absence of a consistence definition of innovation in public healthcare in South Africa. Quantifying something that has not been defined is rather difficult. However, innovations that have transformed healthcare in South Africa have been noted in this research study. The implementation of life-saving pharmaceutical innovations such as antiretroviral therapy has increased the lifespan and quality of life of people living with HIV in South Africa. With the infection rate of HIV and ID being so high in South Africa, another extremely useful healthcare innovation that has been implemented successful in South Africa is the use of point of care HIV and AIDS testing equipment. POC tests for HIV have significantly increased access to testing and care for persons living with HIV in South Africa, especially in rural regions where laboratory facilities are sparse. Lastly, the adoption of telemedicine such as live interactive video conferencing between the doctor and the patient has enabled the conduction of clinical assessments despite there being a distance barrier between the doctor and the patient.

7. CHAPTER 7 - LIMITATIONS OF THE RESEARCH AND AREAS FOR FURTHER RESEARCH

The limitations of the study are acknowledged. The sample size of the participants was very limited though justifiable as adequate by existing literature which is elaborated in chapter three of this study. Due to the limited size of the research participants, generalisation of the research results cannot be guaranteed. A larger number of research participants could not be interviewed because of time constraints. Medical doctors are mostly pressed for time, and officials from the Department of Health are busy alike. Nevertheless, the results of this study are believed to provide a valuable overview of the factors that influence innovation in healthcare, from which meaningful conclusions can be drawn out from. Future researchers should look into increasing the sample size and obtaining a balanced representation of the different specialist medical doctors.

A significant limitation of the study is the dichotomous definition of innovation in healthcare that exists between the two research groups that were interviewed. The disparity of the definition of innovation in healthcare that exists between the two groups can be a basis for future research. Another limitation of the study is that the self-reported nature of interviews raises the prospects of information bias and possible social desirability bias. The results obtained from these interviews can be used as a basis for future researchers to build upon by increasing the number of research participants to be interviewed. Additionally, the research was confined to participants from Durban only, which are not representative of the South African population entirely. It is worth noting that that though the participants were all from Durban, a variety of differences and unique qualities existed among the individuals.

This research identified factors that influence innovation in a positive and negative manner so that these factors can be examined more thoroughly in further research studies. This study hasn't taken other thoughts into consideration such as what constitutes responsible or irresponsible innovation and if addressing or removing some of the factors which have been deemed to be barriers to innovation in healthcare will flood the medical industry untrustworthy or incompetent people. These are significant questions which must be addressed by further research. Future research should also include additional research methodologies such as interviewing combined focus groups consisting of patients and innovation companies as well.

Future researchers will also need to consider including the objective of identifying how to optimise the use of existing innovation in healthcare to the existing study. This could be accomplished by first investigating how different types of innovation can be used to satisfy different needs, rather than just creating new technological products for each need that arises.

It is important for future research studies to examine how organisational culture, workforce development, change management techniques, and leadership styles affect the adoption, diffusion, and sustainability of innovation in healthcare organisations. This is a very important perspective that was not thoroughly explored

by this research study. It is also crucial to think about the ethical, legal and social implications of innovations that become introduced to healthcare. Future research needs to cover moral, privacy and social issues that may arise due to the implementation of healthcare innovation and policies.

To increase the development of technological innovations in healthcare, collaboration between information technology, engineering, medicine, and social sciences must be explored. Future research should look into practical methods for breaking down disciplinary barriers, encouraging interdisciplinary cooperation, and utilising a range of specialties to promote innovation in healthcare delivery.

The findings of this study revealed that there has been a constant annual increase in expenditure on medico legal claims. Scholars interested in this research area need to investigate how the level of implementation in healthcare influences the number of medico legal claims in the public healthcare sector. The findings could potentially answer the question of how to reduce the cost of medico legal claims in healthcare. Scholars and other stakeholders can help advance healthcare innovation in South Africa and eventually improve health outcomes and quality of life for people by addressing these future research areas.

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UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Miss Mbali Rosemary Nkosi

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M211184

NAME: (Principal Investigator)	Miss Mbali Rosemary Nkosi
DEPARTMENT:	Engineering Faculty - School of Mechanical Industrial and Aeronautical Engineering
PROJECT TITLE:	Factors influencing innovation in public healthcare in South Africa: A critical analysis
DATE CONSIDERED:	26/11/2021
DECISION:	Approved unconditionally
CONDITIONS:	This approval applies only to the study sites listed in Annex 1 attached. Further sites may be added on presentation of evidence of management approval to the HREC (Medical)
NOTE:	If contact information regarding student study participants is required, please contact the Registrar's office - <Nicoleen.Potfieter@wits.ac.za>
SUPERVISOR:	Prof R. Siriram
APPROVED BY:	CB Penny Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	01/06/2022

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions.Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. I **agree to submit a yearly progress report.** The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **November** and will therefore be due in the month of **November** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature _____ Date _____

Annex 1

Protocol No. M21/11/84 **Miss Mbali Rosemary Nkosi**

Study sites approved under this Clearance Certificate

Study site	Date of HREC (Med) Approval
Addington Hospital	01/06/2022
eThekwini Health District Offices	01/06/2022

Dr CB Penny
Chair: HREC (Medical)
University of the Witwatersrand, Johannesburg

Date: 01/06/2022

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES