Strengthening the value chain of medical devices: a conceptual framework

by
Anne Mary Margaret Turner

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Supervisor: Prof Sara Grobbelaar
Co-supervisors: Prof Martin Nieuwoudt; Dr. Faatiema Salie

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DECLARATION

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ABSTRACT

The medical device value chain (MDVC) describes every value-adding activity (VA) in *Idea generation*, *Research & Development*, *Production/ Manufacturing*, *Market*, *Distribution & Use*, *Waste Management*, and those that occur *Systemically*. The medical device industry is highly complex and comprises multidisciplinary stakeholders, typically from Academia, Industry, Healthcare or Government. Much literature examines parts of the MDVC or variations thereof. However, a full MDVC map that facilitates a holistic approach to bottleneck alleviation has yet to exist. Additionally, incorporating multiple perspectives is valuable, given the various roles that add value along the chain.

This research project addresses the need for a holistic MDVC map by implementing a Design Science Research (DSR) approach to develop a conceptual framework. The MDVC framework, created in this study, structures how insights can be generated from value chain analysis, fishbone analysis, functional analysis and qualitative analysis to support identifying and alleviating MDVC bottlenecks. By mapping every VA, bottlenecks can be located, targeted and alleviated.

The research design implemented is divided into two phases and five components. Phase one is theoretical and incorporates two rigour cycles to inform the first design cycle. A preliminary review, two systematic literature reviews and one conceptual literature review identify the necessary MDVC categories, VAs, bottlenecks, and alleviations used to inform the conceptual framework. The existing frameworks for strengthening MDVCs (or variations thereof) are identified and support the development of domain concepts to which fishbone analysis could contribute. Thereby, an initial framework is developed based on the existing knowledge base.

Phase two is evaluative and incorporates three components to refine the MDVC framework and ensure the practical value of the artefact. The MDVC framework is evaluated using two relevance cycles according to the DSR approach. The first relevance cycle validates the MDVC developed through obtaining feedback from an MDVC stakeholder. The second relevance cycle evaluates the efficacy, quality, and generalisability of the initial MDVC framework through expert reviews. The expert reviews consist of semi-structured interviews and surveys with 17 South African stakeholders representative of the multidisciplinary expertise found in the medical devices industry. The expert reviews confirm the quality and efficacy of the MDVC framework and highlight findings such as the need for a structured process for identifying and alleviating bottlenecks. The results are translated into conceptual and structural improvements during the second design cycle to develop suggestions for a refined MDVC framework.

Bottlenecks in the Western Cape's MDVC are identified systematically as a result. This involved value chain-, fishbone-, functional- and qualitative analysis. Alleviations are also suggested as a result of the value chain- and the qualitative analysis. The findings thus contribute to strengthening the Western Cape's MDVC as bottlenecks are identified across the chain, and alleviations are suggested. This study adds to the foundation of MDVC research. However, future iterations of the MDVC framework and a more vast interviewee pool are necessary to translate these findings into a more meaningful impact. Study limitations and recommendations are discussed last.

OPSOMMING

Die mediese toestelwaardeketting (MDVC) beskryf elke aktiwiteit war waarde gee aan Ideegenerering, Navorsing en Ontwikkeling, Produksie/ Vervaardiging, Mark, Verspreiding en Gebruik, Afvalbestuur, en dié wat Sistemies plaasvind. Die mediese toestelbedryf is baie kompleks en bestaan uit multidissiplinêre belanghebbendes, tipies van die akademie, nywerheid, gesondheidsorg of die regering. Baie literatuur ondersoek dele van die MDVC of variasies daarvan. 'n Volledige MDVC-kaart wat 'n holistiese benadering tot bottelnekverligting fasiliteer, bestaan egter nog nie. Daarbenewens is die inkorporering van veelvuldige perspektiewe waardevol, gegewe die verskillende rolle wat waarde toevoeg langs die ketting.

Hierdie navorsingsprojek spreek die behoefte aan 'n holistiese MDVC-kaart aan deur 'n Design Science Research (DSR)-benadering te implementeer om 'n konseptuele raamwerk te ontwikkel. Die MDVC-raamwerk, wat in hierdie studie geskep is, struktureer hoe insigte gegenereer kan word vanaf waardekettinganalise, visgraatanalise, funksionele analise en kwalitatiewe analise om die identifisering en verligting van MDVC-bottelnekke te ondersteun. Deur elke waardetoevoegende aktiwiteit te karteer, kan probleme geidentifiseer, geteiken en verlig word.

Die navorsingsontwerp wat geïmplementeer is, word in twee fases en vyf komponente verdeel. Fase een is teoreties en sluit twee streng siklusse in om die eerste ontwerpsiklus in te lig. 'n Voorlopige oorsig, twee sistematiese literatuuroorsigte en een konseptuele literatuuroorsig identifiseer die nodige MDVC-kategorieë, waardetoevoegingsaktiwiteite, knelpunte en verligtings wat gebruik word om die konseptuele raamwerk in te lig. Die bestaande raamwerke vir die versterking van MDVC's (of variasies daarvan) word geïdentifiseer en ondersteun die ontwikkeling van domeinkonsepte waartoe visgraat analise kan bydra. Daardeur word 'n aanvanklike raamwerk ontwikkel wat gebaseer is op die bestaande kennisbasis

Fase twee is evaluerend en inkorporeer drie komponente om die MDVC-raamwerk te verfyn en die praktiese waarde van die artefak te verseker. Die MDVC-raamwerk word geëvalueer deur gebruik te maak van twee relevansie siklusse volgens die DSR-benadering. Die eerste relevansie siklus bekragtig die MDVC wat ontwikkel is deur terugvoer van 'n MDVC-belanghebbende te verkry. Die tweede relevansie siklus evalueer die doeltreffendheid, kwaliteit en veralgemeenbaarheid van die aanvanklike MDVC-raamwerk deur kundige resensies. Die deskundige resensies bestaan uit semi-gestruktureerde onderhoude en opnames met sewentien Suid-Afrikaanse belanghebbendes wat verteenwoordigend is van die multidissiplinêre kundigheid wat in die mediese toestelbedryf gevind word. Die deskundige resensies bevestig die kwaliteit en doeltreffendheid van die MDVC-raamwerk en beklemtoon bevindinge soos die behoefte aan 'n gestruktureerde proses om knelpunte te identifiseer en te verlig. Die resultate word in konseptuele en strukturele verbeterings gedurende die tweede ontwerpsiklus vertaal om voorstelle vir 'n verfynde MDVC-raamwerk te ontwikkel.

Probleme in die Wes-Kaap se MDVC word as gevolg daarvan sistematies geïdentifiseer. Dit het waardeketting-, visgraat-, funksionele en kwalitatiewe analise. Verligtings word ook voorgestel as gevolg van die waardeketting- en die kwalitatiewe analise. Die bevindinge dra dus by tot die versterking van die Wes-Kaap se MDVC aangesien probleme met die ketting geïdentifiseer word, en oplosings word voorgestel. Hierdie studie dra by tot die grondslag van MDVC-navorsing. Toekomstige herhalings van die MDVC-raamwerk en 'n groter ondervrapoel is egter nodig om hierdie bevindinge in 'n meer betekenisvolle impak te vertaal. Studiebeperkings en aanbevelings word laaste bespreek.

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LIST OF ACRONYMS AND ABBREVIATIONS

4IR	4th Industrial Revolution
AI	Artificial Intelligence
AIDS	Acquired Immunodeficiency Syndrome
AM	Additive Manufacturing
ANVISA	The Brazilian Health Regulatory Agency
AP	Attention Point
ARTG	Australian Register of Therapeutic Goods
BC	Boundary Condition
BEE	Black Economic Empowerment
CD	Collaboration Coordinator
CDRH	Centre for Devices and Radiological Health
CE mark	Certification indicating conformity with health, safety, and environmental protection standards for products sold within the European Economic Area
COVID-19	Coronavirus Disease (2019)
CSF	Critical Success Factor
CSIR	Council for Scientific and Industrial Research
DE	Desirable Effect
DR	Design Requirement
DRC	Directorate of Radiation Control
DSI	Department of Science and Innovation
DSR	Design Science Research
DSRM	Design Science Research Methodology
DST	Department of Science and Technology
DTIC	Department of Trade, Industry and Competition.
EC	Exclusion Criteria
EEA	European Economic Area
eHealth	Electronic Health
EMA	The European Medicines Agency
EMR	Electronic Medical Record
EU	European Union
EXD	Effort required – Difficulty
FDA	United States Food and Drug Administration
FR	Functional Requirement
GPO	Group Purchasing Organisation
HIC	Health Innovation Centre
HIV	Human Immunodeficiency Virus
HR	Human Resources
HSACF	Health Sector Anti-Corruption Forum
HTA	Health Technology Assessment
IC	Inclusion Criteria
ICT	Information and Communication Technology
IDC	Industrial Development Corporation of South Africa
IEC	International Electrotechnical Commission
IHSD	Integrated Health Service Delivery
IoT	Internet of Things
IP	Intellectual Property
IS	Information Systems
ISO	International Organisation for Standardisation
IT	Information Technology
IVD	In Vitro Diagnostics
IXD	Importance – Difficulty
IXE	Importance – Effort required
LKS	Localized Knowledge Spillover
LMIC	Low- and Middle-Income Countries
LMIS	Logistic Management Information Systems
MAH	Marketing Authorisation Holder

MCA	The Marketing Code Authority
MCC	Medicines Control Council
MD	Medical Device
MDC	Medical Device Company
MDM	Medical Device Manufacturer
MDMSA	Medical Device Manufacturers South Africa
MDSAP	Medical Device Single Audit Program
MDVC	Medical Device Value Chain
MEA	The Middle East and Africa
MECE	Mutually Exclusive and Collectively Exhaustive
MedTech	Medical Technology
MHM	Menstrual Hygiene Management
MNC	Multinational Corporations
NGO	Non-Government Organisations
NHI	National Health Insurance
NPO	Non-Profit Organisation
OEM	Original Equipment Manufacturer
OHSAS	Occupational Health and Safety Assessment Series
PBMA	Program Budgeting and Marginal Analysis
PMA	Premarket Approval
PMDA	Pharmaceuticals and Medical Devices Agency
PoC	Point of Care
PPE	Personal Protective Equipment
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
PRSA	Priority and Resource Allocation
QMS	Quality Management System
QS	Quality System
R-2-M	Route-to-Market
R&D	Research and Development
REC	Research and Ethics Committee
RO	Research Objective
RQ	Research Question
SA	South Africa
SA GMP	The South African Guide to Good Manufacturing Practice for Medicines
SAHPRA	South African Health Products Regulatory Authority
SALDA	South African Laboratory Diagnostics Association
SAMED	South African Medical Technology Industry Association
SAMRC	South African Medical Research Council
SAMTI	South African Medical Technology Industry
SBOM	Software Bill Of Materials
SC	Science Council
SMART	Specific, Measurable, Attainable, Relevant and Time-based
SME	Small-to-Medium Enterprise
STI	Science, Technology and Innovation
SWOT	Strengths, Weaknesses, Opportunities and Threats
TGA	The Therapeutic Goods Administration
TIA	Technology Innovation Agency
TIS	Technology Innovation System
TPD	The Medical Devices Bureau of the Therapeutic Directorate
TRL	Technology Readiness Level
TT	Technology Transfer
TTO	Technology Transfer Office
UCT	University of Cape Town
UE	Undesirable Effect
UN	United Nations
UR	User Requirement
US	United States
USA	United States of America
VA	Value-adding Activity
WC	Western Cape

WCMDC	Western Cape Medical Devices Cluster
WHO	World Health Organisation

Chapter 1 - Introduction

1.1 Overview of Chapter 1

Chapter 1 outlines the motivation for the research conducted in this report. Additionally, it provides a brief background to the topic and the research problem. The research objectives are defined, and the research design maps the route taken to ensure their achievement. Figure 1.1 below illustrates the structure of this chapter within phase 1 of the thesis outline.

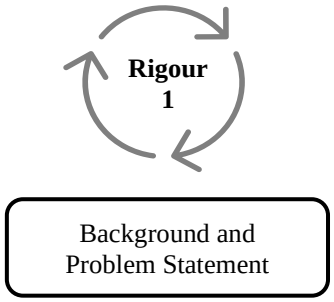
CHAPTER 1			
PHASE	**DSRM ACTIVITY**	**CYCLE & PROCESS FLOW**	**RESEARCH OBJECTIVE**
1: Theoretical Component	**1.** Problem identification & motivation		**RO1:** Determine research gap and define problem statement.

Figure 1.1: Research thesis outline - Chapter 1

1.2 Topic background

1.2.1 The medical device value chain

Medical devices are categorised separately from pharmaceuticals, but both fulfil similar roles in adding value to the healthcare industry. The widely accepted definition of a medical device given by the Global Harmonization Task Force (GHTF) is. as follows [1]:

'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for one or more of the specific medical purposes of:

- *diagnosis, prevention, monitoring, treatment, or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury,*
- *investigation, replacement, modification, or support of the anatomy or of a physiological process,*
- *supporting or sustaining a life,*
- *control of conception,*
- *disinfection of medical devices,*
- *providing information by means of in vitro examination of specimens derived from the human body;*

and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

The medical device value chain (MDVC) describes bringing a medical device from conception to distribution and beyond. The MDVC involves medical device idea generation (through identifying healthcare needs), design, production, marketing, distribution, the support provided to the end-user

and eventual disposal [2]. Value-adding activities (VAs) grouped into these categories (or variations thereof) are often fulfilled by several stakeholders involved in healthcare, academia, industry and government. Generally, healthcare providers play a role in the identification of needs. Universities and research facilities create and expand on scientific/ technological knowledge needed to address the identified needs. The industry translates this knowledge into products for the market. Lastly, the government is responsible for making policies, establishing infrastructure and creating incentives that support the value chain [3].

Value chain analysis can identify existing bottlenecks that hinder the success of a medical device sector. Following this, potential alleviations may be suggested. Value chain analysis has become increasingly paramount with the rise of globalisation. Kaplinsky and Morris (2001) identified three main reasons for this [2]. Firstly, systemic competitiveness is growing in importance now that labour is becoming more divided and production is dispersed globally. Secondly, successfully entering global markets requires production efficiency, and thirdly, it requires an understanding of the dynamics within the value chain. Value chain analysis is helpful as it can explain the growing disconnect between the spread of VAs and incomes. Moreover, a value chain perspective can be used to determine the relationships between particular firms, regions and countries within the global economy.

1.2.2 The South African medical devices industry

De Jager *et al.* (2017) identify the four major institutions involved in MDVCs in South Africa (SA): academia, healthcare, industry, and science and support [4]. Academia includes higher education institutions that perform research on the development of medical devices, e.g. universities, polytechnics, and colleges. Healthcare has bodies focused on patient care, e.g., clinics, hospitals, and medical facilities. Industry includes bodies involved in developing and commercialising medical devices, e.g., companies, firms, organisations, and individuals. Science and support consist of any organisation that contributes to or uses the scientific body of knowledge, e.g., science councils, other research facilities, non-government organisations (NGOs), non-profit organisations (NPOs) and designated special interest groups.

Various intermediaries in SA facilitate strategic networking between key MDVC stakeholders and provide support. The South African Medical Technology Industry Association (SAMED) has three organisations. It has SAMED, the portion of its membership who are predominantly multinational companies that import and distribute. Then there's Medical Device Manufacturers South Africa (MDMSA), which is dedicated to local manufacturers only. Lastly, the South African Laboratory Diagnostics Association (SALDA) look after the *in vitro*/ dry chemistry analysis segment of the market. The Western Cape Medical Devices Cluster (WCMDC) is a regional cluster focused on medical devices. SAMED is not representative of local manufacturers; however, MDMSA and the WCMDC are.

SA's medical device industry is diverse in that it comprises local manufacturers and multinational distributors. SA acts as the primary hub for the sub-Saharan African medical device industry. Moreover, SA is one of the largest markets in the Middle East and Africa (MEA) [5]. However, it makes up only 0.3% of the global market [6]. SA's large population (58.8m in 2019) [7] and advanced industrialised economy (for Africa) support its emerging medical device market.

SA's current dualist healthcare system comprising both private and public healthcare, faces many challenges and demonstrates substantial inequities. Specific MDVC stakeholders argue that National Health Insurance (NHI) is vital to advancing global and social solidarity in a patient-centric, equitable health system, thereby replacing the current system. SAMED suggests that moving from the current approach to NHI should be milestone based to lessen the risk of failed implementation and other

healthcare consequences [8]. However, NHI will unlikely be implemented soon and will thus not be discussed further in this thesis.

1.2.3 The regulatory environment

Given that medical devices directly impact human health, several standards and regulations are applicable [8]. The South African Health Products Regulatory Authority (SAHPRA) is an entity of the National Department of Health created by SA's Government that reports to the National Minster of Health through its board. SAHPRA is responsible for regulating health products in SA. Regulation involves monitoring, evaluating, investigating, inspecting and registering medical devices. The defining three pillars of SAHPRA are safety, efficacy and quality. SAHPRA replaced the Medicines Control Council (MCC) and the Directorate of Radiation Control (DRC) through its establishment in 2017 [9]. The manufacture, importation, exportation and distribution of medical devices and IVDs are subject to control in terms of the provisions of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended [10].

In SA, medical devices are categorised as class A, B, C, or D based on their level of risk. Class A devices are low risk, class B devices are low-moderate risk, class C devices are moderate-high risk, and class D devices are high risk. People who manufacture, import, distribute or export only class A medical devices do not require a SAHPRA establishment license. However, people who manufacture, import, distribute or export class B, C, or D devices require an establishment license [10]. The licence requires a list of the devices handled by the company, the appointment of an authorised representative, and a quality management system in place at the company (it does not have to be certified). A manufacturer's licence fee is R21,000, while the license fee for importers, exporters and distributors is R13,000 [11].

To comply with SAHPRA's establishment licenses, people must obtain market approval or registration for class C or D devices from at least one of the established regulatory authorities given in Table 1.1. Such approvals are referred to as the "originating approval/s" by SAHPRA. Class B, C, or D medical devices require a Certificate of Free Sale from the manufacturing country. This certificate shows that the medical devices are legally sold or distributed in the open market and are approved by the regulatory authorities in the country of origin [10]. Such processes add to the already high price and lengthy timeline of successfully commercialising a medical device in SA.

Table 1.1: Established medical device regulatory authorities/ licences that can be used in South Africa [10]

LOCATION	MEDICAL DEVICE REGULATORY AUTHORITY/LICENSE
United States of America (USA)	• Food and Drug Authority's (FDA's) Centre for Devices and Radiological Health (CDRH) Premarket Approval (PMA) or Premarket Notification 510(k) clearance.
Canada	• Medical Device License to market.
Japan	• Marketing Authorisation Holder (MAH) license.
Australia	• The Therapeutic Goods Administration (TGA), i.e., inclusion in the Australian Register of Therapeutic Goods (ARTG).
Brazil	• ANVISA (National Health Surveillance Agency) approval and registration.
European Union (EU)	• CE certificate to show conformity to all obligations for medical devices as required by the Medical Devices Directives.

The complexity of the legislation, regulations and standards surrounding medical devices in SA is immense (see Table 1.1 and Table 1.2). The regulatory landscape requires much experience to navigate initially. Start-ups require time, capital, and access to guidance to ascertain that their product complies with the appropriate standards and regulations. Since SAHPRA implements a reliance regulatory model, companies must comply with internationally established regulatory requirements to be approved by SAHPRA.

Table 1.2: Standards and descriptions relevant to the South African medical device industry [6]

STANDARD	DESCRIPTION
ISO 13485: 2016 certification	• Latest standard from the International Organisation for Standardisation (ISO). It sets out quality management system requirements, rules and guidelines for any company that designs, manufactures, installs, distributes, or services medical devices.
ISO 11135: 2014	• Specifies requirements for the development, validation, and routine control of a sterilisation process for medical devices.
ISO 14000	• A family of standards related to environmental management to help organisations minimise how their operations negatively affect the environment, comply with applicable laws, regulations, and other environmentally oriented requirements, and continually improve these.
ISO/IEC (International Electrotechnical Commission) 17020: 2012	• Conformity assessment that specifies the requirements for the operation of various types of bodies performing inspection.
MDSAP	• Medical Device Single Audit Program (MDSAP) for medical device manufacturers in the following jurisdictions: USA, Australia, Canada, Japan & Brazil.
OHSAS 18001	• Occupational Health and Safety Assessment Series (OHSAS).
Title 21 CFR Part 807	• United States Food and Drug Administration (FDA) Medical Device Establishment Registration & Medical Device Listing.
ISO 9001	• Covers requirements for quality management systems but emphasises risk management, the work environment and medical device documentation and reporting.
ISO 14644-1	• Specifies the degree of air cleanliness in terms of concentration of airborne particles in cleanrooms and clean zones in a facility (ISO 1-9).
Quality System (QS) Regulation – 21 CFR Part 820	• FDA's QS requirements for facilities used for designing, purchasing, packaging, labelling, storing, installing, and servicing medical devices.

1.2.4 Existing information

Much information exists on identifying bottlenecks in the MDVC and strengthening the medical device sector in SA. Despite this, particular bottlenecks still need to be addressed, which suggests not a lack of solutions but rather a lack of action and successful implementation of existing alleviations. A Deloitte report came out in 2014 commissioned by the Department of Trade, Industry and Competition (DTIC). The report aimed to guide the development of a strategy for the medical devices sector of SA. It found that imports supplied 90% of the medical devices market. Additionally, challenges facing the South African medical devices sector were identified, and factors to promote the growth of the medical devices sector were given (See Table 1.3). This study is nine years old. Thus, the information in Table 1.3 is recognised as potentially out of date. However, certain challenges still need to be solved: corruption and the high cost of acquiring international regulation and standards. This shows how bottlenecks can remain unalleviated for a long time despite their identification. Additionally, some of the factors to promote growth are still applicable, such as, "use of procurement strategies such as designation to boost local industry."

Table 1.3: Challenges facing the South African medical devices sector and factors to promote the growth of the medical devices sector [12]

Challenges facing the South African medical devices sector	Factors to promote the growth of the medical devices sector
• Lack of government support. • Cost of acquiring international regulations and standards. • Lack of local regulations and standards. • Access to skilled staff. • Overall production costs. • Access to the global market.	• More effective state-business relations and communication. • Formalisation of processes of engagement between private and public entities. • Revive and enhance existing incentive schemes. • Human capital development.

Challenges facing the South African medical devices sector	Factors to promote the growth of the medical devices sector
• Access to project funding. • Labour unrest. • Access to scientific and communication technology. • Intellectual Property (IP) policy (including patent protection). • Corruption.	• Attaining and maintaining international standards and best practices. • Use of public procurement strategies such as designation to boost local industry. • Promoting an innovation-centric manufacturing culture. • Aligning local regulations with best practices. • IP rights protection (patent, copyright and trademark). • Increase the level of interest in translating scientific research into application. • Promotion of the South African market to international medical device companies.

Furthermore, The University of Cape Town (UCT) released a Route-to-Market (R-2-M) guide for inventors looking to commercialise medical device innovations in 2018 [11]. This guide discusses approaching medical device innovation, Technology Readiness Levels (TRLs), the role of the technology transfer office (TTO), research contracts and innovation. Moreover, Intellectual Property (IP) protection is discussed along with the regulation of medical devices, ethics, other permissions, seed- and innovation funding, and commercialisation from a UCT perspective. UCT's R-2-M guide for medical devices can be likened to Stanford's Biodesign Methodology, developed in 2001, which provides stakeholders with steps to produce healthcare innovations [13]. Figure 1.2 details the nine TRLs for medical devices. Figure 1.3 illustrates UCT's R-2-M.

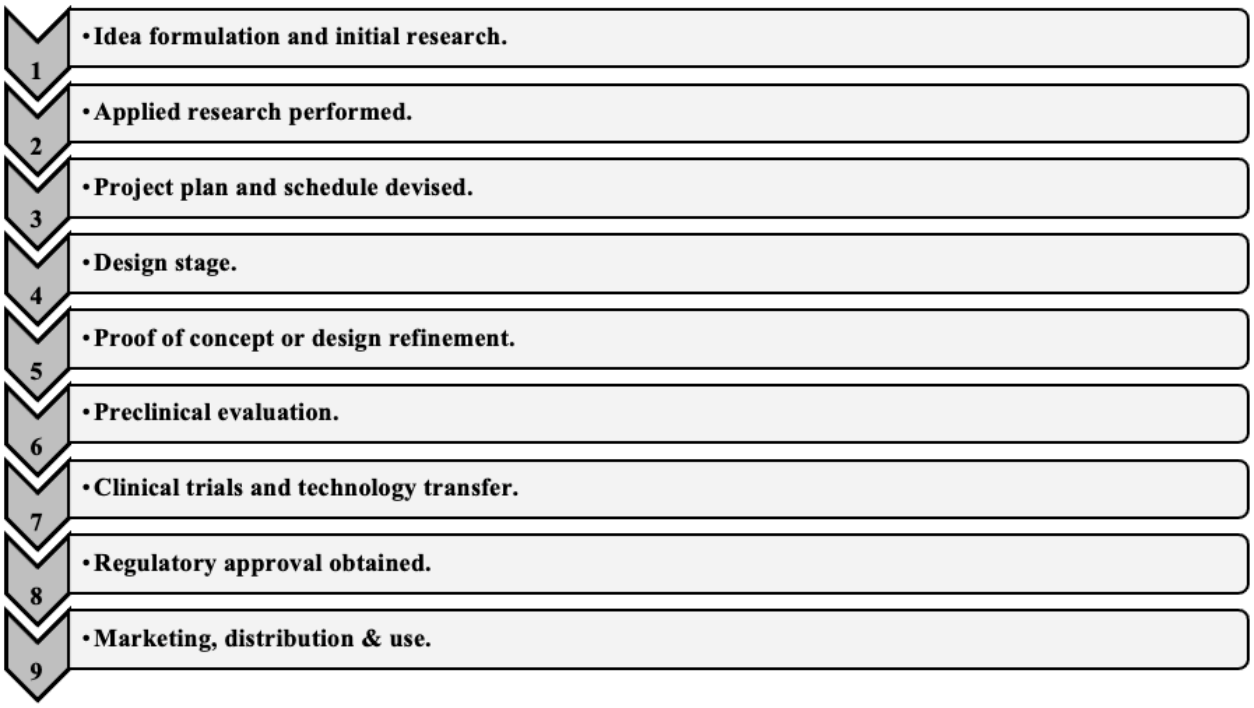


Figure 1.2: Technology readiness levels for medical devices (Adapted from [11], [14]–[16])

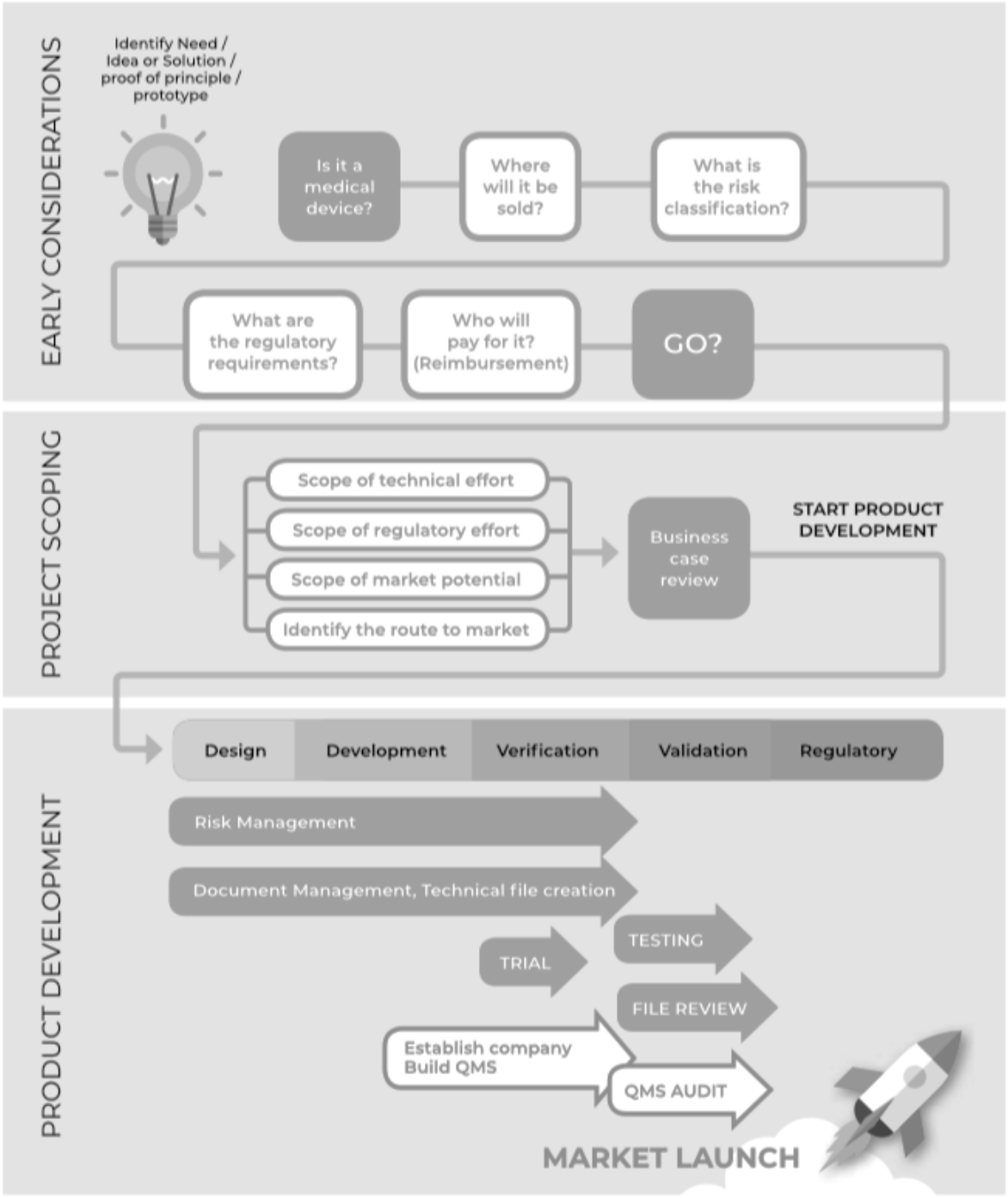


Figure 1.3: UCT's route to market for medical devices (Taken from [11])

Most recently, a series of medical device stakeholder forums were conducted between 2017 and 2022 in SA, spear-headed by the South African Medical Research Council (SAMRC). The outcome of these meetings was a landscaping analysis of the medical device sector published in 2022. This report is the most modern mapping of SA's medical device sector. It describes the medical device industry's size, characteristics, and dynamics. Moreover, it provides information on local capabilities, expertise and MDVC stakeholders. The VAs focused on included: product development, testing, manufacturing, market introduction and commercialisation. Additionally, MDVC gaps and barriers were identified [6]. One of the biggest bottlenecks in the MDVC identified was the absence of a working South African regulatory authority. Table 1.4 illustrates a Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis of SA's medical device industry conducted in the report.

Table 1.4: SWOT analysis for the South African medical devices industry according to prior reports [6]

STRENGTHS	WEAKNESSES
• Political stability in SA, solid and independent institutions, judiciary, and security services. • Limited threat of terrorism. • Industrialised economy & rich mineral resources. • Financial hub & stable banking sector. • Much of SA's public debt is denominated in local currency. • Observance of contracts and intellectual property rights. • Quality transport infrastructure. • Large population. • Low staff turnover in the medical device industry. • Strong private healthcare sector. • Steady demand for medical devices. • Licensing requirements promoting compliance and product safety. • Public funding of the sector. • Weak Rand, a driver for local development and manufacture. • Increased Government spending on equipment as part of the NHI. • Recent private equity investment in the sector. • Government support for exports and innovation in the Western Cape (WC). • Access to sub-Saharan African markets. • Established exports of hi-tech, high-value medical device products.	• High structural unemployment, poverty, and political disenfranchisement. • Corruption. • Economy over-dependent on primary commodities. • Currency volatility. • Labour market rigidities. • Very high crime rate. • Lengthy business registration, closing and opening turnarounds. • Poor healthcare infrastructure, particularly in rural areas. • Private healthcare sector is out of reach for most of the Black population. • Many rural facilities are under-used or idle due to poor organisation. • HIV/ AIDS overburdening the system. • Chronic shortage of medical personnel. • Purchasing procedures are complex and fragmented. • Small domestic market size, and only ~5% of devices used are manufactured locally. • Low levels of Research and Development (R&D). • Inconsistent quality of local manufacture. • Lack of device-level licensing/ registration. • Medical device research is underfunded. • Registration of products in overseas markets is expensive. • Medical aid schemes power over the pricing of medical devices. • Lack of stakeholder/ role-player alignment.
OPPORTUNITIES	**THREATS**
• Emerging party-political diversity. • Microeconomic reforms, including improved skills training, to alleviate poverty. • Emergence of the affluent Black middle class. • Private security firms filling gaps left by the police. • Inter-regional trade agreements facilitate trade flows and reduce costs. • Greater interregional freight connections envisaged. • Government health funding to increase in real terms. • Expansion of HIV treatment, reducing pressure on the public healthcare system. • National Health Insurance (NHI) scheme prompting investment in the public healthcare system. • Public-private partnership growth. • Establishment of the new medical device regulator (SAHPRA). • New regulations will establish an internationally aligned regulatory framework. • Aesthetic medical device market growth. • Alternative clinical therapies are presenting untapped sources of innovation. • Serving low-income, under-served populations who have difficulties accessing specialists.	• High levels of HIV/ AIDS impact economic growth. • Political/ policy uncertainty undermining investor confidence. • Cost of compliance to Black Economic Empowerment (BEE) requirements. • Land reform uncertainty. • Health policy affected by politics, alleged cronyism, and corruption. • NHI implementation depends on private practitioners contracting with the public sector uptake, which has been slow. • Increased imports, especially cheap imports of inferior quality. • Inefficient public procurement and payment. • Exchange rate volatility. • Skills loss due to emigration. • Cost of certification for local manufacturing and exporting. • Increasingly burdensome regulatory landscape increasing costs for local players.

1.3 Key problems in SA's MDVC

1.3.1 The impact of COVID-19 and SA's reliance on imports

The COVID-19 pandemic hit SA early in 2020 and shocked the healthcare sector. Moreover, it highlighted the central role that medical devices play in providing high-value healthcare. This shock was not limited to SA. Medical device sectors worldwide had to scramble to meet the inflated demand for Personal Protective Equipment (PPE) and ventilators, amongst other products. Furthermore, the COVID-19 pandemic revealed SA's dependence on imported medical devices and the lack of local medical device production [3]. Despite healthcare being a critical area for service delivery in SA, it has been estimated that 95% of the market value of medical devices is imported. These imports are predominantly from China [17]. Additionally, the pandemic resulted in the deferral of many medical procedures, restricting the medical device market growth in 2020 [18].

Creating a robust medical device sector is good for the economy as it would lessen SA's dependence on imports. Moreover, localising the manufacturing of medical devices could attract and keep expertise and skills within SA. Furthermore, strengthening global access to cost-effective, value-adding medical devices is vital. It encourages quick responses to emergencies such as the COVID-19 pandemic, improves healthcare quality and affordability and builds economies through job creation [19].

1.3.2 SAHPRA Backlog and corruption in SA

A study evaluated the challenges SAHPRA faces in assuming its new role. Additionally, it provided recommendations to address SA's issues of inadequate financial and human resources, stakeholder collaboration, paper-document-driven management systems, service delivery and regulatory review processes. SAHPRA has developed a significant backlog, resulting in extended timelines for product registration [20]. The regulatory authority in SA is viewed as a barrier rather than as a collaborator. This view may have changed since 2018.

In the same vein, well-established providers were blindsided by the corruption and fraud perpetrated through government tenders following the onset of the COVID-19 pandemic. President Cyril Ramaphosa launched the Health Sector Anti-Corruption Forum (HSACF) in 2019 in response to corruption [21]. There is a need for independent statutory bodies to implement and regulate standards in SA. Following the COVID-19 crisis, the South African government has clarified that they aim to localise medical device manufacturing.

1.3.3 Lack of medical device start-ups in SA

A study by Maharaj and Sunjka (2019) concluded that local medical device manufacturers face various challenges which largely contribute to the lack of medical device manufacturing start-ups in SA [22]. Such challenges include the high capital investment required, the prohibitive and unaligned regulatory framework, brand representation, end-users' reluctance to switch to smaller brands, and cash flow and liquidity problems. These challenges faced by South African medical device manufacturers serve as significant bottlenecks in South African MDVCs. Additionally, the study provided recommendations to alleviate these bottlenecks, such as their suggestion to realign South African medical device regulations with globally well-established regulations. Furthermore, a study by de Jager *et al*. (2017) highlighted that there need to be more translational collaborations among the four sectors of institutions involved in MDVCs, namely academia, healthcare, industry, and science and support. A lack of translational collaboration is a bottleneck in South African MDVCs.

Identifying MDVC bottlenecks and investigating existing solutions will allow for developing strategic recommendations. A framework can be developed for the Western Cape (WC). Grobbelaar *et al*. (2016) found that encouraging regional innovation should involve refocusing existing functions, resources and activities rather than recreating the system [23]. Moreover, inclusive innovation should be encouraged when looking to strengthen MDVCs in developing countries such as SA to include marginalised groups at each value chain level, thereby combatting existing inequalities.

1.4 Research gap

There is much literature regarding the MDVC and MDVC stakeholders in SA. Also, many alleviations to MDVC bottlenecks exist. However, there needs to be more action and implementation of alleviations in South African MDVCs. Contributing to this, the MDVC has not been entirely mapped, i.e., a complete list of all the value-adding activities (VAs) included in the MDVC has yet to be generated. Moreover, much of the literature focuses only on specific sections of the MDVC, i.e., on specific VAs.

Furthermore, terminology regarding the names/ roles of MDVC stakeholders is overlapping and often confusing. Therefore, the research gap this project will address is that there currently needs to be a systematic way for MDVC stakeholders to holistically map their MDVC and identify/ alleviate bottlenecks that cause undesirable effects (UEs) for them. UEs identified in SA include medical device shortages and a shortage of successful start-ups.

It would be beneficial to create an exhaustive list of VAs in the MDVC and identify the stakeholders that perform said activities in SA. A framework wherein stakeholders can map their exact position in local and global MDVCs could then be created. This framework could assist MDVC stakeholders in identifying their most pressing bottlenecks and where they occur (i.e., what VAs can be improved/ added/ eliminated and who is involved in their performance). Following this, alleviations can be suggested strategically. A complete map of the MDVC will allow MDVC stakeholders to see where they fit into local/ global value chains. This map will give them a holistic view of identifying bottlenecks that cause UEs. Moreover, it will enable them to identify the associated stakeholders to collaborate/ communicate with to alleviate the bottlenecks. Additionally, the implementation of alleviations can be executed with precision.

SAHPRA registers manufacturers, importers, exporters and distributors, and this data could be published to assist stakeholders in finding other compliant stakeholders to complete needed VAs. Moreover, it could group stakeholders based on location/ expertise to encourage local collaboration. Mapping the MDVC and including every VA will help facilitate future research regarding identifying bottlenecks and alleviations thereof in the MDVC. Although there are several papers focused on various steps/ VAs within the MDVC, none take a holistic approach to alleviate bottlenecks.

Therefore, this research project aims to develop a framework to assist stakeholders by streamlining the identification and alleviation of MDVC bottlenecks. Decision support tools can be incorporated to guide decisions focusing on interpretability.

1.5 Research question and objectives

1.5.1 Research questions

The main research question (MRQ) that this study will aim to answer is:

MRQ – What constitutes an artefact in conjunction with value chain analysis to strengthen a medical device sector?

Further sub-questions were formulated to address the MRQ:

RQ1 – To what extent has the MDVC been mapped?
RQ2 – How can an artefact be used to identify bottlenecks in the MDVC?
RQ3 – What are the MDVC bottlenecks, and what UEs do they exacerbate?
RQ4 – Are there existing alleviations of MDVC bottlenecks, and what desirable effects (DEs) would they encourage?
RQ5 – What are the most pressing bottlenecks in the Western Cape's MDVC, and what alleviations could be applied?

1.5.2 Research objectives

The research methodology for this study is split into two phases. The first phase represents the theoretical component, and the second represents the practical component. The first phase is divided into the first three Design Science Research Methodology (DSRM) activities and includes the first two rigour cycles and the first design cycle. This phase achieves research objectives 1-5 (see below) and is covered in Chapters 1-6. DSRM is explained in more detail in Chapter 3. The second phase is divided into the last three DSRM activities and includes the first two relevance cycles, the second and third design cycles, and the third rigour cycle. This phase is covered in Chapters 7 and 8. Figure 1.4 details the research design.

Specific research objectives (RO) addressed in each phase:

Phase 1:

- **RO1:** Determine the research gap and define the problem statement.
- **RO2:** Establish a research design that can address the research gap and problem.
- **RO3:** Establish a literature base that can be used to determine the objectives/ design requirements of an artefact (solution).
- **RO4:** Translate relevant concepts from literature into artefact design requirements.
- **RO5:** Develop the preliminary artefact.

Phase 2:

- **RO6:** Review the preliminary artefact with an appropriate expert and refine the artefact accordingly.
- **RO7:** Review evaluation methodologies.
- **RO8:** Evaluate the artefact using an appropriate methodology.
- **RO9:** Analyse and discuss results.
- **RO10:** Present final artefact design and conclusion.

1.6 Research design overview

PHASE	1: Theoretical Component			2: Practical Component		
DSRM ACTIVITY	1. Problem identification & motivation.	2. Define objectives of solution.	3. Design & development.	4. Demonstration.	5. Evaluation.	6. Communication.
CYCLE	Rigour 1	Rigour 2	Design 1	Relevance 1	Relevance 2	Design 3
PROCESS FLOW	Background and Problem Statement → Research Design	Literature Review: MDVC bottlenecks and alleviations → Literature Review: Frameworks	Preliminary Framework	Expert Review → Design 2 → Refined Framework	Semi-structured interviews & survey	Final Framework → Rigour 3 → Findings and Conclusion
RESEARCH OBJECTIVE	**RO1:** Determine research gap and define problem statement. **RO2:** Establish a research design that can address the research gap & problem.	**RO3:** Establish a literature base that can be used to determine the objectives/ design requirements of an artefact (solution).	**RO4:** Translate relevant concepts from literature into artefact design requirements. **RO5:** Develop preliminary artefact.	**RO6:** Review preliminary artefact with an appropriate expert and refine artefact accordingly. **RO7:** Review evaluation methodologies.	**RO8:** Evaluate artefact using an appropriate methodology. **RO9:** Analyse and discuss results.	**RO10:** Present final artefact design and conclusions.
CHAPTER	**CH1, 2 & 3**	**CH4 & 5**	**CH6**	**CH7**	**CH7**	**CH8**

Figure 1.4: Research design influenced by DSR cycles and DSRM activities

Figure 1.4 illustrates the research design overview that is guided by an established DSRM. The research methodology is split into two components, namely, the theoretical component and the practical component. Design Science Research (DSR) cycles are also incorporated. Additionally, the research objectives and corresponding chapters are noted. This research design is elaborated on in Chapter 3. Figure 3.7 serves as the final version and is explained in depth.

1.7 Research contributions

The framework is not specific to the Western Cape and can thus be used by other medical device sectors with similar economic environments. The research conducted during this study will contribute towards medical device sector development and value chain analysis literature.

1.8 Ethical considerations

The practical evaluation of the framework required ethical clearance from the Research Ethics Committee (REC) at Stellenbosch University. The semi-structured interviews conducted in this study involved gathering MDVC expert opinions. The researcher was well-informed regarding the physical and psychological risks or discomforts that participants could have experienced. Hence, safeguards were implemented to mitigate these risks effectively.

1.9 Research document outline

Table 1.5: Research document outline

CHAPTER	TITLE	RESEARCH OBJECTIVES	RESEARCH QUESTIONS ADDRESSED
1	**Introduction**	**RO1:** Determine research gap and define problem statement.	**RQ1** – To what extent has the MDVC been mapped? **RQ3** – What are the MDVC bottlenecks, and what UEs do they exacerbate?
2	**Value chain analysis**	**RO1:** Determine research gap and define problem statement.	**RQ1** – To what extent has the MDVC been mapped?
3	**Research design and methodology**	**RO2:** Establish a research design that can address the research gap & problem.	**RQ2** – How can an artefact be used to identify bottlenecks in the MDVC?
4	**Systematic literature review of the MDVC, its bottlenecks, existing tech-based alleviations and MDVC stakeholders**	**RO3:** Establish a literature base that can be used to determine the objectives/ design requirements of an artefact (solution).	**RQ1** – To what extent has the MDVC been mapped? **RQ3** – What are the MDVC bottlenecks, and what UEs do they exacerbate? **RQ4** – Are there existing alleviations of MDVC bottlenecks, and what DEs would they encourage?
5	**Systematic Literature Review of the MDVC and variations thereof**	**RO3:** Establish a literature base that can be used to determine the objectives/ design requirements of an artefact (solution).	**RQ1** – To what extent has the MDVC been mapped? **RQ3** – What are the MDVC bottlenecks, and what UEs do they exacerbate? **RQ4** – Are there existing alleviations of MDVC bottlenecks, and what DEs would they encourage?

CHAPTER	TITLE	RESEARCH OBJECTIVES	RESEARCH QUESTIONS ADDRESSED
6	**Framework design requirements**	**RO4:** Translate relevant concepts from literature into artefact design requirements. **RO5:** Develop preliminary artefact.	**RQ2** – How can an artefact be used to identify bottlenecks in the MDVC?
7	**Framework demonstration and evaluation**	**RO6:** Review preliminary artefact with an appropriate expert and refine artefact accordingly. **RO7:** Review evaluation methodologies. **RO8:** Evaluate the artefact using an appropriate methodology. **RO9:** Analyse and discuss results.	**RQ1** – To what extent has the MDVC been mapped? **RQ3** – What are the MDVC bottlenecks, and what UEs do they exacerbate? **RQ4** – Are there existing alleviations of MDVC bottlenecks, and what DEs would they encourage? **RQ5** – What are the most pressing bottlenecks in the Western Cape's MDVC, and what alleviations could be applied?
8	**Conclusions & recommendations**	**RO10:** Present final artefact design and conclusions.	**RQ3** – What are the MDVC bottlenecks, and what UEs do they exacerbate? **RQ4** – Are there existing alleviations of MDVC bottlenecks, and what DEs would they encourage? **RQ5** – What are the most pressing bottlenecks in the Western Cape's MDVC, and what alleviations could be applied?

1.10 Chapter 1 – Summary

Table 1.6 illustrates the RQs and ROs partially addressed in Chapter 1. RQ1 and RQ3 are partially answered through a preliminary literature review. RO1 is contributed to in that the research gap is introduced. There needs to be more literature that examines the MDVC as a whole. However, there is a large amount that examines parts of it. Thus, the extent to which the MDVC has been mapped needs to be determined. The problem statement has been defined as the absence of a full MDVC that can be used to identify and alleviate MDVC bottlenecks that cause UEs in medical device sectors such as the WC's. UEs in the WC identified include medical device shortages and a lack of start-ups. Bottlenecks contributing to these are detailed in the SWOT analysis in Table 1.4. Despite the challenges, there are existing alleviations that, if strategically implanted, could encourage DEs. The medical device industry is complicated and multidisciplinary stakeholders are involved, necessitating collaboration at multiple levels. To fully map the value chain of medical devices, multiple perspectives representative of the various stakeholders should be overlapped. The research design overview is given but not discussed. This will be done in Chapter 3.

Table 1.6: Research questions answered and research objectives addressed in Chapter 1

PHASE 1: THEORETICAL		
RESEARCH QUESTIONS	**CH1 CONTRIBUTIONS**	☑
RQ1: To what extent has the MDVC been mapped?	• A holistic MDVC map incorporating multiple stakeholder perspectives was not found in the preliminary literature search. • Various sections of the MDVC have been examined.	☑

RQ3: What are the MDVC bottlenecks, and what UEs do they exacerbate?	• Bottlenecks in SA's MDVC include corruption and an immature regulatory authority, amongst others, which exacerbate UEs such as a lack of start-ups and medical device shortages.	☑
RESEARCH OBJECTIVES	**CH1 CONTRIBUTIONS**	☑
RO1: Determine research gap and define problem statement.	• The extent to which the MDVC has been mapped is unclear. • A holistic way to identify and alleviate bottlenecks in the MDVC is needed.	☑

Chapter 2 - Value chain analysis

2.1 Overview of Chapter 2

Chapter 2 introduces value chain analysis as a theoretical lens/ perspective. Moreover, the objectives of value chain analysis are given. Lastly, the relevance of value chain analysis in the medical device sector is discussed. Figure 2.1 illustrates Chapter 2 within the research thesis outline.

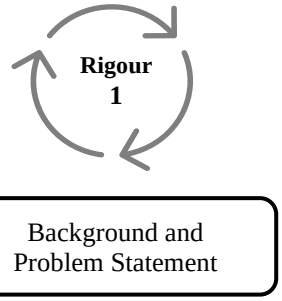
<table>
<tr><th colspan="4">CHAPTER 2</th></tr>
<tr><th>PHASE</th><th>DSRM ACTIVITY</th><th>CYCLE & PROCESS FLOW</th><th>RESEARCH OBJECTIVE</th></tr>
<tr><td>1: Theoretical Component</td><td>1. Problem identification & motivation.</td><td> 
</td><td>RO1: Determine research gap and define problem statement.</td></tr>
</table>

Figure 2.1: Research thesis outline - Chapter 2

2.2 Taking a value chain perspective

A *value chain* is a tool initially described by Porter in 1985 [24]. It disaggregates buyers, suppliers and firms into discrete interrelated activities that generate value. This tool is valuable as a competitive advantage can be linked to these specific activities. Moreover, they provide a framework for creating organisational boundaries. Figure 2.2 illustrates Porter's generic value chain.

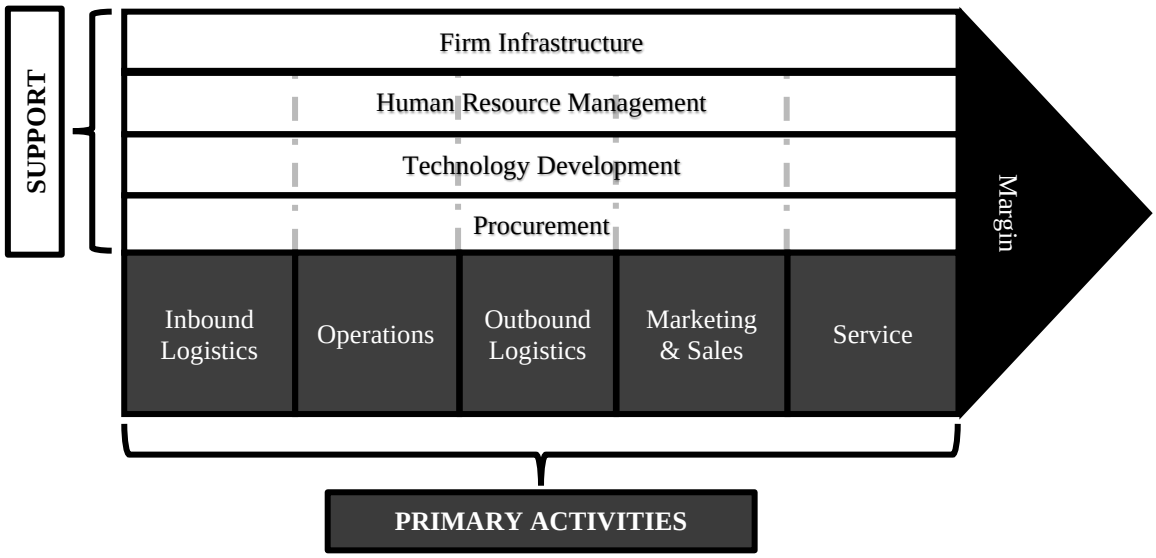


Figure 2.2: The generic value chain [24]

However, the idea of the value chain has been adapted to encompass value activities (VAs) across multiple collaborating firms in place of Porter's single-firm perspective. Modern value chain analysis involves mapping the flow of goods/ services up and down the chain and between different chains. Moreover, the value chain encompasses all the activities involved in bringing a product from

conception through production, distribution and disposal after use [2]. Value chain analysis can be used to identify bottlenecks within the medical device sector. Moreover, findings can guide the formation of strategic recommendations to alleviate the bottlenecks identified. Kaplinsky and Morris (2001) consider the value chain to take the general form depicted in Figure 2.3, wherein there are four links in a simple value chain, namely, (1) design and product development, (2) production, (3) marketing, and (4) consumption/ recycling. As represented by the double-sided arrows, intra-chain linkages have a two-way nature. Real-world value chains such as the MDVC are often much more complex than those described in Figure 2.2 and Figure 2.3 in that they will consist of more links. Moreover, the MDVC will differ depending on the medical device being produced.

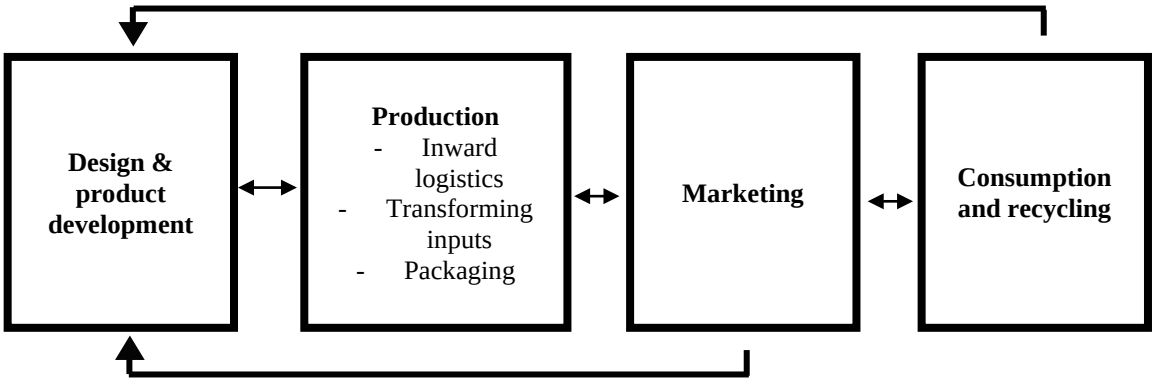


Figure 2.3: Four links in a simple value chain [2]

The concept of the value chain has overlapping interpretations in the literature. Porter (1985) identified activities that occur in the different links of the value chain (see Figure 2.2) [24]. Moreover, he referred to intra-link activities as the value chain. His described value system is essentially the value chain described in Figure 2.3 wherein inter-chain linkages (linkages between firms) are incorporated [2]. Similarly, Womack and Jones (1997) published an influential work on lean production wherein they refer to what is now generally considered the value chain as the 'value stream' [25]. Also, the concept of filière (French for 'thread') is comparable to that of the value chain concepts in Figure 2.2 and Figure 2.3 [26]. Gereffi (1994) introduced the concept of global commodity chains, which are much the same as value chains with a strong focus on power relations within the chain. He identifies buyer- and producer-driven commodity chains [28].

Three forms of value chain governance have been distinguished. Firstly, *legislative governance* describes the basic rules determining participation in the value chain (including meeting international standards). Next, *judicial governance* checks compliance with the aforementioned basic rules. Lastly, *executive governance* is a form of proactive governance that directly or indirectly helps value chain participants adhere to the defined rules of the value chain. All three forms of governance may be executed by parties internal or external to the chain [2].

As demonstrated in Figure 2.4, a value chain is different from a supply chain. The focus of supply chains is upstream, integrating supplier and producer processes, improving efficiency and reducing waste. Value chains focus downstream on generating value from the perspective of the customer. Business and research literature often need to clarify this distinction [29]. Production and exchange are highly complex when performed on a global scale. Hence, value chains differ within and between sectors, as do national and local contexts. Understanding the final market is crucial in value chain analysis. Value chain analysis begins with determining what point of entry to focus on [2].

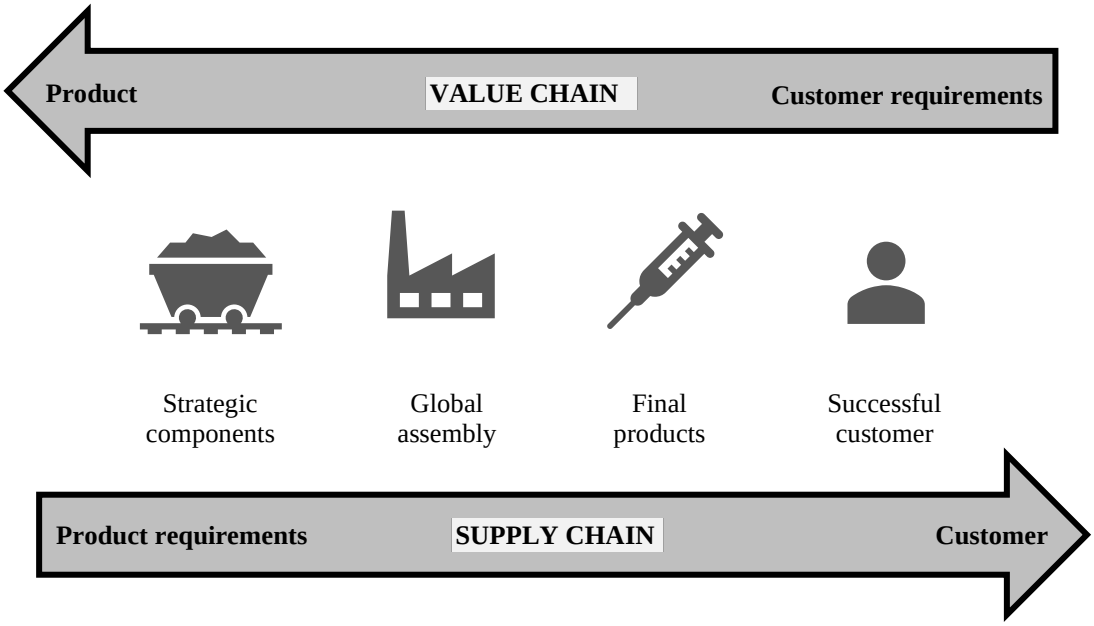


Figure 2.4: A comparison of a value chain versus a supply chain [29]

Table 2.1 describes the objectives of value chain analysis. Given that this research project aims to strengthen a regional medical devices sector, it will not involve conducting a value chain analysis of a single firm/ MDVC stakeholder. These objectives will be incorporated into the framework developed to assist MDVC stakeholders in mapping and improving their MDVC.

Table 2.1: Value chain analysis objectives [2]

OBJECTIVES	BRIEF DESCRIPTION	STEP PERFORMED IN PROJECT
1. Determine the point of entry.	• This will define which links and which activities to focus on within the MDVC. • Will be determined through systematic literature reviews supplemented by opinions from stakeholders (obtained via semi-structured interviews).	• The point of entry will include mapping the entirety of the MDVC from identifying a need through to device disposal.
2. Map the MDVC over the last 5 years (provides an adequate dynamic picture).	• This will involve the construction of a tree of input-output relationships that should include: - Gross output values. - Net output values (gross output – input cost). - The physical flow of commodities along the chain. - The flow of services, consultants, and skills along the chain. - Employment (characteristics). - Imports and exports (including regions involved). • Gathering information for this step may include obtaining primary sources.	• This step will not be performed due to time constraints. • Instead, semi-structured interviews with MDVC stakeholder will be performed to gather insight into the MDVC value-adding activities.
3. Determine product segments and critical success factors (CSFs) in final markets.	• This will require the mapping of market size and market growth. • The final market in the value chain must be decomposed into different market segments. • Gathering information for this step may include obtaining primary sources.	• CSFs will be determined through literature review (Chapters 4 and 5). • Market size and growth will be investigated through literature review (Chapters 4 and 5).

OBJECTIVES	BRIEF DESCRIPTION	STEP PERFORMED IN PROJECT
4. Determine how producers access final markets.	• This will involve determining whether the value chain is buyer-driven or producer-driven. • Key buyers must be identified. • The dynamics of the buying function must be determined. • Chart the CSFs which buyers exercise. • Identify buyers' strategic judgements about specific sources of supply. • Gathering information for this step may include obtaining primary sources.	• This step will not be performed due to time constraints. • Instead, semi-structured interviews with MDVC stakeholder will be performed to gather insight into the MDVC value-adding activities.
5. Benchmark production efficiency.	• This entails analysing the productive efficiency of different parties in the value chain. • Must distinguish between practices and performance when benchmarking. • Benchmarking may involve obtaining a mix of quantitative and qualitative data through firm visits. • Must determine a firm's relative production efficiency to one of the following: - The firm's historic performance. - The performance of firms doing very similar things. - The performance of firms within the same sector that don't produce the same product.	• This step will not be performed due to time constraints.
6. Identify the key governors in the chain: - **Legislative governors (who make the rules).** - **Executive governors (who implement the rules).** - **Judicial governors (who enforce the rules).** - **Also, identify rules/ standards of the chain.**	• This involves determining which firm/ stakeholder within the value chain has the most power. • Power can reflect the ability to control other firms/ stakeholders within the value chain or it may reflect the ability to act without adhering to the power of other firms/ stakeholders within the value chain.	• This step will be achieved through literature review and semi-structured interviews with MDVC stakeholders.
7. Upgrade the value chain where possible by: - **Improving the process.** - **Improving the product.** - **Altering functional positions in the value chain.** - **Moving firms out of the value chain into another value chain.**	• This will include determining agency (identifying parties responsible for upgrades). • Distinguish between factors that block upgrading activities and those that enable upgrading activities.	• This will involve semi-structured interviews.

OBJECTIVES	BRIEF DESCRIPTION	STEP PERFORMED IN PROJECT
8. Analyse the distribution of the MDVC.	• Determine the locational dimension of the value chain (global, national, and local). • How do small-to-medium enterprises (SMEs) fit into global value chains? • Determine decomposition of incomes in the value chain.	• This step will be achieved through literature review and semi-structured interviews with MDVC stakeholders.
9. Incorporate a knowledge focus into value chain analysis.	• Skilled and unskilled workers. • International mobility of skills and knowledge. • Use of information technology (IT) in value chains.	• The knowledge focus will be bottleneck identification and analysis.
10. Determine how SMEs fit into global value chains.	• Will involve primary research (semi-structured interviews with stakeholders).	• This will involve semi-structured interviews.

2.3 Chapter 2 – Summary

Table 2.2 illustrates the RQs and ROs partially addressed in Chapter 2. RQ1 is contributed to in that value chain analysis is discussed, and the methodology is laid out. It is necessary to fully understand value chain analysis to determine the extent the MDVC has been mapped. The history of value chain analysis is discussed along with similar versions found in the literature. Various steps that can be included in value chain analysis are outlined in Table 2.1. Only some of these steps will be performed in this study. What will be done wholly or to an extent are the following steps: (1) a point of entry will be determined, (3) CSFs will be determined, (6) key governors in the chain will be identified, (7) the value chain will be upgraded where possible, (8) the distribution of the MDVC will be analysed, (9) a knowledge focus will be incorporated into value chain analysis and (10) how SMEs fit into global value chains will be determined. The numbering corresponds to the numbering in Table 2.1. RO1 is partially addressed as the research gap is better defined by elaborating on value chain analysis.

Table 2.2: Research questions answered and research objectives addressed in Chapter 2

PHASE 1: THEORETICAL		
RESEARCH QUESTIONS	**CH2 CONTRIBUTIONS**	☑
RQ1: To what extent has the MDVC been mapped?	• To answer this, it is important to have a solid understanding of value chain analysis. Value chain analysis is discussed comprehensively in Chapter 2. • A holistic MDVC map incorporates multiple stakeholder perspectives. • There are a variety of ways to approach value chain analysis.	☑
RESEARCH OBJECTIVES	**CH2 CONTRIBUTIONS**	☑
RO1: Determine research gap and define problem statement.	• The extent to which the MDVC has been mapped is unclear. • Value chain analysis is discussed and elaborated on in order to guide its incorporation in the research design.	☑

Chapter 3 - Research design and methodology

3.1 Overview of Chapter 3

Chapter 3 gives a brief overview of research. Moreover, a description of Design Science Research (DSR) as the overarching research methodology is given. Additionally, fishbone analysis is discussed. Lastly, the research design in section 3.6 incorporates the perspective/ lens, overarching research methodology and specific methodologies selected to meet the project's objectives. The research for this project is qualitative and follows the Design Science Research Methodology (DSRM) to develop the final artefact. The content of Chapter 3 relating to the DSRM process within the context of this thesis is illustrated in Figure 3.1.

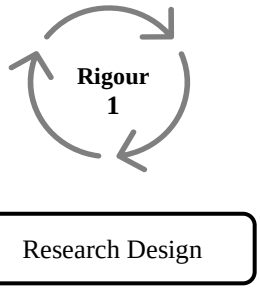
CHAPTER 3			
PHASE	**DSRM ACTIVITY**	**CYCLE & PROCESS FLOW**	**RESEARCH OBJECTIVE**
1: Theoretical Component	**1.** Problem identification & motivation.		**RO2:** Establish a research design that can address the research gap & problem.

Figure 3.1: Research thesis outline - Chapter 3

3.2 Brief introduction to research

When conducting a research project, the researcher must create a plan and a research design. The research design should incorporate a theoretical lens, an overarching methodology, and methods/ procedures/ processes that will allow the researcher to meet their objectives. This design will involve the collection and analysis of sources containing data that is qualitative or quantitative. A mixture of both (mixed methodologies) may also be used. Various research terms are used when discussing the research paradigm (see Figure 3.2).

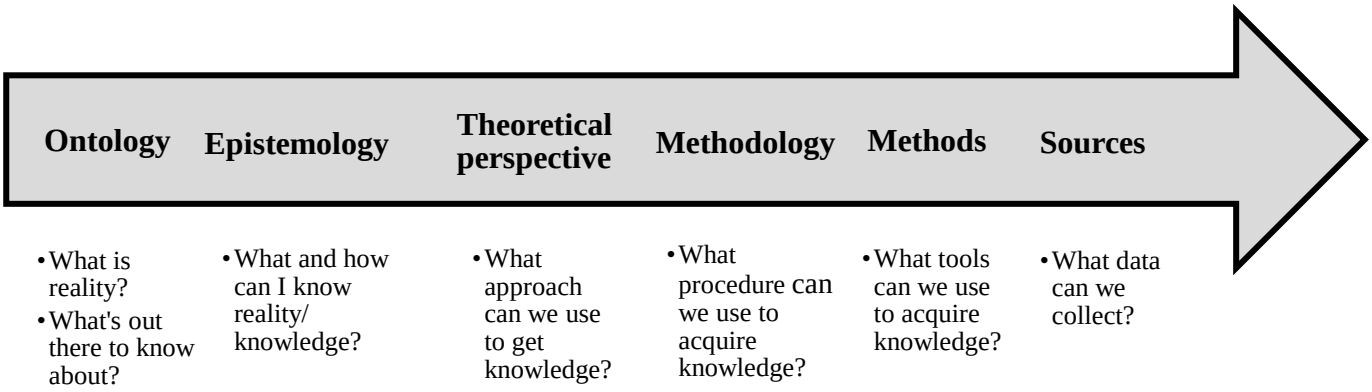


Figure 3.2: Research terms and the relationship between them (adapted from [30]–[32])

Ontology describes the set of concepts and categories within the domain of the research project. Hence, critical properties and relationships are highlighted. *Epistemology* describes the theory of knowledge concerning its methods, validity, and scope. A *theoretical perspective* includes the set of

assumptions about reality that inform questions and their answers. It can be likened to a *lens* through which a problem is examined. *Methodology* describes the systematic/ particular procedures for approaching/ achieving research objectives. Sources hold information in one form or another (qualitative/ quantitative/ mixed). Table 3.1 compares *qualitative*, *quantitative*, and *mixed methods*.

Table 3.1: Qualitative, quantitative, and mixed methods [33]

QUALITATIVE	QUANTITATIVE	MIXED
Emerging methods.	Predetermined methods.	Both predetermined and emerging methods.
Open-ended questions.	Instrument-based questions.	Both open- and close-ended questions.
Interview data, observation data, document data, and audio-visual data.	Performance data, attitude data, observational data, and census data.	Multiple forms of data drawing on all possibilities.
Text and image analysis.	Statistical analysis.	Statistical and text analysis.
Themes/ patterns interpretation.	Statistical interpretation.	Across databases interpretation.

The reality of the medical device sector (i.e., the ontology component of the research design) is that it is highly complex, given that it is comprised of a variety of multidisciplinary stakeholders. This has been determined through preliminary research that justified the proposal of this project (Chapter 1). Systematic reviews, performed in Chapters 4 and 5, highlight the existing knowledge surrounding the strengthening of medical device sectors (i.e., the epistemology of the research design). A theoretical perspective was used to guide the acquisition of relevant knowledge. Applying a value chain lens to this research allowed for a holistic view of the medical device sector. By following Design Science Research (DSR) as an overarching methodology, the appropriate methods were structured in a way that allowed for a valuable research outcome in the form of an artefact (framework). Appropriate design requirements are determined in Chapter 6 based on key concepts determined in Chapters 4 and 5. Chapter 7 involves collecting primary data in the form of expert rankings, and Chapter 8 summarises the study's conclusions.

ATLAS.ti is a powerful software tool that can be used to code literature findings systematically to facilitate and strengthen qualitative analysis. It can store a variety of data forms, from videos to text, making it a suitable tool for use in this study.

3.3 Design Science Research

Design Science Research (DSR) has been defined as a research paradigm wherein the designer answers questions relevant to human problems by creating innovative artefacts. In doing this, the designer contributes new knowledge to the body of scientific evidence. The designed artefacts are both useful and fundamental in understanding the problem at hand [34]. An 'artefact' describes something artificial [35]. Such artefacts must improve existing solutions or provide novel solutions to existing problems. IT artefacts represent the end goal of DSR projects and are broadly defined as (1) constructs (vocabulary and symbols); (2) models (abstractions and representations); (3) methods (algorithms and practices); (4) instantiations (implemented and prototype systems) or (5) better design theories [34].

The aim of DSR is to improve the environment by introducing new innovative artefacts and artefact-building processes [35]. DSR shows the potential to bridge the gap between relevance and rigour in information systems (IS) research. DSR boasts both practical relevance (given its focus on useful artefacts) and scientific rigour (via the formulation of design theories) [36].

Hevner (2007) analyses DSR as an incorporation of three closely related cycles of activity: (1) the Relevance Cycle, (2) the Rigour Cycle and (3) the central Design Cycle [38]. Figure 3.3 visualises the three cycles. The Relevance Cycle links the contextual environment of the research project to the

design science activities. The Rigour Cycle links the design science activities with the knowledge base that informs the research project. The central Design Cycle iterates between building and evaluating the design artefacts and the research processes [34].

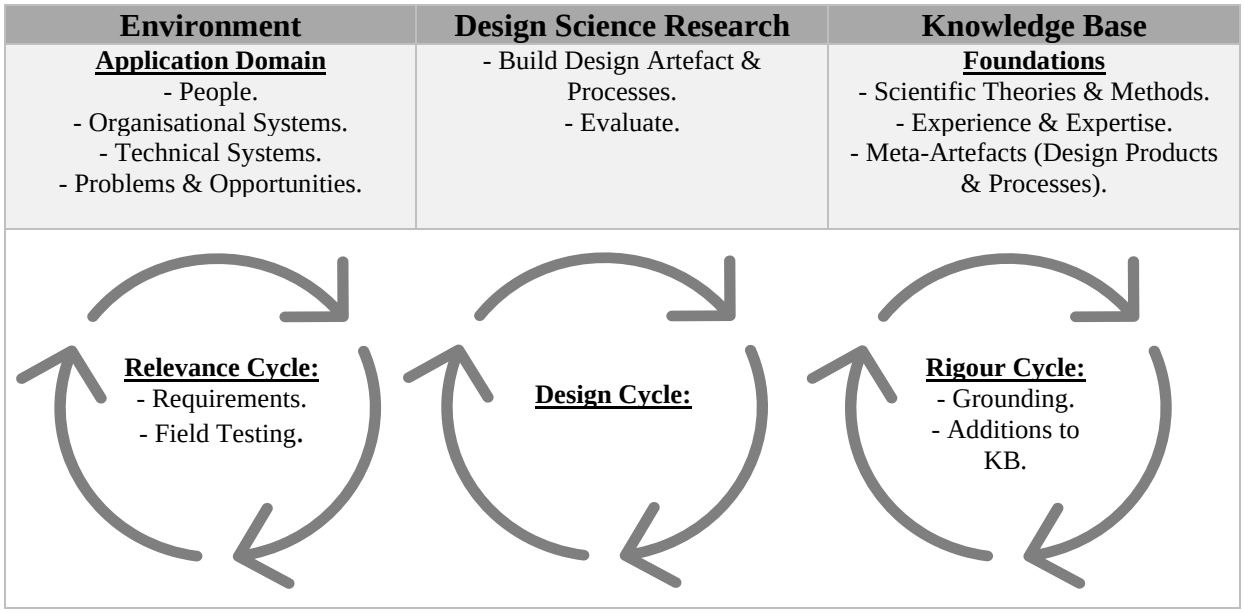


Figure 3.3: Design Science Research Cycles ([38], [39])

Central to DSR is developing an artefact as a tangible or theoretically useful research product. In the case of this project, the artefact is a conceptual framework. According to Miles and Huberman (1994), "A conceptual framework explains, either graphically or in narrative form, the main things to be studied- the key factors, constructs, or variables- and the presumed relationships among them. Frameworks can be rudimentary or elaborate, theory-driven or commonsensical, descriptive, or causal." A conceptual framework that maps the MDVC can provide a holistic approach to identifying and alleviating bottlenecks in the industry. A conceptual framework is a fitting artefact, given that this study area is not well documented. The MDVC has not been mapped in its entirety. Existing literature examines certain sections of the MDVC but not as a whole. Additionally, one of the key features of conceptual frameworks is their *capacity for modification* [41], i.e., they are subject to reconceptualisation and adaptation [42]. The medical devices industry rapidly evolves; thus, the MDVC should be consistently modified to be helpful in the industry.

3.4 Design Science Research Methodology

Peffers *et al.* (2007) motivate and present a design science research methodology (DSRM) for conducting DSR in ISs [43]. The DSRM includes six activities: (1) *problem identification & motivation*, (2) *definition of the objectives for a solution*, (3) *design & development*, (4) *demonstration*, (5) *evaluation* and (6) *communication*. Figure 3.4 illustrates the DSRM Process Model. The DSRM was demonstrated and evaluated through its presentation in four case studies. The six steps are elaborated on below:

(1) *Problem identification & motivation.* Identifying the problem allows for the design task to be outlined. In turn, an artefact can be developed that will solve the problem. Motivation is needed to justify the creation of a solution.

(2) *Define the objectives for a solution.* The complexity of the problem needs to be unpacked. A review of the existing knowledge base is necessary to ascertain whether current solutions exist, and if so, it is essential to determine how they can be improved.

(3) *Design & development.* Developing a design research artefact includes an embedded research contribution in its design. It includes a set of interrelated concepts and principles that facilitate comprehension of the problem so that it can be alleviated.

(4) *Demonstration.* Showcasing the artefact in practice is necessary to prove that it can be used to alleviate the problem.

(5) *Evaluation*. Testing the artefact against the design requirements developed through a literature review determine its effectiveness and utility in practice.

(6) *Communication.* Reflection on the evaluation results can lead to further refinement and improvement of the design theory or artefact. Additionally, the artefact's value should be communicated to those who may benefit from it.

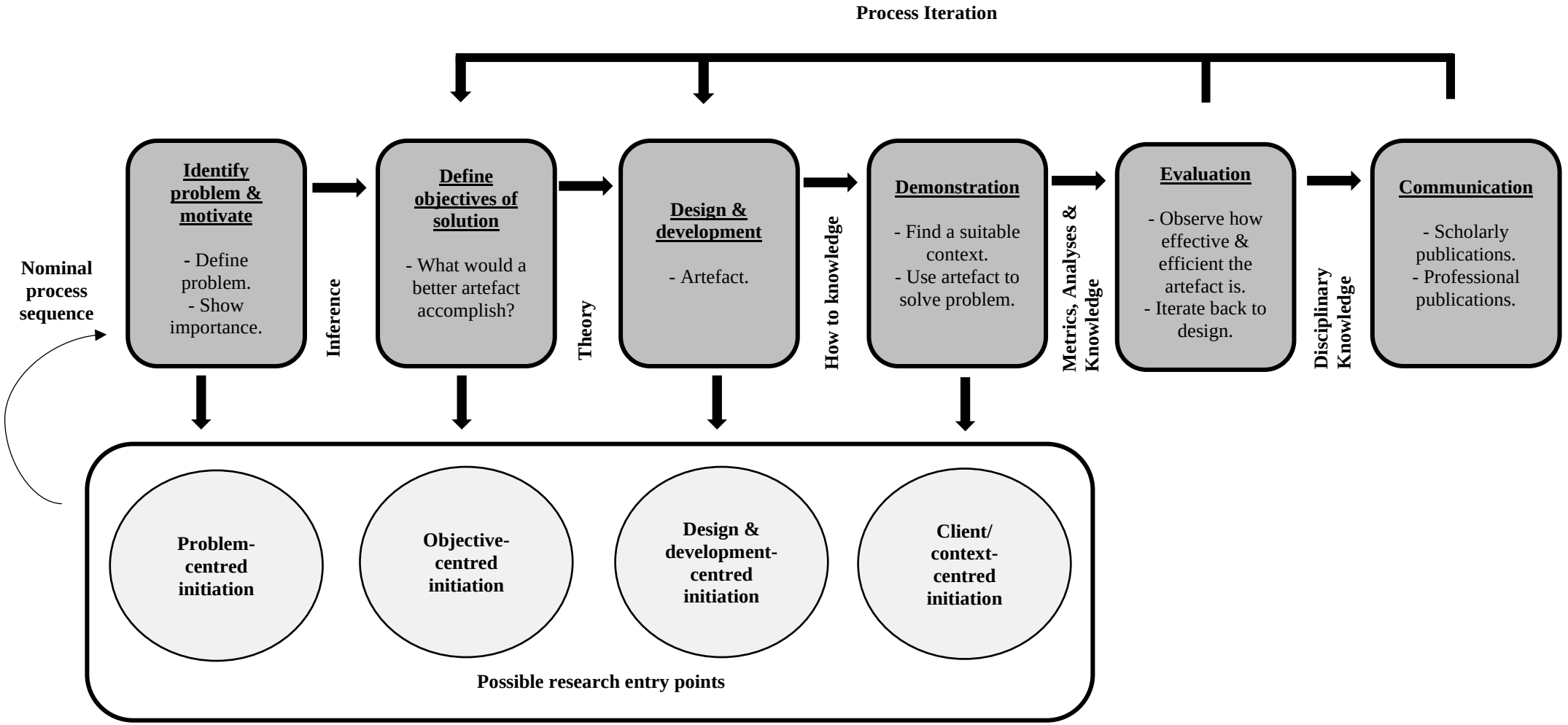


Figure 3.4: DSRM Process Model (Taken from [43])

3.5 Fishbone analysis & the mutually exclusive and collectively exhaustive (MECE) principle

A *fishbone diagram* is also known as a *cause and effect diagram*, an *Ishikawa diagram* or a *Herringbone diagram*. A *fishbone diagram* is a graphical tool used to brainstorm the causes of an effect. *Fishbone analysis* is the systematic method utilised in problem-solving that evaluates interactions between causes and their collective effect. This process of analysis yields a fishbone diagram. The head of the fishbone diagram represents the effect/ problem and is placed on the right-hand side with an arrow pointing towards it. The ribs represent the causes and the categories thereof (they are linked to the central middle arrow with more arrows). Causes are positioned based on their level of importance or detail. Moreover, causes are grouped into categories. This arrangement allows for relationships and hierarchy to be illustrated [44]. Smaller bones coming off the ribs represent the sub-causes. Figure 3.5 illustrates a basic fishbone diagram. To identify causes and sub-causes, brainstorming participants must keep asking, 'why?'.

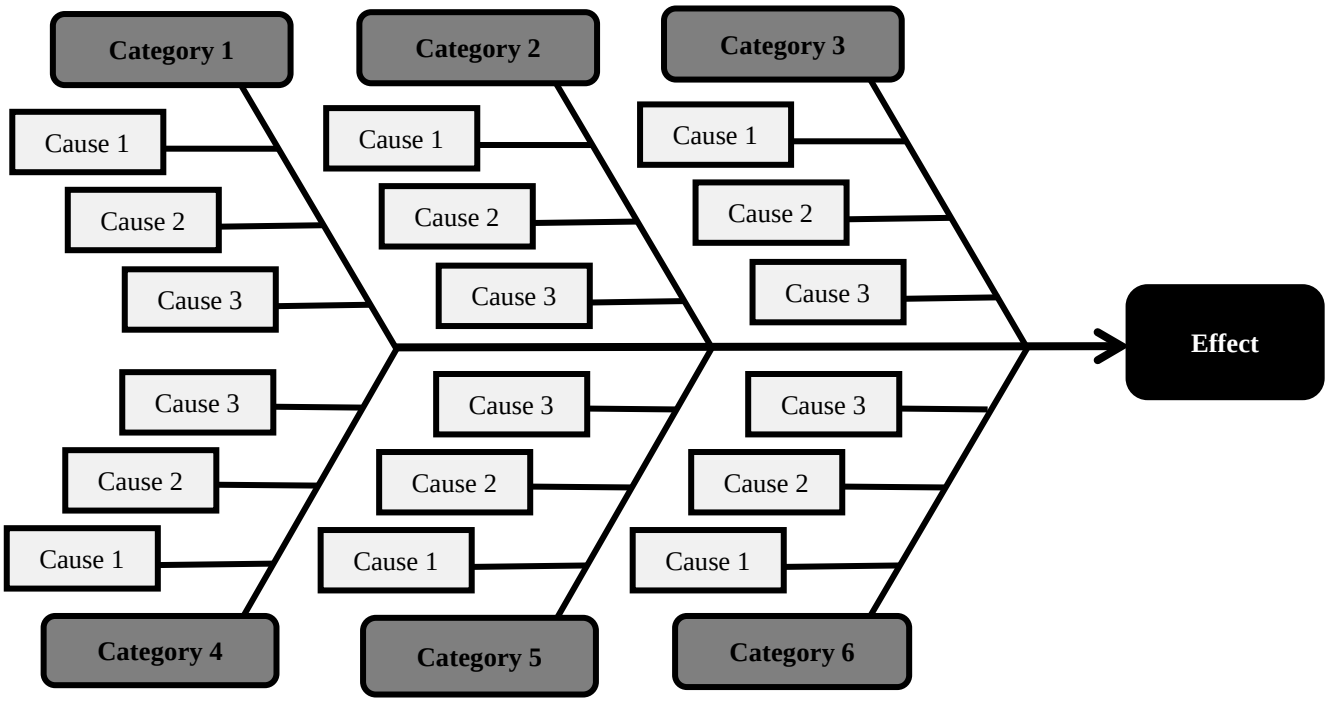


Figure 3.5: A basic fishbone diagram (adapted from [44])

Fishbone diagrams have been widely utilised in industry. There are many advantages to using fishbone diagrams. However, there are also some drawbacks (see Table 3.2). One of the most notable advantages of using fishbone diagrams is that they clarify existing problems, facilitate stakeholder understanding/ consensus and encourage the successful development of objectives and implementation of solutions [45]. However, fishbone diagrams provide no time dimension, and they may prove unhelpful if not developed systematically. To alleviate some of the drawbacks of fishbone diagrams, they can be supplemented by applying the mutually exclusive and collectively exhaustive (MECE) principle. In the MECE principle, *mutually exclusive* entails separating the problem causes without repetition. *Collectively exhaustive* implies that each aspect must be considered systematically to encourage a comprehensive understanding of the problems/ causes [46]. The MECE principle allows for focusing fishbone diagrams and identifying correct solutions [45].

Table 3.2: Advantages and drawbacks of fishbone analysis (information taken from [44], [45])

Advantages	Drawbacks
• Fishbone diagrams emphasise the bigger picture. • Fishbone diagrams can be used to increase stakeholder consensus. This consensus is achieved through discussion and the exchange of opinions. • Fishbone diagrams are useful during the planning phase of Science and Technology programs. • Fishbone analysis allows for the clear identification of problems and their potential root causes. • This, in turn, allows for research outputs/ outcomes to demonstrate solutions. • Fishbone diagrams assist in the linking of interventions to the correct stakeholder. • Fishbone diagrams are handy when dealing with large-scale integrated programs with multiple sub-programs. • Fishbone analysis allows for the ranking of different effects/ problems with regard to importance/ detail. • Fishbone diagrams systematically visualise the relationship between effects and their causes. • Fishbone diagrams can be used to transform problems into goals and objectives. Moreover, they can be used to build good indicators to measure these goals and objectives. • Fishbone diagrams are helpful in the process of assigning tasks and responsibilities. • Fishbone diagrams concisely convey information which facilitates understanding of the problems identified. • Fishbone analysis is systematic, allowing researchers to shift their thinking from technology-driven to problem-oriented. • Fishbone diagrams are effective when analysing problems with multiple independent dimensions.	• The relationship between a problem and its causes is convoluted in a complex environment. This, in turn, complicates the development of a fishbone diagram. - This disadvantage can be alleviated through the application of the MECE principle. • If there are many stakeholder groups, then fishbone diagrams may not reflect the issues of every group. • It is unclear how to most effectively identify causes and effects. • It is unclear how to speed up the process of achieving stakeholder consensus. • Fishbone diagrams lack a time dimension and are not useful in planning the milestones of a project.

Several generic fishbone diagram schemes have been developed, some based on the MECE principle, such as ‘the marketing 4P’ and ‘the environment analysis PEST’ [45]. Table 3.3 gives the generic schemes used in fishbone analysis and their respective categories. These schemes can be adapted based on the topic of analysis at hand, or completely new schemes can be developed.

Table 3.3: Generic fishbone diagram schemes

Scheme name	Categories included
The 6 classic categories	People, equipment, materials, environment, management and process.
The marketing 4P	Product, pricing, promotion and placement.
The environmental analysis PEST	Political, economic, social and technological.
3M and P	Methods, materials, machinery and people.
4P	Policies, procedure, people and plant.
The four Ms	Machine, method, material and measurement.
The six Ms	Man, mother nature, measurement, material, method and machine.
The four Ps • Commonly used in the service industry.	Products, place, promotion and price.

Li and Lee (2011) developed a series of steps to develop fishbone diagrams, summarised in Table 3.4 [45]. The steps include: clarifying the core problem, identifying the specific dimensions and diagram

development, stakeholder analysis involvement and objective analysis (reverse fishbone diagram development). A *reverse fishbone diagram* is essentially a fishbone diagram wherein the problem (undesired effect) becomes the goal (the desired effect), and the causes (bottlenecks) of the problem become the objectives (i.e., the alleviations of bottlenecks) to achieve the goal (the desired effect) (see Figure 3.6).

Table 3.4: Fishbone diagram construction steps [45]

Step	Explanation
1. Clarify the **core problem**. - Core problems should define the difference between the ideal circumstances and the current circumstances. - Core problems should be solvable. - Core problems are usually key drivers of other problems.	• This step involves identifying stakeholders and including them in a brainstorming session. • The brainstorming session should result in the identification and clarification of problems/ objectives. • Problems/ objectives should be written out in detail (who is involved, what the problem/ objective is and when/ where it occurs). • Operational definitions should be used in the problem statements created.

2. Identify **specific dimensions** and develop fishbone diagram.	• This step involves the determination of the major factors involved.
	• Possible causes of the problem must be identified (through literature review & brainstorming with stakeholders).
	• A brief description of each cause must be given.
	• Establish the main categories/ causes under which other causes will be listed.
	• Defined categories may be used (see Table 3.3).
	• Category development can be done through:
	  o A literature review.
	  o A value chain analysis.
	  o An inductive review of actual experience in the industry.
	• Principles for the fishbone problem tree:
	  o Sub-causes should be independent.
	  o Problem description should be negative and in an "adjective + noun" format.
	  o If a sub-cause applies to two categories, it is written in two positions.

3. Involve stakeholder analysis. - Stakeholder analysis is a crucial part of the logical framework approach.	• Identify the stakeholders. This allows for the appropriate allocation of resources and minimal changes in the scope of the work, and it encourages the success of the objectives. • Stakeholder analysis allows for a problem tree (a fishbone diagram) to be transformed into an objective tree (a reverse fishbone diagram). • The analysis allows for the goals/ objectives to be target-group specific.
4. Build up an objective analysis (a reverse fishbone diagram) based on the problem analysis.	▪ This step involves identifying critical success factors (CSFs). ▪ In the reverse fishbone diagram, the core effect/ goal is put on the left-hand side with the central arrow pointing towards it. ▪ The language used in the reverse fishbone diagram is generally positive and in the form of "verb + noun". ▪ Essentially, in the reverse fishbone diagram, the problem statements are reversed and treated in a positive light. ▪ The goals and objectives should be specific, measurable, attainable, relevant and time-based (SMART) to facilitate progress measurement.

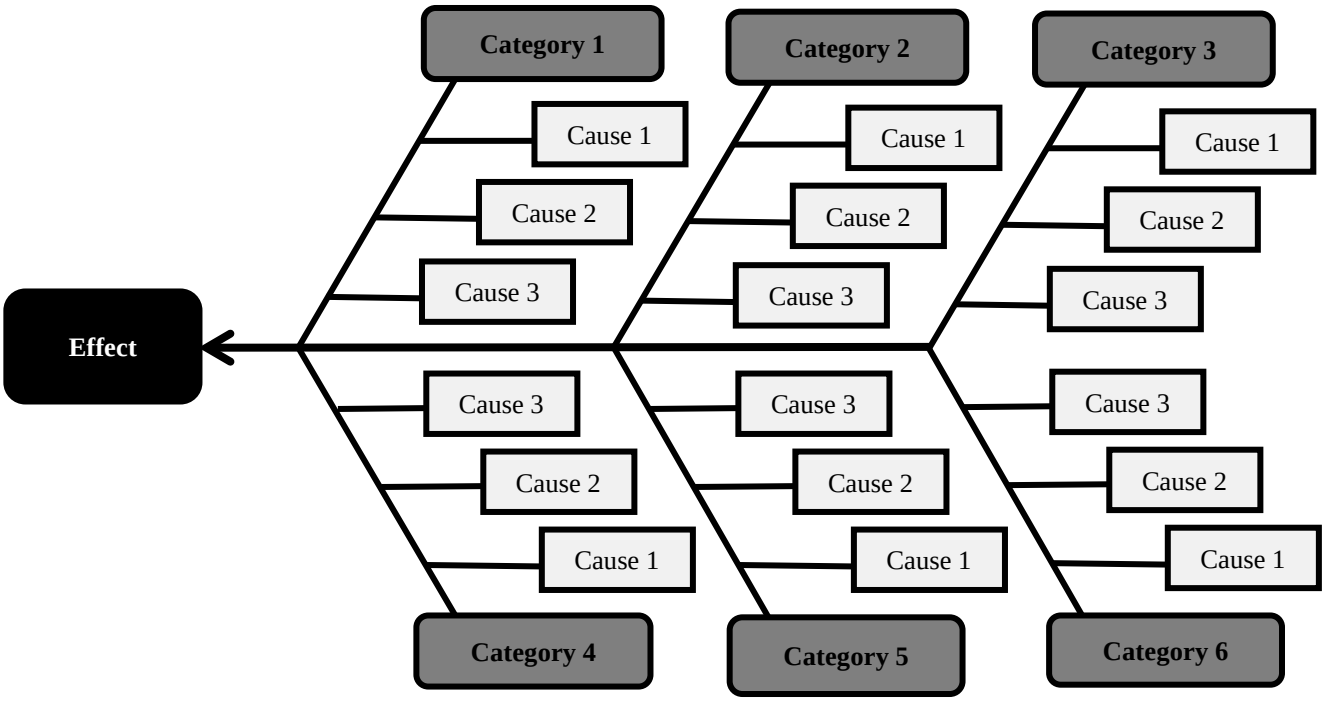


Figure 3.6: A reverse fishbone diagram (Adapted from [45])

Bose (2012) evaluated the supply chain and business processes of St. James Hospital and the Lucas Engineering System through two consecutive fishbone analyses [47]. The first fishbone diagram scheme used was 'the classic 6 categories' (see Table 3.3), as their analysis reveals the causes of any problem regardless of its type or severity. The initial fishbone analysis uncovered the primary problem (effect). It was put as the head in the second and most crucial fishbone analysis, which identified why the problem was happening, where it was happening, the efficiency of people involved and the efficiency of the process itself. Subsequently, the study successfully identified the problem areas: a lack of proper equipment, a faulty process, misdirected personnel, poor management of materials, an improper environment and inefficient management.

3.6 Final research design

The final research design is demonstrated in Figure 3.7. This design incorporates value chain analysis as the lens through which the problem is examined. Bottlenecks must be identified and alleviated to strengthen medical device sectors. Value chain analysis allows for a holistic perspective in identifying and alleviating bottlenecks. DSR was chosen as the overarching approach as it aims to create scientifically rigorous and practically useful artefacts. Hence, the research outcome will be valuable. DSRM is followed to ensure a valuable research output. The six DSRM activities are split between two phases: the *theoretical component* and the *practical component.* The *theoretical component* incorporates the first two rigour cycles and the first design cycle. Solving the problem is shown to be valuable, and the existing knowledge base is examined to guide the development of a preliminary solution (artefact). The *practical component* includes the first two relevance cycles, the second and third design cycles as well as the third rigour cycle. Essentially, the artefact's value is demonstrated and tested to guide future refinement and communicate its practical value. Each DSR cycle builds on the previous one and contributes to developing an innovative artefact that can solve the problem systematically or build on existing research. Additionally, the ROs established in Chapter 1 are laid out corresponding to the Chapters in which they are completed or contributed to.

PHASE	1: Theoretical Component			2: Practical Component		
DSRM ACTIVITY	1. Problem identification & motivation.	2. Define objectives of solution.	3. Design & development.	4. Demonstration.	5. Evaluation.	6. Communication.
CYCLE	Rigour 1	Rigour 2	Design 1	Relevance 1	Relevance 2	Design 3
PROCESS FLOW	Background and Problem Statement → Research Design	Literature Review: MDVC bottlenecks and alleviations → Literature Review: Frameworks	Preliminary Framework	Expert Review → Design 2 → Refined Framework	Semi-structured interviews & survey	Final Framework → Rigour 3 → Findings and Conclusion
RESEARCH OBJECTIVE	**RO1:** Determine research gap and define problem statement. **RO2:** Establish a research design that can address the research gap & problem.	**RO3:** Establish a literature base that can be used to determine the objectives/ design requirements of an artefact (solution).	**RO4:** Translate relevant concepts from literature into artefact design requirements. **RO5:** Develop preliminary artefact.	**RO6:** Review preliminary artefact with an appropriate expert and refine artefact accordingly. **RO7:** Review evaluation methodologies.	**RO8:** Evaluate artefact using an appropriate methodology. **RO9:** Analyse and discuss results.	**RO10:** Present final artefact design and conclusions.
CHAPTER	**CH1, 2 & 3**	**CH4 & 5**	**CH6**	**CH7**	**CH7**	**CH8**

Figure 3.7: Final research design

3.7 Chapter 3 – Summary

Table 3.5 illustrates the RQs and ROs partially addressed in Chapter 3. RQ2 isn't answered, but it is contributed to as artefacts, and their development is discussed. Moreover, methodologies that can be used to develop this study's artefact are introduced. Fishbone analysis is introduced as a possible way to present the artefact. RO3 is achieved as a research design is given in Figure 3.7.

Figure 3.7illustrates the final version of the research design overview first demonstrated in Figure 1.4 (Chapter 1). The research design is split into a theoretical component and a practical component. The theoretical component comprises two rigour cycles that inform the first design cycle. A preliminary review, two systematic literature reviews and one conceptual literature review identify the necessary MDVC categories, value-adding activities, bottlenecks, and alleviations used to inform the conceptual framework. Existing frameworks for strengthening MDVCs (or variations thereof) are identified and support the development of domain concepts to which fishbone analysis could contribute. Chapters 1-6 cover the theoretical component.

The practical component is evaluative and incorporates the last three DSRM activities to refine the MDVC framework and ensure the practical value of the artefact. The MDVC framework is evaluated using two relevance cycles according to the DSR approach. The first relevance cycle validates the MDVC developed through obtaining feedback from an MDVC stakeholder. The second relevance cycle evaluates the efficacy, quality, and generalisability of the initial MDVC framework through expert reviews. Expert reviews consist of semi-structured interviews and surveys with seventeen South African stakeholders representative of the multidisciplinary expertise found in the medical devices industry. The expert reviews will evaluate the quality and efficacy of the MDVC framework and highlight key findings. The results will be translated into conceptual and structural improvements during the second design cycle to develop suggestions for a refined MDVC framework. Chapters 7 and 8 cover the practical component.

Table 3.5: Research questions answered and research objectives addressed in Chapter 3

PHASE 1: THEORETICAL		
RESEARCH QUESTIONS	**CH3 CONTRIBUTIONS**	☑
RQ2: How can an artefact be used to identify bottlenecks in the MDVC?	• Artefacts and their systematic development are discussed. • Methodologies that can assist in artefact development are introduced and elaborated on.	☑
RESEARCH OBJECTIVES	**CH3 CONTRIBUTIONS**	☑
RO2: Establish a research design that can address the research gap & problem.	• DSR is discussed and incorporated as the overarching research approach. • DSRM is chosen to guide the development of an innovative artefact (useful research output). • Fishbone analysis is introduced to visualise the interaction between bottlenecks and the UEs that they exacerbate. Additionally, it can graphically represent alleviations that encourage DEs. • The final research design is presented and discussed.	☑

Chapter 4 - Systematic literature review of the MDVC, its bottlenecks, existing tech-based alleviations and MDVC stakeholders

4.1 Overview of Chapter 4

Chapter 4 is the result of a systematic literature review. It focuses on RO3 as it establishes a literature base that can be used to determine the objectives of the artefact. This chapter's primary goal is to determine how MDVC bottlenecks are identified and alleviated. Additionally, the MDVC is mapped, the external environment is discussed, MDVC stakeholders are identified, and existing MDVC bottlenecks and alleviations thereof are explored. Figure 4.1 below illustrates the structure of this chapter.

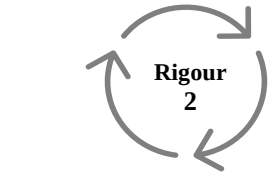
CHAPTER 4			
PHASE	**DSRM ACTIVITY**	**CYCLE & PROCESS FLOW**	**RESEARCH OBJECTIVE**
1: Theoretical Component	**2.** Define objectives of solution.	 Literature Review: MDVC bottlenecks and alleviations	**RO3:** Establish a literature base that can be used to determine the objectives/ design requirements of an artefact (solution).

Figure 4.1: Research thesis outline - Chapter 4

4.2 The systematic literature review process

The literature database was compiled following the PRISMA-P 2015 Checklist ([48], [49]) to ensure its integrity and reproducibility. Table 4.1 shows the research questions for the literature review.

Table 4.1: Research questions

ID	Research Question (RQ)
Q1	What tools/ frameworks have been used to map the MDVC?
Q2	What VAs occur in the MDVC? Moreover, which stakeholders perform these activities?
Q3	What bottlenecks disrupt VAs in the MDVC? Moreover, what are the UEs of these MDVC bottlenecks?
Q4	What technology-based alleviations of these bottlenecks have been suggested/ implemented? Moreover, what are the DEs of these alleviations?
Q5	What tools/ frameworks have been used to analyse MDVC bottlenecks/ alleviations thereof?

Figure 4.2 illustrates the literature review process. Answering the research questions will determine the extent to which the MDVC has been mapped. The common bottlenecks and technology-based alleviations thereof will also be explored.

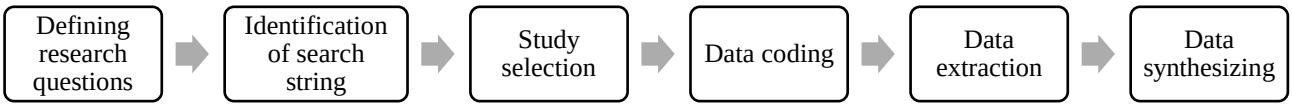


Figure 4.2: The systematic literature review process

The following digital databases were used to find the studies needed in this literature review: Web of Science, Scopus, and PubMed. The following search criterion was set:

[("value chain" OR "supply chain" OR "cluster" OR "innovation system" OR "ecosystem" OR "inclusive innovation") AND ("medical devices" OR "healthcare" OR "health" OR "medical machine" OR "medical apparatus") AND ("technology" OR "eHealth" OR "infrastructure")].

The search was conducted on 19/05/2021 and yielded 1319 sources. A total of 749 were found in the Web of Science database, 61 in the Scopus database and 509 in the PubMed database (see Figure 4.3). The exclusion criteria (EC) are provided in Table 4.2. Following title-, abstract- and full-text screening, 40 sources were selected based on predefined inclusion criteria (IC) (see Table 4.3). Five additional sources were included from the reference lists of the selected sources to facilitate correct referencing of original ideas. Figure 4.3 illustrates the data selection process using the PRISMA 2020 flow diagram for updated systematic reviews.

Table 4.2: Exclusion criteria

No.	Criterion
EC1	Not related to medical devices or does not answer any RQs.
EC2	Non-English publication.
EC3	Duplicated publication.
EC4	The publication is older than 2017.
EC5	Not open access.

Table 4.3: Inclusion criteria

No.	Criterion
IC1	Maps a variation of the MDVC using a tool/ framework.
IC2	Discusses a VA that should be included in the MDVC.
IC3	Uses a tool/ framework to analyse MDVC bottlenecks.
IC4	Discusses a bottleneck in the MDVC that causes a UE.
IC5	Discusses a tech-based alleviation of a bottleneck in the MDVC that leads to a DE.

The 45 sources selected were then critically analysed through the development of a basic coding system to assist in synthesising ideas (see Figure 4.4). Categories and sub-categories were developed. Undesirable effects (UE:) are the core problems in the MDVC. Bottlenecks (B:) exacerbate these UEs. Desirable effects (DE:) represent the ideal scenario once the bottlenecks have been alleviated. DEs are achieved through the successful implementation of alleviations (A:). Then the medical device value chain or variations thereof (MDVC) were identified to guide the development of a full MDVC map. Value-adding activities (VA:) and the stakeholders (S:) who perform them were also identified to ensure that each process and person involved in the MDVC was identified. Lastly, the external environment (EE:) was examined, including the impact of COVID-19 on the MDVC, where it exacerbated MDVC bottlenecks and accelerated innovations in the form of alleviations.

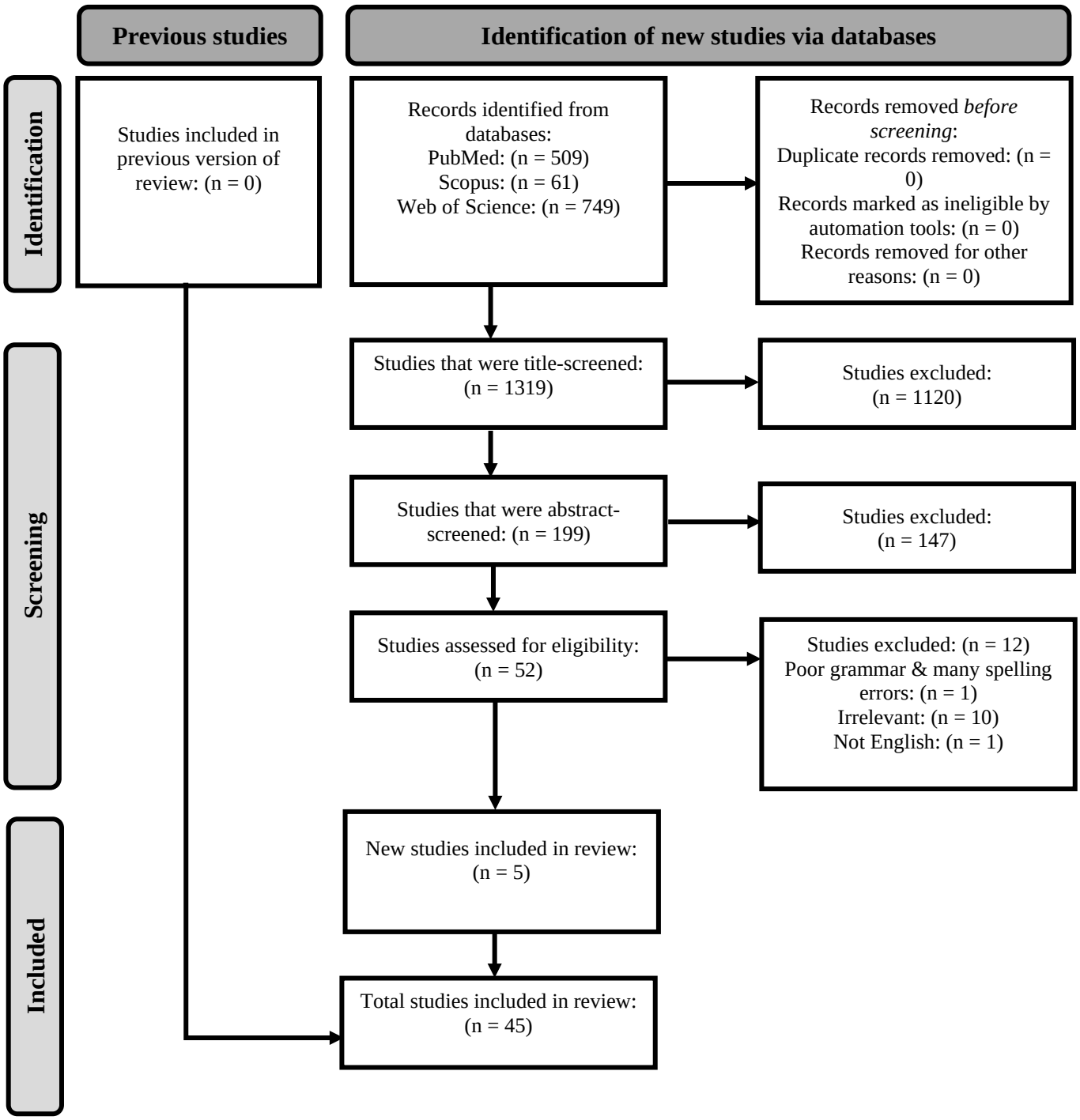


Figure 4.3: The data selection process

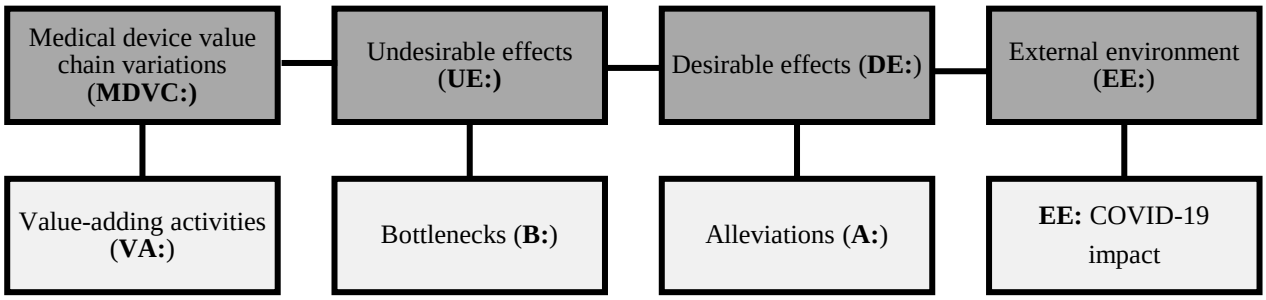


Figure 4.4: Basic coding system

4.3 The MDVC and key stakeholders

The MDVC is complicated and involves several stakeholders from a variety of backgrounds. Therefore, collaboration is necessary to solve innovation challenges in healthcare [50]. The literature search did not yield a source that mapped the MDVC entirely; however, Lawton Smith, Bagchi-Sen, and Edmunds (2018) used the *Healthcare Technology Innovation cycle* as an organising framework for analysis [51]. Their study described the *Healthcare Technology Innovation cycle* as one "that connects engineers and medical professionals, scientists and entrepreneurs, and developers and end-users (medical doctors and patients)". Moreover, their chosen framework implies a circle of stakeholder collaboration. However, it was found that a drawback of the *Healthcare Technology Innovation cycle* was that it lacked a sense of location and broader geography of innovation, which Cooke (2005) and Swiss Biotech (2016) refer to as an *innovation value chain* in the sector. Hence, their health technology innovation framework and the innovation value chain will be used to guide the development of a holistic MDVC.

Intermediaries are stakeholders/ platforms that facilitate effective networking between stakeholders throughout the MDVC [54], [55]. Examples include medical device clusters [51], health innovation centres (HICs) [56], web-based innovation platforms [50], [57], industry-academia collaboration coordinators (CDs) [58] and group purchasing organisations (GPOs) [59], amongst others. Intermediaries have been shown to fulfil similar roles in encouraging strategic networking between key MDVC stakeholders with diverse expertise. Often these intermediaries are geographically localised to facilitate localised knowledge spillovers (LKSs). However, Breschi and Lissoni (2000) argue that LKSs occur not only because proximity facilitates face-to-face *tacit knowledge* transfer but also because the mobility of workers plays a significant role. Researchers from a university are more likely to commercialise their idea in the same region to reduce costs because they have formed business-beneficial relationships with local stakeholders through direct university-industry collaborations. *Tacit knowledge* describes everything a stakeholder knows how to do but cannot explain/ document or that knowledge they have yet to explain/ document. Web-based alternatives could encourage improved collaboration irrespective of proximity.

Three knowledge spillover types are better if local because of time economies: (1) *anticipatory knowledge*, (2) *participatory knowledge*, and (3) *precipitatory knowledge*. These knowledge spillover types correlate to three core knowledge production activities in the MDVC: (1) *exploration knowledge*, (2) *examination knowledge*, and (3) *exploitation knowledge* [52]. These knowledge production activities can be overlapped with the *Healthcare Technology Innovation cycle* phases and the *innovation value chain* steps to guide the mapping of the MDVC. Table 4.4 briefly describes the MDVC variations identified and the VAs they include.

As discussed, the medical device sector relies on multiple disciplines and technologies, including non-science areas such as law, public health, social science and management [51]. The government puts in place infrastructure and policies to support medical device innovation; national/ international

regulatory authorities ensure the safety of medical device end-users, and certification bodies encourage compliance with international standards.

Table 4.4 serves as a guide in mapping the MDVC as VAs from various MDVC variations are given. UCT's route to market and TRLs discussed in Chapter 1 and the generic value chain categories identified in Chapter 2 are also included. The frameworks identified include the *Healthcare Technology Innovation cycle*, the *innovation value chain*, the three knowledge spillover types and their corresponding core knowledge production activities. However, given that the MDVC is highly complex, a second, more inclusive literature review will be performed to map it in Chapter 5 holistically. Moreover, semi-structured interviews with key stakeholders will be done to validate the results in Chapter 7.

Table 4.4: MDVC variations identified

MDVC Variation	Brief description of VAs and MDVC categories included
Generic value chain categories	• The MDVC describes the process of bringing a medical device from conception to distribution and beyond. This involves medical device idea generation (through identifying healthcare needs), design, production, marketing, distribution, the support provided to the end-user and eventual disposal [2].
UCT's route to market for medical devices	• UCT's route to market for medical devices includes three phases: (1) *Early considerations*; (2) *Project scoping*, and (3) *Product development*. *Early considerations* include need identification and development of a proof of concept. *Project scoping* includes conducting a business case review and starting development. *Product development* involves design, development, verification, validation and regulatory compliance [11].
Technology readiness levels	• Technology readiness levels classify technology maturity [11], [14]–[16]: • TRL 1 = Idea formulation and initial research. • TRL 2 = Applied research performed. • TRL 3 = Project plan and schedule devised. • TRL 4 = Design stage. • TRL 5 = Proof of concept or design refinement. • TRL 6 = Preclinical evaluation. • TRL 7 = Clinical trials and technology transfer. • TRL 8 = Regulatory approval obtained. • TRL 9 = Marketing, distribution, and use.
Healthcare Technology Innovation cycle	• The Healthcare Technology Innovation cycle includes three phases: (1) the input, (2) the innovation system, and (3) the output [51].
Innovation value chain	• There are five steps in the innovation value chain: (1) idea, (2) research, (3) development, (4) production and (5) market [53].
Three knowledge spillover types & their corresponding core knowledge production activities	• Three knowledge spillover types have been identified: (1) *Anticipatory knowledge* refers to receiving value-adding knowledge before its general release; (2) *participatory knowledge* refers to readily available complementary local assets or capabilities and (3) *precipitatory knowledge* refers to early access to local inventions, discoveries, or innovations [52]. • Three core knowledge production activities have been identified: (1) *exploration knowledge* is the aim of fundamental research; (2) *examination knowledge* includes feedback from medical device trials/ use and (3) *exploitation knowledge* is the mix of knowledge required to transform research into successful commercial products (e.g., scientific-, technological-, entrepreneurial-, financial- and legal knowledge).

From Table 4.4, seven MDVC categories were developed: (1*) Idea generation*; (2) *Research & Development*; (3) *Production/ Manufacturing*; (4) *Market*; (5) *Distribution & Use*; (6) *Waste Management* and (7) *Systemic*. These categories will be used to group the VAs performed by MDVC stakeholders below in Section 4.4.

4.4 Value-adding activities identified

The seven MDVC categories identified were used to group the various VAs discussed below. The categories incorporated into this initial MDVC will be used when developing fishbone diagrams of each UE (see Figure 4.6) and then again when developing reverse fishbone diagrams of each DE (see Figure 4.8). The VAs identified are listed under each MDVC category in Table 6.3 in Chapter 6.

The first MDVC category is *Idea generation*. The MDVC starts with identifying a healthcare need to generate a medical device idea. Healthcare workers, hospital administrators/ managers and patients fulfil this role and are often assisted by innovators/ entrepreneurs who prompt need identifications based on interviews and observations. Ferriani, Lazerson and Lorenzoni (2020) discuss the value of *anchor entrepreneurship* in industry catalysis by examining the rise of the Italian Biomedical Valley beginning in 1962 [61]. An *anchor entrepreneur* has been described as someone who "performs a generative role across multiple phases and processes to ignite economic change". This case study demonstrates how collaboration and communication between end-users, regulators and innovators are crucial for the eventual adoption of medical devices. Additional literature suggests that hospitals foster medical innovation [62] and that discovery and ideation by hospitals are often done in collaboration with biomedical firms and universities [63], [64].

Hospital managers have been shown to play a role in innovation processes by giving feedback that is often more concerned with cost and efficiency than the user-based feedback of healthcare workers or patients [65]. Additionally, patients have been shown to play a unique role in discovery and ideation [66]. These relationships need to be developed during the early stages of the MDVC, as early as the *Idea generation* category, to ensure that the needs of healthcare workers are fully understood and addressed. Moreover, the needs of the purchasers/ procurers of the medical device need to be considered. On top of this, biomedical innovators need to avoid patent infringement and protect their IP. This involves developing a specific IP strategy that caters to their needs. This strategy is often vital to whether or not their healthcare venture is successful [56].

The second MDVC category is *Research & Development*. Research cannot commence without funding [51]–[53]. *Research & Development* require collaboration and are often conducted by universities, research centres, research hospitals and medical research centres. Intermediaries facilitate this networking and provide guidance/ support [50], [51], [56], [58]. *Development* includes biomedical firms, seed funding bodies, government, national/ international regulatory authorities and certification bodies [53]. Biomedical firms develop medical devices based on the exploration knowledge generated [52]. A proof of concept must be developed, and the device may require preclinical evaluation and clinical trials [53]. Collaboration is again vital at this stage of the MDVC.

The third MDVC category is *Production/ Manufacturing.* Production includes the manufacturing of the product as well as putting in place a supply chain tracing system [53]. The supply chain of the medical device must be tracked from production through to distribution. Thus, this step involves manufacturers as well as logistics firms.

The fourth MDVC category is *Market.* By the *Market* phase, the idea has been commercialised and is now ready to be advertised, sold, and distributed. GPOs facilitate collaboration between manufacturers and medical aids (purchasers of medical devices). This collaboration benefits medical device providers with cost savings, volume discounts and vendor selection [59]. Relationships with purchasers and procurers become valuable at this stage. Thus, it is valuable to develop such relationships earlier in the MDVC.

The fifth MDVC category is *Distribution & Use*. Distributors supply goods to retailers. Medical devices must comply with regulations while being stored/ warehoused and transported. Doctors,

nurses or patients can be the end-users of devices. Hospitals play a significant role in the selection, implementation and dissemination of innovations such as new medical devices. They are also actively involved in post-implementation improvement and adaptation, which may involve updating clinical guidelines [62]. In order to be regulatory compliant, device innovators must obtain their feedback after the device has already been distributed to facilitate the improvement and adaptation of the device if necessary. Additionally, clinical guidelines may require updates.

The sixth MDVC category is *Waste Management*. The literature review yielded minimal information regarding the disposal/ re-use of medical devices. This is likely due to the inclusion of the technology-based alleviation focus in the search string.

The seventh MDVC category is *Systemic*. This category was added to group the VAs that occur at multiple stages or throughout the MDVC. Within the MDVC, there are countless interactions between stakeholders, which are vital for medical device success. Intermediaries foster collaboration between MDVC stakeholders in the development step by connecting them in online/ regional networks. In doing this, intermediaries such as HICs, technology transfer offices (TTOs) and medical device clusters facilitate technology transfer (TT). It is valuable for HICs to be tailored to their specific regional ecosystem as this aids in strengthening their impact on medical device innovation [56]. Rosa *et al.* (2021) demonstrated the value of collaboration between universities, industries and government in the MDVC during the response to COVID-19 [67].

Three types of decision-making frameworks in priority and resource allocation (PRSA) are most used in high-income countries, namely: Program Budgeting and Marginal Analysis (PBMA), Health Technology Assessment (HTA) and Multiple-criteria value assessment [68]. A case study by Mukherjee (2021) suggests that HTA plays a critical role in merging technology, innovation and policy to facilitate advantageous clinical impact [69]. HTA bodies can achieve this by identifying medical devices that do not add value to health systems. These medical devices can then be removed and replaced. Technology in healthcare is not always valuable; thus, medical devices should be consistently evaluated for possible improvements, replacements, and eliminations. This role can be fulfilled by HTAs [69].

Data management, including data acquisition, storage and sharing, is vital in the MDVC. From *Idea Generation*, biomedical firms and hospitals must generate documentation to track the development progress of medical devices [62]. Supply chain monitoring is equally important to ensure regulatory compliance while the device is marketed, distributed and used. The potential of blockchain technology in improving data- and supply management in MDVC variations is repeatedly cited in the literature [59], [70]–[75].

4.5 Undesirable effects (UEs) identified & the MDVC bottlenecks that exacerbate them

UEs are unwanted outcomes at any stage of the MDVC that are exacerbated (made worse) by MDVC bottlenecks. Six UEs and various bottlenecks were identified. Bottlenecks can also be interpreted as poorly performed VAs or the absence of VAs altogether, resulting in a UE: e.g., poor supply chain monitoring can result in the occurrence of counterfeit medical devices.

UE1 is the *lack of medical device adoption*. Healthcare workers or patients will not adopt a medical device that does not meet their needs appropriately. To meet the need, the innovator should communicate with end-users. If there is no established relationship where feedback is obtained and addressed, end-users will be less likely to adopt the medical device [76], [77].

Intermediaries such as HICs demonstrate the value of stakeholder collaboration [55], [56]. Greenhalgh, Fahy and Shaw (2018) highlight the disconnect between stakeholders on the *supply side* and those on the *demand side*, given that both sides operate under different definitions of value [78]. In India, there is a lack of collaboration observed among MDVC institutions and a lack of intermediaries [79]. In Tanzania, it has been shown that considerable ineffective local collaboration between the health and industrial sectors exists, which results in hindered access to medical devices [80]. In addition to relationships with end-users, access to electronic medical records (EMRs) may also be required. Paper-document-driven storage of medical records can make it challenging to share necessary information quickly and ethically.

UE2 is the *lack of medical device start-ups.* The MDVC is lengthy, complex, and very expensive to navigate. Thus, it is difficult for start-ups to succeed. A lack of funding often leads to the demise of start-ups and small-to-medium enterprises (SMEs), thereby eliminating valuable sources of innovation. Biomedical engineering companies often get caught up in perfecting the technical front of the device. However, they need to pay more attention to exploring business and regulatory considerations [56]. The market analysis of medical devices is complicated by shifting reimbursement schedules because the buyer is often different from the end-user [56]. Additionally, the market is often saturated and unattractive to venture capitalists [56]. It is tactical for companies to outsource certain activities, e.g., manufacturing, to save costs in the early stages. Moreover, networking with established biomedical firms in the field is invaluable.

A lack of skilled professionals in a medical device cluster has been identified as a potential bottleneck preventing industry growth [51], [56]. Without the readily available infrastructure and human resources, start-ups will have a more difficult route to market. Additionally, poor governance can limit start-up success. A lack of tax incentives for research translates into fewer patent registrations. Moreover, weak policy initiatives also hinder progress [51].

UE3 is the occurrence of *medical device shortages.* The regulatory requirements associated with medical devices are notorious for being extensive, given their direct impact on human health. Moreover, they are not harmonised across countries, making the process of regulation long, complicated, and expensive. All these factors contribute to regulatory bodies often being viewed as a barrier to overcome instead of as a stakeholder with whom to collaborate [61]. COVID-19 shocked the healthcare system, which led to various medical device and personal protective equipment (PPE) shortages as supply chains struggled to meet the unprecedented demand shocks [67], [69], [81], [82].

UE4 is *medical device-associated pollution.* Waste management did not come up a lot in the literature review. However, the reaction to COVID-19-related PPE shortages was documented extensively [67], [69], [81], [82]. To meet the unprecedented demands of PPE, it was additively manufactured or 3D printed at an accelerated rate leading to huge amounts of waste. It can be assumed that large portions of this waste were not disposed of appropriately, given that the end-users became members of the public in addition to healthcare workers. Thus, users would not have always had access to appropriate medical waste bins such as those found in hospitals.

UE5 is the *lack of alleviation implementation.* Alleviations to bottlenecks are discussed in the literature extensively, such as the use of blockchain technology. However, such alleviations are often not implemented in reality, indicating a disconnect between what is said in literature and what is done in industry. The integration of blockchain is tricky as there are not a lot of promising evaluations and tests that have been done in real-world settings [74]. Also, there are serious security concerns regarding blockchain usage in healthcare, given that medical records are highly classified. Moreover, MDVC stakeholders are wary to engage in the use of blockchain technology [83]. To deal with this concern, blockchain should not be used as a stand-alone technology for storing EMRs, especially in its current form [84]. Studies have suggested directions for future work tackling issues regarding the

adoption of blockchain in healthcare [74], [83]. Another limitation is that cross-border sharing of health data is not yet seamless due to conflicting jurisdictions. More research is needed regarding regulation, standardisation and cross-border health data retrieving policies. Furthermore, blockchain has not been shown to manage exponentially increasing amounts of data efficiently [85]. The integration of blockchain technology with deep learning and other artificial intelligence (AI) has been suggested to overcome its existing challenges, such as interoperability [83].

UE6 is *poor systems*. It has been shown that frameworks in PRSA are relatively unharmonised/ unstandardised, which acts as a bottleneck in the MDVC that leads to inferior medical devices on the market [68]. Without efficient medical device supply chain monitoring, counterfeit devices can occur on the market, which can endanger healthcare workers and patients. Many technologies were developed to combat the ramifications of COVID-19, and it became clear how the role of HTA bodies was underutilised. Mukherjee (2021) suggests that HTAs should be integrated into the health innovation ecosystem to assist in filling the gaps in performance as well as to address the challenges associated with implementation, scalability and sustainability in the healthcare system [69].

Figure 4.5 links the bottlenecks identified to the UEs they exacerbate. This relationship can be better viewed through fishbone analysis. The MDVC categories established in section 4.4 can be used to sort the bottlenecks (See Figure 4.6). Bottlenecks are mapped onto fishbone diagrams in Chapter 7.

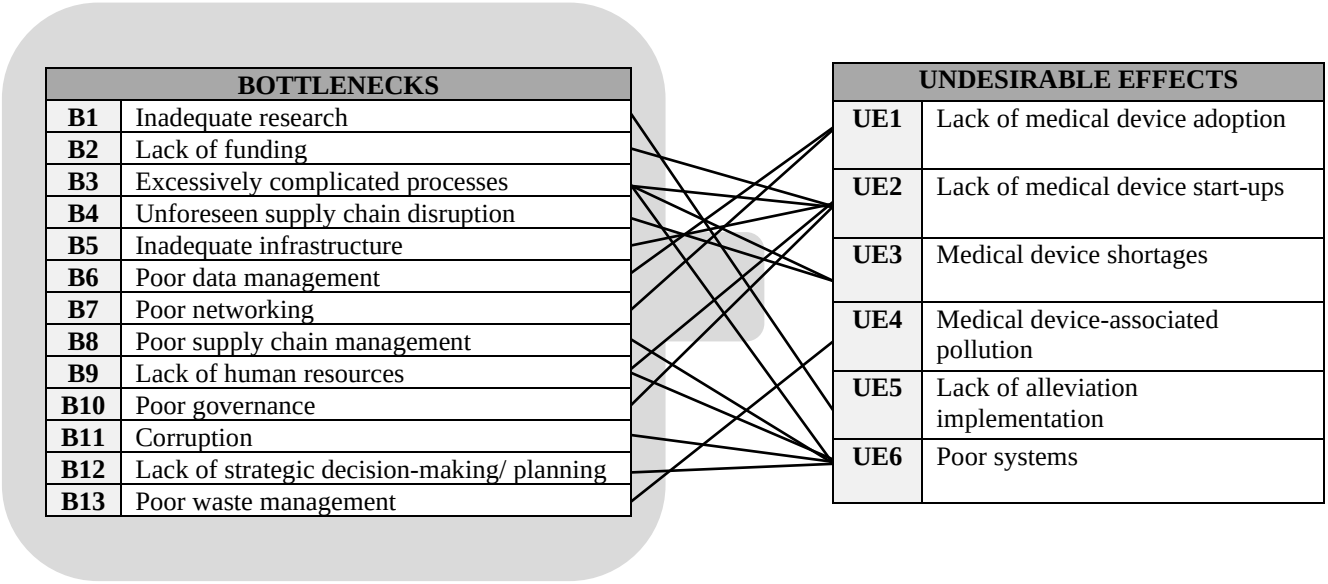


Figure 4.5: Identified bottlenecks linked to the undesirable effects that they exacerbate

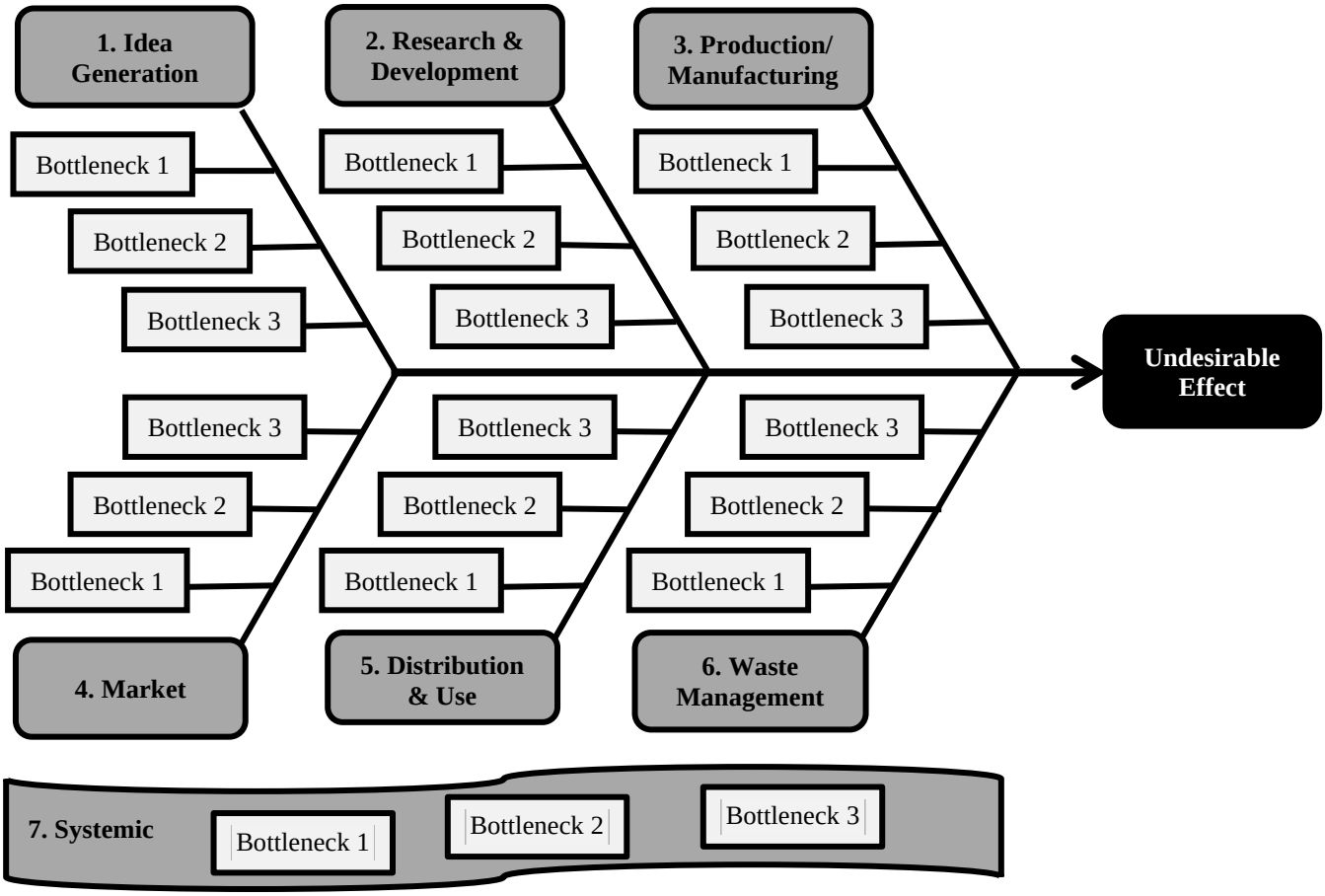


Figure 4.6: Fishbone diagram using the MDVC categories

4.6 Technology-based alleviations that promote desirable effects (DEs)

DEs are essentially the ideal outcomes/ goals that are aimed for at any stage of the MDVC. They are encouraged by alleviations of MDVC bottlenecks. Figure 4.7 gives the DEs identified and the alleviations that encourage them.

DE1 is *adoption of medical device*. Blockchain technology could be a solution to strengthening the traceability of medical devices in the MDVC. In turn, it could assist in identifying and removing counterfeit medical devices [71]. In the instance of a call-back (i.e., a medical device presents problems after distribution and all products must be recalled), it quickens the process and allows for transparency of the MDVC for all stakeholders [72]. Knowing that a device is compliant and not counterfeit strengthens its adoption by end-users. Similarly, strategic networking between end-users and developers/ innovators encourages medical device adoption.

Additionally, blockchain could also be used to store medical records electronically which would eliminate the common errors of patient mismatches in hospitals due to outdated on-paper records. Having medical data stored on a blockchain could give patients more power over their medical history which could allow researchers access to a large database of information that could focus their research (patients would effectively be able to grant access to their medical data anonymously) [73], [74], [85]. However, the matter of informed consent would have to be closely examined to ensure patients were not taken advantage of [72]. Zayas-Cabán, Chaney and Rucker (2020) also discuss how health information technology (IT) infrastructure can be used to advance biomedical research through the

development of 9 priorities [86]. Omar *et al.* (2021) showed that a blockchain-based solution to ineffective MDVC stakeholder collaboration is not only effective but can also be economically feasible [59].

Medical device supply chain transparency can be facilitated using universal barcoding technology [87]. QR codes can also be used to improve medical device supply chain transparency in low-income countries, as shown by the implementation of the EASE app in Africa [88]. Moreover, supply chain transparency and traceability allow for improved communication between MDVC stakeholders. A *software bill of materials* (SBOM) is a list of all software components in a finished product. It has been demonstrated that SBOMs have the potential to benefit certain MDVC stakeholders as they increase the transparency of supply chains. Thus, SBOMs could assist in the building of trust in connected technologies [89].

DE2 is the occurrence of *successful medical device start-ups*. TTOs such as AgorIP assist universities and the health system in providing research outputs using an open innovation approach wherein they connect innovators with relevant experts. AgorIP differs from traditional TTOs in that it includes research outputs from healthcare professionals [90]. However, academic TTOs quickly become overwhelmed, given insufficient capacity or resources to provide much-needed assistance [56]. This further hampers the success of biomedical start-ups with limited expertise in IP.

The benefits of utilising blockchain technology in supply chains include improved data management, transparency, quick response time, smart contract management, operational efficiency, disintermediation, immutability and IP management [70]. It has been shown that ongoing collaboration between regulatory bodies and innovators throughout the design process can encourage medical device success as it did for the developer of PVC tubing [61]. To encourage effective stakeholder collaboration, a study by Daiberl *et al.* (2019) demonstrated the use of web-based open innovation platforms to accelerate medical technology innovation in the current economic climate [50].

Moreover, Bhaskar *et al.* (2020) suggested that a scaled open innovation approach should be part of global supply chains to better prepare the world for crises such as the COVID-19 pandemic [82]. Daiberl *et al.* (2019) describe *open innovation* as "an approach for opening traditionally closed innovation processes to external actors and thus making use of networks of actors when innovating products, services, and business models" [50]. Open innovation platforms are multi-sided in that they include *seekers* (those with problems to solve), *solvers*, and *supporters*. *Supporters* include consultants with expertise in the innovation process, marketing, cluster management, legislation and IP, among other things. Web-based innovation platforms are essentially tech-based intermediaries as they facilitate and encourage effective collaboration among MDVC stakeholders online. Moreover, they provide biomedical start-ups with networks of MDVC stakeholders and the key expertise required to succeed. HICs maximise clinical impact by playing a strengthening role in translating biomedical research into better patient care [55], [56]. It is common for HICs to include a university and an academic medical centre or consortium. HICs offer expertise on the major obstacles within the MDVC (IP strategy, market analysis and regulations) to encourage the translation of biomedical research into clinical impact. HICs can also serve well in fostering the success of innovation endeavours by making their networks available to start-up clients in need of expert team members or consultants. Branding is also important for start-ups as procurers are reluctant to trust new brands over trusted established ones [22].

DE3 is the existence of *agile/ resilient supply chains*. COVID-19 shocked the healthcare system; however, it also allowed for health technology innovations to emerge as essential, such as additive manufacturing (AM) [81], which allowed for the rapid production of PPE to meet demands. Medical device alternatives had to be used in cases where shortages could not be met. In other instances,

devices had to be adapted in terms of how they were used. Essentially, COVID-19 accelerated medical device innovation [67] as stakeholders scrambled to do damage control. Similarly, the need for alternative/ emergency supply chains was revealed.

DE4 is *sustainable waste management*. This did not come up in the literature review but is included as holistic idea generation could be applied when crises such as COVID-19 occur. The recurring pattern in the literature was that AM or 3D printing of single-use PPE allowed manufacturers to meet accelerated demands. However, there was limited research regarding reusable, sustainable options.

DE5 is *successful implementation of alleviations.* Much of the literature discusses the potential benefits of blockchain technology in improving various MDVC VAs from procurement [59] to EMR storage [73]–[75]. However, these articles lack empirical proof of whereby blockchain's potential is realised. Thus, stakeholders are wary of implementing it. Strategic decision-making in research may result in empirical research which stakeholders would trust more.

DE6 is *system improvement.* Web-based innovation platforms could facilitate stakeholder communication through the creation of a network of multi-disciplinary experts. Web-based innovation platforms could fulfil the role of intermediaries. Including regulatory authority representatives on web-based innovation platforms could facilitate their earlier involvement in giving feedback on iterative prototyping. A web-based innovation platform would allow for effective consulting from industry experts who can determine early on whether medical devices will be of value or not. Web-based innovation platforms could facilitate learning, networking, and funding [50]. Funding is essential across the entirety of the MDVC. Lastly, governance in terms of incentives and policies is vital in encouraging MDVC systemic improvement.

Figure 4.7 links the bottleneck alleviations identified to the DEs they encourage. This relationship can be better viewed through reverse fishbone analysis. The MDVC categories established in section 4.4 can be used to sort the alleviations (see Figure 4.8). This is done in Chapter 7.

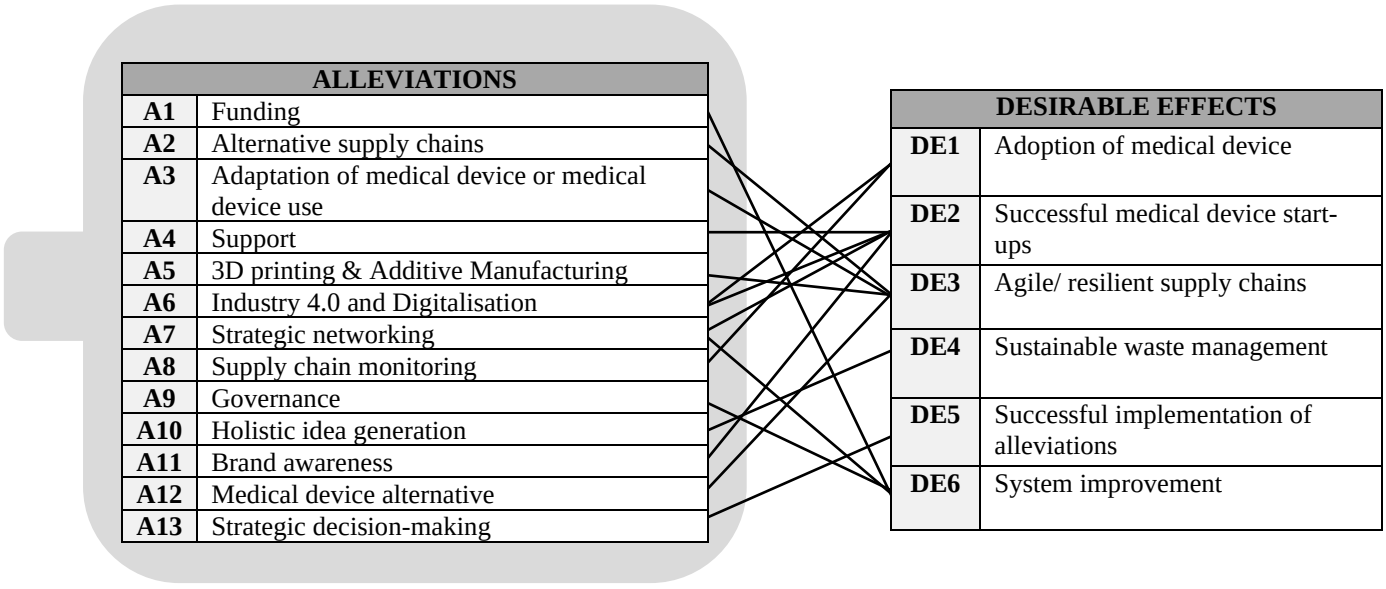


Figure 4.7: Bottleneck alleviations linked to the desirable effects that they encourage

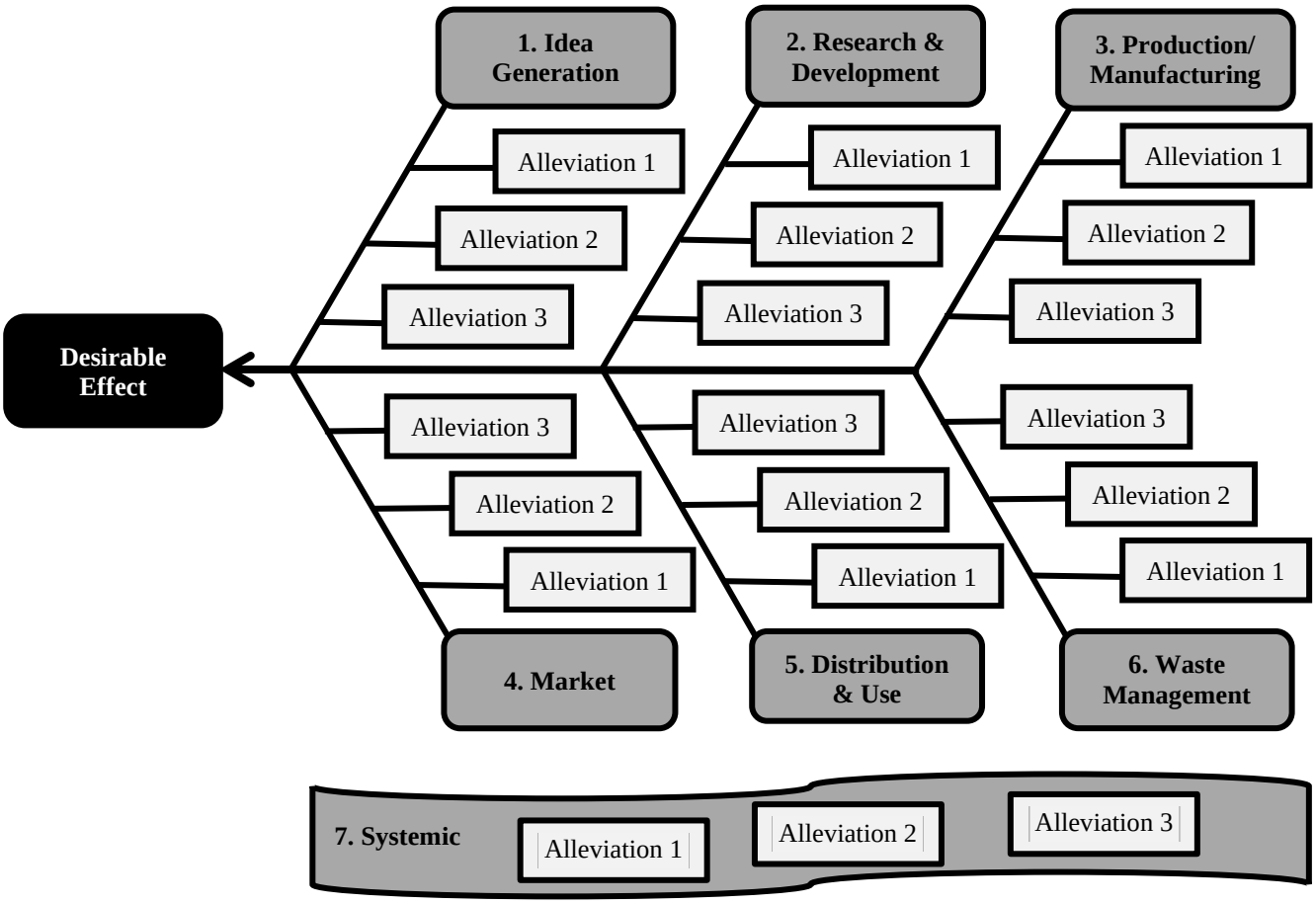


Figure 4.8: Reverse fishbone diagram using MDVC categories

4.7 Chapter 4 – Summary

Chapter 4 builds a literature database that can be used to determine the objectives/ design requirements of an artefact (solution). Thus, RO3 is contributed to. RQ1, RQ2 and RQ4 are partially answered (see Table 4.5). However, questions remain unanswered, necessitating a second systematic literature review in Chapter 5. Dated studies from the reference lists of included sources were added to facilitate the correct referencing of original ideas. Thirteen bottlenecks, six UEs identified, thirteen alleviations and six DEs were identified. These served as the coding system to better analyse the literature. Additionally, seven MDVC categories were established. They will be used to map the results through fishbone analysis in Chapter 7.

Table 4.5: Research questions answered and research objectives addressed in Chapter 4

PHASE 1: THEORETICAL		
RESEARCH QUESTIONS	**CH4 CONTRIBUTIONS**	☑
RQ1 – To what extent has the MDVC been mapped?	• Seven MDVC categories were established by overlapping existing variations found in the literature. • Waste management was not found to be examined through the search. Thus, a second literature review is necessary.	☑
RQ3 – What are the MDVC bottlenecks, and what UEs do they exacerbate?	• Six UEs were identified: (UE1) Lack of medical device adoption, (UE2) Lack of medical device start-ups, (UE3) Medical device shortages, (UE4) Medical device-associated pollution, (UE5) Lack of alleviation implementation and (UE6) Poor systems.	☑

	• Thirteen bottlenecks contributing to these UEs were identified: (B1) Inadequate research, (B2) Lack of funding, (B3) Excessively complicated processes, (B4) Unforeseen supply chain disruption, (B5) Inadequate infrastructure, (B6) Poor data management, (B7) Poor networking, (B8) Poor supply chain management, (B9) Lack of human resources, (B10) Poor governance, (B11) Corruption, (B12) Lack of strategic decision making/ planning and (B13) Poor waste management.	
RQ4 – Are there existing alleviations of MDVC bottlenecks, and what DEs would they encourage?	• Six DEs were identified: (DE1) Adoption of medical device, (DE2) Successful medical device start-ups, (DE3) Agile/ resilient supply chains, (DE4) Sustainable waste management, (DE5) Successful implementation of alleviations and (DE6) System improvement. • Thirteen bottleneck alleviations encouraging these DEs were identified: (A1) Funding, (A2) Alternative supply chains, (A3) Adaptation of medical device or medical device use, (A4) Support, (A5) 3D printing and Additive Manufacturing, (A6) Industry 4.0 and Digitalisation, (A7) Strategic networking, (A8) Supply chain monitoring, (A9) Governance, (A10) Holistic idea generation, (A11) Brand awareness, (A12) Medical device alternative and (A13) Strategic decision-making.	☑
RESEARCH OBJECTIVES	**CH4 CONTRIBUTIONS**	☑
RO3: Establish a literature base that can be used to determine the objectives/ design requirements of an artefact (solution).	• A coding system was applied to the literature findings to identify MDVC categories to be used in Fishbone analysis. • Bottlenecks and the UEs that they contribute to were identified. • Alleviations and the DEs that they encourage were identified.	☑

Chapter 5 - Systematic literature review of the MDVC and variations thereof

5.1 Overview of Chapter 5

Chapter 5 focuses on RO3 as it builds on the literature base from Chapter 4 in order to determine the objectives of the final artefact. The MDVC map is refined, the external environment is elaborated on, MDVC stakeholders are discussed, and existing MDVC bottlenecks and alleviations thereof are explored. The systematic literature review conducted in Chapter 4 did not allow for mapping the entirety of the MDVC. Waste management was not addressed, and alleviations identified were limited to being tech-based. Hence, the systematic literature review in Chapter 5 was conducted without the tech-based alleviation focus to ensure that no alleviation or method of bottleneck identification was overlooked. Figure 5.1 below illustrates the structure of this chapter.

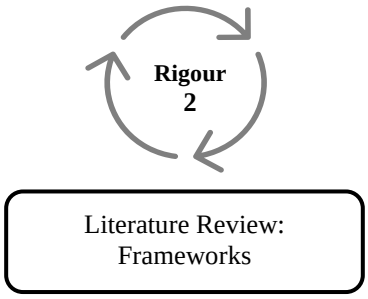
CHAPTER 5			
PHASE	**DSRM ACTIVITY**	**CYCLE & PROCESS FLOW**	**RESEARCH OBJECTIVE**
1: Theoretical Component	**2.** Define objectives of solution.		**RO3:** Establish a literature base that can be used to determine the objectives/ design requirements of an artefact (solution).

Figure 5.1: Research thesis outline - Chapter 5

5.2 The systematic literature review process

To achieve the objective of answering the research questions (RQs), this systematic literature review has been prepared following the PRISMA-P guidelines [48], [49]. The same process for conducting literature reviews used in Chapter 4 was applied in Chapter 5 (see Figure 4.2).

The goal of this literature review was to identify VAs in the MDVC as well as bottlenecks and alleviations thereof. Moreover, it aimed to reveal methods of identifying and alleviating MDVC bottlenecks. To achieve this goal, five RQs were developed (see Table 5.1). The RQs are the same as those used in Chapter 4 except for Q4, as alleviations were not limited to those that are “tech-based”.

Table 5.1: Research questions

ID	Research Question (RQ)
Q1	What tools/ frameworks have been used to map the MDVC?
Q2	What VAs occur in the MDVC? Moreover, which stakeholders perform these activities?
Q3	What bottlenecks disrupt VAs in the MDVC? Moreover, what are the UEs of these MDVC bottlenecks?
Q4	What alleviations of these bottlenecks have been suggested/ implemented? Moreover, what are the DEs of these alleviations?
Q5	What tools/ frameworks have been used to analyse MDVC bottlenecks/ alleviations thereof?

To find the studies needed in this literature review, the following digital databases were used: Web of Science, Scopus and PubMed. The following search criterion was set:

[(medical OR biomedical OR health OR healthcare) AND (device OR apparatus OR equipment OR machine OR tool OR instrument OR implement OR technology OR tech) AND (supply chain OR value chain OR innovation OR landscape OR map OR ecosystem OR system)].

The search resulted in a total of 320 articles on 21/03/2022. A total of 209 articles were found in the Web of Science database, 68 in the Scopus database and 43 in the PubMed database. Only review articles were included as review articles provide a critical evaluation of the data available from existing studies. Additionally, review articles identify gaps in current research. The exclusion criteria (EC) are provided in Table 5.2, and the inclusion criteria (IC) are provided in Table 5.3.

Table 5.2: Exclusion criteria

No.	Criterion
EC1	Not related to medical devices (related to pharmaceuticals); i.e., does not answer RQs 1-5.
EC2	Non-English publication.
EC3	Duplicated publication.
EC4	The publication is older than 2017.
EC5	Not a meta-analysis or a review article.

Table 5.3: Inclusion criteria

No.	Criterion
IC1	Maps a variation of the MDVC using a tool/ framework.
IC2	Discusses a VA that should be included in the MDVC.
IC3	Uses a tool/ framework to analyse MDVC bottlenecks.
IC4	Discusses a bottleneck in the MDVC that causes a UE.
IC5	Discusses an alleviation of a bottleneck in the MDVC that leads to a DE.

Figure 5.2 on the next page illustrates the data selection process using the PRISMA 2020 flow diagram for updated systematic reviews. After selecting the papers, data relevant to research questions were coded in ATLAS.ti. The coding system developed in Chapter 4 was used (see Figure 4.4).

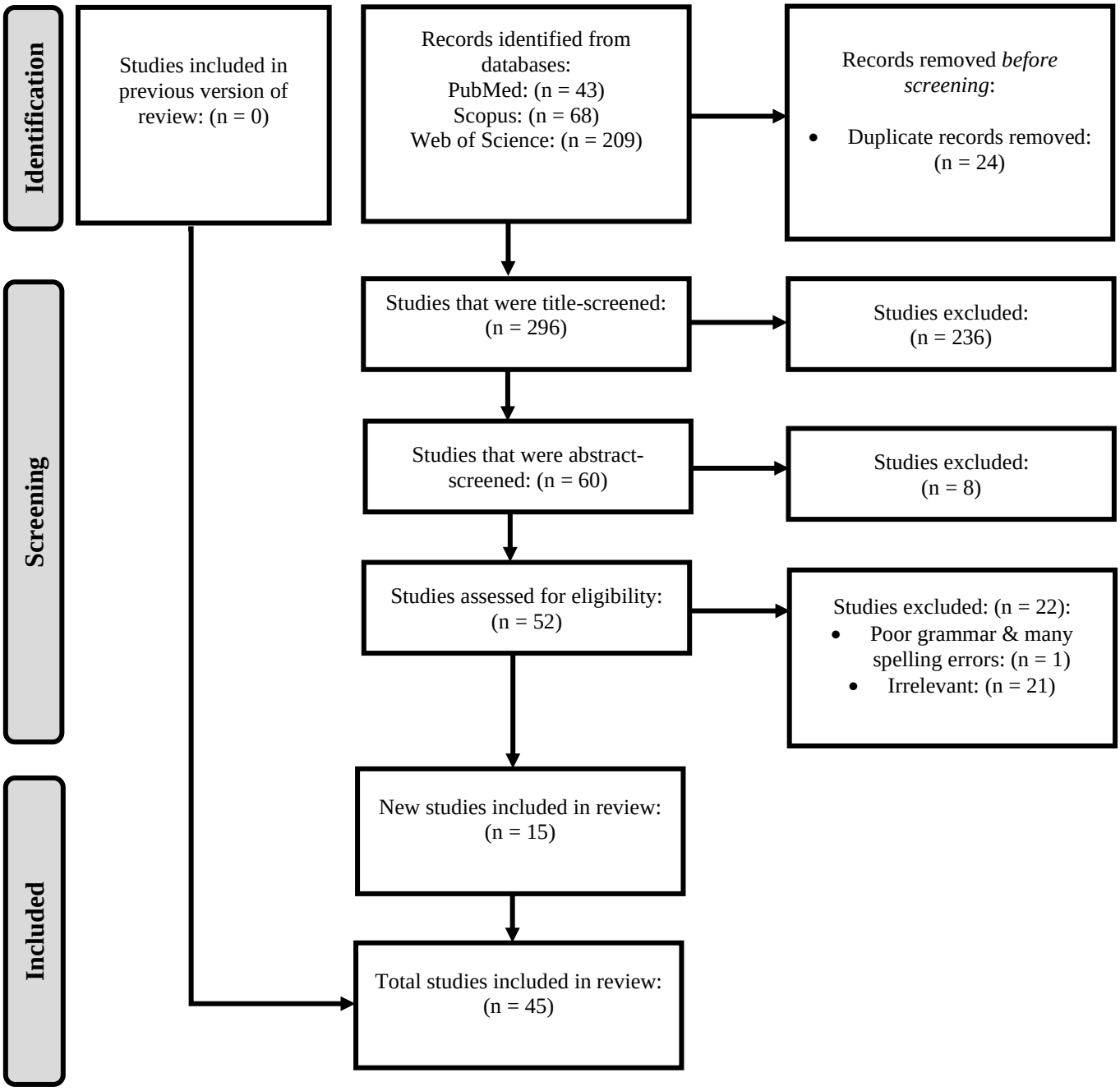


Figure 5.2: The data selection process

5.3 The MDVC and variations of it used to analyse bottlenecks and alleviations thereof

A complete map of the generic MDVC was not found in this systematic literature review. However, seven MDVC variations were found. Table 5.4 names the 7 MDVC variations identified and briefly describes each. The importance of coordination and integration across building blocks and levels of the health system was reinforced during the response to the COVID-19 pandemic [92]. Hence, this was also included as a systemic VA.

Table 5.4: MDVC variations identified

MDVC VARIATION	BRIEF DESCRIPTION
Value chain of PoC diagnostic devices	The value chain of point of care (PoC) diagnostic devices has been mapped and examined to facilitate the identification of bottlenecks preventing their widespread application in resource-limited settings [93]. This mapping included MDVC VAs from the start of research at universities to patient treatment. The following categories were used: (1) *Research*; (2) *Prototype*; (3) *Market introduction* (includes regulations); (4) *Market penetration* (includes distribution), and (5) *Usage*. However, idea generation and waste management were not included.
Conceptual framework for hospital supply chain management	A conceptual framework for hospital supply chain management has been proposed, given the lack of existing literature on sustainable supply chain management in the healthcare sector [94]. The framework is composed of 12 categories of management practices: (1) *strategic management and leadership*; (2) *supplier management*; (3) *purchasing*; (4) *warehousing and inventory*; (5) *transportation and distribution*; (6) *information and technology*; (7) *energy*; (8) *water*; (9) *food*; (10) *hospital design*; (11) *waste* and (12) *customer relationship management*. The *food* category (9) is not applicable in the MDVC, but the other categories can be applied. Performance categories include (1) *economic*; (2) *environmental*, and (3) *social factors*.
Forward supply chain and waste management processes	Forward supply chain and waste management processes include (1) *manufacturing*; (2) *distribution*; (3) *waste generation* (hospitals/ testing centres); (4) *waste collection* (waste store room); (5) *waste transportation*; (6) *waste segregation/ sorting*; (7) *waste treatment* (incineration, gasification) and (8) *waste disposal and recycling* [95]. Idea generation, research & development, and production are not considered.
The sanitation value chain	The sanitation value chain includes (1) *waste generation*; (2) *waste collection*; (3) *waste conveyance*; (4) *waste treatment*, and (5) *waste disposal* [96].
Design control model for medical device development	The design control model is a formal methodology that can be applied to product development activities. It involves the identification of design flaws, the creation of several design concepts as well as the verification and validation of the design's effectiveness. It is composed of the following correlated classes: (1) *user needs*; (2) *design inputs*; (3) *design processes*; (4) *design outputs*; (5) *design verification*; (6) *design validation*, and (7) *design reviews*. This design control model has been suggested by the FDA for medical device development [97]. The model does not consider manufacturing, distribution, storage/ warehousing, or waste management.
The health supply chain system	The health supply chain system in Uganda has been examined to identify bottlenecks contributing to poor access to essential medicines and health supplies [98]. The health supply chain system consists of structures and processes that ensure the sourcing of equipment, commodities and supplies; purchasing and procurement; transportation and distribution of products to the end-user [99], [100]. This definition leaves out idea generation, research and development, end-use, as well as waste management. Each of these could contain bottlenecks that contribute to poor access to essential medicines and health supplies in Uganda.
Fishbone analysis of factors contributing to the PPE shortage	Fishbone analysis has been used to examine the shortage of PPE for US Healthcare Workers. Four categories were identified into which various bottlenecks contributing to the PPE shortage were grouped, namely: (1) *Hospitals*; (2) *Government Failure*; (3) *Demand Shock*; and (4) *Supply Chain* [101]. This MDVC variation did not consider waste management.

5.4 Undesirable effects (UEs) and the MDVC bottlenecks that exacerbate them

The six UEs identified in Chapter 4 were again used. Bottlenecks exacerbating these UEs are discussed and visualised below.

UE1 is the *lack of medical device adoption*. The place of sale/ use is often not considered, resulting in a lack of adoption by end-users as the device is either too expensive or requires infrastructure that is not available [93]. Healthcare workers will not use devices that do not work in their environment. For example, rural healthcare providers prefer PoC diagnostic devices as they can diagnose the patient there and then and do not require expensive laboratory facilities that may be unavailable [93]. There is a need for improved research generalisability, empirical validation, integrative addressing, and deeper analysis of relationships between practices and performance in the health sector [94]. Inadequate funding has been identified as a bottleneck that threatens access to essential medical devices in Uganda [98]. If the end-user cannot afford the device, it will not be adopted. A lack of government incentives has been identified as a bottleneck limiting adequate research in the MDVC of PoC diagnostic devices [93]. Figure 5.3 maps the bottlenecks exacerbating UE1.

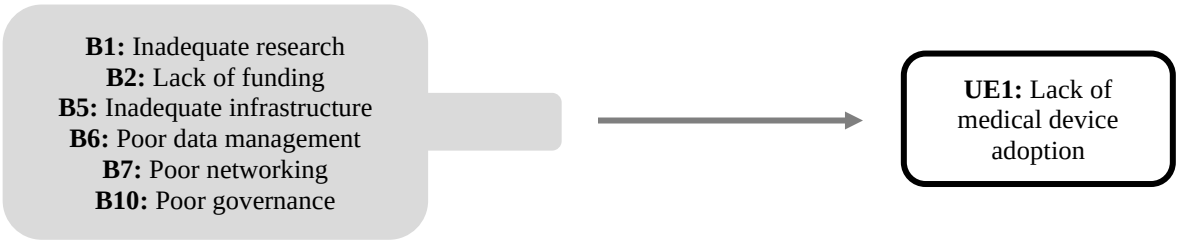


Figure 5.3: Bottlenecks exacerbating UE1: Lack of medical device adoption

UE2 is the *lack of medical device start-ups.* Heavy regulations complicate the implementation of potential smart (computer science-based) solutions [102]. Thus, the implementation and experimentation of new technologies in the medical device manufacturing field are particularly challenging. This limits the creation of medical device innovations and successful start-ups. Figure 5.4 maps the bottlenecks exacerbating UE2.

Figure 5.4: Bottlenecks exacerbating UE2: Lack of medical device start-ups

UE3 is the occurrence of *medical device shortages.* Inadequate funding, a lack of human resources (HR) trained in supply chain management, weak and poorly institutionalised logistic management information systems (LMISs), poor physical infrastructure and rigid government policies regarding task sharing have been identified as bottlenecks that exacerbate contraceptive stockouts in low- and middle-income countries (LMICs) [103]. Poor transportation channels, i.e., inadequate roads, disrupt the transportation of medical devices [93] and lead to their last-mile unavailability [104].

Additionally, the unforeseen onset of the COVID-19 pandemic exacerbated bottlenecks in modern healthcare systems leading to several UEs [105]–[109], including shortages of ventilators [110] and PPE [101], [111]. Lockdowns were implemented globally to prevent the spread of COVID-19. In

turn, internationally operating manufacturers had to shut down their plants which also contributed to critical medical device supply shortages [112]. Hospitals are short-term cost minimizers and, thus, often do not store sufficient PPE reserves, which contributed to the PPE shortages in the US following the onset of the COVID-19 pandemic [101].

Poor data management (including data acquisition, storage, and sharing) has been identified as a bottleneck contributing to poor medical device access [104]. The *infodemic* came along with the COVID-19 pandemic (the worldwide spread of misinformation) [107]. Consumers hoarded PPE, the healthcare system's demand sky-rocketed, and the demand by the general public increased, given that many countries implemented mask mandates [101]. Reliance on imports also put countries at a higher risk of PPE shortage when COVID-19 disrupted traditional supply chains [101]. Much of the global supply of PPE originates in China [113]. Figure 5.5 maps the bottlenecks exacerbating UE3.

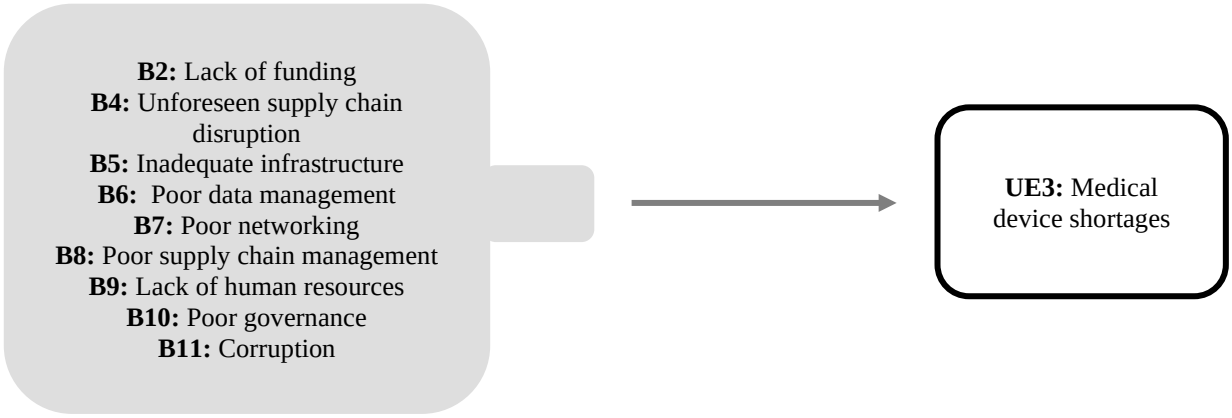


Figure 5.5: Bottlenecks exacerbating UE3: Medical device shortages

UE4 is *medical device-associated pollution.* Menstrual hygiene management (MHM) literature focuses on absorbent access and not on the disposal of menstrual waste. In turn, the disposal of menstrual waste is often neglected in MHM and sanitation value chains. This leads to improper disposal and negative impacts on the users, the sanitation systems and the environment [96]. The COVID-19 pandemic highlighted weaknesses in national healthcare systems, including that of the US. To meet the extreme demand for PPE at the height of the pandemic, MDVC stakeholders opted for disposable solutions given their convenience, while sustainable solutions were often overlooked [114]. PPE usage and packaging materials contributed to increased plastic use amid the pandemic [115]. In the short-term, disposable PPE alleviated the bottlenecks that caused shortages worldwide. However, its long-term consequences were not considered. Such consequences included exacerbated supply chains, financial burden and waste [114]. Figure 5.6 maps the bottlenecks exacerbating UE4.

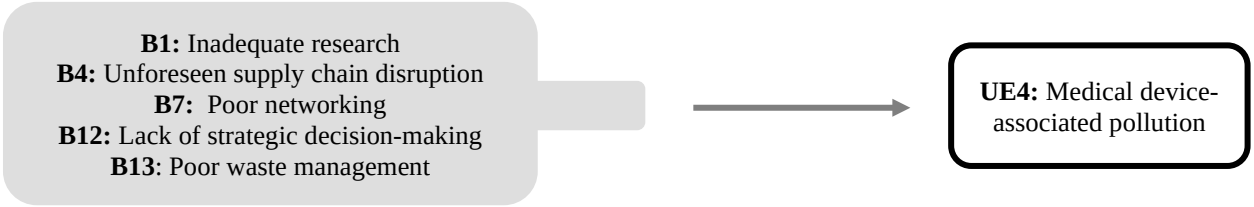


Figure 5.6: Bottlenecks exacerbating UE4: Medical device-associated pollution

UE5 is the *lack of alleviation implementation.* Four broad themes emerged in supply chain research following the COVID-19 pandemic: (1) *impacts of the COVID-19 pandemic*, (2) *resilience strategies*

for managing impacts and recovery, (3) *the role of technology in implementing resilience strategies* and (4) *supply chain sustainability in the light of the pandemic*. However, studies often lacked empirical design and theoretical grounding [105]. This reinforces the bottleneck of inadequate research as there is not a lack of research but rather a lack of useful research for industry stakeholders who value pragmatism.

Much of the literature regarding the application of blockchain technology details the technical performance of blockchain prototype platforms or the technical design of blockchain. Limited literature shows real-world clinical applications and the adoption of blockchain technology [116]. This results in a lack of alleviation implementation. Similarly, studies regarding blockchain applications in the biomedical domain are limited to the conceptual or architectural design phases. Very few studies report on the real-world demonstration and evaluation of blockchain in the biomedical domain [117]. There is not enough research regarding implementing a hybrid blockchain platform to minimise its challenges. Hybrid blockchain challenges relate to portability, resources, interoperability, computational power and scalability [118]. The bottlenecks to adopting blockchain-enabled information sharing include users' lack of understanding and conflict of interest [119]. The use of blockchain technology in healthcare and global health is limited [120]. Many alleviations are still in the early stages of Research & Development (R&D) due to a lack of testing [102].

The health supply chain system in Uganda has received increased investments; however, access to essential medicines and health supplies remains challenging. This reinforces how system weaknesses are not always a result of a lack of interventions but rather the result of the unsuccessful implementation of such interventions. Uganda's health supply chain system has been looked at across all levels to identify bottlenecks. The bottlenecks identified include an ineffective structure to support planning, coordination, and management; inadequate funding; shortage of skilled staff; weak regulatory and governance structures at national and sub-national levels as well as slow adoption and use of Electronic Logistics Information Systems to support supply chain processes and functions [98]. The implementation costs of public health interventions are often not accounted for, leading to unsuccessful implementation [121]. Figure 5.7 maps the bottlenecks exacerbating UE5.

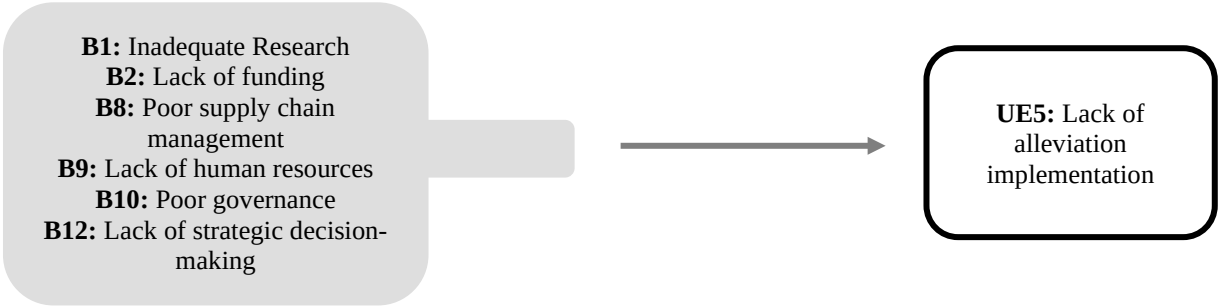


Figure 5.7: Bottlenecks exacerbating UE5: Lack of alleviation implementation

UE6 is *poor systems*. There is limited research that fulfils the requirement of classifying medical devices for management purposes (e.g., inventories, databases, and supply chains) [122], thereby worsening these activities in the MDVC. The MDVC is a system as it is a group of interacting elements that are bound by a set of rules. This system cannot operate without funding at various points [93]. Data regarding the actual cost of supply chain operation is rarely known in the public sector, and thus supply chain management is often not funded strategically [104].

Additionally, several complicated processes exist in the MDVC, which are very difficult to navigate. IP issues have been identified as one of the biggest bottlenecks inhibiting widespread AM implementation [123]. Moreover, regulatory barriers are repeatedly cited as bottlenecks in the MDVC

[93], [98], [122]. Medical devices must comply with current regulations that continuously evolve. The procurement of devices is complex and involves requirement determination, source selection, quotation requests, vendor selection and more [124].

The COVID-19 pandemic disrupted healthcare worldwide. LMICs were at a greater disadvantage given their limited access to resources, poor healthcare infrastructure, and overcrowding [125]. The pandemic revealed a lack of guidance to support supply chain management and practice resilience in primary care [126].

Paper/ non-digital data has been identified as a bottleneck as it cannot be transferred via digital platforms, and thus, the interpretation of it is impaired [104]. The integration and analysis of data from multiple sources are complex. This contributes to a lack of strategic (data-driven) decision-making [104].

Poor infrastructure and weak supply chains were identified as bottlenecks preventing integrated health service delivery (IHSD) [92]. Poor supply chain management (including a lack of integrated services) leads to poor data management, HR challenges and transportation difficulties [104]. Supply chains consist of multiple stakeholders, including suppliers, carriers, and customers. Given the rapid globalisation of supply chains and increased competition, information sharing within supply chains has become fragmented [119]. Global health disparities are exacerbated by error-prone information technology systems, administrative inefficiencies and wasteful global health spending [120]. A shortage of skilled staff has repeatedly been cited as a bottleneck in MDVCs or variations thereof [98]. A lack of HR was also identified as a bottleneck preventing IHSD [92].

Poor governance (including accountability drawbacks) has been identified as an MDVC bottleneck. Formal and informal incentives in public health supply chain systems and the workforce that manages them can be misaligned with public health goals at multiple levels (from warehouse and clinic staff to policymakers). This can lead to inaction, poor decision-making or rent-seeking behaviours [104]. Figure 5.8 maps the bottlenecks exacerbating UE6.

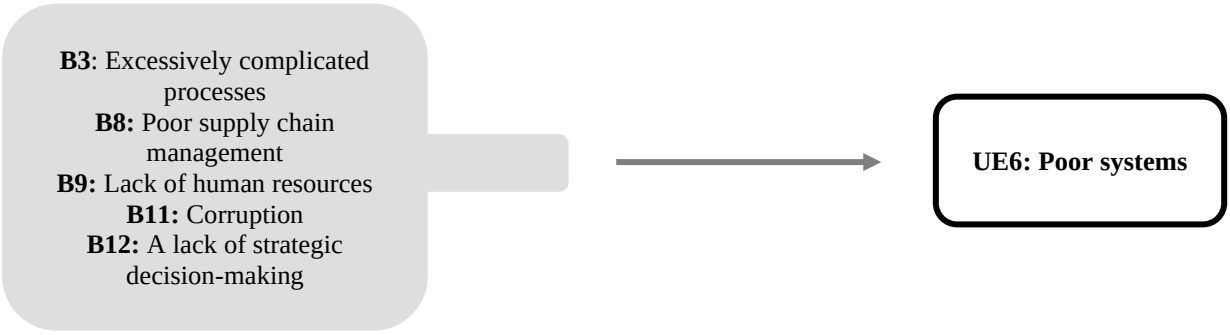


Figure 5.8: Bottlenecks exacerbating UE6: Poor systems

The UEs and their exacerbating bottlenecks can be mapped and analysed through fishbone analysis. The MDVC categories established in section 4.4 can be used to sort the bottlenecks (see Figure 4.6). This is done in Chapter 7.

5.5 Desirable effects (DEs) and the alleviations that encourage them

DEs are essentially the ideal outcomes/ goals at any stage of the MDVC. They are encouraged by alleviations of MDVC bottlenecks.

DE1 is *adoption of medical device*. End-users are more likely to adopt a device if they have a relationship with the developer or if they are included in the development [93]. Figure 5.9 maps the alleviations encouraging DE1.

Figure 5.9: Alleviations encouraging DE1: Adoption of medical device

DE2 is the occurrence of *successful medical device start-ups.* Strategic funding can strengthen various stages of the MDVC. It strengthens research, assists start-ups in overcoming the costly regulatory process and allows companies to scale up [93]. Figure 5.10 maps the alleviations encouraging DE2.

Figure 5.10: Alleviations encouraging DE2: Successful medical device start-ups

DE3 is *agile/ resilient supply chains*. Four themes related to leadership and management of pandemic PPE supply chains have been identified: (1) Leadership and management learning for pandemic PPE supply chain management; (2) Inhibitors of PPE supply chain resilience during a pandemic; (3) Facilitators employed to manage immediate impacts of PPE supply chain demands during a pandemic and (4) Facilitators proposed to ensure longer term resilience of PPE supply chains during pandemics [127]. Shared designs already approved by other regulatory authorities easily obtained government approvals [123]. This highlights the value of information-sharing and support when it comes to navigating the regulatory environment.

Panic buying contributed to stockouts and supply chain disruption amid the COVID-19 crisis. Panic buying is influenced by (1) individuals' perception of the threat of the health crisis and scarcity of products; (2) fear of the unknown; (3) coping behaviour, and (4) social psychological factors (influenced by social networks). Appropriate policies and strategies to manage panicking can be implemented by health professionals, policymakers and retailers. Retailers can play a role in alleviating panic buying by implementing purchasing limits and encouraging online purchases [128]. The reuse, recycling and reconditioning of PPE became necessary to mitigate the challenges imposed by the severe shortage following the onset of the COVID-19 pandemic [129]. Figure 5.11 maps the alleviations encouraging DE3.

Figure 5.11: Alleviations encouraging DE3: Agile/ resilient supply chains

DE4 is *sustainable waste management.* Several alleviations have been suggested to increase supply chain efficiency and PPE's safety and availability and reduce the environmental damage caused [130]. Firstly, the proper use of PPE must be communicated effectively to the end-user (i.e., how to don and doff). Additionally, reusable PPE clothing reduces waste and increases the agility of supply chains in times of crisis. Moreover, it is cost-effective. Also, smart e-textiles are enticing interest. Lastly, government policies promoting the use of sustainable and reusable PPE should be encouraged [130]. Figure 5.12 maps the alleviations encouraging DE4.

Figure 5.12: Alleviations encouraging DE4: Sustainable waste managment

DE5 is the *successful implementation of alleviations.* To overcome inadequate funding, poor supply chain management, a lack of human resources and poor governance in Uganda, the following alleviations were suggested: greater investments to improve policy development and implementation, infrastructure, equipment and support systems, knowledge and skills of supply chain personnel, increased funding and improving governance and accountability [98]. Strategic decision-making can be guided by machine-learning models. However, whether a decision maker accepts the recommendation is a separate issue. It has been noted that in certain contexts (e.g., medicine), a decision-maker is unlikely to follow a recommendation if they cannot understand how it was made.

Therefore, interpretable strategic decision-making should be focused on when creating decision-making tools such as machine-learning models [131]. This also highlights a disconnect between the end-user of an MDVC alleviation and the MDVC alleviation creator. The creator addressed the problem in a technical manner instead of taking a holistic approach incorporating end-user feedback during alleviation development. Figure 5.13 maps the alleviations encouraging DE5.

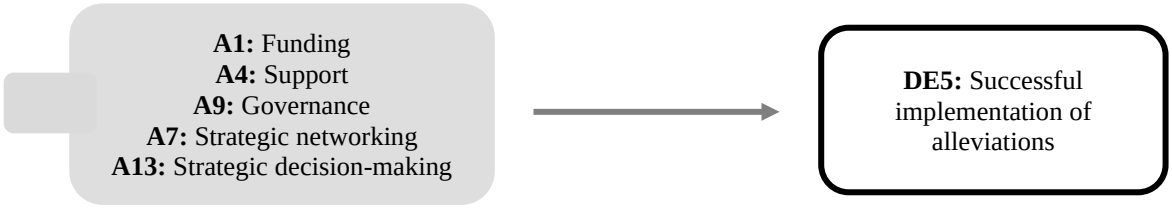


Figure 5.13: Alleviations encouraging DE5: Successful implementation of alleviations

DE6 is *system improvement.* A lack of HR (e.g., lack of necessary competencies and accountability) has been identified as a bottleneck contributing to the unavailability of devices in the last mile of the MDVC. A digital platform has been proposed to alleviate this [104]. Blockchain technology can be used to improve clinical trial management by reducing trial timelines, ensuring transparency and traceability of patient records, facilitating data sharing and ensuring regulatory compliance [107]. The supply chain management crypto and blockchain platform, VeChain, ensures that new KN95 masks imported from China are credible and reliable while collaborating with production offices and facilities [132]. MiPasa is a worldwide scale control and correspondence system controlled by

blockchain innovation which supports gathering, collating and studying data regarding COVID-19's spread and containment. MiPasa was launched by WHO in collaboration with organisations and governments [133]. MiPasa has been described as an "asset that has expectations to help public health officials, the scientific and business network, and people in general" [107]. It has been suggested that future work regarding information hiding and sharing could encourage the adoption of blockchain-enabled information systems in supply chains [119].

Many regulatory measures were introduced temporarily to mitigate the impact of the pandemic. It would be valuable to leverage these approaches to strengthen the regulatory environment [134]. An overview of the regulatory approaches adopted in response to the COVID-19 pandemic revealed the value of accelerated regulation and supply chain agility. Agile approaches were identified and categorised where health/ regulatory authorities had: (1) facilitated product management across the entire lifecycle, notably in expediting medical product use for COVID-19, ensuring the continuity of clinical trials, and addressing supply chain issues; (2) strengthened international cooperation and (3) addressed the regulatory burden with the adoption of electronic and digital tools [134]. Navigable regulations will streamline the route to market for device companies [93]. Figure 5.14 maps the alleviations encouraging DE6.

Figure 5.14: Alleviations encouraging DE6: System improvement

5.6 Chapter 5 - Summary

Chapter 5 builds on the literature database from Chapter 4. RO3 is achieved in that a full literature database is established that can be used to guide the development of artefact requirements in Chapter 6. Dated studies from the reference lists of included sources were added to facilitate the correct referencing of original ideas. RQ1, RQ2 and RQ4 are partially answered (see Table 5.5). Dated studies from the reference lists of included sources were added to facilitate the correct referencing of original ideas. Thirteen bottlenecks, six UEs identified, thirteen alleviations and six DEs were identified. These served as the coding system to better analyse the literature. Additionally, seven MDVC categories were established. They will be used to map the results through fishbone analysis in Chapter 7.

Table 5.5: Research questions answered and research objectives addressed in Chapter 5

PHASE 1: THEORETICAL		
RESEARCH QUESTIONS	**CH5 CONTRIBUTIONS**	☑
RQ1 – To what extent has the MDVC been mapped?	• Seven MDVC categories were established by overlapping existing variations found in the literature. • Waste management found to be examined through the search. Thus, it was included.	☑
RQ3 – What are the MDVC bottlenecks, and what UEs do they exacerbate?	• Six UEs were identified: (UE1) Lack of medical device adoption, (UE2) Lack of medical device start-ups, (UE3) Medical device shortages, (UE4) Medical device-associated pollution, (UE5) Lack of alleviation implementation and (UE6) Poor systems.	☑

	• Thirteen bottlenecks contributing to these UEs were identified: (B1) Inadequate research, (B2) Lack of funding, (B3) Excessively complicated processes, (B4) Unforeseen supply chain disruption, (B5) Inadequate infrastructure, (B6) Poor data management, (B7) Poor networking, (B8) Poor supply chain management, (B9) Lack of human resources, (B10) Poor governance, (B11) Corruption, (B12) Lack of strategic decision making/ planning and (B13) Poor waste management.	
RQ4 – Are there existing alleviations of MDVC bottlenecks, and what DEs would they encourage?	• Six DEs were identified: (DE1) Adoption of medical device, (DE2) Successful medical device start-ups, (DE3) Agile/ resilient supply chains, (DE4) Sustainable waste management, (DE5) Successful implementation of alleviations and (DE6) System improvement. • Thirteen bottleneck alleviations encouraging these DEs were identified: (A1) Funding, (A2) Alternative supply chains, (A3) Adaptation of medical device or medical device use, (A4) Support, (A5) 3D printing and Additive Manufacturing, (A6) Industry 4.0 and Digitalisation, (A7) Strategic networking, (A8) Supply chain monitoring, (A9) Governance, (A10) Holistic idea generation, (A11) Brand awareness, (A12) Medical device alternative and (A13) Strategic decision-making.	☑
RESEARCH OBJECTIVES	**CH5 CONTRIBUTIONS**	☑
RO3: Establish a literature base that can be used to determine the objectives/ design requirements of an artefact (solution).	• A coding system was applied to the literature findings to identify MDVC categories to be used in Fishbone analysis. • Bottlenecks and the UEs that they contribute to were identified. • Alleviations and the DEs that they encourage were identified.	☑

Chapter 6 - Framework design requirements

6.1 Overview of Chapter 6

Chapter 6 begins with a discussion of conceptual framework features. Next, these features are used to guide the development of design requirements that incorporate the relevant concepts identified in Chapters 1, 2, 4 and 5. Finally, existing MDVC conceptual frameworks and variations thereof are analysed to determine the critical VAs and MDVC categories that must be included in a holistic MDVC map. The context of Chapter 6 in terms of the DSRM process is illustrated in Figure 6.1.

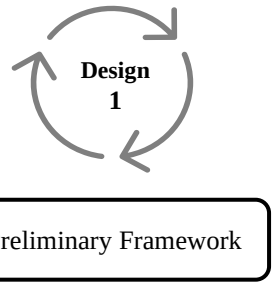
CHAPTER 6			
PHASE	**DSRM ACTIVITY**	**CYCLE & PROCESS FLOW**	**RESEARCH OBJECTIVE**
1: Theoretical Component	**3.** Design & development.		**RO4:** Translate relevant concepts from literature into artefact design requirements. **RO5:** Develop preliminary artefact.

Figure 6.1: Research thesis outline - Chapter 6

6.2 Conceptual framework features

Miles and Huberman (1994) define a conceptual framework as follows [40]:*"A conceptual framework explains, either graphically or in narrative form, the main things to be studied- the key factors, constructs, or variables- and the presumed relationships among them. Frameworks can be rudimentary or elaborate, theory-driven or commonsensical, descriptive, or causal."*. Table 6.1 gives seven key features of conceptual frameworks.

Table 6.1: Key features of conceptual frameworks [41]

FEATURE	DESCRIPTION	REFERENCE(S)
Integrative	The collection of concepts or variables in a framework must exhibit some degree of coherence.	[135], [136]
Evolving	Conceptual frameworks are expected to evolve as the study progresses.	[42], [135], [136]
Constructability	The development of a conceptual framework involves the use of multi-disciplinary approaches.	[137]
Interpretative capacity	A conceptual framework presents hard facts using a soft interpretive approach. Essentially, it represents an integrative summary of issues within a given field of study, wherein the researcher can address a specific problem.	[137]
Indeterministic	A conceptual framework does not predict the exact outcome of activities. Instead, it can encourage specific outcomes.	[137]
Understanding	Conceptual frameworks facilitate the comprehension of phenomena.	[137]
Capacity for modification	Conceptual frameworks are subject to reconceptualisation and adaptation. This occurs following the evolution of research questions or as the result of new data/ publications becoming available.	[42]

Five categories of conceptual framework design requirements have been suggested: (1) *functional requirements*; (2) *user requirements*; (3) *design requirements*; (4) *boundary conditions*, and (5) *attention points* [138]. Each category is discussed on the next page:

1. ***Functional requirements (FR)*:** These are the core specifications often presented regarding the framework's demands or performance.
2. ***User requirements (UR)*:** Use-related requirements deemed necessary specifically from the framework user's perspective.
3. ***Design requirements (DR)*:** Requirements that set the limitations of the design and address the negotiable elements not covered.
4. ***Boundary conditions (BC)***: Framework requirements that must be adhered to unconditionally, e.g., ethical procedures.
5. ***Attention points (AP)*:** These are the conditional framework requirements that should be noted but are not necessary to adhere to (not design restrictions).

These requirements are expanded to guide the development of this framework in Table 6.2. Four *functional requirements* are given to ensure that the framework addresses the research problem/ gap. Namely, the entirety of the MDVC has yet to be mapped; thus, a holistic approach to problem-solving is lacking in the medical device sector. The three *user requirements* ensure that the framework is valuable to users while addressing the research problem. The five *design requirements* ensure a holistic approach to solving the research problem. By incorporating multiple stakeholders and, thus, several perspectives, the problem is examined to a greater extent. Additionally, the *design requirements* encourage solid theoretical support, thereby strengthening the framework's validity and improving the extent to which the MDVC is mapped. The *boundary conditions* specify the non-negotiable elements of the framework. In order to ensure BC1, semi-structured interviews were conducted, which required appropriate ethical clearance. Lastly, the two *attention points* are goals which may or may not be achieved by the framework depending on the results obtained in Chapter 7.

Table 6.2: Framework requirements

FRAMEWORK REQUIREMENT	ID #	DESCRIPTION
Functional requirements	FR1	The framework should map the entirety of the MDVC.
	FR2	The framework should encourage and enable a holistic approach to the identification of MDVC bottlenecks.
	FR3	The framework should encourage and enable the successful identification and implementation of MDVC bottleneck alleviations.
	FR4	The framework should identify how and where actors collaborate in the MDVC.
User requirements	UR1	The framework should assist the user to identify MDVC bottlenecks.
	UR2	The framework should assist the user to identify or implement existing MDVC bottleneck alleviations.
	UR3	The framework should assist the user in identifying MDVC VAs that require the most effort and have barriers that increase their difficulty.
Design requirements	DR1	The framework should incorporate multidisciplinary perspectives.
	DR2	The framework should incorporate theoretical components representative of multiple perspectives.
	DR3	The framework should outline the key MDVC categories.
	DR4	The framework should chronologically list the VAs under their appropriate MDVC category.
	DR5	The framework should have a strong theoretical base.
Boundary conditions	BC1	The framework should assist MDVC actors that operate in the Western Cape.
	BC2	The framework should be clear regarding how MDVC bottlenecks are identified.
Attention points	AP1	The framework should highlight critical MDVC bottlenecks.
	AP2	The framework should present potential MDVC bottleneck alleviations.

6.3 Analysing existing MDVC and fishbone analysis literature

6.3.1 Establishing MDVC categories

Based on the overlap of existing MDVCs and variations thereof, seven MDVC categories were established: (1) *Idea generation*, (2) *Research & Development*, (3) *Production/ Manufacturing*, (4) *Market*, (5) *Distribution and Use*, (6) *Waste Management* and (7) *Systemic*. VAs were identified through preliminary research and the two systematic literature reviews and were sorted under these categories and edited until a list of 74 activities was established. The categories are elaborated on below:

1. ***Idea Generation:*** The activities that contribute to identifying a need and theorizing a solution in the form of a medical device. This category also entails those activities involved in the justification of the medical device's conception, i.e., determining whether its regulation, patenting, development, and use are likely to be successful. Additionally, the capital and timeline needed should be mapped.
2. ***Research & Development:*** The activities that assist in proving that the theoretical solution works in practice. Moreover, the activities that show the device adheres to existing standards and regulations.
3. ***Production/ Manufacturing:*** The activities that allow for the mass production of the device and its sale.
4. ***Market:*** The activities involved in marketing and selling the device successfully.
5. ***Distribution & Use:*** The activities that ensure the device is stored, transported, and used safely.
6. ***Waste Management:*** The activities involved in the lifecycle of the medical device once it has been decommissioned/ disposed of.
7. ***Systemic:*** Activities that are conducted and add value at multiple points in the MDVC. Also, those activities that are performed throughout the MDVC.

The seven categories were established to facilitate fishbone analysis. Fishbone analysis is a form of cause-and-effect analysis wherein the causes of an effect are grouped under categories to facilitate a holistic approach to problem-solving. Bottlenecks are causes of UEs in the MDVC and can be represented graphically on a fishbone diagram. Alleviations are causes of DEs (or goals) and can be represented graphically on a reverse fishbone diagram.

6.3.2 Bottlenecks, undesirable effects, alleviations and desirable effects

Six UEs were identified: (UE1) *Lack of medical device adoption*; (UE2) *Lack of medical device start-ups*; (UE3) *Medical device shortages*; (UE4) *Medical device-associated pollution*; (UE6) *Lack of alleviation implementation* and (UE6) *Poor systems*. Bottlenecks that exacerbated these were sorted under the following codes: (B1) *Inadequate research*; (B2) *Lack of funding*; (B3) *Excessively complicated processes*; (B4) *Unforeseen supply chain disruption*; (B5) *Inadequate infrastructure*; (B6) *Poor data management*; (B7) *Poor networking*; (B8) *Poor supply chain management*; (B9) *Lack of human resources*; (B10) *Poor governance*; (B11) *Corruption*; (B12) *Lack of strategic decision-making*; (B13) *Poor waste management.*

Six DEs were identified: (DE1) *Adoption of medical device*; (DE2) *Successful medical device start-ups*; (DE3) *Agile/ resilient supply chains*; (DE4) *Sustainable waste management*; (DE5) *Successful implementation of alleviations* and (DE6) *System improvement*. Alleviations that encouraged these were sorted under the following codes: (A1) *Funding*; (A2) *Alternative supply chains*; (A3) *Adaptation of medical device or medical device use*; (A4) *Support*; (A5) *3D Printing & Additive Manufacturing*; (A6) *Industry 4.0 & Digitalisation*; (A7) *Strategic networking*; (A8) *Supply chain*

monitoring; (A9) *Governance*; (A10) *Holistic idea generation*; (A11) *Brand awareness*; (A12) *Medical device alternative* and (A13) *Strategic decision-making*.

6.3.3 Organising value-adding activities under MDVC categories

The 74 VAs were identified and ordered through two systematic literature reviews conducted in Chapters 4 and 5. Additional VAs identified through preliminary research in Chapters 1 and 3 were also included. Table 6.3 gives the VAs identified in the order in which they generally occur. Furthermore, they are sorted under their appropriate MDVC category.

Table 6.3 Value-adding activities to be included under each MDVC category

VALUE-ADDING ACTIVITY	REFERENCES
MDVC CATEGORY 1: IDEA GENERATION	
Develop relationships with potential end-users of medical device.	[53], [61]–[63], [93], [97]
Develop relationship with purchasers & procurers of potential medical device.	[59], [65], [66]
Discovery & ideation (identifying needs and coming up with ideas; TRL 1).	[11], [14]–[16], [139]
Acquire research funding.	[51]–[53], [63], [93]
Determine the classification & nomenclature of your proposed medical device.	[122]
Determine where the product will be sold and used (cultural and social considerations regarding the medical device, its use and disposal should be taken into account).	[62], [93], [96], [98]
Determine who will pay for the device (reimbursement).	[59], [62]
Perform due diligence and obtain IP protection.	[53], [56]
Forecast demand of potential medical device.	[11]
Identify route to market.	[53]
MDVC CATEGORY 2: RESEARCH & DEVELOPMENT	
Acquire seed funding.	[53]
Produce exploitation knowledge (knowledge required to transform research into commercial products).	[52]
Facilitate participatory knowledge spillovers in medical device clusters (readily available complementary local assets or capabilities).	[52]
Facilitate precipatory knowledge spillovers in medical device clusters (early access to local inventions, discoveries, or innovations).	[52]
Produce exploration knowledge (aim of fundamental research; TRL 2).	[11], [14]–[16], [52], [93]
Technology transfer.	[53]
Confirm route to market/ project plan (TRL 3).	[11], [14]–[16]
Invention & prototyping.	[93], [139]
Information sharing.	[73], [74], [85], [123], [140]
Development (TRL 4-5).	[11], [14]–[16], [93]
Develop a proof of concept (TRL 5).	[11], [14]–[16], [53]
Preclinical evaluation (TRL 6).	[11], [14]–[16], [52], [53]
Clinical trials I, II & III (TRL 7).	[11], [14]–[16], [52], [53]
Produce examination knowledge (includes feedback from medical device trials/ use).	[11], [14]–[16], [52], [97]
Regulate device (testing, QMS audit & validation; TRL 8).	[11], [14]–[16], [97]
MDVC CATEGORY 3: PRODUCTION/ MANUFACTURING	
Obtain seed funding.	[53]
Forecast demand of developed medical device.	[101], [106]–[112], [141]
Infrastructure investment.	[53]
Establish/ acquire manufacturing capabilities (ISO: 13485).	[95]
Facilitate information sharing.	[141]
Source equipment/ raw materials.	[94], [99], [100]
Determine emergency/ alternative manufacturing capabilities/ supply chains in case of disruptions.	[141]
Obtain marketing authorisation.	[53]
Package medical device.	[2]
Label medical device.	[2]
MDVC CATEGORY 4: MARKET	
Branding of medical device.	[93]

Advertise/ market medical device.	[52], [93]
Obtain endorsement from end-users.	[62]
Procurement of medical device (involves risk mitigation; contract compliance; cost savings; ongoing supplier relationships etc.).	[59], [62], [99], [100], [124]
Purchasing of medical device (aims to minimise the cost of an order).	[99], [100], [142]
Paying for medical device.	[142]
MDVC CATEGORY 5: DISTRIBUTION & USE	
Storage/ warehousing of medical device.	[52], [103], [143]
Inventory management.	[52], [95], [122]
Transportation of medical device.	[93], [99], [100]
Use of medical device (TRL 9).	[11], [14]–[16], [139]
Obtain feedback from end-user of medical device.	[93]
Post implementation improvement and adaptation of medical device.	[62]
Update clinical guidelines.	[62], [139]
Sterilisation & reuse.	[129]
Determine obsolescence & replacement of medical device.	[69], [139]
Decommissioning of medical device.	[69]
Waste generation.	[95]
Waste storage.	[95]
MDVC CATEGORY 6: WASTE MANAGEMENT	
Waste collection.	[95]
Waste transportation.	[95]
Waste segregation/ sorting.	[95]
Waste treatment.	[95]
Waste disposal/ recycling.	[2], [95]
MDVC CATEGORY 7: SYSTEMIC	
Registering stakeholders (SAHPRA).	[11]
Demand forecasting.	[131].
Ensure adequate staffing & train human resources.	[97], [103]
Supply chain monitoring (review distribution networks).	[71], [103]
Supply chain systems diagnostics.	[101], [103]
Ergonomics.	[94]
Data acquisition.	[104]
Data storage.	[104]
Data sharing.	[104]
Obtaining funding.	[53]
Legislative governance (making the rules).	[101], [103]
Executive governance (implementing the rules).	[101], [103]
Judicial governance (enforcing the rules).	[101], [103]
Crisis management planning.	[129]
Implementing alleviations to problems.	[92], [98], [105], [116], [118], [121], [131]
Coordination & integration across building blocks and levels of the MDVC.	[50], [92]

6.4 Chapter 6 – Summary

Chapter 6 is a conceptual literature review that translates the key concepts identified in Chapters 1-5 into artefact design requirements. The artefact is a conceptual framework. RO4 is achieved as five categories of conceptual framework requirements are developed. Additionally, a preliminary framework is given, thereby fulfilling RO5. Dated studies from the reference lists of included sources were added to facilitate the correct referencing of original ideas. Moreover, those found through preliminary research were added where applicable. RQ2 is contributed to as an artefact is developed that can be used to identify bottlenecks in the MDVC. The artefact is a chronological map of all the VAs that are included in the MDVC. By taking this holistic perspective, bottlenecks can be pinpointed, and their collective UE can be alleviated. Table 6.4 demonstrates the RQs contributed to and the ROs achieved in Chapter 6.

Table 6.4: Research questions answered and research objectives addressed in Chapter 6

PHASE 1: THEORETICAL		
RESEARCH QUESTIONS	**CH6 CONTRIBUTIONS**	☑
RQ2 – How can an artefact be used to identify bottlenecks in the MDVC?	• A full chronological MDVC allows for a holistic approach to bottleneck alleviation. • Five categories of conceptual framework design requirements were developed to ensure the artefact addresses the research gap/ problem.	☑
RESEARCH OBJECTIVES	**CH6 CONTRIBUTIONS**	☑
RO4: Translate relevant concepts from literature into artefact design requirements.	• Four FRs, three URs, five DRs, two BCs and two APs were developed (see Table 6.2).	☑
RO5: Develop preliminary artefact.	• A full MDVC map including 74 VAs is given in Table 6.3. • This serves as part of a conceptual framework for MDVC bottleneck identification and alleviation.	☑

Chapter 7 - Framework demonstration and evaluation

7.1 Overview of Chapter 7

Chapter 7 focuses on RO6, RO7, RO8 and RO9. An overview of evaluation methodologies is given. Then, survey development is discussed. Following this, the validity of the design requirements for the framework is evaluated through a survey. An overview of surveys and their advantages and disadvantages is given first. Additionally, the survey candidate inclusion criteria are defined. Then, the survey development and validation process are detailed. Lastly, the response data is presented through a functional analysis followed by a qualitative analysis and discussion. Figure 7.1 below illustrates the structure of this chapter.

<table>
<tr><th colspan="4">CHAPTER 7</th></tr>
<tr><th>PHASE</th><th>DSRM ACTIVITY</th><th>CYCLE & PROCESS FLOW</th><th>RESEARCH OBJECTIVE</th></tr>
<tr><td rowspan="2">2: Practical Component</td><td>4. Demonstration</td><td>Relevance 1
Expert Review
Design 2
Refined Framework</td><td>RO6: Review preliminary artefact with an appropriate expert and refine artefact accordingly.
RO7: Review evaluation methodologies.</td></tr>
<tr><td>5. Evaluation</td><td>Relevance 2
Semi-structured interviews & survey</td><td>RO8: Evaluate artefact using an appropriate methodology.
RO9: Analyse and discuss results.</td></tr>
</table>

Figure 7.1: Research thesis outline - Chapter 7

7.2 An overview of evaluation methodologies

Evaluation describes how merit, worth and something's significance is determined. All evaluation studies have a specific structure (see Figure 7.2). Different MDVC stakeholders evaluating an artefact may draw different conclusions regarding its value. Two forms of artefact evaluation are performed in a DSR project. The first evaluation is done to refine the artefact design, and the second includes

the field testing of the released artefact in the application environment [34]. Both evaluations will involve a survey and semi-structured interviews.

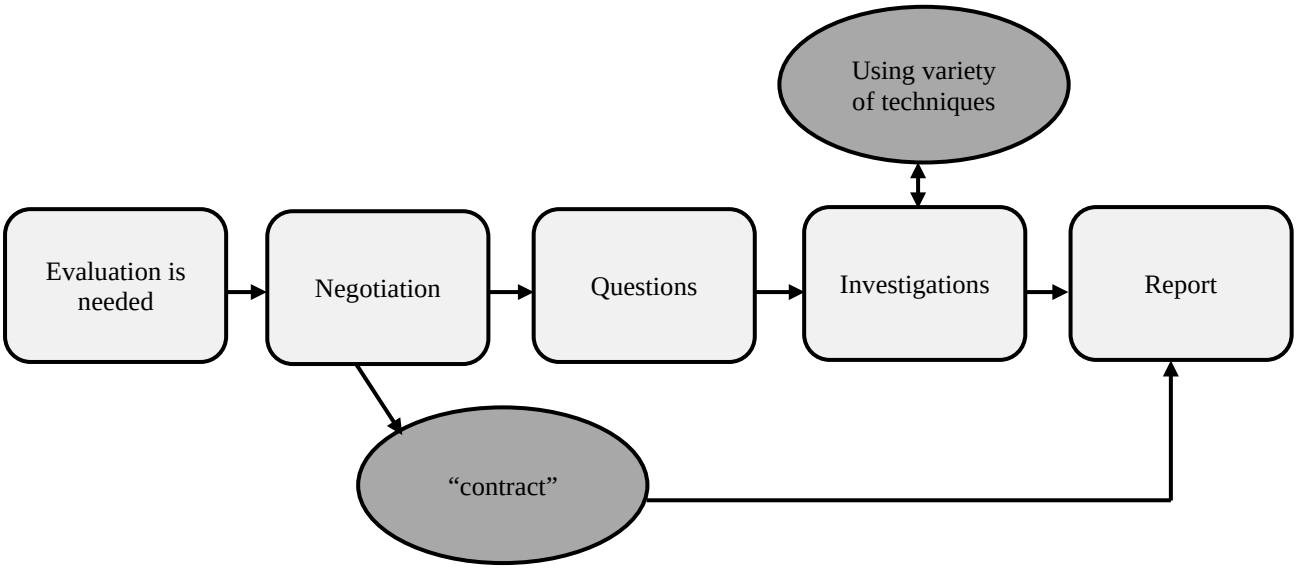


Figure 7.2: Structure of an evaluation study [34]

An artefact (product of DSR) can be evaluated concerning its technical aspects or with regards to its socio-technical aspects, including usefulness and organisational impact. In this thesis, the artefact will be evaluated regarding its socio-technical aspects. The needs and design requirements of the artefact can be evaluated through exploratory semi-structured interviews. After that, confirmatory semi-structured interviews can be used to evaluate the artefact once it is in use [34].

7.3 Survey development

Survey research has been defined as “the collection of information from a sample of individuals through their responses to questions” [144]. It can be used to systematically collect data from various individuals, such as MDVC stakeholders. Surveys serve as a time-efficient data collection method that respects the busy schedules of MDVC stakeholders. Surveys should maintain a consistent focus in that the questions should all directly relate to the research problem and population interviewed.

Two types of error can occur in surveys. Firstly, poor measurement of surveyed cases (*errors of observation*). Secondly, omission of cases that should be surveyed (*errors of non-observation*). Table 7.1 compares the sources of the two errors.

Table 7.1: Comparison of the sources of errors of observation and the sources of errors of non-observation [144]

SOURCES OF ERRORS OF OBSERVATION	SOURCES OF ERRORS OF NON-OBSERVATION
• The way questions are written. • The characteristics of respondents. • The presentation of questions. • The interviewer.	• Inadequate population coverage due to poor sampling frame. • Nonresponse to survey invitation or nonresponse to certain questions.

Survey questions are answered as part of a questionnaire or an interview schedule. A questionnaire contains questions in a self-administered survey, while an interview schedule contains the questions asked by the interviewer in an in-person or phone/ video survey [144].

Irrelevant questions are prevalent in surveys. Additionally, often crucial questions are excluded. To avoid these two happenings, the researcher can use questions supported by prior research, experience, or experts in the field under investigation [144]. The development of the survey instrument used in this study underwent three iterations wherein feedback was obtained by an expert in the academic field of medical devices. These iterations ensured that the questions were relevant and comprehensible and that the interview schedule would be most at 45 minutes. Changes that occurred during the iterations are documented in Table 7.2 below.

Table 7.2 Survey development iterations

SURVEY DEVELOPMENT ITERATION #	FEEDBACK FROM ACADEMIC EXPERT	CHANGES MADE
1	• Too many questions. • Redundant questions.	• Removed redundant questions. • Changed survey format from strictly qualitative questions to a combination of ranking questions and qualitative questions.
2	• Introductory presentation was too long. • Introductory presentation did not cover certain key points and left room for misunderstanding.	• Removed unnecessary information and slides from introductory presentation. • Added two slides that explained fishbone analysis. • Pre-recorded the presentation to ensure that in every interview it would be the same and would take under six minutes.
3	• Font was too small. • Certain questions were unclear and required clarification.	• Enlarged font size to 16 for headings and 14 for questions. • Added definitions in brackets to clarify unclear terms in questions.

The order of the questions in a survey is essential. It should be logical and comprehensible to the interviewee [144]. Given that the survey questions used in this study involve ranking the activities that occur in the MDVC, it made sense to list them in chronological order. Moreover, the activities were grouped into the seven MDVC categories determined through two systematic literature reviews. Interviewees could then disregard a category they were not directly involved in without being asked about every VA sorted under that category. For example, most interviewees were not involved in MDVC category six (*Waste Management*).

Additionally, the questionnaire should be visually attractive, i.e., neat, clear, clean, and spacious [144]. The questionnaire used in this study was built on Excel. The questions (VAs to be ranked) were listed vertically and grouped into their respective MDVC categories to facilitate comprehension. The rankings were listed in columns to the right, and drop-down lists were provided (1-5 & NA). Vertical scrolling was required to go through the list; however, every column fit the screen horizontally. The titles of each column (*MDVC category*, *Value-adding activity*, *Effort*, *Difficulty* & *Importance*) were pinned so that they were visible despite scrolling vertically down the list.

Questions can be *close-ended* or *open-ended*. *Close-ended* questions are those that offer explicit response categories. They are easy to process with computers and to analyse with statistics. *Open-ended* questions do not have clear response choices, allowing respondents to give answers in their own words. Such questions are used when there is limited information about a particular topic, and one wants to learn as much as possible. *Open-ended* questions yield a wealth of information but involve complicated and lengthy administering, documenting, summarising and analysis. *Matrix questions* are a series of questions that deal with a common theme and have the same response choices. The format of these questions streamlines the questionnaire [144].

Table 7.3 compares the various survey designs considered. In-person interviews conducted via Microsoft Team were chosen, given that they have the most advantages.

Table 7.3: A comparison of survey designs [144]

SURVEY DESIGN	ADVANTAGES	DISADVANTAGES
Mailed surveys	• Can be useful if questions are sensitive. • Respondents won't be embarrassed in front of an interviewer.	• Questionnaires should be kept shorter. • Low response rate.
Electronic surveys	• Easy to develop. • Flexible and inexpensive. • Easy for respondents to use.	• Cumbersome for respondents if the survey is too long.
Phone surveys.	• Good response rate.	• Questionnaires should be kept shorter.
Group-administered surveys	• Easy to develop. • Time-saving.	• Require access to the sample in a group setting.
In-person interviews	• Response rates are higher than any other survey design. • Questionnaires can be longer than with mailed or phone surveys. • Questionnaire can be more complex, with open-ended and close-ended questions as well as frequent branching patterns. • Respondents' interpretations of questions can be probed and clarified.	• Respondents are less likely to have the same interview experiences.

7.4 Research participants & data collection

Seventeen MDVC stakeholders were interviewed. Table 7.4 gives the MDVC categories in which each interviewee is involved and the stakeholder groups they associated themselves with at the beginning of the interview (survey). The interviewees are representative of multiple stakeholder groups. Thus, their VA rankings demonstrate a holistic perspective of the MDVC, its bottlenecks and possible alleviations thereof. Unique codes were given to each interviewee to protect their identity.

Table 7.4: Interviewees, the MDVC categories they could rank and their roles in the MDVC

MDVC Stakeholder	MDVC Phases that they're involved in	Stakeholder group (based off prior & current experience)	Experience in the medical device sector	Experience in the WC
#1	Idea Generation; Market; Distribution & Use; Systemic	Healthcare Worker; End-user	30+	☑
#2	Research & Development; Market; Distribution & Use; Systemic	Healthcare Worker; End-user	31+	☑
#3	Research & Development; Production/ Manufacturing; Market; Distribution & Use; Systemic	Healthcare Worker; End-user; Scientist; Innovator; Entrepreneur; Manager; Industry Expert	43+	☑
#4	Idea Generation; Research & Development; Production/ Manufacturing;	Industry Expert; Innovator; Entrepreneur	35+	☑

MDVC Stakeholder	MDVC Phases that they're involved in	Stakeholder group (based off prior & current experience)	Experience in the medical device sector	Experience in the WC
	Market; Distribution & Use; Systemic			
#5	Idea Generation; Research & Development; Production/ Manufacturing; Market; Systemic	Intermediary; Industry Expert; Government Employee (former)	8+	☑
#6	Idea Generation; Research & Development; Production/ Manufacturing; Distribution & Use; Market; Waste Management; Systemic	Manufacturer; Entrepreneur; Innovator; Intermediary; Clinical Engineer; Importer; Distributor; Sales and Marketing Expert	25+	☑
#7	Idea Generation; Research & Development; Production/ Manufacturing; Market; Distribution & Use; Systemic	Innovator; Entrepreneur; Marketing Expert; Researcher; Scientist	7+	☑
#8	Idea Generation; Research & Development; Production/ Manufacturing; Distribution & Use; Systemic	Engineer; Industry Expert; Intermediary; Researcher; Innovator	14+	☑
#9	Idea Generation; Research & Development; Production/ Manufacturing; Market; Distribution & Use; Systemic	Innovator; Entrepreneur; Engineer; Researcher	37+	☑
#10	Idea Generation; Research & Development; Production/ Manufacturing; Market; Distribution & Use; Systemic	Innovator; Entrepreneur; Engineer; Industry Expert	22+	☑
#11	Idea Generation; Research & Development; Production/ Manufacturing; Market; Distribution & Use; Systemic	Manufacturer; Innovator; Entrepreneur; Industry Expert; Financial Expert	37+	☑
#12	Idea Generation; Research & Development; Production/ Manufacturing;	Innovator; Entrepreneur; Engineer; Industry Expert; Part of a University Spin-off	5+	☑

MDVC Stakeholder	MDVC Phases that they're involved in	Stakeholder group (based off prior & current experience)	Experience in the medical device sector	Experience in the WC
	Market; Distribution & Use; Systemic			
#13	Research & Development; Distribution & Use; Systemic	Scientist; Regulator	+16	☑
#14	Idea Generation; Research & Development; Production/ Manufacturing; Market; Systemic	Biomedical Engineer; Physicist; Academic; Innovator	+34	☑
#15	Distribution & Use; Waste Management; Systemic	Waste Management Expert	16+	☑
#16	Idea Generation; Research & Development; Market; Systemic	Healthcare Worker; End-user; Ergonomics Expert	32+	☑
#17	Idea Generation; Research & Development; Systemic	Intermediary; Funder	19+	☑

7.5 Analysis

7.5.1 Survey aim

The survey aimed to identify bottlenecks in the Western Cape's MDVC. This was achieved by ranking each VA in terms of *effort*, *difficulty*, and *importance*. *Effort* describes the time and workload required to complete the VA. *Difficulty* describes the magnitude of the barriers and complications associated with completing the VA. In other words, the *effort* is internal to the business, and the *difficulty* is external to the business (out of their control). Lastly, *importance* describes the significance and value of the VA in the MDVC from the stakeholder's perspective.

In turn, the collected data should reveal the VAs that require the most effort and the VAs with bottlenecks that increase their difficulty. Moreover, each VA's value and significance (importance) will validate its inclusion/ position in the MDVC.

7.5.2 Functional analysis

Ordinal data were captured using Likert scale ratings on the VAs within each MDVC category to gather insight regarding the bottlenecks in the Western Cape's MDVC. Five-point Likert scale ratings (See Table 7.5) were used to ask the participants to rank their VAs regarding their *effort*, *difficulty* and *importance*. Then, the participants were asked to identify the biggest bottlenecks in the Western Cape's MDVC from their experience. Lastly, they were allowed to suggest alleviations. Their responses to these questions are documented in Appendices F and G.

Table 7.5: Likert scale ratings used in survey

	Likert scale ratings	1	2	3	4	5
Value-adding activity	**Effort required**	Least effort	Little effort	Moderate effort	Lots of effort	Most effort
	Difficulty to perform	Very easy (least difficult)	Easy	Moderately difficult	Difficult	Most difficult
	Importance in the MDVC	Least important	Low importance	Moderate importance	High importance	Most important

Figure 7.3 visualises the mappings considered for the Likert scale data. The mappings of the Likert scale data gathered on the MDVC VAs allow for identifying MDVC bottlenecks. Thus, the mappings allow for a form of *gap analysis* as the mappings represent primary research that can then be compared to the systematic literature review findings.

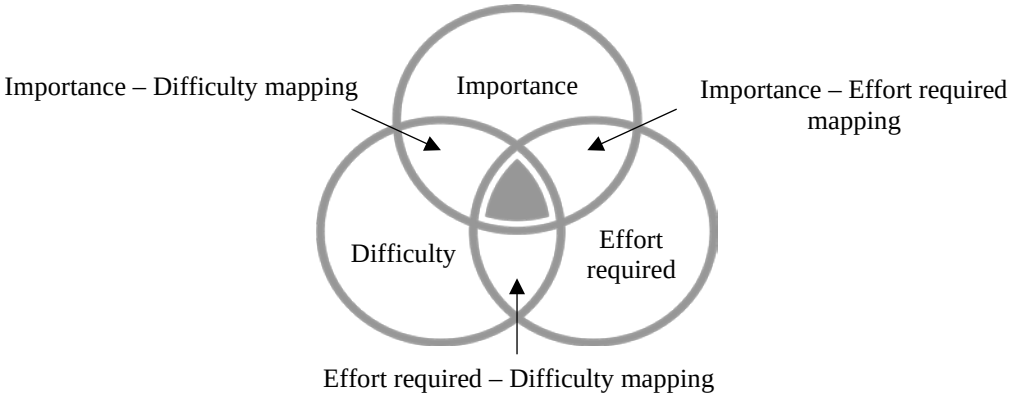


Figure 7.3: Functional analysis approach

Figure 7.4 focuses on identifying MDVC bottlenecks, i.e., areas where alleviations can be applied. This approach is based on the Importance-Performance Analysis work of Martilla and James [145]. *First-priority* bottlenecks are those VAs that receive high-importance rankings, are very difficult to perform and require a lot of effort to accomplish. These VAs represent bottlenecks in the MDVC. *Second-priority* VAs are those that receive low-importance rankings, are very difficult to perform and require lots of effort. *Third-priority* bottlenecks are those that receive high-importance rankings, are easy to perform and require little effort. *Fourth-priority* bottlenecks are those VAs that received low importance rankings, are easy to perform and require little effort. Such VAs are, in fact, not bottlenecks. The priority classification was decided by the author but was guided by prior research.

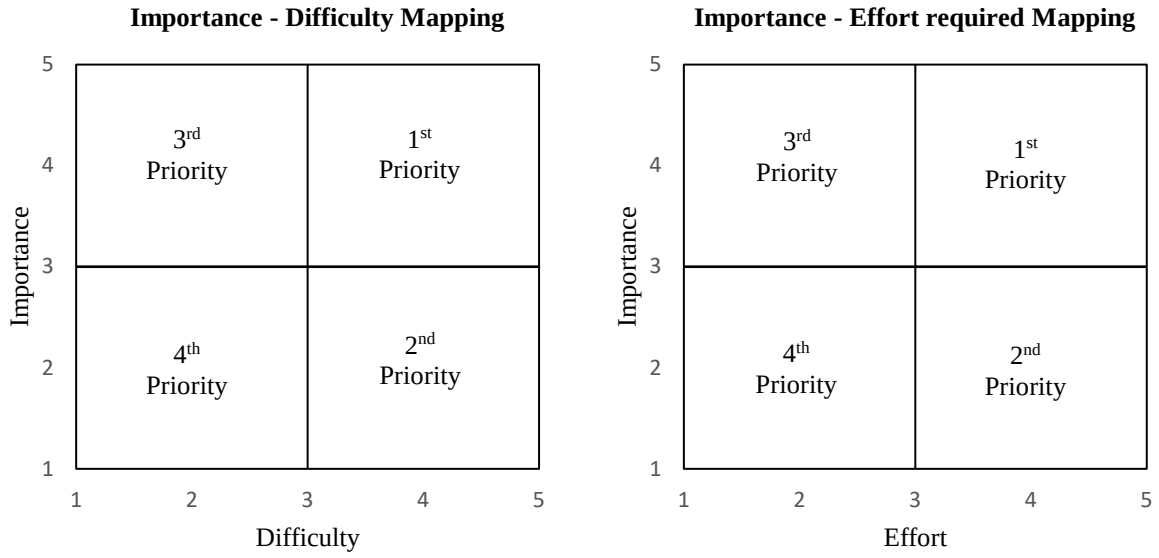


Figure 7.4: Functional analysis mapping and priority focus areas

Figure 7.5 shows an Effort required – Difficulty map. This mapping will not identify bottlenecks but will illustrate the relationship between the effort required to complete VAs and their perceived difficulty.

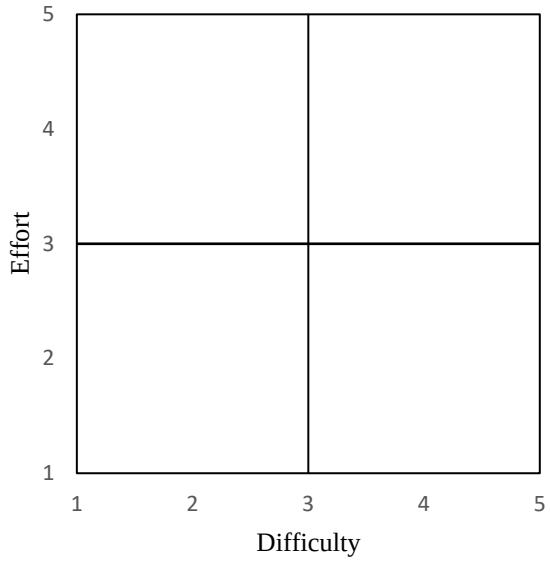


Figure 7.5: Effort required - Difficulty map

7.6 Results

7.6.1 Functional analysis results

A functional analysis was conducted, as mentioned above in section 7.4.2. Mapping the Likert scale data gathered on the VAs (See Table 7.5) allowed for identifying MDVC bottlenecks at specific VAs. This raw data is given in Appendix D. The mappings in Figure 7.6 were developed based on the average importance, difficulty, and effort required rankings the survey respondents gave. The data is separated in terms of the MDVC category. A colour scale is depicted beneath each mapping, and a key detailing the VAs mapped is given.

The highest priority bottlenecks are identified by the Importance – Difficulty (IXD) mapping and the Importance – Effort required (IXE) mapping. The bottlenecks occur at the VAs positioned in the top right quadrants of these mappings. Fishbone diagrams were then generated based on these results in section 7.6.2 below to provide a holistic visualisation of the bottlenecks.

For *Idea generation*, the highest priority VAs are VA4 (*acquiring research funding*), VA2 (*developing relationships with purchasers/ procurers of potential medical devices*) and VA3 (*discovery and ideation*). These were the same for both the IXD and IXE mappings.

For *Research & Development*, the highest priority VAs are VA25 (*regulating the device*), VA23 (*clinical trials*) and VA11 (*acquiring seed funding*). These were the same for both the IXD and IXE mappings.

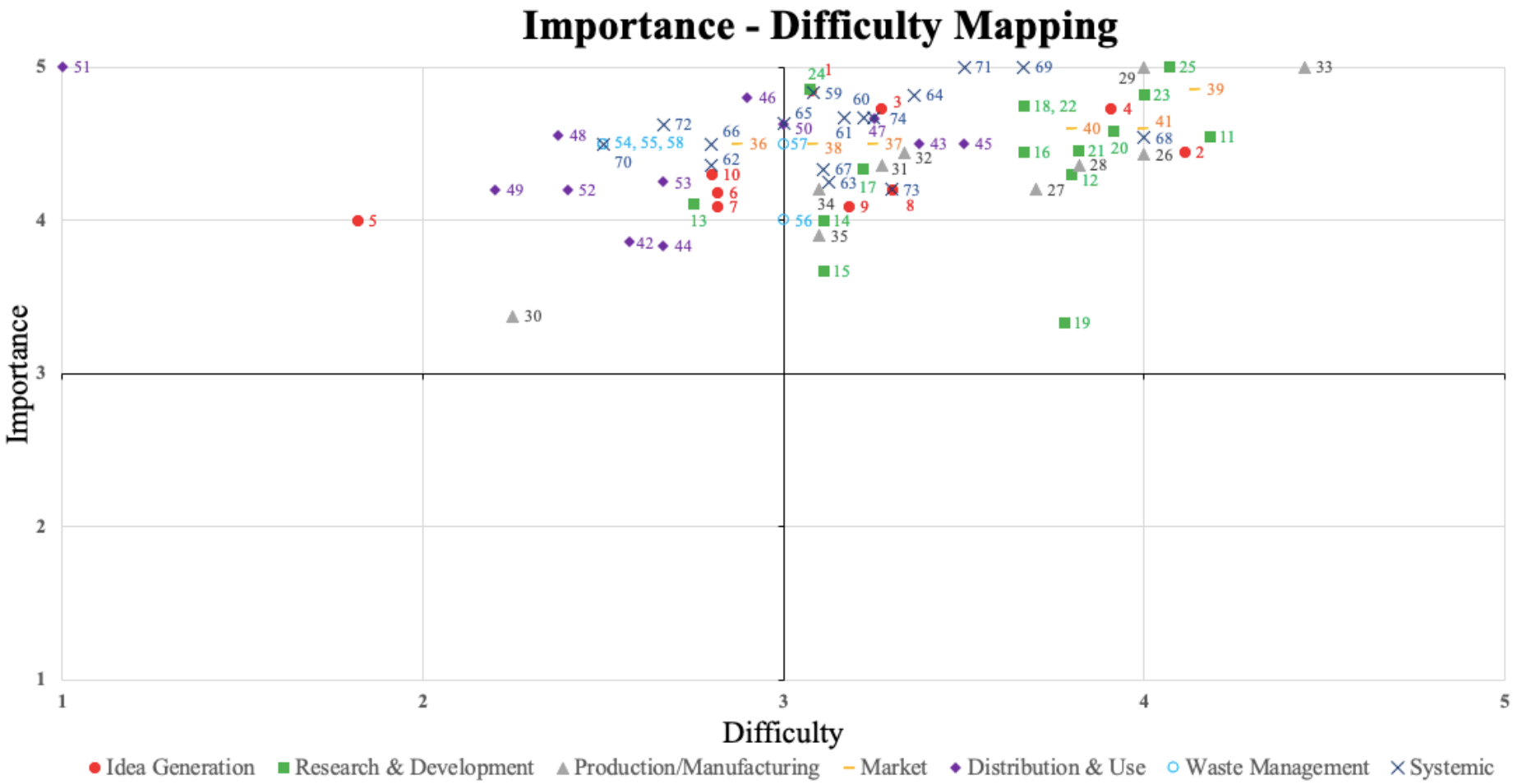
For *Production/ Manufacturing*, the highest priority VAs are VA33 (*obtaining marketing authorisation*), VA29 (*establishing/ acquiring manufacturing capabilities*) and VA26 (*obtaining seed funding*). These were the same for both the IXD and IXE mappings.

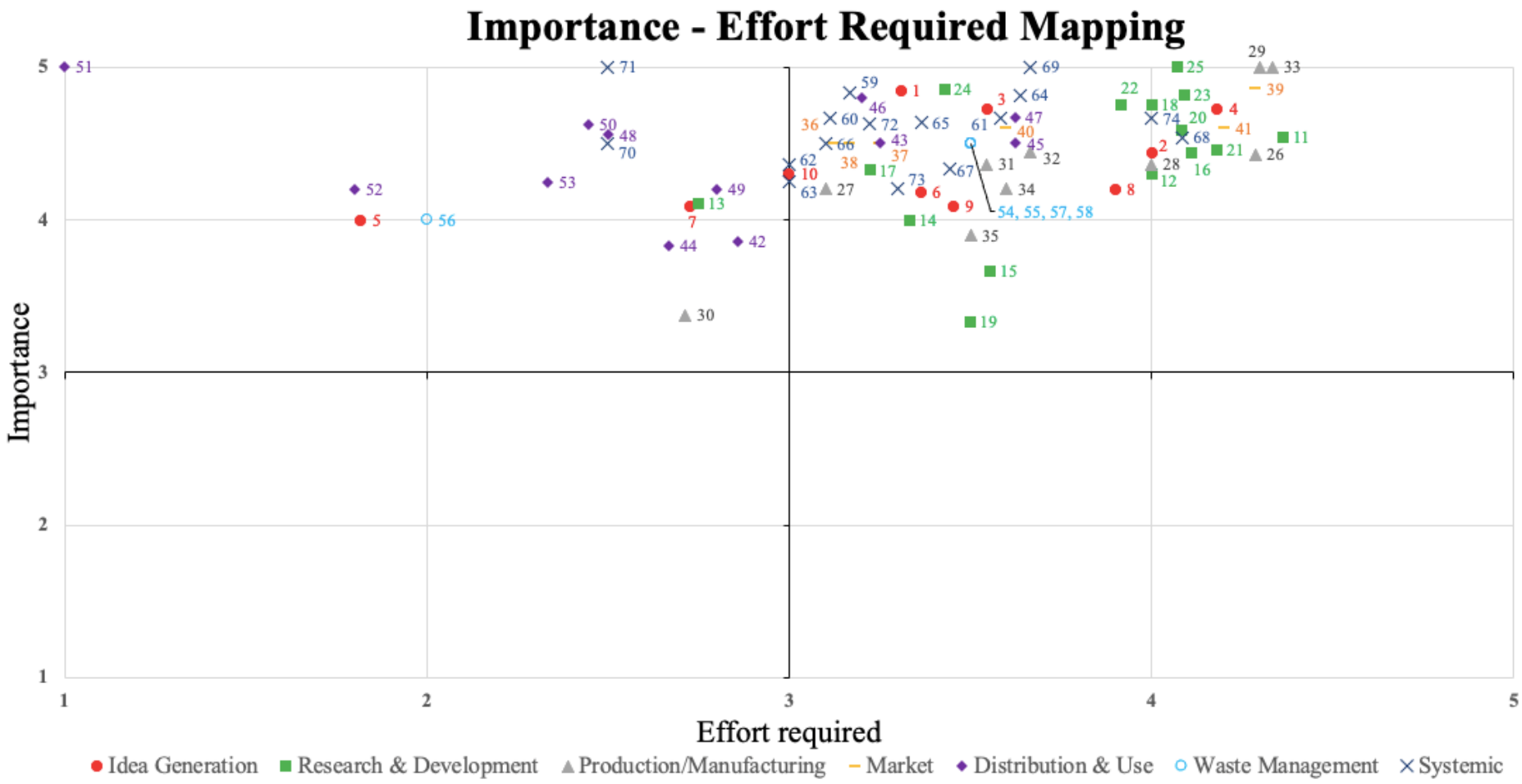
For *Market*, the highest priority VAs are VA39 (*procurement*), VA41 (*payment*) and VA40 (*purchasing*). These were the same for both the IXD and IXE mappings.

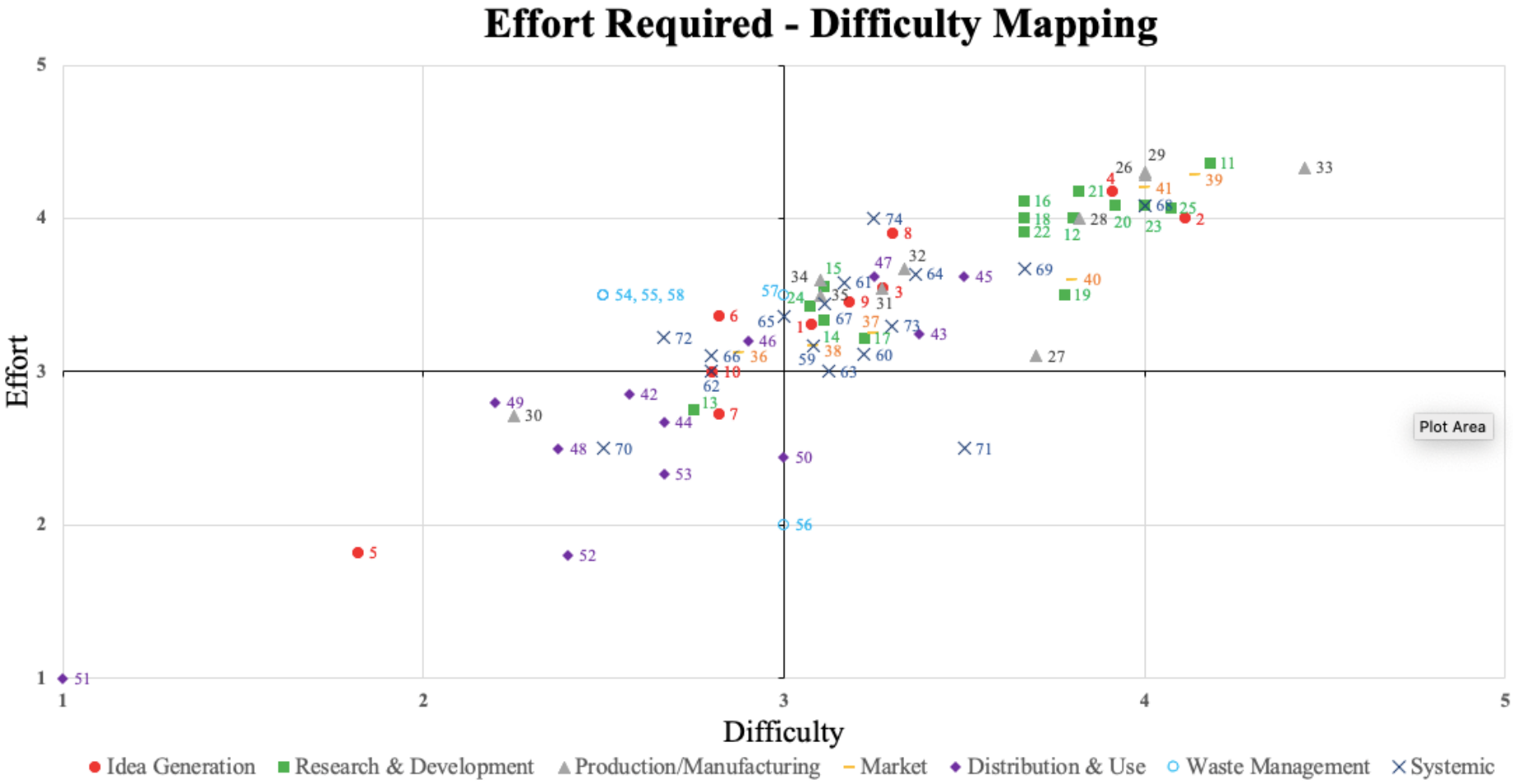
For *Distribution & Use*, the highest priority VAs are VA45 (*medical device use*), VA47 (*post-implementation improvement and adaptation*), VA43 (*inventory management*) and VA46 (*obtaining end-user feedback*). VA45 and VA47 were the same for both the IXD and IXE mappings. However, the IXD mapping identified VA43 as the third highest priority, while the IXE mapping identified VA46. This may be because VA47 (*obtaining feedback from end-users*) is an intensive activity (requires effort) despite having fewer barriers.

For *Waste Management*, the highest priority VAs are VA57 (*waste collection*), VA54 (*waste transportation*), VA55 (*waste segregation/ sorting*), VA56 (*waste treatment*) and VA58 (*waste disposal/ recycling*). VA54, VA55, VA57 and VA58 were the same for the IXD and IXE mappings. However, the IXD mapping included VA56, while the IXE mapping did not. All the VAs in *Waste Management* were identified as bottlenecks. This may be because limited stakeholder rankings were obtained for this section.

For *Systemic*, the highest priority VAs are VA69 (*legislative governance*), VA68 (*obtaining funding*), VA71 (*judicial governance*) as well as VA74 (*coordination and integration across building blocks and levels of the MDVC*). VA69 and VA68 were the same for both the IXD and IXE mappings. However, the IXD mapping identified VA71 in the top three, while the IXE mapping identified VA74. Again this may be because VA74 is more effort-intensive despite having few barriers.







IDEA GENERATION		**13**	Facilitate participatory knowledge spillovers in medical device clusters (readily available complementary local assets or capabilities).	**MARKET**		**57**	Waste treatment
1	Develop relationships with potential end-users of medical device.			**36**	Branding of medical device.	**58**	Waste disposal/ recycling.
2	Develop relationship with purchasers & procurers of potential medical device.			**37**	Advertise/ market medical device.	**SYSTEMIC**	
		14	Facilitate precipatory knowledge spillovers in medical device clusters (early access to local inventions, discoveries, or innovations).	**38**	Obtain endorsement from end-users.	**59**	Registering stakeholders (SAHPRA).
3	Discovery & ideation (identifying needs and coming up with ideas; TRL 1).					**60**	Demand forecasting.
						61	Ensure adequate staffing & train human resources.
4	Acquire research funding.	**15**	Produce exploration knowledge (aim of fundamental research; TRL 2).	**39**	Procurement of medical device (involves risk mitigation; contract compliance; cost savings; ongoing supplier relationships etc.).	**62**	Supply chain monitoring (review distribution networks).
		16	Technology transfer.	**40**	Purchasing of medical device (aims to minimise the cost of an order).	**63**	Supply chain systems diagnostics.
5	Determine the classification & nomenclature of your proposed medical device.	**17**	Confirm route to market/ project plan (TRL 3).			**64**	Ergonomics.
		18	Invention & prototyping.	**41**	Paying for medical device.	**65**	Data acquisition.
		19	Information sharing.				
6	Determine where the product will be sold and used (cultural and social considerations regarding the medical device, its use and disposal should be taken into account).	**20**	Development (TRL 4-5).	**DISTRIBUTION & USE**		**66**	Data storage.
		21	Develop a proof of concept (TRL 5).			**67**	Data sharing.
		22	Preclinical evaluation (TRL 6).	**42**	Storage/ warehousing of medical device.	**68**	Obtaining funding.
		23	Clinical trials I, II & III (TRL 7).	**43**	Inventory management.	**69**	Legislative governance (making the rules).
		24	Produce examination knowledge (includes feedback from medical device trials/ use).	**44**	Transportation of medical device.		
7	Determine who will pay for the device (reimbursement).			**45**	Use of medical device (TRL 9).	**70**	Executive governance (implementing the rules).
		25	Regulate device (testing, QMS audit & validation; TRL 8).	**46**	Obtain feedback from end-user of medical device.		
		PRODUCTION/ MANUFACTURING					
8	Perform due diligence and obtain IP protection.	**26**	Obtain seed funding.	**47**	Post implementation improvement and adaptation of medical device.		
		27	Forecast demand of developed medical device.				
9	Forecast demand of potential medical device.			**48**	Update clinical guidelines.		
		28	Infrastructure investment.	**49**	Sterilisation & reuse.		
10	Identify route to market.	**29**	Establish/ acquire manufacturing capabilities (ISO: 13485).	**50**	Determine obsolescence & replacement of medical device.	**71**	Judicial governance (enforcing the rules).
RESEARCH & DEVELOPMENT		**30**	Facilitate information sharing.	**51**	Decommissioning of medical device.	**72**	Crisis management planning.
		31	Source equipment/ raw materials.	**52**	Waste generation.		
11	Acquire seed funding.	**32**	Determine emergency/ alternative manufacturing capabilities/ supply chains in case of disruptions.	**53**	Waste storage.	**73**	Implementing alleviations to problems.
12	Produce exploitation knowledge (knowledge required to transform research into commercial products).			**WASTE MANAGEMENT**		**74**	Coordination & integration across building blocks and levels of the MDVC.
		33	Obtain marketing authorisation.	**54**	Waste collection.		
		34	Package medical device.	**55**	Waste transportation.		
		35	Label medical device.	**56**	Waste segregation/ sorting.		

Figure 7.6: Functional analysis mappings of MDVC value-adding activities 1-74

7.6.2 Fishbone diagrams and stakeholder-identified bottlenecks/ alleviations

The three highest priority VAs under each MDVC category were mapped onto two fishbone diagrams. Figure 7.7 was generated based on the Importance – Difficulty (IXD) rankings, while Figure 7.8 was based on the Importance – Effort required (IXE) rankings. Table 7.6 compares the highest-priority bottlenecks identified through the IXD mapping versus those identified through the IXE mapping.

Table 7.6: Highest priority bottlenecks identified through the Importance – Difficulty mapping versus those identified through the Importance – Effort required mapping

Highest priority bottleneck locations based off the Importance – Difficulty mapping		Highest priority bottleneck locations based off the Importance – Effort required mapping	
IDEA GENERATION			
VA4	Acquire research funding.	**VA4**	Acquire research funding.
VA2	Develop relationship with purchasers & procurers of potential medical device.	**VA2**	Develop relationship with purchasers & procurers of potential medical device.
VA3	Discovery & ideation (identifying needs and coming up with ideas; TRL 1).	**VA3**	Discovery & ideation (identifying needs and coming up with ideas; TRL 1).
RESEARCH & DEVELOPMENT			
VA25	Regulate device (testing, QMS audit & validation; TRL 8).	**VA25**	Regulate device (testing, QMS audit & validation; TRL 8).
VA23	Clinical trials I, II & III (TRL 7).	**VA11**	Acquire seed funding.
VA11	Acquire seed funding.	**VA23**	Clinical trials I, II & III (TRL 7).
PRODUCTION/ MANUFACTURING			
VA33	Obtain marketing authorisation.	**VA33**	Obtain marketing authorisation.
VA29	Establish/ acquire manufacturing capabilities (ISO: 13485).	**VA29**	Establish/ acquire manufacturing capabilities (ISO: 13485).
VA26	Obtain seed funding.	**VA26**	Obtain seed funding.
MARKET			
VA39	Procurement of medical device (involves risk mitigation; contract compliance; cost savings; ongoing supplier relationships etc.).	**VA39**	Procurement of medical device (involves risk mitigation; contract compliance; cost savings; ongoing supplier relationships etc.).
VA41	Paying for medical device.	**VA41**	Paying for medical device.
VA40	Purchasing of medical device (aims to minimise the cost of an order).	**VA40**	Purchasing of medical device (aims to minimise the cost of an order).
DISTRIBUTION & USE			
VA45	Use of medical device (TRL 9).	**VA47**	Post implementation improvement and adaptation of medical device.
VA47	Post implementation improvement and adaptation of medical device.	**VA45**	Use of medical device (TRL 9).
VA43	Inventory management.	**VA46**	Obtain feedback from end-user of medical device.
WASTE MANAGEMENT			
VA57	Waste treatment.	**VA54**	Waste collection.
VA54	Waste collection.	**VA55**	Waste transportation.
VA55	Waste transportation.	**VA57**	Waste treatment.
VA56	Waste segregation/ sorting.	**VA58**	Waste disposal/ recycling.
VA58	Waste disposal/ recycling.		
SYSTEMIC			
VA69	Legislative governance (making the rules).	**VA74**	Coordination & integration across building blocks and levels of the MDVC.
VA68	Obtaining funding.	**VA69**	Legislative governance (making the rules).
VA71	Judicial governance (enforcing the rules).	**VA68**	Obtaining funding.

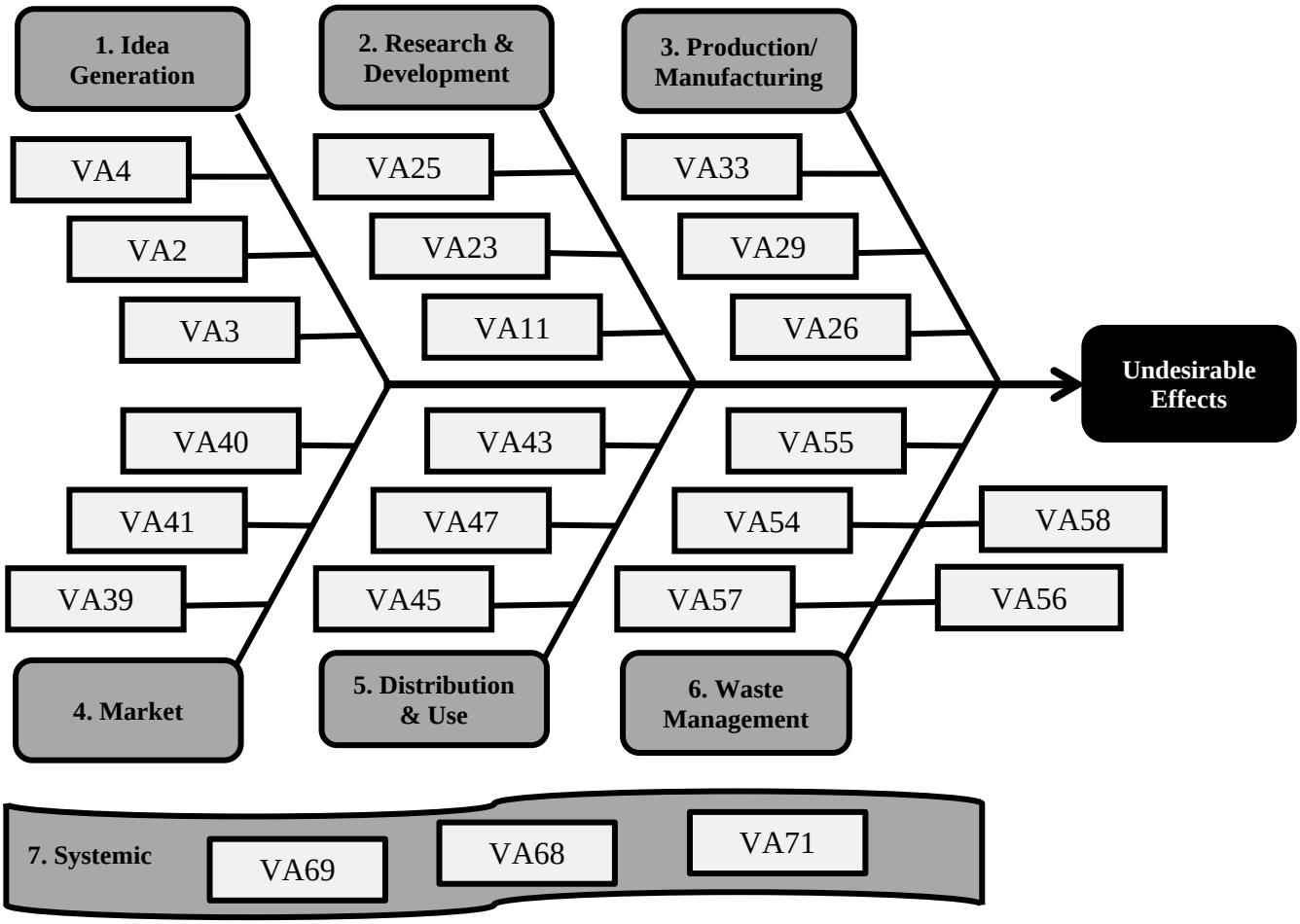


Figure 7.7: Fishbone diagram generated based off the Importance - Difficulty rankings made by stakeholders

As can be inferred from Table 7.6, the IXE and IXD activities were very similar. This is not surprising as difficult activities will require more effort. However, activities that are effort-intensive by nature are not necessarily bottlenecks that can be alleviated because there are only sometimes barriers to be removed. They may be aided by support or guidance.

To populate the fishbone diagrams in Figure 7.7 and Figure 7.8, the VAs with the highest IXD or IXE rankings under each MDVC category were selected. The top three were chosen in order to focus the analysis. However, in both the IXD and IXE mappings, the *Waste Management* VAs scored similar scores, hence adding the extra VAs in Figure 7.7 and Figure 7.8 for this category.

UEs are not specified in the fishbone diagrams, as the functional analysis did not facilitate their identification. However, stakeholders added comments when they ranked the VAs, which were documented in Appendices E, F and G, along with their answers regarding the biggest bottlenecks in the Western Cape's MDVC and what alleviations could potentially be applied. Their responses and feedback are discussed more fully in section 7.6.

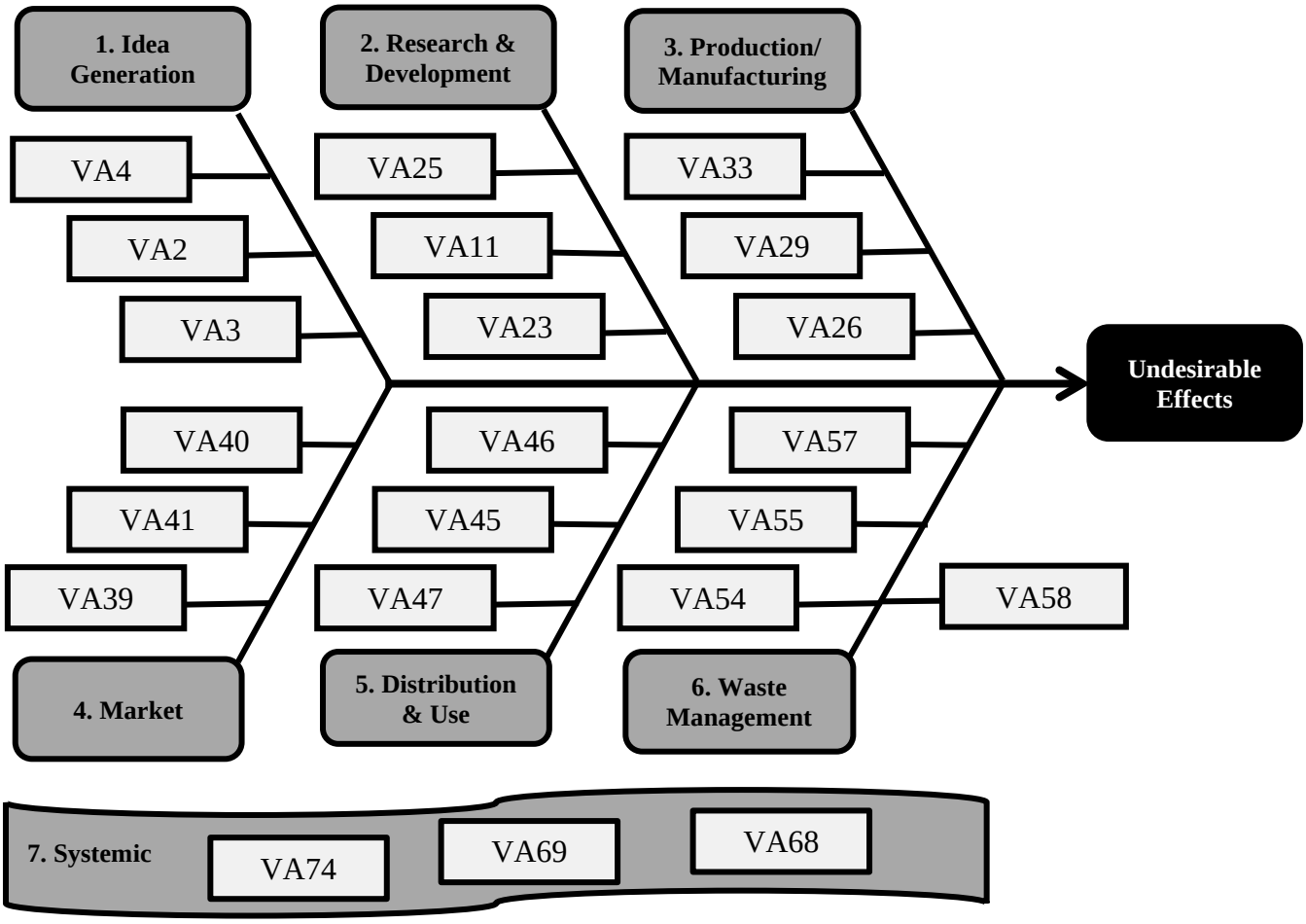


Figure 7.8: Fishbone diagram generated based off the Importance – Effort required rankings made by stakeholders

7.6.1 Qualitative analysis results: stakeholder feedback on MDVC and VAs included

Appendix E highlights stakeholder feedback regarding the VAs included in the MDVC and their order. Every VA was ranked but not by every stakeholder. This was expected as the MDVC stakeholders (S1-S17) interviewed were representative of the multidisciplinary nature of the medical devices industry.

In *Idea generation*, VA1 (*Develop relationships with potential end-users of medical devices*) was described by S17 as "one of the most important things". S14 affirmed this but also noted that it is "the least done". VA2 (*Develop relationship with purchasers & procurers of potential medical device*) was regarded as not critical at this stage by S4, who added that they could "continue to develop without having that relationship". S12 described this as "very difficult" for a start-up company. VA3 (*Discovery & ideation*) yielded mixed responses. S14 added that it "depends on the person's creativity". VA4 (*Acquire research funding*) was described as time-consuming by S9. VA5 (*Determine the classification & nomenclature of your proposed medical device*) "determines your financial model and the risk", according to S4. VA6 (*Determine where the product will be sold and used*) was considered "crucial" by S9. VA7 (*Determine who will pay for the device*) was regarded as "no problem" once established by S4. VA8 *(Perform due diligence and obtain IP protection*) was suggested to be split into two VAs by S12. *Performing due diligence* is critical in the *Idea Generation* phase to prevent infringing on existing IP.

However, patenting medical devices in the early stages was not recommended as patents have a limited life span that should only be started once the device is ready to be manufactured/ commercialised. Additionally, devices change a lot between *Idea Generation* and *Production/ Manufacturing*, which may mean the earlier filed patent is no longer representative of the device. S14 added how *obtaining IP protection* should be done "at the end". VA9 (*Forecast demand of potential medical device*) was viewed as part of "financial work" by S4 and as part of "market analysis" by S14. S12 notes how VA10 (*Identify route to market*) is critical "when you're looking to raise capital".

In *Research & Development*, VA11 (*Acquire seed funding*) yielded mixed responses. The importance of BEE was noted by S4 here. S5 noted that "if your product idea is solid, your funding becomes easier", while S6 described it as "the most difficult thing" because you are not selling to the end-user directly. The technology is not always easily understood by non-engineers/ non-healthcare workers. VA12 (*Produce exploitation knowledge*), VA13 (*Facilitate participatory knowledge spillovers in medical device clusters*), VA14 (*Facilitating precipatory knowledge spillovers in medical device clusters*) and VA15 (*Produce exploration knowledge*) were viewed as similar if not the same by many stakeholders. VA16 (*Technology transfer*) was said to be in the wrong place by S12 and S14. S12 suggested it be "between R&D and Production/ Manufacturing". VA17 (*Confirm route to market*) yielded no comments, but it was ranked.

VA18 (*Invention & prototyping*) is often done in collaboration with end-users. S4 explains how they use an "advisory committee" that includes appropriate healthcare workers. S5 suggests splitting the activity as they are "two very distinct tasks". S8 suggested that VA19 (*Information sharing*) be changed to "*access to information*" as it entails access to sensitive data such as medical records. VA20 (*Development*) was seen as a "part of invention and prototyping" by S4. S8 also noted how splitting up these processes like this is "a very academic thing". On the other hand, S6 recognised this as the step at which they take their "proof of concept" to potential investors. VA21 (*Develop proof of concept*) was also seen to "[fit] into invention and prototyping" by S4.

VA22 (*Preclinical evaluation*) yielded no comments, but it was ranked. VA23 (*Clinical trials I, II & III*) was considered easy by S12 if "you get a clinical research organisation to do most of it for you". VA24 (*Produce examination knowledge*) yielded no comments, but it was ranked. VA25 (*Regulate device*) was highlighted as actually "not a lot of effort" by S13, who noted that it is often viewed as a bottleneck simply because organisations are not yet familiar with the new regulatory area in SA. S16 reiterated this by stating that "it's not that difficult, just laborious", highlighting how not everything that is effort-intensive is necessarily a bottleneck.

In *Production/ Manufacturing*, S12 suggested that VA26 (*Obtain seed funding*) be renamed "series funding". S7 also suggested, "the terminology might be different there". VA27 (*Forecast demand of developed medical device*) was deemed necessary. S4 noted how it "determines what size equipment you're going to buy". S7 also liked the addition of an extra round of demand forecasting at this stage of the MDVC, as "at different points of the value chain, sometimes the needs keep changing". S14 added, "you need to fine-tune what you've done before". VA28 (*Infrastructure investment*) was bypassed by S4, who outsources this "to reduce the money" put into production/ manufacturing. VA29 (*Establish/ acquire manufacturing capabilities*) was suggested to be split into two by S12 because they are "*two very different things*". VA30 (*Facilitate information sharing*) was supported. S7 agreed it was "applicable", and S14 described themselves as "a big one for sharing" but noted that "you need to have some IP protection". VA31 (*Source equipment/ raw materials*) depends on the product. VA32 (*Determine emergency/ alternative manufacturing capabilities/ supply chains in case of disruptions*) is valuable but not always in the budget for many MDVC stakeholders. S4 commented. "we do have options and we are very aware of them, but we can't spend the money".

VA33 (*Obtain marketing authorisation*) was considered redundant and unnecessary by S4, who noted that "regulatory starts with design". VA34 (*Package medical device*) plays a role in determining the quality of the medical device in the opinion of S4, who also considered VA35 (*Label medical device*) in line with traceability.

In *Market*, no comments regarding VA36 (*Branding of medical device*) were given. However, it was ranked. VA37 (*Advertise/ market medical device*) was partly outsourced in some instances to distributors by S4, while they did mention doing "a lot of background marketing". S12 remarked that it "depends on your target market". VA38 (*Obtain endorsement from end-users*) was highly valued by S4: "The more endorsements you can get, the better". S5 advised being careful in doing this because it should not look like you are "paying someone to endorse your product". No comments were given regarding VA39 (*Procurement of medical device*) or VA40 (*Purchasing of medical device*), but both were ranked. VA41 (*Paying for medical device*) was viewed as the same as VA40 by S5 and S6, suggesting that VA39, VA40 and VA41 should be grouped and renamed "reimbursement of medical devices". However, S7 recognised that the split may be necessary now that we are moving towards personalised medicine and patients purchase high-level devices in certain instances.

In *Distribution & Use*, VA42 (*Storage/ warehousing of medical device*) involves regulatory compliance. S3 explained how healthcare warehouses need to be ISO compliant, which entails several rules/ regulations regarding stock storage, refrigeration and products first in and first out. S3 and S4 viewed VA43 (*Inventory management*) as easier once set up but initially a struggle. VA44 is outsourced to service providers by S4. S2 noted that "it's very useful to have a human being showing you" to better facilitate VA45 (*Use of medical device*).

VA46 (*Obtain feedback from end-user of medical device*) is considered "part of your certification" by S4, and S6 describes it as "post market surveillance". VA47 (*Post implementation improvement and adaptation of medical device*) is noted as important "regulatory-wise" by S4. S8 adds that it is difficult once devices are "in production". S16 notes that often problems that arise "are not immediately apparent", thereby highlighting the long-term consideration of VA47 that is required. VA48 (*Update clinical guidelines*) was ranked with few comments given. VA49 (*Sterilisation and reuse*) was suggested to be split by S10 because "you sterilise disposables as well". VA50 (*Determine obsolescence & replacement of medical device*) is described as a "monitoring thing" by S3, while S11 views it as "the hospital's problem". VA51 (*Decommissioning of medical device*) was not disputed, and it was ranked. VA52 (*Waste generation*) and VA53 (*Waste storage*) were suggested as part of *Waste Management* by S15, who also referred to it as "Cradle to grave".

In *Waste Management*, only S15 added meaningful feedback. VA54 (*Waste collection*), VA55 (*Waste transportation*), VA56 (*Waste segregation/ sorting*), VA57 (*Waste treatment*) and VA58 (*Waste disposal/ recycling*) were all considered routine practises that should meet "regulatory requirements". The importance of tracing the waste from cradle to grave was reiterated as it is part of ensuring regulatory compliance.

In *Systemic*, VA59 (*Registering stakeholders*) is necessary in SA's MDVC and other than that, minimal comments regarding its position in the MDVC were given. VA60 (*Demand forecasting*) was accepted as a systemic activity as demand fluctuations occur despite initial predictions; as S3 added, "there are seasonal variations and obviously pandemics". S4 emphasises the value of having an IT system to manage this activity "because it gets quite complex". VA61 (*Ensure adequate staffing & train human resources*) was highly valued but was described as challenging by S3 given that necessary expertise is often in "short supply". VA62 (*Supply chain monitoring*) was not commented on specifically but seemed to be considered as part of regulation throughout the MDVC as it proves compliance. VA63 (*Supply chain systems diagnostics*) was not commented on specifically, but it was

ranked. VA64 (*Ergonomics*) was suggested to occur earlier on during development. S4 noted that they consider it "when [they] design the product" and sometimes have to refer back to it post-implementation, depending on the feedback received. S6 makes use of a consultant to facilitate this. VA65 (*data acquisition*), VA66 (*data storage*) and VA67 (*data sharing*) were repeatedly viewed as one single VA. This was supported by S3, S4, S7, S8, S10 and S14. S8 suggested that it be called "data management".

VA68 (*Obtaining funding*) was viewed as critical. S3 commented, "without funding, you can't function", iterating its importance at multiple levels of the MDVC. VA69 (*Legislative governance*), VA70 (*Executive governance*) and VA71 (*Judicial governance*) obtained minimal comments, but they were ranked. More MDVC stakeholders involved in policy development and regulation could have been included, given that these activities were not ranked as often as others. VA72 (*Crisis management planning*) was deemed nice to have but very difficult and expensive to get right. S4 noted how for them, it entails "data and the storage and the accessibility of that data" as it becomes necessary for communication in a crisis. VA73 (*Implementing alleviations to problems*) was recognised as "root cause analysis" by S3. VA74 (*Coordination & integration across building blocks and levels of the MDVC*) was described as "integral" by S3. S7 noted that it is challenging given that leaders in these institutions "do not have an idea of the space".

7.6.2 Qualitative analysis results: the biggest bottlenecks in the WC's MDVC

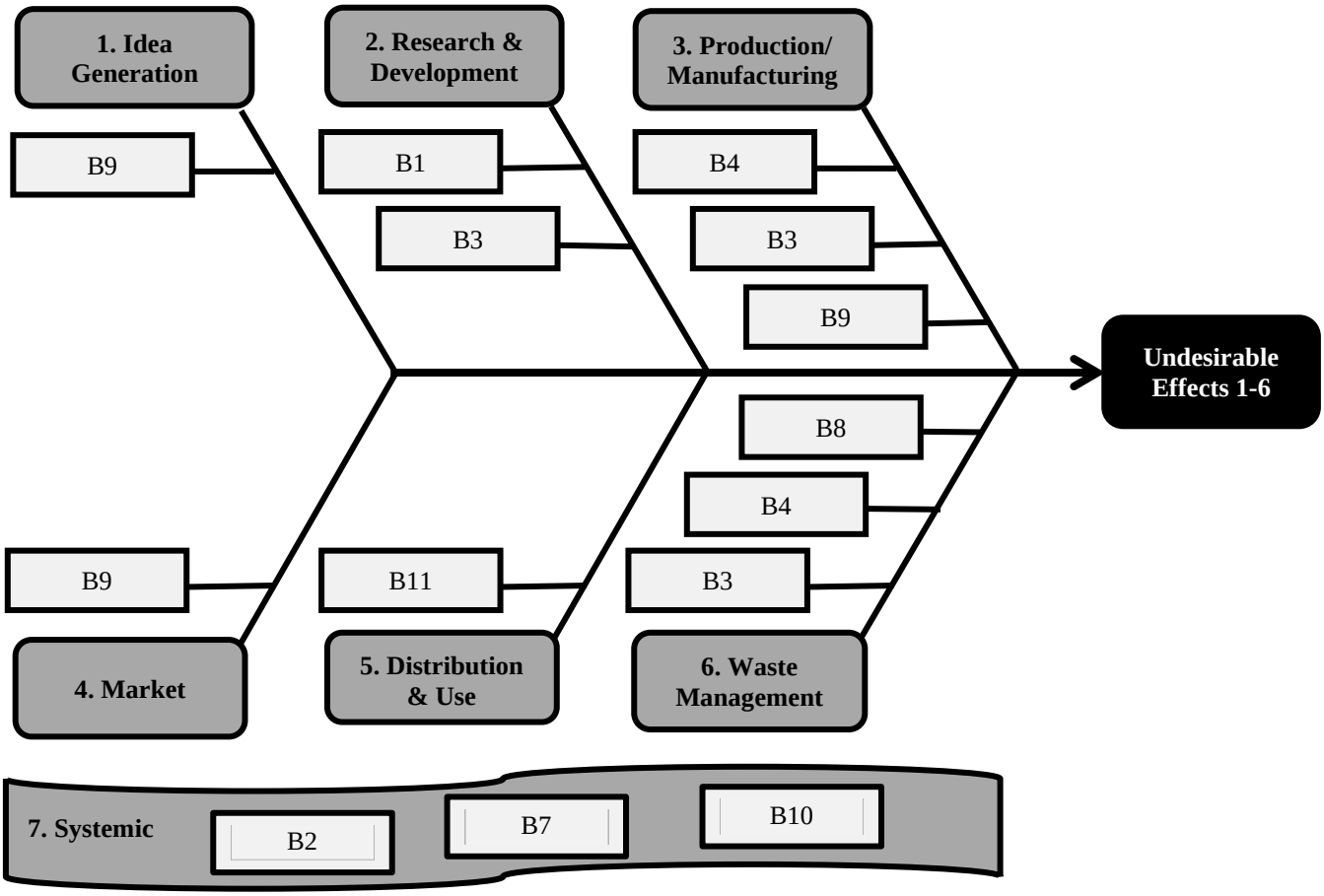
Appendix F documents the biggest bottlenecks in the WC's MDVC identified by the 17 MDVC stakeholders interviewed. The most cited bottlenecks were: (1) the regulatory environment in SA (*B3: Excessively complicated processes & B10: Poor governance*); (2) a lack of funding (*B2*); (3) a lack of policy incentives supporting local procurement (*B10: Poor governance*) and (4) a lack of networking specifically between end-users and developers (*B7: Poor networking*). Quotes were sorted according to the codes established in Chapters 4 and 5 (bottlenecks and UEs).

The regulatory environment in SA is considered complicated and difficult to navigate, given that it is relatively new. SAHPRA recently assumed the role of medical device regulation in 2017. Thus, MDVC stakeholders are still familiarising themselves with the new system. However, there are support and guidance documents available. Specific stakeholders viewed SAHPRA's reliance regulation model as redundant, costly and time-consuming. Others recognised the necessity of their role while noting that they are an alleviation in progress.

A lack of funding was reiterated by many MDVC stakeholders as a pressing bottleneck. A lack of venture capital in SA was explicitly noted as a contributor to a lack of successful start-ups. Moreover, stakeholders added that obtaining grant funding was difficult due to a lack of availability and because meeting the requirements to qualify takes much work.

The lack of policy incentives supporting local procurement was often given as the reason many stakeholders preferred to export their products. Corruption was also touched on as often non-compliant companies will get procurement contracts in place of compliant companies. This was observed during the COVID-19 pandemic. Additionally, a lack of networking between end-users and developers was highlighted. Without this ongoing relationship, end-users are less likely to adopt the medical device produced for various reasons.

Figure 7.9, on the next page, is a fishbone diagram that visualises the bottlenecks suggested by the 17 MDVC stakeholders interviewed. Direct links to UEs were not adequately validated. Thus, UE1 (*Lack of medical device adoption*); UE2 (*Lack of medical device start-ups*); UE3 (*Medical device shortages*); UE4 (*Medical device-associated pollution*); UE5 (*Lack of alleviation implementation*) and UE6 (*Poor systems*) and bottlenecks that exacerbate them are mapped on a single fishbone diagram instead of on multiple. A key with references is provided.



BOTTLENECK	UE(S) ENCOURAGED	STAKEHOLDERS
• B1 (Inadequate research)	• UE1 (Lack of medical device adoption)	• S3
	• UE2 (Lack of medical device start-ups)	• S14
	• UE5 (Lack of alleviation implementation)	• S3
• B2 (Lack of funding)	• UE1 (Lack of medical device adoption)	• S1 & S4
	• UE2 (Lack of medical device start-ups)	• S4; S8; S9 & S11
	• UE6 (Poor systems)	• S4 & S10
• B3 (Excessively complicated processes)	• UE4 (Medical device-associated pollution)	• S3 & S4
	• UE6 (Poor systems)	• S3; S7; S10; S11; S14; S16
• B4 (Unforeseen supply chain disruption)	• UE3 (Medical device shortages)	• S3
	• UE4 (Medical device-associated pollution)	• S15
	• UE6 (Poor systems)	• S11
• B7 (Poor networking)	• UE1 (Lack of medical device adoption)	• S2; S10 & S16
	• UE6 (Poor systems)	• S2; S3; S5; S7 & S14
• B8 (Poor supply chain management)	• UE3 (Medical device shortages)	• S3
	• UE4 (Medical device-associated pollution)	• S15
• B9 (Lack of human resources)	• UE6 (Poor systems)	• S10; S11; S12 & S16
• B10 (Poor governance)	• UE2 (Lack of medical device start-ups)	• S12

BOTTLENECK	UE(S) ENCOURAGED	STAKEHOLDERS
	• UE6 (Poor systems)	• S4; S11; S12; S14; S16 & S17
• B11 (Corruption)	• UE6 (Poor systems)	• S4

Figure 7.9: Fishbone diagram based on MDVC stakeholder feedback

7.6.3 Qualitative analysis results: suggested alleviations to bottlenecks in the WC's MDVC

Appendix G gives the suggested alleviations to the bottlenecks identified by the 17 MDVC stakeholders interviewed. Their feedback is categorised using the same coding system developed in Chapters 4 and 5 (DEs and alleviations). The top-mentioned alleviations were: (1) regulatory harmonisation (*A9: Governance*), (2) funding (*A1*), (3) policy incentives supporting local procurement (*A4: Support & A9: Governance*) and (4) improved networking (*A7: Strategic Networking*).

Some stakeholders viewed SAHPRA as an alleviation in progress that will result in regulatory harmonisation. Others remain sceptical of its value and are discontent with the backlog.

Stakeholders suggested that the WC's medical device sector should be better advertised as a lucrative spot for venture capitalists. Additionally, various stakeholders noted that outsourcing certain VAs such as VA23 (*Clinical trials I, II & III*) and VA29 (*Establish/ acquire manufacturing capabilities*) made them easier and more affordable. This alleviation did not come up in the literature search but practically makes much sense, especially for start-ups that initially lack the money and expertise to do everything in-house. It does reinforce the need for collaboration, as without a network available with outsourcing capabilities, this is not a viable alleviation.

Policy incentives supporting local procurement were repeatedly suggested to strengthen the WC's medical device sector. The triangle supporting procurement is visualised in Figure 7.10. The government needs to put policies in place that support local manufacturers, economical devices must be considered early on, and clinical performance must be strong.

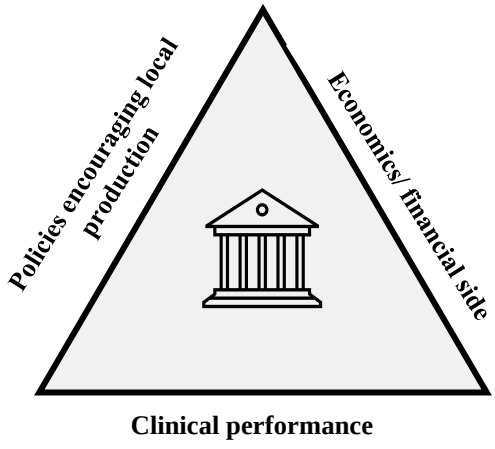
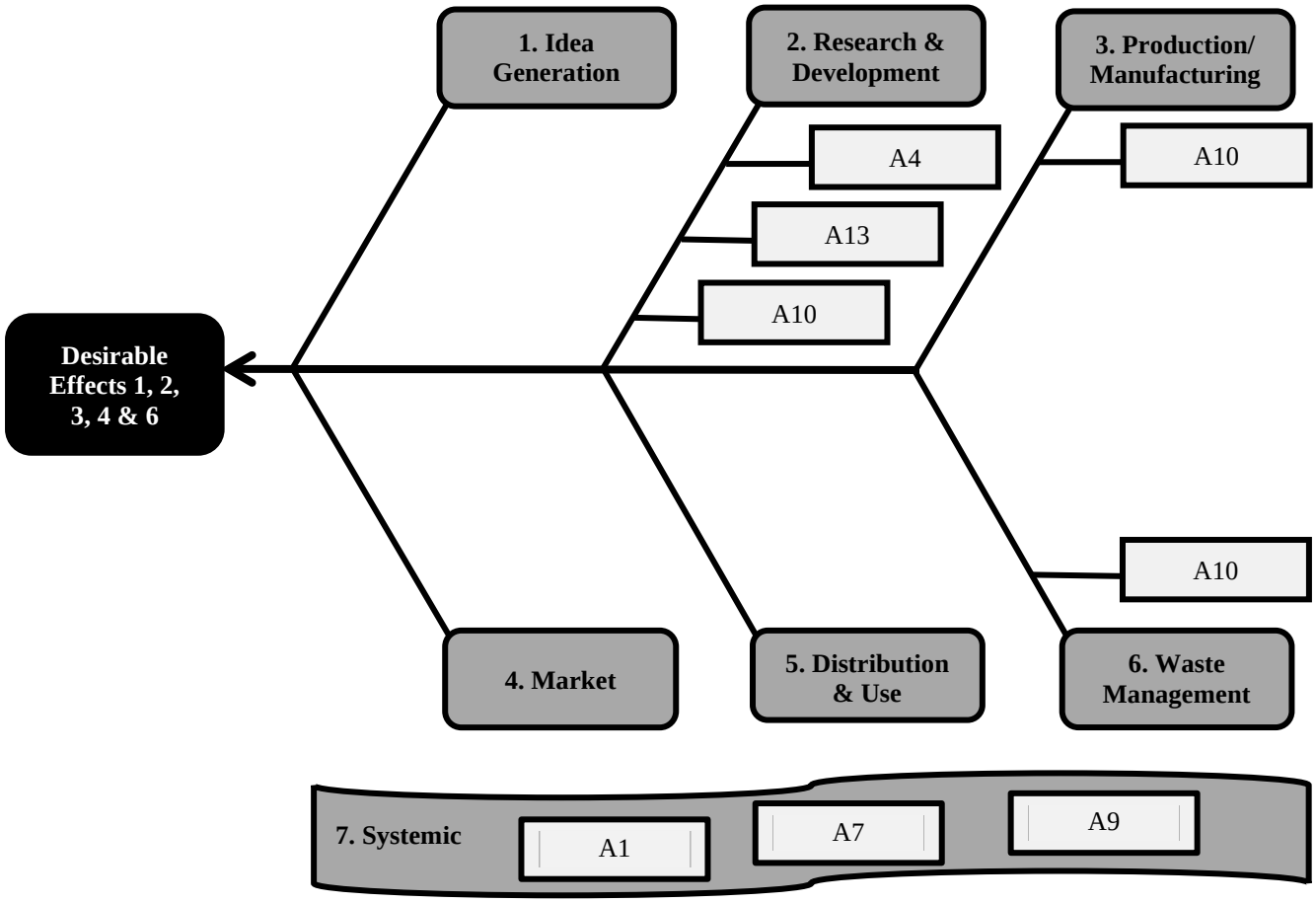


Figure 7.10: Triangle supporting procurement

Figure 7.11 (on the next page) is a reverse fishbone diagram that visualises the key alleviations suggested by the 17 MDVC stakeholders interviewed. Direct links to DEs were not properly validated. Thus, DE1 (*Adoption of medical device*), DE2 (*Successful medical device start-ups*), DE3 (*Agile/ resilient supply chains*), DE4 (*Sustainable waste management*)and DE6 *(System*

improvement) and the alleviations that encourage them are mapped on a single reverse fishbone diagram. DE5 (*Successful implementation of alleviations*) was not mentioned by stakeholders hence, its exclusion in the figure.



ALLEVIATION	DE(S) ENCOURAGED	STAKEHOLDERS
• A1 (Funding)	• DE2 (Successful medical device start-ups)	• S11
• A4 (Support)	• DE6 (System improvement)	• S17
• A7 (Strategic networking)	• DE1 (Adoption of medical device)	• S1; S2; S7 & S16
	• DE2 (Successful medical device start-ups)	• S5 & S8
	• DE3 (Agile/ resilient supply chains)	• S3
	• DE6 (System improvement)	• S6; S7; S10 & S14
• A9 (Governance)	• DE6 (System improvement)	• S3; S4; S7; S10; S11 & S14
• A10 (Holistic idea generation)	• DE3 (Agile/ resilient supply chains)	• S3
	• DE4 (Sustainable waste management)	• S12
• A12 (Medical device alternative)	• DE3 (Agile/ resilient supply chains)	• S3
• A13 (Strategic decision-making)	• DE2 (Successful medical device start-ups)	• S5 & S8
	• DE6 (System improvement)	• S4

Figure 7.11: Reverse fishbone diagram generated based on stakeholder feedback

7.7 Discussion

A total of 17 MDVC stakeholders from various parts of the MDVC provided ranking data regarding the effort, difficulty and importance of 74 VAs sorted under seven MDVC categories. Stakeholder groups were well represented by the interviewees (see Table 7.4). Most stakeholders could rank VAs under *Idea generation*, *Research & Development*, *Production/ Manufacturing*, *Market, Distribution & Use* and *Systemic*. However, only some could rank VAs under *Waste Management.*

The highest priority VAs represent MDVC bottlenecks identified by the interviewees. These correspond to the bottlenecks identified via systematic literature review in Chapters 4 and 5.

Many stakeholders commented that certain VAs were difficult initially but became easier once relationships were developed and systems were implemented. Many bottlenecks disproportionately affect start-ups, given that they are navigating the MDVC for the first time and have to form relationships, set up systems and obtain funding all at once.

Not all VAs received comments. However, most were well-ranked (excluding the *Waste Management* VAs). The activities were often seen as redundant by industry role players who did not see the need for splitting them theoretically when they were done simultaneously in practice. This highlights the disconnect between Academia and Industry.

Stakeholder feedback is summarised in Table 7.7 in order to facilitate the development of a more concise MDVC in future. It would be valuable for the survey to be repeated with more stakeholders and a refined MDVC list of VAs.

Table 7.7: Stakeholder recommended MDVC updates

VA(S)	FEEDBACK	STAKEHOLDER(S)
VA8	• VA8 should be split. • Perform due diligence should remain in *Idea Generation.* • Obtain IP protection should be moved to *Production/ Manufacturing.*	• S12 • S14
VA12, VA13, VA14 & VA15	• These activities are redundant. • They are all representative of *Research*. • They can be merged into one VA named *Research (TRL2).*	• S14
VA16	• Technology transfer should be moved to the end of *Research & Development* or the beginning of *Production/ Manufacturing.*	• S12 • S14
VA18, VA20 & VA21	• These activities are redundant. • They are all representative of *Development*. • They can be merged into one VA named *Development* OR *Invention & prototyping*.	• S4 • S8
VA26	• Obtain seed funding should be renamed Obtain series funding. • The funding required in *Production/ Manufacturing* is higher than seed funding which is typically obtained at the start of *Research & Development.*	• S7 • S12 • S14
VA33	• *Obtain marketing authorisation* should be renamed *Obtain certification* or it should be removed from the list.	• S4
VA39, VA40 & VA41	• Procurement, purchasing, and paying are the same. • They can be merged into one VA named *Reimbursement of medical devices.*	• S5 • S6
VA49	• This should be split • Sterilisation can be moved to *Production/ Manufacturing.* • *Reuse* can remain in *Distribution & Use* but it must be noted that it involves sterilisation.	• S10
VA66, VA67 & VA68	• Data acquisition, Data storage, and Data sharing can be merged into one VA named Data management.	• S8 • S10

7.8 Chapter 7 – Summary

Chapter 7 achieves RO6, RO7, RO8 and RO9. An appropriate expert is used to review and refine the preliminary framework. Evaluation methodologies are reviewed. Subsequently, the artefact is evaluated through semi-structured interviews and surveys with 17 MDVC stakeholders. Lastly, the results are analysed and discussed. RQ1, RQ3, RQ4 and RQ5 are answered. Table 7.8 demonstrates the RQs contributed to and the ROs achieved in Chapter 7.

Table 7.8: Research questions answered and research objectives addressed in Chapter 7

PHASE 2: PRACTICAL		
RESEARCH QUESTIONS	**CH7 CONTRIBUTIONS**	☑
RQ1: To what extent has the MDVC been mapped?	• The seven MDVC categories and 74 VAs that were established through literature review were validated by 17 MDVC stakeholders with experience in the WC.	☑
RQ3: What are the MDVC bottlenecks, and what UEs do they exacerbate?	• Stakeholders validated the bottlenecks and UEs that were identified through systematic literature reviews. • Based on the ranking data obtained from stakeholders, the most pressing bottlenecks under each MDVC category were identified (see Table 7.6). These results were mapped onto fishbone diagrams (see Figure 7.7 and Figure 7.8). • Stakeholders were also asked to identify the most pressing bottlenecks based on their experience in the WC. These were mapped onto another fishbone diagram (see Figure 7.9).	☑
RQ4: Are there existing alleviations of MDVC bottlenecks, and what DEs would they encourage?	• Stakeholders were asked to identify existing alleviations to bottlenecks in the WC's MDVC. Their answers were mapped onto a reverse fishbone diagram (see Figure 7.11).	☑
RQ5: What are the most pressing bottlenecks in the Western Cape's MDVC, and what alleviations could be applied?	• The VAs that represent the most pressing bottlenecks in the WC's MDVC under each MDVC category are given below: - Idea Generation: VA2, VA3 & VA4 - Research & Development: VA11, VA23 & VA25 - Production/ Manufacturing: VA26, VA29 & VA33 - Market: VA39, VA40 & VA41 - Distribution & Use: VA43, VA45, VA46 & VA47 - Waste Management: VA54, VA55, VA56, VA57 & VA58 - Systemic: VA68, VA69, VA71 & VA74 • These results were based on the rankings provided by MDVC stakeholders. • Based on stakeholders' answers to what they thought were the most pressing bottlenecks, the following replies were the most common: - *B1: Inadequate research* - *B2: Lack of funding* - *B3: Excessively complicated processes* - *B4: Unforeseen supply chain disruption* - *B7: Poor networking* - *B7: Poor supply chain management* - *B9: Lack of human resources* - *B10: Poor governance* - *B11: Corruption* • Based on stakeholders' answers to what they thought were possible bottleneck alleviations, the following replies were the most common: - *A1: Funding* - *A4: Support* - *A7: Strategic networking* - *A9: Governance* - *A10: Holistic idea generation*	☑

	- *A12: Medical device alternative* - *A13: Strategic decision-making*	
RESEARCH OBJECTIVES	**CH7 CONTRIBUTIONS**	☑
RO6: Review preliminary artefact with an appropriate expert and refine artefact accordingly.	• An academic expert in the medical device sector was consulted to refine the preliminary artefact. • Three iterations of the MDVC map and survey format were developed.	☑
RO7: Review evaluation methodologies.	• Evaluation methodologies were reviewed. Semi-structured interviews and surveys with experts were chosen based on their advantages.	☑
RO8: Evaluate the artefact using an appropriate methodology.	• The artefact was evaluated through surveys and semi-structured interviews with 17 MDVC stakeholders from the WC.	☑
RO9: Analyse and discuss results.	• The results were analysed and discussed in section 7.6.	☑

Chapter 8 - Conclusions and recommendations

8.1 Overview of Chapter 8

Chapter 8 briefly overviews the artefact (the MDVC framework). Next, the research questions and objectives are reviewed. Following this, the research is summarised. The final framework is then given. The study limitations and recommendations for future work are discussed. Thus, Chapter 8 achieves RO10 in that the final artefact is presented, and conclusions are made. Figure 8.1 below illustrates the structure of this chapter.

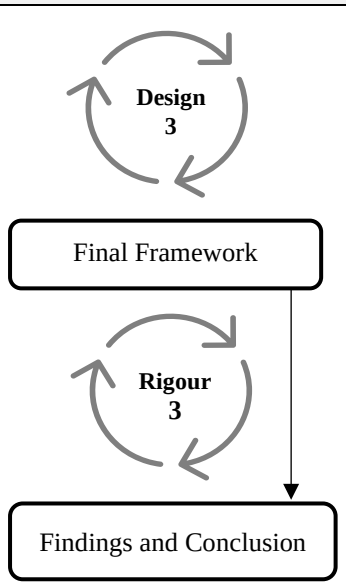
<table>
<tr><th colspan="4">CHAPTER 8</th></tr>
<tr><th>PHASE</th><th>DSRM ACTIVITY</th><th>CYCLE & PROCESS FLOW</th><th>RESEARCH OBJECTIVE</th></tr>
<tr><td>2: Practical Component</td><td>6. Communication</td><td> 
</td><td>RO10: Present final artefact design and conclusions.</td></tr>
</table>

Figure 8.1: Research thesis outline - Chapter 8

8.2 Brief overview of the framework

A holistic map of the MDVC was developed by overlapping existing variations discovered through preliminary research (Chapter 1) and two systematic literature reviews (Chapters 4 and 5). The VAs included, and the MDVC category under which they were sorted were validated by MDVC stakeholders (see Appendix D). Fishbone diagrams were created to visualise and analyse the highest priority bottlenecks identified through the functional analysis. Reverse fishbone diagrams were created based on opinions given by stakeholders interviewed.

8.3 Review of research questions and objectives

8.3.1 RQ1 – To what extent has the MDVC been mapped?

The MDVC has yet to be mapped in its entirety. However, certain sections have been examined to identify bottlenecks and apply alleviations. Several of these section maps were overlapped to develop the seven MDVC categories and 74 VAs included in the framework that was developed.

8.3.2 RQ2 – How can an artefact be used to identify bottlenecks in the MDVC?

A full MDVC map was developed with seven MDVC categories. Within these categories, 74 VAs were chronologically ordered. Seventeen MDVC stakeholders ranked each VA in terms of the effort it requires, its difficulty and its importance. Functional analysis identified the highest priority VAs (bottleneck locations) under each MDVC category. These VAs were visualised using fishbone diagrams to facilitate understanding/ comprehension.

8.3.3 RQ3 – What are the MDVC bottlenecks, and what UEs do they exacerbate?

Thirteen generic bottlenecks (B:) and six undesirable effects (UE:) were identified through preliminary research (Chapter 1) and through two systematic literature reviews (Chapters 4 and 5). Some were validated through semi-structured interviews (See Appendix F). Table 8.1 gives the MDVC bottlenecks identified and the UEs that they contribute to.

Table 8.1: MDVC bottlenecks identified and the undesirable effects that they contribute to

BOTTLENECKS	UNDESIRABLE EFFECTS
• **B1:** Inadequate research • **B2:** Lack of funding • **B3:** Excessively complicated processes • **B4:** Unforeseen supply chain disruption • **B5:** Inadequate infrastructure • **B6:** Poor data management • **B7:** Poor networking • **B8:** Poor supply chain management • **B9:** Lack of human resources • **B10:** Poor governance • **B11:** Corruption • **B12:** Lack of strategic decision making/ planning • **B13:** Poor waste management	• **UE1:** Lack of medical device adoption • **UE2:** Lack of medical device start-ups • **UE3:** Medical device shortages • **UE4:** Medical device-associated pollution • **UE5:** Lack of alleviation implementation • **UE6:** Poor systems

8.3.4 RQ4 – Are there existing alleviations of MDVC bottlenecks, and what desirable effects would they encourage?

Thirteen generic alleviations (A:) and six desirable effects (DE:) were identified through preliminary research (Chapter 1) and through two systematic literature reviews (Chapters 4 and 5). These are listed below in Table 8.2. Some were validated through semi-structured interviews (See Appendix G).

Table 8.2: MDVC bottleneck alleviations and the desirable effects that they encourage

ALLEVIATIONS	DESIRABLE EFFECTS
• **A1:** Funding • **A2:** Alternative supply chains • **A3:** Adaptation of medical device or medical device use • **A4:** Support • **A5:** 3D Printing & Additive Manufacturing • **A6:** Industry 4.0 and Digitalisation • **A7:** Strategic networking • **A8:** Supply chain monitoring • **A9:** Governance • **A10:** Holistic idea generation	• **DE1:** Adoption of medical device • **DE2:** Successful medical device start-ups • **DE3:** Agile/ resilient supply chains • **DE4:** Sustainable waste management • **DE5:** Successful implementation of alleviations • **DE6:** System improvement

ALLEVIATIONS	DESIRABLE EFFECTS
• **A11:** Brand awareness • **A12:** Medical device alternative • **A13:** Strategic decision-making	

8.3.5 RQ5 – What are the most pressing bottlenecks in the Western Cape's MDVC, and what alleviations could be applied?

The highest priority VAs are those that require the most effort, are the most difficult and are of the highest importance according to the rankings made by the 17 MDVC stakeholders interviews. Table 8.3 lists the highest priority VAs under each MDVC category.

Table 8.3: The highest priority VAs under each MDVC category

IDEA GENERATION	
VA4	Acquire research funding.
VA2	Develop relationship with purchasers & procurers of potential medical device.
VA3	Discovery & ideation (identifying needs and coming up with ideas; TRL 1).
RESEARCH & DEVELOPMENT	
VA25	Regulate device (testing, QMS audit & validation; TRL 8).
VA23	Clinical trials I, II & III (TRL 7).
VA11	Acquire seed funding.
PRODUCTION/ MANUFACTURING	
VA33	Obtain marketing authorisation.
VA29	Establish/ acquire manufacturing capabilities (ISO: 13485).
VA26	Obtain seed funding.
MARKET	
VA39	Procurement of medical device (involves risk mitigation; contract compliance; cost savings; ongoing supplier relationships etc.).
VA41	Paying for medical device.
VA40	Purchasing of medical device (aims to minimise the cost of an order).
DISTRIBUTION & USE	
VA45	Use of medical device (TRL 9).
VA47	Post implementation improvement and adaptation of medical device.
VA43	Inventory management.
VA46	Obtain feedback from end-user of medical device.
WASTE MANAGEMENT	
VA57	Waste treatment.
VA54	Waste collection.
VA55	Waste transportation.
VA56	Waste segregation/ sorting.
VA58	Waste disposal/ recycling.
SYSTEMIC	
VA69	Legislative governance (making the rules).
VA68	Obtaining funding.
VA71	Judicial governance (enforcing the rules).
VA74	Coordination & integration across building blocks and levels of the MDVC.

The following alleviations were suggested by MDVC stakeholders: A1, A4, A7, A9, A10, A12 and A13 (see Appendix G).

8.4 Review of research objectives

Table 8.4 Research objective checklist

PHASE 1	
RO1: Determine research gap and define the problem statement. • The MDVC has not been mapped in entirety.	☑
RO2: Establish a research design that can address the research gap and problem. • Discussed in Chapter 3.	☑
RO3: Establish a literature base that can be used to determine the objectives/ design requirements of an artefact (solution). • Completed in Chapters 4 and 5.	☑
RO4: Translate relevant concepts from literature into artefact design requirements. • Given in Chapter 6.	☑
RO5: Develop preliminary artefact. • Presented in Chapter 6 and 7.	☑
PHASE 2	
RO6: Review preliminary artefact with an appropriate expert and refine artefact accordingly. • Conducted in Chapter 7.	☑
RO7: Review evaluation methodologies. • Discussed in Chapter 7.	☑
RO8: Evaluate artefact using an appropriate methodology. • Achieved in Chapter 7.	☑
RO9: Analyse and discuss results. • Done in Chapter 7.	☑
RO10: Present final artefact design and conclusion • Completed in Chapter 8.	☑

8.5 Research summary

The final conceptual framework includes a full MDVC map of 74 VAs sorted under seven categories. These VAs and categories were validated by the 17 MDVC stakeholders that were interviewed. Moreover, the biggest bottlenecks in the WC were identified. Two systematic literature reviews established common bottlenecks and alleviations (See Chapters 4 and 5). Western Cape MDVC stakeholders were then asked to identify bottlenecks and alleviations based on their experience, which is given in Appendix F and G.

8.6 Final framework

Figure 8.2 visualises the framework. Firstly, the MDVC was mapped in its entirety. Then, semi-structured interviews with critical MDVC stakeholders from the WC were conducted to validate the VAs and identify bottlenecks and alleviations. Their answers were coded according to established bottlenecks, UEs, alleviations and DEs identified through the literature review.

MDVC MAPPED IN ITS ENTIRETY:	BOTTLENECKS	UNDESIRABLE EFFECTS	ALLEVIATIONS	& DESIRABLE EFFECTS
• Seven MDVC Categories & 74 VAs identified: 1. **Idea generation:** VAs 1-10. 2. **Research & Development:** VAs 11-25. 3. **Production/ Manufacturing:** VAs 26 – 35. 4. **Market:** VAs 36 – 41. 5. **Distribution & Use:** VAs 42 – 53. 6. **Waste Management:** VAs 54 – 58. 7. **Systemic:** VAs 59 – 74.	• **B1:** Inadequate research • **B2:** Lack of funding • **B3:** Excessively complicated processes • **B4:** Unforeseen supply chain disruption • **B5:** Inadequate infrastructure • **B6:** Poor data management • **B7:** Poor networking • **B8:** Poor supply chain management • **B9:** Lack of human resources • **B10:** Poor governance • **B11:** Corruption • **B12:** Lack of strategic decision-making/ planning • **B13:** Poor waste management	• **UE1:** Lack of medical device adoption • **UE2:** Lack of medical device start-ups • **UE3:** Medical device shortages • **UE4:** Medical device-associated pollution • **UE5:** Lack of alleviation implementation • **UE6:** Poor systems	• **A1:** Funding • **A2:** Alternative supply chains • **A3** Adaptation of medical device or medical device use • **A4:** Support • **A5:** 3D Printing & Additive Manufacturing • **A6:** Industry 4.0 & Digitalisation • **A7:** Strategic networking • **A8:** Supply chain monitoring • **A9:** Governance • **A10:** Holistic idea generation • **A11:** Brand awareness • **A12:** Medical device alternative • **A13:** Strategic decision-making	• **DE1:** Adoption of medical device • **DE2:** Successful medical device start-ups • **DE3:** Agile/ resilient supply chains • **DE4:** Sustainable waste management • **DE5:** Successful implementation of alleviations • **DE6:** System improvement

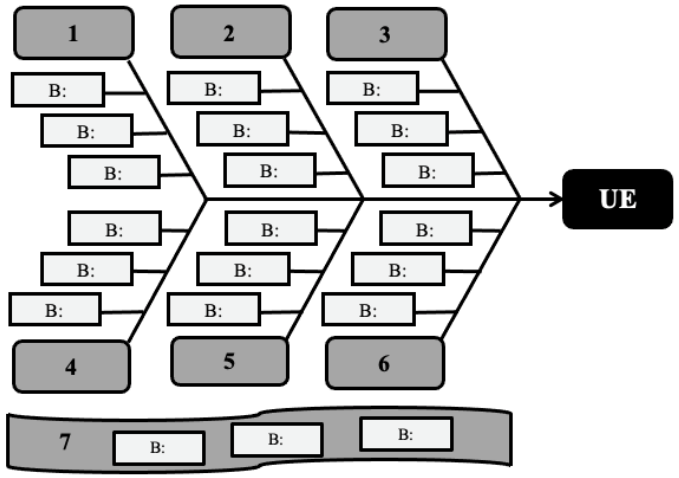
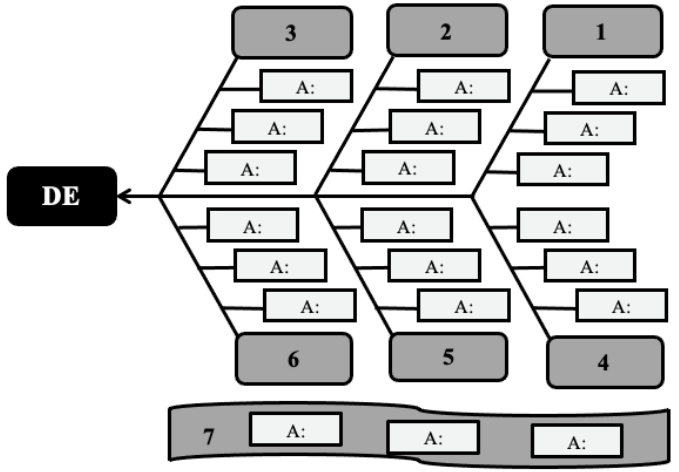
FISHBONE DIAGRAMS – FUNCTIONAL ANALYSIS	REVERSE FISHBONE DIAGRAMS – STAKEHOLDER OPINION
	

Figure 8.2: Final MDVC framework

8.7 Study limitations

The interviewee group is limited, and more stakeholders need to be interviewed to gain a better understanding of *Waste management*. Thus, VAs in that MDVC category were ranked fewer times than the other categories. Additionally, some VAs were considered redundant and unnecessary or were suggested to be moved, split or renamed. More iterations of the framework are needed to ensure that it is as concise as possible. It became clear that there is a significant disconnect between how industry players view the MDVC vs how academics view it.

The links between bottlenecks and UEs, and those between alleviations and DEs, needed to be validated by stakeholders. It would have been an excellent addition to populate the diagrams in another round of interviews wherein stakeholders' feedback could be obtained regarding populated fishbone diagrams and reverse fishbone diagrams more systematically.

Only three databases were searched using limited search strings. *Web of Science*, *Scopus* and *PubMed* were used, given that they have been ranked as the top three databases for academic research. However, there may be better databases for this specific topic.

The systematic literature review research questions presented in both Table 4.1 and Table 5.1 can be confused with the thesis research questions. Additionally, in the search string presented in Chapter 4, the plural term “devices” is used, effectively eliminating singular forms of this word choice. This should be avoided in future.

8.8 Recommendations for future work

This study forms part of the newly forming MDVC research foundation. A holistic MDVC map has been developed, and critical insights from multiple stakeholders have been incorporated. However, more primary research should be done to better this initial map so that it is crisp, clear and concise. Additionally, having a more extensive set of interviewees with a *Waste management* background would improve the validity of the current rankings. More regulatory employees/ representatives could also be included.

Future studies can build on this work by interviewing a more comprehensive range of stakeholders so that every perspective is reflected in the conceptual framework. Similarly, it is valuable to interview separate stakeholder groups, such as end-users vs innovators/ developers, so that their perspectives on MDVC bottlenecks and alleviations can be discussed and compared. Another interesting comparison would be to systematically compare the views of Academics vs Industry players and the views of established medical device companies vs SMEs.

Lastly, SAHPRA was considered a bottleneck and alleviation in progress. This contradictory finding should be further investigated. It would be valuable for SAHPRA’s role to be analysed in depth so that the activities stakeholders struggle with could be better pinpointed and alleviated.

A lack of networking was repeatedly cited as a bottleneck. SAHPRA may hold the key to alleviating this. SAHPRA registered stakeholders could be made visible with their contact details available. This could encourage collaboration between compliant MDVC stakeholders in the WC and SA.

REFERENCES

[1] Study Group 1 of the Global Harmonization Task Force, 'Definition of the Terms "Medical Device" and "In Vitro Diagnostic (IVD) Medical Device"', 2012. [Online]. Available: http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf#search=%22ghtf definition ?Medical Device? 2012%22.

[2] R. Kaplinsky and M. Morris, *A handbook for value chain research*. 2001.

[3] T. Douglas, 'Time to address need for medical devices'. Cape Times, p. 4, 2020.

[4] K. De Jager, C. Chimhundu, T. Saidi, and T. S. Douglas, 'The medical device development landscape in South Africa: Institutions, sectors and collaboration', *S. Afr. J. Sci.*, vol. 113, no. 5–6, pp. 1–8, 2017, doi: 10.17159/sajs.2017/20160259.

[5] Africa Health, 'Market Insights: South Africa Medical Devices Market', 2018.

[6] South African Medical Research Council, 'The Medical Devices Landscape in South Africa', 2022.

[7] 'SA population reaches 58,8 million | Statistics South Africa'. http://www.statssa.gov.za/?p=12362 (accessed Jan. 24, 2022).

[8] 'South African Medical Technology Industry Fact File', 2020.

[9] SAHPRA, 'Who we are', 2022. https://www.sahpra.org.za/who-we-are/ (accessed Jan. 24, 2022).

[10] SAHPRA, 'Guideline for a licence to manufacture, import, export or distribute medical devices & IVDs', *Licensing Medical Devices & IVDs*, no. 9. pp. 1–10, 2019.

[11] B. Goemans and R. McLaughlin, 'R-2-M Medical Devices', 2018.

[12] Deloitte & Touche, 'Research to guide the development of strategy for the Medical Devices Sector of South Africa'. p. 75, 2014, [Online]. Available: http://www.samed.org.za/DynamicData/LibraryDownloads/60.pdf.

[13] J. D. Steinberger, L. D. Mba, D. E. Azagury, T. J. Brinton, J. Makower, and P. G. Yock, 'Needs-Based Innovation in Interventional Radiology : The Biodesign Process', *Tech. Vasc. Interv. Radiol.*, vol. 20, no. 2, pp. 84–89, 2017, doi: 10.1053/j.tvir.2017.04.006.

[14] NASA, 'Technology Readiness Level Definitions'. p. 1, 1989, [Online]. Available: https://www.nasa.gov/pdf/458490main_TRL_Definitions.pdf.

[15] NASA, 'Technology Readiness Level | NASA', 2012. https://www.nasa.gov/directorates/heo/scan/engineering/technology/technology_readiness_level (accessed Nov. 11, 2022).

[16] Tempo Automation, 'Understanding Technology Readiness Level for Medical Devices Development', 2021. https://www.tempoautomation.com/blog/understanding-technology-readiness-level-for-medical-devices-development/.

[17] Fitch Solutions, 'Limited Benefits From Supply Chain Shifts In SSA's Medical Device

Industry', *Fitch Solutions Country Risks and Industry Research*, 2020.

[18] Fitch Solutions, 'Covid-19 Changing South Africa's Medical Device Market Dynamics', May 2020. Accessed: Jan. 15, 2022. [Online]. Available: https://www.fitchsolutions.com/medical-devices/covid-19-changing-south-africas-medical-device-market-dynamics-28-05-2020?fSWebArticleValidation=true&mkt_tok=NzMyLUNLSC03NjcAAAGB_REfyic7phxdRctgNCzcosY38Y8VxmBY4IzF9Cf3n6Sx01Kqp3YKhzhXs2qIuQD-pxVKpE5UJCUq-mhOmdNbK90aonUmiILvBMbKagkyI9sIsppERA.

[19] WHO, 'Medical devices', 2022. https://www.who.int/health-topics/medical-devices#tab=tab_1 (accessed Jan. 24, 2022).

[20] A. Keyter, S. Banoo, S. Salek, and S. Walker, 'The South African Regulatory System: Past, Present, and Future', *Front. Pharmacol.*, vol. 9, no. December, pp. 1–13, 2018, doi: 10.3389/fphar.2018.01407.

[21] Presidency, 'Launch of Health Sector Anti-Corruption Forum', *The Presidency Republic of South Africa*, 2019. https://www.thepresidency.gov.za/press-statements/launch-health-sector-anti-corruption-forum.

[22] I. Maharaj and B. P. Sunjka, 'A strategic framework for start-up medical device manufacturers in South Africa', *South African J. Ind. Eng.*, vol. 30, no. 3, pp. 63–76, 2019, doi: 10.7166/30-3-2243.

[23] S. S. S. Grobbelaar, N. Gwynne-Evans, and A. C. Brent, 'From enterprise development to inclusive innovation - A systemic instruments framework for regional innovation support', *African J. Sci. Technol. Innov. Dev.*, vol. 8, no. 2, pp. 233–246, 2016, doi: 10.1080/20421338.2016.1159401.

[24] M. E. Porter, *Competitive advantage: creating and sustaining superior performance*. New York, 1985.

[25] J. P. Womack and D. T. Jones, 'Lean thinking−banish waste and create wealth in your corporation', *J. Oper. Res. Soc.*, vol. 48, no. 11, pp. 1144–1150, 1997, doi: 10.1057/palgrave.jors.2600967.

[26] P. Raikes, M. F. Jensen, and S. Ponte, 'Global commodity chain analysis and the French filière approach: Comparison and critique', *Econ. Soc.*, vol. 29, no. 3, pp. 390–417, 2000, doi: 10.1080/03085140050084589.

[27] G. Gereffi, 'Commodity chains and global capitalism', M. Korzeniewicz and R. P. Korzeniewicz, Eds. London: Praeger Publishers, 1994, pp. 1–14.

[28] G. Gereffi, 'Commodity chains and global capitalism', in *Commodity chains and global capitalism*, London: Praeger Publishers, 1994, pp. 95–123.

[29] A. Feller, D. Shunk, and T. Callarman, 'Value Chains Versus Supply Chains', *BPTrends*, vol. March 2006, pp. 1–7, 2006.

[30] S. Patel, 'The research paradigm – methodology, epistemology and ontology – explained in simple language', 2015. http://salmapatel.co.uk/academia/the-research-paradigm-methodology-epistemology-and-ontology-explained-in-simple-language/ (accessed Mar. 28, 2022).

[31] C. Hay, 'What's "Political" About Political Science?', in *Political Analysis: A Critical Introduction*, PALGRAVE, 2002, pp. 59–86.

[32] M. Crotty, *The Foundations of Social Research*. SAGE Publications Inc., 1998.

[33] J. W. Creswell, *Research Design: Qualitative, Quantitative and Mixed Methods Approaches*, 4th ed. SAGE Publications Inc., 2014.

[34] A. Hevner and S. Chatterjee, *Design Research in Information Systems*. Springer, 2010.

[35] H. A. Simon, *The Sciences of the Artificial*, Third. MIT Press, 1996.

[36] R. Baskerville, A. Baiyere, S. Gregor, A. Hevner, and M. Rossi, 'Design science research contributions: Finding a balance between artifact and theory', *J. Assoc. Inf. Syst.*, vol. 19, no. 5, pp. 358–376, 2018, doi: 10.17705/1jais.00495.

[37] A. R. Hevner, 'A Three Cycle View of Design Science Research', *Scand. J. Inf. Syst.*, vol. 19, no. 2, pp. 87–92, 2007, doi: http://aisel.aisnet.org/sjis/vol19/iss2/4.

[38] R. Hevner Alan, 'A Three Cycle View of Design Science Research', *Scand. J. Inf. Syst.*, vol. 19, no. 2, pp. 87–92, 2007, [Online]. Available: https://www.researchgate.net/publication/254804390_A_Three_Cycle_View_of_Design_Science_Research.

[39] A. R. Hevner, S. T. March, J. Park, and S. Ram, 'Design Science in Information Research', *Manag. Inf. Syst. Q.*, vol. 28, no. 1, pp. 75–105, 2004.

[40] M. B. Miles and A. M. Huberman, *Qualitative Data Analysis - An Expanded Sourcebook*, Second. London: SAGE Publications Inc., 1994.

[41] C. N. Ngongoni, 'The Role of Innovation Intermediaries in Developing Healthcare Innovation Ecosystems: Value Co-Creation through Platforms', no. March, pp. 1–259, 2014.

[42] S. Ravitch and M. Riggan, *Reason & Rigor: How Conceptual Frameworks Guide Research*. SAGE Publications Inc., 2012.

[43] K. Peffers, T. Tuunanen, M. A. Rothenberger, and S. Chatterjee, 'A Design Science Research Methodology for Information Systems Research', *J. Manag. Inf. Syst.*, vol. 24, no. 3, pp. 45–77, 2007, doi: 10.2753/MIS0742-1222240302.

[44] K. Ishikawa, 'Cause-and-effect diagram (CE diagram)', in *Guide to Quality Control*, no. 2, Tokyo: Asian Productivity Organization, 1976, pp. 18–29.

[45] S. S. Li and L. C. Lee, 'Using fishbone analysis to improve the quality of proposals for science and technology programs', *Res. Eval.*, vol. 20, no. 4, pp. 275–282, 2011, doi: 10.3152/095820211X13176484436050.

[46] B. Minto, 'Questioning the summary statement', in *The pyramid principle*, Pitman Publishing, 1991, pp. 126–140.

[47] T. K. Bose, 'Application of Fishbone Analysis for Evaluating Supply Chain and Business Process- A Case Study on the ST James Hospital', *Int. J. Manag. Value Supply Chain.*, vol. 3, no. 2, pp. 17–24, 2012, doi: 10.5121/ijmvsc.2012.3202.

[48] D. Moher *et al.*, 'Preferred reporting items for systematic review and meta-analysis protocols (prisma-p) 2015 statement', *Syst. Rev.*, vol. 4, no. 1, pp. 1177–1185, 2015, doi: 10.1186/2046-4053-4-1.

[49] L. Shamseer *et al.*, 'Preferred reporting items for systematic review and meta-analysis protocols (prisma-p) 2015: Elaboration and explanation', *BMJ*, pp. 1–25, 2015, doi: 10.1136/bmj.g7647.

[50] C. F. Daiberl, S. J. Oks, A. Roth, K. M. Möslein, and S. Alter, 'Design principles for establishing a multi-sided open innovation platform: lessons learned from an action research study in the medical technology industry', *Electron. Mark.*, vol. 29, no. 4, pp. 711–728, 2019, doi: 10.1007/s12525-018-0325-2.

[51] H. Lawton Smith, S. Bagchi-Sen, and L. Edmunds, 'Innovation cycles and geographies of innovation: A study of healthcare innovation in Europe', *Eur. Urban Reg. Stud.*, vol. 25, no. 4, pp. 405–422, 2018, doi: 10.1177/0969776417716220.

[52] P. Cooke, 'Rational drug design, the knowledge value chain and bioscience megacentres', *Cambridge J. Econ.*, vol. 29, no. 3, pp. 325–341, 2005, doi: 10.1093/cje/bei045.

[53] Swiss Biotech, 'Swiss Biotech Report 2016', 2016. [Online]. Available: https://www.swissbiotech.org/wp-content/uploads/2019/04/swiss-biotech-report-2016.pdf.

[54] J. Howells, 'Intermediation and the role of intermediaries in innovation', *Res. Policy*, vol. 35, no. 5, pp. 715–728, 2006, doi: 10.1016/j.respol.2006.03.005.

[55] K. Cresswell, R. Williams, N. Carlile, and A. Sheikh, 'Accelerating innovation in health care: Insights from a qualitative inquiry into United Kingdom and United States innovation centers', *J. Med. Internet Res.*, vol. 22, no. 9, pp. 1–12, 2020, doi: 10.2196/19644.

[56] A. L. Siefert *et al.*, 'The Yale Center for Biomedical Innovation and Technology (CBIT): One Model to Accelerate Impact from Academic Health Care Innovation', *Acad. Med.*, vol. 94, no. 4, pp. 528–534, 2019, doi: 10.1097/ACM.0000000000002542.

[57] H. Herman, S. S. Grobbelaar, and C. Pistorius, 'The design and development of technology platforms in a developing country healthcare context from an ecosystem perspective', *BMC Med. Inform. Decis. Mak.*, vol. 20, no. 1, pp. 1–24, 2020, doi: 10.1186/s12911-020-1028-0.

[58] Y. Amano-Ito, 'Introduction of medical device development through industry–academia collaboration by the hamamatsu method', *Adv. Biomed. Eng.*, vol. 9, pp. 112–116, 2020, doi: 10.14326/abe.9.112.

[59] I. A. Omar, R. Jayaraman, M. S. Debe, K. Salah, I. Yaqoob, and M. Omar, 'Automating Procurement Contracts in the Healthcare Supply Chain Using Blockchain Smart Contracts', *IEEE Access*, vol. 9, pp. 37397–37409, 2021, doi: 10.1109/ACCESS.2021.3062471.

[60] S. Breschi and F. Lissoni, 'Knowledge Spillovers And Local Innovation Systems: A Critical Survey', in *40th Congress of the European Regional Science Association: 'European Monetary Union and Regional Policy'*, 2000, pp. 1–39, [Online]. Available: http://hdl.handle.net/10419/114910.

[61] S. Ferriani, M. H. Lazerson, and G. Lorenzoni, 'Anchor entrepreneurship and industry catalysis: The rise of the Italian Biomedical Valley', *Res. Policy*, vol. 49, no. 8, p. 104045, 2020, doi: 10.1016/j.respol.2020.104045.

[62] T. Thune and A. Mina, 'Hospitals as innovators in the health-care system: A literature review and research agenda', *Res. Policy*, vol. 45, no. 8, pp. 1545–1557, 2016, doi: 10.1016/j.respol.2016.03.010.

[63] N. Rosenberg, 'Some critical episodes in the progress of medical innovation: An Anglo-American perspective', *Res. Policy*, vol. 38, no. 2, pp. 234–242, 2009, doi: 10.1016/j.respol.2008.12.007.

[64] T. Schlich, *Surgery, Science and Industry: Revolution in Fracture Care, 1950s-1990s*, no. December. 2002.

[65] M. García-Goñi, A. Maroto, and L. Rubalcaba, 'Innovation and motivation in public health professionals', *Health Policy (New. York).*, vol. 84, no. 2–3, pp. 344–358, 2007, doi: 10.1016/j.healthpol.2007.05.006.

[66] A. C. Bullinger, M. Rass, S. Adamczyk, K. M. Moeslein, and S. Sohn, 'Open innovation in health care: Analysis of an open health platform', *Health Policy (New. York).*, vol. 105, no. 2–3, pp. 165–175, 2012, doi: 10.1016/j.healthpol.2012.02.009.

[67] M. F. F. Rosa *et al.*, 'Direct from the COVID-19 crisis: research and innovation sparks in Brazil', *Heal. Res. Policy Syst.*, vol. 19, no. 1, pp. 1–7, 2021, doi: 10.1186/s12961-020-00674-x.

[68] B. V. Seixas, F. Dionne, and C. Mitton, 'Practices of decision making in priority setting and resource allocation: a scoping review and narrative synthesis of existing frameworks', *Health Econ. Rev.*, vol. 11, no. 1, pp. 1–11, 2021, doi: 10.1186/s13561-020-00300-0.

[69] K. Mukherjee, 'Integrating technology, innovation and policy: COVID-19 and HTA', *Heal. Policy Technol.*, vol. 10, no. 1, pp. 16–20, 2021, doi: 10.1016/j.hlpt.2021.01.003.

[70] P. Dutta, T. M. Choi, S. Somani, and R. Butala, 'Blockchain technology in supply chain operations: Applications, challenges and research opportunities', *Transp. Res. Part E Logist. Transp. Rev.*, vol. 142, no. July, p. 102067, 2020, doi: 10.1016/j.tre.2020.102067.

[71] H. Juma, K. Shaalan, and I. Kamel, 'A Survey on Using Blockchain in Trade Supply Chain Solutions', *IEEE Access*, vol. 7, pp. 184115–184132, 2019, doi: 10.1109/ACCESS.2019.2960542.

[72] M. N. Kamel Boulos, J. T. Wilson, and K. A. Clauson, 'Geospatial blockchain: Promises, challenges, and scenarios in health and healthcare', *Int. J. Health Geogr.*, vol. 17, no. 1, pp. 1–10, 2018, doi: 10.1186/s12942-018-0144-x.

[73] J. Adler-Milstein, P. J. Embi, B. Middleton, I. N. Sarkar, and J. Smith, 'Crossing the health IT chasm: Considerations and policy recommendations to overcome current challenges andenable value-based care', *J. Am. Med. Informatics Assoc.*, vol. 24, no. 5, pp. 1036–1043, 2017, doi: 10.1093/jamia/ocx017.

[74] A. Dubovitskaya, P. Novotny, Z. Xu, and F. Wang, 'Applications of Blockchain Technology for Data-Sharing in Oncology: Results from a Systematic Literature Review', *Oncol.*, vol. 98, no. 6, pp. 403–411, 2020, doi: 10.1159/000504325.

[75] S. Khezr, M. Moniruzzaman, A. Yassine, and R. Benlamri, 'Blockchain technology in healthcare: A comprehensive review and directions for future research', *Appl. Sci.*, vol. 9, no. 9, pp. 1–28, 2019, doi: 10.3390/app9091736.

[76] N. C. Campling, D. G. Pitts, P. V. Knight, and R. Aspinall, ‘A qualitative analysis of the effectiveness of telehealthcare devices (i) are they meeting the needs of end-users?’, *BMC Health Serv. Res.*, vol. 17, no. 1, pp. 1–9, 2017, doi: 10.1186/s12913-017-2408-8.

[77] K. Noel and B. Ellison, ‘Inclusive innovation in telehealth’, *npj Digit. Med.*, vol. 3, no. 1, pp. 2–4, 2020, doi: 10.1038/s41746-020-0296-5.

[78] T. Greenhalgh, N. Fahy, and S. Shaw, ‘The bright elusive butterfly of value in health technology development: Comment on “providing value to new health technology: The early contribution of entrepreneurs, investors, and regulatory agencies”’, *Int. J. Heal. Policy Manag.*, vol. 7, no. 1, pp. 81–85, 2018, doi: 10.15171/ijhpm.2017.65.

[79] D. Abrol, T. Sundararaman, H. Madhavan, and K. J. Joseph, ‘Building inclusive health innovation systems: lessons from India’, *Cad. saúde pública*, vol. 32, no. supl.2, pp. e00045215–e00045215, 2016, [Online]. Available: http://www.scielosp.org/scielo.php?script=sci_arttext&pid=S0102-311X2016001205010.

[80] M. Mackintosh, P. Tibandebage, M. Karimi Njeru, J. Kariuki Kungu, C. Israel, and P. G. M. Mujinja, ‘Rethinking health sector procurement as developmental linkages in East Africa’, *Soc. Sci. Med.*, vol. 200, no. January, pp. 182–189, 2018, doi: 10.1016/j.socscimed.2018.01.008.

[81] G. A. Longhitano, G. B. Nunes, G. Candido, and J. V. L. da Silva, ‘The role of 3D printing during COVID-19 pandemic: a review’, *Prog. Addit. Manuf.*, vol. 6, no. 1, pp. 19–37, 2021, doi: 10.1007/s40964-020-00159-x.

[82] S. Bhaskar *et al.*, ‘At the Epicenter of COVID-19–the Tragic Failure of the Global Supply Chain for Medical Supplies’, *Front. Public Heal.*, vol. 8, no. November, pp. 1–9, 2020, doi: 10.3389/fpubh.2020.562882.

[83] C. C. Agbo and Q. H. Mahmoud, ‘Blockchain in healthcare opportunities, challenges, and possible solutions’, *Int. J. Healthc. Inf. Syst. Informatics*, vol. 15, no. 3, pp. 82–97, 2020, doi: 10.4018/IJHISI.2020070105.

[84] M. Gaynor, J. Tuttle-Newhall, J. Parker, A. Patel, and C. Tang, ‘Adoption of blockchain in health care’, *J. Med. Internet Res.*, vol. 22, no. 9, pp. 1–10, 2020, doi: 10.2196/17423.

[85] S. Khezr, M. Moniruzzaman, A. Yassine, and R. Benlamri, ‘Blockchain technology in healthcare: A comprehensive review and directions for future research’, *Appl. Sci.*, vol. 9, no. 9, 2019, doi: 10.3390/app9091736.

[86] T. Zayas-Cabán, K. J. Chaney, and D. W. Rucker, ‘National health information technology priorities for research: A policy and development agenda’, *J. Am. Med. Informatics Assoc.*, vol. 27, no. 4, pp. 652–657, 2020, doi: 10.1093/jamia/ocaa008.

[87] L. Hara, R. Guirguis, K. Hummel, and M. Villanueva, ‘More than bar codes: Integrating global standards-based bar code technology into national health information systems in Ethiopia and Pakistan to increase end-to-end supply chain visibility’, *Glob. Heal. Sci. Pract.*, vol. 5, no. 4, pp. 678–685, 2017, doi: 10.9745/GHSP-D-16-00350.

[88] H. O. Egharevba, O. Fatokun, M. Aboh, O. O. Kunle, S. Nwaka, and K. S. Gamaniel, ‘Piloting a smartphone-based application for tracking and supply chain management of medicines in Africa’, *PLoS One*, vol. 14, no. 7, pp. 1–14, 2019, doi:

10.1371/journal.pone.0217976.

[89] S. Carmody *et al.*, 'Building resilient medical technology supply chains with a software bill of materials', *npj Digit. Med.*, vol. 4, no. 1, pp. 2–7, 2021, doi: 10.1038/s41746-021-00403-w.

[90] G. H. Davies, J. Flanagan, D. Bolton, S. Roderick, and N. Joyce, 'University knowledge spillover from an open innovation technology transfer context', *Knowl. Manag. Res. Pract.*, vol. 19, no. 1, pp. 84–93, 2021, doi: 10.1080/14778238.2020.1746204.

[91] S. Bhaskar *et al.*, 'At the Epicenter of COVID-19–the Tragic Failure of the Global Supply Chain for Medical Supplies', *Front. Public Heal.*, vol. 8, no. November, pp. 1–9, 2020, doi: 10.3389/fpubh.2020.562882.

[92] M. Z. Hasan *et al.*, 'Integrated health service delivery during COVID-19: A scoping review of published evidence from low-income and lower-middle-income countries', *BMJ Glob. Heal.*, vol. 6, no. 6, pp. 2–4, 2021, doi: 10.1136/bmjgh-2021-005667.

[93] B. Heidt *et al.*, 'Point of care diagnostics in resource-limited settings: A review of the present and future of PoC in its most needed environment', *Biosensors*, vol. 10, no. 10, 2020, doi: 10.3390/BIOS10100133.

[94] V. Duque-uribe, W. Sarache, and E. Valentina, 'Sustainable Supply Chain Management Practices and Sustainable Performance in Hospitals : A Systematic Review and Integrative Framework', 2019.

[95] R. W. Ahmad *et al.*, 'Blockchain-Based Forward Supply Chain and Waste Management for COVID-19 Medical Equipment and Supplies', *IEEE Access*, pp. 44905–44927, 2021, doi: 10.1109/ACCESS.2021.3066503.

[96] M. F. Elledge *et al.*, 'Menstrual hygiene management and waste disposal in low and middle income countries—a review of the literature', *Int. J. Environ. Res. Public Health*, vol. 15, no. 11, 2018, doi: 10.3390/ijerph15112562.

[97] M. Tarfaoui, M. Nachtane, I. Goda, Y. Qureshi, and H. Benyahia, '3D Printing to Support the Shortage in Personal Protective Equipment Caused by COVID-19 Pandemic', *Materials (Basel).*, vol. 13, no. 15, pp. 1–21, 2020.

[98] E. Lugada, H. Komakech, I. Ochola, S. Mwebaze, M. Olowo Oteba, and D. Okidi Ladwar, 'Health supply chain system in Uganda: current issues, structure, performance, and implications for systems strengthening', *J. Pharm. Policy Pract.*, vol. 15, no. 1, pp. 1–11, 2022, doi: 10.1186/s40545-022-00412-4.

[99] M. Imran, C. Kang, and M. Babar Ramzan, 'Medicine supply chain model for an integrated healthcare system with uncertain product complaints', *J. Manuf. Syst.*, vol. 46, pp. 13–28, 2018, doi: 10.1016/j.jmsy.2017.10.006.

[100] H. Stadtler, 'Supply Chain Management and Advanced Planning', in *Supply Chain Management and Advanced Planning*, Third., H. Stadtler and C. Kilger, Eds. Berlin, 2005.

[101] J. Cohen and Y. van der M. Rodgers, 'Contributing factors to personal protective equipment shortages during the COVID-19 pandemic', *Prev. Med. (Baltim).*, vol. 141, no. April, p. 106263, 2020, doi: 10.1016/j.ypmed.2020.106263.

[102] T. K. Lepasepp and W. Hurst, ‘A systematic literature review of industry 4.0 technologies within medical device manufacturing’, *Futur. Internet*, vol. 13, no. 10, 2021, doi: 10.3390/fi13100264.

[103] B. Mukasa, M. Ali, M. Farron, and R. Van de Weerdt, ‘Contraception supply chain challenges: a review of evidence from low- and middle-income countries’, *Eur. J. Contracept. Reprod. Heal. Care*, vol. 22, no. 5, pp. 384–390, 2017, doi: 10.1080/13625187.2017.1394453.

[104] R. M. Visconti and D. Morea, ‘Healthcare digitalization and pay-for-performance incentives in smart hospital project financing’, *Int. J. Environ. Res. Public Health*, vol. 17, no. 7, 2020, doi: 10.3390/ijerph17072318.

[105] P. Chowdhury, S. K. Paul, S. Kaisar, and M. A. Moktadir, ‘COVID-19 pandemic related supply chain studies: A systematic review’, *Transp. Res. Part E Logist. Transp. Rev.*, vol. 148, no. August 2020, p. 102271, 2021, doi: 10.1016/j.tre.2021.102271.

[106] A. Manero *et al.*, ‘Leveraging 3D printing capacity in times of crisis: Recommendations for COVID-19 distributed manufacturing for medical equipment rapid response’, *Int. J. Environ. Res. Public Health*, vol. 17, no. 13, pp. 1–17, 2020, doi: 10.3390/ijerph17134634.

[107] D. Marbouh *et al.*, ‘Blockchain for COVID-19: Review, Opportunities, and a Trusted Tracking System’, *Arab. J. Sci. Eng.*, vol. 45, no. 12, pp. 9895–9911, 2020, doi: 10.1007/s13369-020-04950-4.

[108] W. T. Liao, M. Y. Hsu, C. F. Shen, K. F. Hung, and C. M. Cheng, ‘Home Sample Self-Collection for COVID-19 Patients’, *Adv. Biosyst.*, vol. 4, no. 11, pp. 1–5, 2020, doi: 10.1002/adbi.202000150.

[109] L. Carenzo *et al.*, ‘Hospital surge capacity in a tertiary emergency referral centre during the COVID-19 outbreak in Italy’, *Anaesthesia*, vol. 75, no. 7, pp. 928–934, 2020, doi: 10.1111/anae.15072.

[110] K. Iyengar, S. Bahl, Raju Vaishya, and A. Vaish, ‘Challenges and solutions in meeting up the urgent requirement of ventilators for COVID-19 patients’, *Diabetes Metab. Syndr. Clin. Res. Rev.*, vol. 14, no. 4, pp. 499–501, 2020, doi: 10.1016/j.dsx.2020.04.048.

[111] C. N. Okeagu and A. Resident, ‘Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID- 19 . The COVID-19 resource centre is hosted on Elsevier Connect , the company ’ s public news and information ’, no. January, 2020.

[112] E. J. Emanuel *et al.*, ‘Fair Allocation of Scarce Medical Resources in the Time of Covid-19’, *N. Engl. J. Med.*, vol. 382, no. 21, pp. 2049–2055, 2020, doi: 10.1056/nejmsb2005114.

[113] M. L. Ranney, V. Griffeth, and A. K. Jha, ‘Critical Supply Shortages - The Need for Ventilators and Personal Protective Equipment during the Covid-19 Pandemic’, *N. Engl. J. Med.*, vol. 382, no. 18, p. e41, 2020, [Online]. Available: nejm.org.

[114] N. Baker *et al.*, ‘COVID-19 Solutions Are Climate Solutions: Lessons From Reusable Gowns’, *Front. Public Heal.*, vol. 8, no. November, pp. 1–7, 2020, doi: 10.3389/fpubh.2020.590275.

[115] N. Parashar and S. Hait, ‘Plastics in the time of COVID-19 pandemic: Protector or polluter?’,

Sci. Total Environ., vol. 759, p. 144274, 2021, doi: 10.1016/j.scitotenv.2020.144274.

[116] W. Y. Ng *et al.*, 'Blockchain applications in health care for COVID-19 and beyond: a systematic review', *Lancet Digit. Heal.*, vol. 3, no. 12, pp. e819–e829, 2021, doi: 10.1016/S2589-7500(21)00210-7.

[117] G. Drosatos and E. Kaldoudi, 'Blockchain Applications in the Biomedical Domain: A Scoping Review', *Comput. Struct. Biotechnol. J.*, vol. 17, pp. 229–240, 2019, doi: 10.1016/j.csbj.2019.01.010.

[118] A. Alkhateeb, C. Catal, G. Kar, and A. Mishra, 'Hybrid Blockchain Platforms for the Internet of Things (IoT): A Systematic Literature Review', *Sensors*, vol. 22, no. 4, 2022, doi: 10.3390/s22041304.

[119] P. K. Wan, L. Huang, and H. Holtskog, 'Blockchain-Enabled Information Sharing within a Supply Chain: A Systematic Literature Review', *IEEE Access*, vol. 8, pp. 49645–49656, 2020, doi: 10.1109/ACCESS.2020.2980142.

[120] D. Vervoort, C. R. Guetter, and A. W. Peters, 'Blockchain, health disparities and global health', *BMJ Innov.*, vol. 7, no. 2, pp. 506–514, 2021, doi: 10.1136/bmjinnov-2021-000667.

[121] H. Sohn, A. Tucker, O. Ferguson, I. Gomes, and D. Dowdy, 'Costing the implementation of public health interventions in resource-limited settings: A conceptual framework', *Implement. Sci.*, vol. 15, no. 1, pp. 1–8, 2020, doi: 10.1186/s13012-020-01047-2.

[122] E. Iadanza, S. Cerofolini, C. Lombardo, F. Satta, and M. Gherardelli, 'Medical devices nomenclature systems: a scoping review', *Health Technol. (Berl).*, vol. 11, no. 4, pp. 681–692, 2021, doi: 10.1007/s12553-021-00567-1.

[123] M. Kunovjanek and C. Wankmüller, 'An analysis of the global additive manufacturing response to the COVID-19 pandemic', *J. Manuf. Technol. Manag.*, vol. 32, no. 9, pp. 75–100, 2020, doi: 10.1108/JMTM-07-2020-0263.

[124] Y. Xu, H. Y. Chong, and M. Chi, 'A Review of Smart Contracts Applications in Various Industries: A Procurement Perspective', *Adv. Civ. Eng.*, vol. 2021, 2021, doi: 10.1155/2021/5530755.

[125] A. Angrup, R. Kanaujia, P. Ray, and M. Biswal, 'Healthcare facilities in low- And middle-income countries affected by COVID-19: Time to upgrade basic infection control and prevention practices', *Indian J. Med. Microbiol.*, vol. 38, no. 2, pp. 139–143, 2020, doi: 10.4103/ijmm.IJMM_20_125.

[126] V. Haldane *et al.*, 'National primary care responses to COVID-19: A rapid review of the literature', *BMJ Open*, vol. 10, no. 12, pp. 1–10, 2020, doi: 10.1136/bmjopen-2020-041622.

[127] S. Best and S. J. Williams, 'What Have We Learnt About the Sourcing of Personal Protective Equipment During Pandemics? Leadership and Management in Healthcare Supply Chain Management: A Scoping Review', *Front. Public Heal.*, vol. 9, no. December, pp. 1–10, 2021, doi: 10.3389/fpubh.2021.765501.

[128] K. F. Yuen, X. Wang, F. Ma, and K. X. Li, 'The psychological causes of panic buying following a health crisis', *Int. J. Environ. Res. Public Health*, vol. 17, no. 10, 2020, doi: 10.3390/ijerph17103513.

[129] G. Harris and A. Adalja, 'ICU preparedness in pandemics: Lessons learned from the coronavirus disease-2019 outbreak', *Curr. Opin. Pulm. Med.*, vol. 27, no. 2, pp. 73–78, 2021, doi: 10.1097/MCP.0000000000000749.

[130] N. Karim *et al.*, 'Sustainable personal protective clothing for healthcare applications: A review', *ACS Nano*, vol. 14, no. 10, pp. 12313–12340, 2020, doi: 10.1021/acsnano.0c05537.

[131] V. V. Mišić and G. Perakis, 'Data analytics in operations management: A review', *Manuf. Serv. Oper. Manag.*, vol. 22, no. 1, pp. 158–169, 2020, doi: 10.1287/msom.2019.0805.

[132] Editor's Desk, 'Blockchain And Crypto Firm VeChain Utilized to Confirm Authenticity of Coronavirus KN95 Masks', *Blockchain Magazine*, 2020.

[133] G. Singh and J. Levi, 'MiPasa project and IBM Blockchain team on open data platform to support Covid-19 response', *IBM Supply Chain and Blockchain Blog*, 2020. https://www.ibm.com/blogs/blockchain/2020/03/mipasa-project-and-ibm-blockchain-team-on-open-data-platform-to-support-covid-19-response/ (accessed Apr. 01, 2022).

[134] W. R. Bolislis *et al.*, 'Regulatory Agilities in the Time of COVID-19: Overview, Trends, and Opportunities', *Clin. Ther.*, vol. 43, no. 1, pp. 124–139, 2021, doi: 10.1016/j.clinthera.2020.11.015.

[135] M. B. Miles, A. M. Huberman, and J. Saldana, *Qualitative Data Analysis: A Methods Sourcebook*, Third. SAGE Publications Inc., 2014.

[136] J. A. Maxwell, *Qualitative Research Design: An Interactive Approach*, Third. California: SAGE Publications Inc., 2013.

[137] Y. Jabareen, 'Building a Conceptual Framework: Philosophy, Definitions, and Procedure', *Int. J. Qual. Methods*, vol. 8, no. 4, pp. 49–62, 2009, doi: 10.1177/160940690900800406.

[138] J. E. van Aken, B. Hans, and H. van der Bij, *Problem Solving in Organizations: A Methodological Handbook for Business Students*. Cambridge University Press, 2007.

[139] R. Tarricone *et al.*, 'Lifecycle evidence requirements for high-risk implantable medical devices: a European perspective', *Expert Rev. Med. Devices*, vol. 17, no. 10, pp. 993–1006, 2020, doi: 10.1080/17434440.2020.1825074.

[140] N. Vordos *et al.*, 'How 3D printing and social media tackles the PPE shortage during Covid – 19 pandemic', *Saf. Sci.*, vol. 130, no. May, p. 104870, 2020, doi: 10.1016/j.ssci.2020.104870.

[141] S. Belhouideg, 'Impact of 3D printed medical equipment on the management of the Covid19 pandemic', *Int. J. Health Plann. Manage.*, vol. 35, no. 5, pp. 1014–1022, 2020, doi: 10.1002/hpm.3009.

[142] L. R. Burns, R. A. Degraaff, P. M. Danzon, J. R. Kimberly, W. L. Kissick, and M. V Pauly, *The Wharton School Study of the Health Care Value Chain*. 2002.

[143] A. Ahmed, A. Azam, M. M. Aslam Bhutta, F. A. Khan, R. Aslam, and Z. Tahir, 'Discovering the technology evolution pathways for 3D printing (3DP) using bibliometric investigation and emerging applications of 3DP during COVID-19', *Clean. Environ. Syst.*, vol. 3, no. May, p. 100042, 2021, doi: 10.1016/j.cesys.2021.100042.

[144] J. Check and R. K. Schutt, 'Research Methods in Education', in *Research Methods in*

Education, SAGE Publications Inc., 2012.

[145] J. A. Martilla and J. C. James, ‘Importance-Performance Analysis’, *J. Mark.*, vol. 41, no. 1, pp. 77–79, 1977.

Appendix A: Informed consent form

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM FOR ONLINE SURVEYS/QUESTIONNAIRES

TITLE OF RESEARCH PROJECT: Strengthening the value chain of medical devices: the case of the Western Cape

We would like to invite you to take part in a research project which involves the completion of an online questionnaire. Your participation is **entirely voluntary,** and you are free to decline to participate or to stop completing the questionnaire at any time, even if you have agreed to take part initially.

This study aims to… / What is the study about?

Medical devices are vital to modern healthcare. They serve many roles in diverse settings. The Western Cape boasts a strong medical device sector however, the COVID-19 pandemic highlighted that there is room for improvement. Value chain analysis is a systematic method that can be used to evaluate an industry sector. This method will be used to identify bottlenecks in the Western Cape's medical device value chain and suggest possible solutions in the form of a framework. This will involve defining the medical device value chain (every process involved from idea generation to device use and eventual disposal of the device). Moreover, it will entail breaking down these processes and identifying the stakeholders involved at each part to uncover the root causes of the bottlenecks and suggest implementable alleviations. The framework may also be used to assist other regions in strengthening their medical device sectors.

Anne Turner is conducting this study guided by supervisors, Professor Sara Grobbelaar, Professor Martin Nieuwoudt and Dr. Faatiema Salie. This study serves as Ms Turner's thesis topic to fulfil the requirements of a Master's in Biomedical Engineering (Research).

Participants will be asked questions based on their opinion regarding the bottlenecks identified, the solutions proposed and regarding the usability of the framework.

You are being asked to participate because…/ Why are you being asked to participate?

You have been invited to participate in this study as you fit the definition of a medical device value chain stakeholder in the Western Cape. Moreover, you have great experience in the field and thus, your expert opinion would be highly valuable to this study.

Your contact details were obtained via social media and/or through public websites.

If you agree to participate you will be requested to…/ What will participating in the study entail?
If you agree to take part in this study, you will be asked to participate in a semi-structured interview wherein your feedback regarding bottlenecks in the Western Cape's medical device value chain will be requested in a systematic way. The session will be conducted online via Microsoft Teams and will be 45 minutes long. All interview sessions will be recorded for data collection purposes. If surveys are used, they will be conducted online as well.

The potential benefits of this research are… / Will you benefit from taking part in this research?

This study may benefit you as a medical device value chain stakeholder in that your concerns will be heard and hopefully addressed in the development of this framework.
Your name/email will be delinked from the survey responses (i.e., your identity will not be revealed to other participants).

The potential risks involved in participating in this research are…/ Are there any risks involved in your taking part in this research?

There are minimal risks associated with this study and you may withdraw at any time. The 45-minute (maximum length) interview sessions will be conducted between 8am and 5pm during the week or on Saturdays between 9am and 4pm to accommodate differing schedules.

Your identity will not be disclosed or published if you decide to participate or not. The only form of personal data required is your job title and area of expertise – however, to protect your privacy, your name and the name of your employer or the company you work for will not be disclosed. Your name will be replaced by an ID code in the thesis.

Any information that you share during this study will be uploaded to the principal investigator's laptop, to her hard drive and to her private Atlas.ti account (all password protected). However, online surveys will not be run from a "secure" https server of the kind typically used to handle credit card transactions, so there is a small possibility that responses could be viewed by unauthorized third parties (e.g., computer hackers).

The information collected in this study may be used in future studies however, all recordings will be deleted following the completion of the study in 2023. You will not have access to the recordings however, you will have an opportunity to give feedback regarding what is transcribed from the sessions.

You can phone the Principal Investigator of this study, Anne Turner, at 0715770850 or email her at 20928394@sun.ac.za if you have any questions about this study or encounter any problems.

This study has been approved by the **Research Ethics Committee: Social, Behavioural and Education Research at Stellenbosch University (Project ID#: 23732).** The study will be conducted according to the ethical guidelines and principles of South Africa's Department of Health Ethics in Health Research: Principles, Processes and Studies (2015).

RIGHTS OF RESEARCH PARTICIPANTS:

You have the right to decline answering any questions and you can exit the survey/semi-structured interview at any time without giving a reason. If you have questions, concerns, or complaints regarding your rights as a research participant, please contact Mrs Clarissa Robertson [cgraham@sun.ac.za; 021 808 9183] at the Division for Research Development.

You will receive a copy of this information and consent form for you to keep safe.

By accepting a Microsoft Teams meeting invitation from Anne Turner (20928394@sun.ac.za), you are confirming that you are:

- over 18 years old;
- have read and understood the above explanation about the study; and
- you agree to participate.
- You also understand that your participation in this study is strictly voluntary.

Permission to have all anonymous data shared with journals:
When this study is finished, we would like to publish results of the study in journals. The journal may require us to share your anonymous data with them before they publish the results. Therefore, we would like to obtain your permission to have your anonymous data shared with journals.

Tick the Option you choose for anonymous data sharing with journals (Anne Turner will allow you to decide at the beginning of the online interview)

I agree to have my anonymous data shared with journals during the publication of the results of this study.

☐

OR

I do not agree to have my anonymous data shared with journals during the publication of the results of this study.

☐

Appendix B: Semi-structured interview slideshow

Strengthening the value chain of medical devices: the case of the Western Cape

By Anne Turner (Biomedical Engineering Master's student)

Supervisor: Professor Sara Grobbelaar

Co-supervisors: Professor Martin Nieuwoudt & Dr Faatiema Salie

BACKGROUND

What is a value chain?

- **The medical device value chain (MDVC)** describes the process of bringing a medical device from conception to distribution and beyond. This involves medical device idea generation (through the identification of healthcare needs), design, production, marketing, distribution, support provided to the end user and eventual disposal.
- **Value-adding activities (VAs)** that are grouped into these categories (or variations thereof) are often fulfilled by several different stakeholders involved in healthcare, academia, industry and government amongst others. Generally, healthcare providers play a role in the identification of needs; universities and research facilities create and expand on scientific/technological knowledge needed to address the identified needs; industry is involved in the translation of this knowledge into products that can be put on the market and lastly, government is responsible for making policies, establishing infrastructure and creating incentives that support the value chain.

Key definitions

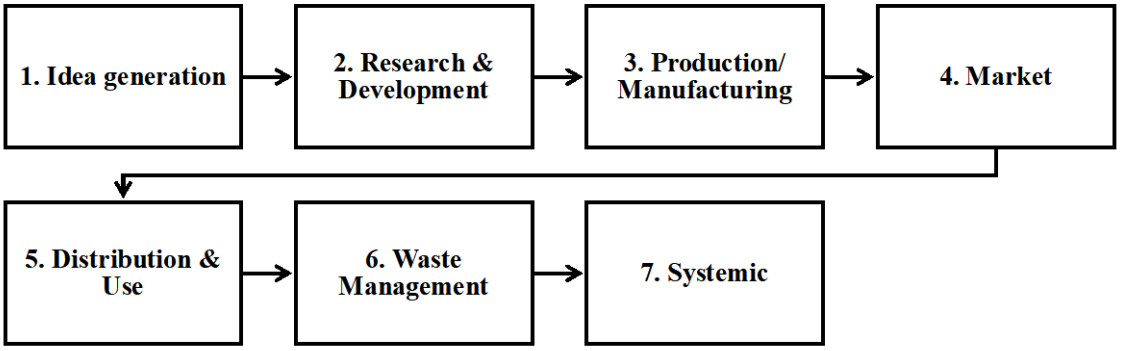
- **Bottleneck** = cause of a delay in a process or system.
- **Undesirable effect** = unwanted outcome that is exacerbated by MDVC bottlenecks.
- **Alleviation** = the action or process of making a problem less severe.
- **Desirable effect** = the ideal outcome that is supported by strategically implemented alleviations of bottlenecks.

Research Gap Identified

RESEARCH GAP: Through my literature review, I found that the MDVC has not yet been mapped in its entirety. Much of the literature focuses on specific parts/aspects only, given the multidisciplinary and complex nature of the medical devices industry.

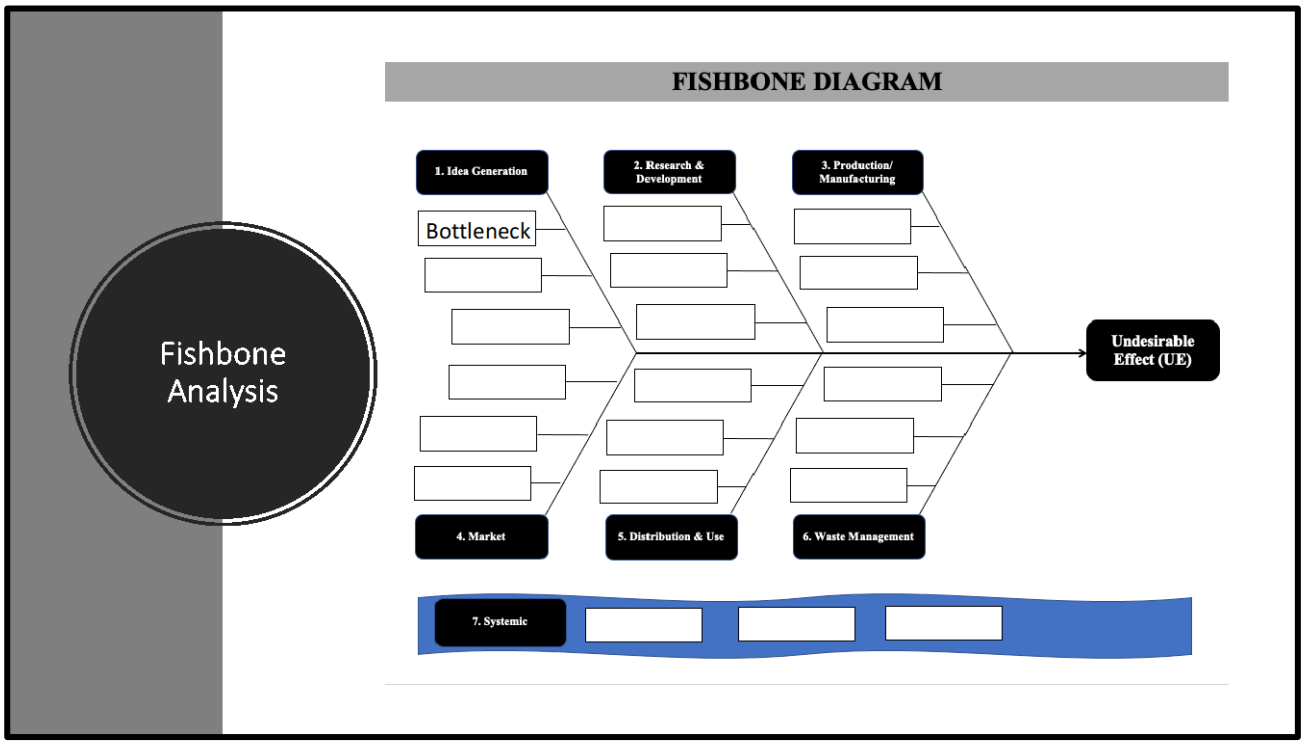
- Thus, I overlapped existing MDVCs and variations thereof against generic value chain categories in order to develop a full MDVC Map. Moreover, value adding activities (VAs) were also identified and sorted under their relevant MDVC category.
- This will be valuable as it will allow for a holistic approach to identifying MDVC bottlenecks and existing alleviations thereof that can then be implemented.

7 MDVC Categories



Value-adding activity	Effort	Importance	Difficulty
E.g., Acquire research funding	1 (Least effort required)	5 (Most important)	3 (Moderately difficult)

1. What bottleneck do believe occurs during this value-adding activity?
2. What alleviation do you think could be applied to mitigate this bottleneck?



Identified bottlenecks & the undesirable effects they cause

BOTTLENECKS

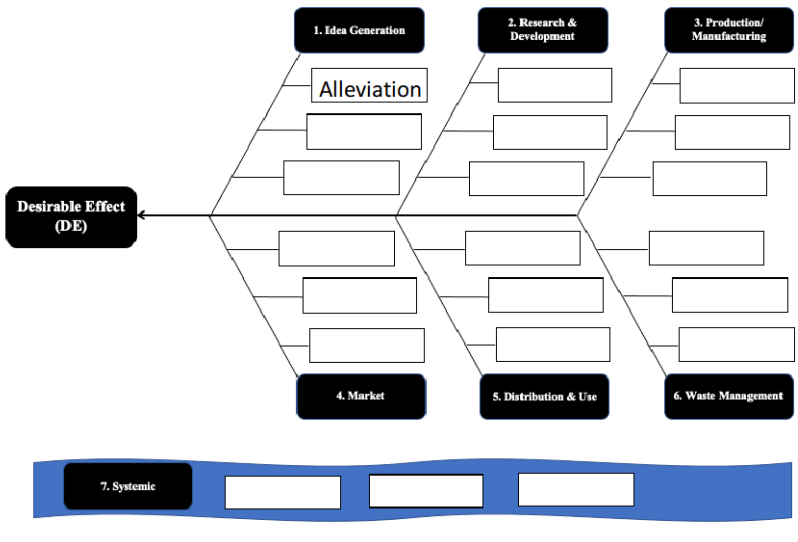
- B1: Inadequate research
- B2: Lack of funding
- B3: Excessively complicated processes
- B4: Unforeseen supply chain disruption
- B5: Inadequate infrastructure
- B6: Poor data management
- B7: Poor networking
- B8: Poor supply chain management
- B9: Lack of human resources
- B10: Poor governance
- B11: Corruption
- B12: Lack of strategic decision making/planning
- B13: Poor waste management
- B14: Other

UNDESIRABLE EFFECTS

- UE1: Lack of medical device adoption
- UE2: Lack of medical device start-ups
- UE3: Medical device shortage
- UE4: Medical device associated pollution
- UE5: Lack of alleviation implementation
- UE6: Poor systems
- UE7: Other

Fishbone Analysis

REVERSE FISHBONE DIAGRAM



Identified alleviations & the desirable effects they encourage

ALLEVIATIONS

- A1: Funding
- A2: Alternative supply chains
- A3: Adaptation of MD or MD use
- A4: Support
- A5: 3D Printing & Additive Manufacturing
- A6: Industry 4.0 & Digitalization
- A7: Strategic networking
- A8: Supply chain monitoring
- A9: Governance
- A10: Holistic idea generation
- A11: Brand awareness
- A12: MD alternative
- A13: Strategic decision-making
- A14: Other

DESIRABLE EFFECTS

- DE1: Adoption of MD
- DE2: Successful medical device start-ups
- DE3: Agile/resilient supply chains
- DE4: Sustainable waste management
- DE5: Successful implementation of alleviations
- DE6: System improvement
- DE7: Other

Conclusion of this presentation

- **Informed consent:**
  - Has been emailed to you.
  - Will be re-looked at at the start of the interview.
- **Will be starting the interview now unless you have any questions.**
- Thank you for agreeing to participate!

Appendix C: Data collection sheet

MEDICAL DEVICE VALUE CHAIN CATEGORY	VALUE-ADDING ACTIVITIES	EFFORT	DIFFICULTY	IMPORTANCE	TOTAL	NA TOTAL
Idea Generation	Develop relationships with potential end-users of medical device.					
	Develop relationship with purchasers & procurers of potential medical device.					
	Discovery & ideation (identifying needs and coming up with ideas; TRL 1).					
	Acquire research funding.					
	Determine the classification & nomenclature of your proposed medical device.					
	Determine where the product will be sold and used (cultural and social considerations regarding the medical device, its use and disposal should be taken into account).					
	Determine who will pay for the device (reimbursement).					
	Perform due diligence and obtain IP protection.					
	Forecast demand of potential medical device.					
	Identify route to market.					
Research & Development	Acquire seed funding.					
	Produce exploitation knowledge (knowledge required to transform research into commercial products).					

	Facilitate participatory knowledge spillovers in medical device clusters (readily available complementary local assets or capabilities).					
	Facilitate precipatory knowledge spillovers in medical device clusters (early access to local inventions, discoveries, or innovations).					
	Produce exploration knowledge (aim of fundamental research; TRL 2).					
	Technology transfer.					
	Confirm route to market/ project plan (TRL 3).					
	Invention & prototyping.					
	Information sharing.					
	Development (TRL 4-5).					
	Develop a proof of concept (TRL 5).					
	Preclinical evaluation (TRL 6).					
	Clinical trials I, II & III (TRL 7).					
	Produce examination knowledge (includes feedback from medical device trials/ use).					
	Regulate device (testing, QMS audit & validation; TRL 8).					
Production/ Manufacturing	Obtain seed funding.					
	Forecast demand of developed medical device.					
	Infrastructure investment.					
	Establish/ acquire manufacturing capabilities (ISO: 13485).					
	Facilitate information sharing.					
	Source equipment/ raw materials.					

	Determine emergency/ alternative manufacturing capabilities/ supply chains in case of disruptions.					
	Obtain marketing authorisation.					
	Package medical device.					
	Label medical device.					
Market	Branding of medical device.					
	Advertise/ market medical device.					
	Obtain endorsement from end-users.					
	Procurement of medical device (involves risk mitigation; contract compliance; cost savings; ongoing supplier relationships etc.).					
	Purchasing of medical device (aims to minimise the cost of an order).					
	Paying for medical device.					
Distribution & Use	Storage/ warehousing of medical device.					
	Inventory management.					
	Transportation of medical device.					
	Use of medical device (TRL 9).					
	Obtain feedback from end-user of medical device.					
	Post implementation improvement and adaptation of medical device.					
	Update clinical guidelines.					
	Sterilisation & reuse.					
	Determine obsolescence & replacement of medical device.					
	Decommissioning of medical device.					

	Waste generation.					
	Waste storage.					
Waste Management	Waste collection.					
	Waste transportation.					
	Waste segregation/ sorting.					
	Waste treatment.					
	Waste disposal/ recycling.					
Systemic	Registering stakeholders (SAHPRA).					
	Demand forecasting.					
	Ensure adequate staffing & train human resources.					
	Supply chain monitoring (review distribution networks).					
	Supply chain systems diagnostics.					
	Ergonomics.					
	Data acquisition.					
	Data storage.					
	Data sharing.					
	Obtaining funding.					
	Legislative governance (making the rules).					
	Executive governance (implementing the rules).					
	Judicial governance (enforcing the rules).					
	Crisis management planning.					
	Implementing alleviations to problems.					

	Coordination & integration across building blocks and levels of the MDVC.					

- Drop-down lists of 1-5, including a Not Applicable (NA) option, were set under the *EFFORT*, *DIFFICULTY*, and *IMPORTANCE* columns.
- A SUMIF(numbers) function was applied to cells under the *TOTAL* column.
    - Block changed colour according to the following range:
    - Red = 15.
    - Yellow = 9.
    - Green = 3.
- A COUNTIF(NA) function was applied to cells under the *TOTAL NA* column.

Appendix D: Average ranking data

MDVC CATEGORY	VALUE-ADDING ACTIVITIES	EFFORT (AVERAGE)	DIFFICULTY (AVERAGE)	IMPORTANCE (AVERAGE)
Idea generation	Develop relationships with potential end-users of medical device.	3,307692308	3,076923077	4,846153846
	Develop relationship with purchasers & procurers of potential medical device.	4	4,111111111	4,444444444
	Discovery & ideation (identifying needs and coming up with ideas; TRL 1).	3,545454545	3,272727273	4,727272727
	Acquire research funding.	4,181818182	3,909090909	4,727272727
	Determine the classification & nomenclature of your proposed medical device.	1,818181818	1,818181818	4
	Determine where the product will be sold and used (cultural and social considerations regarding the medical device, its use and disposal should be taken into account).	3,363636364	2,818181818	4,181818182
	Determine who will pay for the device (reimbursement).	2,727272727	2,818181818	4,090909091
	Perform due diligence and obtain IP protection.	3,9	3,3	4,2
	Forecast demand of potential medical device.	3,454545455	3,181818182	4,090909091
	Identify route to market.	3	2,8	4,3
Research & Development	Acquire seed funding.	4,363636364	4,181818182	4,545454545
	Produce exploitation knowledge (knowledge required to transform research into commercial products).	4	3,8	4,3
	Facilitate participatory knowledge spillovers in medical device clusters (readily available complementary local assets or capabilities).	2,75	2,75	4,111111111

	Facilitate precipatory knowledge spillovers in medical device clusters (early access to local inventions, discoveries, or innovations).	3,333333333	3,111111111	4
	Produce exploration knowledge (aim of fundamental research; TRL 2).	3,555555556	3,111111111	3,666666667
	Technology transfer.	4,111111111	3,666666667	4,444444444
	Confirm route to market/ project plan (TRL 3).	3,222222222	3,222222222	4,333333333
	Invention & prototyping.	4	3,666666667	4,75
	Information sharing.	3,5	3,777777778	3,333333333
	Development (TRL 4-5).	4,083333333	3,916666667	4,583333333
	Develop a proof of concept (TRL 5).	4,181818182	3,818181818	4,454545455
	Preclinical evaluation (TRL 6).	3,916666667	3,666666667	4,75
	Clinical trials I, II & III (TRL 7).	4,090909091	4	4,818181818
	Produce examination knowledge (includes feedback from medical device trials/ use).	3,428571429	3,071428571	4,857142857
	Regulate device (testing, QMS audit & validation; TRL 8).	4,071428571	4,071428571	5
Production/ Manufacturing	Obtain seed funding.	4,285714286	4	4,428571429
	Forecast demand of developed medical device.	3,1	3,7	4,2
	Infrastructure investment.	4	3,818181818	4,363636364
	Establish/ acquire manufacturing capabilities (ISO: 13485).	4,3	4	5
	Facilitate information sharing.	2,714285714	2,25	3,375
	Source equipment/ raw materials.	3,545454545	3,272727273	4,363636364
	Determine emergency/ alternative manufacturing capabilities/ supply chains in case of disruptions.	3,666666667	3,333333333	4,444444444
	Obtain marketing authorisation.	4,333333333	4,444444444	5
	Package medical device.	3,6	3,1	4,2
	Label medical device.	3,5	3,1	3,9

Market	Branding of medical device.	3,125	2,875	4,5
	Advertise/ market medical device.	3,25	3,25	4,5
	Obtain endorsement from end-users.	3,166666667	3,083333333	4,5
	Procurement of medical device (involves risk mitigation; contract compliance; cost savings; ongoing supplier relationships etc.).	4,285714286	4,142857143	4,857142857
	Purchasing of medical device (aims to minimise the cost of an order).	3,6	3,8	4,6
	Paying for medical device.	4,2	4	4,6
Distribution & Use	Storage/ warehousing of medical device.	2,857142857	2,571428571	3,857142857
	Inventory management.	3,25	3,375	4,5
	Transportation of medical device.	2,666666667	2,666666667	3,833333333
	Use of medical device (TRL 9).	3,625	3,5	4,5
	Obtain feedback from end-user of medical device.	3,2	2,9	4,8
	Post implementation improvement and adaptation of medical device.	3,625	3,25	4,666666667
	Update clinical guidelines.	2,5	2,375	4,555555556
	Sterilisation & reuse.	2,8	2,2	4,2
	Determine obsolescence & replacement of medical device.	2,444444444	3	4,625
	Decommissioning of medical device.	1	1	5
	Waste generation.	1,8	2,4	4,2
	Waste storage.	2,333333333	2,666666667	4,25
Waste Management	Waste collection.	3,5	2,5	4,5
	Waste transportation.	3,5	2,5	4,5
	Waste segregation/ sorting.	2	3	4
	Waste treatment.	3,5	3	4,5
	Waste disposal/ recycling.	3,5	2,5	4,5

Systemic	Registering stakeholders (SAHPRA).	3,166666667	3,083333333	4,833333333
	Demand forecasting.	3,111111111	3,222222222	4,666666667
	Ensure adequate staffing & train human resources.	3,583333333	3,166666667	4,666666667
	Supply chain monitoring (review distribution networks).	3	2,8	4,363636364
	Supply chain systems diagnostics.	3	3,125	4,25
	Ergonomics.	3,636363636	3,363636364	4,818181818
	Data acquisition.	3,363636364	3	4,636363636
	Data storage.	3,1	2,8	4,5
	Data sharing.	3,444444444	3,111111111	4,333333333
	Obtaining funding.	4,083333333	4	4,538461538
	Legislative governance (making the rules).	3,666666667	3,666666667	5
	Executive governance (implementing the rules).	2,5	2,5	4,5
	Judicial governance (enforcing the rules).	2,5	3,5	5
	Crisis management planning.	3,222222222	2,666666667	4,625
	Implementing alleviations to problems.	3,3	3,3	4,2
	Coordination & integration across building blocks and levels of the MDVC.	4	3,25	4,666666667

Appendix E: Stakeholder feedback on the MDVC

VALUE-ADDING ACTIVITY	STAKEHOLDER COMMENTS
MDVC CATEGORY 1: IDEA GENERATION	
Develop relationships with potential end-users of medical device.	• S4: "You can't really start unless you've got a relationship with the end-user, because you've got to test it. First, before you start the design, you want to find out the pros and cons and what their hassles are. Without a relationship, it's very difficult to know where you're going." • S5: "Your idea will come from a need, but the industry doesn't always fully understand the need because of a lack of data and relationships." • S14: "I would say that is the most important thing, but yet it is the least done." • S17: "That's one of the most important things that they should be doing."
Develop relationship with purchasers & procurers of potential medical device.	• S4: "But to know who I'm going to sell it to. It would be fantastic if I always knew but, that's the risk of being an entrepreneur. In other words, I'm going to take the risk because I know I'm developing something well because I've worked with end-users, and I've worked with the distributor who's going to help me sell it." – Response with regards to not establishing relationships with purchasers and procurers this early on. • S4: "I can continue to develop without having that relationship." • S12: "For a start-up company to try and you know get a system or to get a Clicks to essentially buy your devices or to get someone at a hospital, the procurement department at a hospital to buy your equipment or technology, is very difficult."
Discovery & ideation (identifying needs and coming up with ideas; TRL 1).	• S4: "Sometimes this is an easy process in that it's just such a fantastic product that we go through this very quickly. Other times, we've got to uhm and ahh and look at it… We've also got a financial side to look at. We've got to say, is this really better? Is this going to be too expensive to create? It may not be competitive. So, this is an area where you've got to spend a lot of time." • S14: "Yeah, that depends on the person's creativity."
Acquire research funding.	• S9: "I spend most of my time trying to raise funding."
Determine the classification & nomenclature of your proposed medical device.	• S4: "The higher the classification, pretty much linearly, the more cost involved. There's more risk to the patient. There's more effort that's going to be put in, and then your research and development costs go through the roof. So, this is important to me only from the point of view that I try do nothing more than a Class 2A. Because, I just don't have the expertise to start getting involved in products much bigger than that." • • S4: "From a research point of view, this is very important to know because it determines your financial model and the risk and all that sort of stuff."
Determine where the product will be sold and used (cultural and social considerations regarding the medical device, its use and disposal should be taken into account).	• S4: "We think about that in the design." • S9: "Knowing where your market is, is crucial."
Determine who will pay for the device (reimbursement).	• S4: "It's all set-up systems that are in operation, no problem."

Perform due diligence and obtain IP protection.	• S4: “OK, so this is about Western Cape, but so when it comes to South Africa and selling it, this isn't so important. But we can't just make money out of out of South Africa. We've got to get our volumes. We've got to sell overseas. Overseas companies will not sell anything where they are at risk of being sued because it's very litigious, countries like the US. So, it's very important for them that I have an IP because if there's an IP, then they are pretty much guaranteed nobody's going to come sue them for the product.” • S12: “We’ve had challenges where we’ve patented things in the ideation stage and then by the time we get to production, we’ve lost three years of our IP. So, as a business, you need to evaluate where you want to do the IP protection. It can go into the production stage as well.” • S12: “What you develop during the ideation phase will guaranteed change once you get to the production phase. And sometimes the changes can be so fundamental that your patent no longer covers essentially what you're actually taking into market.” • S14: “You'd keep the whole thing quiet for as long as possible. And then at the end, determine whether you're going to do your IP protection or not.”
Forecast demand of potential medical device.	• S4: “Forecasting is the start of any financial work.” • S14: “It’s doing your market analysis.”
Identify route to market.	• S12: “These things become important, especially when you’re looking to raise capital for your medical device.”
MDVC CATEGORY 2: RESEARCH & DEVELOPMENT	
Acquire seed funding.	• S4: “I just know I’m not going to get funding. I have to decide how I’m going to fund it myself.” • S4: “In this country, to get seed funding, BEE is very important.” • S5: “If your product idea is solid, your funding becomes easier.” • S6: “So this this is the most difficult thing… If one comes up with an idea; to find seed funders or VC's and people like that; they're not difficult to find, but they're difficult to impress because many of them don't understand the technology, don't understand the application. And then because they don't understand, they don't fund. And so, when we talk about funding, we're looking at grant funding. Uh, and it's taken us seven years to get grant funding from government.” • S12: “Sometimes to raise capital for a medical device you don't even need an invention or a prototype. You can essentially raise capital on the basis of a concept or an idea.”
Produce exploitation knowledge (knowledge required to transform research into commercial products).	• S5: “I would say, having access to experts in the university at that stage, that can help guide you.”
Facilitate participatory knowledge spillovers in medical device clusters (readily available complementary local assets or capabilities).	• S14: “It’s lovely to be in an environment like that where you have the spillover.”
Facilitate precipatory knowledge spillovers in medical device clusters (early access to local inventions, discoveries, or innovations).	• S6: “What we call the Triple Helix.” • S14: “Same as the above.”
Produce exploration knowledge (aim of fundamental research; TRL 2).	• S14: “We’ve sort of answered that above.”
Technology transfer.	• S12: “That’s basically the space between R&D and Production/ Manufacturing.” • S12: “You need to make sure that the manufacturers understand exactly what you’re looking to do.”

	• S14: " I wouldn't even think of that at this stage."
Confirm route to market/ project plan (TRL 3).	• No comments but it was ranked.
Invention & prototyping.	• S4: "This is how we do market research and how we work with our advisory committee." • S4: "We don't follow any protocol, whatever. But it's pretty standard. So, it would be it would be a garage type thing. Then it would be 3D printing as many prototypes until we get what we want. Then we will go to making a commercial type of product. So, it won't have all the finishes and it'll be as cheap as we can do it, but it will be when you put in your hand, it's got to be robust and feel like the commercial product." • S4: "It's sometimes the equipment that we're going to need to assemble…For this last product, we had to find a way to cut a razor blade in two halves. Believe it or not. So, we had to develop a machine for that." • S5: "Those are two very distinct tasks. But invention is probably the most difficult because there are not many opportunities to invent something anymore, anything that has meaningful purpose." • S8: "Building a prototype is relatively easy." • S8: "Like processors, with the prototyping you can buy a little processor that costs R1000 but when you're going into production, you can't; you can only buy one that costs R50."
Information sharing.	• S8: "So that's not really information sharing. Its access to information."
Development (TRL 4-5).	• S4: "We see it as part of invention and prototyping". • S6: "This is the level at which we would be looking to, for example, the Department of Science and Technology to take our proof of concept and actually impress on the Department of Health that this product is good and requires further investment and commercialisation." • S8: "So these technology readiness levels, it's a very academic thing. You know you go to production houses; you talk to them, they don't know what you're talking about. We don't, they don't classify things in those kinds of terms."
Develop a proof of concept (TRL 5).	• S4: "Fits into invention and prototyping." • S4: "That *proof of concept* would be a pre-commercialization of the product."
Preclinical evaluation (TRL 6).	• No comments but it was ranked.
Clinical trials I, II & III (TRL 7).	• S12: "You get a clinical research organisation to do most of it for you. You just help them to develop the protocol."
Produce examination knowledge (includes feedback from medical device trials/ use).	• No comments but it was ranked.
Regulate device (testing, QMS audit & validation; TRL 8).	• S4: "Goes hand in hand with production and manufacturing". • S13: "It's not a lot of effort to be honest with you. It's a matter of an organisation complying to the requirements or the regulations and the Act. And because this is a new area, most organisation are not yet there." • S13: "Most companies are not willing to comply." • S16: "It's not that difficult, just laborious."
MDVC CATEGORY 3: PRODUCTION/MANUFACTURING	
Obtain seed funding.	• S7: "I think there is need for funding at that stage, but maybe the terminology might be different there." • S12: "I would say seed/series funding. You would raise seed funding in certain countries otherwise you'd raise series funding. Series funding is in the tens of millions of US dollars." • S14: "You need tens of millions now. It's commercialisation funding, which is 10x seed funding."
Forecast demand of developed medical device.	• S4: "That determines what size equipment you're going to buy, and what size injection moulding machine, for instance." • S4: "That's the entrepreneurial side; sometimes you've got to take a chance."

	• S7: “I like the fact that you brought that over here because I think that at different points in the value chain, sometimes the needs keep changing. It has just occurred to me right now when I’ve seen this over here again.” • S12: “I think that all falls under your seed funding process because you need to do that in order to raise capital.” • S14: “You need to fine-tune what you’ve done before.”
Infrastructure investment.	• S4: “I go an out-source model to reduce the money I have to put into production and manufacturing.”
Establish/ acquire manufacturing capabilities (ISO: 13485).	• S4: “If you want to start your own factory, then this is a big effort. This is hard because it can take time and cost a lot of money and it costs a lot of money to maintain. It's not just a once-off thing. You’ve got to be audited every couple of years.” • S6: “This is a very contentious subject. It took us three years and about R300,000 to do that.” • S12: “As a manufacturer you can sometimes take responsibility for manufacturing, but you don't actually do it; you actually outsource it.” • S12: “Basically it’s two very different things when you’re looking at manufacturing and getting IS0: 13485.” – Response with regards to how ISO: 13485 is not always necessary in SA when you outsource manufacturing/ injection moulding to accredited ISO: 9001 facilities.
Facilitate information sharing.	• S5: “It's a nice to have but doesn't always happen and people tend to hold on to their own information because it's their IP.” • S6: “So we've got two industry bodies here that look after local manufacturing and those industry bodies have about 80 members and those 80 members, to a fair degree, share information. And there's a certain level of trust amongst those members and they tend to share information freely. Obviously, nothing that's going to put your IP at risk. But there is a fair amount of good, honest sharing.” • S7: “I think it's applicable and I think it should be given due consideration.” • S8: “It’s not really applicable. If the device is going to make money, then people don’t share that kind of information.” • S14: “I’m a big one for sharing, but you need to have some IP protection.”
Source equipment/ raw materials.	• S4: “Sometimes it's very easy and it's not a big deal. And other times. Yeah. I mean, I've just with this latest product; I've really battled to find one of the raw materials.”
Determine emergency/ alternative manufacturing capabilities/ supply chains in case of disruptions.	• S4: “We do have options and we are very aware of them, but we can't spend the money. So, it could even be on a supply chain when we might keep more components than we need.” • S4: “We do minor things because of this, but it is a huge risk in our business.” • S7: “I think I think the starting point would be starting to plan. During the pandemic, we noticed that there was barely any planning going on for emergency use authorisation, emergency devices. The manufacturing capabilities were low in the nation. So, I think the pandemic taught us something moving forward that if and I pray this doesn't happen again. But if this happens, we are better prepared. We're in a much better place.”
Obtain marketing authorisation.	• S4: “Rather than *marketing authorisation*, it’s certification.” • S4: “You’re best-off manufacturing in ISO: 13485, having a proper technical file, doing proper design files.” • S4: “As you’re doing design and development, you better be thinking regulatory because you’ve got to manage the design and development files… That’s going to be part of your regulatory side and getting your registration.” • S4: “Regulatory starts with design.” • S4: “It’s part of something else. I wouldn’t even have this in my checklist.”
Package medical device.	• S4: “I’ve learned through a recall that you put a lot more effort into this than you think.”

	• S4: "And before you can determine packaging, you've got to determine you know, are you sterilizing or are you not sterilizing? Then you've got to determine in what environment is it being used; so where does it go? You've got to think of volumes per pack… you don't want to put 100 into a box and they only use 10 a year." • S4: "Some medical devices need to be held intact." • S4: "Packaging also is a very early-on determiner of quality. If the packaging is really poor, people might not want the product because it would look bad quality."
Label medical device.	• S4: "That forms part of your certifications and regulations." • S4: "If it's sterile, you've got to put on there that it's sterile and how it's been sterilized. You've got to make sure the manufacturer contact details are on there and you've got to put warning signs." • S4: "You've got to work together with your certification or auditing body or with the FDA or whatever to find out what the minimum requirements are." • S4: "UDI is a big thing… So basically, when you scan the barcode, it gives you the expiry date and the manufacturing information. It's all about traceability."
MDVC CATEGORY 4: MARKET	
Branding of medical device.	• No comments but it was ranked.
Advertise/ market medical device.	• S4: "My distributors to their marketing, but I do a lot of background marketing. So that could be trade shows, that could be our website, that could be social media." • S4: "It's not going to determine whether I'm successful or a failure." • S12: "It depends on your target markets and if it's B2B or B2C."
Obtain endorsement from end-users.	• S4: "The more endorsements you can get, the better". • S5: "Getting access to them for that endorsement is not easy and you want to be neutral and not seen as paying someone to endorse your product."
Procurement of medical device (involves risk mitigation; contract compliance; cost savings; ongoing supplier relationships etc.).	• No comments but it was ranked.
Purchasing of medical device (aims to minimise the cost of an order).	• No comments but it was ranked.
Paying for medical device.	• S5: "Same as purchasing." • S6: "This should probably read *reimbursement of medical devices*." • S7: "We're moving towards personalized medicine. So, we have most patients purchasing medical devices. We saw that during the pandemic with the test kits and the patient monitors."
MDVC CATEGORY 5: DISTRIBUTION & USE	
Storage/ warehousing of medical device.	• S3: "Healthcare warehouses need to be ISO compliant which entails several rules/regulations regarding stock storage, refrigeration, products first in and first out" • S4: "You've got to meet ISO regulations. You've got to rotate the stock right. You've got to store it correctly. So, it's important."
Inventory management.	• S4: "We run a proper IT system and do that really properly."
Transportation of medical device.	• S4: "We arrange it, we don't transport it, so we use service providers to do that. So, it either goes by ship, by air or by local sales it's trucked."

Use of medical device (TRL 9).	• S1: “It’s very useful to have a human being showing you how to use it [medical device] rather than a set of instructions. It’s useful to have personal contact.”
Obtain feedback from end-user of medical device.	• S4: “This is becoming quite important because it’s part of your certification. They want you to continually run feedback and particularly if you got adverse stuff as you documented. You’ve got to tell them what you've done to mitigate and to improve because this is part of the quality and making sure the product gets better and better.” • S6: “That would be post market surveillance.”
Post implementation improvement and adaptation of medical device.	• S4: “It’s becoming, regulatory-wise, very important.” • S8: “It's really hard to change things once they're in production.” • S16: “The other issue with medical devices is that often problems that come up with the device aren’t immediately apparent.”
Update clinical guidelines.	• S4: “If we pick up something from the feedback, then we will update.”
Sterilisation & reuse.	• S10: “It's not always together because you sterilize disposables as well.” •
Determine obsolescence & replacement of medical device.	• S3: “For all our branch lab analysers, that’s generally a five-year placement. By which time the device is either finished physically or obsolete in that better ones have come out. We do watch that, and we sometimes replace earlier than the five years if we must; so, it’s more like a monitoring thing.” • S11: “That’s the hospital’s problem.”
Decommissioning of medical device.	• No comments but it was ranked.
Waste generation.	• S15: “Waste generation is basically all your institutions that generate the waste. For example, your hospitals, your clinics, your doctor's practices, any healthcare institution where they work with needles or any medical devices as such.” • S15: “We call it *cradle to grave* from the point waste is generated up until the point we dispose of the waste.” • S15: “Waste generation happens at the facility.” – Facility means the hospital/ clinic etc.
Waste storage.	• S15: “Waste storage also happens at the facility. Once the containers are full, they keep it in temporary storage up until the appointed service provider comes.”
MDVC CATEGORY 6: WASTE MANAGEMENT	
Waste collection.	• S15: “You need to appoint a service provider that will come and collect your waste. They will issue you with a data sheet as proof because you must track that waste from your facility up until it goes to a legal compliant site where they will dispose of it.”
Waste transportation.	• S15: “If you have systems in place, if you have trucks that are compliant to be on the road and your drivers know what to do, the process is practically streamlined, so it’s not that difficult.” • S15: “That is also part of your collection. You need to make sure your vehicle is compliant to be on the road. With a specialised body vehicle, you have to have two compartments, one where you put your clean containers and one where you put all your full containers. You don’t want cross-contamination.”
Waste segregation/ sorting.	• S15: “Waste segregation is actually important because you get different waste types with different Hazard Ratings.” • S15: “They have a colour-coded system at the facility where you collect the waste.” • S15: “We do not open the bins because we’re not allowed to. They’re triple seal containers. So whatever the generator placed inside that container we deem as medical waste.”
Waste treatment.	• S15: “You want to make sure your process falls within the legal compliance and regulatory requirements.” • S15: “Facilities like ours need to be authorized by the National Department of Environmental Affairs in order to run and be authorised to treat the waste.”

	• S15: “We have an incinerator and a microwave sterilized treatment process.”
Waste disposal/ recycling.	• S15: “We generate by products. That waste is then taken to a Class A site (according to the waste classification regulations).”
MDVC CATEGORY 7: SYSTEMIC	
Registering stakeholders (SAHPRA).	• S4: “It's a once-off effort and then there's a little bit of admin. So yeah, there's effort to start, but monthly, annually; it's not a lot at all. Once you're done, it's done.”
Demand forecasting.	• S3: “I think it’s important because I mean we demand forecast for all our testing, because there are seasonal variations in testing and obviously pandemics are a different story. But, even for normal testing, we are always busier in January/February, quieter in June/July and then busy again in October/November. So, we have an automated ordering system that looks at the previous months and the full cost of the coming months. We order according to that otherwise we tend to overstock or understock.” • S4: “We have an IT system to manage a lot of this because it gets quite complex.”
Ensure adequate staffing & train human resources.	• S3: “Medical technologists, medical doctors and medical nurses are all in short supply. We are forever sourcing and training and repeat-training.” • S3: “Without the people, we can’t function.”
Supply chain monitoring (review distribution networks).	• No comments but it was ranked.
Supply chain systems diagnostics.	• No comments but it was ranked.
Ergonomics.	• S4: “We spend a lot of time looking at ergonomics when we design the product. There’s not much you can do once it’s on the market.” • S4: “No product is perfect straight after design and development… You learn a lot, really, once it's on the market, that's when you really, truly learn. And then maybe in three to five years’ time you might then do a total new tooling and then fix the ergonomics, fix a couple of the issues, maybe add a few extra features.” • S6: “We’ve got a retired anaesthetist who has a Master’s in Ergonomics, believe it or not, who we consult with.” • S12: “We do look at the ergonomics of our device in terms of human factor studies; that forms a huge part of our clinical trials.” • S14: “Ergonomics is critical.”
Data acquisition. Data storage. Data sharing.	• S3: “It’s all routine now and automated so it’s not difficult.” • S4: “And all of that has got a lot to do with traceability. Traceability is very important, so you better keep data.” • S7: “It's important throughout the value chain” • S8: “I would make this data management.” • S10: “You could almost handle all three of them together.” • S14: “There’s quite a lot of information that you need to be careful of... You’ve got the POPI Act and all that to consider.” – Response with regards to the sensitivity of certain data.
Obtaining funding.	• S3: “We’re a partnership so half the funding comes from the partners and the other half comes from the bank. So, we don’t go to other people or external parties for funding.” • S3: “Without funding, you can’t function.”
Legislative governance (making the rules).	• S6: “We contribute to the Healthcare Master Plan which has members from the Department of Health, the Department of Trade and Industry on that board.”

Executive governance (implementing the rules).	• No comments but it was ranked.
Judicial governance (enforcing the rules).	• No comments but it was ranked.
Crisis management planning.	• S3: “Before and after COVID, we don’t have many crises. Things flow along.” • S3: “If it happens, it’s important at the time.” • S4: “There's not much you can do. You’ve got to keep all your data on your systems… Crises management for me is all about that data and the storage and the accessibility of that data. Because when the crisis hits, you need that information. You need to be able to communicate.”
Implementing alleviations to problems.	• S3: “What we do a lot of is called root cause analysis. So, if there’s a problem, we go analyse it properly and go right down to the root cause and then fix the root cause of that, so it doesn’t happen again.”
Coordination & integration across building blocks and levels of the MDVC.	• S3: “With our big suppliers, we have frequent meetings. It’s an integral part of the business, but it happens in the background.” • S7: “Very many leaders in these institutions do not have an idea of the space. So that's another challenge. You know, they would rather be better positioned in another part of the organisation, but they are where they are. And because of that, it's causing a lot of friction. Things are not shifting. Things are not moving. So that's just something I just wanted to bring up over there.” • S12: “As an engineer again, it's probably quite difficult. So, you just need to go and speak to people really.”

Appendix F: Bottlenecks in the Western Cape's MDVC

UE1: LACK OF MEDICAL DEVICE ADOPTION	
B1: Inadequate research	• S3: "It's important to do independent research, not just manufacturer-derived research, which is often biased." – Response regarding forecasting the demand of diagnostic devices.
B2: Lack of funding	• S1: "Funding is limited in the public sector, so they don't really want to buy new devices at all." • S4: "A doctor at Tygerberg had a situation where women, after giving birth, sometimes get uncontrollable bleeds and they can bleed to death. So, they have this very expensive device which is essentially just a balloon that you put into the uterus. You pump it up, it creates pressure, almost like you've got a cut and you hold pressure over the cut. It then allows the blood to clot, and it stops the bleed and the woman survives it. Without that, you can't get there to stop the bleed. She would die. The government didn't have money to develop this thing, so he (local medical device company owner) very cleverly went and took a condom. He then, with a cable tie, tied some surgical tubing to the condom. He then put a funnel at the top of the surgical tubing and put the condom into the uterus and then poured water via the funnel into the condom. The condom, depending on the height of the funnel, creates more pressure because there's more water, more pressure onto the condom, but then expands. And he can then get to a desirable pressure, which then pushes against the uterus and then stops the bleeding. So, PATH, an NGO that looks for opportunities to improve healthcare in Africa, gave him a whole lot of money to develop a better product. The product would be his (he'd keep the IP), they'd give him the money so that he could develop and sell it for a fair margin."
B7: Poor networking	• S2: "They designed ventilators with poorly placed switches where you could switch them off by mistake". • S2: "They designed oxygen valves with a tube that is always in the way. If they had just asked us to trial them, we could have pointed out those problems before they launched the thing." • S2: "We have in the past sent feedback to the [Medical device] companies and some of them are better than others in terms of responding to the problem. Others just ignore it." • S10: "A lack of understanding of the client's needs." – Response with regards to the biggest bottlenecks in the Western Cape's MDVC. • S16: "The feedback situation in the medical devices industry is not well established."
UE2: LACK OF MEDICAL DEVICE START-UPS	
B1: Inadequate research	• S14: "If it's a technology that you're developing and making, there's often no market because it's a publication that's going to come out of it. They're more interested in their academic careers than looking into something that can sell. This is changing." – Response with regards to the focus on publishing instead of commercialisation in universities.
B2: Lack of funding	• S4: "I have got some money at times, but unfortunately I've had to self-fund." • S8: "I think the biggest issue that we have is that to produce something, you can't manufacture 10 at a time. To get value, you've got to manufacture thousands of whatever you're building. So, you have to set up a production line; to set up a production line can take you three months. You've got to train people. You've got to have work instruction."

	• S9: “One of the major sources of funding is venture capital. Venture capital in South Africa is at a pathetic stage. I've seen it over the last 10 years, and it hasn't really improved at all. So, venture capital, the actual people willing to provide the funding, there's just not enough such companies around. So, the major problem is the availability of the funding.” • S11: “We don't have any sort of seed capital culture here. The banks are extremely conservative, and government does nothing to support that. There’s little to encourage start-ups in this country.”
B10: Poor governance	• S12: “There aren't enough medical device companies.” • S12: “So many biomedical engineers are lost to different industries. A lot of our friends and colleagues go and work for consulting companies or move abroad, and we need to be able to retain those skill sets to essentially give biomedical engineers and people in our space, you know, job opportunities as well. So, I think that's also major bottleneck.”
UE3: MEDICAL DEVICE SHORTAGES	
B4: Unforeseen supply chain disruption	• S3: “During COVID, the bottlenecks started right at the factory because the factories weren’t geared up to make enough of the stuff. Nobody foresaw the size of the pandemic; so big companies like Roche and Abbott were just under-geared for at least a year. They took a long time to get enough production going.”
B8: Poor supply chain management	• S3: “The states (USA) put a legal block on the export of Abbott PCR tests. We just couldn’t get them… So for a long time, they were either legally blocked from entering the country or just weren’t being produced in sufficient numbers.” – Response regarding PCR test shortages in SA during the COVID-19 pandemic
UE4: MEDICAL DEVICE-ASSOCIATED POLLUTION	
B3: Excessively complicated processes	• S3: “We used to, a long time ago, reuse some test tubes and things. But that has all stopped now with the new regulations”. • S4: “It is something that weighs on my brain a lot because when you say that it’s use, and disposal should be taken into account. I think it’s a big issue because we’re trying to green this earth and I’m very aware that I’m not helpful on that level. I’ve been making it worse. But you know, I don’t know how you don’t do that. We are adding architecture around the surgical blade. We can’t do it any other way than with plastic. It does mean there’s more waste. It is an issue.”
B4: Unforeseen supply chain disruption	• S15: “During COVID-19, the challenges we had were because the volume of the waste exceeded our treatment capacity.”
B8: Poor supply chain management	• S15: “You don’t want your waste to end up at a dumpsite as you don’t want illegal dumping to occur. So, you need to track your waste that is collected.”
UE5: LACK OF ALLEVIATION IMPLEMENTATION	
B1: Inadequate research	• S3: “We have about 500 warehouses and to get the receipting, issuing and stock taking done using a software system is difficult. We’re still struggling with that.” – Response with regards to inventory management. • S3: “We’re touching on it, but not too a large extent yet, no.” – Response with regards to making use of QR codes and/or barcoding technology and/or RFIDs in inventory management.
UE6: POOR SYSTEMS	
B2: Lack of funding	• S4: “CE Marking is a big issue. In fact, we may be pulling out of the European market now because the cost of CE Marking has just gone through the roof. It's a big problem. Everybody's in big trouble with this at the moment. It's a major, major issue.” • S10: “The lack of venture capital in the Western Cape.” – Response with regards to the biggest bottlenecks in the Western Cape’s MDVC.
B3: Excessively complicated processes	• S3: “The initial research and development and getting the approvals (FDA approval/ CE Marking) is a bottleneck.” • S3: “Our next bottleneck in terms of getting things into the country has been SAHPRA. If the thing (device) is FDA approved or CE approved, they should just rubber stamp it and allow us to use it. But they don’t; they go through their own whole evaluation process which can take six

	months to a year. When you've got a disease like COVID or monkey pox or whatever going on; you'd like to get those things (devices) fast-tracked and not to takes so long to be approved." • S7: "The greatest bottleneck, most likely, is the fact that the government, or the Department of Health, has not yet streamlined the procurement processes for medical devices. The speed of translation in the medical device space is dependent on the evolution of the procurement space." • S10: "The biggest bottleneck is the regulatory requirements." • S11: "Most of us have to go overseas for our certifications and we don't have the skill set locally." – Response with regards to regulation in South Africa. • S11: "The massive cost and complexity of international regulation and the fact that we don't have any skill sets in terms of consultants. We even have to go overseas to get consultants to help us get certified. So, I'd say that's the biggest stumbling block to innovation in this country because you can innovate, but you can't get it to market." • S14: "I think many people would have said it was regulatory but it's not a bottleneck; it's just something we have to go through… SAHPRA are still trying to find their feet… There's a lot of inefficiencies in the system… I know that one will eventually resolve." – Response with regards to the biggest bottlenecks in the Western Cape's MDVC. • S16: "I think there are big regulatory bottlenecks largely because of the inefficiencies with SAHPRA."
B4: Unforeseen supply chain disruption	• S11: "Eskom is our biggest disruption."
B7: Poor networking	• S2: "Communication is one of the most difficult things". • S3: "We still have great trouble with that." – Response with regards to crisis management planning. • S5: "There are not enough relationships at the university level or at the early business level." • S7: "Stakeholders in the medical device industry are not communicating." • S7: "What we saw during COVID is that it brought about collaborations, which was amazing… But then after the pandemic, everyone scattered so it's like collaborations no longer exist." • S7: "So I just think that one of the challenges is that there's so many different platforms, but we are not inviting the relevant people." • S14: "The medical device sector still operates in silos.
B9: Lack of human resources	• S10: "A lack of business expertise." – Response with regards to bottlenecks in the Western Cape's MDVC. • S11: "Things have deteriorated in the last 20 years in terms of technical training, in terms of the value that is placed on technical skills. People don't actually grow up thinking that would be a worthwhile job to have." – Response with regards to the lack of value placed on technical skills in South Africa. • S12: "The backlog at SAHPRA is quite tough and I mean they're doing what they can. They're doing the most and they're doing a great job. But they just need more support to try and get the devices approved a lot faster. So, it's not their fault, it's just that they need more support, and they need more resources. So that's a major bottleneck." • S12: "I think in the Western Cape, for example, we were struggling to find manufacturers. So, you know companies that are able to do injection-moulding, mould manufacturing, etcetera or tooling. And we actually had to go to Johannesburg to try and get that done. So that was a major bottleneck for us which requires us to essentially fly to Johannesburg every two weeks, etcetera. And obviously that incurs cost etcetera. But it's the only way to get it done." • S16: "SAHPRA are severely resource limited, particularly as far as skills are concerned and that is certainly hampering the industry and the availability of novel products."
B10: Poor governance	• S4: "SAHPRA is meant to prosecute and meant to control the imports. In other words, no medical device should come into this country through customs, unless they show their SAHPRA license. But SAHPRA is failing. They're not doing their job properly. They're not even enforcing that.

	They're not even at customs. They don't even have a staff member at customs who's checking any medical device to see all these things are there. So, we are also being failed by a system where we have to spend all the money and be SAHPRA licensed and get ISO: 13485 and spend all the money. We pay these big licence fees. But, when COVID hit; stationary shops were selling and getting all the tenders, 100 million Rand tenders, and they weren't even registered." • S11: "Our technical support structures are being eroded by a lack of government interest and support at an educational level and at a financial incentive level." • S12: "I think SAHPRA approval is a major issue for a lot of companies." • S14: "I think the other thing is the lack of local purchasing… With the tender system, you still find these big companies bullying their way into the market here and actually excluding local suppliers and local manufacturers." • S14: "In the private sector, you still get many of the doctors having these relationships with the international companies and not having relationships with the local companies." • S16: "There are a lot of individual procurement policies and systems in place which are not really scientifically based. Procurement is haphazard and it's not based on user performance to the extent that it should be. It's probably economically driven and often by a false economy because the buyer is often not the user." • S17: "Regulatory and procurement policies." – Response with regards to the biggest bottlenecks in the Western Cape's MDVC.
B11: Corruption	• S4: "It's a lot easier for me to sell in the USA than it is for me to sell in South Africa. They pay me way more than what I get paid here. So that's why I go overseas. It financially just makes a lot more sense."

Appendix G: Bottleneck alleviations in the Western Cape's MDVC

DE1: ADOPTION OF MEDICAL DEVICE	
A7: Strategic networking	• S1: "It's very useful to have a human being showing you how to use it [medical device] rather than a set of instructions. It's useful to have personal contact." • S2: "They need to introduce a new device with the rep that's attached to that device so that the rep can personally train every person that's going to use that device". • S2: "For certain devices, an explanatory video is not sufficient." • S2: "I'm quite happy to chat to someone, but I don't feel like writing an essay for someone." – Response with regards to giving feedback on a medical device. • S7: "Being able to meet, to interact with them, medical personnel, and all that. That's extremely important, because if you don't get the problem right from the onset, they will not buy your device. They will not see a need for your device." • S16: "Procurement should look at intuitiveness as well." – Response with regards to how the instructions for using medical devices aren't always properly looked at.
DE2: SUCCESSFUL MEDICAL DEVICE START-UPS	
A1: Funding	• S11: "There should be massive support to cover the costs for start-ups because often the innovation comes from smaller companies."
A7: Strategic networking	• S5: "Building relationships with existing companies or with existing innovators that have gone through the journey can really help." • S8: "You can't spend days training people… If anything stops, it costs you money." – Response with regards to saving money once in production. • S8: "You've got to have the volumes… To have volumes, you have to go overseas." – Response regarding making money in the South African medical devices industry. • S8: "The biggest challenge that we have is getting into the international market." • S8: "To make it affordable in South Africa, you have to sell all the volumes that you can in America. Make the dollars, then bring it back to South Africa to bring the price down so, we can afford those things."
A13: Strategic decision-making	• S9: "One of the benefits of getting either FDA or CE Mark is that you can then export your product." • S14: "It's very important to have a market in mind before you get involved in a master's or PhD project where you're going to be developing a new technology."
DE3: AGILE/ RESILIENT SUPPLY CHAINS	
A7: Strategic networking	• S3: "It (information sharing) is part of assisting each other to help the patient". – Response with regards to sharing needed medical device designs in emergencies.

A10: Holistic idea generation **A12:** Medical device alternative	• S3: “For example, the way the manufacturer said we should do the DNA extraction, or the RNA extraction was on one of their automated extraction machines. But we found that it was slow, and the plastic ware and reagents weren’t always available because there was a worldwide shortage at that stage. So, we developed our own manual ordinary extractions using heat blocks and buffers. And that we validated ourselves and then put forward to NHLS (National Health Laboratory Service) and SAHPRA. And they stamped that. But it’s the exception but not the rule.” – Response with regards to dealing with COVID-19 associated time pressures and supply shortages. • S3: “Everything (PCR tests, plastic, machine analysers) was in short supply, so we were sort of driven by desperation to innovate locally and find our own solutions.” – Response with regards to dealing with supply shortages amidst the pandemic.
DE4: SUSTAINABLE WASTE MANAGEMENT	
A10: Holistic idea generation	• S12: “From a waste generation perspective, a lot of our devices are reusable, and we made it that way essentially to reduce waste generation.”
DE5: SUCCESSFUL IMPLEMENTATION OF ALLEVIATIONS	
NA	• NA.
DE6: SYSTEM IMPROVEMENT	
A1: Funding	• S1: “Funding and communication”, were suggested as alleviations that would encourage system improvement. • S4: “Everything in that there comes down to money.” – Response with regards to having emergency/alternative supply chains in case of disruptions. • S9: “We've maybe got to try and develop a medical aid, medical device, venture capital, whole ecosystem in this country. It simply doesn't exist.” • S12: “Despite what a lot of people say, there's definitely funding available.”
A4: Support	• S17: “We need more training of those within companies on how to do regulatory and how to put together dossiers, what the process is, how to identify what kind of classification and what registration is needed. Templates and all that kind of thing.” • S17: “We already provide regulatory support. We have a partnership with CSIR. It’s free for innovators. They can go to CSIR through this grant that we have, and they can get advice on what class their device fits into and what kind of registration they need, what files to put together, the templates, who can do the testing for them etc.”
A7: Strategic Networking	• S6: “But I think there is light at the end of the tunnel because with the number of stakeholders in the industry, with the crisis we've had with PPE; there definitely seems to be a lot more collaboration and cooperation between universities, manufacturers, Health Departments and Government in general. They’re looking to streamline the procurement and acquisition of medical devices.” • S7: “It's important for each and every stakeholder to be aware of the information that is passing around because it is actually available. You know. So, for example, the innovators will blame the regulatory authorities for being stringent and all that. But then this is a medical device field. There is need for stringency.” • S7: “But now the issue is, and this came from the regulatory perspective, is the need for interactions, say invitations from academic institutions to the regulatory authority, just inviting them to talk about the regulatory space, to talk about what they need to do to move from stage one stage seven or eight (TRL).” • S7: “I think it's just important for us to continuously educate ourselves on the translation space.” • S10: “Promotion of funding as well as showcasing technology.” – Response regarding improving the networking amongst funders and technologists.

	• S10: “And then my other one is the business one. Don't forget that the one because that that's the one that you need to become less of an engineer to make sure products are successful. Keep it simple.” – Response regarding the importance of sales in the MDVC and how engineers need to market their product in a way that’s understandable to the user. • S14: “Linking up with industry in the early stages is vital. It's something that’s seldom done at universities. They do something because it's, you know, the promoter decides it's a good thing to do. But they don't generally link up with industry. And if they did link up with industry right up front and have industry work with them through the whole value chain, and ultimately help them take it to market and maybe even be the company that does that, that would be the ideal.” • S14: “During the COVID-19 pandemic, things were happening rapidly because people were collaborating.”
A9: Governance	• S3: “I think we’d have trouble with a SAHPRA certified kit because the American company sponsoring the trial wouldn’t know who they were. I think we have to rely on the overseas accreditation or stamp of approval.” – Response with regards to the possibility of SAHPRA solely regulating medical devices. • S4: “If corruption gets cleaned up; the local medical industry will get better.” • S7: “The bulk purchases of Chinese equipment end up reducing the cost significantly… I think the government really needs to align and organize the procurement space across African countries.” • S10: “I'd say alleviating that would be for SAHPRA to align themselves with Europe.” – Response regarding alleviating the regulatory bottleneck. • S10: “To standardise medical device regulation across the world.” - Response regarding alleviating the regulatory bottleneck. • S11: “The smaller countries and the third world countries should actually be relying on the quality systems of first world countries.” • S14: “The tender system should favour local manufacturing. It shouldn’t be based just on price because it’s more than just price; by favouring local, you are also booming local companies that might be more expensive but are creating more jobs. So, the whole ecosystem grows. For the benefit of the country, it’s not just looking at that single item that you buy and saying, well we could have got it cheaper from China/the States/ Europe. The offshoot of buying local, even if it’s more expensive, is that it has far greater impact.” • S14: “Buying local will build the local industry.”
A13: Strategic decision-making	• S4: “With COVID, we realized that we didn't have PPE. So, there's a big drive at the moment to build local manufacture and the supply chains. And if that happens, I think you'll see a lot of push to get all these things right.”